

Continuous Wound Infiltration After Hallux Valgus Surgery

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Abstract

Background: Hallux valgus surgery is associated with significant early postoperative pain. The aim of this study was to investigate the use of continuous wound infiltration (CWI) with ropivacaine for pain management after hallux valgus surgery.

Methods: In this prospective, randomized, double-blind, and placebo-controlled single-center trial, 50 patients undergoing distal metatarsal osteotomy for idiopathic hallux valgus were allocated to CWI with ropivacaine 2 mg/mL at a rate of 2 mL/h or placebo for 24 hours postoperatively. Average and peak pain levels on the verbal numeric rating scale (NRS; 1–10) during the first 48 hours after surgery were recorded as primary outcome parameters. Secondary outcome parameters included consumption of narcotics, clinical outcome, incidence of postoperative complications, and patient satisfaction.

Results: No significant difference in mean ($P = .596$) and peak ($P = .353$) postoperative pain level was found for CWI with either ropivacaine (mean NRS 1.9 ± 0.8 ; peak NRS 3.5 ± 2.0) or placebo (mean NRS 2.0 ± 0.7 ; peak NRS 3.9 ± 1.7) during the early postoperative course. Furthermore, no significant difference between both groups was detected regarding narcotic consumption ($P = .354$) and all other secondary outcome parameters. Two severe complications (local dysesthesia with CWI, catheter accidentally fixed by a suture) and 5 catheter dislocations were observed.

Conclusion: CWI with ropivacaine 2 mg/mL at a rate of 2 mL/h for 24 hours after hallux valgus surgery did not reduce postoperative pain level in an inpatient setting.

Level of Evidence: Level I, prospective randomized trial.

Keywords: foot and ankle surgery, hallux valgus surgery, bunionectomy, continuous wound infiltration, continuous wound infusion

Introduction

Hallux valgus surgery is one of the most frequently performed orthopedic surgeries and either done under general or local anesthesia. It is usually associated with significant postoperative pain, especially during the first 24 hours postoperatively. Hence multimodal pain management is suggested to improve patient satisfaction.^{13,30,35,44,45,50} Methods of multimodal analgesia include, among other modalities, the use of neuraxial, regional, and local anesthesia. Local anesthesia can be applied using a single-shot technique or continuously using a tunneled catheter—so-called “continuous wound infiltration / infusion” (CWI). Previous studies showed that the CWI of local anesthetics provides sufficient postoperative analgesia and reduces postoperative narcotic consumption without an increased risk of complications.^{9,18,22,28,31,39,46} Furthermore, the cost effectiveness of CWI has been shown.^{17,43} So far, the use of CWI has mainly been investigated in abdominal, cardiothoracic, and gynecological-obstetric surgery.^{7,8,16–19,37,42} Apart from

abdominal surgery, the use of CWI has also been reported after orthopedic surgeries such as joint arthroplasty,^{1,10,14} spine surgery,^{9,23,49} shoulder surgery,^{5,12,22} and anterior cruciate ligament reconstruction.²⁷

We hypothesized that there would be a significant difference in mean and peak postoperative verbal NRS (numeric rating scale) pain level and need for narcotics between the 2 groups of continuous wound infiltration for 24 hours postoperatively with (1) ropivacaine or (2) placebo. The aim of

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this study was to investigate the effect of CWI for postoperative pain control after elective hallux valgus surgery.

Methods

Approval

The study has been approved by the local ethics committee (Medical University of Innsbruck; number AN2014-0034) and has been performed in accordance with the ethical standards outlined in the 1964 World Medical Association Declaration of Helsinki and its later amendments following the Consolidated Standards of Reporting Trials (CONSORT) guidelines. Furthermore, the study was registered at EudraCT (European Clinical Trial Database, European Medicines Evaluation Agency, London, Great Britain; EudraCT Number: 2013-005106-64) and at ClinicalTrials.gov (NCT02182999) in accordance with the International Committee of Medical Journal Editors (ICMJE) guidelines for trial registration. The Austrian Federal Office for Safety in Health Care (Austrian Medicines and Medical Devices Agency, Vienna, Austria) approved the study. All patients involved in the study gave their informed consent before their inclusion in the study. The study was designed as a prospective, randomized, double-blind, and placebo-controlled single-center trial.

Participants / Eligibility criteria

All patients undergoing a distal metatarsal osteotomy (only chevron or scarf osteotomy) and lateral release with or without concomitant osteotomy of the proximal phalanx of the greater toe (Akin osteotomy) for idiopathic hallux valgus deformity at the Department of Orthopedic Surgery, Medical University of Innsbruck, between May 2014 and March 2017 were screened for eligibility in the study. Exclusion criteria were defined as follows: (1) hallux valgus surgery other than mentioned above or concomitant with other procedures (eg, arthrodesis of the lesser toes), (2) denial to participate and give informed consent, (3) patients with neurologic diseases that affected the sensory-motor function, (4) patients with any surgery during the previous month on the affected lower extremity, (5) allergies or other comorbidity that would prohibit standardized pain regime (eg, renal insufficiency, severe heart or liver impairment, uncontrolled asthma, history of peptic ulcer), and (6) patients who chose a general anesthesia for the procedure.

A total of 294 osteotomies of the first metatarsal were performed for idiopathic hallux valgus deformity at the Department of Orthopedic Surgery, Medical University of Innsbruck, between May 2014 and March 2017. After screening for eligibility, 50 patients were enrolled in the study. Follow-up was completed by 39 patients, while primary outcome parameters were analyzed in 42 patients. Further detailed information on participants' flow are presented in the CONSORT guidelines flow diagram (Figure 1).

Baseline demographic and clinical characteristics for each group are shown in Table 1. In 38 cases, a chevron osteotomy was performed; in 11 cases, hallux valgus correction was achieved using a scarf osteotomy; and in 1 case the surgeon decided to perform a metatarsophalangeal (MTP) arthrodesis intraoperatively. An additional Akin osteotomy was performed in 14 patients.

Interventions

In accordance with the standardized procedures of our department, a foot block using 15 mL of equal parts lidocaine 20 mg/mL (without epinephrine) and bupivacaine 5 mg/mL was applied preoperatively according to Wooden et al⁴⁸ to anesthetize the superficial and deep peroneal nerve, the saphenous nerve, and the posterior tibial nerve. To prevent falsification of results, local anesthetics were administered in a standardized manner in each patient.

After exsanguination, correction of hallux valgus was performed using a lateral soft-tissue release and a distal chevron or diaphyseal scarf osteotomy.^{4,47} Lateral release included incision of the lateral metatarsosesamoidal ligament, release of the adductor hallucis tendon, and incision of the lateral metatarsophalangeal joint capsule through an additional dorsal skin incision in the first dorsal web space. Up to two 2.5-mm cannulated screws (FRS; DePuy Orthopedics, Warsaw) were inserted for fixation of the osteotomy, and a medial capsulorrhaphy was performed. An Akin osteotomy was carried out additionally in case of hallux valgus interphalangeus.

For CWI catheter placement (Figure 2), the intact skin was punctured with a split cannula at a short distance (20-30 mm) proximal and lateral from the proximal end of the dorsomedial skin incision at the end of the operative procedure. A multiperforated catheter (InfiltraLong 600, 19G × 420 mm; Pajunk, Geisingen, Germany) was inserted through the split cannula right up to the end of the wound, and the cannula then was removed by splitting it apart. Subsequently, the catheter was advanced distally around the medial and plantar side of the first metatarsal head using a small clamp, until the tip of the catheter pointed toward the interdigital space. The catheter was then connected to the filter and the perfusor line and filled with either ropivacaine 2 mg/mL or saline 9 mg/mL to allow for CWI at a rate of 2 mL/h for 24 hours via a perfusor (Perfusor compact; B. Braun Melsungen, Melsungen, Germany). The wound was closed and a sterile corrective dressing was applied.

Postoperative care and pain management was standardized in every patient. On the day of surgery, the foot was placed in a foam positioning splint and cooled using ice packs for approximately 15 to 20 minutes 3 times a day. The CWI catheter was removed while changing the dressing the morning after surgery. Patients were instructed to keep their leg elevated whenever possible and to avoid exercise or overexertion, especially during the first 14 days after surgery. Full weightbearing was allowed

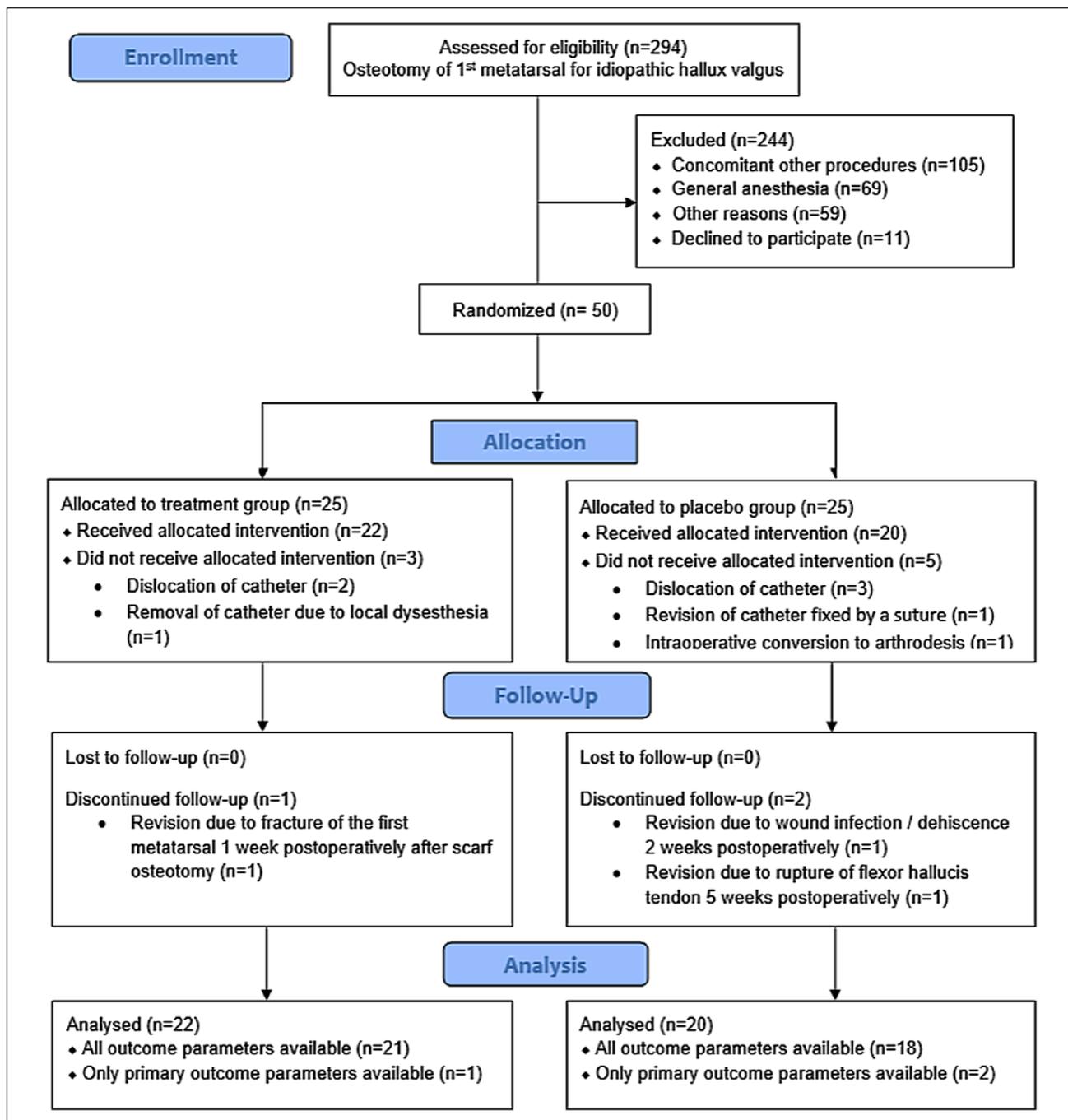


Figure 1. CONSORT guidelines flow diagram.

immediately after surgery using surgical shoes with stiff soles for 6 weeks.

For postoperative pain management, naproxen 500 mg (Naprobene; ratiopharm Arzneimittel Vertriebs-GmbH, Vienna, Austria) was administered twice a day. Patients received 1.3 mg hydromorphone (Hydal, Mundipharma GmbH, Vienna, Austria) as a rescue medication for NRS pain score greater than 3. All medications were recorded by

the nursing staff. Patients were routinely discharged the second day after surgery and 500 mg of naproxen twice a day was prescribed for 5 days.

Study Outcomes and Outcome Assessment

Patients were followed for 6 weeks after the procedure. The primary outcome parameters of this study were average

Table 1. Baseline (Preoperative) Characteristics of the Treatment and Placebo Groups.

Variable	Treatment Group ^a	Placebo Group ^a	P Value
Sex, n (%)			.000
Male	5 (20)	5 (20)	
Female	20 (80)	20 (80)	
Age, y	58.0 ± 13.1 (25.8-78.5)	52.5 ± 17.2 (18.8-79.5)	.209
Body mass index	25.8 ± 4.2 (19.1-35.9)	24.0 ± 4.0 (18.7-33.1)	.138
Site, n (%)			.156
Right	15 (60)	9 (36)	
Left	10 (40)	16 (64)	
Operation type, n (%)			.496
Chevron	18 (72)	20 (83)	
Scarf	7 (28)	4 (17)	
Mean NRS pain score	2.9 ± 1.9 (0-7)	3.1 ± 1.8 (0-7)	.746
Peak NRS pain score	6.1 ± 2.3 (1-10)	6.3 ± 1.9 (3-9)	.745
ROM first metatarsophalangeal joint, deg	64.6 ± 21.0 (25.0-120.0)	68.8 ± 21.1 (40.0-130.0)	.615
AOFAS forefoot score, points	56.8 ± 11.3 (32.0-80.0)	59.6 ± 11.1 (30.0-75.0)	.255

Abbreviations: AOFAS, American Orthopaedic Foot & Ankle Society; NRS, numeric rating scale; ROM, range of motion.

^aThe values are given as the mean and the standard deviation, with the range in parentheses, unless otherwise indicated.



Figure 2. Continuous wound infiltration catheter placed in the dorsomedial skin incision and connected to the filter.

pain and peak pain level on the verbal numeric rating scale (NRS; 1-10, higher numbers indicating increasing pain level) during the first 48 hours after surgery. The secondary outcome parameters included postoperative rescue opioid consumption, clinical outcome (AOFAS forefoot score, range of motion [ROM] of MTP joint of the greater toe), incidence of postoperative complications, and patient satisfaction with surgery on a numeric rating scale (1-10). Baseline demographic and clinical characteristics (gender, age, body mass index, side, and type of operation) were recorded for all patients.

NRS scores for pain were recorded by members of the nursing staff every 4 hours after the procedure until discharge, with the exception of the control at 4 AM in the morning (16 hours, 40 hours), when most patients were asleep. The nursing staff was not directly involved in the study and blinded regarding the treatment group. Patients were instructed to rate their pain level on a scale from 0 to 10, with 0 meaning “no pain” and 10 indicating “pain as bad

as it could be.” Narcotic consumption and medication-related side effects were monitored.

Complications were closely monitored and treated as soon as detected. They were categorized as severe or minor. The need to stop CWI because of clinically significant adverse side effects (eg, severe local side effects, central nervous toxic side effects, cardiovascular side effects) or to perform operative revision due to wound catheter placement was considered to be a severe complication. Other failures of treatment that interfered with the primary outcome of CWI treatment were considered to be minor complications.

Further pain and clinical evaluations were performed as part of the routine postoperative outpatient visits 1, 2, and 6 weeks after the procedure by independent health care professionals, who were not directly involved in the study and blinded to the treatment group. Furthermore, AOFAS forefoot score, ROM of MTP joint of the greater toe, postoperative complications, and patient satisfaction with surgery (NRS 0-10) were investigated as part of a routine examination 6 weeks after the procedure.

Sample Size Estimation

A sample size of 17 patients in each group was previously calculated on the basis of a significance level of .05, a power of 80%, an anticipated pooled standard deviation (SD) of 1.0 of the mean verbal NRS pain level, and a minimal clinically important difference in the mean verbal NRS pain level of 1.0 points between the groups. Anticipating a loss to follow-up, we planned to recruit a total of 50 patients (25 patients each group).

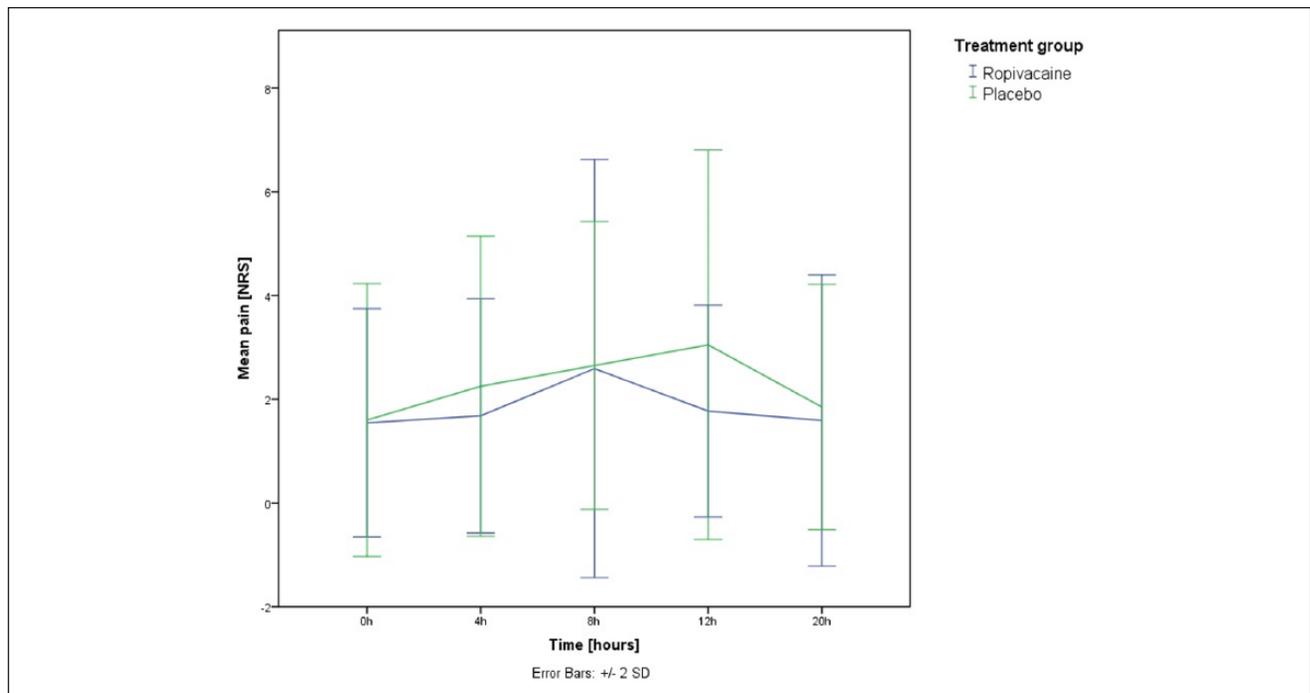


Figure 3. Mean (SD) numeric rating scale pain scores in the 2 groups with continuous wound infiltration with ropivacaine and placebo at 0, 4, 8, 12, and 20 hours postoperatively.

Randomization and Blinding

A randomization sequence was generated by computer software (<http://www.randomizer.org>). A randomization list from 1 to 50 was created, each number encoding for treatment or placebo group. The numbers were placed in 50 individual sealed opaque envelopes marked 1 to 50. The randomization list was stored in a locked room and could only be accessed by one independent member of the nursing staff, who prepared the study medication but did not take part in patient care. Allocation was performed after the protocol was explained to the potential participants. All participants agreed to take part in the study and signed the informed consent form. An independent person opened each patient's randomization envelope a few minutes before the start of surgery to assign the intervention. A 50-mL perfusor syringe was filled with either ropivacaine 2 mg/mL (Ropinaest 2 mg/mL, Injektionsloesung; Gebro Pharma GmbH, Fieberbrunn, Austria) or saline 9 mg/mL according to patient's randomization number. Patients, attending surgeons, and all staff concerned with postoperative care of the patients were blinded to the treatment group. The randomization list was not opened until after the data from the last patient had been collected and recorded.

Statistical Methods

Outcome was analyzed by intention to treat. The variables collected were tabulated with an Excel spreadsheet. Data

was then transferred to a SPSS table and statistical analysis was performed using SPSS Statistics 22 (IBM Analytics, Armonk, NY). Differences among groups were analyzed with Mann-Whitney *U* test for non-normally distributed variables and with independent Student *t* test for normally distributed variables. Categorical variables were analyzed using Fisher exact test. Data were expressed as mean \pm SD if not otherwise indicated. $P < .05$ was considered to be statistically significant.

Results

Pain Level

For mean and peak postoperative verbal NRS pain level, no significant difference between the 2 groups with continuous wound infiltration with ropivacaine (mean NRS 1.9 ± 0.8 ; peak NRS 3.5 ± 2.0) and placebo (mean NRS 2.0 ± 0.7 ; peak NRS 3.9 ± 1.7), respectively, was found during the early postoperative course ($P = .596$). NRS pain scores in both groups were similar preoperatively, in the recovery room, and at 4, 8, 12, 20, and 24 hours postoperatively (Figure 3). Mean and peak postoperative verbal NRS pain level did not differ significantly between chevron (mean NRS 1.9 ± 0.7 ; peak NRS 3.7 ± 1.9) and scarf (mean NRS 2.1 ± 0.8 ; peak NRS 3.7 ± 1.7) osteotomy ($P = .530$) and cases with (mean NRS 2.1 ± 1.0 ; peak NRS 4.2 ± 2.2) and without (mean NRS 1.8 ± 0.7 ; peak NRS 3.5 ± 1.7) additional Akin osteotomy ($P = .423$).

Table 2. Secondary Outcome Parameters of the Treatment and Placebo Groups.

Variable	Treatment Group ^a	Placebo Group ^a	P Value
Mean NRS pain score at 1 wk	2.3 ± 1.7 (0-7)	1.5 ± 1.3 (0-4)	.130
Peak NRS pain score at 1 wk	4.3 ± 2.2 (1-10)	3.8 ± 2.6 (0-10)	.319
Mean NRS pain score at 2 wk	1.7 ± 1.4 (0-5)	1.7 ± 1.6 (0-5)	.777
Peak NRS pain score at 2 wk	3.5 ± 2.1 (0-8)	3.4 ± 2.4 (0-10)	.655
Mean NRS pain score at 6 wk	1.1 ± 1.4 (0-5)	1.1 ± 1.5 (0-4)	.892
Peak NRS pain score at 6 wk	2.5 ± 2.5 (0-8)	2.3 ± 2.0 (0-7)	.819
ROM first metatarsophalangeal joint at 6 wk, degrees	40.0 ± 14.5 (10-65)	46.6 ± 14.3 (15-70)	.137
AOFAS forefoot score at 6 wk	75.7 ± 10.8 (49-90)	75.8 ± 8.9 (57-90)	.881
Overall satisfaction with surgery	9.0 ± 1.3 (5-10)	9.1 ± 1.3 (5-10)	.595
Satisfaction with pain management	9.0 ± 1.2 (6-10)	9.3 ± 1.2 (5-10)	.259

Abbreviations: AOFAS, American Orthopaedic Foot & Ankle Society; NRS, numeric rating scale; ROM, range of motion.

^aThe values are given as the mean and the standard deviation, with the range in parentheses.

Mean narcotic consumption during the first 48 hours after surgery did not differ significantly between both groups ($P = .354$), although there was a trend toward a lower need for rescue medication (hydromorphone) in the treatment group ($1.4 \text{ mg} \pm 1.7$) compared with the control group ($2.5 \text{ mg} \pm 2.5$). For all other secondary outcome parameters, there was no statistically significant difference (Table 2).

Complications

Two severe complications and 5 minor complications were observed. One patient complained about severe diffuse local dysesthesia of the foot, which completely resolved after catheter removal. One revision had to be performed because the wound infiltration catheter was accidentally fixed by a suture. Catheter dislocation occurred in 5 cases. All other 3 revisions (1 fracture of the first metatarsal after scarf osteotomy, 1 wound dehiscence / infection, 1 rupture of flexor hallucis tendon) were considered by the Data Monitoring Committee to be unrelated to CWI catheter use. No central nervous system or cardiac toxicity due to infiltration of the local anesthetics was observed.

Discussion

In this randomized, double-blind, placebo-controlled trial, no significant difference in mean and peak postoperative pain level was found for CWI with either ropivacaine or placebo after hallux valgus surgery. Furthermore, no significant difference between both groups was detected regarding narcotic consumption and all other secondary outcome parameters. However, there was a trend toward a lower need for rescue medication (hydromorphone) in the ropivacaine group, although this difference did not reach statistical significance. These findings might be explained by the fact that all patients were visited regularly by the nursing staff in an inpatient setting and hydromorphone was

given immediately when pain exceeded NRS 3. Furthermore, the need for rescue medication varied widely between the patients (0-9.1 mg of hydromorphone), and this study was not designed to detect a difference in narcotic consumption. In sum, the role of CWI in pain control versus other modalities seemed to be of minor importance, since no difference to placebo was noted regarding postoperative pain levels.

We investigated the use of CWI as a form of multimodal pain management after hallux valgus surgery. Multimodal pain management has shown to improve postoperative pain management and reduce side effects of opioid monotherapy.²⁹ Typically, multimodal pain regimen in orthopedic procedures includes scheduled administration of acetaminophen and/or nonsteroidal anti-inflammatory drugs (NSAIDs) in combination with narcotics (opioids) as needed to supplement regional anesthesia techniques. Regional anesthesia techniques can be utilized as single-shot or continuous epidural infusions, peripheral nerve blocks, local periarticular injections (or local infiltration anesthesia [LIA]), or CWI. Epidural infusions are associated with a profound neuromuscular block, which limit its utility in the postoperative period after orthopedic procedures with regard to mobilization. Peripheral nerve blocks in foot surgery are challenging because of the great variations of the nerves around the ankle and foot, yet effective pain control using continuous popliteal sciatic^{33,41,50} or posterior tibial^{6,24} nerve blocks after forefoot surgery has already been reported. However, these techniques usually require experience in dealing with ultrasound-guided needle placement and might therefore not be applicable to every orthopedic surgeon. On the contrary, placement of a wound catheter for CWI locally can be easily performed by the attending surgeon at the end of surgery. Furthermore, sciatic neuropathy due to popliteal fossa nerve blocks has become a matter of concern.^{2,3,15,25} Recently, the use of extended-release bupivacaine as local analgesic has also been described after foot and ankle surgery,^{20,26} but so far its use has not yet been investigated adequately.

The effect of CWI of the great toe depends on meticulous catheter placement. We placed a multiperforated wound catheter in such a way that the local anesthetic was distributed to the branches of the deep and superficial peroneal nerves and to the medial plantar nerve. Care must be taken to insert the catheter laterally close to the dorsal pedis artery in order to anesthetize the medial terminal branch of the deep peroneal nerve, which supplies the first web space, and the medial dorsal cutaneous branch of the superficial peroneal nerve, which supplies the medial part of the dorsum of the foot. The medial plantar branch of the tibial nerve, which usually provides sensation to the skin of the plantar adjacent sides of the toes 1 to 3, can be anesthetized in proximity to the abductor hallucis tendon by passing the catheter below the first metatarsal shaft from the medial side into the interdigital space.

In this study, we used a rate of 2 mL/h of ropivacaine 2 mg/mL over 24 hours for CWI in an inpatient setting to ensure blinding of the study medication by avoiding the need to refill the 50-mL perfusor syringe. However, continuous ropivacaine infusions delivered for a longer period, coupled with multiple boluses of ropivacaine 5 mg/mL, appear to be safe and might further increase the effect of CWI.¹¹ Furthermore, CWI might also be used in an outpatient setting using portable pain pumps. Our dosing regimen did not result in systemic central nervous or cardiac toxicity. Because the wound catheter was not placed intra-articularly, the risk of chondrolysis appears to be low, although cartilage might be exposed through the capsulotomy.^{21,32,34,36,38,40} We are not aware of any case of chondrolysis in our series. However, we observed 7 complications that interfered with postoperative CWI therapy, and full follow-up was only completed by 39 patients. At the beginning of the study, catheter displacement at the wound site occurred in 5 cases, which led us to additional fixation of the catheter to the skin by the use of Steri-Strips. Furthermore, 1 catheter was accidentally fixed by a suture and had to be removed operatively. One patient in the treatment group complained about diffuse local dysesthesia of the foot likely caused by ropivacaine infiltration, which completely and immediately disappeared after catheter removal. One case of postoperative wound infection was considered by the Data Monitoring Committee to be unrelated to CWI catheter use. However, elevated hydrostatic pressure caused by pumping fluid into the subcutaneous space might also reduce circulation and thereby increase the risk of wound dehiscence.

Strengths and Limitations

The strength of this study is its randomized, double-blinded, controlled fashion with adequate methods of randomization and allocation, as well as the absence of any industry conflicts of interest.

We recognize that our study has several limitations:

1. Operations were not always performed at the same time and by the same surgeon, substantially influencing our findings. However, all operations were performed in the morning and all surgeons were carefully instructed regarding correct placement of the CWI catheter. Furthermore, pre- and postoperative care was standardized in every patient.
2. The immediate short-term pain relief afforded by injected bupivacaine and all other pain management modalities used (NSAIDs, narcotics, ice packs) interfered with short-term interpretation of the benefit of infused ropivacaine. However, because local anesthetics were administered in a standardized manner in each patient and because mean and peak pain level during the first 48 hours after surgery were evaluated as the primary outcome parameter, we do not believe that this has substantially influenced our findings.
3. Because of the above-mentioned complications, all outcome parameters were only analyzed for 39 of 50 patients, which might have influenced our results. However, based on our sample size estimation, we do not think that this had a substantial impact on our findings.
4. Because verbal NRS for pain was assessed by the nursing staff and narcotics were given if pain exceeded NRS 3, reported mean postoperative pain scores might not reflect the real pain situation and the results might not be applicable in an outpatient setting. Furthermore, pain NRS evaluates only pain intensity and might therefore not capture the complexity of the pain experience.
5. Possible long-term complications might not have been recognized because of the limited follow-up of 6 weeks. However, we are not aware of any long-term complication in our series so far.
6. Although it will be important in the future to do a cost analysis to determine cost-effectiveness, this study was not designed to do so and the necessary charge and reimbursement data were not available.
7. Further studies are warranted to confirm the use of CWI because this study was conducted in a single center, which is associated with a lower external validity.

Conclusion

CWI with ropivacaine 2 mg/mL at a rate of 2 mL/h for 24 hours after hallux valgus surgery did not reduce postoperative pain level in an inpatient setting. Further studies are needed to elucidate the use of CWI or other regional anesthesia techniques for pain management after foot and ankle surgery.

Declaration of Conflicting Interests

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