

Improving Analgesia after Hallux Valgus Surgery: Transdermal Fentanyl Patch in Combination with Popliteal Nerve Block as Part of Multimodal Analgesia Approach

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Abstract

Background: The last decade there has been an exponential increase in opioid-related deaths in the United States. This increase has been proven to be correlated with the high prescribing rates of strong opioids, such as morphine and oxycodone. The current research setup evaluated the feasibility of adequate peri-operative pain control in hallux valgus surgery with the combination of single dose popliteal nerve block plus one-time application of a transdermal fentanyl patch.

Methods: A prospective observational study was conducted on 100 patients undergoing corrective osteotomy of the first metatarsal due to hallux valgus. A transdermal fentanyl patch (<70 kg 12 µg/h, >70 kg 24 µg/h) was applied on the upper arm one hour prior to surgery. Surgery was performed after ultrasound-guided popliteal nerve block. Patients filled in questionnaires between 6-72 hours after surgery to evaluate pain (Visual Analogue Scale), nausea (Post-Operative Nausea Vomiting-score), activity (activity and ambulation score) and intake of pain medication.

Results: Minimum and maximum mean perioperative pain was 0.46 (SD 1.47) (6 h post-operative) and 3.94 (SD 2.76) (36 h post-operative), respectively on the Visual Analogue Scale. After discharge, 2% of patients required additional analgesia with strong opioids such as oxycodone. 64% of patients had less pain than expected prior to surgery. At 24-hour and 36-hour post-operatively, nausea was noted in 35% and 23% of patients, respectively.

Conclusions: The one-time use of a weight-adjusted dose of transdermal fentanyl patch combined with single dose ultrasound-guided nerve block can be efficient when part of a multimodal analgesia approach to treat post-operative pain after hallux valgus surgery.

Keywords: Forefoot surgery; Opioid abuse; Opioid crisis; Pain management; Peri-operative analgesia

Introduction

For several years opioids have been used to relief postoperative pain because they were thought to be safe and harmless [1]. During the last decade there has been an exponential increase in opioid use related deaths in the United States [2]. Several studies were able to demonstrate a correlation between the total number of opioid related deaths and a rise in the amount of prescribed opioids [2-4]. Surgeons are important contributors in the prescription of strong opioids, such as morphine and oxycodone [3,5]. In order to treat acute perioperative pain, alternative analgesia strategies were developed, such as peripheral nerve blocks [6]. It offers several advantages including good patient comfort, adequate postoperative pain control, high patient satisfaction [7] and decreased postoperative narcotic consumption [8]. In general the effect of the popliteal nerve block maintains for about 13-15 hours [9]. As postoperative pain is often more persistent than 13-15 hours, for example after hallux valgus surgery patients experience moderate to severe pain 2-3 days post-operative [10], additional pain treatment is necessary. In order to avoid prescribing per-oral opioids and thus restrict the ambulatory use of strong opioids such as morphine and oxycodone, an alternative strategy to provide prolonged and adequate pain treatment has been used. A fentanyl patch was applied one hour before surgery in the hospital in combination with the ultrasound guided popliteal nerve block. Purpose of this strategy was that by the time the highest blood concentration of the patch has reached, approximately 12 to 24 hours after application, the effect of the nerve block wears off and prolonged pain control is achieved as the steady state of the patch maintains for up to 72 hours [11,12].

The primary aim of this research paper was to evaluate whether sufficient pain control could be achieved after hallux valgus surgery with the use of the combination of a transdermal fentanyl patch and an single dose ultrasound-guided popliteal nerve block. The second goal was to assess the known, and feared, post-operative complications of opioid-related drugs: post-operative nausea and vomiting [13]. Finally, the intake of any additional pain medication was evaluated in case of excessive postoperative pain despite the ultrasound-guided nerve block and transdermal fentanyl patch.

Materials and Methods

The current study was approved by the Ethical Commission. A prospective observational study was performed including all patients over 18 years old and in a good mental condition, undergoing hallux valgus surgery in the period between September 2017 and May 2018. Patients with revision surgery were excluded. In total, 100 consecutively patients were enrolled. Surgery was performed

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by two senior foot and ankle surgeons and included different first metatarsal corrective osteotomies, with or without osteotomy of lesser metatarsals. The transdermal fentanyl patch was applied on the upper arm of the patient by the nursing staff on the orthopedic ward one hour prior to surgery. One patch was used per patient. The dose of the fentanyl patch was adjusted according to the weight of the patient. Patients <70 kg received a transdermal fentanyl patch of 12 µg/h, patients over 70 kg were treated with a transdermal patch of 25 µg/h. All patients received pre-operatively a single dose ultrasound-guided popliteal nerve block, performed by an experienced anesthesiologist. Patients did not undergo general anesthesia. The popliteal block was achieved with Ropivacaine 0.75%, 20 cc per patient. At discharge, all patients received a prescription for paracetamol (1 g max 4 times a day) and tramadol (50 mg max 4 times a day). Patients were instructed to take additional pain medication only when necessary and to start with paracetamol. Patients were instructed to remove the transdermal patch after 72 hours, or earlier if adverse effects occurred.

Patient-reported outcome measures were evaluated with questionnaires, which were filled in on paper. Pain was assessed using a visual analogue scale at 6, 12, 24, 48, 60 and 72 hours after surgery. Post-operative nausea and vomiting (PONV) score was inquired at 6, 12, 24, 36, 48, 60 and 72 hours post-operative, as well as the influence on the patients daily functioning. The PONV-score gives an answer to the questions 'Did you have to vomit?/Did you experience severe nausea?'. The following responses are possible: 0=no, 1=1 time/episode of severe nausea, 2=2 times/2 episodes of severe nausea, 3=3 times/3 episodes of severe nausea. The influence of post-operative nausea on patients daily functioning was evaluated as follows: 0=not at all, 1=sometimes, 2=most of the time, 3=all the time. The ambulation score at 6, 12, 24, 26, 48, 60 and 72 hours after surgery was assessed: 1=not able to sit up in bed, 2=able to sit up in bed, 3=able to sit on the bed with the foot hanging down, 4=able to walk with human assistance, 5=able to walk with crutches [9]. The global pain experience after surgery was evaluated with the following question: 1=more pain than expected, 2=pain as expected, 3=less pain than expected, 4=not sure about this. Additionally, patients were asked whether additional pain medication was necessary due to excessive pain (0=no, 1=yes) and if so, which drug was used.

Categorical data were compared using Fisher's exact test and chi-squared test. Normally distributed continuous variables were compared using independent t-tests for unpaired data sets and one-way analysis of variance (ANOVA) for multiple data sets. The Mann-Whitney test was used for non-parametric data. Statistical significance was set at a p<0.05 for all analyses. All statistical analysis was performed using SPSS software version 22 (IBM Corp., Armonk, New York). The research hypothesis was that the combination of the one-time application of transdermal fentanyl patch with ultra-sound guided popliteal nerve block would provide adequate pain control and patient satisfaction following hallux valgus surgery.

Results

In total, 85 females and 15 males were enrolled. The average age was 59.4 years (SD 11.4). The distribution of the performed types of hallux valgus corrective surgeries is displayed in the Table 1. Evolution of mean and maximum VAS-score is summarized in Figure 1. In the direct postoperative period (6 until 12 hours postoperative) most patients (81 resp. 68%) did not need additional pain medication. There was a peak in intake (86% of all patients) of extra pain medication

at 36 hour after surgery. Two patients declared to take strong opioids (oxycodone) after discharge. Most of the patients did not experience nausea (97%, 89%, 65%, 77%, 86%, 90% and 98% at resp. 6, 12, 24, 36, 48, 60 and 72 hours post-operative). In most cases nausea had only a mild or no effect on daily functioning (Figure 2).

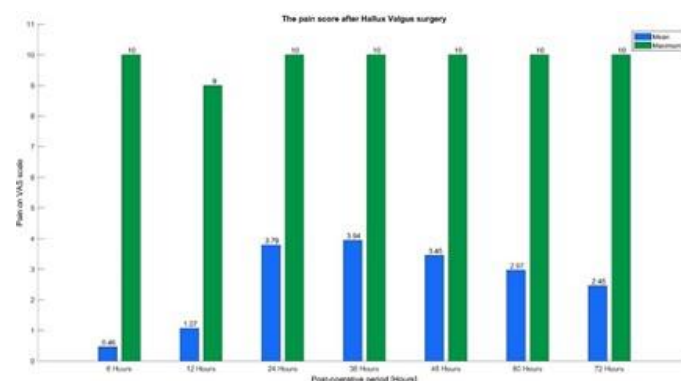


Figure 1: VAS-score at 6, 12, 24, 36, 48, 60 and 72 hours post-operative, with mean scores (blue) and maximum scores (green).

Surgery	Percentage of patients
Scarf osteotomy	2
MTP1 fusion	10
Distal chevron osteotomy	6
Scarf osteotomy+Akin osteotomy	61
Distal chevron osteotomy+Akin osteotomy	6
Scarf osteotomy+Akin osteotomy+Weil/Chevronette	9
MTP1 fusion+Weil/Chevronette/Hoffman	3
Distal chevron osteotomy+Weil/Chevronette/Gautier	3
Total	100

Table 1: Types of surgery included. N=number of patients.

However, at 24 and 36 hours more patients were seen with severe nausea (nausea affects daily functioning 'most of the time' or 'all the time') compared to the other time intervals (p<0.05). The intake of additional tramadol was associated with nausea at 24 and 60 hours post-operative compared to the intake of only paracetamol (p=.01 and p=.03 respectively). There is an increase in activity score throughout the postoperative interval despite the increase in nausea at 24 and 36 postoperative. Premature removal of the patch was seen in 14 patients. In 10 patients the patches were removed at 24 hours. Removal of the patch was associated with nausea (p<.001 at 12, 48, 60 and 72 hours postoperative, p=.02 and p=.04 at 24 and 36 hours post-operative respectively). VAS scores seems to be higher in patients who removed the patch early, but this was not statistically significant (p=.589 and p=.129 at 24 and 36 hours postoperative). Global patient satisfaction and pain perception was depicted in Figure 3.

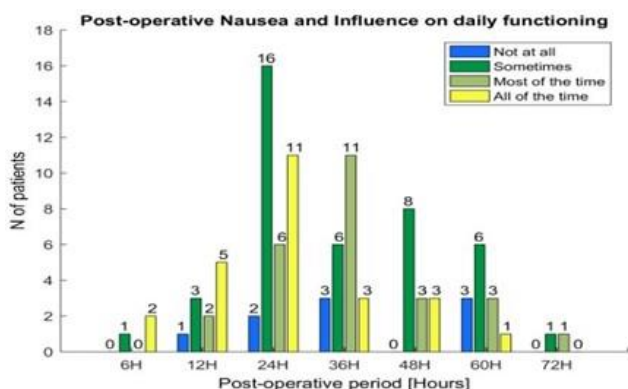


Figure 2: PONV score at 6, 12, 24, 36, 48, 60 and 72 hours post-operative and effect on daily functioning. Blue: No effect on daily functioning, Dark Green: sometimes effect on daily functioning, Light green: nausea effects functioning most of the time daily functioning, Yellow: daily functioning is all the time affected by nausea.

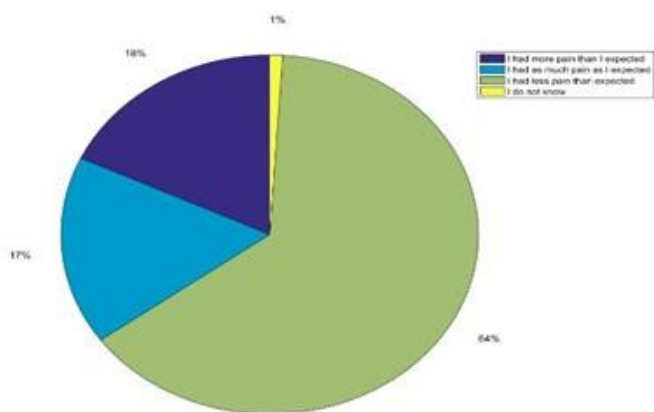


Figure 3: Global satisfaction 72 hours after fore-foot surgery.

Discussion

According to previous literature, the one-time administration of a weight adjusted dose of transdermal fentanyl patch is a safe and effective if used in combination with other modalities [13,14]. Transdermal fentanyl patches have been used for chronic pain for decades. Though recent studies prove it's efficacy in the acute post-operative setting [10,14,15]. It has been demonstrated that acute post-operative pain control can be achieved with transdermal fentanyl at dose 12-50 µg/h without severe adverse effects [15]. In this study, 65% of patients were satisfied with the patch and experienced less pain than expected. This finding is according Xu et al. who demonstrated higher patient satisfaction with transdermal patches comparing to intravenous administration of pain medication [14]. In the current study adequate pain control is represented by moderate VAS-scores. Mean maximum VAS score was 3.94, which is lower than previous reported median pain scores of 5.1 after hallux valgus surgery [16]. Still, most patients (68-84%) needed additional pain medication after 24 hours. It might indicate that the use of the transdermal patch may not be sufficient alone, but can be efficient when part of a multimodal analgesia approach [10,17].

In this study, maximal VAS-score was noted at 36 hours post-

operative, which is translated in a peak in intake (86% of all patients) of extra pain medication at 36 hour post-operative. It is still unclear why pain accelerated after 24 hours to a maximum at 36 hours, as previous literature pointed out that pain levels are particularly high the first 24 hours after surgery [18]. Previous studies showed that patients receiving regional anesthesia for foot and ankle surgeries reported peroral narcotic use up to 56 days postoperatively [19]. Patients most often received 30 tablets of opioids after orthopedic surgery jet this was excessive compared with consumption [20] and excess pills are a significant contributor to opioid-related overdoses [21]. Although the transdermal fentanyl patch is a strong opioid as well, by administering the patch in the controlled setting of the hospital and no other strong opioids were prescribed at discharge, a reduction in ambulatory use of opioids is pursued. Yet in this study, two patients reached out to stronger opioids such as oxycodone after discharge, although not prescribed by the surgeon.

As the perioperative analgesia strategy in this study included transdermal fentanyl patches, concerns could be made about the possible side effects. Major side effects, such as respiratory depression and apnea, did not occur. Minor side effects, such as nausea and vomiting remained a problem in this study. But nausea seemed to be mild for most patients and did not interfere with their daily functioning. Pain perception has been found to be very variable, with VAS scores varying from 0 to 9 or 10 at any given moment during the analyzed perioperative interval. Patients, who took most pain medication, still had the highest pain scores. There was a trend to lower VAS-scores for patients who used paracetamol exclusively compared to the other groups. Patients who took opioids other than tramadol reported the highest pain scores. These findings are similar to previous literature that stated that among orthopedic surgery patients, greater intake of opioids is associated with greater pain intensity [22]. Major limitation of the study is the absence of a control group. Though the efficacy of transdermal fentanyl patches versus placebo was already pointed out by other authors [13]. But to evaluate if we can reduce ambulatory use of per-oral opioids by applying a pre-operative fentanyl patch, a randomized placebo controlled study should be conducted.

Conclusion

In conclusion, In an era where surgeons need to be aware of the threat of overprescribing opioids, the one-time use of a weight adjusted dose of transdermal fentanyl in combination with a single dose ultra-sound guided nerve block can be efficient when part of a multimodal analgesia approach to treat post-operative pain after hallux valgus surgery. In this study, good pain control with minimal VAS-scores during the direct post-operative period was achieved. The majority of treated patients was satisfied and experienced less pain than they expected. There is a justified concern about adverse events, specifically nausea and vomiting. The nauseous effect is exaggerated by the use of the transdermal patch in combination with tramadol.

Ethics Approval and Consent to Participate

This project was approved by the Ethical Committee of HHZHLier. Informed consent was provided by all participants.

Competing Interests

The authors declare that they have no competing interests

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