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Comparison of Single Dose Diclofenac Sodium Vs Paracetamol Suppository for Pain Relief Following Inguinal Surgery in Children

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Abstract

Context: Management of post-operative pain in children is challenging due to the side effects of the drugs like opioids and pain during intramuscular administration. *Aims:* To compare the quality of post-operative analgesia between rectally administered paracetamol and diclofenac as Assessed by Pain Discomfort Scale (APDS). *Settings and Design:* We compared the efficacy of pre-operatively administered rectal paracetamol 40 mg/kg and diclofenac 1 mg/kg. in 60 randomised children undergoing elective inguinal hernia surgeries. *Materials and Methods:* The patients were given general anesthesia with fentanyl for intra-operative pain relief. Post-operative pain was assessed using AIIMS Pain and Discomfort Scoring system (APDS) and the duration of analgesia was noted. *Statistical analysis used:* The difference between the Paracetamol and Diclofenac Group with respect to duration of analgesia, intra-operative fentanyl use and heart rate at awakening was compared using independent t-test. APDS score was compared using Mann Whitney's test. A p-value < 0.05 was considered significant. *Results:* Intra-operative fentanyl requirement was similar in both the Groups. Post-operative pain scores were lower in Diclofenac Group. Duration of analgesia was longer in Diclofenac Group compared to Paracetamol Group (12.5 hrs vs 7.6 hrs). Three patients in Diclofenac Group had vomiting and gastritis. *Conclusions:* Better post-operative pain relief of 1 mg/kg of rectal diclofenac without significant bleeding makes it an attractive option for management of post-operative pain in children. However, anti-gastritis prophylaxis may be desirable to prevent the complications.

Keywords: Rectal Diclofenac; Paracetamol; Post-operative Pain; Children.

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Introduction

Post-operative pain management in a pediatric patient is challenging. Classically, NSAIDs and opioids have been used in this setting. However, opioids cause sedation, respiratory depression and emesis which are undesirable in an already drowsy and uncomfortable patient. Intramuscular NSAIDs are obviously unacceptable due to the pain during administration. Oral administration, on the other hand, is difficult especially if the patient is drowsy and because it may accentuate the tendency to vomit. In this scenario, rectal administration of drugs looks very desirable. NSAIDs and paracetamol are drugs which have been used rectally to effectively manage the post-operative pain.[1] Moreover, these drugs when administered immediately after the induction of anesthesia, may

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reduce the intra-operative requirement of opioids there by, reducing the sedation in the immediate post-operative period.

This study was designed to compare the quality of post-operative analgesia between rectally administered paracetamol and diclofenac sodium.

Materials and Methods

After getting Institute Ethics Committee approval and consent from the parents, sixty patients aged more than *2 years* undergoing elective inguinal surgery under ASA I were included in the study. The patients who had hypersensitivity to either of the two drugs, gastritis, bleeding disorders, those who are having renal, liver or cardiac disease or those who were ASA II or above were not included in the study. The patients were randomised by sealed envelope technique to Group I (Paracetamol) and Group II (Diclofenac sodium). The patients were pre- medicated with oral midazolam *0.5 mg/kg thirty minutes* before surgery and induced with sevoflurane before an appropriate size laryngeal mask airway was inserted. Fentanyl was given at *1 μgm/kg*. Before surgery, rectal suppository was inserted depending on the group the patient belonged to by an investigator who was aware of randomization but was not involved in any aspect of assessment of the patients. Diclofenac was given at a dose of *1 mg/kg* and paracetamol at *40 mg/kg* dose. Anesthesia was maintained with sevoflurane and nitrous oxide. If at any time there was evidence of inadequate analgesia with heart rate or blood pressure rising more than 20% above baseline, fentanyl at a dose of *0.2 μgm/kg* I.V. increments was given. At the end of the procedure LMA was removed and the patient was shifted to recovery room for *30 minutes* before transferring to the post-operative ward.

The APDS score (AIIMS Pain and Discomfort Score)[2] was recorded at *0.5, 2, 4, 8, 12* and *24 hours* after the end of the surgery. Whenever the child had an APDS score of 4 or more a rescue dose of analgesia was administered. The time interval between the insertion of suppository and the first analgesic dose was calculated as the duration of analgesia. Rescue analgesia was given in the form of I.V. paracetamol at a dose of *15 mg/kg*.

Method of Analysis

Sample size was calculated using PS software version 2.1.31 assuming a minimum clinical difference of 3. Alpha value of 5% and power of 80% was set. Sample size was calculated as 29.

The analysis was done using SPSS Version 17. The data was summarized using descriptive statistics such as mean, median, standard deviation, interquartile range and proportions. The difference between the paracetamol and Diclofenac Group with respect to duration of analgesia, intra-operative fentanyl use and heart rate at awakening were compared using independent *t*-test. APDS score was compared using Mann Whitney's test. A p-value < 0.05 was considered significant. For comparing categorical variable like sex, Chi-square test was used in **Table 1**.

Table 1: APDS Scoring system

Respiratory rate	+ 20% of pre-operative	0
	+ 20–50% of pre-operative	1
	>+ 50% of pre-operative	2
Heart rate	+ 10% of pre-operative	0
	+ 20% of pre-operative	1
	+ 30% of pre-operative	2
Discomfort	Calm	0
	Restless	1
	Agitated	2
Cry	No cry/cry respond to water food or parental presence	0
	Responds to tender loving care	1
	Not responds to tender loving care	2
Pain at the site of operation	No pain	0
	States pain vague	1
	Can localize pain	2

Results

For all 60 patients enrolled in the study, demographic and clinical data are shown in **Table 2**. There was no significant difference among the groups with respect to age, weight, sex and duration of surgery.

Table 2: Demographic and Clinical data

Parameters	Paracetamol (n = 30)	Diclofenac (n = 30)	p value
Age (*years*)	6.1 (2.9)	6.0 (2.8)	0.85
Weight (*kg*)	17.2 (5.1)	17.7 (5.4)	0.73
Male : Female	21 : 9	24 : 6	0.55
Duration of surgery (*min*)	21.2 (5.3)	20.8 (4.1)	0.80

Data expressed as mean (SD).

Fentanyl requirement (**Table 3**) was similar in both the Groups during the surgery and till *30 min* after surgery (Diclofenac group 1.4 mg/kg, Paracetamol group 1.4 mg/kg).

Table 3: Fentanyl consumption during intra-operative period, duration of action of paracetamol and diclofenac suppository, HR and APDS score at *30 min* interval.

Parameters	Paracetamol (n = 30)	Diclofenac (n = 30)	p-value
Fentanyl consumption (*μg/kg*)	1.4 (0.2)	1.4 (0.2)	0.654
Duration (*hours*)	7.6 (1.6)	12.5 (4.0)	<0.001
HR at *30 min* (beats *per minute*)	104.2 (19.9)	101.4 (12.2)	0.520
APDS at *30 min*	2.9 (1.8)	1.3 (1.3)	<0.001

Data are expressed as mean (SD).

Pain scores **(Fig. 1)** were significantlylower for the diclofenac group post-operatively compared to Paracetamol Group. APDS score at *30 min*, *2nd hour*, *8th hour* and *12th hour* were significantly lower for Diclofenac Group when compared to paracetamol ($p < 0.05$). However, at *4th hour* both the Groups had similar scores.

The mean duration of analgesia (**Fig. 2)** as measured by the time of insertion of suppository to the time of rescue analgesia was significantly ($p < 0.001$) longer in the Diclofenac Group (*12.5 hours*) compared to the Paracetamol Group (*7.6 hours*).

Heart rate, respiratory rate and mean arterial pressure were not significantly different between the two groups in the post-operative period (Figs. 3-5).

Vomiting occurred in 3 patients in the Diclofenac Group and one of them had mild epigastric pain. No such event was recorded in the Paracetamol Group shows in **Table 4**. No incidence of increased bleeding which required intervention was recorded in both the groups.

Table 4: Complications

Complications	Paracetamol (n = 30)	Diclofenac (n = 30)
Vomiting	0	3
Epigastric discomfort	0	1

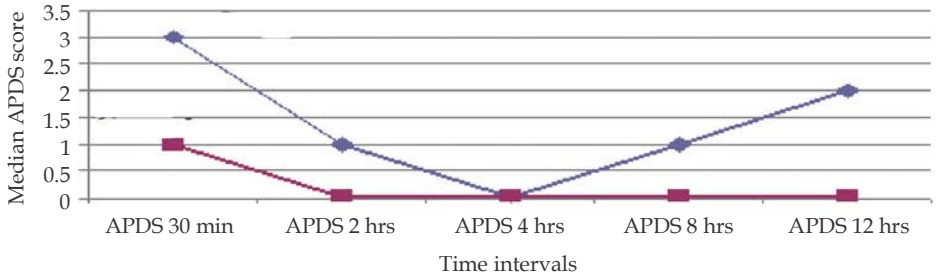

Fig. 1: Median APDS score at different intervals in Group I (Paracetamol) and Group II

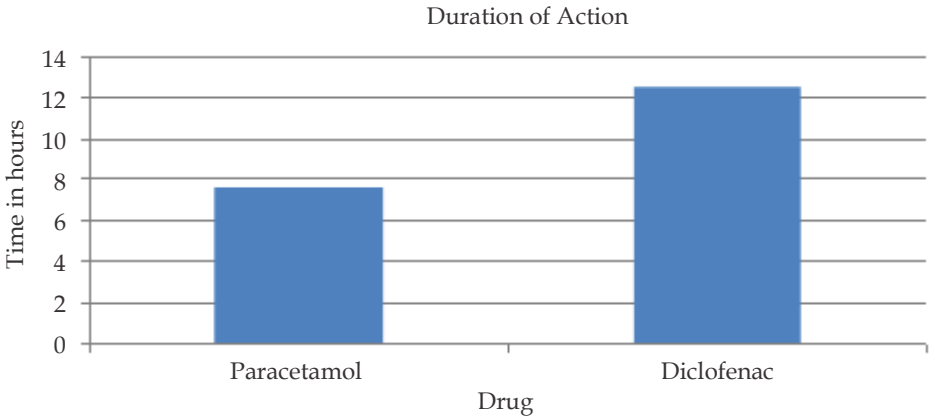

Fig. 2: Duration of Action

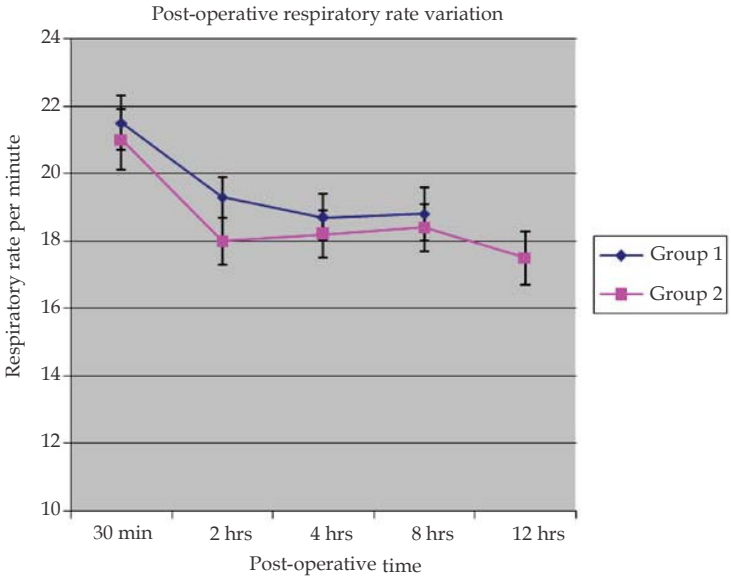

Fig. 3: Respiratory rate in the post-operative period

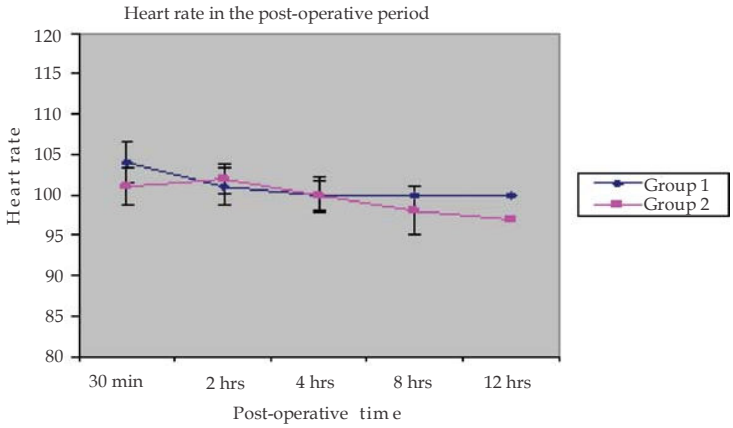

Fig. 4: Heart rate in the post-operative period

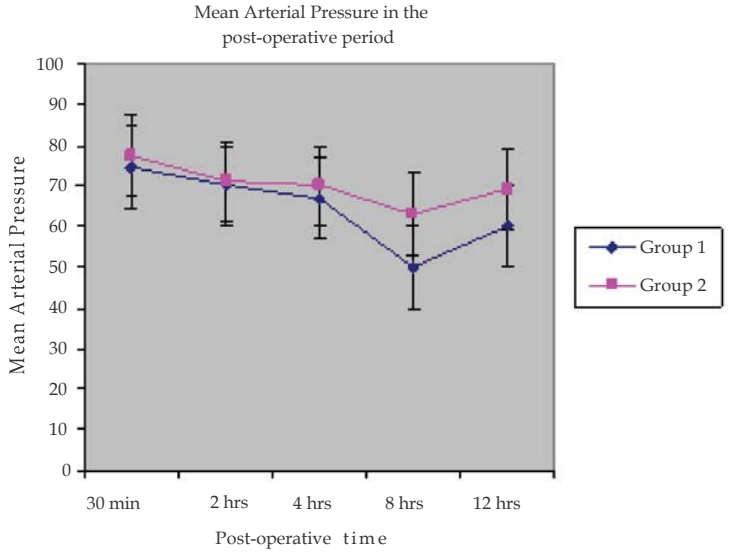

Fig. 5: Mean Arterial Pressure in the post-operative period

Discussion

Various combinations of drugs and dosages of rectaly administered drugs have been studied for the effectiveness of post-operative analgesia. The results were varied, partly because of difference in the dosage of the drugs administered.[1,3] Higher doses, predictably, provided better analgesia but side effects were higher, especially with diclofenac. Diclofenac was used in doses varying from *0.65-3 mg/kg*.[3,4] Similarly paracetamol has been found to be safe up to *90 mg/kg*.[4] This study compared *40 mg/kg* paracetamol with *1 mg/kg* diclofenac.

Fentanyl requirements in both the groups were similar in the intra-operative period and till *30 minutes* after surgery (Table 3). Time for maximum concentration for rectally administered paracetamol is about 2.5 hours[5] and for diclofenac is about 50 mins.[6] Plasma concentrations of both the drugs most probably did not attain their peak concentration at the time of awakening. This, in addition to the short duration of anesthesia, may explain why there was no difference in the fentanyl consumption in our study. However, at *30 min*, the pain scores were lower in Diclofenac Group and continued to remain low at 2, 8 and *12 hour* post-operatively. When used in surgeries expected to last more than *an hour*, rectal diclofenac may be able to reduce the intra-operative opioid usage. Analgesic property of paracetamol has been postulated to result from a central effect whereas diclofenac acts through central as well as peripheral action.[7] Besides this, the early onset of action of the diclofenac suppositories due to better bioavailability,[6] could have contributed to the early action of diclofenac.

Curiously, at the *4th hour*, both the groups had similar pain scores (Fig. 1). A similar finding was noted by Schmidt *et al.*[3] who noted that rectal diclofenac given pre-operatively offers no advantage over paracetamol with respect to post-operative analgesia in patients undergoing tonsillectomy in the first *4 hours* post-operatively.

Though the APDS score were higher in Paracetamol Group, it was still adequate to provide post-operative analgesia in the early post-operative period. There were no significant difference between the groups with respect to heart rate. respiratory rate and mean arterial pressure (**Figs. 3-5**). This shows that both the drugs can provide adequate post-operative analgesia in children undergoing elective inguinal surgery, though the duration may be less with paracetamol. Three children in the diclofenac group had adequate analgesia with single dose of *1 mg/kg* till discharge. They did not require any further analgesic supplement in the post-operative period. A previous study on patients undergoing ENT surgeries reported post-operative analgesia up to *14 hours* with a single dose of rectal diclofenac.[8] This unusually long duration could have been partially because of the less extensive surgeries performed in their study but it attests to the persistant effectiveness of rectal diclofenac as peri-operative analagesic.

Three children in the diclofenac group had vomiting and mild epigastric pain in the post-operative period. Such events can be avoided by pre-medicating these children with H_2 receptor antagonists and by routinely giving these drugs in the post-operative period. No such events were recorded in the Paracetamol Group.

Rectal diclofenac has been reported to increase peri-operative bleeding as it reduces platelet aggregation,[3] However, in our diclofenac group no such complication was observed. This could partly because of the lower dosage we used. A similar finding was observed by Adarsh *et al.*[9] using *1 mg/kg* of diclofenac in cleft palate surgeries in children, proving that it is an optimal dosage offering adequate analgesia and at the same time providing an acceptable safety profile against peri-operative bleeding.

Conclusion

In this study, we compared the analgesic efficacy of single dose suppository of paracetamol versus diclofenac for post-operative analgesia. The results demonstrate that the quality of analgesia was significantly better and of longer duration in the diclofenac group with acceptable complication rates for bleeding and gastritis.

Key Messages

Both Paracetamol and Diclofenac provide adequate post-operative analgesia in children. However, the quality and duration of analgesia may be better and longer with Diclofenac sodium.

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