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Common data items in seven European oesophagogastric cancer surgery registries: Towards a European Upper GI Cancer Audit (EURECCA Upper GI)

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Abstract

Aims: Seven countries (Denmark, France, Ireland, the Netherlands, Poland, Sweden, United Kingdom) collaborated to initiate a EURECCA (European Registration of Cancer Care) Upper GI project. The aim of this study was to identify a core dataset of shared items in the different data registries which can be used for future collaboration between countries.

Methods: Itemlists from all participating Upper GI cancer registries were collected. Items were scored 'present' when included in the registry, or when the items could be deducted from other items in the registry. The definition of a common item was that it was present in at least six of the seven participating countries.

Results: The number of registered items varied between 40 (Poland) and 650 (Ireland). Among the 46 shared items were data on patient characteristics, staging and diagnostics, neo-adjuvant treatment, surgery, postoperative course, pathology, and adjuvant treatment. Information on non-surgical treatment was available in only 4 registries.

Conclusions: A list of 46 shared items from seven participating Upper GI cancer registries was created, providing a basis for future quality assurance and research in Upper GI cancer treatment on a European level.
Introduction

At current times, society, stakeholders and caregivers focus more and more on effectiveness and efficiency in healthcare. Differences in hospital performance and outcomes between different providers and different countries may vary considerably. As a result, quality assurance is increasingly acknowledged as a crucial factor in the (oncological) surgical care process and many clinical audit programs have been initiated in recent years. Audits can identify shortcomings in the care process on any level in the health care system (i.e., on a hospital, regional or national level) and can aid clinicians in improving the standard level of care by providing feedback to participating clinics. Many improvements have been achieved by various national surgical audits, as have been described particularly in the field of colorectal cancer surgery.

In 2010, a number of European colorectal cancer surgery audits started an initiative to distil a ‘core dataset’ from the existing audit data forms, thereby creating a European outcome based registry for preoperative, surgical and postoperative treatment of colorectal cancer. The project is known as the European Registration of Cancer Care (EURECCA). Until recently, the colorectal initiative was the only European quality assurance project in oncologic care.

Following the EURECCA colorectal initiative, under the auspices of the European Society for Surgical Oncology (ESSO) and the European Network of Excellence on gastric and oesophagogastric junction cancer (EUNE), a EURECCA Upper GI project was initiated wherein several European national and regional oesophagogastric cancer registries and audits collaborate with the aim to develop a European oesophagogastric cancer audit. The first step in this project was to describe a ‘common data item list’. Such a list of shared items on a European level may prove beneficial for existing national audits, because treatment results can then be compared to a wider range of centres in different settings. Moreover, the European Upper GI cancer audit list of data items can serve as an example for new audits, indicating which items were found to be important by most countries and which items may be considered ‘optional’ in a dataset—only to be included when the extra registration effort can be made. Lastly, the core set of items may give insight into what research can be done in a European setting in the future.

The purpose of the current study was to compare the data sets used by the seven participating European oesophagogastric cancer registries and audits and to identify a list of common items. This core dataset can be used for future collaboration in the EURECCA Upper GI project.
**Methods**

From the participating registries and audits, item lists were collected. These items were entered in a database and assigned to a main category and a subcategory. Items were scored ‘present’ if they appeared on an item list or when they could be calculated using other items in the same registration. The type of data (categorical, number, yes/no, free text) was scored. After all the items were entered in the database, a report was sent back to the representatives of each organisation to check for errors or incompleteness. Adjustments were made where appropriate. In the corrected and completed database, shared data items between the registries were identified as well as similarity in data type and categories. Following the colorectal EURECCA initiative, the definition of a ‘shared data-item’ or ‘common data item’ was that at least six of the seven participating registries scored the item. Definitions of items were compared among the different registries. This way comparability was investigated.

Software used for data input and analyses was SPSS 20 (PASW, Chicago).

**Results**

Seven countries (Denmark, France, Ireland, the Netherlands, Poland, Sweden, United Kingdom, figure 1) supplied complete items lists from an existing registry or audit. In six countries, the registry included both patients with oesophageal cancer and patients with gastric cancer. In one country (Poland), only a gastric cancer database was available. Some audits focused mainly on the surgical care process, other audits also had detailed information on non-surgical treatment. Inclusion criteria also varied.

The number of registered items varied between 40 (Poland) and 650 (Ireland). The items were categorized into the following subgroups: patient administrative/medical condition, staging/diagnostics, neo adjuvant treatment, surgery, postoperative course/complications, pathology, adjuvant treatment and survival/follow up. Only 4 registries had information on non-surgical patients. It was therefore decided that only data-items concerning patients undergoing surgical treatment (including multimodality treatment in the neoadjuvant and adjuvant setting) could be used. A total of 46 items was present in at least six of seven datasets, thereby forming the common data set.

The complete list of common data items is given in Table 1. Postoperative complications were scored in all registries, but there are differences in the definitions (Table 2).
Discussion

By comparing the datasets of the seven participating registries, 46 items were identified as a shared item to enter a core dataset for a surgical outcomes registration of oesophagogastric cancer patients. The most vital variables regarding patient, disease, preoperative staging, operation, pathology and mortality are included. Furthermore, data on the use of pre- and postoperative adjuvant treatment are included.

Outcomes between different providers and different countries may vary considerably. Donabedian has proposed a model to evaluate patient care in terms of structure, process, and outcome measures, which forms the basis of many clinical audits. A clinical audit is a quality instrument that collects detailed clinical data from different health care providers. Audits have two main goals: firstly, identification of shortcomings in the care process on a hospital, regional or national level, for instance in terms of guideline adherence or in outcomes such as postoperative mortality; and secondly, improving the standard level of care and reducing the variation in outcomes between centres by feeding back benchmark information to participating clinics.

In 2010, the European Cancer Organisation (ECCO) initiated a European colorectal cancer surgical quality assurance program: EURECCA colorectal. Its goal was to provide insight into differences in treatment and outcomes of patients undergoing colorectal cancer resections, in order to reduce unwanted variation in treatment patterns and to spread best practice. By identifying data-items already registered in nine participating European countries, a common European dataset was created. With this collaborative research, more insight is gained in the differences among countries regarding, for example, the use of (neo)adjuvant therapy for rectal cancer. The EURECCA colorectal initiative formed the basis for a successful European multidisciplinary consensus meeting in Perugia, Italy, in December 2012. Consensus was reached on many key diagnostic and treatment issues, thereby defining many core treatment strategies in colorectal cancer treatment. Implementation of the various issues on which consensus was reached will be monitored with the European registry.

Using the European Upper GI core dataset, an inventory of differences in treatment patterns can be made and linked to outcome measures such as morbidity, mortality, and surgical margins. The EURECCA Upper GI core dataset offers enough patient data to perform statistical corrections for patient- and tumour factors, necessary for a fair comparison between different treatment strategies. Moreover, collective data from the core dataset may answer questions concerning the optimal treatment for elderly patients, which are often excluded from randomized trials, but in daily practice form a significant proportion of the patient population with oesophagogastric cancer. The
EURECCA Upper GI project provides (surgical) teams participating in the national projects with the opportunity to benchmark their performance on a European level. This way, EURECCA can stimulate quality improvement projects throughout Europe, on a European, national and local level.

Although the first step has been taken, some challenges remain. Firstly, not all European countries were able to participate because of limited availability of nationwide or regional registries and audits. The objective is to get as many countries to participate in the project as possible. In figure 1, newly participating countries are shown. A second challenge is the data validity. The current participating national audits have different degrees of coverage on a national level. Results from registries in countries with lower case-ascertainment may not be generalizable to the entire country, possibly hampering comparability of data. Moreover, many registries consist of self-reported data and validity of data should be investigated. Thirdly, definitions for postoperative complications differ among countries. In order to compare the data from the different registries, agreement has to be obtained concerning the definition of all complications used in the registries. Lastly, the items that are registered in all but one participating country should be added to the registry in that particular country. Ideally, participating datasets are fully harmonized.

In June 2013, at the 10th International Gastric Cancer Congress in Verona, Italy, a collaborative meeting was held. The setup and results of each registry (figure 1) and audit were presented to share experience and to provide an opportunity for other countries in Europe to start participating in the collaborative project. Already, the project has created a pilot for a clinical registry in the Spanish region of Catalonia which was presented. In addition the Italian Research Group for Gastric Cancer has plans to extract ‘core data’ from their established regional database.

In conclusion, in this study, a core dataset with patient, tumour, treatment and outcome parameters of oesophagogastric cancer surgery was identified. This dataset can help starting clinical audits or other registries setting up their database. The main goal is to compose a European, widely accepted set of data items, which can be used to compare and improve different treatment modalities. By comparing the registries, it is possible to identify differences in patterns of care. Also, benchmarking of outcomes can be expanded to a European level. This way, differences in outcomes can be identified and specific research questions, for example concerning elderly patients, may be answered using a common dataset.
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1. the Netherlands: J.W. van Sandick, On behalf of the Dutch Upper GI Cancer Audit
2. Ireland: J. Reynolds, On behalf of the National Upper GI & Gastric Cancer Registry
3. France: C. Mariette, On behalf of the French Eso-Gastric Tumors working group
4. Denmark: L. Jensen, On behalf of the Danish Group of Esophageal, Gastro-esophageal Junction and Gastric Cancer
5. Sweden: J. Johansson, On behalf of the National quality registry of Esophageal and Gastric cancer
6. Poland: P. Kolodziejczyk, On behalf of the Polish gastric cancer registry
7. United Kingdom: R.H. Hardwick, On behalf of the National Oesophago-Gastric Cancer Audit
8. Spain (Catalonia region): M. Pera, Section of Gastrointestinal Surgery, Parc de Salut Mar and Institute de Recerca Hospital del Mar, Universitat Autònoma del Barcelona, Barcelona, Spain.
10. Italy: F. Roviello, Department of Medical, Surgical and neurological Sciences, Unit of Surgical Oncology, University of Siena, Italy
Figure caption

Figure 1. Countries participating and involved in the EURECCA Upper GI project
<table>
<thead>
<tr>
<th>Main category</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient administrative / medical condition</strong></td>
<td>Date of birth / age, Gender, ASA score</td>
</tr>
<tr>
<td><strong>Staging/diagnostics</strong></td>
<td>Upper GI endoscopy, Localization of tumour (ICD 10), GOJ tumours: Siewert classification, Histological type of the tumour adeno/SCC (from biopsy), Preoperative CT scan, Preoperative endoscopic ultrasound, Staging laparoscopy, cT classification (TNM7), cN classification (TNM7), cM classification (TNM7)</td>
</tr>
<tr>
<td><strong>Neoadjuvant treatment</strong></td>
<td>Neoadjuvant treatment, Neoadjuvant treatment; type</td>
</tr>
<tr>
<td><strong>Surgery</strong></td>
<td>Resection performed?, Oesophageal operation: approach transhiatal / trans thoracic, Oesophagectomy: type, Gastrectomy: type, Reconstruction type, Location of anastomosis, Nodal dissection, Date of surgery</td>
</tr>
<tr>
<td><strong>Postoperative course / complications</strong></td>
<td>Postoperative surgical complication, Postoperative complications: anastomotic leakage, Postoperative complications: chylous leakage, Postoperative general complication, Postoperative complications: bleeding, Postoperative complications: pulmonary complications, Postoperative complications: cardiac complications, Reoperation, Date of discharge</td>
</tr>
<tr>
<td><strong>Pathology</strong></td>
<td>Location of bulk of the tumour (stomach or oesophagus), Histological type adenocarcinoma/SCC, Involvement of vertical resection margins, Involvement of circumferential resection margin, Number of lymph nodes examined, Number of positive lymph nodes, pT classification (TNM6-7), pN classification (TNM6-7), pM classification (TNM6-7), Radicality of resection (R0,R1,R2)</td>
</tr>
<tr>
<td><strong>Adjuvant treatment</strong></td>
<td></td>
</tr>
<tr>
<td>----------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Adjuvant treatment</td>
<td></td>
</tr>
<tr>
<td>Adjuvant treatment, type</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Mortality</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>30-day mortality</td>
<td></td>
</tr>
<tr>
<td>In-hospital mortality</td>
<td></td>
</tr>
</tbody>
</table>

Table 1: main categories with the shared data-items in the EURECCA Upper GI core dataset

ASA = American Society of Anaesthesiologists
ICD = International Classification of Diseases
GOJ = Gastric Oesophageal Junction
SCC = Squamous Cell Carcinoma
AC = Adenocarcinoma
Table 2: definitions of postoperative complications in the seven participating registries and audits participating in the EURECCA Upper GI project.

<table>
<thead>
<tr>
<th></th>
<th>the Netherlands</th>
<th>United Kingdom</th>
<th>France</th>
<th>Ireland</th>
<th>Sweden</th>
<th>Denmark</th>
<th>Poland</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anastomotic leak</strong></td>
<td>Radiological or clinical y/n</td>
<td>Not otherwise specified</td>
<td>Radiological leak y/n</td>
<td>Not otherwise specified</td>
<td>Radiological or clinical y/n</td>
<td>Not otherwise specified</td>
<td>Not otherwise specified</td>
</tr>
<tr>
<td><strong>Chylous leak</strong></td>
<td>If special diet/TPN/intervention is required</td>
<td>Not otherwise specified</td>
<td>drainage&gt; 7 days or reintervention</td>
<td>Not otherwise specified</td>
<td>Not otherwise specified</td>
<td>Not otherwise specified</td>
<td>Not otherwise specified</td>
</tr>
<tr>
<td><strong>Pulmonary complications</strong></td>
<td>Pneumonia, pleural effusion, ARDS, thoraxempyema reintubation</td>
<td>Pneumonia ARDS pulmonary embolism Pleural effusion y/n</td>
<td>Pneumonia pulmonary embolism y/n</td>
<td>Pneumonia ARDS pulmonary embolism atelectasis pulmonary failure y/n</td>
<td>Pneumonia pulmonary failure (atelectasis or ARDS) pulmonary embolism drainage for pleural effusion y/n</td>
<td>Not otherwise specified</td>
<td>Not otherwise specified</td>
</tr>
<tr>
<td><strong>Cardiac complications</strong></td>
<td>Arrhythmia myocardial infarction</td>
<td>Not otherwise specified</td>
<td>myocardial infarction</td>
<td>Arrhythmia myocardial infarction</td>
<td>Arrhythmia myocardial infarction</td>
<td>Not otherwise specified</td>
<td>Not otherwise specified</td>
</tr>
</tbody>
</table>
References

Leiden 22/11/2013

Dear Editorial board,

On behalf of C. van de Velde and Bill Allum and other authors, there is no conflict of interest.

Kind regards

Wobbe de Steur

Daniel Henneman