Measurement inaccuracy reported via the Manufacturer and User Facility Device Experience database for an implantable pulmonary artery pressure sensor: recalibration direction and magnitude results

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INTRODUCTION: Remote monitoring using an implantable pulmonary artery pressure (PAP) sensor (CardioMEMS HF system) in patients with heart failure (HF) has been consistently shown to reduce HF hospitalizations [1]. The success of this approach relies on the accurate measurement of diastolic PAP (dPAP) over time to allow early interventions such as diuretic intensification [2]. However, it remains unclear how the measurement accuracy changes over time after the initial calibration at the time of device implantation.

PURPOSE: This study aims to identify measurement inaccuracy events and to quantify the magnitude and direction of required device recalibration for CardioMEMS devices as reported in a large-scale regulatory device database.

METHODS: We used the publicly accessible Manufacturer and User Facility Device Experience (MAUDE) data maintained by the US Food and Drug Administration (FDA). The summary search was performed for the CardioMEMS pulmonary artery pressure sensor for the entire product life cycle from January 2009 to February 2024 [3,4]. The entries related to the measurement accuracy under 'Device Problems' categories were obtained. Tested accuracy was reported to have been within ±10mmHg of a reference pressure measurement throughout simulated use for 10 years [5]. Normal range for dPAP is ~8mmHg to 15mmHg [6].

RESULTS: A total of 2656 entries were obtained. Following categories were identified for the reported entries: device sensing problem (N=999, 38%); incorrect measurement (N=1349, 52%); incorrect measurement, inappropriate waveform (N=279, 11%), and incorrect, inadequate, or imprecise results or readings (N=29, 1%). After excluding 56 entries for missing information, 2600 entries were included for the analysis. A total of 1676 (64%) entries reported the need for recalibration of the CardioMEMS device. A mean PAP difference (defined as the difference of the mean PAP reference value measured at the time of recalibration minus the CardioMEMS reading obtained during the reference measurement) is shown in **Figure 1**. Compared to the reference pressure values at the time of recalibration, 488 (29%) of CardioMEMS readings were higher and 1188 (71%) were lower. The absolute recalibration pressure difference was 14.5 ± 9.3 mmHg (mean ± standard deviation, range 0.02-59.3 mmHg). The recalibration by more than 10 mmHg was reported in 1040 (40%) entries.

CONCLUSIONS: Suspected measurement inaccuracy with CardioMEMS device is not uncommon and often necessitate recalibration. Almost one-half (40%) of the recalibrations required more than 10 mmHg correction. These results should inform clinicians to consider recalibration along the course of CardioMEMS monitoring if there is discordance between clinical assessment and the values from the device.

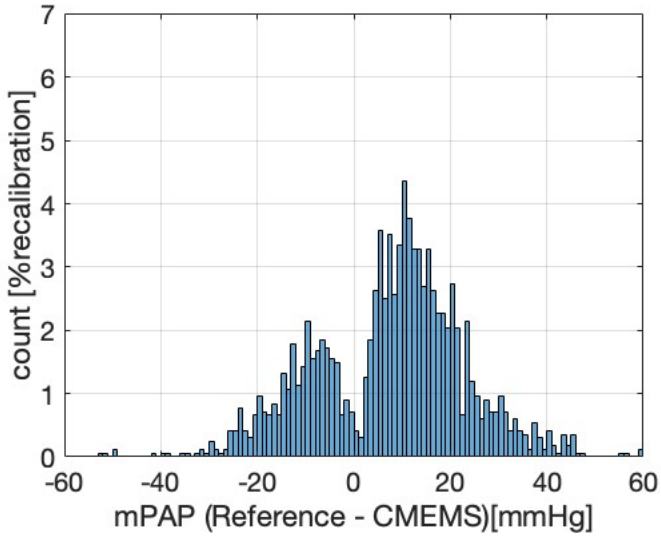

Figure 1.

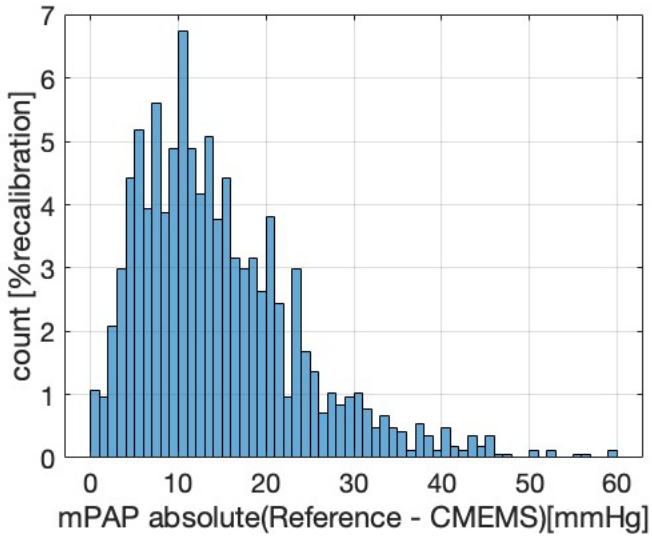

Figure 2.

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