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Effect on Hospital Length of Stay of Tourniquet Use During Internal Fixation of Ankle Fractures: Randomized Controlled Trial

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ABSTRACT

Approximately 50% of ankle fractures require internal fixation. A tourniquet is often used to create a bloodless operative field, but its effect on hospital length of stay (LOS) is unclear. This article reports a parallel-group observer-blinded randomized trial of the effect of tourniquet use on LOS. One hundred eighty-eight adult patients requiring internal fixation of ankle fracture were randomized to surgery with or without a tourniquet. LOS was analyzed on intention-to-treat principles using Poisson regression. As a secondary outcome, duration of operation was analyzed by analysis of covariance. Mean LOS was 1.79 ± 1.50 days in the tourniquet group and 1.65 ± 1.11 days in the no-tourniquet group. The covariate-adjusted rate ratio for LOS (reference group: no tourniquet) was 1.084 (95% confidence interval 0.871, 1.348; $p = .470$). Sensitivity analyses (unadjusted intention-to-treat analysis and as-treated analysis) gave similar nonsignificant results. The covariate-adjusted mean difference in duration of operation was 3.03 minutes (95% confidence interval $-4.96, 11.02$; $p = .455$), favoring the tourniquet group; sensitivity analyses again gave similar results. Adverse events did not differ significantly between groups. In conclusion, the use of a tourniquet during internal fixation does not significantly influence hospital LOS, of which preinjury medical condition of the patient appears to be the most important determinant.

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Ankle fractures are common injuries, accounting for approximately 9% of all fractures and occurring at a rate of 187 in 100,000 people each year (1). This equates to roughly 121,000 ankle fractures yearly in the United Kingdom. Approximately half are deemed to be unstable and subsequently require operative fixation. Operative management is commonly carried out using a tourniquet to create a bloodless field (2); however, tourniquet use during lower-limb surgery has been associated with a range of adverse events, including vascular injury, postoperative swelling, joint stiffness, increased postoperative pain, neurapraxia, increased risk of infection, and deep vein thrombosis (3,4). In a recent systematic review of 4 studies, tourniquet use in foot and ankle surgery was also shown to lead to an increased hospital length of stay (LOS) (5).

If the use of a tourniquet delays recovery after fixation of ankle fracture, this will be evidenced by a longer hospital LOS, as previously reported

(6,7). Accordingly, the objective of this multicenter, parallel-group, randomized study was to determine whether the use of a tourniquet during surgery for patients with closed ankle fractures affected the hospital LOS.

Patients and Methods

Recruitment and Randomization

Adult patients with closed ankle fractures were invited to take part in a randomized trial of tourniquet versus no tourniquet use for the operative management of ankle fractures. Patients were recruited from the University Hospitals of North Midlands (UHM) NHS Trust, Cambridge University Hospitals NHS Trust, and the Princess Royal Hospital, Telford, between 2012 and 2016. In total, 471 patients were assessed for eligibility, and 188 were subsequently recruited and randomized.

Eligible patients were skeletally mature adults (≥ 18 years) with an isolated, displaced, closed ankle fracture (Weber classification A, B, or C), for whom an operative procedure (rather than conservative treatment) was indicated. Exclusions included patients with open fractures, pilon fractures, previously malunited fractures, peripheral vascular disease precluding tourniquet use, and patients with bilateral fractures or multiple injuries. Patients who were not ambulatory before the fracture, were unable to complete questionnaires, or had a language barrier that could not be overcome through hospital translation services were also excluded.

Eligible patients were identified on admission and, after plain radiographs were obtained to confirm the fracture type, were given a study information sheet and invited to participate in the trial. A research nurse or a research-trained registrar obtained written informed consent, checking that the patient understood what the study involved and providing the opportunity to ask questions. Patients were then allocated to tourniquet or

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no tourniquet in a 1:1 ratio using an online third-party computerized randomization service at the University of York. Randomization was stratified by age (18 to 50 years, >50 years), using randomly permuted blocks of 4 and 6.

Fracture type was classified according to the Weber classification (8). Weber grade A indicates a fracture below the talar dome, grade B denotes a fracture of the distal fibula at the level of the tibiofibular syndesmosis, and grade C indicates a fracture of the distal fibula proximal to the tibiofibular syndesmosis. Additionally, patients were classified before surgery using the American Society of Anesthesiologists (ASA) physical status system (9). Grade 1 on the classification indicates a normal healthy patient, grade 2 a patient with mild systemic disease, and grade 3 a patient with severe systemic disease. The Olerud Molander Ankle Scale score was also recorded (10).

Interventions

The timing of surgery was determined by soft tissue swelling. Whenever possible, the operation occurred within 24 hours of injury, but if the tissues were too swollen, surgery was delayed until swelling had subsided sufficiently. Operative details were recorded, including duration of operation and tourniquet time. At surgery, the patient was placed in the supine position with a sandbag under the buttock of the affected side. For those patients randomized to have a tourniquet, this was applied above the knee, and the leg was prepared, draped, and elevated before tourniquet inflation. For all patients, fibular fixation was by plate and screws via a lateral incision, after reduction of the fracture; medial fixation was then undertaken if required. Wounds were closed, and a dressing was applied. A plaster backslab was applied to all patients to maintain 90° ankle dorsiflexion, and the tourniquet (if used) was deflated. The patient stayed in hospital until assessed as clinically fit for discharge. Patients returned home with walking aids in the backslab. Two weeks after surgery, patients returned to the outpatient clinic to have the wound checked and stitches removed.

Any serious adverse events were recorded, and appropriate action was taken in accordance with good clinical practice guidelines (11). Data on hospital LOS, operation duration, and intraoperative or immediate postoperative complications were collected or verified from patients' records. Authors H.M. and D.M. were among the participating surgeons.

Blinding

Operating staff were necessarily aware of whether or not a tourniquet was used, but patients were not told until after the study. For determination of LOS, patients were assessed for discharge home by a clinician blinded to tourniquet allocation. Statistical analysis was blind to treatment group allocation.

Outcome Measures

The primary outcome measure (LOS) was defined as the number of days after surgery a patient stayed in hospital before being considered clinically fit for discharge rather than when the patient actually left hospital. Patients fit for discharge on the same day as surgery were ascribed an LOS of 0. Patients were assessed daily, and the decision on fitness to go home was taken by at least 1 clinician not involved in the surgery. Secondary outcomes were the duration of the operative procedure and the occurrence of intraoperative or immediate postoperative adverse events.

Sample Size

The sample size was calculated based on prior data showing a mean LOS (time until fit for discharge) of 4.38 days, with a standard deviation (SD) of 2.72, for patients having ankle fracture surgery. These data showed LOS to be only moderately positively skewed.

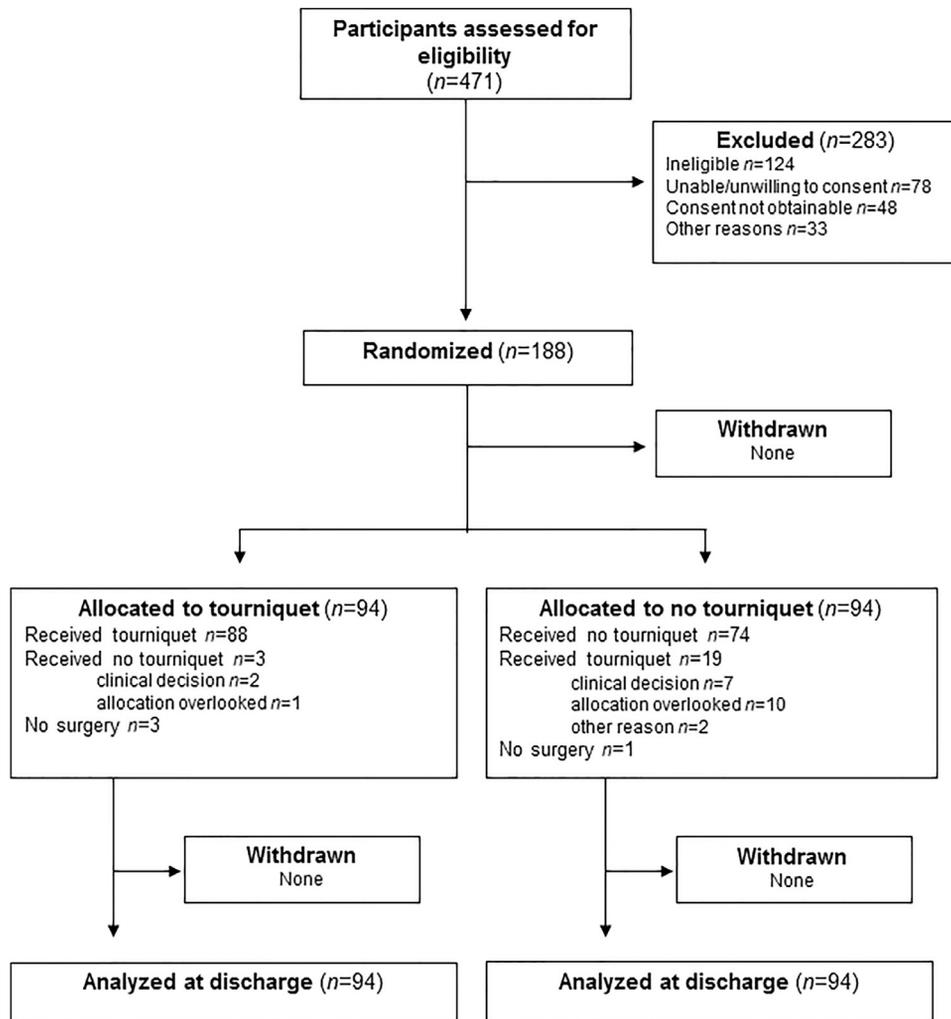


Fig. 1. CONSORT diagram showing the progression of patients through the trial.

A difference in LOS ≥ 1.5 days was considered important. In view of the tendency for preliminary data to underestimate the SD in the main trial (12), the observed SD was inflated by 15% to 3.13. Accordingly, to detect a 1.5-day reduction in mean LOS with 90% power at a 5% 2-sided significance level, data from a minimum of 93 patients in each comparison group were required (186 in total).

Statistical Analysis

The primary analysis followed intention-to-treat (ITT) principles and was in accordance with a predetermined statistical analysis plan. The assumptions of statistical models were checked before analysis. Because the distribution of residuals did not meet the assumptions of linear regression, LOS was compared between groups using Poisson regression, adjusting for Weber classification, ASA grade, sex, body mass index (BMI), treatment center, and time from fracture to surgery, and including the stratification factor (age) in the model; these covariates were determined a priori. The duration of the operation, for those patients who underwent surgery, was analyzed by analysis of covariance, adjusting for the same covariates. Before conducting adjusted analyses, any missing baseline values were imputed, following recent recommendations (13).

An unadjusted ITT analysis and an "as-treated" analysis, whereby patients were analyzed according to the intervention actually received, were carried out as sensitivity analyses (14). Subgroup estimates of differences in LOS between tourniquet and no tourniquet were calculated for subgroups defined by sex, age (18 to 50 years, >50 years), Weber classification (B, C), and ASA classification (1, 2, 3). These subgroup analyses were exploratory, and no formal statistical testing was performed.

Statistical significance was set at $p \leq .05$ (2-tailed), and 95% confidence intervals (CIs) were calculated for between-group estimates. Analysis was conducted in SPSS Version 23 (IBM Inc, Armonk, NY).

Ethical Approval

Ethical approval for the study was obtained from the Staffordshire Research Ethics Committee (Ref 11/WM/0420) after a full review.

Results

The progression of patients through the trial is shown in a CONSORT diagram (Fig. 1). Between August 2012 and August 2015, a total of 471 patients were screened for eligibility, of which 188 were subsequently randomized. Of those randomized to a tourniquet, 3 had surgery without a tourniquet (clinical decision $n=2$; randomization missed $n=1$) and 3 did not have surgery. Of those randomized to no tourniquet, 19 had surgery with a tourniquet (clinical decision $n=7$; randomization missed $n=10$; other reason $n=2$), and 1 did not have surgery. Following ITT principles, all patients were entered in the analysis.

Patients' baseline characteristics are shown in Table 1. All variables were well balanced across the groups, except there was a slightly higher percentage of males in the tourniquet group and some imbalance in right versus left fractures.

Fig. 2 shows LOS for both treatment groups. Mean length of stay was 1.79 ± 1.50 days in the tourniquet group and 1.65 ± 1.11 days in the no-tourniquet group; 1.72 ± 1.32 days for both groups combined. Median (interquartile range) LOS was 1.00 (1.00, 2.00) in both treatment groups. The results of the Poisson regression are shown in Table 2 for the primary analysis (ITT adjusted) and the sensitivity analyses (ITT unadjusted, and as treated). The treatment effect shown is the anti-logged coefficient from the regression model and represents a rate ratio, with the no-tourniquet group as reference; a ratio >1 therefore indicates a greater LOS with use of a tourniquet.

In the primary ITT analysis, there was a very small and statistically nonsignificant difference in LOS; this was on average 7.2% greater in the tourniquet group. The difference in LOS was much smaller than the 1.5-day difference considered to be clinically important. The sensitivity analysis based on an unadjusted ITT analysis gave a similar nonsignificant result: LOS was estimated as 8.4% greater in the tourniquet group. In the as-treated sensitivity analysis, the difference was again small and nonsignificant but favored the tourniquet group: LOS was on average 3.8% shorter than in the no-tourniquet group.

Fig. 3 shows mean differences in LOS from the adjusted ITT analysis by subgroups defined by sex, age (18 to 50 years, >50 years), Weber

Table 1

Baseline characteristics (N = 186)

	Tourniquet (n = 94)	No Tourniquet (n = 94)
Age (y), mean \pm SD	48.36 \pm 14.33	48.34 \pm 17.24
BMI, mean \pm SD*	29.50 \pm 6.47	28.39 \pm 6.43
Sex, n (%)		
Male	41 (44)	35 (37)
Female	53 (56)	59 (63)
Regular smoker, n (%)		
Yes	26 (28)	22 (23)
No	68 (72)	72 (77)
Affected ankle, n (%)		
Left	54 (57)	37 (39)
Right	40 (43)	57 (61)
Mechanism of fracture, n (%)		
Low energy	80 (85)	82 (87)
High energy	12 (13)	8 (9)
Crush injury	1 (1)	2 (2)
Other	1 (1)	2 (2)
ASA grade, n (%)		
1	55 (59)	55 (59)
2	35 (37)	38 (40)
3	4 (4)	1 (1)
Weber classification, n (%)		
A	0 (0)	0 (0)
B	75 (80)	62 (66)
C	19 (20)	32 (34)
Center; n (%)		
University Hospitals of North Midlands	83 (88)	82 (87)
Cambridge	9 (10)	9 (10)
Telford	2 (2)	3 (3)
Time between fracture and surgery, mean \pm SD [†]	6.14 \pm 3.66	5.22 \pm 3.64
OMAS total score, mean \pm SD [‡]	98.09 \pm 5.87	97.90 \pm 7.20

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; OMAS, Olerud Molander Ankle Scale; SD, standard deviation.

* Nineteen missing values, $n_1=86$, $n_2=83$.

[†] Three patients did not receive surgery, so time to operation calculated in terms of when surgery was scheduled.

[‡] One missing value; $n_1=94$, $n_2=93$.

classification (B, C), and ASA grade (1, 2, 3). The estimates for the Weber classification subgroups were very similar to the overall estimate. Estimates for male patients and those >50 years appeared to favor nonuse of tourniquet, whereas those for female patients and those aged 18 to 50 years appeared to favor tourniquet use. The subgroups defined by ASA grade show some variation, but it should be noted that there are

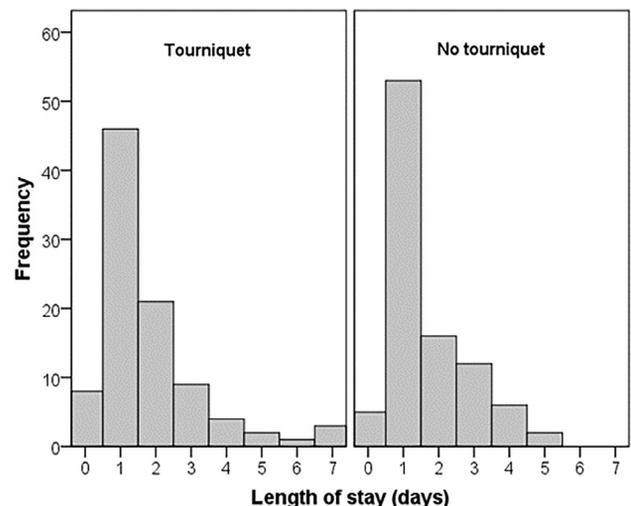


Fig. 2. Length of stay in the tourniquet and no-tourniquet groups.

Table 2
Results of the Poisson regression analysis on length of stay (N = 186)

Analysis	Tourniquet (mean, days)	No Tourniquet (mean, days)	Effect (rate ratio)*	95% Confidence Interval	p Value
Primary					
ITT analysis, adjusted†	1.74	1.62	1.072	0.854, 1.346	.549
Sensitivity					
ITT analysis, unadjusted	1.79	1.65	1.084	0.871, 1.348	.470
As-treated analysis, adjusted†,‡	1.65	1.71	0.962	0.764, 1.212	.744

Abbreviation: ITT, intention-to-treat.

* Reference group is no tourniquet.

† Adjusted for Weber classification, sex, body mass index, treatment center, time from fracture to surgery, sex, and age.

‡ Based on n = 107 and n = 77 for tourniquet and no-tourniquet groups, respectively.

only 5 patients in ASA grade 3, and the estimate for this subgroup is therefore very imprecise (as indicated by the very wide CI).

The mean duration of the operative procedure was 71.98 ± 25.54 minutes for the tourniquet group and 76.37 ± 27.71 minutes for the no-tourniquet group. The covariate-adjusted mean difference in the ITT analysis (no tourniquet minus tourniquet) was 3.03 minutes (95% CI -4.96, 11.02; p = .455). The unadjusted ITT mean difference was 4.39 minutes (95% CI -3.35, 12.12; p = .264). In the as-treated sensitivity analysis, the mean duration of the operative procedure was 73.11 ± 23.64 minutes for the tourniquet group (n = 107) and 76.58 ± 29.51 minutes for the no-tourniquet group (n = 77). The covariate-adjusted mean difference was very similar to that of the ITT analysis at 2.35 minutes (95% CI -5.62, 10.31; p = .562).

Owing to the small effect of tourniquet use on LOS, an additional unplanned analysis was undertaken to determine the relative effect of other potential predictors. The following variables, in addition to tourniquet use, were entered in a Poisson regression model, following a check for collinearity: age, BMI, time from fracture to surgery, time to operation, duration of operation, Olerud Molander Ankle Scale score, sex, Weber classification, ASA grade, regular smoker, mechanism of fracture (Table 1 provides categorical variable values). Because these represent a mixture of dichotomous, multinomial, and numeric variables, rate ratios from the regression analysis are not comparable. The p value from a likelihood ratio test of each variable was therefore used as an indirect index of its strength as a predictor of LOS. Table 3 gives the results of the analysis. Variables are presented in ascending order of their associated p values, and hence in descending order of predictive strength. ASA grade (higher grade predicts longer LOS) and time from

fracture to surgery (shorter time predicts longer LOS) were significant independent predictors. Ignoring statistical significance, BMI, age, and duration of operation were additionally stronger predictors than tourniquet use. It should be noted that no sample size calculation had been performed for these unplanned analyses.

Adverse Events

Seven patients experienced intraoperative complications (Table 4); 2 (2.2%) in the tourniquet group and 5 (5.4%) in the no-tourniquet group

Table 3
Predictors of length of stay (N = 169)

Predictor	Likelihood Ratio χ^2	Degrees of Freedom	p Value
ASA grade	10.571	2	.005
Time from fracture to surgery	4.996	1	.025
BMI	3.024	1	.082
Age	.879	1	.349
Duration of operation	.826	1	.363
Tourniquet use	.806	1	.369
Sex	.507	1	.476
Weber classification	.068	1	.795
Mechanism of fracture	.826	3	.843
Regular smoker	.015	1	.904
OMAS score	<.001	1	.999

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; OMAS, Olerud Molander Ankle Scale.

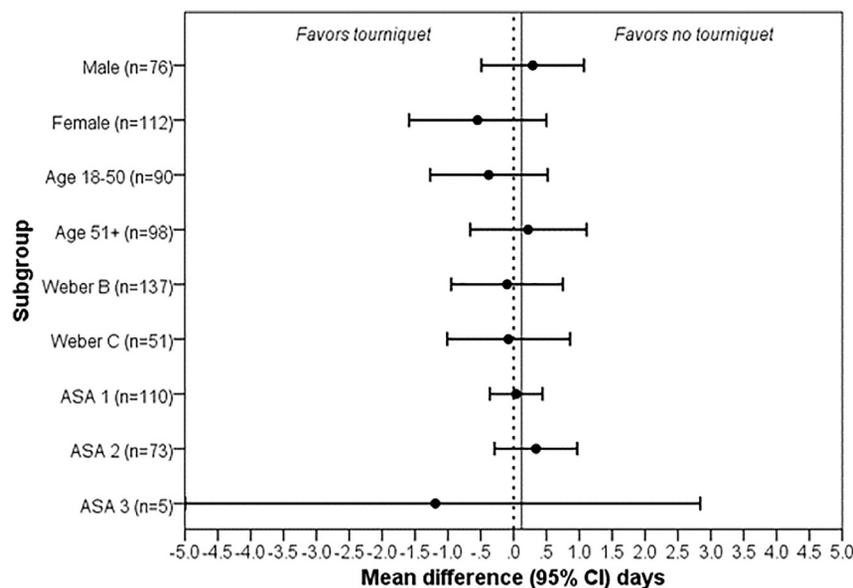


Fig. 3. Length of stay for subgroups. Figures are mean difference in days (tourniquet group minus no-tourniquet group) with 95% confidence interval (CI). Negative differences favor the tourniquet group; positive differences favor the no-tourniquet group. The solid vertical reference line indicates the overall mean difference. The dashed vertical reference line indicates a mean difference of 0.

Table 4
Intraoperative complications in patients undergoing surgery (N = 184)

Complication	Tourniquet Group (n = 91)	No-Tourniquet Group (n = 93)
Vascular injury	0	1
Blood loss (250 mL)	0	1
Aspiration	0	1
Drill bit snapped	1	1
Other equipment/staff issues	1	1

(odds ratio with no tourniquet as reference category 0.396 [95% CI 0.075, 2.093]; $p = .444$, Fisher's exact test). One patient experienced severe pain after surgery when a cast was applied (an alternative cast was subsequently applied); this was considered to be unrelated to the study interventions. No patients required admission to an intensive care unit, and none were readmitted for further surgery on the affected ankle. There was 1 serious adverse event. A patient in the no-tourniquet group required prolonged hospitalization after desaturation in the recovery room; this was considered to be unrelated to the study interventions.

Discussion

The nonuse of a tourniquet did not produce a statistically significant or clinically important difference in the primary outcome measure, and this study did not therefore confirm previous evidence that use of a tourniquet increases LOS (5–7). In the exploratory analysis, the only 2 variables that significantly affected LOS were the ASA grade, which is a measure of preexisting health before the ankle injury has occurred, and time from fracture to surgery. Those patients with an ASA grade of 1 had a mean hospital LOS of 1.35 days, and those with an ASA 2 had a mean hospital LOS of 2.24 days. Sixty percent of patients were ASA grade 1, and 35.5% of patients were ASA grade 2. Those patients with a shorter time from fracture to surgery had a longer LOS. The reason for this is unclear from our data.

The mean overall length of stay in our study of 1.72 days was considerably shorter than the mean of 4.38 days in the preliminary data that we had collected and shorter than the mean 3.50 and 4.50 days of postoperative stay reported by Lloyd et al (15) and Singh et al (16), respectively. Consequently, the targeted reduction in length of stay of 1.5 days appeared to be unrealistic. It is not clear why length of stay was so much shorter in our study. It does not appear to reflect the decision to assess length of stay in terms of medical fitness for discharge, because the mean length of stay until actual discharge was similar, at 1.99 days. Instead, it may reflect changes in practice within the participating hospitals since the preliminary data were collected.

It has recently been reported that patients who have surgery for closed ankle fractures within 24 hours of injury have shorter length of stay than those operated on later (16). Our data do not confirm this. The mean length of stay for those operated on within 24 hours (1.89 days; $n = 46$) was greater than that for those operated on later (1.66 days; $n = 142$).

There was a higher rate of protocol deviation in the no-tourniquet group (a tourniquet was used for 19 patients) than in the tourniquet group (only 3 patients had no tourniquet). This may reflect the surgeon's personal preference for use of a tourniquet to provide a bloodless field. The as-treated analysis, which reflects this protocol deviation, showed LOS to be slightly shorter with tourniquet use, but the difference was nonsignificant. Confirming previous findings (5), tourniquet use did not have a significant effect on operative time, although duration of operation was slightly shorter in the no-tourniquet group than in the tourniquet group (72.34 vs 76.37 minutes).

The strengths of our study include the fact that we have a complete set of data on LOS and on operation time for patients undergoing

surgery, and statistical analysis was blinded, allowing us to reach unbiased conclusions regarding LOS. All staff assessing patients' fitness for discharge were blinded to tourniquet use, reducing the risk of bias in clinical decision making. Broad inclusion criteria assist the generalizability of our findings. The availability of other medical data, including ASA grade, and time from injury to surgery has allowed us to perform further exploratory statistical analysis on other factors that affect LOS, although because these were unplanned analyses for which the study was not specifically powered, they must be interpreted with caution. Similarly, the subgroup analyses were exploratory and should be interpreted accordingly. The high rate of protocol deviation in the no-tourniquet group suggests, in some instances, a lack of clinical equipoise, although the as-treated analysis indicates that this is unlikely to have seriously biased the statistical comparisons.

In conclusion, our study has demonstrated that hospital LOS after operative management of closed ankle fractures in skeletally mature adults is not significantly affected by the use of a tourniquet during surgery. Preinjury medical condition of the patient appeared to be the single most influential factor identified affecting hospital LOS.

Acknowledgments

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