Safety and Efficacy of Single-Stage versus Two-Stage Intramedullary Nailing for Synchronous Impending or Pathologic Fractures of Bilateral Femur from Metastatic Disease and Multiple Myeloma

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INTRODUCTION: Although intramedullary nail (IMN) fixation is often utilized for surgical treatment of patients with metastatic bone disease of the femur, there is no consensus on the timing of IMN in patients who present with synchronous bilateral disease: single stage (SS) vs two stage (TS). Although TS was preferred historically due to theoretical increased risks with SS, few recent studies have supported SS, but those studies lacked direct detailed comparison. As such, the optimal surgical timing (SS vs. TS) still remains unclear. Therefore, the objective of this study was to investigate the safety and efficacy of staging (SS vs. TS) of IMN as a treatment for synchronous bilateral impending or pathologic femur fractures secondary to metastatic disease and multiple myeloma.

METHODS: This study was a retrospective comparative analysis of a prospectively maintained Institutional Review Board approved single-surgeon database in an urban academic setting. Adult patients (≥18 years old) with synchronous bilateral femur disease secondary to multiple myeloma and/or metastasis undergoing bilateral femoral SS or TS (same admission) IMN were included. Extracted variables included patient demographics and details of the surgical procedure (e.g., age, gender, primary tumor, fracture type, laterality, cement augmentation, venting), measures of patient safety (complications, survivorship, mortality, blood loss and transfusion, implant failure), and measures of efficacy (postoperative length of stay [LOS], total time in operating room), time from surgery to initiation of rehabilitation and adjuvant therapy, patient costs estimated by 2022 US $3025.00 per day of total hospital LOS, 2022 US $46.04 per minute of OR time, and 2022 US $5579.18 per day of ICU stay). Descriptive and statistical analyses, including 2-sided Fisher's exact and Student's t-tests to compare categorical and continuous variables, respectively, and Kaplan-Meier estimates of patient survivorship were performed in R Statistical Software using a p-value of <0.05 as threshold for statistical significance.

RESULTS: Between May 2011 and June 2024, 130 femoral IMNs were inserted in a total of 65 patients for synchronous impending or pathologic fractures of bilateral femora for metastatic disease or multiple myeloma. 15 and 50 patients had bilateral femoral IMN in a SS and TS approach, respectively. There were no significant differences between the SS and TS cohorts in demographics and procedural variables (all, $p > 0.05$). Kaplan-Meier median survivorship was determined to be 233 days for the overall patient population and there was no significant difference between SS and TS. There was no intraoperative mortality in both cohorts, and no significant difference in same admission mortality (SS: 0 [0.00%] vs. TS: 3 [6.00%]; $p = 1.00$). There was a total of 36 complications (all medical), and there was no difference between the cohorts (SS: 10 [35.71%] vs. TS: 27 [27.55%]; $p = 0.788$). There were 8 intraoperative complications, all of which were medical (SS: 4 [18.18%] vs. TS: 4 [4.26%]; $p = 0.041$), and included hypotension requiring pressors, heart rate derangements, and hemodynamic instability requiring ICU admission. A greater proportion of SS patients were admitted to the ICU as a result of preoperative planning due to the nature of their procedure and overall medical condition; however, the difference between cohorts was not significant (SS: 2/15 [13.33%] vs. TS: 5/50 [10.00%]; $p = 0.658$). There were 28 postoperative complications with no differences between cohorts (SS: 6 [21.43%] vs. TS: 22 [22.45%]; $p = 0.783$). With our relatively short follow-up time, there was no surgical complication in either group including infection, reoperation, and implant failure. There were no differences in the rates of total ($p = 0.154$) or intraoperative ($p = 1.00$) complications between the first versus second nail for TS procedure. There were no significant differences between SS and TS IMN in intraoperative, 24-hour postoperative, and total admission blood transfusions, and estimated blood loss (all, $p > 0.05$). Postoperative LOS was significantly shorter following SS procedures compared to TS procedures ($p < 0.001$). Mean OR time was significantly shorter in the SS cohort compared to combined procedure time in the TS cohort ($p = 0.003$). Mean time from surgery to initiation of weightbearing was significantly shorter following SS procedures ($p < 0.001$). Mean total estimated patient cost consisting of the sum of LOS, OR time, and ICU stay was significantly less in the SS cohort compared to the TS cohort ($p<0.001$). There was no significant difference between the SS and TS cohorts regarding mean time from surgery to initiation of definitive adjuvant therapy ($p=0.066$).

DISCUSSION AND CONCLUSION: This study supports a SS approach in select patients with synchronous bilateral impending or pathologic femur fractures. While there was a higher rate of intraoperative complications in the SS compared to TS cohort, other measures of patient safety (postoperative complications, survivorship and mortality, and blood loss and transfusion) were all comparable. In terms of efficacy, SS had the advantage of a shorter LOS and total OR time, time from surgery to initiation of weightbearing, and total estimated patient cost. Furthermore, time to adjuvant therapy approached statistical significance. This is the only comprehensive analysis of its kind that addresses many limitations in the sparse existing literature on this topic. Nevertheless, higher-powered studies may further elucidate the proposed benefits of SS bilateral femoral IMN in these patients.