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Klinik Çalışma

Single or double distal locking in intramedullary nailing of tibial shaft fractures: a prospective randomized study

Tibia cisim kırıklarının intramedüller çivilemesinde tek veya çift distal kilitleme: Prospektif randomize bir çalışma

Onur HAPA, Hasan Hilmi MURATLI, Halil Yalçın YÜKSEL, Levent ÇELEBİ, Dağhan DOĞRUYOL, Ali BİÇİMOĞLU

BACKGROUND

The number of distal locking screws may have an effect on union, complication rates and operation time. The purpose of this study was to determine the effect of one or two distal locking screws in unreamed intramedullary nailing of closed or grade 1 open, simple or wedge tibial shaft fractures on the incidence of malunion, delayed union, non-union, and screw failure.

METHODS

Fifty-seven patients (39 male, 18 female; mean age 38.5±10.7 years) were randomized to two groups as either one or two distal locking screws and were evaluated prospectively for the incidences of malunion, delayed union, non-union, and screw failure. Twenty-nine patients were included in the two distal screws group and 28 patients in the single distal screw group. Groups were then subdivided to end fractures (proximal+distal end fractures) or mid-shaft fractures and re-evaluated for the incidences of complications. Mann-Whitney U, chi-square and T tests were used for statistical analysis.

RESULTS

Mean follow-up was 2.4 years (range, 1.5-4.7 years). There was no case of malunion in either group. The incidences of delayed union, non-union or screw failure were not different (p>0.05). However, complication rate for end fractures in the two screw group was higher than that in the one screw group (p:0.04).

CONCLUSION

For non-complex, closed or grade 1 open tibial shaft fractures, locking of an intramedullary nail with a single distal screw is safe, and may help to decrease operation time and radiation exposure.

Key Words: Bone; distal locking; fractures; tibial fractures.

AMAÇ

Distal kilit sayısının kaynamaya, komplikasyon oranına ve ameliyat süresine etkisi olabilir. Bu çalışmada, bir veya iki distal kilit vidasının, kapalı veya tip 1 açık, basit veya kama tipi tibia cisim kırıklarında oymasız yapılan intramedüller çivilemede yanlış, gecikmiş kaynama, kaynamama ve vida yetersizliği görünme sıklığına etkisi incelendi.

GEREÇ VE YÖNTEM

Elli yedi hasta (39 erkek, 18 kadın; ortalama yaş 38,5±10,7) prospektif olarak tek distal kilit veya iki distal kilit gruplarına ayrıldı. Gruplar yanlış, gecikmiş kaynama, kaynamama ve vida yetersizliği sıklığı açısından değerlendirildi. Yirmi dokuz hasta iki vida grubunda, 28 hasta tek vida grubundaydı. Gruplar daha sonra uç kırıklar (üst uç+alt uç) ve orta cisim kırıklar olarak ayrıldı ve komplikasyon sıklığı açısından incelendi. İstatistiksel değerlendirme, Mann-Whitney U, ki-kare ve T testleriyle yapıldı.

BULGULAR

Ortalama takip süresi 2,4 yıldı (dağılım 1,5-4,7 yıl). İki grupta da yanlış kaynama yoktu. Gecikmiş kaynama, kaynamama veya vida yetersizliği gruplar arasında farklı değildi (p>0,05). Fakat, komplikasyon oranı iki vida grubun da uç kırıkları için tek vida grubuna göre daha fazla idi (p=0,04).

SONUÇ

Kompleks olmayan, kapalı veya tip 1 açık kırıklarda tek distal kilitleme güvenli olup, cerrahi süreyi ve radyasyon maruziyetini azaltmaya yardımcı olabilir.

Anahtar Sözcükler: Kemik; distal kilitleme; kırıklar; tibia kırıkları.

3rd Department of Orthopaedics and Traumatology,
Ankara Numune Education and Research Hospital, Ankara, Turkey.

Ankara Numune Eğitim Araştırma Hastanesi,
3. Ortopedi ve Travmatoloji Kliniği, Ankara.

Correspondence *(İletişim):* Onur Hapa, M.D. Çelikkent Sitesi A-2, No: 6 Çayyolu, Ankara, Turkey.
Tel: +90 - 312 - 240 32 70 Fax *(Faks)*: +90 - 374 - 270 45 85 e-mail *(e-posta):* onurhapa@gmail.com

Closed and grade 1 open tibia diaphysis fractures are best treated by closed intramedullary nailing.[1-3] The number of distal locking screws may have an impact on screw failure and time to union. Distal locking screws increase the operation time and radiation exposure for both the patient and surgeon.[4,5] Kneifel and Buckley[6] found more distal screw failures with one distal locking screw than with two after unreamed tibia intramedullary nailing, but non-union rates were not different between groups. However, one distal screw may not be sufficient for rotational and axial stability, especially in comminuted and segmental fractures.

In our study, we aimed to compare one versus two distal locking screws in patients with closed or grade 1 open non-complex fractures, for incidences of delayed union, non-union, malunion, and screw failure.

MATERIALS AND METHODS

From January 1999 to December 2004, 182 patients with fractures of the tibial diaphysis were admitted to our center. Fractures were grouped according to the level of fracture (proximal, middle or distal third) and classified using AO/OTA classification.[7,8]

Types 2 and 3 open fractures and AO type C fractures were excluded from this study. Patients with fractures at least 3 cm distal to the tibial tuberosity and 3 cm proximal to the ankle were included in the study. Fifty-seven patients, meeting the inclusion criteria, were randomized to two groups as either one or two distal locking screws after unreamed tibia intramedullary nailing. Twenty-nine patients had two and 28 patients only one distal locking screw. None of the patients was lost to follow-up.

All patients had a preoperative calcaneal traction pin. In the closed fractures group, 1 g of cefazolin was administered prophylactically at the time of induction of anesthesia and repeated daily for 72 hours postoperatively. Grade 1 open fractures were debrided and irrigated within 24 hours of the injury. Patients with open fractures received a combination of antibiotics effective against gram-positive and gram-negative organisms and anaerobes immediately, and these were continued for 72 hours.

The operation was performed within 48 hours. Patients were positioned supine on a fracture table with traction applied through the calcaneal pin. Exposure was through a midline skin incision through the patellar tendon. Depending on the measured width of the medullary canal, either a 9 mm or 10 mm intramedullary nail was used. Proximal locking was done with the appropriate target devices. Distal locking was performed free-hand using image intensifier. Strict intraoperative precautions were taken to avoid a rotational error of more than 10°.

Delayed union was defined as a failure of formation of callus at a minimum of three cortices on anteroposterior and lateral radiographs in the third month postoperatively. Non-union was defined as radiological evidence of atrophic union or hypertrophic nonunion and presence of pain at fracture site 24 weeks after the operation.[9,10]

Treatment protocols were dynamization for delayed union and exchange nailing for non-union. An angular deformity of >10°, rotational deformity of >10° and shortening of >1 cm were regarded as malunion.[11] Angular deformity was measured on anteroposterior and lateral radiographs at their last follow-up. Tibial length was measured both clinically and radiologically (at the ortho-roentgenographs) and the difference between the operated and contralateral leg was calculated. Rotational angulation was measured with the patient sitting with pending legs, as the angle between the sagittal plane and a line touching the medial border of the hallux and medial border of the heel.[10]

End fractures (proximal and distal fractures) were grouped and results and complications were compared to the group of midshaft fractures.

Postoperatively, patients were kept on partial weight-bearing for six weeks and allowed to progressively increase weight-bearing after confirmation of callus on radiographs.

Mann-Whitney U test was used to compare shortness and degree of rotation; chi-square test to compare incidences of delayed union, non-union and screw failure and to compare groups for fracture type, localization, and gender; and T test to compare groups for age. Regional Ethical Committee approval was obtained. Values of $p < 0.05$ were considered to indicate statistical significance.

RESULTS

The mean follow-up was 2.4 years (range, 1.5-4.7 years). Thirty-nine patients were male and 18 were female. Their mean age was 38.5±10.7 years. Thirty-three fractures (57.9%) were type A and 24 fractures (42.1%) were type B. Eighteen (31.5%) were type 1 open and 39 (68.4%) were closed fractures. Twenty-three fractures (40.3%) were distal, 29 (50.8%) midshaft and 5 (8.7%) proximal.

Patient and fracture characteristics and complication rates between groups are summarized in Table 1. There were no significant differences in age, gender and fracture types between the two groups ($p>0.05$).

None of the patients had angular deformity of more than 10°. Mean shortening was 0.41 cm (median value: 0 cm) and 0.36 cm (median value: 0 cm) in the one and two distal screws groups, respectively, and the difference between groups was not significant ($p>0.05$).

Table 1. Patient, fracture characteristics, complications

	Two screws (n:29)	One screw (n:28)
Age	38.9±10.1	38.1±11.5
Sex	19 male, 10 female	20 male, 8 female
Fracture type	15 A, 14 B	18 A, 10 B
Open (O), Closed (C)	10 O, 19 C	8 O, 20 C
Localization (D, M, P)	12 D,14 M, 3 P	11 D, 15 M, 2 P
Complications	11	5
Delayed union	5 (1M, 4D)	2 (1M, 1D)
Non-union	2 (1M, 1P)	0
Screw failure	4 (2D, 2P)	3 (1M, 2D)

D: Distal; M: Middle; P: Proximal.

Rotational deformity was 3.39° (median value: 5°) in the one distal screw group and 1.72° (median value: 0°) in the two screws group, and the difference was statistically significant (p=0.027).

Based on these findings, there was no case of malunion in either group. There were two delayed unions in the single locking group and 5 delayed unions in the double locking group. Two patients in the double locking distal screws group were diagnosed as non-union and treated later following the protocol described above. There was no case of non-union in the single distal screw group. Incidences of delayed union and non-union were not significantly different between groups (p>0.05).

Screw failures were diagnosed on plain radiographs as bent or broken locking screws. Four locking screws failed (2 proximal, 2 distal) in the double distal locking group while 3 screws failed (2 distal, 1 proximal) in the single distal screw group (Fig. 1a, 1b, 1c). The difference between groups was not significant (p>0.05).

End-fractures led to 9 of the total 11 complications (incidence of delayed union+ incidence of non-union+ incidence of screw failure) in the group with two screws and to 3 of 5 complications in the group with one screw, and the difference between groups was significant (p=0.04).

There were no bent or broken intramedullary nails. There was no case of deep infection or osteomyelitis during the follow-up period.

Fig. 1. Type A distal third tibial shaft fracture: **(a)** Preoperative anteroposterior view. **(b)** Postoperative view. **(c)** One year later: fracture union with bent distal locking screw and 1 cm shortening.

DISCUSSION

Displaced and unstable fractures of the tibial diaphysis are treated mostly by intramedullary nailing. Intramedullary nailing has lower complication rates when compared with external fixation or cast immobilization.[12,13] Both current nailing methods, reaming or not reaming, have their specific advantages and disadvantages. A major drawback of unreamed tibial intramedullary nailing is the higher necessity of secondary procedures for nail or screw failure or to achieve union.[14,15] The reported incidence of screw failure ranges from 6% to 52% and compares to our 12.2%.[9,10,14-21]

Gaebler et al.,[9] in a multicentric study, found a rate of 9.2% for delayed union and 2.6% for non-union in unreamed intramedullary nailing using the same definitions of delayed union and non-union as in our study. However it was a multicentric study using different implants and different postoperative mobilization and weight-bearing protocols. Delayed union was higher in type C fractures when compared to type A and B fractures. There was no difference between type A and type B fractures for incidences of delayed and non-unions. Our delayed union incidence was slightly higher (12.2%).

Previous studies related malunion to screw failure in unreamed intramedullary nailing.[14,15] We did not detect any malunion or any case of delayed or non-union in patients with screw failure. Auto-dynamization following screw failure leads to quicker fracture union without problems.

Kneifel and Buckley[6] had detected more screw failures with single than with double distal locking. Two distal locking screws may prevent auto-dynamization due to a more rigid construct. The price of less distal screw failures may well be an increase in union problems with two distal locking screws. However, we did not find any difference between groups for incidences of screw failure. Auto-dynamization at proximal or distal screws may also occur with two distal screws.

In a study of 18 closed or type 1 open femoral fractures treated with intramedullary nailing with one distal locking screw, no non-union was reported. There were two delayed unions and four cases of malunion; however, comminuted fractures were also included. In addition, 11 fractures received open reduction. It was concluded that it is safe to use one distal locking screw except for proximal supracondylar or distal infraisthmal femoral fractures.[22]

A major limitation in our study was the use of a clinical method to measure malrotation. However, none of our patients had problems due to rotational deformities like cosmetic problems or gait disorders. In a previous study, using computerized tomography, a mean of 6.7° of rotational difference between the nailed tibia and contralateral tibia was detected.[23] Of these, more than 20% had rotational deformities over 10°. However, there was no matching of results with clinical symptoms, and interobserver and intraobserver differences amounted to 8°.

There is a tendency to non-union with two distal locking screws when compared to one distal screw.[6] In our study, there were more delayed unions and non-unions in the two distal screws group. However, the difference was not significant, probably due to the low number of cases in each group, especially the proximal and distal end fractures, and to our exclusion of types 2 and 3 open fractures or segmental fractures.

Our exclusion criteria probably made it possible to make the two groups homogeneous, leading to a more correct comparison of one distal screw with two distal screws. Overall, we did not find any difference between one distal locking screw and two distal locking screws regarding the incidences of delayed union, non-union, malunion, and screw failure in noncomplex type A and type B, closed or type 1 open fractures. There is a tendency towards increased rotational deformity and shortening with one distal screw. This difference may become obvious in comminuted, segmental fractures.

Distal locking screws increase the surgical time and radiation exposure for both the patient and surgeon during intramedullary nailing. Grover and Wiss,[4] in their prospective study of 182 femoral fractures treated by closed intramedullary nails, comparing one versus two distal locking screws, reported an increase in radiation emittance and operation time in the two distal locking screws group compared to the one distal locking screw group. The distal screws were placed percutaneously using fluoroscopy and the free-hand technique. Levin et al.,[5] in a study of tibial fractures treated by closed intramedullary nailing, reported approximately the same amount of radiation dose exposure during distal locking of the screws with the radiation exposure during the remainder of the operation (closed nailing+proximal locking of the screws). Based on these studies, it may be speculated that decreasing the number of the distal locking screws may help to decrease the operation time and the radiation exposure. However, as a second limitation of our study, operation time and the amount of radiation exposure were not measured. This subject warrants further studies to evaluate the effect of distal locking screw number on the amount of radiation exposure and operation time.

In this study, we compared the use of one versus two distal locking screws. However, this comparison must be repeated in larger series and/or reamed

intramedullary nailed fractures to draw more definite conclusions and lower union and osteosynthesis problems.

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