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Review Article

MANAGEMENT OF DISTAL TIBIAL METAPHYSEAL FRACTURES WITH THE SIGN INTRAMEDULLARY NAIL IN NEPAL: A RETROSPECTIVE STUDY

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ABSTRACT

Objectives: To evaluate the effectiveness of the Surgical Implant Generation Network (SIGN) intramedullary (IM) nail in distal tibial metaphyseal fractures.

Design: Retrospective Case Series.

Setting: Trauma centers (National trauma center, Nepal) from 2017 to 2019. Patient/Participants: One hundred sixty patients with 162 distal tibial metaphyseal fractures (AO/OTA 43-A).

Intervention: SIGN IM nailing was performed using hand reaming and without the use of an image intensifier.

Main Outcome Measurements: The primary outcome measures were the rate of union and complications. The secondary outcome measures were the effect of open fractures on outcomes, effectiveness and safety of open reduction of closed fractures, and risk factors for the development of malalignment and possible solutions.

Results: The average age of patients was 35.3 years. Seventy-nine percent were male. Sixty percent of the fractures were closed. The mean time to surgery was 4.1 days. Fracture union occurred in 97.3% of fractures with an average time to union of 105 days. Open reduction of closed fractures was performed in 51 fractures. Nonunion occurred in 3 patients (1.8%). Acceptable alignment (,5 degrees deformity) was found in 134 fractures (83%). Infection occurred in 14 patients (8.6%). Revision surgery was required in 10 fractures (6.2%).

Conclusions: In developing settings, distal metaphyseal tibial fractures can be managed successfully with the SIGN IM nail. There is an increased risk for complications (P = 0.001) and infection (P = 0.0004) in open fractures. Open reduction of closed distal tibia fractures is safe and effective. Malalignment can be improved with fibula stabilization but indications remain unclear. For surgeons interested in international mission work, the SIGN IM nail is an effective tool in managing distal tibial fractures.

Key Words: tibial fracture, metaphyseal fracture, rigid locking nails

INTRODUCTION

Trauma is a global epidemic that has largely been neglected by international health experts until recent years[1, 2]. Most traumatic injuries, including musculoskeletal trauma, occur in low- and middle-income countries.[2-5] Most patients in the developing world are young men who are frequently the financial providers for their households, often living on less than $2–$3 per day. Extended time off work negatively impacts the patient's household forcing them further into poverty, often too deep to recover[6]. Tibial fractures are among the most commonly seen extremity injuries in the developing world. Most of these fractures are high-energy injuries, resulting from road traffic accidents, and may result in significant morbidity for the patient if not treated appropriately. In addition to the direct consequences encountered by the patient, the indirect consequences of such injuries are often equally devastating too[2]. Fractures involving the distal metaphysis are particularly difficult to manage and controversial in terms of proper treatment. The distal metaphysis does not offer the same stability and cortical contact as the diaphysis to an intramedullary (IM) implant, thus increasing the challenge of controlling the distal segment. Non operative treatment– including casting, functional bracing, etc—is the mainstay of treatment throughout the developing world and has produced good results[7]. Advocates of surgical fixation cite better control of alignment, earlier range of motion and mobility, quicker time to union, and earlier return to work as the benefits of surgical intervention[8, 9].IM fixation is the standard of care for diaphyseal fractures and multiple articles have reported excellent results in distal metaphyseal fractures as well. The Surgical Implant Generation Network (SIGN) IM nail was developed for the treatment of long bone fractures in the developing nations. The SIGN IM nail has been placed in over 130,000 patients worldwide and used extensively in disaster relief settings[10]. Our purpose was to retrospectively review the use of the SIGN IM nail in distal third extraarticular tibial fractures at developing country, a study that, to our knowledge, has not been performed, and compare these results with the published literature from the developed nations.

PATIENTS AND METHODS

Setting:

This study was performed at National trauma center, Nepal is a 426 bed mission hospital, and Bir Hospital was developed into the National Academy of Medical Sciences (NAMS) on its glorious 114 years in 2002. This was another landmark achievement in the fields of medical education and health services which has provided great optimism and opportunities for the doctors working under the Ministry of Health to teach and to be taught and is a teaching hospital with multiple residency programs. It serves as a referral center for much of Nepal. National Academy of Medical Sciences (NAMS) have been selected because it is located as developing country referral hospital and all are staffed by full-time orthopaedic surgeons who are very familiar with the SIGN IM nail and have consistently shown excellent results.

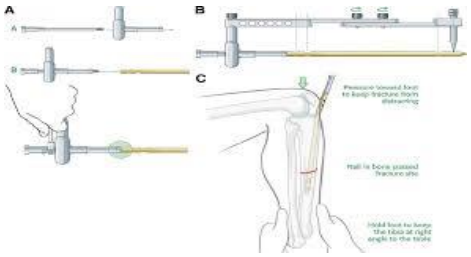

Figure 1: showing setup of SIGN IM.

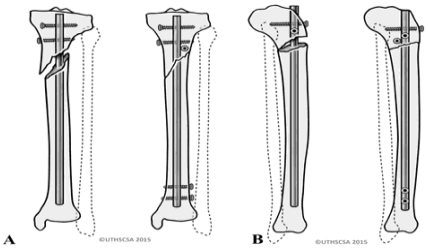

Figure 2: showing reduction of fracture by IM.

Study Design:

National Academy of Medical Sciences (NAMS) admitted 160 patients between September 2017 and April 2019 with acute, distal, extra articular metaphyseal tibial fractures treated with the SIGN IM nails. We included fractures distal to the isthmus of the diaphysis and extending through the flare of the distal tibia (AO/OTA 43A)[11].Only patients with at least 1 postoperative visit were included in the study. Patients who presented with pathologic fractures, non-unions, malunions, or delayed treatment for more than 4 weeks were excluded. All patients were treated with the SIGN IM nail under the supervision of the senior authors (Orthopaedic surgeon). A retrospective review of the prospectively collected data on the SIGN online surgical database was performed[12]. Data collected included patient demographics, time to surgery, fracture type, presence of fibular fracture and fibular fixation, type of fracture reduction, implant size, and number of interlocking screws. During follow-up visits, the data for the length of follow-up, radiographic appearance of alignment and fracture union, time to union, knee's range of motion, presence of infection, signs of hardware failure, and need for revision surgery were collected. The study was approved by National Academy of Medical Sciences (NAMS).

Postoperative Follow-up:

Postoperative follow-up is a well-known obstacle in performing quality orthopaedic research in developing countries. Follow-up evaluation is often cost-prohibitive for patients [who live on a few dollars (US) per day] to miss work, arrange transportation over sometimes large distances to the hospital, and pay for the clinic visit and radiographs. Patients who are experiencing no complications have an even greater disincentive to return to the clinic, especially when they see no need to be reevaluated. On discharge, patients' contact information was obtained, but many patients were either unable or unwilling to respond to the attempts made by the hospital staff to reach them. It was all too common to have patients present for 1 visit to have sutures removed and then never return.

Data Analysis:

Our primary outcome measures were the rate of union and complications. The secondary outcome measures were the effect of open fractures on the outcomes, the effectiveness and safety of open reduction of closed fractures, and risk factors for the development of malalignment and possible solutions. We assessed several variables with statistical analysis including the relationship of open fractures to complication rate, infection, malalignment, and need for revision surgery. We also looked at the association between fibular

fixation and malalignment and whether open reduction of closed fractures posed an increased risk. All analyses were performed with the Fischer exact test to obtain 2-tailed P values.

Operative Technique:

The SIGN IM nail (SIGN Fracture Care International, Richland, WA) is a solid, stainless-steel, and IM implant designed for poor-resource settings without power instrumentation, fluoroscopy, or fracture tables. The same nail is used to treat fractures of tibia, femur (antegrade and retrograde), and humerus. The standard SIGN surgical technique for tibia was used in all patients[13] .

Postoperative Protocol:

Early mobilization and range of motion were encouraged in all the patients, although the weight-bearing status varied with surgeon preference. The fracture type, stability of fracture fixation, and other associated factors (patient's weight, medical comorbidities, etc) all influenced whether a patient was allowed for full, partial, or non-weight bearing. Postoperative radiographs were obtained on either the day of surgery or postoperative day one. Patients stayed in the hospital for 2–3 days, depending on their progress with therapy. Postoperative dressings were removed 2–3 days after surgery. On discharge, the patients were given either a walker or crutches and instructed to follow-up in 10–14 days. During follow-up visits, radiographs were reviewed for fracture union.

RESULTS

Study Population The study population consisted of 160 patients with 162 fractures. The characteristics of the patients and fractures are detailed. The average age of patients was 35.3, 13.1 years (range, 16–90) with 127 male patients (79%). Road traffic accidents were the most common cause of injury. The mean time of surgery was 4.1 days= 5 (range, 0–27). Forty percent (65 fractures) were open fractures, with Gustilo/ Anderson type 2 being the most common type encountered (n = 33)[14]. One hundred fifty-one fractures (93%) had an associated fibula fracture. Closed reductions were performed in 50 fractures (31%) while 112 fractures were open reduced (69%). Fifty-one closed fractures underwent an open reduction. Fluoroscopy was only available at one of the institutions and was used in 7 patients (4%). Twelve patients (7.4%) underwent fibular fixation in addition to their IM nail. Fracture Union and Postoperative Follow-up Fracture union (defined as bridging callus on radiographs and ambulation without pain) was found in 109 patients who had sufficient follow-up. The overall rate of fracture union was 97.3%. Time to union was 105 days (range, 29–605 days). Three patients, all with open fractures at presentation, developed nonunions (defined as no healing at or more than 6 months). An additional 50 patients did not have sufficient follow-up (ie, less than 3 months) to determine fracture union. The average number of follow-up visits per patient was 1.98 with an average length of total follow-up per patient of 134 days (range, 7–968 days).

Fracture Alignment Acceptable alignment, defined as a deformity of less than 5 degrees in any plane, was found in 83% (n = 134) of the fractures. A total of 37 deformities .5 degrees were found in 28 patients. Coronal plane malalignment composed most of the deformities (70%) with ten patients having deformities .10 degrees. Valgus was the most common deformity noted overall, although varus was more common in those patients

with an intact fibula or proximal fibular shaft fracture. Although open fractures produced more malalignment than closed fractures, it was not statistically significant (P = 0.056). Tibial and fibular fractures at or near the same level were associated with a higher tendency toward malalignment, particularly valgus malalignment. Of the 28 patients with malalignment, 20 had a fibular fracture at the same level or within 3 cm of the level of the tibial fracture. Nineteen patients had coronal plane malalignment, with valgus deformities in 71%. Of note, ten fractures with a fibular fracture at the same level as the tibia fracture, or within 3 cm, underwent surgical fixation of their fibula and none experienced coronal malalignment, although one patient experienced an 8 degrees recurvatum deformity.

Complications and Revision Surgery Overall, 54 complications occurred in 44 patients (27%). Complications are discussed further in Table 2. Nonunion occurred in 3 patients, all of whom had presented with open fractures. Infection occurred in 14 patients (8.7%), with 9 deep and 5 superficial infections. Malalignment .5 degrees occurred in 28 patients. One patient, who suffered an ipsilateral patella fracture at the time of injury, experienced knee stiffness postoperatively, although he regained full motion 18 months after surgery. The remainder of patients regained full knee range of motion. One patient had an intraoperative fracture at the site of the distal locking screw and was placed in a splint postoperatively, but healed uneventfully. One patient experienced a persistent postoperative foot drop. Hardware failure occurred in 6 patients. Revision surgery was required for 10 patients (6.1%). Although most of fractures in this study was closed, open fractures accounted for 63% of the total complications encountered. Overall, 27 open fractures experienced complications, whereas 17 closed fractures had complications. Eighty-six percent (12/14) of infections occurred in patients who had presented with open fractures. Open fractures showed a statistically significant increased risk for developing complications compared to closed fractures (P = 0.001) along with increased risk of infection (P = 0.0004).

DISCUSSION

IM nailing of distal metaphyseal tibial fractures is reported in the literature as a very successful surgery, although the indications for its use remain unclear[15]. Tibial fractures involving the metaphyseal region are difficult to treat because they lack the inherent stability provided by the cortex of the diaphysis and rely heavily on fixation with interlocking screws. Previous studies have reviewed the treatment of distal tibia fractures with both IM nails and plate fixation and found good results with both[16, 17].However, treatment of these fractures has not been previously reported with the SIGN IM nail in developing countries that currently use it. Our study reviewed 162 distal tibial fractures treated with the SIGN IM nail and showed excellent results comparable with studies from more developed nations regarding union rates, rates of malalignment, incidence of infection, and need for revision surgery. Complications in distal tibial fractures treated with IM fixation are common, and difficulties with fracture union and need for additional surgeries to attain union, are well reported in the literature[8, 9, 16, 18]. Overall in our study, 44 patients (27%) experienced a complication. Although some of these complications are to be expected in developing settings, others are very similar to studies from developed nations. A systematic review of 1125 distal tibial fractures treated with IM rods in

developed nations showed a nonunion rate of 5.5% and a revision surgery rate of 16.4%[18]. Our study reported 3 non unions (1.8%) and ten fractures (6.2%) that required additional surgeries. Most of the complications (63%) occurred in patients who presented with open fractures. Open reduction of closed fractures is very common in developing countries because fluoroscopy is often unavailable. Only one hospital included in this study had access to a fluoroscopy machine. However, no standardized technique of open reduction exists. Surgeon tendencies also vary between hospitals, with some surgeons openly reducing all closed fractures, while the other hospitals surgeons rarely doing so, with excellent results seen in both. We report 51 (53%) closed fractures that underwent an open reduction, although these patients account for only 11% (n = 5) of the patients who experienced complications. Open reduction of closed fractures showed no statistically significant increased risks compared with those closed fractures that underwent closed reduction (P = 0.059). Thus, open reduction of closed fractures can be performed safely in developing settings without an increased complication rate. Infection is a difficult problem in distal tibial fractures. Young et al23 reviewed over 17,000 tibial fractures in developing countries that were treated with the SIGN IM nail and reported an infection rate of 6.9%. A systematic review of distal tibial fractures treated with IM nails from developed nations showed an overall infection rate of 4.3%[18, 19]. In our study, infection occurred in 14 patients (8.6%). Open fractures were a statistically significant risk factor for the development of infection (P = 0.0004) and accounted for 86% (n = 12) of infections in our study. Nine infections were deep and required many additional surgeries including implant removal, debridements, antibiotic spacer placement, external fixation, iliac crest bone grafting, and exchange nailing. Angular malalignment is a known risk with IM nailing of distal metaphyseal tibial fractures. Significant morbidity, such as increased ankle pain and accelerated degenerative changes, has been reported with as little as 5 degrees of malalignment of the distal tibia[20]. Maintaining control of the distal fragment is difficult because the metaphysis consists of mostly cancellous bone and lacks the cortical contact of the diaphysis. Thus, the stability of fracture fixation is dependent on good purchase with the distal interlocking screws. Techniques such as blocking screws and fibula fixation have been reported in the literature as ways to reduce malalignment[20]. In our study, malalignment .5 degrees in any plane was found in 17.3% (n = 28) of patients, a result very comparable to the 16.2% malunion rate reported in a recent systematic review .Valgus was the most common deformity overall, although varus deformities were more commonly seen in patients with an intact fibula or very proximal fibular shaft fractures[21]. Risk factors for malalignment include either technical error or other mechanical forces acting on the surgical construct[22]. According to the literature, open fractures are a risk factor for malalignment and in our study, they accounted for 57% (n = 16) of fractures with malalignment, although not statistically significant (P = 0.056).[16] The level of the fibular fracture may also play a role in malalignment. As reported in the literature, fibular fractures at the same level as tibial fractures have higher tendencies toward malalignment, particularly valgus. In our total of 28 reported fractures with malalignment, 15 (54%) had tibial and fibular fractures at the same level, and an additional 7 fractures had tibial and fibular fractures within 3 cm of one another. Coronal malalignment occurred in 91% (n = 20) with valgus being the most common. Additionally, tibial and fibular fractures at the same level accounted

for 77% of the deformities, which is greater than ten degrees. Early postoperative weight-bearing may also be a risk factor and may contribute to malalignment rates[9]. The role and indications of fibular fixation is a point of disagreement within the literature. Biomechanical studies have shown that an intact fibula and interosseous membrane play a small, although signi ficant, role in bearing-weight sharing, approximately 6.4%–16.7% of the total load.30–32 Cadaver studies have further proven that the stability is improved when the fibula is fixed along with a tibial IM nail.[23] Corroborated this clinically by noting improved fracture alignment and reduction in those patients for whom adjunctive fibular fixation was performed and recommended fibular fixation in unstable distal tibial–fibular fractures. Other studies, however, have shown an increase in the rate of nonunion when the fibula is either intact or stabilized alongside an IM nail, presumably because of reduced compression on the tibia fracture[16]. In our study, 12 patients underwent fibular fixation alongside their SIGN IM nailing—5 with plate fixation and 7 with IM rods—with 10 fractures having tibial and fibulae fractures at the same level. None of these patients experienced coronal malalignment, although one patient had a recurvatum deformity of 8 degrees, and one nonunion occurred. Overall, our numbers are too few to draw substantial conclusions from. Further investigation is required into the exact role of fibular fixation in these fractures. The strengths of this study include a large number of fractures compared with previous studies, and all fractures being fixed with the same type of implant. Although, all have considerable experience in using the SIGN IM nail. Weaknesses of the study include the retrospective nature of the study and its reliance on an online surgical database. Although the data are collected prospectively, our study was a retrospective review of the postoperative follow-up, inherent to developing countries, which is another weakness. Having standardized times for postoperative evaluation would allow more broad conclusions. Postoperative protocols also corroborated this clinically by noting improved fracture alignment and reduction in those patients for whom adjunctive fibular fixation was performed and recommended fibular fixation in unstable distal tibial–fibular fractures. Other studies, however, have shown an increase in the rate of nonunion when the fibula is either intact or stabilized alongside an IM nail, presumably because of reduced compression on the tibia fracture[16]. In our study, 12 patients underwent fibular fixation alongside their SIGN IM nailing—5 with plate fixation and 7 with IM rods—with 10 fractures having tibial and fibulae fractures at the same level. None of these patients experienced coronal malalignment, although one patient had a recurvatum deformity of 8 degrees, and one nonunion occurred. Overall, our numbers are too few to draw substantial conclusions from. Further investigation is required into the exact role of fibular fixation in these fractures. The strengths of this study include a large number of fractures compared with previous studies, and all fractures being fixed with the same type of implant. Although the National Academy of Medical Sciences (NAMS), have considerable experience in using the SIGN IM nail. Weaknesses of the study include the retrospective nature of the study and its reliance on an online surgical database. Although the data are collected prospectively, our study was a retrospective review of the postoperative follow-up, inherent to developing countries, which is another weakness. Having standardized times for postoperative evaluation would allow more broad conclusions. Postoperative protocols also vary between others hospitals and may contribute to some of the complications. In conclusion, in the

developing world, the SIGN IM nail is an effective surgical implant for treating distal metaphyseal tibial fractures with high rates of fracture union, and low rates of nonunion, malalignment, and need for revision surgery. Open fractures are associated with increased rates of complications and infections. Open reduction of closed distal tibial fractures is a safe and varies between others hospitals and may contribute to some of the complications.

CONCLUSION

In the developing world, the SIGN IM nail is an effective surgical implant for treating distal metaphyseal tibial fractures with high rates of fracture union, and low rates of nonunion, malalignment, and need for revision surgery. Open fractures are associated with increased rates of complications and infections. Open reduction of closed distal tibial fractures is a safe and effective technique for managing these fractures. Although its indications remain unclear, Fibular fixation offers promising results in preventing malalignment with a possible risk of nonunion. For those surgeons interested in international missions or disaster relief, the SIGN IM nail is a reliable and effective tool for managing distal tibial fractures in low resource settings. Effective technique for managing these fractures. Although its indications remain unclear, Fibular fixation offers promising results in preventing malalignment with a possible risk of nonunion. For those surgeons interested in international missions or disaster relief, the SIGN IM nail is a reliable and effective tool for managing distal tibial fractures in low resource settings.

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