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Effectiveness of a Web-Based Electronic Prospective Data Collection Tool for Surgical Data in Shoulder Arthroplasty

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Abstract

Background: The purpose of this study was to demonstrate the validity and efficiency of the Outcomes Management and Evaluation (OME) system, a prospectively designed electronic data collection tool, for collecting comprehensive and standardized surgical data in shoulder arthroplasty.

Methods: Surgical data from the first 100 cases of shoulder arthroplasty that were collected into the OME database were analyzed. Surgeons completed a traditional narrative operative note and also an OME case report using an encrypted smartphone. A blinded reviewer extracted data from the operative notes and implant logs in the electronic medical records (EMR) by manual chart review. OME and EMR data were compared with regard to data counts and agreement between 39 variables related to preoperative pathology, including rotator cuff status and glenoid wear, and surgical procedures. Data counts were assessed using both raw percentages and with McNemar's test (with continuity correction). Agreement of nominal variables was analyzed using Cohen's unweighted kappa (κ) and of ordinal variables using the linearly weighted Cohen's test. Efficiency was assessed by calculating the median time needed to complete OME.

Results: Compared to the EMR, the OME database had significantly higher data counts for 56% (22 of 39) of the variables assessed. A high level of proportional and statistical agreement was demonstrated between the data in the two datasets. 10 of 39 variables had 100% agreement but could not be statistically compared because both datasets had the same single response under those

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variables. Among the 29 variables that were compared, 79% (23 of 29) of variables had >80% raw proportional agreement, and 69% (20 of 29) of variables showed at least substantial agreement (κ) > 0.6). The median time for completing OME surgery data entry was 92 seconds (IQR 70 – 126).

Conclusion: The prospectively designed, electronic data entry system (OME) is an efficient and valid tool for collecting comprehensive and standardized surgical data on shoulder arthroplasty.

Level of Evidence: Level IV

Keywords

Shoulder; shoulder arthroplasty; electronic medical record; web-based operative report; implant documentation; data processing

> As the United States healthcare system evolves from a volume-driven compensation model towards outcome-based and value-driven models, there is an increased importance in assessing the value associated with varied surgical interventions. In order to assess value, we must be able to determine the quality and cost of a particular procedure $22-24$. Quality can be assessed by collecting surgical outcomes data while cost is attributed to preoperative workup, implants, hospitalization, and postoperative recovery. Reliable perioperative data are therefore required to better assess quality, cost, and thereby, the value of surgical procedures.

> The number of shoulder arthroplasty procedures performed in the United States continues to rise, with current estimates ranging from 55,000–80,000 per year, and increases of 300% or more expected in the coming years ^{5; 16; 19}. Surgical outcomes are influenced not only by type of implant used but by many preoperative and intraoperative measures including but not limited to rotator cuff status, presence and degree of glenoid and/or humeral bone loss, and implant design 13 ; 14 ; 33 . In the past, these data have been collected by retrospective manual extraction from the patient medical record $9:11$. This creates many challenges to perform high-quality research due to the variability in documentation in operative reports and manual extraction errors from electronic medical records (EMR). Operative reports infrequently report quantitative data, thereby significantly limiting the precision of research and quality measurements $^{23; 27}$. Furthermore, error rates in the extraction of data from EMRs have been reported to range from 8–23%, and efforts to increase accuracy also increase cost 20 . Such errors can be reduced by increasing quality assurance measures and with a more thorough data review, which can be both costly and time consuming.^{2; 20} Alternatively, large prospectively collected structured datasets can be developed to compile variables that potentially affect outcomes and/or costs. Such databases would permit the use of multivariate analysis to assess the primary outcome measures, particularly when these variables are uniformly defined and collected.

> Many existing structured databases, such as Medicare, Nationwide Inpatient Sample (NIS), and ACS National Surgical Quality Improvement Program (ACS NSQIP), are not diseasespecific, consistent or standardized, thus creating incomplete datasets and limiting the ability to conduct high quality studies. In regards to shoulder arthroplasty, existing outcomes databases include the Kaiser Permanente Shoulder Arthroplasty Registry, the Nordic Arthroplasty Register Association, and the Australian Orthopedic Association National

Joint Replacement Registry. However, these databases have the limitations of not providing comprehensive, consistent, standardized, disease-specific data in order to undertake highquality research $1; 7; 25$. Currently, no prospectively collected, standardized, disease-specific database exists that gathers high-quality data after shoulder arthroplasty.

To address the need for high-quality, standardized data of common orthopedic procedures, the Cleveland Clinic Department of Orthopaedic Surgery developed the Outcomes Management and Evaluation (OME) system, a prospectively designed electronic data collection tool to allow for cost-effective, scientifically valid, and scalable data collection of patient- and surgeon-reported data surrounding a surgical episode for elective knee, hip, and shoulder surgery 4; 6; 12; 18; 26; 29. The purpose of this study was to evaluate the efficiency and validity of OME as a prospective data collection tool for surgical data in shoulder arthroplasty. We hypothesized that compared to a manually-extracted dataset from the narrative operative report within the EMR, the OME system would have higher completion rates with at least substantial agreement for clinically relevant surgical variables in patients undergoing shoulder arthroplasty, while avoiding excess time to complete the data collection tool.

Materials and Methods

OME Database Design

The design and development of the OME database has been described in detail previously. It is built upon the Research Electronic Data Capture (REDCap) platform to be able to collect scientifically valid, scalable data in a cost-effective manner 4; 6; 12; 18; 26; 29. Surgical data are entered prospectively using a web-based electronic data collection tool within 48 hours of surgery by the operating surgeon using a smartphone, laptop, or desktop computer to access an email link sent by the system immediately after procedure completion. As of April 2020, OME has baseline data (PROMs and surgeon-entered variables) on 97% of approximately 49,000 elective knee, hip, and shoulder surgeries, including nearly 3,000 cases of shoulder arthroplasty, from 73 orthopedists at 16 sites within the Cleveland Clinic Health System. OME's design and implementation were approved by Cleveland Clinic's Institutional Review Board and the system was vetted by the Information Security Department.

Patient Selection

For the present study, the surgical data of the first 100 shoulder arthroplasty records collected into the OME database starting in July 2015 were reviewed. The first 100 cases were chosen to represent the initial adaptation of this web-based electronic prospective data collection tool. There were no exclusion criteria.

OME Surgical Data Collection

In patients undergoing shoulder arthroplasty, OME collects surgical data on preoperative and pathologic details such as surgical history, diagnosis, rotator cuff status, presence and location of glenoid bone loss, and glenoid morphology, as well as *procedural details* such as type of subscapularis takedown/repair, performance of biceps tenodesis, need for

glenoid bone grafting, implant type, and type of humeral fixation (Table 1, Supplementary Table). These variables were identified from the literature or by expert opinion as potential predictors of operative outcomes by the clinicians involved in the OME system design. Built-in branching logic is used to accelerate data entry, showing only fields applicable to each pathology and procedure, which prevents surgeons from having to answer irrelevant or unnecessary items; these un-encountered checkboxes and data-fields help streamline surgeon data entry. However, incomplete forms cannot be submitted within OME, thus ensuring that a standardized and complete dataset is obtained for every patient surgery. Total time required to complete the surgical data form is also collected to measure caregiver burden. For shoulder arthroplasty, a total of 39 variables related to preoperative pathology, including rotator cuff status and glenoid wear, and surgical procedures, were extracted from OME for comparison with data from the EMR (Table 1, Supplementary Table).

EMR Data Extraction

The surgeons' narrative operative notes and the implant logs were obtained from the Epic EMR system (Epic Systems, Verona Wisconsin) for this patient cohort and queried for the same variables collected in OME by an examiner blinded to the OME data. When information about implants was not specifically stated in the operative note, the information was obtained from the implant log. When information on a variable was not present in the operative note, it was considered as "absent" in reporting data counts, but as an "implied negative" for agreement analysis (i.e., surgeons intentionally omitting non-applicable information with the implicit understanding that the item was negative or not present). Specifically, an "implied negative" was assumed when the following variables were not present in the operative note because it was felt that surgeons would, more likely than not, mention these points in the operative notes if they were applicable: past surgical history of the left/right shoulder, presence of glenoid biconcavity, presence of a tear in the subscapularis or superior-posterior rotator cuff, rotator cuff repair, presence of glenoid bone grafting, presence of glenoid reaming or soft tissue interposition for hemiarthroplasty, use of cemented humeral stem fixation, use of an augmented glenoid component, and use of a long glenoid baseplate central peg/screw.

Statistical Analysis

Before the EMR and OME datasets were statistically compared, discrepancies between the two datasets were identified and rechecked and verified. Subsequently, the EMR and OME data were analyzed for completion counts and agreement. Comparison between surgeon operative reports and OME completion counts was made utilizing McNemar's test with continuity correction. For assessment of agreement, variables were categorized as ordinal or nominal. Agreement between nominal variables was made using Cohen's unweighted Kappa values while linearly weighted Cohen's test was used for ordinal variables. Nominal variables received the same penalty for mismatches between the operative report and OME data regardless of the degree of disagreement. Ordinal variables received a variable amount of penalty depending on how different the mismatch was between the operative report data and the OME data. Four variables (superior-posterior rotator cuff status, superior-posterior rotator cuff tear size, subscapularis status, and subscapularis tear size) were considered ordinal. A kappa value of 1.00 indicates perfect agreement; 0.81–0.99 almost perfect

agreement; 0.61–0.80 substantial agreement, 0.41–0.60 moderate agreement; 0.21–0.40 fair agreement; 0.00–0.20 slight agreement and <0.00 poor agreement ¹⁷. A 95% confidence interval (CI) was calculated for all values of agreement. In addition to these formal agreement metrics, the raw proportion of records for each variable showing agreement were also used to assess raw proportional agreement. Data were analyzed with R software (R version 3.3.3 (2017–03-06), Vienna, Austria)

Results

The first one hundred cases of shoulder arthroplasty (primary or revision) were entered into the Cleveland Clinic's OME database by 5 surgeons between July 2015 and September 2015. The median time to complete OME surgical data entry for these 100 cases was 92 seconds (interquartile range, 70 – 126 seconds).

Completion rates

EMR and OME completion counts of the 39 variables assessed are listed in Table 1. Completion counts were significantly higher in OME compared to operative reports in 22 (56%) of the variables analyzed ($p < 0.05$). Notably, the presence/absence of glenoid wear or bone loss was mentioned in 52 out of 100 cases in the EMR compared to all 100 cases in OME ($p<0.001$), and the Walch classification was mentioned in only 4 cases in the EMR compared to the 58 cases in OME where it was appropriate to be assessed ($p<0.001$). Similarly, the status of the rotator cuff was noted significantly less in the narrative operative reports, with subscapularis tendon status recorded in 39 out of 100 cases in the EMR compared to all 100 cases in OME $(p< 0.001)$ and the superior-posterior rotator cuff status recorded in 70 out of 100 cases in the EMR compared to all 100 cases in OME ($p<0.001$). The remaining 17 variables showed no statistically significant differences in completion counts between EMR and OME, with the absolute completion counts being the same or higher in OME for all but 2 variables (Table 1). No variable had significantly higher completion counts in EMR than OME.

Data agreement

The agreement scores of data extracted from EMR and OME are listed in Table 2. Formal agreement statistics could not be calculated for 10 of the 39 variables for which the operative note and OME were in complete agreement, because only one option appeared in each data source despite multiple options being available. Among the 29 variables that were compared, agreement proportions exceeded 80% for 23 (79%) of the variables and only dipped below 50% for 1 (3%) of the variables ("Glenoid bone graft location"). The kappa values were perfect ($\kappa = 1.00$) for 5 (17%), almost perfect (κ : 0.81–0.99) for 9 (31%), substantial (κ: 0.61–0.80) for 6 (21%), moderate (κ: 0.41–0.60) for 3 (10%), fair (0.21–0.40) for 4 (14%), and slight (0.0–0.20) for 2 (7%) of variables. Therefore, there was at least substantial agreement between EMR and OME in 20 (69%) of the 29 compared variables.

Discussion

The gap in overall quality between retrospective and prospective orthopedic research can be directly attributed to the limitations of extracting data from the medical record in retrospective studies $27:28$. With regards to surgical outcomes, the variability in quantitative data incorporated into operative reports by different surgeons creates inefficiencies ultimately hindering retrospective data collection and can also increase costs 20 . The purpose of this study was to evaluate the validity and efficiency of OME as a prospective data collection tool for surgical data in shoulder arthroplasty. In the current study, we demonstrated that OME allows the prospective collection of relevant surgical data in a thorough and efficient manner. Data on preoperative pathology and surgical procedures performed were captured by the surgeon most commonly in less than two minutes per case. As hypothesized, compared to a manually extracted dataset from the narrative operative report within the EMR, the OME system had higher completion rates and at least substantial agreement with the majority of the relevant surgical variables in patients undergoing shoulder arthroplasty.

Completion rate was significantly higher in OME than EMR for 22 (56%) of the surgical variables relevant to shoulder arthroplasty. Notably, this occurred in the majority of preoperative pathologic variables collected in OME (12 of 16 variables), including the presence/absence of glenoid wear or bone loss, Walch classification, and the status of the rotator cuff. Similar significant discrepancies between the EMR and OME were also seen for the presence of a glenoid biconcavity, subscapularis tear size, and superior-posterior rotator cuff tear size. All of these are important variables measuring preoperative pathology which have been shown to impact outcomes in shoulder arthroplasty^{813; 14; 30; 33}. The absence of important pathologic variables in the operative report for a large proportion of patients undergoing shoulder arthroplasty demonstrates some of the limitations in the use of the EMR for retrospective research and quality assessment and highlights the benefit of utilizing a prospectively designed and standardized database like OME. The branching logic implemented in OME also allows for efficient yet relevant and complete surgical documentation by streamlining the data capture process on a prospectively designed set of clinically relevant surgical variables. The discrete data collection format of OME also allows for efficient data extraction and retrieval because of its underlying REDCap platform, in contrast to manual data abstraction from operative notes that is associated with high error rates, and increased time and cost.²⁰

The validity of the OME data is evidenced by the high level of proportional and statistical agreement between operative notes and OME data when the data for a given variable were available in both. Agreement proportions exceeded 80% for 79% of the 29 statistically compared variables (the other 10 studied variables had 100% agreement but could not be statistically compared because both data sets had the same single response under those variables), and 69% of these variables demonstrated at least substantial statistical agreement (Cohen's unweighted κ > 0.6) between the two data sources. The Kappa-values were "fair" or worse (κ < 0.4) for 21% of the variables. This finding suggests situations where raw agreement was high because certain values were very common in both datasets, leading to substantial overlap at this value, but κ was low due to disagreements when the variable took

less typical values. For example, data on humeral prosthesis neck type (standard/variable) in anatomic TSA showed high proportional agreement (30 of 37 cases, or 81%) because 28 cases in both operative notes and OME reported use of a standard neck prosthesis, but κ was low (0.3) because only 2 of the other 9 cases agreed on use of a variable neck prosthesis, with the remaining 7 cases marked as having a standard neck in OME and a variable neck in the operative notes.

Discrepancies between EMR and OME could arise for multiple reasons. For example, many of the discrepancies can be explained by lack of standardized content and verbiage in the surgeons' dictated operative notes, whereas standardized responses were mandated in the prospectively-designed OME database. We also found several examples of inaccurate EMR data. One scenario was 17 cases where the operative report mentioned "glenoid wear" to indicate the presence of arthritis, but not necessarily indicating any type of glenoid bone loss. During EMR data extraction this can be confused as presence of glenoid wear/bone loss, when a case may be a typical Walch A1 glenoid. Another scenario was observed in a case where the operative report had no mention of glenoid bone loss, yet in OME it was entered by the surgeon as posterior glenoid bone loss with a B2 Walch classification. A review of this patient's preoperative imaging (Figure 1) demonstrated posterior glenoid bone loss with biconcavity, consistent with a B2 Walch classification. Such important data omissions and errors in data entry and abstraction are well recognized issues in operative report data 31 and would compromise any retrospective outcome study data utilizing EMR. To address these shortcomings, computerized templates are being increasingly used to help increase consistency of data input and collection, improve the quality and completeness of surgical data, 10 and also reduce the need for transcription services thereby reducing costs ³⁰. However, templates lack the streamlining features of branching logic of prospective disease-specific registries and may not require key variables to be entered into the dataset.²¹

The advantages of the OME system and its incorporated branching logic design include the ability to increase the consistency and completeness of reported data parameters, and increase efficiency of data entry and extraction 18. Data are collected in a time-efficient manner, with a median of only 92 seconds required to complete OME surgical data entry for a given shoulder arthroplasty case. This coupled with mandatory data entry and the accessibility and ease of use of the platform with surgeon smartphones and other portable devices increases completeness and compliance. Another advantage of OME is the ability to collect detailed implant data prospectively in a standardized manner and directly link the implant data to preoperative diagnosis to more easily create treatment groups for analysis. In contrast, many surgical databases use CPT or ICD-9/10 codes to try to sort patients for analysis. However, both CPT and ICD-9/10 codes can lack the necessary level of detail to correctly match up implant type with preoperative diagnoses across cases, leading to challenges with creating accurate treatment groups for analysis. In addition, while many surgical databases have the ability to record implant manufacturer, implant type, and size, OME also provides the ability to collect more specific implant related data such as whether cement was used, humeral and glenoid bone stock, and whether bone grafting was needed. Furthermore, OME is designed to allow for the incorporation of new variables (e.g., to include new implant types and models as they become available for use) and update or

refine existing variables (e.g., to include the modified Walch classification system when introduced).

There are limitations to the current study and OME. First, there is currently no "gold standard" for surgical documentation to which to compare OME. The operative note is the most commonly used mode of recording surgical data, however, it is neither prospectively designed nor standardized. Consequently, it is difficult to fully gauge the accuracy of the OME database and discrepancies between the operative report and OME could be due to data entry errors in either source. Both sources rely on surgeons' accurate data entry and errors can occur as a surgeon completes the operative report or inputs information into the OME system. Second, the reliability of OME is affected by the reliability of the data it collects. For example, the Walch classification has been shown to have only fair to moderate inter-observer reliability 32 . Third, there is a potential for implicit bias in the study because the study variables and their available options were chosen based on the OME data dictionary and then looked for in the operative notes. Surgeons are required to enter a standardized dataset in OME, which though relatively comprehensive is not exhaustive and will be limited by its pre-defined classifications for certain variables. The operative notes may contain other important data that may not be present in OME, and some data that are absent in the operative notes may also be present in other locations in the EMR, such as in preoperative notes, implant logs, or preoperative imaging. Finally, for agreement analysis we assumed missing data in the operative notes as "implied negatives" for certain variables; however, it is possible that some other variables that were missing could also have been "implied negative" by the surgeon, but the retrospective nature of the study does not allow us to determine the accuracy of our assumption.

Future Directions

Collection of standardized prospective data captured in an electronic format in OME will allow investigation of the relationships between patient, disease, and surgical factors, and PROMs.3; 6; 34 The underlying structure of OME as a secure REDCap database also provides the ability to utilize this data collection tool across institutions for prospective multicenter cohort studies or clinical trials ¹⁸. Improvement in orthopedic outcomes research will become increasingly important as health care economics dictate justification of elective arthroplasty based on efficacy and outcomes.^{3; 15} Future areas of research include using OME data to investigate the relationship between patient, disease, and surgical factors, including implant type and PROMs, and outcomes following shoulder arthroplasty.

Conclusions

The OME data capture system demonstrated higher completion rates compared to operative notes for most variables examined after shoulder arthroplasty, and the validity of the OME system was evidenced by the high level of proportional and statistical agreement between OME data and operative notes when the data for a given variable were available in both. OME surgical data were captured by the surgeon most commonly in less than two minutes per case. This prospectively designed, electronic data entry system is a valid and efficient tool for collecting comprehensive and standardized data on shoulder arthroplasty.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.

A case of posterior glenoid bone loss that was not mentioned in the operative report. (A) Axillary radiograph of the left shoulder showing arthritic findings, including posterior glenoid bone loss and glenoid biconcavity, as well as posterior subluxation of the humeral head. (B) Axial CT scan also showing posterior glenoid bone loss and glenoid biconcavity, consistent with the B2 Walch classification documented in OME.

Table 1:

EMR vs. OME data completion rates.

Table 2:

EMR vs. OME data agreement scores

NA, not analyzed; OME, Outcomes Management and Evalution.

Variables with only one value observed are unable to have agreement measure calculated despite the fact that they have perfect agreement in the colloquial sense.

* kappa value based on linearly weighted Cohen's test for ordinal variables