COMPARATIVE STUDY OF EFFICACY OF POST OP ANALGESIA IN CHILDREN USING RECTAL DICLOFENAC SUPPOSITORY, CAUDAL BLOCK WITH BUPIVACAINE AND A COMBINATION OF BOTH

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ABSTRACT

BACKGROUND

Management of postoperative pain in neonates and children is a challenging job for anaesthesiologist since pain is responded by infants with an autonomic response. Multimodal analgesia has been invariably used in adults for postoperative pain management and less often in children assuming the underdeveloped pain pathway and perception of pain in children. This study aimed to compare the efficacy of postoperative analgesia using rectal diclofenac suppository, caudal analgesia and a combination of both.

MATERIALS AND METHODS

A prospective randomized controlled study was conducted in a Government tertiary care hospital with 90 children grouped into three groups. Group I received 1 mg/kg of 0.25% Bupivacaine caudal analgesia, Group II received rectal diclofenac sodium 1 mg/kg and Group III received a combination of both.

RESULTS

Results were analysed using t test, chi square test and ANOVA.

CONCLUSION

Analysis of results showed that the analgesia produced by a combination of caudal analgesia with diclofenac suppository was superior compared to using diclofenac suppository or caudal analgesia alone.

KEYWORDS

Postoperative analgesia, Paediatrics, Caudal epidural, Diclofenac rectal suppository, Bupivacaine.

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BACKGROUND

Neonates and young children are not able to perceive pain and react to pain as older children and adults because sensory thresholds are lower in neonate and reflex responses are exaggerated. The motor component of withdrawal reflexes is less coordinated and tends to involve whole body movements. Pain can be treated at peripheral level using local anaesthetic infiltration, peripheral nerve blockade using local anaesthetic, opioids, and alpha 2 agonists. This study compared the effect of rectal diclofenac suppository, caudal analgesia and a combination of both for acute postoperative pain in elective ilioinguinal surgeries as a randomized controlled prospective study involving 90 children allocated into three groups. The effects were compared between the three groups and results were analysed using appropriate statistical tests.

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MATERIALS AND METHODS

Aims and Objectives

To compare the impact of postoperative pain relief and the incidence of postoperative complications using caudal epidural administration of 1 mg/kg of 0.25% Bupivacaine, 1 mg/kg of rectal diclofenac suppository and a combination of both in 90 children between ages 1-11 years who underwent ilioinguinal surgeries.

Inclusion Criteria

1. ASA Grade I Children
2. Children 1-11 years
3. Children for elective ilioinguinal surgeries.

Exclusion Criteria

1. Children less than 1 year of age
2. Spinal deformity/sacral deformity
3. Coagulopathies
4. Platelet disorders
5. Infection at site
6. Generalized sepsis
7. H/o asthma
8. H/o Renal and liver diseases

A randomized controlled study was done to compare caudal epidural analgesia with 1 mg/kg of 0.25% bupivacaine, 1 mg/kg of diclofenac suppository and a combination of both for postoperative analgesia. The study was conducted at a tertiary care government hospital and included 90 children in the age group 1-11 years scheduled ilioinguinal surgeries were randomly divided into groups for study. The age and weight of each child was recorded. All the children had their last feed at about 3 a.m. in the morning.

Group I: Received caudal epidural block with 1 mg/kg of 0.25% bupivacaine.

Group II: Received rectal diclofenac sodium suppository (1 mg/kg)

Group III: Received both caudal epidural block with 1 mg/kg 0.25% bupivacaine and rectal diclofenac sodium suppository (1 mg/kg).

All the children were premedicated with 50 mg/kg of oral trichlofos syrup 1 hr prior to surgery and the diclofenac sodium suppository was inserted for Group II and Group III children once they were calm and tranquil.

All the operations were carried out under general anaesthesia. Intravenous line was secured with 22G IV canula onto a vein on the dorsum of hand. Precordial stethoscope, pulse oximeter, NIBP, ECG, SPO2 monitors were attached. Premedication of injection fentanyl 2 microgram/kg was administered. Anaesthesia was induced with titrated doses of injection Propofol along with N_2O: O_2, 50:50 with halothane 1%. An appropriate sized LMA was positioned in situ, bilateral air entry was checked and LMA was fixed, anaesthesia was maintained with 67% N_2O and 33% O_2 and halothane 1-2% using Jackson Rees modification of Ayre's T piece with spontaneous respiration. After induction of general anaesthesia, Group I and III children received caudal epidural injection of 1 mg/kg of 0.25% bupivacaine using 23G needle. Intraoperatively balanced salt solution was infused according to body weight. Heart rate, respiratory rate, blood pressure were recorded at an interval of 5 minutes. LMA was removed at a deep plane of anaesthesia. Children remained in the recovery room until they were fully awake and then shifted to the postoperative ward.

The Children were assessed by the staff nurse who was not aware of group allocation. Assessment of pain, sedation, pulse rate, B.P., SPO_2 and complication like nausea and vomiting, respiratory depression, urinary retention etc., was done at 0,1/2.1.2.3.4.5.6.10 and 12 hrs post operatively. Pain was assessed using FLACC pain scale and rescue analgesia of syrup paracetamol 15 mg/kg was given at pain score 4 or above. Sedation was assessed using Ramsay sedation score. A score of 4 and above was used as criterion for recovery from sedation related to anaesthetic drugs. Oral feeds were allowed after 6 hrs. All the children were examined prior discharge for neurological deficits.

Ethics

The study was conducted after the approval of the Ethical Committee and an informed written consent from the children's parents or guardians after explaining in the regional language was obtained.

Statistics

On comparison of age, sex, weight, duration of surgeries between groups showed that there is no significant difference between groups.

Variable	Group I	Group II	Group III	F	P value
AGE (years)	5.5 ± 2.59 SE- 0.4732 95% CI of Mean- (4.53-6.46) GROUP I	6.45 ± 2.54 SE-0.4644 95% CI of Mean- (5.50-7.39) GROUP II	5.68 ± 2.41 SE-0.3784 95% CI of Mean (4.91-6.45) GROUP III	1.313 F	.274 P value
Gender Male Female	 27(90%) 3(10%)	 27(90%) 3(10%)	 23(76.7%) 7(23.3%)	Chi-square 2.877 df =2	P value 0.237
Weight (kg)	15.73 ± 3.92 SE (0.716) 95% CI of Mean (14.27-17.20)	17.70±.47 SE (0.817) 95% CI of Mean (16.03-19.37)	16.03±3.15 SE (0.574) 95% CI of Mean (14.86-17.21)	ANOVA f value 2.231	P value 0.114
Duration of Surgery (minutes)	32.67 ± 9.07 SE (1.656) 95% CI of Mean (29.28-36.05)	33.17/ ± 9.42 SE (1.720) 95% CI of Mean (29.65-36.68)	30.83 ± 7.32 SE (1.337) 95% CI of Mean (30.43-34.03)	ANOVA F value 0.605	P value 0.549

Table 1. Demographic Characteristics Using ANOVA

Comparing the Age, gender, weight and duration of surgery between groups showed that there was no significant difference between the three groups.

Pulse Rate	Group I	Group II	Group III	F	SIG
PR 30 MIN POSTOP	*87.93 ± 12.74 **SE (2.326) ***95% CI of Mean (83.13-93.69)	92.67 ± 12.237 SE (3.33) 95% CI of Mean (85.86-99.48)	84.27 ± 14.81 SE (2.705) 95% CI of Mean (78.75-89.80)	2.234	.113
PR at 1 hr Post op	88.27 ± 12.33 SE (2.252) 95% CI of Mean (83.66-92.87)	91.23 ± 15.28 SE (2.801) 95% CI of Mean (85.49-96.98)	83.23 ± 13.81 SE (2.521) 95% CI of Mean (78.08-88.39)	2.540	.085
PR at 2 hrs post op	88.57 ± 12.328 SE (2.251) 95% CI OF MEAN (83.96-93.17)	89.9 ± 21.41 SE (3.911) 95% CI of Mean (81.26-91.21)	86.53 ± 14.134 SE (2.581 95% CI of Mean (84.92-91.75)	.319	.728
PR at 4 hrs Post op	91.23 ± 11.743 SE (2.144) 95% CI of Mean (86.85-95.62)	95.45 ± 11.534 SE (2.142) 95% CI of Mean (91.06-99.84)	92.47 ± 11.695 SE (2.154) 95% CI of Mean (88.06-98.87)	1.009	.369
PR at 5 Hrs Post op	93.07 ± 13.784 SE (2.605) 95% CI of Mean (87.73-98.42)	96.33 ± 10.092 SE (1.942) 95% CI of Mean (92.34-100.33)	94.9 ± 11.938 SE (2.217) 95% CI of Mean (90.36-99.44)	.507	.604
PR at 6 hrs Post op	92.64 ± 10.751 SE (2.292) 95% CI of Mean (87.87-97.4)	97.82 ± 9.323 SE (1.988) 95% CI of Mean (93.68-101.95)	96.35 ± 11.085 SE (2.174) 95% CI of Mean (91.87-100.82)	1.445	.243
PR at 7 hrs post op	93.50 ± 11.915 SE (0.957) 95% CI of Mean (90.45-96.55)	90.6 ± 2.966 SE (1.327) 95% CI of Mean (86.92-94.28)	90.33 ± 17.898 SE (10.333) 95% CI of Mean (45.87-134.79)	.158	.856

Table 2. Postoperative Pulse Rate Variation Using ANOVA

Time	Sum of Squares	D f	Mean Square	Fisher F-value	SIG (P value)
30 min Post op	0.021	2	0.01	0.964	0.385
1 hr. Post op	0.083	2	0.042	0.967	0.384
2 hrs. Post op	62.926	2	31.463	140.385	0.134
3 hrs. Post op	139.875	2	69.938	143.432	0.354
4 hrs. Post op	156.472	2	78.236	262.413	0.638
5 hrs. Post op	259.029	2	129.514	3910.15	0.767

Table 3. Comparison of Pain Scores at 30 min, 1, 2, 3, 4, 5 hrs Postoperatively

*Mean pulse rate +/- Standard deviation.

**Standard error.

***95% Confidence interval of Mean.

Comparing the pulse rate variation between groups at 30 min, 1, 2, 3, 4, 5, 6, 7 hrs postoperatively revealed that there is no significant difference in the variation of pulse rate between the three groups postoperatively.

The comparison of pain scores between the three groups using the FLACC pain scale revealed that there was no significant difference between the three groups post operatively at 30 minutes, 1, 2, 3, 4 and 5 hrs post operatively.

Comparison of sedation scores between groups are as follows.

Time	Sum of Squares	D f	Mean Square	Fischer F-Value	SIG (P value)
30 min. Post op	2.222	2	1.111	2.071	0.132
1 hr. Post op	41.489	2	8.500	5.694	0.085
2 hrs. Post op	17.222	2	8.611	2.383	0.098
3 hrs. Post op	0.868	2	0.434	0.628	0.536

Table 4. Comparison Of Sedation Scores Between Groups

Sedation of children postoperatively was assessed using Ramsay sedation score. Analysis of data collected between the three groups postoperatively at 30 minutes, 1, 2, 3 hrs postoperatively revealed that there was no significant difference in the sedation score of children between the three groups.

Comparison of Duration of Analgesia is as follows.

Group	Mean ± SD (hrs)*
I	4.5667 ± 0.97911
II	5.56667 ± 0.568321
III	7.53333 ± 0.507416

Table 5. Comparison of Duration of Analgesia

*Mean duration of analgesia in Hours ± standard deviation

Children belonging to Group III had prolonged duration of analgesia. The duration of analgesia observed between Group I and II were not significantly different and it was comparable between the above two groups.

Rescue Analgesia	Group I	Group II	Group III	F-value	SIG (P value)
First dose of Rescue analgesia (Time of administration postoperatively)	**4.57 ± 0.679 *SE (0.124) 95% CI of Mean (4.31-4.82)	**5.6 ± 0.675 *SE (0.123 95% CI of Mean (5.35-5.85)	**5.89 ± 1.369 *SE (0.093) 95% CI of Mean (7.31-7.69)	169.602	.000***
Second Dose of rescue analgesia (time of administration postoperatively)	8.57 ± 0.679 SE (0.124) 95% CI of Mean (8.31-8.82)	9.6 ± 0.675 SE (0.123) 95% CI of Mean (9.35-9.85)	11.17 ± 1,984 SE (0.362 95% CI of Mean 10.43-11.91)	31.782	0.000***
Third Dose of rescue analgesia (time of administration postoperatively)	12.00 ± 0.111 SE (0.012) 95% CI of Mean (11.75 – 12.15)	11.11 ± 0.151 SE (0.125) 95% CI of Mean (10.81-11.34)	11.12 ± 0.131 SE (0.113) 95% CI of Mean (11.01-11.38)	48.379	0.615

Table 6. Comparison of Administration of Rescue Analgesia between Groups

*Mean time (postoperatively) ± Standard deviation.
** SD – Standard Error.
***P value of <0.001 was significant.

RESULTS

All the children from the three groups were matched for Age, Sex, Weight and Duration of surgery. Postoperative pulse rate between the three groups at 30 min, 1, 2, 3, 4, 5, 6, 7 hrs showed no significant statistical difference. The postoperative pain scores between groups also remained insignificant. Sedation scores between groups were also comparable. On comparing postoperative complications between groups there was one child with urinary retention in Group I and three children with urinary retention in Group III which was statistically insignificant. There was no incidence of nausea and vomiting, respiratory depression, Apnoea or Pruritus among the three groups of children postoperatively. The Mean duration of analgesia was 4.5 hrs. in Group I, 5.5 hrs. in Group II and was 7.5 hrs in Group III, the highest among all the groups. With regard to rescue analgesia provided there was a statistically significant difference between Group I and II in the time of administration of second dose of rescue analgesia. This showed the effectiveness of rectal diclofenac suppository administered in Group I children provided better analgesia in the early postoperative period compared to caudal block in children belonging to group III. In Group III the quality of analgesia remained the same during early and late postoperative period. The FLACC pain score did not correlate with the above findings inferred with respect to Group I and Group II children which could have been due to the observer variance in assessing the severity of pain.

DISCUSSION

Multimodal analgesia has been the mode of analgesia for adults and has been sparingly used in paediatric population. This was because of the suspected incidence of neurological complications associated with caudal block. In our study we did not encounter any such neurological complications. In our study the duration of analgesia with caudal epidural using 0.25% Bupivacaine was 5.5 hrs whereas in the study conducted by A.R.Wolf[1] the duration of analgesia was 7 hrs. Ivani G[2] used 0.125% levobupivacaine 1 mg/kg for caudal epidural block in children which produced less early postoperative motor blockade but shorter duration of postoperative analgesia when compared to a solution of 0.25% levobupivacaine. In a study conducted by Gupta et al.[3] the Mean pain scores were higher in Group II at 30 min but they were comparable at 1 hr which proved that rectal diclofenac has less analgesic effect in the immediate postoperative period compared to caudal epidural block. A similar effect was observed in a study conducted by Bhattacharya Dipasari. This could be because of delay in absorption of the drug from the rectal mucosa.[4,5] In the study of Moores et al,[6] it was suggested that rectal diclofenac suppository reduced the severity of late onset postoperative pain and was not effective in the immediate postoperative period. Also, Tigersedt et al,[7] did not observe

any immediate effect of intravenous diclofenac in the early postoperative phase in adults after general surgery.

Rectal suppository takes 1 hr. to reach adequate serum levels to produce analgesia. In our study, we administered the rectal diclofenac at the time of administering premedication, prior to starting of the procedure resulting in quality of analgesia which was comparable to caudal block. The diclofenac suppository administered in such a manner produces effective post op analgesia in the immediate as well as late postop period. This is concluded by the second dose of rescue analgesia that is administered that has been statistically insignificant between Group I and Group II. When a combination of both caudal epidural analgesia and rectal diclofenac suppository has been administered it provides an excellent analgesia in the early as well as in the late postoperative period in contrast to caudal epidural which is less effective in the late postoperative period. Also, children administered diclofenac suppository were awake earlier compared to those administered caudal block.

Administration of rectal suppository neither needs expertise as with administering caudal block nor does it require bowel preparation. We excluded known asthmatics from this study. But a study by Short J.A.[8] suggested that diclofenac suppository can be safely used in children.

Future studies need to be conducted with a larger sample sizes to substantiate the above observed effect.

CONCLUSION

Multimodal analgesia in the form of rectal diclofenac suppository in combination with caudal epidural analgesia provides good postoperative analgesia in the early as well as in the late postoperative period in comparison to caudal epidural block that provides analgesia only in the early postoperative period. Also administering rectal diclofenac 1 hr. prior to the onset of surgery provides good analgesia in the early as well as late postoperative period than administering it at the end of surgery.

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