ORIGINAL ARTICLE

Intramedullary nailing versus minimally invasive plating in the treatment of distal tibial extra-articular fractures: Comparison of cost analysis in Turkey

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ABSTRACT

BACKGROUND: Minimally invasive percutaneous plate osteosynthesis (MIPO) and intramedullary nailing (IMN) are the two most commonly used methods for distal tibial extra-articular fractures; however, the ideal treatment is still on debate. The aim of this study was to compare MIPO and IMN in the treatment of distal tibial extra-articular fractures in terms of cost analysis according to health insurance records in Turkey.

METHODS: The data of patients who underwent either MIPO or IMN for the treatment of distal tibial extra-articular fractures between 2013 and 2018 were analyzed in this retrospective study. Patients' clinical data, as well as the overall expenses from the first admission until return to work including hospitalization, and all outpatient controls had been reviewed from the hospital's billing department. The total amount of money paid per month by Turkish National Social Security Institution to the patient until the patient's returns to work were also recorded.

RESULTS: 118 consecutive patients (35 female-83 male) with the mean age of 37.2±13.4 were participated to the study. IMN group consisted of 57 patients with a mean age of 36.7±12.8 years, and MIPO group consisted of 61 patients with a mean age of 37.8±13.6 years. No significant differences were observed between study groups in terms patients' age, gender, fracture classification (AO/OTA: Arbeitsgemeinschaft für Osteosynthesefragen/Orthopedic Trauma Association), soft-tissue injury (Tscherne classification), presence of type I open fracture, and presence of accompanying fibula fracture. There was no statistical difference between two groups in terms of pre-operative hospital stay (p=0.713). However, the mean length of hospital stay was significantly higher in the MIPO group (p=<0.001). The means of number of total outpatient controls, time to union, and return to work were also significantly higher in the MIPO group (p=0.005, p<0.001 and p<0.001, respectively). The mean hospital cost until discharge and the mean total cost until return to work were significantly higher in the MIPO group (p=0.001 and 0.001, respectively). The mean total costs of hospital stay and outpatient controls were also significantly higher in the MIPO group (p=0.001 and 0.004, respectively). The mean implant costs did not significantly differ between groups (p=0.179).

CONCLUSION: According to the results acquired from the present study, IMN is a better option compared to MIPO for the treatment of extra-articular distal tibial fractures in terms of costs paid by the national health insurance in Turkey.

Keywords: Cost analysis; distal tibial fractures; extra-articular; intramedullary nailing; minimally invasive plating.

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INTRODUCTION

Common definition of distal tibial fractures includes distal extra-articular tibial fractures which are located between 4 and 12 cm from the tibial plafond. The thin, flute-shaped metaphyseal bone along with a short distal fracture segment may be difficult to realign or stabilize by conservative treatment.[1] To date, the choice of implant for the surgical management of this type of fracture is still a controversy according to the literature. A variety of treatments has been used, including plating, intramedullary nailing (IMN), and external fixation. Traditional open reduction with internal fixation using plate fixation has been linked to soft tissue complications and nonunion.[2] Consequently, recent less invasive techniques were introduced to treat these fractures. The most commonly used methods are closed IMN and minimally invasive plate osteosynthesis technique (MIPO).

IMN of distal tibial fractures avoids disturbing soft tissue coverage and protects vascular supply resulting in high rates of union.[3] Some authors stated that IMN is an effective technique for stabilizing distal tibia.[4,5] However, fractures in the region of distal tibial metaphysis when stabilized with IMN face a technical challenge due to the incongruity difference between diameters of medullary canals of proximal and distal fragments[6] bringing the risk of malunion and need for secondary procedures.[7–9]

MIPO of the distal tibia needs small incisions to insert the plate and screws with the assistance of external guide. The plate is tunneled under the soft tissues and allows for the application without extensive dissection.[10] Studies have shown that the extraosseous blood supply is better preserved when the plate is applied in this fashion, and it seems to facilitate fracture union, decrease problems with infection, and minimize the need for bone grafting when compared with traditional plating.[11]

In the literature, many clinical studies compared IMN and MIPO previously.[12–23] These studies compared methods in terms of clinical and radiographic outcomes. Given rapidly escalating health-care costs, and the need to allocate finite health-care resources more efficiently, money spent on these treatments is also important as clinical outcomes. Therefore, the aim of this study was to compare MIPO and IMN in the treatment of distal tibial extra-articular fractures in terms of cost analysis according to health insurance records in Turkey.

MATERIALS AND METHODS

Study Design and Patient Population

This retrospective study was approved by institutional ethical review board and conducted in accordance with the Declaration of Helsinki. Patients who underwent either MIPO or IMN for the treatment of distal tibial extra-articular fractures at a tertiary referral hospital between 2013 and 2018 were reviewed from our medical records. Active worker patients aged between 18 and 55 years old with the diagnosis of distal metaphyseal fracture of the tibia which was located between 4 cm and 12 cm from the tibial plafond treated by either closed IMN or MIPO were included. Patients with pathological fractures (n=7), rheumatologic disorders (n=3), chronic systemic diseases such as diabetes mellitus and renal failure (n=11), immunodeficiency states (n=1), accompanying fractures and/or dislocations (n=13), fractures associated with nerve or vascular injury requiring repair (n=1), types II and III open fractures according to Gustilo and Anderson classification (n=13), and grade 3–4 fractures according to Tscherne classification (n=13) were excluded. Patients who had special health insurance other than Turkish National Social Security Institution (n=15) were also excluded due to the difference of payments which might affect the results. A total of 118 patients were participated in the study, and patients were grouped according to the treatment method. IMN group consisted of 57 patients with a mean age of 36.7±12.8 years, and MIPO group consisted of 61 patients with a mean age of 37.8±13.6 years.

Surgical Technique

The decision regarding the choice of implant made by the operating surgeon. All patients received prophylactic first-generation cephalosporin 30 min before the procedure.

In the IMN group, all patients were operated through conventional infrapatellar approach. All tibia fractures were managed with closed indirect reduction along with internal fixation. Reamed intramedullary tibial nail, end cap, and a median of four locking screws were used during surgery. In the MIPO group, all tibia fractures were managed with closed indirect reduction along with internal fixation. One distal tibia anatomical plate and a median of nine screws were used to fix the fractures.

Fibula fractures close to the syndesmosis were managed with open reduction along with internal fixation. One distal fibula anatomical plate and a median of 6 screws were used to fix the fibula fractures. Six fibular fractures in the IMN group and twelve fibular fractures in the MIPO group were stabilized with plate fixation.

Post-operative Follow-up

Post-operative intravenous antibiotics were continued for 24 h. All patients received low-molecular-weight heparin for thromboembolic prophylaxis until the end of the post-operative 4th week. Ankle and knee joint exercises were started at post-operative 1st day. Patients who had no wound problems such as drainage from wound, erythema, and swelling around wound were discharged at post-operative 2nd day. Patients in the IMN group were allowed early weight bearing as tolerated because of achieving a more stable fixation than the MIPO group. Patients in the MIPO group were allowed weight bearing after 6 weeks when radiologic evidence of

progress toward union was seen. The first follow-up after surgery was performed on the 15th post-operative day and sutures removed. Successive follow-ups were planned once every month. Patients with wound problems were controlled more frequently at early stages.

Data Evaluation

Patients demographics (age and gender), classification of the fracture according to the Arbeitsgemeinschaft für Osteosynthesefragen/Orthopedic Trauma Association (AO/OTA),[24] accompanying fibula fracture, presence of Gustilo type I open fracture, and severity of soft-tissue damage according to Tscherne classification were noted from our medical records. Total hospital stays (day), time to union (week), total number of follow-up visits, and all post-operative complications such as wound problems, infection, non-union, and need for secondary surgery were recorded.

All radiographs were reviewed by 3 of the authors. These authors were not aware of the study during data collection. However, it was impossible to blind the IMN and MIPO groups due to implants seen in radiographs. The union time and fracture type were proved if two or three of authors agreed about the diagnosis. Radiographic healing was defined as the bridging of callus at least three cortices. The patient could return to work after the last follow-up for bone union and wound healing. Deep infection rates, wound problems, non-union rates, and requirement for physical therapy in both groups were recorded.

Cost-analysis Measurement

The overall expenses from the first admission until the time to return to work, including hospitalization, and all outpatient controls paid by the SSI to the hospital have been acquired from the hospital's billing department. The money paid monthly by the national insurance institution to the patient until return to work was also calculated. The national insurance institution in Turkey pays the patient 2/3 of his salary monthly until the patient returns to work. Calculations were made assuming that all patients receive salaries at the minimum wage of 2300 Turkish Lira (TL) (410,71 $). The overall bill paid by the insurance to the hospital was calculated and valued regarding 2019 prices. All costs that paid by the insurance were expressed in TL and converted into US Dollars at the average exchange rate of year 2019. All costs were summarized at Table 1.

Statistical Analysis

Statistical analysis was performed by using SPSS 25.0 (SPSS Inc., IBM, NY, USA). Numerical variables were given as means

Table 1. The summary of unit cost values

Unit cost values	Payment in USD*
Hospital costs	
Average payment for distal tibia fracture fixation surgery	304.10 $
Average payment for hospital stay per day	8.03 $
IMN (Mean implant cost for each patient)	
End cap	15.17 $
Nail	241.07 $
Mean four locking screws	103.57 $
Total	359.81 $
MIPO (Mean implant cost for each patient)	
Distal tibia anatomical plate	196.42 $
Mean nine locking screws	168.75 $
Total	365.17 $
Fibular fixation	
Distal fibula plate	142.85 $
Mean six locking screws	112.5 $
Total	255.35 $
Postoperative costs	
Average payment for outpatient control per patient	8.92 $
Average payment for physical therapy per 10 sessions	34.28 $
Average incapacity salary per month	273.8 $

*According to the average TL/USD exchange rate of 2019, IMN: Intramedullary nailing; MIPO: Minimally invasive plate osteosynthesis technique.

and standard deviations, and categorical variables were given as frequencies and percentages. The distribution of the variables was analyzed using Kolmogorov–Smirnov test. Comparison of means was performed by student's t-test; comparison of frequencies was performed by Chi-square test. Statistical significance was accepted when p-value is below 0.05.

RESULTS

Patients demographics and clinical characteristics were demonstrated in Table 2. The mean follow-up was 14.5 weeks (range, 11–40 weeks) for the IMN group and 21.5 weeks (range, 10–130 weeks) for the MIPO group. No significant differences were observed between study groups in terms patients' age, gender, fracture classifications (AO/OTA classification), soft-tissue injury (Tscherne classification), presence of type I open fracture, and presence of accompanying fibula fracture (Table 2).

There was no statistical difference between two groups in terms of pre-operative hospital stay (p=0.713). However, the mean length of hospital stay was significantly higher in the MIPO group (p≤0.001). The means of number of total outpatient controls, time to union, and return to work were also significantly higher in the MIPO group (p=0.005 p<0.001 and p<0.001, respectively). At the latest follow-up, all fractures were healed in the appropriate final alignment that was defined as <5 degrees of angular deformity in both AP and

Table 2. The demographic data and clinical characteristics of the patients

	MIPO group (n=61)	IMN group (n=57)	p-values
Age, mean±SD	37.8±13.6	36.7±12.8	0.897
Gender, n (%)			0.970
Female	18 (29.5)	17 (29.9)	
Male	43 (70.5)	40 (70.1)	
Tscherne Classification, n (%)			0.837
Grade 0	20 (32.7)	21 (36.9)	
Grade 1	28 (45.9)	26 (45.7)	
Grade 2	13 (21.4)	10 (17.4)	
AO/OTA Classification, n (%)			0.997
42A	26 (42.7)	24 (42.1)	
42B	20 (32.8)	19 (33.4)	
42C	15 (24.5)	14 (24.5)	
Open fracture, n (%)	7 (11.5)	6 (10.6)	0.869
Fibula fracture, n (%)	46 (75.4)	43 (75.5)	0.997

IMN: Intramedullary nailing; MIPO: Minimally invasive plate osteosynthesis technique; AO/OTA: Arbeitsgemeinschaft für Osteosynthesefragen/Orthopedic Trauma Association; SD: Stardard deviation.

Table 3. The comparison of the study groups according to length of hospital stay, postoperative controls, time to union, and complications

	MIPO Group (n=61)	IMN Group (n=57)	p-values
Length of preoperative hospital stay (days)	2.8±2.5	2.6±2.9	0.713
Length of hospital stay (days)	8.3±3.3	6.2±4.0	**<0.001**
Mean number of outpatient control	6.2±4.1	4.6±1.1	0.005
Mean time to union (weeks)	15.46±4.15	10.16±4.32	**0.001**
Return to work (weeks)	16.51±4.18	11.18±4.31	**0.001**
Physical therapy requirement	2	1	0.558
Local complications	6	3	0.349
Medical complications	2	1	0.599
Secondary surgery	2	2	0.945

*Bold p-values indicate statistical significance. IMN: Intramedullary nailing; MIPO: Minimally invasive plate osteosynthesis technique.

Table 4. The comparison of study groups by means of costs

Average total cost in USD*	MIPO Group (n=61)	IMN Group (n=57)	p-values
Total cost until discharge	1631.6±531.6	1343.3±393.9	**0.001**
Total cost until return to work	2950.7±1355.1	2326.9±509.8	**0.001**
Hospital stay	66.6±26.4	49.94±32.1	**0.001**
Outpatient control	55.8±36.6	41.3±10.4	**0.004**

*According to average TL/USD exchange rate of 2019. **Bold p-values indicate statistical significance. IMN: Intramedullary nailing; MIPO: Minimally invasive plate osteosynthesis technique.

lateral views and <1.0 cm of shortening. One patient in each group underwent autologous iliac bone grafting due to lack of union at 6th month. One patient in each group underwent early implant removal, debridement, prolonged antibiotherapy, and re-fixation due to deep infection. The number of physical therapy requirement, post-operative local and medical complications, as well as need of secondary surgery did not significantly differ between groups (Table 3).

The mean intervention costs from admission until discharge were 1343.3 $ for the IMN group and 1631.6 $ for the MIPO group, with a mean difference of 288.3 $. The mean total costs that paid by the insurance from admission until return to work were 2326.9 $ for the IMN compared with 2950.7 $ for the MIPO group, with a mean difference of 623.8 $. The mean hospital cost until discharge and total cost until return to work were significantly higher in the MIPO group (p=0.001 and 0.001, respectively). The mean total costs of hospital stay and outpatient controls were also significantly higher in the MIPO group (p=0.001 and 0.004, respectively). The mean implant costs did not significantly differ between groups (p=0.179). There was a significant relationship between total hospital stay and total cost (Table 4). The total cost increases as the hospital stay increases (p=0.014/r=0.322 for IMN and p=0.009/r=0.329 for MIPO).

DISCUSSION

Our results demonstrated that IMN is a better option than MIPO for the treatment of distal tibial extra-articular fractures in terms of decreased costs. Although many clinical studies have compared the clinical and radiographic outcomes of IMN and MIPO in the treatment of distal tibial fractures, there is still debate on the choice of intervention.[13,22,23] Mao et al.[25] reviewed 1863 extra-articular fractures of the distal tibia and reported that rates of deep infection, delayed union, and removal of instrumentation were similar for patients who underwent two types of fixation but that nail fixation was significantly associated with more malunions. Hu et al.[26] compared these two methods in their meta-analyses and found no significant difference between IMN and plate fixation with regard to the operation time, radiation time, non-union, deep infection, delayed union, union time, AOFAS, and Disability Rating Index. Authors reported that IMN was superior in terms of functional improvement of the ankle and reduction of post-operative wound superficial infection, whereas plate fixation was more advantageous in achieving anatomical reduction and decreasing knee pain.

There is limited data in the literature about the money spent on IMN and anatomical locking plate in the management of distal tibial fractures. Maredza et al.[27] suggested that nail fixation is a cost-effective alternative to locking plate fixation. Costa et al.[28] found that recovery within all outcomes was faster in the IMN group and costs were lower. In accordance with the literature, we found that national insurance of our country paid less for the treatment of extra-articular distal tibial fractures managed by IMN than MIPO.

Yang et al.[15] retrospectively compared IMN and plate fixation for distal tibia fractures and reported a significantly shorter time to union in their IMN group compared to plating. In their meta-analysis, Xue et al.[16] mentioned that time to union was significantly longer in the MIPO group. In compliance with the literature, the mean time to union was significantly longer in the MIPO group in our study (15 vs. 10 weeks). Our results showed that the most important reason that increased the post-operative cost paid by the insurance is longer time to union. Longer time to union caused later return to work and increased the money paid by the insurance to the patient monthly and the money paid for outpatient controls.

A meta-analysis of randomized controlled studies indicated that there was no significant difference in deep infection occurrence between IMN and MIPO groups.[26] In line with the literature, we observed no significant difference in deep infection in both groups. Deep infection increases the total cost because it causes recurrent operations, prolonged hospital stays, and delayed return to work. In our study, we encountered deep infection in one patient both in MIPO and IMN groups, therefore, we found that these two infected patients did not create a disadvantage in terms of mean total cost statistically to the group they belonged to. On the other hand, non-union was encountered once for each IMN and MIPO groups. Although the treatment of these patients was more expensive than the others, this also did not affect the total cost statistically. The reason that both MIPO and IMN groups

had similar non-union rates and deep infection rates may be resulted from exclusion of patients with Gustilo-Anderson Type 2/3 open fractures, Tscherne type 3/4 soft tissue injuries, and chronic systemic diseases such as diabetes. According to a recent analysis of 358 patients with open tibia fracture, the important causes that increase the cost are deep infection and a total length of stay in hospital.[29]

In this study, hospital stay is significantly longer in the MIPO group than IMN (8.3 vs. 6.2 days), and there is a significant relationship between total hospital stay and total cost. The total cost increases as the hospital stay increases. This finding may be resulted from larger skin incisions required for the MIPO technique which may contribute to wound problems and increased post-operative pain. According to the literature, patients treated with IMN had fewer wound problems compared to the patients treated with MIPO.[19,20] In our study, we encountered more wound problems in the MIPO group, although the difference was not statistically significant. Delayed wound problem can also cause delayed return to work, increase the number of outpatient controls conclusively increase the total cost.

According to our findings, there was no significant difference in total cost of implants used in both groups. In our study, six fibular fractures were stabilized with plate fixation in IMN group, and twelve fibular fractures were stabilized with plate fixation in MIPO group. Although it did not affect the total cost statistically, treatment of the accompanying distal fibula fracture also increases the total cost. The stability of the distal tibia constructs appears greater for IMNs than for plates (standard or locked) in the distal tibia so that fixation of the fibula is not needed frequently in patients undergoing IMN.[18]

The main limitation of this study is its retrospective design that only evaluated the costs paid by national insurance. The other costs paid by the patients and their relatives were not evaluated. In addition to that, we set the salaries of workers at a minimum wage that did not reflect the actual salary of the patients. However, we aimed to compare two techniques in a standardized fashion which were performed in a single center in the same manner. It is difficult to standardize the patients' actual salaries, and costs paid by the patients except paid by the national insurance. It is also difficult to standardize the implants used during surgery which may be affected by the surgeon's choice. Therefore, we calculated the costs of implants by a standardized method commonly used for the fixation of the fractures. The main strength of our study is being the first study in the literature evaluating cost-analysis of two common methods for the treatment of distal tibial extra-articular fractures in Turkey.

In conclusion, according to the results acquired from the present study, IMN is a better option compared to MIPO for the treatment of extra-articular distal tibial fractures in terms of costs paid by the national health insurance in Turkey. Our results demonstrated a significantly longer time to union as well as a significantly longer time of hospital stay in the MIPO group which caused a prolonged return to work and an increase in the amount of money paid by the insurance.

Ethics Committee Approval: This study was approved by the Health Sciences University Metin Sabancı Baltalimanı Bone Diseases Training and Research Hospital Ethics Committee (Date: 18.09.2019, Decision No: 354).

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ORİJİNAL ÇALIŞMA - *ÖZET*

Tibia distal eklem dışı kırıklarının tedavisinde kanal içi çivileme ve minimal invaziv plaklama: Türkiye'de maliyet analizinin karşılaştırılması

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AMAÇ: Minimal invaziv perkütan plak osteosentezi (MIPO) ve kanal içi çivileme (IMN) distal tibia eklem dışı kırıkları için en sık kullanılan iki yöntemdir; ancak ideal tedavi halen tartışmalıdır. Bu çalışmanın amacı, distal tibia eklem dışı kırıklarının tedavisinde MIPO ve IMN'yi Türkiye'deki sağlık sigortası kayıtlarına göre maliyet analizi açısından karşılaştırmaktır.

GEREÇ VE YÖNTEM: Bu geriye dönük çalışmada 2013–2018 yılları arasında distal tibia eklem dışı kırıkları tedavisi için MIPO veya IMN uygulanan hastaların verileri incelendi. Hastaların klinik verileri ve ilk yatıştan işe dönüşe kadar hastaneye yatış dahil toplam masraflar ve tüm ayakta tedavi kontrolleri hastanenin faturalandırma bölümünde gözden geçirildi. Sosyal Güvenlik Kurumu (SGK) tarafından işe dönene kadar hastaya aylık ödenen toplam para miktarı da kaydedildi.

BULGULAR: Çalışmaya yaş ortalaması 37.2±13.4 olan 118 ardışık hasta (35 kadın–83 erkek) katıldı. İntramedüller çivileme (IMN) grubu yaş ortalaması 36.7±12.8 yıl olan 57 hastadan, MIPO grubu ise yaş ortalaması 37.8±13.6 yıl olan 61 hastadan oluşmaktaydı. Çalışma grupları arasında hastaların yaşı, cinsiyeti, kırık sınıflamaları (AO/OTA sınıflandırması), yumuşak doku yaralanması (Tscherne sınıflandırması), tip I açık kırık varlığı ve eşlik eden fibula kırığı varlığı açısından anlamlı fark gözlenmemiştir. Ameliyat öncesi hastanede kalış süresi açısından iki grup arasında istatistiksel fark yoktu (p=0.713). Ancak ortalama hastanede kalış süresi MIPO grubunda anlamlı olarak daha yüksekti (p=<0.001). MIPO grubunda toplam ayaktan tedavi kontrolü sayısı, kaynama süresi ve işe dönüş süresi de anlamlı olarak daha yüksekti (sırasıyla, p=0.005 p<0.001 ve p<0.001). Taburculuğa kadar ortalama hastane maliyeti ve işe dönüşe kadar ortalama toplam maliyet MIPO grubunda anlamlı olarak daha yüksekti (sırasıyla, p=0.001 ve 0.001). MIPO grubunda ortalama hastanede yatış ve ayaktan tedavi kontrolleri maliyetleri de anlamlı derecede yüksekti (sırasıyla, p=0.001 ve 0.004). Ortalama implant maliyetleri gruplar arasında anlamlı farklılık göstermedi (p=0.179).

TARTIŞMA: Mevcut çalışmadan elde edilen sonuçlara göre IMN, Türkiye'de ulusal sağlık sigortası tarafından ödenen maliyetler açısından eklem dışı distal tibia kırıklarının tedavisinde MIPO ile karşılaştırıldığında daha iyi bir seçenektir.

Anahtar sözcükler: Distal tibia kırıkları; eklem dışı; intramedüller çivileme; maliyet analizi; minimal invaziv plaklama.

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