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Outcomes of Nails vs. Plates For Humeral Shaft Fractures: A Medicare Cohort Study

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Abstract

Objectives—This study was performed to determine 1) the incidence of humeral shaft fractures within the Medicare non-cancer population, 2) the trends in utilization of humeral shaft fixation techniques by plate-and-screw devices and intramedullary nails, 3) differences in procedure times, and 4) the outcomes of individuals as measured by rate of secondary operations and one-year mortality.

Design/Setting—Retrospective comparative cohort analysis. A cancer-free Medicare Part B claims sample derived from a 5% sample from the years 1993-2007 was analyzed.

Patients/Intervention—Our cohorts were generated by diagnostic and procedural codes for humeral shaft fractures.

Main Outcome Measurement—The incidence of humeral shaft fracture and trend in operative fixation was evaluated for all years of data. Surgical times were assessed by anesthesia CPT codes. Outcomes and complications were assessed by CPT codes. The proportion of individuals experiencing complications and one-year mortality were compared by proportion hazards.

Results—We identified 1,385 claims for humeral shaft fractures over 15 years, with an adjusted rate of between 12.0 and 23.4 fractures per 100,000 beneficiaries. We identified 511 individuals who received surgical treatment for humeral shaft fractures, 451 of whom had complete one-year follow-up data. Nail fixation was more prevalent than plate fixation most years, and had shorter anesthesia time by 27.1 minutes ($P < 0.0001$). There were no significant differences in the complication rates between the two groups as measured by incidence of secondary operations and one-year mortality.

Conclusions—Intramedullary nails are used for the majority of operative humeral shaft fractures among Medicare beneficiaries. Nailing has a shorter mean operative time. The two surgical techniques had no significant differences in terms of risk of secondary procedures and one-year mortality.

Introduction

Fractures of the midshaft of the humerus account for 1% to 3% of all fractures (1, 2), but up to 90% of non-pathological fractures are treated by casting, splinting, or functional bracing (3-5). Controversy remains regarding the preferred choice of surgical treatment. Current literature suggests that plate-and-screw fixation is more popular than nailing because of

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higher complication rates and technical difficulty associated with nailing (6). However, due to the rarity of the need for surgical fixation, it is difficult to recruit enough patients for an individual randomized controlled trial (RCT's) with sufficient power to compare outcomes. A meta-analysis in 2006 by Bhandari *et al* evaluated three small RCT's (7, 8), and suggested that there may be a lower relative risk of secondary operations in those receiving plates as opposed to those receiving nails (9), but with the inclusion of a 4th RCT (10), the meta-analysis was repeated and the difference was found to be insignificant (11). In that analysis 11 out of the 107 individuals receiving plates and 23 out of 96 individuals receiving nails had undergone secondary operations. The most recent analysis favors plates, but this was driven by the outcomes of shoulder complications after the addition of a small randomized control trial of 34 patients (12).

Administrative databases have the advantage of scale to provide data on uncommon events, and Medicare Part B data contains comprehensive longitudinal information about covered services used by enrollees in the program. Medicare Part B records CPT (Current Procedural Terminology) codes and ICD-9 (International Classification of Diseases, Ninth Revision) codes, which allows for the generation of cohorts along specific treatments received and the tracking of certain outcomes as measured by utilization of services.

The objectives of this study were to determine 1) the incidence of humeral shaft fractures within the Medicare non-cancer population, 2) the trends in utilization of humeral shaft fixation techniques by plate-and-screw devices and intramedullary nails, 3) differences in procedure times, and 4) the outcomes of individuals as measured by rate of secondary operations and one-year mortality.

Patients and Methods

A retrospective comparative cohort analysis was performed with the non-cancer sample from the SEER (Surveillance, Epidemiology and End Results)-Medicare program. This data set was constructed from a 5% sample of Medicare beneficiaries residing in the 17 SEER regions in which individuals reported as cancer patients were removed. This left a cancer-free sample. Since intramedullary nails are used almost exclusively for cancer patients with pathological fractures, we used these convenience control samples from SEER-Medicare to avoid this important confounder. Considering the commensurate results from the previous meta-analysis, we noted a 10.3 % rate of secondary operations after plate procedures and a 24.0 % rate of secondary operations after nail procedures (11). For a study of equal sample arms (α of 0.05 and power of 0.80) we estimated that 119 individuals would be needed in each cohort to demonstrate a difference between 10.3% and 24.0% in a two-sided test. Claims data from 1993 to 2007 was used, and as we were ultimately interested in specific procedures with distinct CPT codes, we limited our study to Medicare Part B claims.

To estimate the incidence of humeral shaft fractures, we queried for the presence of ICD-9 diagnostic codes 812.21 and 812.31 (closed and open fractures of the humerus shaft, respectively). To try to remove potential rule-out diagnosis codes or miscodings, we required the presence of two ICD-9 codes to have occurred within 30 days for a diagnosis to be considered a true diagnosis. The annual incidence of humerus fractures was calculated for each study year, adjusted for age and sex based on a fixed population from 2000 US Census Standard Population.

Operative repair of humeral shaft fractures was identified by CPT code. Beneficiaries that had undergone surgery for the treatment of humeral shaft fractures, either by intramedullary nail or by plate-and-screw techniques, were included. Age, sex, race, and comorbidity were considered potential confounders. Comorbidity scores were calculated with algorithms

provided by the SEER-Medicare program (13) using Part B data. We identified individuals who had an event of surgical treatment for a humeral shaft fracture by identifying CPT codes of 24515 (“open treatment of humeral shaft fracture with plate/screws, with or without cerclage”) and 24516 (“treatment of humeral shaft fracture, with insertion of intramedullary implants, with or without cerclage and/or locking screws”) within the sample. We only considered claims filed by orthopedic surgeons (HCFA specialty code 20), and excluded modifiers that would suggest that the claim was not the primary claim for the procedure, as described in Appendix A

We excluded individuals who had a concurrent ICD-9 code of pathological fracture (733.0, 170, 170.4, and 195.4), as these have specific recommendations for treatment. We excluded concurrent ICD-9 codes for malunion and nonunion of fracture (733.8, 733.81, and 833.82) or concurrent CPT codes for repair of nonunion of the humerus (24430 and 24435), as we were only interested in new fractures. We also excluded those with unspecified disorders of bone and cartilage (733.90). This method is analogous to those previously described for comparing intramedullary nails and sliding hip screws for intertrochanteric fractures (14), and for comparing outcomes following primary and revision total hip arthroplasty (15). We compared this number with the number of total fractures calculated previously.

We identified the claims for each individual for up to one year. We estimated anesthesia time and converted to it to surgical time by Theil's Estimation in accordance with technique by Silber *et al* (16). We took CPT codes of anesthesia that occurred within 7 days of the index date for our cohort of 514 patients. These codes began with 016 and 017, and represented anesthesia administered for procedures of the shoulder/axilla and upper arm/forearm, respectively. We excluded a small number of claims that lasted for more than 400 minutes.

To measure rates of secondary operations and one year mortality, we included individuals who had complete follow-up information for one year. This included residents of the United States who had been enrolled in both Medicare Parts A and B and who were not members of health maintenance organizations for the duration of interest. Secondary operations were defined as subsequent surgery on the upper limb, such as a removal of hardware, rotator cuff repair, nonunion repair, neurolysis, or repeat treatment of the upper limb. The specific codes utilized are provided in Appendix B. We limited our longitudinal search of complications to claims that were submitted by orthopedic surgeons (specialist code “20”). We considered secondary operations and one-year mortality following surgery.

Parametric comparisons were performed to compare anesthesia time, and were conducted with the analysis of covariance adjusting for age, race, gender, and comorbidity. Hazard ratios according to the Cox proportions model were calculated for rates of secondary surgery and one-year mortality, adjusting for age, race, gender, and comorbidity.

Results

We identified 1,385 claims with diagnoses codes of 812.21 and 812.31 from 1993 to 2007 in Medicare Part B. The adjusted rate of fractures varied between 12.0 and 23.5 fractures per 100,000 beneficiaries. The raw counts of surgery code and adjusted rates for each year are plotted in Figure 1.

A flow-chart describing the creation of our treatment cohorts is presented in Figure 2. From 1993 to 2007, we identified 511 individuals undergoing primary operative treatment for nonpathological humeral shaft fractures (201 receiving plates, 310 receiving nails). The two groups were similar in age, race, sex, and comorbidity (Table 1). We found that more individuals received nails than plates in each year except 1993, 1997, and 2007 (Figure 3).

Operative fixation of non-pathological fractures accounted for approximately 25% to 45% of all total fractures seen in our sample.

We found a significant difference in anesthesia time, with intramedullary nailing procedures being shorter by 27.1 minutes ($P<0.0001$). This is equivalent to 22.3 minutes of surgical time by Theil's estimation (16). There were 174 valid anesthesia claims for the upper arm/shoulder or elbow/wrist for individuals who had received plates, and 251 for individuals that received intramedullary nails. We excluded 8 claims for plates and 12 claims for nails for long OR times.

We retained 172 patients with plates and 279 patients with nails with one-year follow-up information. Our primary outcome of secondary operations had a difference in rates of 14.5% vs. 15.4% for plates and nails, respectively. The adjusted hazard ratio was 1.01 ($P=0.98$). The ninety-day and one-year mortality was also found to be similar, with an adjusted hazard ratio of 1.22 ($P=0.69$) and 0.99 ($P=0.99$), respectively. Kaplan-Meier curves were plotted for the number of days before a secondary operation and one-year mortality (Figures 4 and 5).

Discussion

Although Medicare data have been used to study the outcomes of other more common procedures such as total hip arthroplasty and intertrochanteric fractures (14, 17), this study is the first to use Medicare data to compare the trends and outcomes of surgical treatments for humeral shaft fractures. Our study showed that operative fixation accounted for a significant portion of all fractures seen in our sample size. Compared to traditional plate-and-screw fixation, intramedullary nails were more prevalent, required less operative time, and exhibited no difference in postoperative complications and one-year mortality.

The strengths of our study come from the size of the Medicare database, a resource useful for studying rare events. To our knowledge, this is the only comparative effectiveness study for humeral shaft fractures to utilize administrative claims data, and the largest single comparative cohort study on the topic performed to date. Our method could reliably capture occurrences of major procedures and complications severe enough to warrant further treatment, and deaths (18-20). Claims data is more accurate in documenting events that impact payment, making this method more robust for capturing incidences of treatment, subsequent operations, and mortality (18).

However, our observations suffer from the disadvantage of limited clinical insight available with administrative data. Many qualitative factors that go into clinical decision-making and assessment are unavailable: there is no information regarding patient or physician preferences (21), radiographs, classifications of fractures, or functional outcome scores such as for shoulder pain. Osteoporosis would also be an important confounder in this age group, but would be impossible to adjust for as the diagnostic code for osteoporosis is under-reported (22). Furthermore, fractures that do not warrant operative or immediate treatment other than observation would be under-reported, and as such we would underestimate the true incidence of fracture. This would affect both the assessment of multi-trauma and an incidence of humeral shaft fractures as a whole.

Nevertheless, our results provide an updated perspective on the epidemiology and outcomes of humeral shaft fractures. Shaft fractures occurred at a rate of 12.0 to 23.5 per 100,000 beneficiaries. This is roughly in agreement with a previous epidemiological study, which quoted rates of 14.5 per 100,000 individuals in Sweden (1). The same study found that fracture incidence rose to 20 per 100,000 in the 60 to 70 year old age bracket and 60 in those greater 90 years old. Our findings were somewhat lower than those found their study. This

could be due to an underreporting of ICD-9 codes in Part B claims when no overt treatment is warranted. Furthermore, our sample excluded the majority of pathological fractures from eliminating cancer patients. However, when taken together the rate of fractures do appear to be increasing.

Our results provide counterevidence to some current opinions regarding humeral shaft fractures. The rate of operative fixation in the elderly population may be greater than expected. Operative fixation of non-pathological fractures accounted for 25% to 50% of all fractures seen during this time period, and the rate also seems to be increasing. The inclusion of pathological fracture fixations would have only served to increase the rate. Overall, both the rate of fracture and the rate of fixation per fracture in our Medicare non-cancer sample have increased.

Furthermore, plating is often cited as the preferred treatment in current literature due to lower technical demand (6), rates of secondary operations, and shoulder impingements (23). However, in our study we found nailing to have remained popular. For twelve out of the fifteen observed years, nails had been more popular than plates. This difference could be due to age group differences and the prevalence of osteoporosis, however the current recommendations for the use of intramedullary nails for osteoporosis are conflicting (24, 25). Investigation into device usage patterns in the elderly warrants further attention in future comparison trials.

Our data also suggests that nailing may be a less technically demanding procedure than plating, if one considers shorter procedure times as a surrogate measure for ease. One RCT addressing this issue found that plate procedures were shorter than nails at 84 vs. 95 minutes (8). We found adjusted anesthesia times to be 164.7 vs. 137.6 minutes for plates vs. nails, which correspond to surgical times of 111.3 minutes for plates and 89.0 minutes for nails. The perception of technical difficulty could be partially accounted for by the initial learning curve of using nails in earlier years and the individual surgeons' preferences in previous studies, yet nailing ultimately avoids the extensive dissection and exposure that is necessary for plating.

Our rates of secondary operations have been consistent with some RCT's, except there was a much smaller difference in rates of secondary operations than previously seen in randomized control trials and meta-analysis (10). A recent large retrospective study of 91 patients reported that rates of secondary operations were 14.3% for plates and 16.3% for nails (26). These rates were much closer to our findings of 14.5% vs. 15.4%.

This study is of interest as a historical review of the popularity of intramedullary nails, and to researchers who are considering any prospective trials in humeral shaft fractures. Our data is consistent with previous trials indicating that the rates of secondary operations are between 10 and 25%. However, differences between rates of reoperation may be smaller than expected. The data on humeral shaft fractures is constantly evolving, and a large scale clinical trial is certainly warranted, especially one that focuses more on the elderly. We believe that if a formal clinical study were to assign secondary operations to be the primary outcome, it should be powered to demonstrate a clinically relevant difference.

It is interesting that nails have been popular despite a nearly two-fold difference in implant costs. At our institution, the cost of an 8-hole plate with four locking screws and four non-locking screws is \$1324, while the cost of an intramedullary nail with both proximal and distal interlocking screws is \$2542. Given the essentially equivalent outcomes for the two procedures, an increased use of plating could result in substantial savings to the health care system, but would come at a cost of increased surgical times.

At present, our results provide counterevidence to current beliefs drawn from small scale studies: amongst the elderly, surgery for humeral shaft fractures may be more common than previously reported, and intramedullary nails have been a popular fixation technique for humeral shaft fractures.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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This study was reviewed by our institutional review board and determined to be exempt.

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Figure 1.

Incidence of humeral shaft fractures from Medicare Part B data. Reported are both the raw count for the number of individuals with ICD-9 codes of 812.21 or 812.31 occurring twice over 30 days, and the rate of fracture per 100,000 beneficiaries adjusted for age and sex.

Figure 2.

Flow chart for the development of our cohorts. 511 individuals had undergone surgical treatment for humeral shaft fractures by orthopedic surgeons. 404 of these individuals had anesthesia claims filed by anesthesia providers on within 7 days of surgery that lasted for less than 400 minutes. 451 of the initial 511 individuals had complete one-year follow-up information. Demographic information for the 511 individuals is available in Table 1. Demographic information for the 451 and 404 cohorts is available in a supplemental table.

Proportion of Fractures Undergoing Operative Treatment

Figure 3.

Number of procedures performed for humeral shaft fractures in our sample. Nails have been more prevalent than plates for most years except 1993, 1997, and 2007. As a whole, the number of operations per fractures has increased.

Figure 4.
Unadjusted survival curves for secondary operation. No difference was observed in the timeframe.

Figure 5.
Unadjusted survival analysis one-year mortality. No difference was observed in the timeframe.

Table 1
Characteristics of Medicare Beneficiaries Treated for a Humeral Shaft Fracture

Number (%)	Plate-and-screw (n = 201)	Intramedullary Nails (n = 310)
Gender		
Male	42 (20.9%)	77 (24.8%)
Female	159 (79.1%)	233 (75.2%)
Age, years mean (SE)	73.0 (SE 0.9)	74.7 (SE 0.7)
Race		
White	181 (90.0%)	281 (90.6%)
Non-white	20 (10.0%)	29 (9.4%)
Charlson Comorbidity Index		
0	103 (51.2%)	152 (49.0%)
1	59 (29.4%)	89 (28.7%)
2	23 (11.4%)	36 (11.6%)
3	16 (8.0%)	33 (10.7%)