Journal of Neonatal Surgery
ISSN(Online): 2226-0439
Vol. 14, Issue 32s (2025)
https://www.jneonatalsurg.com

OPEN ACCESS

A Comparative Study of Topical Ketamine and Diclofenac Sodium as Oral Rinse in The Management of Post Tonsillectomy Pain

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Cite this paper as: Dr. Lasya Raj Narasareddy, Dr. Siddartha Seekala, Dr. Sindhuja Nagisetty, Dr. Jagruthi Koduru, (2025) A Comparative Study of Topical Ketamine and Diclofenac Sodium as Oral Rinse in The Management of Post Tonsillectomy Pain. *Journal of Neonatal Surgery*, 14 (32s), 4577-4583.

ABSTRACT

Introduction: Tonsillectomy is one of the commonest procedures performed by an otorhinolaryngologist, representing approximately 20-40% of the surgeries performed.[1] Tonsillectomy is associated with unacceptable pain during the first 24 hours after surgery.[2] Pain management in the immediate postoperative period following tonsillectomy is very essential to ensure proper oral intake. There are various methods of administering analgesics- oral, per-rectal, intravenous, intramuscular, topical. Topical approaches have the advantage of pain control with good patient acceptability in the immediate postoperative period.[3] Topical approach helps in delivering the drug at the site of action and hence has better pain relief, with less systemic side effects due to less systemic absorption.

Ketamine and Diclofenac Sodium are non-opioid analgesics which can be used in reducing post tonsillectomy pain in adults. Ketamine, a potent N-Methyl-D-Aspartate (NMDA) receptor channel blocker, acts on central nervous system as well as peripheral receptors. It has an analgesic, anti-inflammatory property and inhibits wind up pain and hyperalgesia. It has anti-hyperalgesic effects in subanaesthetic doses. Diclofenac, a non-steroidal anti-inflammatory drug (NSAID) has analgesic properties. It is a Cyclooxygenase (COX) inhibitor and reduces the production of prostaglandins which are the chemical mediators of pain. There are various methods of analysing pain- Visual Analogue scale (VAS), objective pain scale, faces pain scale, behavioural rating scale, numerical rating scale (NRS). Visual Analogue Scale (VAS) is a validated pain measuring scale for adults.

Aims: To compare the effectiveness of Ketamine and Diclofenac Sodium given as oral rinse in reducing post tonsillectomy pain in adults.

Material And Methods: Data was collected from a sample of 60 patients aged 18-30 years who have undergone tonsillectomy in a tertiary care centre from April 2024 to March 2025. Informed consent was taken from the patients and their bystanders. 30 cases for each group were selected by using simple random sampling method. Tonsillectomy was performed by dissection and snare method. Patients in group 1 received Ketamine solution 20 mg dissolved in 10 ml saline. Patients in group 2 received Diclofenac Sodium tablet (dispersible) 50 mg in 10 ml saline. The drugs were administered as an oral rinse -2 times on the day of surgery and at an interval of 8 hours on the first postoperative day. Baseline VAS score was assessed. Pain was assessed half an hour after giving each oral rinse. The onset and duration of analgesia, the time of first oral feed, the need for first rescue analgesic, and side effects of the drugs were noted.

Results: Topical Ketamine has longer duration of analgesia compared to topical Diclofenac Sodium. The patients in Ketamine group had lesser need for rescue analgesics and were able to have their first oral feed earlier when compared to those in Diclofenac group. There were no adverse effects in either groups.

Conclusion: Topical Ketamine and topical Diclofenac Sodium can be used to reduce post tonsillectomy pain without any adverse effects; topical Ketamine being comparatively better.

Keywords: *Ketamine, Diclofenac Sodium, Tonsillectomy, VAS score.*

1. INTRODUCTION

Tonsillectomy is one of the commonest surgical procedures performed by an otorhinolaryngologist, representing approximately 20-40% of the surgeries performed.[1] Patients in immediate postoperative period will have severe pain during swallowing which will interfere with their oral intake. Pain management in the immediate postoperative period following tonsillectomy is very essential to ensure proper oral intake. Various opioid and non-opioid analgesics have been tried to minimise post tonsillectomy pain with side effects of their own. The problem of post tonsillectomy pain relief has been a clinical dilemma despite the use of various surgical and anaesthetic techniques since post tonsillectomy medication should provide adequate pain relief with minimal side effects. There are various methods of administering analgesics- oral, per-rectal, intravenous, intramuscular, topical. Topical approach will help in delivering the drug at the site of action and hence has better pain relief. It has the advantage of less systemic side effects due to less systemic absorption. Topical therapy in post tonsillectomy also has good patient acceptability as the patient need not swallow the drug as there will be severe pain in the immediate postoperative period which will interfere with swallowing. Therefore topical agents would seem to be an ideal and safe option in reducing post tonsillectomy pain.

Ketamine and Diclofenac Sodium are non-opioid analgesics which can be used in reducing post tonsillectomy pain in adults. Ketamine, a potent N-Methyl-D-Aspartate (NMDA) receptor channel blocker, acts on central nervous system as well as peripheral receptors. It has an analgesic, anti-inflammatory property and inhibits wind up pain and hyperalgesia. It has anti-hyperalgesic effects in subanaesthetic doses. Diclofenac, a non-steroidal anti-inflammatory drug (NSAID) has analgesic properties. It is a Cyclooxygenase (COX) inhibitor and reduces the production of prostaglandins which are the chemical mediators of pain. There are various methods of analysing pain. Visual Analogue Scale (VAS) is a validated pain measuring scale for adults. It comprises of a horizontal line measuring 10 centimetres (cm). The markings will be from 0 to 10. A score of 0 indicates no pain and 10 indicates worst possible pain. A score from 0 to 4 millimetre (mm) indicates no pain, 5 to 44 mm indicates mild pain, 45 to 74 mm indicates moderate pain and 75 to 100 mm indicates severe pain.[4]

2. AIM OF THE STUDY

We aim to study and compare the efficacy and safety of topical Ketamine and Diclofenac Sodium given as oral rinse in reducing post tonsillectomy pain in the immediate postoperative period. The onset of analgesia, the duration of analgesia, the time of first oral intake, the need for rescue analgesics and the adverse effects of the drugs were monitored and compared.

3. MATERIALS AND METHODS

This study was carried out in 60 patients in the age group of 18-30 years who have undergone tonsillectomy in a tertiary care centre from April 2024 to March 2025. Informed consent was taken from the patients and their bystanders. Patients with immunocompromised status, diabetics, hypertensives, epileptics, bleeding disorders, impaired renal function were excluded from the study. 30 cases for each group were selected by using simple random sampling method. The analysis was done using the following parameters- the mean, the standard deviation, standard error, T-test and chi-square test.

Method of study:

- All patients underwent tonsillectomy by dissection and snare method under general anaesthesia.
- Patients were randomly divided into 2 groups of 30 each.

Group 1 received Ketamine solution- 20 mg dissolved in 10 ml saline.

Method of preparation of topical Ketamine: Ketamine is available as 10 ml vial containing 500 mg of Ketamine. 1 ml contains 50 mg Ketamine. Dilute 1 ml of Ketamine in 4 ml Normal Saline (NS) to make a concentration of 10 mg/ml of Ketamine. Take 2 ml of the diluted solution (containing 20 mg Ketamine) and administer the solution in 10 ml saline.

Group 2 received Tab Diclofenac Sodium (dispersible) 50 mg. dissolved in 10 ml saline. In both groups, the solution was administered as an oral rinse.

The first dose of the drug was given 4 hours after the surgery and the second dose 8 hours after the first dose. The next 3 doses were given on the first postoperative day at an interval of 8 hours. Patients are advised to gargle the solution under supervision for 2 minutes and then spit. Postoperative pain was assessed on the basis of VAS. Baseline VAS score was assessed. Pain was assessed half an hour after giving each oral rinse. Pulse rate, blood pressure, Oxygen saturation of the patients were monitored. The duration of action of the drugs were measured and compared. The time of first rescue analgesic (Intramuscular Diclofenac) was assessed for both the drugs. The time of first oral intake was assessed. Patients were monitored for any adverse effects of the drugs.

4. RESULTS

60 patients who underwent tonsillectomy in the age group of 18-30 years were included in this study, who were divided into 2 groups of 30 each. In our study, majority of the subjects were in the age group of 26-30 years (21 patients accounting for

35%), and the least were in the age group of 21-25 years (10 patients accounting for 16.7%). Females comprised roughly two-thirds of the study group. The mean onset of action of Ketamine was 3.3 minutes and that of Diclofenac was 5.4 minutes (P value 0.000). The duration of analgesia lasted for a mean of 5.66 hours for Ketamine and 5.13 hours for Diclofenac, the difference between the two being statistically significant (P value 0.007). The VAS scores were significantly lower in Ketamine group compared to Diclofenac group indicating that the patients in Ketamine group had a better pain relief than in Diclofenac group (P value 0.044). Administration of Ketamine had no significant effects on pulse rate & blood pressure.

Figure 1: Bar diagram showing the difference between the mean onset of action of the drugs. It is shown that Ketamine has faster onset of action compared to Diclofenac, and is statistically significant (P=0.00).

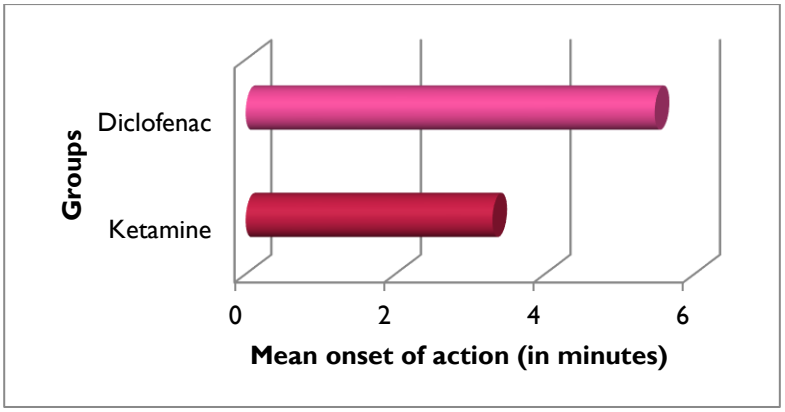

Figure 2: Bar diagram showing the mean duration of analgesic action of the drugs. Topical Ketamine has longer duration of action compared to Diclofenac, and is statistically significant (P=0.007).

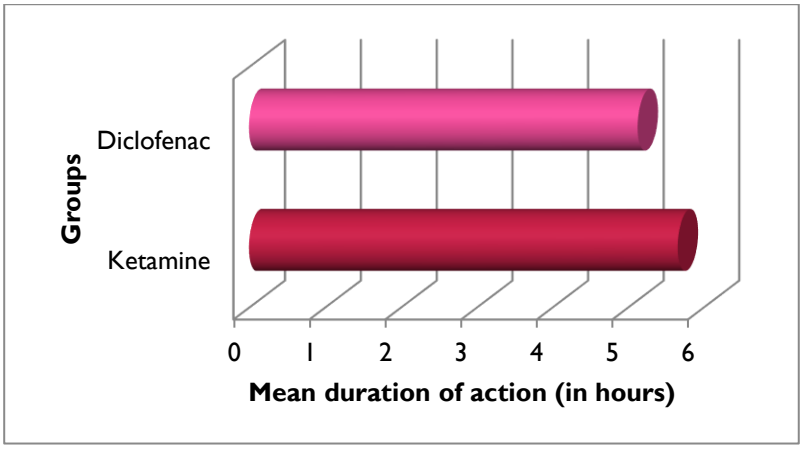

Figure 3: Line diagram comparing the VAS scores of both the drugs. Ketamine has lower VAS score than Diclofenac, indicating that Ketamine had better pain relief compared to Diclofenac, and is statistically significant. (P=0.00).

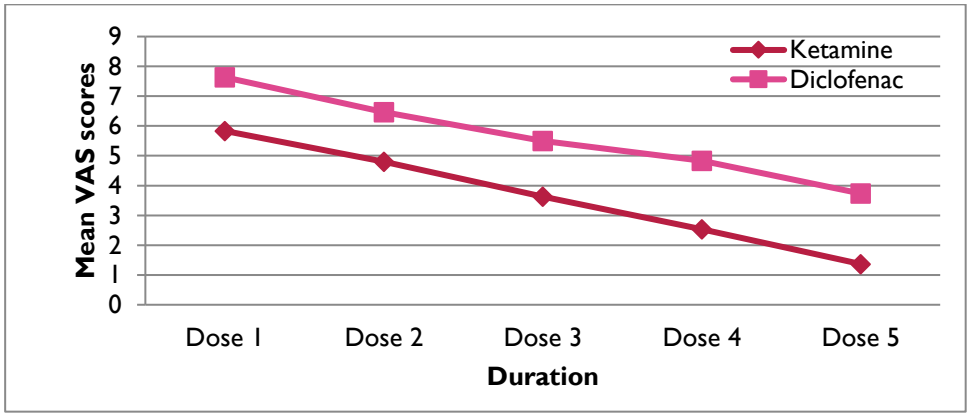

Table 1: Table showing the VAS scores in both study groups and VAS difference.

T-Test

Group Statistics					
	DRUG	**N**	**Mean**	**Standard Deviation**	**Standard Error Mean**
VAS 1	**Ketamine**	30	5.8333	1.17688	.21487
	Diclofenac	30	7.6333	.61495	.11227
VAS 2	**Ketamine**	30	4.8000	1.09545	.20000
	Diclofenac	30	6.4667	.77608	.14169
VAS 3	**Ketamine**	30	3.6333	1.21721	.22223
	Diclofenac	30	5.5000	.86103	.15720
VAS 4	**Ketamine**	30	2.5333	1.47936	.27009
	Diclofenac	30	4.8333	1.08543	.19817
VAS 5	**Ketamine**	30	1.3667	1.44993	.26472
	Diclofenac	30	3.7333	1.33735	.24417
VAS DIFFERENCE	**Ketamine**	30	4.4667	.97320	.17768
	Diclofenac	30	3.9000	1.15520	.21091

Table 2: Table showing the significance of VAS difference. It shows that the VAS difference between the two groups is statistically significant and Ketamine has lower VAS score and thus better pain relief compared to Diclofenac Sodium.

Independent T test			
	t-test for Equality		
	T	**Df**	**Sig(2-tailed)**
VAS 1	-7.425	58	.000
VAS 2	-6.800	58	.000
VAS 3	-6.857	58	.000

VAS 4	-6.866	58	.000
VAS 5	-6.572	58	.000
VAS DIFFERENCE	2.055	58	.044

Key to tables:

VAS- Visual Analogue Scale

VAS 1- Visual Analogue Scale at first dose

VAS 2- Visual Analogue Scale at second dose

VAS 3- Visual Analogue Scale at third dose

VAS 4- Visual Analogue Scale at fourth dose

VAS 5- Visual Analogue Scale at fifth dose

5. DISCUSSION

Tonsillectomy is one of the commonest procedures performed by otorhinolaryngologists the world over, and is associated with severe pain especially in the first 24 hours after surgery. A variety of surgical and anaesthetic techniques have been employed for post tonsillectomy pain relief. An ideal method of analgesia is one which reduces the pain with minimal side effects. Analgesics can be administered through various routes to relieve post tonsillectomy pain. Topical analgesia has an advantage of excellent pain relief and good patient acceptability compared to other routes of administration of drugs, especially in the immediate postoperative period. There are various studies for effective post tonsillectomy pain relief in children, but very few in adults. Also, studies demonstrated that the pain in the postoperative period following tonsillectomy is less in children compared to adults. The recovery after tonsillectomy is faster in children compared to adults. There are various studies demonstrating the efficacy of topical Ketamine in post tonsillectomy pain relief and the efficacy of topical Diclofenac in various oral conditions.

In our study, the mean onset of action of Ketamine was 3.3 minutes and that of Diclofenac was 5.4 minutes (P value 0.000). The duration of analgesia lasted for a mean of 5.66 hours for Ketamine and 5.13 hours for Diclofenac, the difference between the two being statistically significant (P value 0.007). In a study done by Canbay et al, patients were divided into 2 groups. In group C, normal saline was given as 30 ml gargle; in group K, Ketamine 40 mg was given mixed in 30 ml saline. It was shown that Ketamine gargle significantly reduced the incidence and severity of postoperative sore throat (POST).[5] Joshi G et al conducted a prospective study in which 75 patients undergoing radiotherapy were divided into 3 groups: Group K (Ketamine 20 mg in 5 ml saline); Group D (Diclofenac-dispersible tablet dissolved in 5 ml saline); Group L (Lignocaine viscous 5 ml). Patients were asked to swish and swallow this mixture 4 times a day. Patients in Ketamine group had pain relief within minutes following mouthwash.[6]

In our study, there was a significant difference in the VAS scores in both the groups after the study drugs were administered (P value 0.044). The VAS scores were significantly lower in Ketamine group compared to Diclofenac group indicating that the patients in Ketamine group had a better pain relief than in Diclofenac group. Administration of Ketamine had no significant effects on pulse rate, blood pressure as seen in a study done by Erhan OL et al in which 60 patients planned for adenotonsillectomy were included. Subjects were randomly assigned to 2 equal groups and 2 ml 0.9% saline for group S, and 0.5mg/kg Ketamine and saline 2ml in volume for group K were administered into the tonsillar region. There were no significant differences between groups according to age, sex, weight, intermittent SAP and pulse rates.[7]

In our study, the patients in the Ketamine group had their first oral feed 1.13 hours (mean) after the first dose, whereas those in Diclofenac group had after 1.71 hours (mean); the difference between the two being significant. The time of first oral intake was earlier in Ketamine group with a standard deviation (SD) of 0.61495 compared to Diclofenac group- SD of 0.66544 which was statistically significant (P=0.001). Similar results were obtained in a study by Elkahim M et al in which 50 children were randomized to receive premedication with either Ketamine 0.1 mg/kg IM or placebo given 20 min before induction of a standard general anaesthesia for tonsillectomy. Ketamine group reported significantly lower pain scores both at rest and on swallowing.[8] In our study, the time to first oral intake and duration of IV hydration were significantly shorter and the quality of oral intake was significantly better in the Ketamine group ($P < 0.05$). This observation is also supported by another study by Geeta Joshi et al in which topical Ketamine was given for pain relief in patients with radiation-induced mucositis. In this study, they showed that the patients treated with Ketamine are able to chew food earlier than those treated with Lignocaine or Diclofenac mouthwash.[6]

In our study, out of 60 patients; 2 patients in Diclofenac group and 1 patient in Ketamine group required rescue analgesic (IM Diclofenac), but this difference was not statistically significant (P value 0.237).

There were no side effects of Ketamine in our study, which is similar to a study by Mihan J Javid et al, in which Ketamine reduced postoperative analgesic medications consumption without increasing the risk of complications.[9] In a study by Dal et al, it was shown that low dose Ketamine given IV or by peritonsillar infiltration perioperatively provides efficient pain relief without side effects in children undergoing adenotonsillectomy[10]; whereas in a study by Ryan AJ, Lin F, Atayee RS which assessed the effectiveness and safety of Ketamine mouthwash for mucositis pain, Ketamine was given as a mouthwash 20 mg in 5 ml saline; out of which 4 of 8 patients had adverse effects that could have been associated with the Ketamine mouthwash; all side effects were transient and subsided when the Ketamine mouthwash was stopped.[11] In a study by Sizer C et al, post tonsillectomy pain was effectively managed with Ketamine with minimal side effects.[12] In another study by Geeta Joshi et al in which topical Ketamine was given for pain relief in patients with radiation-induced mucositis, 2 patients receiving Ketamine reported giddiness, which was transient.[6] In a study by Seyed Abbas et al, it was shown that Ketamine and Lidocaine sprays have better pain relief in post tonsillectomy patients.[13]

There were no side effects of Diclofenac in our study, which is comparable to a study by Geeta Joshi et al in which topical Ketamine, Lignocaine and Diclofenac (dispersible) were compared for pain relief in patients with radiation-induced mucositis.[6] A study by Tramer et al evaluated the efficacy and safety of a mouthwash containing Diclofenac 0.074% in patients who have undergone oral or periodontal surgery. The patients rinsed with Diclofenac mouthwash for 1 min twice a day for 7 days. There were no side effects.[14] It is also comparable to a study by Kotecha B et al in which there are no side effects of Diclofenac.[15]

6. CONCLUSION

This study showed that topical Ketamine and Diclofenac can be used in the management of post tonsillectomy pain, Ketamine being comparatively better in reducing the pain, without any adverse effects.

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