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ORIGINAL ARTICLE
Hand/Peripheral Nerve

Comparing Minor Hand Procedures Performed with or without the Use of a Tourniquet: A Randomized Controlled Trial

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Background: Carpal tunnel syndrome and trigger finger are two of the most common conditions treated by the hand surgeon. During these procedures, a tourniquet is often used to minimize bleeding and improve visualization of the operative field. However, it may be associated with pain and discomfort. To date, there are few prospective studies investigating the safety and patient-centered outcomes of tourniquet-free minor hand procedures.

Methods: This is a randomized controlled trial comparing patients undergoing open carpal tunnel or trigger finger release with or without the use of a tourniquet. Perioperative subjective patient experience was investigated for both techniques. This was measured based on a numerical rating scale for pain, anxiety, and overall satisfaction. In addition, this was an equivalence trial in terms of operative time, bleeding scores, and perioperative complication rates.

Results: A total of 67 patients were recruited. Both groups were similar with respect to distribution of age, sex, handedness, anti-platelet use, and tobacco use. Median scores for operative time, anxiety, and overall satisfaction were comparable between the 2 groups. With regard to patient discomfort, median scores were significantly higher in the tourniquet group when compared with the no tourniquet group (3.58 versus 1.68, respectively, $P = 0.02$). Bleeding scores for the tourniquet group were significantly lower than for the no tourniquet group (1.14 versus 1.90, respectively, $P = 0.001$).

Conclusions: The application of wide awake local anesthesia no tourniquet (WALANT) in minor hand surgery procedures has been shown to decrease tourniquet-associated discomfort, improving perioperative patient experience. Additionally, it demonstrated the noninferiority of the tourniquet-free technique with respect to operative time and the rate of perioperative complications.
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INTRODUCTION

Carpal tunnel syndrome and trigger finger (TF) are two of the most common conditions treated by the hand surgeon.[1] During carpal tunnel and TF release, obtaining a bloodless surgical field is paramount to properly identify anatomic structures and to prevent iatrogenic injury.

A tourniquet is often used to minimize bleeding and improve the view of the operative field. However, it can be associated with pain and discomfort.[2] For this reason, some surgeons advocate for tourniquet-free procedures, suggesting that similar hemostasis can be achieved with the xylocaine and epinephrine injection alone.[3] Although data from several retrospective studies on the matter confirm the safety of not using a tourniquet,[2,4,5] 57% of Canadian surgeons, and up to 95% of American surgeons still use a tourniquet for these minor procedures when done in a wide-awake setting.[6–8] To date, there are few prospective studies investigating the safety and patient-centered outcomes of tourniquet-free minor hand procedures.[2,9–11] Therefore, this single-center, prospective, randomized controlled trial (RCT) aimed to compare the perioperative patient experience and short-term postoperative outcomes of minor hand procedures performed with and without the use of a tourniquet.

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It was hypothesized that eliminating the use of the tourniquet will increase the overall patient satisfaction by decreasing the perioperative pain and discomfort. In addition, it was thought that, when properly used, an epinephrine-containing local anesthetic alone would allow for intraoperative hemostasis comparable to that achieved by the conventional use of an epinephrine-containing local anesthetic and tourniquet. Finally, it was believed that performing surgery without a tourniquet will not prolong the operative times or increase the complication rates.

METHODS

This study followed the CONSORT 2010 guidelines for the reporting of an RCT. Ethics approval was obtained from the Ethics Review Board of Maisonneuve-Rosemont Hospital in Montreal. It was also registered at ClinicalTrials.gov (no.: NCT04354415) (Fig. 1).

Trial Design

This was an RCT comparing patients undergoing open carpal tunnel or TF release with or without the use of a tourniquet. This was a parallel study by design where the allocation ratio between the 2 groups was set to be 1:1.

Participants

Patients were recruited on the day of the procedure. Upon arrival, they were presented with the research project and given the information pamphlet and consent forms. Sufficient time to read these documents was allocated.

The inclusion criteria for this trial were: (1) all patients must have been over the age of 18 at the time of surgery, and (2) must have had an electromyographically confirmed carpal tunnel syndrome and/or a clinically significant triggering or locking digit. Patients must have been able to understand and complete the pre- and postoperative questionnaires, which were administered in either English or French. Patients were excluded if they had (1) contra-indications for subcutaneous epinephrine use, (2) a history of digital gangrene, (3) Buerger's disease, (4) previous replantation, (5) Raynaud's disease, or (6) sclerodactyly.

Interventions

Traditionally, when performing hand surgery with use of a tourniquet, the surgical site is infiltrated with a solution containing a local anesthetic mixed with epinephrine only once the patient is already on the operating table. Immediately after infiltration, the arm is cleaned with an antiseptic solution, sterile drapes are placed, the arm is exsanguinated, the tourniquet is inflated at 250 mm Hg (or 100 mm Hg over the patient systolic blood pressure), and the surgery begins. The time between injection and incision is approximately 5 minutes or less. This timeframe is sufficient for a complete sensory block but does not allow epinephrine's vasoconstrictive properties to take full effect.[12,13]

In the tourniquet-free technique, local anesthetic plus epinephrine is injected in the surgical site before entering the operating room, thereby allowing epinephrine to take full effect. Once in the room, the patient's arm is disinfected and draped in a similar fashion, and surgery proceeds without inflation of the tourniquet. A system was implemented so that before patient A's surgery began, patient B was injected in a separate room. By the time patient B's surgery began, a minimum of 30 minutes had elapsed since his injection. Other than the differences in tourniquet use, all other procedure-specific elements were identical, namely the size and location of the incision, the surgical technique, skin closure, type of dressing, rehabilitation, and postoperative follow-up. For the purpose of this RCT, the solution used by the hand surgeons included 8 cm^3 of 2% xylocaine with epinephrine (1:100,000) mixed with 3 cm^3 of 0.5% Marcaine with epinephrine (1:200,000). In total, 8 ml was used for the CT releases and 4 ml for the TF releases.

Outcomes

The aim of the trial was to demonstrate the superiority of the no tourniquet technique with respect to the patients' subjective experience perioperatively. This was measured based on a numerical rating scale (NRS) for pain, anxiety, and overall satisfaction. As secondary outcomes, operative time, bleeding control, and short-term complication rates were looked at and compared between the 2 groups.

Data collected included patient demographics, comorbidities, anti-platelet use, and smoking status. Pain/discomfort score and anxiety level questionnaires were completed in the pre- and immediate postoperative period. A satisfaction level questionnaire was also completed in the postoperative period. The questionnaires administered for pain, anxiety, and satisfaction were based on a 10-point NRS. Peri- and postoperative complication data (at 1 week), including nerve or tendon damage, hematoma, infection, and wound dehiscence/breakdown, were collected.

The surgeon's questionnaire was completed in the immediate postoperative period. It included operative time, tourniquet time, any perioperative complications (nerve or tendon laceration), and time between epinephrine injection and the first cut. Additionally, bleeding level was noted by the surgeon based on a 3-point ordinal scale: 1—no bleeding, 2—minor bleeding controlled with dabbing, and 3—bleeding requiring electrocauterization.

Sample Size

To achieve statistical significance, at least 31 patients were needed in each group to show a minimal decrease of 33% on the NRS scales with an α error of 0.05 and a power of 80%. In the pain management literature, the American Pain Society suggests that a decrease of 30%–33% is considered as a clinically significant relief of pain when using the NRS.[14]

Randomization

Once patients meeting the inclusion criteria consented, they were randomized into 1 of the 2 study groups. Simple randomization was performed using a coin flip. Random sequence allocation, patient enrollment, and assignment were performed by the first author on the day of the surgery. Once the patient had been randomized to 1 of the 2 groups, this information was transmitted to the

CONSORT
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CONSORT 2010 Flow Diagram

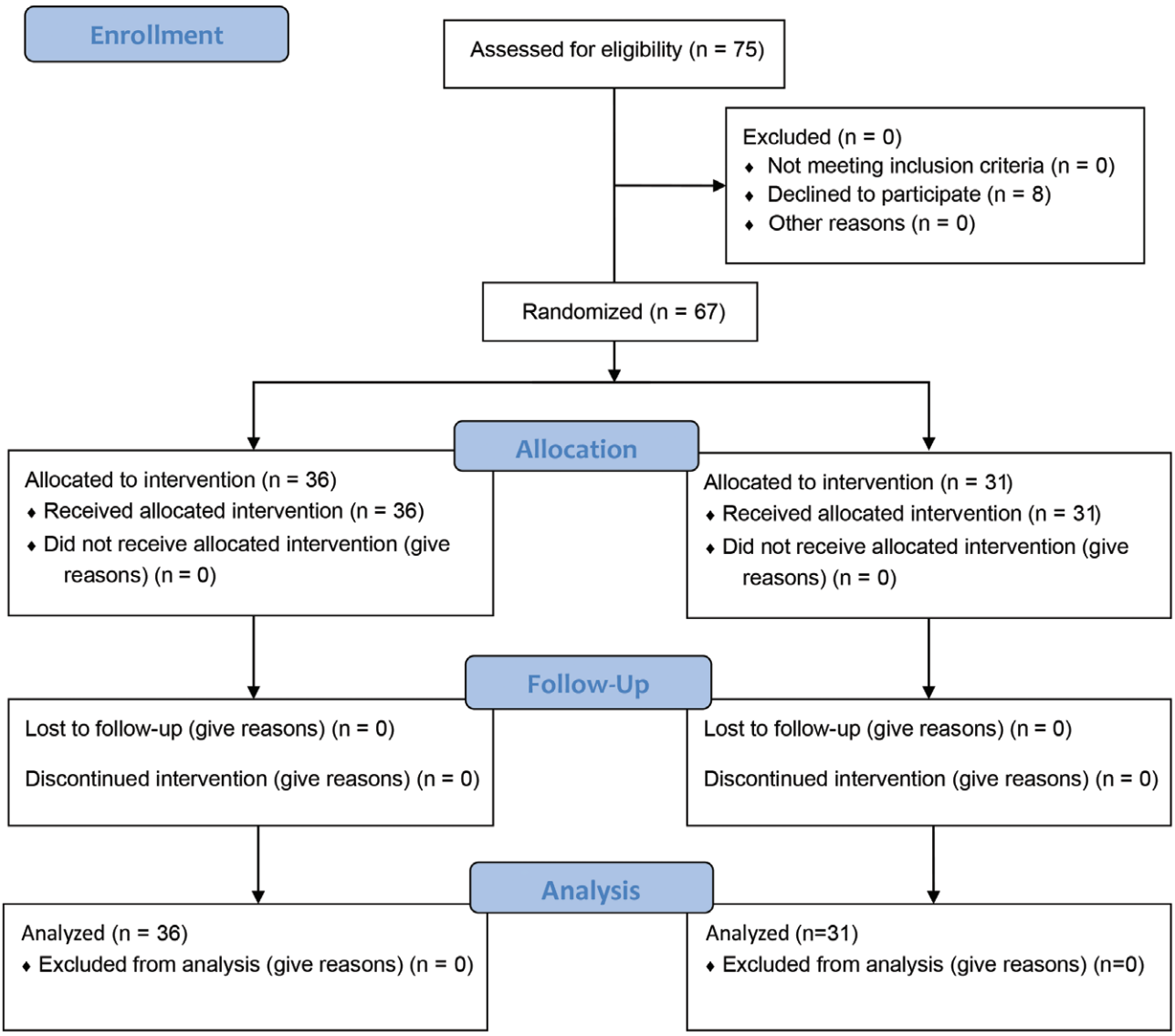

Fig. 1. Consort 2010 flow diagram.

operating room nurses and the surgeon. No blinding was performed for the purpose of this study.

Data Analysis

Data analysis was done using SPSS Statistics, version 25. Independent samples *t*-tests were used to assess the differences in age between the 2 groups. A chi-square test of homogeneity was used to determine whether a significant difference existed for the dichotomous dependant variables tested. These included: the difference in the gender distribution, handedness, tobacco use, anti-platelet use, and operated hand. Additionally, the chi-square

test was used to compare complication rates between the 2 groups.

For not normally distributed and for ordinal data, the Wilcoxon Mann-Whitney U test was used. This assessed the difference between the 2 groups for operative time, time between epinephrine injection and start of surgery, NRS scores for discomfort, anxiety and satisfaction, and for perioperative bleeding. $P < 0.05$ was considered statistically significant.

RESULTS

Seventy-five consecutive patients were initially assessed for eligibility. Eight patients declined to be randomized because of their preference to undergo the procedure without the use of the tourniquet. These patients were excluded from the study. A total of 67 patients were included. After randomization, 36 patients were assigned to the tourniquet group, and 31 patients to the no tourniquet group. Because randomization was performed after consent was obtained, all randomized patients were included in the analysis (see Fig. 1).

Patients were recruited between October 2018 and June 2019. Recruitment ended once the minimum sample size for each group was met. Follow-up was limited to 1-week postoperative in the context of the study. None of the 67 patients were lost to follow-up.

An independent-samples *t*-test showed no statistically significant difference in age between the tourniquet and no tourniquet groups (55.1 ± 2.5 years versus 60.3 ± 2.6 years, $P = 0.610$). The 2 groups were similar with respect to sex distribution, handedness, tobacco use, anti-platelet use, and operated hand. Only 2 minor postoperative complications were noted (wound infections); both patients were in the no tourniquet group ($P = 0.210$). No intraoperative complications (tendon or nerve laceration) were noted in either group (Table 1).

Mann-Whitney U tests were run to determine if there were differences in operative time, time between epinephrine injection and start of surgery, bleeding scores and NRS scores for discomfort, anxiety, and overall satisfaction. Operative times were not significantly different between the 2 groups when separating CT and single-digit TF release procedures ($P = 0.585$ and 0.635, respectively). Additionally, no statistically significant difference was found for time between injection and start of surgery between the 2 groups ($P = 0.293$).

Median NRS scores for anxiety and overall satisfaction were similar between the 2 groups. For patient discomfort, scores were statistically higher in the tourniquet when compared with the no tourniquet groups (3.58 versus 1.68, respectively, $P = 0.02$). Bleeding levels for the tourniquet group were significantly lower than for the no tourniquet group (1.14 versus 1.90, respectively, $P = 0.001$) (Tables 2–3).

DISCUSSION

In CT and TF release, there are several ways in which the surgeon can achieve intraoperative hemostasis.[15] Tourniquets are routinely used to restrict blood flow and control bleeding, thus creating a bloodless surgical field. However, they can be unpleasant, painful, and stress-inducing for patients when inflated.[16,17] These compressive devices are commonly used in elective outpatient hand and wrist surgeries and can require sedation, regional block, or general anesthesia to prevent patient suffering.[18]

Many surgeons, especially in our institution, have begun performing wide-awake local anesthesia without tourniquet (WALANT) as an effective and low risk alternative to the use of tourniquet and general anesthesia. This technique has been proved to improve the patient's experience and to help avoid unnecessary pain.[11,12] Another advantage is that it can be performed in the

Table 1. Baseline Characteristics and Complications

	Tourniquet (n = 36)	No Tourniquet (n = 31)	*P*
Age, years*	55.1 ± 14.8	60.3 ± 14.3	0.610
Gender†			
Men, %	30.6	38.7	0.483
Women, %	69.4	61.3	
Handedness†			
Right, %	91.7	100	0.243
Left, %	8.3	0	
Anti-platelet use†			
Yes, %	25.0	19.4	0.580
No,%	75.0	80.6	
Tobacco use†			
Yes, %	25.0	12.9	0.212
No, %	75.0	87.1	
Complications†			
Yes, %	0	6.5	0.210
No, %	100	93.5	

*Independent Samples Student's *T*-test was performed to compare means for normally distributed variables.
†Chi-square was used to measure associations between frequencies. Fisher exact test was used when expected counts were <5.

Table 2. Time and Bleeding Differences

	Tourniquet (n = 36)	No Tourniquet (n = 31)	*P*
Operative time (min) CT (n = 47)	8.38	8.96	0.585
Operative time (min) TF (n = 20)	6.9	5.8	0.635
Time between injection and first cut (min)	32.5	42.1	0.293
Bleeding level*	1.14	1.90	**0.001**

Mann-Whitney U test was performed to compare means for not normally distributed and ordinal variables.
$P < 0.05$ was considered statistically significant, and value in bold face indicates significance.
*Bleeding level was noted by the surgeon based on a 3-point ordinal scale: 1—no bleeding; 2—minor bleeding controlled with dabbing; 3—bleeding requiring use of electrocautery.

Table 3. Patient-centered NRS Scores

	Tourniquet (n = 36)	No Tourniquet (n = 31)	*P*
Anxiety NRS	3.11	2.61	0.629
Discomfort NRS	3.58	1.68	**0.02**
Overall satisfaction NRS	9.89	9.90	0.849

Mann-Whitney U test was performed to compare means for not normally distributed and ordinal variables.
$P < 0.05$ was considered statistically significant, and the value in bold face indicates significance.

minor operating room.[19,20] Although the majority of the literature on the use of WALANT has focused on clinical, physiologic, and economic outcomes,[8,20,21] few studies have focused primarily on patient-centered outcomes.[11]

The primary purpose of this study was to compare the patient's perioperative experience when undergoing minor hand procedures with and without tourniquet use. Comparing patients' intraoperative pain/discomfort in both groups, the no tourniquet group displayed superior results and was the preferred technique. The mean difference of almost 2 points noted on the NRS for pain/discomfort is consistent with the available data published in other RCTs.[2,9,10] A more recent systematic review published by Olaiya et al pooled data from observational studies, and came to a similar conclusion stating that their results were not only statistically significant but also clinically impactful.[22] While a reduction on the NRS scale with respect to perioperative pain/discomfort was seen in the no tourniquet group, it should be mentioned that the overall patient satisfaction was similar in both groups. Additionally, the perioperative anxiety experienced by patients showed no statistical difference between the 2 groups.

While the primary endpoint was patient-centered, the secondary aim of this study was to demonstrate the noninferiority of the no tourniquet technique with respect to operative time and complication rates. With respect to operative time, the pooled data by Olaiya et al did demonstrate a small increase when comparing the no tourniquet group with the tourniquet group (mean difference of 1.82 minutes).[22] In our study, when looking at operative time, for the carpal tunnel release procedures, there was a mean difference in operative time of 0.58 minutes favoring the tourniquet group. However, for the TF releases, the mean difference in operative time was 1.1 minutes in favor of the no tourniquet group. Both of these differences were not statistically significant. In addition, the operative time did not account for the time it took for application of the tourniquet, arm elevation, and exsanguination, which would have likely caused it to increase for the tourniquet group.

The optimal effect of epinephrine, which enables maximal vasoconstriction and hemostasis of the surgical field, has been proven to be >25–30 minutes after local injection as opposed to the 7-minute wait traditionally taught.[12,13] Waiting for the maximal effect of epinephrine before the first incision has shown a threefold reduction in bleeding compared with a shorter wait time and, therefore, has decreased the need for a tourniquet.[12,13] As part of the protocol for this study, it was assured that all patients received their injection of local anesthetic plus epinephrine at least 30 minutes before the commencement of surgery. A major limitation of the recent systematic review published by Olaiya et al pertained to the preoperative preparation time, which is an important outcome for surgeons. For the purpose of this study, a system was implemented so that before patient A's surgery began, patient B was injected in a separate room. By the time patient B was operated on, the elapsed time was 32.5 minutes in the tourniquet group and 42.1 minutes in no tourniquet group. This difference was not statistically significant.

With respect to hemostasis, the tourniquet group displayed a lower degree of bleeding. Although the scores were higher in the no tourniquet group, the bleeding was controlled by simply dabbing the incision site and no electrocautery was required in either group. This difference in bleeding did not result in an increase in operative time.

There are many complications that may arise in CT and TF release. These include tendon laceration, nerve laceration, infection, and incomplete release.[23] In our study, even though bleeding levels may have been significantly higher in the no tourniquet group, there were no intraoperative complications in either group, displaying their equivalence in that respect.

Although the results obtained are promising, there are certain limitations to this RCT. The study was not blinded, introducing a certain degree of potential bias to the results. However, the primary outcome was patient reported and, therefore, the lack of blinding of the investigators should not have played a role on that variable. Although all patients in both groups received the injection 30 or more minutes before the procedure, due to the limitations in our hospital functioning, it was impossible to assure that each patient received the injection at the same time preoperatively.

The WALANT approach, which has been performed in Canada for over 40 years, is now a technique used by surgeons all around the world for many types of hand surgeries.[21] The aim of this prospective randomized control trial was to add to the current body of evidence supporting its use and to specifically focus on patient-centered outcomes. This trial supports the literature that the use of WALANT is associated with enhanced perioperative patient experience due to decreased tourniquet-associated discomfort. Additionally, it demonstrated the noninferiority of the tourniquet-free technique with respect to operative time and perioperative complication rates.

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