INTRODUCTION

Tourniquet use has been described in broad perspectives over the years. In the Roman Empire, a pneumatic tourniquet was used to control bleeding during an amputation.1 In 1864, the usage of a tourniquet to create a bloodless surgical field gained popularity by Joseph Lister.2,3 The importance of tourniquet use was mainly seen in hand surgery because of the rich vascularity of the hand. However, hand surgery was often performed under general or regional anesthesia, where patients did not experience pain from the tourniquet.

Since the introduction of the Wide Awake Local Anesthesia, No Tourniquet (WALANT) method in the early 21st century by Lalonde,4 minor hand surgical procedures are performed more often without a tourniquet. By adding epinephrine to the local anesthesia, a vasoconstrictive effect is created, which causes minor blood loss during surgery.5

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Several studies have been conducted on the effects of tourniquet use on perioperative pain. A systematic review by Evangelista et al examined whether there was a difference in WALANT technique versus regional and local anesthesia with tourniquet concerning perioperative and short-term outcomes. They found no difference between both methods in terms of patient satisfaction and complications. However, the effect of no-tourniquet use on long-term clinical results and complications is still unknown.

Carpal tunnel release (CTR) and trigger finger release (TFR) are two of the most common minor hand surgery procedures usually performed in an outpatient clinic under local anesthesia. Because of the relatively short operation time, well below the reported discomfort time a patient can tolerate a tourniquet, the tourniquet is still often used and mostly depends on surgeon preference. The advantage of tourniquet use is the bloodless field during the operation and a better visualization of the anatomical structures. No use of a tourniquet might result in more blood loss in the operation field leading to increased operation time, less clear view resulting in less effective surgery, and more complications. However, in a previous study, we showed that there is no difference in operation time and short-term complications between minor hand surgical procedures performed with or without a tourniquet. In addition, we have demonstrated that even in minor hand surgery of short duration, patients experienced tourniquet use as painful as the injection with local anesthesia.

The effect of tourniquet use on clinical outcome in minor hand surgery is hardly known. The primary aim of this study was to assess the effect of tourniquet use versus no-tourniquet use on patient-reported outcomes 1 year after CTR or TFR. Secondly, we determined the difference in long-term complications and scar tissue formation. We hypothesized that there would be no difference in patient-reported outcome measures (PROMs) and complications between the tourniquet and no-tourniquet groups but expected more scar tissue present in the tourniquet group, due to reperfusion after deflating the tourniquet, causing more hematoma and scarring.

METHODS

Study Design and Setting

We performed a randomized controlled trial according to the Consolidated Standards of Reporting Trials, and the trial was registered in the Trial Register (trialregister.nl, identifier NL 8499). Data were collected between May 2019 and August 2020 at the Jeroen Bosch Hospital, Den Bosch, the Netherlands, and processed using Research Electronic Data Capture (REDCap), a secure web platform for online databases and surveys. All patients signed informed consent, and the trial was approved by the local Medical Research Ethical Committee (P1906). Each patient was assigned to one of the study arms (tourniquet or no tourniquet) using permuted block randomization, with random block sizes between four and eight subjects to maintain unpredictability.

Patient Selection

A total of 163 patients were approached who underwent open CTR or TFR under local anesthesia. Inclusion criteria were (1) patients 18 years or older with either a trigger finger or clinical and nerve conduction study proven carpal tunnel syndrome (CTS) and (2) the eligibility to read and understand the Dutch language. Exclusion criteria were (1) patients with persistent or recurrent symptoms of CTS or trigger finger; (2) patients refusing local anesthesia; (3) patients unable to provide informed consent; or (4) patients in whom coumarins could not be interrupted perioperatively. The following demographic variables were collected: age, sex, affected side, hand dominance, tobacco use, medication use including anticoagulant use, comorbidities, Neuro Conductive Study grade of CTS, type of surgery, and surgeon level of expertise.

Operative Procedure

The CTR (open procedure with a mini-incision) and TFR (horizontal V-shaped incision) were performed in an outpatient clinic by either a surgeon specialist (expertise level 5) or surgical trainee under supervision (level 1). Conditions (preparation, induction, and anesthesia mixture) were previously described in our recently published study and were similar in both study groups, except for the use of the tourniquet. The anesthesia mixture used was 1% lidocaine with 1:200 000 epinephrine. Operation time started when the injection was given, and the tourniquet was inflated immediately after the injection (if applicable). We only waited for the nociceptive effect of the anesthesia and not the vasoconstrictive effect. The operation time ended after applying a pressure bandage, after which the tourniquet was deflated if used. The mean intraoperative time (12 minutes) for both study arms and pain (injection, tourniquet, and overall pain) has been described in our previous article as well.

Outcomes

Patient-reported Outcome Measurements

The primary outcome of this study was the Quick Disabilities of the Arm, Shoulder and Hand questionnaire (QuickDASH) at 12 months of follow-up. It measures self-reported physical function and symptoms related to upper-limb musculoskeletal disorders and consists of 11 items. A higher score means more disability. The QuickDASH was used for patients undergoing CTR as well as TFR. A secondary outcome measure of this study
was the Boston Carpal Tunnel Questionnaire (BCTQ), consisting of two domains: the symptom severity scale (SSS) (11 items) and functional status scale (FSS) (8 items), wherein a higher score indicates more symptoms or disability. The BCTQ questionnaire was only conducted for patients undergoing CTR. PROMs were collected preoperatively and at 3 months, 6 months, and 12 months postoperatively. All questionnaires were sent out by post, and patients were contacted by phone if no response occurred within 2 weeks.

Ultrasound
Ultrasound was only performed on patients who underwent CTR. The most important measurement performed by ultrasound was the thickness of scar tissue in the region of the median nerve (in mm). Other measurements were the cross-sectional area (CSA) of the median nerve, proximal (CSAp, in mm²) and at carpal tunnel level (CSAc, in mm²), and the difference between them (ΔCSA, in mm²). The fifth measurement was the palmar bowing of the flexor retinaculum ([PBFR]; bowing ratio/displacement (in mm) between the flexor retinaculum and the attachments of the flexor retinaculum from the level of hook of hamate/pisiform to trapezium/saphoid). The sixth and seventh measurements were the longitudinal and transverse diameter of the flexor retinaculum (in mm), and the eighth was the thickness of the (rest)retinaculum (in mm). The scar tissue is divided into three categories based on thickness: (1) none/minor, less than 1 mm; (2) mild, between 1 and 2 mm; and (3) severe, more than 2 mm. A ΔCSA of greater than 2 mm² or in case of a bifid median nerve greater than 4 mm² was consistent with an imaging diagnosis of CTS. At 6 months postoperatively, all patients who underwent CTR were invited for an ultrasound. All examinations were conducted by one musculoskeletal radiologist with 30 years of experience in musculoskeletal sonography. All wrists were evaluated in a neutral position with the palm up and the fingers slightly flexed (in a relaxing position). The radiologist was blinded to the study results and tourniquet usage.

Complications
Complications were scored according to the International Consortium for Health Outcome Measurement (ICHOM) Complications in Hand and Wrist conditions classification, after 12 months of follow-up. The ICHOM is a modified version from the Clavien-Dindo classification for general surgery. Complications were graded depending on the required treatment. When an intervention was needed, the highest grade complications were reported.

Sample Size Calculation
In a previous study with the same patient group, tourniquet use on perioperative pain was studied. A priori power analysis showed that a minimum sample of 128 participants (64 in each study arm) was needed to detect a difference in the mean pain score between the two study arms with an effect size of 0.5 and a two-tailed alpha of 0.05 with 80% statistical power using an independent samples Student t test. We included an additional 10% of patients (142 total) to account for potential loss to follow-up. For the present study also, a minimum sample of 128 (64 in each arm) participants was needed to detect a difference in the mean QuickDASH score at 12 months postoperatively between the two study arms with an effect size of 0.5 and a two-tailed alpha of 0.05 with 80% statistical power using an independent samples Student t test.

Statistical Analysis
We checked continuous data for normal distributions with histograms and quantile–quantile plots. Normally distributed data were displayed as mean values, including standard deviations (SDs), and skewed data were displayed as mean values, including interquartile ranges.

In our primary analysis, patients were analyzed according to their randomization group. To answer our primary research question, we used mixed models to evaluate the difference between the groups in the change in QuickDASH score over the follow-up period, as indicated by the interaction between time point and randomized allocation. The QuickDASH score (at baseline and after 3, 6, and 12 months of follow-up) was used as a dependent variable. The repeated measures and covariance structure were modeled as unstructured. The model was estimated with the restricted maximum likelihood approach. The randomized allocation was used as an independent variable. The follow-up period and the interaction between follow-up and randomized allocation were entered into the model as fixed factors. We did not find any violation of the model assumptions: linearity, homoscedasticity, and normality of residuals. Secondary analyses included (1) analysis of the difference in BCTQ between the randomization groups by a mixed model (as described above) at the different time points; (2) analysis of different echo parameters [the thickness of scar tissue in the region of the median nerve (mm), the CSA of the median nerve (CSAp in mm², CSAc, in mm² and ΔCSA, in mm²), PBFR (mm), longitudinal and transverse diameter of the flexor retinaculum (mm), and (rest)retinaculum (mm)]; and (3) analysis of the difference in adverse event rates. Continuous variables were compared using the Student t test and categorical variables using a chi-square test. Because of the potential for a type I error caused by multiple comparisons, findings for analyses of secondary endpoints should be seen as exploratory. All computations were performed in R v4.0.1 (R Project for Statistical Computing, Vienna, Austria). A P value less than 0.05 was considered significant.

RESULTS

Demographics
Of the 163 patients approached for participation, 15 declined and six did not meet the inclusion criteria. The remaining 142 patients [52 men (38%), mean age 59 years (SD, 13)] were randomly assigned to one of the two study arms. Seven patients (5%) were lost to follow-up at 12 months of follow-up: four in the tourniquet group
and three in the no-tourniquet group (Fig. 1). Table 1 provides an overview of the demographic and clinical characteristics.

**Patient-reported Outcome Measures**

Both groups showed improved QuickDASH scores over the 12 months \( (P < 0.001; \text{Table 2}) \), of which most improvement was observed during the first 3 months of follow-up. At intake, the tourniquet group showed a somewhat higher score than the no-tourniquet group [difference between groups, 6.2; 95\% confidence interval (CI) (0.0–12.4)]. There were no differences in the QuickDASH Scores at 3 [–1.2 (–7.5 to 5.0)], 6 [0.2 (–6.0 to 6.5)], and 12 months [3.4 (–2.8 to 9.7)] between the two groups (Table 2).

Concerning the BCTQ outcomes, both groups showed improved SSS and FSS scores over the 12 months (both \( P < 0.001; \text{Table 2} \)). Most improvements in the SSS and FSS scores were seen during the first 3 months of follow-up. Similarly, there were no differences in the SSS and FSS scores at 3, 6, and 12 months between the two groups (Table 2).

**Ultrasound**

Table 3 shows the outcomes of the variables measured by ultrasound. The majority of patients had minor to no development of scar tissue (n = 46), and only four patients developed severe scar tissue. No differences between the tourniquet and no-tourniquet groups were found, including scar tissue. Figure 2 shows ultrasound images with the measurement of scar tissue in three patients, where

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**Fig. 1. Flow chart according to Consolidated Standards of Reporting Trials.**
Table 1. Demographic and Clinical Characteristics of All Patients (n = 135)

| Characteristics | All Patients | Tourniquet | No Tourniquet | Difference between Groups (95% CI) |
|-----------------|-------------|------------|---------------|----------------------------------|
| Tissue           |             | Yes        | No            |                                  |
| n               | 135         | 67         | 68            |                                  |
| Age, mean ± SD  | 60 ± 13     | 58 ± 15    | 62 ± 12       |                                  |
| Sex, n (%)      |             |            |               |                                  |
| Men             | 51 (38)     | 25 (37)    | 26 (38)       |                                  |
| Women           | 84 (62)     | 42 (65)    | 42 (62)       |                                  |
| Diabetes mellitus| 11 (8.1)    | 4 (6.0)    | 7 (10)        |                                  |
| Comorbidities, n (%) |    |            |               |                                  |
| Trainee         | 91 (67)     | 48 (72)    | 43 (63)       |                                  |
| Specialist      | 44 (33)     | 19 (28)    | 25 (37)       |                                  |
| Surgeon         | 78 (58)     | 36 (54)    | 42 (62)       |                                  |
| Side, n (%)     |             |            |               |                                  |
| Right           | 78 (58)     | 36 (54)    | 42 (62)       |                                  |
| Left            | 57 (42)     | 31 (46)    | 26 (38)       |                                  |
| Dominant        | 78 (58)     | 36 (54)    | 42 (62)       |                                  |
| Tourniquet      |             |            |               |                                  |
| CSAn, mean in mm ± SD | 11.8 ± 4.3 | 11.3 ± 4.3 | 12.2 ± 5.0   | 1.4 ± 0.9 (0.6 to 2.2)          |
| CSAc, mean in mm ± SD | 15.1 ± 5.4 | 13.4 ± 3.3 | 15.2 ± 5.5   | 1.8 ± 1.0 (0.7 to 2.9)          |
| EMG (n = 75 CTS patients), n (%) | | | | |
| Sensory decreased | 32 (24) | 14 (21) | 18 (26) | 0.06 (0.0 to 0.13) |
| Motor decreased | 41 (30) | 21 (31) | 20 (29) | 0.13 (0.0 to 0.26) |
| Bilaterally | 7 (5) | 3 (4) | 4 (6) | 0.12 (0.0 to 0.24) |

Table 2. Results of QuickDASH and BCTQ

| Measurements | Tourniquet | No Tourniquet | Difference between Groups (95% CI) |
|-------------|-----------|---------------|----------------------------------|
| QuickDASH   |           |               |                                  |
| Intake      | 45.6 (41.2–50.0) | 39.4 (35.0–43.8) | 6.2 (-0.9 to 12.4) |
| 3 mo        | 16.9 (12.4–21.3) | 18.1 (13.7–22.5) | -1.2 (-7.5 to 5.0) |
| 6 mo        | 13.2 (8.8–17.6) | 13.0 (8.6–17.4) | 0.2 (-6.1 to 6.5) |
| 12 mo       | 15.5 (11.0–19.9) | 12.0 (7.6–16.5) | 3.4 (-2.9 to 9.7) |
| BCTQ        |           |               |                                  |
| SSS         | 3.08 (2.89–3.26) | 3.00 (2.81–3.18) | 0.08 (-0.18 to 0.34) |
| 5 mo        | 1.63 (1.48–1.82) | 1.64 (1.46–1.83) | 0.01 (-0.28 to 0.25) |
| FSS         | 1.49 (1.30–1.68) | 1.37 (1.18–1.57) | 0.12 (-0.15 to 0.39) |

Discussion:

Today, a tourniquet is still often used in minor hand surgery and depends on surgeons’ preference. Even though patients experience discomfort from the tourniquet, it does not influence the pain experience of the whole surgical procedure.22 In a previous study, we found no differences in operation time and short-term complications between patients who were operated on with or without a tourniquet. However, it is unknown whether tourniquet usage affects long-term clinical outcomes in minor hand surgery. In this randomized controlled trial of patients undergoing CTR and TFR, no difference was found in PROMs 1 year postoperatively between patients operated on with and without a tourniquet. Furthermore, no difference was found in the long-term complication rate and thickness of scar tissue.

Only short-term studies have been performed comparing clinical outcomes of patients treated with or without a tourniquet.23 These studies reported comparable improvements in patient-reported outcomes 6 weeks and 3 months after CTR and like in our study, no significant differences were found between the tourniquet and no-tourniquet groups. De Kleermaeker et al.24 stated that the clinical outcome after approximately 8 months is of most interest since patients who are free of symptoms within 8 months postoperatively have an 80% chance to remain asymptomatic after 9 years, in contrast to patients not free of symptoms after 8 months. We, therefore, feel that the follow-up of 12 months of our study should be long enough to make some conclusions concerning recovery after CTR. Our study shows that most improvement was seen in the first 3 months postoperatively, but PROM scores continue to improve for at least 12 months for both conditions. Importantly, no difference was found in the extent of course of improvement between the tourniquet and no-tourniquet groups 1 year postoperatively. We conclude that tourniquet use does not affect the recovery or persistence of symptoms.
The surgical procedures lasted less (in both groups 12 minutes) than the time it takes for the maximum vasoconstrictive effect of epinephrine to occur (25 minutes after injection of local anesthetic with epinephrine). For that reason, we expected that the increased blood flow after the release of the tourniquet would lead to more hematoma and subsequently to more scar formation in the tourniquet group compared with the no-tourniquet group. The formation of postoperative scar tissue around the nerve was determined by ultrasound, which is less invasive and less expensive than magnetic resonance imaging.

Steinkohl et al\textsuperscript{26} stated that 6 months is the interval considered necessary for restitution of postoperative swelling, so we expected to measure the most apparent results of scar tissue and other findings at 6 months of follow-up.

In addition, it was one of the aims of this study to reveal the clinical relevance of the thickness of the scar, and we expected more scar tissue formation in the tourniquet group due to the reperfusion effect after deflating the tourniquet. More scar tissue might subsequently affect the recovery of CTS and might cause persistent or recurrent complaints of CTS. In addition, the effect of scar tissue on PROMs is not known until now. Therefore, we wanted to investigate whether there is a difference in scar formation between patients operated on with a tourniquet and those without and whether the scar formation affects PROM and CTS symptoms recovery. However, in contrast to what was expected, we observed no difference between the two groups in the formation of hematoma and scar tissue postoperatively. Scar tissue around the nerve might induce recurrence of CTS.\textsuperscript{27,28} In accordance with the findings concerning scar tissue formation, no patients with recurrence of symptoms were seen within the first year postoperatively in both the tourniquet and no-tourniquet groups. We conclude that tourniquet usage does not affect the risk of recurrence of symptoms of CTS, and the clinical relevance is low.

We did not use postoperative electromyography to evaluate differences between both study groups since studies have shown that electromyography seldom normalizes after CTR and that despite clinical improvement, abnormal values might still be present.\textsuperscript{29–31} Unfortunately, the same holds for an ultrasound. Different studies report a lack of correlation between ultrasound parameters, such as CSA changes, and clinical outcomes.\textsuperscript{29,30,32} Despite this, we consciously have chosen to use ultrasound because we were particularly interested in differences in scar tissue formation and not in changes of (Δ)CSA.

Tourniquet use did not influence the complication rate. We report a relatively high complication rate compared with previous studies on CTR and TFR.\textsuperscript{2,6–8,10,33,34} This difference can be explained by the new scoring system of ICHOM we used. This system was developed to increase transparency and standardization of reporting complications and define all deviations from the normal postoperative course, even minor (eg, additional hand therapy), complications.

The strength of our study is the randomized controlled study design and the low rate of loss to follow-up (5%). One might say that a limitation of the study is not having electromyography and ultrasound measurements both preoperatively and postoperatively. However, various studies have shown no correlation between clinical outcomes and changes in electromyography and ultrasound postoperatively.\textsuperscript{26–31} This might also be the case in our study. The mean ΔCSA in both groups was 4 mm\textsuperscript{2}, indicating that patients still have an imaging diagnosis of CTS; however, our results do show an improvement in PROMs, and none of the patients reported having persistent or recurring symptoms.
Table 4. ICHOM Classification: Complications and Reoperations within 12 Months after TFR or CTR

| Grade | Complication (N) at 12 Mo | Tourniquet | No Tourniquet |
|-------|--------------------------|------------|---------------|
| I     | 13 complications in 13 patients (ie, 10% of the patients had a grade I complication) | 3 (2.2%) | 0 |
|       | Scar tenderness          | 2          | 1             |
|       | Temporary sensory changes| 0          | 0             |
|       | Additional hand therapy  | 4          | 3             |
|       | Dehiscence               | 2          | 1             |
| II    | 13 complications in 13 patients (ie, 10% of the patients had a grade II complication) | 6 (4.4%) | 3 |
|       | Infection requiring antibiotics | 2 | 1 |
|       | Hematoma                 | 2          | 1             |
|       | Tendinitis (steroid injection) | 0 | 2 |
|       | Recurrent tendinitis (steroid injection) | 2 (1.5%) | 0 |
| III   | Six complications in six patients (ie, 4% of the patients had a grade IIIA complication) | 3 (2.2%) | 1 |
|       | TVR (other finger)       | 1          | 2             |
|       | TVR (after CTR)          | 2          | 1             |
| IIIIB | 0 complications (ie, 0% of the patients had a grade IIIB complication) | 0 |
|       | Repeated surgery for CTR or TVR | 0 | 0 |
|       | Nerve repair             | 0          | 0             |
| IIIIC | 0 complications (ie, 0% of the patients had a grade IIIB complication) | 0 |

*Pvalue; no significant differences were found between the two groups.
CRPS, complex regional pain syndrome.

CONCLUSIONS

Our study shows that long-term clinical outcomes and formation of scar tissue and course of recovery of symptoms for patients undergoing CTR or TFR with or without a tourniquet are similar in both groups. Also, complications are not influenced by tourniquet use. Tourniquet usage is recommended by us to be a conjoined decision between surgeon and patients.

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PATIENT CONSENT STATEMENT

Informed consent was obtained from all individual participants included in the study.

ETHICAL APPROVAL STATEMENT

Medical Ethics Review Committee Brabant, Netherlands.

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