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

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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 Diclofinac 1mg./ Kg 8th hourly and Group P received paractemol 40mg/kg bolus dose, 20mg/kg every 6th 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 4th 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, Paracetmol, 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 [1].

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, Tiruapti. 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 Diclofinac 1mg./ Kg 8th hourly with that of paractemol 40mg/kg bolus dose, 20mg/kg every 6th 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.
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 6th hourly for Group P and 8th 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 | Group D | Group P |
|--------------|---------|---------|
| 5-8 years    | 23      | 19      |
| 9-12 years   | 27      | 31      |

**Table 3: Sex Distribution**

| Sex         | Group D | (%)    | Group P | (%)    |
|-------------|---------|--------|---------|--------|
| 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**

| Time       | Mean D4 | Mean D8 | Mean D12 | Mean D16 | Mean D20 | Mean D24 |
|------------|---------|---------|----------|----------|----------|----------|
| 2          | 0.50    | 0.50    | 0.50     | 0.50     | 0.50     | 0.50     |
| N Valid Missing | 50.0  | 50.0    | 50.0     | 50.0     | 50.0     | 50.0     |
| Mean       | 1.0700  | 1.3300  | 1.3400   | 1.3300   | 1.3300   | 1.3200   |
| Median     | 1.0000  | 1.5000  | 1.5000   | 1.5000   | 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**

| Time       | Mean D4 | Mean D8 | Mean D12 | Mean D16 | Mean D20 | Mean D24 |
|------------|---------|---------|----------|----------|----------|----------|
| 2          | 0.50    | 0.50    | 0.50     | 0.50     | 0.50     | 0.50     |
| 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.

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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. [13].

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. [14] 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 meinech 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.

References
1. Hanallah RS. Post operative analgesia in paediatric patients. Canadian Journal of Anaesthesia. 1992; 39:649-54.
2. Dommerby H, Rasmussen OR. Diclofenac – pain relieving effect after tonsillectomy. Actaotolaryngol. 1984; (1-2):185-92.
3. Watters CH, Patterson CC, Mathews HM, Campbell W. Diclofenac sodium for post tonsillectomy pain in children. Anaesthesia. 1988; 43(8):641-3.
4. Baer GA, Rasarius MG, Kolehmainen S, Selms. The effect of paracetamol or diclofenac administered before operation on post operative pain and behaviour after adenoidectomy in small children, Anaesthesia. 1992; 47(12):1078-80.
5. Robinson PM, Ahmed I. Diclofenac and post tonsillectomy haemorrhage. Clinical otolaryngology. 1994; 19(4):344-345.
6. Tawalbeh MI, Nawasreh OO, Husban AM. Comparative study of diclofenac sodium and paracetamol for treatment of pain after adenotonsillectomy in children. Saudi Medj. 2001; 22(2):121-3.
7. Bone ME, Fell D. A comparison of rectal diclofenac with intramuscular Papaveretum or placebo for pain relief following tonsillectomy. Anaesthesia. 1988; 43(4):277-80.
8. Swamepoel P, Semple, Oral versus rectal diclofenac for postoperative tonsillectomy pain in children. Anaesthesia. 1999; 54:297-310.
9. Schmidt A, Bjorkman S, Akeson J. Pre operative rectal diclofenac versus paracetamol for tonsillectomy; effects on pain and blood loss. Acta Anaesthesiol Scand. 2001; 45:48-52.
10. Ewah BN, Robb PJ, Raw M. Post operative pain, nausea and vomiting following paediatric day care tonsillectomy. Anaesthesia. 2006; 61:116-122.
11. Moores MA, Wandlers JG, Fell D. Paediatric post operative analgesia. A comparison of rectal diclofenac with caudal bupivacaine after inguinal herniotomy, Anaesthesia. 1990; 45(2):156-8.
12. Steen Meinech, Janne Romsing, Jorgen Martin R, Tramer. NSAIDS and the risk of operative site bleeding after tonsillectomy, Anaesthesia and Analgesia. 2003; 96:68-77.
13. Lau H, Wong C, Goh LC, Patil NG, Lee F. Prospective randomized trial of pre- emptive analgesics following ambulatory inguinal hernia repair: intravenous ketorolac versus diclofenac suppository. PMID: 12534378
14. Romsing J, Ostergaard D, Drozoziewic D, Schultz ZP, Rayn G. Diclofenac or acetaminophen for analgesia in paediatric tonsillectomy out patients.