Multicenter, retrospective comparison of implant survival, complications and cost between plate and screw and intramedullary nail fixation for metastatic lesions of the diaphyseal humerus

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Background: The humerus is a common site of metastatic disease that can be fixated with either plate and screw or intramedullary nail (IMN) constructs. A multicenter retrospective comparison study was undertaken to compare implant survival, complication rate and cost between the two constructs. No prior studies have included a cost comparison.

Methods: Databases of two academic practices were queried retrospectively to identify patients with metastases of the humerus. Inclusion criteria were a lesion in the proximal metaphysis to distal diaphysis and amenable to both implant options with available cost data. Follow-up was at least 6 months barring death or discharge to hospice sooner. Demographic, clinical and outcome data was recorded. Costs were estimated based on contract pricing. Operating room (OR) costs were estimated using per minute OR costs proposed by other investigators.

Results: One hundred and one humeri in 96 patients were included (72 plates and 29 nails). The most common malignancies were renal cell, myeloma and lung. Half presented with a displaced fracture. Demographics were similar in both groups. Lesions were larger in the plate group. Surgical times were longer in the plate group, 146 *vs.* 75 min, P<0.001. Estimated blood loss (EBL) was higher in the plate group, 510 *vs.* 221 mL, P<0.001. A trend toward increased failure was seen in the plate group, 12.5% *vs.* 0% (P=0.056). The most common complications in the plate group were pain, stiffness and swelling compared to pain, refracture and PE in the nail group. Local disease progression was equivalent. Implant costs were higher in the IMN group ($2,753 *vs.* $1,553, P<0.001), while OR costs were lower ($2,349 *vs.* $4,395, P<0.001). Overall cost of implantation was lower in the IMN group ($5,102 *vs.* $5,949, P=0.005).

Conclusions: IMN of metastases of the humerus offers a faster, potentially more durable construct with lower blood loss, faster OR times and decreased cost of implantation.

Keywords: Humerus; nail; plate; cost; metastasis; fracture

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Introduction

The humerus is a common site of long bone metastases (1,2). Osteosynthesis of completed or impending pathologic fractures consists of two predominant options: open reduction and internal fixation (ORIF) with plates and screws or intramedullary nailing (IMN). ORIF allows for intralesional resection of the tumor and cement stabilization but requires larger incisions and potentially longer operative times. Percutaneous IMN allows for shorter operative times and can prophylax the entire bone but does not reduce local tumor burden, leads to rotator cuff impingement and has a potentially higher implant cost. Prior studies of metastatic humeral lesions have suggested a higher reoperation rate and higher estimated blood loss (EBL) for plate compared to nail fixation (3-6). This study represents the largest direct comparison of the two constructs of which we are aware and the only study to include implant costs for each construct. The goals of our study were to (I) compare the implant survival of plates/screw with IMNs (II) compare the complication and reoperation rates of the two constructs (III) determine the average implant costs for each construct (IV) determine the overall cost difference between each construct including implant costs and cost of operating room (OR) time between the two groups. We hypothesized that each construct would have equal implant survival, IMN would have a shorter OR time and IMNs would cost more even after accounting for potential differences in OR time. We present the following article in accordance with the STROBE reporting checklist (available at https://aoj.amegroups.com/article/view/10.21037/aoj-20-101/rc).

Methods

We utilized prospectively collected patient databases of the Orthopaedic Oncology Departments at Vanderbilt University Medical Center (January 1998 to October 2018) and at the Hospital of the University of Pennsylvania (January 2013 to October 2018). The databases were queried retrospectively to identify all eligible patients with metastatic lesions of the humerus amenable to either IMN or ORIF. Patients were included if they had a pathologically confirmed metastatic lesion between the surgical neck and 3 cm proximal to the olecranon fossa, if the fracture pattern was amenable to both implant options, if appropriate cost data was available and if they had at least 6 months of follow-up or died and/or were discharged to hospice sooner than 6 months. Patients were excluded if metastases were suspected but not confirmed, if the fracture was not amenable to both implants, if treated with a surgery other than osteosynthesis, if insufficient data was available or if they were alive but had less than 6 months of post-operative follow-up. Patients were included in the cost analysis regardless of length of follow-up. Demographic and clinical data was recorded from the electronic medical record and digital imaging system including age, sex, diagnosis, linear lesion size measured proximal to distal, surgical time from skin incision to final closure and implants chosen. Choice of implant was based on surgeon preference. Implant costs were calculated based on Vanderbilt contract pricing. The names of the implant companies have been kept anonymous to comply with institutional non-disclosure agreements. OR times were calculated between skin incision and completion of skin closure. OR costs were calculated using the average cost per minute of OR time at a teaching hospital as estimated by other investigators ($29.88/min) (7). Complications were recorded. Implant failure was defined as an implant complication requiring reoperation for revision or conversion to a different implant. These variables were compared between the two groups and reported below along with 95% CI. The use of neoadjuvant and adjuvant radiation and use of preoperative embolization was left to the discretion of the treating surgeons (RW, GH, KW, HS, JH). Radiation dosing, field and technique employed was at the discretion of treating radiation oncologists. Actual dosage was difficult to determine as many patients received radiation at outside institutions. Typical radiation doses ranged from 20–30 Gy delivered to the entire humerus. Institutional review board approval was given for each institution and no external source of funding was used.

Due to the surgeon preference nature of implant selection, selection bias was a significant concern. To address the concern, this investigation was undertaken between two different institutions as noted above, with differing treatment strategies. Vanderbilt University Medical Center generally favors plate fixation, while University of Pennsylvania favors nail fixation.

Statistical analysis

Determinations of normal distribution for nonparametric data were made using a Kolmogorov-Smirnov test of normality. Normally distributed data was evaluated using a two-tailed *t*-test. Non-normally distributed data was analyzed using a Mann-Whitney U test. Chi-Squared test was used for binomial data in which all values were greater

Table 1 Demographic and lesion data

Parameters	ORIF	IMN	P value
Gender, % [n]			0.114
Male	65.3 [47]	48.3 [14]	
Female	34.7 [24]	51.7 [15]	
Age (yrs), mean	63.3	65.2	0.415
Lesion size (cm)	7.2, 95% CI: (6.4, 8.1)	5.2, 95% CI: (4.1, 6.3)	0.003
Side, % [n]			0.269
Left	56.9 [41]	44.8 [13]	
Right	43.1 [31]	55.2 [16]	
Fracture type, % [n]			0.432
Displaced	50.0 [36]	58.6 [17]	
Impending	50.0 [36]	41.4 [12]	

ORIF, open reduction and internal fixation; IMN, intramedullary nailing.

Table 2 Histologic diagnosis

Diagnosis	Number	Percentage
Renal cell	26	25.7
Multiple myeloma	24	23.8
Lung	15	14.9
Breast	9	8.9
Carcinoma of unknown primary	5	5
Melanoma	4	4
Lymphoma	4	4
Prostate	3	3
Thyroid	2	2
Hepatocellular	2	2
Squamous cell	2	2
Colorectal	1	1
Sarcoma	1	1
Paraganglioma	1	1
Intracranial adenoid cystic carcinoma	1	1
Urothelial	1	1

than 5. Fisher's exact test was used for binomial data in which one or more values were less than 5.

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by ethics committee of Vanderbilt University Medical Center (IRB#: 180518) and individual consent was waived due to the retrospective, chart review nature of this investigation.

Results

Demographic and clinical data

We identified a total of 101 humeri in 96 eligible patients, 72 treated with ORIF and 29 with IMN fixation. Patients were predominantly male (60.3% *vs.* 39.7%) with an average age of 63.8 years at the time of surgery. Average follow-up was 15.5 months (range, 0.1–110 months) post operatively. A total of 52.5% of patients presented with a displaced fracture. The two groups did not differ in regards to age, sex distribution, side nor displacement at presentation (*Table 1*). Lesions were significantly larger in the craniocaudal dimension in the ORIF group than the IMN group, 7.2, 95% CI: (6.4, 8.1) *vs.* 5.2, 95% CI: (4.1, 6.3) cm, P=0.0027. The three most common primary malignancies were renal cell (25.7%), myeloma (23.8%) and lung (14.9%) (*Table 2*).

Clinical outcomes

Surgical times were significantly longer in the ORIF group, 146 [135, 156] *vs.* 75 [68, 82] min, P<0.001. EBL was significantly higher in the ORIF group, 510 [376, 645] *vs.* 221 [139, 303] mL, P<0.001. Radiation was used in a similar percentage of patients after ORIF (68.1%) and after IMN (75.9%), P=0.6034. A trend toward a higher rate of failure requiring revision was seen in the ORIF group, 12.5% *vs.* 0% in the IMN group, but this did not reach statistical significance (P=0.056). Four revisions in the ORIF group were for loss of fixation, three for disease progression, one for new traumatic fracture and one for instability/persistent bleeding. Three patients in the ORIF group experienced loss of fixation that did not require revision and one patient in the IMN group experienced disease progression that was treated with further adjuvant therapies. These events occurred at an average of 15.1 months post operatively. Three patients in the IMN group experienced a refracture around the nail that did not require revision.

The overall rate of complication was 33.3% in the plate group and 44.8% in the nail group—a difference that was not statistically significant (P=0.278). The most common complications experienced in the plate group were pain (15.3%), stiffness (15.3%) and edema/swelling (5.6%). This is compared to pain (20.7%), refracture (10.3%) and pulmonary embolism (PE) (6.9%) in the nail group. Local disease progression was noted in 13.8% of humeri in the plate group compared to 7.1% in the nail group, which was not statistically significant (P=0.488). Excluding myeloma patients in whom the medullary canal is often broadly involved, this gap widens to 20% progression in the plate group and 5.8% progression in the nail group. This failed to reach statistical significance (P=0.425). At final follow-up, 38.6% of patients had either died or were discharged to hospice at an average of 5.6 months postoperatively—a rate that did not differ between the two groups.

Cost analysis

We analyzed cost in all 130 humeri that fit the lesion parameters, 29 of which had been excluded from the outcome analysis for limited follow-up. Eighty-nine patients were treated with plate and screw fixation, 41 with IMN. Implant costs were significantly higher in the IMN group, $2,753 ($2,655, $2,851) *vs.* $1,553 ($1,381, $1,726), P<0.001, even after accounting for the number of screws and use of bone cement. The average nail size was 8.6 mm (SD, ±0.8) by 24.8 mm (SD, ±1.4) and utilized an average of 3.4 (SD, ±0.6) interlock screws or blades. Cement was used in only one humerus in the nail group. In the plate group, implant selection varied widely among 4 to 12 hole large frag broad, large frag narrow and small frag plates, 3 to 12 hole pre-contoured proximal humeral locking plates and other pre-contoured plates. An average of 10.8 (SD, ±3.8) screws were used per humerus, 3.6 (SD, ±4.6) locking screws and 7.2 (SD, ±3.1) nonlocking screws. An average of 1.9 batches of cement were used per humerus, split evenly between antibiotic laden (0.94±0.7) and non-antibiotic laden (0.92±0.8). No cement was used in 4 humeri in the plate group.

OR times were lower in the IMN group, 78.6 [71.5, 85.7] *vs.* 147 [138, 156] min, P<0.001. OR costs were significantly lower in the IMN group, $2,349 ($2,137, $2,561) *vs.* $4,395 ($4,128, $4,663), P<0.001.

Including both implant and OR costs, the overall cost for implantation was lower in the IMN group, $5,102 ($4,921, $5,283) *vs.* $5,949 ($5,579, $6,318), P=0.005.

Discussion

Metastatic lesions of the humerus are the second most common site in the long bones, presenting as either impending or completed pathologic fracture (1,2). Much like non-metastatic fractures, proximal metadiaphyseal and diaphyseal lesions can reasonably be treated with either ORIF or IMN. This analysis suggests several advantages to the use of IMN fixation over plate and screw fixation for pathologic lesions of the humeral diaphysis. This is bolstered by our series representing one of the largest comparative studies in the literature. Larger series exist, but they included lesions throughout the entire humerus that were treated with a wider variety of surgical approaches (3-6). This study sought to elucidate the preferred method for treating pathologic fractures specifically of the humeral diaphysis and proximal metadiaphysis for which both surgical options are clinically valid.

Our investigation found a lower EBL with the use of IMNs, similar to previous investigations of humeral metastatic lesions (3,5). Distinct to other investigations, operative times were significantly longer in the plate group (5). The authors believe this difference to be due predominantly to the difference in surgical technique between plating and nailing, but this is confounded by the statistically significant increased linear size of the metastatic lesions in the plate group. Despite this confounder, the effect sizes for both EBL and operative time—289 mL and 71 minutes respectively—are large enough that they are unlikely to be solely attributable to lesion size. Given the medical frailty common to patients with metastatic cancer, decreased blood loss and shortened anesthetic time are potentially more impactful than in healthier patients with more robust physiologic reserve.

Implant outcomes have varied in previous investigations with failure classification differing among studies and outcomes separately favoring plates, nails or neither (3-6). Classified as reoperation, our series suggests a higher failure rate in the plate group but this did not reach statistical significance. Prior studies with larger subgroups of patients suggest similar trends. A 2015 systematic review suggests a 9.3% reoperation rate for plates compared to 4.4% for nails, but a direct comparison was not attempted to determine statistical significance (4). A 2016 case series suggests a similarly higher rate of reoperation of 10% *vs.* 6.7% but again direct statistical comparison was not performed (5). A 2012 review suggested a much higher rate of 22% for plates compared to 7% for nails, but they included only 21 plate constructs, 10 of which were in the distal humerus (6). Finally, an older, direct comparison of 20 plate constructs and 18 nails from 1996 reports a higher reoperation rate for nails (17% *vs.* 4%), but two of the three reoperations were for early loss of fixation in unlocked nails (3). Due to advances in nail technology and the near universal use of interlock screws, this is unlikely to apply to more current nail techniques. Our study is the largest to attempt direct comparison between the two treatment methods.

Although continued pain was noted in a similar percentage of patients, the results are tempered by the 10% rate of refracture in the nail group. Due to the design and function of IMNs such complications can be treated nonoperatively, as they did not result in loss of fixation in our series. Since refracture as well as disease progression are common after treatment of metastatic lesions, humeral nails offer the advantage of broader points of fixation and allow a surgeon to abide by the oncologic principle of instrumenting the entire bone.

A novel component of our series is the cost comparison. The markedly higher implant costs were completely and significantly outweighed by the decreased OR time and OR cost in the nail cohort. This results in the cost analysis favoring nail fixation over plate. Although we did not specifically factor in failure rate in our analysis nor the cost of reoperation, the 12.5% reoperation rate in the plate and screw fixation would seemingly drive this cost advantage even higher.

Shoulder dysfunction must also be considered when comparing the two implant options. While this was not the specific focus of our investigation, rotator cuff symptoms were reported in 1 of the 29 IMN patients. Prior comparisons between plate and nail fixation of non-pathologic fractures of the humeral diaphysis have suggested a higher rate of shoulder impingement and loss of motion after humeral nailing (8-10). Ultrasound evaluation of the rotator cuff after IMN fixation have shown an 8–12.5% rate of rotator cuff lesions and a 20% rate of biceps tendinopathy (11,12). While for more proximal fractures, plate fixation similarly risks impingement, it does not confer direct risks to shoulder dysfunction when used for diaphyseal fractures. Since restoration of function is such a vital component in the treatment of metastatic bone disease, this should be factored into decision making. It should be noted that direct comparisons of shoulder function in traumatic humeral shaft fractures have shown no difference between the two treatment methods (9,13). This suggests that the impingement and rotator cuff lesions do not result in a functional deficit. While the authors do not believe that the risks to rotator cuff outweigh the benefits enumerated, the risk for shoulder dysfunction should be discussed with patients. Surgeons should also have a clear post-operative therapy protocol to minimize iatrogenic dysfunction.

A high rate of PE was noted in the nail fixation group. A review of studies reporting on the rate of PE after the treatment of both metastatic and non-metastatic humeral fracture suggests a rate between 1.3% and 5.1% (5,14). The rate reported in the nail group of 6.9% is not significantly higher and is likely attributable to the small sample size. The overall rate in this series is 2%, within the range reported in the literature. Regardless, this suggests that PE is a significant risk after surgical treatment of humeral metastatic lesions. This emphasizes the importance of an evidence based VTE prophylaxis plan in the postoperative period to limit this potentially life-threatening complication. The typical regimen at both institutions is the use of low molecular weight heparin while the patient is admitted post operatively transitioning to aspirin upon discharge to complete a month of prophylaxis. Patients on anticoagulation at baseline were restarted on their home regimen between 24 and 48 hours post-operatively.

Radial nerve palsy is a commonly reported complication after treatment of humeral shaft fractures and metastatic lesions with rates ranging between 1.3% and 17% for all implant types (2,3,6,10,15,16). A 2013 meta-analysis showed no difference between plate and nail fixation for traumatic fractures (10). Two patients in our study had post-operative nerve dysfunction, both in the plate fixation group. One had a brachial plexopathy thought to be due to positioning or intraoperative traction. One had a radial nerve palsy for a rate of 1.4% in keeping with reported rates in the literature.

Both were completed resolved at 1 year follow-up. No episodes of nerve dysfunction were noted in the nail fixation group.

Local disease progression was not a direct focus of our investigation, but the rate of local progression showed a trend counter to what would be expected between the two treatment modalities. Inclusive and exclusive of myeloma, which typically has broad marrow involvement, a statistically not significant trend toward a higher rate of local progression was noted in the plate group compared to the nail group. The numbers in the plate group—13.8% including myeloma and 20% excluding—are in keeping with previously reported rates of local disease progression after stabilization. Several studies have suggested a rate between 12% and 41% (17-19). However, the rates reported in the nail group—7.1% including myeloma and 5.8% excluding—are lower that previously reported rates. These patients save for one received no intralesional treatment and received an equivalent dose of radiation. This is likely due to the relatively small sample size in the nail group. Also, a higher percentage of plate patients (19.4%) compared to nail patients (4.7%) did not have longer term follow-up imaging to assess for disease progression, which may artificially inflate the percentage of progression in the plate group. Finally, the smaller lesion size in the nail group may also contribute to the lower rate of local recurrence. Regardless, our findings do not support intralesional resection resulting in a lower risk of local disease progression.

Our study has several limitations. The first is that it is a retrospective review. Although patient demographics were equivalent, lesion size was not. Thus, there is a level of variability common to retrospective reviews that limits the findings of our study. However, in the setting of metastatic disease, true standardization is incredibly difficult. The lesions themselves differ in size, pathologic grade, chemosensitivity and radiosensitivity, among other factors. The relative size and multicenter nature of our investigation mitigate these limitations, but we recommend future, prospective, multicenter investigation to obtain numbers large enough to further define optimal treatment.

Second, our study does not incorporate functional outcome measures. Due to the mortality rates reported and those expected for the remaining patients since their last follow-up, we did not think that a significant number of patients would be alive to report outcome measures. We recommend the inclusion of functional outcome scores such as the ASES or TESS in future investigations.

Third, the sample sizes were unbalanced between the two groups, and the nail group was small. This limits the power of our study. This again highlights the benefit of multicentered investigation.

Fourth, our cost analysis does not utilize actual OR costs. Given the significant intraoperative variability from case to case that is unrelated to implant cost—prolonged intubation or extubation, use of a foley, nerve block placement, recovery room delays to name a few—the authors thought this would confound any differences observed in cost. Similarly, surgeon cost was immaterial. The current procedural terminology (CPT) code is the same for prophylactic fixation as would have been billed for patients without a displaced fracture. For displaced pathologic fractures, the relative value unit (RVU) difference between plate fixation (CPT 24515) and nail fixation (CPT 24516) is only 0.07 according to the 2021 Centers for Medicare & Medicaid Services (CMS) guidelines, i.e., a difference of only $3.50 assuming $50/RVU. Overall, the authors selected the variables thought to most directly reflect the cost contributions from the implant choice itself.

Fifth, our cost analysis does not incorporate the difference in reoperation rate between the two groups. We recommend a study dedicated solely to cost analysis to allow for incorporation of variations in pricing between institutions, post-operative length of stay, the cost of reoperation and the cost of complications.

Conclusions

IMN for pathologic humeral shaft fractures was faster, had less blood loss, was less likely to require revision and was less expensive when the amount of OR time saved was included. However, the ORIF group had larger tumors and less expensive implant costs. The data did not demonstrate a difference in complication or local recurrence rates. These results represent those of two academic medical institutions, with both rural and urban populations across multiple sources of metastatic disease. The authors believe these results are applicable to patients similar to the ones included in this investigation.

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