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ORIGINAL PAPER

Treatment of distal tibial fractures: prospective comparative study evaluating two surgical procedures with investigation for predictive factors of unfavourable outcome

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Abstract

Purpose The aim of this study is to compare clinical and radiological outcome of intramedullary nailing (IMN) and locked plate (LP) in patients affected by fracture of the distal tibia (DTF). We performed also an analysis to identify predictive factors of unfavourable outcome.

Methods Data about patients with DTF treated at our first level trauma centre between 2008 and 2017 were collected. Patients were divided in group 1 (IMN) and group 2 (LP). The inclusion criteria were age at least 18 years at the time of diagnosis and unilateral DTF (closed or Gustilo 1). Demographic variables and data related to surgical procedure and hospitalization were registered. X-ray at follow-up was reviewed to identify malunions and nonunions. Clinical outcome was evaluated using scores and registering any complication.

Results One hundred two patients were included in group 1 and 81 in group 2. In group 2 were documented higher operating time and hospitalization. The mean union time was 20.2 weeks for IMN and 24.8 weeks for LP group ($p = 0.271$). The rate of infections and wound complications was higher in group 2 while malunion and anterior knee pain were more frequent in group 1. No difference in scores for clinical outcome was documented after six months. The full-weight bearing time was significantly longer in the LP group ($p = 0.019$). At multivariate analysis, no variables showed a predictive power for unfavourable outcome.

Conclusions Clinical and radiological results of LP and IMN appear similar. No predictive factors of unfavourable outcome were identified.

Keywords Distal tibial fracture · Plate fixation · Intramedullary nailing · Outcome · Fibular fracture

Introduction

Distal tibial fractures are the most common long bone fractures. Published data suggest an incidence of 17 per 100,000 person-years [1], although more recent reports indicate that the incidence is declining [2].

In most cases, they are due to a force directed from the foot towards the leg in the environment of outstanding high energy traumatic events, as falling down, traffic accident, motorcycle accident or sport injury [3, 4].

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The best treatment for displaced, extra-articular fractures of the distal tibia remains controversial. These fractures are particularly difficult to manage due to the limited soft tissue coverage that often are damaged by trauma, poor vascularity of the area, and proximity of the fracture to the ankle joint. Infections, nonunion, and malunion are well-recognized complications [5].

Surgical treatment options include intramedullary nailing, plate-and-screw osteosynthesis, and external fixation. External fixators may be used as definitive treatment in selected cases and in emergency in order to realign the limb and stabilize the fracture. Nailing and plate fixations are most commonly used for extra-articular fractures, once the soft tissue conditions allow it [5, 6].

The development of locking plates has led to a recent increase in the use of plate fixation; however, recent studies have shown that the incidence of soft tissue complications

with the use of these plates may be more than what is currently thought off [7].

The aim of this study is to compare clinical and radiological outcome of intramedullary nailing (IMN) and locked plating (LP) in patients affected by fracture of the distal tibia.

Materials and methods

The Local Research Ethics Service approved the study, which was conducted following the principles of Declaration of Helsinki. All patients signed informed consent.

Data about patients with distal tibial fractures (DTFs) treated at our first level trauma centre between January 2008 and January 2017 were collected. Patients were divided in group 1 (IMN) and group 2 (LP).

The inclusion criteria were age at least 18 years at the time of diagnosis and unilateral closed or Gustilo and Anderson type I DTF (AO–43 A) with or without a fibular fracture. Patients affected by pathological and multiple fractures, brain trauma, mental impairment, difficulty in communication and previous lower limb fractures were excluded. Furthermore, patients were excluded if they had comorbidities exerting a negative effect on the healing process such as diabetes mellitus, renal disease, rheumatologic disorders, and immune-deficiency states. X-plain films and CT scans were used to determine the location and AO classification of the fracture.

Age, sex, time between fracture and surgery along with side of the fracture were collected. Furthermore, all data related to surgical procedure and hospitalization were registered.

Surgery

Surgery was performed under general or regional anaesthesia. All patients had thromboprophylaxis and antibiotic prophylaxis. In our hospital, both intramedullary nail and plate fixation were used as part of routine clinical practice and all surgeons were familiar with both surgical procedures. For intramedullary nail fixation, an intramedullary nail is inserted at the proximal end of the tibia and passed down the hollow centre (medullary canal) of the bone in order to hold the fracture in the correct anatomical position. The reduction technique, the surgical approach, the type and size of the nail, the configuration of the proximal and distal interlocking screws, and any supplementary device or technique depended on the pattern of the lesion in accordance with standard clinical practice (Figs. 1 and 2).

For plate fixation, a plate is inserted at the distal end of the tibia and passed under the skin into the surface of the bone (Figs. 3 and 4). Again, the details of the reduction technique, the surgical approach, the type and position of the plate, the number and configuration of fixed-angle screws, and any supplementary device or technique was conducted in accordance with standard clinical practice (specifically fixed-angle screws must be used in at least some of the distal screw holes).

Fig. 1 Preoperative X-ray of case 1

In patients with associated distal fibular fracture, osteosynthesis was performed first in cases characterized by syndesmotic injury.

All patients received the same standardized, written physiotherapy protocol detailing the exercises they needed to perform for rehabilitation following their injury.

Partial weight bearing started after skin closure considering the stability of the synthesis.

Outcome measurements

Clinical and radiological follow-ups were done at one, three, six and 12 months after surgery.

Clinical results were assessed using the Olerud–Molander Ankle Score (OMAS) [8] and the Disability Rating Index (DRI) [9] during each medical evaluation.

X-plain views were used to assess the accuracy of reduction. Malunion was defined as angulation or rotational deformity. In AP view, varus/valgus deformity was evaluated by measuring the angle between the lines drawn perpendicular to the proximal and distal tibia articular surfaces. In lateral view, the ante-/recurvation deformity was measured similarly and 8° of posterior slope was subtracted. The measurement of rotation deformity was based on the angle between the lateral edge of the patient's foot and the surface of the bed. The left and right sides were compared [10]. Malreduction was defined as $>5°$ varus/valgus, $>5°$ ante-/recurvation deformity, or $>15°$ rotation difference. Shortening was defined as a left/right difference in the length of the tibia of >1 cm [10–12].

Fracture healing was defined as the time when the patient had no pain or tenderness on the fracture site, walking painless

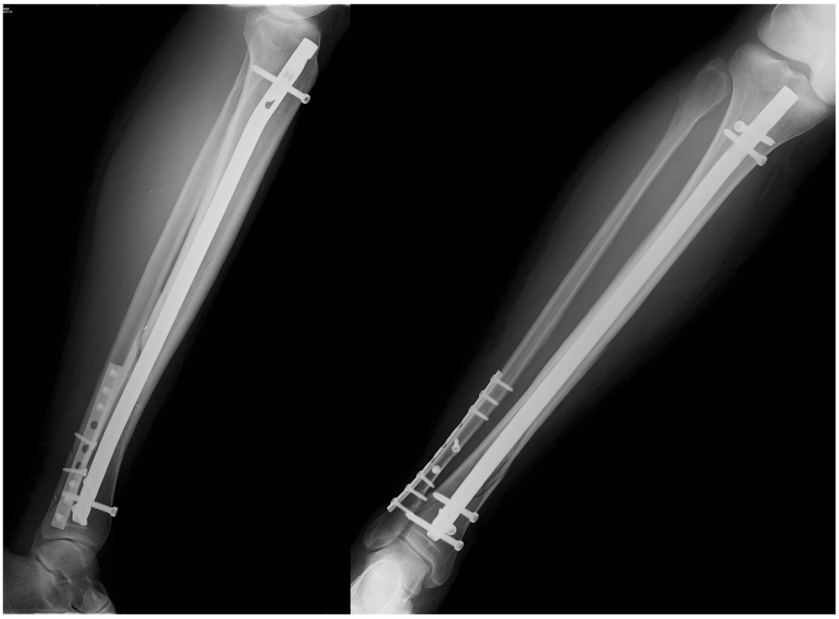

Fig. 2 Post-operative X-ray of case 1 treated with intramedullary nailing

with full weight bearing, and the bridging callus was seen to cross the fracture on three of four X-ray views. A healing time from six to nine months was considered to be a delayed union. Nonunion was defined as a fracture that failed to unite by the ninth month after the operation [10].

Statistical analysis

The statistical analysis was performed by using the Statistical Package for the Social Sciences (SPSS version 22.0; SPSS, Chicago, IL, USA). For all the texts, probability less than 0.05 was considered significant. The data for continuous variables was presented as median and interquartile range (IQR) due the non-normal distribution of continuous variables; data was expressed as counts and percentages for categorical variables

Fig. 3 Pre-operative X-ray of case 2

Fig. 4 Post-operative X-ray of case 2 treated with plates and screws

(wound complications, malreduction, shortening, nonunion). The Mann–Whitney *U* test was used to compare outcome measures of continuous variables. The chi-squared test and Fisher's exact test were used to compare categorical variables.

A multivariate analysis including pre-operative and operative variables has been performed in order to identify predictive factors of unfavourable outcome. We have considered as unfavourable outcome the presence of wound complications, infections, malunion, and anterior knee pain.

Results

Overall, the complete case series included 183 patients, excluding patients lost at follow-up. In group 1 were included 102 patients, and in group 2 were allocated 81 patients.

In group 2, 44 patients were treated through mini-invasive plating osteosynthesis (MIPO) and 37 using standard surgical approach.

Demographic data of both groups were similar as reported in Table 1. Data related to surgical procedure and hospitalization are also reported in Table 1 showing higher operating time and hospitalization in group 2 (respectively $p = 0.003$ and $p = 0.047$). A fibular fracture was associated in 45 cases in group 1 (surgical treatment with plate and screws in 19 cases, and with Kirschner wire in 2 cases) and in 32 cases in group 2 (surgical treatment with plate and screws in 17 cases).

The mean union time was 20.2 weeks for the IMN group (16.8–24.2) and 24.8 weeks for the LP group (range 18.1–27.5). This difference was not result being statistically significant ($p = 0.271$), as well as similar results were observed comparing patients who underwent associated fibular fixation and subjects who did not.

Data related to complications are reported in Table 2. The infection rate was 0% in group 1 while in group 2 was 3.7% with three patients developed infection ($p = 0.127$). The three infected patients were treated by removing the synthesis means and implanting a temporary external fixation, and adequate antibiotic therapy was prescribed. After the infection was healed, a new surgical procedure to implant a second locked plate was performed. All cases resulted healed after the second operation without any other problems.

Wound complications were observed in two cases (2.4%) in group 2 and never in group 1 ($p = 0.253$).

In group 1, 11 patients developed malunion: three varus deformities, four valgus deformities, three ante-recurvatum malalignment, and one rotational malalignment. Instead in group 2, three patients developed malunion: one varus deformity, one valgus deformity, and one rotational malalignment.

Nonunion was never observed in both groups.

The clinical outcome of the two groups is described in Table 2. The early registered OMAS and DRI scores at three months were statistically significantly better in group 1 ($p = 0.008$ and 0.005, respectively); however, this difference disappeared in subsequent follow-up.

The full-weight bearing time was significantly longer in the LP group compared to the IMN group (13.7 ± 4.2 weeks versus 10.3 ± 2.6 weeks, respectively). This difference was statistically significant ($p = 0.019$).

In group 1, five patients developed anterior knee pain (4.9%). This rate was in accordance with those reported in previously published clinical studies. In our case series was used a trans-tendinous approach in 68 patients and a paratendinous approach in 34 patients. In group 1, a dynamization of the nail was performed in 39 cases out of 102, after a mean time of 67.3 days (50–81 days). In IMN group were positioned three distal screws in 48 cases, two distal screws in different plane (antero-posterior and medio-lateral) in 35 cases, and two distal screws in medio-lateral direction in 19 cases.

Reoperation for nail or plate removal was reported in 72 cases in group 1 and in 57 cases in group 2. No cases of mobilization of screws were registered.

The results of multivariate analysis are reported in Table 3. Our analysis excluded that any of considered factors have a predictive power in order to influence outcome.

Discussion

The distal tibia has limited soft tissue cover, insufficient vascularity of the area, and is in the close proximity to the ankle joint, which is unique compared with other parts of the body [1]. At present, the main surgical procedures for the treatment of DTF are intramedullary nails, locked plates, and external fixation [5, 6].

IMN and plate LP are most commonly used as definitive treatment for DTF once the soft tissue conditions allow it [9].

A systematic review of the literature showed seven randomized clinical trials comparing nail with plate fixation for this injury [3, 9, 13–17]. Two trials found no difference in functional scores but showed a difference in wound complications, with more infections in the plate group [3, 13]. However, both these trials used standard "nonlocking" plates rather than the newer fixed-angle locking devices. In the third, the investigators found no difference in the time to union on radiographs but more than 20% of the patients in the trial were lost to follow-up [14]. A fourth trial did not find any difference in the Foot Function Index, but only 25 patients were included in total [15]. The fifth and sixth studies compared the results of external fixation with both LP and IMN and concluded that all three surgical procedures were efficient methods for treating distal tibia fractures but that their complication profiles were different [16, 17].

The seventh trial is the largest and was recently published reporting that among patients 16 years or older with an acute,

Table 1 Demographic and operative data of the two groups

	IMN (102 pts)	LP (81 pts)	*p*
Age, mean (range)	47.2 (19–78)	42.6 (21–73)	0.417
Male/female	60/52	38/43	0.683
Right/left side	65/37	51/30	0.521
Mechanism of injury			0.742
Low energy fall	44	34	
High energy fall	5	7	
Road traffic accidents	21	14	
Crush injury	23	10	
Contact sports	3	8	
Other	6	6	
BMI (range)	24.1 (18.3–27.6)	23.7 (20.1–28.1)	0.413
Smoker	33/102	16/81	0.597
ASA I/II/III	41/46/15	39/31/11	0.291
Closed/Gustilo 1	68/34	62/19	0.184
Time trauma/surgery, days (range)	3.2 (1–7)	3.7 (1–9)	0.583
Operating time, min (range)	78 (52–118)	112 (78–156)	*0.003*
Hospitalization, days (range)	2.2 (1–4)	4.8 (1–8)	*0.047*

The italic entries represent the values with statistical significance

Table 2 Comparative results of clinical and radiological outcome

	IMN (102 pts)	LP (81 pts)	*p*
Clinical outcome			
Wound complication	0	2	0.194
Infection	0	3	0.084
Anterior knee pain	5	0	0.067
Metal removal	72	57	0.493
3 months			
OMAS (range)	49.8 (40–62)	34.2 (28–51)	*0.008*
DRI (range)	40.6 (32–59)	56.7 (42–65)	*0.005*
6 months			
OMAS (range)	68.3 (56–81)	59.1 (49–70)	0.074
DRI (range)	21.5 (13–38)	30.3 (18–39)	0.098
12 months			
OMAS (range)	79.6 (67–89)	71.2 (65–91)	0.244
DRI (range)	11.8 (6–18)	14.3 (8–24)	0.326
Full-weight bearing, weeks (range)	10.3 (8.2–14.8)	13.7 (10.1–17.6)	*0.019*
Radiological outcome			
Malunion			
Varus	3	1	0.085
Valgus	4	1	0.071
Recurvatum	3	0	0.093
Rotational	1	1	0.748
Shortening	0	0	–
Delayed union	0	0	–
Nonunion	0	0	–
Metal removal	72	57	0.493

The italic entries represent the values with statistical significance

Table 3 Multivariate analysis documenting the absence of predictive factors of unfavourable outcome

	HR	95% CI	*p*
Age	0.823	0.546–1.291	0.344
Male	1.350	0.911–1.839	0.792
Right side	1.146	0.626–1.472	0.826
BMI > 25	0.359	0.128–0.891	0.215
Smoker	0.632	0.257–1.387	0.093
ASA III	1.319	0.846–1.834	0.137
Gustilo 1	1.811	1.320–2.504	0.189
Time trauma/surgery	1.273	0.795–1.427	0.541
Associated fibular fracture	0.786	0.251–1.684	0.212
Treatment with IMN	1.528	0.890–2.118	0.463
Operating time	1.725	1.101–2.469	0.198
Hospitalization	1.381	0.687–1.736	0.352

displaced, extra-articular fracture of the distal tibia, neither nail fixation nor locking plating resulted in superior disability status at six months [9].

In summary, previous trials have indicated that different forms of fixation for patients with a fracture of the distal tibia may have different complication profiles but failed to show a difference in functional outcomes. Specifically, malalignment and knee pain have been associated with nailing, while infections, wound complications, and implant prominence are frequently reported after tibial plating [3, 9, 13–17].

Considering results of previous studies, Maredza et al. published a trial-based economic evaluation, suggesting that nail fixation is a cost-effective alternative to locking plate fixation reporting that there is an economic justification for IMN over LP fixation for DTF [18]. They reported that mean UK National Health Service and personal social services costs were significantly lower for patients treated with nail fixation over those treated with locking plate. There was a small increase in quality-adjusted life years (QALYs) gained in the nail fixation group, although this did not reach statistical significance. These cost-effectiveness results remained robust to several sensitivity analyses [18].

The role of fibular fixation in patients with DTF remains controversial. Fibular synthesis may improve the ability to obtain and maintain reduction, but as a result of increased stability of the construct may also increase rates of nonunion [19–21].

Authors agree with Torino et al. [20] who suggest that concurrent fibular fixation is indicated in distal metaphyseal fractures with syndesmotic injury.

In literature, no predictive variables of unfavourable outcome in patients with DTF have been clearly defined. From our multivariate analysis merged the absence of a predictive power for all considered variables. Particularly our results showed as a Gustilo 1 open fracture had the same risk of unfavourable outcome of a closed fracture, in accordance with results of Schemitsch et al. [22]. In the same way, we documented as the presence of an associated fibular fracture did not directly influence the outcome.

In our prospective study, we documented a statistically significant longer operative time associated with higher length of hospitalization in patients treated with LP. The incidence of infection and wound complications were higher in this group, not reaching statistical significance. Malunion rate resulted higher in IMN group, as the report of anterior knee pain, without statistical significance. Considering clinical outcome, we documented as the early reported score was statistically significantly higher in IMN group at three months, loosing these relevance in the later follow-up evaluation at six and 12 months. Nevertheless, regarding the time of permission to apply full weight bearing, our results showed a shorter interval in IMN group. Finally, considering the longer operative time, hospitalization, and time to reach full-weight bearing, our results (even if we do not have a cost analysis of the two groups) confirms as a treatment with LP could be considered as more expensive than an IMN.

There are several limitations of present study: (1) the sample size was small; (2) it was a single-centre investigation; (3) a randomized controlled trial with a larger sample size and longer follow-up would be persuasive.

In conclusion, in this study, intramedullary nailing and locking plate fixation showed no significant difference in clinical and radiological outcome after six months of follow-up. Patients treated with LP showed a longer operative time, hospitalization, and time to reach full-weight bearing. The choice of the correct surgical procedure must take into appropriate consideration the above mentioned factors, the pattern of fracture, and the condition of soft tissues. No predictive factors of unfavourable outcome were identified.

Compliance with ethical standards

The Local Research Ethics Service approved the study, which was conducted following the principles of Declaration of Helsinki. All patients signed informed consent.

Conflict of interest The authors declare that they have no conflict of interest.

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