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ORIGINAL STUDY

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Improving postoperative analgesia in hallux valgus surgery: oral opioids suppression by addition of a single transdermal fentanyl patch: a prospective evaluation

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The last decade there is an exponential increase in opioid related deaths. This is proven to be correlated with the rising medical prescription rates of strong opioids. We investigated whether pain after hallux valgus surgery under popliteal nerve block could be adequately controlled without the prescription of oral opioids, with a single transdermal fentanyl patch. In this prospective observational study with 100 patients undergoing corrective first metatarsal osteotomies we prospectively investigated the adverse effects and need for extra pain medication. The transdermal fentanyl patch was applied one hour before surgery, prior to the ultrasound guided popliteal nerve block. Patients filled out a questionnaire every 6 hours to evaluate the pain [VAS-score], nausea [PONV-score], activity [acivity and ambulation score] and the intake of extra medication.

Postoperative pain was well controlled [Mean VAS 2,53]. The maximum mean VAS score [3.93] was recorded 36 hours postoperatively. 63.8% of patients had less pain than expected. No major adverse effects were reported by the patients. Nausea was mainly mild and the majority of patients reported 'no effect' or 'sometimes' effect on daily activities.

In an era where surgeons need to be aware of the threat of overuse of strong opioids, the use of a single transdermal fentanyl patch in combination with an ultrasound guided nerve block can be a good alternative in hallux valgus surgery. The use of the patch seems to obviate the need for oral opioids after discharge. Nausea and vomiting were a concern – as expected –, but only at 24 and 36 hours. On the other hand nausea did not seem to affect activity, as there was a gradual increase in activity score over time.

Keywords: hallux; valgus; correction; analgesia; fentanyl; patch.

INTRODUCTION

Opioids have been used for several years to relieve postoperative pain because they were thought to be safe and not harmful *(2)*. In the last two decades there is an exponential increase in opioid related deaths in the United States of America *(2)*. 115 Americans die every day from an opioid overdose *(7)*. This

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revealed the problem of empirical overprescription of opioids by health care workers. The amount of prescriptions for opioids quadrupled between 1999 and 2010 *(2,7)*. Many studies have shown that the opioid overdose deaths were correlated to the raise in prescription of strong opioids *(1,2,3,7)*. Surgeons are important contributors in the overprescription of strong opioids.

Taking this into consideration, we wanted to change our pain management after hallux valgus surgery. The use of preoperative ultrasound guided popliteal blocks has become a general practice in foot surgery. It offers the advantage of long lasting postoperative analgesia. However, the analgesic effect of the nerve block wears off after about 12 hours, at which point several patients experience substantial pain *(1)*. Instead of oral opioids patients received a single transdermal fentanyl patch. Patients typically report three days of significant pain after corrective metatarsal osteotomies. The fentanyl patch provides a continuous drug delivery with good patient compliance *(5)*. Fentanyl concentrations peak at 12 to 24 hours after application and maintain this concentration for approximately 72 hours *(1,5,6)*. A steady state is reached at 24 hours and is maintained as long as the patch is in place *(5)*. The most frequently observed adverse events with transdermal fentanyl administration are nausea and vomiting *(6)*.

Our aim was to prospectively assess the efficacy of a transdermal fentanyl patch for postoperative pain control, applied one hour before hallux valgus surgery. The second goal was to assess postoperative nausea and vomiting, a well-known adverse effect of opioids. Postoperative nausea may interfere with fast ambulation and therefore with the patients' rehabilitation *(4)*. Thirdly, we wanted to investigate if patients still needed oral pain medication in addition to the Enhanced Recovery after Surgery Protocol above.

MATERIALS AND METHODS

The current study was approved by the Ethical Commission of the H. Hart Hospital Lier. Our study was a prospective observational study. We enrolled 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, until we had 100 patients. All patients filled out VAS (Visual Analogue Scale) for pain and Postoperative Nausea and Vomiting and Activity scores. There were 6 missing results in the 'global satisfaction rating'. The transdermal fentanyl patch was applied by the nursing staff on the orthopedic ward one hour before surgery. The dose of the fentanyl patch was adjusted according to the weight of the patient: under 70 kg received a patch of 12 µg/h, over 70 kg of 25 µg/h. Preoperatively (40 minutes before surgery), all patients received an ultrasound guided popliteal nerve block, performed by an experienced anesthesiologist. The nerve block was achieved with 20 cc Naropin 0.75%, which lasts for about 12-14 hours. At discharge, all patients received a prescription for paracetamol (1g max 4 times daily, first line) and Tradonal 50mg (Max 4 times daily, second line: if first line was insufficient to control pain). Patients were instructed to remove their fentanyl patch after three days and only take additional pain medication if needed, starting with paracetamol. No additional patches were provided. Pain was assessed using a VAS at 6, 12, 24, 48, 60 and 72 hours after surgery. Postoperative nausea and vomiting score ('Did you have to vomit? / did you experience severe nausea?' 0=no, 1= 1 time/episode or severe nausea, 2= 2 times, 3= 3 times/3 episodes) was inquired at the same time intervals, as well as the influence on the patients daily functioning (0= not at all, 1= sometimes, 2= most of the time, 3= all the time). We also asked the patients if they took any additional pain medication (0=no, 1= yes) and what type. The ambulation score was assessed at the same time intervals :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. The final question related to the overall pain experience after surgery :1 = more pain than expected, 2 = pain as expected, 3 = less pain than expected, 4 = not sure about this.

RESULTS

The included patients underwent hallux valgus surgery between September 2017 and May 2018.

Mean age was 58.67 years, 85 were female and 15 male. Surgery was performed by two senior Foot and Ankle Fellowship trained surgeons. Surgeries included different corrective first metatarsal procedures: scarf or distal chevron osteotomy (with or without akin osteotomy) or first metatarsophalangeal fusion, with or without osteotomy of the lesser metatarsals (weil osteotomy) (Table 1). A maximum mean VAS score of 3.93 was seen 36 hours postoperatively. Afterwards it decreased to 3.30, 2.84 and 2.41 at 48h, 60h and 72h respectively (Table 2). There was a large variation in VAS, at any time interval, varying between 0 and 9 to 10. (Figure 1). In the first 6 to 12 hours after surgery 81% and 68% of patients did not need extra pain medication, indicating properly placed popliteal blocks. There was an 86 percent peak in intake 36 hours postoperatively, corresponding to the maximal VAS-score. Fourteen patients removed the fentanyl patch before 36 hours, 10 after 24 hours. After 72 hours the remaining patches were removed, as instructed preoperatively (Figure 2). At any time in the postoperative period, most patients were satisfied. During hospital admission (first 24 hours) some patients required extra oral medication. One patient declared to have taken analgesia with oxycodone after discharge from the hospital at 36 and 48 hours and 2 patients at 60 hours (Figure 4). These opioids were prescribed by their general practitioner. During the immediate postoperative

Table 1. — Types of surgery included

	N patients
Scarf osteotomy	2
MTP1-arthrodesis	10
Distal chevron osteotomy	6
Scarf + akin osteotomy	61
Distal chevron + akin osteotomy	6
Scarf + akin + weil/chevronette osteotomy	9
MTP1 - arthrodesis + weil/chevronette/hoffman	3
Distal chevron + weil/chevronette/gauthier	3
Total	100

N= number of patients.

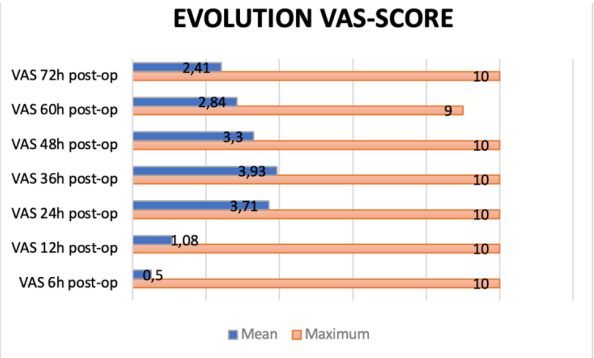

Figure 1. — Postoperative VAS-score, mean scores in blue and maximum scores in orange

Table 2.

		6 h		12 h		24 h		36 h		48 h		60 h		72 h	
Group A: paracetamol Group B: Tradonal + paracetamol		A	B	A	B	A	B	A	B	A	B	A	B	A	B
Nausea	No	7	5	10	10	20	27	22	39	30	37	27	39	32	30
	Yes	2 (22%)	0 (0%)	3 (23%)	1 (9%)	3 (13%)	21 (44%)	5 (18%)	17 (30%)	2 (6%)	10 (21%)	0 (0%)	7 (15%)	0 (0%)	1 (3%)
Total		***9***	***5***	***13***	***11***	***23***	***48***	***27***	***56***	***32***	***47***	***27***	***46***	***32***	***31***
Chi-square Test		0.2726 (NS)		0.3698 (NS)		0.0110		0.2552 (NS)		0.0695 (NS)		0.0342		0.3096 (NS)	

Nausea (Yes/no) at time 6,12,24,36,48,60 and 72 hours post-operatively in group A: patients taking only extra paracetamol versus Group B: patients taking tradonal with or without extra paracetamol. Other patients were excluded as these groups were too small for statistical analysis. Chi-square test was performed, statistically significance as $p<0.05$).

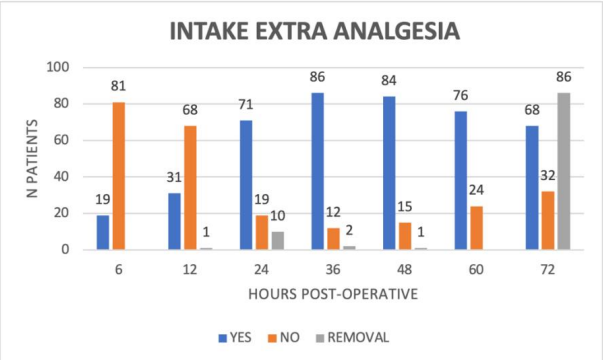

Figure 2. — Intake of extra analgesics at 6, 12, 24, 36, 48, 60 and 72 hours post-operatively. Blue indicates yes, orange no. Grey indicates patch removal time.

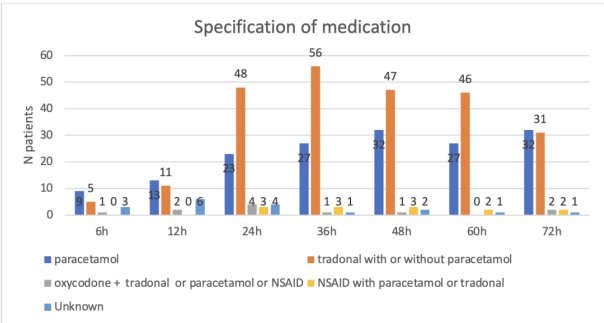

Figure 3. — Specification of medication intake at 6, 12, 24, 36 and 60h postoperatively.

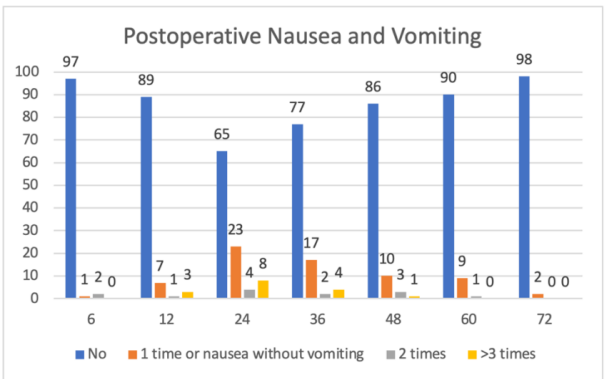

Figure 4. — POVN-score : postoperative nausea and vomiting score (part A) at 6, 12, 24, 36, 48, 60 and 72 hours postoperatively. Number of patients who experienced: blue: no vomiting, orange: once vomiting or serious nausea, grey: twice vomiting, yellow: more than 3X vomiting.

period most patients did not experience any severe nausea. There was no nausea or vomiting in the

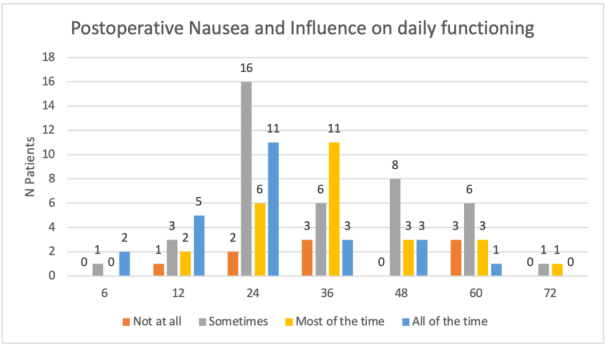

Figure 5. — PONV-score : postoperative nausea and vomiting score (part B) at 6, 12, 24, 48, 60 and 72 hours postoperatively. Orange: no effect on daily functioning, Grey: sometimes effect on daily functioning, Yellow: nausea effects daily functioning most of the time, Blue: daily functioning is all the time affected by nausea.

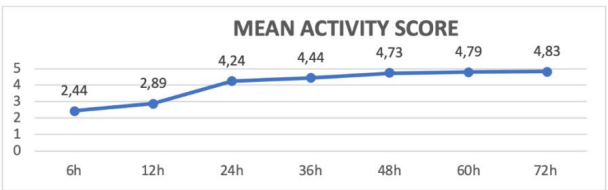

Figure 6. — Mean activity score at 6, 12, 24, 48, 60 and 72 hours postoperatively. 1: not able to sit up in bed. 2:able to sit up in bed. 3: able to sit on the edge of the bed with feet hanging down over the side. 4: able to walk with human assistance. 5: able to walk with walking aid.

Figure 7. — Global satifsfaction 72 hours after forefoot surgery.

majority of patients (97, 89, 65, 76, 86, 90 and 98 patients at respectively 6, 12, 24, 36, 48, 60 and 72 hours postoperatively). Most nausea was noted at 24 and 36 hours (35% and 23% of patients) (Figure 4), with only minor repercussions on daily functioning ('no effect' or 'sometimes effect'). At

24 and 36 hours we noticed more patients with a severe nausea, affecting daily functioning 'most of the time' or 'all the time'. Seventeen and 14 patients, at respectively 24h and 36h, experienced nausea 'most of the time' or 'all of the time'. (Figure 5). Nausea did not seem to affect activity, as there was an increase throughout time (Figure 6). The pain perception in patients varied widely, as there was a great variety in VAS score at any moment, ranging between 0 and 10. 63.80% of patients experienced less pain than expected, 17% as much as expected and 18,10% more than expected (Figure 7).

DISCUSSION

According to previous studies administration of transdermal fentanyl patches is safe and effective for analgesia, if combined with other modalities *(4,10)*. It has been used successfully in major shoulder surgery, total knee arthroplasty and total hip arthroplasty *(4)*. As hallux valgus patients typically report three days of significant pain after a corrective metatarsal osteotomy, we used a single transdermal fentanyl patch, providing continuous drug delivery during 72 hours. All patches were removed after three days and not replaced.

At this moment, only one study also evaluated postoperative pain control with fentanyl patches after foot surgery. In contrast to the study of J.H. Song et al., we only included hallux valgus surgery to obtain a more representative and comparable study group. We also applied the fentanyl patch one hour prior to surgery in order to reach the steady state of the fentanyl by the time the effect of the popliteal nerve block wears off. Song et al. used a 25 µg patch for every patient, we adjusted the doses according to the weight of the patient. Moreover, all patients in their study received a femoral nerve block instead of a popliteal nerve block. Despite these differences, we had similar findings: a fentanyl patch combined with an ultrasound guided nerve block provides effective pain control after forefoot surgery *(1)*. We noted very low VAS-scores, so the protocol with patch and nerve block seemed to be effective. The use of strong opioids was almost entirely eliminated after discharge [98%]. We used a low dosage because we were concerned about the side effects of the fentanyl patch. Side effects were no problem for most of the patients, although 35% experienced nausea at 24 and 23% at 36 hours postoperatively. Luckily, in this rather big portion of patients nausea was mild. Only 17% and 14%, at respectively 24 and 36 hours, were functionally impaired by the nausea. We found that pain perception varied greatly, with VAS scores between 0 and 10 at any moment.

There were some limitations in this study. First of all there was no control group. Other authors have already pointed out the efficacy of transdermal fentanyl patches versus placebo *(4)*. Secondly, we did not investigate treatment of the experienced nausea by anti-emetics.

CONCLUSION

In an era where surgeons need to be aware of the danger of overprescribing strong opioids, the use of transdermal fentanyl in combination with an ultrasound guided nerve block can be a good alternative to treat postoperative pain after hallux valgus surgery. This Enhanced Recovery after Surgery Protocol provided our patients good pain control with minimal VAS-scores during the immediate postoperative period. The intake of strong opioids was almost completely eliminated by the use of the transdermal fentanyl patch. The majority of treated patients were satisfied and experienced less pain than expected. There is a concern about adverse events of the patches, specifically nausea and vomiting. Nausea was not frequent and only mild (at 24 and 36 hours postoperatively) with only 17% and 14% of patients impaired in their daily functioning. Whether this nausea is easily treatable with anti-emetics remains uncertain.

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