



# International Journal of Medical Anesthesiology

E-ISSN: 2664-3774

P-ISSN: 2664-3766

[www.anesthesiologypaper.com](http://www.anesthesiologypaper.com)

IJMA 2019; 2(2): 91-93

Received: 13-05-2019

Accepted: 17-06-2019

**Dr. D Satyanarayana**

Assistant Professor, M.D.

Department of Anesthesiology,

SVRRGGH / S.V. Medical

College, Tirupati, Andhra

Pradesh, India

**Dr. D Obulopathy**

Assistant Professor, M.S.

Department Orthopaedics,

S.V. Medical College Tirupati,

Andhra Pradesh, India

## A comparative study of efficacy of diclofenac sodium and paracetamol as rectal suppositories in post-operative pain relief in children undergoing adenotonsillectomy

**Dr. D Satyanarayana and Dr. D Obulopathy**

DOI: <https://doi.org/10.33545/26643766.2019.v2.i2b.36>

### Abstract

**Background:** Due to less compliance in children to injectables, under treatment of post-operative pain occur in a substantial percentage of children. Such pain in children may pose cardiovascular, respiratory and metabolic disturbances in the immediate post operative period and anxiety, fear, and sleep disturbances in later life.

**Aim and Objectives:** To assess and compare the analgesic efficacy of Diclofenac sodium and Paracetamol, administered as rectal suppositories, during immediate post-operative period in children undergoing adenotonsillectomy.

**Materials and Methods:** A total of 100 ASA grade I / II Children in the age group of 5 – 12 years admitted to undergo elective adenotonsillectomy were included in this study and allocated to two groups of 50 each. Group D patients received Diclofenac 1mg./ Kg 8<sup>th</sup> hourly and Group P received paracetamol 40mg/kg bolus dose, 20mg/kg every 6<sup>th</sup> hourly suppositories for post-operative pain relief. Postoperative pain assessment was done with Objective pain scale and scoring system every 2 hours for a period of 24 hours.

**Results:** The 4<sup>th</sup> hourly mean of the pain scores were almost the same in both the groups. Also none of the patients had a pain score of more than 5 and hence none of them received rescue analgesics.

**Conclusion:** Diclofenac sodium and Paracetamol, administered as rectal suppositories, in children undergoing adenotonsillectomy are effective means of pain relief during immediate post-operative period. Both the drugs are equal on their analgesic efficacy.

**Keywords:** Diclofenac sodium, Paracetamol, Aden tonsillectomy, Analgesic efficacy

### Introduction

Using rectal suppository for an anaesthetized child for post-operative pain relief will be amenable to avoid injections. And further 50% of the drug absorbed from the rectum will bypass the liver. So the potential for hepatic first pass metabolism thus is less than that for an oral dose <sup>[1]</sup>.

**Study area and design:** This study was conducted as a prospective interventional study, in the department of anesthesiology at SVRR Govt. General Hospital, Tirupati a tertiary referral hospital attached to S.V. Medical College, Tirupati. The study was conducted from July 2017 to March 2019 over a period of 20 months.

**Aim and Objectives:** To assess the analgesic efficacy of Diclofenac sodium and Paracetamol, administered as rectal suppositories, during immediate post-operative period in children undergoing adenotonsillectomy. This study also compared the analgesic efficacy of Diclofenac 1mg./ Kg 8<sup>th</sup> hourly with that of paracetamol 40mg/kg bolus dose, 20mg/kg every 6<sup>th</sup> hourly for post-operative pain relief.

### Materials and Methods

A total of 100 children undergoing adenotonsillectomy were included in this study. Surgical indication and the consent of willingness of the parents were taken as inclusion criteria. A written consent was obtained from the parents. The surgeons were informed and acceptance gained at each procedure. Exclusion criteria consisted of bleeding diathesis, Bronchial asthma, inflammatory lesions of the rectum and anal canal, use of NSAID's within 10 days prior to the surgery and those with history of allergy to any of the NSAIDs.

**Corresponding Author:**

**Dr. D Obulopathy**

Assistant Professor, M.S.

Department Orthopaedics,

S.V. Medical College Tirupati,

Andhra Pradesh, India

Hb%, Total count, Differential count, Bleeding time, Clotting time and urine for albumin and sugar were done as pre operative investigations. The children were assessed for anesthetic fitness as out-patients. ASA grade I and II children were selected. For all children, pre-operative starvation was for a period of 6 hours. Baseline BP, PR and SpO2 were recorded. Patients were alternately allocated into two groups. Other confounding factors were excluded unbiased.

Group P: Receiving Paracetamol suppository 40mg/kg as loading dose  
20mg/kg, 6th hourly  
Group D: Receiving Diclofenac 1mg/kg, suppository, 8th hourly

All the children received Inj. Glycopyrrolate 0.01mg/kg and Inj. Midazolam 0.1mg/kg intramuscularly 45 minutes prior to surgery as pre medication. The total surgical procedure was done under general anesthesia. The total duration of the surgical procedure and blood loss were noted. Intra-operative fluid therapy was done according to Holiday and Segar 4:2:1 formula. Patients were extubated and post-operative suppositories were kept 6<sup>th</sup> hourly for Group P and 8<sup>th</sup> hourly for Group D.

Postoperative pain assessment was done with Objective pain scoring system every 2 hours for a period of 24 hours. If the pain scoring was more than 5, we had planned to give Inj Tramadol 1mg/kg as rescue analgesic. Post-operative pain assessment was done by an observer blinded to the study.

**Objective pain scale and scores**

**Table 1:** Objective pain scale and scores

Observation	Criteria	Score
Systolic blood pressure	± 10 % of Pre-op value	0
	>20% of Pre-op value	1
	>30% of Pre-op value	2
Crying	Not crying	0
	Crying but responds to TLC *	1
	Crying not responds to TLC*	2
Movement	None	0
	Restless	1
	Thrashing around	2
Agitation	Asleep or calm	0
	Mild agitation	1
	Hysterical	2
Verbalization of Pain	Asleep, States no pain	0
	Vague, Can't localize	1
	Localize pain	2

**Observations and Results**

Hundred ASA grade I and II patients were taken up in this study. Among them, 50 belonged to Group D, diclofenac group and 50 belonged to Group P, Paracetamol group. All children were in the age group of 5-12 years. In the postoperative period they were monitored by an observer blinded to the study.

Age and sex distribution:

From table 1, it is clear that the number of children between 5 and 8 years, between 9 and 12 years are very close. This shows that the age was not a confounding factor. The sex distribution of the patients is shown in table 2.

**Table 2:** Age distribution in Childrens

Age in years	No. of Patients	
	Group D	Group P
5-8 years	23	19
9-12 years	27	31

**Table 3:** Sex Distribution

Sex	Group D		Group P	
	No. of patients	(%)	No. of patients	(%)
Male	28	56%	30	60%
Female	22	44%	20	40%

The sex distribution in both the groups is also not much different. Hence there is no bias in the age and sex distribution.

**The mean duration of surgery**

Both values are almost the same in both the groups (Table 3). This means that there was no difference in the duration of surgery in both the groups. All the surgeries were done by surgeons of equal experience in the field and they followed the same technique. None of the surgeries were unusually prolonged for the reason of bleeding.

**Table 4:** Mean pain scores of Diclofenac & Paracetamol

	Mean duration of surgeries (in minutes) ± SD
Group D	39.6 ± 8.050
Group P	39.34 ± 7.952

**Mean pain scores**

Table 4 and 5 show the mean pain scores at 4,8,12,16,20 and 24 hours of post-operative duration recorded for Group D and Group P respectively.

Statistics – Group D

(D – Diclofenac, Numbers represent hours)

**Table 5:** Mean pain scores of Diclofenac at different time intervals

	Mean D4	Mean D8	Mean D12	Mean D16	Mean D20	Mean D24
N Valid Missing	50 0	50 0	50 0	50 0	50 0	50 0
Mean	1.0700	1.3300	1.3400	1.2300	1.3300	1.3200
Median	1.0000	1.5000	1.5000	1.0000	1.5000	1.0000
S.D	0.3196	0.4803	0.5194	0.3228	0.4908	0.5322

Statistics – Group P (P- Paracetamol, Numbers represent hours)

**Table 6:** Mean pain scores of Paracetamol at different time intervals

Table 5	Mean D4	Mean D8	Mean D12	Mean D16	Mean D20	Mean D24
N Valid Missing	50 0	50 0	50 0	50 0	50 0	50 0
Mean	1.1900	1.4400	1.5500	1.3900	1.4100	1.2800
Median	20.5000	1.2500	1.5000	1.5000	1.5000	1.0000
S.D	0.4151	0.6197	0.5912	0.5080	0.5411	0.5639

The pain scoring was done once every 2 hours by an observer blinded to the study for 24 hours using the objective pain scale. In this sample only the 3rd Pair i.e at 12th hour the pain score is higher in Group P (1.55) when compared to Group D (1.34) which is statistically significant marginally (P=0.043 of < 5). There is no significant difference in pain scores in both the groups.

## Discussion

This study was a randomized single blinded trial. It was conducted to compare the analgesic efficacy of diclofenac and paracetamol for post tonsillectomy pain. There were 50 patients in each group. Group D received 1mg/kg of Diclofenac suppository 8th hourly and group P received Paracetamol suppositories of 40 mg/kg loading dose and 20mg/kg 6th hourly. The pain scores were evaluated 2 hourly by the objective pain scale. The 4th hourly mean of the pain scores were almost the same. There was no difference in the pain scores in both the groups as is evident from the statistical analysis using the student's t-test and paired sample test. This means that Diclofenac offered no special advantage over Paracetamol and the analgesic efficacy of both the drugs was equal. These results correlated well with study results obtained by A.Schmidt *et al.* [18].

In this study none of the patients had increased blood loss as assessed by the surgeons and the duration of the surgery. None of the patients were taken up for post tonsillectomy bleed. All the surgeries were performed by surgeons of similar experience in the field and using same technique. Also none of the patients had a pain score of more than 5 and hence none of them received rescue analgesics.

These results also correlate well with the study results obtained by Romsing *et al.* [12]. They reported that Diclofenac was no more effective than high dose acetaminophen for analgesia but Diclofenac resulted in a lower incidence of nausea and vomiting in patients following tonsillectomy. But they compared oral preparations which may have some practical difficulty in administering as these patients have pain on swallowing.

The study by Baer *et al.* [4] and another study by Tawalbeh *et al.* [6] suggested that diclofenac was better than paracetamol. But in the Baer *et al.* group, they used a lower dose of acetaminophen than in this study. Tawalbeh *et al.* had compared an oral preparation with rectal diclofenac. As there will be pain on swallowing in the post operative period, comparing results of rectal diclofenac with an oral paracetamol, may not be appropriate.

Regarding blood loss and NSAIDs the study by A.schmidt *et al.* [9] has stated that there is increased blood loss with diclofenac as pre operative analgesic. This was also noted by P.M. Robinson *et al.* [5]. But a comprehensive analysis done by Steen meinche *et al.* from 25 studies suggest that there is no evidence supporting increased intra operative blood loss or increased post operative bleeding or re admission because of bleeding. In this study also there were no cases of reactionary haemorrhage and none of the patients required surgical control for bleeding post operatively.

## Conclusion

Diclofenac sodium and Paracetamol, administered as rectal suppositories, in children undergoing adenotonsillectomy are effective means of pain relief during immediate post-operative period. Both the drugs are equal on their analgesic efficacy. There was no significant increase in bleeding with the rectal diclofenac group.

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