

Are Narcotic Analgesics Necessary After Soft Tissue Tumor Excision? The Role of Meloxicam in Orthopaedic Oncology Surgery

Blumstein A¹, Gentile PM², Kellish A³, Hunter K⁴, Kim TW^{1,2} and Gutowski CJ^{1,2*}

¹Cooper Medical School of Rowan University, Camden, NJ, USA

²Cooper Bone and Joint Institute, Cooper University Healthcare, Camden, NJ, USA

³Thomas Jefferson University Hospital, Department of Orthopaedic Surgery, Philadelphia, PA, USA

⁴Cooper University Healthcare, Camden, NJ, USA

*Corresponding author

Gutowski CJ, Cooper Medical School of Rowan University, Cooper Bone and Joint Institute, Cooper University Healthcare, Camden, NJ, USA.

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ABSTRACT

Introduction: Efforts have been made within the medical community to limit the prescription of these opioids, and surgeons have looked towards alternative approaches to control postoperative pain. Meloxicam, a nonsteroidal anti-inflammatory drug (NSAID), may serve as a replacement for, or supplement to, opioids in this setting. This study investigates patient preferences related to these analgesics and evaluates whether meloxicam can serve as an alternative to opioids for patients undergoing ambulatory soft tissue tumor excision.

Methods: 28 patients who underwent resection of a benign soft tissue tumor were given prescriptions for oxycodone and meloxicam, with instructions to fill and consume the prescriptions “based on their comfort level.” Each patient completed a daily pain journal postoperatively to record pain fluctuations and pill consumption. Statistical analysis was conducted using a Wilcoxon Rank Sum test for the pain level calculations, as well as the subset analyses of tumor size, depth and location. Fisher Exact tests were used in comparing demographic, clinical, and medication-related data between the two groups.

Results: Less than 50% of patients filled the oxycodone prescription, while all patients filled meloxicam. An even smaller percentage of those patients who filled the narcotic prescription, actually consumed oxycodone. A greater proportion of patients with large tumors (>5cm) consumed narcotics. The two groups experienced equivalent levels of average pain, though a trend did exist patients with large tumors and those who underwent upper extremity surgery experienced higher VAS scores.

Conclusion: This pilot study serves as proof-of-concept regarding the operation of a prospective trial of various analgesic strategies in orthopedic oncology. Non-inferiority of meloxicam as an effective analgesic for patients undergoing soft tissue tumor excision is suggested by our results, which support the role that non-narcotic analgesics should play in achieving adequate post-operative pain control in ambulatory soft tissue tumor excision.

Keywords: Soft Tissue Tumor Excision, Post-Operative Analgesia, Opioids, Meloxicam, Orthopaedic Oncology

List of Abbreviations

nonsteroidal anti-inflammatory drugs - NSAIDs
cyclooxygenase-2 - COX-2
Visual Analog Scale - VAS

over the counter - OTC
body mass index - BMI
upper extremity - UE
lower extremity - LE

Introduction

Over the last decade, the United States opioid epidemic has highlighted the harmful individual and societal effects of narcotic

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pain medications. Orthopaedic surgeons are among the leading prescribers of opioids in the US, contributing significantly to this issue [1,2]. A 2019 study revealed that one in three patients will chronically use opioids following an orthopaedic procedure, despite many receiving opioid education [3]. A more recent study demonstrated that over 10% of orthopaedic patients who were prescribed opioids for acute postoperative pain were still using them six months later, highlighting a significant risk of dependence associated with current prescribing practices [4]. In many instances, orthopaedic surgeons vastly overestimate the number of pills needed to achieve post-operative pain control, resulting in over-prescription of opioid medication for example, Chapman found that patients who underwent carpal tunnel release surgery were prescribed an average of 20 opioid pills, yet they only consumed 4.3 pills on average [5,6]. However, it has been shown that orthopaedic surgeries are among the most painful postoperatively; in a study comparing postoperative pain intensity in various surgical specialties, 22 of the 40 highest ranked surgeries by pain were orthopaedic/trauma surgeries of the extremities [7]. This finding may provide some explanation for the need to prescribe strong and effective analgesics in this specific field. In response to these observations, the medical community has sought to limit the prescription of opioids, with a shift towards multimodal and non-narcotic strategies to control postoperative pain.

Although numerous studies have evaluated opioid consumption in patients undergoing orthopaedic surgery, there is limited information available specifically regarding opioid consumption among orthopaedic oncology patients. Each year, more than 500,000 individuals are diagnosed with a benign soft tissue tumor, many of whom undergo surgical excision due to pain, local tissue destruction, cosmetic appearance, or concern for malignant transformation [8]. Post-operative pain control in these patients traditionally involves a combination of 5mg oxycodone, acetaminophen, and non-steroidal anti-inflammatory drugs (NSAIDs) [9]. In 2018, "Nonopioid Analgesia Following Soft-Tissue Tumor Surgery" was published in US Pharm, which presented guidelines constructed by an expert panel and described the use of NSAIDs in patients undergoing benign soft tissue tumor excisions, reporting evidence of >50% reduction in pain [9]. Therefore, NSAIDs represent a promising supplement to, or replacement for, opioids in the field of orthopaedic oncology.

Meloxicam, an NSAID that inhibits the cyclooxygenase-2 (COX-2) enzyme to selectively suppress production of pro-inflammatory cytokines that modulate the inflammatory and pain responses, offers several advantages over opioids. Its long half-life (>20 hours), and lack of dose adjustments for various comorbidities and drug interactions, make it easier to administer to a diverse patient population [10,11]. It does carry low risk of peripheral edema, hypertension, and other vascular risks however, meloxicam is not classified as a scheduled medication by the FDA and does not carry the risk of abuse associated with opioids [12]. While opioids are generally considered more potent analgesics than NSAIDs when compared as classes, there is a paucity of research comparing the specific analgesic effects of meloxicam compared to oxycodone in the setting of postoperative pain management in orthopaedic oncology. This study will investigate if meloxicam, specifically, can achieve

adequate control of postoperative pain and thereby serve as an appropriate alternative to opioids in patients undergoing ambulatory soft tissue tumor excision. This information can be used by orthopaedic oncology surgeons to provide patients with effective analgesic strategies which are associated with fewer side effects and a low potential for abuse.

Materials and Methods

After Institutional Review Board approval was achieved for this prospective observational study, 47 patients were enrolled between January 1, 2020 and January 5, 2023. Patients over the age of 18 who were diagnosed with a benign soft tissue tumor and underwent ambulatory surgical excision by one of two fellowship-trained orthopaedic oncology surgeons (TWK and CJG) were invited and consented to participate. Inclusion and exclusion criteria are listed in Table 1. Surgeries were performed under anesthesia and local anesthetic was injected at the surgical site by discretion of the treating surgeon. No regional anesthesia was administered (nerve blocks, etc.) Upon discharge from the hospital on the afternoon of surgery, participants were provided prescriptions for two 2-week courses of analgesics: oxycodone (5mg tablets) and meloxicam (15mg tablets). Patients were instructed to fill prescriptions and consume these medications "based on their comfort level." The investigator explained that this instruction related to their physical pain levels as well as their emotional/social comfort level with consuming narcotics, reminding the patient of their potential for addiction, abuse, and diversion. Patients were also reminded that meloxicam isn't as strong a pain medication as oxycodone is, but they were encouraged to consider that their postoperative pain may not necessitate narcotics. The decision to fill and consume the two prescriptions was ultimately left up to the patient and observed as a primary outcome variable. For the following 14 days, participants completed a daily pain journal provided to them upon discharge. Consumption of meloxicam and/or oxycodone was recorded, along with multiple measurements of their pain using the Visual Analog Scale (VAS). At their 2-week follow-up office appointment, patients returned their pain journals and remaining pills to perform a pill count to confirm accuracy of their consumption records. They also completed an 8-question survey using a Likert Scale which evaluated their perception of the prescribed analgesics. At the end of their postoperative visit, all patients were debriefed by the attending surgeon.

Table 1: Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Individuals who have been treated between 1/1/2020 - 1/5/2023	Individuals requiring the placement of a wound VAC (vacuum-assisted closure device) or second surgical procedure for wound closure
Individuals who have undergone surgical treatment by an Orthopaedic oncology surgeon at our institution	Individuals with a documented history of an opioid allergy or adverse effect due to opioid medication
Individuals who have a diagnosis of a benign soft tissue tumor	Individuals on chronic opioid therapy

Individuals over the age of 18	Individuals with a history of substance abuse
Individuals who underwent ambulatory surgery (discharged to home on day of surgery)	Individuals requiring a muscle flap for closure of their surgical wound
	Individuals diagnosed with a soft tissue sarcoma
	Individuals under the age of 18
	Individuals who are unable to swallow whole tablets
	Individuals with a GFR <30ml/min
	Individuals who are pregnant or may become pregnant
	Individuals who required postoperative overnight admission to the hospital

Data relating to patients' baseline demographics, tumor characteristics, and surgical procedures were recorded. Upon completion of data collection, 12 participants were excluded due to multiple incomplete data, and an additional 7 participants who only consumed over the counter (OTC) pain medications were removed from further analysis.

Statistical analysis

After data collection, patients were categorized into two groups based upon whether they consumed only meloxicam (Group 1), or if they supplemented their regimen with oxycodone (Group 2). The primary outcome of this study was pain on each postoperative day using the VAS, and pain levels at multiple time points were compared. If a patient was missing data for a certain day, his or her data point was not included in the calculations for that day. Further subset analyses were performed to assess for any impact of tumor characteristics (size, depth, and location)

on pain and analgesic consumption. Statistical analysis was conducted using a Wilcoxon Rank Sum test for the pain level calculations, as well as the subset analyses of tumor size, depth and tumor location. Fisher Exact tests were used in comparing demographic, clinical, and medication-related data between the two groups. A p-value less than or equal to 0.05 represented a statistically significant finding.

Results

Demographic data

The final sample included 28 patients, as 19 of the initial 47 were dropped due to inadequate records and/or abstinence from pain medications completely. All 28 filled their prescriptions for meloxicam, while 13 of them (46.4%) additionally filled their prescriptions for oxycodone. Of the 13 participants who filled prescriptions for oxycodone, 10 consumed the narcotic at some point during the 2-week postoperative period, constituting 76.9% of the patients who filled the prescription and 35.7% of the total 28-person cohort. These patients comprised Group 2. The remaining 18 participants (64.3%) consumed meloxicam only during the study and comprised Group 1. The average age of our sample was 52.7 years; Group 1 averaged 56.3 years of age, while group 2 averaged 46.2 years of age. Females constituted 54% of our sample, with 10 women in Group 1 and 5 women in Group 2. In terms of race, our total sample included 22 Caucasian participants, 2 African American participants, and 4 participants of other races. In Group 1, 16 participants were Caucasian, 0 were African American, and 2 identified as "other", while in Group 2, 6 participants were Caucasian, 2 participants were African American, and 2 participants identified as "other". The average body mass index (BMI) of the sample was 29.2; in Group 1, the average BMI was 30.3, while in Group 2, the average BMI was 27.4. Only 1 participant consumed pre-operative narcotics and was assigned to Group 2. These data are displayed in Table 2. None of these demographic variables were found to have significant association with narcotic consumption pattern.

Table 2: Demographics and Medication Consumption Data

Variable	Total Cohort N (%)	Group 1 N (%)	Group 2 N (%)	P-value
Sample Size	28 (100)	18 (64.3)	10 (35.7)	
Age (years)	52.7 (SD = 16.1)	56.3 (SD = 14.5)	46.2 (SD = 17.5)	0.11
Female sex	15 (54)	10 (55.6)	5 (50)	1.00
Race				
Caucasian	22 (78.6)	16 (88.9)	6 (60.0)	0.15
African American	2 (7.1)	0 (0.0)	2 (20.0)	0.12
Other	4 (14.3)	2 (11.1)	2 (20.0)	0.60
BMI (kg/m ²)	29.2 (SD = 5.8)	30.3 (SD = 5.8)	27.4 (SD = 5.6)	0.21
Pre-operative narcotic use	1 (3.6)	0 (0.0)	1 (10.0)	0.36
Filled narcotic prescription				0.003
Yes	13 (46%)	15 (83.3)	10 (100)	
No	15 (54%)	3 (16.7)	0 (0)	
Consumed narcotic				P < 0.001
Yes	10 (36%)	0 (0)	10 (100)	
No	18 (64%)	18 (100)	0 (0)	

Filled Meloxicam Prescription				1
Yes	28 (100%)	18 (100)	10 (100)	
No	0 (0%)	0 (0)	0 (0)	
Consumed Meloxicam				1
Yes	28 (100%)	18 (100)	10 (100)	
No	0 (0%)	0 (0)	0 (0)	

Pain scores

Collectively, the 28 patients averaged a VAS score of 4.5 (SD = 2.3) in the first 3 postoperative days, 3.8 (SD = 2.4) during the first week, 2.0 (SD = 2.2) during the second week, and 3.1 (SD = 2.3) over the 14-day study period. The average pain scores in Group 1 (meloxicam only) for the first 3 days, the first week, the second week, and over 14 days were 3.6 (SD = 2.5), 2.7 (SD = 2.1), 1.1 (SD = 1.9), and 2.1 (SD = 2.0), respectively. The average pain scores in Group 2 (oxycodone consumed at some point) over the same time periods were 5.4 (SD = 2.1), 4.8 (SD = 2.6), 2.8 (SD = 2.4), and 4.1 (SD = 2.5), respectively. Comparing VAS scores between treatment groups showed that there were no statistically significant differences in pain levels over the first 3 days ($p = .13$), the first week ($p = .15$), the second week ($p = .27$) or the entire 14 days ($p = .11$) following benign soft tissue tumor resection, although a trend did exist at every time point that those who consumed oxycodone reported greater experienced pain levels (see Table 3 and Figure 1).

Tumor Characteristics

Table 4 demonstrates the clinical characteristics of the tumors excised from patients within the two groups. Table 5 demonstrates the relationship between reported VAS scores at various time points, and these tumor-related characteristics.

Table 3: VAS score vs. Analgesic

Post-op time	Average Score – Entire Cohort	Average Score- Group 1	Average Score- Group 2	P-value
First 3 days	4.5 (2.3)	4.1 (2.3)	5.4 (2.1)	0.13
Week 1	3.8 (2.4)	3.2 (2.2)	4.8 (2.6)	0.15
Week 2	2.0 (2.2)	1.6 (2.0)	2.7 (2.3)	0.27
Entire 2 weeks	3.1 (2.3)	2.6 (2.1)	4.1 (2.5)	0.11

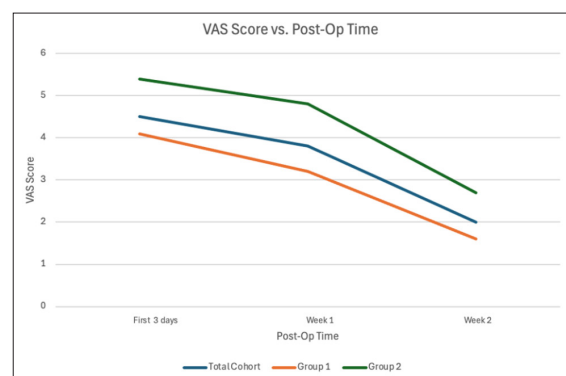


Figure 1: VAS Score vs. Post-Op Time

Table 4: Clinical Tumor-Related Data

Variable	Total Cohort N (%)	Group 1 N (%)	Group 2 N (%)	P-value
Tumor Location				0.695
Upper Extremity	14 (50)	8 (44.4)	6 (60)	
Lower Extremity	13 (46.4)	9 (50)	4 (40)	
Other	1 (3.6)	1 (5.6)	0 (0)	
Tumor Depth				0.678
Superficial to fascia	9 (32)	5 (27.8)	4 (40)	
Deep to fascia	19 (68)	13 (72.2)	6 (60)	
Tumor Size				0.046
Small (< 5 cm)	14 (50)	12 (66.7)	2 (20)	
Large (≥ 5 cm)	14 (50)	6 (33.3)	8 (80)	

Table 5: VAS Score vs. Tumor Characteristics

Post-op time	Tumor Depth			Tumor Size			Tumor Location		
	Superficial (9)	Deep (19)	P-value	<5 cm (14)	≥5 cm (14)	P-value	Upper Extremity (14)	Lower Extremity (14)	P-value
3 Days (SD)	4.5 (2.6)	4.6 (2.2)	0.94	4.1 (2.6)	5.0 (1.9)	0.29	5.1 (1.7)	3.7 (2.5)	0.1
Week 1 (SD)	3.9 (2.6)	3.7 (2.3)	0.78	3.4 (2.5)	4.2 (2.3)	0.25	4.3 (2.0)	3.0 (2.5)	0.07
Week 2 (SD)	2.1 (2.2)	1.9 (2.2)	0.95	1.8 (2.2)	2.2 (2.1)	0.62	2.2 (2.3)	1.5 (2.1)	0.36
14 Days (SD)	3.4 (2.5)	3.0 (2.3)	0.84	2.8 (2.4)	3.4 (2.3)	0.38	3.6 (2.1)	2.3 (2.3)	0.05

Depth

In the study sample, 9 patients (32%) had tumors that were superficial to the fascia, while 19 (68%) tumors were deep to the fascia. Regarding the decision to consume narcotics, there was no association between the depth of the tumor and oxycodone consumption: of all patients with deep tumors, 31.6% of patients were in Group 2, while of all patients with superficial tumors, 44.4% of patients were in Group 2 ($p = 0.678$). Patients who underwent surgical excision of superficial tumors experienced pain levels of 4.5 (SD 2.6), 3.9 (SD = 2.6) 2.1 (SD = 2.2), and 3.4 (SD = 2.5), over the first 3 days, the first week, the second week, and the whole 14-day period, respectively. At the same time points, pain scores for patients with deep tumors averaged 4.6 (SD = 2.2), 3.7 (SD = 2.3) 1.9 (SD = 2.2), and 3.0 (SD = 2.3), respectively. There were no statistically significant differences in the pain scores at any timepoint.

Size

Regarding size of the tumors, 14 (50%) tumors were <5 cm in diameter (small), while 14 (50%) were >5 cm in diameter (large). Patients with small tumors experienced pain levels of 4.1 (SD = 2.6), 3.4 (SD = 2.5), 1.8 (SD = 2.2), and 2.8 (SD = 2.4), over the first 3 days, the first week, the second week, and 14 days, respectively. At the same time points, pain scores for patients with large tumors averaged 5.0 (SD = 1.9), 4.2 (SD = 2.3), 2.2 (SD = 2.1), and 3.4 (SD = 2.3), respectively. There were no statistically significant differences in pain between these groups in the first 3 days ($p = .29$), the first week ($p = .25$), the second week ($p = .62$), or over 14 days ($p = .38$), though trends existed at each time point that larger tumors were associated with higher pain scores. Accordingly, a greater proportion of the patients with large tumors consumed narcotics and were included in Group 2 (57.1%), compared to those with small tumors (only 14.3%) ($p = 0.046$).

Location

Finally, 14 (50%) tumors were excised from the upper extremity (UE), while 13 (46%) tumors were excised from the lower extremity (LE). One participant was excluded from analysis of tumor location due to the tumor's unique location on the trunk. Regarding the decision to consume narcotics, there was no association between tumor location and narcotic consumption rates; of all patients with tumors in the upper extremity, 42.9% were in Group 2, while of all patients with tumors in the lower extremity, 30.8% were in Group 2 ($p = 0.695$). Following resection of UE soft tissue tumors, patients experienced average pain levels of 5.1 (SD = 1.7), 4.3 (SD = 2.0), 2.2 (SD = 2.3), and 3.6 (SD = 2.1), over the first 3 days, the first week, the second week, and 14 days, respectively. Patients with tumors excised from the LE experienced average pain levels of 3.7 (SD = 2.5), 3.0 (SD = 2.5), 1.5 (SD = 2.1), and 2.3 (SD = 2.3) over the first 3 days, the first week, the second week, and 14 days, respectively. The higher pain score associated with upper extremity tumor excision over the 14-day study period was found to be statistically significant ($p=0.05$), though there were no statistically significant differences in pain during the other focused time points: first 3 days ($p = .1$), the first week ($p = .07$) and the second week ($p = .36$).

Discussion

The purpose of this pilot study was to prospectively observe the analgesic consumption habits of patients recovering from soft

tissue tumor excision, and consider these findings in the context of their postoperative pain scores. Our hypothesis was that when patients are presented with an alternative analgesic option to a narcotic, they will opt to use the alternative without exposing themselves to a significant increase in their postoperative pain. We found that when presented with an opportunity to fill and consume narcotic analgesics, less than 50% of patients filled the prescription. Moreover, an even smaller percentage of those patients who filled the prescription pre-emptively actually consumed the oxycodone. This finding may reflect a number of factors barring patients from feeling safe consuming postoperative narcotics and mirror the findings of prior studies. Rahman investigated a number of psychobehavioral factors impacting opioid use following spine surgery and found that fear of addiction affected 71% of patients' decisions surrounding consumption of opioids. Yet, most patients reported skepticism that a non-opioid medication could control their post-operative pain [13]. This described lack of confidence in the available pain management options highlights the need to study various regimens and identify medication options that adequately control pain without risk for addiction, in order to advise surgical patients in an evidence-based manner.

While our sample size is limited, these early data suggest that oxycodone is considered neither desirable nor necessary by most patients after mass excision in the ambulatory setting. This finding should be particularly meaningful to clinicians, as it challenges the traditional practice of prescribing opioids to all postoperative patients going home the day of surgery. Instead, it serves as evidence to suggest that many patients would prefer an alternative option to narcotics, if presented with the choice by their physician.

Upon comparison of VAS pain scores between patients who consumed meloxicam only and those of patients who supplemented their meloxicam with oxycodone, the results indicated patients in both groups experienced equivalent levels of average pain control with a suggestion of the oxycodone group having higher pain scores at all time points (although statistical significance was not achieved by this difference.) This suggests non-inferiority of meloxicam as an effective analgesic in patients undergoing ambulatory soft tissue tumor excision. It is unclear if the oxycodone was consumed by the 10 patients when pain was severe and uncontrolled by meloxicam alone, or whether it was taken in a pre-emptive way to avoid severe pain. In either case, it was not effective in achieving pain levels that were lower than those achieved by meloxicam alone; the patients who consumed oxycodone were no more comfortable than those who did not. While narcotic pain medication may be necessary after larger sarcoma surgeries, such as those involving bony resections or requiring inpatient admission, ambulatory soft tissue tumor excision is less extensive and our data suggest that postoperative pain from these procedures may be adequately controlled with non-narcotic strategies at least in most cases [7].

Analysis of tumor characteristics and VAS scores indicated that neither tumor size nor depth significantly impacted levels of experienced pain across all time points. An expected trend existed towards larger tumors being more painful at all time points, though this was not a statistically significant finding. Resultantly, a higher proportion of patients who underwent

large tumor excision consumed narcotics. Although comparison between upper and lower extremity tumors met the level of statistical significance in pain levels, we are not convinced that the difference we detected is clinically significant or could drive a difference in analgesic consumption.

While the findings of this pilot study are noteworthy, this investigation is not without limitations. Our small sample size and limited power may have led to failure to uncover differences when they truly exist. The unequal group sizes, with only 35.7% of the total cohort in the oxycodone group, may reduce the validity of the conclusions drawn. Additionally, our analysis was limited by the unblinded and nonrandomized nature of the patients into the two groups; there may be inherent differences between patients who self-selected into Group 1 versus Group 2. These differences, such as their anxiety levels surrounding the anticipation of pain, or their tolerances for pain, may have introduced sampling bias and influenced observed consumption patterns and reported VAS scores. This bias may limit the generalizability of our findings to a broader population. All participants in Group 2 consumed both oxycodone and meloxicam, making conclusions about these drugs' individual contributions to pain control difficult to draw. Finally, the reliance on self-reported data may have limitations due to biases inherent in self-report surveys, potentially weakening the strength and applicability of the conclusions.

Despite these limitations, this pilot study serves as proof-of-concept regarding the operation of a prospective trial of various analgesic strategies in the orthopaedic oncology population, an area of scarcity within the literature. Our future goal is to assess the generalizability of these initial findings in a larger randomized study. The findings reported here should encourage orthopaedic surgeons performing ambulatory mass excisions to discuss analgesic options with their patients at time of discharge, and consider providing a non-narcotic option such as meloxicam with the expectation of non-inferior pain control being achieved for most patients [14-16].

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