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COMPARISON OF PAIN CONTROL EFFECT OF TAPENTADOL AND NAPROXEN SODIUM AFTER THIRD MOLAR EXTRACTIONS – A RANDOMIZED DOUBLE-BLIND SPLIT-MOUTH STUDY

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ABSTRACT

Introduction: The surgical removal of impacted mandibular third molars is a common procedure in oral and maxillofacial surgery and is associated with varying degrees of postoperative discomfort. Pain, trismus, and swelling are frequent complaints, that significantly impact a patient's quality of life post-surgery. To address this issue, effective pain management is essential. This study compares the effectiveness of an opioid(tapentadol) and non-steroidal

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anti-inflammatory drug (Naproxen Sodium) in managing pain after impacted third molar extractions

Materials and Methods: A randomized, double-blind, split-mouth study was conducted on 186 patients. Patients were divided into two groups of 93, with one group receiving Tapentadol and the other Naproxen Sodium. Pain levels were assessed on postoperative days one and three using a Visual Analog Scale (VAS).

Results: The findings indicate no statistically significant difference in pain control between the two drugs on postoperative day one. However, Tapentadol demonstrated slightly greater efficacy on postoperative day three, with more patients reporting no pain compared to Naproxin Sodium.

Conclusion: While both drugs provided effective pain relief, Tapentadol showed marginal superiority on day three. Future studies with larger sample sizes are recommended to explore this finding further.

KEYWORDS: Double-blind study, Split-mouth design, Visual Analog Scale (VAS), Postoperative pain, Trismus, Swelling.

INTRODUCTION:

Pain is a universal human experience and a common complaint in healthcare settings. It serves as a physiological response and protective mechanism, alerting the body to potential or actual tissue damage. Dental pain, particularly after third molar extractions, is one of the most acutely painful post-operative conditions.[(1)] Wisdom teeth typically erupt between ages 17 and 30. While they often align with other teeth without issue, they may become impacted in the jawbone or gums, leading to complications such as cavities, gum disease, or infections. Impaction is the term used for this. A number of oral health issues, such as cavities, gum disease and infection, can be brought on by impacted wisdom teeth.[(2)]Impacted teeth are classified based on factors like angulation, position relative to the anterior ramus border, and depth of impaction. Pain, swelling, trismus, and dry sockets are common post-operative complications following lower third molar extractions. Pain management typically involves steroids, opioids, and NSAIDs, each with distinct benefits and drawbacks.[(3)]

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To ascertain the degree of difficulty in extracting impacted teeth, many classifications were created. The impacted tooth's angulation, position with relation to the anterior border of the ramus, the crown of the second molar, the depth of impaction, and the kind of tissue covering the impacted tooth are the most commonly used categories.While distoangular, class III (impacted molar is completely embedded in ramus) and group C (impacted tooth is below the cervical line of the second molar) impactions are the most difficult to remove, class I (impacted tooth is anterior to the anterior border of ramus) and Class II (impacted tooth's occlusal plane is at the same level as the second molar's occlusal plane) impactions in the mandible are the easiest to remove.[4]

Pain, edema, mild to severe trismus, and dry socket are the typical postoperative complications following lower tooth extraction surgery. Compared to asymptomatic patients, individuals who suffer from these consequences have a worse quality of life. After the impacted tooth is extracted, swelling typically goes away in 5-7 days, but trismus goes away in 7-10 days.[5] If swelling gets worse after the third day, it could be an infection instead of postsurgical edema. Because of alterations in the central and peripheral nerve systems, the surgical trauma associated with the excision of impacted wisdom teeth causes pain. Steroids, opioids, and non-steroidal anti-inflammatory medicines (NSAIDs) are among the many types of medications used to manage pain.[6]

NSAIDs are frequently used in dental practices to treat pain and edema following procedures. After third molar surgery, non-steroidal anti-
inflammatory medicine (NSAID) usage is also typical.

These medications are used to manage the most common post-operative problems, including trismus, face inflammation, and discomfort following surgery. The vast majority of NSAIDS are used to treat mild to severe pain. With analgesic, antipyretic, and anti inflammatory properties, naproxen sodium is a non
selective inhibitor of COX I and II and a derivative of propionic acid.Nonetheless, it is linked to gastrointestinal issues such as stomach bleeding, gastrointestinal perforations, and gastric ulcers.[7] Opioids are considered as gold standard for treatment of moderate to severe pain. Opioids are underutilized, nevertheless, since patients and clinicians may be reluctant to use them because of

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the possibility of adverse effects, abuse, tolerance, withdrawal, and liability. When compared to NSAIDs, analgesics that are equally efficacious but have better compliance are useful additions to the analgesic toolbox.[8] Combining MOR agonist with monoamine reuptake inhibition is one tactic used to increase the compliance of mu-opioid receptor (MOR) agonists. Tramadol used to be the most widely used opioid. Tramadol has been used as a centrally acting analgesic for thirty years.However, there is a significant risk of drug misuse with Tramadol. Tapentadol is an entirely novel centrally acting analgesic that works by combining noradrenaline reuptake inhibition with mu-opioid receptor agonism in one molecule. In contrast to opioids and nonsteroidal anti-inflammatory medications, it has a better side effect profile. Tapentadol is a helpful analgesic for treating chronic, and acute pain because of its dual mode of action.[9]

OBJECTIVE: To compare the effectiveness of pain control between Tapentadol and Naproxen sodium in patients undergoing impacted third molar extractions.

OPERATIONAL DEFINITION:

Pain: An unpleasant sensation, as scored on a visual analog scale. Or it is localized or generalized unpleasant bodily sensation or complex of sensations that causes mild to severe physical discomfort and emotional distress and typically results from bodily disorder (such as injury or disease).

MATERIALS AND METHODS:

This study will be a randomized, double-blind split-mouth clinical trial.Randomization will be carried out via simple randomization in which participants falling into the inclusion criteria of the study will be selected for the research and asked to sign the consent form.This randomized, controlled, double-blind, split-mouth experiment will be conducted at the Department of Oral and Maxillofacial Surgery, Dr. Ishrat-ul-Ebad Khan Institute of Oral Health Sciences, DUHS. Individuals will receive tablets containing naproxen sodium when undergoing extraction of the opposite impacted tooth. Consenting patients will be given medicines randomly. Patients will be given two chits containing either Tapentadol or naproxen sodium drug and allowed to pick one on the first surgical day and will be given the other remaining chit at the next surgical visit. Both patients nor the author will not be informed which drug is prescribed. Experimenters will be recruited to prescribe the drug. The experimenters can be house officers or fellow post-graduate

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trainees of the author. Scoring for pain analysis after the extraction of the impacted tooth will be done by the author or the co-author of this study via the VAS scoring system for pain analysis.The patient will be called for follow-up on the third postoperative day, and VAS scoring will be done and noted at that visit.[10] The Questionnaire is structured and will be interviewer-administered. It will comprise primary bio-demographic data (such as name, age, sex, Etc.) and questions for VAS scoring for pain analysis following the extraction.The patients were given a questionnaire and told to fill it out, including noting how much pain they were experiencing on a visual analog scale (VAS) and how many analgesic pills they had used from the first to the third postoperative day.

Study design:

A randomized, double-blind, split-mouth clinical trial was conducted.

Setting:

Department of Oral and Maxillofacial Surgery, Dow University of Health Sciences, Ojha Campus

Duration of Study:

6-8 months.

Sample Size:

186 patients (93 per group), calculated using the WHO Sample Size Calculator.

Using the WHO Sample Size Calculator, the sample size was calculated by taking statistics of the pain control effect of the drug tapentadol 100 mg as 50%(9) and drug naproxen sodium as 70% (by considering a 20% difference in effect), power of test as 80% and 95% confidence level and 5% level of significance. The sample size came out as 93 people for each group. As a split-mouth study will be done, the total sample size collected would be 93 x 2 = 186.

Sampling Technique:

A consecutive sampling technique will be used.

Inclusion Criteria:

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Patients aged 18-40 years with bilateral third molar impactions.

Absence of systemic disease .[10]

Patients that give their acceptance of the usage of their data and the administration of the drug will be

the participants of the study.

Exclusion Criteria:

Pregnant or immuno-compromised patients.

Patients with wisdom teeth associated with any pathology or fully erupted teeth.

Patients previously treated with radio or chemotherapy.[11]

Data Collection: Pain was measured using a VAS on days one and three postoperatively. Patients were randomly assigned to receive either Tapentadol or Naproxen Sodium during their first surgical visit, with the other drug administered at the next visit.

Data for this study will be collected at Dr. Ishrat-ul-Ebad

Khan Institute of Oral health sciences, department of oral and maxillofacial surgery OPD.

Patients falling into the inclusion criteria of the study will be selected for the research purpose.

Patients will be told about the research and its purpose.

Consent will be signed by the patient or their attendant. The Questionnaire is structured and will be interviewer-administered. It will comprise primary bio-demographic data (such as name, age, sex, Etc.) and questions for VAS scoring for pain analysis following the extraction. The patients were given a questionnaire and told to record their degree of discomfort using a visual analogue scale (VAS) and how many analgesic tablets they had used from the first to the third postoperative day.(12)

DATA ANALYSIS PROCEDURE:

Statistical Analysis: Data were analyzed using SPSS version 26. P-values < 0.05 were considered statistically significant.

RESULT:

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186 patients were choose according to inclusion criteria ,undergoes third molar extractions prescribed analgesics divided into 2 groups, 93 were allocated to receive Tapentadol and 93 patients were allocated to receive Naproxen Sodium. As the data for this study were collected at different time points, analysis for the longitudinal study was done.The main outcome variable, pain level was measured in 2-ordered categories. Table 1 and 2 shows the results of 1st and 3rd post-operative day.

Naproxen Sodium and tapendatol on post-operative Day 1 respectively

		Frequency	Percent	Frequency	Percent
Valid	no pain	44	47.3	47	50.5
	mild to moderate pain	48	51.6	45	48.4
	severe pain	1	1.1	1	1.1
	Total	93	100.0	93	100.0

Table 1 shows the results the of the 1st postoperative day. There is little bit variation in intensity of pain on 1st postoperative day in both drugs, a little favoring results can be seen for Tapendatol.

Naproxen Sodium and tapendatol on 3rd post operative day respectively

		Frequency	Percent	frequency	Percent
Valid	no pain	47	50.5	57	61.5
	mild to moderate pain	45	48.3	35	37.6
	severe pain	1	1.1	1	1.1
	Total	93	100.0	93	100.0

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Table 2 shows results of the 3rd postoperative day. There is a variation in intensity of pain on 3rd postoperative day in both drugs ,more favoring results can be seen for Tapendatol that more numbers can be seen with “no pain” .

Chi-Square Tests

	Value	Df	Asymptotic Significance (2-sided)
Pearson Chi-Square	150.778[a]	4	.000
Likelihood Ratio	84.622	4	.000
Linear-by-Linear Association	60.984	1	.000
N of Valid Cases	92		

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5 cells (55.6%) have expected count less than 5. The minimum expected count is .01.

Pain levels on postoperative days one and three were recorded.

Postoperative Day 1:

•Tapentadol: 50.5% reported no pain, 48.4% mild to moderate pain.

•Naproxen Sodium: 47.3% reported no pain, 51.6% mild to moderate pain.

Postoperative Day 3:

•Tapentadol: 61.5% reported no pain, 37.6% mild to moderate pain.

•Naproxen Sodium: 50.5% reported no pain, 48.3% mild to moderate pain.

Chi-square tests indicated a statistically significant difference in pain levels on day three ($P < 0.004$), favoring Tapentadol.

DISCUSSION:

This study compared the efficacy of NSAIDs (Naproxen Sodium) and opioids (Tapentadol) for postoperative pain management after third molar extractions. Both drugs were effective, with similar outcomes on day one. However, Tapentadol showed marginally better results on day three, likely due to its dual mechanism of action.[13]

The effectiveness and safety of NSAID analgesics in treating acute postoperative dental pain have been demonstrated in a research. They are suitable for treating mild to moderate pain and are constrained by the ceiling effect.[14] Patients who have acid reflux illness, renal impairment, or a propensity for bleeding should not use NSAIDs. While some of these adverse effects are mitigated by COX-2-inhibiting NSAIDs, others raise the risk of cardiovascular side effects, such

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as MI. NSAIDs are typically linked to dyspepsia, heartburn, and nausea. Significant gastrointestinal side effects, renal side effects, and cardiovascular adverse effects are also linked to it. They are typically used in conjunction with H2 receptor antagonists or proton pump inhibitors to reduce the side effects of related to gastrointestinal issues.[15]

However, following the surgical extraction of the impacted teeth, individuals have reportedly experienced excruciating agony. Additionally, there are a number of post-operative problems that affect a patient's quality of life in the days following surgery, such as pain, edema, trismus and trauma.[16] It has been demonstrated that naproxen is quite successful in lowering mild to moderate pain, and NSAIDs are now widely used to treat post-operative pain, while in Europe, people with severe chronic pain that can only be effectively treated with opioid analgesics are prescribed Tapentadol PR according to some studies.[17]

One generic form of non-steroidal anti-inflammatory medication (NSAID) is naproxen that inhabits the COX-1 and COX-2 enzymes, which decreases prostaglandin synthesis.[18] It acts as an anti-inflammatory to lessen swelling and an analgesic to relieve pain. It works well as an analgesic for acute dental pain, although in certain situations, other medications may be used if further relief is required. It works well as an analgesic for severe tooth pain, although in certain situations, acetaminophen may be given if further relief is required. In severe situations, opiates may also be administered in combination with steroids or NSAIDs. It is an excellent option for the majority of persons with dental pain because of these combined effects.[19] But patients prefer to take single pain reliever with fewest side effects, in order to provide pain relief following surgical extraction.[20]

According to data, tapentadol is a centrally acting analgesic which acts both as a μ-opioid receptor (MOR) agonist and as a noradrenaline reuptake inhibitor (NRI)[21] that, is quite effective, has a good profile, and acts quickly. One of the great advantages in the treatment of moderate to severe acute pain is improved GI tolerability.[22] Its efficacy for chronic pain is similar to that of traditional opioids, but it has an improved side effect profile, which could contribute to improved compliance. Tapentadol ER could be effective in a wide spectrum of patients with moderate to severe chronic pain such as osteoarthritic pain, DNP, and cancer pain.[23] It may also prove to be an effective option for those dealing with pain at work. Although

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more clinical data is needed on its long-term efficacy in various populations and potential for abuse and toxicity, its excellent safety profile and patients' high levels of satisfaction compared to mu opioids in long-term acute and chronic pain trials make tapentadol an exciting addition to the therapeutic armamentarium in pain management.[24]

In addition, patients who undergo surgery typically have moderate-to-severe pain for a few days after the procedure, which necessitates analgesic medication. For the treatment of acute pain in adults, tapentadol is also authorized as an oral medication. We evaluated tapentadol IR for effects on moderate-to-severe pain after minor oral surgery, which is an established pain model for the assessments of analgesia, the results of which can be generalized to other surgical procedures.[25] The model is ideal for evaluating analgesia for a number of reasons. The pain model employs standardized surgical and anesthetic procedures, with less interpatient variability in pain. Furthermore, patients undergoing surgery experience a predictable and sustained level of moderate-to-severe pain following the procedure that requires analgesic treatment for several days.

In a study on postsurgical dental pain, patients undergoing third molar extraction were randomized to receive single doses of Tapentadol (50, 75, 100, or 200 mg), morphine 60 mg, ibuprofen 400 mg, or placebo.[26] The results of the study showed that single doses of Tapentadol 75 mg or higher effectively reduced pain in a dose-related fashion and were well-tolerated relative to morphine. The tolerability of Tapentadol has been evaluated in trials in which patients with acute pain received multiple oral doses. The most common adverse effects noted with Tapentadol were nausea, vomiting, constipation, dizziness, somnolence, headache, and pruritis; these effects are typical of a MOR agonist. The incidence of these adverse effects has been reported to be lesser with Tapentadol in comparison to that by other opioids.[27]

We evaluated both drug comparisons on postoperative days 1 and 3 with $P < 0.004$. So, basically, with a comparison of both drugs, there is no significant difference between these two drugs for pain control on postoperative day 1, but there is a slight variation in pain control on the 3rd postoperative day; tapentadol is marginally superior in comparison with naproxen sodium.

CONCLUSION: Tapentadol and Naproxen Sodium effectively manage postoperative pain following third molar extractions. Tapentadol offers marginally superior pain control on day

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three, particularly for patients with gastrointestinal or renal concerns. Further studies with larger sample sizes are recommended to validate these findings.

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