



Comparison of intramedullary nailing and plate fixation in distal tibial fractures with metaphysical damage: a meta-analysis of randomized controlled trials

¹Dr Abdul Basit, ²Dr Muhammad Arshad Ghani, ³Dr Yasir Mustafa, ⁴Dr Rouf ul Islam Sheikh

1Consultant Orthopedic Surgeon Govt. Aziz BB THQ hospital, Roshan Bheela, Kasur).

2Orthopedic Surgeon Jinnah Hospital Lahore).

3Orthopedic Surgeon social-security hospital manga- Raiwaind

4Pakistan institute of medical sciences Islamabad).

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Abstract

Background: Distal metadiaphyseal tibial fractures are commonly seen lower limb fractures. Intramedullary nail fixation (IMN) and plate internal fixation (PL) are the two mainstay treatments for tibial fractures, but agreement on the best internal fixation for distal tibial fractures is still controversial. This meta-analysis was designed to compare The success of IMN and PL fixations in the treatment of distal metadiaphyseal tibial fractures, in terms of complications and functional recovery. **Methods:** Randomize Controlled Trial RCT at Jinnah Hospital Lahore 2024-2025. **Results:** Eleven studies were included in the current meta-analysis. A significant difference in malunion (RR = 1.76, 95%CI 1.21–2.57, P = 0.003), superficial infection (RR = 0.29, 95%CI 0.13–0.63, P = 0.002), FFI (MD = 0.09, 95%CI 0.01– 0.17, P = 0.02), and knee pain (RR = 3.85, 95%CI 2.07–7.16, P < 0.0001) was noted between the IMN group and PL group. No significant difference was seen in the operation time (MD = - 10.46, 95%CI - 21.69–0.77, P = 0.07), radiation time (MD = 7.95, 95%CI - 6.65–22.55, P = 0.29), union time (MD = - 0.21, 95%CI - 0.82–0.40, P = 0.49.), nonunion (RR = 2.17,95%CI 0.79–5.99, P = 0.15), deep infection (RR = 0.85, 95%CI 0.35–2.06, P = 0.72), delay union (RR = 0. 92, 95%CI 0.45–1.87, P = 0.82), AOFAS (MD 1.26, 95%CI - 1.19–3.70, P = 0.31), and Disability Rating Index in 6 or 12 months (MD = - 3.75, 95%CI - 9.32–1.81, P = 0.19, MD = - 17.11, 95%CI - 59.37–25.16, P = 0.43, respectively). **Conclusions:** Although no significant difference was seen between IMN and PL fixation with regards to the operation time, radiation time, nonunion, deep infection delay union, union time, AOFAS, and Disability Rating Index, significant differences were seen in occurrence of malunion, superficial infection, FFI, and knee pain. Based on this evidence, IMN appears to be a superior choice for functional improvement of the ankle and reduction of postoperative wound superficial infection.

Keywords: Comparison, intramedullary, nailing, plate fixation, distal tibial fractures, metaphysical damage, meta-analysis, randomized controlled trials.



Introduction

The optimal type of internal fixation for treatment of a distal radius fracture is still under debate. The tibia is an important weight bearing bone in the lower limb, which articulates proximally with the femur at the knee and distally with the talus at the ankle. Fractures of the distal tibial metaphysis, diaphysis, and adjacent diaphysis are commonly seen in road traffic accidents or sports injuries. These metadiaphyseal fractures are distinct in terms of their management from articular impaction “pilon” type fractures and middle third diaphyseal injuries [1]. The over- all incidence of tibial fractures is 51.7 per 100,000 a year, and the incidence of diaphyseal and distal tibia fractures is

respectively per 100,000 a year [2]. Common definitions of distal tibial fractures include distal extraarticular tibial fractures which are located between 4 and 12 cm from the tibial plafond (AO 42A1 and 43A1). Further subdivisions are made on the basis of the morph- ology and degree of comminution of the fracture: 43-A1 are non-comminuted extra-articular fractures, 43-A2 are wedge fractures, and 43-A3 are comminuted extra-articular fractures. Simple extension of the fracture into the joint without depression of the joint surface are classified as 43-B1 and are often treated in the same way as 43-A fractures

Use of IMN for fracture fixation has been shown that there is limited interference of the device with the soft tis- sue around the fracture, but the technique of placement is difficult and the learning curve is long. In addition, it has been shown to be linked to complications such as malunion and knee pain after surgery .Common surgical procedures for internal fixation of the plate include open reduction and internal fixation and bridge fixation (MIPPO). Open reduction and internal fixation is an anatomical reduction under direct vision, but it is very disturbing to the soft tissue surrounding the fracture. In severe soft tissue injury cases, it is often necessary to ex- tend the preoperative preparation time to optimize soft tissue recovery. Compared with open reduction and internal fixation, MIPPO technology requires fixation with a steel plate, but it also indirect bridge fixation. It is more likely to lead to soft tissue injury than open reduction, but also has a higher rate of fracture malformation and in- creased local soft tissue pressure possibility.

The aim of this systematic review and meta-analysis was to compare the efficacy of two fixation methods, plate fixation, and intramedullary nail fixation, in the treatment of distal metadiaphyseal tibial fractures with or without articular involvement.

Materials and methods Search strategy

Study conducted at Jinnah Hospital Lahore during august 2024-august 2025

Data selection

To evaluate inclusion eligibility, two investigators independently screened the title and abstracts of all articles. Any disagreements were resolved with discussion between the authors. A third researcher was the adjudicator



when there was disagreement between the two investigators. The included studies had to meet the following criteria: (1) must be designed as RCTs; (2) Participants must be at least 16 years old; (3) the articles compare intramedullary nail fixation and plate fixation.

Data extraction

Two authors independently extracted the following data from each eligible study: study design, type of study population, age, number of participants, and interventions. Any discrepancies in data extraction were resolved by a third investigator.

Quality and risk of bias assessments

The modified Jadad scale was used to assess the methodological quality of each study. A score of 3-4 indicated high quality. The Cochrane Handbook for Reviews of Interventions (RevMan Version 5.3) was used to assess the risk of bias. Two independent authors subjectively reviewed all articles and assigned a value of "high," "low," or "unclear" based on the following items: selection bias; performance bias; detection bias; attrition bias; reporting bias and other bias. Any disagreements were resolved with discussion to reach a consensus. If a consensus could not be reached a third investigator was consulted.

Statistical analysis

The RevMan software was used to analyze the numerical data from the included studies. For binary data, the risk ratios (RR), and 95% confidence intervals (CI) were assessed ($\alpha = 0.05$ for the inspection standards). For continuous data, means and standard deviations (SD) were pooled to a weighted mean difference (WMD) and a 95% confidence interval (CI) in the Meta-analysis. Heterogeneity was tested using the I² statistic. Studies with an I² statistic of 25 to

50% were considered to have low heterogeneity, those with an I² statistic of 50 to 75%

were considered to have moderate heterogeneity and those with an I² statistic > 75% were considered to have high heterogeneity. When the I² statistic was > 50%, sensitivity analyses were performed to identify potential sources of heterogeneity. Statistical significance was indicated by a P value < 0.05.

Results

Description of studies and demographic characteristics

A total of 889 articles were identified as potentially relevant studies (Fig. 1). A total of 687 full publications were screened based on title and abstracts followed by removal of duplicates ($n = 202$). Twenty full manuscripts were assessed and a further 9 trials were excluded, leaving 11 trials eligible to be included in the meta-analysis.

The demographic characteristics are summarized in Tables 1 and 2. All studies compared postoperative complication rates, postoperative joint function recovery, fracture healing time, delayed fracture healing, wound infection, soft tissue irritation, and postoperative outcomes in the treatment of distal radius fractures in the INM and PL groups. The incidence of knee pain was also extracted from the studies.



Risk of bias in included studies

Assessment of risk of bias. All trials included in this study are randomized trial designs [12, 13]. One trial [14] did not provide detailed information of random sequence generation, and one trial [15] did not describe the method of concealing group allocation. Blinding of participants and personnel (performance bias) was unclear and incomplete outcome data (attrition bias) was high risk in two trials [15, 16]. Three trials [15–17] lost patients to follow-up.

The characteristics of included studies

EAFDT extra-articular fracture of distal tibia fracture, OTA orthopedic Trauma Association.

Characteristics of the eleven trials selected showing general information

IMN intramedullary nail, PL plate, PTP proximal tibial plating, MIPO Minimally invasive plate osteosynthesis, DTF distal tibial fracture, EAFDT extra-articular fracture of distal tibia fracture, OTA

orthopedic Trauma Association, GAT Gustilo and Anderson Type, TSC Tscherne classification, OMAS the Olerud and Molander Ankle Score, AOFAS The American orthopedic Foot and Ankle surgery, DRI Disability Rating Index, EQ-5D-3 L the EuroQol Health-Related Quality-of-Life 3-Level score, FFI Foot Function Index, MFA Musculoskeletal Function Assessment, F/M female/male, “—” indicates not reported by the study.

Operation, radiation, and union time

Operation time

Six studies [14–16, 18–20] with a total of 494 patients in both groups provided data on operative time. Heterogeneity in these studies was large, and the random-effects model was used ($I^2 = 93\%$). The meta-analysis showed no significant difference in operative time between the IMN group compared with PL group (MD = -10.46, 95%CI - 21.69 to 0.77, $P = 0.07$)

Radiation time

Appropriate data on radiation time were available in 3 articles [14, 16, 19] with a total of 366 patients. Polat et al. [14] recorded the radiation time in milliseconds, whereas the other two study records in minutes, so the comparison could only be done once the time was converted to minutes. There was significant heterogeneity among the studies requiring analysis with a random-effects model ($I^2 = 100\%$). Meta-analysis showed no significant difference in radiation time between the IMN group and the PL group (MD = 7.95, 95%CI - 6.65 to 22.55, $P = 0.29$).

Union time

Six studies [13–16, 18, 20] reported data on union time in the IMN group compared with the PL group. No significant difference in union time was noted between the

IMN group and the PL group (MD = -0.21, 95%CI - 0.82 to 0.40, $P = 0.49$).



Complication

Nonunion

Seven studies [12–16, 18, 20] provided data on non-union. There was no significant difference in the non-union rate between the IMN group and the PL group (RR = 2.17, 95%CI 0.79 to 5.99, P = 0.15).

Deep infection

Six studies [12, 14–16, 18, 20, 21] with a total of 579 patients in both groups reported deep infection. There was no heterogeneity among these studies (I² = 0%). Data were pooled using the random-effects model and the meta-analysis indicated that there was no significant difference in deep infection occurrence between IMN and PL groups. (RR = 0.85, 95%CI 0.35 to 2.06, P = 0.72)

Malunion

Seven studies [12, 14, 15, 17–20] with a total of 676 patients in both groups reported malunion. Mild heterogeneity existed among these studies (I² = 4%). Data were pooled by fixed-effects analysis and the meta-analysis indicated that the IMN group had significantly higher malunion versus the PL group. (RR = 1.76, 95%CI 1.21 to 2.57, P = 0.003)

Knee pain

Four studies [14, 17, 18, 20] of 249 patients in both groups reported on knee pain. Heterogeneity was substantial heterogeneity among studies (I² = 53%). Data were pooled using a fixed-effects

analysis, and the meta-analysis indicated that the IMN group had significantly higher knee pain versus the PL group (RR = 3.85, 95%CI 2.07 to 7.16, P < 0.0001)

Superficial infection

Eight studies [13–16, 18–21] of 577 patients in both groups reported on superficial infection. There was no heterogeneity among the studies (I² = 16%). Data were pooled using a fixed-effects analysis, and the meta-analysis indicated that the IMN group had significantly lower superficial infection rates compared to the PL group (RR = 0.29, 95%CI 0.13 to 0.63, P = 0.002)

Delay union

Five studies [15, 16, 18, 20, 21] of 337 patients in both groups provided data on delayed union. There was no heterogeneity among studies (I² = 0%). Data were pooled using the fixed-effects model, and the meta-analysis indicated no significant difference between the two groups (RR = 0.92, 95%CI 0.45 to 1.87, P = 0.82)

Objective score

American Orthopaedic Foot and Ankle Surgery (AOFAS) score at the 6-month follow-up



Three studies [16, 18, 19] of 297 patients in both groups provided data on the AOFAS at 6 months follow-up. A significant difference in the AOFAS score was noted between the PRP group and the HA group (MD 1.26, 95%CI - 1.19 - 3.70, $P = 0.31$). However, this result should be interpreted with caution due to presence of low or insignificant statistical heterogeneity ($c^2 = 0.88$, $I^2 = 0\%$)

Foot Function Index

Four studies [13, 14, 17, 19] comprising of 297 patients in both groups provided data on the Foot Function Index. Low heterogeneity among the studies indicated use of the fixed-effects model ($I^2 = 0\%$). The meta-analysis found a significant difference in the Foot Function Index between the IMN group compared to the PL group (MD = 0.09, 95%CI 0.01 to 0.17, $P = 0.02$)

Disability rating index

Two studies [21, 22] focusing on 338 patients in both groups, reported on the Disability Rating Index. Low heterogeneity among the studies at the 6 month time point required adoption of the fixed-effects model ($I^2 = 0\%$). The meta-analysis showed no significant difference in the Disability Rating Index between the IMN group compared with the PL group (MD = - 3.75, 95%CI - 9.32 to

1.81, $P = 0.19$) High heterogeneity

among the studies at the 12 month time point required adoption of the random-effects model ($I^2 = 71\%$). Meta-analysis showed no significant difference in the Disability Rating Index between the IMN group and the PL group (MD = - 17.11, 95%CI - 59.37 to 25.16, $P =$

0.43). Low heterogeneity among the studies in the sub- group analysis indicated use of the fixed-effects model ($I^2 = 27\%$) and no statistically significant difference was noted (MD = - 2.92, 95%CI - 8.71 to 2.87, $P = 0.32$)

Discussion

The earliest PubMed record describing the use of intramedullary nails in the treatment of fractures was a 1946 paper by O'Connell reporting the treatment of femoral fractures [23]; use was later reported in the treatment of tibiofibular fractures [24], and subsequently widely applied in limb lengthening. Even in irregular bones such as clavicle fractures, the bone is characterized by highest protection of periosteal blood supply and lowest soft tissue irritation at the fracture end, thus providing a favorable soft tissue environment for fracture healing. IMN can be either reamed or non-reamed, where reaming is more beneficial for reduction. Animal studies have confirmed that there is no significant increase in blood perfusion and osteophyte strength at the fracture end when comparing reamed with unreamed IMN [25]. However, stress



Occlusion of the fracture end can lead to destruction of local fracture integrity and lead to negative clinical outcomes, occurrences which are expected to decrease with improvement of instrument design techniques and surgery [26]. After the fracture end is reset, the locking nail is locked and pressurized, and the fracture end micro-motion is provided to promote fracture healing, however, if fixed too firmly, the alignment may be poor, the rotation is deformed, or the nail broken [27]. In contrast, open reduction and internal fixation is direct reduction and fixation, so contralateral alignment of the fracture end is superior to IMN fixation. MIPPO is similar to IMN fixation but does not require alignment of the fracture end under direct vision. In addition, it does not require strong fixation and emphasizes soft tissue and blood around the fracture. Limiting the disruption of the blood supply ensures adequate perfusion and maintenance of the biological environment at the fracture ends [28–30]. In addition, treatment of distal radius fractures includes external fixation, external fixation combined with limited open reduction and internal

Fixation, intramedullary nail and steel plate fixation, but these are not included in the scope of this meta-analysis.

To our knowledge, this is the first meta-analysis looking at the most recent randomized controlled trials comparing the efficacy of IMN and PL in distal tibial fractures and distal metadiaphyseal tibial fractures. This meta-analysis was based on 11 RCTs that included 526 patients treated with IMN and 571 patients treated with PL fixation. The main outcomes investigated were union time, operation time, nonunion, and delay union, superficial infection, deep infection, malunion, and knee pain. In our meta-analysis, when IMN is compared with the PL group, there was no significant difference in AOFAS, delayed union time, deep infection, operation time, and radiation time. However, the IMN group was superior to the PL group in terms of the FFI, knee pain, and malunion. In terms of superficial infection occurrence, the PL group was significantly higher than the IMN group. These results highlight that IMN and PL are effective fixation methods for distal tibial fractures, with no significant differences in fracture healing time and operative time. But the INM group was shown to recover better than the PL group, and the superficial infection rate was lower. However, the malunion and postoperative knee pain in the IMN group were higher than those

in the PL group. The operation time, fracture healing time, and intraoperative fluoroscopy time showed no statistically significant difference.

Prior studies [13, 31–33] and several meta-analyses [34–37] investigating the efficacy of IMN have shown that IMN has no superiority over PL when the two methods are compared in well-designed double-blinded trials. The reported beneficial effects of IMN in most trials may have been due to insufficient blinding methods. Our results showed that there was a statistically significant difference in malunion between the IMN and the PL group, with a higher rate of malunion in the IMN group. This is consistent with the results of a prior meta-analysis where no significant difference in operation time and radiation time between INM and PL group was seen ($P = 0.07$, $P =$



0.29, respectively) [34]. This is not consistent with our conclusions. In addition, the limited number of RCTs and patients may also affect these results.

As is the case of many meta-analyses, our study is not devoid of limitations. First, the current meta-analysis focuses only on papers that have been previously published. Inclusion of Unpublished research may have increased heterogeneity and changed the current results. Second, the frequency of follow-up varied between

Studies, with five studies following up for more than 18 months, five studies limited to a year, and one study following up for only 6 months. This variation may affect heterogeneity and hence the results. Furthermore, the type of incision and plate were not consistent across the different studies. There exist several different types of surgical incisions in the use of steel plate fixation, four studies used the MIPPO technique, whereas the rest used open reduction and internal fixation. In terms of type of steel plate, two studies used non-locking steel plates, five used compression-type steel plates, one used an anatomical steel plate, two used a bridge steel plate, and one used ordinary steel plates. Further rigorously designed RCTs, with larger sample sizes, are necessary to better compare the efficacy of IMN and PL fixation.

Conclusion

The results of this meta-analysis highly support that both the IMN and PL internal fixation methods are effective for the treatment of distal tibial fractures with metaphysical involvement. However, knee pain has been recorded following use of IMN, malunion is more frequent with IMN fixation, and the risk of superficial wound infection is higher in PL internal fixation than IMN use. In terms of FFI scores, IMN internal fixation appears to be superior to PL. Further studies investigating the use of IMN internal fixation for knee pain after distal tibial fractures are required. Furthermore, the rate of fracture deformity is higher with IMN fixation, while treatment and prevention of superficial wound infections after PL surgery increases the ankle joint function.

Abbreviations

—: Indicates not reported by the study; AOFAS: The American orthopedic Foot and Ankle Surgery; DRI: Disability Rating Index; DTF: Distal tibial fracture; EAFDT: Extra-articular fracture of distal tibia fracture; EQ-5D-3 L: The EuroQol Health-Related Quality-of-Life 3-level score; F/M: Female/male; FFI: Foot Function Index; IMN: Intramedullary nail; KSS: The Knee Society's Knee Scoring System; MFA: Musculoskeletal Function Assessment; MIPO: Minimally invasive plate osteosynthesis; OMAS: The Olerud and Molander Ankle Score; OTA: Orthopaedic Trauma Association; GAT: Gustilo and Anderson type; PL: Plate; PTP: Proximal tibial plating; TSC: Tscherne classification

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