Research in Molecular Medicine

# Preemptive Pain Management With Oral Oxycodone and Meloxicam in Adult Tonsillectomy

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## ABSTRACT

**Background:** Tonsillectomy is a common surgery that can cause postoperative pain. Preemptive analgesia, given before surgery, aims to block pain signals. Opioids and nonsteroidal anti-inflammatory drugs (NSAIDs), like meloxicam, are often used for pain management, though opioids may have undesirable side effects. This study compared the effectiveness of oral oxycodone and meloxicam in providing preemptive pain control following tonsillectomy in adults.

**Materials and Methods:** This three-arm, double-blind, randomized clinical trial was conducted at Bu-Ali Sina Hospital, Iran. Seventy adult participants were randomly assigned to one of two groups: oxycodone or meloxicam. Both medications were administered 60 minutes before surgery. Postoperative care included standard monitoring, ondansetron, and intravenous acetaminophen. The primary outcome was postoperative pain occurrence, while secondary outcomes assessed pain intensity using the numeric rating scale (NRS) and analgesic consumption. Data analysis was conducted using SPSS software, version 25.

**Results:** Of 70 participants, 67 completed the study. Adverse effects, including stomachache, headache, and nausea, were similar between the meloxicam and oxycodone groups. Pain intensity assessments revealed no significant differences at 30 minutes, 60 minutes, 6 hours, or 24 hours post-surgery, but after 12 hours, the oxycodone group experienced lower pain intensity (mean=2.62) compared to the meloxicam group (mean=3.5), indicating better preemptive pain control with oxycodone.

**Conclusion:** Oxycodone provides superior preemptive pain control compared to meloxicam after tonsillectomy in adults. Further studies are needed to optimize preemptive analgesia strategies.

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## Introduction

Tonsillectomy is a surgical procedure involving the removal of tonsils as a substitute for treating patients with diseases related to the tonsils. It can be performed with or without adenoidectomy, and it involves completely removing the tonsils, including their capsule, by separating the peritonsillar space between the tonsil capsule and the muscular wall [1]. Tonsillectomy has been widely used since the early 20th century to address chronic infections and obstructions caused by the palatine tonsil [2]. Tonsillectomy has become one of the most common surgical procedures globally, initially used to address chronic infections and later evolving to treat sleep-disordered breathing in children. In the United States, over 500,000 tonsillectomies and 289,000 adenoidectomies are performed annually on children under 15 years old [3, 4]. Tonsillectomy is indicated for various reasons, including treating airway obstruction disorders, like sleep apnea, pharyngitis, chronic tonsillitis, recurrent infections, peritonsillar abscesses, airway obstruction due to hypertrophy of the adenoids, significant size differences in tonsils, lymphoma, dysphagia, tonsillar halitosis, sinusitis due to adenoiditis, and otitis media [5-10]. Tonsillectomy, despite being a relatively straightforward surgical procedure, may lead to complications that endanger the patient's life. Common complications include pain, bleeding, fever, dehydration, nausea, and vomiting [11-14].

Postoperative nausea and pain can lead to reduced or delayed oral intake, resulting in dehydration, one of the common reasons for hospital readmission after tonsillectomy. Pain management is crucial, and preemptive analgesia, such as prescribing pain relievers before surgery, has been introduced. Opioids are commonly used for moderate to severe pain control after surgery, and oxycodone, in particular, has advantages over morphine [15, 16]. Oxycodone has better oral bioavailability, crosses the blood-brain barrier more efficiently, and has been reported to have fewer side effects than morphine [17]. The use of opioid analgesics for acute and painful conditions has led to their overuse and a public health crisis [18]. Physicians are seeking non-narcotic alternatives, such as nonsteroidal anti-inflammatory drugs (NSAIDs) and acetaminophen. While short-term opioid use under clinical supervision, such as in-hospital use for postoperative pain, may be appropriate, non-narcotic or combination therapy is preferred. Although an ideal pain reliever has yet to be developed, effective drug regimens, including oxycodone, are available for acute pain control [19].

Oxycodone significantly reduces pain after tonsillectomy and alters muscle reactions toward pain relief. Research on meloxicam suggests considerable analgesic effects in hernia surgery and knee arthroplasty compared to postoperative use [20, 21], and it demonstrates significant pain relief in tooth impaction compared to ibuprofen [22]. However, a study comparing meloxicam orally with a pain pump containing acetaminophen and sufentanil found the pump to be more effective in pain control [5]. Acute postoperative pain is a common and serious concern, often requiring analgesics. Preemptive analgesia aims to control pain before surgery to prevent heightened central sensitivity postoperatively [23, 24]. Preemptive analgesia is a pain management strategy that disrupts the central processing of afferent inputs from injured tissues and is initiated before surgery. Postoperative pain can be significantly controlled by preemptive administration of analgesics before the surgery compared to their postoperative administration. Various drugs, including systemic opioids, NSAIDs, and neuraxial blockades, have been evaluated [21].

Opioids have long been used for the treatment of acute postoperative pain [25-29]. However, the associated side effects, such as respiratory depression, nausea, vomiting, pruritus, decreased bowel movements, and the risk of long-term addiction, have limited their use [30, 31]. Oxycodone is a semi-synthetic opioid analgesic [15]. Studies on concerns regarding opioid use have shown that their use for surgical procedures does not lead to long-term abuse [32, 33]. NSAIDs are commonly used for pain relief, reducing fever, and providing anti-inflammatory properties. Non-selective NSAIDs are commonly used in minor surgeries and can help reduce pain and morphine consumption in major surgeries [34]. Meloxicam, an NSAID, has been used for the treatment of acute pain and inflammation for some time. Oxycodone significantly reduces post-tonsillectomy pain [35]. Investigations on meloxicam have shown considerable analgesic effects in patients undergoing hernioplasty. Acute postoperative pain is a common and significant concern for patients after surgery, often requiring the prescription of analgesics. Preemptive analgesia aims to control pain in the preoperative period, to reduce excessive central sensitization that occurs during the postoperative period [16, 23, 24, 36].

Tonsillectomy, while commonly performed for various conditions, is often associated with significant postoperative pain. Effective pain management, particularly through preemptive analgesia, is critical in reducing post-surgical discomfort. This study compared the effectiveness of oral oxycodone and meloxicam in providing

preemptive analgesia for adults undergoing tonsillectomy. Considering the importance of post-tonsillectomy pain control as a crucial factor in patient satisfaction with surgical outcomes and the limited knowledge regarding the effects of oxycodone and meloxicam in adults, we designed this study to compare the preemptive analgesic effects of these two drugs. Our objective was to reduce post-tonsillectomy pain, enhance patient satisfaction, and improve postoperative recovery to resume normal activities more swiftly.

## Materials and Methods

This study was a three-arm, double-blind, randomized clinical trial designed to assess and compare the efficacy of two pharmacological agents—oxycodone and oral meloxicam—in preventing post-tonsillectomy pain in adult patients. The trial was conducted at Bu-Ali Sina Teaching Hospital in Sari, Iran, ensuring a methodical approach to evaluating the research objectives.

### Participants and group allocation

Seventy adult participants who met the inclusion criteria for tonsillectomy were recruited from the Ear, Nose, and Throat (ENT) Ward of Bu-Ali Sina Hospital. Participants were evenly allocated into two intervention groups (group O and group M) with 35 patients each. The inclusion criteria included adults aged 18-60 years undergoing elective tonsillectomy, without significant comorbidities, such as chronic pain or active infections. Participants were excluded if they had allergies to opioids or NSAIDs, or if they were pregnant or breastfeeding. Randomization of the patients was performed using a block randomization method facilitated by a computer-generated random allocation software to eliminate selection bias. The randomization was conducted by a researcher not involved in the direct care of the participants.

### Medications and administration

The preemptive analgesic medications were administered exactly 60 minutes before surgery. Patients in group O received a 5 mg rapid-release oxycodone tablet, while those in group M received a 15 mg meloxicam oral tablet. Both drugs were prepared and packaged in identical, numbered containers by a pharmacist, who ensured blinding by including placebos where necessary. The active drugs and placebos were mixed in the same packages, ensuring that neither the participants nor the nursing staff were aware of the allocated treatment. This double-blind methodology ensured unbiased results and enhanced the study's scientific integrity.

### Preparation and blinding

The oxycodone tablets were obtained from a pharmaceutical supplier, and their dosage was chosen based on clinical practice guidelines for post-surgical pain management. Meloxicam, an NSAID, was selected due to its well-established efficacy in managing postoperative pain and inflammation. Both drugs were delivered orally as prescribed, and the packaging was designed to prevent any unintentional unblinding of the treatment group. The medications were stored under controlled conditions to ensure consistency in administration. Each patient's medication was assigned a unique identification number, and both patients and nurses administering the drug were blinded to the assignment, maintaining the study's integrity.

### Preoperative and intraoperative protocol

The preoperative period included standard monitoring procedures, including electrocardiogram (ECG), pulse oximetry, non-invasive blood pressure (NIBP), and bispectral index (BIS) monitoring. Preoperative anxiety was minimized through the use of midazolam (1 mg), and anesthesia induction was achieved with fentanyl (2 µg/kg) and propofol (2 mg/kg). Neuromuscular blockade was facilitated with rocuronium (0.6 mg/kg). Throughout the surgical procedure, BIS monitoring was used to ensure adequate depth of anesthesia, with propofol and remifentanil titrated to maintain the desired level of sedation.

### Postoperative care

Post-surgery, all patients were administered ondansetron (4 mg) to prevent nausea and vomiting. Intravenous acetaminophen (1 g) was provided if the numeric rating scale (NRS) pain score exceeded 4 in the recovery room. The primary outcome was the occurrence of postoperative pain (yes/no), while the secondary outcomes included the measurement of pain intensity at various time points (baseline, 30 minutes, 60 minutes, 6 hours, 12 hours, and 24 hours post-operation) using the NRS, and monitoring the total analgesic consumption.

### Data analysis

Descriptive statistics, including frequency tables for qualitative variables and Mean±SD for quantitative variables, were used to summarize the data. Pain inten-

sity scores and analgesic consumption were compared between groups using statistical tests, including the chi-squared test for categorical variables and the t-test or repeated measures analysis of variance (ANOVA) for continuous variables. Statistical significance was set at a 5% level, and all analyses were performed using SPSS software, version 25. The aim of the analysis was to compare the effectiveness of oxycodone and meloxicam in managing post-tonsillectomy pain and provide insights into optimizing pain management protocols for similar surgical procedures.

Through this methodology, the study endeavored to provide a rigorous and transparent evaluation of oxycodone and meloxicam as preemptive analgesics in post-tonsillectomy pain management, ultimately contributing to the improvement of clinical practices in pain management for adult patients undergoing tonsillectomy.

## Results

Seventy individuals participated initially, divided into the meloxicam (n=33) and oxycodone (n=32) groups. Three individuals were excluded, two due to elevated blood pressure during surgery and one due to uncontrollable bleeding. Despite three withdrawals, 67 individuals underwent assessment.

Adverse effects, including stomachache, headache, edema, indigestion, drowsiness, and nausea/vomiting, were monitored post-operation and at discharge. The Mann-Whitney U test revealed no statistically significant difference in the total number of adverse effects between the meloxicam (mean=33.73, total=1079.5) and oxycodone (mean=33.28, total=1131.50) groups (Table 1).

Pain intensity: Pain intensity was evaluated at baseline and after 30 minutes, 60 minutes, 6 hours, 12 hours, and 24 hours in both groups. While no statistically significant differences were observed at baseline and most time points, a significant divergence in pain intensity emerged after 12 hours between the meloxicam (mean=3.5) and oxycodone (mean=2.6176) groups (Table 2).

Table 3 presents the number, Mean±SD of pain intensity, along with the differences in pain intensity at baseline and after 30 minutes, 60 minutes, 6 hours, 12 hours, and 24 hours in the meloxicam and oxycodone receiving groups. According to this table, there was a statistically significant difference in pain intensity between the meloxicam and oxycodone receiving groups after 12 hours, while at other time points, this difference was not statistically significant at the 0.05 level (Table 3) (Figure 1).

**Table 1.** Total number of adverse effects

| Variable | Group | No. | Mean Score | Total Score |
|---|---|---|---|---|
| Total number of side effects | Meloxicam-receiving group | 32 | 33.73 | 1079.5 |
| | Oxycodone-receiving group | 34 | 33.28 | 1131.5 |
| | Total | | 66 | |

**Table 2.** Pain intensity at different time points

| Group | NRS Score | | | | | |
|---|---|---|---|---|---|---|
| | Baseline | After 30 Minutes | After 60 Minutes | After 6 Hours | After 12 Hours | After 24 Hours |
| Meloxicam | 5.0625 | 4.1563 | 3.375 | 3.875 | 3.5 | 2.3125 |
| Oxycodone | 4.5882 | 4.0882 | 3.1471 | 3.4706 | 2.6176 | 1.9118 |
| Total | 4.8182 | 4.1212 | 3.2576 | 3.6667 | 3.0455 | 2.1061 |

**Table 3.** Number, mean, and standard deviation of pain intensity at baseline and after 30 minutes, 60 minutes, 6 hours, 12 hours, and 24 hours

| NRS Score | Group | Mean±SD | No. | t | P |
|---|---|---|---|---|---|
| Baseline | Meloxicam-receiving group | 5.0625±3.43546 | 32 | 0.611 | 0.544 |
| | Oxycodone-receiving group | 4.5882±2.86163 | 34 | | |
| | Total | 4.8182±3.13741 | 66 | | |
| After 30 minutes | Meloxicam-receiving group | 4.1563±3.01726 | 32 | 0.104 | 0.918 |
| | Oxycodone-receiving group | 4.0882±2.2746 | 34 | | |
| | Total | 4.1212±2.64002 | 66 | | |
| After 60 minutes | Meloxicam-receiving group | 3.375±2.1813 | 32 | 0.491 | 0.625 |
| | Oxycodone-receiving group | 3.1471±1.55957 | 34 | | |
| | Total | 3.2576±1.87543 | 66 | | |
| After 6 hours | Meloxicam-receiving group | 3.875±1.87943 | 32 | 0.894 | 0.375 |
| | Oxycodone-receiving group | 3.4706±1.79621 | 34 | | |
| | Total | 3.6667±1.83415 | 66 | | |
| After 12 hours | Meloxicam-receiving group | 3.5±1.91766 | 32 | 2.068 | 0.043 |
| | Oxycodone-receiving group | 2.6176±1.5377 | 34 | | |
| | Total | 3.0455±1.77532 | 66 | | |
| After 24 hours | Meloxicam-receiving group | 2.3125±2.11656 | 32 | 0.867 | 0.389 |
| | Oxycodone-receiving group | 1.9118±1.62122 | 34 | | |
| | Total | 2.1061±1.87394 | 66 | | |

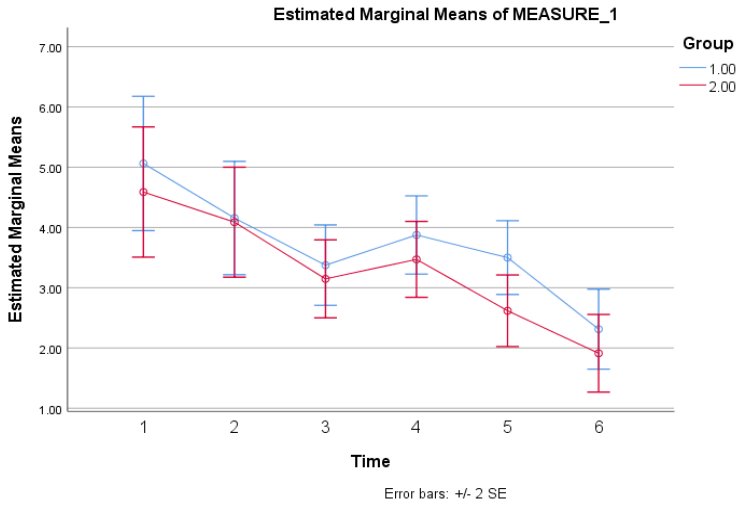


**Figure 1.** Difference between the two groups receiving meloxicam (1) and oxycodone (2) in terms of pain intensity at baseline and after 30 minutes, 60 minutes, 6 hours, 12 hours, and 24 hours

## Discussion

Tonsillectomy is a common procedure used in the treatment of patients with tonsil-related diseases [2, 37]. Since the first tonsillectomy was performed by Schmidt Sarmiento in São Paulo in 1920, this surgical intervention has been utilized to address chronic infections and obstructions caused by palatine tonsils [3, 4]. Despite its relatively straightforward technique, tonsillectomy can be associated with various complications, including pain, bleeding, fever, dehydration, nausea, and vomiting [5]. The majority of patients undergoing this procedure experience acute pain, with 80% describing it as moderate to severe [11]. In adults, tonsillectomy often requires dissection and coagulation, leading to more severe and prolonged pain [19]. Both pain and nausea can lead to reduced or delayed oral intake and subsequent dehydration, which is a common cause of hospital readmission post-tonsillectomy. While the surgery is recognized for its efficacy, the procedure is not without complications, with pain being a predominant concern among patients. Our study aimed to contribute to the discourse on post-tonsillectomy pain management by comparing the effectiveness and safety of two analgesic agents, meloxicam and oxycodone.

The results of this study showed that there were no significant differences in mean age, body mass index (BMI), surgery time, anesthesia time, tonsil grade, and gender between the two groups receiving meloxicam and oxycodone. The distribution of these variables was uniform and accurate, indicating that the two groups were well-matched. The total number of adverse effects after surgery and at the time of discharge in both experimental groups, including stomachache, headache, edema, indigestion, drowsiness, and nausea and vomiting, did not show any statistically significant differences. This suggests that meloxicam and oxycodone had a comparable side effect profile in this study. In our study, the pain intensity score 12 hours post-operation showed a significant difference between the two groups receiving meloxicam and oxycodone. However, this difference was not statistically significant at other time points. This finding is consistent with a study by Qian et al., which demonstrated that pre-emptive analgesia can effectively reduce postoperative pain or the need for analgesics [38]. Cramer et al. [39] indicated that NSAIDs, especially when combined with acetaminophen, are highly effective analgesics for postoperative pain. This contradicts the misconception that NSAIDs are less potent and carry an unacceptable risk of bleeding compared to opioid agents. In contrast, the combination of ibuprofen and acetaminophen, known as multimodal analgesia, was more effective than opioid regimens. Selective inhibition of cyclooxygenase-2 reliably avoids the antiplatelet effects. The results of this study, which involved meloxicam, a type of NSAID, for postoperative pain control, showed that it worked similarly to opioid agents, except that the test subjects reported more pain after 12 hours post-operation. This difference may be due to the study's use of other NSAIDs, like ibuprofen, as a second-line treatment alongside the primary treatment.

The study by Wu et al. [20] aimed to compare the analgesic efficacy and safety between oral meloxicam and oral morphine administered before and after surgery in patients undergoing knee arthroscopy. The results indicated that oral oxycodone was more potent than morphine for postoperative pain relief and had fewer side effects. Therefore, when seeking to control pain, particularly with oral medications, oxycodone is a more effective choice, consistent with our study's use of this drug. Our study did not show any differences in pain intensity between the meloxicam and oxycodone oral formulations. Future studies should investigate the differences in efficacy between oral and intravenous meloxicam.

Our results revealed no significant differences in demographic and procedural variables between the meloxicam and oxycodone groups, ensuring the robustness of our study's design. The examination of adverse effects indicated a comparable side effect profile for both drugs, suggesting their relative safety in the context of post-tonsillectomy recovery. However, a noteworthy finding was the significant difference in pain intensity scores at the 12-hour postoperative mark, where subjects in the meloxicam group reported higher pain levels compared to the oxycodone group. Although, except for one case, the two groups of meloxicam and oxycodone recipients did not show a significant difference in terms of pain criteria, the side effects and dependence associated with opioid agents lead us to consider using these drugs less and shifting our approach toward replacing them with non-opioid analgesics that have fewer side effects and similar efficacy.

This particular observation warrants careful consideration, especially in light of the broader literature on postoperative pain management. Qian et al.'s study emphasized the efficacy of pre-emptive analgesia in reducing postoperative pain [38], aligning with our finding regarding increased pain intensity in the meloxicam group at 12 hours. It suggests the importance of timing in the administration of analgesic agents, raising the possibility that a more nuanced approach to dosing or timing may optimize the effectiveness of meloxicam in mitigating post-tonsillectomy pain.

Expanding our perspective to other studies, Vaiman et al.'s investigations underscored the efficacy of oxycodone in post-tonsillectomy pain relief, supporting our findings and emphasizing its potential to reduce complications [32]. Studies by Cheung et al. [15] and Shakeri et al. [40] reinforced the efficacy of oral oxycodone and meloxicam, respectively, in managing postoperative pain across diverse surgical contexts. This broader evidence aligns with our study's emphasis on the versatility of these medications in pain management strategies. Hou et al.'s study indicated the significance of timing in pain management, advocating for early pre-emptive meloxicam administration [20]. This aligns with our observation regarding a significant difference in pain intensity at the 12-hour mark, emphasizing the temporal nuances in effective pain control.

Considering the potential for opioid-related complications, studies by Martinez et al. [30] and Bergman et al. [41] supported the notion of tailored pain management strategies, with a nuanced approach to medication selection and timing. These studies collectively reinforce the importance of individualized approaches, urging a shift toward opioid-sparing methods for enhanced patient outcomes.

Another study by Qian et al. in 2020 emphasized the importance of preventive analgesia and suggested that opioid agents are typically used when pain relief is insufficient [38]. Opioids commonly used for post-tonsillectomy pain relief include morphine, oxycodone, sufentanil, and fentanyl, but they tend to increase the risk of apnea in individuals using opioid agents and may even lead to depression. As stated earlier, due to the lack of a significant difference between the two groups, we recommend using NSAID drugs for post-tonsillectomy pain control before surgery.

Considering the variables measured in our study, we also found no significant difference between individuals receiving meloxicam and oxycodone orally. Therefore, if there is a preference for using oral drugs to control pain, NSAIDs are a better option. The use of opioid agents should be limited to specific indications.

## Conclusion

This study contributes valuable insights into the comparative effectiveness and safety of meloxicam and oxycodone in post-tonsillectomy pain management. The observed difference in pain intensity at the 12-hour mark prompts further exploration of the timing and dosing considerations for meloxicam. The broader literature supports the versatility of both meloxicam and oxycodone, emphasizing the need for individualized, opioid-sparing approaches in the evolving landscape of postoperative pain management.

## Ethical Considerations

### Compliance with ethical guidelines

This study was approved by the Research Ethic Committe of Mazandaran University Medical Sciences, Sari, Iran. The study was performed in accordance with the principles of the Declaration of Helsinki.

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### Authors contribution's

All authors participated in the design of the study and approved the final version of the manuscript.

### Conflict of interest

The authors declared no conflict of interest.

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