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Narcotic Sparing Multimodal Anesthesia Versus Standard of Care Anesthesia for Hallux Valgus Patients Undergoing a Percutaneous Distal Metatarsal Osteotomy: A Randomized Controlled Trial.

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Abstract:	<p>Background: Hallux valgus surgery often results in significant post-operative pain, requiring narcotics. Percutaneous distal metatarsal osteotomy is a minimally invasive approach with benefits such as minimal scarring, immediate weight bearing, and reduced pain. This study investigates whether multimodal analgesia, ankle block anesthesia, and minimally invasive surgery can help reduce the need for short-acting narcotics.</p> <p>Methods: A total of 114 patients aged 18-70 with BMI \leq 40 undergoing hallux valgus surgery were randomized into Narcotic-sparing (NS) and Standard (S) groups. The NS group (n=56) received acetaminophen, naproxen, pregabalin, and Ralivia (tramadol extended release) pre-operatively, along with a post-operative regimen including rescue hydromorphone. The S group (n=58) followed standard protocols with hydromorphone as the primary analgesic. Pain (VAS scores) and short-acting narcotic use were recorded post-operatively, alongside steps and sleep using smartwatches.</p> <p>Results: NS patients used significantly fewer short-acting narcotics in the first week, averaging 5.24 pills (20.96 MME) vs. 13.53 pills (54.12 MME) in the S group ($p < 0.0005$). Notably, of all patients in the study, 27.2% did not consume any short-acting narcotics post-operatively (43.1% in NS group and 10.7% in S group). Pain scores at 24 and 48 hours were significantly lower in the NS group ($p=0.001$, $p=0.012$), but no was found at 72 hours and 7 days. Steps and sleep were comparable between groups.</p> <p>Conclusion: Multimodal analgesia combined with a minimally invasive approach effectively reduces short-acting narcotic use while maintaining excellent pain control. This study guides surgeons in tailoring short-acting narcotic prescriptions based on average consumption.</p>

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Title: Narcotic sparing multimodal anesthesia versus standard of care anesthesia for hallux valgus patients undergoing a percutaneous distal metatarsal osteotomy: A Randomized Controlled Trial

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Narcotic Sparing Multimodal Anesthesia Versus Standard of Care Anesthesia for Hallux Valgus Patients Undergoing a Percutaneous Distal Metatarsal Osteotomy: A Randomized Controlled Trial.

Background: Hallux Valgus surgery can result in moderate to severe post-operative pain requiring the use of narcotic medication. The percutaneous distal metatarsal osteotomy is a minimally invasive approach offering advantages such as minimal scarring, immediate weight bearing and reduced post-operative pain. This study aims to determine if a combination of multimodal analgesia, ankle block anesthesia and minimally invasive surgery can help reduce the need for short-acting narcotics.

Methods: 114 ambulatory patients aged 18-70 with BMI \leq 40 undergoing percutaneous hallux valgus surgery were randomized into Narcotic-sparing (NS) or Standard (S) groups. There were 56 in NS and 58 in the S group. The NS group received acetaminophen, naproxen, pregabalin 75mg and 100mg Ralivia (tramadol extended release) before surgery and acetaminophen, naproxen, pregabalin 150mg one dose and Ralivia 100mg BID for 5 days, as well as a rescue short-acting narcotic (hydromorphone 1mg pills) after surgery. The S group received acetaminophen and naproxen prior to surgery and acetaminophen, naproxen and hydromorphone (1mg) post-operatively, our current standard. Visual analog scales (VAS) were used to assess pain and short-acting narcotic consumption was recorded post-operatively. Patients wore a smart watch to record the number of daily steps and sleep hours. Two-sided t-tests were used to compare the VAS scores and narcotic consumption.

Results: During the first post-operative week, the NS group consumed significantly fewer short-acting narcotics than the S group, with 5.24 pills (20.96 MME) vs 13.53 pills (54.12 MME) on average ($p < 0.0005$). At 24, 48, 72 hours, and 7 days, patients in the NS group recorded a mean average of 0.66, 2.38, 3.75, and 5.241 pills respectively. The S group recorded a mean average of 2.84, 7.82, 10.54, and 13.536 pills. Of all the patients included in the study, 27.2% did not consume

any short-acting narcotics post-operatively (43.1% in the NS group and 10.7% in the S group) and the average total short-acting narcotic consumption was under nine tablets. For the VAS scores at 24, 48, 72 hours, and seven days the NS group's average scores were 2.31, 3.16, 2.81, 2.14 respectively and the S group's average scores were 3.57, 4.09, 2.98, 1.85. The pain experienced by patients was better in the NS group at 24 ($p= 0.001$) and 48 ($p= 0.012$) hours, but no difference was found at 72 hours and 7 days. There was no significant difference for the number of daily steps and hours of sleep per night between both groups (avg 1800 steps/day and 8 hours sleep/night).

Conclusion: Hallux valgus remains a common orthopedic foot problem for which surgical treatment results in moderate to severe post-operative pain. This study demonstrates that a minimally invasive approach to hallux valgus surgery, using multimodal analgesia, regional blocks, and long-acting Tramadol, significantly reduces the need for short-acting narcotics and allows for early mobilization and excellent pain control. Given the current narcotic epidemic, changing prescribing habits is crucial and this study allows surgeons to modulate the number of short-acting narcotic prescriptions based on average consumption.

Keywords: Hallux Valgus, Tramadol, Multimodal Anesthesia, Percutaneous Distal Metatarsal Osteotomy, Ankle Block

Level of Clinical Evidence: 1

Introduction

Hallux Valgus (HV), commonly referred to as bunions, is characterized by a medial protrusion of the first metatarsal head and a lateral deviation of the first toe, which can lead to crowding of the other toes.¹ The prevalence of HV varies depending on factors such as age, gender, and genetics.² In the general population, the prevalence of hallux valgus is estimated to be between 23% and 36%.³ However, the condition is more common in women (about 3 women for 1 man) and its prevalence increases with age.³

The initial treatment remains conservative with shoe modification and orthoses in case of flat feet or metatarsalgia, pain control, taping or toe stretchers.⁴ Although these techniques may alleviate symptoms, permanent improvement of the deformity is not possible, especially if the patient has reached skeletal maturity.^{4,5} As such, surgical treatment of hallux valgus may be necessary when conservative measures fail to provide relief of painful symptoms and shoe wear remains challenging.⁶ The current body of literature describes an overwhelming number of different techniques for surgical treatment of hallux valgus (>100).^{5,7}

Over the years, minimally invasive approaches in forefoot surgery have become increasingly popular as they have demonstrated many advantages and positive outcomes when compared to traditional open approaches. Bösch et al. was one of the first to describe and publish a minimally invasive approach to hallux valgus correction.⁸ In this technique, the incision is less than 1 cm and does not utilize any of the typical soft-tissue releases that have been described in open approaches. This procedure does not involve fixation beyond a temporary pin (K-wire) that is removed at 4 weeks.⁸ This percutaneous distal metatarsal osteotomy approach offers many

advantages including minimal scarring, immediate weight bearing, and decreased postoperative pain, which facilitates bilateral surgery and makes the procedure suitable for ambulatory care. It has also shown to be reproducible across multiple centers and is effective in correcting intermetatarsal (IMA) and hallux valgus (HAV) angles.⁹

Hallux Valgus correction surgeries can result in moderate to severe postoperative pain, requiring the use of narcotic medication.^{1,10} Typically patients use an average of 150 Morphine Milligram Equivalents (MME) post-operatively (20 tablets of oxycodone 5mg or 19 tablets of hydromorphone 2mg). Utilization rate surpasses 50% of prescribed pills.^{10,11} The current trend in anesthesia management during hallux valgus and forefoot surgery is multimodal pain control, including peripheral nerve blocks, local incisional infiltration, and anti-inflammatory adjuvants.¹² Despite this, opioid agonists remain the mainstay for postoperative pain in orthopedic surgery.¹³⁻
¹⁷ In fact, due to anecdotally high post-operative pain, patients tend to fear surgical treatment for hallux valgus.¹⁸ The administration of opioids after surgery is associated with side effects, including nausea, drowsiness, and respiratory issues.^{12,19} Commonly prescribed narcotics for postoperative pain control, such as dilaudid and morphine, are addictive, and carry a risk of dependency.²⁰ The opioid crisis in North America, marked by a fourfold increase in opioid-related deaths since the 1990s, highlights the need for alternatives.²¹ Opioid use in musculoskeletal pain has doubled over the past two decades, with orthopedic surgeons being amongst the highest prescribers.²² Approximately 20% of patients with a first opioid prescription progress to episodic use, and 6% remain long-term users. Up to 50% of those on opioids for 3 months continue usage 5 years later.²³ It is evident that orthopedic surgeons can have a direct impact on the ongoing opioid epidemic by focusing on identifying feasible alternatives to opioids for pain management.

Tramadol, a less potent opioid with about one-tenth of the potency of morphine, is a viable alternative. It has a lower potential for dependence and works primarily through the noradrenergic and serotonergic systems, and much less on the opioid receptor system.^{17,24,25}

Regional anesthesia, particularly via peripheral nerve blocks, decreases post-operative care time, improves recovery, and allows for earlier hospital discharge with prolonged pain relief.^{12,26,27} The percutaneous approach can be effectively performed as an outpatient procedure using ultrasound-guided ankle blocks with intravenous sedation.⁹ Despite the advances of regional anesthesia, many centers still do not utilize this technique for hallux valgus surgery or only use it as an adjunct to other forms of anesthesia.²⁷

In efforts to eliminate the use of short-acting narcotics, we undertook a randomized clinical control trial comparing a group of patients that received perioperative multimodal anesthesia with the use of long-acting tramadol versus our current standard of care for hallux valgus surgery. Both groups underwent a percutaneous distal metatarsal osteotomy. The primary outcomes of interest were pain, pain relief, patient satisfaction with pain management, narcotic consumption, and need for rescue narcotic medication (dilaudid or morphine). We hypothesized that the use of an ultrasound guided ankle block with perioperative adjuvant medications would reduce or eliminate narcotic use for control pain in the first 48 hrs postoperatively.

Materials and Methods

Following ethics board approval, a total of 120 ambulatory patients between the ages of 18-70, American Society of Anesthesiologists (ASA) classification 1-2 with BMI \leq 40 undergoing

percutaneous hallux valgus surgery were recruited at their one month pre-operatively visit and randomized into Narcotic-sparing (NS) or Standard (S) groups. Stratified randomization was carried out on those patients using a computer-generated sequence of random numbers and a sealed envelope technique. The randomization occurred on morning of the procedure to allow for the appropriate administration of preoperative medications. One hour prior to surgery, the NS group (56 patients) received acetaminophen, naproxen, pregabalin 75mg and 100mg Ralivia. Following the procedure, they received acetaminophen, naproxen, a single dose of pregabalin 150mg, and Ralivia 100mg twice daily for 5 days. Additionally, they were provided with hydromorphone 1mg pills as a rescue narcotic post-surgery.

The S group (58 patients) received acetaminophen and naproxen one hour prior to surgery and acetaminophen, naproxen, and hydromorphone (1mg) post-operatively, our current standard. Patients in both groups underwent ultrasound-guided regional anesthesia according to standard technique. This was followed by a distal percutaneous osteotomy of the 1st metatarsal as described by Siddiqui et al with adjunct lesser toe procedures if indicated. Sedation provided during the procedure included Midazolam, Propofol and Fentanyl as needed.

Visual analog scales (VAS) for pain and narcotic consumption were recorded at 6, 12, 24, 36, 48, 72 hours and 7 days post-operatively. Patients wore a smart watch to track daily steps and sleep hours. A two-sided t-test was used to compare VAS scores and narcotic consumption. Patients requiring minor adjuvant procedures for lesser toe deformities like extensor tendon lengthening or interphalangeal fusion of toes 2-4, were included, as hallux valgus often causes these deformities, and their correction is typically not very painful. Patients were excluded if they

couldn't give consent, had any unsuccessful block, allergies to study medications, pre-existing neuropathy coagulopathy, pulmonary disease, renal or hepatic failure, pregnancy, prior foot surgery in the corresponding, more than two adjunct forefoot procedures, chronic pain syndromes, or psychiatric comorbidities.

Pain, pain relief, satisfaction with pain management and narcotic consumption or need for rescue narcotic medication were recorded by the patient on a chart at 6, 12, 24, 36, 48 hrs, 2 weeks, 4 weeks, and 12 weeks post-operatively. Phone interviews at 24 and 48 hours by a blinded research assistant will also record the duration of sensory blockade as well as the onset of pain and pain scores at the two time points. Onset of pain was assessed by determining the onset of foot pain > 3 using a 0-10 scale (0 = no pain; 10 = worst imaginable pain). Sensory block duration was assessed by inquiring "when did numbness/tingling in the foot wear off?". VAS was used to assess pain. The blinded research assistant tabulated total intra- and post-operative opioid consumption and assessed patient satisfaction at 24 and 48 hours using a 1-5 scale (1 = not satisfied; 5 = very satisfied). Furthermore, quality of recovery was assessed at 48 hours using the QoR-15 questionnaire. Demographic data such as sex, age, weight, height, type of surgery and any complications or adverse events were documented.

Descriptive statistics were used for demographic and clinical variables. Chi-square tests were used to confirm there was no significant differences in the percentage of bilateral surgeries between groups. Independent t-tests were used to test if there were group differences in pain and quantity of narcotic at 24 hours, 48 hours, 72 hours and at 1-week post-surgery, and also for mean number of steps and sleep time (1-week post-surgery). As box-plots and histogram showed

the presence of outlier(s) and problems with distribution, non-parametric Mann-Whitney tests were performed to check t-tests results. As the results of Mann-Whitney tests confirmed the t-tests results, only the t-tests results are presented. Correlations (usual Pearson correlation and Spearman nonparametric correlations based on rank) were also performed to check the linear relationship between pain and anxiety and narcotic and anxiety. A significance level of 0.01 was selected to mitigate the effects of multiple tests.

Results

Out of the initial 120 patients enrolled, 114 were ultimately part of the study, with 6 excluded due to loss of follow-up and/or incomplete data. This resulted in 56 patients in the NS group and 58 in the S group. These 114 patients represented a total of 182 feet, with 87 left feet (47.8%) and 95 right feet (52.2%). The study cohort comprised 90.3% females (n=103) and 9.7% males (n=11) (Figure 1).

During the first post-operative week, the NS group consumed an average of 5.24 pills of 1mg dilaudid (20.96 MME) while the S group consumed an average of 13.53 pills (54.12 MME), and this was statistically significant ($p < 0.0005$). At 24, 48, 72 hours, and 7 days, patients in the NS group consumed an average of 0.66, 2.38, 3.75, and 5.241 pills, while patients in the S group consumed an average of 2.84, 7.82, 10.54, and 13.536 pills, respectively. The average number of narcotics consumed by all patients during the first post-operative week is 9.32 (37.28 MME) (Figure 2). Interestingly, of the total number of patients included in the study, 27.2% did not

consume any narcotics post-operatively. This includes 25 patients (43.1%) in the NS group and 6 patients (10.7%) in the S group.

For the VAS scores at 24, 48, 72 hours, and 7 days the NS group's average scores were 2.31, 3.16, 2.81, 2.14 and the S group's average scores were 3.57, 4.09, 2.98, 1.85, respectively. This difference was statistically significant at 24 ($p= 0.001$) and 48 hours ($p= 0.012$), but there was no difference at 72 hours and 7 days post-operatively. There was no difference in the average amount of steps walked daily nor in the amount of sleep daily between the NS group and the S group with a mean of 1827.59 vs 1869.40 steps daily and 8h01 minutes of sleep vs 8h02 minutes of sleep, respectively (Figure 3a-c).

Discussion

Hallux Valgus (HV) is a common orthopedic foot condition that affects a significant portion of the population, especially women and older adults.^{3,28-30} While conservative treatments can provide some relief, surgical intervention is often necessary when pain and deformity become severe.⁶ Traditionally, open surgical procedures have been the norm for correcting HV deformities, but advancements in minimally invasive approaches, such as the percutaneous distal metatarsal osteotomy, have provided patients with more favourable outcomes, including minimal scarring, immediate weight bearing, and reduced postoperative pain.^{9,31-35}

Postoperative pain management has been a challenge in HV surgery, often requiring the use of narcotics, which come with associated risks, including addiction.^{10,11,20} The opioid epidemic in North America underscores the urgency of finding alternatives to opioid-based pain control in

orthopedic surgery.²¹⁻²³ Tramadol, a long-acting, less potent opioid, has shown promise as a means of providing effective pain relief while minimizing the risk of dependence.^{17,24} Additionally, regional anesthesia, such as ultrasound-guided ankle blocks, can enhance the postoperative experience for patients undergoing minimally invasive forefoot surgery.^{12,26,36,37}

Effect of Pain on Mobilization, Walking, and Sleeping

Pain management in HV surgery is critical not only for patient comfort but also for promoting early mobilization. Postoperative pain can significantly impact a patient's willingness and ability to move, which, in turn, can affect their overall recovery.^{18,38-40} Our study data indicates that patients in both groups demonstrated satisfactory levels of walking and sleeping. Notably, despite a reduced use of narcotics, the NS group exhibited no significant differences in comparison to the S group regarding the average number of daily steps and hours of sleep per night, underscoring a comparable feeling of comfort between both groups.

Moreover, inadequate pain management can also disrupt a patient's sleep, further affecting their overall well-being and recovery.⁴¹ Our findings showed that patients in the long-acting group experienced significantly less pain during the postoperative period. Effective pain control not only helps patients manage discomfort but also allows them to rest and recover more comfortably, promoting a better overall healing process.

Impact of Nerve Block and Percutaneous Technique on Hospitalization and Disposition

Patients undergoing the minimally invasive percutaneous procedure with ultrasound-guided ankle blocks typically experience shorter hospital stays.^{26,27,42} In other words, because patients were pain free upon waking, once their sedation wore off they were able to be discharged.

The advantages of this approach are expedited discharge, reduced overall burden on healthcare facilities and enhanced patient convenience.^{9,36,37,43,44}

Effect of Nerve Block and Percutaneous Technique on Patient Pain

The multimodal anesthesia approach, including the nerve block and percutaneous technique, effectively reduced patient pain compared to standard methods. This is evident from the lower pain scores and decreased narcotic consumption in both groups relative to the literature. Moreover, patients in the narcotic-sparing group reported lower pain scores at 24 and 48 hours. The combination of these techniques provides patients with a more comfortable postoperative experience, minimizing their reliance on opioids and promoting a quicker return to daily activities.

Tramadol as a Narcotic Class and Its Unique Characteristics

Tramadol is categorized as an atypical opioid analgesic with a unique pharmacological profile. Unlike traditional opioids like morphine and oxycodone, tramadol combines opioid agonism with serotonin and norepinephrine reuptake inhibition, which contributes to its analgesic effects.²⁵ Its lower potential for dependence and addiction makes it a valuable alternative for pain management, particularly in cases where minimizing the risk of opioid dependency is crucial.

Average Number of Narcotic Pills Consumed Postoperatively in Foot and Ankle Surgery

Our study found that patients in the NS group, who received multimodal anesthesia including tramadol, consumed significantly fewer narcotic pills postoperatively than those in the

S group. This reduction supports efforts to manage postoperative pain responsibly and address the opioid epidemic. In the S group, narcotic use was relatively low, averaging 13.53 pills (54.12 MME) in the first week, providing valuable data to guide prescription habits of surgeons that are titrated to the patient's needs.

Limitations

A limitation of this study is the absence of a true control group, which would normally receive standard interventions like spinal or general anesthesia, non-ultrasound guided blocks, and an open surgical technique. However, at our institution, multimodal anesthesia with regional nerve blocks and percutaneous surgery is the standard due to its well-documented favourable results, therefore establishing a conventional control group would have been unethical.

Conclusion

In conclusion, the use of a nerve block alongside percutaneous surgical techniques, complemented by tramadol and non-opioid pain management methods, was effective in reducing postoperative pain and diminishing reliance on narcotic medications. Moreover, the utilization of multimodal regional analgesia led to a considerable decrease in narcotic consumption compared to existing literature. Importantly, despite the decreased use of narcotics, this innovative combined approach to hallux valgus surgery facilitates early mobilization and excellent pain control.

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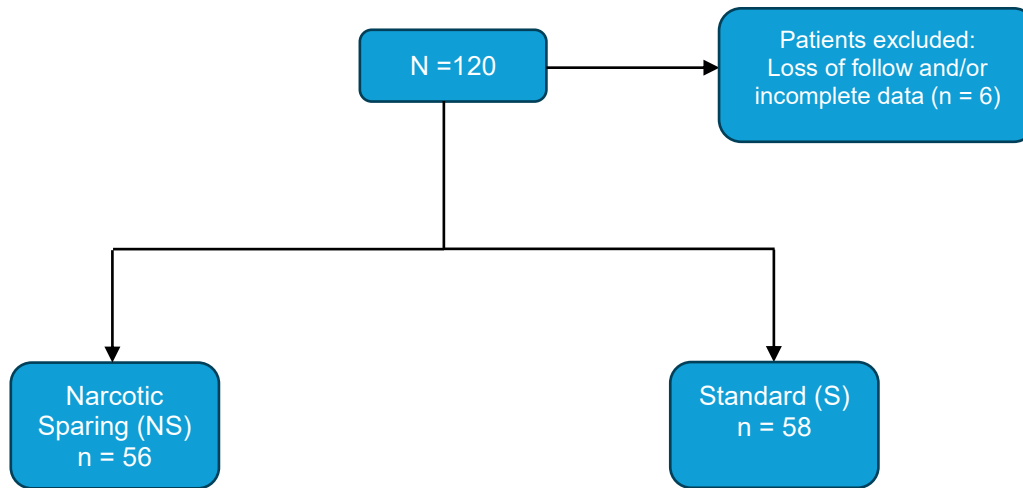


Figure 3. Patient Flowchart

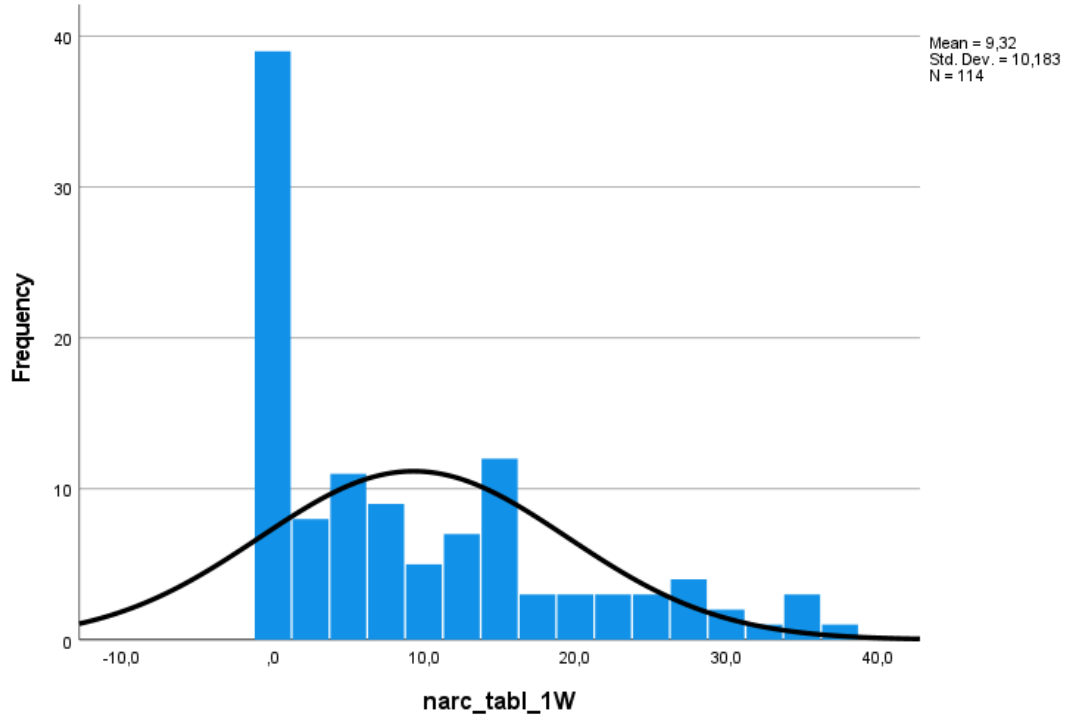


Figure 1. Narcotic consumption across both groups 1 week post-operatively

