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Original Research

Comparison of Clamp Reduction and Manual Reduction of Syndesmosis in Rotational Ankle Fractures: A Prospective Randomized Trial

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ABSTRACT

An optimal outcome of surgical treatment for a syndesmotic injury depends on accurate reduction and adequate fixation. It has been suggested that the use of a reduction clamp for reduction of the syndesmosis results in better reduction and a lower rate of redisplacement than manual reduction. However, these concepts have never been scientifically evaluated. We compared these 2 methods in a prospective randomized trial. A total of 85 acute ankle rotational fractures combined with syndesmotic injury were randomized to syndesmosis reduction with either a reduction clamp or manual manipulation. Reduction of the syndesmosis was assessed radiographically by measuring the tibiofibular clear space, tibiofibular overlap, and the medial clear space immediately postoperatively and at the final follow-up examination. Ankle joint range of motion, visual analog scale score, Olerud–Molander ankle scoring system, and complications were obtained at the last follow-up visit to assess the clinical outcomes. Of the 3 radiographic measurements, the tibiofibular clear space and tibiofibular overlap differed significantly between the 2 groups ($p < .05$). The clinical outcomes did not differ significantly between the 2 groups ($p > .05$). Although differences were found in the radiographic measurements, most syndesmoses in both groups were within the normal range at the final follow-up visit, and the 2 methods of syndesmosis reduction provided similar clinical outcomes. Accordingly, the results of the present study suggest that both of these methods are effective and reliable for reduction of the syndesmosis in rotational ankle fractures.

Numerous studies have suggested that malreduction of syndesmosis in rotational ankle fracture is associated with worse outcomes (1–4). Although various reduction and fixation methods are available for anatomic restoration of the syndesmosis, it is difficult to accurately reduce and assess syndesmosis after an ankle injury (5–8). Recently, the most common operative method used to reduce the syndesmosis has involved placement of a pointed reduction clamp around the distal tibia and fibula to maintain reduction of the syndesmosis with fixation (9–13). Although many newly introduced fixative devices have shown good results, the traditional transsyndesmotic screw fixation method is still popular for fixation of the syndesmosis (11,14–16).

Previous cadaveric studies have identified the advantages and precautions of using clamp reduction in the syndesmosis. Clamp placement in the neutral anatomic axis reduced the syndesmosis most accurately in a cadaveric model, although slight overcompression was frequently observed. However, placing the clamp obliquely resulted in malreduction of an unstable syndesmosis (9,13). It is clear that, with appropriate use, accurate reduction can be achieved with a reduction clamp. Given the preference for clamp reduction, questions remain regarding whether this method is mandatory for syndesmosis injuries. To reduce the syndesmosis, large reduction clamps or forceps are needed. Although most institutions have enough instruments, concern exists regarding the availability of these items. In addition, overcompression was frequently observed with the use of a reduction clamp (9,17). Although Tornetta et al (18) found no limitation in ankle dorsiflexion despite maximum syndesmotic overcompression in a cadaveric study, the clinical result of this observation is uncertain.

In addition to clamp reduction, manual reduction and stabilization have been used. The latter emerging method might decrease the risk of malreduction and overcompression associated with using clamps. Without the requirement for a special instrument, manual reduction could be readily applied to injuries of the syndesmosis (19). However, the results of manual reduction of the syndesmosis have never been scientifically evaluated. Therefore, this issue should be investigated to establish the efficacy of manual reduction of the syndesmosis.

The aim of the present study was to compare the results of clamp reduction and manual reduction for syndesmosis injury in rotational

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ankle fractures using radiographic outcome measures in a prospective, randomized trial.

Patients and Methods

A total of 85 consecutive patients with 85 acute rotational ankle fractures combined with syndesmotic injury who presented to our institution from January 2010 to September 2015 were recruited for the present study. All fractures were Lauge-Hansen supination external rotation, Weber B type, or pronation external rotation, Weber C type. The exclusion criteria were <12 months of follow-up data available, age <16 years (skeletally immature), concomitant tibia shaft fracture, open fracture, history of previous fracture, and/or other notable ankle injury. Patients with marked comminution or displacement of articular surfaces considered for primary external fixation were also excluded (Fig. 1). Our ethical committee approved the study, and all the patients gave written informed consent. The basic demographic data, including age, gender, body mass index, injury mechanism, and fracture type were collected for all 85 patients.

Using sealed envelopes, the patients were randomly allocated, when the stress test result was positive, to either reduction with a reduction clamp or manual manipulative reduction. All the envelopes were evenly predetermined for each group, and the patients were unaware of the randomization process. After anatomic reduction and internal fixation of the lateral and medial malleolar or repair of the deltoid ligament, the syndesmosis stress test was performed. A bone hook was applied to the distal fibula, and lateral force was applied to the distal fibula in the coronal plane to assess the degree of syndesmosis widening. The hook test was considered positive if >2 mm of lateral fibula movement was observed. The senior orthopedic surgeon (H.J.K.), who was also the primary surgeon for all the cases, determined whether the results were positive or negative. Under fluoroscopic guidance, the syndesmosis was reduced and maintained with a reduction clamp or manual manipulation (Fig. 2). One or two 2.5-mm holes were drilled approximately 1.5 to 2 cm above and parallel to the distal tibia joint line (through a plate hole if possible). Three cortices were drilled, and then one of two 3.5-mm cortical screws was inserted. In the manual reduction group, the surgeon used manual manipulation and stabilization with a thumb to generate the reduction force. Once the syndesmosis was considered to have been reduced, another hand drilled and inserted the screw. Postoperatively, radiographs were taken, and a short leg splint was applied for 2 weeks. Forefoot-touch partial weightbearing and active ankle motion exercises were allowed at 2 weeks postoperatively. Full weightbearing was allowed at 6 weeks. No patient underwent hardware removal before the 12-month follow-up examination.

The patients were followed up at 2 weeks, 6 weeks, 3 months, 6 months, and 12 months postoperatively with radiographic and clinical examinations. Radiographic measurements, including the tibiofibular clear space and tibiofibular overlap in the anteroposterior view and medial clear space in the mortise view, were performed by 2 orthopedic surgeons (Y.H.P., J.H.A.), who were unaware of the reduction method used, as described by Miller (20). The acceptable range of reduction was defined as <5 mm of tibiofibular clear space, >6 mm of tibiofibular overlap, and <4 mm of medial clear space (21–24). If 1 radiographic measurement demonstrated an abnormal value, it was defined as syndesmosis malreduction (5). Pain was assessed using a visual analog scale (VAS) (25). Functional outcome was evaluated using the Olerud–Molander ankle scoring system (OMAS), which has been accepted as a reliable and validated ankle-specific function rating scale for ankle fractures in published studies (26). In addition, ankle dorsiflexion and plantarflexion range of motion (ROM) were assessed using a goniometer. All goniometric measurements were taken by a single orthopedic surgeon (H.J.K.) at an outpatient clinic using a standard 30-cm goniometer to measure non-weightbearing active dorsiflexion and plantarflexion. The proximal arm of the goniometer was aligned with the fibula, the distal arm was aligned parallel to the fifth metatarsal, and the rotational axis was slightly below the distal tip of the lateral malleolus. The time required to return to usual work was also documented.

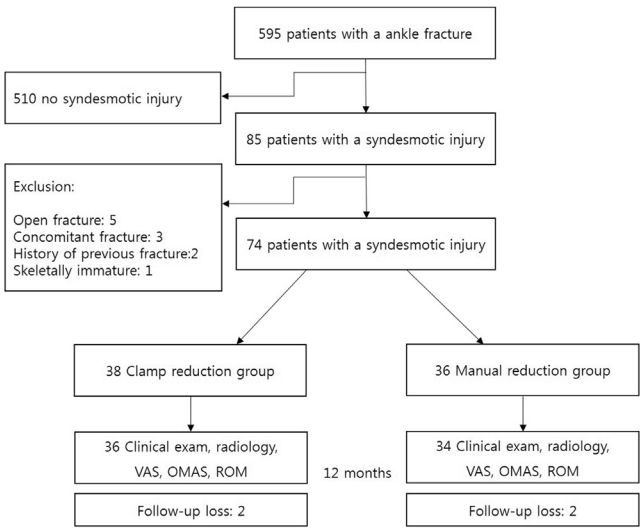

Fig. 1. Flowchart of the study. OMAS, Olerud–Molander ankle scoring system; ROM, range of motion; VAS, visual analog scale.

Statistical Analysis

Data normality was assessed using the Kolmogorov-Smirnov test. The baseline characteristics, radiographic measurements, and clinical outcomes of the 2 groups were compared using unpaired t tests for continuous parameters and the χ^2 test for categorical data. The interobserver and intraobserver reliability of the radiographic measurements were determined using Pearson's correlation. Significance was defined at $p < .05$, and statistical analyses were performed using SPSS, version 21.0 (IBM Corp., Armonk, NY).

Results

Of the 85 patients, 70 completed the study; 28 patients (40%) were female. Their mean age was 43.9 (range 19 to 83) years. In 39 patients (56%), the fracture had resulted from a simple fall. The other fractures had resulted from a sports injury in 16 patients, motor vehicle accident in 12, or other mechanisms in 3 patients. Of the 70 patients, 33 (47%) had a fracture on the right side. No patient had bilateral fractures.

Of the 70 patients, 36 (51.4%) were randomized to treatment with a reduction clamp and 34 (48.6%) to treatment with manual manipulation. The 2 groups did not differ significantly in demographic or fracture characteristics (Table 1). The tibiofibular clear space and tibiofibular overlap differed between the 2 groups immediately postoperatively and at the final follow-up examination ($p < .05$). The clamp reduction group had a smaller tibiofibular clear space and greater tibiofibular overlap. The medial clear space in the clamp reduction group showed a trend toward narrowness compared with the manual reduction group. However, no significant difference was found between the 2 groups (Table 2). Although the reduction was gradually redisplaced during the follow-up period in both groups, most radiographic measurements (62 patients, tibiofibular clear space [86%]; 63 patients, tibiofibular overlap [90%]; and 65 patients, medial clear space [93%]) were within acceptable ranges.

Strong correlations were found between the measurements of the tibiofibular clear space, tibiofibular overlap, and medial clear space when measured by 2 orthopedic surgeons (Y.H.P., J.H.A.; Pearson's $R = 0.903$, Pearson's $R = 0.894$, and Pearson's $R = 0.906$, respectively). The intraobserver variability was also high (Y.H.P., Pearson's $R = 0.918$, Pearson's $R = 0.920$, and Pearson's $R = 0.898$; J.H.A., Pearson's $R = 0.887$, Pearson's $R = 0.891$, and Pearson's $R = 0.895$, respectively).

At the final follow-up examination, the VAS score, OMAS score, dorsiflexion and plantarflexion ROM, and time required to return to usual work showed satisfactory results that were not significantly different between the 2 groups (Table 3). The rate of syndesmotic screw breakage was also similar between the 2 groups (13 patients [36%] in the clamp reduction group and 15 patients [44%] in the manual reduction group; $p > .05$). The overall complication rate was 8.3% in the clamp reduction group and 5.9% in the manual reduction group. Superficial infections (2 patients in the clamp reduction group and 1 patient in the manual reduction group) resolved with local wound care and oral antibiotics in the outpatient clinic. No patient required rehospitalization. Each group had 1 patient with syndesmotic calcification, which is considered instability of syndesmosis. However, these patients did not complain of severe ankle disability, and their clinical outcomes were compatible with those of the other patients. Therefore, these patients did not undergo further intervention.

Discussion

It is widely believed that accurate reduction and adequate fixation of syndesmosis injuries will result in superior radiographic and