

ORIGINAL RESEARCH ARTICLE :

COMPARISON OF PREOPERATIVE RECTAL DICLOFENAC AND RECTAL PARACETAMOL & THEIR COMBINATION FOR POSTOPERATIVE ANALGESIA IN PAEDIATRIC PATIENTS

Dr.Shweta Patel

Resident doctor in Anaesthesia,

Smt NHL Medical college Ahmedabad Gujarat India

Dr Manisha S.Kapdi Associate professor of anaesthesia

Smt NHL Medical college Ahmedabad, Gujarat,India

ABSTRACT

Background

Acute postoperative pain has adverse effects on the various physiological functions of the body.It can cause haemodynamicderrangement,delay in ambulation.In paediatric population it causes anxiety, apprehension & behaviour changes.

Aims& objectives

We conducted a randomized observational study to compare the efficacy of preoperative rectal diclofenac ,paracetamol & their combination for postoperative analgesia , haemodynamic stability, cost-effective ness, adverse effects in paediatric age group. ,

Material methods

children (2– 12 yrs) undergoing minor surgical procedures were randomly allocated into 3 groups, of 30 patients each

group A received diclofenac suppository2 mg/kg post induction .

group B received paracetamol 20 mg/kg suppository post induction.

Group C received combination of Diclofenac 1mg/kg & paracetamol 10 mg/ kg suppositories

Pain was assessed by the "Hanallah pain scale" which denotes pain based on 5 parameters, systolic blood pressure, crying, movements, agitation (confused, excited), and complaints of pain.

Conclusion

We concluded that though, diclofenac sodium, paracetamol & their combination are good postoperative analgesics when given by rectal route in pediatric patients undergoing minor surgeries, combination group provides better analgesia than others when given by rectal route in pediatric patients in terms of haemodynamics, post-operative analgesia, cost-effectiveness, adverse effects.

Keywords

Postoperative pain, paediatric patients, Rectal diclofenac sodium, Rectal paracetamol, diclofenac sodium- paracetamol combination suppository

Introduction

pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage. This process of cutting tissue, traction and tissue injury leads to stimulation of free nerve endings and specific nociceptors leading to intraoperative and postoperative pain. This acute pain has adverse effects on the patient's moral as well as various physiological functions of the body. So adequate control of postoperative pain is essential for good outcome as well as it is one of the factors which reduce the hospital stay. Pain relief can be achieved by various methods like systemic opioids, NSAIDs, central neuroaxial block either intrathecal or epidural opioids, local anaesthetic or by peripheral nerve block and infiltration of wound by

local anaesthetics. Historically children have been under treated for pain and for painful stimuli because of wrong belief that they neither suffer or feel pain nor respond to or remember the painful experience to the same degree that adults do. An unproved safety and efficacy of the analgesics and worries about the risk of opioid induced respiratory depression added more reasons for the under treatment of pain in children The society of paediatric anesthesia clearly defines the alleviation of pain as a basic human right irrespective of age, medical condition, treatment, service response for the patient care or medical institution. The aim of this study was to compare the effect of preoperative rectal diclofenac sodium and preoperative rectal paracetamol,& their combination in terms of heart rate, systolic blood pressure, SpO2, postoperative pain scores, duration of postoperative analgesia and side-effects.

Methods

In this study, 90 patients of either sex, age between 2– 12 years, belonging to ASA grades I,II undergoing various surgical procedures were studied.

Following patients were excluded from this study:

1. ASA grade III,IV or V
2. Patients with congenital heart disease
3. Patients scheduled for neurosurgery
4. Duration of surgery>180 min
5. Patients with anal/rectal pathology
6. Patients with known renal disease

Group Allocation:

These patients were randomly allocated to three groups. Randomisation was done by computer generated numbers by internet. Execution of Randomisation after induction.

Group A –patients received diclofenac 2 mg/kg suppository immediately following induction.

Group B –patients received paracetamol 20 mg/ kg suppository immediately following induction.

Group C - patients received Diclofenac 1 mg/mg & paracetamol 10 mg/kg suppositories after induction.

Preoperative written informed consent was taken from parent/guardian.

Patients were kept NBM Starvation protocol was followed in each case.

In the operating room, monitors, pulseoximeter, blood pressure cuff and ECG monitor were attached. An Intravenous line was secured and inj. ringer lactate solution was started.

All patients were premedicated with Inj. Glycopyrrolate 0.004mg/kg, Inj. Ranitidine 1 mg/kg, Inj. Midazolam 0.02mg/kg, Inj. Ondansetron 0.08 mg/kg.

Patients in both groups were preoxygenated with 100% O₂.

Induction was done with Inj. thiopentone 6mg/kg, with loss of eyelash reflex as the anaesthetic endpoint. After confirming that patient could be ventilated on mask, skeletal muscle relaxation was obtained with Inj. atracurium 0.5mg/kg. patients were ventilated with reservoir bag and mask for 3min.

Endotracheal intubation was done with proper sized uncuffed armoured portex endotracheal tube. Bilateral equal Air entry was checked, and tube fixed by adhesive tape.

Patients in group I received Diclofenac suppository 2 mg/kg post induction.

Patients in group II received Paracetamol suppository 20mg/kg post induction.

In group III ,patients received combination of Diclofenac 1mg/mg& paracetamol 10 mg/mg suppositories after induction.

Patients were maintained on O₂+N₂O & sevoflurane 0.8-1%with Inj.Atracurium & have controlled ventilation on pressure mode of ventilation of Drager workstation.

Vital parameters, Heart rate, systolic blood pressure and SpO₂ , ETCO₂ were monitored every 10 min intraoperatively and their mean values found out.At the end of surgery ,Patients were extubated after reversal of neuromuscular blockade by inj glycopyrolate 0.002 mg/ kg & inj neostigmine 0.05 mg/ kg

Pain was assessed by the “Hanallah pain scale²”. This is a pain scale which categorizes pain based on 5 parameters, like systolic blood pressure,crying ,movements ,agitation(confused, excited) , complains of pain

At 0 hrs after extubation, heart rate,systolic blood pressure,SpO₂ and Hanallah Pain Scale were recorded. These parameters were also observed at 1,2 and 6 hrs after surgery in the recovery room and ward. Rescue analgesic was given routinely after 6 hrs postoperatively or when HPS score was>5 in the form of Inj.diclofenac IV 1mg/kg. All patients were observed for any side-effects in the postoperative period for 6 hrs.in the ward, and any complication if occurred was treated in the conventional manner.The data obtained was statistically analysed. by Armonk NY USA software version 17

Qualitative data were analysed by ANOVA (Analysis of variance)

Categorical data were analysed by chi square tests.

The P value of >0.05 was considered as statistically in significant.(NS)

P<0.05 was statistically significant.(S)

P<0.001 was highly significant (HS)

HANALLAH PAIN SCALE

PARAMETER	FINDING	POINTS
SBP	↑< 20% of preoperative BP	0
	↑ 20-30% of preoperative BP	1
	↑>30% of preoperative BP	2
CRYING	not crying	0
	responds to age appropriate nurturing	1
	does not respond to nurturing	2
MOVEMENTS	no movements relaxed	0
	restless moving about in bed constantly	1
	thrashing (moving wildly)	2
	rigid (stiff)	2
AGITATION	asleep or calm	0
	can be comforted to lessen the agitation(mild)	1
	cannot be comforted (hysterical)	2

Results

Demographics:

Parameter	Group A	Group B	Group C	Pvalue
Age	7.88+/-2.42	7.96+/-2.56	7.75+/-1.98	> 0.05
Gender	16: 14	15 : 15	14:16	>0.05
Weight	18.24+/-4.95	17.52+/-5.02	17.82+/-4.89	> 0.05
Duration of surgery	50.4 +/-2.8	52.8 +/-1.6	53.2 +/-1.2	>0.05

Table shows comparable demographic parameters in each group (P>0.05)

HPS Score

HPS Score	Group A	Group B	Group C	P value
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1 hour	1+/-0.4	1+/-0.9	1+/-0.2	< 0.05
2 hour	2+/-0.4	2+/-0.7	2+/-0.1	<0.05
6 hour	5+/-0.5	5+/-0.7	5+/-0.1	<0.05

Adverse reactions

Parameter	Group A	Group B	Group C	P value
Nausea	7(23.10%)	3(10%)	1(3.33%)	P<0.05
Vomiting	3(10%)	1(3.33%)	-	P<0.05
Intraoperative Blood loss	-	-	-	-

We found that rectal Diclofenac and Paracetamol, & their combination, possess analgesic action, but the postoperative pain scores in patients who received rectal Diclofenac & paracetamol suppositories are better as compared to those in the paracetamol group, & Diclofenac group the difference between the pain scales being statistically significant ($p < 0.05$).

We also found that though the difference in mean heart rate and systolic blood pressure at various events in the groups is not statistically significant, diclofenac - paracetamol combination group shows greater stability with respect to effect on heart rate, especially postoperatively.

Incidence of nausea was more with diclofenac suppository, though not statistically significant.

We concluded that rectal diclofenac sodium, paracetamol & their combination are good postoperative analgesics in pediatric patients undergoing minor surgeries. Diclofenac paracetamol combination provides cost-effective analgesia & better Haemodynamic stability.

Discussion

postoperative pain in children may trigger biochemical and physiologic stress response and cause impairment in pulmonary, cardiovascular, neuroendocrinal, gastrointestinal, immunological, and metabolic function.

We conducted a randomized study to compare the efficacy of intraoperative rectal diclofenac and rectal paracetamol & their combination for postoperative analgesia in pediatric age group was conducted in a tertiary care Hospital. We found that rectal Diclofenac and Paracetamol & combination of both possess analgesic action, but the postoperative pain scores in patients who received rectal Diclofenac paracetamol combination are better as compared to those in the paracetamol group & Diclofenac group.

These findings were consistent with the findings of Baer GA, Rorarius MG, Kolehmainen S, Selin S. in Dec 1992²⁰ who compared the effects of rectally administered diclofenac (12.5 mg) with paracetamol (125 mg) on pre- and postoperative behaviour and the need for supplementary analgesia in 44 children scheduled for adenoidectomy (with or without myringotomy). The children who had received diclofenac were significantly quieter ($p < 0.05$), easier to handle ($p < 0.01$) and cried less ($p < 0.05$) than those in the paracetamol group. During recovery, children in the diclofenac group needed fewer supplementary doses of intravenous pethidine than those receiving paracetamol ($p < 0.001$).

Similarly, O'Donnell A, Henderson M in March 2007⁸ studied management of postoperative pain in children following extractions of primary teeth under general anaesthesia: a comparison of paracetamol, Voltarol and no analgesia. Children reported significantly less pain when rectal Voltarol was provided prior to the extractions, as compared

to paracetamol or no analgesia. The greatest amount of pain was reported by the group who had received no analgesia. Jyoti Borkar, Nandini Dave in 2002² studied the analgesic Efficacy of Caudal Block versus Diclofenac Suppository and Local Anesthetic Infiltration Following Pediatric Laparoscopy. They studied 50 children undergoing laparoscopy for diagnostic and therapeutic purposes. Their ages ranged from 3 to 13 years, and all belonged to American Society of Anesthesiologists (ASA) class I or II. Anesthesia was carried out using the standard procedure. Patients were randomly assigned to one of two groups. Group 1 received caudal block with bupivacaine 1 ml/kg after anesthetic induction. Group 2 received diclofenac suppository 3 mg/kg post induction and local anesthetic infiltration at the port sites at the end of the procedure. Pain was assessed using the Hannallah objective pain scale at 15, 30, 60, 120, and 360 minutes postextubation. The pain scores were comparable in both groups at all times. They found the analgesic efficacy of diclofenac suppository combined with local anesthetic infiltration at port sites comparable to caudal block. The same pain scale was used in our study.

We observed that though the difference in mean heart rate at various events in the groups was not statistically significant but combination showed greater stability with respect to effect on heart rate, especially postoperatively.

Leont'ev DV, Babaev BD, et al In 2005¹⁵ conducted a study to comparatively assess the adequacy of postoperative analgesia using nonsteroidal anti-inflammatory drugs (NSAIDs) and paracetamol in children undergone "minor" surgical interventions. The efficiency of postoperative analgesia was evaluated, by using central hemodynamic parameters that many investigators consider to be one of the major criteria for the adequacy of anesthesia. Comparative analysis of the efficiency of postoperative analgesia of the above agents has

indicated that diclofenac and paracetamol have a sufficient analgesic activity and at the same time do not show the adverse reactions unique to narcotic analgesics.

Regarding adverse reactions, The incidence of nausea was 23.30% in diclofenac group, while 76.70% had no side effects, In the paracetamol group, the incidence of nausea was 10.00%, while 90.00% had no side effects ,in combination group it was 4% incidence of nausea.

Pluim MA, Wegener JT,et al in1999¹⁰ compared tramadol suppositories and rectal acetaminophen/codeine for postoperative pain relief. There was no difference in pain scores between the two groups. The incidence of nausea and vomiting was significantly higher in the tramadol-treated (84%) than in the acetaminophen/codeine treated group (31%). The relative risk of experiencing an episode of nausea under treatment with tramadol was 2.7 (95% confidence interval: 1.3-5.3; P = 0.0001) as compared with acetaminophen/codeine.

In our study, there were no complications such as increased intraoperative haemorrhage or increased postoperative blood loss, in any group.

Baer GA, Rorarius MG, Kolehmainen S, Selin S. (20)in Dec 1992 compared the effects of rectally administered diclofenac (12.5 mg) with paracetamol (125 mg) on pre- and postoperative behavior and the need for supplementary analgesia in 44 children scheduled for adenoidectomy (with or without myringotomy). There were no obvious differences between the groups in intra-operative bleeding (as estimated by the surgeon), or in measured blood loss. No postoperative complications became evident.

Limitations:

There was no control group in our study as we want to give analgesia to each child.

Conclusion:

In nutshell all suppositories give analgesia to children in each group but in comparison Rectal Diclofenac paracetamol combination suppository provided safe effective & cost-effective analgesia than Rectal Diclofenac sodium suppository, Rectal paracetamol suppository alone.

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