

OTA Humanitarian Scholar Presentation

SIGN Intramedullary Nailing Improves Early Postoperative Quality of Life and Function as Compared to Skeletal Traction for Management of Femoral Shaft Fractures in Malawi

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Purpose: Femoral shaft fractures cause significant morbidity in low- and middle-income countries (LMICs). Intramedullary (IM) nailing, the gold standard treatment in developed countries, remains underutilized in LMICs such as Malawi given limited expertise and availability of fluoroscopy. Although technology permitting image- unassisted IM nailing is now available in LMICs, skeletal traction remains the standard of care. This prospective study aimed to compare postoperative quality of life, functional outcomes, and radiographic healing between patients treated with SIGN (Surgical Implant Generation Network) IM nailing (IMN) and skeletal traction (ST) in Malawi.

Methods: Adults with femoral shaft fractures (AO/OTA 32A-C) were enrolled from March 2016 to July 2018 at 2 central and 3 district hospitals in Malawi. Patients were managed by image-unassisted IMN (SIGN) or ST, as determined by their treatment team. Baseline demographics, injury, and treatment characteristics were recorded on enrollment. Patients were followed up at 6 weeks and 3, 6, and 12 months postoperatively. Quality of life was assessed via EuroQol-5 Dimensions (EQ-5D), functional status via Short Musculoskeletal Function Assessment (SMFA), and radiographic healing by mRUST (modified radiographic union in tibial fractures) score.

Results: Of 270 enrolled patients (IMN 111, ST 159), there were no differences in baseline characteristics ($P>0.05$). EQ-5D-assessed quality of life (minimum clinically important difference [MCID] = 0.10) was decreased in patients treated with skeletal traction versus IMN at 6 weeks (0.28 vs 0.49, $P<0.001$) and 3 months (0.63 vs 0.72, $P = 0.016$) postoperatively but comparable at 6 months (0.81 vs 0.82, $P = 0.70$). Functional status as assessed by SMFA Function and Bothersome indices (MCID = 4) was likewise worse in patients treated with traction versus IMN at 6 weeks (Function 52.2 vs 41.6, $P<0.001$; Bothersome 50.4 vs 39.6, $P<0.001$) and 3 months (Function 35.5 vs 27.5, $P = 0.001$; Bothersome 33.1 vs 26.0, $P = 0.01$). SMFA Function but not Bothersome index was worse in skeletal traction patients at 6 months (Function 21.5 vs 15.2, $P = 0.01$; Bothersome 19.2 vs 15.0, $P = 0.16$). There was no difference between cohorts in mRUST score at any time point ($P>0.05$). There was no difference in the rate of reoperation (IMN: 1.4% vs ST: 1.8%, $P = 0.77$), nonunion (IMN: 0.4% vs ST: 1.4%, $P = 0.21$), or leg-length discrepancy (IMN: 36% vs ST: 38%, $P = 0.66$) between groups at 6 months.

Conclusion: Quality of life and function were significantly improved in the early postoperative period in patients with femoral shaft fracture treated with image-unassisted IMN, as compared to ST. By final follow-up, there was no difference in quality of life or function between groups, and radiographic healing was similar.

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.