

Intramedullary Nailing Versus Sliding Hip Screw Intertrochanteric Evaluation: The INSITE Trial

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Purpose: The optimal device for surgical fixation of intertrochanteric hip fractures remains under debate. The INSITE trial is an international, randomized controlled trial (RCT) comparing patient-important outcomes between ambulatory patients treated with intramedullary nails (IMNs) versus sliding hip screws (SHSs) in those with intertrochanteric hip fractures.

Methods: We randomized 850 ambulatory patients 18 years and older with low-energy intertrochanteric (AO type 31-A1 or 31-A2) fractures requiring internal fixation across 25 international sites to treatment with either IMN (n = 423), or SHS (n = 427). Our primary outcome was health-related quality of life (HRQOL) via the EuroQol-5 Dimensions (EQ-5D) at 1 year post-fracture. Secondary outcomes included revision and fracture healing rates, adverse events, as well as the Parker mobility score and Harris Hip Score. We used independent t tests to compare unadjusted continuous outcomes between groups. We used a generalized linear mixed model to compare the EQ-5D between groups while adjusting for age, fracture stability, prefracture living and functional status, and American Society of Anesthesiologists (ASA) class. We included random effects to account for clustering at the treatment center level. We used Fisher exact and χ^2 tests to compare the rates of categorical outcomes between groups. All fractures were assessed as healed at 1-year follow-up, therefore we compared fracture healing between groups at 13 weeks. We tested for interaction terms to determine if the treatment effect was modified by stable versus unstable fractures, or a fracture on the contralateral side. Patients who died between baseline and 1 year were included in the primary analysis and given a health utility value of zero at 1 year. We performed a sensitivity analysis to determine if excluding patients who died within 1 year affected the results.

Results: A total of 704 patients (83% follow-up, 346 treated with IMN, 358 treated with SHS) were included in the primary analysis, 83 of whom died within 1 year. We found no significant differences between groups for the EQ-5D, both including (P = 0.42), and excluding patients who died within 1 year (P = 0.14). Further, after adjusting for relevant covariables, we found no difference in EQ-5D between groups (P = 0.99). In the SHS group, 16 patients (4.9%) underwent revision surgery within 1 year, compared to 10 patients (3.2%) in the IMN group. This difference was not significant (P = 0.26). In the SHS group, 84.5% of fractures were assessed as healed at 13 weeks, compared to 89.6% in the IMN group (P = 0.09). There were no between-group differences for any adverse events, Parker mobility scores, or Harris Hip Scores at 1 year (P >0.05). No significant interactions were observed for fracture stability or previous fracture and treatment group.

Conclusion: We found no significant differences in HRQOL, revision surgeries, fracture healing rate, or adverse events between ambulatory patients treated with IMN or SHS for trochanteric hip fractures.