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Value of tourniquet use in anterior ankle arthroscopy- a randomized controlled trial

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TITLE: Value of tourniquet use in anterior ankle arthroscopy - a randomized controlled trial

ABSTRACT:

Background

A tourniquet is usually used during anterior ankle arthroscopy to allow for improved visibility and reduced operation time. However, this has not been demonstrated to be true in clinical studies on knee arthroscopy, while limited tourniquet time has been described as a possible factor to lower the complication rate of ankle arthroscopy. The purpose of this randomized controlled trial was to examine the effect of tourniquet use on arthroscopic visualization, operative time, postoperative intra-articular bleeding, postoperative pain scores and outcome of anterior ankle arthroscopy.

Methods

A consecutive series of 50 patients who were scheduled for anterior ankle arthroscopy were randomized to have the surgery done either without the tourniquet inflated (25 patients) or with the tourniquet inflated (25 patients). The patients were evaluated by the course of the surgery, postoperative intra-articular bleeding, pain during the early postoperative period and using the subjective and objective functional scores to evaluate the condition of the ankle before and 3 and 6 months after the surgery.

Results

The results between the groups were comparable regarding the duration of the operative procedure, consumption of sterile saline, visualisation and functional scores. Notable difference between the groups in favour of the non-tourniquet group was present regarding postoperative bleeding, but was not statistically significant. Statistically significant difference in favour of the non-tourniquet group was found regarding postoperative pain during several days in the early postoperative period.

Conclusion

Our study has shown that anterior ankle arthroscopy may be performed adequately without the use of a tourniquet and that it has the same operative course as in cases in which the tourniquet is used and functional outcomes which are not worse than in cases in which the tourniquet is used.

Level of evidence: Level I, prospective randomized controlled trial

Keywords: Ankle; Arthroscopy; Tourniquet; Bleeding

INTRODUCTION

Ankle arthroscopy has become a standard surgical technique for the treatment of a variety of ankle pathologies. During the past 30 years, the technique has undergone modification and standardization to improve surgical performance and outcomes. Arthroscopic procedures of the ankle joint are performed through anterior and/or posterior ankle arthroscopy, depending on the localization of the pathology. Currently, anterior ankle arthroscopy is mostly performed by means of a 2-portal dorsiflexion method with intermittent soft tissue distraction, while posterior ankle arthroscopy is mostly performed by means of a two-portal hind foot approach.[1,2,16,17,21] A thigh tourniquet is typically used with ankle arthroscopy.[2,19-21] With this technique an overall complication rate of 3.5 % in 1305 procedures was noted.[21] Zengerink and van Dijk emphasized a limited tourniquet time as a possible factor to lower the complication rate even more.[21]

Tourniquet use is thought to allow for improved visibility and reduce operation time. However, this has been demonstrated not to be true in clinical studies on knee arthroscopy.[6,8,15] In addition, Smith and Hing suggested in their meta-analysis of nine studies regarding tourniquet use in knee arthroscopy that a number of methodological limitations are present in the studies and that there is limited evidence that the tourniquet assists in arthroscopic knee surgery.[13]

In a meta-analysis published in 2012, including 5 randomized controlled trials describing tourniquet use in knee arthroscopy, Zhang et al. concluded that the use of a tourniquet is no longer advisable for routine arthroscopic knee surgery.[22] Regarding the possible complications, which are infrequent, but may have potentially devastating consequences, the routine use of a tourniquet in ankle arthroscopy should be questioned.

Zaidi et al. performed a feasibility study on 63 nonrandomized patients undergoing anterior ankle arthroscopy with or without a tourniquet, and found no significant difference between groups with respect to duration of operation, maximum intra-operative fluid pressures or visibility and postoperative complications.[20] Inflating the tourniquet during the procedure was not necessary in any of the cases where the tourniquet was not used. The limitations of this feasibility study are that it did not assess neither the influence of tourniquet use on the postoperative rehabilitation and recovery nor the postoperative intra-articular bleeding. The purpose of the present randomized controlled trial was to examine the effect of tourniquet use on arthroscopic visualization and operative time, postoperative intra-articular bleeding, postoperative pain scores and outcome of anterior ankle arthroscopy. The primary hypothesis was that the postoperative intra-articular bleeding after anterior ankle arthroscopy without tourniquet use will be comparable to bleeding in procedures performed with a tourniquet.

MATERIALS AND METHODS

The study was conducted after approval was obtained from the local ethics committee. A consecutive series of patients who were scheduled for anterior ankle arthroscopy at our institution from May 2014 to July 2015 were randomized either to the tourniquet (T) group, with the tourniquet inflated, or to the non-tourniquet (NT) group, with the tourniquet not inflated during the procedure. The patients were blinded for the randomization procedure during the whole study period. At the time the study was planned, to the best of our knowledge, there were no similar studies to provide data for sample size calculation. Therefore, a study describing tourniquet use in arthroscopic anterior cruciate ligament reconstruction was used instead. Based on the data on mean intra-articular bleeding described by Nakayama et al., sample size

was calculated using alpha value of .05 and power (1-beta) of .80.[11] Sample size was calculated in NCSS/PASS software package, using methodology described by Machin and Zar, resulting in a required group size of 22 subjects.[4] A Consolidated Standards for Reporting Trials (CONSORT) flow chart is shown in Figure 1.

Exclusion criteria were age over 55 years and below 16 years, pregnancy, any other lower limb vascular or neuro-musculo-skeletal pathology, prior surgical procedure on the same ankle, superficial skin infection of the ankle, pronounced oedema of the extremities, tumour in the ankle area, and surgical procedure that required both a posterior and anterior arthroscopic approach or additional endoscopic procedure on the tendons around the ankle.

Patients eligible for study participation were thoroughly informed about the study and then signed an informed consent form. All evaluations were performed by a single examiner not involved in patient care and blinded to the randomization group of included patients. All study patients underwent clinical evaluation with the American Orthopaedic Foot & Ankle Society (AOFAS) Ankle Hindfoot score, the Foot and Ankle Disability Index (FADI) score and the Tegner Activity score.[3,9,14] Scores were reassessed at an intermediate check at 3 months post-surgery and at the final follow-up 6 months after the surgery. A pain diary was given to all study patients. In this way, average pain on a 100-mm visual analogue scale (VAS) was assessed by study patients at postoperative days 1 to 13. Patients were also asked to document any concomitant medication (especially analgesic) used during the early postoperative period.

All of the cases were performed by a single surgeon (senior author, IB). All patients were under spinal anaesthesia, placed supine and a pneumatic tourniquet of adequate size was applied around the upper thigh. At that time, for the sake of the

blinding procedure, the surgeon left the operating room. Only then were patients randomly assigned to either NT group, in which the tourniquet was not inflated, or the T group, in which the tourniquet was inflated to 350 mm Hg. Randomization was done using the Web site Randomization.com (http://www.randomization.com) by an independent physician. When used, the tourniquet was inflated after exsanguination of the limb by elevating it for 60 seconds. The limb was thoroughly scrubbed and surgically prepared by the surgeon's assistant. After the leg was draped with sterile dressings, the surgeon re-entered the operating room and marked course of the superficial peroneal nerve and/or its branches onto the skin with a sterile felt pen (Figure 2). Standard anteromedial and anterolateral portals were performed by means of a 2-portal dorsiflexion method.[2,17,21] An accessory anteromedial or accessory anterolateral portal were used if necessary. No distraction device was used during the operative procedure. A 4-mm 30-degree arthroscope was used for all procedures. The arthroscopic pump (Arthrex AR-6475 Continuous Wave III ©; Arthrex Inc., 1370 Creekside Blvd., Naples, FL 34108-1945, USA) for fluid management was used in all patients with the intra-articular pressure and the flow set each to 50 mmHg during the whole procedure. No epinephrine injections or other drugs were used at either portal site or irrigation fluid. If the impaired visualization impeded the procedure, the surgeon could have asked to inflate the tourniquet at any time during surgery. A radiofrequency wand was used in both groups to stop the intra-articular bleeding. It was forbidden for the surgeon to palpate whether the tourniquet was inflated or not during the procedure. At the end of the operative procedure a number 12 closed suction drain was placed by the surgeon through the anterolateral portal into the joint. After this, the surgeon left the operating room for the sake of the blinding procedure. The surgeon's assistant then closed the wounds with

a No. 3-0 non-absorbable suture, applied a sterile dressing and sterile wrapping, deflated the tourniquet if necessary and removed it.

Outcome measures were recorded by the surgeon after surgery. Outcomes were as follows: intra-operative visualization, duration of procedure and the volume of the sterile saline spent during the procedure. Visualization was graded by the surgeon using the combined score for visibility and ease of procedure according to Johnson et al., the final result being described as excellent, good, fair or poor.[6] For the purpose of this study, operative time was defined as the time elapsed from skin incision to the closure of all wounds.

The drain was removed 24 hours after surgery in all patients and the examiner noted the volume in the drain reservoir and documented the clinical condition of the operated ankle.

Postoperative instructions were standardized according to surgery performed and provided to each patient in writing. All patients started with active and passive range of motion exercises from the first postoperative day, and all of them used a posterior night splint for the ankle in the neutral position for 3 weeks after surgery (a standard departmental protocol after anterior ankle arthroscopy).

All patients were followed-up and evaluated by the same examiner, not involved in patient care, at postoperative weeks 2, 6, 12, and 24. During each visit any complications were noted and documented.

All statistical analyses were conducted with Dell Statistica data analysis software system (Dell Inc. (2015). Dell Statistica (data analysis software system), version 12. software.dell.com). The values of nominal and interval variables are shown in contingency tables. Values of continuous variables are shown as the average value

and standard deviation or median value and interquartile range, depending on the normality of distribution. Normality of distribution was tested by both, Kolmogorov-Smirnov and Shapiro-Wilk tests. Appropriate parametric or non-parametric methods were then used to test statistical hypotheses. Statistical significance (alpha, Type I error) was set at .05.

RESULTS

A total of 50 consecutive patients meeting the inclusion and exclusion criteria were recruited for the study (CONSORT flow chart in Figure 1). The patients' demographic and general data are presented in Table 1. At randomization, the groups were comparable regarding the demographic criteria. Forty-nine patients were available at final follow-up, 6 months after the surgery.

The results between the groups were comparable regarding the duration of the operative procedure and the consumption of sterile saline. In the NT group the visualization was excellent in 19 and good in 5 patients, while in the T group it was excellent in all patients. Visualisation was thus statistically marginally different between two groups (P=.053, Yates correction applied).[18] None of the procedures in the NT group required the tourniquet to be inflated after the beginning of the procedure.

Although the mean volume measured in the drain reservoirs 24 hours postoperatively showed a notable difference between the groups (162.8 and 96.2 ml in T and NT groups) the difference was not statistically significant (P=.584). After additional analysis, the median values showed no differences between the groups (50.0 ml in both groups, P=.587).

Pain values, assessed by patients in both groups over the 13-day postoperative period are shown in Figure 3. Statistically significant differences were found on postoperative days 5 (P=.047), 6 (*P*=.028), 7 (*P*=.026), 10 (*P*=.029) and 13 (*P*=.016) in favour of the NT group. Groups were comparable in terms of analgesic consumption.

At preoperative evaluation, statistically marginally significant difference between the groups was found for AOFAS score (76.7 for the NT group and 70.8 for the T group, respectively, *P*=.057, Figure 4). Statistically significant differences were present at 3 and 6 months follow-up visits (*P*=.006 and *P*=.007, respectively). Because the marginal difference was already present at the preoperative period, a percentage of improvement was used to additionally evaluate the score at 3 and 6 months postoperatively. The results were similar between the groups at both 3 (improvement of 23.8% for the NT group vs. 20.2% for the T group, respectively, *P*=.712) and 6 months follow-up (improvement of 27.8% in NT group vs. 25.2% in T group, respectively, *P*=.794). Similar differences between the groups were found for the FADI score as well. At the preoperative evaluation the values were 81.3 for the NT group and 66.4 for the T group (*P*= .001). The results were comparable between the groups at both 3 (improvement of 20.6% in NT group vs. 28.5% in T group, respectively, *P*=.397) and 6 months follow-up (improvement of 23.8% in NT group vs. 32.4% in T group, respectively, *P*=.415). Unlike the AOFAS and FADI scores, the Tegner Activity score had comparable results between the groups, both preoperatively (2.92 for the NT group and 2.32 for the T group, *P*= .101) at 3 months (4.25 for the NT group and 3.36, *P*= .104) and at 6 months postoperatively (4.88 for the NT group and 3.92, *P*=.076).

During the early postoperative period, two complications were noticed. In one patient in the NT group secretion of the synovia at the anterolateral portal area was noticed on the second postoperative day after removal of the drain, probably due to a loose skin suture. Because of the on-going secretion additional skin suture was placed on the fifth postoperative day, after which the wound healed without any additional complications. In a patient in the T group an erythema around the arthroscopic portal was noticed and was suspicious of the superficial infection. The erythema spontaneously diminished during hospital stay and no accompanying symptoms, such as fever or increased inflammatory markers, were noticed. In both patients the clinical condition of the operated ankle was without complications during the follow-up exams, as was in all the other patients.

DISCUSSION

The results of this randomized controlled trial confirm the statements of the Zaidi et al. feasibility study that anterior ankle arthroscopy is practicable without a tourniquet and we found that there is no real difference compared to the tourniquet group in arthroscopic visualization, operative time, postoperative intra-articular bleeding, and outcome scores.[20] The only statistically significant difference was the lower pain values according to VAS noticed during 5 of 13 postoperative days in the NT group. Kirkley et al. also found a trend towards less postoperative pain after knee arthroscopy without the use of the tourniquet when compared to the group in which the tourniquet was used.[8] According to their results they suggested the presence of a time factor during knee arthroscopy for tourniquet-related pain, which was less in the deflated-tourniquet group for procedures lasting longer than 30 minutes. This complies with the results of this study where the average duration of surgery was at least 40 minutes in each group.

The arthroscopic visualization, according to the classification by Johnson et al., was excellent in all patients in the T group and in 19 patients (76%) in the NT group, which was determined to be of marginal statistical significance (P=.053). In this study we have used an arthroscopic pump and have maintained fluid pressure at 50 mmHg during the entire procedure, as was described in other studies, as well.[7,15] On the other hand, Zaidi et al. started all of their procedures with a fluid pressure initially set at 30 mmHg and increased it in increments of 10 mmHg up to a maximum of 50 mmHg, as requested by the surgeon. Furthermore, they had to increase the initial fluid pressure in 51.6% of patients in the tourniquet group and in 59.3% of patients in the non-tourniquet group to achieve satisfactory visualization.[20] Therefore, we find it more accurate for future studies to set a fixed value for fluid pressure on the arthroscopic pump.

The duration of operation was similar between the groups, which is consistent with previous randomized controlled trials involving knee arthroscopy and with the Zaidi et al. feasibility study.[5,11,20] Although use of dilute epinephrine saline irrigation was shown to be effective in decreasing the need for tourniquet use in arthroscopic surgery, no drug was used in our patients to diminish the intra-operative bleeding during the procedure.[12] Thus, we have shown the influence of the tourniquet itself and we recommend this kind of perioperative procedure for any further studies, to make sure the results are not biased by the use of any drugs used during the operative procedure.

This study is, to our knowledge, the first randomized controlled trial designed to compare functional outcomes of anterior ankle arthroscopy with regards to tourniquet use. No differences were found according to functional outcomes between the groups after a thorough analysis. Although the AOFAS score is only partially

validated and the FADI score is not validated, we believe that the scores reflected well the clinical condition of the operated ankle.[10] Furthermore, the AOFAS score is a widely accepted score for evaluation of procedures like ankle arthroscopy and other procedures in the ankle area.

This study was designed to show whether or not the postoperative bleeding will be greater if we do not use the tourniquet during anterior ankle arthroscopy. Trial with significantly more patients is needed to confirm this. Specifically, to detect differences based on our bleeding volumes data with alpha of .05 and power of .80, two groups of 130 subjects should be included in a randomized study (post-hoc analysis on our data, same methodology as described in materials and methods section).

All operative procedures were performed by a single surgeon, who has long-term experience in arthroscopy of the ankle and other smaller joints. Although it is an obvious advantage, it is our opinion that the results could be different in the hands of a younger, less experienced surgeon. Furthermore, as described in other studies that evaluated tourniquet use in arthroscopic surgery, it is difficult to make the operating surgeon truly blinded for the procedure, in contrast to follow-up evaluations.[8,15] Arthroscopic portal bleeding and venous filling in the NT group could have helped an experienced surgeon to guess correctly to which group the patient belonged. Another possible limitation is that all of the procedures were performed under spinal anaesthesia. The influence of type of anaesthesia on visualization, intra-operative bleeding, postoperative pain and outcome scores in patients undergoing anterior ankle arthroscopy with and without the tourniquet should be tested in a future study.

Conclusion

This study is, to our knowledge, the first randomized controlled trial used to evaluate tourniquet use in anterior ankle arthroscopy. Results of our study have shown that anterior ankle arthroscopy may be performed adequately without the use of a tourniquet with the same operative course as in cases in which the tourniquet is used. In addition, we have shown that functional outcomes without the tourniquet are not worse than in cases in which the tourniquet is used. Further studies are required to clarify the ideal strategy for tourniquet use in anterior ankle arthroscopy.

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LEGENDS:

Figures

Figure 1- Consolidated Standards for Reporting Trials (CONSORT) flow chart.

Figure 2- Marking of the intermediate cutaneous branch of the superficial peroneal nerve with a sterile felt pen.

Figure 3- Evaluation of pain during the first 13 days after surgery on the visual analogue scale (VAS). Legend: NT- non-tourniquet group, T- tourniquet group. Statistically significant difference between the groups (P<.05) is indicated with asterisks.

Figure 4- American Orthopaedic Foot & Ankle Society (AOFAS) Ankle Hindfoot score

at the preoperative level, 3 months postoperatively and 6 months postoperatively. Legend: NT- non-tourniquet group, T- tourniquet group.

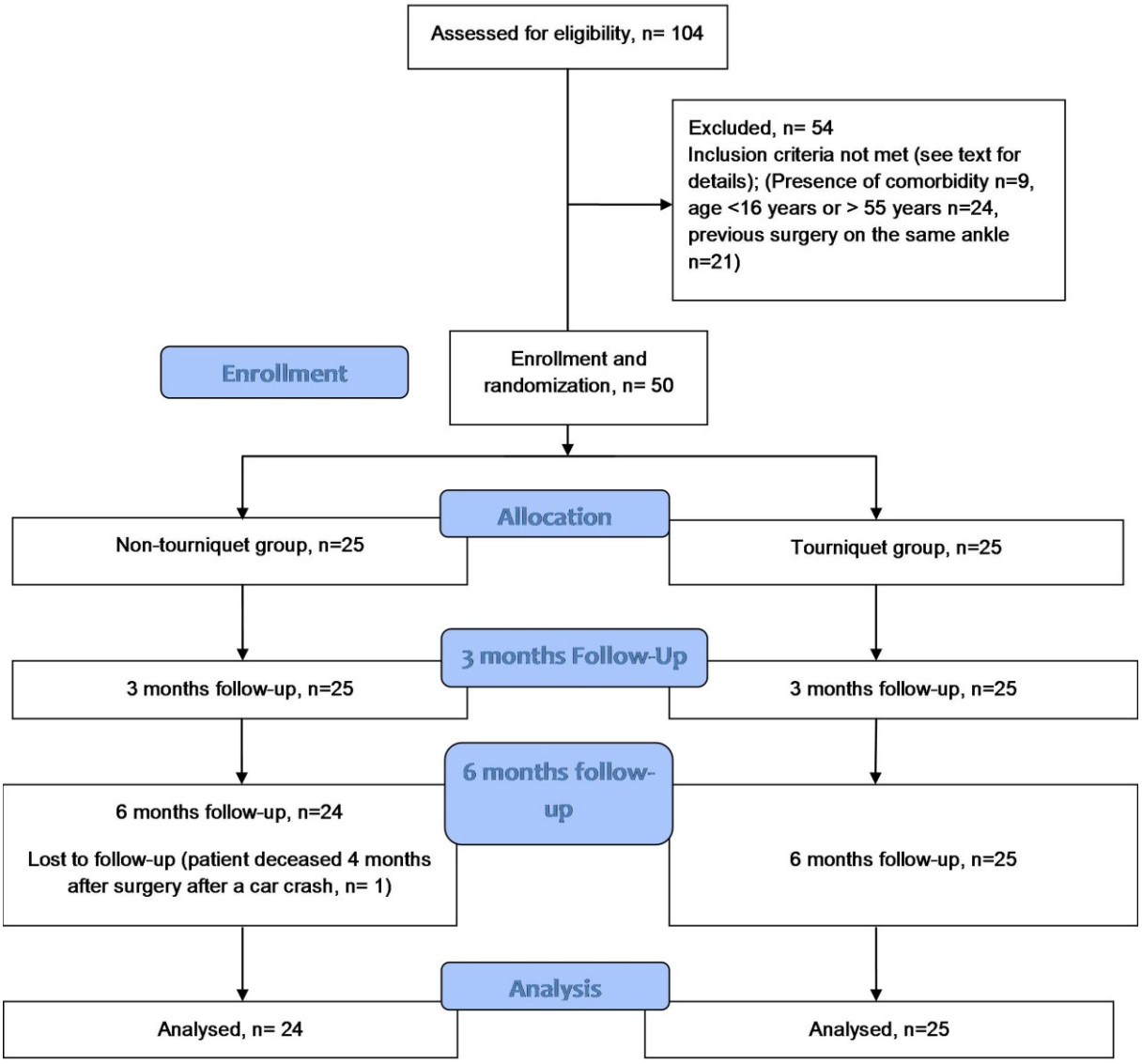
Tables:

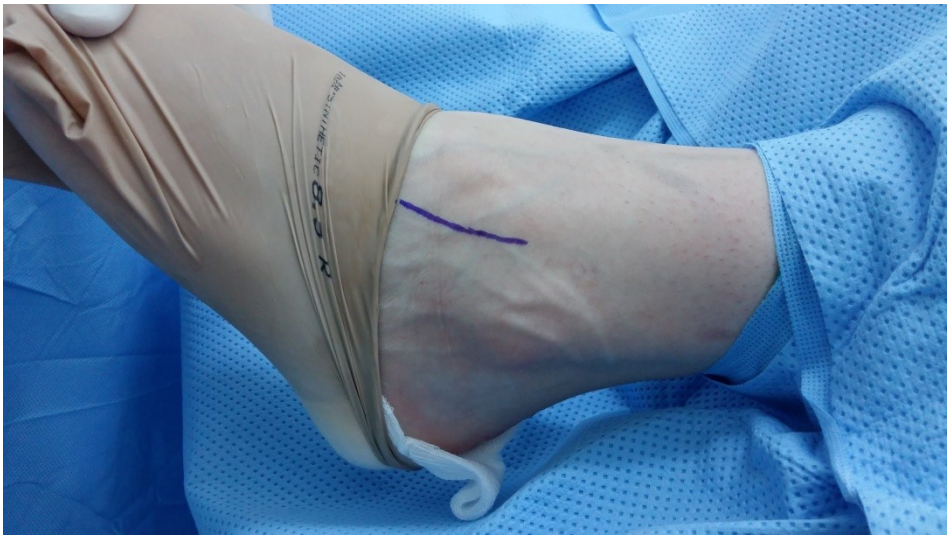
Table 1- Demographic and general data.

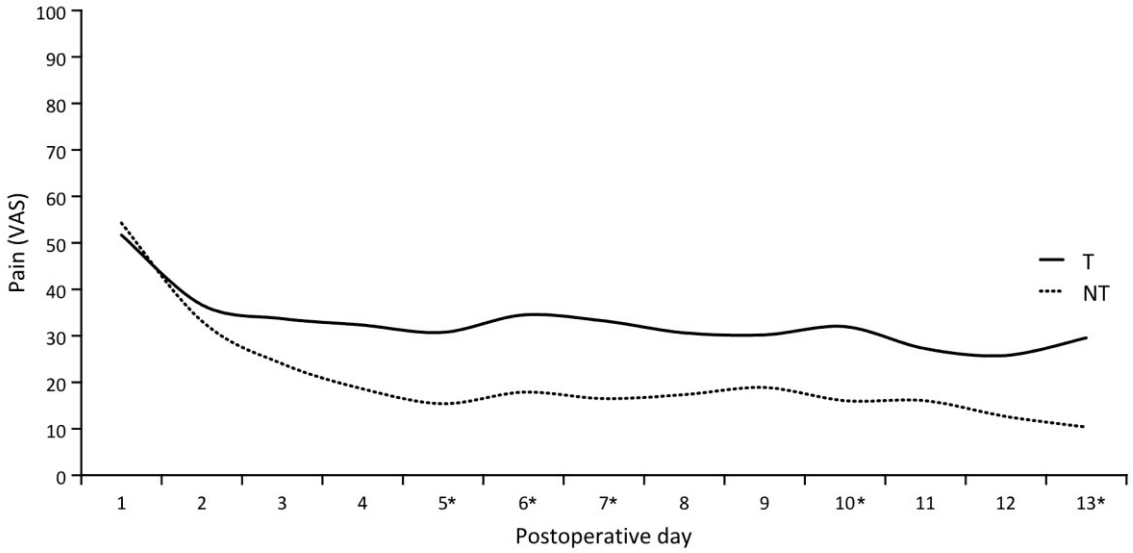
Legend:

[a]Normally distributed data, presented as mean (SD) and compared across treatments groups with the *t* test.

[b]Nonnormal data, presented as median (IQR) compared nonparametrically across treatment groups with the Mann–Whitney *U*-test.


Assessed for eligibility, n= 104
Excluded, n= 54
Inclusion criteria not met (see text for details); (Presence of comorbidity n=9, age <16 years or > 55 years n=24, previous surgery on the same ankle n=21)
Enrollment
Enrollment and randomization, n= 50
Allocation
Non-tourniquet group, n=25
Tourniquet group, n=25
3 months Follow-Up
3 months follow-up, n=25
3 months follow-up, n=25
6 months follow-up
6 months follow-up, n=24
Lost to follow-up (patient deceased 4 months after surgery after a car crash, n= 1)
6 months follow-up, n=25
Analysis
Analysed, n= 24
Analysed, n=25




100
90
80
70
60
50
40
30
20
10
0
Pain (VAS)
1
2
3
4
5*
6*
7*
8
9
10*
11
12
13*
Postoperative day
T
NT

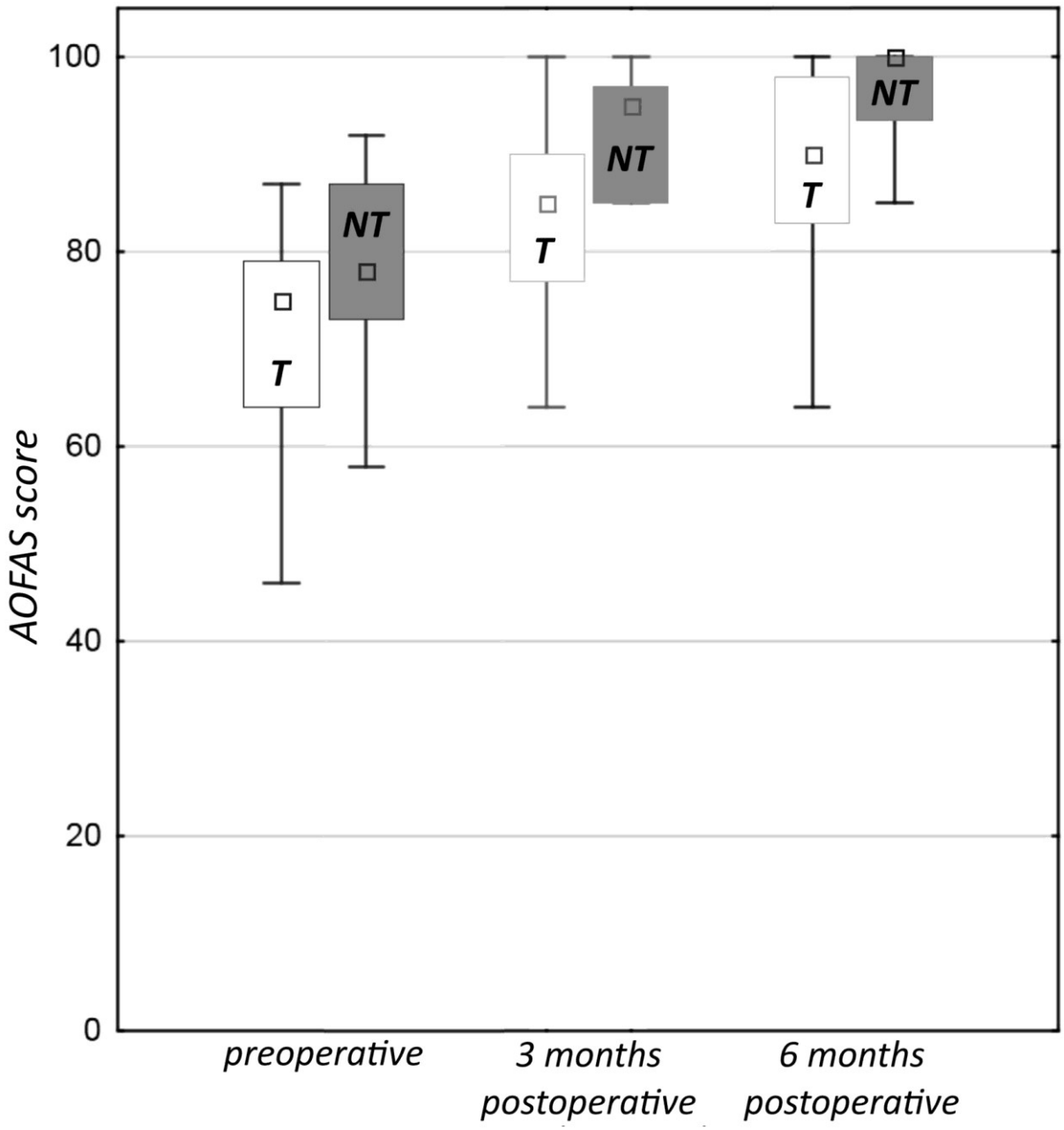

AOFAS score
100
80
60
40
20
0
T
NT
T
NT
T
NT
preoperative
3 months
postoperative
6 months
postoperative

Table 1- Demographic and general data

	Non-tourniquet group (n=24)	**Tourniquet group (n=25)**	***P* value**
Patient characteristics			
Age (years) [a]	32.3 (12)	33.7 (12.3)	.930
Body mass index (kg/m^2) [a]	25.4 (3.49)	25.7 (4.18)	.865
Male sex (n)	13	9	.254
Left side involvement (n)	9	10	.771
Outcome measures			
Duration of operation (minutes) [a]	50 (18.4)	41(17.4)	.079
Volume of used sterile saline (litres) [b]	6.25 (3-12)	6 (3-21)	.359
Postoperative intraarticular bleeding (mililitres)[b]	50.0 (10-150)	50.0 (40-160)	.587
Leading diagnosis			
Osteochondral lesion of the talus	13	6	
Anterolateral impingement	7	13	
Anterior bony impingement	4	6	

Legend: [a]Normally distributed data, presented as mean (SD) and compared across treatments groups with the *t* test. [b]Nonnormal data, presented as median (IQR) compared nonparametrically across treatment groups with the Mann–Whitney *U*-test.