Analysis of the Stabilization of Gustilo Grade I and II Open Tibia Fractures in the Acute Stage

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ABSTRACT

Introduction: The internal fixation of open leg fractures in the acute stage, that is, within 24 hours of trauma, is guite controversial. The objective of this article is to assess infections associated with acute intramedullary nailing fixation -versus deferred fixationof Gustilo type I and II open fractures. Patients and Methods: A retrospective cohort study was conducted on the acute treatment of patients with open leg fractures admitted to the hospital between 2015 and 2018. The infection rate was analyzed during the first 6 postoperative months after intramedullary nailing, and acute fixation patients were compared against deferred fixation patients. Results: Acute internal fixation with intramedullary nail in patients with open leg fractures does not increase, but rather decreases, the infection rate in the postoperative control. Conclusion: The study supports acute intramedullary nailing in patients with open tibial fractures.

Key words: Acute internal fixation; open fractures; infections; damage control. Level of Evidence: II

Evaluación de la estabilización de fracturas expuestas de pierna grados I y II de Gustillo en la etapa aguda

RESUMEN

Introducción: La fijación interna de las fracturas de pierna expuestas en la etapa aguda, es decir, dentro de las 24 h del trauma es un tema controvertido. El objetivo de este estudio fue evaluar las infecciones asociadas a la colocación de clavos endomedulares en la etapa aguda y a la colocación diferida, en la fijación de fracturas expuestas de pierna grados I y II de Gustillo. Pacientes y Métodos: Se realizó un estudio de cohorte retrospectivo sobre el tratamiento en la etapa aguda de los pacientes que ingresaron en el hospital con fracturas expuestas de pierna entre 2015 y 2018. Se analizó la tasa de infecciones durante los primeros 6 meses después de la cirugía y se comparó la fijación en la etapa aguda con la fijación diferida. Resultados: La fijación interna con clavos endomedulares en la etapa aguda, en pacientes con fracturas expuestas de pierna no aumentó, sino que disminuyó la tasa de infecciones en el control posoperatorio. Conclusión: El estudio avala la colocación de clavos endomedulares en la etapa aguda, en pacientes con fractura de tibia expuestas.

Palabras clave: Fijación interna; etapa aguda; fracturas expuestas; infecciones; control de daños. Nivel de Evidencia: II

INTRODUCTION

The treatment of tibial diaphyseal fractures is of particular interest in daily practice, due to its frequency and its difficult management. Many of these lesions are open, because, on their anteromedial aspect, they have little soft tissue coverage.^{1,2} They are usually the result of high-energy trauma, most often caused by accidents on public spaces.^{3,4} The prognosis is based on the initial degree of displacement of the fracture, bone comminution,^{1,3,5} and the severity of soft tissue injury.^{4,6,7} The complication rate is high and includes infections, soft tissue defects, and delayed union.⁸ Damage to the soft tissue surrounding the bone decreases vascular supply, increasing its

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vulnerability to nonunion and infection.^{1,9} With the aim of reducing the rate of infections, management protocols were developed, which include surgical wound exploration, irrigation with sterile solution, bone stabilization, prophylactic antibiotic therapy, and early soft tissue coverage.^{3,7-10}

Despite the importance of appropriate treatment of exposed tibial fractures, the optimal method of definitive stabilization is unclear.¹¹ Fixation in the acute stage of exposed fractures has numerous beneficial effects, for example, protecting soft tissue from further injury from fracture fragments, improving wound care and healing, promoting early rehabilitation and mobilization, and decreasing the risk of infection.¹² However, concern about infection has led to the traditionally accepted view that immediate internal fixation in open fractures is contraindicated.¹³ Over time, this approach changed, the prognosis of exposed fractures improved with the development of wound care and this gave more freedom to stabilize the bone. Furthermore, studies were published showing the infection rate of fixation in the acute stage of exposed fractures, with controversial results.¹³ Currently, instability of the fracture has been shown to perpetuate infection.¹⁴ To reduce the chances of infection, a stable fixation of the fracture is considered in the acute stage. Among the most common stabilization methods we find external fixators^{8,15}, which are available in most centers that are prepared to receive patients with this type of trauma. External fixators provide stabilization of the fracture, with minimal soft tissue invasion. They require more surgical interventions for the removal of the fixator, and the eventual placement, in one or two stages, of an intramedullary nail. Moreover, in cases in which the external fixator is not considered as the definitive treatment, the procedure for the removal of the fixator is added. In general, studies show that the external fixator has higher rates of adverse events than intramedullary nailing, such Schanz pin infection, loosening, poor patient adherence to treatment and poor union¹⁶⁻¹⁹

IM nails are the treatment of choice for open diaphyseal tibial fractures.^{7,17,18,20} This fixation allows for axial alignment, early weight bearing, and rapid mobilization of the knee and ankle.⁹ But most trauma centers do not have them available for use in the acute stage. The general approach in most open leg fractures consists of admission to the operating room for washing and debridement of the wound, transcalcaneal traction or immobilization with a splint, control of the wound and waiting a reasonable time until improvement of the wound or obtainment of the osteosynthesis material, for the internal stabilization surgery.

In the management of polytraumatized patients, the presence of long bone fractures has been shown to correlate with the development of systemic inflammatory response syndrome and is strongly associated with multiple organ failure, sepsis, length of hospital stay, and mortality.²¹ The concept of "Early Total Care" is based on damage control surgery for early stabilization of fractures in a polytraumatized patient, in order to avoid second hit damage. In 2017, Gasser et al.²² stated that they are in favor of the concept "Early Total Care" in clinically stable patients and advise stabilization with external fixation methods in unstable patients to reduce surgical time and patient aggression, although this is controversial, since, in expert hands, the placement time of an IM nail can be very short and with minimal aggression, depending on the characteristics of the fracture. Since 2015, our hospital has had a bank of intramedullary nails available for acute use.

The objective of this study was to evaluate the infections associated with the placement of IM nail in patients with exposed fractures, during the acute stage, that is, within 24 h of hospital admission.

MATERIALS AND METHODS

A retrospective, database cohort study was conducted in a 3^{rd} level Hospital specialized in trauma care, on acute fixation of 54 patients with exposed tibial fractures. The Traumatology service database was analyzed and it was found that in the period of time from 01/01/2015 to 12/31/2018, 188 patients with leg fractures were admitted, of which 84 were exposed.

In our sample, we included patients with Gustilo grade I and II exposed leg fractures, who had undergone definitive treatment in our hospital (IM nailing). Each group was controlled for the length of hospitalization and a follow-up was conducted during the first 6 months after surgery. The exclusion criteria were: patients with Gustilo III soft tissue deficits, patients who did not undergo the minimum 6-month follow-up, lack of bone maturation, pathological fractures, floating knee. Patients who received an external tutor by decision of the general practitioner were excluded, due to a large deficit in soft tissue coverage, a large comminution of the fracture site, or an associated vascular injury.

Fifty-four patients met these criteria. Polytraumatized patients were evaluated on admission according to the *Advanced Trauma Life Support* (ATLS) protocol and all types of associated injuries were excluded. When they were admitted, the patients with exposed fractures underwent a mechanical debridement of the wounds, they were immobilized with a splint and the corresponding radiographic studies were performed. Fractures were classified according to the system proposed by the *Arbeitsgemeinschaft für Osteosynthesefragen* (AO). The exposure wound was categorized according to Gustilo-Anderson. By protocol of infectious prophylaxis, all patients receive intravenous doses of antibiotics upon admission, before entering the operating room and for one day after surgery—1 g of cephalothin every 6 h in Gustilo grade I exposures. Allergic patients were administered clindamycin and an association of clindamycin plus gentamicin in the case of a grade II Gustilo fracture. All patients were admitted to the operating room for surgical debridement of the wound.

Regarding the definitive treatment, the patients were divided into two groups: group 1, admission to the operating room for the placement of IM nail within 24 h; and group 2, immobilization with transcalcaneal traction or cruropedic splint, and deferred internal fixation, once the wound had evolved well and the general condition of the patient was good. In all patients, the minimal reaming nail placement technique was used, where the reaming is only done to probe the medullary diameter of the tibia and to facilitate insertion.

The medical records, the admissions to the operating room, together with the database of the infection committee were analyzed to evaluate the occurrence of any infectious process related to the surgical site in the first 6 months after surgery. Patient data included sex, age, fracture pattern, comorbidities, complications, and days of hospitalization. Infectious complications were reviewed and divided into superficial and deep. Clinical criteria for superficial infection include increased pain and tenderness at the fracture site, entry of the nail or entry of the locks, episodes of fever or chills, night sweats, erythema in any of the wounds or discharge, or abnormalities of the laboratory parameters: white blood cells, erythrocyte sedimentation or C-reactive protein. The criterion for deep infection was defined as the presence of a positive culture from bone or intramedullary sample collection in a sample taken from a surgical toilet. Upon the suspicion of some type of infectious process, all patients underwent surgical debridement and drainage of collections to rule out a deep infectious process.

The average and absolute frequencies were calculated for the qualitative type variables and descriptive statistics for the quantitative type variables: average and standard deviation, median, minimum and maximum. The Mann - Whitney U test was applied to study whether there were statistically significant differences at 5% in terms of acute IM nailing and length of stay. The data were processed with SPSS v 20.

FINDINGS

Our sample comprised 54 patients with type I and II Gustilo open leg fracture, who received follow-up for 6 months. Forty-five patients were men and 9 were women, the age ranged from 18 to 65 years. Within this group, there were 6 diabetic patients, 10 hypertensive patients, 20 heavy smokers and 35 drug addicts. The fracture patterns were as follows: A1 (9 patients), A2 (3 patients), A3 (22 patients), B1 (3 patients), B2 (6 patients), B3 (2 patients), C1 (4 patients), C2 (2 patients) and C3 (3 patients), according to the AO classification. Regarding the exposure wound, we found that 12 patients had type I exposure wounds according to the Gustilo and Anderson classification, of which 5 belonged to group 1 and 7 to group 2, and 42 patients corresponded to type II, 6 in group 1 and 36 in group 2. Primary closure was performed on all wounds; there were no patients with soft tissue coverage deficits in the study. Patients who did not comply with the relevant controls after treatment (1 in group 1 and 2 in group 2) were excluded. It was analyzed whether the infectious process appeared up to 6 months after surgery. Among the evaluated patients, 10 cases of infectious processes were detected (Figure 1). Group 1 was formed by 12 men and 1 female, with an average age of 38 years and an average hospital stay of 5.7 to 7.7 days (Table 1). There were no cases of infection during the period studied. Group 2 was formed by 33 men and 8 women, with an average age of 50 years and an average hospital stat of 8.9-11.8 days (Table 1, Figure 2). Eight of the 10 patients suffered a deep infection; methicillin-resistant Staphylococcus aureus was isolated in culture from at least two of the three samples, both soft tissue and bone tissue. Two had a superficial infection (Table 2). All patients who suffered an infectious process had a Gustilo grade II exposure wound and belonged to group 2. The IM nail was removed in all patients with deep infection; it was not necessary to remove it in patients with superficial infection.



Figure 1. Shows the comparative percentage of infected vs. uninfected patients.

Table 1. Comparison of hospitalization days in the two group

Descriptive Statistics	Acute IM nail		
	Yes	No	
Average ± SD	5.8 ±7.7	11.8 ± 8.9	
Median	3	10	
Minimum	2 3		
Maximum	27	58	

SD = Standard Deviation

DISCUSSION

Defining the optimal bone stabilization method for immediate stabilization of exposed tibial fractures is controversial.^{3,9,16} Management is aimed at antibiotic therapy, tetanus prophylaxis, copious irrigation, early debridement, early coverage of soft tissues, and at providing stability and limiting infection rates, with multidisciplinary and emergency management protocols.^{3,9,12} Different stabilization methods are available: 1) external fixator, 2) IM nailing, 3) plate, 4) IM ENDER nail.^{9,12} The placement of external tutors is considered a good option as a stabilizer.^{8,15,23} But high rates of complications associated with the external tutor are reported, such as infection of the Schanz nail, loosening, poor patient adherence to treatment, misalignment and poor consolidation,^{3,4} and there is a risk of infection from placement of an IM nail after an external tutor.^{4,9} These complications have limited the use of the external fixator as a definitive form of fixation.^{8,16-19,22} Bhandari¹⁷ and other authors, such as Agrawal et al.¹ and Kakar and Tornetta³ have confirmed that both reamed and unreamed IM nails cause fewer complications than external tutor fixation, for example, reduced risk of revision surgery, poor consolidation and superficial infection.^{3,24}



Figure 2. Comparison of hospitalization days in patients with acute and deferred intramedullary nailing.

Infections	Acute IM nail		Total
	Yes	No	
Deep	0	8	8
Superficial	0	2	2
Total	0	10	10

IM nailing is known to be the gold standard for the treatment of tibial diaphyseal fractures.^{3,4,8,20,22} But there is scant literature supporting intramedullary fixation of open fractures in the acute stage. When analyzing the scant scientific evidence, the studies are controversial, with few patients and analyzing various techniques. Regarding the placement technique, we did not find a study with a high level of evidence that defines whether we should use the reamed or unreamed technique. For the placement of reamed IM nails we use the minimal reaming technique; there are studies that show that the rate of complications, such as infection or lack of consolidation,⁸ does not increase and the damage to the vasculature and risk of thermal necrosis are reduced.^{8,25,26} The concept of minimal reaming is currently a reaming-to-socket method, where reaming is used only until the medullary cavity of the tibia sounds or "vibrates", to ease the path to nail insertion. Thus, the possibility of thermal damage is minimized.⁸ This technique allows a longer and thicker nail to be placed than the unreamed IM nails, such as loosening and lack of consolidation, and increased need for revision surgery,^{8,16} or compromised stability of the fracture site, was demonstrated.¹ In a prospective randomized controlled trial of 45 exposed tibia fractures conducted in 2000, Finkemeier et al.²⁶ found no significant differences between reamed and unreamed nailing

with respect to consolidation, number of additional procedures, or infection. That same year, Bhandari et al.¹⁷ stated that reamed nails reduce the risk of reoperation. In a prospective review of 51 patients in 2004, Ziran et al.⁸ found that patients who received unreamed nails in the acute stage had more postoperative events than those who received unreamed [*sic*] ones and found similar rates of nonunion and infection in the two treatment groups. In 2007, Kakar and Tornetta³ reported an infection rate as low as 3%, after the placement of immediate unreamed IM nails among 161 patients with Gustilo grade I, II, IIIA and IIIB open tibial fractures, indicating safety and efficacy of treatment. In 2012, Schemitsch et al.²⁷stated that reaming reduced postoperative events, and that patients with exposed fractures had a higher risk of complications if they underwent the placement of reamed nails, compared to patients who received unreamed nails. But we consider that acute nailing is not taken into account in this study. In 2016, Uchiyama⁴ evaluated 93 patients with Gustilo grade I, II and IIIA fractures, and found that the infection rate is higher in those patients with deferred IM nailing than with unreamed IM nailing in the acute stage. In particular, the deep infection rate was significantly higher in the deferred group than in the acute IM nailing group.

Yokohama et al.⁹ state that the decision between immediate or deferred intramedullary nailing should be based on the experience of the trauma staff, the degree of contamination of the wound, the extent of the soft tissue injury and the degree of associated vital organ injury.

It is worth mentioning that fixation with IM nail in the acute stage should be considered to prevent deep vein thrombosis, since rehabilitation begins earlier, avoiding prolonged immobilization.⁴ At the same time, the hospital stay is reduced, which reduces health expenses when comparing the cost as a function of effectiveness between immediate or deferred IM nail. In addition, in the treatment of polytraumatized patients, fixation of long bone fractures also reduces the risk of acute respiratory distress syndrome and multiple organ failure, probably by calming the systemic inflammatory response.¹² Not all trauma centers in Argentina have osteosynthesis material to perform fixation in the acute stage; we believe that it is appropriate for more centers to implement this practice due to the advantages of treatment for the patient and the decrease in health costs.²⁸

Another point of discussion about the placement of IM nail as a fixation method in the acute stage is in exposed Gustilo grade III fractures with large soft tissue coverage deficits. In our Service, this practice is not performed. There is literature in favor of it^{1,3} and against it,⁹ but it is very scarce and with a very low level of evidence.

The weaknesses of this study are: its retrospective design and the small sample of patients with IM nail placed in the acute stage. This raised the possibility of designing a future study with an adequate management protocol, endorsed by the hospital's ethics committee, for internal fixation in the acute stage of exposed tibial fractures in our hospital. In turn, there is the possibility of adding internal fixation of Gustilo grade III exposed fractures in the acute stage to the protocol.

CONCLUSIONS

The placement of IM nails in the acute stage by means of the minimal reaming technique, in Gustilo grades I and II exposed tibia fractures, which is a quick and easy technique to perform, in centers with availability of osteosynthesis material to place in polytraumatized patients, does not increase the infection rate when compared with deferred fracture fixation. In our sample, there were no infectious processes when fixation with IM nail was performed in the acute stage during the period studied and the hospitalization time of these patients decreased with a statistically significant sample. This statement serves as a starting point to conduct a prospective study to help us adopt behaviors in public health.

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