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Key variables in managing femoral pathological fractures and search for objective parameters for decision-making

Key variables in managing femoral pathological fracture

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Abstract

Aim: Bone invasion in advanced cancers represents later stages and requires individualized treatment strategies based on patient related variables. The objective of this study is to ascertain the significance of age, location, serum levels of Ca, urea, albumin, and accordingly calculated MEP (Metastatic Early Prognostic) score, in planning the treatment of femoral impending and pathological fractures. The secondary aim was to compare complication rates between osteosynthesis and prosthetic replacement and to place this analysis on the time axis.

Material and Methods: This retrospective cohort was conducted at a tertiary care hospital with a dedicated orthopedic oncology team. The database search was performed for surgically treated femoral pathological/impending fractures between 2010 and 2020. Demographic data, mortality, fracture location, levels of Ca, urea, albumin, and follow-up X-rays were collected. Surgical procedures were categorized as prosthetic replacement or osteosynthesis for comparative analysis. Complications and the necessity of secondary interventions were noted accordingly.

Results: A total of 109 patients met the inclusion criteria. The average follow-up period was 9.1 months, with a mean survival time of 12.96 months. High serum urea levels, low albumin levels, high calcium levels were associated with increased one-year mortality. Osteosynthesis procedures had a higher need for secondary surgeries compared to prosthetic reconstruction. A threshold of one year has shown to be the critical limit before mechanical complications related to osteosynthesis occur.

Discussion: Secondary surgery rates were higher in the fixation group with survival exceeding one year, suggesting a greater consideration for prosthetic replacement in that group. Markers such as urea, albumin, and calcium levels can provide insights into mortality rates when evaluating surgical treatment options.

Keywords

Metastatic Bone Disease, Bone Metastasis, Orthopaedic Oncology, MEP Score, Mortality, Life Expectancy

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Introduction

Bone invasion is the third most prevalent site of metastatic disease, following the lung and liver. While it is worth noting that axial skeletal involvement is generally more prevalent than appendicular skeletal involvement, discussions regarding the treatment of pathological fractures often focus on the lower extremities since most of the patients requiring surgical intervention are in this group. Pelvis and proximal femur are the most frequently involved localizations after the spine. [1,2].

Femoral lesions often result in pathological fractures, significantly impacting the patient's ability to mobilize and increasing mortality rates. Despite the prevalence of bone metastases, comprehensive knowledge regarding the most appropriate treatment methods remains incomplete. To enhance the treatment process for patients with bone metastases, it is crucial to identify objective data that can guide physicians in making informed decisions and optimizing treatment options at critical junctures [3].

The incidence of metastatic bone lesions requiring treatment in patients with malignancy is increasing due to advances in early diagnosis and effective treatment modalities, as well as the implementation of new treatment and screening programs. Managing these fractures necessitates approaches that go beyond general trauma principles and require more individualized strategies. Factors such as the life expectancy, age, tumor type, extent or number of metastatic diseases, fracture location, and overall patient condition play a crucial role in determining the treatment strategy [4].

The primary objective of the study was to identify the survival rate and its correlation with the various variables (Ca, Albumin, Urea) and MEP (Metastatic Early Prognostic) score in patients who underwent surgery for pathologic fractures due to metastatic femoral lesions. The secondary objective was to compare complication rates among cases undergoing different surgical procedures, and to analyze these results over an axis of time (osteosynthesis versus prosthetic replacement).

Material and Methods

This retrospective cohort study was conducted at a tertiary care hospital that boasts a dedicated multidisciplinary orthopedic oncology team with a longstanding tradition spanning over thirty years. Ethical approval from the institutional board was obtained (21-10T/4).

The database search was conducted regarding femoral pathological fractures or impending fractures treated surgically between January 2010 - December 2020. The search was conducted through operation records so that patients that did not receive the surgical intervention were not included in the scope of this study. Exclusion criteria were cases with pathological fractures related to primary bone lesions, pathological fractures that are not related to the femur, and those with insufficient medical records. Data of patients who did not attend their follow-up visits in the 1st month, despite no mortality, were deemed insufficient and therefore excluded from the study. A total of 220 patients were identified initially. After exclusion, a total of 109 cases were eligible for final analysis.

Demographic variables, such as age, gender, side, follow-up period, and the time between operation and exitus, were collected. Data on mortality were also obtained from the national health database. Additionally, the original tumor sites were noted for patients with confirmed pathological diagnoses. Lesions were classified into two main groups according to their location: proximal, and diaphyseal femoral fractures. Fractures occurring between the subtrochanteric region and the distal diaphyseal metaphyseal region were categorized as diaphyseal fractures. Furthermore, cases were labeled as impending fractures or pathological fractures.

Serum urea, albumin, calcium, and corrected calcium values from the latest preoperative control were obtained. The Metastatic Early Prognostic (MEP) scores were calculated accordingly using these parameters as previously described [5]. Assigned scores regarding MEP score were as follows: Albumin below 35g/l received one point, urea level above 46.8 mmol/l received one point and corrected calcium above 10.2 mg/dl received two points.

Due to the specific nature of this population, strict follow-up protocols could not be implemented. However, efforts were made to obtain postoperative follow-up X-rays at the 2nd, 6th, 12th, and 24th weeks. These X-rays were evaluated for lysis, fracture healing, implant failure, tumor progression, and periprosthetic fracture. Overall complications, secondary surgeries and surgery-related complications were also recorded. Among the performed surgeries, proximal femur replacement, osteosynthesis with plate, cephalomedullary nailing, and intramedullary nailing with or without cement application were noted. The analyses were conducted by comparing two groups: prosthetic replacement and osteosynthesis.

Efforts have been made to describe mortality risk, specifically focusing on one-year mortality rates. Independent risk factors assigned for analysis included age, serum calcium (Ca) levels, albumin levels, and urea levels. Regression analyses were employed in this group, utilizing data from 62 eligible patients who had a complete dataset for studied variables.

Statistical Analysis

The statistical software package SPSS 25.0 (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.) was utilized for the analysis. A significance level of 0.05 was chosen for determining the statistical significance. Variables were compared using the Kaplan-Meier method in univariate analyses. For multivariate analysis, assessment was performed using Cox-regression analysis. The Pearson's chi-square test was employed to examine the relationship between categorical variables. Continuous variables underwent ROC analysis, with the appropriate cutoff value was determined based on the Youden index.

Ethical Approval

Ethics Committee approval for the study was obtained.

Results

The average follow-up period was 9.1 months, ranging from 1 to 125 months. The mean survival time was determined to be 12.96 months with a 95% confidence interval.

Regarding the demographic characteristics, the mean age was 63 (+/-5.5) years, there were a total of 56 female and 53 male patients. Among them, 29 had breast cancer metastases, 21 had metastases of hematological malignancies, 20 had metastases of lung cancer, and 16 had metastases from urinary system malignancies. The distribution of femoral fractures based on location was as follows: 27 cases of neck/trochanteric fractures, 54 cases of subtrochanteric fractures, and 28 cases of diaphyseal fractures. Among these patients, 16 underwent surgery due to impending fractures, while 93 patients underwent surgery for pathological fractures (Figure 1).

The survival times of patients who underwent planned surgery for impending lesions, were found to be longer compared to those who underwent surgery after the fracture. However, due to heterogeneity between the groups, this difference could not be statistically demonstrated (p:0,252).

Analyzing the cases in terms of prognostic biochemical markers, it was observed that preoperatively obtained high serum urea levels (p:0.005), low albumin levels (p:0.002) and high serum corrected calcium levels (p:0.053) were significantly associated with one-year mortality. Based on individuals with a MEP (Metastatic Early Prognostic) score of 0, the risk for those with a score of 2 was found to be 2.3 times higher (p: 0.035). However, for individuals with a score of 1, the risk was 1.7 times higher, but this difference was not statistically significant (p: 0.159).

There were no significant difference in mortality rates between two groups (osteosynthesis (n=44, 40.3%) and prosthetic reconstruction (n=65, 59.6%)), the need for secondary surgical intervention was significantly higher in the osteosynthesis group (p:0.003). There was no difference between the groups in terms of the diagnosis of the primary tumor.

Out of a total of 109 patients, 39 patients died within the first year. Among the 70 remaining survivors, 20 cases had a follow-up period exceeding 2 years. Among the 39 patients who died in the first year, 12 had metastases of lung carcinoma, 12 had metastases from other carcinomas, 4 had hematological malignancies, 7 had breast malignancies, and 3 had prostate malignancies. Out of these 39 patients, 23 received prosthetic implants, while 16 received osteosynthesis. Among the 39 patients, 22 deaths occurred within the first 4 months, and 28 deaths occurred within the first 6 months.

Secondary interventions were required for 9 out of 16 patients who survived beyond 1 year and had received osteosynthesis initially. Secondary surgeries were required within the timeframe of 1 to 4 years. Among the patients who received osteosynthesis, 56% of cases with a lifetime exceeding one year required secondary surgical intervention. Among the patients who required secondary surgery, 6 had breast cancer, 3 had renal cell carcinoma (RCC), and 1 had lung cancer. Cases with complications are listed in Table 1.

Among the 62 patients included in the regression analysis, the mean age was 65.98 years with a standard deviation of 12.3. Out of these patients, 29 (46.8%) were female, and 33 (53.2%) were male. Among the cases, 52 were classified as actual fractures, while 10 were categorized as impending fractures. Osteosynthesis was performed on 27 (43.5%) patients, whereas 35 (56.5%) patients underwent prosthetic replacement (Figure 2).

The MEP scores are categorized into four groups: 0, 1, 2, and

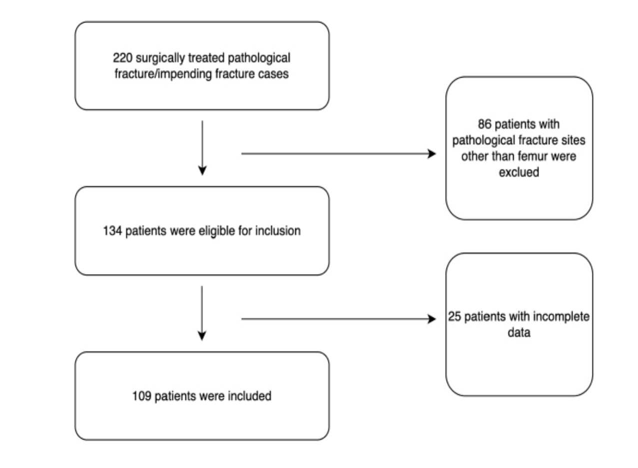

Figure 1. Flow-chart for patient inclusion process.

Figure 2. Failed osteosynthesis for subtrochanteric fracture, salvaged with prosthetic replacement.

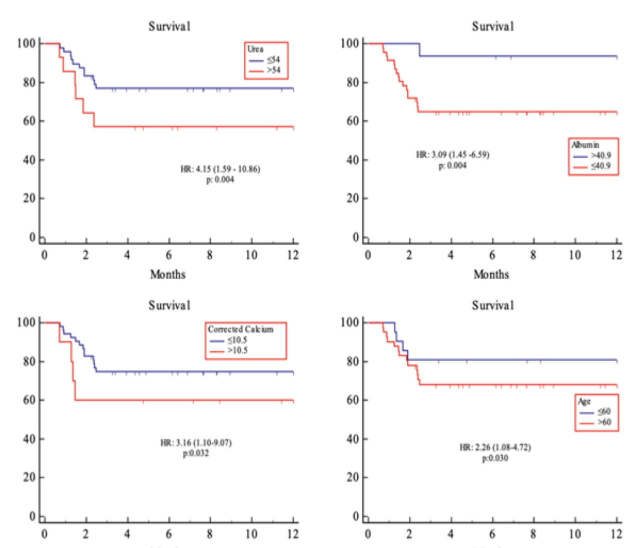

Figure 3. Univariate analysis for one-year mortality.

Table 1. Cases with complications.

Age	Gender	Primary tumor	Location	First surgery	Time to complication	Complication	Treatment
56	M	Renal cell ca	Subtrochanteric	Plate osteosynthesis	12 months	Implant failure	Plate osteosynthesis
63	F	Breast	Diaphyseal	Plate osteosynthesis	11 months	Implant failure	Plate osteosynthesis> intercalary prosthesis> infection> spacer> total femur replacement
48	M	Renal cell ca	Subtrochanteric	Dynamic hip screw	12 months	Implant failure	Plate osteosynthesis
55	F	Plasmacytoma	Subtrochanteric	Proximal femoral nail	48 months	Non-union, bone resorption	Proximal femoral replacement
55	F	Breast	Subtrochanteric	Intramedullary nail	12 months	Non-union	Proximal femoral replacement
45	M	Renal cell ca	Subtrochanteric	DHS with cement application	28 months	Tumor progression- implant failure	Proximal femoral replacement
57	F	Uroepithelial	Diaphyseal	Intramedullary nail	1 month	Tumor progression, lymph-oedema	Radiotherapy
73	F	Lung	Diaphyseal	Intramedullary nail	6 months	Tumor progression	Radiotherapy
53	F	Breast	Diaphyseal	Plate osteosynthesis	48 months	Peri-implant fracture, tumor progression	Distal femoral replacement
66	F	Breast	Diaphyseal	Plate with cement application	13 months	Implant failure	Double plate osteosynthesis
56	M	Lung	Diaphyseal	Plate osteosynthesis	1 month	Implant failure after fall	Plate osteosynthesis
64	M	Lung	Subtrochanteric	Proximal femoral replacement	1 month	Dislocation	Closed reduction
54	F	Breast	Diaphyseal	Intramedullary nailing	24 months	Non-union	Intramedullary nail revision
44	M	Hematologic malignancy-Plasmacytoma	Subtrochanteric	Proximal femoral replacement	13 months	Implant failure- stem fracture	Proximal femoral replacement

Table 2. Evaluation of different patterns of the MEP score utilization.

MEP Groups		3-month mortality			One-year Mortality		
		HR	95% CI	p	HR	95% CI	p
(0) (1) (2) (3-4)	1 vs 0	1.37	0.51-4.82	0.736	2.63	1.-1-6.83	0.47
	2 vs 0	2.5	0.51-8.22		2.92	1.02-8.35	0.45
	>2 vs 0	1.62	0.31-8.49		3.9	0.98-9.77	0.054
(0-1) (2-3-4)		1.57	0.53-4.61	0.413	0.014	0.89-4.54	0.091
(0) (1) (2-3-4)	1 vs 0	1.57	0.51-4.82	0.556	2.59	0.096-6.13	0.042
	2-3-4 vs 0	1.88	0.58.6.13		2.97	1.24-7.12	
(0) (1-2-3-4)		1.66	0.63-4.36	0.305	2.50	1.22-5.16	0.013

Table 3. Mortality predictors at one year. Multivariate analyses.

	Univariate Model			Multivariate Model¥		
	HR	95% CI	p	OR	95% CI	p
Age (>60/ <60)	2.26	1.08-4.72	0.030			
Urea (>54 /<54)	4.15	1.59-10.86	0.004	2.267	1.051-4.890	0.037
Albumin (g/L) (≤40.9 >40.9)	3.9	1.45-6.59	0.004	4.145	1.219-14.096	0.023
Corrected Calcium (mg/L) (>10.5/≤10.5)	3.16	1.10-9.07	0.032	2.561	1.130-5.807	0.024

¥Cox Regression - Method Backward Stepwise (Wald), *Statistically significant

3-4, as originally defined. However, when compared according to original categorization, it was observed that the MEP score did not provide a reliable prediction for 3-month and 1-year mortality (p:0.736 p:0.47). To predict mortality based on the MEP score, the grouping was modified as follows: 0-1 were combined into one category, and 2-3-4 were considered as a separate category. Unfortunately, no meaningful data could be derived from this grouping either (p:0.413, p:0.091). Again, the grouping was modified as 0 and 1 and 2-3-4. Regarding this grouping technique, one-year mortality prediction was significant (p:0.042). Again, when grouped with 0 vs. 1-2-3-4, 1-year mortality risk prediction was successful (p:0.013), while 3 months mortality prediction was not achieved (p: 0.305). (Table 2).

We could not find any ground for the utilization of MEP Score as its current form for pathological fractures and moved on with establishing threshold values for calcium, albumin, and urea in our study population. We then analyzed the impact of these variables on mortality prediction, using the Youden index, we identified a threshold value of 40.9 (Sen: 90 CI:73.5-97.9 Spe: 59.4 CI:40.6-23.7) for serum albumin, 54 (Sen: 36,7 CI:19.9-56.1 Spe:90.6 CI: 75-98) for urea, and 10.5 (Sen:26.67 CI:12.3-45.9 Spe:93.75 CI:79.2-99.2) for corrected calcium and threshold of age of 60 years (Sen:80 CI:61.4-92.3 Spe:46.98 CI: 29.1-65.3). The values exhibited high concordance with the internationally recognized standard ranges.

Further analysis was conducted after categorical classification, using these threshold values. The Kaplan-Meier survival analysis on one-year mortality risk revealed that age, serum albumin, corrected calcium urea level were independent risk factors. Cox-regression analysis after the univariate model revealed that elevated urea and corrected calcium levels and lowered albumin levels independently emerged as risk factors for one-year mortality (Table 3) (Figure 3).

Discussion

One of the major findings of this study was the importance of considering the patient's one-year survival expectation as a primary consideration in determining the treatment approach, particularly regarding the ongoing debate of osteosynthesis versus prosthetic replacement. Factors such as the patient's anticipated life expectancy, overall health condition, and fracture location along with the soft tissue involvement emerged as the primary determinants for selecting the appropriate surgical treatment. The primary goal is to accomplish all these objectives simultaneously, without necessitating any secondary interventions, which could be a big insult to patient's well-being. The aim is to provide better function, palliate pain, and improve or protect the quality of life [6]. In cases with a short survival expectation, minimally invasive surgeries or radiation therapy may be preferred. However, predicting mortality risk is not an easy task and additional objective parameters could be useful in the decision-making process [7].

The MEP score was described by Downie et al. and has been proven to predict risk of early mortality rate after admission with metastatic proximal femoral lesion. In this retrospective cohort study, we have tried to test the adaptability of this scoring system in the decision-making process for metastatic bone disease of the femur. Although we have failed to demonstrate the strong correlation with MEP scores and mortality rates, all three examined markers (Ca, Urea, Albumin) were found to have predictive value over 1-year mortality risk. Although the MEP scoring system was identified as a mortality predictor in proximal femoral metastatic diseases, our findings indicate that these markers can also be utilized as a one-year mortality predictor, which can strongly influence treatment decision.

The correlation between serum markers and mortality has been proposed in various fields of medicine, suggesting that it generally reflects the overall condition of the patient and impairments should be addressed prior to interventions when feasible [8,9]. However, the significance and importance of these variables in relation to pathological fracture treatment have not been fully elucidated. Despite the utilization of diverse classification and scoring systems and various clinical or laboratory variables to enhance the management of pathological fractures, the underlying principle remains consistent: personalized treatment [10–12]. Therefore, it appears reasonable to incorporate these serum variables into the decision-making process, along with consideration of the critical one-year survival threshold.

When compared with prosthetic replacement, minimally invasive osteosynthesis has a number of advantages. This technique has been shown to be characterized by shorter operation time, less blood loss, and smaller surgical incisions [13]. However, it is important to consider the potential requirements for postoperative weight-bearing restrictions and the risk of complications in cases where the fracture fails to achieve bony union as disadvantages of this approach [14]. On the other hand, prosthetic replacement has some other advantages. These include removal of tumor tissue, which reduces the tumor burden, facilitates early mobilization, and allows for follow-up protocol without the need for fracture union. However, it is important to note that prosthetic replacement has certain drawbacks that should be avoided in these already vulnerable patients, such as longer operation time, greater blood loss, and wider surgical incisions [15]. Overall, reported treatment failure rates in prosthetic treatment are lower with increased implant longevity [16,17].

It is important to note that some of these issues related to prosthetic replacement could be prevented through effective preoperative preparation and the use of proper surgical techniques, thus bringing this option forth. At our center, when dealing with femoral pathological fractures, our primary approach involves employing prosthetic replacement in most of cases. This approach is based on our center's longstanding tradition and extensive experience with femoral proximal resection prostheses. In contrast to the literature, which has reported prosthetic dislocations in up to 20% of cases, our series showed a significantly lower rate of only 3% [18]. This outcome can be attributed to our mastered technique employed during femur proximal resection prostheses. This technique involves performing an osteotomy of the trochanter major and subsequently securing it back to the prosthesis while securing the iliopsoas muscle on the prosthesis.

Patients treated with plate osteosynthesis in our series were selected with certain characteristics such as relatively intact bone stock, relatively long life expectancy, and sufficient bone stock. However, despite these careful patient selection considerations, we observed a high incidence of complications among patients treated with plating techniques. As a result, our clinical practice has gradually shifted towards two alternative options: intramedullary nailing and prosthetic replacement. In line with our clinical experience, the current literature also emphasizes the superiority of intramedullary nail applications as an effective method of osteosynthesis in pathological fractures, particularly for cases involving the proximal and midshaft regions of the femur. We have adopted this approach in parallel with our own observations, except in cases of distal diaphyseal fractures, where alternative strategies may be more suitable [19].

Bone invasion frequently indicates advanced stages of various cancers, as the median survival rates for several malignancies are less than one year. For instance, the overall median survival following a diagnosis of bone invasion is approximately 6 months for lung cancer, and 6-9 months for bladder cancer. However, certain cancers exhibit relatively longer median survival rates, such as 12 months for renal cell carcinoma, 12-53 months for prostate cancer, and 19-25 months for breast cancer. Notably, thyroid cancers can achieve median survival rates as high as 48 months following bone invasion [20].

Limitations

This study had several limitations, primarily stemming from its retrospective design and high rate of missing data. Additionally, evolving treatment and follow-up protocols over time in this patient group could have biased our results to some extent. Another limitation is the inability to present a standardized surgical protocol due to the significant inter-patient variables and the requirement for personalized treatment approaches. Furthermore, an additional limitation is the absence of consideration for non-surgical adjuvant treatments received by the patients as a variable. This oversight could be regarded as a limitation in terms of comprehensively assessing the impact of different treatment modalities.

Conclusion

The need for secondary surgery is considerably higher in cases that have undergone osteosynthesis for pathological femur fractures, particularly among individuals with a life expectancy exceeding one year. In such cases, mprosthetic replacement should be kept in mind as treatment of choice.

Furthermore, when evaluating surgical treatment options based on anticipated survival time, certain biochemical markers such as urea and albumin and corrected calcium levels may provide insights into one-year mortality rates. These variables can be employed either individually or as a component of a comprehensive approach to aid in this assessment. We find it unlikely that the MEP scoring system, in its current form, is practically adaptable for clinical use.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and human rights statement

All procedures performed in this study 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.

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Conflict of interest

The authors declare no conflict of interest.

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