Union Time in Minimal Invasive Plate Osteosynthesis Versus Closed Intramedullary Nailing in Closed Distal Tibial Fracture: A Retrospective Study

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Background: *Distal tibial metaphyseal fracture is the second most common fracture of tibia. Treatment of this fracture is challenging due to the large medullary cavity, covering with subcutaneous, less muscular layer and vascular supply. Closed interlocking intramedullary nailing (IMN) and minimally invasive plate osteosynthesis (MIPO) are two surgical methods widely used to fix this fracture. However, a better union outcome had not been identified.*
Objectives: *To compare the rate of union within 12 weeks of IMN group versus MIPO group.*
Materials and Methods: *This is a retrospective cohort study, enrolled the patients with closed distal tibial fracture who were admitted to Orthopaedic ward, Khon Kaen Hospital, from 1 January 2017 to 30 June 2020. The primary outcome was rate of union within 12 weeks.*
Results: *Of 116 enrolled patients, 63 patients were in MIPO group and 53 were in IMN group. Mean ± SD age was 36.9±16.7 years; 87 were men (75%). The union rate within 12 weeks was 38 of 63 patients (60.3%) in MIPO group and 23 of 53 patients (43.3%) in IMN group, the union rate within 12 weeks was not statistically different in two groups (AOR 1.81; 95%CI 0.78-4.20 p=0.17). The secondary outcomes were not significantly different, except the total operation time (minutes) in MIPO group was significantly higher than IMN group (94.5±18.2 vs 75.3±19.8 p=0.01).*
Conclusions: *The use of MIPO technique versus IMN technique for treating closed distal tibial fracture was not significantly different in the rate of union within 12 weeks.*

Keywords: *Closed distal tibial fracture, Closed interlocking intramedullary nailing, Minimally invasive plate osteosynthesis, MIPO, IMN, Union*

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Introduction

Tibia is the most common fracture of long bones because a subcutaneous layer covered it throughout its length. The blood supply to the tibia is more precarious than that of other bones and bulky muscles enclosed it. Therefore, delayed union, nonunion and infection are relatively common complications of tibial fracture.

Distal tibial metaphyseal fracture, which is 3–10% of total tibial fracture is difficult to manage due to a large medullary cavity less muscular layer and vascular supply[1,2]. According to the goals of treatment are to obtain a healed, well-aligned fracture, pain-free weight bearing, functional range of motion of the knee and ankle joints and low incidence of complications, open reduction with plate and screw fixation allows anatomic reduction and stable fixation for these fractures. However, soft tissue complications, particularly wound dehiscence and infection are significant problems of the open surgical technique, as well as disruption of vascularity, which may lead to nonunion.

Nowadays, closed interlocking intramedullary nailing (IMN) and minimally invasive plate osteosynthesis (MIPO) are treatment methods in this fracture type that are extensively used because the fracture is closed to or extended into the ankle joint and the tibia has little overlying muscle.

MIPO technique, the indirect reduction is performed, small stab incisions without evacuation of the fracture hematoma are used and the plate is placed by sliding over the periosteum without disturbing the vascularity[3-5]. However, this surgical method requires proficient surgical skills and high radiation exposure risk.

IMN is widely accepted as the treatment of choice for most open and closed tibial diaphyseal fractures[1]. However, reduction and stable fixation of distal tibial fractures with IMN are often technically challenging due to a large medullary cavity within a short distal fragment[2,6-7]. Malalignment has been frequently reported after

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intramedullary stabilization of distal tibia fractures. IMN has also been associated with knee pain in several studies[4,8,9]. From the current studies, the duration of bone union of these two surgical techniques was not different but wide range of union time (12-24 weeks)[3,10-13]. This study was performed to evaluate the rate of union within 12 weeks of MIPO versus IMN surgical techniques in closed distal tibial fracture.

Materials and Methods

Study design

We conducted a retrospective cohort study at Department of Orthopaedic Surgery, Khon Kaen Hospital between 1 January 2017 and 30 June 2020. The study was conducted in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations[14]. The study protocol was approved by The Institutional Review Board of Khon Kaen Hospital under a waiver of informed consent with the approval number KEXP63048.

Participants and Eligibility Criteria

Patients with closed distal tibial fracture who were admitted to Orthopaedic ward, Khon Kaen hospital were screened for eligibility. The inclusion criteria as followings; (i) age ≥ 18 years, (ii) closed distal tibial fractures (iii) Time to surgery within 2 weeks after injury. The exclusion criteria as followings; (i) multiple organ injury, (ii) ipsilateral fibula fracture and/or ankle instability that need fixation of fibula, (iii) pregnancy, (iv) pathological fracture, (v) metabolic bone diseases, including osteoporosis, rickets, osteomalacia, osteogenic imperfecta, (vi) rheumatologic disorder, (vii) incomplete/missing data.

Operative procedure

Surgical technique for Closed Intramedullary Nailing (IMN)

The fractures were realigned by closed indirect reduction and intramedullary nail using a reamed technique. Either spinal anaesthesia or general anaesthesia was used. Intravenous prophylactic antibiotics were given for 24 hrs. Preoperative radiographs of the uninjured tibia was used to select the proper nail diameter. The length of nail should permit the proximal end to be countersunk with the distal end centered the distal epiphysis. Nailing can be done using either a fracture table or a standard radiolucent operating table.

Surgical technique for Minimally Invasive Plate Osteosynthesis (MIPO)

The fractures were performed closed indirect reduction and percutaneous plating using the titanium LC-DCP system. Either spinal anaesthesia or general anaesthesia was used. Intravenous prophylactic antibiotics were given for 24 hrs. The patient was placed supine on a radiolucent table with the leg resting on a 15 cm high cushion with the knee flexed about 20°. Another small cushion placed under the patient's heel was used to restore the anatomical forward bending of the distal part of an intact tibia and a tourniquet was used. The plate was adjusted to fit on the distal tibia's medial aspect and then subcutaneously introduced through a small incision proximal to the medial malleolus.

Postoperative management and follow-up

After surgery, the fractured leg was protected by a lower leg slab for 4–6 weeks and the patients were allowed weight-bearing according to attending physicians'decision. The patients were followed by the orthopaedic surgeon at approximately 3-week intervals and anteroposterior and lateral view of plain radiography was performed every follow up period until union. Union was defined as the visualization of callus tissue in at least three cortices on plain radiologic film anteroposterior and lateral view.

Objectives of the study

To evaluate the rate of union within 12 weeks after treating with minimal invasive plate osteosynthesis versus closed intramedullary nailing in closed distal tibial fracture.

Outcomes

The primary outcome was the rate of union within 12 weeks after minimal invasive plate osteosynthesis versus closed intramedullary nailing in closed distal tibial fracture. The secondary outcomes were operation time, amount of blood loss, hospital stay, the rate of postoperative infection, malunion and nonunion.

The operational definitions

Union time: The union time of fractures is measured by plain radiologic film anteroposterior and lateral view, which shows a complete medullary bridging callus of at least 3 cortices.

Operative time: timing of operative procedure is measured from time at skin incision to skin closure.

Estimate blood loss: volume of blood loss that recorded from time at skin incision to skin closure.

Wound infection: all wound problems which recorded within 2 weeks after the operation.

Malunion[16]: malalignment in varus/valgus > 5 degree, or antero-posterior angulation > 10 degree or mal rotation > 10 degree and shortening > 15 mm.

Nonunion: no radiographic signs of bone healing within 9 months after operative bone fixation.

Two orthopaedic attending staff who have experienced at least 5 years evaluated and made the consensus decision about all radiographic results.

Data management

Data were collected from electronic medical records, nursing charts, operative notes, anesthetic record forms, radiographic imaging from picture archiving and communication system (PACS). The data were entered into case record form (CRF) and subsequently entered into the electronic spreadsheet.

Data collection included: Primary outcome and secondary outcomes as described above Demographic variables: age, sex, comorbidities, body weight, body mass index, routes of arrival, causes of injury, time to operation, fracture side.

Statistical analysis

Sample size was calculated by conventional method for multivariable logistic binary regression as 10 events per covariate rule.

$$\text{Sample Size} = \frac{1 \times (\text{number of events}) \times 10}{P\text{union}}$$

Covariates that affected to union of tibial fracture were assessed from previous study Covariate[16]: 1. Age > 60 years olds 2. Male 3. Tobacco smoker 4. Body mass index > 40 5. Diabetes 6. Nonsteroidal anti-inflammatory drugs (NSAIDs) user 7. High-energy fracture 8. Infection 9. Opioid use P union = Prevalence of union = 0.9 (From previous study) [17]

$$\text{Sample size} = \frac{1 \times 9 \times 10}{0.9}$$

Estimate incomplete data 10%, Total sample size = 110

All baseline variables were examined using descriptive statistic. Continuous variables were presented using either mean and standard deviation or median and range. The t-test or Mann-Whitney test were used to analysis between groups differences. Categorical variables were presented using frequent count and percentage and Chi square test was used to determine the baseline differences.

For the primary and secondary outcomes, the binary outcomes were analysed and presented as odds ratio (OR) and 95% confidence interval. The important demographic variables that influencing the outcomes, ($p<0.1$) were included in multivariable analysis by using multiple logistic regression and presented as adjusted odds ratio (AOR) and 95% confidence interval. For continuous outcomes (total operation time, hospital stay) were analysed by a generalized linear model. Statistical significance determined as $p<0.05$. All data analysis were performed using STATA version 16.

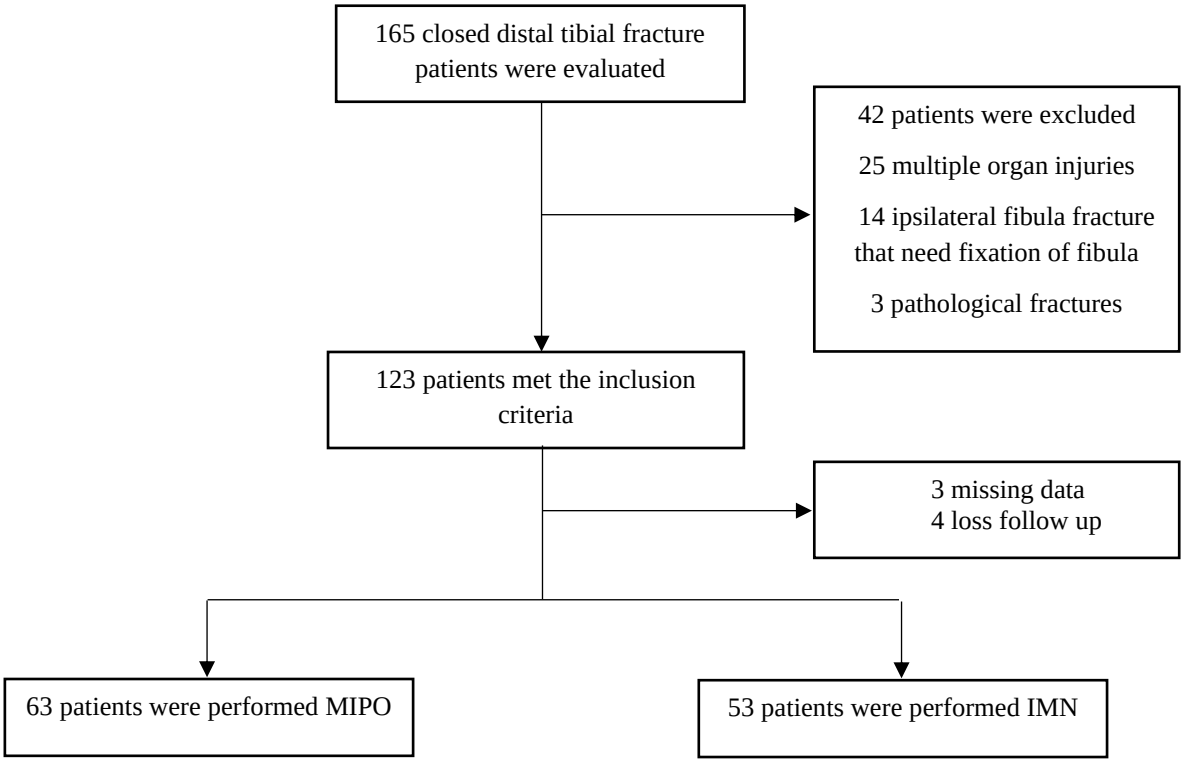

Fig.1 Flow diagram demonstrating the screening and enrollment of the patients.

Results

From 1 January 2017 through 30 June 2020, 165 patients were screened for the eligibility criteria and 116 patients were enrolled in the study (Figure1). There were 63 patients in MIPO group and 53 patients in IMN group. The mean age of the patients was 39.3±17.3 years in MIPO group and 34.0±15.7 years in IMN group. There were 87 males and 29 females in the study with 60.34% having right tibia involvement.

The most common cause of injury was road traffic accident in 91.3% of patients followed by sports injury (e.g., football, skateboard), fall and assault**.** There were not differences in age, sex, body weight, BMI, comorbidities, route of arrival, causes of injury, fracture side and time to surgery between two groups. History of smoking was found 19% in MIPO group and 5.7% in IMN group (Table1).

Table 1 Characteristics of the Patients at Baseline.

	MIPO (n=63)	**IMN (n=53)**	***P*-value**
Age (year)	39.3±17.3	34.0±15.7	0.08
Male sex (%)	44 (69.8)	43 (81.1)	0.16
Body weight (kg)	58.7±9.3	60.0±6.7	0.40
Body mass index (kg/m^2)	20.4±3.8	19.9±1.9	0.41
Comorbidities no. (%)			
Hypertension	7 (11.1)	6 (11.3)	0.97
Diabetes Mellitus	6 (9.5)	9 (16.9)	0.23
Route of arrival no. (%)			0.62
Refer	45 (71.4)	40 (75.4)	
EMS	18 (28.5)	13 (24.5)	
Causes of injury no. (%)			0.32
Traffic	59 (93.7)	47 (88.7)	
Body assault	1 (1.6)	0 (0)	
Fallings	1 (1.6)	0 (0)	
Sports	1 (1.6)	4 (7.6)	
Others	1 (1.6)	2 (3.8)	
Smoking no. (%)	12 (19)	3 (5.7)	0.03
Right side fracture no. (%)	38 (60.3)	32 (60.4)	0.99
Time to surgery (IQR) day	2 (2,4)	2 (2,4)	0.38

Table 2 Primary and Secondary outcomes.

	MIPO (n=63)	**IMN (n=53)**	**OR (95% CI)**	**Adjusted OR[a] (95% CI)**	***P*-value**
Primary outcome					
Union within 12 weeks	38	23	1.98 (0.88-4.45)	1.81 (0.78-4.20)	0.17
Secondary outcomes					
Nonunion	0	0	-	-	-
Malunion	2	3	0.54 (0.04-4.99)	0.66 (0.07-5.60)	0.65
Surgical site infection	2	1	1.70 (0.09-10.25)	1.00 (0.06-17.36)	1.00
Blood transfusion	0	0	-	-	-
Total operation time (min)	94.5±18.2	75.3±19.8	-	-	0.01
Hospital stay (day)	7.03±1.26	6.94±1.25	-	-	0.38

a: Adjusted for Age, Smoking

Primary outcome

The rate of union within 12 weeks was found in 38 of 63 patients (60.3%) in MIPO group and 23 of 53 patients (43.3%) in IMN group (OR 1.98; 95%CI 0.88-4.45) (Figure 2, 3) after adjusting for age and history of smoking, the union rate within 12 weeks was not statistically different in two groups (AOR 1.81; 95%CI 0.78-4.20 p=0.17) (Table2).

Secondary outcomes

The overall malunion rate was 5 of 116 patients (4.3%), 2 patients in MIPO group and 3 in IMN group. The rate of malunion was not different between two groups (AOR 0.66; 95% CI 0.07-5.60 p=0.65). The surgical site infection rate was also not different in two groups (AOR 1.00; 95% CI 0.06-17.36 p=1.00). None of the patients developed nonunion and received blood transfusion. The total operation time in MIPO group was significantly higher than IMN group (94.5±18.2 vs 75.3±19.8 p=0.01) (Table2).

(a) (b) (c)

Fig. 2 (a) radiographic findings of ankle showing distal tibial fracture (b,c) radiographic findings anteroposterior and lateral postoperative after minimally invasive plate osteosynthesis.

(a) (b) (c)

Fig. 3 (a) radiographic findings of ankle showing distal tibial fracture (b,c) radiographic findings anteroposterior and lateral postoperative after closed interlocking intramedullary nailing.

Discussion

The distal tibial fracture is one of the most challenging fractures for orthopaedic surgeons because of subcutaneous location, minimal vascularity, difficulty to reduction to achieve stable fixation. Several complications including, wound infection, malalignment, delayed union and nonunion often be reported. Currently, both MIPO and IMN are the most commonly be used to treat these fractures. However, which is the ideal treatment is still controversial. Some authors argued that IMN was superior, while some authors suggested that the MIPO technique provided better functional and clinical results[3,18,19].

From the systematic review and meta-analysis reported the union time of the distal tibial fracture treating with IMN versus MIPO was 12-24 weeks[20]. There was no significant difference in union time between the two groups. Moreover, Polat et al conducted a randomized controlled study that showed mean union time of MIPO was also not different from IMN method (133.9±15.2 days and IMN was 128.8±13.3 days) [17]. In general, the time to union of adult long bone fractures is about 12-16 weeks; therefore, we conducted this study to evaluate rate of union within 12 weeks after MIPO versus IMN in closed distal tibial fracture. The result of our study found that the rate of union within 12 weeks was not different which similar to the results from the previous study[20]. Postoperative malalignment has not been a major problem in our study, as in a previous study by Guo et al.[12] There were no nonunion cases, suggesting the advantage of the closed application of IMN and MIPO for the reserve of soft tissues and fixation of the fracture. Our study found the total operative time in MIPO group was significantly longer than IMN group. Various reasons might explain this result, first this procedure required technical expertise and surgical experience, second most orthopaedic surgeons have more familiar with IMN procedure than MIPO.

The sample size of our study was calculated by including most of covariates that have already known as factors contributing to union of tibial fracture; therefore underpower error was diminished and result of the primary outcome was plausible.

There were some limitations of this study. First, this was a retrospective study therefore, some inevitable bias and missing data might occur. Second, the postoperative treatment such as rehabilitation program, initiation weight bearing was depended on each physician's decision which might affect the results. Third, plain radiography was performed in 3 weeks interval, the analysis of union

time might be deviated if the callus formations that met criteria occurred before time of follow up. Fourth, the radiographic findings were evaluated by only two orthopaedic attending staff, interpretation disagreement might occur and another staff should be required to make the decision.

Conclusions

In closed distal tibial fracture patients, the treatment with MIPO was not different in the rate of union within 12 weeks compared with IMN.

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การติดของกระดูกหน้าแข้งส่วนปลายที่ได้รับการผ่าตัดแบบ Minimally Invasive Plate Osteosynthesis เปรียบเทียบกับ Closed Intramedullary Nailing ในกระดูกหน้าแข้งส่วนปลายหักแบบปิด: การศึกษาย้อนหลัง

อรุณ วรนุช, พบ, พรทิพา ตันติบัณฑิต, พบ

บทนำ: *กระดูกหน้าแข้งส่วนปลายหักเป็นภาวะที่พบได้บ่อยเป็นอันดับสองของกระดูกหน้าแข้งหักทั้งหมดซึ่งมีความยุ่งยากในการรักษาเนื่องจากขนาดโพรงกระดูกที่กว้างและบานออก มีกล้ามเนื้อและเส้นเลือดมาเลี้ยงกระดูกตำแหน่งดังกล่าวน้อย ทำให้พบปัญหาของภาวะกระดูกติดช้า และภาวะกระดูกไม่ติดได้มากกว่าตำแหน่งอื่นของกระดูกหน้าแข้ง การรักษาโดยวิธีผ่าตัดแบบ Closed intramedullary Nailing (IMN) และ Minimally Invasive Plate Osteosynthesis (MIPO) เป็นวิธีที่นิยมใช้ในปัจจุบัน อย่างไรก็ตามยังคงไม่มีข้อสรุปว่าวิธีใดได้ผลดีกว่าในด้านการติดของกระดูก*

วัตถุประสงค์: *เพื่อเปรียบเทียบอัตราการติดของกระดูกหน้าแข้งส่วนปลายภายในระยะเวลา 12 สัปดาห์ที่ได้รับการรักษาด้วยการผ่าตัดแบบ MIPO เปรียบเทียบกับ IMN*

ระเบียบวิธีวิจัย: *เป็นการศึกษาแบบย้อนหลังในกลุ่มผู้ป่วยกระดูกหน้าแข้งส่วนปลายหักแบบปิดที่เข้ารับการรักษาที่หอผู้ป่วยศัลยกรรมกระดูกและข้อ โรงพยาบาลศูนย์ขอนแก่น ระหว่างวันที่ 1 มกราคม พ.ศ.2560 ถึง วันที่ 30 มิถุนายน พ.ศ. 2563 วัตถุประสงค์หลักเพื่อเป็นการศึกษาอัตราการติดของกระดูกหน้าแข้งส่วนปลายภายในระยะเวลา 12 สัปดาห์หลังการผ่าตัด*

ผลการศึกษา: *มีผู้เข้าร่วมการศึกษาทั้งสิ้น 116 ราย ผู้ป่วยที่ได้รับการรักษาด้วยวิธี MIPO 63 รายและ IMN group 53 ราย อายุเฉลี่ยของผู้ป่วยคือ 36.9±16.7ปี เป็นเพศชาย 87 ราย (75%) พบอัตราการติดของกระดูกภายใน 12 สัปดาห์ในกลุ่ม MIPO 38 ราย (60%) และ กลุ่ม IMN 23 ราย (43.3%) ซึ่งพบว่าไม่มีความแตกต่างอย่างมีนัยสำคัญทางสถิติ (AOR 1.81; 95%CI 0.78-4.20 p=0.17) ระยะเวลา (นาที) ที่ใช้ในการผ่าตัดในกลุ่ม MIPO นานกว่ากลุ่ม IMN group (94.5±18.2 vs 75.3±19.8 p=0.01) ซึ่งแตกต่างอย่างมีนัยสำคัญทางสถิติ*

สรุป: *ไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติในการติดของกระดูกหน้าแข้งส่วนปลายหักแบบปิดภายในระยะเวลา 12 สัปดาห์ในผู้ป่วยที่ได้รับการผ่าตัดโดยวิธี IMN เปรียบเทียบกับวิธี MIPO*