ORIGINAL ARTICLE

Comparison of analgesic efficacy of diclofenac sodium suppository over acetaminophen suppository for post tonsillectomy pain relief in pediatric age group: randomized study

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ABSTRACT

Background & Objective: Tonsillectomy in children is the most commonly performed surgery in various otorhinolaryngology departments all over. Acute postoperative pain has adverse effects on the patients' morale as well as on physiological functions of the body. We aimed to compare the analgesic efficacy of diclofenac suppository over acetaminophen suppository for post tonsillectomy pain relief in pediatric age group.

Methodology: 60 patients undergoing elective tonsillectomy were randomized into Group 'A' (diclofenac group) and Group 'B' (acetaminophen group). In diclofenac group patients received 2 mg/kg diclofenac, while in acetaminophen group patient received 20 mg/kg per rectum after induction of general anesthesia. Induction of anesthesia was same in both groups. Patients were monitored from 0 min (immediately after extubation, then after 10 min, 20 min and then 1 hourly till patients received rescue analgesic. Heart rate , mean arterial pulse, respiratory rate, pain at rest, pain on mouth opening, pain on swallowing and drowsiness were monitored. Pain was assessed by visual analogue scale (VAS) on a linear scale numbered from 0 to 10.

Results: 14 (46.67%) patients needed rescue analgesic at 11th hr in Group-A, while 16 (53.33%) patients in Group-B needed it at 8th hr, the difference being statistically significant (P<0.001). Mean time to rescue analgesia in Group-A was 11.63 hrs and in Group-B was 7.53 hrs, the difference was statistically significant (P<0.001). Visual analogue score (VAS) between the two groups showed significant increase in mean VAS in Group-B as compared to Group-A which was statistically significant. (P < 0.001).

Conclusion: We conclude that both diclofenac and acetaminophen suppositories were good postoperative analgesics when given by rectal route in pediatric age group undergoing tonsillectomy. Diclofenac sodium suppository provides better analgesia and its duration of action is longer as compared to acetaminophen suppository.

Key words: Diclofenac suppository; Acetaminophen suppository; Tonsillectomy; Postoperative pain

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INTRODUCTION

Pain in children is a complex phenomenon, as it is difficult to differentiate crying or restlessness due to pain from that of hunger or fear. Pain triggers complex biochemical and physiological stress responses and induces impairment in pulmonary, cardiovascular, neuroendocrine, gastrointestinal, immunological as well as metabolic functions.[1] Generally, oral administration is the route of choice in the daily practice of pharmacotherapy. However, in some circumstances this becomes impractical (during nausea and vomiting). Rectal route represents a practical alternative and rectal administration of drugs

is now well accepted. Tonsillectomy in children presents potential hazards related to site of operation, bleeding, respiratory complications and pain. Effective and safe analgesia in children can be provided by regional anesthetic techniques, though this is not commonly practiced technique for post tonsillectomy pain. There may be a risk of life threatening upper airway obstruction after a bilateral glassopharyngeal nerve block, the main nerve supply to the tonsil. Thus, alternative drugs and routes of administration have been sought. However, children generally dislike being inserted suppositories when awake,[2] so these are commonly inserted at anesthesia induction. In our country, both diclofenac sodium and acetaminophen suppositories re readily available, so we aimed to compare the analgesic efficacy of the former with the later suppository for post tonsillectomy pain in pediatric age group.

METHODOLOGY

After approval from the institutional ethics committee this prospective, randomized double blind study was conducted over a period of one year at our institution. Written informed consent was obtained from the patients of the children. A total of 60 patients**,** aged 5-15 years**,** ASA physical status I undergoing elective tonsillectomy under general anesthesia were randomly allocated into two groups, Group-A (diclofenac group) and Group-B (acetaminophen group) using computer generated randomization list. Exclusion criteria was inflammatory conditions of rectum and anus, anorectal bleeding, proctitis, constipation, mental retardation, allergy to diclofenac and acetaminophen. Group allocation was done by an anesthesiologist who was not the part of study design. Drugs were administered by the anesthesiologist who was not the part of data collection and analysis. In the operating room, intravenous cannula was secured and standard monitors (ECG, NIBP and SpO_2) were placed. Monitoring included heart rate (HR), mean arterial pressure (MAP), pulse-oximetry (SpO_2), and end tidal CO_2 ($EtCO_2$). All patients were premedicated with inj. glycopyrrolate 4 μg/kg, inj. ranitidine 1 mg/kg, inj. midazolam 0.03 mg/kg and inj. fentanyl 2 μg/kg.

General anesthesia was induced with pentothal sodium 4-7 mg/kg. Orotracheal intubation was facilitated by 0.1 mg/kg vecuronium. Intubation was done with the appropriate sized endotracheal tube by trained anesthesiologists in all cases. Immediately after induction of general anesthesia, either diclofenac sodium suppository (2 mg/kg) or acetaminophen suppository 20 mg/kg were introduced gently and as deep as possible in to the rectum after prior lubrication of the anal opening with K-Y jelly in patients in Group-A and Group-B respectively. Acetaminophen suppositories were available in sizes 80, 170 and 250 mg (Anamol™ suppository) while diclofenac suppositories (Jonac™ suppository) were available in sizes 12.5 mg and 100 mg. A total rectal dose as close as possible was administered by placing one or a combination of two or three suppositories. The anesthesia was maintained with sevoflorane in oxygen and nitrous oxide. Neuromuscular relaxation was maintained by intermittent bolus injections of vecuronium 0.03 mg/kg according to TOF response. At the completion of surgery, residual neuromuscular block was antagonized with neostigmine and atropine, and each patient was extubated when he/she was able to execute simple verbal command, and transferred to postanesthesia care unit (PACU). Patients were monitored from 0 min (immediately after extubation, then after 10 and 20 min, and then hourly, till patients received rescue analgesic. Pulse, mean arterial pulse and respiratory rate, pain at rest, pain on mouth opening and pain on swallowing, as well as drowsiness were monitored. Pain was assessed by visual analogue scale (VAS) on a linear scale numbered from 0 to 10 (0 - No pain, 10 - Worst pain). On the other side of the scale were face pictures with different facial expressions corresponding to the numbers on the other side. Children who were unable to co-operate and use the numbered side were assessed according to the pictures. Side effect, e.g. bleeding, nausea, vomiting, were observed in the postoperative period in the PACU and complications if any, were treated in the conventional manner. Drowsiness was monitored according to a four point scale wherein [(1) Awake, (2) Slightly drowsy, (3) Drowsy but arousable, (4) Sleeping].

Children having VAS score >5 were given syrup ibuprofen 0.5 mg/kg as a rescue analgesic and the time was noted. Study ended once the patients received the rescue analgesic.

Statistical analysis: Data were entered in Microsoft Excel. Data analysis was done with the help of PSPP software (GNU Operating System). Power of the study with the available mean and standard deviation for variables in our study was calculated and found to be more than 80%. Sample size of 30 patients in each group was deduced. For continuous data unpaired 'T' test was used for intergroup comparison, while for descriptive data Chi-square tests with Yates correction was used. Comparison between the two groups was done by applying above tests and calculating the P value. $P < 0.05$ was considered significant.

RESULTS

Our data analysis shows that age, weight and gender were comparable in both the groups ($P>0.05$) (Table 1).

Preoperative hemodynamic variables in two groups showed no significant difference ($P > 0.05$).

Postoperatively, mean pulse rate decreased from 118.20 (0

Table 1: Comparison of Age and Body weight between two groups

Variable	Group-A (Mean ± SD)	Group-B (Mean ± SD)	T-value	P-value
Age (yr)	9.53 ± 1.78	8.67 ± 1.69	1.937	0.058
Wt (kg)	21.00 ± 5.97	18.70 ± 2.54	1.944	0.057
M : F**	17 : 13	16 : 14		0.795

*Insignificant; **Pearson Chi-SquareValue 0.067

Table 2: Comparison of Pain at rest at varied time interval between Group-A and Group-B

Pain at rest	Groups		Unpaired T-test applied		
	Group-A (Mean ± SD)	Group-B (Mean ± SD)	T-value	P-value	Significance
Zero min	0.13 ± 0.35	0.03 ± 0.18	1.401	0.167	Not Significant
10 min	0.03 ± 0.18	0.03 ± 0.18	0.000	1.00	Not Significant
20 min	0.03 ± 0.18	0.10 ± 0.31	-1.027	0.309	Not Significant
1 hr	0.03 ± 0.18	0.10 ± 0.40	-0.826	0.412	Not Significant
2 hr	0.03 ± 0.18	0.10 ± 0.31	-1.027	0.309	Not Significant
3 hr	0.03 ± 0.18	0.07 ± 0.25	-0.584	0.561	Not Significant
4 hr	0.03 ± 0.18	0.10 ± 0.31	-1.027	0.309	Not Significant
5 hr	0.00 ± 0.00	0.20 ± 0.93	-1.185	0.241'	Not Significant
6 hr	0.03 ± 0.18	1.03 ± 1.94	-2.920	0.005	Significant
7 hr	0.17 ± 0.75	2.15 ± 2.34	-4.482	3.89E-05	Significant
8 hr	0.20 ± 0.93	4.28 ± 1.78	-10.604	6.09E-14	Significant
9 hr	0.17 ± 0.76	5.50 ± 0.71	-9.890	8.47E-11	Significant

min) to 86.80 (13th hr) in Group-A, and decreased from 120.40 (0 min) to 89.00 (9th hr) in Group-B. A decrease in pulse rate from baseline values was noted to be 26.44% and 26.08 in Group-A and B respectively, which was not statistically significant (P>0.05).

Similarly mean arterial pressure decreases from 86.33 (0 min) to 85.60 at 13th hr in Group-A as compared to 9th hr in Group-B. Decrease in mean arterial pressure from baseline values was 1.07% and 0.94% in Group-A and B respectively. By applying unpaired T test the difference was not statistically significant (P > 0.05).

Mean respiratory rate decreased from 21.67/min (0 min) to 16/min (13th hr) in Group-A, while 21.80 (O min) to 17.00(9th hr) in Group-B. Group-A shows 26.16% and Group-B shows 22.01 % decrease in respiratory rate from their baseline values . Our data analysis shows that neither of the two drugs shows respiratory depression.

Pain score at rest showed that, pain scores were significantly less in both the groups till 5th hr. (mean VAS in Group-A 0.00 and Group-B 0.2) and the difference between the two groups was not significant (P>0.05). In Group-B, there was increase in pain from 6th hr, with significant increase seen at 9th hr (mean VAS = 5.50). By applying unpaired T test difference was statistically significant (P<0.001). Pain increased in Group-A from 10th hr onwards but no significant increase in pain was seen even till 13th hr (mean VAS = 4.8) (Table 2).

Pain Score on mouth opening showed that pain scores were significantly less in both the groups till 5th hr (mean VAS in Group-A 0.00 and in Group-B 0.23) and the difference between the two groups was not significant (P > 0.05). In Group-B, there was increase in pain from 6th hr (mean VAS 1.27) with significant increase seen at 8th and 9th hr (mean VAS 8th hr 5.56, 9th hr 6.50), which was statistically significant (P < 0.001). Pain increased in Group-A from 10th hr (mean VAS 0. 76) but significant increase was seen at 12th and 13th hr. (Mean VAS 12th hr

Table 3: Comparison of mean pain (VAS) scores on mouth opening at varied time intervals

Time interval	Group-A (Mean ± SD)	Group-B (Mean ± SD)	T-value	P-value	Significance
0 min	0.23 ± 0.63	0.13 ± 0.51	0.680	0.499	Not Significant
10 min	0.10 ± 0.40	0.07 ± 0.37	0.336	0.738	Not Significant
20 min	0.17 ± 0.53	0.40 ± 0.86	-1.270	0:209	Not Significant
1 hr	0.07 ± 0.37	0.07 ± 0.37	0.000	1.000	Not Significant
2 hrs	0.07 ± 0.37	0.20 ± 0.61	-1.027	0.309	Not Significant
3 hrs	0.07 ± 0.37	0.23 ± 0.63	-1.260	0.213	Not Significant
4 hrs	0.07 ± 0.37	0.20 ± 0.61	-1.027	0.309	Not Significant
5 hrs	0.00 ± 0.00	0.23 ± 0.97	-1.316	0.193	Not Significant
6 hrs	0.10 ± 0.40	1.27 ± 2.36	-2.937	0.005	Significant
7 hrs	0.23 ± 0.97	2.81 ± 2.80	-4.881	9.75E-06	Significant
8 hrs	0.27 ± 1.14	5.56 ± 1.62	-13.686	7.85E-18	Significant
9 hrs	0.38 ± 1.21	6.50 ± 0.71	-7.328	4.51E-08	Significant

Table 4: Comparison of mean pain (VAS) scores on swallowing at varied time intervals

Time interval	Group-A (Mean ± SD)	Group-B (Mean ± SD)	T-value	P-value	Significance
0min	0.43 ± 1.01	0.30 ± 0.92	0.537	0.593	Not Significant
10 min	0.53 ± 1.11	0.17 ± 0.65	1.567	0.123	Not Significant
20 min	0.60 ± 1.00	1.07 ± 1.46	-1.442	0.155	Not Significant
1 hr	0.30 ± 0.79	0.57 ± 1.17	-1.036	0.305	Not Significant
2 hrs	0.07 ± 0.37	0.27 ± 0.83	-1.211	0.231	Not Significant
3 hrs	0.10 ± 0.55	0.17 ± 0.65	-0.430	0.668	Not Significant
4 hrs	0.10 ± 0.55	0.20 ± 0.76	-0.584	0.561	Not Significant
5 hrs	0.00 ± 0.00	0.40 ± 1.25	-1.755	0.085	Not Significant
6 hrs	0.13 ± 0.51	1.43 ± 2.69	-2.922	0.005	Significant
7 hrs	0.17 ± 0.91	3.27 ± 3.24	-5.020	5.97E-06	Significant
8 hrs	0.30 ± 1.21	6.67 ± 1.94	-14.800	4.12E-19	Significant
9 hrs	0.28 ± 1.07	7.50 ± 0.71	-9.364	2.87E-10	Significant

-5.11, 13th hr -6.00). (Table 3)

Pain score on swallowing: Pain scores were significantly less in both the groups till 5th hr (mean VAS Group-A- 0.00 and Group-B- 0.4) and difference between the two groups was not significant (P>0.05). In Group-B, there is increase in pain from 6th hr (mean VAS -1.43) with significant increase was seen at 8th and 9th hr (mean VAS 8th hr-6.67 and 9th hr-7.50) which was statistically significant (P<0.001). Pain increased from 10th hr onwards (mean VAS 0.86) in Group-A, but significant increase was seen at 12th and 13th hr (mean VAS 12th hr - 6.00 and 13th hr - 7.40) (Table 4).

Mean VAS scores between the two groups were comparable till 5th hr (mean VAS, Group-A = 0.00 and Group-B = 0.83), but there was a significant difference between mean VAS in both the groups from 6th hr. onwards with significant increase in mean VAS in Group-B at 8th and 9th hrs (mean VAS 8th hr-5.50 and 9th hr. 6.50), whereas in Group-A from 11th to 13th hrs (mean 11th hr- 6.93, 12th hr. - 9.50, 13th hr. - 6.20) which was statistically significant (P < 0.001) (Table 5).

14 patients received rescue analgesic at 11th hr in Group-A, while 16 patients received rescue analgesic in Group-B at 8th hr. By applying chi-square test, the difference was statistically significant (P < 0.001).

Mean time to rescue analgesia was 11.63 ± **1.07** hrs and 7.53 ± **0.82** hrs in in Group-A and B respectively, the difference was statistically significant (P < 0.001).

Table 5: Comparison of mean VAS scores at varied time intervals between Group A and B

Time interval	Group-A (Mean ± SD)	Group-B (Mean ± SD)	T-value	P-value	Significance
Zero min	0.80 ± 1.94	0.47 ± 1.48	0.749	0.45	Not Significant
10 min	0.67 ± 1.47	0.27 ± 0.98	1.240	0.220	Not Significant
20min	0.80 ± 1.32	1.57 ± 2.27	-1.598	0.115	Not Significant
1hr	0.40 ± 1.22	0.73 ± 1.62	-0.901	0.371	Not Significant
2hr	0.17 ± 0.65	0.57 ± 1.28	-1.529	0.132	Not Significant
3hr	0.20 ± 1.10	0.47 ± 1.33	-0.847	0.401	Not Significant
4hr	0.20 ± 1.10	0.50 ± 1.38	-0.931	0.356	Not Significant
5hr	0.00 ± 0.00	0.83 ± 2.97	-1.536	0.130	Not Significant
6hr	0.00 ± 0.00	1.24 ± 2.33	-2.929	0.005	Significant
7hr	0.17 ± 0.91	2.73 ± 2.78	-4.771	1.44E-05	Significant
8hr	0.20 ± 1.10	5.50 ± 1.65	-13.372	1.85E-17	Significant
9hr	0.24 ± 0.99	6.50 ± 0.71	-8.742	1.27E-09	Significant

Side effects, such as nausea, vomiting, were minimal i.e. 1% in both of the groups. Postoperative bleeding was not observed in any of the groups. Drowsiness was observed in both groups up to 20 min of postoperative period. The drowsiness scores dropped from 2 (slightly drowsy) at zero min to 1 (completely awake) at 20 min, but the difference between the two groups was not significant ($P > 0.05$).

DISCUSSION

Tonsillectomy with or without adenoidectomy is one of the most common surgical procedures performed in children. Potential hazards related to the procedure include bleeding, respiratory complications and pain. Pain is the most significant obstacle to the rehabilitation of a patient following tonsillectomy, influencing the length of hospital stay and ability to return to normal activity.[3]

Pain in tonsillectomy patients is heightened on mouth opening and swallowing because the muscles used for swallowing e.g. palatoglossus, palatopharyngeus, styloglossus, superior constrictor etc. are in close relation with the tonsils. Hence the dissection for tonsillectomy for removal of the tonsils leads to spasm of these muscles making swallowing painful and difficult. We therefore, included and assessed there specific parameters in our study; pain at rest, pain on mouth opening, and pain on swallowing.

With the introduction of non- steroidal anti-inflammatory drugs (NSAID's) may of the above problems were overcome. Owing to their mechanism of action, they prove to be particularly useful in conditions where a degree of tissue inflammation contributes to pain. Most of these NSAID's are available as oral and injectable preparations. Intramuscular injections of analgesics are not quite acceptable to small children, keeping in mind the fear of painful needle pricks as well as injection abscesses.

The introduction of the suppository formulation of therapeutic agents has been a real breakthrough in pain management. Duration of analgesia is longer because of first pass metabolism, administration is easy and incidence of systemic side-effects is much less. Peak plasma concentrations of diclofenac sodium suppository[4] are reached after 90 to 150 min after insertion of suppository while peak plasma concentration of acetaminophen suppository[5] are reached after 60 to 240 min after insertion. We placed both the suppositories immediately after induction of anesthesia.

Available NSAID's are aspirin, indomethacin, diclofenac sodium, ibuprofen, ketorolac, acetaminophen etc. Diclofenac sodium has analgesic and anti-inflammatory properties while acetaminophen has analgesic and weak anti-inflammatory properties. Both lack sedative properties which is an advantage after upper airways surgeries, where fully awake patient is desirable. We therefore, decided to compare the analgesic efficacy of diclofenac sodium suppository with acetaminophen suppository to let us decide which one to be used in routine.

We found that both diclofenac and acetaminophen were good postoperative analgesics when given by rectal route. Diclofenac sodium provides better analgesia and duration of action is longer as compared to acetaminophen. Tawalbeh MI, Nawasreh OO[6] et al. studied diclofenac sodium and paracetamol for the treatment of pain after adenotonsillectomy in children. They found diclofenac sodium had a significant effect on decreasing the pain associated with swallowing postoperatively and on the

general condition of the patient. These finding were consistent with our study. In our study mean VAS scores were significantly higher in acetaminophen group. Also duration of analgesia was longer in diclofenac group than acetaminophen group. Mean time to rescue analgesia in Group-A was 11.63 hrs and in Group-B was 7.53 hrs, the difference was statistically significant.

Bhagat et al[7] studied preoperative rectal diclofenac for perioperative analgesia in ENT surgery. The study concludes the use of preoperative rectal diclofenac has substantial effect as an adjunct intraoperative analgesic. It considerably delays the onset of postoperative pain, and is adequate as a sole analgesic for early postoperative period. In our study 14 patients received rescue analgesic at 11th hr. in Group-A, while 16 patients received rescue analgesic in Group-B at 8th hr.

Side effects like nausea, vomiting, were seen to be very minimal i.e. 1% incidence in both the groups. Drowsiness was seen in both the groups up to 20 min of postoperative period but the difference between the two groups was not significant. Drowsiness in early postoperative period may be due to due to effect of general anesthetic agents. Our data analysis shows that neither of the two groups had any effect on postoperative consciousness.

As we compared the above findings with the available literature in the field, we found that in 1988, Waters and Patterson studied effect of diclofenac sodium for post tonsillectomy pain in children. In a double-blind study, comparing diclofenac with a pethidine and a control group, diclofenac was shown to be effective analgesic. No significant difference in analgesic efficacy was demonstrated between the two drugs, although patients who received diclofenac tended to be less drowsy postoperatively than those who received pethidine. Both the groups showed vomiting in later period in their study. They have suggested that swallowed blood, sore throat and fluid intake had more influence than the analgesic drugs.[8]

Alternative options for pain relief in children are non-opioid and opioid analgesics. Non-opioid analgesic includes acetaminophen 10 - 20 mg/kg which can be given by oral, intravenous or rectal route. NSAIDs include diclofenac sodium 1 - 2 mg/kg (oral, rectal, intramuscular or intravenous routes) and ketorolac 0.5 mg/kg (intravenous route) is another group of drugs. Tramadol 1-2 mg/kg (oral and intravenous) and opioid analgesics including fentanyl 2 μg/kg (intravenous route).

LIMITATIONS

Our study had some notable limitations including a small sample size, under-dosing or overdosing of the drugs used due to fixed preparations in suppository form. Future scope: the analgesic suppositories due to efficacy and ease of administration under anesthesia can be used in all pediatric surgery patients.

CONCLUSION

Rectal route of administration is easy and effective way of administration with least side effects for both diclofenac sodium and acetaminophen .The suppository form of diclofenac sodium is better than acetaminophen suppository for post tonsillectomy analgesia in view of its longer duration of action and good analgesic effect.

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Conflict of Interest: None

Authors' contribution: PU: Conduction of study work; VT: Concept.

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