Research Article

Prophylactic Versus Postfracture Stabilization for Metastatic Lesions of the Long Bones: A Comparison of 30-day Postoperative Outcomes

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Abstract

Introduction: The goals of orthopaedic treatment for most patients with osseous metastases are to control pain, maintain function, and maximize quality of life and time at home. The aim of this study was to determine differences in 30-day postoperative morbidity and mortality between patients who underwent prophylactic versus postfracture stabilization for metastatic lesions of long bones.

Methods: The American College of Surgeons National Surgical Quality Improvement Program database was queried for patients who underwent prophylactic fixation (n = 461) or postfracture stabilization (n = 856) for pathologic fractures because of metastatic lesions of long bones from 2006 to 2016. The groups were compared with respect to several potential confounders using Student t, Kruskal-Wallis, and χ^2 tests. Logistic and Poisson regression models (inclusion threshold of $P < 0.1$) were used to assess the associations of functional status with outcomes. The alpha level was set at 0.05.

Results: Prophylactic fixation was associated with a lower risk of major medical complications (odds ratio = 0.64; 95% confidence interval [CI], 0.45 to 0.93; $P = 0.02$), discharge to a care facility rather than home (odds ratio = 0.48; 95% CI, 0.36 to 0.63; $P < 0.01$), and lower risk of a longer hospital stay (incidence risk ratio = 0.86; 95% CI, 0.74 to 0.96; $P = 0.01$) compared with postfracture stabilization. No significant difference was found in the risk of unplanned revision surgery or 30-day postoperative mortality between the two groups.

Conclusion: Although prevention of pathologic fractures caused by metastatic disease may not always be possible, patients who underwent prophylactic stabilization had a lower risk of major complications within 30 days postoperatively and shorter hospital stays compared with patients who underwent postfracture stabilization.

Level of Evidence: Level IV, retrospective cohort

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Ethics approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

J Am Acad Orthop Surg 2019;27: e709-e716

DOI: 10.5435/JAAOS-D-18-00345

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Patients who sustain a pathologic fracture caused by osseous metastatic disease have poor long-term outcomes.[1-4] This phenomenon may be explained partially by the dissemination of malignant cells after pathologic fractures, as well as the functional impairment and immobility associated with the pain caused by such fractures. Such findings suggest a possible role for prophylactic fixation in decreasing complications and improving survival rates in this patient population. However, little

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research exists with respect to outcomes between patients with metastatic disease of the long bones who undergo prophylactic versus postfracture stabilization.[1,5-7] Research challenges include small sample sizes, as well as ethical concerns regarding prospective interventional studies in this setting.

Few studies have reported improved survival rates in patients who underwent prophylactic versus postfracture stabilization for metastatic disease of the long bones, and differences in short-term outcomes are unclear.[5,7] Given the importance of short-term outcomes, such as complications and duration of hospital stay, for patients' well-being and for health care resource utilization, a direct comparison between these two patient groups is needed. Despite their inherent limitations, large databases such as the American College of Surgeons' National Surgical Quality Improvement Program (NSQIP) database are well equipped for this investigation,[8] given that a sound algorithm for patient identification can be identified.

Our aims were to compare the following outcomes in patients with metastatic disease of the long bones who underwent prophylactic versus postfracture stabilization of pathologic fractures excluding arthroplasty: 30-day postoperative major medical complications, 30-day mortality, total duration of hospital stay, nonroutine discharge, and 30-day postoperative revision surgeries.

Methods

Our study used deidentified patient information and did not require institutional review board approval.

Database

This is a retrospective cohort study using NSQIP data from 2006 to 2016. NSQIP data are collected prospectively and include preoperative risk factors, surgical procedures, and 30-day postoperative complications. After undergoing appropriate training, "surgical clinical reviewers" capture data through various methods (eg, medical record review, telephone, and letters). The NSQIP has been shown to have a 95% success rate in data capture and 95% interrater reliability in all variables.[9]

Rationale and Patient Selection

We queried the NSQIP (orthopaedic surgery) database to identify patients with a principal diagnosis of "neoplastic disease" using *International Classification of Diseases, Ninth Revision* (*ICD-9*)[10] codes 140x to 239x and *ICD-10* codes C00x to D49x. This cohort was then queried using the following Current Procedural Terminology (CPT)[11] codes to define the two groups as prophylactic fixation (eg, 23491, 24498, 27187, 27495, and 27745) or treatment of a pathologic fracture (eg, humerus: 23615, 24515, 24516, 24545, 24546, 24575, and 24579; femur: 27244, 27245, 27269, 27506, 27507, 27511, 27513, 27514, and 27235; and tibia: 27535, 27756, 27758, and 27759) (Figure 1, Appendix, Supplemental Digital Content 1, http://links.lww.com/JAAOS/A303). Only patients with a principal diagnosis of "pathologic fracture" (*ICD-9* code 733.1 or *ICD-10* code M84.45) who had concomitant disseminated cancer, underwent radiation therapy, or were treated with chemotherapy (NSQIP variables) were included. This method inherently excludes patients undergoing prophylactic fixation or open treatment for a fracture caused by osteoporosis, infection, or trauma. Although arthroplasty may be used for treatment of impending or postfracture stabilization, we excluded patients whose osseous metastases were treated with arthroplasty because the *ICD* and CPT codes available in the NSQIP database limited accurate identification of patients appropriate for inclusion.

Data Points and Outcomes

Preoperative patient factors analyzed were age, sex, body mass index (BMI), comorbidities, current smoking status, and the American Society of Anesthesiologists (ASA) physical status classification system score. Our outcomes of interest were the following: (1) major medical complications within 30 days postoperatively, which was defined as having at least one of the following events: cardiac arrest, death, mechanical ventilation for more than 48 hours, myocardial infarction, pneumonia, pulmonary embolism, sepsis, septic shock, stroke, or unplanned reintubation; (2) mortality within 30 days postoperatively; (3) duration of hospital stay (from the day of admission to the day of discharge, with postoperative day 1 considered the first day); (4) nonroutine discharge, which was defined as being discharged to a facility rather than home, such as an acute or long-term rehabilitation facility, hospice care, or skilled nursing facility (1,119 patients [85%] had complete information on discharge status and were included in this analysis); and (5)

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revision surgery within 30 days postoperatively, which included a return to the operating room at the hospital where the index procedure was performed or at an outside hospital (1,037 patients [79%] had complete information on revision surgery).

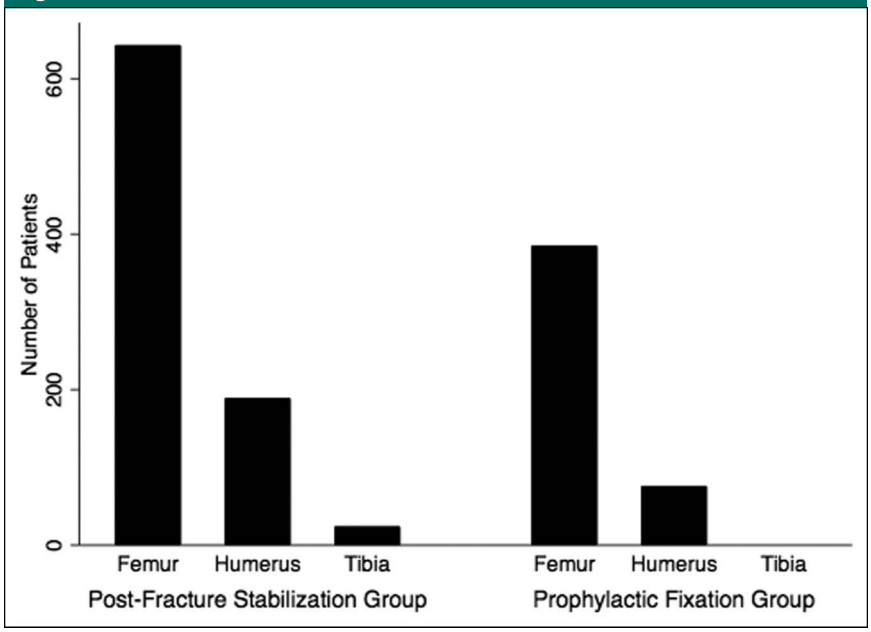
Statistical Analysis

To identify potential confounders, we compared the prophylactic fixation and postfracture stabilization groups with respect to several baseline patient characteristics. Student *t* tests or Kruskal-Wallis tests were used for continuous variables, and χ^2 tests were used for categoric variables. Univariate analysis of outcomes was performed similarly. Multivariable logistic regression results with $P < 0.1$ on univariate analysis were used to compare the two groups with respect to major complications, revision surgery, duration of hospital stay, and discharge status. Discharge status, major medical complication, and revision surgery were treated as binary outcomes, and the results of multivariate logistic regression analysis were reported as odds ratios (ORs) with 95% confidence intervals (CIs). Because of the highly skewed nature of the duration of hospital stay, we used Poisson regression analysis and reported results as incidence risk ratios with 95% CIs. Multicollinearity between the covariates was assessed using the variance inflation factor. A mean variance inflation factor of less than 10 for each model was considered acceptable. Robust estimates of the standard error were used in all regression analyses. Statistical analyses were performed using Stata, version 15, software (StataCorp LP). Significance was assigned at $P < 0.05$.

Patient Sample

Overall, 1,416 patients met the initial inclusion criteria, of whom 1,317 patients (93%) had complete data on preoperative and surgical factors and were included in our analysis. Among those, 461 patients (35%) were in the prophylactic stabilization group. The mean (±SD) age of the study population was 65 ± 13 years, and 744 patients (56%) were women. The mean BMI was 28 ± 6.7 kg/m^2, and 272 patients (21%) were current smokers. Most patients had an ASA classification of III (n = 837; 64%), which is representative of patients with metastatic disease. The most common comorbidities were hypertension (n = 688; 52%) and diabetes mellitus (n = 221; 17%). In total, 1,142 patients (87%) had widely disseminated cancer (Table 1).

Figure 1



Graph showing the distribution of lesions by site among patients who underwent prophylactic fixation (n = 461) or postfracture stabilization (n = 856) for pathologic fractures because of metastatic neoplastic lesions of long bones from 2006 to 2016 per the American College of Surgeons' National Surgical Quality Improvement Program database.

Comparison of the Two Groups

Patients in the postfracture group were older (mean age, 66 ± 13 versus 63 ± 14 years; $P < 0.01$) and had a slightly lower BMI (27 ± 6.6 versus 28 ± 7.0 kg/m^2; $P = 0.05$) compared with those in the prophylactic group. The distributions of women and current smokers were similar between the groups ($P > 0.05$), as was the distribution of the ASA class (P = 0.24). Of the comorbidities assessed, only disseminated cancer was significantly different, with patients in the postfracture group being more likely to have a diagnosis of disseminated cancer (90%) compared with those in the prophylactic group (80%) ($P < 0.01$). The surgical time was similar between the groups (P = 0.89) (Table 1).

Results

Univariate Analysis

On univariate analysis, four end points showed a significant difference between impending and completed pathologic fractures. The proportion of patients who experienced a major

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Table 1

Baseline Patient Characteristics and Surgical Factors of 1,317 Patients With Metastatic Neoplasms to the Long Bones Who Underwent Prophylactic Fixation of Impending Pathologic Fracture Versus Open Fracture Fixation for Completed Fracture From 2006 to 2016, American College of Surgeons' National Surgical Quality Improvement Program Database

Variable	Prophylactic Fixation Group (*n* = 461), *n* (%)	Postfracture Fixation Group (*n* = 856), *n* (%)	*P* Value
Age (y)	63 ± 14[a]	66 ± 13[a]	<0.01
Female sex	260 (56)	484 (57)	0.96
Body mass index (kg/m^2)	28 ± 7.0[a]	27 ± 6.6[a]	0.05
ASA class			
I	3 (0.7)	3 (0.4)	0.24
II	76 (16)	120 (14)	—
III	299 (65)	538 (63)	—
IV	82 (18)	193 (23)	—
V	1 (0.2)	1 (0.1)	—
Comorbidities			
Ascites	3 (0.7)	9 (1.1)	0.47
Bleeding disorder	40 (8.7)	84 (9.8)	0.50
Chronic steroid use	73 (16)	130 (15)	0.76
Congestive heart failure	5 (1.1)	9 (1.1)	0.95
COPD	37 (8.0)	78 (9.1)	0.50
Current smoking	97 (21)	175 (20)	0.80
Diabetes mellitus	73 (16)	148 (17)	0.50
Dialysis	3 (0.7)	13 (1.5)	0.17
Hypertension	228 (49)	460 (54)	0.14
Renal failure	0 (0.0)	1 (0.1)	0.46
Disseminated cancer	371 (80)	772 (90)	<0.01
Surgical factors			
Surgical time (min)	96 ± 50[a]	96 ± 54[a]	0.89
Preoperative transfusion	30 (6.5)	52 (6.1)	0.76

ASA = American Society of Anesthesiologists, COPD = chronic obstructive pulmonary disease
[a] Data presented as mean ± SD.

medical complication within the 30-day postoperative period was larger in the postfracture group (16%) compared with the prophylactic group (9.8%) ($P < 0.01$). The postfracture group had a significantly larger proportion of patients who died within 30 days of the procedure (10%) compared with the prophylactic group (6.1%) ($P = 0.01$). In addition, patients in the postfracture group had a significantly longer mean hospital stay (8.2 ± 9.0 days) compared with those in the prophylactic group (6.9 ± 8.1 days) ($P < 0.01$). In total, 318 patients (44%) in the postfracture group were discharged to a facility rather than home compared with 99 patients (25%) in the prophylactic group ($P < 0.01$). The two groups had similar rates of 30-day revision surgery ($P = 0.08$) (Table 2).

Multivariate Analysis

On the basis of the results of the univariate analysis, we included age, BMI, and disseminated cancer as covariates in the multivariable regression analysis; only three end points remained statistically significant. Using the fracture group as reference, prophylactic stabilization was associated with lower odds of major medical complications (OR = 0.64; 95% CI, 0.45 to 0.92; $P = 0.02$) and discharge to a care facility rather than home (OR = 0.48; 95% CI, 0.36 to 0.63; $P < 0.01$). Prophylactic stabilization was associated with a lower risk of a longer hospital stay (incidence risk ratio = 0.86; 95% CI, 0.74 to 0.96; $P = 0.01$). No significant differences were found in the odds of revision surgery (OR = 0.42; 95% CI, 0.16 to 1.13; $P = 0.09$) (Table 3) or 30-day postoperative mortality (OR = 0.65; 95% CI, 0.42 to 1.01; $P = 0.057$) between the two groups.

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Table 2

Univariate Comparison of Outcomes Between Patients With Metastatic Neoplasms to the Long Bones Who Underwent Prophylactic Fixation of Impending Pathologic Fracture Versus Open Fracture Fixation for Completed Fracture From 2006 to 2016, American College of Surgeons' National Surgical Quality Improvement Program Database

Variable	Prophylactic Fixation Group (*n* = 461), *n* (%)	Postfracture Fixation Group (*n* = 856), *n* (%)	*P* Value
Duration of hospital stay (d)	6.9 ± 8.1[a]	8.2 ± 9.0[a]	<0.01
Discharge to a facility rather than home[b]	99 (25)	318 (44)	<0.01
Unplanned revision surgery[c]	5 (1.4)	21 (3.1)	0.08
Any major complication	45 (9.8)	135 (16)	<0.01
Cardiac arrest	0 (0)	4 (0.5)	0.14
Cerebrovascular accident	2 (0.4)	5 (0.6)	0.72
Death	28 (6.1)	88 (10)	0.01
Myocardial infarction	2 (0.4)	4 (0.5)	0.93
Pneumonia	11 (2.4)	28 (3.3)	0.37
Pulmonary embolism	4 (0.9)	16 (1.9)	0.16
Reintubation	3 (0.7)	9 (1.1)	0.47
Sepsis	3 (0.7)	13 (1.5)	0.17
Septic shock	2 (0.4)	4 (0.5)	0.93
Ventilator dependence	1 (0.2)	5 (0.6)	0.35

[a] Data presented as mean ± SD.
[b] Data on disposition status were available for 1,119 patients.
[c] Data on unplanned revision surgery were available for 1,037 patients.

Table 3

Multivariate Odds Outcomes for Patients Who Underwent Prophylactic Fixation of Impending Pathologic Fracture Versus Open Fracture Fixation for Completed Fracture (Referent)

Outcomes	Unadjusted OR (95% CI)	*P* Value	Adjusted OR (95% CI)	*P* Value
Major medical complication	0.58 (0.40–0.83)	<0.01	0.64 (0.45–0.93)	0.02
Unplanned revision surgery	0.43 (0.16–1.15)	0.09	0.42 (0.16–1.13)	0.09
Discharge to a facility rather than home	0.44 (0.33–0.57)	<0.01	0.48 (0.36–0.63)	<0.01
Duration of hospital stay	0.84[a] (0.77–0.96)	<0.01	0.86[a] (0.74–0.96)	0.01

CI = confidence interval, OR = odds ratio
[a] Data presented as incidence risk ratio (95% CI).

Discussion

Patients who underwent surgical stabilization for a pathologic fracture secondary to metastatic disease had worse short-term postoperative outcomes compared with those who underwent prophylactic stabilization. Postfracture stabilization was associated with a higher risk of postoperative complications, being discharged to a care facility rather than home, and longer hospital stays.

Although pathologic long bone fractures are a clear indication for surgery in most patients, identifying lesions at risk of fracture can be challenging. Harrington's[12] traditional definition of an impending pathologic fracture includes cortical bone destruction of at least 50%, a lesion of 2.5 cm or greater in the proximal part of the femur, a pathologic avulsion fracture of the lesser trochanter, or persistent pain despite radiation therapy. The Mirels[13] scoring system bases the risk of fracture associated with metastatic bone lesions on the following parameters: site, radiographic appearance, size, and related pain. A score of 9 or greater is associated with an increased risk of fracture within 6 months after radiation and is commonly viewed as an indication

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for fixation, whereas a score of 8 is viewed as borderline. The utility of the Mirels score, however, is often conceptual rather than as a strict numerical decision-making tool. Although relatively simple, the Mirels score relies on pain, which is subjective and not present in all patients with impending pathologic fractures.[14] Fidler[15] reported that 9 of 19 patients who underwent prophylactic fixation for impending fracture experienced no pain preoperatively. Howard et al[16] described interobserver and intraobserver variability in Mirels scores. They found that, overall, considerable intraobserver variability was noted, and at lower Mirels scores, interobserver variability was larger. A study by Van der Linden et al[17] of 102 patients with femoral metastases found the positive predictive value of the Mirels score to be 14%, highlighting the underlying weakness of fracture risk prediction. For this reason, several assessment tools have been developed to predict fracture risk more accurately.

Nazarian et al[18] developed an assessment tool using CT-based rigidity analysis for estimating the risk of impending fracture. CT-based rigidity analysis has a higher sensitivity (100% versus 67%), specificity (61% versus 48%), and higher positive predictive value (17% versus 9.8%) than Mirels score for predicting impending femoral pathologic fractures.[19] Although CT-based rigidity analysis is potentially more accurate than the Mirels score in identifying impending fractures, it is not available in all clinical settings.[20] Another assessment tool is finite-element analysis. Finite-element models assess bone geometry and quality, as well as distribution of bone mineral density using CT scans.[21] Although several studies have shown that finite-element models have superior accuracy in predicting pathologic fractures compared with clinical expert prediction, data were based on a small number of anatomic specimens.[22-25] Furthermore, finite-element models require sophisticated software for image processing, which is not available in all clinical settings.[26] In consideration of the potential risks, benefits, and alternatives to prophylactic stabilization for an impending pathologic fracture, a deeper understanding of the risk of postoperative complications and surgical outcomes associated with each treatment option is important.

Among patients with metastatic bone disease, those with a completed pathologic fracture have a greater risk of death (1-year survival rates of 22% to 40%) than those without a pathologic fracture.[27,28] Therefore, a better understanding of the 30-day postoperative mortality risk in this patient population may be warranted. Studies have reported a higher risk of death in patients undergoing stabilization for pathologic fractures versus those treated prophylactically.[5,7] Arvinius et al[5] found that among 65 patients with metastases to the femur, a significantly smaller proportion of patients treated prophylactically had immediate postoperative death (5%) compared with patients treated for completed fractures (11%) (P = 0.041). Furthermore, the authors estimated the mean survival time to be significantly longer in patients treated prophylactically (14 months) compared with those treated after fracture (11 months) (P = 0.032). Our results are consistent with these findings, showing a higher rate of short-term postoperative complications in the postfracture group compared with the prophylactic group. This phenomenon suggests the possibility that higher complication rates contribute to mortality risk in the postfracture stabilization group. Another potential explanation for this observation may be the larger physiologic insult caused by a fracture, followed by fixation compared with prophylactic fixation alone.[7] However, despite similar baseline characteristics between the two groups, we cannot rule out physiologic differences between these populations to explain some of the difference in outcomes.

Discharge disposition is important for patients with cancer, particularly for those who may be terminally ill. Our results show that patients who sustained a pathologic fracture were significantly more likely to be discharged to a care facility rather than home. Ward et al[29] found that among patients treated with reconstruction-type nails for metastatic bone disease, patients who sustained pathologic fracture were significantly less likely to be discharged home (45%) compared with patients treated prophylactically (74%). These findings may have psychosocial implications because patients typically wish to spend more time at home with their families and less time in hospitals or rehabilitation centers. This phenomenon may also reflect an increased use of inpatient hospice care among patients treated for pathologic fracture. Other considerations are the implications for health care resource management, utilization, and cost. Blank et al[30] estimated the mean total cost of prophylactic stabilization to be nearly $25,000 less than fixation of a completed fracture (P = 0.036).

Our results show that patients who underwent postfracture stabilization had longer hospital stays compared with those who underwent prophylactic stabilization. Longer hospital stays after postfracture stabilization have been reported in previous studies. Blank et al[30] found that the average hospital stay after postfracture stabilization was significantly longer (8 days) than that after prophylactic fracture stabilization (4 days) (P = 0.001). Similarly, average

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hospital stay was significantly longer among patients who underwent postfracture stabilization in series by Arvinius et al[5] (16 versus 8.2 days; P = 0.012) and Ward et al[29] (11 versus 6 days; P = 0.001). This phenomenon may be partially explained by a higher complication rate in the postfracture group. However, it is possible that the difference in the duration of hospital stay may be attributed to inpatient admission before surgery for some patients with completed pathologic fractures.

The current analysis excluded patients whose osseous metastases were treated with arthroplasty. We know that the proximal femur is a common site for osseous metastasis. Furthermore, some data support better long-term implant survival for some proximal femoral lesions treated with arthroplasty compared with intramedullary nail or plate-and-screw constructs.[31,32] However, given the available *ICD* and CPT codes in the NSQIP database, the ability to capture all appropriate patients for inclusion was limited in those who underwent arthroplasty. This phenomenon is attributable to the lack of specific CPT codes dedicated to arthroplasty for treatment/palliation of metastatic disease as opposed to arthroplasty for other orthopaedic conditions. Therefore, the number of patients included in the analysis is limited by the exclusion of patients treated with arthroplasty.

Our study has several limitations. The NSQIP database does not offer granular surgical or pathologic details, such as the type of implant used, or radiographic measurements, such as the fracture size or displacement. However, such factors are more likely to affect longer-term survival or mechanical outcomes rather than short-term postoperative outcomes and medical complications. Our findings depend on accurate coding and reporting, and although the NSQIP database reports a high rate of successful data capture, pathologic fractures and impending pathologic fractures requiring stabilization are still likely underreported. Therefore, certain outcomes (such as complications) are generalizable only with that limitation considered. In addition, prophylactic fixation of impending pathologic fracture was determined by using CPT codes. However, no information was available on the criteria used to diagnose impending pathologic fractures. Because of the lack of strict guidelines for diagnosing impending pathologic fracture, the diagnosis depends on the clinical judgment of the surgeon, which may introduce interobserver bias. Furthermore, because treatment with arthroplasty was excluded, our results cannot be generalized to patients with impending or completed pathologic fractures treated with arthroplasty. Finally, retrospective studies are subject to selection bias; however, ethical considerations preclude researchers from performing higher-quality interventional studies in this patient population. Despite these limitations, our study offers important insights into the short-term outcomes of patients treated with two options that orthopaedic oncologists may encounter frequently.

Conclusion

The aim of this study was to determine the difference in 30-day postoperative morbidity and mortality in patients treated with prophylactic fixation versus postfracture stabilization for completed pathologic fractures in patients with metastatic bone disease. Patients who underwent treatment for completed fractures had a higher risk of postoperative complications, were more likely to be discharged to a facility rather than home, and had longer postoperative hospital stays.

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