LEABHARLANN CHOLÁISTE NA TRÍONÓIDE, BAILE ÁTHA CLIATH | TRINITY COLLEGE LIBRARY DUBLIN
Ollscoil Átha Cliath | The University of Dublin

Terms and Conditions of Use of Digitised Theses from Trinity College Library Dublin

Copyright statement

All material supplied by Trinity College Library is protected by copyright (under the Copyright and Related Rights Act, 2000 as amended) and other relevant Intellectual Property Rights. By accessing and using a Digitised Thesis from Trinity College Library you acknowledge that all Intellectual Property Rights in any Works supplied are the sole and exclusive property of the copyright and/or other IPR holder. Specific copyright holders may not be explicitly identified. Use of materials from other sources within a thesis should not be construed as a claim over them.

A non-exclusive, non-transferable licence is hereby granted to those using or reproducing, in whole or in part, the material for valid purposes, providing the copyright owners are acknowledged using the normal conventions. Where specific permission to use material is required, this is identified and such permission must be sought from the copyright holder or agency cited.

Liability statement

By using a Digitised Thesis, I accept that Trinity College Dublin bears no legal responsibility for the accuracy, legality or comprehensiveness of materials contained within the thesis, and that Trinity College Dublin accepts no liability for indirect, consequential, or incidental, damages or losses arising from use of the thesis for whatever reason. Information located in a thesis may be subject to specific use constraints, details of which may not be explicitly described. It is the responsibility of potential and actual users to be aware of such constraints and to abide by them. By making use of material from a digitised thesis, you accept these copyright and disclaimer provisions. Where it is brought to the attention of Trinity College Library that there may be a breach of copyright or other restraint, it is the policy to withdraw or take down access to a thesis while the issue is being resolved.

Access Agreement

By using a Digitised Thesis from Trinity College Library you are bound by the following Terms & Conditions. Please read them carefully.

I have read and I understand the following statement: All material supplied via a Digitised Thesis from Trinity College Library is protected by copyright and other intellectual property rights, and duplication or sale of all or part of any of a thesis is not permitted, except that material may be duplicated by you for your research use or for educational purposes in electronic or print form providing the copyright owners are acknowledged using the normal conventions. You must obtain permission for any other use. Electronic or print copies may not be offered, whether for sale or otherwise to anyone. This copy has been supplied on the understanding that it is copyright material and that no quotation from the thesis may be published without proper acknowledgement.

Ultrasound to enhance assessment of the fetal head position prior to instrumental delivery

A dissertation submitted to the University of Dublin for the Degree of Doctorate in Philosophy

Meenakshi Ramphul

Trinity College Dublin, April 2013

Department of Obstetrics and Gynaecology

Trinity College Dublin

Supervisor: Professor Deirdre J. Murphy

Declaration

I declare that this thesis has not been submitted as an exercise for a degree at this or any other University. The work, upon which this thesis is based, was carried out in collaboration with a team of researchers and supervisors who are duly acknowledged in the text of the thesis. The Library may lend or copy this thesis upon request.

Signed: Date:



10/04/2014

TRINITY COLLEGE
5 JAN 2015
LIBRARY DUBLIN

Thesis 10830

Summary

Background

This thesis is aimed at investigating the role of ultrasound to enhance diagnosis of the fetal head position prior to instrumental delivery in order to make instrumental deliveries safer.

Methods

There are four components to this thesis: (i) a literature review to explore the evidence regarding the use of ultrasound on the labour ward and particularly to diagnose the fetal head position in labour; (ii) a questionnaire survey to establish current practice of obstetricians in the United Kingdom and Ireland relating to assessment of women before instrumental delivery; (iii) a validation study to establish the accuracy of an ultrasound scan performed by a novice ultrasonographer in the second stage of labour and, also, to establish the acceptability of ultrasound in labour to women and the clinicians looking after them; and (iv) a randomised controlled trial to evaluate the role of ultrasound to enhance the diagnosis of the fetal head position prior instrumental delivery.

Results

The literature review found the reported accuracy of digital vaginal examination to diagnose the fetal head position varied from 20% to 75% but only two small studies evaluated the use of ultrasound to diagnose the fetal head position prior to instrumental delivery. We identified a variety of strategies used by obstetricians when there is difficulty or uncertainty in diagnosing the fetal head position on clinical examination and a lack of consensus regarding the use of ultrasound in this setting. The validation study demonstrated that an ultrasound scan to diagnose the fetal head position is accurate and acceptable to women in labour and to the clinicians looking after them. The IDUS randomised controlled trial has shown that an ultrasound scan can enhance the diagnosis of the fetal position before instrumental delivery without delaying the time to delivery. Despite enhanced diagnosis of the fetal head position, there were no clear differences in maternal or neonatal complications.

Conclusion

The findings of this thesis support the use of ultrasound prior to instrumental delivery to identify the more complex cases of fetal malposition. However, the use of ultrasound did not reduce the incidence of maternal and neonatal complications, suggesting that the accurate diagnosis of a fetal malposition, in itself, is not sufficient to avoid adverse outcomes. Further work is required to enhance the skill of mid-cavity rotational instrumental delivery when a fetal malposition has been identified.

Acknowledgements

I wish to thank my supervisor Professor Deirdre Murphy for her invaluable help, support and patience. It has been a privilege working with Professor Murphy who inspired me to pursue a career in Obstetrics and Gynaecology and who has been my mentor since the start of my career. I will be eternally grateful for this opportunity.

I would like to acknowledge the wonderful team I worked with during this research. I would like to thank Dr Mairead Kennelly, I am grateful for the skills she taught me and for her continual advice during this research. I wish to thank Dr Gerry Burke and Dr Soha Said from the Mid-Western Regional Hospital, Limerick for their contribution and for their commitment to IDUS. I would like to thank my research colleague, Dr Wendy Ooi, for her hard work in Limerick. I wish to thank Dr Alan Montgomery for his statistical expertise, advice and patience. I also wish to thank Dr Yvonne O'Brien for her assistance with the questionnaire survey and the hard work she put in.

I will forever be indebted to the women who took part in this research. I am grateful for the support of all the labour ward midwives and my colleagues (registrars and consultants) in the Coombe Women & Infants' University hospital and the Mid-Western Regional hospital – without their support, this research would not have been possible.

I am grateful to the Health Research Board for funding IDUS and to Dr Chris Fitzpatrick, Master, Coombe Women & Infants University Hospital, for his support. I am also grateful to Professor Patricia Crowley for her continual support and guidance –thank you for always making time to listen to me.

I wish to thank Piaras Fahey and Claire Dunney for their help with the IDUS database – you made it manageable. My other colleagues, Dr Brian Cleary, Dr Richard Deane, Dr Aoife Mullally and Dr Sharon Sheehan provided encouragement and advice, especially when things got tough.

I am very thankful to my friends, Maria, Triona, Katie and Ruaidhri, and my sister, Anu, for always being there for me.

Finally, I would like to thank my parents, Leela and Harris, for their endless encouragement, their belief in my abilities and for giving me every opportunity. Thank you for your love and generosity.

I dedicate this thesis to my parents, Harris and Leela.

Table of contents

Declaration .....

Summary i

Acknowledgements iii

Table of contents vi

List of tables xii

List of figures xiv

List of abbreviations xv

Publications xvi

Conference presentations xvii

Chapter 1 Introduction 1

1.1 Introduction 2

1.2 Instrumental delivery rates in Ireland 3

1.3 Indications and assessment for instrumental delivery 6

1.3.1 Classification of instrumental delivery 6

1.3.2 Indications 9

1.3.3 Contraindications 10

1.3.4 Pre-requisites for instrumental delivery 13

1.3.5 Assessment prior to instrumental delivery 15

1.3.6 Fetal head malpositions 20

1.4 Instrumental delivery in theatre 22

1.5 Choice of instruments 23

1.5.1 Forceps 24

1.5.2 Vacuum 25

1.6 Complications of instrumental delivery 26

1.6.1 Maternal morbidity 26
1.6.2 Neonatal morbidity 28
1.7 Failed instrumental delivery 32
1.8 Aims and objectives 33
1.9 Thesis Outline 34
Chapter 2 Literature review: The role of ultrasound in labour particularly to diagnose the fetal head position 35
2.1 Introduction 36
2.2 The role of ultrasound on the labour ward 36
2.3 Safety and acceptability 38
2.4 Overview of ultrasound approaches used in labour 38
2.5 The role of ultrasound in the first and second stages of labour 39
2.6 Engagement and station of the fetal head 39
2.6.1 Transabdominal ultrasound 39
2.6.2 Translabial ultrasound 40
2.6.3 Descent of the fetal head 41
2.6.4 Fetal head to perineum distance 42
2.7 The fetal head position in labour 43
2.7.1 Transabdominal ultrasound 43
2.7.2 Translabial and transvaginal ultrasound 44
2.7.3 Error rates of ultrasound 44
2.7.4 Fetal head position prior to instrumental delivery 45
2.7.5 Fetal head position to predict mode of delivery 45
2.8 Discussion 49
Chapter 3 Strategies to enhance assessment of the fetal head position prior to instrumental delivery – a survey of obstetric practice in the United Kingdom and Ireland. 50

3.1 Introduction 51
3.2 Material and methods 51
3.2.1 The questionnaire survey as a form of assessment 51
3.2.2 Developing the questionnaire survey 52
3.2.3 Ethics committee approval 53
3.2.4 Statistical analysis 53
3.3 Results 53
3.4 Discussion 62
3.4.1 Summary of findings 62
3.4.2 Strengths and weaknesses 62
3.4.3 Comparison with the literature 62
3.4.4 Practice implications and future work 63
3.5 Conclusion 64

Chapter 4 Establishing the accuracy and acceptability of abdominal ultrasound to define the fetal head position in the second stage of labour – a validation study. 65

4.1 Introduction 66
4.2 Methods 67
4.2.1 Study population 67
4.2.2 Eligibility criteria 67
4.2.3 Interventions 67
4.2.4 Ethics committee approval 70
4.2.5 Statistical analysis 70
4.3 Results 71
4.4 Discussion 76
4.4.1 Summary of findings 76
4.4.2 Strengths and limitations 76
4.4.3 Comparison to the literature 76

4.4.4 Practice implications 77
4.4.5 Future work 77
4.5 Conclusion 78
Chapter 5 CHAPTER – IDUS Randomised Controlled Trial: Study design and methods 79
5.1 Introduction 80
5.2 Methods 82
5.2.1 The randomised controlled trial as a form of evaluation 82
5.2.2 Randomisation 82
5.2.3 Blinding 82
5.2.4 Reporting 83
5.2.5 Setting 83
5.3 Recruiting women for research in labour 85
5.4 Recruitment process 88
5.4.1 Inclusion criteria 88
5.4.2 Exclusion criteria 89
5.4.3 Allocation to trial groups 89
5.5 Intervention 89
5.5.1 Usual care arm 89
5.5.2 Intervention arm 90
5.6 Data from medical records 94
5.7 Data entry and checking 94
5.8 Baseline Characteristics 94
5.9 Outcome measures 95
5.9.1 Primary outcome 95
5.9.2 Secondary outcomes 102
5.10 Follow-up 102
5.11 Trial end 102

5.12 Statistical analysis 103
5.13 Feasibility 103
5.14 Sample size 104
5.15 Timetable 106
5.16 Study set-up 106
5.16.1 Funding 106
5.16.2 Ethical committee permission 106
5.16.3 Trial registration 106
5.16.4 Research Team 107
5.16.5 Data management 107
5.16.6 Trial management group (TMG) 107
5.16.7 Trial steering committee (TSC) 110
5.16.8 Data monitoring committee (DMC) 110
5.16.9 Safety considerations 111
5.16.10 Protocol publication 111
5.16.11 Study promotion 111
5.17 Summary 111

Chapter 6 IDUS Randomised Controlled Trial: Results 112

6.1 Introduction 113
6.2 Study population 113
6.3 Allocation 116
6.4 Baseline characteristics 116
6.5 Analysis of primary outcome 121
6.5.1 Intention to treat analysis 121
6.5.2 Sensitivity analysis 121
6.5.3 Subgroup analysis 123
6.5.4 Cluster effect 123
6.6 Analysis of secondary outcomes 124

6.7 Summary 131

Chapter 7 IDUS Randomised Controlled Trial: Discussion 132

7.1 Summary of findings 133

7.2 Strengths and weaknesses 133

7.3 Comparison with existing literature 134

7.4 Discussion 134

7.5 Clinical implications 135

7.6 Interpreting the implication of fetal head position errors using illustrative cases ... 135

7.7 Future studies 142

7.8 Conclusion 142

Chapter 8 Thesis summary and conclusion 143

8.1 Summary of thesis 144

8.1.1 Literature review 144

8.1.2 Questionnaire survey 145

8.1.3 Validation study 145

8.1.4 Randomised controlled trial 146

8.2 Clinical implications 146

8.3 Primary outcome and sample size 148

8.4 Research implications 148

8.5 Conclusion 150

List of tables

Table 1.1 Operative delivery rates for nulliparous women across maternity units in Ireland in 2009. 5
Table 1.2 Classification for operative vaginal delivery. 8
Table 1.3 Indications and contra-indications for instrumental deliveries 12
Table 1.4 Pre-requisites for instrumental deliveries. 14
Table 1.5 Maternal and fetal factors where continuous electronic fetal monitoring is recommended. 16
Table 1.6 Factors associated with the occipito-posterior position. 21
Table 1.7 Relative merits of vacuum extraction and forceps. 23
Table 1.8 Classification of perineal tears 26
Table 2.1 Current uses of ultrasound in labour 37
Table 2.2 Studies evaluating accuracy of transvaginal digital examination compared to ultrasound in diagnosing the position of the fetal head in labour 46
Table 3.1 Demographic of respondents. 54
Table 3.2 Clinical features assessed prior to instrumental delivery 57
Table 3.3 Factors associated with uncertainty in determination of the fetal head position. 58
Table 3.4 Approaches used to enhance determination of fetal head position 59
Table 3.5 Perceived accuracy in assessment of fetal head position. 60
Text box 3.1 Qualitative data- comments in the free text section of the questionnaire 61
Table 4.1 Inconsistency between fetal head position findings of novice and expert ultrasonographer 73
Table 4.2 Accuracy of scan findings and time taken by the novice ultrasonographer analysed in consecutive blocks of ten. 74
Table 4.3 Inconsistency between clinical assessment of fetal head position and expert ultrasonographer 75
Table 4.4 Inconsistency in fetal head position (occipito-anterior / occipito-posterior) between clinical assessor and expert ultrasonographer. 75
Table 5. 1. Guideline for consent. 87
Table 5.1 Sample size calculations. 105
Table 5.2 Members of the IDUS Trial Management group. 108
Table 5.3 Contributions of IDUS study group members 109
Table 5.4 Members of Trial Steering Committee. 110

Table 6.1 Maternal and neonatal baseline characteristics. 117
Table 6.2 Baseline characteristics of labour and delivery factors..... 119
Table 6.3 Primary outcome: intention to treat and sensitivity analyses. 122
Table 6.4 Secondary outcomes – maternal morbidity. 126
Table 6.5 Secondary outcomes – neonatal morbidity. 126
Table 6.6 Secondary outcomes – procedure related outcomes. 127
Table 6.7 Choice of instruments. 128
Table 6.8 Degree of certainty of the fetal head position. 128
Table 6.9 Error profiles in the two arms. 128
Table 6.10 Postnatal complications 129
Table 7.1 Illustrative cases in the ultrasound group where the ultrasound diagnosis of the fetal head position was accepted and management changed as a result. 138
Table 7.2 Illustrative cases – ultrasound findings not accepted. 140
Table 7.3 Illustrative cases – standard care group – incorrect diagnosis & potential difference in management. 141

List of figures

Figure 1.1 Landmarks of the fetal skull. 17
Figure 1. 2 Fetal head position 19
Figure 1.3 a. Non-rotational forceps, b. Rotational forceps (Kielland's) 24
Figure 1.4 a. Silastic cup (silicone); b. Kiwi™ Omnicup (plastic); c. Metal cup. 25
Figure 1.5. a. Swelling on fetal head after vacuum delivery (chignon) b. Forceps marks 29
Figure 1.6. Traumatic injury after forceps delivery. 29
Figure 1.7 Anatomical location of cephalhaematoma, subgaleal haematoma and subdural haemorraghe 30
Figure 4. 1 Sagittal view of the fetal spine. 68
Figure 4.2 Transverse view of the fetal spine. 68
Figure 4.3 Transverse view of the fetal cranium – landmarks of midline cerebral echo and falx cerebri shown in this left occipito-transverse position. 69
Figure 4.4 Transverse view showing fetal orbits and nose indicating an occipito-posterior position. 69
Figure 4.6 Flow diagram of recruitment 71
Figure 5.1. Patient recruitment for trial duration. 84
Figure 5.2. Obtaining informed consent in labour. 86
Figure 5. 3 Data sheet: digital vaginal examination findings 90
Figure 5.4 Ultrasound image depicting the direct OA position 91
Figure 5.5 Ultrasound image depicting the fetal spine in an anterior position. 92
Figure 5.6 Ultrasound image depicting the LOT position with a fetal ear visible anteriorly 92
Figure 5.7 Ultrasound image depicting the OP position. 93
Figure 5.8 Optimally placed vacuum. 97
Figure 5.9 Sub-optimally placed vacuum. 98
Figure 5.10 Sequential instruments with sup-optimally placed vacuum. 99
Figure 5.11 Optimally placed forceps 100
Figure 5.12 Sub-optimally placed forceps. 101
Figure 6.1 CONSORT flow diagram. 114
Figure 6.2 Percentages of women recruited at each centre. 115
Figure 6.3 Frequency of landmarks used to diagnose the fetal head position on ultrasound .. 130

List of abbreviations

ACOG	American College of Obstetrics and Gynecology
BMC	BioMed Central
BMI	Body mass index
BPD	Biparietal diameter
CI	Confidence Interval
CS	Caesarean section
EFM	Electronic fetal monitoring
HC	Head circumference
HRB	Health Research Board
IDUS	Instrumental Delivery & UltraSound
IQR	Interquartile range
NICU	Neonatal Intensive Care Unit
OA	Occipito-anterior
OP	Occipito-posterior
OR	Odds Ratio
OT	Occipito-transverse
PPH	Post-partum haemorrhage
RCOG	Royal College of Obstetricians & Gynaecologists
RCT	Randomised controlled trial
SOGC	Society of Obstetricians & Gynaecologists of Canada
SpR	Specialist registrar
TAS	Transabdominal ultrasound
TCD	Trinity College Dublin
TVS	Transvaginal ultrasound
WHO	World Health Organisation

Publications

Peer reviewed publications

Murphy DJ, Burke G, Montgomery AA, **Ramphul M**. Study Protocol. IDUS – Instrumental Delivery & UltraSound. A multi-centre randomised controlled trial of ultrasound assessment of the fetal head position versus standard care as an approach to prevent morbidity at instrumental delivery. BMC Pregnancy & Childbirth. 2012 Sep 13;12(1):95. PMID:2970933

Ramphul M, O'Brien Y, Murphy DJ. Strategies to enhance assessment of the fetal head position prior to instrumental delivery – a survey of obstetric practice in the United Kingdom and Ireland. European Journal of Obstetrics Gynecology & Reproductive Biology. 2012 Aug 22. [Epub ahead of print] PMID:22921846

Ramphul M, Kennelly M, Murphy DJ. Establishing the accuracy and acceptability of abdominal ultrasound to define the foetal head position in the second stage of labour: a validation study. European Journal of Obstetrics Gynecology & Reproductive Biology. 2012 Jul 2. [Epub ahead of print] PMID: 22762840

Commissioned Publications

Ramphul M, Murphy DJ. The role of ultrasound on the labour ward. Expert Reviews in Obstetrics & Gynaecology. 2012, Nov; 7 (6): 615- 625.

Ramphul M, Murphy DJ. Operative vaginal delivery – Chapter 2: Indications and assessment for instrumental delivery. RCOG Press. In Press.

Conference presentations

Ramphul M, Ooi PV, Burke G, Kennelly MM, Said SAT, Montgomery AA, Murphy DJ. IDUS – Instrumental Delivery & UltraSound. A multi-centre randomised controlled trial of ultrasound assessment of the fetal head position versus standard care as an approach to prevent morbidity at instrumental delivery. Podium presentation of poster. RCOG Congress, Liverpool, United Kingdom, June 2013.

Ramphul M, Ooi PV, Burke G, Kennelly MM, Said SAT, Montgomery AA, Murphy DJ. IDUS – Instrumental Delivery & UltraSound. A multi-centre randomised controlled trial of ultrasound assessment of the fetal head position versus standard care as an approach to prevent morbidity at instrumental delivery. Oral presentation. European Congress of Intrapartum Care, Amsterdam, Netherlands, May 2013.

Ramphul M, O'Brien Y, Murphy DJ. Strategies to enhance assessment of the fetal head position prior to instrumental delivery – a survey of obstetric practice in the United Kingdom and Ireland. Poster presentation. Irish Congress of Obstetrics, Gynaecology and Perinatal Medicine, Ireland, November 2012.

Ramphul M, Kennelly M, Murphy DJ. Establishing the accuracy and acceptability of abdominal ultrasound to define the foetal head position in the second stage of labour: a validation study. Poster presentation. Irish Congress of Obstetrics, Gynaecology and Perinatal Medicine, Ireland, November 2012.

Ramphul M, Kennelly MM, DJ Murphy. Establishing the accuracy and acceptability of abdominal ultrasound to define the foetal head position in the second stage of labour: a validation study. Poster presentation. RCOG Annual Academic Meeting and Blair Bell Research meeting December 2011.

Chapter 1 Introduction

1.1 Introduction

Instrumental deliveries are commonly performed in Ireland with almost 10,000 women a year having a vacuum or forceps delivery.[1] The risks of maternal and neonatal morbidity are increased with instrumental deliveries, although with careful practice these risks are low.[2] The rate of instrumental delivery is falling, while that of caesarean section at full dilatation is rising.[2-6] However, operative delivery rates (instrumental delivery or caesarean section at full dilatation) vary extensively between institutions and countries, particularly for first time mothers with a singleton pregnancy and women with previous caesarean sections. [3]

Instrumental delivery has an important role to play in modern obstetric care. Women who have an instrumental delivery are far more likely to have a spontaneous vaginal delivery in a subsequent pregnancy than women who have an emergency caesarean section.[7] Careful patient assessment, observing the rules of safe obstetric practice, and working within the appropriate clinical indications for instrumental deliveries should ensure that the benefits of recommending instrumental delivery outweigh the risks.

Instrumental deliveries with a fetal malposition (occipito – transverse or occipito – posterior) are more challenging and are associated with greater failure and with higher rates of maternal and neonatal morbidity. This thesis outlines a programme of work examining the use of ultrasound to enhance assessment of the fetal head position before instrumental deliveries with four distinct components: i) a literature review was done to evaluate the existing evidence on the use of ultrasound to diagnose the fetal head position in labour and particularly before instrumental delivery; ii) a questionnaire survey in the United Kingdom (UK) and Ireland to evaluate current strategies used to diagnose the fetal head position before instrumental delivery, especially when there is difficulty doing so, and to obtain clinicians' views regarding the use of ultrasound in this setting ; iii) a validation study evaluating the accuracy of an abdominal ultrasound to diagnose the fetal head position in the second stage of labour by a novice ultrasonographer and also evaluating the acceptability of this intervention to women in labour and the clinicians looking after them; iv) a randomised controlled trial comparing clinical examination alone (standard care) to clinical examination and an ultrasound scan before instrumental delivery to diagnose the fetal head position.

1.2 Instrumental delivery rates in Ireland

The rate of instrumental deliveries varies extensively between institutions and countries, particularly for first time mothers with a singleton pregnancy, and women with previous caesarean sections. [3] Over the last two decades, there has been a decline in the rate of instrumental delivery while the caesarean section rate has been constantly rising, including the number of caesarean sections performed at full dilatation. [3-6 8 9] This decline can be attributed to a number of factors, specifically the risk of morbidity associated with instrumental delivery, the increase in litigation, loss in obstetricians' skills and women's choices. [4 6 8] Dupuis, commenting on the decline in the rate of instrumental delivery stated *"whether such changes can be due to patient and physician reluctance to the use of instruments because of fear of trauma is unknown"*.[8] A ten year audit of operative deliveries in a London maternity hospital found an increase in the number of caesarean sections performed at full dilatation both after failed attempt at instrumental delivery and immediately, without attempt at instrumental delivery. [4]

The decline in instrumental delivery is occurring worldwide. Moreover, there has particularly been a decline in the use of forceps with a concomitant rise in the use of vacuum devices. [3 9 10] In 2010, the overall instrumental delivery rate in the USA was 3.6% with an overall caesarean section rate of 32.8%. [11] Vacuum deliveries accounted for 3.0% of all deliveries while forceps accounted for 0.6%. [11] A survey of obstetrics practice across Europe carried out in 2000 reported instrumental delivery rates varying from 3% in Perugia, Italy to 40% in Barcelona, Spain with caesarean section rates varying from 12% in Paris, France to 32% in Athens, Greece. [12] In developing countries, where access to maternity services remains poor, the rate of instrumental delivery is low. [13]

In contrast, the instrumental delivery rate remains high in the UK and Ireland at 12 to 17% and the rate of caesarean section is lower at 24 to 28% in most centres. [1 14] The instrumental delivery rate for nulliparous women is higher at 25 to 33%.

Table 1.1 reports the rate of operative deliveries in maternity units in Ireland in 2009. Data were obtained from:

1. Irish Childbirth Trust: Cuidiu.ie – a voluntary organisation that provides information to parents in order for them to make informed choices about pregnancy, childbirth and

breastfeeding. They also provide a detailed consumer guide to maternity services in Ireland.[1]

(BirthchoiceUK.com is a similar organisation in the United Kingdom) [14]

2. Annual reports of Dublin maternity units– the three Dublin maternity units (Coombe Women & Infants University Hospital, National Maternity Hospital and Rotunda Hospital) produce annual reports of activity in obstetrics and gynaecology.

The two centres involved in this programme of research are highlighted in red in Table 1.1.

Table 1.1 Operative delivery rates for nulliparous women across maternity units in Ireland in 2009.*

	n	Vacuum Delivery (%)	Forceps Delivery (%)	Total instrumental delivery rates (%)	Total Caesarean section rates†(%)
Coombe Women & Infants University Hospital ‡	3,595	18.4	14.8	33.2	26.2
Midwestern Regional Maternity Hospital, Limerick ‡	2,153	23.9	3.4	27.3	24.4
National Maternity Hospital	4,407	15.6	9.7	25.3	22.1
Rotunda Hospital	4,131	23.8	9.2	33.0	29.7
Cork University Hospital	3,751	11.8	5.5	17.3	27.7
Portiuncula Hospital	852	29.6	3.5	33.1	30.2
University Hospital Galway	1,421	22.7	9.5	32.2	30.0
Kerry General Hospital	768	11.1	4.7	15.8	30.1
Our Lady of Lourdes Drogheda	1,422	20.5	8.9	29.4	30.8
Mayo General Hospital	717	12.6	7.0	19.6	27.5
South Tipperary General Hospital	605	26.1	2.0	28.1	35.5

*there are 22 maternity units in Ireland but only 11 reported the rates of operative deliveries.

† includes elective and emergency caesarean sections.

‡ IDUS trial centres.

1.3 Indications and assessment for instrumental delivery

The decision whether or not to perform an instrumental delivery is a complex one. Choosing the most appropriate mode of delivery, conducted under optimal circumstances, in the most appropriate place, by a competent operator, are the key elements for safe delivery of a healthy infant while maintaining a positive experience for the mother and her partner. The risks of maternal and neonatal morbidity are increased with instrumental deliveries, although with careful practice these risks are low. [2] Close attention needs to be paid to the indication for instrumental delivery and to clinical assessment prior to any attempt at the chosen procedure.

There are two alternatives to instrumental delivery. The first alternative, continued pushing aiming for a spontaneous vaginal birth, may be unwise if there is evidence of fetal compromise or minimal progress due to diminished maternal reserve. The second alternative, a caesarean section at full dilatation, is a complex intervention associated with increased risks of maternal morbidity (major haemorrhage, extended hospital stay) and neonatal morbidity (higher rates of admission to the neonatal unit). [15] Overall, women who have vaginal deliveries (albeit with assistance) tend to be more satisfied with the birth than those who have emergency caesarean sections. [16] The risk of intrapartum complications in subsequent pregnancies is greatly reduced if a safe instrumental delivery can be completed rather than a second stage caesarean section. [7]

Most of this section has been based on the recommendations made by the Royal College of Obstetricians and Gynaecologists (Greentop Guideline number 26), the American College of Obstetricians and Gynecologists (ACOG Practice Bulletin number 17) and the Society of Obstetricians and Gynaecologist of Canada (SOGC Clinical Practice Guidelines number 148).[17-19]

1.3.1 Classification of instrumental delivery

Instrumental deliveries are classified primarily by the station and position of the fetal head. (Table 1.2) The station of the fetal head refers to descent of the leading part of the skull within the birth canal in relation to the maternal ischial spines.[20] The position refers to the orientation of the fetal occiput (in a vertex presentation) in relation to the maternal pubic symphysis. The fetal station must be at the level of the ischial spines (station 0) or below to fulfil the criteria for safe instrumental delivery. In most circumstances this correlates with zero fifths of the fetal

head palpable abdominally (a deeply engaged presenting part). The exception is with a deflexed occipito-posterior position at the level of the ischial spines, where there may be up to (but no more than) one fifth of the fetal head palpable abdominally for the classification to be considered mid-cavity and therefore potentially suitable for instrumental delivery.[21] Occipito-anterior positions are less challenging for instrumental delivery than occipito-transverse or occipito-posterior positions (fetal malpositions, requiring rotation). Instrumental deliveries are further sub-classified into those that require or do not require rotation.

A standard classification should be used to enable clear communication, benchmarking, audit and comparisons between studies. The Royal College of Obstetricians and Gynaecologists (RCOG) uses criteria adapted from the guideline of the American College of Obstetricians and Gynecologists (ACOG). (Table 1.2) [17] [18] The first important stage in training obstetricians for instrumental delivery is to ensure consistency and accuracy in assessment of the station and position of the fetal head and therefore in classification of the planned instrumental delivery. The supervising obstetrician should be confident that this competency has been achieved before indirect supervision is provided.

Table 1.2 Classification for operative vaginal delivery.[18]

Outlet	Fetal scalp visible without separating labia Fetal skull has reached the pelvic floor Sagittal suture is in the anterio-posterior diameter or right or left occiput anterior or posterior position (rotation does not exceed 45°) Fetal head is at or on the perineum
Low	Leading point of the skull (not caput) is at station plus 2cm or more and not on the pelvic floor Two subdivisions: • rotation of 45° or less from the occipito-anterior position • rotation of more than 45° including the occipito-posterior position
Mid	Fetal head is no more than 1/5th palpable per abdomen Leading point of the skull is above station plus 2cm but not above ischial spines Two subdivisions: • rotation of 45° or less from the occipito-anterior position • rotation of more than 45° including the occipito-posterior position
High	Not included in the classification as operative vaginal delivery is not recommended in this situation where the head is 2/5th or more palpable abdominally and the presenting part is above the level of the ischial spines

Adapted from the American College of Obstetricians and Gynecologists 2011[17]

1.3.2 Indications

Instrumental deliveries are performed when delivery needs to be expedited and may be indicated for conditions of the fetus or the mother or both. (Table 1.3) The overall premise should be to offer instrumental delivery when the benefits outweigh the risks. [21]

The most common indication for instrumental delivery is inadequate progress in the second stage of labour. In nulliparous women, a delay in the second stage is diagnosed when birth is not imminent after three hours, with regional anaesthesia, from the diagnosis of full cervical dilatation (total passive and active second stage) or after two hours without regional anaesthesia. [22] In multiparous women, this is diagnosed when delivery is not imminent after two hours with regional anaesthesia (total passive and active second stage) or one hour without regional anaesthesia. [22] It should be noted that where a woman has been pushing effectively for 30 to 40 minutes with no discernible progress, earlier assessment may be appropriate as a fetal malposition, malpresentation or cephalo-pelvic disproportion may be present.[21] In these circumstances a senior assessment should be sought with regards to ongoing management, rather than persisting with two hours of unproductive pushing that may exacerbate the problem.[21]

Suspected fetal compromise, as revealed by a non-reassuring or pathological fetal heart rate pattern on cardiotocography, is also a common indication for instrumental deliveries.[22] Special circumstances include suspected sepsis (maternal pyrexia, maternal tachycardia, fetal tachycardia, foul smelling amniotic fluid), intrauterine growth restriction, preterm labour, intrapartum vaginal bleeding, previous caesarean section and fetal heart rate abnormalities in a second twin. In these circumstances the fetal reserve may be diminished and the decision to intervene should take account of the potential for a more rapidly deteriorating acid-base status in the fetus.[21]

Maternal conditions that indicate instrumental delivery are most commonly maternal distress or fatigue. Less common medical conditions that preclude prolonged maternal effort include maternal cardiac disease, hypertensive crisis, cerebrovascular disease or respiratory compromise.[21]

Most indications are relative and there may be more than one indication to perform an instrumental delivery, for example in cases where there is maternal fatigue with suspected fetal compromise after one hour of pushing. When to intervene is therefore a balance of risks and benefits and will depend on individual clinical circumstances and maternal preferences. [18]

1.3.3 Contraindications

Instrumental deliveries are contraindicated when the cervix is less than ten centimetres dilated and when the fetal head is not deeply engaged (station above the ischial spines and/or more than one fifth of the fetal head palpable abdominally).[18] (Table 1.4) Instrumental deliveries are relatively contraindicated in cases of fetal bleeding disorders (e.g. suspected thrombocytopenia) or a predisposition to fracture (e.g. osteogenesis imperfecta). (Table 1.3) However in some circumstances, it may be more traumatic for the fetus to be delivered abdominally, for example in advanced labour with the fetal head deep in the pelvis.[18] In cases of blood-borne viral infections such as Hepatitis B/C and HIV, instrumental deliveries are not contraindicated but as there is an increased risk of fetal abrasion or scalp trauma, it is sensible to avoid potentially difficult mid-cavity or rotational procedures. [18]

Forceps can be used for some malpresentations such as face presentation in a mento-anterior position or for the after-coming head of a breech.[18 21] In cases of brow or a mento-posterior face presentation, instrumental delivery should not be attempted unless the brow can be flexed to a vertex presentation or deflexed to a face presentation and the mento-posterior face presentation requires rotation to mento-anterior which can be achieved manually.[21] These procedures require specialist expertise and are not suitable for novice practitioners.

Vacuum deliveries are contra-indicated for preterm deliveries at gestations of less than 34 completed weeks as there is a risk of cephalhaematoma, intracranial haemorrhage, subgaleal haemorrhage and neonatal jaundice.[18] It has also been suggested that the vacuum extractor should be avoided at less than 36 completed weeks gestation because of the risk of subgaleal and intracranial haemorrhage.[23 24] However, there is insufficient evidence to establish the safety of the vacuum extractor at gestations between 34 and 36 weeks. As a general rule, most obstetricians avoid vacuum delivery at gestations less than 36 completed weeks.

Maternal consent is a prerequisite for instrumental delivery, therefore refusal to consent to instrumental delivery is a contra-indication.[18] However, the alternatives and associated risks must be clearly outlined to the woman and her partner.[21] Prolonged pushing may be detrimental to the fetus, particularly in cases of suspected fetal compromise or uncertain fetal reserve. The woman needs to be aware that there is increased maternal and neonatal morbidity associated with caesarean section at full dilatation when performed with the head low in the pelvis and this may be more traumatic than an instrumental delivery. [15] Ideally these discussions should take place in the antenatal period, or earlier in the course of the labour if limitations have been expressed in the birth plan.[21] A similar approach is required where a woman has stated a preference for a particular choice of instrument.

Table 1.3 Indications and contra-indications for instrumental deliveries.[18 22]

Type	Indication (relative)	Contra-indication (relative)	Instrument- specific contraindication
Inadequate progress	Nulliparous: lack of continuing progress for 3hrs* with regional anaesthesia or 2hrs* without regional anaesthesia Multiparous: lack of continuing progress for 2hrs* with regional anaesthesia or 1hr* without regional anaesthesia	Suspected cephalo-pelvic disproportion	
Fetal	Presumed fetal compromise	Predisposition to fracture (e.g. osteogenesis imperfecta) Malpresentation (brow, face mento-posterior)	**Vacuum:** Gestation < 34-36 weeks Face presentation Fetal bleeding disorders **Mid-cavity/ Rotational forceps:** Fetal bleeding disorders
Maternal	Fatigue/exhaustion Medical conditions that preclude maternal effort such as cardiac disease, hypertensive crisis, cerebrovascular disease	Refusal to consent	

*total of active and passive second stage of labour

1.3.4 Pre-requisites for instrumental delivery

Before performing an instrumental delivery, a careful assessment of the clinical situation, clear communication with the mother, partner and healthcare personnel, and expertise in the planned procedure are essential.[18] (Table 1.4)

The indication for the procedure should be established and clearly documented. Informed consent should be obtained from the woman after explicit counselling regarding the indication, advantages and disadvantages, and nature of the procedure.[18] This may be difficult to achieve in what is essentially an emergency setting, but information should be given to the woman between contractions and where possible the birth plan of the mother should be taken into account and discussed.[21] The principles of obtaining valid consent in labour should be followed and consent advice from the RCOG on instrumental deliveries should be followed. [18]

The alternatives to an instrumental delivery: continued pushing or caesarean section should also be discussed with the woman, outlining the advantages and disadvantages of each option. For instrumental deliveries in the delivery room, verbal consent should be obtained and clearly documented in the notes, with an endeavour to obtain written consent when possible. However, for instrumental deliveries in theatre, written consent should be obtained. [18]

A systematic abdominal and vaginal examination should be performed to establish the size of the fetus, engagement, position, station and attitude of the fetal head, the pelvic dimensions and the adequacy of analgesia, as outlined in section 1.3.5. For low or outlet deliveries, infiltration of local anaesthetic into the perineum may suffice but a pudendal block may be required.[21] For mid-cavity deliveries, especially rotational procedures, regional anaesthesia (epidural or spinal) is optimal. Prior to the procedure, the bladder should be emptied by 'in and out' catheterisation to reduce the risk of urethral or bladder damage.[18] If an indwelling catheter is in situ, the bulb should be deflated.

The operator should have the appropriate knowledge, skills and experience required.[18] Trainees should be adequately supervised by more senior obstetricians, especially in cases of mid-cavity or rotational deliveries. Instrumental deliveries can be associated with maternal and fetal morbidity, particularly in cases of sequential use of instruments (vacuum followed by

forceps) and failed instrumental deliveries (vacuum and/or forceps followed by caesarean section), which are often related to inexperience of the operator. [15 25]

Table 1.4 Pre-requisites for instrumental deliveries.[18]

Full abdominal and vaginal examination	• Head is no more than 1/5th palpable per abdomen. • Station at spines or below. • Cervix is fully dilated and membranes ruptured. • Diagnosis of the exact fetal head position (to ensure proper placement of instrument). • Assessment of caput and moulding (irreducible moulding may indicate cephalo-pelvic disproportion). • Pelvis is deemed adequate.
Preparation of mother	• Clear explanation should be given and informed consent obtained. • Appropriate anaesthesia. • Maternal bladder should be emptied. In-dwelling catheter should be removed or balloon deflated. • Aseptic technique.
Preparation of staff	• Operator should have knowledge, experience and skill necessary. • Adequate facilities are available (appropriate equipment, bed, lighting). • Back-up plan in place in case of failure to deliver. When conducting mid-cavity deliveries, theatre staff should be immediately available to allow a caesarean section to be performed without delay (less than 30 minutes). A senior obstetrician competent in performing mid-cavity deliveries should be present if a junior trainee is performing the delivery. • Anticipation of complications that may arise (e.g. shoulder dystocia, postpartum haemorrhage). • Personnel present that are trained in neonatal resuscitation.

* Adapted from the Society of Obstetricians and Gynaecologists of Canada 2004.[19]

1.3.5 Assessment prior to instrumental delivery

General considerations

An open and positive first impression is important in building rapport and trust with the woman and her carer's. [21] The obstetrician should attempt to gauge the atmosphere and morale within the room and respond sensitively and with empathy to the woman's situation. Birth partners will sometimes advocate on behalf of the woman but care should be taken especially if there are communication difficulties.[21] A professionally trained interpreter should be used wherever possible for women who speak a different language or who are hearing impaired.

Clinical history to date

Before attempting an instrumental delivery, it is important to review the woman's medical and antenatal history carefully to exclude any contraindications to instrumental delivery and to anticipate any potential complications (e.g. cephalo-pelvic disproportion, shoulder dystocia, neonatal injury or postpartum haemorrhage).[21] The past obstetric history, presence of diabetes, antenatal diagnosis of fetal concerns (abnormal growth, oligohydramnios, abnormal fetal Doppler studies, fetal anomaly) and maternal blood results (serology, anaemia, rhesus) may be of particular relevance. The partogram should be assessed, looking at progress in the first stage of labour, efficiency of uterine contractions and the use of oxytocin. The maternal body mass index, vital signs and hydration status should be noted. Particular attention should be paid to a maternal pyrexia or tachycardia, hypertension or haematuria. [21]

Review of the fetal status

The fetal status should be assessed as a matter of priority as this will determine the need for urgency in terms of intervention. Women identified as high risk antenatally or in labour should be offered continuous electronic fetal monitoring (EFM) with cardiotocography (CTG).[22] (Table 1.5) The four features of the fetal heart recording (baseline fetal heart rate, variability, accelerations, decelerations) and the uterine contractions (care should be taken to record uterine activity adequately) should be noted to classify the trace as normal, suspicious or pathological. [22] Any fetal blood samples (FBS) taken in the first or second stage of labour should also be noted. Meconium stained liquor should be considered as a possible sign of fetal compromise although this may be a normal finding in prolonged pregnancies.[21] Absence of liquor should also be considered abnormal and may reflect undetected placental insufficiency.

A degree of urgency is required for CTGs that are classified as pathological and for fetal blood samples with pH below 7.20. [22]

Table 1.5 Maternal and fetal factors where continuous electronic fetal monitoring is recommended.[22]

Maternal	Fetal
Pre-eclampsia	Intra-uterine growth restriction (IUGR)
Diabetes	Prematurity (gestation <37weeks)
Prolonged rupture of membranes >24 hrs	Meconium stained liquor
Previous caesarean section	Abnormal Doppler artery velocimetry
Antepartum haemorrhage or vaginal bleeding in labour	Oligohydramnios
Induced labour	Breech presentation
Prolonged pregnancy (>42 weeks)	Multiple pregnancies
Maternal pyrexia	
Epidural analgesia	
Oxytocin augmentation	
Maternal medical disorders	

Abdominal examination

A systematic abdominal examination using Leopold's four manoeuvres should be undertaken.[21] The fetal lie and presentation should be confirmed and the fetal size should be assessed clinically. A small for gestational age fetus is an important finding in terms of potential diminished fetal reserve in labour and also ease of delivery.[21] A clinically large fetus may be associated with cephalo-pelvic disproportion and failed instrumental delivery or with shoulder dystocia and subsequent postpartum haemorrhage.[21] Engagement of the fetal head occurs when the widest transverse diameter of the fetal head (biparietal diameter- BPD) passes through the pelvic inlet.[20] Engagement of the fetal head should be ascertained abdominally and is described in terms of 'fifths' palpable, depending on how much of the head is palpable abdominally. Instrumental deliveries should only be attempted where no more than one fifth of the head is palpable abdominally and in the majority of cases there will be

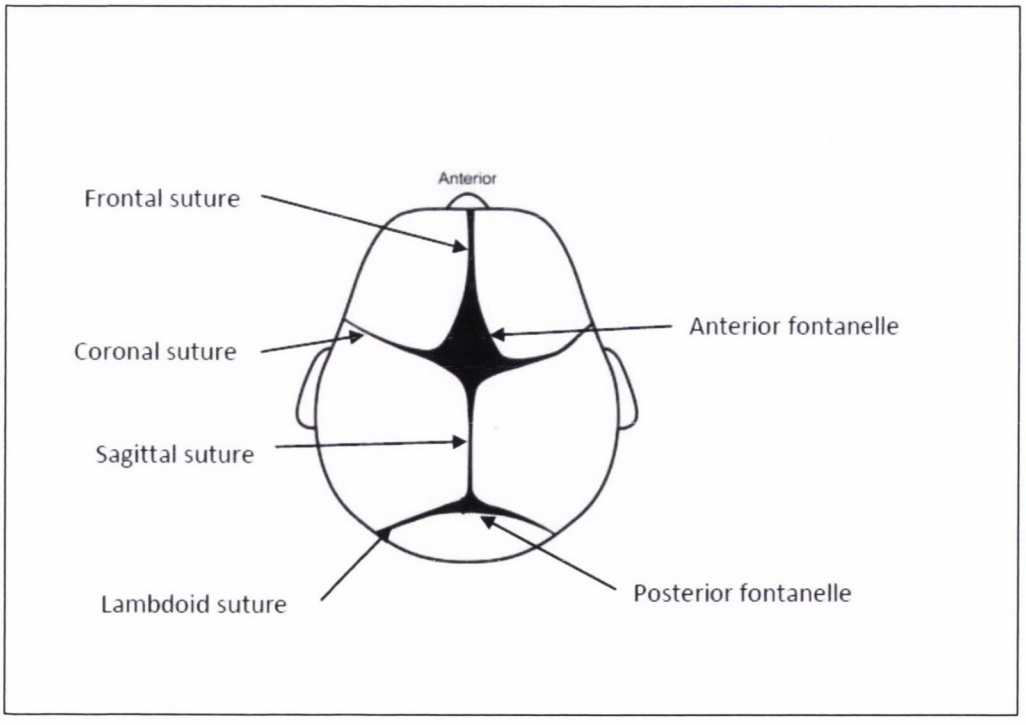
zero fifths palpable abdominally.[18] The position of the fetal back should also be sought to help define the position of the fetal head, although in practice this is often difficult.[21]

Vaginal examination

A systematic vaginal examination should be performed to confirm full cervical dilatation, a cephalic vertex presentation, the position, station and attitude (degree of flexion) of the fetal head, the degree of caput (scalp swelling) and moulding (closure and overlap of the skull bones), and to form a subjective impression of the pelvic dimensions. In addition it is extremely helpful to assess whether rotation (if required) and descent occur during a contraction with active pushing.[21]

Palpation of each fontanelle (anterior and posterior) and the suture lines of the fetal skull should be carried out to determine the fetal head position as accurately as possible. (Figures 1.1, 1.2) However, digital vaginal examination is not always accurate, especially in the presence of caput, moulding and asynclitism. [26 27]

Figure 1.1 Landmarks of the fetal skull.



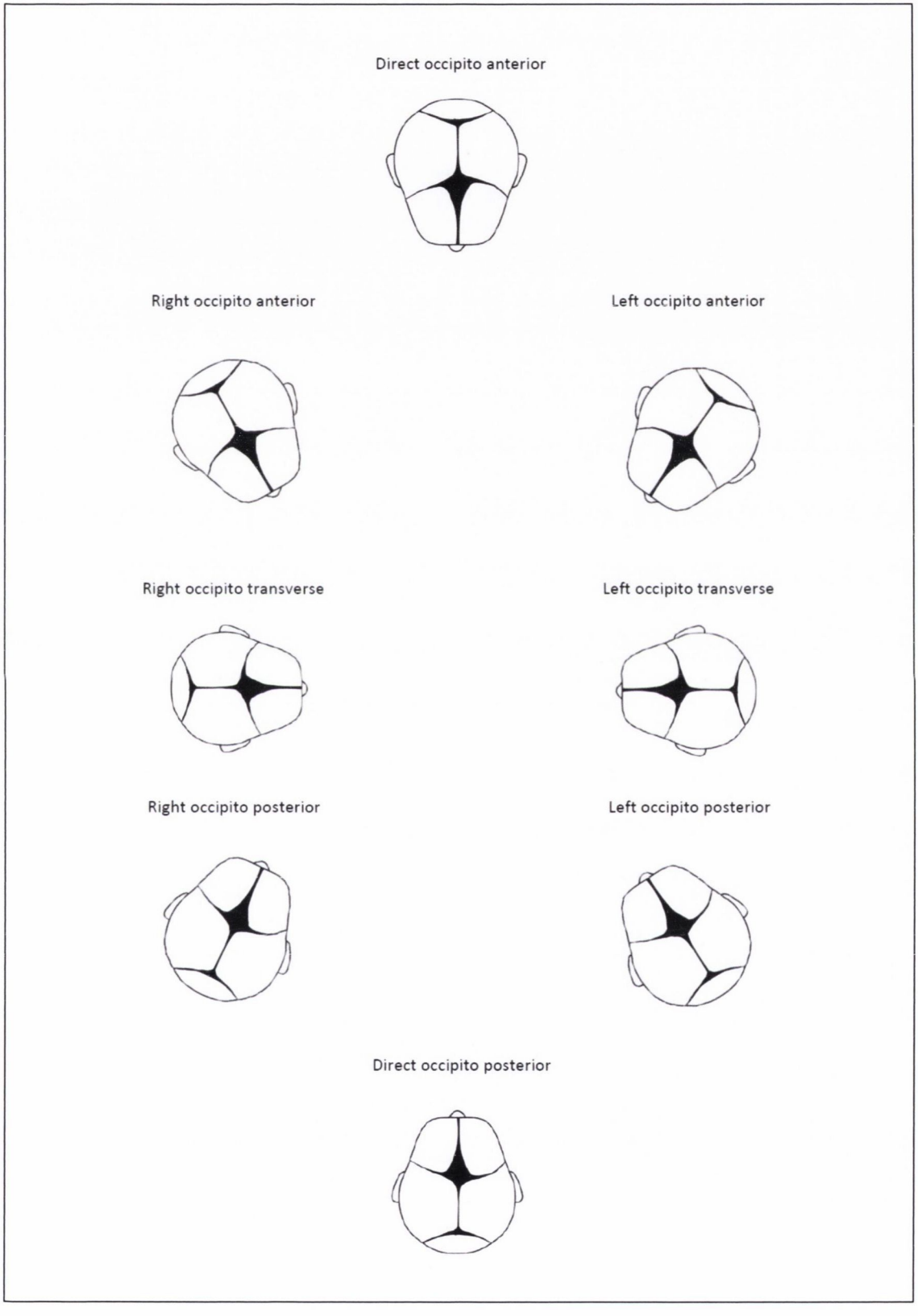
The station of the fetal head should be ascertained routinely on vaginal examination. However, similar to inaccuracy of the fetal head position, there is evidence that vaginal assessment of the station of the fetal head is not always reliable. [28]

The position and station of the fetal head are important indicators of the level of skill required of the operator and will also have an impact on the choice of instrument and where the delivery is carried out (labour room versus operating theatre).[21] Rotation and descent of the presenting part with maternal effort during a contraction is a good prognostic factor for successful instrumental delivery, and cases with minimal or no descent should be treated with caution.[21] Similarly, the presence of marked caput or moulding of the fetal skull bones should be established, as irreducible moulding may be a warning sign for cephalo-pelvic disproportion.[21]

Observation period

Observation of the maternal effort and the woman's psychological status during active pushing often helps the operator decide when to intervene and what instrument to use.[21] The perspective of the woman and the midwife caring for her will assist the decision-making process. This may not be possible in cases of emergency such as fetal bradycardia.

Figure 1. 2 Fetal head position.[21]



1.3.6 Fetal head malpositions

The fetal head enters the pelvis in an occipito-transverse (OT) position and subsequently rotates to an occipito-anterior (OA) position during the cardinal movements of labour. [20] However, in 15% of labours, the fetus enters the pelvis in the occipito-posterior (OP) position.[29] Most of these will rotate to an anterior position during labour but some persist, and additionally, some of the fetuses that enter the pelvis in the OA or OT position can rotate and deliver in the OP position. [29] Overall, the incidence of OP at delivery is estimated to be around 5% with higher incidences in nulliparous women. [29-33] Factors associated with the OP position are summarised in Table 1.6. The incidence of persistent OT position (termed deep transverse arrest) is more scarcely reported but causes similar problems to persistent OP positions. [31]

Fetal head malpositions (occipito-transverse and occipito-posterior) in labour are associated with prolonged first and second stages of labour, oxytocin augmentation, use of epidural analgesia, chorioamnionitis, assisted vaginal delivery, third and fourth degree perineal lacerations, caesarean delivery, excessive blood loss, and postpartum infection. [25 31 33-36] Trial of instrumental delivery in theatre is twice as likely to fail in OP positions. [15 25 37 38] Moreover, failure to identify fetal head malpositions (especially the occipito-posterior position) before instrumental deliveries is one of the factors that increases the likelihood of sequential use of instruments and caesarean section after a failed instrumental delivery.[34]

Table 1.6 Factors associated with the occipito-posterior position.[30-33 35]

Factors	Reference
Maternal factors	
African- American ethnicity	Cheng *et al*
Maternal age (older – especially ≥ 35 years)	To *et al*, Cheng *et al*
Maternal height (shorter)	To *et al*
High BMI	To *et al*
Nulliparous	To *et al*, Ponkey *et al*, Fitzpatrick *et al*
Neonatal factors	
Increasing fetal weight (especially ≥ 4.0 kg)	To *et al*, Sizer *et al*
Labour factors	
Epidural analgesia	To *et al*, Sizer *et al*, Fitzpatrick *et al*

1.4 Instrumental delivery in theatre

Instrumental deliveries that are anticipated to have a higher rate of failure should be carried out in a place where immediate safe recourse to caesarean section can be undertaken.[18] Fetal hypoxic-ischaemic injuries have been attributed to delay between a failed instrumental delivery and a caesarean section. Failure rates are higher for mid-cavity deliveries, women with a high body mass index (>30 kg/m2), babies with a birth weight over 4000g and malpositions of the fetal head, in particular the occipito-posterior position.[15 25 34]

Transfer to theatre for an instrumental delivery with preparations in case of a caesarean section has the advantages of facilitating optimal anaesthesia, enhanced clinical assessment, and where appropriate hospital protocols are in place, senior support for the delivery. There will be a delay in the decision to delivery interval associated with transferring a woman to theatre compared to delivering in the labour room, but this has not been found to be associated with adverse neonatal outcomes.[39] The decision to delivery interval for carrying out an instrumental delivery in a labour room has been reported to be 15 minutes compared to 30 minutes for deliveries in theatre (including successful instrumental deliveries, caesarean sections after failed instrumental delivery and immediate caesarean sections). [39] The decision to transfer the woman to theatre should balance the benefits in terms of safety, should instrumental delivery fail, with the potential negatives in terms of delay in the decision to delivery interval and the additional anxiety for the woman and her partner.

1.5 Choice of instruments

The choice of forceps or vacuum extractor will depend on the clinical circumstances and on the operator's competencies and personal preferences. Forceps delivery may be preferred in instances where there is diminished maternal effort (e.g. maternal exhaustion, dense epidural block, general anaesthesia), for preterm deliveries (< 34-36 weeks gestation), for rotational deliveries, after a failed attempt at vacuum extraction, for delivery of the after-coming head in breech deliveries and for low-cavity deliveries with suspected fetal coagulopathy or thrombocytopenia. A vacuum delivery may be preferred where analgesia is limited, for low-cavity or outlet deliveries, and for rotational deliveries in preference to manual rotation or rotational forceps. The relative merits of vacuum extraction and forceps have been explored in a Cochrane systematic review of randomised controlled trials and are summarised in Table 1.7. [10]

Table 1.7 Relative merits of vacuum extraction and forceps. [10]

	Advantages	Disadvantages
Vacuum extractor	Less maternal perineal and vaginal trauma	Cephalhaematoma more likely
	Less analgesia required	Retinal haemorrhage more likely
		Use of sequential instruments more likely
Forceps	Successful vaginal birthmore likely with single instrument	Maternal perineal and vaginal trauma more likely
		Increased analgesia requirements
		Neonatal facial nerve palsy more likely

1.5.1 Forceps

There are over 700 different types of forceps and there have been no randomised controlled trials comparing forceps types. (Figure 1.3) The three main types (outlet, mid-cavity and rotational) can be used in specific situations but require differing levels of expertise. [3] Forceps are more likely to be successful at completing vaginal birthwith a single instrument than vacuum. [10 34] Forceps are usually faster than vacuum extraction, which may be critical in cases of fetal bradycardia, cord prolapse or placental abruption. [40] However, compared to vacuum, forceps are associated with a higher risk of vaginal trauma, third and fourth degree tears, facial injuries to the neonate and increased analgesia requirements. [10] Rotational delivery with Kiellands forceps carries additional potential risks and requires specific expertise and training. Manual rotation followed by direct traction forceps may be preferred depending on the operator's skills and experience. [18]

Figure 1.3 a. Non-rotational forceps, b. Rotational forceps (Kielland's)

a.



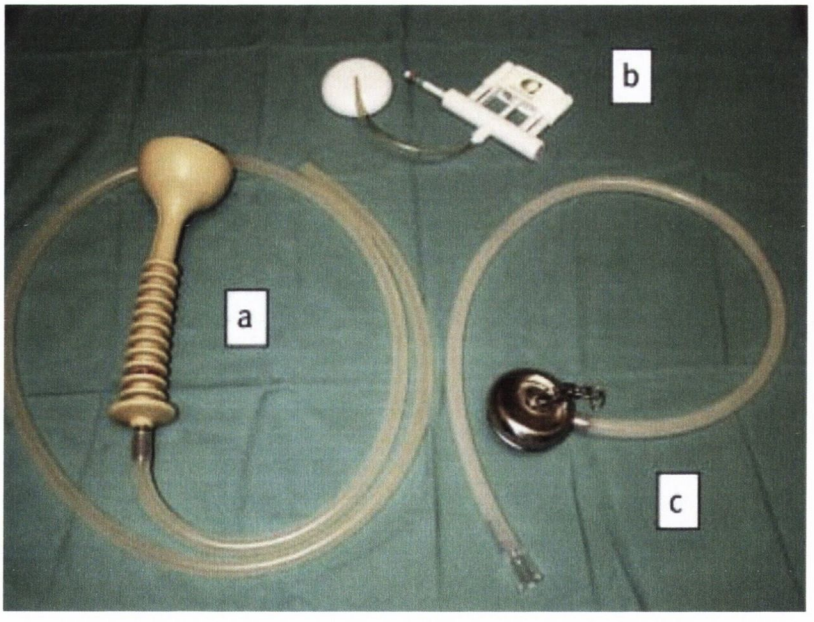
b.



1.5.2 Vacuum

Vacuum cups can be metal, plastic or silicone. (Figure 1.4) The vacuum extractor is being used increasingly as the instrument of first choice. This is likely to reflect the need for less analgesia/anaesthesia and the lower incidence of maternal pelvic floor trauma. [10] However, compared to forceps delivery, vacuum extraction is associated with an increased risk of neonatal cephalhaematoma, retinal haemorrhage and maternal concern about wellbeing of the neonate. [10] A Cochrane systematic review showed that the metal cup was more likely than soft cups to result in a successful vaginal birth with no difference in maternal perineal trauma. [10] However, the metal cup was associated with an increased risk of neonatal bruising, cephalhaematoma and scalp injury.[10] Two randomised controlled trials comparing a disposable vacuum device (Kiwi™ OmniCup) with standard vacuum cups reported high rates of instrument failure requiring sequential use of forceps (20 to 30%) with a significantly higher incidence of failure with the disposable device. [41 42]

Figure 1.4 a. Silastic cup (silicone); b. Kiwi™ Omnicup (plastic); c. Metal cup.



1.6 Complications of instrumental delivery

Complications are inevitable to some degree with any operative procedure. Appropriate use of instrumental delivery by well trained obstetricians should minimise the risk of complications and alleviate the risks to the mother and baby of delaying birth. In fact, increased morbidity is mainly associated with excessive pulls, sequential use of instruments and caesarean section after a failed instrumental delivery. [25]

1.6.1 Maternal morbidity

Poorly conducted instrumental deliveries are associated with an increased incidence of extensive perineal tears, vaginal wall and cervical lacerations, postpartum haemorrhage, prolonged hospital stay, long term pelvic floor sequelae and psychological distress. [10 43]

1.6.1.1 Perineal tears

The risk of extensive perineal tear (third and fourth degree tear) at spontaneous vaginal deliveries is estimated at 1%. [44] Instrumental deliveries, particularly forceps deliveries, increase that risk to up to 7%. [10 15] Vaginal trauma is also reported to be increased with forceps deliveries.[10] With forceps deliveries, the risk of perineal and vaginal trauma is increased with or without the use of an episiotomy. [10] Moreover, there is a higher risk of extensive perineal tears involving the sphincter at instrumental deliveries when the fetal head is in the OP position, after adjusting for variables such as body mass index, race, nulliparity, length of second stage, episiotomy, birth weight, head circumference. [32 45]

Table 1.8 Classification of perineal tears.[44]

First degree	Injury to perineal skin only
Second degree	Injury to perineum involving perineal muscles but not involving the anal sphincter
Third degree	Injury to perineum involving the anal sphincter complex:
3a	Less than 50% of external anal sphincter torn
3b	More than 50% of external anal sphincter torn
3c	Both the external and internal anal sphincters torn
Fourth degree	Injury to perineum involving the anal sphincter complex (external and internal anal sphincters) and anal epithelium

1.6.1.2 Post- partum haemorrhage (PPH)

PPH remains one of the leading causes of maternal mortality and morbidity worldwide. [43 46] It is defined as estimated blood loss of more than 500mls within 24 hours of delivery and can be further classified as major PPH when blood loss exceeds 1,000 mls. [43] Trauma of the vaginal tract, as seen at instrumental deliveries, is a risk factor for PPH. [43] In fact, instrumental deliveries are associated with a two-fold increase in the risk of PPH compared to spontaneous vaginal deliveries (odds ratio 2, 95% confidence interval 1.56 – 2.07). [43 47-53]

1.6.1.3 Urinary and anal incontinence

The risk of maternal pelvic floor injury is increased with any type of vaginal birthcompared to caesarean section but the risk is higher with instrumental deliveries. [50-52] Typically this presents as urinary or anal incontinence, or both, months to years after giving birth. Women who undergo instrumental deliveries are more likely to have symptoms suggestive of urinary incontinence at 6 weeks, 1 year and 3 years after the delivery when compared to women who have had caesarean sections at full dilatation. [50 51] Similarly, symptoms of anal incontinence are more frequent in women who undergo instrumental deliveries, in particular forceps delivery, compared to caesarean deliveries. [52]

1.6.1.4 Psychological effect

Women who have an operative delivery in the second stage of labour, be it an instrumental delivery or caesarean section, often feel unprepared for these types of deliveries and can experience anxieties regarding subsequent deliveries. [53] In fact, instrumental deliveries can create a sense of failure in women and have negative psychological effects. [10] Birth choices are affected by many factors including cultural background, ethnicity and socio-economic status. (10) Occasional patients request delivery by elective caesarean section in first pregnancies without any specific indication or risk factors and a minority of patients request delivery by caesarean section rather than instrumental vaginal delivery in the event of intervention being required in the second stage of labour. (Add NICE guideline ref) [10] However, there is evidence that women who have vaginal deliveries (albeit with assistance) tend to be more satisfied with the birth than those who have emergency caesarean sections. [16]

1.6.2 Neonatal morbidity

For the neonate, poorly conducted instrumental deliveries can be associated with traumatic injuries, depressed skull fractures, hypoxic-ischaemic encephalopathy, cerebral haemorrhage and rarely perinatal death.

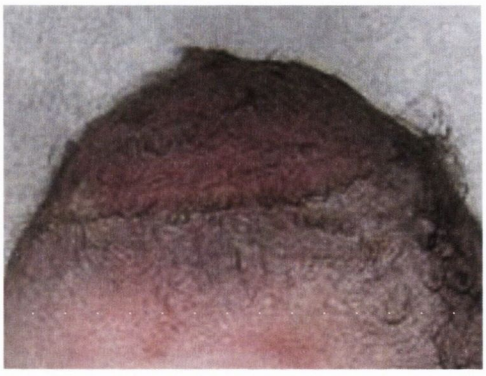
1.6.2.1 Traumatic injuries

Most bruising and superficial lacerations resolve within days of delivery. (Figure 1.5) Forceps delivery is associated with increased risk of bruising, lacerations and facial injuries but these can also occur with vacuum delivery. (Figure 1.6) [54]

The risk of severe fetal trauma (cerebral haemorrhage, fracture, laceration and brachial plexus injury) is increased with instrumental delivery compared to spontaneous vaginal birth but is still low. [15 55] The incidence of depressed skull fractures is higher at instrumental deliveries compared to spontaneous vaginal deliveries. [8] Furthermore, misdiagnosis of the fetal head position with subsequent asymmetrical application of forceps is one of the main reasons for higher incidences of fetal skull fractures associated with forceps. [8]

Figure 1.5. a. Swelling on fetal head after vacuum delivery (chignon) b. Forceps marks. [56]

a.



b.



Figure 1.6. Traumatic injury after forceps delivery.[56]

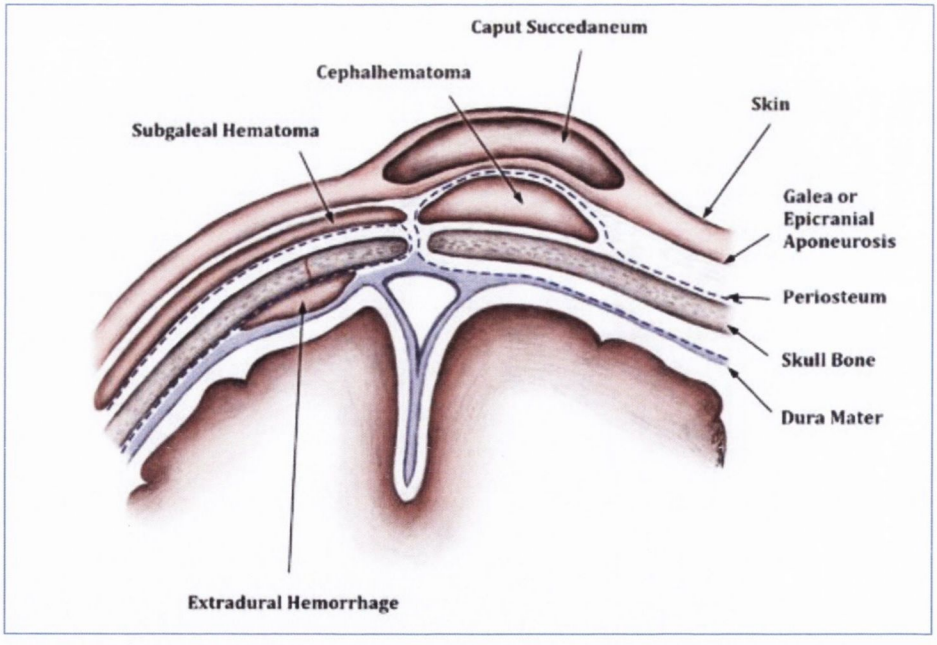


1.6.2.2 Cerebral haemorrhage

Cephalhaematomas occur when there is bleeding into the fetal scalp due to separation from the underlying structures. They occur more commonly with vacuum delivery than forceps as previously mentioned.[10] Subgaleal haemorrhage is bleeding in the potential space between the skull periosteum and the scalp galea aponeurosis. Once again, the risk of subgaleal haemorrhages is particularly increased with vacuum delivery. [10 57 58]

Intracranial haemorrhage includes subdural, subarachnoid, intraventricular and intra-parenchymal haemorrhages. Towner *et al* reported that risk of intracranial haemorrhage is increased to 1 in 860 with vacuum delivery and 1 in 664 with forceps delivery compared to 1 in 1900 deliveries with spontaneous vaginal deliveries. [59] Another large American cohort study reported increased risk of intracranial haemorrhage similar with instrumental deliveries compared to spontaneous vaginal birthbut they found this risk to be similar whether vacuum or forceps was used.[2]

Figure 1.7 Anatomical location of cephalhaematoma, subgaleal haematoma and subdural haemorraghe.[60]



1.6.2.3 Shoulder dystocia

Shoulder dystocia is defined as a vaginal cephalic birth that requires additional obstetric manoeuvres to deliver the fetus after the head has delivered and gentle traction has failed.[61] It occurs in 0.2 – 2.0% deliveries and can be associated with extensive maternal and neonatal morbidity.[61 62] In particular, shoulder dystocia is associated with increased risk of postpartum haemorrhage and extensive perineal tears for the mother.[61] For the neonate, there is an increased risk of brachial plexus injury, intrapartum asphyxia leading to neurological impairment and even death. [61 62]

Instrumental delivery is an independent risk factor for shoulder dystocia. [2 61-63] Other independent risk factors include fetal macrosomia, maternal height and weight, diabetes mellitus, prolonged first and second stages of labour, induction of labour and oxytocin augmentation of labour. [61-63]

1.6.2.4 Death

Towner *et al* analysed data on 583,340 infants with birthweight of 2.5 to 4.0 kg born to nulliparous women in the early 1990's in California. [59] Their aim was to quantify risks associated with different modes of delivery including spontaneous vaginal birth, vacuum delivery, forceps delivery, vacuum followed by forceps delivery, caesarean section without labour, caesarean section in labour and caesarean section after failed instrumental delivery. They reported the risk of neonatal death before discharge as 0.2 per 1000 infants born by spontaneous vaginal birth, 0.3 per 1000 infants born by vacuum delivery, 0.5 per 1000 infants born by forceps delivery, 0.6 per 1000 infants born by vacuum followed by forceps delivery and 0.8 per 1000 infants born by caesarean section (regardless of whether caesarean section was in labour or not).[59]

Another American study of 11,639,388 neonates born after 35 weeks gestation in New Jersey reported the incidence of neonatal death at spontaneous vaginal birth to be 3.7 per 10,000 deliveries compared to 4.7 per 10,000 deliveries at vacuum delivery and 5.0 per 10,000 deliveries for at forceps delivery.[2]

1.7 Failed instrumental delivery

The likelihood of failed instrumental delivery increases with failure to identify fetal head malpositions (especially the occipito-posterior position) and/or misjudging the fetal size (especially neonatal head circumference >37cm) or ignoring signs of cephalo-pelvic disproportion. [34] Furthermore, fetal head station and maternal obesity may also contribute to failed instrumental delivery. [15] The consequences of failed instrumental delivery are sequential use of instruments (the use of vacuum followed by forceps) or second stage caesarean section, which are both associated with increased maternal and neonatal morbidities. [34]

Sequential use of instruments is associated with greater maternal morbidity when compared to the use of a single instrument. These include higher risk of anal sphincter tear (third and fourth degree tears), postpartum haemorrhage and urinary incontinence. [2 34] Additionally, sequential use of instruments is associated with greater neonatal morbidity, in particular low umbilical artery pH (<7.1), scalp trauma, intracranial haemorrhage, admission to the neonatal care unit and neonatal death. [2 34 59] Towner *et al* reported an increased risk of intracranial haemorrhage of 1 in 277 births with sequential use of instruments compared to a risk of 1 in 854 with successful vacuum delivery alone.[59] They also reported an increased risk of seizures of 1 in 400 with sequential use of instruments compared to 1 in 854 with successful vacuum delivery alone. [59]

Similarly, caesarean sections in the second stage are associated with increased risk of maternal and neonatal morbidity. [15] In particular, caesarean sections after a failed attempt at instrumental delivery can be extremely challenging with impaction of the fetal head and the risk of intra-operative trauma. This includes extension of the uterine incision, bladder and ureteric trauma. [15 25 64] There is also a higher risk of massive obstetric haemorrhage requiring blood transfusion and prolonged hospital stay with these deliveries. [5 25] Furthermore, there is a higher risk of perinatal asphyxia and admission to the neonatal intensive care unit in neonates delivered by caesarean section at full dilatation. [15 64] Towner *et al* reported an increased risk of intracranial haemorrhage of 1 in 333 births at caesarean section after failed instrumental delivery compared to a risk of 1 in 854 with successful vacuum delivery. [59] They also reported the risk of seizures in babies delivered by caesarean section after failed instrumental delivery as increased to 1 in 142 births.[59]

1.8 Aims and objectives

The overall aim of this research was to assess the use of ultrasound to determine the fetal head position prior instrumental delivery. It examined the existing evidence, explored clinical practice, benchmarking this against clinical guidelines, assessed whether a quick and readily available ultrasound scan could be used to enhance the diagnosis of the fetal head position before instrumental deliveries as a way to reduce the risk of maternal and neonatal morbidity.

There were four distinct components to this research:

1. Literature review - to evaluate existing evidence on the use of ultrasound to diagnose the fetal head position in labour and particularly before instrumental delivery.

2. Questionnaire survey – to establish the current practice of obstetricians in the United Kingdom and Ireland with regards to assessment of women in labour prior to instrumental delivery.

3. Validation study – to compare the diagnosis of the fetal head position in the second stage of labour by ultrasound scan performed by a novice sonographer and by clinical assessment, to that of an expert sonographer (gold standard); and to evaluate the acceptability of ultrasound in the second stage of labour to women and clinicians looking after them.

4. Randomised controlled trial - this compared clinical assessment alone to clinical assessment and an ultrasound scan before instrumental delivery to diagnose the fetal head position.

1.9 Thesis Outline

Chapter 2 reviews studies published to date which examine the use of ultrasound in labour, particularly to diagnose fetal head station and position. The focus was on diagnosis of the fetal head position before instrumental delivery.

Chapter 3 reports a survey of current practice of obstetricians, in the United Kingdom and Ireland, with regards to assessment of women in labour prior to instrumental delivery. The focus of this survey was on current strategies used to enhance diagnosis of the fetal head position. Furthermore, clinicians' views on the role of ultrasound to diagnose the fetal head position in labour were sought.

Chapter 4 reports a validation study designed to compare the diagnosis of the fetal head position in the passive second stage of labour by an ultrasound scan performed by a novice sonographer and by clinical assessment, to that of an expert sonographer (gold standard); and to evaluate the acceptability of ultrasound in the second stage of labour to women and clinicians (obstetricians and midwives).

The findings from the literature review, survey and validation study were used to inform the design of the IDUS (Instrumental Delivery & UltraSound) randomised controlled trial reported in Chapters 5 to 7. The methodology of the IDUS trial is reported in chapter 5, the results are presented in chapter 6 and the trial is discussed in chapter 7.

Chapter 8 summarises the thesis and explores implications for future research and patient care.

Chapter 2 Literature review: The role of ultrasound in labour particularly to diagnose the fetal head position.

2.1 Introduction

This chapter summarises the existing evidence, which will provide context for the subsequent chapters in the thesis. The first section gives an overview of the role of ultrasound in the first and second stages of labour. The second section provides a detailed review of the published literature on the role of ultrasound to determine the fetal head position in labour.

2.2 The role of ultrasound on the labour ward

The value of obstetric ultrasound in the antenatal period is well established. It is used to determine gestational age (first 20 weeks), for prenatal diagnosis of fetal abnormalities (all stages of pregnancy), and to assess fetal growth and well-being (mainly third trimester). As ultrasound machines have become more compact and mobile, they have become more readily available on labour wards and are being increasingly used in labour. While the use of transabdominal ultrasound assessment in labour is the most commonly described approach in the literature, transperineal and translabial approaches have also been reported and more recent techniques, including the use of high resolution imaging (including three-dimensional ultrasound) and pulsed Doppler ultrasound, are being developed. Table 2.1 summarises the current uses of ultrasound on the labour ward.[65]

Table 2.1 Current uses of ultrasound in labour.[65]

Indication	Evidence summary
Confirm presentation	
Singleton (preterm/term)	Limited data
Multiple pregnancy (especially twin 2)	Accepted practice
Clinical uncertainty	Logical basis
Estimate fetal weight/Gestation	
Unbooked patient	Mainly observational data
Threshold of viability	Accepted practice
Preterm/Very Preterm	Accurate for low birth weight
Macrosomic fetus	Inaccurate for macrosomia
Assessment of fetal well-being	
Biophysical profile	Limited data, routine use not justified
Liquor volume	Conflicting data
Doppler velocimetry	Research setting only
Fetal head in the first and second stage of labour	
Engagement & station	Limited data with different techniques used
Descent	Limited data with different techniques used
Position	Mainly observational data, potentially helpful
Cord abnormalities	
Nuchal cord	Limited data
Vasa praevia	Case reports
Other	
Placental location	Accepted practice
Reduced fetal movement	Accepted practice
Confirm intra-uterine death	Logical basis

2.3 Safety and acceptability

The use of ultrasonography in pregnancy is considered to be safe.[66 67] There have been concerns regarding the potential effects of thermal and mechanical effects of ultrasound on the developing fetus, but to date there is no scientific evidence to support them.[67 68] A systematic review found no association with adverse maternal or neonatal outcomes, impaired physical or neurological development, or increased risk for childhood malignancies.[66] However, adequate training of the operator is required to obtain accurate and reliable information.[67] To date, few studies have addressed the acceptability of ultrasound to women in labour. An Italian study evaluating the use of translabial ultrasound in labour reported that none of the 60 participants complained of discomfort but no formal objective assessment of patient acceptability was carried out.[69] Further research is required to establish acceptability prior to routine or more widespread use of ultrasound in labour.

2.4 Overview of ultrasound approaches used in labour

There are several ultrasound approaches described in the literature. The commonest one is a transabdominal ultrasound assessment, which is an approach most obstetricians would be familiar with. The use of transvaginal, transperineal/translabial ultrasounds has also been described in particular to identify fetal head engagement, station and position in labour (see sections 2.6 and 2.7). Of note, although different terminologies are used, transperineal ultrasound, as first described by Barbera *et al*, involves positioning a transducer covered by a sterile glove between the labia majores below the pubic symphysis in a midsagittal position; which is the exact same probe positioning used for translabial ultrasound. [69 70] One presumes that training is required before an operator becomes skilled at these techniques although the literature is currently lacking on this topic. However, a German study of 44 women in the second stage of labour found that transperineal/translabial ultrasound to define the angle of progression was reliable, regardless of the fetal head station or the operator's level of ultrasound experience.[71] These approaches also require high level disinfection along with the use of probe covers to avoid contamination.[72] [73] Another specific limitation of transperineal/translabial ultrasound, when measuring fetal head to perineum distance (see section 2.6.4), relates to the compression of tissues when pressure is applied, which may alter actual distances.

2.5 The role of ultrasound in the first and second stages of labour

Transabdominal, transperineal/translabial and transvaginal ultrasound assessments may be used to diagnose fetal head engagement, descent, station of the presenting part and position in both the first and the second stage of labour. Accurately diagnosing the station and position of the fetal head is critical when the second stage of labour is not progressing well and, in particular, when a decision has to be made to perform an operative delivery (assisted vaginal delivery or caesarean section). Some studies have looked at using ultrasound as a tool to predict abnormal labour and therefore predict mode of delivery.[74-76]

2.6 Engagement and station of the fetal head

Engagement can be clinically ascertained by abdominal examination (when no more than two-fifths of the head are palpable) or on vaginal examination (when the fetal head is at station +0 or below).

A prospective study conducted in France investigated the reliability of vaginal assessment of the fetal head station and engagement by 32 residents and 25 attending physicians using a birth simulator and mannequin equipped with a real-time sensor.[28] All 11 stations as described by the ACOG classification (see Chapter 1) were simulated and presented to each clinician in random order and the clinicians were asked to define the station and engagement in each case. The main outcome was the rate of error between the real fetal head station (given by the sensor) and the clinically determined fetal head station. The mean error was 30% (95% CI 25 – 35%) for residents and 34% (95% CI 27- 41%) for attending physicians, showing that vaginal assessment of head station and engagement is not always reliable.[28]

2.6.1 Transabdominal ultrasound

Intrapartum transabdominal ultrasound may be used to assess engagement and station of the fetal head. A prospective study comparing vaginal examination to transabdominal ultrasound (deemed the gold standard) to determine fetal head engagement in 222 women in labour found a high agreement between the two methods with a rate of 85.6% (95% CI 80.8 – 90.3%).[77] In this study, a line demarcating the pelvic inlet was drawn by placing the ultrasound probe

transversely over the suprapubic area and directing it towards the sacral promontory; the BPD was then obtained and engagement was said to have occurred if the BPD was below this imaginary line. Interestingly, the majority of disagreements occurred with the fetal head at station -1 and no disagreements occurred at station +1 or lower.

2.6.2 Translabial ultrasound

Another technique described to assess engagement of the fetal head is intrapartum translabial/transperineal ultrasound (ITU). Henrich *et al* evaluated the correlation between head descent evaluated on ITU during active pushing and successful vacuum extraction.[78] They assessed the widest fetal head diameter, fetal head movement (head descent) with respect to the 'infrapubic line' (an imaginary line perpendicular to the long axis of the symphysis pubis extending to the dorsal part of the pelvis) and the head direction with respect to the symphysis, referring to occiput anterior position as 'head up' sign.[78] The authors found that objective head descent below the infrapubic line and a 'head up' sign (head pointing ventrally) was a good prognostic factor for successful vacuum extraction (11 out of 20 cases), while no descent was associated with difficult or failed extraction.[78]

A prospective study in Australia of 139 women between 35 and 40 weeks gestation assessed the validity and reproducibility of this technique with abdominal and vaginal examinations.[79] On translalabial ultrasound, head engagement was determined by two different methods which essentially measure the distance between the presenting part and the symphysis pubis. In the first method, a line was drawn through the inferoposterior symphyseal margin and the minimal distance between this line and the presenting part was measured; in the second method, a line vertical to the central axis of the symphysis pubis, placed through the sympheseal margin, was drawn and, again, the minimal distance between this line and the presenting part was measured.[79] This study found that fetal head engagement defined by ITU had a strong correlation with clinical assessment.[79]

Several other studies have demonstrated that ITU can be used to diagnose the station of the fetal head in labour accurately. An Italian study with 60 women in the second stage of labour found that the accuracy of fetal head station diagnosed by ITU was comparable to that of digital examination. [70] Another prospective study, with 50 labouring women, where ITU was used to

determine head station, direction and angle of descent mostly in the second stage of labour, found this technique to be simple and reproducible.[80]

2.6.3 Descent of the fetal head

Angle of progression

ITU has been used to measure the 'angle of progression' (angle between the symphysis pubis and the leading part of the fetal skull) during labour which is deemed a more physiological measure of head descent than head station.[69] As the maternal ischial spines are not visible on ultrasound, the angle between the pubic symphysis and the leading part of the the fetal skull is measured.[81] Barbera *et al* were the first to describe the use of translabial/transperineal ultrasound to define the angle of progression in order to predict mode of delivery.[69] The authors found that during the second stage, an increasing angle of progression was associated with vaginal deliveries, with an angle of 120 being associated with spontaneous vaginal deliveries.[69]

A German study of 44 women in labour, with cephalic singleton pregnancies, demonstrated the reliability of ITU for measurement of angle of progression regardless of fetal head station or ultrasound expertise.[71] They compared the measurements obtained by experienced obstetricians to three midwives with no ultrasound experience and three obstetricians with less than five years experience. In this study, only fetuses in direct occipito-anterior position were included and the angle of progression was quantified by measuring the angle between the a line placed through the midline of the pubic symphysis along the pubic ramus and a line running from the inferior apex of the symphysis tangentially to the most anterior part of the fetal skull.[71] The authors found that measuring the angle of progression on translabial/transperineal ultrasound was reliable regardless of the fetal head station or the operator's level of ultrasound experience.[71] Using this measurement technique again, the same group looked at the relationship between fetal head station obtained on open magnetic resonance imaging (MRI) and the angle of progression measured by ITU in 31 women at term before labour.[82] They found a significant correlation between the two methods and suggested, through statistical assumptions, that an angle of 120^0 corresponded to station + 0.[82] Kalache *et al* also looked at the angle of progression in 41 women at term with failure to progress in the second stage of labour and found a strong relationship between angle of progression of 120^0 with successful vacuum extraction or spontaneous vaginal birth.[83]

An Italian group evaluated the reproducibility of three-dimensional (3D) transperineal ultrasound to measure head direction, head progression distance and angle, using a novel software (SonoVCAD labour) in 30 women in the second stage of labour.[84] They found that their measurements were reproducible but that this technique was only useful when the fetal head was below station +2.[84] This greatly limits the practical application of the technique.

2.6.4 Fetal head to perineum distance

ITU has also been used to measure fetal head to perineum distance to determine head descent in labour in order to predict mode of delivery.[85] A total of 110 women with singleton cephalic fetuses, in all positions, with prolonged first stage of labour were included.[85] Each woman had a vaginal assessment of the fetal head station and an ultrasound assessment with two-dimensional (2D) and three- dimensional (3D) transperineal ultrasound; on ultrasound fetal head descent was quantified by measuring the shortest distance from the fetal head to the perineum and the angle between the pubic symphysis and the fetal head (as described by Barbera et al).[85] They found that when the fetal head- perineum distance was ≤40mm, vaginal delivery was achieved in 93% cases of (95% CI 83-97%) and when angle of progression was ≥110^{0}, vaginal delivery was achieved in 87% cases (95% CI 75-93%) with similar results from both 2D and 3D techniques.[85]

In summary, although the above studies suggest that there may be a role for evaluating engagement, station and descent of the fetal head with ultrasound in labour, different techniques were used in each study and small numbers of patients were included. Ultrasound is not currently used in routine clinical practice to assess engagement, station and descent of the fetal head and the existing data do not support routine implementation of this approach

2.7 The fetal head position in labour

Studies that reported the use of ultrasound to determine the fetal head position are summarised in Table 1.2. They were identified by searches of Medline from 1965 to 2012 and of the Cochrane Library for relevant systematic reviews, meta-analyses, randomised controlled trials, and other clinical studies. The date of the last search was December 2012. The search strategy consisted of MeSh or keywords related to: instrumental delivery, vacuum, forceps, fetal head position, ultrasound, digital examination, randomised controlled trial. In addition, when reviewing published reference lists, key articles cited were also retrieved and reviewed. Language restrictions were not applied. Studies were included if they reported data regarding accuracy of diagnosis of the fetal head position in labour. Overall, the reported accuracy of digital vaginal examination to diagnose the fetal head position varied from 20% to 75%.[26 27 86-91]

2.7.1 Transabdominal ultrasound

A study of 496 women in labour with singleton cephalic fetuses in a British setting, investigated the accuracy of digital vaginal examination in diagnosing the fetal head position by comparing clinical findings to findings on transabdominal ultrasound. [26] Overall, digital examination was inaccurate in 33.5% cases but the accuracy increased with increasing cervical dilatation, especially in the absence of caput succadeneum.[26] These findings were also reflected in a Greek study where the accuracy of digital examination in the first stage of labour was found to be 31% in the first stage of labour versus 66% in the second stage of labour.[86] Interestingly, in this study of 148 labouring women, fetal head position by digital examination was not possible in over half of cases in the first stage and in a third of cases in the second stage.[86] Sherer *et al* also demonstrated high error rates in diagnosis of the fetal head position by digital examination in both the first and second stage of labour, 53% and 39% respectively.[87 88]

A prospective study of 110 women in the second stage of labour carried out in France found that in 20% of cases, the findings of the fetal head position on vaginal examination differed from transabdominal ultrasound scan, with a higher rate of 50% in cases of malposition (occipito – posterior or occipito-transverse).[27]

A German study evaluating the use transabdominal ultrasound in the first and second stages of labour for persistent occipito-posterior (OP) positions found that assessing the fetal spine

position was a useful diagnostic adjunct to the define the fetal head position in the second stage of labour. [92]

The use of transabdominal ultrasound has also been described to detect fetal head asynclitism and the occipito-transverse (OT) position in labour.[93] Malvasi *et al* found ultrasonography superior at detecting both compared to vaginal examination. They reported two signs on ultrasound to diagnose asynclitism in the OT position. The 'squint sign' was classified as 'anterior squint sign' when the anterior orbit was visualised and when more parietal bone presented anteriorly to the suprapubic bone; and the 'posterior squint sign' when the posterior orbit was visualised and the parietal bone presented posteriorly to the suprapubic bone. They also nominated a 'thalamus or cerebellum sunset sign'.[93]

2.7.2 Translabial and transvaginal ultrasound

Fuchs *et al* first described the use of translabial ultrasound in a case report to diagnose the fetal head position prior to vacuum delivery by identifying fontanelles and suture lines of the fetal skull.[94] Since then, a prospective study was conducted in Italy which found that transabdominal and translabial ultrasound assessment of the fetal head position was better than vaginal examination, particularly in cases of occipito-transverse position. [93]

One study compared a combined approach of transvaginal and transabdominal ultrasound assessments to vaginal examination to diagnose fetal head position in 60 women in the second stage of labour.[91] The overall inaccuracy rate of vaginal examination was 22%, but interestingly the authors reported that vaginal examination and transabdominal scan could not define the fetal head position in seven cases (12%) and in nine cases (15%) respectively.[91]

2.7.3 Error rates of ultrasound

Few studies have addressed error rates among novice ultrasonographers. Two studies have reported error rates of transabdominal scanning within a research setting. These studies reported error rates of 6.8% and 7.9%while a further study reported failure to diagnose the fetal head position in 15%.[89 91 95] Chou *et al* reported an error rate of 8% for combined transabdominal and transperineal ultrasound versus 29% error rate for vaginal examination.[90] Interestingly, the authors of a prospective study of a hundred women which set out to

evaluate the learning curves of digital examination and transabdominal ultrasound to determine the fetal head position in labour, reported that it was easier to become skilled in ultrasonography than digital examination.[95]

2.7.4 Fetal head position prior to instrumental delivery

We found only two studies evaluating the role of ultrasound assessment to determine the fetal head position before instrumental deliveries. Akmal *et al* compared the accuracy of vaginal examination to transabdominal ultrasound examination in 64 women undergoing instrumental delivery and found that vaginal examination was incorrect in 27% cases with errors being more likely with occipito-posterior positions and if the head was at the level of the ischial spines.[96] Wong *et al* carried out a randomized trial of fifty women undergoing vacuum extraction for prolonged second stage.[97] Women were randomly allocated to digital examination or digital examination with transabdominal ultrasound prior to delivery.[97] A midwife measured the distance between the centre of the chignon (vacuum induced swelling of the fetal scalp) and the flexion point immediately after delivery. In the group with digital examination and ultrasound assessment (n=25), the mean distance between the centre of the chignon and the flexion point was 2.1+/- 1.3cm versus 2.8 +/- 1.0 cm in the group with digital examination alone, a small but statistically significant difference.[97]

2.7.5 Fetal head position to predict mode of delivery

It has been suggested that ultrasound assessment of the fetal head position at the start of labour can predict the mode of delivery. A systematic review looked at whether an ultrasound assessment of the fetal head position prior to or at the beginning of active labour can predict the mode of delivery.[76] Eleven cohort and cross-sectional studies were included. They found that ultrasound assessment of the fetal head position was 0.39 (95% CI 0.32 – 0.48) sensitive and 0.71 (95% CI 0.67 0 0.74) specific for a caesarean delivery. There is therefore as yet no role for routine ultrasonography in this context.[76]

Table 2.2 Studies evaluating accuracy of transvaginal digital examination compared to ultrasound in diagnosing the position of the fetal head in labour.[26]
27 86-91 93 95-97

Author, citation	Study design	Exposures	Outcome measures	Results	Conclusions
Kreiser D et al J Matern-Fetal Neo M 2001; 10(4): 283-6	Prospective study 44 women in labour (2^{nd} stage)	DVE vs TAS (gold standard)	DVE & TAS findings compared to actual fetal head position at delivery and restitution of the fetal head – if different, considered to be wrong and quantified as =90°, <90° or >90°	TAS less error than DVE: 6.8% vs 29.6%, $p = 0.011$	TAS is more accurate
Akmal S et al J Matern-Fetal Neo M 2002, 12(3): 172-7	Prospective study 496 women in labour (1^{st} & 2^{nd} stages)	DVE vs TAS (gold standard)	Agreement of DVE within ±45° of TAS correct	DVE in agreement with TAS in 163 cases (49.9%)	Digital examination inaccurate in 50% of cases
Sherer DM et al Ultrasound Obst Gyn 2002; 19(3): 258-63	Prospective study 102 women in labour (1^{st} stage)	DVE vs TAS (gold standard)		DVE in absolute agreement with TAS 24 cases (24%) and this increased to 48 cases (47%) when margin of ± 45° allowed	High error rate with digital examination
Sherer DM et al Ultrasound Obst Gyn 2002; 19(3): 264- 8	Prospective study 112 women in labour (2^{nd} stage)	DVE vs TAS (gold standard)	Absolute error when DVE not consistent with TAS; and inconsistency of >45°	Absolute error of DVE 65% DVE incorrect by > 45° in 44 cases (39%)	Ultrasound improves accuracy

DVE: digital vaginal examination TAS: transabdominal ultrasound

Author, citation	Study design	Exposures	Outcome measures	Results	Conclusions
Souka AP et al J Matern-Fetal Neo M 2003; 13(1): 59-63	Prospective study 148 women in labour (1^{st} & 2^{nd} stages)	DVE vs TAS (gold standard)	Agreement of DVE within ±45° of TAS correct	Accuracy of DVE 31.3% in 1^{st} stage & 65.7% in 2^{nd} stage, more likely to be inaccurate in OP position	Digital examination is less accurate than ultrasound, especially in OP position.
Akmal S et al Ultrasound Obst Gyn 2003; 21(5):437-40	Prospective study 64 women undergoing instrumental delivery	DVE vs TAS	Agreement of DVE within ±45° of TAS correct	Error rate of DVE 26.6% (17 cases), higher for OP and OT	DVE inaccurate in a quarter of cases before instrumental delivery
Dupuis O et al Eur J Obstet Gynecol Reprod Biol 2005; 123)2): 193-7	Prospective study 110 women in labour (2^{nd} stage)	DVE vs TAS (gold standard)	Agreement of DVE within ±45° of TAS correct	In 20% of the cases, DVE differed significantly ($>45^{0}$) from TAS, higher in OP & OT positions	Transabdominal ultrasound can increase accuracy
Zahalka N et al AJOG 2005; 193(2): 381-6	Prospective study 60 women in labour (2^{nd} stage)	DVE vs TAS vs TVS	Agreement of DVE within 60° of TAS correct	Discrepancy between DVE & TAS 21.7% Discrepancy between DVE & TVS 23.3% 5 cases where DVE erroneously diagnosed position as being OA when it was OP	TAS and TVS more accurate than transvaginal digital examination

DVE: digital vaginal examination TAS: transabdominal ultrasound TVS: transvaginal ultrasound

Author, citation	Study design	Exposures	Outcome measures	Results	Conclusions
Chou R et al AJOG 2004; 191: 521- 4	Prospective study 88 women in labour (2nd stage)	DVE vs TAS	DVE & TAS findings compared to actual fetal head position at delivery (direct visualisation of position at vaginal delivery after spontaneous restitution of the head or at caesarean section). Considered correct if DVE/TAS within 45° of actual position.	Accuracy of DVE 71.6% vs 92% accuracy for TAS, p = 0.018	TAS more accurate than DVE
Wong GY et al Int J Gynaecol Obstet 2007; 98(2):120-3	RCT 40 women undergoing vacuum extraction	DVE vs TAS	Accuracy of vacuum cup placement with respect to the flexion point	Mean distance between chignon & flexion point: 2.1 ± 1.3 cm in DVE+TAS group vs 2.8cm ± 1.0 cm in VE group (p=0.039)	TAS improves vacuum cup placement
Rozenberg P et al Ultrasound Obst Gyn 2008; 31(3):332 - 7	Prospective study One novice doing both TAS and VE 100 women (≥ 7cm dilated)	DVE vs TAS	Learning curve of a novice at diagnosis of the fetal head position by DVE & TAS compared to an expert	Error rate of DVE 50% over first 50cases, down to 28% over last cases vs 8% error with TAS	Learning and accuracy of diagnosis of the fetal head position easier & higher with TAS
Malvasi et al J Matern-Fetal Neo M 2012; 25(5): 508-12	Prospective study 150 women in labour (1st and 2nd stages)	DVE vs TAS	Ultrasonographic signs of fetal head asynclitism & transverse position; & accuracy of DVE versus TAS	TAS signs of asynclitism: 'squint sign' and 'sunset of thalamus & cerebellum'	DVE inferior to TAS at diagnosing asynclitism & transverse position

DVE: digital vaginal examination TAS: transabdominal ultrasound

2.8 Discussion

There may be a role for ultrasound assessment of the fetal head position in labour. However, in most studies, ultrasound assessment was performed by experienced ultrasonographers and was assumed to be the gold standard. Furthermore, only two small studies were found which looked at ultrasound specifically before instrumental delivery to diagnose the fetal head position.

In summary, although promising, the use of ultrasound to diagnose the fetal head position in labour needs to be formally evaluated within the setting of a clinical trial before its routine use can be advocated.

Chapter 3 Strategies to enhance assessment of the fetal head position prior to instrumental delivery – a survey of obstetric practice in the United Kingdom and Ireland.

3.1 Introduction

As outlined in chapter 1, instrumental deliveries are commonly performed in the United Kingdom and Ireland with rates of 12-17% in most centres.[1 14] Although knowing the exact position of the fetal head is a pre-requisite for safe instrumental delivery as explained in Chapter 1, the evidence in Chapter 2 suggests that clinical assessment with digital examination alone may be unreliable.[18 26 27 86-91] The potential role of abdominal ultrasound assessment to diagnose the fetal head position has also been discussed in Chapter 2, but as previously highlighted, the use of ultrasound in this setting is poorly evaluated and further research is required before it can be recommended for routine use in clinical practice.

The aim of this study was to establish current practice in the United Kingdom and Ireland, relating to clinical assessment of women prior to instrumental delivery, the factors associated with difficulty in assessment of the fetal head position and whether there would be support for a randomised controlled trial evaluating the use of ultrasound prior to instrumental delivery. It was performed within the context of the randomised controlled trial (RCT) which compared routine clinical assessment alone to clinical assessment and an ultrasound assessment to diagnose the fetal head position before instrumental delivery, described in detail in Chapters 5 to 7.

3.2 Material and methods

3.2.1 The questionnaire survey as a form of assessment

A questionnaire survey is deemed to be an objective method of gathering information about an individual's knowledge, beliefs, attitudes and behaviours.[98] It is a research method used to gather information from a subset of individuals intended to be representative of the population being studied. It is used in instances when it may not be cost-effective or possible to obtain the desired information from the entire target population, especially when the target population is spread over a broad geographical location.[99] The potential drawbacks of this research method include low response rates, poor quality data and bias.[98 99] However, we chose this cost-effective method to investigate current strategies used to diagnose the fetal head position by carefully selecting the sample and designing a concise questionnaire with close-ended questions which was administered via mail to eliminate interviewer bias.

3.2.2 Developing the questionnaire survey

A questionnaire was developed, composed of a series of closed answer questions with additional space for free text comments. (Appendix 1) Introductory questions asked about the respondent's qualifications, age and gender as well as the number of deliveries and rate of instrumental delivery in the maternity unit where they worked. The questionnaire focused on the assessment of a patient prior to instrumental delivery, factors associated with difficulty in determination of the fetal head position, approaches used to enhance determination of the fetal head position prior to instrumental delivery, perceived accuracy/inaccuracy rates in the assessment of the fetal head position, the need for a trial of ultrasound assessment of the fetal head position prior to instrumental delivery and potential willingness to participate in a future clinical trial. The responses were categorised into always, frequently, rarely and never and the inaccuracy rate was categorised from 0-5% up to greater than 30%.

The questionnaire was piloted on obstetric consultants and registrars employed at the investigators' hospital in order to resolve any inconsistencies or ambiguity in the questions.

The finalised questionnaire was sent to all lead labour ward consultants and nominated registrars who were midway through specialist training in obstetrics in the United Kingdom and the Republic of Ireland in May 2011. Consultant-led obstetric units were identified from the websites www.birthchoiceuk.com and www.cuidiu-ict.ie. Each unit was contacted by telephone to establish the correct contact details of the lead labour ward consultant and the lead midwife was asked to nominate a mid-training specialist registrar working in that unit. Pre-paid return envelopes were enclosed with the questionnaire to aid response. Any recipient who felt that the questionnaire was not relevant to their current practice was asked to send back the questionnaire uncompleted.

Obstetricians who had not returned the questionnaire within three weeks were sent a reminder letter and another questionnaire. A further reminder and questionnaire were sent to non-responders two weeks thereafter. A final attempt was made to contact non-responders by telephone if they had not subsequently returned the questionnaire within one week, with failure to respond being accepted as a wish not to participate in the survey.

3.2.3 Ethics committee approval

Ethical committee approval from the Coombe Women & Infants University Hospital was granted for this study.

3.2.4 Statistical analysis

Statistical analyses, including non-parametric tests, were performed using PASW statistical software version 18 for windows.

3.3 Results

Of the 431 questionnaires sent, 323 obstetricians replied (response rate 75%). Of the responders, 176 (54%) were lead labour ward consultants and 147 (46%) were obstetric trainees. Annual birth rates ranged from 200 to 9,900 with a median of 3,500 deliveries (interquartile range (IQR) 2,500 deliveries). Instrumental delivery rates ranged from 2% to 30% with a median of 14% (IQR 4%). Of the responders, 180 (55%) were female, 238 (72%) were in the age group of 30 to 49 years and 256 (78%) had passed their examination for the the Membership of the Royal College of Obstetricians and Gynaecologists (MRCOG). Table 3.1 reports the demographics of the respondents in more details.

Table 3.1 Demographic of respondents.

	Consultants (%)	Trainees (%)
Female gender	91/162 (56.2)	89/144 (61.8)
Age group		
<30 years old	0	23/145 (15.9)
30- 39 years old	24/173 (13.9)	98/145 (67.6)
40-49 years old	96/173 (55.5)	19/145 (13.1)
50- 59 years old	47/173 (27.2)	3/145 (2.1)
>50 years old	6/173 (3.5)	2/145 (1.4)
MRCOG	161/161 (100)	95/146 (65.1)

The clinical features most consistently examined for prior to instrumental delivery by both lead labour ward consultants and obstetric registrars were fetal position (99%), fetal station (99%), caput (98%), moulding (98%) and engagement of the presenting part (98-99%). (Table 3.2) Similar proportions of consultants and trainees assessed for asynclitism (95% vs 93%, p= 0.37), degree of head flexion (91% vs 88%, p=0.28) and fetal size clinically (94% vs 91%, p= 0.50). Only 76% of lead labour ward consultants and trainees assessed the maternal pelvis prior to instrumental delivery.

The factors most frequently reported to be associated with difficulty in determination of the fetal head position were inadequate maternal pain relief (81% consultants, 92% trainees), clinical inexperience (86% consultants, 82% trainees) and fetal caput (80% consultants, 84% trainees). (Table 3.3) Other factors reported in free text included inadequate positioning of the patient, full maternal bladder and previous failed attempt at vacuum delivery.

When experiencing difficulty or uncertainty in determination of the fetal head position prior to instrumental delivery consultants and trainees frequently feel for fetal ears, orbits or nose to enhance diagnosis. (Table 3.4) More trainees than consultants when experiencing difficulty in diagnosing the fetal head position would seek a second opinion (40% vs 5%, p <0.0001), reassess the woman in an operating theatre (80% vs 68%, p=0.048) or abandon the procedure

in favour of a caesarean section (14% vs 6%, p = 0.035). While some consultants (18.7%) and trainees (23.1%) use abdominal ultrasound to aid diagnosis of the fetal head position, only one consultant and one trainee reported using transperineal or transvaginal ultrasound respectively. Almost one in ten obstetricians would frequently attempt an instrumental delivery based on best guess of the fetal head position (9% consultants vs 11% trainees, p = 0.52)

When lead labour ward consultants were asked how often they thought they make an incorrect diagnosis of the fetal head position at instrumental delivery, 87% rated their own inaccuracy rate in the diagnosis as less than 10%. (Table 3.5) When asked how often other consultant obstetricians (not lead labour ward consultants) make an incorrect diagnosis of the fetal head position at instrumental delivery, lead labour ward consultants rated other consultant obstetricians as being incorrect more often. Most lead labour ward consultants (83%) believed that an obstetric trainee who is midway through specialist training would make an incorrect diagnosis of the fetal head position in more than 10% of cases. However, when trainees were asked how often they would make an incorrect diagnosis of the fetal head position at instrumental delivery, the majority of trainees (76%) rated themselves as being incorrect in less than 10% cases. Trainees in this survey perceived that other obstetric trainees of average clinical ability would make an incorrect diagnosis in more than 10% of cases.

The need for a randomised controlled trial (RCT) evaluating the use of ultrasound assessment of the fetal head position prior to instrumental delivery elicited opposing responses with half of the lead labour consultants agreeing that there is a need for such a trial and 21% saying they did not know whether there was a need for a trial at all. More trainees (63%) agreed that there was a need for a randomised controlled trial.

One of the commonest reasons given by lead labour ward consultants in the free text section for not supporting a trial was that ultrasound assessment of the fetal head position was already part of their current practice. However other lead labour ward consultants commented that they were always able to determine the fetal head position on clinical examination. One of the major concerns expressed in the free text section was that ultrasound assessment should not be a substitute for clinical vaginal and abdominal examinations. (Text box 3.1) (Appendix 2) Other concerns included access to a good quality scanner and trainees in

particular highlighted the need for training in intrapartum scanning. Nonetheless the majority of consultants (64%, n = 113) and trainees (80%, n = 118) would participate in a potential RCT.

Table 3.2 Clinical features assessed prior to instrumental delivery.

		Always/frequently n (%)	Rarely/never n (%)	No response n (%)
Fetal size clinically	Consultant	165 (93.7)	10 (5.6)	1 (0.6)
	Trainee	134 (91.1)	11 (7.5)	2 (1.4)
Engagement	Consultant	175 (99.4)	0	1(0.6)
	Trainee	145 (98.6)	1 (0.7)	1 (0.7)
Caput	Consultant	174 (98.8)	1 (0.6)	1(0.6)
	Trainee	145 (98.6)	1 (0.7)	1 (0.7)
Moulding	Consultant	174 (98.8)	1 (0.6)	1 (0.6)
	Trainee	145 (98.6)	1 (0.7)	1 (0.7)
Fetal station	Consultant	175 (99.4)	0	1 (0.6)
	Trainee	146 (99.3)	0	1 (0.7)
Fetal position	Consultant	175 (99.4)	0	1 (0.6)
	Trainee	146 (99.3)	0	1 (0.7)
Asynclitism	Consultant	167 (94.9)	7 (4)	2 (1.1)
	Trainee	136 (92.5)	9 (6.1)	2 (1.4)
Degree of flexion	Consultant	160 (90.9)	14 (8)	2 (1.1)
	Trainee	129 (88.3)	17 (11.5)	1 (0.7)
Maternal pelvis	Consultant	135 (76.7)	31 (17.6)	10 (5.7)
	Trainee	112 (76.2)	31 (21.1)	4 (2.7)

Table 3.3 Factors associated with uncertainty in determination of the fetal head position.

		Always/frequently n (%)	Rarely/never n (%)	No Response n (%)
Inadequate maternal pain relief	Consultant	142 (80.7)	31 (17.6)	3 (1.7)
	Trainee	135 (91.8)	12 (8.2)	0
Maternal obesity	Consultant	97 (55.2)	75 (42.6)	4 (2.3)
	Trainee	104 (70.8)	42 (28.6)	1 (0.7)
Prolonged labour	Consultant	82 (46.5)	90 (51.1)	4 (2.3)
	Trainee	89 (60.6)	57 (38.7)	1 (0.7)
Fetal caput	Consultant	140 (79.6)	33 (18.7)	3 (1.7)
	Trainee	124 (84.3)	22 (15)	1 (0.7)
Fetal moulding	Consultant	88 (55.7)	75 (42.6)	3 (1.7)
	Trainee	104 (70.7)	42 (28.6)	1 (0.7)
Asynclitism	Consultant	79 (44.9)	94 (53.4)	3 (1.7)
	Trainee	94 (63.9)	51 (43.7)	2 (1.4)
Clinical inexperience	Consultant	151 (85.8)	15 (8.5)	10 (5.7)
	Trainee	121 (82.3)	21 (14.3)	5 (3.4)

Table 3.4 Approaches used to enhance determination of fetal head position.

		Always/frequently n (%)	Rarely/never n (%)	No response n (%)
Feel for a fetal ear	Consultant	154 (87.5)	17 (9.7)	5 (2.8)
	Trainee	125 (85)	22 (15.0)	0
Feel for orbits/nose	Consultant	96 (54.5)	71 (40.3)	9 (5.1)
	Trainee	60 (40.8)	85 (57.8)	1 (0.7)
Seek a second opinion	Consultant	8 (4.5)	156 (88.7)	12 (6.8)
	Trainee	59 (40.1)	88 (59.9)	0
Reassess in an operating theatre	Consultant	119 (67.6)	49 (27.8)	8 (4.5)
	Trainee	118 (80.3)	29 (19.7)	0
Attempt instrumental delivery based on best guess	Consultant	15 (8.5)	154 (87.5)	7 (4.0)
	Trainee	16 (10.9)	129 (87.8)	2 (1.4)
Use abdominal ultrasound	Consultant	33 (18.7)	139 (79.0)	4 (2.3)
	Trainee	34 (23.1)	113 (76.9)	0
Use transperineal ultrasound	Consultant	1 (0.6)	171 (97.1)	4 (2.3)
	Trainee	1 (0.7)	146 (99.3)	0
Use transvaginal ultrasound	Consultant	1 (0.6)	168 (95.5)	7 (4.0)
	Trainee	0	147 (100.0)	0
Abandon procedure in favour of caesarean section	Consultant	11 (6.3)	154 (87.5)	11(6.3)
	Trainee	20 (13.6)	126 (85.7)	1 (0.7)

Table 3.5 Perceived accuracy in assessment of fetal head position.

		0-5% n(%)	6-10% n(%)	11-20% n(%)	21-30% n(%)	>30% n(%)	Don't know n(%)	No response n (%)
How often do you think **you** make an incorrect diagnosis of the fetal head position at instrumental delivery?								
Responses:	Consultant	108 (61.4)	45 (25.6)	15 (8.5)	5 (2.8)	2 (1.1)	0	1 (0.6)
	Trainee	56 (38.1)	55 (37.4)	28 (19.0)	5 (3.4)	1 (0.7)	0	2 (1.4)
How often do you think a **consultant obstetrician** of average clinical ability make an incorrect diagnosis of the fetal head position at instrumental delivery?								
Responses:	Consultant	66 (37.5)	66 (37.5)	22 (12.5)	5 (2.5)	2 (1.1)	13 (7.4)	2 (1.1)
	Trainee	77 (52.4)	39 (26.5)	12 (8.2)	2 (1.4)	1 (0.7)	15 (10.2)	1 (0.7)
How often do you think an **obstetric trainee** (midway through specialist training) of average clinical ability make an incorrect diagnosis of the fetal head position at instrumental delivery?								
Responses:	Consultant	2 (1.1)	23 (13.1)	65 (36.9)	56 (31.8)	25 (14.2)	3 (1.7)	2 (1.1)
	Trainee	14 (9.5)	45 (30.6)	46 (31.3)	19 (12.9)	7 (4.8)	15 (10.2)	1 (0.7)

Text box 3.1 Qualitative data- comments in the free text section of the questionnaire.

Good idea. I think it would aid diagnostic skills – not replacing examination by other means but enhancing it. *Consultant.*

I think that using ultrasound is a very valuable ancillary method to confirm and refine diagnosis of uncertainty concerning position of fetal head in the second stage of labour. *Consultant.*

I already use ultrasound in cases of uncertainty and I am convinced of its benefit. My participation in a trial may disadvantage patients. *Consultant.*

Excellent idea. As the experience of trainees decreases, additional means to determine position would be welcome as the alternative is consultants on the labour ward 24/7. *Consultant.*

I learnt using transabdominal scan for checking fetal position when I am unsure of position on clinical examination. I found it very useful tool. *Trainee.*

Ultrasound training a concern – we have trouble getting basic ultrasound training as it is. *Trainee.*

Training in ultrasound in England is so poor that inaccuracies of the scan would be worse than vaginal examination findings. *Trainee.*

I am appalled! If a doctor can't determine position he needs improved analgesia and/or a more experienced opinion. I am doing about 24 Kielland forceps per year and have delivered only 2 babies unknowingly OP over the past 11 years. *Consultant.*

Your hands and fingers are your 'eyes' when doing a vaginal examination prior to instrumental delivery. What happens if you don't have access to an ultrasound scanner? Learn the basics first! *Consultant.*

Ultrasound should not be advocated to replace clinical assessment and experience. I would expect trainees to gain the necessary skills alongside a consultant. *Consultant.*

In my relatively small experience, trainees who tend to use scan do so because they aren't very good at vaginal examinations and ultrasound distracts them from trying to work out the position. *Consultant.*

Kiwi has created a 'suck it and see' mentality which shouldn't happen if forceps are being used. *Consultant*

3.4 Discussion

3.4.1 Summary of findings

This national survey of strategies to enhance assessment of women prior to instrumental delivery, found that obstetricians are largely consistent in the clinical assessment of women prior to instrumental delivery adhering to the recommendations of practice guidelines.3 In contrast, varying strategies are adopted when there is difficulty or uncertainty in determining the fetal head position. Most obstetricians reported their rate of incorrect diagnosis of the fetal head position as being less than 10%, although one in eight consultants and one in four trainees reported inaccuracy rates of more than 10%. Views varied on the value of abdominal ultrasound as a strategy to improve the accurate determination of the fetal head position prior to instrumental delivery but the majority of obstetricians would be willing to participate in a randomised controlled trial.

3.4.2 Strengths and weaknesses

We achieved a high response rate representing a wide spectrum of obstetric opinion in the United Kingdom and Ireland. There did not appear to be any difficulty in completing the questionnaire and the free text responses enhanced the quality of the information obtained. However, it is possible that the non-responders hold views that are at strong variance with the study findings.

3.4.3 Comparison with the literature

We found that the majority of consultants and trainees assessed the fetal head position, fetal station, caput, moulding and engagement of the fetal head abdominally as recommended by current clinical guidelines although one in four did not assess the maternal pelvis prior to instrumental delivery.[18] Consultants and trainees frequently sought additional anatomical landmarks such as the fetal ears, orbits or nose when experiencing difficulty or uncertainty with determination of the fetal head position. However there was marked variation in other approaches used to help diagnose the fetal head position with trainees more likely than consultants to seek a second opinion, to re-assess the woman in an operating theatre or to abandon instrumental delivery in favour of a caesarean section. Perhaps more worrying was the reported practice of attempted instrumental delivery based on best guess of the fetal head

position by almost 10% of obstetricians. These findings mirror concerns raised in an editorial debating the rise in second stage caesarean sections and reinforce the importance of high quality training in intrapartum care. [100]

The commonest factors associated with difficulty in diagnosing the fetal head position were inadequate maternal pain relief, fetal caput and clinical inexperience. The consultant obstetricians and trainees rated their own accuracy rate as better than that of their peers and both groups agreed that consultants have higher accuracy rates than trainees. The results are perhaps unsurprising given that the consultant obstetricians are lead consultants for the labour ward with specialist intrapartum expertise and the trainees were nominated by a labour ward sister rather than randomly selected. However, our findings highlight that there is an acknowledged perception of difficulty in determining the fetal head position prior to instrumental delivery and that this can reflect both the clinical circumstances and the clinician's experience. In keeping with our findings, several studies have found digital vaginal examination for determination of the fetal head position to be accurate in between only 20% and 75% of cases.[26 27 86-91]

3.4.4 Practice implications and future work

In this survey, a minority of obstetricians reported use of transabdominal ultrasound to help in the diagnosis of the fetal head position. A French study of a hundred women which set out to evaluate the learning curves of digital examination and transabdominal ultrasound to determine the fetal head position in labour, reported that it was easier to become skilled in ultrasonography than digital examination.[95] These data suggest that there may be a role for ultrasound assessment of the fetal head position in labour prior to performing an instrumental delivery. The free text responses from consultant obstetricians were interesting in that some were already enthusiastic advocates of ultrasound in the second stage of labour and others saw it as detrimental to the acquisition of clinical skills.

The results of this survey suggest that there is sufficient support for a trial investigating the use of ultrasound before instrumental and that ultrasound may enhance the diagnosis of the fetal head position and potentially identify cases where consultant input may be required.

3.5 Conclusion

This survey found that while obstetricians are largely consistent in the routine clinical assessment of women prior to instrumental delivery, there is great variation in strategies used to accurately determine the fetal head position when assessment is more difficult. The conflicting opinions on the role of abdominal ultrasound in enhancing determination of the fetal head position prior to instrumental delivery supports the need for evaluation within a randomised controlled trial.

There is currently insufficient evidence that an abdominal ultrasound assessment will in fact enhance the diagnosis of the fetal head position before instrumental delivery and it is both timely and important to investigate this within a high-quality randomised controlled trial. Furthermore, it is important to establish any potential pitfalls of introducing an intervention in labour in what is essentially an emergency situation. Therefore, ultrasound training and timing; as well as acceptability of the ultrasound assessment to women in labour and clinicians looking after them need to be investigated first.

Chapter 4 Establishing the accuracy and acceptability of abdominal ultrasound to define the fetal head position in the second stage of labour – a validation study.

4.1 Introduction

As discussed in Chapter 1, accurate determination of the fetal head position in the second stage of labour is clinically important, as malpositions of the fetal head, particularly the occipito-posterior position, are associated with longer labours and higher rates of instrumental delivery and caesarean section.[30 32]

Chapter 2 highlighted the studies evaluating the accuracy of digital vaginal examination in determining the fetal head position versus ultrasound as a gold standard. These found digital vaginal examination to be accurate in between 22% and 75% of cases.[26 27 86-91]

It is necessary to explore the accuracy of ultrasound determination of the fetal head position in the hands of novice ultrasonographers. A French study of a hundred women which set out to evaluate the learning curves of digital examination and transabdominal ultrasound to determine the fetal head position in labour, reported that it was easier to become skilled in ultrasonography than in digital examination.[95] These data suggest that there may be a role for ultrasound assessment of the fetal head position in labour prior to performing an instrumental delivery. However few studies have addressed error rates in ultrasound assessment among novice ultrasonographers. Two studies have reported error rates within a research setting of 6.8% and 7.9% respectively. [91 95]

Furthermore, the acceptability of such an intervention to women in labour and to the midwives and obstetricians caring for them needs to be explored.

The objectives of this study were firstly to compare the diagnosis of the fetal head position by a novice and an expert ultrasonographer; secondly, to compare the diagnosis of the fetal head position by a clinician (obstetrician or midwife) and an expert ultrasonographer; and lastly, to evaluate the acceptability of ultrasound assessment in the second stage of labour to women, and, to midwives and obstetricians looking after them.

4.2 Methods

4.2.1 Study population

We recruited nulliparous or multiparous women, at term (≥ 37 weeks gestation) with singleton cephalic fetuses who were aiming for a vaginal delivery, from January to May 2011. This study was undertaken on the labour ward at the Coombe Women and Infants University Hospital in Dublin, Ireland, a unit with almost 9,000 deliveries per year, an instrumental delivery rate of 17% and an epidural rate of 70% in nulliparous women.

4.2.2 Eligibility criteria

Women were considered eligible if the midwife looking after them assessed them to be capable of providing written informed consent. (Appendices 8 and 9) We excluded women who were less than eighteen years of age, women who were unable to speak or understand English and women who had received systemic opiates within the preceding four hours.

4.2.3 Interventions

Once the second stage of labour was diagnosed, an ultrasound assessment was performed by a single novice sonographer followed by a single expert sonographer. Neither operator revealed their findings to each other. The novice sonographer was an entry level research fellow (year one obstetric registrar) with basic ultrasound skills having no previous experience in intrapartum ultrasound. The expert sonographer was a sub-specialist in fetal and maternal medicine. The ultrasound assessments were carried out in the passive second stage of labour to allow sufficient time for the two sonographers, especially the novice, to adequately determine the fetal head position. For all ultrasound assessments, image- directed pulsed Doppler equipment (Sonosite Titan™) with a multifrequency sector array transabdominal transducer, and a 3.5MHz sector ultrasound probe, was used. (Appendix 4)

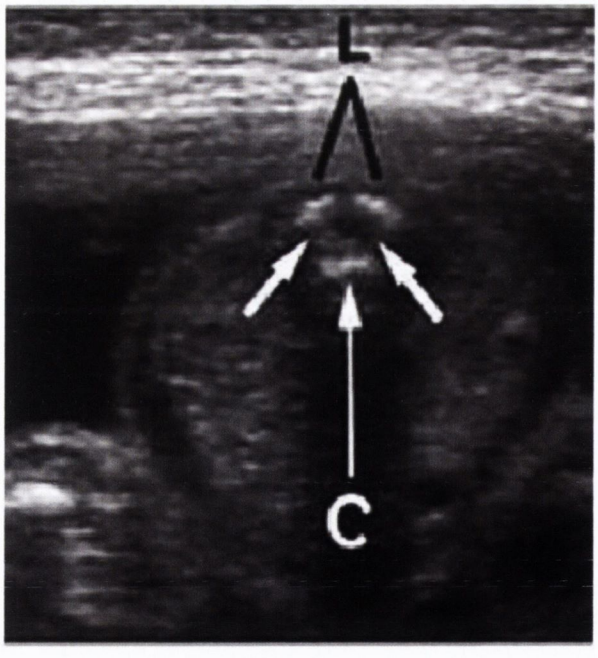
The maternal position was optimised to a supine position or left lateral tilt. The ultrasound transducer was first placed transversely over the maternal abdomen and moved longitudinally to identify landmarks for the fetal spine and head position. A sagittal view of the fetal spine was obtained first and this was documented as direct anterior, direct posterior, right lateral,

left lateral and unknown. (Figure 4.1) Using a rotation of the transabdominal probe through 90 degrees, the transverse view of the fetal spine was obtained. (Figure4. 2)

Figure 4. 1 Sagittal view of the fetal spine.



Figure 4.2 Transverse view of the fetal spine.



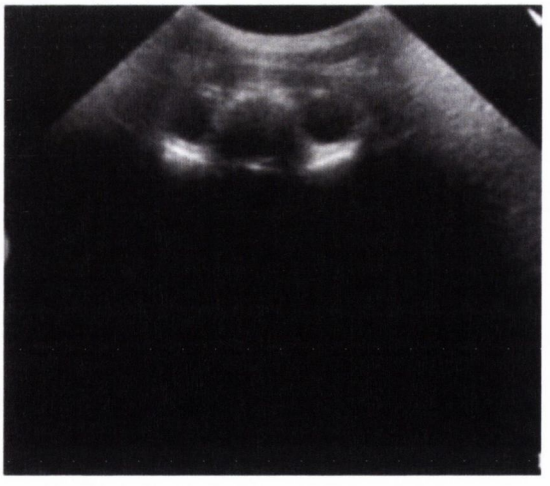
Following this, a sliding motion towards the fetal head enabled a view of the fetal cranium. The following midline fetal cranial structures were looked for: midline cerebral echo, falx cerebri

and thalamus (figure 4.3) and /or anterior or posterior cranial structures such as orbits, nuchal region (figure 4.4). The fetal head position was classified as OA for direct occipito-anterior, ROA and LOA for right and left occipito-anterior respectively; OP for direct occipito-posterior, ROP and LOP for right and left occipito-posterior; ROT and LOT for right and left occipito-transverse respectively. Documentation of the position of the fetal head and spine was accompanied by printed images and the findings were recorded by way of a cross on a data sheet depicting a circle, similar to a clock with eight quadrants each of 45^{0}. (Appendix 8, 9)

Figure 4.3 Transverse view of the fetal cranium – landmarks of midline cerebral echo and falx cerebri shown in this left occipito-transverse position.



Figure 4.4 Transverse view showing fetal orbits and nose indicating an occipito-posterior position.



Following the ultrasound assessments, the women were assessed by abdominal and digital vaginal examination by the duty obstetrician or midwife within fifteen minutes of the

ultrasound assessments to preclude marked changes of the fetal head position. The fetal head position was recorded on a data sheet which depicted the same circle with eight (45^{o}) quadrants as described previously. The station of the vertex with respect to the maternal ischial spines, the presence of any caput succadeneum or moulding of the fetal head were recorded. The degree of certainty with regards to the fetal head and spine position was recorded on a Likert scale from 1 to 10 (1 very uncertain, 10 completely certain). (Appendix 12) The ultrasonographers and the health professionals carrying out the clinical examination were blinded to each others' findings.

The primary outcome of interest was error in the diagnosis of the fetal head position. The diagnosis of the fetal head position by the expert sonographer was considered the gold standard. The diagnosis was considered correct if it was within 45 degrees of the expert ultrasonographer's findings. The most clinically significant errors are those where there is a misdiagnosis between occipito-anterior and occipito-posterior (OA-OP errors) or a difference of 180 degrees with a misdiagnosis between left and right occipito-transverse. The acceptability of the ultrasound assessment was assessed qualitatively by questionnaires completed separately by the woman, the midwife and the obstetrician at a suitable interval following the study procedures. (Appendix 13 – 15)

4.2.4 Ethics committee approval

Ethical approval was granted by the Coombe Women & Infants University Hospital Research Ethics Committee on the 5th October 2010. (Appendices 3 to 5)

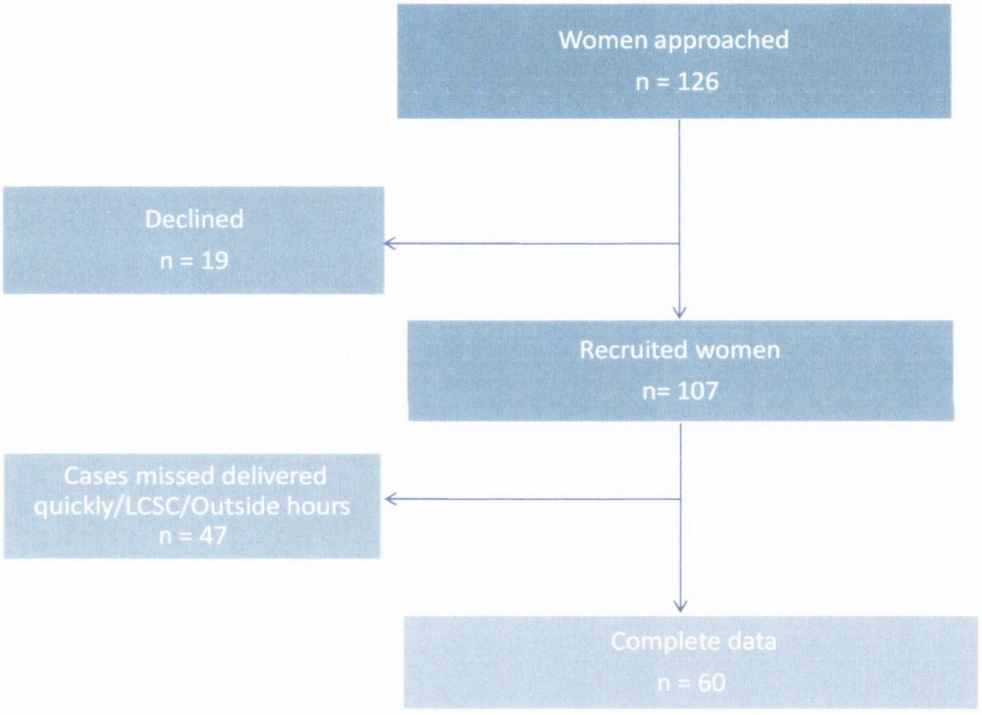
4.2.5 Statistical analysis

Statistical analyses were performed using PASW statistics version 18. Descriptive statistics are presented for the proportion of cases with accurate diagnosis of the fetal head position or conversely the error rate. Comparisons between the expert and novice ultrasonographer were assessed in blocks of ten consecutive cases recording the accuracy rate and the median time (and interquartile range) taken by the novice to complete the scans.

4.3 Results

Of the 126 women approached, 107 agreed to participate and 60 had complete data sets with a total of three assessments performed, by the expert ultrasonographer, the novice ultrasonographer and a clinician. (Figure 4.6)

Figure 4.6 Flow diagram of recruitment.



Data sets were incomplete in cases of delivery by emergency caesarean section in the first stage, quick spontaneous vaginal deliveries (no time for the 3 assessments to be performed), and deliveries after the sonographers had left the labour ward. The median maternal age was 30 years (range 18-39), 35 (58%) women were nulliparous and 37 (62%) were Irish. The body mass index (BMI) recorded at booking was normal (defined as BMI 18-25) in 41 (68%) women, two (3%) were obese (defined as BMI 31-35) and two (3%) were morbidly obese (BMI > 35). All women had ruptured membranes, confirmed full cervical dilatation (10cm) and the fetal

head was no more than 2cm above the ischial spines. A total of 50 (83%) women had regional analgesia/anaesthesia.

It was technically possible for both the expert and novice ultrasonographer to define the fetal head position in all 60 (100%) cases. The frequency of the fetal head positions as determined by the expert sonographer (gold standard) was as follows: two (3%) OA, twenty-seven (45%) LOA, nine (15%) ROA, three (5%) LOT, one (2%) ROT, eleven (18%) LOP and seven (12%) ROP.

Overall, the ultrasound findings of the novice and expert ultrasonographer were consistent in 52 (87%) cases for the fetal head position and in 37 (62%) cases for the fetal back position. While most of the errors made by the novice ultrasonographer were minor due to incorrect probe orientation leading to situs inversion (right-left errors), there were no OA-OP errors. (Table 4.1) The median time taken to perform the ultrasound assessment was 60 (IQR 87.5) seconds by the novice and 5 (IQR 5) seconds by the expert. The novice became faster with an increasing number of cases, median of 150 (IQR 83) seconds for the first ten cases and 10 seconds (IQR 10) for the final ten cases. (Table 4.2) However, the improved speed initially led to concern about accuracy and after review of the first fifty cases the novice sonographer was made aware of this before undertaking the last ten cases.

The clinical assessment was in agreement with the expert ultrasound findings in 35 (58%) cases with 25 (42%) errors; 8 (13%) OA-OP errors. (Tables 4.3 and 4.4 respectively) When asked to quantify how certain clinicians were of their findings on a Likert scale ranging from one (very uncertain) to ten (completely certain), six (10%) clinicians had values of five or less, twenty-four (40%) reported values of seven or less and twenty-six (43%) clinicians were certain with values of nine or more. Four (7%) clinicians did not record the degree of certainty on the Likert scale.

There were fifty-nine (98%) completed questionnaires for the woman in labour, midwife and obstetrician. (Table 4.5) The majority (92-100%) were satisfied with the recruitment process for this study. No woman found the ultrasound assessment intrusive or bothersome but one woman (2%) found it uncomfortable. Fifty-six (95%) women said they would participate in a study like this again while all midwives and obstetricians who completed the questionnaire said they would support a study like this again.

Table 4.1 Inconsistency between fetal head position findings of novice and expert ultrasonographer.

Expert Ultrasound	Novice Ultrasound	Reason for discordant result
LOA	ROA	Probe orientation
ROA	ROT	Maternal tilt – angle not corrected
ROA	LOA	Probe orientation
LOP	LOT	Maternal tilt – angle not corrected
LOA	ROA	Probe orientation
LOA	ROA	Probe orientation
ROP	LOP	Probe orientation
LOP	LOT	Maternal tilt – angle not corrected

Table 4.2 Accuracy of scan findings and time taken by the novice ultrasonographer analysed in consecutive blocks of ten.

Cases	1-10	11-20	21-30	31-40	41-50	51-60
Accuracy – fetal head position	8/10 (80%)	9/10 (90%)	9/10 (90%)	9/10 (90%)	8/10 (80%)	9/10 (90%)
Accuracy – fetal back position	7/10 (70%)	7/10 (70%)	7/10 (70%)	7/9* (78%)	5/8 * (63%)	6/10 (60%)
Median time in seconds (Inter Quartile Range)	150 (83)	90 (53)	60 (45)	53 (43)	10 (10)	10 (10)

* denominator refers to number of cases in which fetal back position was defined.

Table 4.3 Inconsistency between clinical assessment of fetal head position and expert ultrasonographer.

Grade of clinician	Any error (%)	OA-OP error (%)
Junior Registrar (n = 22)	9 (41)	4 (18)
Registrar Year 1-3 (n = 12)	7 (58)	3 (25)
Registrar Year 4-5 (n = 11)	3 (27)	1 (9)
Consultant (n = 6)	3 (50)	0
Midwife (n = 9)	3 (33)	0
Total (n=60)	25 (42)	8 (13)

Table 4.4 Inconsistency in fetal head position (occipito-anterior / occipito-posterior) between clinical assessor and expert ultrasonographer.

Clinician Grade	Expert Ultrasound	Clinical assessment	Possible Reason
Junior Registrar	LOA	ROP	
Junior Registrar	LOA	ROP	
Junior Registrar	ROP	LOA	
Junior Registrar	ROP	LOA	
Registrar year 1-3	LOP	ROA	
Registrar year 1-3	LOA	LOP	
Registrar year 1- 3	LOP	ROA	
Registrar year 4-5	ROP	LOA	++ caput ++ moulding

4.4 Discussion

4.4.1 Summary of findings

We found that a novice sonographer can acquire ultrasound skills for accurate determination of the fetal head position in the second stage of labour quickly and easily. Accuracy of 90% was achieved after twenty consecutive scans and remained high showing that these skills are reproducible when a systematic approach is taken. However, agreement for the fetal back position was only 62% suggesting that ultrasound assessment of the fetal back is less likely to enhance diagnosis of a fetal malposition. The scan was performed unobtrusively with little or no discomfort to the patient or inconvenience to the health professionals caring for her.

4.4.2 Strengths and limitations

The study included a broad range of women with varying body mass index, analgesia, mobility and racial origin. There was a high rate of epidural analgesia reflecting a 70% uptake among nulliparous women in our patient population. We developed a standardised approach to ultrasound assessment that could be replicated by trainees and trainers in other centres. We considered the option of assessing a number of novice sonographers but felt that the scientific validity was enhanced by limiting the study to a single novice and single expert ultrasonographer. A potential limitation of the study was that women who were distressed with pain in labour were not included nor women in the active second stage of labour. In keeping with the ethical requirements for consent we did not approach women who were distressed and the passive second stage of labour was chosen as the fetal head position is likely to change during active pushing within the interval required for three independent blinded assessments. It is possible that ultrasound assessment may prove more challenging for women who are distressed or actively pushing.

4.4.3 Comparison to the literature

Similar to the study by Rozenberg *et al,* we found that a trainee in obstetrics can acquire the ultrasound skills necessary to accurately define the fetal head position in the second stage of labour easily.[95] The error rate of the novice sonographer in this study was 13%, which was higher than two other studies which reported error rates of 6.8% and 7.9% within a research setting. [91 95]

While other studies have reported error rates of 20 to 75 % for the diagnosis of the fetal head position by clinical examination, we found that clinical assessment was inaccurate in 42% of cases across a range of health professionals. [26 27 86-91]

It is crucial to correctly diagnose the fetal head position when the second stage of labour is not progressing well and particularly when there is a decision to perform an instrumental delivery. The fetal head position will ultimately determine the choice of instrument, the venue for delivery and whether or not assistance by a more senior obstetrician is requires. We found that in eight cases (13%), digital examination identified the sagittal suture correctly but the anterior and posterior fontanelles were incorrectly designated leading to 'OA-OP errors'. Out of 60 clinical assessments, only twenty-six clinicians (43%) reported being sure of their findings and indeed some of these proved wrong.

4.4.4 Practice implications

Abdominal ultrasonography is not used widely to confirm the position of the fetal head in the second stage of labour. Portable ultrasound machines are available on most labour wards and there is the potential for abdominal ultrasound assessment prior to instrumental delivery to enhance the accuracy of the diagnosis of the fetal head position thereby increasing safety by reducing sequential use of instruments and second stage caesarean sections.[34 100] It is important to emphasise, however, that ultrasound should not be viewed as a substitute for good clinical skills and the greatest potential use for abdominal ultrasound assessment in the second stage of labour may be as a training tool for improving vaginal examination skills.

4.4.5 Future work

It will be important in future studies to assess ultrasound in the active second stage of labour and to compare the findings to the fetal head position at delivery. We took this into account when designing the randomised controlled trial evaluating the role of ultrasound in assessing the fetal head position prior to instrumental delivery. This is outlined in the following chapters.

4.5 Conclusion

An abdominal ultrasound scan is an accurate, reproducible and acceptable method of confirming the fetal head position in the passive second stage of labour. Further research is required to establish whether ultrasound diagnosis of the fetal head position could be used to enhance the safety of instrumental delivery where morbidity often relates to failure to recognise a fetal malposition. Should the intervention prove effective, we would need to establish the resources required to implement it into routine obstetric practice.

Chapter 5 CHAPTER – IDUS Randomised Controlled Trial: Study design and methods

5.1 Introduction

Instrumental deliveries are commonly performed in Ireland with nearly 1 in 3 first time mothers being delivered by vacuum or forceps.[1] As highlighted in Chapter 1, instrumental delivery can be associated with an increased risk of maternal and neonatal morbidity but with careful practice these risks are low.[2 25 59 101] In fact, increased morbidity is mainly associated with excessive pulls, sequential use of instruments and caesarean section after a failed instrumental delivery .[25] Failure to identify fetal head malpositions, especially the occipito-posterior position, before instrumental delivery is one of the factors that increases the likelihood of sequential use of instruments and caesarean section after a failed instrumental delivery. [34]

The particular challenges associated with fetal head malpositions were also explored in Chapter 1. They are known to be associated with increased prolonged first and second stages of labour, oxytocin augmentation, use of epidural analgesia, chorioamnionitis, assisted vaginal delivery, third and fourth degree perineal lacerations, caesarean delivery, excessive blood loss, and postpartum infection.[15 25 31 33 37 38] Furthermore, trial of instrumental delivery in theatre is twice as likely to fail in OP position. [15 25 36-38]

One of the pre-requisites for safe instrumental delivery reviewed in Chapter 1 is knowing the exact fetal head position.[17 18] Traditionally, diagnosis of the fetal head position is made on vaginal digital examination by delineating the suture lines of the fetal skull and the fontanelles. However, the literature review reported in Chapter 2 found that diagnosis of the fetal head position by digital vaginal examination can be unreliable, especially in cases of OP positions.[26 27 86 96] The accuracy of digital vaginal examination to diagnose the fetal head position in labour in this literature review varied from 20% to 75%.[26 27 86-91] The use of an abdominal ultrasound to enhance the diagnosis of the fetal head position as reported in Chapter 2 has only been explored in small prospective studies and few of those have addressed the accuracy rate of the intervention.[91 95] Furthermore, only two of these studies evaluated the role of ultrasound to determine the fetal head position before instrumental deliveries.[96 97]

Moreover, it is evident from the questionnaire survey reported in Chapter 3 that when there is difficulty or uncertainty in diagnosing the fetal head position, obstetricians use varied strategies to aid diagnosis. Trainees were more likely than consultants to seek a second

opinion (40% vs 5%, p <0.0001), reassess in an operating theatre (80% vs 68%, p=0.048) or abandon the procedure in favour of caesarean section (14% vs 6%, p = 0.035). Only one in five obstetricians reported using abdominal ultrasound to aid diagnosis but polarised views were expressed regarding the use of ultrasound in that setting.

We designed a multi-centre randomised controlled trial (RCT) evaluating the role of ultrasound in assessing the fetal head position prior to instrumental delivery to address the need for high quality data in this field. We aimed to compare routine clinical assessment of the fetal head position alone versus clinical and ultrasound assessment of the fetal head position prior to instrumental delivery to determine whether the use of an inexpensive and quick intervention can reduce the incidence of incorrect diagnosis of the fetal head position. The hypothesis was that an abdominal ultrasound scan performed in addition to routine clinical examination will reduce the incidence of incorrect diagnosis of the fetal head position which will reduce the risk of maternal and perinatal morbidity associated with instrumental delivery.

This chapter details the study design of this RCT, which has the acronym IDUS (Instrumental Delivery and UltraSound). The methodology, study set-up, ethics approval, recruitment process, data collection and analysis and trial oversight are also explained.

5.2 Methods

5.2.1 The randomised controlled trial as a form of evaluation

The randomised controlled trial allows the effect of a single 'new' intervention to be assessed by creating a scientific setting whereby two groups are the same except that one group gets the 'new' intervention. It is considered the gold standard for the accurate assessment of healthcare interventions. The ideal RCT will produce objective results unaffected by bias. [102] Systematic error is minimised within an RCT by the rigorous methodological safeguards of randomisation and blinding; and random error can be mathematically determined. A well designed, properly executed and managed RCT of sufficient size can provide reliable evidence on the efficacy of the intervention being studied.

5.2.2 Randomisation

Proper randomisation yields unpredictability thereby reducing selection bias and blinding (if possible) can reduce observer bias.[103] For randomisation to be successful it is essential that not only the sequence generated is unpredictable but also that this sequence is concealed from investigators until allocation occurs.

5.2.3 Blinding

Blinding aims at preventing ascertainment bias and also protects the random sequence even after allocation has occurred. However, blinding is not always possible.

The IDUS RCT was largely an open study. Blinding of women and the health-professionals caring for them in relation to an ultrasound intervention during labour is not possible. We considered the possibility of performing an ultrasound scan in the usual care arm and not disclosing the findings but considered it unethical to withhold information about apparent incorrect diagnosis of the fetal head position. Furthermore, this design seemed flawed at the outset as it assumed the ultrasound intervention to be better than clinical examination.

5.2.4 Reporting

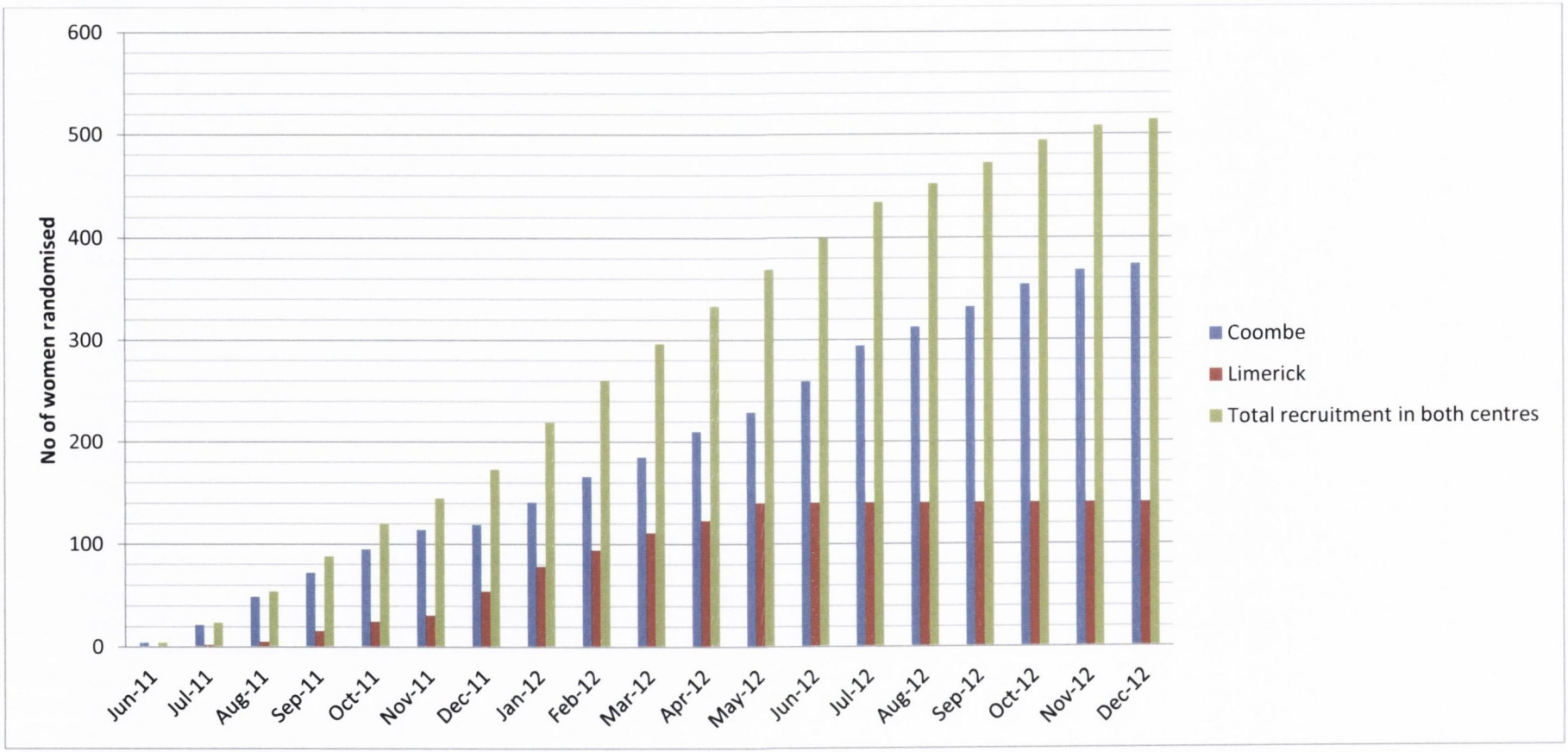
Transparent reporting of the RCT in scientific journals is essential in endorsing the reliability and validity of the trial findings.[104] To combat the inaccurate and incomplete reporting of trials, a group of journal editors, scientists, methodologists and trialists developed an evidence based and standardised set of recommendations: the CONSORT (CONsolidated Standards Of Reporting Trials) statement. Its objectives were to facilitate reporting of trials by authors thereby aiding interpretation and appraisal by editors, peer reviewers and readers.[104 105] It consists of a checklist of 25 items focusing on reporting of trial design, analysis, results and interpretation. It also includes a flow diagram which demonstrates the progress of participants throughout the trial. CONSORT is an evolving document which is regularly reviewed and updated. The most recent version of the CONSORT statement dates in 2010.[105]

5.2.5 Setting

Recruitment was planned to take place in two maternity hospitals: the Coombe Women and Infants' University Hospital, Dublin and Midwestern Regional Maternity Hospital, Limerick. Both are university teaching hospitals. There are over 9000 deliveries per year in the Coombe Women and Infants' University Hospital and over 6000 deliveries a year in the Midwestern Regional Maternity Hospital.

Recruitment started in July 2011 in the Coombe Women and Infants' University Hospital and in September 2011 in the Midwestern Regional Maternity Hospital after the appointment of a research fellow to that site. The recruitment process and timelines for recruitment are shown in figure 5.1. Recruitment concluded in 2012.

Figure 5.1. Patient recruitment for trial duration.



5.3 Recruiting women for research in labour

Intrapartum research poses particular challenges as women are vulnerable at that time due to fear, uncertainty and pain. Yet, it is essential that high quality research is conducted addressing the specific healthcare needs of women in labour and that women are given an opportunity to participate in such research. [106]

Informed consent is an ongoing agreement by a person to receive treatment, undergo procedures or participate in research after the risks, benefits and alternatives have been adequately explained to them. The general principles of obtaining valid consent should be followed when recruiting women. [107] The most appropriate time to gain informed consent for intrapartum research is determined by the nature of the study.

Studies evaluating events with an occurrence risk of 1 in 1 to 1 in 10 (such as research on partograms, CTGs, operative vaginal deliveries, second degree perineal tears etc) should be made known to women during the antenatal period and the researcher can obtain written informed consent before, or at the start, of labour.[106] If the event happens in labour consent should be confirmed. On the other hand, for events with an occurrence risk of 1 in 10 to 1 in 100 (such as anal sphincter tears, fetal blood sapling etc), providing information on the study in the antenatal period carries the risk of overburdening women with too much information. The University of Liverpool School of Reproductive and Developmental Medicine in collaboration with the North West Obstetrics and Gynaecology Clinical Trials Collaborative have suggested an alternative pathway shown in Figure 5.2.[108] In this instance, trial information is provided to women who become eligible during the intrapartum or immediate postpartum period prior to obtaining written informed consent.[108] For events with an occurrence risk of less than 1 in 100 (such as shoulder dystocia, uterine inversion etc), it is prudent to avoid unnecessary physical and psychological stress which might be caused by providing detailed information about rare situations. In these cases, it may be more appropriate to provide trial information to the woman if the event happens or when the suspected risk of occurrence for the woman in question exceeds the background risk of 1 in 100.[108]

In fact, recruiting to intrapartum research is recognised as difficult. A large number of women may need to be approached in the antenatal period, of whom only a small proportion will

ultimately be invited to participate in the trial. Furthermore the additional challenge of labour itself which can be unpredictable with events occurring at any time of the day, any day of the week further complicates the recruitment process. Often, funding is not sufficient to permit 24/7 cover of the labour ward by researchers. Therefore, when designing intrapartum trials, a pragmatic but ethical, sensitive and cost-effective approach is essential for the success of the trial.

Figure 5.2. Obtaining informed consent in labour.[108]

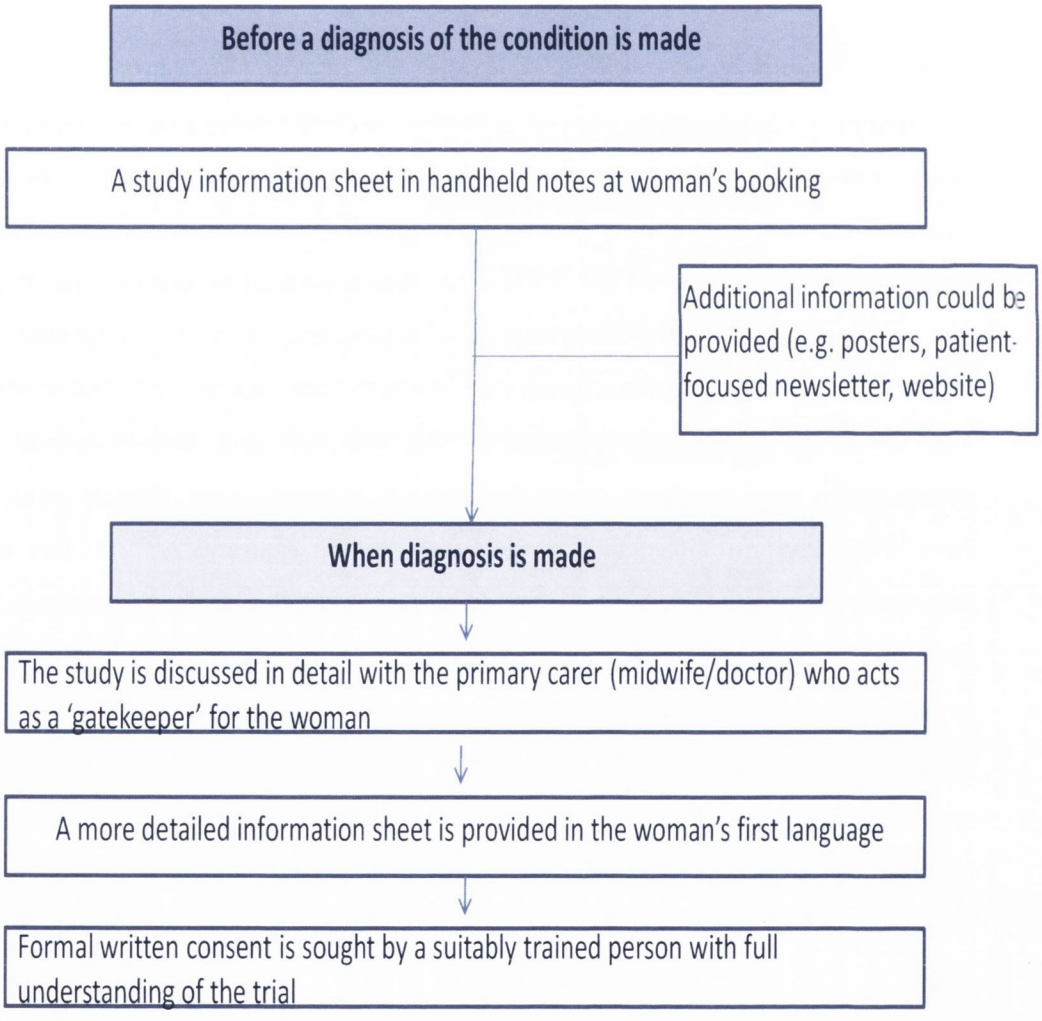


Table 5. 1. Guideline for consent.[107]

Guideline of information to be given when formal written consent is sought by a suitably trained person:
Name of proposed procedure or course of treatment
Description of proposed procedure/treatment
Intended benefits of the procedure/treatment
Serious & frequently occurring risks of the procedure/treatment
Any extra procedures which may become necessary during the procedure/treatment

5.4 Recruitment process

Recruitment of women to the study followed a three stage process.

1. All potentially eligible women were given written information about the study in the antenatal clinic. The leaflet explained the trial purpose and design, making it clear that women would only become eligible for the study if they required an instrumental delivery. (Appendix 21)The leaflet contained contact details to allow women to discuss the study further if they wish.

2. Once a woman presented in early labour or for induction of labour, a research fellow sought written informed consent if the following criteria were satisfied: (Appendix22)
    a. the midwife looking after the woman assessed her to be capable of providing informed consent.
    b. the woman had adequate pain control.
    c. the woman had not used systemic opiates in the previous four hours.

3. Once consent was given the woman was not consulted again unless she required an instrumental delivery.

After confirmation that all criteria were met, the researcher obtained the allocation via a web-based system. Our resources allowed us one researcher per site, therefore it was not feasible to provide recruitment on the labour ward 24 hours a day, 7 days a week. In order to get as representative a sample as possible for the RCT, the researchers carried out shifts over different time periods over different days of the week. In addition, the researcher from the Midwestern Regional Maternity Hospital was relocated to the Coombe Women and Infants' University Hospital for one month in June 2012 in order to provide 24 hour recruitment on the labour ward- the two researchers doing 12 hour shifts each in opposition to one another.

5.4.1 Inclusion criteria

This study was limited to nulliparous women at term (≥37 weeks' gestation) with singleton cephalic pregnancies, aiming to deliver vaginally who require an instrumental delivery in the second stage of labour.

5.4.2 Exclusion criteria

Women with a contraindication to instrumental delivery, or who had a limited understanding of English or were under 18 years of age were excluded. Eligibility was also at the discretion of the responsible obstetrician in cases where there was urgency due to suspected fetal compromise ("fetal distress").

5.4.3 Allocation to trial groups

Allocation of eligible women who consented to participate in the trial was concealed using a fully automated centralised web-based system provided by the Bristol Randomised Trials Collaboration. The randomisation sequence was created by using block sizes of 4, 8 and 12 and stratified by centre, in a 1:1 ratio for usual care versus intervention.

5.5 Intervention

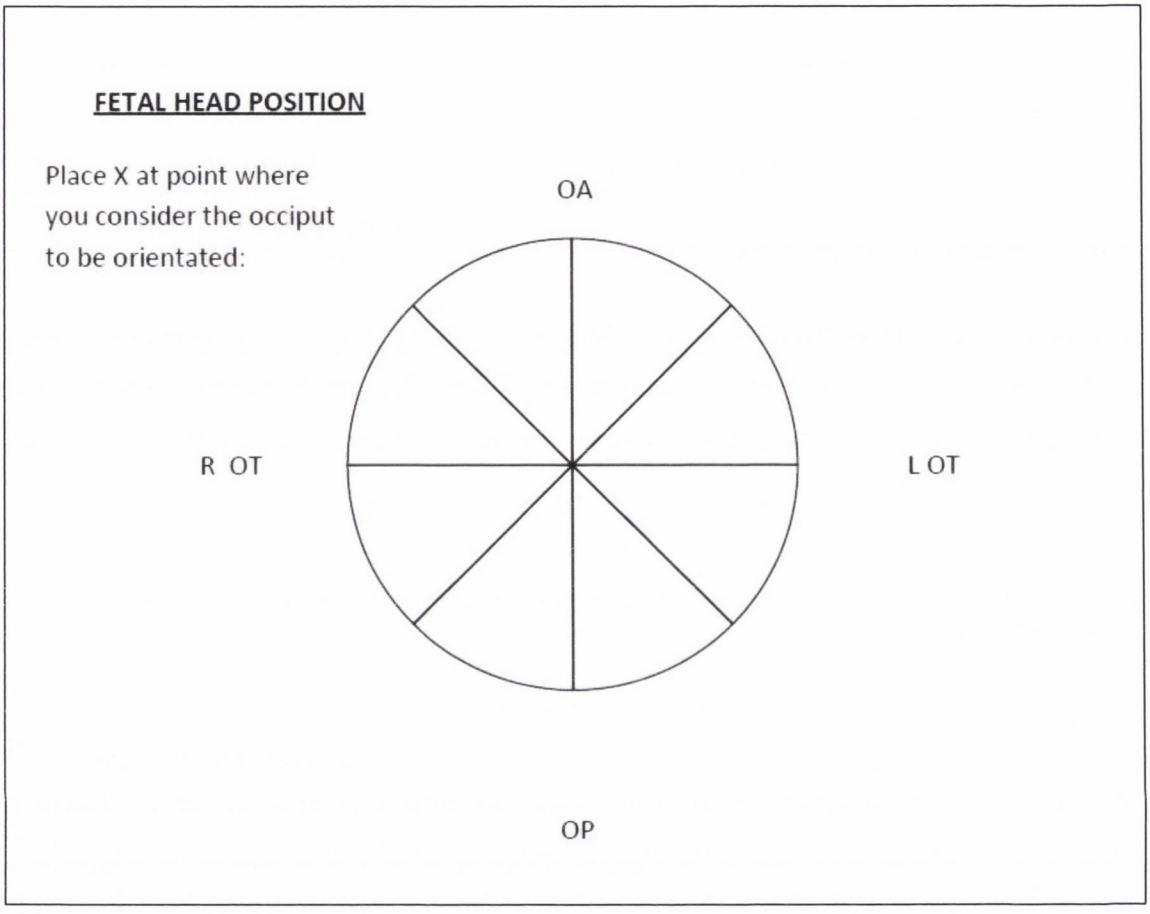
5.5.1 Usual care arm

Women allocated to receive usual care were managed according to Royal College of Obstetricians and Gynaecologists (RCOG) guidelines and the local hospital protocol. [18] The women were assessed by abdominal and digital vaginal examination prior to instrumental delivery. Following clinical assessment, location of the fetal occiput in relation to pelvic landmarks was indicated visually by way of a cross on a data sheet depicting a circle, like a clock, divided into 24 sections, each of 15 degrees. (Figure 5.3) The position was then be classified as OA for direct occipito-anterior, ROA and LOA for right and left occipito-anterior respectively; OP for direct occipito-posterior, ROP and LOP for right and left occipito-posterior; ROT and LOT for right and left occipito- transverse respectively. The degree of certainty with regards to the fetal head position was recorded on a Likert scale from 1 to 10 (1 very uncertain, 10 completely certain).

The obstetrician then proceeded to instrumental delivery. The full clinical assessment, delivery procedure, delivery outcome and measures of early morbidity was recorded on a standard instrumental delivery proforma.

The mother and the neonate were followed-up until hospital discharge.

Figure 5. 3 Data sheet: digital vaginal examination findings.



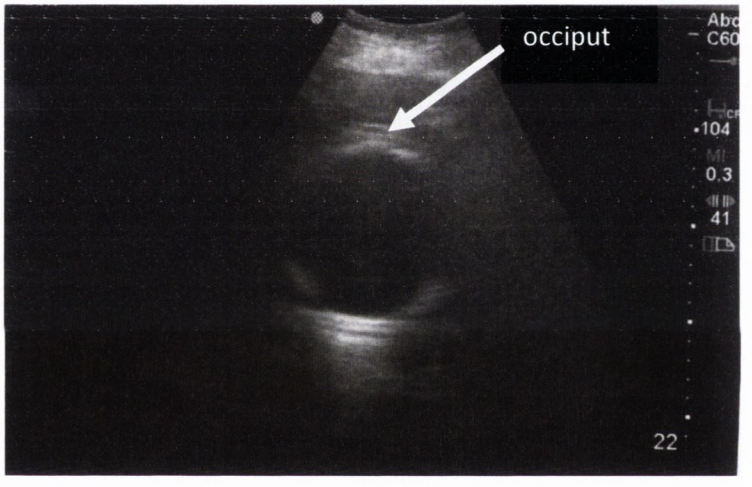
5.5.2 Intervention arm

Women in the intervention group were managed in the same way. In addition they received an ultrasound scan to assess the position of the fetal head and spine. Immediately before or after the clinical examination and before application of the instrument, the fetal head position was determined sonographically by a trained research fellow. The research fellow was trained before the start of the trial as described in Chapter 4. (Appendix 5) For all ultrasound assessments, image- directed pulsed Doppler equipment (Sonosite Titan) with a multifrequency sector array transabdominal transducer, and a 3.5 MHz sector ultrasound probe, was used.

With the patient in a supine position the ultrasound transducer was first placed transversely over the maternal abdomen and moved longitudinally to identify landmarks for the fetal spine

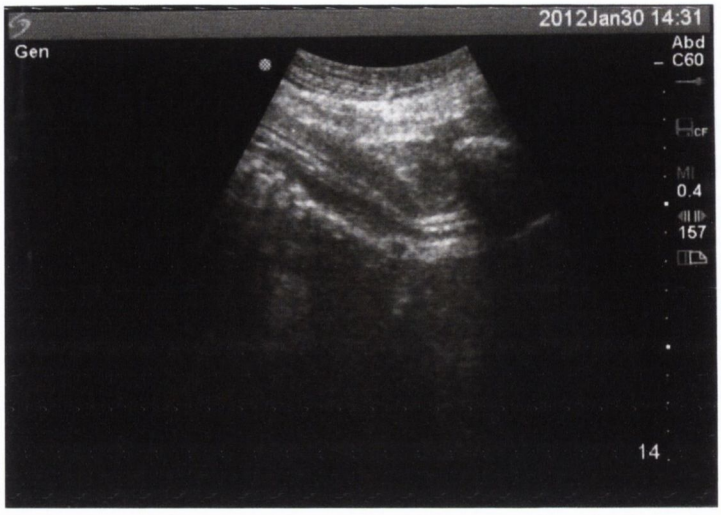
and head position as described in the validation study. The transabdominal probe was then rotated through 90 degrees, to obtain the transverse view of the fetal spine. Following this, a sliding motion towards the fetal head was made to obtain a view of the following midline fetal cranial structures: midline cerebral echo, falx cerebri and thalamus and anterior or posterior cranial structures including the orbits and nuchal region. The fetal head position was classified as previously described. The obstetrician wasinformed of the ultrasound findings to facilitate decision making and may then proceed to instrumental delivery.

Figure 5.4 Ultrasound image depicting the direct OA position.*



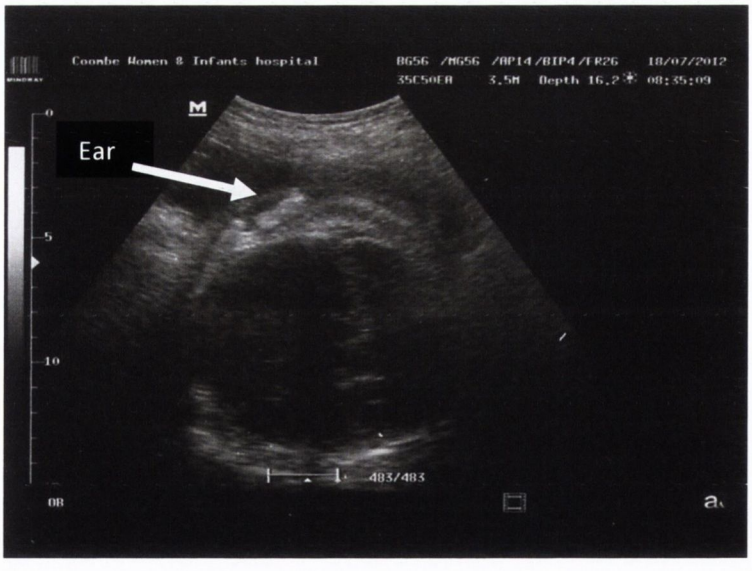
*This image was taken on a portable ultrasound machine on the labour ward during the RCT and represents realistic intrapartum portable ultrasound images.

Figure 5.5 Ultrasound image depicting the fetal spine in an anterior position.*



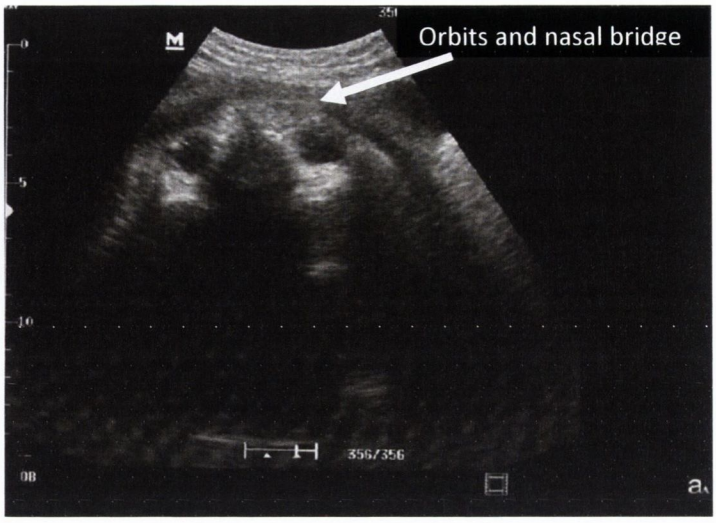
*This image was taken on a portable ultrasound machine on the labour ward during the RCT and represents realistic intrapartum portable ultrasound images.

Figure 5.6 Ultrasound image depicting the LOT position with a fetal ear visible anteriorly.*



*This image was taken on a portable ultrasound machine on the labour ward during the RCT and represents realistic intrapartum portable ultrasound images.

Figure 5.7 Ultrasound image depicting the OP position.



*This image was taken on a portable ultrasound machine on the labour ward during the RCT and represents realistic intrapartum portable ultrasound images.

5.6 Data from medical records

Information about each woman's medical and obstetric history was collected from antenatal clinical records at the time of recruitment. Details of the delivery and postnatal recovery were collected from midwifery, anaesthetic, obstetric and paediatric notes. (Appendices 26 and 27)

5.7 Data entry and checking

As data were received, they were entered onto a password protected PASW database by members of the research team. All data were double-checked for quality. Erroneous values were verified against source data and corrected as appropriate.

5.8 Baseline Characteristics

Baseline assessment included initial patient characteristics. This documented socio-demographic characteristics and self-reported health. Whilst it may be tempting to collect as much information as possible, it is important to focus on relevant information. It is essential to ensure all prognostic factors and end points are included. While block randomisation controls possible imbalance in group size that may arise by chance, it does not control possible imbalance in the characteristics at baseline of the groups. In any one trial it is extremely unlikely that the groups will be exactly balanced. It is therefore important to assess and report the baseline characteristics of the treatment groups, with particular reference to potential prognostic factors. This is useful general information to help the reader assess the comparability of the treatment groups, as well as providing general information to help the reader assess the trial's external validity. However, the common practice of undertaking significance tests of baseline characteristics is not appropriate.

Socio-demographic, past medical and obstetric history information was collected in order to characterise participants at trial entry. Marital status was defined as married, single supported, single unsupported or unknown. Participants' date of birth was used to calculate their age on the day of delivery. Maternal weight, height and BMI were routinely recorded at the booking visit in the two centres and these values were collected. Gestational age at booking was also recorded. Each participant's smoking status, alcohol intake and drug use was also recorded.

5.9 Outcome measures

5.9.1 Primary outcome

The primary outcome measure was incorrect diagnosis of the fetal head position. Most errors of clinical diagnosis occur when the position is classified as occipito-anterior but is in fact occipito-transverse or occipito-posterior. Incorrect diagnosis of the fetal head position was established according to any of the following criteria:

1. Position of the head at the time of delivery

If the position of the fetal head was classified as occipito-anterior and delivered occipito-posterior the diagnosis of the fetal position was considered incorrect.

2. Instrument markings on the neonatal head and face

The neonatologist or midwife who attended the delivery examined the baby and he/she recorded the markings of the instrument on a drawing of the head and lateral aspects of the face. (Appendix 25) The recorded markings were used to indicate misplacement of the instrument at a distance from the flexion point (vacuum) or over the face (forceps). If for example the recorded position prior to instrumental delivery was occipito-anterior and the instrument placement suggests an occipito-transverse or occipito-posterior position the diagnosis of the fetal position was considered incorrect. Furthermore, the diagnosis was considered incorrect if the markings were more than 45^{o} from the documented fetal head position.

3. Position at caesarean section

If the delivery was completed by caesarean section the operator recorded the position of the head at delivery. If the position of the fetal head was defined as occipito-anterior but was in an occipito-posterior position at caesarean section, the diagnosis of the fetal position was considered incorrect. This information was cross-referenced with the instrument markings recorded by the midwife/neonatologist in cases where there was an initial attempt at instrumental delivery.

The primary outcome was validated independently by a single investigator who was not involved in scanning by reviewing the trial documents (fetal head position recorded by the obstetrician, diagrammatic records of instruments markings on the neonate and documented

position of the head position at delivery as described above). Trial allocation was concealed from this person. Two additional data items were recorded:

1. where the position was correctly identified the application of the instrument was classified as optimal or sub-optimal based on the instrument markings .
    a. For vacuum, instrument placement was considered optimal when the cup marking included the flexion point (3cm anterior to the posterior fontanelle) and the posterior fontanelle ; and was also centrally placed. (Figures 5.8 to 5.10)
    b. For forceps, instrument placement was considered optimal when the blade markings were bilaterally and symmetrically over the malar bones. (Figures 5.11 to 5.12)

2. where there was discordance between the findings of the obstetrician and ultrasonographer the researcher recorded whether the ultrasound finding was accepted or not.

Figure 5.8 Optimally placed vacuum.

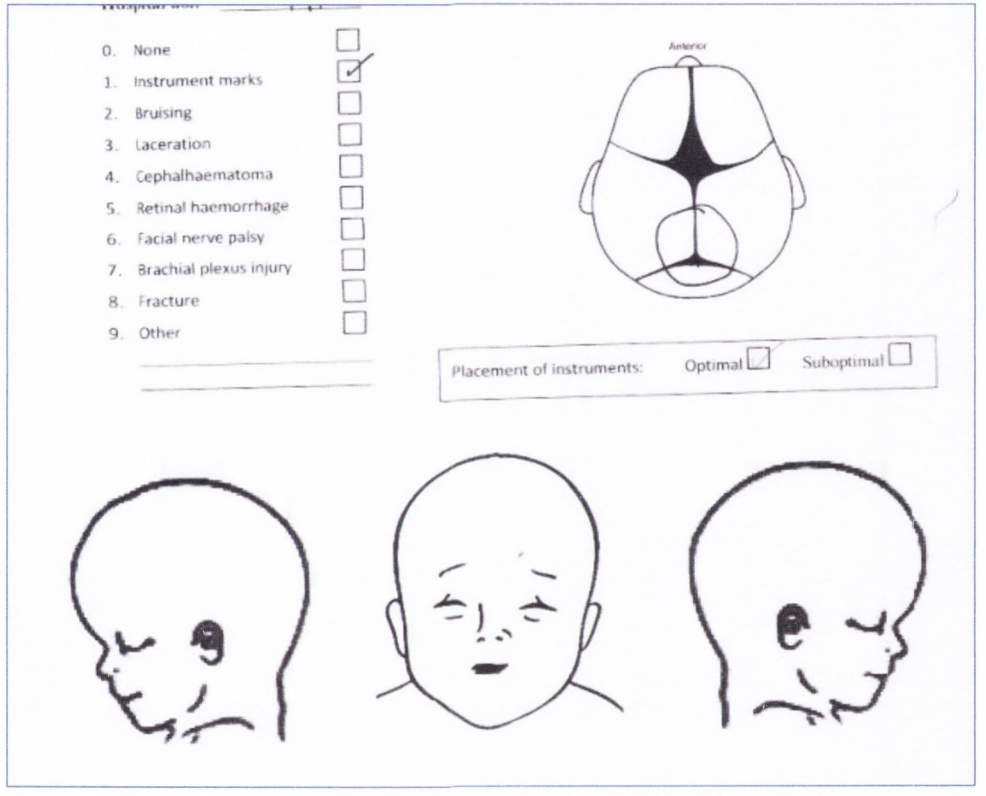
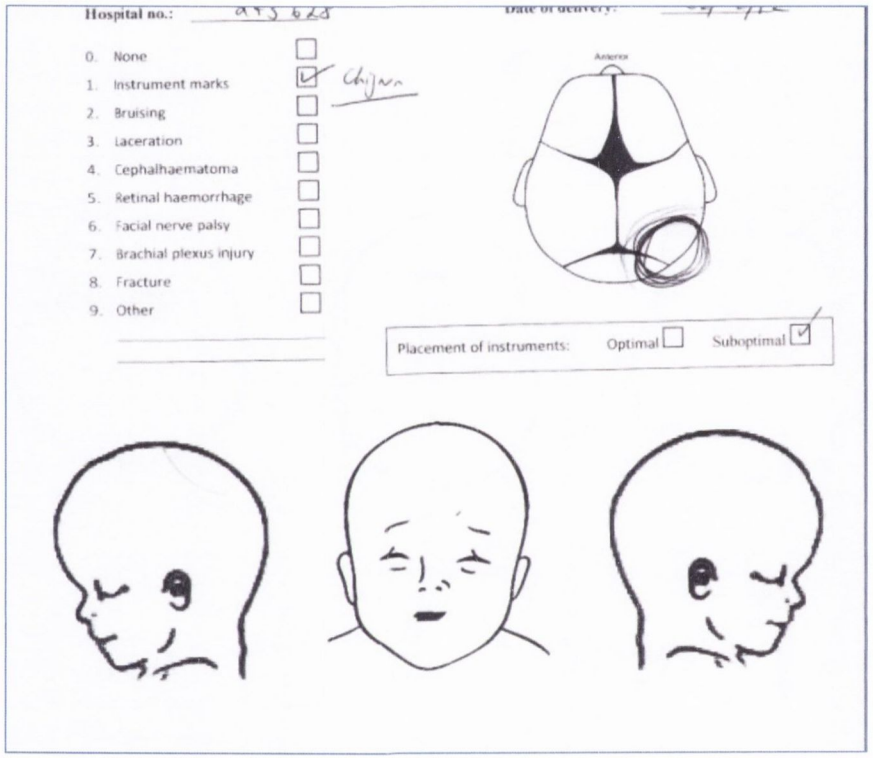
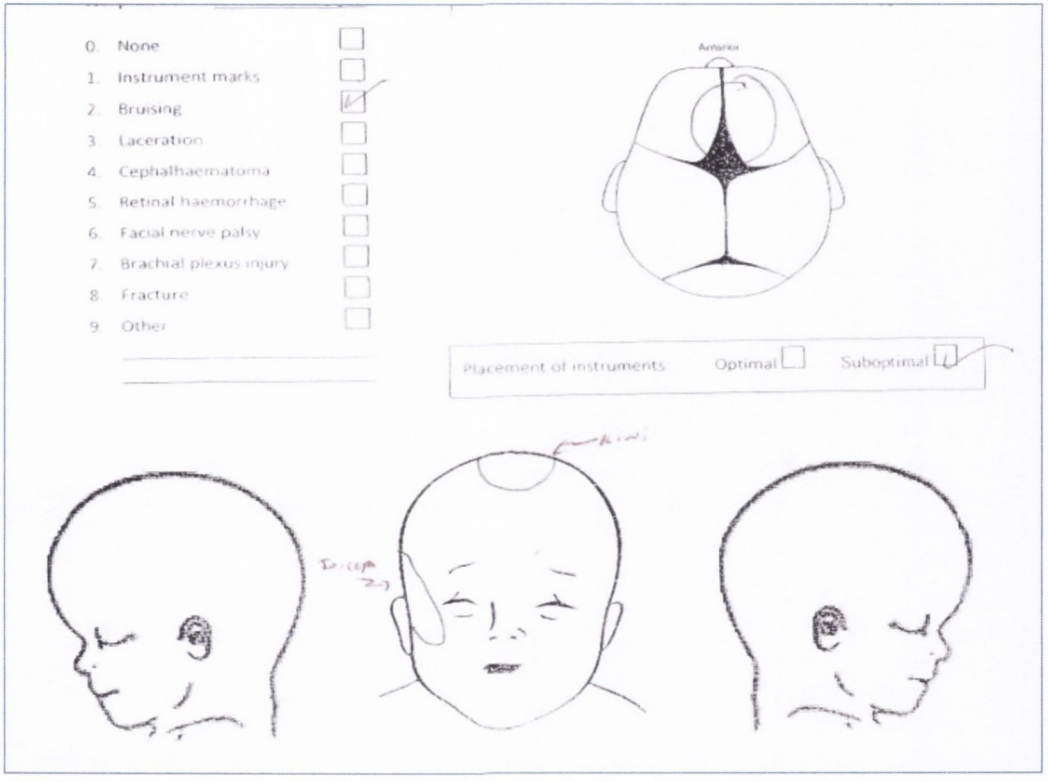


Figure 5.9 Sub-optimally placed vacuum. *



*Sup-optimal vacuum placement – cup does not include the flexion point and is eccentrically placed. The diagnosis of the fetal head position was considered correct in this case: the fetal head position was classified as ROP before delivery and was in an OA position at delivery.

Figure 5.10 Sequential instruments with sup-optimally placed vacuum.*



*Sup-optimal vacuum placement – cup does not include the flexion point and is eccentrically placed. The diagnosis of the fetal head position was considered incorrect in this case: the fetal head position was classified as OA before delivery and was in an OP position at delivery.

Figure 5.11 Optimally placed forceps.

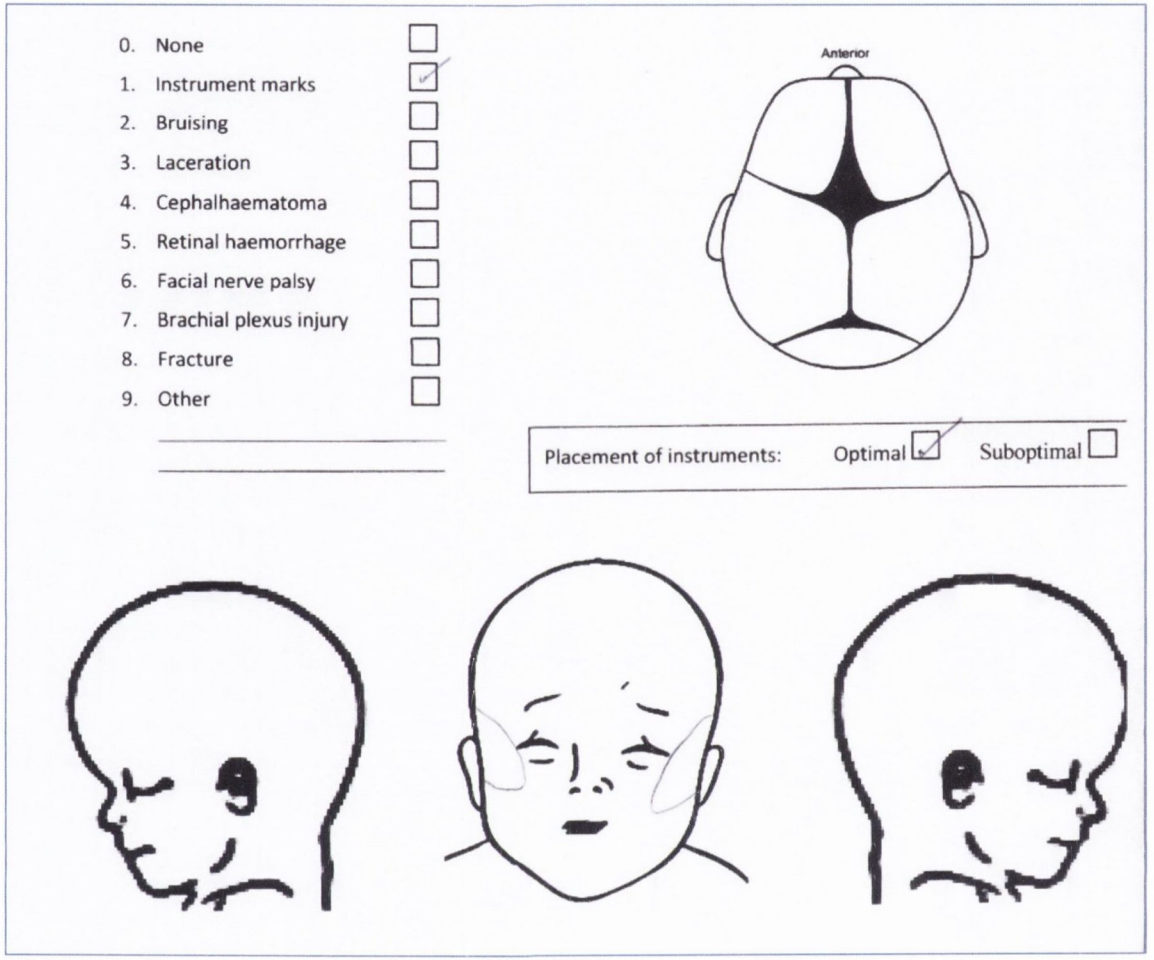
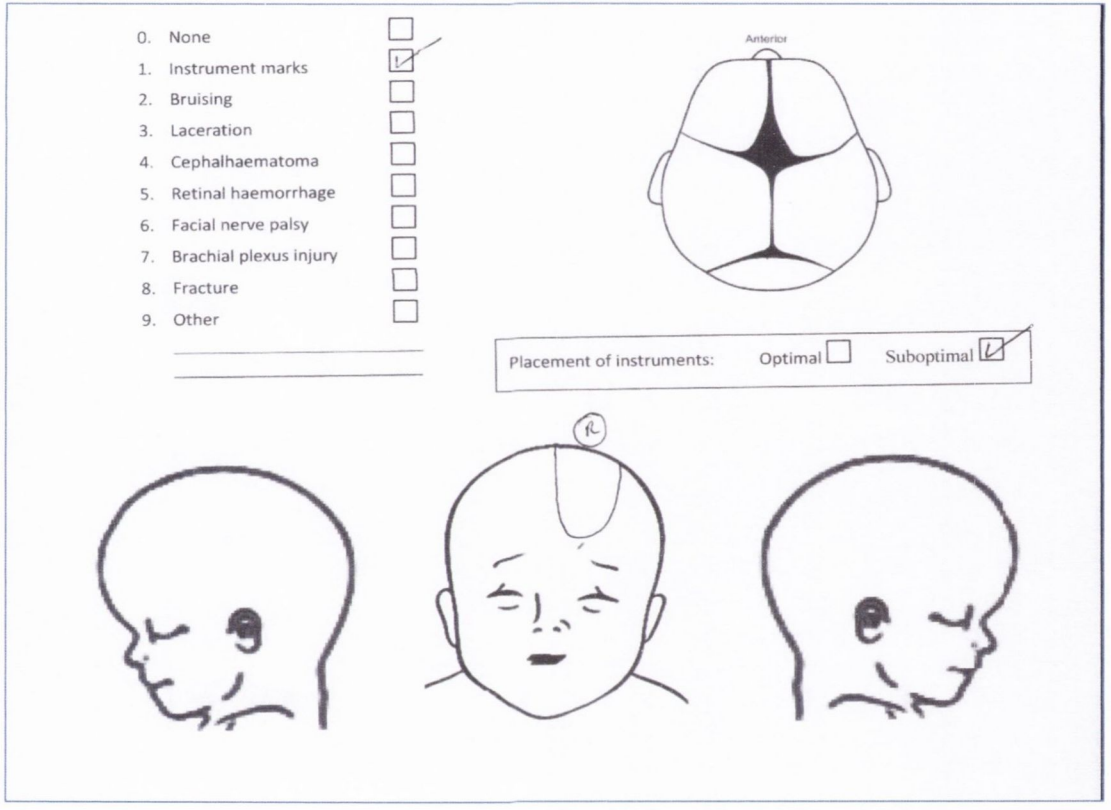


Figure 5.12 Sub-optimally placed forceps.*



*Sup-optimal forceps placement – the diagnosis of the fetal head position was considered incorrect in this case: the fetal head position was classified as OA before delivery and was in an OT position at delivery.

5.9.2 Secondary outcomes

Secondary maternal outcomes included extensive perineal tearing involving the anal sphincter (third or fourth degree tears), postpartum haemorrhage, shoulder dystocia, and length of postnatal hospital stay. Primary post partum haemorrhage was defined as an estimated blood loss at delivery and in the first 24 hours of more than 500mls. Postnatal stay was considered prolonged if more than 3 days' duration. Maternal and neonatal complications were defined clinically according to the attending clinicians.

Secondary neonatal outcomes included trauma, low Apgar scores, low arterial blood gases and admission to the neonatal intensive care unit (NICU). Neonatal trauma included bruising, laceration, cephalhaematoma, retinal haemorrhage, facial nerve palsy, brachial plexus injury and fractures. Paired cord blood gases were taken routinely in both centres as part of routine clinical practice to measure arterial and venous pH and base excess. Arterial pH below 7.10 and base excess greater than −12.0 mmol/l were used as the threshold to define significant fetal acidosis.

Procedural issues were recorded in terms of place of delivery, need for senior obstetric support, transfer to theatre, use of sequential instruments, failure of instrumental delivery or proceeding directly to caesarean section and the decision to delivery interval.

5.10 Follow-up

Clinical follow-up of the mother and neonate was completed prior to hospital discharge.

5.11 Trial end

The trial was considered complete after the final review of the last subject participating in the trial. Trial completion was notified to the Competent Authority and the Ethics Committee using the appropriate form.

5.12 Statistical analysis

Data analysis and reporting proceeded according to CONSORT guidelines for randomised controlled trials, and were conducted blinded to group status by me and checked by the trial statistician, Alan Montgomery. All analyses were conducted using SPSS 18 and Stata 12.The first stage of analysis was to use descriptive statistics to describe recruited individuals in relation to those eligible, and to investigate comparability of the trial arms at baseline. The primary analysis involved an intention-to-treat comparison between the two groups for the primary outcome adjusted for stratification/minimisation factors – this included study centre. The primary analysis used binary logistic regression models. We also performed sensitivity analyses on the primary outcome and investigated clustering effects by operator.

Secondary outcomes were analysed following the same general approach as for the primary analysis, using linear or logistic regression models for continuous or binary outcomes as appropriate. We also carried out a series of planned subgroup analyses by including appropriate interaction terms in the regression models to establish any differential effects in relation to operator experience and centre.

All the results were presented as point estimates (odds ratios or difference in means), 95% confidence intervals and p values.

5.13 Feasibility

As described in Chapter 4, an ultrasound examination to diagnose the fetal head position in the second stage of labour is accurate and acceptable to women in labour and to the clinicians looking after them. Interventional studies in the second stage of labour require great sensitivity in terms of appropriate recruitment, randomisation and follow-up. A large number of women need to be approached in the antenatal period of whom only a small proportion will ultimately be invited to participate in the trial. The number of women who are eligible but not recruited needs to be recorded.The pressure that obstetricians and women are under when planning instrumental delivery needs to be taken into account when designing a second stage clinical trial.. Our research team has extensive experience of performing studies in this context and the proposed study design and sample size reflects an accurate estimate of what is feasible within the proposed time frame and available resources.

5.14 Sample size

The rate of inaccurate diagnosis (difference of more than 45 degrees) was hypothesized to be 20% in the usual care arm (clinical assessment alone) and 10% in the intervention arm (clinical assessment and ultrasound). With 225 women per arm, the study had 80% power with 5% two-sided alpha, to detect the hypothesized 10% difference. However, it is possible that inaccuracy rates are being under- or over- estimated. It could be argued that any difference in effect on the primary clinical outcome would be worth detecting. Rather, given the need for timely delivery of evidence, we have specified detectable differences for realistic sample sizes recruited within a reasonable time frame within the constraints of the available funding.

The combined annual birth rate for the two recruiting hospitals is 13,500, and around 40% of women will be nulliparous, of whom 30% will have an instrumental delivery. We estimate that there will be a total of 3240 instrumental deliveries among nulliparous women over the 24 month recruitment period based on hospital statistics for 2007. Allowing for 30-50% exclusion and non-consent, 95% collection of the primary outcome, and recruiting for 24 months during office hours yields a conservative estimate of 450 participants (225 per arm) for analysis. (Table 5.1) This would enable detection of a between-group difference of 10–13 percentage points (odds ratio 0.44 to 0.55) with 80% power and 5% two-sided alpha, and would certainly be considered by women and clinicians as worthwhile. These conservative recruitment estimates take account of eligibility criteria, non-English speaking women and the potential difficulty of randomisation and ultrasound evaluation in the context of suspected "fetal distress".

Table 5.1 Sample size calculations.

Incidence of incorrect diagnosis of fetal position in control group	Incidence of incorrect diagnosis of fetal position in ultrasound group	Sample size (≥ 80% power, 2-sided α = 0.05)
20%	10%	438 (219 each arm) OR 0.44
30%	18%	428 (214 each arm) OR 0.51
40%	27%	442 (221 each arm) OR 0.55

5.15 Timetable

Total 36 months: Commencing 01.12.10 - Estimated completion date 30.06.13

Month 0 – 6: validate datasets; regulatory approvals; validation study; finalise recruitment procedure; raise awareness.

Month 7– 25: recruitment; data collection and follow-up.

Month 26 – 32: data analysis and reporting; peer-review publications; presentations.

5.16 Study set-up

5.16.1 Funding

This study was funded by a Research Project Grant from the Health Research Board of Ireland – HRA_POR/2010/55. (Appendix 18) Annual reports were submitted to the Health Research Board. The funding sources had no involvement in any aspects of trial design, writing of the trial reports, or the decision to submit the paper for publication.

5.16.2 Ethical committee permission

Ethical committee approval from the Coombe Women & Infants University Hospital and the Mid-Western Regional Maternity Hospital, Limerick, was granted for this study. (Appendices 6 and 7)

5.16.3 Trial registration

The trial was registered at controlled-trials.com and was assigned the registration number: ISRCTN72230496. (Appendix 19)

5.16.4 Research Team

Research fellow positions were advertised and interviews were held. A full time research fellow was appointed to each centre. I was acting as trial co-ordinator at both centres but with responsibility for recruiting predominantly at the Coombe Women & Infants University Hospital.

5.16.5 Data management

Data was collected on a case report form (CRF) at the time of recruitment by a trained researcher. (Appendix 26, 27) The researcher was also responsible for ensuring that the details of the delivery were recorded and documented according to the study protocol. The inpatient maternal and neonatal notes were marked so that they could easily be recovered following discharge from hospital. After discharge the CRF was collected by the local researcher and the completeness of the data checked against the woman's and neonate's notes. Any errors were followed up at this time. The data were entered by me into a computer database (password protected) at the Coombe Women and Infants University Hospital.

5.16.6 Trial management group (TMG)

This group was in charge of the everyday running of the trial. The full group had regular meetings and as required. These meetings took place at the Coombe Women & Infants University Hospital with tele-conferencing facilities available. Table 5.2 lists the members of the TMG and their contribution. Day-to-day decision making were by Prof. Deirdre Murphy, Dr. Gerard Burke and me, with meeting of the full committee as above. (Table 5.3)

Table 5.2 Members of the IDUS Trial Management group.

Name	Initials	Job title	Location during trial
Meenakshi Ramphul	MR	Research Fellow (Trial co-ordinator)	Coombe Women & Infants University Hospital
Deirdre J Murphy	DJM	Professor of Obstetrics and Head of Department (Principal Investigator)	Trinity College Dublin and Coombe Women & Infants University Hospital
Mairead Kennelly	MK	Consultant Obstetrician & Gynaecologist, Feto-maternal specialist	Coombe Women & Infants University Hospital
Wendy Poh Vei Ooi	WO	Research Fellow	Midwestern Regional Hospital, Limerick
Gerry Burke	GB	Consultant Obstetrician & Gynaecologist	Midwestern Regional Hospital, Limerick
Soha TA Said	STAS	Consultant Obstetrician & Gynaecologist	Midwestern Regional Hospital, Limerick
Alan Montgomery	AM	Reader in Health Services Research	University of Bristol
Maureen Mcleod	MM	Research midwife (recruitment advice)	University of Dundee
Sharon Sheehan	SS	Obstetric Clinical Fellow (recruitment advice)	St Michael's Hospital, Bristol

Table 5.3 Contributions of IDUS study group members.

Task	Major Contribution	Supporting or Supervisory Contribution
Initial idea for study	DJM, GB	
Developing the study protocol	DJM, AM, MR	SS,MM,MK
Obtaining funding	DJM, AM, GB	
Obtaining ethics approval	DJM, MR	
Ultrasound training	MK, STAS, GB	
Conducting validation study	MR, MK	DJM
Organising Trial Steering Committee Meetings	MR	DJM
Recruiting research fellow	DJM,MK, MR	
Recruiting to IDUS	MR,WO	DJM, GB
Determination of primary outcome measure	DJM	MR, WO
Producing annual reports: Health Research Board of Ireland and Ethics Committees	MR	DJM
Data collection	MR, WO	DJM
Data entry	MR	DJM
Data checking	MR	DJM
Statistical analysis	MR, AM	DJM
Writing study publications	MR, DJM	AM, MK, GB,WO,SATS

Note: My contribution is highlighted in red

5.16.7 Trial steering committee (TSC)

A trial steering committee was set up which had overall oversight of the trial. The TSC met prior to commencement of the trial and regularly thereafter. Meetings were again held at the Coombe Women & Infants University Hospital with tele-conferencing facilities. Dr Geraldine Gaffney was appointed as the independent chair. Table 5.4 Lists all the members of the TSC and their contribution.

Table 5.4 Members of Trial Steering Committee.

Position	Name	Institution
Chair	Geraldine Gaffney	University Hospital Galway
Member	Andrew Weeks	Liverpool Women's Hospital, UK
Member	Rebecca Cannings-John	Institute of Primary Care & Public Health, Cardiff University School of Medicine, UK

5.16.8 Data monitoring committee (DMC)

A Data Monitoring Committee (DMC) is an independent group of experts who monitor patient safety and treatment efficacy data while a clinical trial is ongoing. It consists of at least one statistician and one clinician with expertise in the relevant research field. The primary role of the DMC is to protect patient safety. If serious adverse events (SAEs) are more common in the experimental arm compared to the control arm, then the DMC would have to strongly consider termination of the trial. On the other hand, in the rare situation that the experimental arm is shown to be undeniably superior to the control arm the DMC may recommend termination of the trial.

After discussion with the TSC and review by the independent Chair, we decided not to set up a data monitoring committee. The reasons were, firstly, serious adverse events in this trial were deemed to be inherent complications of the procedure (instrumental delivery) and unlikely to be related to the intervention (ultrasound). We arranged to report any serious adverse events, should they occur, to the Chairperson. Secondly, we did not plan to do any interim analysis which would reveal any differences between the trial arms before the scheduled end of the trial.

5.16.9 Safety considerations

Serious adverse events (SAEs) were recorded and reported to the regulatory authorities. SAEs included maternal death, surgery (other than caesarean section), admission to intensive care unit or perinatal death. In the event of a SAE occurring, a form was completed by the local researcher and faxed to the trial co-ordinating centre at the Coombe Women's Hospital within 72 hours. The chair of the TSC and the chair of the relevant ethics committees were informed.

5.16.10 Protocol publication

The study protocol was published in BMC Pregnancy & Childbirth on the 13th September 2012. (Appendix 28)

5.16.11 Study promotion

The IDUS study was publicised to obstetricians and midwives through oral presentations and written information in both centres. Prior to the start of recruitment, we sent letters to all consultant obstetricians in both centres advising them of the trial and requesting permission to recruit patients booked with them. These signed agreements were kept with trial data. We also wrote to all the midwifery managers on the labour ward, gave presentations specifically to midwives to ensure adequate completion of the neonates' form and spoke to staff midwifes individually or in small groups to raise awareness.

A patient information leaflet advertising the trial was available to women in the antenatal period from the antenatal clinic area. (Appendix 21)

5.17 Summary

This chapter has detailed the design of the IDUS randomised controlled trial. The following chapter will report the results of this trial.

Chapter 6 IDUS Randomised Controlled Trial: Results

6.1 Introduction

This chapter outlines the results of the IDUS RCT described in the previous chapter. Firstly, it will provide details of the study population, including participant flow and characteristics of trial participants at baseline. This will include baseline characteristics of the mothers and babies and details of the labour. Then, data relating to the primary and secondary outcomes will be reported using descriptive statistics and multivariable regression analyses where appropriate. The results of the subgroup analyses will also be reported.

6.2 Study population

Between June 2011 and December 2012, we enrolled a total of 514 women who had an instrumental delivery, from two teaching hospitals in Ireland with a combined birth rate of 13,500 (40% nulliparous; instrumental delivery rate of 33% for nulliparous women). Women were randomly assigned to the ultrasound scan or clinical examination arm once the decision for instrumental delivery was made. The researchers rotated through different shifts on the labour ward to get a representation of deliveries across the 24 hour period as previously described in Chapter 5.

Figure 6.1 shows the participant flow and figure 6.2 shows the percentages of women recruited in each trial centre. Out of 1371 eligible women, 471 were not randomised because they had a spontaneous vaginal delivery, 249 had an emergency caesarean section in labour, 135 had instrumental deliveries but were not randomised because the researchers were not present and two women had an instrumental delivery but the labour ward staff withdrew the women from the trial prior to allocation.

Figure 6.1 CONSORT flow diagram.

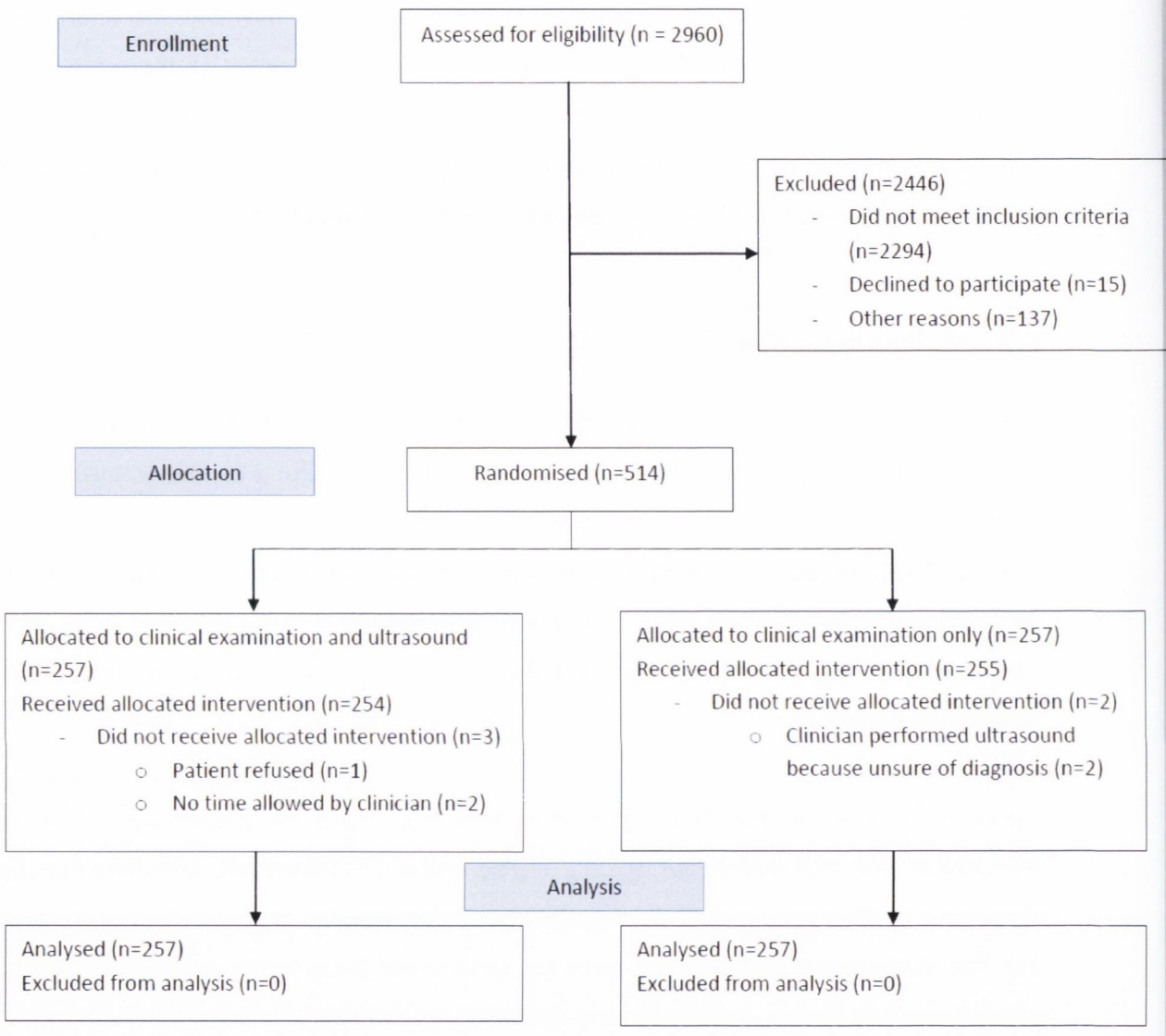
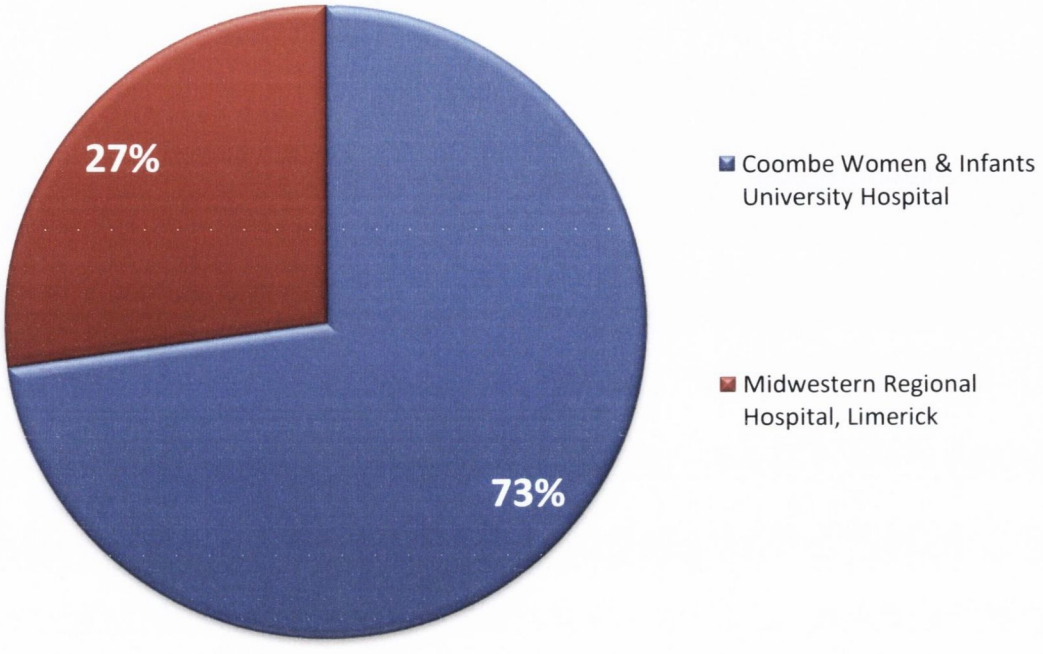


Figure 6.2 Percentages of women recruited at each centre.



6.3 Allocation

Of the 514 women randomised, 257 were allocated to the ultrasound and clinical examination (ultrasound) group, and 257 women were allocated to the clinical examination only (standard care) group. In the ultrasound group, three women did not receive the intervention: one woman declined the intervention after initially giving informed written consent; and two obstetricians opted out of the study after randomisation because of urgency due to suspected fetal distress. In the standard care group, two women had an ultrasound scan by the obstetrician looking after them to diagnose the fetal head position despite trial allocation.

6.4 Baseline characteristics

Baseline characteristics were similar between the two groups except for the following. (Tables 6.1, 6.2) There were fewer women in the ultrasound scan arm who had senior obstetricians looking after them; slightly more women in the ultrasound scan arm had a pathological cardiotocograph (CTG).

Table 6.1 Maternal and neonatal baseline characteristics.

	Ultrasound n=257 (%)	Standard care n=257 (%)
Maternal		
Mean maternal age, years (SD)	28.7 (5.1)	29.0 (5.1)
Ethnic group		
White	236 (91.8)	240 (93.4)
Asian	12 (4.7)	9 (3.5)
Black	2 (0.8)	5 (1.9)
Other ethnic group	7 (2.7)	3(1.2)
Married (%)	145 (56.4)	139 (54.1)
BMI*		
Mean BMI (SD)	24.9 (4.7)	24.3 (4.5)
Overweight: BMI 25.0 – 29.9	71 (27.6)	53 (20.6)
Obese: BMI ≥30.0 – 39.9	25 (9.7)	27 (10.5)
Morbidly obese: BMI ≥ 40	3 (1.2)	1 (0.4)
Chronic medical disorder†	47 (18.3)	44 (17.1)
Cigarette smoker	28 (10.1)	21 (8.2)
Alcohol (light)	3 (1.2)	2 (0.8)
Pre-eclampsia	5 (2.0)	4 (1.6)
Neonatal		
Birthweight <2.5 kg	3 (1.2)	2 (0.8)
Gender male	135 (52.5)	125 (48.6)
Head circumference > 37 cm	33 (12.8)	29 (11.3)
Mean birth weight, g (SD)	3,531 (427)	3,529 (443)
(range)	(2,400 – 4,790)	(2,430 – 4, 830)
Birthweight ≥ 4.0kg (%)	38 (14.8)	41 (16.0)

Legend:

* Body mass index measured as booking weight divided by the square of height (kg/m^2) (n = 255 in ultrasound group, n = 246 in standard care group).

†Diabetes, endocrine disease, cardiac disease, hypertension, renal disease, inflammatory bowel disease.

Table 6.2 Baseline characteristics of labour and delivery factors.

	Ultrasound n =257 (%)	Standard care n=257 (%)
Analgesia		
Epidural analgesia	215 (83.7)	218 (84.8)
Pudendal block	10 (3.9)	5 (1.9)
Spinal anaesthesia	13 (5.1)	10 (3.9)
Local analgesia	8 (3.1)	9 (3.5)
Labour details		
Primary indication for induction – suspected fetal compromise	180 (70.0)	175 (68.1)
Induction of labour	129 (50.2)	129 (50.2)
Mean first stage of labour, hours (SD) (range)	6.8 (3.6) (0.8 – 19.3)	6.9 (3.6) (0.3 – 19.8)
Mean total second stage of labour, hours (SD) (range)*	1.9 (1.0) (0.1 – 4.6)	1.9 (1.0) (0.1 – 4.8)
Mean active second stage of labour, hours (SD)(range)	0.9 (0.6) (0.1 – 2.8)	0.9 (0.5) (0 – 2.5)
Oxytocin use in first stage of labour	149 (48.5)	158 (51.8)
Oxytocin use in second stage of labour	180 (70.0)	186 (72.4)
Pathological CTG in second stage of labour†	167 (65.0)	155 (60.3)
Meconium stained liquor	54 (21.0)	56 (21.8)
Procedure-related		
Senior obstetrician‡	78 (30.4)	87 (33.9)
Fetal malposition ¶	114 (44.4)	115 (44.7)
Engagement of fetal head ≤ one fifth palpable abdominally	249/249 (100)	243/244 (99.6)
Fetal head station at the ischial spines or below	252/254 (98.1)	247/255 (96.9)
Caput succedaneum > 1cm ‖	61/251 (24.3)	70/249 (28.1)
Moulding > +1**	10/249 (4.0)	7/241 (2.9)
Time of day: 08 00 -17 00	149 (58.0)	159 (61.9)
Time of day: 17 01 – 24 00	86 (33.5)	79 (30.7)
Time of day: 24 01 – 07 59	22 (8.6)	18 (7.0)
Spontaneous vaginal delivery	11 (4.3)	10 (3.9)

Legend:

Percentages refer to completed responses

*Included the passive and active phases of second stage of labour

† Cardiotocograph (CTG) showing persistent late decelerations, tachycardia (>160 beats per minute) with decelerations, bradycardia (<100 beats per minute) for >10minutes in second stage

‡ Senior obstetrician as primary operator: ≥ 3 years specialist training (including consultants)

¶Occipito-transverse and occipito-posterior positions of the fetal head

‖caput succedaneum refers to the oedematous swelling formed on the presenting part of the fetal scalp during labour and is measured in centimetres.

**moulding refers to the change in shape of the fetal head as it adapts to the pelvic canal. It is classified as none when the fetal skull bones are normally separated, + when the bones touch, ++ when the bones overlap but separate easily with digital pressure and +++ when the bones overlap but are not separable with digital pressure.

6.5 Analysis of primary outcome

6.5.1 Intention to treat analysis

The incidence of incorrect diagnosis was significantly lower in the ultrasound group compared to the usual care group (ultrasound 4/257, 1.6%; usual care 52/257, 20.2%, adjusted odds ratio 0.06, 95% confidence interval (CI) 0.02 to 0.19, p value <0.001). (Table 6.3)

6.5.2 Sensitivity analysis

At baseline, there were small differences between the groups for pathological CTG and the number of cases performed by senior obstetricians. Sensitivity analyses adjusting for centre, pathological CTG and grade of operator yielded similar results with adjusted ratio 0.06, 95% CI 0.02 – 0.18, p value <0.01.

Table 6.3 Primary outcome: intention to treat and sensitivity analyses.

	Ultrasound no (%)	Standard care no (%)	Odds ratio (95% CI)	Adjusted odds ratio† (95% CI)	p value	Adjusted odds ratio‡ (95% CI)	p value
Incorrect diagnosis of the fetal head position	4/257* (1.6)	52/257 (20.2)	0.06 (0.02 – 0.18)	0.06 (0.02 – 0.19)	<0.001	0.06 (0.02 – 0.16)	<0.001

* In 2 cases, the scan opinion was not accepted by the obstetrician (in one case the obstetrician classified the position as OT but this was OP at delivery, in the other case, the obstetrician classified the position as OA but this was OT at delivery). In the other 2 cases, the ultrasound scan was not performed due to urgency because of fetal distress – in both cases, the obstetricians classified the position as OA but this was OP at delivery.

†Odds ratio was calculated on models adjusted for centre because of stratification.

‡Sensitivity analysis: odds ratio was calculated on models adjusted for centre, pathological CTG and senior obstetrician.

6.5.3 Subgroup analysis

There was a significant interaction seen between ultrasound and study centre. The benefit of ultrasound to reduce the incorrect diagnosis was greater in the Coombe centre than the Limerick one (odds ratio 0.03 in the Coombe centre, odds ratio 0.41 in the Limerick centre; interaction co-efficient 13). This finding is probably due to the overall lower rates of incorrect diagnoses in the Limerick centre where more senior obstetricians performed the delivery and where vacuum deliveries were predominantly performed in some cases making incorrect diagnosis more difficult to establish.

6.5.4 Cluster effect

Where a single obstetrician delivers a number of women, the outcome for women delivered by the same obstetrician may differ from the outcome of other women delivered by individual obstetricians, regardless of the intervention being studied. [109] This concept is described as a cluster effect.[109]

We carried out further analyses to investigate whether the effect of the intervention differed according to individual obstetricians. We had collected this data retrospectively and as we no longer had a researcher in the Midwestern Regional Hospital, Limerick at the time of analysis, we only had data on named obstetricians for the Coombe Women and Infants' University (357 cases with 46 different obstetricians).

The mean number of case per obstetrician was 8 (range 1 – 35). We applied a randoms-effect logistic regression model on the primary outcome to allow for clustering effect by operator. Similarly to the subgroup analyses, we found that ultrasound was more effective than standard care in the Coombe centre: odds ratio 0.028 (0.007 – 0.122), p value <0.0001. The intra cluster coefficient (ICC) was 0.11 (95% CI 0.21 – 1.9). This means that the proportion of variance in the outcome that is due to individual operator effect is 11%. The p value for comparison of the random-effects applied here versus the standard logistic regression model used for the intention to treat analysis was 0.11.

6.6 Analysis of secondary outcomes

The incidence of extensive perineal tearing, postpartum haemorrhage, shoulder dystocia and prolonged postnatal stay in hospital were not significantly different between the two groups. (Tables 6.4) Similarly, the incidence of neonatal trauma, fetal acidosis and admission to the NICU were not significantly different between the two groups. (Table 6.5)

Importantly, the decision to delivery interval was not longer in the ultrasound group (ultrasound group, mean 13.8 minutes, SD 8.7 versus standard care group, mean 14.6 minutes, SD 10.1, difference in means -0.78, 95% CI -2.42 to 0.85, p 0.35). (Table 6.6)The mean time taken to perform the ultrasound scan was thirty seconds (range 5 to 120 seconds, standard deviation 22 seconds).

There were no significant differences in need for senior obstetric support, transfer to theatre or use of sequential instruments. (Table 6.6) There was a trend in the ultrasound group that women were less likely to have an immediate caesarean section than an instrumental delivery with one instrument but the numbers were small and the evidence was not strong (2/257, 0.8% versus 8/257, 3.1%; odds ratio 0.24, 95% confidence interval 0.05-1.16, p 0.07). On the other hand, there were more instrumental deliveries with more than 3 pulls in the ultrasound group compared to the standard care group, but again not statistically significant (34/257, 13.2% versus 23/257, 8.9%; odds ratio 1.54, 95% confidence interval 0.88 – 2.70, p 0.13).

Table 6.7 shows the choice of instruments in the two groups.

Overall, the ultrasound scan diagnosis was accepted in 242/257 (94.2%) cases and not accepted in 9/257 (2.5%) cases (unrecorded in 6 cases). The reported degree of certainty of the fetal head position on a Likert scale did not differ between the two groups. (Table 6.8)

In 155 (60%) cases, more than one fetal landmark was used to diagnose the fetal head position on ultrasound. The most commonly used landmarks were the nuchal region, occiput, midcerebral echo and orbit. Figure 6.3 Shows the detailed frequency of landmarks used to diagnose the fetal head position on ultrasound.

Table 6.9 shows the error types in the two groups. OA-OP errors are where the fetal head position was diagnosed as OA when it was in fact OP. OP-OA errors were the inverse: the fetal head position was thought to be OP when in fact it was OA. Left-right errors were for example when the fetal head position was diagnosed as ROT but was in fact LOT. Errors of more than 90^0 but less that 180^0 was for example when the position was thought to be OA but was in fact ROP. The ultrasound arm corrected 50 cases of potential incorrect diagnosis of the fetal head position. There were fewer OA-OP errors recorded in the ultrasound group compared to the standard care group but more left-right errors. (Table 6.9)

The rate of sub-optimal application of instruments was similar in the ultrasound and standard care groups: 64/240 (26.7%) versus 74/238 (31.1%) respectively (odds ratio 0.77, 95% confidence interval 0.51 – 1.15, p value 0.20). (Figures 6.4 and 6.5)

The number of postnatal complications reported by clinicians was small. (Table 6.10) There was a trend towards an increased rate of urinary tract infections (UTI) and perineal infection in the ultrasound group, but this was not statistically significant. Other complications reported by clinicians in the postnatal database were: urinary retention, mastitis and dural headache. However these were not systematically recorded on our CRF and were not analysable.

Table 6.4 Secondary outcomes – maternal morbidity.

	Ultrasound (n=257)	Standard care (n=257)	Odds ratio (95% CI)	p value
Blood loss >500mls (PPH)*	49 (19.1)	43 (16.7)	1.16 (0.73 – 1.83)	0.53
3rd/4th degree perineal tear	10 (3.9)	7 (2.7)	1.42 (0.53 – 3.80)	0.49
Shoulder dystocia	9 (3.5)	13 (5.1)	0.67 (0.28 – 1.60)	0.37
Median length of stay in days (IQR)	3 (2-3)	3 (2-3)	-	-
Prolonged length of stay (>3days)	52 (20.2)	42 (16.3)	1.29 (0.82 – 2.02)	0.27

Legend:

Percentages refer to completed responses.

*PPH – postpartum haemorrhage.

Table 6.5 Secondary outcomes – neonatal morbidity.

	Ultrasound (n=257)	Standard care (n=257)	Odds ratio (95% CI)	p value
Neonatal trauma*	20 (7.8)	17 (6.6)	1.13 (0.57 -2.22)	0.72
Apgar score < 7 at 5 min	0	2 (0.8)	NA	NA
Arterial pH <7.10, /n	8/203 (3.9)	9/191 (4.7)	0.81 (0.31- 2.16)	0.68
NICU admission†	31 (12.1)	30 (11.7)	1.05 (0.61 – 1.79)	0.87
Baby discharge status: uncertain or abnormal neurological status	3 (1.2)	3 (1.2)	1.00 (0.20- 5.02)	0.996
Neonatal death	1 (0.4)‡	0	NA	NA

Legend:

Percentages refer to completed responses.

*Excluding bruising and skin abrasions, including facial nerve palsy, Erb's palsy, fractures, retinal haemorrhage, encephalopathy and cephalhaematoma.

†NICU – neonatal intensive care unit.

‡ Baby died from cardiac anomalies associated with DiGeorge Syndrome.

Table 6.6 Secondary outcomes – procedure related outcomes.

	Ultrasound (n=257)	Standard care (n=257)	Odds ratio (95% CI)	p value
Mean DDI in minutes (SD)*	13.8 (8.7)	14.6 (10.1)	-	0.35
Transfer to theatre	19 (7.3)	29 (11.3)	0.64 (0.34 -1.15)	0.15
Any caesarean section	12 (4.7)	18 (7.0)	0.65 (0.31- 1.38)	0.26
Caesarean section after failed instrumental delivery	10 (3.9)	10 (3.9)	1.00 (0.41 – 2.45)	1.00
Cesarean section immediately	2 (0.8)	8 (3.1)	0.24 (0.51 – 1.16)	0.07
Sequential use of instruments	24 (9.3)	21 (8.2)	1.16 (0.63- 2.14)	0.64
More than 3 pulls with instrument	34 (13.2)	23 (8.9)	1.54 (0.88-2.70)	0.13
Second operator involved in instrumental delivery	44 (17.1)	45 (17.5)	0.96 (0.60-1.52)	0.85
Consultant (attending) called due to a complication	4 (1.6)	5 (1.9)	0.80 (0.21 – 1.15)	0.74
Suboptimal placement of instruments	64/240 (26.7)	74/238 (31.1)	0.77 (0.51- 1.15)	0.20

Legend:

Percentages refer to completed responses.

* The time between the decision to intervene to the delivery of the infant.

Table 6.7 Choice of instruments.

Instruments	Ultrasound	Standard care
Non-rotational forceps	68 (26.5)	65 (25.3)
Manual rotation	34 (13.2)	33 (12.8)
Vacuum*	168 (65.4)	162 (63.0)
Rotational forceps	6 (2.3)	7 (2.7)

*Includes kiwi, silastic and metal cups.

Table 6.8 Degree of certainty of the fetal head position.*

	Ultrasound n = 257	Standard care n = 257	OR (95% confidence interval)	p value
Degree of certainty ≤ 5	8 (3.1)	12 (4.7)	0.63 (0.25 – 1.58)	0.33
Degree of certainty ≤ 7	24 (9.3)	30 (11.7)	0.75 (0.43 – 1.33)	0.32
Degree of certainty ≥ 9	194 (75.5)	181 (70.4)	1.17 (0.77 – 1.78)	0.46

* based on Likert scale ranging from 0 (very uncertain) to 10 (completely certain).

Table 6.9 Error profiles in the two arms.

	OA-OP error	OP-OA error	Left-Right error	≥90° but ≤ 180° error	Unknown position	Total errors
Clinical examination v/s ultrasound scan	10	7	12	8	13	50
Clinical examination v/s position at delivery	20	6	4	16	6	52

Table 6.10 Postnatal complications (as reported by clinicians).

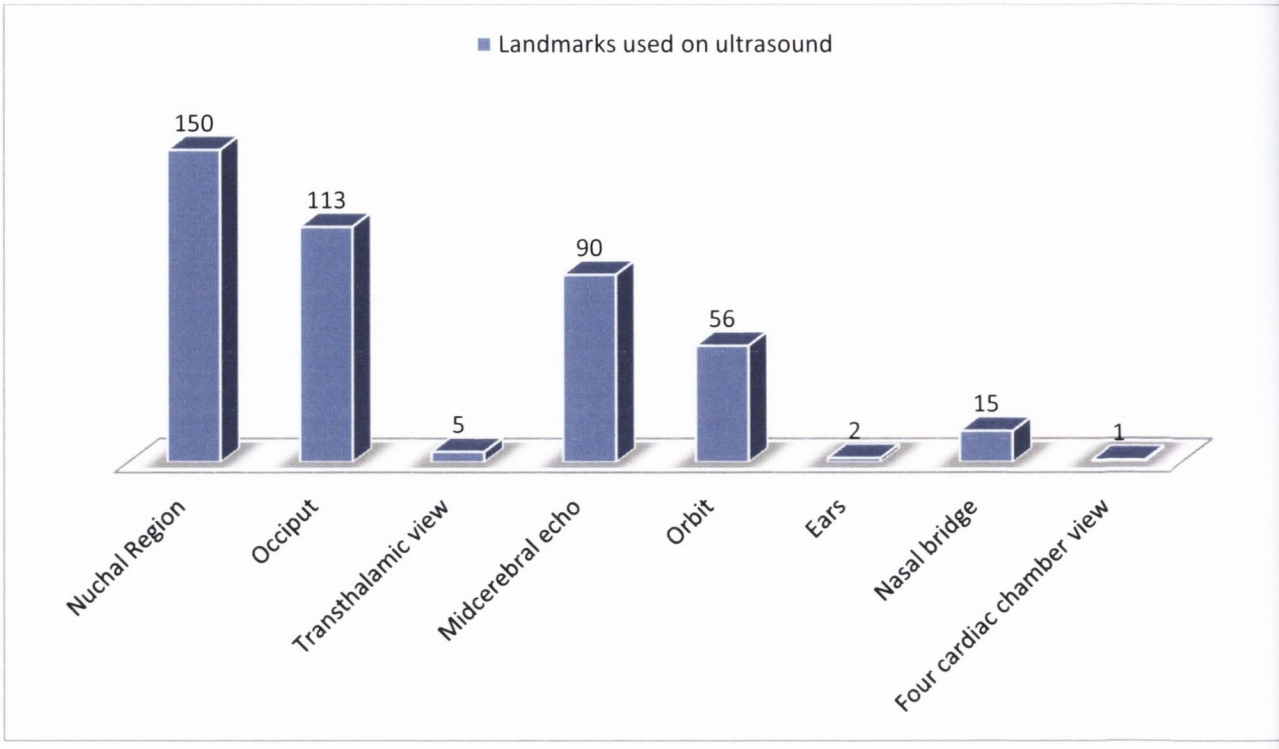
	Ultrasound n=257	Standard care n=257	Odds ratio (95% CI)	p value
Urinary tract infection	5 (1.9)	1 (0.4)	5.08 (0.589 – 93.78)	0.139
Perineal infection	8 (3.1)	3 (1.2)	2.72 (0.71 – 10.37)	0.143
Retained products of conception	0	1 (0.4)	NA	NA
Endometritis	1 (0.4)	2 (0.8)	0.50 (0.05 – 5.53)	0.57
Wound infection	9 (3.5)	7 (2.7)	1.30 (0.48 – 3.54)	0.61
Antibiotics required postnatally	40 (15.6)	32 (12.5)	1.30 (0.79 – 2.14)	0.31
Secondary PPH*	0	1	NA	NA
Pyrexia of unknown origin	5 (1.9)	0	NA	NA
Hospital re-admission	4 (1.6)	3 (1.2)	1.34 (0.30 – 6.04)	0.70

Legend:

Percentages refer to completed responses.

*postpartum haemorrhage (>500mls blood loss) more than 24 hrs after delivery but less than 12 weeks postanatally.

Figure 6. 3 Frequency of landmarks used to diagnose the fetal head position on ultrasound*



*more than one landmark was used in 255 cases

6.7 Summary

The full results of the IDUS randomised controlled trial have been presented in this chapter. Over the next chapter, a detailed discussion regarding these findings as well as the strengths and limitations of the RCT will be presented. Future research potential will also be explored

Chapter 7 IDUS Randomised Controlled Trial: Discussion

7.1 Summary of findings

The results of this multicentre randomised trial show that an ultrasound assessment prior to instrumental delivery reduces the incidence of incorrect diagnosis of the fetal head position compared to clinical examination alone. The use of ultrasound did not introduce a delay in completing the delivery. Enhanced diagnosis of the fetal head position did not reduce the incidence of maternal or neonatal complications. There were no significant differences in instrument choice or mode of delivery between the two groups despite enhanced diagnosis of the fetal head position, which may reflect operator preferences or short-comings in the management of fetal malposition.

7.2 Strengths and weaknesses

The strengths of the trial include its large size, multicentre design and the high compliance with group allocation after randomisation. The study population included a range of women with varying body mass index, different types of anaesthesia and the full range of indications for instrumental delivery, including fetal distress. Operators at all levels of experience were included. The results are generalisable to other centres where instrumental deliveries are performed.

The limitations of this trial should be considered. While the researchers attempted to capture a variety of deliveries throughout the day and night, the majority of women were recruited during 'regular' working hours. We may have missed deliveries at night time where less experienced obstetricians managed complex cases without direct supervision. Furthermore, it was challenging in some cases to differentiate between incorrect diagnosis of the fetal head position and suboptimal instrument placement, particularly in cases of vacuum delivery. It is possible that the rate of incorrect diagnosis was even higher in the standard care group. We had considered an alternative study design where we would perform an ultrasound scan on every woman and randomise to reveal or conceal the findings for fetal head position. This was deemed unethical, as concealing a fetal malposition from an inexperienced operator could result in significant morbidity, and flawed in terms of equipoise, as ultrasound would have been assumed to be more accurate than clinical examination.

7.3 Comparison with existing literature

The incidence of incorrect diagnosis of the fetal head position by clinical examination alone was 20% which is at the lower end of the published literature.[26 27 86-91] Most studies have compared ultrasound assessment and clinical examination in the first or second stage of labour rather than immediately before instrumental delivery. Ultrasound assessment in this context is technically easier because the fetal head is not as low in the pelvis and there is no time pressure to deliver. Equally, there may be less care taken with clinical examination given that an accurate diagnosis is less critical to safety unlike with instrumental delivery. The two studies that looked at accuracy of vaginal examination before instrumental delivery had findings similar to ours. [96 97] A cohort study of 64 women reported an incorrect diagnosis rate of 27% for vaginal examination compared to ultrasound, with errors more likely with OP positions.[96] A randomized trial of fifty women undergoing vacuum extraction for prolonged second stage used cup placement as the primary outcome.[97] Cup placement was closer to the flexion point and therefore more optimal in the group assigned to ultrasound compared to vaginal examination only.

7.4 Discussion

The decision to delivery interval is an important consideration for instrumental delivery.[39] It was reassuring that the addition of an ultrasound scan as part of the assessment did not introduce a delay in delivery. The RCOG guidelines highlight the greater risk of failed instrumental delivery with a fetal malposition and recommend transfer to an operating theatre to allow early recourse to caesarean section.[18] We were surprised that the enhanced diagnosis of fetal malposition in the ultrasound group did not appear to influence management decisions and equally that the higher rate of incorrect diagnoses in the standard care group did not affect the rate of sequential instruments or failed instrumental deliveries. These findings reflect the complexity of decision-making at instrumental delivery. There are other factors such as engagement, station of the presenting part, fetal size, and maternal pelvic dimensions that may contribute to procedural decisions, and ultimately the approach taken will depend on operator preference, skills and experience.[34] Maternal and neonatal complications in this study were low and comparable to previous published data. [5 25 34] Given that enhanced diagnosis of fetal malposition had little impact on the management decisions made by operators it is perhaps unsurprising that morbidity rates were similar in both groups.

One potential explanation is that ultrasound enhanced the diagnosis of fetal malpositions but not the operators ability to deal with it.

7.5 Clinical implications

We need to consider how our findings could be interpreted clinically. The use of ultrasound on the labour ward is increasing with ready access to portable ultrasound equipment. [65] Our previous work, described in Chapter 3, demonstrated that transabdominal ultrasonography is acceptable to women in labour and to clinicians looking after them. Furthermore, trainees in obstetrics can acquire the skills to perform an accurate ultrasound scan diagnosis of the fetal head position in labour within a short timeframe.[95] The downside of introducing ultrasound assessment is that it may compromise the skill of clinical assessment which encompasses more than just the fetal head position. Given that knowledge of the fetal head position is a prerequisite for safe instrumental delivery, we feel that ultrasound assessment has a role to play, perhaps in teaching clinical assessment skills as well as in validating clinical findings.

7.6 Interpreting the implication of fetal head position errors using illustrative cases

Key cases in the ultrasound and standard care groups will be described to illustrate particular points regarding challenges in the management of instrumental deliveries.

1. Cases where the management of the delivery was appropriately changed once the ultrasound findings of the fetal head position were revealed to the obstetrician (who accepted the diagnosis of the fetal head position on ultrasound). (Table 7.1)

- The choice of instruments was influenced by the ultrasound in some cases – cases 1044 and 1348, described in Table 7.1, illustrate this.

- The venue of delivery was also influenced by the ultrasound findings
    - In case 1352, a trial of instruments in theatre for fetal bradycardia was called initially as the fetal head position was unknown, but once the ultrasound scan was performed and revealed a DOA position, the obstetrician carried out an

instrumental delivery successfully in the room. Case 1465 and 1480 also highlight how the ultrasound assessment allowed the obstetrician to safely and successfully carry out the instrumental delivery in the labour room.

- Case 1449 highlights how the ultrasound correctly diagnosed a fetal head malposition (DOP) which prompted the obstetrician to call for senior help and change the venue of the delivery to theatre.

2. The other sample of cases we chose to highlight were those rare cases in the ultrasound group where the fetal head diagnosis on ultrasound was not accepted by the obstetrician. (Table 7.2)

- Case 1008 illustrates an attempted vacuum followed by forceps delivery which failed in the room. The obstetrician persisted in the belief that the head was LOT, in spite of ultrasound findings of DOP. The delivery was completed by caesarean section after failed sequential use of instruments.

- Similarly, in case 2075, the ultrasound diagnosis of the fetal head position – LOT, was not accepted. The obstetrician carried on with the planned non-rotational forceps delivery based on clinical examination findings and the neonate was delivered in an OT position with associated trauma.

- In case 1232, again the obstetrician maintained the diagnosis of the fetal head position as being DOA in spite of ultrasound findings showing DOP position. However, after applying non-rotational forceps which did not lock, the obstetrician accepted the scan findings, changed instrument and performed a successful vacuum delivery.

3. Standard care group cases – incorrect diagnosis. (Table 7.3)

- In case 1031, a decision for immediate caesarean was made based on clinical findings. The maternal height was 160cm, the abdominal examination was not recorded but on vaginal examination the fetal head was LOP at the level of the ischial spines with caput +2 and moulding +2. The fetal head position at delivery was DOA and the birth weight was 3.410 kg. It may have been possible to attempt or complete an instrumental delivery if the correct position had been known.

- Case 1133 highlights how a DOA position was clinically mistaken for DOP and the patient was moved to theatre when, arguably, the delivery could have been achieved safely and more quickly in the delivery room if the fetal head position had been correctly diagnosed.

- On the other hand, case 1183 highlights an OA-OP error which ended as a caesarean section after failed instrumental delivery in the delivery room. This scenario is stressful for all concerned and introduces a decision to delivery delay.

- Cases 1435 and 1502 illustrate the 'suck it and see' attitude mentioned in Chapter 3. In both cases, the obstetrician attempted a vacuum delivery with a kiwi omnicup despite not knowing the exact fetal head position.

Table 7.1 Illustrative cases in the ultrasound group where the ultrasound diagnosis of the fetal head position was accepted and management changed as a result.

Case	Gestation	Birthweight (kg)	Fetal head position on clinical examination	Fetal head position on ultrasound	Station	Duration of second stage	Instrument(s) used	Venue *	Number of pulls	Mode of delivery †	DDI (min)	Maternal morbidity	Neonatal morbidity
1044	39+2	3.765	LOT	DOA	+1	2hrs 45min	Non-rotational forceps (changed from kiwi™)	LW	2	ID	18	nil	nil
1348	41+1	3.060	DOA	LOP	0	44min	Kiwi™ (changed from non-rotational forceps)	LW	3	ID	11	nil	nil
2054	37 +4	3.450	LOA	ROP	+2	3hrs 15min	Metal cup post	LW	2	ID	8	nil	nil
1214	40	4.070	Unknown	DOA	0	2hrs 30min	Non-rotational forceps	LW	3	ID	11	nil	NICU‡ for 2 days for grunting
1352	37+5	3.400	Unknown	DOA	+1	1 hr 55min	Kiwi™	LW	2	ID	9	nil	Nil

*LW – labour ward; OT – operating theatre †ID- instrumental delivery ‡NICU – neonatal intensive care unit

Case	Gestation	Birthweight (kg)	Fetal head position on clinical examination	Fetal head position on ultrasound	Station	Duration of second stage	Instrument used	Venue*	Number of pulls	Mode of delivery †	DDI (min)	Maternal morbidity	Neonatal morbidity
1449	41	3.310	DOA	DOP	+1	3hrs	Rotational forceps	OT	2	ID	24	Nil	Nil
1465	39+5	3.570	LOP	DOA	0	1 hr 50min	Non-rotational forceps	LW	2	ID		Nil	NICU‡ 2 days for grunting
1480	39+3	3.385	LOA	ROP	+1	9min	Manual rotation then non-rotational forceps	LW	2	ID	9	Nil	Nil

*LW – labour ward; OT – operating theatre †ID- instrumental delivery ‡NICU – neonatal intensive care unit

Table 7.2 Illustrative cases – ultrasound findings not accepted.

Case	Gestation	Birthweight (kg)	Fetal head position on clinical examination	Fetal head position on ultrasound	Station	Duration of second stage	Instrument(s) used	DDI (min)	Number of pulls	Mode of delivery*	Maternal morbidity	Neonatal morbidity
1008	40+4	3.750	LOT	DOP	0	3hrs 44min	Kiwi™ then non-rotational forceps	44	3	CS after failed ID	1° PPH†	Nil
1232	38	3.23	DOA	LOP	0	24min	Non-rotational forceps – did not lock → kiwi™	15	4	ID	Nil	Nil
2075	39+5	3.250	DOA	LOT	+1	3hrs 6min	Non-rotational forceps	16	3	ID	1° PPH	Nil

*ID- instrumental delivery; CS – caesarean section †PPH – postpartum haemorrhage

Table 7.3 Illustrative cases – standard care group – incorrect diagnosis & potential difference in management.

Case	Gestation	Birthweight	Fetal head position	Station	Duration of second stage	Instrument(s) used	Number of pulls	Mode of delivery*	Fetal head position at delivery	DDI (min)	Maternal morbidity	Neonatal morbidity
1031	40	3.410	LOP	0	3hrs 30min	No attempt	0	CS immediately	DOA	25	Nil	Nil
1133	41	4.100	DOP	+1	3hrs 30min	Non-rotational forceps	2	ID in theatre	DOA	38	Nil	Nil
1183	39+6	4.230	LOA	+1	40min	Non-rotational forceps then kiwi	3	CS after failed ID in room	LOP		1^{o} PPH†	Low Apgar, alive & well
1435	40+1	3.510	Unknown	+2	6min	Kiwi	2	ID	DOA	15	Nil	Nil
1502	41+4	3.780	Unknown	1	48min	Kiwi	1	CS after failed ID	ROT	30	1^{o} PPH	Nil

*ID- instrumental delivery; CS – caesarean section †PPH – postpartum haemorrhage

7.7 Future studies

The rate of sub-optimal instrument placement was high in the trial (26.7 to 31.1%), regardless of group allocation. Sub-optimal instrument placement is not only due to misdiagnosis of the fetal head position, but also a marker of skills. We are planning to carry out a prospective cohort study of all instrumental deliveries for nulliparous women in the main trial centre (Coombe Women & Infants' University Hospital) to further investigate instrument placement and other factors associated with complex instrumental deliveries such as time of day. The prospective cohort study will also provide valuable information on the generalisability of the trial.

A formal health economic evaluation to establish the cost-effectiveness of an ultrasound intervention before instrumental delivery is required.

Moreover, future work should address enhancement of skills with regards to mid-cavity rotational instrumental deliveries when a fetal malposition has been identified.

7.8 Conclusions

In conclusion, our study shows that ultrasound assessment prior to instrumental delivery reduces the incidence of incorrect diagnosis of the fetal head position without delaying the decision to delivery interval. Improved diagnosis of fetal head position did not influence management decisions nor did it reduce maternal and neonatal morbidity. Our findings support the use of ultrasound before instrumental delivery to identify complex fetal malpositions and this could be implemented safely and cheaply into routine clinical care. Further work is required to enhance the skill of mid-cavity rotational instrumental delivery when a fetal malposition has been identified.

Chapter 8 Thesis summary and conclusion

8.1 Summary of thesis

The aim of this thesis was to assess the use of ultrasound to diagnose the fetal head position prior to instrumental delivery. This chapter summarises the four components of the research and explores the overall implications for clinical practice and future research.

8.1.1 Literature review

The use of obstetric ultrasound in the antenatal period is well established and, as ultrasound machines have become more compact and mobile, many of its applications have been extrapolated to the labour ward, very often without any supporting evidence. We found some prospective studies evaluating the accuracy of clinical examination to diagnose the fetal head position in labour but few studies addressed the accuracy of ultrasound and its acceptability to women in labour. Overall, the reported accuracy of digital vaginal examination to diagnose the fetal head position varied from 20% to 75%.[26 27 86-89 91] Only two studies reported error rates of transabdominal scan within a research setting of 6.8% and 7.9% respectively with another study reporting failure to diagnose the fetal head position in 15%.[95 91 89] We found only two studies evaluating the role of ultrasound assessment to determine the fetal head position before instrumental deliveries. A cohort study of 64 women undergoing instrumental delivery compared the accuracy of vaginal examination to transabdominal ultrasound. They reported an error rate of 27% for vaginal examination, with errors being more likely with OP position and if the fetal head was at the level of the ischial spines.[96] Wong *et al* carried out a randomized trial of fifty women undergoing vacuum extraction for prolonged second stage.[97] Women were randomly allocated to digital examination or digital examination with transabdominal ultrasound prior to delivery.[97] A midwife measured the distance between the centre of the chignon (vacuum induced swelling of the fetal scalp) and the flexion point immediately after delivery. In the group with digital examination and ultrasound assessment (n=25), the mean distance between the centre of the chignon and the flexion point was 2.1+/-1.3cm versus 2.8 +/- 1.0 cm in the group with digital examination alone, a small but statistically significant difference.[97]

The literature review highlighted that there may be a role for ultrasound assessment of the fetal head position in labour, but the intervention required formal evaluation within a clinical trial.

8.1.2 Questionnaire survey

At the start of this research, we conducted a questionnaire survey in the United Kingdom and Ireland to establish current practice relating to clinical assessment of women prior to instrumental delivery, the factors associated with difficulty in assessment of the fetal head position and whether there would be support for a randomised controlled trial evaluating the use of ultrasound prior to instrumental delivery. We found that obstetricians are largely consistent in the clinical assessment of women prior to instrumental delivery adhering to the recommendations of practice guidelines.[18] In contrast, we found that varied strategies are adopted when there is difficulty or uncertainty in determining the fetal head position. When experiencing difficulty in diagnosing the fetal head position, both consultants and trainees frequently feel for fetal ears, orbits or nose to enhance diagnosis; however more trainees than consultants would seek a second opinion (40% vs 5%, $p < 0.0001$), reassess the woman in an operating theatre (80% vs 68%, $p=0.048$) or abandon the procedure in favour of a caesarean section (14% vs 6%, $p = 0.035$). We found that less than 1 in 5 consultants and less than 1 in 4 trainees use abdominal ultrasound to aid diagnosis of the fetal head position. Almost one in ten obstetricians would attempt an instrumental delivery 'frequently' based on best guess of the fetal head position (9% consultants vs 11% trainees, $p = 0.52$.) Most obstetricians reported their rate of incorrect diagnosis of the fetal head position as being less than 10% although one in eight consultants and one in four trainees reported inaccuracy rates of more than 10%. Views were polarised regarding the value of abdominal ultrasound as a strategy to improve the accurate determination of the fetal head position prior to instrumental delivery. These results and the conflicting opinions on the role of abdominal ultrasound in enhancing determination of the fetal head position prior to instrumental delivery supported the need for evaluation within a randomised controlled trial.

8.1.3 Validation study

Before starting the trial, we deemed it essential to validate the ultrasound intervention to diagnose the fetal head position. In particular, we set out to establish the accuracy of an ultrasound scan to diagnose the fetal head position in the hands of a novice and also the acceptability of the intervention to women in labour and the clinicians looking after her. With that in mind, we designed the validation study. The objectives of this study were firstly to compare the diagnosis of the fetal head position by a novice and an expert ultrasonographer;

secondly, to compare the diagnosis of the fetal head position by a clinician (obstetrician or midwife) and an expert ultrasonographer; and lastly, to evaluate the acceptability of ultrasound assessment in the second stage of labour to women, and, to midwives and obstetricians looking after them. We found that a novice sonographer can easily acquire the ultrasound skills required to determine of the fetal head position in the second stage of labour and perform the ultrasound examination in under two minutes in virtually all cases. Accuracy of 90% was achieved after twenty consecutive scans and remained high showing that these skills are reproducible when a systematic approach is taken. However, agreement for the fetal back position was only 62% suggesting that ultrasound assessment of the fetal back is less likely to enhance diagnosis of a fetal malposition. The scan was performed unobtrusively with little or no discomfort to the patient or inconvenience to the health professionals caring for her. An abdominal ultrasound scan is an accurate, reproducible and acceptable method of confirming the fetal head position in the passive second stage of labour.

8.1.4 Randomised controlled trial

The IDUS randomised controlled trial showed that an ultrasound assessment prior to instrumental delivery reduces the incidence of incorrect diagnosis of the fetal head position compared to clinical examination alone. The use of ultrasound did not introduce a delay in completing the delivery. Enhanced diagnosis of the fetal head position did not reduce the incidence of maternal or neonatal complications. There were no significant differences in instrument choice or mode of delivery between the two groups which may reflect operator preferences or short-comings in the management of fetal malposition.

8.2 Clinical implications

The results of the IDUS randomised controlled trial support the routine use of ultrasound to enhance diagnosis of the fetal head position before instrumental delivery. The ultrasound scan reduces the incidence of incorrect diagnosis of the fetal head position compared to clinical examination alone, without increasing the decision to delivery interval.

We must consider how this intervention would be implemented. The introduction of ultrasound before instrumental delivery could be safely and cheaply integrated into routine clinical practice. A portable ultrasound machine of reasonable quality would need to be

available on the labour ward, however this is already the case in most labour wards in the developed world. The most important aspect to implementing this intervention is the training of operators to ensure accuracy of the ultrasound findings. This training could be integrated as part of labour ward skills training and could be carried out in a similar way to the validation study we completed. Initially, the trainee would perform ultrasound scans to diagnose the fetal head position in the passive second stage while being supervised by a senior obstetrician with experience in intrapartum scanning. It is important that the trainee is exposed to all fetal head malpositions during this process and as such, we expect that 30 – 60 cases would be required to achieve competency in scanning for the fetal head position in the second stage of labour. Subsequently, the trainee would routinely perform an ultrasound scan before carrying out an instrumental delivery, in order to enhance the diagnosis of the fetal head position. It is important to highlight that clinical assessment will still have a crucial role to play before instrumental deliveries and that the aim of this intervention is to complement clinical assessment rather than replacing it.

Another approach would be to use an ultrasound scan to enhance diagnosis of the fetal head position only in cases when there is uncertainty or difficulty in doing so clinically. However, in the IDUS trial we found that obstetricians misdiagnosed the fetal head position even when they expressed no uncertainty or difficulty in doing so. The inherent difficulty with vaginal examination to diagnose the fetal head position at the end of labour and active pushing is that the fetal skull landmarks such as the anterior and posterior fontanelles, and suture lines, can become distorted by caput succadeneum and moulding as the head goes through the maternal pelvis.

The IDUS trial found that improved diagnosis of the fetal head position did not reduce the incidence of maternal and neonatal complications suggesting that the accurate diagnosis of a malposition, in itself, is not sufficient to avoid adverse outcomes. Operative deliveries in the second stage of labour are challenging. The decision making process and skills required for midcavity rotational deliveries are complex. Correctly diagnosing a fetal malposition in the second stage of labour is essential for the safe delivery of the mother and infant, but only if obstetricians are equipped with the skills to manage those complex deliveries, be it in the form of rotational vaginal deliveries or caesarean section. This study highlights the need for the improved training in this area. Junior obstetricians should be directly supervised by senior,

more skilled, obstetricians for those deliveries, especially as with reduced working hours trainees have less experience in dealing with these cases.

There was a suggestion in the ultrasound group that women were less likely to have an immediate caesarean section than an instrumental delivery with one instrument but the numbers were small and the evidence was not strong. It is possible that with a bigger sample size we may have had a more definite answer to some of our secondary outcomes.

8.3 Primary outcome and sample size

The primary outcome of the IDUS randomised trial was the incorrect diagnosis of the fetal head position. Based on the literature, failure to recognise a fetal head malposition is one of the main factors associated with failed instrumental deliveries, albeit not the only factor. We considered making our primary outcome failed instrumental delivery: sequential use of instruments or caesarean section after failed instrumental delivery, but each of the outcomes is multi-factorial. Indeed, obstetric skills and experience, engagement, station of the presenting part, fetal size, and maternal pelvic dimensions are all factors that contribute to the success or failure of an instrumental delivery.

We could have inflated our sample size in order to explore rarer secondary outcomes such as immediate caesarean section, by including more centres and running the trial for longer. However, we did not have the resources to do so. Furthermore, there was increased risk of contamination as the trial progressed and obstetricians who participated in the trial were converted to the benefits of performing an ultrasound scan to diagnose the fetal head position. Had we continued the trial, the true effect of the intervention could have been difficult because of this increasing lack of equipoise amongst obstetricians.

8.4 Research implications

We had a high rate (26.7 to 31.1%) of sub-optimal instrument placement in the trial, regardless of group allocation. Sub-optimal instrument placement is not only due to misdiagnosis of the fetal head position, but also a marker of clinical skill and the limitations posed by maternal and fetal anatomy. We plan to carry out a prospective cohort study of all instrumental deliveries for nulliparous women in the main trial centre (Coombe Women & Infants' University Hospital)

to further investigate instrument placement and other factors, such as time of day, associated with complex instrumental deliveries. The prospective cohort study will also provide valuable information on generalisability of the trial.

A formal health economic evaluation to establish the cost-effectiveness of an ultrasound intervention before instrumental delivery is required.

Moreover, future work should address enhancement of skills with regards to mid-cavity rotational instrumental deliveries when a fetal malposition has been identified.

8.5 Conclusion

It was both important and timely to evaluate the use of ultrasound to diagnose the fetal head position prior to instrumental delivery. We identified a variety of strategies used by obstetricians when there is difficulty or uncertainty in diagnosing the fetal head position on clinical examination and a lack of consensus regarding the use of ultrasound in this setting. The validation study showed that an ultrasound scan to diagnose the fetal head position is accurate and acceptable to women in labour and the clinicians looking after them. The IDUS randomised controlled trial has shown that an ultrasound assessment enhances the diagnosis of the fetal position before instrumental delivery without delaying the delivery. Despite enhanced diagnosis of fetal malpositions, there were no differences in maternal or neonatal complications. Future studies should address whether widespread use of ultrasound can reduce the rate of immediate caesarean section in the second stage of labour. Further research is also required to establish approaches to enhance the skill of mid-cavity rotational instrumental delivery when fetal malpositions have been identified.

References

1. Consumer guide to maternity services in Ireland [Internet]. Ireland; 2010. Available from: http://www.bump2babe.ie/column/N/statistics/ (last accessed: 15 February 2013).

2. Demissie K, Rhoads GG, Smulian JC, Balasubramanian BA, Gandhi K, Joseph KS, et al. Operative vaginal delivery and neonatal and infant adverse outcomes: population based retrospective analysis. *BMJ* 2004;329(7456):24-9.

3. Patel RR, Murphy DJ. Forceps delivery in modern obstetric practice. *BMJ* 2004;328(7451):1302-5.

4. Loudon JA, Groom KM, Hinkson L, Harrington D, Paterson-Brown S. Changing trends in operative delivery performed at full dilatation over a 10-year period. *J Obstet Gynaecol* 2010;30(4):370-5.

5. Unterscheider J, McMenamin M, Cullinane F. Rising rates of caesarean deliveries at full cervical dilatation: a concerning trend. *Eur J Obstet Gynecol Reprod Biol* 2011;157(2):141-4.

6. Evaluation of Cesarean Delivery. Washington, DC: American College of Obstetricians and Gynecologists, 2000.

7. Bahl R, Strachan B, Murphy DJ. Outcome of subsequent pregnancy three years after previous operative delivery in the second stage of labour: cohort study. *BMJ* 2004;328(7435):311.

8. Dupuis O, Silveira R, Dupont C, Mottolese C, Kahn P, Dittmar A, et al. Comparison of "instrument-associated" and "spontaneous" obstetric depressed skull fractures in a cohort of 68 neonates. *American Am J Obstet Gynecol* 2005;192(1):165-70.

9. Macleod M. Episiotomy use at operative vaginal delivery. *PhD Thesis*. University of Dundee, 2011.

10. O'Mahony F, Hofmeyr GJ, Menon V. Choice of instruments for assisted vaginal delivery. *Cochrane Database Syst Rev* 2010(11):CD005455.

11. Martin J, Hamilton B, Ventura S, Osterman M, Wilson E, Matthews T. Births: Final data for 2010. *National vital statistics report* 2010;61(1).

12. Alran S, Sibony O, Oury J-F, Luton D, Blot P. Differences in management and results in term-delivery in nine European referral hospitals: descriptive study. *Eur J Obstet Gynecol Reprod Biol* 2002;103(1):4-13.

13. Althabe F. Choice of instruments for assisted vaginal delivery: RHL commentary. *The WHO Reproductive Health Library* 2011.

14. BirthChoiceUK [Internet]. United Kingdom; 2010. Available from: http://www.birthchoiceuk.com/Professionals/Frame.htm (last accessed 15 February 2013).

15. Murphy D, Liebling R, Verity L, Swingler R, Patel R. Cohort study of the early maternal and neonatal morbidity associated with operative delivery in the second stage of labour. *Lancet* 2001(358):1203-7.

16. DiMatteo MR, Morton SC, Lepper HS, Damush TM, Carney MF, Pearson M, et al. Cesarean childbirth and psychosocial outcomes: a meta-analysis. *Health Psychol* 1996;15(4):303-14.

17. American College of Obstetricians and Gynecologists. ACOG. Practice Bulletin 17. Operative vaginal delivery.Washington DC: 2000.

18. Royal College of Obstetricians and Gynaecologists. Operative vaginal delivery. *Greentop guideline No. 26.* January 2011. Bahl R, Strachan B, Murphy DJ.

19. Cargill Y, MacKinnon C. Guidelines for operative vaginal birth.SOGC Clinical Practice Guidelines. *J Obstet Gynaecol Can* 2004;26(8):747-53.

20. Cunningham F, Leveno K, Bloom S, Hauth JC, Rouse S, Spong C. Williams Obstetrics. 23rd edition ed: McGraw Hill, 2009:1385.

21. Ramphul M, Murphy D. Indications and assessment for operative vaginal birth in ROBuST (RCOG Operative Birth Simulation Training) course manual. Edited by Attilakos G, Draycott T, Gale A, Siassakos D, Winter C. Cambridge University Press 2013.

22. Intrapartum care. Clinical guideline 55. *National Institute for Health and Clinical Excellence.* London: National Institute for Health and Clinical Excellence.

23. Rosemann G. Vacuum extraction of premature infants. *S Afr J Obstet Gynaecol* 1969;7:10-12.

24. Vacca A. The trouble with vacuum extraction *Curr Obstet Gynaecol* 1999;9:41-5.

25. Murphy D, R L, Patel R, Verity L, Swingler R. Cohort study of operative delivery in the second stage of labour and standard of obstetric care. *Br J Obstet Gynaecol* 2003;110:610-5.

26. Akmal S, Tsoi E, Kametas N, Howard R, Nicolaides KH. Intrapartum sonography to determine fetal head position. *J Matern Fetal Neonatal* 2002;12(3):172-77.

27. Dupuis O, Ruimark S, Corinne D, Simone T, Andre D, Rene-Charles R. Fetal head position during the second stage of labor: Comparison of digital vaginal examination and transabdominal ultrasonographic examination. *Eur J Obstet Gynecol Reprod Biol* 2005;123(2):193-97.

28. Dupuis O, Silveira R, Zentner A, Dittmar A, Gaucherand P, Cucherat M, et al. Birth simulator: Reliability of transvaginal assessment of fetal head station as defined by the American College of Obstetricians and Gynecologists classification. *Am J Obstet Gynecol* 2005;192(3):868-74.

29. Gardberg M, Laakkonen E, Salevaara M. Intrapartum sonography and persistent occiput posterior position: a study of 408 deliveries. *Obstet Gynecol* 1998;91:746-9.

30. Sizer A, Nirmal D. Occipitoposterior position: associated factors and obstetric outcome in nulliparas. *Obstet Gynecol* 2000;96(5):749-52.

31. To WW, Li IC. Occipital posterior and occipital transverse positions: reappraisal of the obstetric risks. . *Aust N Z J Obstet Gynaecol.* 2000;40(3):275-9.

32. Fitzpatrick M, McQuillan K, O'Herlihy C. Influence of persistent occiput posterior position on delivery outcome. *Obstet Gynecol* 2001;98(6):1027-31.

33. Cheng YW, Shaffer BL, Caughey AB. Associated factors and outcomes of persistent occiput posterior position: A retrospective cohort study from 1976 to 2001. *J Matern Fetal Neonatal Med.* 2006;19(9):563-8.

34. Murphy D, Macleod M, Bahl R, Strachan B. A cohort study of maternal and neonatal morbidity in relation to use of sequential instruments at operative vaginal delivery. *Eur J Obstet Gynecol Reprod Biol* 2011;156(1):41-45.

35. Ponkey SE, Cohen AP, Heffner LJ, Lieberman E. Persistent fetal occiput posterior position: Obstetric outcomes. *Obstet Gynecol* 2003;101(5):915-20.

36. Majoko F, Gardener G. Trial of instrumental delivery in theatre versus immediate caesarean section for anticipated difficult assisted births. *Cochrane Database Syst Rev.* 2008;8(4):CD005545.

37. Ebulue V, Vadalkar J, Cely S, Dopwell F, Yoong W. Fear of failure: are we doing too many trials of instrumental delivery in theatre? *Acta Obstet Gynecol Scand.* 2008;87(11):1234-8.

38. Ben-Haroush A, Melamed N, Kaplan B, Yogev Y. Predictors of failed operative vaginal delivery: a single-center experience. *Am J Obstet Gynecol.* 2007;197(3):308.e1-5.

39. Murphy DJ, Koh DK. Cohort study of the decision to delivery interval and neonatal outcome for emergency operative vaginal delivery. *Am J Obstet Gynecol* 2007;196(2):145 e1-7.

40. Okunwobi-Smith Y, Cooke I, MacKenzie IZ. Decision to delivery intervals for assisted vaginal vertex delivery. *Br J Obstet Gynaecol* 2000;107(4):467-71.

41. Groom K, Jones B, Miller N, Paterson-Brown S. A prospective randomised controlled trial of the Kiwi Omnicup versus conventional ventouse cups for vacuum-assisted vaginal delivery. *Br J Obstet Gynaecol* 2006;113(2):183-9.

42. Attilakos G, Sibanda T, Winter C, Johnson N, Draycott T. A randomised controlled trial of a new handheld vacuum extraction device. *Br J Obstet Gynaecol* 2005;112(11):1510-5.

43. Royal College of Obstetricians & Gynaecologists. Prevention and management of postpartum haemorrhage. *Greentop Guideline No 52*. April 2011. Arulkumaran S, Mavrides E, Penney G.

44. Royal College of Obstetricians & Gynaecologists. The management of third- and fourth-degree perineal tears. *Greentop Guideline No.29*. March 2007. Fernando R, Williams A, Adams E.

45. Wu JM, Williams KS, Hundley AF, Connolly A, Visco AG. Occiput posterior fetal head position increases the risk of anal sphincter injury in vacuum-assisted deliveries. *Am J Obstet Gynecol* 2005;193(2):525-8.

46. CMACE. Saving mothers' lives: reviewing maternal deaths to make motherhood safer—2006-08. The Eighth Report on Confidential Enquiries into Maternal Deaths in the United Kingdom. *Br J Obstet Gynaecol* 2011;118(Suppl. 1):1 - 203.

47. Combs CA, Murphy EL, Laros RK, Jr. Factors associated with postpartum hemorrhage with vaginal birth. *Obstet Gynecol* 1991;77(1):69-76.

48. Stones RW, Paterson CM, StG Saunders NJ. Risk factors for major obstetric haemorrhage. *Eur J Obstet Gynecol Reprod Biol* 1993;48(1):15-18.

49. Sheiner E, Sarid L, Levy A, Seidman DS, Hallak M. Obstetric risk factors and outcome of pregnancies complicated with early postpartum hemorrhage: a population-based study. *J Matern Fetal Neonatal Med* 2005;18(3):149-54.

50. Bahl R, Strachan B, Murphy DJ. Pelvic floor morbidity at 3 years after instrumental delivery and cesarean delivery in the second stage of labor and the impact of a subsequent delivery. *Am J Obstet Gynecol* 2005;192(3):789-94.

51. Liebling RE, Swingler R, Patel RR, Verity L, Soothill PW, Murphy DJ. Pelvic floor morbidity up to one year after difficult instrumental delivery and cesarean section in the second stage of labor: a cohort study. *Am J Obstet Gynecol* 2004;191(1):4-10.

52. Pretlove SJ, Thompson PJ, Toozs-Hobson PM, Radley S, Khan KS. Does the mode of delivery predispose women to anal incontinence in the first year postpartum? A comparative systematic review. *Br J Obstet Gynaecol* 2008;115(4):421-34.

53. Murphy DJ, Pope C, Frost J, Liebling RE. Women's views on the impact of operative delivery in the second stage of labour: qualitative interview study. *BMJ* 2003;327(7424):1132.

54. Johnson JH, Figueroa R, Garry D, Elimian A, Maulik D. Immediate maternal and neonatal effects of forceps and vacuum-assisted deliveries. *Obstet Gynecol* 2004;103(3):513-8.

55. Baskett TF, Allen VM, O'Connell CM, Allen AC. Fetal trauma in term pregnancy. *Am J Obstet Gynecol* 2007; 197(5):499e.1-7.

56. Google Image search for forceps injuries. Ireland; 2013. Available from: https://www.google.ie/search?q=forceps+injuries&hl=en&biw=1280&bih=656&source=lnms&tbm=isch&sa=X&ei=NDJUUb65DtSDhQfF9YCwCQ&sqi=2&ved=0CAcQ_AUoAQ#imgrc=ZN6TiS7qGTvBhM%3A%3BD8g4A67vhnMeVM%3Bhttp%253A%252F%252F3.bp.blogspot.com%252F_RT4GpfqZhIU%252FRx_oXj-zk4I%252FAAAAAAAABF0%252FyP9T99sUbKc%252Fs320%252Fblackchild.jpg%3Bhttp%253A%252F%252Fdarkdaughta.blogspot.com%252F2007%252F10%252Fwordless-i-amforceps-injuries_4520.html%3B320%3B241 (last accessed 28 March 2013).

57. Chadwick LM, Pemberton PJ, Kurinczuk JJ. Neonatal subgaleal haematoma: associated risk factors, complications and outcome. *J Paediatr Child Health* 1996;32(3):228-32.

58. Vacca A. Birth by vacuum extraction: neonatal outcome. *J Paediatr Child Health* 1996;32(3):204-6.

59. Towner D, Castro MA, Eby-Wilkens E, Gilbert WM. Effect of mode of delivery in nulliparous women on neonatal intracranial injury. *N Engl J Med* 1999;341(23):1709-14.

60. Google Image search for forceps injuries. Ireland; 2013. Available from: http://nursingcrib.com/nursing-notes-reviewer/maternal-child-health/difference-between-caput-succedaneum-and-cephalhematoma/ (last accessed 28 March 2013).

61. Royal College of Obstetricians & Gynaecologists . Shoulder dystocia. *Greentop Guideline No. 42.* March 2012. Crofts J, Draycott T, Montague I, Winter C, Fox R.

62. Gupta M, Hockley C, Quigley MA, Yeh P, Impey L. Antenatal and intrapartum prediction of shoulder dystocia. *Eur J Obstet Gynecol Reprod Biol* 2010;151(2):134-39.

63. Dyachenko A, Ciampi A, Fahey J, Mighty H, Oppenheimer L, Hamilton EF. Prediction of risk for shoulder dystocia with neonatal injury. *Am J Obstet Gynecol* 2006;195(6):1544-9.

64. Allen VM, O'Connell CM, Baskett TF. Maternal and perinatal morbidity of caesarean delivery at full cervical dilatation compared with caesarean delivery in the first stage of labour. *Br J Obstet Gynaecol* 2005;112(7):986-90.

65. Ramphul M, Murphy D. Role of ultrasound on the labor ward. *Expert Review of Obstetrics & Gynecology* 2012;7(6):615-25.

66. Torloni MR, Vedmedovska N, Merialdi M, Betran AP, Allen T, Gonzalez R, et al. Safety of ultrasonography in pregnancy: WHO systematic review of the literature and meta-analysis. *Ultrasound Obstet Gynecol* 2009;33(5):599-608.

67. Eskandar O, Eckford S, Watkinson T. Safety of diagnostic imaging in pregancy. Part 2: magnetic resonance imaging, ultrasound scanning and Doppler assessment. *The Obstetrician & Gynaecologist.* 2010;12(3):171-7.

68. Whitworth M, Bricker L, Neilson JP, Dowswell T. Ultrasound for fetal assessment in early pregnancy. *Cochrane Database Syst Rev* 2010(4):CD007058.

69. Barbera AF, Pombar X, Perugino D, Lezotte DC, Hobbins J. A new method to assess fetal head descent in labor with transperineal ultrasound. *Ultrasound Obstet Gynecol* 2009(33):313-19.

70. Ghi T, Farina A, Pedrazzi A, Rizzo N, Pelusi G, Pilu G. Diagnosis of station and rotation of the fetal head in the second stage of labor with intrapartum translabial ultrasound. *Ultrasound Obstet Gynecol* 2009;33(3):331-36.

71. Duckelmann AM, Bamberg C, Michaelis SA, Lange J, Nonnenmacher A, Dudenhausen JW, et al. Measurement of fetal head descent using the 'angle of progression' on transperineal ultrasound imaging is reliable regardless of fetal head station or ultrasound expertise. *Ultrasound Obstet Gynecol* 2010;35(2):216-22.

72. Chalouhi G, Salomon LJ, Marelle P, Bernard J, Ville Y. Hygiene in endovaginal gynecologic and obstetrical ultrasound. *J Gynecol Ostet Biol Reprod* 2009;38(1):43-50.

73. Amis S, Ruddy M, Kibbler C, Economides D, MacLean A. Assessment of condoms as probe covers for transvaginal sonography. *J Clin Ultrasound* 2000;28(6):295-8.

74. Dietz HP, Lanzarone V, Simpson JM. Predicting operative delivery. *Ultrasound Obstet Gynecol* 2006;27(4):409-15.

75. Yeo L, Romero R. Sonographic evaluation in the second stage of labor to improve the assessment of labor progress and its outcome. *Ultrasound Obstet Gynecol* 2009;33(3):253-58.

76. Verhoeven CJ, Ruckert ME, Opmeer BC, Pajkrt E, Mol BW. Ultrasonographic fetal head position to predict mode of delivery: a systematic review and bivariate meta-analysis. *Ultrasound Obstet Gynecol* 2012;40(1):9-13.

77. Sherer DM, Abulafia O. Intrapartum assessment of fetal head engagement: comparison between transvaginal digital and transabdominal ultrasound determinations. *Ultrasound Obstet Gynecol* 2003;21(5):430-36.

78. Henrich W, Dudenhausen J, Fuchs I, Kamena A, Tutschek B. Intrapartum translabial ultrasound (ITU): sonographic landmarks and correlation with successful vacuum extraction. *Ultrasound Obstet Gynecol* 2006;28(6):753-60.

79. Dietz HP, Lanzarone V. Measuring engagement of the fetal head: validity and reproducibility of a new ultrasound technique. *Ultrasound Obstet Gynecol* 2005;25(2):165-68.

80. Tutschek B, Braun T, Chantraine F, Henrich W. A study of progress of labour using intrapartum translabial ultrasound, assessing head station, direction, and angle of descent. *Br J Obstet Gynaecol* 2011;118(1):62-69.

81. Sherer DM. Intrapartum ultrasound. *Ultrasound Obstet Gynecol* 2007;30(2):123-39.

82. Bamberg C, Scheuermann S, Slowinski T, Duckelmann AM, Vogt M, Nguyen-Dobinsky TN, et al. Relationship between fetal head station established using an open magnetic resonance imaging scanner and the angle of progression determined by transperineal ultrasound. *Ultrasound Obstet Gynecol* 2011;37(6):712-16.

83. Kalache KD, Duckelmann AM, Michaelis SAM, Lange G Cichon J, Dudenhausen JW. Transperineal ultrasound imaging in prolonged second stage of labor with occipitoanterior presenting fetuses: How well does the 'angle of progression' predict the mode of delivery? *Ultrasound Obstet Gynecol* 2009;33(3):326-30.

84. Ghi T, Contro E, Farina A, Nobile M, Pilu G. Three-dimensional ultrasound in monitoring progression of labor: a reproducibility study. *Ultrasound Obstet Gynecol* 2010;36(4):500-06.

85. Torkildsen EA, Salvesen KÅ, Eggebø TM. Prediction of delivery mode with transperineal ultrasound in women with prolonged first stage of labor. *Ultrasound Obstet Gynecol* 2011;37(6):702-08.

86. Souka AP, Haritos T, Basayiannis K, Noikokyri N, Antsaklis A. Intrapartum ultrasound for the examination of the fetal head position in normal and obstructed labor. *J Matern Fetal Neonatal* 2003;13(1):59-63.

87. Sherer DM, Miodovnik M, Bradley KS, Langer O. Intrapartum fetal head position I: Comparison between transvaginal digital examination and transabdominal ultrasound assessment during the active stage of labor. *Ultrasound Obstet Gynecol* 2002;19(3):258-63.

88. Sherer DM, Miodovnik M, Bradley KS, Langer O. Intrapartum fetal head position II: Comparison between transvaginal digital examination and transabdominal ultrasound assessment during the second stage of labor. *Ultrasound Obstet Gynecol* 2002;19(3):264-68.

89. Kreiser D, Schiff E, Lipitz S, Kayam A, Avraham A, Achiron R. Determination of fetal occiput position by ultrasound during the second stage of labor. *J Matern Fetal Neonatal Med* 2001;10(4):283-6.

90. Chou R, Kreiser D, Taslimi M, Druzin M, El-Sayed Y. Vaginal versus ultrasound examination of fetal occiput position during the second stage of labor. *Am J Obstet Gynecol* 2004;191:521-4.

91. Zahalka N, Sadan O, Malinger G, Liberati M, Boaz M, Glezerman M, et al. Comparison of transvaginal sonography with digital examination and transabdominal sonography for the determination of fetal head position in the second stage of labor. *Am J Obstet Gynecol* 2005;193(2):381-86.

92. Blasi I, D'Amico R, Fenu V, Volpe A, Fuchs I, Henrich W, et al. Sonographic assessment of fetal spine and head position during the first and second stages of labor for the diagnosis of persistent occiput posterior position: a pilot study. *Ultrasound Obstet Gynecol* 2010;35(2):210-15.

93. Malvasi A, Stark M, Ghi T, Farine D, Guido M, Tinelli A. Intrapartum sonography for fetal head asynclitism and transverse position: sonographic signs and comparison of diagnostic performance between transvaginal and digital examination. *J Matern Fetal Neonatal Med* 2012; 25(5):508-12.

94. Fuchs I, Tutschek B, Henrich W. Vizualisation of the fetal fontanels and skull sutures by three-dimensional translabial ultrasound during the second stage of labor. *Ultrasound Obstet Gynecol* 2008;31:484-86.

95. Rozenberg P, Porcher R, Salomon LJ, Boirot F, Morin C, Ville Y. Comparison of the learning curves of digital examination and transabdominal sonography for the determination of fetal head position during labor. *Ultrasound Obstet Gynecol* 2008;31(3):332-37.

96. Akmal S, Kametas N, Tsoi E, Hargreaves C, Nicolaides KH. Comparison of transvaginal digital examination with intrapartum sonography to determine fetal head position before instrumental delivery. *Ultrasound Obstet Gynecol* 2003;21(5):437-40.

97. Wong GY, Mok YM, Wong SF. Transabdominal ultrasound assessment of the fetal head and the accuracy of vacuum cup application. *Int J Gynaecol Obstet* 2007;98(2):120-23.

98. Boynton PM, Greenhalgh T. Selecting, designing, and developing your questionnaire. *BMJ* 2004;328(7451):1312-5.

99. Coons SJ. Responses to survey research: transparency and representativeness are key. *Clin Ther* 2007;29(3):466-8.

100. Spencer C, Murphy D, Bewley S. Caesarean delivery in the second stage of labour. *BMJ* 2006;333(7569):613-4.

101. Whitby EH, Griffiths PD, Rutter S, Smith MF, Sprigg A, Ohadike P, et al. Frequency and natural history of subdural haemorrhages in babies and relation to obstetric factors. *Lancet* 2004;363(9412):846-51.

102. Kaptchuk TJ. The double-blind, randomized, placebo-controlled trial: gold standard or golden calf? *J Clin Epidemiol* 2001;54(6):541-9.

103. Schulz KF. Randomised trials, human nature, and reporting guidelines. *Lancet* 1996;348(9027):596-8.

104. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux PJ, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ* 2010;340:c869.

105. The CONSORT Group [Internet]. Available from: http://www.consort-statement.org/ (last accessed 1 March 2013).

106. Royal College of Obstetricians and Gynaecologists. Obtaining valid consent to participate in research while in labour.*Clinical Governance Advice No. 6a*. August 2010. Ismail K, Selman T.

107. Royal College of Obstetricians and Gynaecologists. Obtaining valid consent. *Clinical Advice No. 6.* December 2008. Morris EP.

108. Vernon G, Alfirevic Z, Weeks A. Issues of informed consent for intrapartum trials: a suggested consent pathway from the experience of the Release trial [ISRCTN13204258]. *Trials* 2006;7:13.

109. Roberts C, Roberts SA. Design and analysis of clinical trials with clustering effects due to treatment. *Clin Trials* 2005;2(2):152-62.

Appendices

Appendix 1. Questionnaire survey.

Use of Ultrasound to enhance assessment of the fetal head position prior to Instrumental Delivery IDUS QUESTIONNAIRE

Study Number ☐

Please provide the following background information:

Obstetric Grade:	Consultant	☐	Trainee	☐
MRCOG:	Yes	☐	No	☐
Gender :	Male	☐	Female	☐

Age in years: <30 ☐ 30-39 ☐ 40-49 ☐ 50-59 ☐ >59 ☐

Number of deliveries per year in your unit: _____

Overall instrumental delivery rate in your unit: (TOTAL vacuum/forceps) _____%

SCENARIO

For the following questions please consider the management in terms of a nulliparous woman in spontaneous labour at term with epidural analgesia, a cephalic presentation, clear liquor draining and a normal CTG. She has been pushing for more than one hour in the second stage of labour and requires assistance. The midwife thinks the presenting part is at station spines +1 and she is uncertain of the fetal position.

PART ONE – Assessment

1. When assessing a patient prior to instrumental delivery do you assess the following?

	Always	Frequently	Rarely	Never
i) Fetal size clinically	☐	☐	☐	☐
ii) Engagement of the presenting part	☐	☐	☐	☐
iii) Caput	☐	☐	☐	☐
iv) Moulding	☐	☐	☐	☐
v) Fetal station	☐	☐	☐	☐
vi) Fetal position	☐	☐	☐	☐
vi) Asynclitism	☐	☐	☐	☐
vii) Degree of flexion	☐	☐	☐	☐
viii) Maternal pelvis	☐	☐	☐	☐

vii) Other? Please state _____

1

PART TWO – Uncertain findings

2. When experiencing difficulty or uncertainty with determining the fetal head position prior to instrumental delivery do you use any of the following approaches?

	Always	Frequently	Rarely	Never
i) Feel for a fetal ear	☐	☐	☐	☐
ii) Feel for fetal orbits / nose	☐	☐	☐	☐
iii) Seek a second opinion	☐	☐	☐	☐
iv) Reassess in an operating theatre	☐	☐	☐	☐
v) Attempt instrumental delivery based on best guess	☐	☐	☐	☐
vi) Use abdominal ultrasound	☐	☐	☐	☐
vii) Use transperineal ultrasound	☐	☐	☐	☐
viii) Use transvaginal ultrasound	☐	☐	☐	☐
ix) Abandon procedure in favour of caesarean section	☐	☐	☐	☐

vi) Other? Please state _____

PART THREE – Difficulty factors

3. Do you consider that any of the following factors contribute to difficulty or uncertainty in determining the fetal head position prior to instrumental delivery?

	Always	Frequently	Rarely	Never
i) Inadequate maternal pain relief	☐	☐	☐	☐
ii) Maternal obesity	☐	☐	☐	☐
iii) Prolonged labour (second stage > 2 hours)	☐	☐	☐	☐
iv) Fetal caput	☐	☐	☐	☐
v) Fetal moulding	☐	☐	☐	☐
vi) Asynclitism	☐	☐	☐	☐
vii) Clinician inexperience	☐	☐	☐	☐

viii) Other? Please state _____

PART FOUR – Accuracy rate

4. How often do you think you make an incorrect diagnosis of the fetal head position at instrumental delivery?

0-5%	6-10%	11-20%	21-30%	>30%
☐	☐	☐	☐	☐

5. In your opinion, how often does a consultant obstetrician of average clinical ability make an incorrect diagnosis of the fetal head position at instrumental delivery?

0-5%	6-10%	11-20%	21-30%	>30%	Don't know
☐	☐	☐	☐	☐	☐

6. In your opinion, how often does an obstetric trainee (midway through specialist training) of average clinical ability make an incorrect diagnosis of the fetal head position at instrumental delivery?

0-5%	6-10%	11-20%	21-30%	>30%	Don't know
☐	☐	☐	☐	☐	☐

PART FIVE – RCT Participation

We are planning a randomised controlled trial (RCT) of ultrasound assessment of the fetal head position versus standard care as an approach to prevent morbidity at instrumental delivery.

	Yes	No	Don't know
7. Do you think there is a need for a trial of ultrasound assessment of the fetal head position prior to instrumental delivery?	☐	☐	☐
8. If your unit was a study centre would you consider participating in such a trial?	☐	☐	☐

Thank you for your time and co-operation.

Should you have any further comments regarding this questionnaire please note them below.

.....

.....

.....

.....

Appendix 2. Survey comments.

Survey comments

002- Trainee:

You are assuming 100% accuracy of scanning which cannot be proven

004- Trainee:

Your proposed trial assumes a level of scan expertise in all those taking part. It also assumes that seeing the position on scan ensures better placement of the ventouse cup, can you make this leap of faith?

006- Trainee:

Option of 'sometimes' in always/frequently/rarely/never.

018- Trainee:

Training to reduce inter and intra observer variability using scan would be important – development of scan protocol/sections viewed etc would help strengthen trial.

022 – Trainee:

I think early assessment of fetal head position is essential. There is some resistance from midwives about deeper vaginal exams early in labor to assess position as they feel it is too invasive. I disagree, I think that handing over care of a patient late in labor leads to worse outcomes.

023 – Consultant:

Happy to participate. Good luck. meabh.nibhuinneain@hse.ie

024- Trainee:

Ultrasound scanning experience, machines and availability of USS machines on labour wards in units involved would have to be standardised- in our unit scanning experience is limited and the machine on LW is of very poor quality.

027- Consultant:

Would value any refs to previous experience with 'IDUS' in the literature.

029- Consultant:

Basic vaginal examination skills are sadly lost with most of our trainees. It is too easy to put on a kiwi and hope!!

033 – Consultant:

I think that assessment of the station of the fetal head is frequently incorrect and that many doctors in training cannot determine correct station and will underestimate, e.g. say spines -1 rather than

1

spines 0 or spines +1, in order to justify a section at full dilatation and perhaps this is an area to look also look at.

036 - Trainee:

I think there is a need for proper training in ultrasound before this could be undertaken to aid veracity of the results from the study.

042 – Consultant:

Good idea!

052 – Consultant:

Ultrasound can be a useful adjunct where there is clinical uncertainty but it should not replace good clinical examination skills. My concern is that trainees appear to be relying more and more on ultrasound rather than knowing their clinical skills.

058- Consultant:

We can only undertake funded research or research that is part of the national portfolio.

059 – Trainee:

USS may help in difficult VE's but I think in the majority of cases it is not needed.

062 – Consultant:

I don't consider that training in UUS is time well spend for this purpose v/s time spent training in better clinical diagnosis of position.

064- Consultant:

My consultant colleagues don't tend to discuss cases where they have got it wrong so I can only comment on my own experience – both for how often I get it wrong and how often my trainees do. I only do obstetrics and spend a lot of time on the labour ward.

067 – Trainee:

I will be happy if I get training opportunity for trial of USS assessment of fetal head position prior to instrumental delivery as I find it very useful.

069 – Trainee:

I am concerned about training in ultrasound for this purpose and furthermore ultrasound should not be a substitution for clinical examination.

076 - Consultant:

My only reservation is that most of our juniors' ultrasound skills would not be up to this and I would not be up to this and I would worry that they might ignore other features looked for on VE.

078 – Consultant:

I have used ultrasound to help with diagnosing fetal head position in past (as a trainee) when in dilemma and it has proved very useful.

082 – Consultant:

Not sure who would do the scan as most trainees would not be able to tell fetal position on ultrasound.

084 – Consultant:

OP position leads to high failure rate because position not corrected before delivery.

085 – Trainee:

Excellent study, I would like to participate if possible (email address given).

093 – Trainee:

Training in ultrasound in England is so poor that inaccuracies of the scan would be worse than VE findings.

115 – Trainee:

I am going to rotate to Lancaster Royal Infirmary. It would be useful to introduce this practice in the labour ward.

118 – Trainee:

I wouldn't participate because I have recently moved to another unit. The unit I am in now has a very unportable portable scanner with poor quality images.

A few years ago, I did scan 6 patients in labour to see if I could see eyes/orbits to determine position.

124 – Consultant:

I am appalled! If a doctor can't determine position he needs:

1. Improved analgesia
2. A more experienced opinion

I am doing about 24 Kielland forceps per year and have delivered only 2 babies unknowingly OP over the past 11 years. Our CS rate was 15.7% last year.

(Signed)

136 – Consultant:

I already use ultrasound in cases of uncertainty and I am convinced of its benefit. My participation in a trial may disadvantage patients.

137 – Consultant:

We are struggling to get even basic ultrasound training for the trainees in our unit. This would be logistically impossible.

140 – Consultant:

I think that ultrasound to determine fetal position prior to instrumental delivery should be standard practice as it removes uncertainties about the position.

142 – Consultant:

Interesting point –to read re abandoning ID in favour of cs (signed)

146 – Consultant:

Please let me know fi such a trial is going ahead and I will discuss .... at labour ward forum.

156 – Consultant:

I personally dislike the use (and .....it's use) However, I am sure there is a place for it on the..... and it may improve clinical assessment, as a complement to using one's hands/fingers.

160 – Consultant:

Not experienced inability to determine position after proper examination (comment after Part 2).

Ultrasound should not be advocated to replace clinical assessment and experience. I would expect trainees to gain the necessary skills alongside a consultant.

170 – Consultant:

Limitation of USS is skill of operator. The trial will not be useful unless there are clear boundaries re USS competence. Many practitioners are better clinically than with USS at assessing position. There will be a need for training if USS proves to be useful. I actually find it a very useful adjunct but then I am a competent sonographer.

174 – Consultant:

You have not explained how the ultrasound will be done.

178 – Consultant:

I would be very keen to be involved in a trial at Good Hope Hospital.

181- Trainee:

Ultrasound should be routine.

192 – Consultant:

I am not sure that we have the ultrasound skills available at all times to conduct the trial – unless you think that there is a way around this?

204- Consultant:

Most centres practice ultrasound assessment prior to all instrumental → our trainees are encouraged to scan.

218 - Consultant:

In general people don't look hard enough for an OP position as the clues are often there during labour.

225 – Trainee:

A good study. Looking forward to read the outcome. (signed)

238 - Consultant:

Currently many of the trainees are not trained in USS.

240 - Consultant:

A London group (?Nicolaides et al) appear to have done this study before.

243 – Trainee:

It's hard enough to get ultrasound training for basic competencies let alone assessing fetal position in labour!!

245 – Trainee:

Left contact info – 'You may contact me'.

246- Consultant:

Trainees just do not have as much experience nowadays. Also, kiwi has created a 'suck it and see' mentality which shouldn't happen if forceps are being used.

248- Consultant:

Quite a few of us already use USS to determine fetal head position prior to instrumental delivery.

251 – Trainee:

Question 5 : slightly higher than trainee because consultants rarely perform instrumentals at their level.

I frequently use USS at full dilatation and it will be a good RCT.

256 - Consultant:

I would not consider participating because I would not manage difficult presentation/instrumental without USS. However other consultants do not use USS and pragmatic approach would be to compare USS users and non-users standardised to length of experience and current hours on the labour ward.

257 – Trainee:

USS is operator dependent. How do you control for this in a trial?

263 – Trainee:

USS assessment requires skills and training → may be used by skilful staff only. Also equipment availability may vary.

266 - Consultant:

1. A... ability to scan in late labour (2nd stage) and interpretation is also very important
2. Station of head is also extremely important factor in the outcome of instrumental delivery
3. Assessment of head position is more relevant in forceps than ventouse provided cup is applied over posterior fonatanelle

267 – Trainee:

The danger is that we will rely on scan and not clinical skill to diagnose position. By the end of training a good trainee should rarely get position wrong. Perhaps more direct consultant supervision is more appropriate!!!

270 - Consultant:

We don't have a scanner that can confidently assess fetal position!

271 – Trainee:

Frequently and rarely are too far apart quantitatively – should have occasionally.

289 – Trainee:

This study is around ultrasound use prior to instrumental delivery. It is quite obvious that ultrasound training represents a great deficiency for O&G trainees in the UK. So I wonder who will do the ultrasound prior to delivery.

303 – Trainee:

There have been trials by Akmal et al regarding USS prior to instrumental delivery. Having worked with Dr Akmal and taught to assess position by USS, I find this very helpful in practice.

304 - Consultant:

I feel that as an obstetrician you should concentrate in training on how to assess position and suitability for instrumental delivery. Fetal position is not only important examination finding and the trainees who come back from 'OPE' in ultrasound can scan and do everyone but lack the ability of being able to pick up moulding or inadequate pelvis or when to abandon the procedure.

323 - Trainee:

Depends on USS training clinicians have had.

It depends on expertise of USS and misuse of USS in cases of fetal distress when there is no time and quality of USS machine on labour ward is usual very poor. The 3 important factors are 1) by whom 2) case selection 3) good quality of USS machine

368 - Consultant:

If you can train someone to perform an ultrasound scan with accuracy, they clearly have 'skill' and could be trained to assess position by palpation.

378 - Consultant:

First and foremost improve the training of midwives – almost invariably fetal position in labour is unrecorded or 'undefined'!

380 - Consultant:

Excellent idea. As the experience of trainees decreases, additional means to determine position would be welcome as the alternative is consultants on the labour ward 24/7.

381 – Trainee:

Abdominal USS is something I always consider if having difficulty defining fetal position – position of spine helps identify OP/OA and very useful in differentiating between MA/MP or brow.

382 - Consultant:

You hands/fingers are your 'eyes' when doing a VE prior to instrumental delivery. What happens if you don't have access to an USS scanner?! Learn the basics first!

384 - Consultant:

I am highly trained in obstetric ultrasound and would find accurate diagnosis on scan as difficult as clinical examination and think it would be even more difficult to master for inexperienced trainees.

387 – Trainee:

I feel that VE is a clinical skill and this needs improvement with practice. USS will make people reluctant to learn this skill.

388 - Consultant:

USS is definitely better than clinical assessment but whether that translates to clinical improvement I don't know – depends what the trial is looking for.

389 – Trainee:

I frequently ask for consultant presence if I suspect malposition. Use of USS depends on whether the consultant is familiar with the equipment available on the LW.

393 – Trainee:

1. Part 1 – you may get less ticks for always as it could be for any instrumental delivery eg vertex seen at perineum, whereas I would always check for all these parameters for difficult OVD or trial of OVD
2. Congratulations for selecting very important research topic. In my experience, I have seen obstetricians taking over confident decisions for serious matter like this and hence adverse outcomes – this should be rectified!
3. Since I started doing TAS for OVD, I have experienced only one wrong position in last 3 years, which was when I did not use the scan.

404 - Consultant:

Don't get trained in obstetric USS, nor are a number of my colleagues. Also worry that this will lead to further de-skilling of trainees and over-reliance on scans.

420 - Consultant:

Interesting concept. (?hospital) should be exposed. (signed)

421 – Trainee:

Excellent idea.

426 - Consultant:

Very extravagant postage – 92p instead of 66p!

438 - Consultant:

We would like to participate in the trial. I would be more than happy to contribute. In the past I was very much interested in conducting this trial but never managed to materialise. Please do contact me for further questions. (signed)

447 – Trainee:

Well ultrasound is very useful and there are already studies to prove that, I use ultrasound to confirm my findings before applying instrument. I am not sure there is a need for RCT to prove it is useful. It is logical. But you have to be trained in scanning to use it.

463 – Trainee:

I learnt using transabdominal scan for checking fetal position when I am unsure of position on clinical examination. I found it very useful tool. I think it is an excellent RCT. (signed)

Appendix 3. Ethics letter for validation study.

Excellence in the Care of Women and Babies
Foirfeacht i gCúram Ban agus Naíonán

MC/MJ

05 October 2010

Prof. Deirdre Murphy
Consultant

Re.: Study No. 16 – 2010. Instrumental delivery and Ultrasound.

Dear Prof. Murphy

This Study was discussed at length by the Committee. The Study was approved in principle subject to the following conditions:

(1) The operator performing the Ultrasound must be trained and signed off as being so by the lead Ultrastenographer in the Department of Fetal Maternal Medicine.
(2) The Ultrasound machine used for scanning must be fit for purpose and have documentary evidence to support this.
(3) The applicants are to liaise with the Neonatologists with regard to documenting marks made on the babies' heads by the forceps.
(4) Informed consent should be sought after 36 weeks with the final consent being taken early in labour.

The applicants will be asked to supply documentary evidence from Dr. Mairead Kennelly to the Chairman of the Research Ethics Committee indicating that the Ultrastenographer performing the study has been trained and accredited to the required standard before the application can be fully approved.

Yours sincerely

Dr Michael Carey
Chairman

Appendix 4.Ultrasound quality check.

Biomed Services
Coolkenno, Tullow, Co. Carlow
Tel 087 6859766. Fax 059 9156927
Email info@biomedservices.ie

Contact:
Hospital/Clinic: Coombe Hospital
Address:

System:
Model: Sonosite Titan
Serial Number: 03/FWN

Physical Inspection and Cleaning

Console Covers/Fixings	☑Inspect	☐Clean	☐N/A	
Monitor	☑Inspect	☐Clean	☐N/A	
Keyboard/Touch Panel	☑Inspect	☐Clean	☐N/A	
Trackball	☑Inspect	☐Clean	☐N/A	
Peripherals	☑Inspect	☐Clean	☐N/A	
Transducers	☑Inspect	☐Clean	☐N/A	
Power Supply	☑Inspect	☐Clean	☐N/A	
Fans/Airflow Paths	☐Inspect	☐Clean	☑N/A	
Cables/Connectors	☑Inspect	☐Clean	☐N/A	

Functional Checks

B-Mode Function	☑Inspect	☐Clean	☐N/A	
M-Mode Function	☑Inspect	☐Clean	☐N/A	
Doppler Function	☑Inspect	☐Clean	☐N/A	
Colour Mode Function	☑Inspect	☐Clean	☐N/A	
3D-Mode Function	☐Inspect	☐Clean	☑N/A	
Touch Panel	☐Inspect	☐Clean	☑N/A	
TGC Function	☐Inspect	☐Clean	☑N/A	
Data Storage Function	☑Inspect	☐Clean	☐N/A	

Probes:

Probe 1	Type C60S-2MHz		Serial Number 031MZ8	
Cabling/Housing	☑Inspect	☐Clean	☐N/A	SMALL BREAK ON CABLE NO WIRES EXPOSED
Membrane	☑Inspect	☐Clean	☐N/A	
Image	☑Inspect	☐Clean	☐N/A	
Probe 1	Type		Serial Number	
Cabling/Housing	☐Inspect	☐Clean	☐N/A	
Membrane	☐Inspect	☐Clean	☐N/A	
Image	☐Inspect	☐Clean	☐N/A	
Probe 1	Type		Serial Number	
Cabling/Housing	☐Inspect	☐Clean	☐N/A	
Membrane	☐Inspect	☐Clean	☐N/A	
Image	☐Inspect	☐Clean	☐N/A	

Phantom Image Check

Probe 1	Probe 2	Probe 3	Limits
Dead Zone 2mm	Dead Zone	Dead Zone	<10mm
Vertical 10.1	Vertical	Vertical	10mm ±1.0mm
Horizontal 20.2	Horizontal	Horizontal	20mm ± 2.0mm
Axial/Lateral OK	Axial/Lateral	Axial/Lateral	Closest Target
Grey Scale OK	Grey Scale	Grey Scale	Check printout
Max Penetration 22cms	Max Penetration	Max Penetration	Max Achieved measurement

Problems Found Steering on transducer broken - OK to use

Electrical Safety Check ☑OK
Engineer Signature Luke Byrne

Appendix 5. Letter of competency for scanning in second stage of labour.

26th May 2011

Dear Dr Carey and Members of the Ethics Committee,

RE: Study Number 16 – 2010 Instrumental Delivery and Ultrasound

This is to confirm that Dr. Meena Ramphul has been trained in 2D grayscale ultrasound in the assessment of fetal head position / fetal spine position in the second stage of labour.

This process has involved one to one teaching and assessment of interoperator variability with high concordance rates at completion of the assessment process.

I am happy to sign Dr. Ramphul off as competent in this particular aspect of ultrasound assessment, for the purpose of her PhD research.

Yours sincerely,

Dr Mairead Kennelly

Senior Lecturer and Consultant in Obstetrics and Fetal Medicine,

UCD Centre for Human Reproduction,

Coombe Women and Infants University Hospital,

Dublin 8

Appendix 6. Ethics letter – Coombe Women & Infants' University Hospital.

MC/MJ

29 June 2011

Prof. Deirdre Murphy
Consultant
Coombe Women & Infants University Hospital

Re.: Study No. 16 – 2011 – Instrumental Delivery and Ultrasound

Dear Prof. Murphy

At the recent research ethics committee meeting held on the 15th June 2011, correspondence was received from Dr Mairead Kennelly confirming the competence of Dr Meena Ramphul in ultrasound scanning of the fetal head and spine in the second stage of labour. This study is now therefore approved.

Yours sincerely

Dr Michael Carey
Chairman

Appendix 7. Ethics letter – Mid- Western Regional Hospital, Limerick.

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

HSE West,
Mid-Western Regional Hospital,
Dooradoyle,
Limerick, Ireland.

Tel: 00353 (0) 61 301111
Fax: 00353 (0) 61 301165
Website: www.hse.ie

9th August, 2011.

Dr. Meenakshi Ramphul,
Coombe Women & Infants University Hospital,
DUBLIN.

RE: Protocol Title:
A multi-centre randomized controlled trial of ultrasound assessment of the fetal head position versus standard care as an approach to prevent morbidity at instrumental delivery.

Dear Dr. Ramphul,

The Research Ethics Committee at the Mid-Western Regional Hospital, Limerick has received a submission for ethical approval for the above study.

The following documents were reviewed and approved by the Research Ethics Committee:

Application to the Research Ethics Committee	*Approved*
Ethics Committee Approval from the Coombe Women & Infants UniversityHospital	*Approved*
Patient Information Sheet	*Approved*
Consent Form	*Approved*

This approval is valid for one year from the date(s) accepted above unless otherwise noted on this document.

From an insurance perspective, please note that cover does not extend to those parties not employed by the Health Service Executive (HSE), or non-HSE Institutions.

Yours sincerely,

Fionnuala O'Brien,
Medical Directorate.
(For and on behalf of the Research Ethics Committee).

Appendix 8. Validation study - patient information sheet.

Instrumental Delivery and UltraSound

Validation Study

IDUS

PATIENT INFORMATION SHEET

You are being invited to take part in a research study. Before you decide whether to take part, it is important that you understand why the research is being done and what it will involve. Please take time to read this information carefully and discuss it with others. Please ask us if there is anything that is not clear or if you would like more information. Take your time to decide whether or not you wish to take part.

What is the purpose of this study?
This study will work out how exact obstetricians are at finding out the position of the baby's head. If the exact position of the baby's head is known there is more chance of successful delivery and less chance of trauma to the woman or the baby. This is the beginning for a bigger study that will look at the position of the baby's head before an instrumental delivery (vacuum or forceps).

Why have I been chosen?
We are carrying out the study in maternity units in Dublin and Limerick. We are trying to contact every woman who is aiming for a vaginal delivery. We would hope to have around 50 women like you taking part in the study.

Do I have to take part?
It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign the consent form. After deciding to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive from your doctor or midwife in any way. If you decide not to take part, your delivery will be managed in the usual way through discussion with your obstetrician, midwife and anaesthetist.

This study has received approval from the Coombe Hospital's Research Committee.

What will happen during the study?
We are trying to work out how exact obstetricians are at finding out the position of the baby's head. If you decide to take part, you will be scanned by a Consultant and a Research registrar when you are fully dilated. This will be followed by an examination by the Registrar on duty.

Will my taking part in this study be kept confidential?
All information that is collected about you during the course of the research will be kept strictly confidential. A researcher on the study will need to look at your hospital records for information about your pregnancy and delivery. All published information will have your name and address removed so that you cannot be recognised from it. We will ask for your consent to inform your GP that you are taking part in the study.

What will happen to the results of the study?
The study will last for approximately 3 years in total. We hope that the results will provide clear information for women and doctors about the most accurate method to diagnose the fetal head position before an instrumental delivery. A report will be produced at the end of the study, and the main results will be published

in medical journals. This can sometimes take a year or more after the end of the study. If you would like us to send you a copy of the results, please let us know at some time during your involvement in the study.

Who is organising and funding the research?
The study is being organised jointly by Trinity College Dublin and the Coombe Women and Infants' University Hospital. The study is funded by the Health Research Board of Ireland.

What do I do now?
If you feel happy to participate in the study we will ask for your written consent.

Contact for further information
If you have any other questions about the study at any time you can contact:

Dr. Meena Ramphul	Prof Deirdre Murphy
Research Fellow	Professor of Obstetrics and Consultant Obstetrician

Appendix 9. Validation study - patient consent form.

VALIDATION STUDY

IDUS

CONSENT FORM

NB. ***This form must be completed and signed by the research subject in the presence of someone with knowledge of the research designated by the Principal Investigator. This may be a doctor, nurse, clinical research assistant or other member of the research team who must countersign the form as witness to the subject's signature.***

Please tick (✓) appropriate box

Have you read and understood the Subject Information Sheet? Yes ☐ No ☐

Have you been given an opportunity to ask questions and further discuss this study? Yes ☐ No ☐

Have you received satisfactory answers to all of your questions? Yes ☐ No ☐

Have you now received enough information about this study? Yes ☐ No ☐

Who have you spoken to? Dr/Mr/Mrs/Miss .....

Do you understand that your participation is entirely voluntary? Yes ☐ No ☐

Do you understand that you are free to withdraw from this study:

At any time? Yes ☐ No ☐

Without having to give a reason for withdrawing? Yes ☐ No ☐

Without this affecting your present or future medical care? Yes ☐ No ☐

Do you agree that your records in this research and supporting medical records be made available for inspection by monitors from:

Trinity College? Yes ☐ No ☐
Regulatory authorities? Yes ☐ No ☐

Do you agree to take part in this study? Yes ☐ No ☐

Do you agree to your family doctor (GP) being informed of your participation in this study? Yes ☐ No ☐

Subject's signature ..... Date .....

Subject's name in block capital letters .....
Telephone contact (Subject) .....(Home) ..... (Work)

Signature witnessed by ..... Date .....

Witness name in block captal letters .....

Appendix 10. Validation study – ultrasound form: expert sonographer.

Instrumental Delivery and UltraSound

IDUS

US FORM – Expert Sonographer

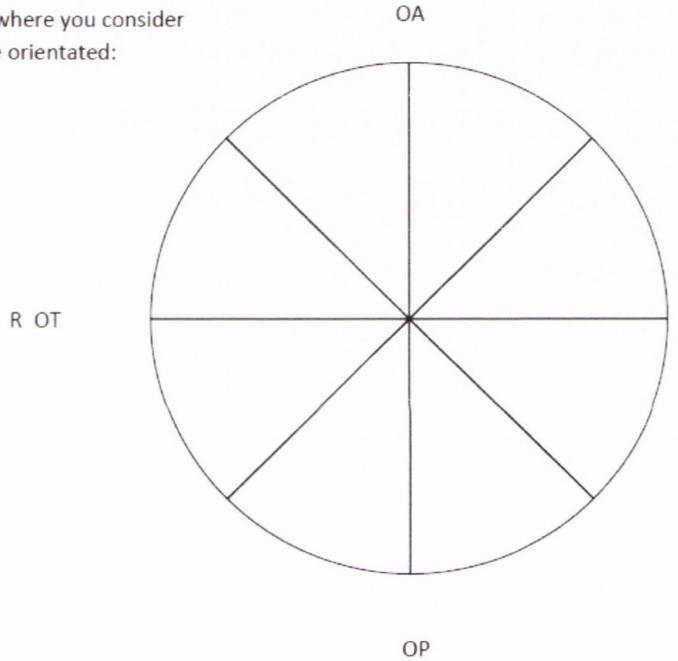
Study no.: _____ **Patient Initials:** _____

Hospital no.: _____ **Date of delivery:** _____

Start Time : ..... End time : .....

FETAL HEAD POSITION

Place X at point where you consider the occiput to be orientated:



Diagnosis made by visualising:

- Nuchal region ☐
- Occiput ☐
- Transthalamic view ☐
- Midcrebral echo ☐
- Orbit ☐
- Other _____

Degree of certainty

1----------2----------3----------4----------5----------6----------7----------8----------9----------10

Very uncertain Completely certain

FETAL BACK POSITION

State where you consider the fetal back to lie:

Direct anterior ☐ Direct posterior ☐ Left lateral ☐ Right lateral ☐ Don't know ☐

Degree of certainty

1----------2----------3----------4----------5----------6----------7----------8----------9----------10

Very uncertain Completely certain

Appendix 11. Validation study – ultrasound form: novice sonographer.

Instrumental Delivery and UltraSound

IDUS

US FORM – Novice Sonographer

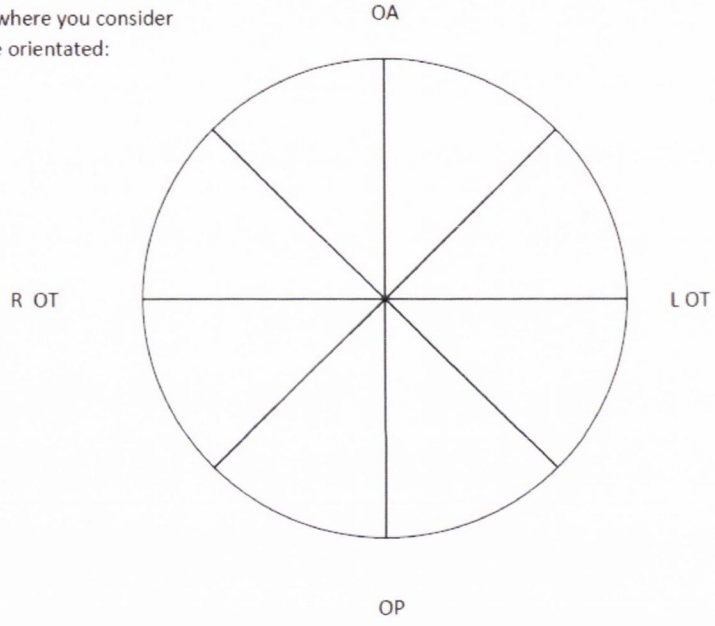
Study no.: _____ **Patient Initials:** _____

Hospital no.: _____ **Date of delivery:** _____

Start Time : ..... End time : .....

FETAL HEAD POSITION

Place X at point where you consider the occiput to be orientated:



Diagnosis made by visualising:

- ☐ Nuchal region
- ☐ Occiput
- ☐ Transthalamic view
- ☐ Midcrebral echo
- ☐ Orbit

Degree of certainty

1----------2----------3----------4----------5----------6----------7----------8----------9----------10

Very uncertain Completely certain

FETAL BACK POSITION

State where you consider the fetal back to lie:

Direct anterior ☐ Direct posterior ☐ Left lateral ☐ Right lateral ☐ Don't know ☐

Degree of certainty

1----------2----------3----------4----------5----------6----------7----------8----------9----------10

Very uncertain Completely certain

Appendix 12. Validation study – clinical examination findings form.

Instrumental Delivery and UltraSound

IDUS

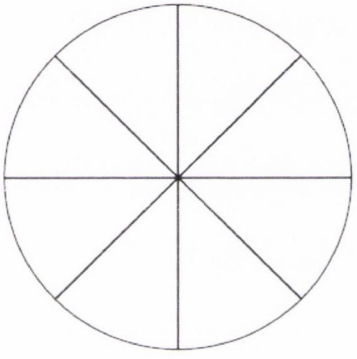
CLINICAL EXAMINATION FINDINGS

Study no.: _____ **Patient Initials:** _____

Hospital no.: _____ **Date of delivery:** _____

FETAL HEAD POSITION

Place X at point where you consider the occiput to be orientated:



Engagement on abdominal examination:

0/5 ☐ 1/5 ☐

Vaginal examination:

Station

Spines -1 ☐ spines-2 ☐
Spines+0 ☐ spines+1 ☐
Spines+2 ☐ spines+3 ☐

Caput

0 ☐ + ☐
++ ☐ +++ ☐

Moulding

0 ☐ + ☐
++ ☐ +++ ☐

Grade of operator: .....

Degree of certainty

1----------2----------3----------4----------5----------6----------7----------8----------9----------10

Very uncertain Completely certain

FETAL BACK POSITION

State where you consider the fetal back to lie:

Direct anterior ☐ Direct posterior ☐ Left lateral ☐ Right lateral ☐ Don't know ☐

Degree of certainty

1----------2----------3----------4----------5----------6----------7----------8----------9----------10

Very uncertain Completely certain

Appendix 13. Validation study- patient questionnaire.

IDUS

Instrumental Delivery and Ultrasound Patient Questionnaire

Study Number ☐ Hospital Number ☐

1. With regard to your participation in this study:

	Yes	No
i) Were you satisfied that you received enough information prior to taking part?	☐	☐
ii) Were you satisfied that you had enough time to consider taking part?	☐	☐
iii) Were you satisfied with all aspects of the recruitment process?	☐	☐

If you answered No to any of these questions, please state why below

.....

2. With regard to use of ultrasound in the second stage of labour:

	Yes	No
i) Did you find this intrusive?	☐	☐
ii) Did you find this uncomfortable?	☐	☐
iii) Did this bother you in any way?	☐	☐

If you answered Yes to any of these questions, please state why below

.....

	Yes	No	Don't know
3. Would you consider participating in a study like this again?	☐	☐	☐

Thank you for your time and co-operation.

Should you have any further comments regarding this questionnaire please note them below

.....

.....

.....

.....

Appendix 14. Validation study- midwife questionnaire.



Instrumental Delivery and Ultrasound
Midwife Questionnaire

Study Number ☐ Hospital Number ☐

1. With regard to your patient's participation in this study:

	Yes	No
i) Were you satisfied that she received enough information prior to taking part?	☐	☐
ii) Were you satisfied that she had enough time to consider taking part?	☐	☐
iii) Were you satisfied with all aspects of the recruitment process?	☐	☐

If you answered No to any of these questions, please state why below

.....

2. With regard to use of ultrasound in the second stage of labour:

	Yes	No
i) Did you find this intrusive?	☐	☐
ii) Did you feel uncomfortable providing care in this context?	☐	☐
iii) Did the intervention bother you in any way?	☐	☐

If you answered Yes to any of these questions, please state why below

.....

	Yes	No	Don't know
3. Would you support future participation in a study like this again?	☐	☐	☐

Thank you for your time and co-operation.

Should you have any further comments regarding this questionnaire please note them below

.....

.....

.....

.....

Appendix 15. Validation study- obstetrician questionnaire.

IDUS

Instrumental Delivery and Ultrasound
Obstetrician Questionnaire

Study Number ☐ Hospital Number ☐

1. With regard to your patient's participation in this study:

	Yes	No
i) Were you satisfied that she received enough information prior to taking part?	☐	☐
ii) Were you satisfied that she had enough time to consider taking part?	☐	☐
iii) Were you satisfied with all aspects of the recruitment process?	☐	☐

If you answered No to any of these questions, please state why below

.....

2. With regard to use of ultrasound in the second stage of labour:

	Yes	No
i) Did you find this intrusive?	☐	☐
ii) Did you feel uncomfortable providing care in this context?	☐	☐
iii) Did the intervention bother you in any way?	☐	☐

If you answered Yes to any of these questions, please state why below

.....

	Yes	No	Don't know
3. Would you support future participation in a study like this again?	☐	☐	☐

Thank you for your time and co-operation.

Should you have any further comments regarding this questionnaire please note them below

.....

.....

.....

.....

Appendix 16. Validation study – case report form.

Instrumental Delivery and Ultrasound

IDUS

VALIDATION STUDY - CASE REPORT FORM

Study no.: _____ **Patient Initials:** _____

Hospital no.: _____ **Date of delivery:** _____

DEMOGRAPHIC DATA

1. Mother's age (years) ____
2. Mother's profession _____
3. Mother's ethnic origin ☐
4. Mother's marital status ☐

MATERNAL FACTORS

5. Infertility ☐
6. Diabetes ☐
7. Cardiac disease ☐
8. Endocrine disease ☐
9. Hypertension at booking ☐
10. Renal disease ☐
11. Inflammatory bowel disease ☐
12. Smoking ☐
13. Alcohol ☐
14. Drug abuse ☐
15. Other _____

PAST OBSTETRIC/GYNAE HISTORY

16. Parity __+__
17. Complications
    - Previous pelvic surgery ☐
    - Previous pelvic infection ☐
    - Previous abnormal smear ☐
    - Previous LLETZ ☐
    - Previous PPH ☐

Previous cervical suture ☐

PRE-DELIVERY DETAILS

18. Maternal weight at booking _____ kg
19. Maternal height _____ cm
20. BMI ____ kg/m^2

1

DELIVERY DETAILS

First stage of labour

21. Gestation at delivery ___wks___days
22. Onset of labour ☐
23. If IOL, reason ☐
24. Membrane rupture ☐
25. Duration of 1st stage of labour(hrs) ____
26. Monitoring in labour ☐
27. CTG classification ☐
28. Oxytocin use ☐
29. FBS ☐
30. No. of FBS _____
31. Latest result:
    a. Ph _____
    b. Base excess _____
32. Colour of liquor ☐
33. Analgesia ☐

Second stage of labour

34. Oxytocin use ☐
35. Monitoring ☐
36. CTG classification ☐
37. Colour of liquor ☐
38. Maternal pyrexia (T>38^{0}) ☐
39. Maternal tachycardia (HR>100 bpm) ☐
40. Anaesthesia ☐

Clinical Findings

41. Vaginal examination
    a. Station ☐
    b. Position at outset ☐
    c. Caput ☐
    d. Moulding ☐
    e. Asynclitism ☐
42. Degree of certainty (head): 0-10 ☐
43. Fetal Back position ☐
44. Degree of certainty (back): 0-10 ☐
45. Grade of clinician ☐

US Findings – Expert Sonographer

46. Fetal Head Position at outset ☐
47. Diagnosis made by visualizing:
    a. Nuchal region ☐
    b. Occiput ☐
    c. Transthalamic view ☐
    d. Midcerebral echo ☐
48. Degree of certainty (head): 0-10 ☐
49. Fetal Back position ☐
50. Degree of certainty (back):0-10 ☐
51. Time taken for ultrasound (seconds)_____

US Findings – Novice Sonographer

52. Fetal Head Position at outset ☐
53. Diagnosis made by visualizing:
    a. Nuchal region ☐
    b. Occiput ☐
    c. Transthalamic view ☐
    d. Midcerebral echo ☐

2

54. Degree of certainty (head): 0-10 ☐
55. Fetal Back position ☐
56. Degree of certainty (back):0-10 ☐

57. Time taken for ultrasound (seconds) _____

OUTCOMES

58. USS findings same - expert & novice ☐
59. USS findings (expert) same as VE ☐
60. USS findings (novice) same as VE ☐

PATIENT SURVEY

61. With regard to your participation in this study:
    a. Were you satisfied you received enough information prior to taking part ☐
    b. Were you satisfied you had enough time to consider taking part ☐
    c. Were you satisfied with all aspects of the recruitment process ☐
62. If answered 'No' to any of the above, reason: _____
63. With regard to use of ultrasound in the second stage of labour:
    d. Did you find this intrusive ☐
    e. Did you find this uncomfortable ☐
    f. Did this bother you in any way ☐
64. If answered 'Yes' to any of the above, reason: _____
65. Would you consider participating in a study like this again ☐

OBSTETRICIAN SURVEY

66. With regard to your patient's participation in this study:
    a. Were you satisfied she received enough information prior to taking part ☐
    b. Were you satisfied she had enough time to consider taking part ☐
    c. Were you satisfied with all aspects of the recruitment process ☐
67. If answered 'No' to any of the above, reason: _____
68. With regard to use of ultrasound in the second stage of labour:
    d. Did you find this intrusive ☐
    e. Did you find this uncomfortable ☐
    f. Did the intervention you in any way ☐
69. If answered 'Yes' to any of the above, reason: _____
70. Would you consider participating in a study like this again ☐

MIDWIFE SURVEY

71. With regard to your patient's participation in this study:
    a. Were you satisfied she received enough information prior to taking part? ☐

b. Were you satisfied she had enough time to consider taking part? ☐

c. Were you satisfied with all aspects of the recruitment process? ☐

72. If answered 'No' to any of the above, reason: _____

73. With regard to use of ultrasound in the second stage of labour:

d. Did you find this intrusive? ☐

e. Did you find this uncomfortable? ☐

f. Did the intervention you in any way? ☐

74. If answered 'Yes' to any of the above, reason: _____

75. Would you consider participating in a study like this again ☐

Appendix 17. Validation study – codes for case report form.

STANDARD CODES	0	NO
	1	YES
	999	NOT KNOWN
Times in 24 hour clock		

IDUS

CODES AND DEFINITIONS FOR IDUS VALIDATION STUDY

DEMOGRAPHIC DATA

3. Mother's ethnic origin:
0. Irish (Caucasian)
1. Caucasian (non- Irish)
2. Caribbean black
3. African black
4. Indian
5. Pakistani
6. Bangladeshi
7. Chinese
8. Other

4. Mother's marital status: (supported if has partner)
0. Married
1. Single supported
2. Single unsupported
3. Single unknown

MATERNAL FACTORS

5. Previous infertility
0. None
1. Donor semen/ Donor egg
2. Clomiphene
3. Pergonal
4. In-vitro fertilisation/ ICSI
Record that which requires greatest intervention

6. Diabetes:
0. None
1. IDDM Type 1 or 2
2. Gestational Diabetes in any previous pregnancy

7. Cardiac disease: present at the time of booking including corrected cardiac anomalies.

8. Endocrine disease: other than diabetes, present at the time of booking.

9. Hypertension at time of booking: BP >/= 140 or >/= 90 on two separate occasions.

10. Renal disease:

0. None
1. Recurrent UTIs
2. Structural abnormality
3. Renal disease

11. Inflammatory bowel disease

0. None
1. Ulcerative colitis/Crohn's
2. Other

12. Smoking:

0. None
1. 1 - 10/day
2. 11 - 20/day
3. > 20/day

13. Alcohol:

0. None
1. Light = 1-5 units/week
1. Moderate = 6-20 units/week
2. Heavy = >20 units/week

14. Drug abuse

0. None
1. Non-IVDU
2. IVDU (intravenous drug use)

DELIVERY DETAILS

22. Onset of labour

0. Spontaneous
1. Induced

23. Indication of IOL

0. Postdates
1. Maternal causes
2. Fetal causes

24. Membrane rupture

0. Spontaneous
1. Artificial rupture of membrane
2. Prolonged rupture of membrane

26. Monitoring in labour

0. Intermittent auscultation
1. CTG

2

27, 36. CTG classification (EFM guidelines)

0. Normal
1. Suspicious (1 feature in non-reassuring category, remainder normal)
2. Pathological (≥2 features non-reassuring or ≥1 abnormal)

Feature	Baseline (bpm)	Variability	Decelerations	Accelerations
Reassuring	110 – 160	≥ 5	None	Present
Non-reassuring	100 – 109 161- 180	<5 for <40min to <90min	- Early decels. - Variable decels. - Single prolonged decel. up to 3min	*Absence of accels in otherwise normal CTG is of unknown significance*
Abnormal	<100 >180 Sinusoidal pattern ≥ 10min	<5 for ≥ 90min	- Atypical/variable decels. - Late decels. - Single prolonged decel. >3min	

32, 37. Colour of liquor

0. Clear
1. Blood stained
2. Meconium

33. Analgesia

0. Nil
1. Entonox
2. Opiates
3. Epidural
4. Spinal

40. Anaesthesia

0. Nil
1. Entonox
2. Epidural
3. Spinal
4. Pudendal block
5. Local anaesthetic

41 a. Vaginal examination - Station

0. Spines +0
1. Spines +1
2. Spines +2
3. Spines +2
4. Spines -1
5. Spines -2
6. Unrecorded

41 b, 45, 50. Fetal head position	0. Direct OA 1. R OA 2. L OA 3. R OT 4. L OT 5. Direct OP 6. R OP 7. L OP 8. Unrecorded
41 c. Caput	0. Nil 1. + 2. ++ 3. +++ 4. Unrecorded
41 d. Moulding	0. Nil 1. + 2. ++ 3. +++ 4. Unrecorded
43, 49, 55. Fetal Back Position	0. Direct anterior 1. Direct posterior 2. Left lateral 3. Right lateral 4. Unknown 5. Unrecorded
45. Grade of clinician	0. SHO 1. Junior Registrar 2. Registrar (year 1-3) 3. Senior registrar (year ≥ 4) 4. SpR 1-3 5. SpR 4-5 6. Consultant

Appendix 18. Grant award letter from the Health Research Board, Ireland.

Health Research Board

An Bord Taighde Slainte
73 Sráid Bhagóid Íochtarach
Baile Átha Cliath 2, Éire
t +353 1 2345000
f +353 1 6612335
e hrb@hrb.ie
w www.hrb.ie

Health Research Board
73 Lower Baggot Street
Dublin 2, Ireland
t +353 1 2345000
f +353 1 6612335
e hrb@hrb.ie
w www.hrb.ie

Professor Deirdre Murphy
Department of Obstetrics and Gynaecology
Coombe Women's Hospital
Cork Street
Dolphin's Barn
Dublin 8

17 August 2010

HRB Funding to Trinity College Dublin
Health Research Awards 2010
(HRA_POR/2010/55)

Dear **Professor Deirdre Murphy**,

I enclose a copy of the grant letter dated 17 August 2010 issued to Trinity College Dublin regarding funding for a **Health Research Award** to enable you to undertake a 3 year research project entitled "Ultrasound assessment of fetal head position to prevent morbidity at instrumental delivery (IDUS)". You should liaise with Trinity College Dublin regarding the completion of the acceptance documentation and, in particular, the declaration to be completed by you containing confirmation that you have read, understand and agree to abide to the terms and conditions of the grant. You will note from the grant letter that the offer of the grant will lapse unless the completed documentation is returned by the close of business on 10 September 2010.

I look forward to working with you and Trinity College Dublin in supporting the funded activity.

Yours sincerely

Enda Connolly
Chief Executive

Appendix 19. IDUS Trial registration.

ISRCTN72230496 - Ultrasound assessment of the fetal head position to prevent morbidity at instrumental delivery.

Dear All,

I am pleased to inform you that the following ISRCTN has been assigned to your trial:

ISRCTN72230496 - http://www.controlled-trials.com/ISRCTN72230496

When quoting the ISRCTN, please make sure that no space is inserted between the ISRCTN and the actual number. Please refer to the link below for further guidance notes about how to use the ISRCTN.

http://www.controlled-trials.com/isrctn/sample_documentation.asp

I would also like to remind you that CCT's sister company, BioMed Central (http://www.biomedcentral.com) , publishes a wide range of Open Access biomedical journals, in particular the journal Trials, dedicated to publishing protocols, results and other issues relevant to clinical trials. If you would like to publish your trial protocol and/or results papers in Open Access, please visit Trials for more information http://www.trialsjournal.com.

Please also note that as of January 2011 selected BioMed Central journals offer a 20% discount on the article processing charge to protocol authors who have registered their trial with the ISRCTN register managed by Current Controlled Trials. Authors should request a waiver during the submission process and provide their ISRCTN. For more information on this scheme, and to find out whether your protocol can be published with a discount, view the publish your study protocol page at BioMed Central.

If you have any further questions about the use of the ISRCTN, please do not hesitate to contact me.

Best wishes,
Rebecca

Rebecca Green
Senior Database Editorial Assistant

Current Controlled Trials
236 Gray's Inn Road
London, WC1X 8HB

T: +44 (0)20 3192 2245
F: +44 (0)20 3192 2011
E: Rebecca.Green@controlled-trials.com
W: www.controlled-trials.com

Appendix 20. IDUS letter to consultants

Instrumental Delivery & UltraSound

Dear

Re: A multi-centre randomised controlled trial of ultrasound assessment of the fetal head position versus standard care as an approach to prevent morbidity at instrumental delivery.

We have recently been awarded funding from the Health Research Board (HRB) for a randomised controlled trial evaluating the role of ultrasound in assessing the fetal head position before instrumental deliveries. This is a collaborative project between the Coombe Women & Infants University Hospital and the Mid-Western Regional Maternity Hospital, Limerick and we would be very grateful if we could enlist your support. The objective of the study is to determine whether an ultrasound scan performed in addition to routine clinical assessment prior to instrumental delivery reduces the incidence of incorrect diagnosis of the fetal head position.

Nulliparous women will be informed of the study in the antenatal period. They will then be recruited at term (≥37 weeks' gestation) and written consent will be confirmed prior to induction of labour provided the following criteria are met: the midwife looking after the woman assesses her to be capable of providing informed consent; the woman has adequate pain control; and the woman has not used systemic opiates in the last four hours. Once consent has been given the mother will not be consulted again unless she requires an instrumental delivery. If the woman needs an instrumental delivery, she will be randomised in either the usual care arm (routine clinical assessment) or the intervention arm (routine clinical assessment and ultrasound scan). The primary outcome is to compare the incidence of incorrect diagnosis of the fetal head position. Women with a contraindication to instrumental delivery, or who have a limited understanding of English or are under 18 years of age will be excluded. Eligibility will also be at the discretion of the responsible obstetrician in cases where there is urgency due to suspected fetal compromise ("fetal distress").

We plan to recruit 450 women over two years between the two centres. In the first instance, we are planning to do a validation study which will then be followed by recruitment for the randomised controlled trial. Ethical approval from the Coombe Women and Infants' University Hospital has been granted. We do not envisage any disruption to the care of women in labour nor any increased workload on your part and we are very grateful for any support you feel you can offer.

If you have anything that you would like to discuss, either about the study in general, or any patient in particular, please do not hesitate to contact me.

Many thanks,

Yours sincerely,

Meenakshi Ramphul
Trial Co-ordinator

Deirdre Murphy
Professor of Obstetrics & Gynaecology



Re: A multi-centre randomised controlled trial of ultrasound assessment of the fetal head position versus standard care as an approach to prevent morbidity at instrumental delivery.

Consultant Name: _____

I agree to my patients being approached for study participation ☐

I do not agree to my patients being approached for study participation ☐

I require further information about this study ☐

Consultant signature: _____

Date signed: _____

Please return to Meenakshi Ramphul, The Coombe Women & Infants University Hospital.

Professor Deirdre J Murphy MD MRCOG
Professor of Obstetrics & Head of department
Trinity College Dublin
Coombe Women & Infants University Hospital,
Dublin 8

Dr Meenakshi Ramphul MRCPI
Research Fellow
Trinity College Dublin
Coombe Women & Infants
University Hospital, Dublin 8

Dr Mairead Kennelly MD MRCOG MRCPI
Consultant & UCD Senior Lecturer
Coombe Women & Infants University Hospital,
Dublin 8

Dr Chris Fitzpatrick MRCOG FRCPI
Master
Coombe Women & Infants
University Hospital, Dublin 8

Appendix 21. IDUS- patient information sheet

Instrumental Delivery and UltraSound

A randomised controlled trial of an ultrasound intervention versus usual care to determine the accuracy of the diagnosis of the fetal head position.

IDUS

PATIENT INFORMATION SHEET

You are being invited to take part in a research study. Before you decide whether to take part, it is important that you understand why the research is being done and what it will involve. Please take time to read this information carefully and discuss it with others. Please ask us if there is anything that is not clear or if you would like more information. Take your time to decide whether or not you wish to take part. Please note that while we are asking you to agree in principle to participate in the study you will only be eligible if you require an instrumental delivery (vacuum or forceps).

What is the purpose of this study?
This study will work out how exact obstetricians are at finding out the position of the baby's head before an instrumental delivery (vacuum or forceps). If the exact position of the baby's head is known there is more chance of successful delivery and less chance of trauma to the woman or the baby. Both ultrasound scanning and clinical examination are part of usual practice. The study design will allow us to evaluate the role of ultrasound in a scientific manner.

Why have I been chosen?
We are carrying out the study in maternity units in Dublin and Limerick. We are trying to contact every woman who is aiming for a vaginal delivery. On average, 33% of first time mothers (1 in 3) will have an instrumental delivery. Over a two year period we would hope to have around 450 women like you taking part in the study.

Do I have to take part?
It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign the consent form. After deciding to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive from your doctor or midwife in any way. If you decide not to take part, your delivery will be managed in the usual way through discussion with your obstetrician, midwife and anaesthetist.

This study has received approval from the Coombe Hospital's Research Committee. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from Trinity College, University of Dublin and the Regulatory Authorities.

What will happen during the study?
We are trying to work out how exact obstetricians are at finding out the position of the baby's head before an instrumental delivery (vacuum or forceps). Sometimes because we do not know which intervention is best, we need to make comparisons. People who need an instrumental delivery (vacuum or forceps) will be put into groups and then compared. The groups are selected by a computer which has no information about the individual – i.e. by chance. You would have an equal chance of receiving either of the interventions. The two groups will be compared at the end of the study to find out which approach is best at finding out the position of the baby's head position. If you consent to participate in the study, your participation would be confirmed

again immediately prior to the instrumental delivery (vacuum or forceps) and it is at this point that you would be allocated to one of the interventions.

If you need an instrumental delivery, depending on which group you are in, you may have:
(1) Routine clinical assessment (abdominal and vaginal examinations as per routine practice)
(2) Routine clinical assessment and an abdominal ultrasound scan
In both groups, you will be reviewed after delivery and on the post-natal ward to assess your health and well-being.

If you do not need an instrumental delivery, you will not be enrolled in the study.

Will my taking part in this study be kept confidential?
All information that is collected about you during the course of the research will be kept strictly confidential. A researcher on the study will need to look at your hospital records for information about your pregnancy and delivery. All published information will have your name and address removed so that you cannot be recognised from it. We will ask for your consent to inform your GP that you are taking part in the study.

What will happen to the results of the study?
The study will last for approximately 3 years in total. We hope that the results will provide clear information for women and doctors about the most accurate method to diagnose the fetal head position before an instrumental delivery. A report will be produced at the end of the study, and the main results will be published in medical journals. This can sometimes take a year or more after the end of the study. If you would like us to send you a copy of the results, please let us know at some time during your involvement in the study.

Who is organising and funding the research?
The study is being organised jointly by Trinity College Dublin and the Coombe Women and Infants' University Hospital. The study is funded by the Health Research Board of Ireland.

What do I do now?
If you feel happy to participate in the study we will ask for your written consent.

Contact for further information
If you have any other questions about the study at any time you can contact:

Dr. Meena Ramphul
Research Fellow

Prof Deirdre Murphy
Professor of Obstetrics and Consultant Obstetrician

Appendix 22. IDUS - consent form.

Instrumental Delivery and UltraSound



CONSENT FORM

NB. ***This form must be completed and signed by the research subject in the presence of someone with knowledge of the research designated by the Principal Investigator. This may be a doctor, nurse, clinical research assistant or other member of the research team who must countersign the form as witness to the subject's signature.***

	Please tick (✓) appropriate box			
Have you read and understood the Subject Information Sheet?	Yes	☐	No	☐
Have you been given an opportunity to ask questions and further discuss this study?	Yes	☐	No	☐
Have you received satisfactory answers to all of your questions?	Yes	☐	No	☐
Have you now received enough information about this study?	Yes	☐	No	☐
Who have you spoken to? Prof / Dr / Mr / Ms				
Do you understand that your participation is entirely voluntary?	Yes	☐	No	☐
Do you understand that you are free to withdraw from this study:				
At any time?	Yes	☐	No	☐
Without having to give a reason for withdrawing?	Yes	☐	No	☐
Without this affecting your present or future medical care?	Yes	☐	No	☐
Do you agree that your records in this research and supporting medical records be made available for inspection by monitors from:				
Trinity College?	Yes	☐	No	☐
Regulatory authorities?	Yes	☐	No	☐
Do you agree to take part in this study?	Yes	☐	No	☐
Do you agree to your family doctor (GP) being informed of your participation in this study?	Yes	☐	No	☐

Subject's signature ..... Date .....

Subject's name in block capital letters .....

Telephone contact (Subject) .....(Home) ..... (Work)

Signature witnessed by ..... Date .....

Witness name in block capital letters .....

Appendix 23. IDUS – clinical examination findings form.

Instrumental Delivery and UltraSound

IDUS

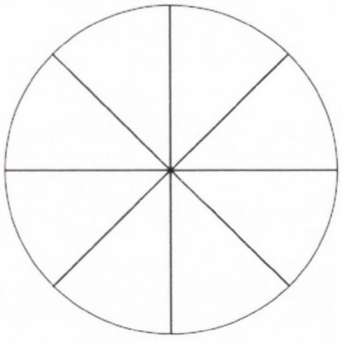
CLINICAL EXAMINATION FINDINGS

Study no.: _____ **Patient Initials:** _____

Hospital no.: _____ **Date of delivery:** _____

FETAL HEAD POSITION

Place X at point where you consider the occiput to be orientated:



Engagement on abdominal examination:

0/5 ☐ 1/5 ☐

Vaginal examination:

Station

Spines -1 ☐ spines-2 ☐
Spines+0 ☐ spines+1 ☐
Spines+2 ☐ spines+3 ☐

Caput

0 ☐ + ☐
++ ☐ +++ ☐

Moulding

0 ☐ + ☐
++ ☐ +++ ☐

Asynclitism Yes ☐ No ☐

Grade of operator: .....

Degree of certainty

1----------2----------3----------4----------5----------6----------7----------8----------9----------10

Very uncertain Completely certain

FETAL BACK POSITION

State where you consider the fetal back to lie:

Direct anterior ☐ Direct posterior ☐ Left lateral ☐ Right lateral ☐ Don't know ☐

Degree of certainty

1----------2----------3----------4----------5----------6----------7----------8----------9----------10

Very uncertain Completely certain

Appendix 24. IDUS – ultrasound form.

Instrumental Delivery and UltraSound

IDUS

US FORM

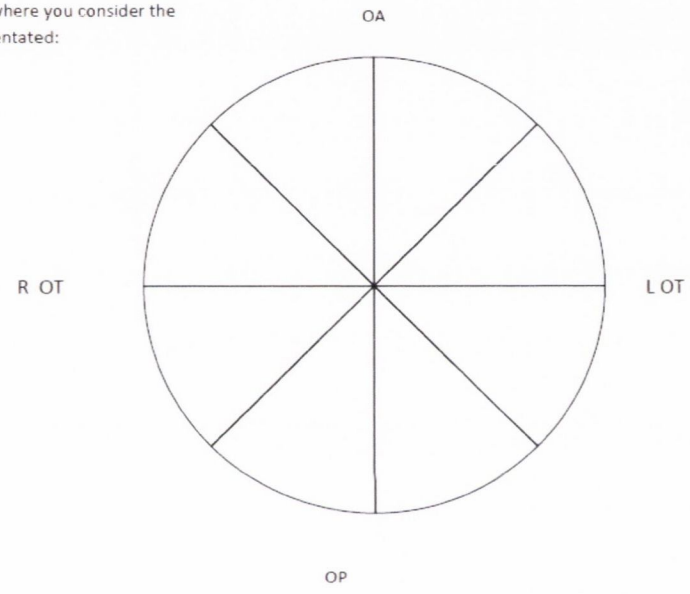
Study no.: _____ **Patient Initials:** _____

Hospital no.: _____ **Date of delivery:** _____

Start Time : ..... End Time : .....

FETAL HEAD POSITION

Place X at point where you consider the occiput to be orientated:



Diagnosis made by visualising:

- Nuchal region ☐
- Occiput ☐
- Transthalamic view ☐
- Midcrebral echo ☐
- Orbit ☐

Degree of certainty

1----------2----------3----------4----------5----------6----------7----------8----------9----------10

Very uncertain Completely certain

FETAL BACK POSITION

State where you consider the fetal back to lie:

Direct anterior ☐ Direct posterior ☐ Left lateral ☐ Right lateral ☐ Don't know ☐

Degree of certainty

1----------2----------3----------4----------5----------6----------7----------8----------9----------10

Very uncertain Completely certain

Quality of image Optimal ☐ Suboptimal ☐

Agreement between scan & initial findings ☐

Scan opinion accepted Yes ☐ No ☐

Appendix 25. IDUS – neonates form.

Instrumental Delivery and UltraSound

IDUS

NEONATOLOGIST / MIDWIFE TO COMPLETE

Please complete this form and indicate instrument markings on diagrams below.

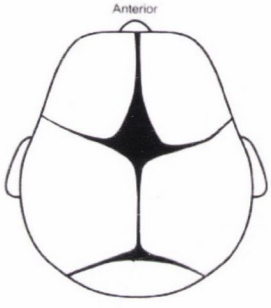
Study no.: _____ Patient Initials: _____

Hospital no.: _____ Date of delivery: _____

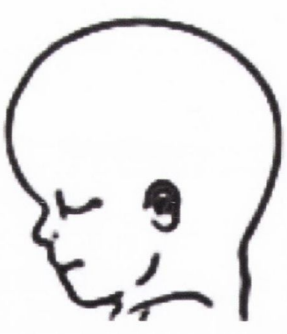
0. None ☐
1. Instrument marks ☐
2. Bruising ☐
3. Laceration ☐
4. Cephalhaematoma ☐
5. Retinal haemorrhage ☐
6. Facial nerve palsy ☐
7. Brachial plexus injury ☐
8. Fracture ☐
9. Other ☐

_____

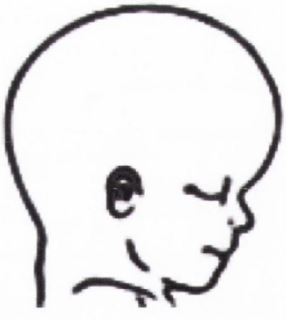
_____



Placement of instruments: Optimal ☐ Suboptimal ☐

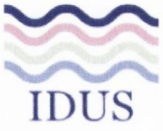






Appendix 26. IDUS – case report form.

Instrumental Delivery and Ultrasound



CASE REPORT FORM

Study no.: _____ **Patient Initials:** _____

Hospital no.: _____ **Date of delivery:** _____

DEMOGRAPHIC DATA

1. Mother's age ____
2. Mother's occupation _____
3. Mother's ethnic origin ☐
4. Mother's marital status ☐

MATERNAL FACTORS

5. Infertility ☐
6. Diabetes ☐
7. Cardiac disease ☐
8. Endocrine disease ☐
9. Hypertension at booking ☐
10. Renal disease ☐
11. Inflammatory bowel disease ☐
12. Cervical suture ☐
13. Smoking in pregnancy ☐
14. Alcohol in pregnancy ☐
15. Drug abuse in pregnancy ☐
16. PET ☐
17. Suspected IUGR ☐
18. Small for Gestational Age ☐
19. Other _____

PAST GYNAE HISTORY

20. Complications
    - Previous pelvic surgery ☐
    - Previous pelvic infection ☐
    - Previous abnormal smear ☐
    - Previous LLETZ ☐

PRE-DELIVERY DETAILS

21. Maternal weight at booking _____ kg
22. Maternal height _____ cm
23. BMI ____ kg/m^2

*Study No:*_____

DELIVERY DETAILS

First stage of labour

24. Gestation ___wks___days
25. Onset of labour ☐
26. If IOL, reason ☐
27. If IOL, PGE2 received ☐
28. Membrane rupture ☐
29. Duration of 1st stage of labour(hrs) _____
30. Monitoring ☐
31. CTG classification ☐
32. Oxytocin use ☐
33. FBS ☐
34. No. of FBS _____
35. Latest result:
    a. Ph _____
    b. Base excess _____
36. Colour of liquor ☐
37. Analgesia ☐

Second stage of labour

38. Oxytocin use ☐
39. Colour of liquor ☐
40. Monitoring ☐
41. CTG classification ☐
42. FBS in 2nd stage ☐
43. Latest FBS result pH_____BE_____
44. Maternal pyrexia ☐
45. Maternal tachycardia ☐
46. Anaesthesia ☐
47. Duration of 2nd stage (hrs):
    a. Total_____
    b. Active_____

Assisted Vaginal Delivery

48. Primary indication for delivery ☐
49. Secondary indication for delivery ☐
50. Planned place of delivery ☐
51. Grade of operator ☐
52. Grade of supervisor ☐
53. Engagement on abdominal exam. ☐
54. Vaginal examination
    a. Station ☐
    b. Position at outset ☐
    c. Caput ☐
    d. Moulding ☐
    e. Asynclitism ☐
55. Degree of certainty (head) ☐
56. Fetal Back position ☐
57. Degree of certainty (back) ☐
58. Primary instrument ☐
59. Secondary instrument ☐
60. Manual rotation ☐
61. No of pulls _____
62. No of contractions _____
63. No of operators _____
64. Operative vaginal delivery completed ☐
65. Mode of delivery ☐
66. Fetal Head Position at delivery ☐
67. Decision time _____
68. Delivery time _____
69. Decision – delivery interval (min) _____
70. Cord gases: Venous pH__BE__ arterial pH__ BE_

*Study No:*_____

Third stage of labour

71. Shoulder dystocia ☐
72. Episiotomy ☐
73. Extended episiotomy ☐
74. Perineal tear ☐
75. Oxytocin bolus ☐
76. Additional uterotonic ☐

If Yes, which agent (s) _____
77. Third stage ☐
78. Estimated blood loss (mls) _____
79. Duration of 3rd stage of labour (min) _____
80. Other _____

POST-DELIVERY COURSE

81. 1° Postpartum haemorrhage ☐
(bld loss >500mls within24hrs of delivery)
82. Post-delivery in-patient days ____
83. Complications
    a. UTI ☐
    b. Perineal infection ☐
    c. Retained products ☐
    d. Endometritis ☐
    e. Wound infection ☐
    f. Antibiotics ☐
    g. 2° Postpartum haemorrhage ☐
    h. Pyrexia unknown origin ☐
    i. Hospital re-admission ☐
    j. Other _____

BABY DETAILS

84. Birthweight (kg) _____
85. Sex ☐
86. Apgar score at 1 min _____
87. Apgar score at 5 min _____
88. Neonatal trauma ☐
89. Repeat pH ☐
90. Postnatal analgesia ☐
91. Cranial ultrasound ☐
92. MRI ☐
93. CFAM ☐
94. Admission to SCBU ☐
95. Reason for SCBU admission ☐
96. Duration of SCBU admission (days) _____
97. Head circumference _____cm
98. Discharge status ☐

Details, if abnormal:
_____
_____

RCT OUTOCOME

99. Fetal head position ☐

*Study No:*_____

USS FINDINGS

100. Fetal Head Position at outset ☐
101. Diagnosis made by visualizing:
   a. Nuchal region ☐
   b. Occiput ☐
   c. Transthalamic view ☐
   d. Midcerebral echo ☐
   e. Orbit/nasal bridge ☐
102. Degree of certainty (head): 0-10 ☐
103. Fetal Back position ☐
104. Degree of certainty (back):0-10 ☐
105. Time taken for ultrasound (seconds)_____
106. Quality of image ☐
107. Agreement between USS & initial findings ☐
108. USS opinion accepted ☐

*Study No:*_____

Appendix 27. IDUS – codes for case report form.

STANDARD CODES	0 NO 1 YES
Times in 24 hour clock	
Likert scale not completed	0



CODES AND DEFINITIONS FOR INSTRUMENTAL DELIVERY & ULTRASOUND RCT

DEMOGRAPHIC DATA

3. Mother's ethnic origin:
0. Irish (Caucasian)
1. Caucasian (non- Irish)
2. Caribbean black
3. African black
4. Indian
5. Pakistani
6. Bangladeshi
7. Chinese
8. Other

4. Mother's marital status: (supported if has partner)
0. Married
1. Single supported
2. Single unsupported
3. Single unknown
4. Unrecorded

MATERNAL FACTORS

5. Previous infertility
0. None
1. Donor semen/ Donor egg
2. Clomiphene
3. Pergonal
4. In-vitro fertilisation/ ICSI
5. Unrecorded
Record that which requires greatest intervention

6. Diabetes:
0. None
1. IDDM Type 1 or 2
2. Gestational Diabetes in any previous pregnancy
3. Unrecorded

7. Cardiac disease: present at the time of booking including corrected cardiac anomalies.

8. Endocrine disease: other than diabetes, present at the time of booking.

9. Hypertension at time of booking: BP >/= 140 or >/= 90 on two separate occasions.

10. Renal disease:
0. None
1. Recurrent UTIs
2. Structural abnormality
3. Renal disease
4. Unrecorded

1

11. Inflammatory bowel disease

0. None
1. Ulcerative colitis/Crohn's
2. Other
3. Unrecorded

13. Smoking in pregnancy:

0. None
1. 1 - 10/day
2. 11 - 20/day
3. > 20/day
4. Unrecorded

14. Alcohol in pregnancy:

0. None
1. Light = 1-5 units/week
1. Moderate = 6-20 units/week
2. Heavy = >20 units/week
3. Unrecorded

15. Drug abuse in pregnancy:

0. None
1. Non-IVDU
2. IVDU (intravenous drug use)
3. Unrecorded

20. Previous abnormal smear

0. No
1. Yes
2. Never performed

DELIVERY DETAILS

25. Onset of labour

0. Spontaneous
1. Induced
2. Unrecorded

26. Indication of IOL

0. Postdates
1. Maternal causes
2. Fetal causes
3. Prolonged rupture of membranes
4. Unrecorded
5. Not applicable

28. Membrane rupture

0. Spontaneous rupture of membrane
1. Artificial rupture of membrane (ARM)
2. Forewater ARM
3. ARM in labour
4. Unrecorded

30. Monitoring in labour

0. Intermittent auscultation
1. CTG

2

31, 41. CTG classification (EFM guidelines)
– state worst

0. Normal
1. Suspicious (1 feature in non-reassuring category, remainder normal)
2. Pathological (≥2 features non-reassuring or ≥1 abnormal)

Feature	Baseline (bpm)	Variability	Decelerations	Accelerations
Reassuring	110 – 160	≥ 5	None	Present
Non-reassuring	100 – 109 161- 180	<5 for <40min to <90min	- Persistent Early decels. - Variable decels. - Late deccels. - Single prolonged decel. up to 3min	*Absence of accels in otherwise normal CTG is of unknown significance*

36, 39. Colour of liquor

0. Clear
1. Blood stained
2. Meconium – state grade

37. Analgesia

0. Nil
1. Entonox
2. Opiates
3. Epidural
4. Spinal

46. Anaesthesia

0. Nil
1. Entonox
2. Epidural
3. Spinal
4. Pudendal block
5. Local anaesthetic
6. General anaesthesia

48. Primary Indication for delivery

0. Prolonged 2nd stage (>2hrs)
1. Fetal compromise
2. Other, please state

49. Secondary indication for delivery

0. None
1. Prolonged 2nd stage (>2hrs)
2. Fetal compromise
3. Other, please state

50. Planned place of delivery

0. Labour room
1. Theatre

51. Grade of operator

0. SHO
1. Junior Registrar
2. Registrar (year 1-3)
3. Senior registrar (year ≥ 4)
4. SpR 1-3
5. SpR 4-5
6. Consultant

3

52. Grade of supervisor	0. Nil 1. Junior Registrar 2. Registrar (year 1-3) 3. Senior registrar (year ≥ 4) 4. SpR 1-3 5. SpR 4-5 6. Consultant – present at onset 7. Consultant – present due to complication
53. Engagement on abdominal examination	0. 0/5 1. 1/5 2. > 1/5 3. Unrecorded
54 a. Vaginal examination - Station	0. Spines +0 1. Spines +1 2. Spines +2 3. Spines +2 4. Spines -1 5. Spines -2 6. Unrecorded
54 b, 66, 100. Fetal head position	0. Direct OA 1. R OA 2. L OA 3. R OT 4. L OT 5. Direct OP 6. R OP 7. L OP 8. Unrecorded
54 c. Caput	0. Nil 1. + 2. ++ 3. +++ 4. Unrecorded
54 d. Moulding	0. Nil 1. + 2. ++ 3. +++ 4. Unrecorded
56, 103. Fetal Back Position	0. Direct anterior 1. Direct posterior 2. Left lateral 3. Right lateral 4. Unknown 5. Unrecorded

4

58. Primary instrument	0. Kiwi vacuum 1. Silastic vacuum 2. Non – rotational forceps 3. Rotational forceps 4. No attempt at instrument 5. Metal cup – anterior 6. Metal cup – posterior 7. Forceps applied – not locking→ removed w/out pulling
59. Secondary instrument	0. None 1. Kiwi vacuum 2. Silastic vacuum 3. Non – rotational forceps 4. Rotational forceps 5. Metal cup – anterior 6. Metal cup - posterior
60. Manual rotation	0. Not attempted 1. Attempted
65. Mode of delivery	0. Spontaneous vaginal Delivery 1. Assisted vaginal delivery – 1 instrument 2. Assisted vaginal delivery – 2 instruments 3. Caesarean section after failed instrumental 4. Caesarean section immediately
74. Perineal tear	0. 1st degree 1. 2nd degree 2. 3rd degree – 3a 3. 3rd degree – 3b 4. 3rd degree – 3c 5. 4th degree 6. Intact
77. Third stage	0. CCT 1. MROP

BABY DETAILS

85.Sex:	0.Male 1.Female
88. Neonatal trauma	0. None 1. Instrument marks 2. Bruising 3. Laceration 4. Brachial plexus injury 5. Facial palsy 6. Retinal haemorrhage 7. Intracranial haemorrhage 8. Suspected fracture 9. Other
90, 91, 92. Imaging (USS/MRI/CFAM) results	0. None 1. Yes, normal 2. Yes, abnormal

5

94. Reason for SCBU admission	1. Tachypnoea/RDS 2. Hypoglycaemia 3. Other, state
98. Discharge status	0. Alive, well 1. Alive, uncertain status – for follow-up 2. Alive, abnormal neurologically – for follow-up 3. Alive, orthopaedic referral 4. Alive, physio referral 5. Intrapartum death 6. Neonatal death

RCT OUTCOME

99. Diagnosis of fetal head position	0. Correct 1. Incorrect 2. Uncertain

USS FINDINGS

106. Quality of image	0. Optimal 1. Suboptimal
107/ 108	0. NO, 1. Yes, 2. Unrecorded

6

Appendix 28. BMC Pregnancy & Childcare. IDUS protocol.

Murphy et al. BMC Pregnancy and Childbirth 2012, 12:95
http://www.biomedcentral.com/1471-2393/12/95

BMC
Pregnancy & Childbirth

STUDY PROTOCOL Open Access

Study Protocol. IDUS – Instrumental delivery & ultrasound. A multi-centre randomised controlled trial of ultrasound assessment of the fetal head position versus standard care as an approach to prevent morbidity at instrumental delivery

Deirdre J Murphy[1], Gerard Burke[2], Alan A Montgomery[3], Meenakshi Ramphul[1,4*] and The IDUS StudyGroup

Abstract

Background: Instrumental deliveries are commonly performed in the United Kingdom and Ireland, with rates of 12 – 17% in most centres. Knowing the exact position of the fetal head is a pre-requisite for safe instrumental delivery. Traditionally, diagnosis of the fetal head position is made on transvaginal digital examination by delineating the suture lines of the fetal skull and the fontanelles. However, the accuracy of transvaginal digital examination can be unreliable and varies between 20% and 75%. Failure to identify the correct fetal head position increases the likelihood of failed instrumental delivery with the additional morbidity of sequential use of instruments or second stage caesarean section. The use of ultrasound in determining the position of the fetal head has been explored but is not part of routine clinical practice.

Methods/Design: A multi-centre randomised controlled trial is proposed. The study will take place in two large maternity units in Ireland with a combined annual birth rate of 13,500 deliveries. It will involve 450 nulliparous women undergoing instrumental delivery after 37 weeks gestation. The main outcome measure will be incorrect diagnosis of the fetal head position. A study involving 450 women will have 80% power to detect a 10% difference in the incidence of inaccurate diagnosis of the fetal head position with two-sided 5% alpha.

Discussion: It is both important and timely to evaluate the use of ultrasound to diagnose the fetal head position prior to instrumental delivery before routine use can be advocated. The overall aim is to reduce the incidence of incorrect diagnosis of the fetal head position prior to instrumental delivery and improve the safety of instrumental deliveries.

Trial registration: Current Controlled Trials ISRCTN72230496

Keywords: Fetal head position, Second stage of labour, Intrapartum ultrasound, Randomised controlled trial

* Correspondence: ramphulm@tcd.ie
[1]Academic Department of Obstetrics & Gynaecology, Trinity College Dublin & Coombe Women & Infant's University Hospital, Dublin 8, Ireland
[4]Coombe Women & Infants University Hospital, Dublin 8, Ireland
Full list of author information is available at the end of the article

BioMed Central

© 2012 Murphy et al.; licensee BioMed Central Ltd. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/2.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Background

Instrumental deliveries are commonly performed in the United Kingdom and Ireland, with rates of 12 – 17% in most centres [1,2]. Knowing the exact fetal head position is a pre-requisite for safe instrumental delivery. Traditionally, diagnosis of the fetal head position is made on transvaginal digital examination by delineating the suture lines of the fetal skull and the fontanelles [3]. However, accurate diagnosis of the fetal head position by transvaginal digital examination can be unreliable [4].

Malpositions in labour in a vertex-presenting fetus are known to be associated with increased prolonged first and second stages of labour, oxytocin augmentation, use of epidural analgesia, chorioamnionitis, assisted vaginal delivery, third and fourth degree perineal lacerations, caesarean delivery, excessive blood loss, and postpartum infection [5-9]. Trial of instrumental delivery in theatre is twice as likely to fail in occipito-posterior (OP) positions and failed trials are associated with increased neonatal and maternal morbidity and trauma [8,10,11].

We propose a randomised controlled trial to evaluate the use of ultrasound to diagnose the fetal head position prior to attempting instrumental delivery.

The hypothesis is that an abdominal ultrasound scan performed in addition to routine clinical assessment reduces the incidence of incorrect diagnosis of the fetal head position which will reduce the risk of maternal and perinatal morbidity.

Literature review

A search of Medline from 1965 to 2011 and of the Cochrane Library was undertaken, for relevant systematic reviews, meta-analyses, randomised controlled trials, and other clinical studies. The date of the last search was June 2011. We intend to update this before publishing the results of the trial but at the time of finalising the trial protocol, there were no key changes since the search in June 2011. The main keywords used were: instrumental delivery, vacuum, forceps, fetal position, ultrasound, digital examination, randomised controlled trial. In addition, when reviewing published reference lists, key articles cited were also retrieved and reviewed.

The literature relating to the accuracy of digital vaginal examination versus ultrasound as the gold standard is presented in Table 1. Accuracy varied from 20% to 75% [4,12-19]. The authors of a prospective study of a hundred women which set out to evaluate the learning curves of digital examination and transabdominal ultrasound to determine the fetal head position in labour, reported that it was easier to become skilled in ultrasonography than digital examination [19]. Few studies have addressed error rates in ultrasound determined fetal head position among novice ultrasonographers and only two studies have reported error rates of transabdominal scan within a research setting (6.8% and 7.9% respectively) with another study reporting inability to diagnose the fetal head position in 15% [16,17,19]. We found only two studies evaluating the role of ultrasound assessment to determine the fetal head position before instrumental deliveries [20,21]. Akmal *et al.* compared the accuracy of vaginal examination to transabdominal ultrasound examination in 64 women undergoing instrumental delivery and found that vaginal examination was incorrect in 27% cases with errors being more likely with occipito-posterior positions and if the head was at the level of the ischial spines [20]. Wong *et al.* carried out a randomized trial of fifty women undergoing vacuum extraction for prolonged second stage where women were randomly allocated to either digital examination (n = 25) or digital examination together with transabdominal intrapartum ultrasound (n = 25) prior to vacuum extraction by the attending obstetrician [21]. A midwife measured the distance between the centre of the chignon and the flexion point immediately after delivery. The mean distance between the centre of the chignon and the flexion point was 2.1+/−1.3 cm in the group with digital examination and ultrasound assessment and 2.8+/−1.0 cm in the group with digital examination alone, a small but statistically significant difference [21].

National survey of current practice

We carried out a questionnaire survey in consultant-led maternity units in the United Kingdom and Ireland to establish the current practice of obstetricians with regards to the assessment of women in labour prior to instrumental delivery [22]. Clinical assessment prior to instrumental delivery, factors associated with difficulty in determining the fetal head position, approaches used to enhance determination of the fetal head position, perceived accuracy rates in assessment of the fetal head position and willingness to participate in a clinical trial of ultrasound assessment of the fetal head position prior to instrumental delivery were explored. There were conflicting opinions on the role of abdominal ultrasound in enhancing determination of the fetal head position prior to instrumental delivery, indicating the need for evaluation within a randomised controlled trial [22]. More than half the obstetricians agreed that there was a need for a trial and would participate in such a trial.

Validation study

Prior to starting this study, it was important to compare the accuracy of diagnosis of the fetal head position in the second stage of labour by ultrasound scan performed by a novice sonographer and by clinical assessment, to that of an expert sonographer (gold standard); and to evaluate the acceptability of ultrasound in the second stage of labour to women and clinicians [23]. We

Table 1 Studies evaluating accuracy of transvaginal digital examination compared to ultrasound in diagnosing the position of the fetal head in labour

Author, citation	Study design	Exposures	Outcome measures	Results	Conclusions
Akmal S et al. J Matern-Fetal Neo M 2002; 12(3): 172-7	Prospective study 496 women in labour (1st & 2nd stages)	DVE vs TAS (gold standard)	Agreement of DVE within ±45° of TAS correct	DVE in agreement with TAS in 163 cases (49.9%)	Digital examination inaccurate in 50% of cases
Souka AP et al. J Matern-Fetal Neo M 2003; 139(1): 59- 63	Prospective study 148 women in labour (1st & 2nd stages)	DVE vs TAS (gold standard)	Agreement of DVE within ±45° of TAS correct	Accuracy of DVE 31.3% in 1st stage & 65.7% in 2nd stage, more likely to be inaccurate in OP position	Digital examination is less accurate than ultrasound, especially in OP position.
Sherer DM et al. Ultrasound Obst Gyn 2002; 19(3): 258-63	Prospective study 102 women in labour (1st stage)	DVE vs TAS (gold standard)		DVE accurate in 24 cases (24%)	High error rate (76%) with digital examination
Sherer DM et al. Ultrasound Obst Gyn 2002; 19(3): 264- 8	Prospective study 112 women in labour (2nd stage)	DVE vs TAS (gold standard)	Absolute error when DVE not consistent with TAS; and inconsistency of >45°	Absolute error of DVE 65% DVE incorrect by >45° in 44 cases (39%)	Ultrasound improves accuracy
Dupuis O et al. Eur J Obstet Gynecol Reprod Biol 2005; 123(2): 193-7	Prospective study 110 women in labour (2nd stage)	DVE vs TAS (gold standard)	Agreement of DVE within ±45° of TAS correct	In 20% of the cases, DVE differed significantly (>45°) from TAS, higher in OP & OT positions	Transabdominal ultrasound can increase accuracy
Kreiser D et al. J Matern-Fetal Neo M 2001; 10(40): 283-6	Prospective study 44 women in labour (2nd stage)	DVE vs TAS (gold standard)	DVE & TAS findings compared to actual fetal head position at delivery and restitution of the fetal head – if different, considered to be wrong and quantified as =90°, <90° or >90°	TAS less error than DVE: 6.8% vs 29.6%, $p = 0.011$	TAS is more accurate
Zahalka N et al. AJOG 2005; 193(2): 381-6	Prospective study 60 women in labour (2nd stage)	DVE vs TAS vs TVS	Agreement of DVE within 60° of TAS correct	Discrepancy between DVE & TAS 21.7% Discrepancy between DVE & TVS 23.3% 5 cases where DVE erroneously diagnosed position as being OA when it was OP	TAS and TVS more accurate than transvaginal digital examination
Chou R et al. AJOG 2004; 191: 521- 4	Prospective study 88 women in labour (2nd stage)	DVE vs TAS	DVE & TAS findings compared to actual fetal head position at delivery (direct visualisation of position at vaginal delivery after spontaneous restitution of the head or at caesarean section). Considered correct if DVE/TAS within 45° of actual position.	Accuracy of DVE 71.6% vs 92% accuracy for TAS, p = 0.018	TAS more accurate than DVE
Rozenberg P et al. Ultrasound Obst Gyn 2008; 31(3):332 - 7	Prospective study One novice doing both TAS and VE 100 women (≥ 7 cm dilated)	DVE vs TAS	Learning curve of a novice at diagnosis of the fetal head position by DVE & TAS compared to an expert	Error rate of DVE 50% over first 50cases, down to 28% over last cases vs 8% error with TAS	Learning and accuracy of diagnosis of the fetal head position easier & higher with TAS
Akmal S et al. Ultrasound Obst Gyn 2003; 21(5):437-40	Prospective study 64 women undergoing instrumental delivery	DVE vs TAS	Agreement of DVE within ±45° of TAS correct	Error rate of DVE 26.6% (17 cases), igher for OP and OT	DVE inaccurate in a quarter of cases before instrumental delivery

Table 1 Studies evaluating accuracy of transvaginal digital examination compared to ultrasound in diagnosing the position of the fetal head in labour *(Continued)*

Wong GY et al.	-	RCT 40 women undergoing vacuum extraction	DVE vs TAS	Accuracy of vacuum cup placement with respect to the flexion point	Mean distance between chignon & flexion point: 2.1 ± 1.3 cm in DVE + TAS group vs 2.8 cm ± 1.0 cm in VE group (p = 0.039)	TAS improves vacuum cup placement

DVE: Digital vaginal examination.
TAS: Transabdominal ultrasound.
TVS: Transvaginal ultrasound.
OA: occipito-anterior, OP: occipito-posterior, OT: occipito-transverse.

recruited sixty women who had: (i) an abdominal scan performed by a novice; (ii) an abdominal scan performed by an expert ultrasonographer; and (iii) a clinical assessment performed by an obstetrician or midwife; in the passive second stage of labour. Each assessor was blinded to the findings of the others. The ultrasound findings of the novice and expert ultrasonographer were consistent in 52 (87%) cases for the fetal head position and the novice made no occipito-anterior/occipito-posterior (OA-OP) errors. The clinical diagnosis of the fetal head position was incorrect in 25 (42%) cases with 8 (13%) OA-OP errors [23]. We used these findings as an estimate of the primary outcome for the power calculation. Women and clinicians did not consider the ultrasound assessment to be intrusive. In summary, we found that an abdominal scan by a novice ultrasonographer is an accurate and acceptable method of diagnosing the fetal head position in the second stage of labour [23].

Aims and objectives

The aim of this study is to compare routine clinical assessment of the fetal head position alone versus clinical and ultrasound assessment of the fetal head position prior to instrumental delivery.

The primary outcome is to compare the incidence of incorrect diagnosis of the fetal head position

The secondary outcomes are:

- to compare the incidence of neonatal trauma, low Apgar scores, fetal acidosis or admission to the neonatal unit
- to compare the incidence of primary postpartum haemorrhage, third and fourth degree perineal tears or prolonged postnatal admission
- to compare the incidence of sequential use of instruments, instrumental delivery with more than one operator, failed instrumental delivery, transfer to theatre or caesarean section
- to compare the decision-delivery intervals

Methods

Recruitment and intervention

Recruitment of women to the study will follow a three stage process.

(1) All potentially eligible women will be given written information about the study in the antenatal clinic. A leaflet and covering letter will explain the trial purpose and design, making it clear that women will only become eligible for the study if they require an instrumental delivery. The leaflet will contain contact details to allow women to discuss the study further if they wish.

(2) Once a woman has presented in early labour or for induction of labour, a research fellow will seek written informed consent if the following criteria are satisfied:

i) the midwife looking after the woman assesses her to be capable of providing informed consent.
ii) the woman has adequate pain control.
iii) the woman has not used systemic opiates in the last four hours.

(3) Once consent has been given the mother will not be consulted again unless she requires an instrumental delivery. After confirmation that all criteria are met, the research midwife/fellow will obtain the allocation.

Inclusion criteria

This study will be limited to nulliparous women at term (≥37 weeks' gestation) with singleton cephalic pregnancies, aiming to deliver vaginally who require an instrumental delivery in the second stage of labour.

Exclusion criteria

Women with a contraindication to instrumental delivery, or who have a limited understanding of English or are under 18 years of age. Eligibility will also be at the discretion of the responsible obstetrician in cases where there is urgency due to suspected fetal compromise ("fetal distress").

Allocation to trial groups

Allocation of eligible women who consent to participate in the trial will be concealed using a fully automated centralised web-based system provided by the Bristol Randomised Trials Collaboration. The randomisation sequence will be created by using block sizes of 4, 8 and 12 and stratified by centre, in a 1:1 ratio for usual care versus intervention.

Intervention

Usual care arm

Women allocated to receive usual care will be managed according to Royal College of Obstetricians and Gynaecologists (RCOG) guidelines and the local hospital protocol [3]. The women will be assessed by abdominal and digital vaginal examination prior to instrumental delivery. Following clinical assessment, location of the fetal occiput in relation to pelvic landmarks will be indicated visually by way of a cross on a data sheet depicting a circle, like a clock, divided into 24 sections, each of 15 degrees (Figure 1). The position will then be classified as OA for direct occipito-anterior, ROA and LOA for right and left occipito-anterior respectively; OP for direct

Instrumental Delivery and UltraSound

IDUS

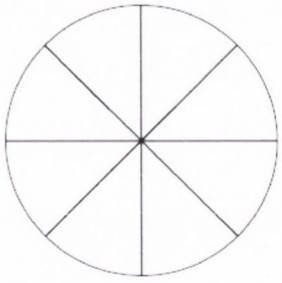
CLINICAL EXAMINATION FINDINGS

Study no.: _____ Patient Initials: _____

Hospital no.: _____ Date of delivery: _____

FETAL HEAD POSITION

Place X at point where you consider the occiput to be orientated:



Engagement on abdominal examination:

0/5 ☐ 1/5 ☐

Vaginal examination:

Station

Spines-1 ☐ spines-2 ☐
Spines+0 ☐ spines+1 ☐
Spines+2 ☐ spines+3 ☐

Caput

0 ☐ + ☐
++ ☐ +++ ☐

Moulding

0 ☐ + ☐
++ ☐ +++ ☐

Asynclitism Yes ☐ No ☐

Grade of operator: .....

Degree of certainty

1----------2----------3----------4----------5----------6----------7----------8----------9----------10

Very uncertain — Completely certain

FETAL BACK POSITION

State where you consider the fetal back to lie:

Direct anterior ☐ Direct posterior ☐ Left lateral ☐ Right lateral ☐ Don't know ☐

Degree of certainty

1----------2----------3----------4----------5----------6----------7----------8----------9----------10

Very uncertain — Completely certain

Figure 1 Data sheet: digital vaginal examination findings.

occipito-posterior, ROP and LOP for right and left occipito-posterior; ROT and LOT for right and left occipito- transverse respectively. The obstetrician may then proceed to instrumental delivery. The full clinical assessment, delivery procedure, delivery outcome and measures of early morbidity will be recorded on a standard instrumental delivery proforma. The mother and the neonate will be followed-up until hospital discharge.

Intervention arm

Women in the intervention group will be managed in the same way. In addition they will receive an ultrasound scan to assess the position of the fetal head and spine. Immediately before or after the clinical examination and before application of the instrument, the fetal head position will be determined sonographically by a trained research fellow. The research fellow will be trained before the start of the trial by a consultant sub-specialist in fetal and maternal medicine and perform a minimum of thirty five ultrasound assessments in the second stage of labour as described in the validation study [23]. For all ultrasound assessments, image- directed pulsed Doppler equipment (Sonosite Titan) with a multifrequency sector array transabdominal transducer, and a 3.5 MHz sector ultrasound probe, will be used.

With the patient in a supine position the ultrasound transducer will first be placed transversely over the maternal abdomen and moved longitudinally to identify landmarks for the fetal spine and head position as described in the validation study [23]. The transabdominal probe is then rotated through 90 degrees, to obtain the transverse view of the fetal spine. Following this, a sliding motion towards the fetal head will be made to obtain a view of the following midline fetal cranial structures: midline cerebral echo, falx cerebri and thalamus and anterior or posterior cranial structures including the orbits and nuchal region. The fetal head position will then be classified as previously described. The obstetrician will be informed of the ultrasound findings to facilitate decision making and may then proceed to instrumental delivery.

Outcome measures

Primary outcome

The primary outcome measure is incorrect diagnosis of the fetal head position. Most errors of clinical diagnosis are where the position is classified as occipito-anterior but is in fact occipito-transverse or occipito-posterior. Incorrect diagnosis of the fetal head position will be established according to any of the following criteria:

i) Position of the head at the time of delivery

If the position of the fetal head was classified as occipito-anterior and is delivered occipito-posterior the diagnosis of the fetal position will be considered incorrect.

ii) Instrument markings on the neonatal head and face

The neonatologist or midwife who attends the delivery will examine the baby. He/she will be asked to record the markings of the instrument on a drawing of the head and lateral aspects of the face (Figure 2). The recorded markings will be used to indicate misplacement of the instrument at a distance from the flexion point (vacuum) or over the face (forceps). If for example the recorded position prior to instrumental delivery was occipito-anterior and the instrument placement suggests an occipito-transverse or occipito-posterior position the diagnosis of the fetal position will be considered incorrect. Furthermore, the diagnosis will be considered incorrect if the markings are more than 45^0 from the documented fetal head position.

iii) Position at caesarean section

If the delivery is completed by caesarean section the operator will record the position of the head at delivery. If the position of the fetal head was defined as occipito-anterior but is in an occipito-posterior position at caesarean section the diagnosis of the fetal position will be considered incorrect. This information will be cross-referenced with the instrument markings recorded by the neonatologist in cases where there was an initial attempt at instrumental delivery.

The primary outcome will be validated independently by a single investigator who is not involved in scanning or the delivery by reviewing the trial documents (fetal head position recorded by the obstetrician, diagrammatic records of instruments markings on the neonate and documented position of the head position at delivery as described above). Trial allocation will be concealed from this person. Two additional data items will be recorded; i) where the position has been correctly identified the application of the instrument will be classified as optimal or sub-optimal based on the instrument markings and ii) where there is discordance between the findings of the clinician and ultrasonographer the researcher will record whether the ultrasound finding was accepted or not.

Secondary outcomes

Secondary neonatal outcomes will include trauma, low Apgar scores, low arterial blood gases and admission to the neonatal intensive care unit (NICU). Neonatal trauma will include bruising, laceration, cephalhaematoma, retinal

Instrumental Delivery and Ultra Sound

IDUS

NEONATOLOGIST / MIDWIFE TO COMPLETE

Please complete this form and indicate instrument markings on diagrams below.

Study no.: _____ Patient Initials: _____

Hospital no.: _____ Date of delivery: _____

0. None ☐
1. Instrument marks ☐
2. Bruising ☐
3. Laceration ☐
4. Cephalhaematoma ☐
5. Retinal haemorrhage ☐
6. Facial nerve palsy ☐
7. Brachial plexus injury ☐
8. Fracture ☐
9. Other ☐

_____

_____



Placement of instruments: Optimal ☐ Suboptimal ☐



Figure 2 Data sheet: instrument markings on neonatal head and face.

haemorrhage, facial nerve palsy, brachial plexus injury and fractures. Paired cord blood gases will be taken routinely to measure arterial and venous pH and base excess. Arterial pH below 7.10 and base excess greater than −12.0 mmol/l will be used as the threshold to define significant fetal acidosis.

Secondary maternal outcomes will include extensive perineal tearing involving the anal sphincter (third or fourth degree tears), postpartum haemorrhage, shoulder dystocia, and length of postnatal hospital stay. Primary post partum haemorrhage is defined as an estimated blood loss at delivery and in the first 24 hours of more than 500mls. Postnatal stay will be considered prolonged if more than 3 days' duration. Maternal and neonatal complications will be defined clinically according to the attending clinicians.

Procedural issues will be recorded in terms of place of delivery, need for senior obstetric support, transfer to theatre, use of sequential instruments, failure of instrumental delivery or proceeding directly to caesarean section and the decision to delivery interval.

Follow-up

Clinical follow-up of the mother and neonate will be completed prior to hospital discharge.

Trial end

The trial will be considered complete after the final review of the last subject participating in the trial. Trial completion will be notified to the Competent Authority and the Ethics Committee using the appropriate form.

Statistical analysis

Data analysis and reporting will proceed according to CONSORT guidelines for randomised controlled trials, and will be conducted blinded to group status by the trial statistician and researcher. The first stage of analysis will be to use descriptive statistics to describe recruited individuals in relation to those eligible, and to investigate comparability of the trial arms at baseline. The primary analysis will involve an intention-to-treat comparison between the two groups for the primary outcome adjusted for stratification/minimisation factors – this will include study centre. Secondary outcomes will be analysed in a similar way. All analyses will use appropriate (that is, logistic or linear) regression models, with results presented as point estimates (odds ratios or difference in means), 95% confidence intervals and p values. Further secondary analyses will involve planned subgroup analyses and will use multivariable regression models with appropriate interaction terms to ascertain any differential effects in relation to, choice of instrument and operator experience.

Feasibility

We have completed a prospective cohort study and multi-centre randomised controlled trial comparing restrictive versus routine use of episiotomy at instrumental delivery [24,25]. Interventional studies in the second stage of labour require great sensitivity in terms of appropriate recruitment, randomisation and follow-up. A large number of women need to be approached in the antenatal period of whom only a small proportion will ultimately be invited to participate in the trial. The number of women who are eligible but not recruited needs to be recorded. Obstetricians and midwives are under pressure when planning instrumental delivery in the second stage of labour which needs to be taken in to consideration when designing a second stage clinical trial. Our research team has extensive experience of performing studies in this context and the proposed study design and sample size reflects an accurate estimate of what is feasible within the proposed time frame and available resources.

Sample size

The rate of inaccurate diagnosis (difference of more than 45 degrees) was hypothesized to be 20% in the usual care arm (clinical assessment alone) and 10% in the intervention arm (clinical assessment and ultrasound). With 225 women per arm, the study will have 80% power with 5% two-sided alpha, to detect the hypothesized 10% difference. However, it is possible that inaccuracy rates are being under- or over- estimated. It could be argued that any difference in effect on the primary clinical outcome would be worth detecting. Rather, given the need for timely delivery of evidence, we have specified detectable differences for realistic sample sizes recruited within a reasonable time frame within the constraints of the available funding.

The combined annual birth rate for the two recruiting hospitals is 13,500, and around 40% of women will be nulliparous, of whom 30% will have an instrumental delivery. We estimate that there will be a total of 3240 instrumental deliveries among nulliparous women over the 24 month recruitment period based on hospital statistics for 2007. Allowing for 30-50% exclusion and non-consent, 95% collection of the primary outcome, and recruiting for 24 months during office hours yields a conservative estimate of 450 participants (225 per arm) for analysis. This would enable detection of a between-group difference of 10–13 percentage points (odds ratio 0.44 to 0.55) with 80% power and 5% two-sided alpha, and would certainly be considered by women and clinicians as worthwhile. These conservative recruitment estimates take account of eligibility criteria, non-english speaking women and the potential difficulty of

Competing interests

All authors and their relations have no financial connections with companies that may have an interest in the submitted work, and no non-financial interests that may be relevant to the article.

Authors' contribution

Prof D.J. Murphy and Dr G. Burke had the original idea for the trial. Prof D.J. Murphy, Dr A. Montgomery and Dr M. Ramphul designed the trial. Prof D.J. Murphy and Dr M. Ramphul drafted the paper which was revised by all authors. Prof DJ Murphy is the guarantor. All authors read and approved the final manuscript.

Details of ethics approval

We received ethical approval from the Ethics Research Committee in the Coombe Women & Infants University Hospital on the 5th October 2010 and from the Ethics Research Committee in the Mid-Western Regional Maternity Hospital, Limerick on the 9th August 2011. Women will provide written consent.

Funding

The trial is being funded by the Health Research Board of Ireland (grant reference number POR/2010/55). The funding source had no role in the trial design, writing of the report, or the decision to submit the paper for publication.

Acknowledgements

We thank the Coombe Women & Infants University Hospital and the Midwestern Regional Hospital, Limerick and the research staff involved. We thank the additional members of the IDUS group: Dr G. Burke (obstetrician), Dr A. Montgomery (epidemiologist/statistician), Dr S. Sheehan (obstetrician), Dr M. Macleod (research midwife), Dr P.V Ooi (research fellow).

Author details

[1]Academic Department of Obstetrics & Gynaecology, Trinity College Dublin & Coombe Women & Infant's University Hospital, Dublin 8, Ireland. [2]Mid-Western Regional Maternity Hospital, Ennis Road, Limerick, Ireland. [3]Primary Care Research, Department of Community Based Medicine, University of Bristol, 25 Belgrave Road, Bristol BS8 2AA, UK. [4]Coombe Women & Infants University Hospital, Dublin 8, Ireland.

Received: 24 August 2012 Accepted: 7 September 2012
Published: 13 September 2012

References

1. *BirthChoiceUK [Internet]*. United Kingdom;; 2010. Available from: http://www.birthchoiceuk.com/Professionals/Frame.htm.
2. *Consumer guide to maternity services in Ireland [Internet]*. Ireland;; 2010. Available from: http://www.bump2babe.ie/column/N/statistics/.
3. Bahl R, Strachan B, Murphy DJ: *Royal College of Obstetricians and Gynaecologists. Operative vaginal delivery. Greentop guideline No. 26*. 2011.
4. Akmal S, Tsoi E, Kametas N, Howard R, Nicolaides KH: **Intrapartum sonography to determine fetal head position.** *J Matern Fetal Neonatal Med* 2002, **12**(3):172–177.
5. Ponkey SE, Cohen AP, Heffner LJ, Lieberman E: **Persistent fetal occiput posterior position: Obstetric outcomes.** *Obstet Gynecol* 2003, **101**(5):915–920.
6. To WW, Li IC: **Occipital posterior and occipital transverse positions: reappraisal of the obstetric risks.** *Aust N Z J Obstet Gynaecol* 2000, **40**(3):275–279. Aug.
7. Cheng YW, Shaffer BL, Caughey AB: **Associated factors and outcomes of persistent occiput posterior position: A retrospective cohort study from 1976 to 2001.** *J Matern Fetal Neonatal Med* 2006, **19**(9):563–568. Sep.
8. Murphy DJ, Liebling R, Patel R, Verity L, Swingler R: **Cohort study of operative delivery in the second stage of labour and standard of obstetric care.** *Br J Obstet Gynaecol* 2003, **110**:610–615.
9. Majoko F, Gardener G: **Trial of instrumental delivery in theatre versus immediate caesarean section for anticipated difficult assisted births.** *Cochrane Database Syst Rev* 2008, **8**(4):CD005545.
10. Ebulue V, Vadalkar J, Cely S, Dopwell F, Yoong W: **Fear of failure: are we doing too many trials of instrumental delivery in theatre?** *Acta Obstet Gynecol Scand* 2008, **87**(11):1234–1238.
11. Ben-Haroush A, Melamed N, Kaplan B, Yogev Y: **Predictors of failed operative vaginal delivery: a single-center experience.** *Am J Obstet Gynecol* 2007, **197**(3):308. e1-5.
12. Souka AP, Haritos T, Basaylannis K, Nolikokyri N, Antsaklis A: **Intrapartum ultrasound for the examination of the fetal head position in normal and obstructed labor.** *J Matern Fetal Neonatal Med* 2003, **13**(1):59–63.
13. Sherer DM, Miodovnik M, Bradley KS, Langer O: **Intrapartum fetal head position I: Comparison between transvaginal digital examination and transabdominal ultrasound assessment during the active stage of labor.** *Ultrasound Obstet Gynecol* 2002, **19**(3):258–263.
14. Sherer DM, Miodovnik M, Bradley KS, Langer O: **Intrapartum fetal head position II: Comparison between transvaginal digital examination and transabdominal ultrasound assessment during the second stage of labor.** *Ultrasound Obstet Gynecol* 2002, **19**(3):264–268.
15. Dupuis O, Ruimark S, Corinne D, Simone T, Andre D, Rene-Charles R: **Fetal head position during the second stage of labor: Comparison of digital vaginal examination and transabdominal ultrasonographic examination.** *Eur J Obstet Gynecol Reprod Biol* 2005, **123**(2):193–197.
16. Kreiser D, Schiff E, Lipitz S, Kayam A, Avraham A, Achiron R: **Determination of fetal occiput position by ultrasound during the second stage of labor.** *J Matern Fetal Neonatal Med* 2001, **10**(4):283–286.
17. Zahalka N, Sadan O, Malinger G, Liberati M, Boaz M, Glezerman M, *et al*: **Comparison of transvaginal sonography with digital examination and transabdominal sonography for the determination of fetal head position in the second stage of labor.** *Am J Obstet Gynecol* 2005, **193**(2):381–386.
18. Chou R, Kreiser D, Taslimi M, Druzin M, El-Sayed Y: **Vaginal versus ultrasound examination of fetal occiput position during the second stage of labor.** *Am J Obstet Gynecol* 2004, **191**:521–524.
19. Rozenberg P, Porcher R, Salomon LJ, Boirot F, Morin C, Ville Y: **Comparison of the learning curves of digital examination and transabdominal sonography for the determination of fetal head position during labor.** *Ultrasound Obstet Gynecol* 2008, **31**(3):332–337.
20. Akmal S, Kametas N, Tsoi E, Hargreaves C, Nicolaides KH: **Comparison of transvaginal digital examination with intrapartum sonography to determine fetal head position before instrumental delivery.** *Ultrasound Obstet Gynecol* 2003, **21**(5):437–440.
21. Wong GY, Mok YM, Wong SF: **Transabdominal ultrasound assessment of the fetal head and the accuracy of vacuum cup application.** *Int J Gynecol Obstet* 2007, **98**(2):120–123.
22. Ramphul M, O'Brien Y, Murphy DJ: **Strategies to enhance assessment of the fetal head position prior to instrumental delivery – a survey of obstetric practice in the United Kingdom and Ireland.** *Eur J Obstet Gynecol Reprod Biol* 2012, Epub ahead of print.
23. Ramphul M, Kennelly M, Murphy DJ: **Establishing the accuracy and acceptability of abdominal ultrasound to define the fetal head position in the second stage of labour – a validation study.** *Eur J Obstet Gynecol Reprod Biol* 2012, **164**(1):35–39. Epub 2012 Jul 2.
24. Macleod M, Strachan B, Bahl R, Howarth L, Goyder K, Van de Venne M, *et al*: **A prospective cohort study of maternal and neonatal morbidity in relation to use of episiotomy at operative vaginal delivery.** *Br J Obstet Gynaecol* 2008, **115**(13):1688–1694.
25. Murphy DJ, Macleod M, Bahl R, Goyder K, Howarth L, Strachan B: **A randomised controlled trial of routine versus restrictive use of episiotomy at operative vaginal delivery – a multi-centre pilot study.** *Br J Obstet Gynaecol* 2008, **115**:1695–1702.

doi:10.1186/1471-2393-12-95
Cite this article as: Murphy *et al.*: Study Protocol. IDUS – Instrumental delivery & ultrasound. A multi-centre randomised controlled trial of ultrasound assessment of the fetal head position versus standard care as an approach to prevent morbidity at instrumental delivery. *BMC Pregnancy and Childbirth* 2012, **12**:95.