Original Article

Indian Journal of Anesthesia and Analgesia
Volume 8 Number 1 January-February 2021
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.8121.8

A comparison of Caudal Bupivacaine to Bupivacaine Infiltration with Rectal Diclofenac Suppository for Postoperative Analgesia in Pediatric Patients Undergoing Below Umbilical Surgeries

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Abstract

Aim: To compare the analgesic effects of caudal block using 1ml/kg of 0.25% bupivacine to a combination of local infiltration with 0.5ml/kg of 0.25% bupivacaine with rectal diclofenac suppository 2mg/kg in the management of postoperative pain following below umbilical surgeries in pediatric patients of age group 2-7 years.

Materials and Methods: 100 patients belonging to both sexes, aged between 2-7 years, with ASA Status I, II who were posted for below umbilical surgeries under general anaesthesia were included in the study The patients were randomly allocated into two groups. Group A : Patients received caudal block with 1ml/kg of 0.25% Bupivacaine Group B : Patients received local wound infiltration with 0.25% Bupivacaine 0.5ml/kg and rectal diclofenac suppository 2mg/kg .

Observation and Results: The pain scores, total duration of analgesia, number of rescue analgesics required, time for micturition and postoperative complications,if any were compared in both the groups.

Conclusion: We conclude that both caudal block and local infiltration with reactal diclofenac suppository are equ ally effective for postoperative analgesia in below umbilical surgeries.

Keywords: Bupivacaine; Diclofenac; Postoperative analgesia; Caudal block.

How to cite this article:

P Krishna Prasad, B Sowbhagyalakshmi, M Santhi Sree / A comparison of Caudal Bupivacaine to Bupivacaine Infiltration with Rectal Diclofenac Suppository for Postoperative Analgesia in Pediatric Patients Undergoing Below Umbilical Surgeries. Indian J Anesth Analg. 2021;8(1):55-61.

Introduction

Pain in children is a complex phenomenon, as it is difficult to differentiate crying or restlessness due to pain from that of hunger or fear. Pain triggers complex biochemical and physiological stress responses and induces impairement in pulmonary, cardiovascular, neuroendocrinal, gastrointestinal, immunological, and metabolic functions.[1-2] It is now accepted that acute post-operative pain

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Received on 06.12.2020, **Accepted on** 23.01.2021.

management is an integral part of the practice of paediatric anaesthesia.[3]

Pain relief can be achieved by various methods like systemic opioids, NSAIDS, central neuraxial block either intrathecal or epidural opioids, local anesthetic or by peripheral nerve block and infiltration of wound by local anesthetics, while the various non-pharmacological modalities are hypnosis, TENS, acupuncture and psychotherapy.[4]

Regional anaesthesia is an essential part of modern anesthesia practice, conveying many significant advantages such as superior analgesia, reduced MAC, hemodynamic stability,obtundation of hormonal stress response, reduced intra operative blood loss and improved GI function.[5] Regional anesthesia undertaken when the child is under GA can give prolonged analgesia in the postoperative period. Caudal block provides excellent analgesia for any surgery below umbilicus such as herniotomy, orchidopexy. Long acting local anesthetic alone or in combination with adjuncts prolong analgesia with minimal side effects.[6]

Infiltration of wound edges with local anesthetics (field block) or by directly instilling local anesthetic into a wound effectively provides intraoperative and postoperative analgesia for many minor and some major surgeries. The most commonly used local anesthetics for infiltration are lignocaine, bupivacaine and ropivacaine. Traditionally strong analgesics such as opioids have been used intraoperatively where as NSAIDS and paracetamol are most commonly given at the end of surgery as part of multimodal approach to postoperative analgesia.

Rectal route of drug administration is safe, easy and convenient for absorption in the pediatric age group as it bypasses the liver avoiding hepatic first pass metabolism.

This study was conducted to compare the analgesic efficacy of caudal bupivacaine to bupivacaine infiltration with rectal diclofenac suppository in pediatric patients undergoing below umbilicl surgeries.The pain scores, duration of analgesia, requirement of rescue analgesics and postoperative complications,if any were compared in both the groups.

Aims and Objectives

It is a prospective, randomized, comparative, observer- blinded study to compare the analgesic effects of caudal block using 1ml/kg of 0.25% bupivacine to a combination of local infiltration with 0.5ml/kg of 0.25% bupivacaine with rectal diclofenac suppository 2mg/kg in the management of postoperative pain following below umbilical surgeries in pediatric patients of age group 2-7 years.

Our aims and objectives are to compare:

1. Post operative hemodynamics
2. Pain scores in both the groups
3. Total duration of analgesia in both the groups
4. Number of rescue analgesics required
5. Time for micturition in both the groups
6. Complications if any, post operatively

Materials and Methods

Study Design and Equipment

After obtaining institutional ethical committee approval and informed consent from the parents, this prospective, randomised, comparative study was conducted in Rangaraya medical college/ Govt. General Hospital, Kakinada.

Inclusion Criteria

1. Age 2-7 years
2. Elective surgeries
3. ASA status I, II physical status.

Exclusion Criteria

1. Patient or parent refusal
2. History of allergy to any drugs used in the study
3. History of bleeding diathesis
4. Infection to site of caudal injection

Methods

100 patients belonging to both sexes, aged between 2-7 years, with ASA Status I, II who were posted for below umbilical surgeries under general anaesthesia were included in the study. Clinical examination and routine investigations were done to all patients. All of them had a thorough pre-anesthetic evaluation. Solid foods restricted for 8hrs, but clear fluids allowed upto 2hrs prior to surgery. Children were brought to the operating room and venous access achieved with a 22-Gauge i.v canula. Monitors such as pulse oximeter, ECG, and NIBP were connected. Patients were pre-medicated with

0.02mg/kg Atropine, 0.03mg/kg Midazolam. All patients underwent general anaesthesia with 3-5mg/kg Thiopentone Sodium and Endotracheal intubation was facilitated by Atracurium 0.5mg/kg. Maintained with 50% oxygen, 50% nitrous oxide, and sevoflurane at a concentration ranging from 0.5% to 2%. The patients were randomly allocated into two groups by picking random lots from a sealed bag.

Group A: Patients received caudal block with 1ml/kg of 0.25% Bupivacaine

Group B: Patients received local wound infiltration with 0.25% Bupivacaine 0.5ml/kg and rectal diclofenac suppository 2mg/kg.

In Group A, at the end of surgery patient is tilted on the lateral side and caudal

Block was performed under complete aseptic conditions by using loss of resistance technique. In Group B local wound infiltration was done before closure of the skin incision and diclofenac suppository placed per-rectally at the end of the surgery.

Vitals such as Pulse rate, MAP, Respiratory rate and Oxygen saturation were monitored through out the surgery. After completion of surgery, anesthetic agents were discontinued, anaesthesia was reversed with 0.05mg/kg Neostigmine and 0.02mg/kg

Atropine. 100% oxygen was administered through face mask for 3-5 minutes. The total duration of surgery was noted. When fully awake and hemodynamically stable, children were transfered to the PACU.

Postoperative hemodynamics Pulse rate and MAP were monitored for 8 hrs in the postoperative period. Postoperative pain was assessed using

FLACC Scale.

Flacc Scale

The Face, Legs, Activity, Cry, Consolability scale combines five types of pain behaviours ,including facial expression,leg movement, activity,cry and consolability and has been shown to have good inter-rate variability and validity in children. It is widely used because it is quick, versatile and can be applied to infants and older children including those with developmental disabilities. Pain was assessed at 0,15,30,45, 60min and every two hours thereafter until 8 hours following surgery or until patient requires rescue analgesic, whichever happened earlier was considered as the end point of observation. At the score ≥4 rescue analgesic i.v paracetamol 15mg/kg was given. The number of rescue analgesics required was also noted. The time for first micturition, the incidence of vomiting, urinary retention,or any relavant side effects were recorded. Children werealso monitored for effects of inadvertent intraarterial injection and intrathecal spread of the local anesthetic.

The data was statistically analysed and expressed as Mean ± S.D.

P value < 0.05 was considered significant.

Observations and Results

All the 100 patients enrolled completed the study. Both groups were similar in their demographic profile and baseline hemodynamic parameters like heart rate, mean arterial pressure (Tab.1).

Table 1: Demographic Data.

	Group A	Group B	P Value
Age (mean±SD)	4.80±0.93	4.84±0.84	0.8216
Sex (M:F)	34:16	36:14	
Weight (in kgs)	14.84±2.15	15.04±2.22	0.5485
ASA status(I/II)	39:11	35:15	

Data was expressed as mean +/- SD, ratio, absolute numbers.

P value found to be insignificant.

Table 2: Type of Surgery.

Type of Surgery	Group A	Group B
Herniotomy	23	24
High Ligation	10	7
Circumcision	9	10
Orchidopexy	8	9

Duration of Surgery

The duration of surgery between the two groups was compared using independent T test. Group A had a mean duration of 45.68 minutes, Group B had a mean duration of 46.90 minutes. It was found to be insignificant with a p value of 0.475 (Tab.3).

Table 3: Duration of surgery.

	Group A	Group B	P Value
Duration of surgery (mins)	45.68±1.74	46.90±1.30	0.475

Baseline Haemodynamic Parameters

Table 4: Baseline haemodynamic parameters.

	Group A (mean± SD)	Group B (mean± SD)	P Value
Heart rate	98.60±7.39	98.12±7.01	0.7391
MAP	56.07±3.14	56.40±3.25	0.8101

Data expressed as mean ± SD in both groups. P> 0.05 statistically not significant. The baseline hemodynamic parameters are equal in both the groups (Tab.4).

Table 5: Comparison of Post-Operative Haemodynamics between the two Groups.

	Group	Heart Rate (bpm) (Mean±SD)	P Value	MAP (mm of Hg) (Mean±SD)	P Value
15 mins	Group A	99.9±11.4	0.5302	57.90±4.40	0.4505
	Group B	101.30±12.8		58.50±4.30	
30 mins	Group A	100.8±10.7	0.5898	58.80±4.51	0.4628
	Group B	101.50±12.6		59.40±4.40	
45 mins	Group A	101.01±12.60	0.6023	59.03±4.50	0.5392
	Group B	101.56±13.02		59.65±4.42	
60 mins	Group A	101.13±11.7	0.6355	59.07±4.56	0.5469
	Group B	102.10±13.2		59.91±4.42	
2HR	Group A	101.31±10.9	0.6864	59.43±4.50	0.5434
	Group B	102.10±12.6		59.93±4.44	
4 HR	Group A	102.10±11.4	0.7244	59.92±4.41	0.5628
	Group B	102.70±12.06		60.04±4.54	
6 HR	Group A	102.60±12.52	0.7940	60.20±4.46	0.7818
	Group B	102.86±11.01		60.40±4.51	
8 HR	Group A	102.86±11.72	0.8427	60.54±2.26	0.8147
	Group B	103.90±11.01		60.86±3.15	

Data expressed as mean ± SD in both groups. P value is not statistically significant.

Postoperative hemodynamics are comparable between both the groups. (Tab.5)

Table 6: Comparison of Pain Scores between two Groups.

	Group A	Group B	P Value
15 MINS	1.22 ±0.41	1.28±0.45	0.487
30 MINS	1.72±0.45	1.60±0.49	0.205
45 MINS	1.96±0.34	1.94±0.31	0.759
60 MINS	2.08±0.34	2.04±0.34	0.557
2 HRS	2.74±0.44	3.00±4.36	0.675
4 HRS	3.20±0.61	3.26±0.66	0.638
6 HRS	4.20±0.75	4.32±0.74	0.422
8 HRS	5.24±0.62	5.24±0.55	1.000

Pain scores are compared at 15mins, 30mins, 45mins, 60mins, 2hrs, 4hrs, 6hrs and 8hrs postoperatively. Data expressed as mean ± SD. P value insignificant at all time intervals.Pain scores are equal in both the groups with no significant difference (Tab.6).

Table 7: Total Duration of Analgesia in two Groups.

	Group A	Group B	P Value
Duration in mins	227.17±19.52	226.36±19.10	0.834

Data expressed as mean ± SD. P value is insignificant. The total duration of postoperative analgesia is equal in both the groups (Tab.7).

Table 8: Requirement of Rescue Analgesics in two Groups.

	Group A	Group B	P Value
Number of rescue analgesics	0.48±0.50	2.06±0.51	0.0001*

Data is expressed as mean ± SD. P value significant (0.0001). Requirement of rescue analgesic is more in Group B compared to Group A. Two or more rescue analgesics were required in local infiltration with diclofenac suppository group (Tab.8).

Table-9 Comparison of time for Micturition in two Groups.

	Group A	Group B	P Value
Time for micturition in mins	274.17±18.80	187.37±24.79	0.0001*

Data is expressed as mean ± S.D. P value significant (0.0001)

Time for micturition in Group A is 274.17±18.80 minutes while in Group B it is 187.37±24.79 minutes.

Time for micturition is prolonged in caudal group(Tab.9) .

Side Effects

All the 100 children enrolled in the study were observed for any side effects in the post operative period such as Hypotension, bradycardia, nausea, vomiting and bleeding. None of them reported any of the above side effects.

Discussion

Pain is a subjective symptom that can be difficult to evaluate with regard to intensity, duration, tolerance, and threshold in pediatrics. Pain in newborns, infants, and children has the same negative effects as in adults. Thus, it is now widely accepted that infants and children require appropriate pain relief in the post-operative period.[7] Postoperative pain management not only minimizes patient suffering but also can reduce morbidity and facilitate rapid recovery and early discharge from hospital, which can reduce hospital costs.

Treatment of postoperative pain in children includes the use of i.v. opioids, nonopioid analgesics and regional nerve block techniques. This can delay the return to normal activity and discharge from

the hospital. Regional techniques for postoperative pain control in children such as caudal block or peripheral nerve block are well-established in postoperative pain control in children.

Postoperative pain is considered as the fifth vital sign of the patient. There is sensitisation of nerve endings leading to spontaneous firing of nerve fibres which constantly drives a pain system in the spinal cord after surgery. Regional anesthesia provides optimal postoperative analgesia as part of a balanced multi-modal approach to pain management.Caudal epidural analgesia is one of the most popular and commonly performed regional blocks in paediatric anaesthesia. It is a reliable and safe technique that can be used with general anaesthesia for intra and postoperative analgesia in patients undergoing infraumblical surgeries.

The weaker or milder analgesics with antipyretic activity, of which acetaminophen (paracetamol), salicylate (aspirin), ibuprofen, naproxen, ketoprofen and diclofenac are common examples, comprise a heterogenous group of NSAIDs and non opioid analgesics.[8]

These analgesic agents are administered enterally via the oral route or, on occasion, the rectal route. Parenterally administered agents including ketorolac, acetaminophen, and recently diclofenac are available for use when the oral or rectal route is not appropriate. Multiple studies and systemic reviews have shown opioid sparing and decreased pain associated with use of acetaminophen and NSAIDs, as well as cost effectiveness and reduced risk of opioid related adverse effects.[9]

Caudal epidural not only reduces the dose of general anesthetics but also attenuates the stress responses to surgery.[10-11] Performing caudal block in an anesthetized child demands proper positioning, identifying proper space and the cumbersome manoeuvre of positioning and repositioning without compromising the airway.

In this study we compared the analgesic efficacy of 1 ml/kg of 0.25% caudal bupivacaine (Group A) to 0.5ml/kg of 0.25% bupivacaine infiltration with rectal diclofenac suppository 2mg/kg (Group B) in pediatric patients undergoing below umbilical surgeries.The pain scores, total duration of analgesia, number of rescue analgesics required, time for micturition and postoperative complications,if any were compared in both the groups.

Demographic data such as age, sex, weight and ASA physical status insignificant in both the groups (Tab.1). There is no significant difference in the duration of surgery for both the groups (Tab.2, Tab3). The baseline and postoperative hemodynamic parameters are comparable between both the groups (Tab. 4, Tab. 5). Pain scores were assessed by FLACC scale at 15mins, 30 mins, 45mins, 60 mins 2 hrs, 4 hrs, 6 hrs and 8 hrs postoperatively (Tab 6). The pain scores and total duration of analgesia are equal in both the groups with no significant difference (Tab.7). Whereas the rescue analgesic requirement is more in group B(2.06±0.51) compared to Group A(0.48±0.50) (Tab.8). The time for micturirtion is significantly prolonged in Group A(274.17±18.80 mins) compared to Group B(187.37±24.79 mins) (Tab.9)

Moores et al.[12] compared the effects of rectal diclofenac with 0.25% bupivacaine administered caudally for postoperative analgesia in pediatric inguinal herniotomy.

Forty-three children were assigned randomly to receive either 1 ml/kg caudal bupivacaine 0.25% or rectal diclofenac 0.25 mg/kg intraoperatively to provide postoperative analgesia. They found that caudal bupivacaine although provided more pain-free patients at first; later the incidence of pain was similar in both groups and concluded that rectal diclofenac is a useful alternative to caudal blockade in this group of patients. In our study, none of the patients presented with pain in the early postoperative period, i.e. up to 220 min postoperatively. This may be because of the additional local infiltration of bupivacaine received by those in the diclofenac group in our study.

Seyed et al.[13] compared the analgesic effects of an acetaminophen (NSAID) suppository, bupivacaine wound infiltration, and caudal block with bupivacaine on postoperative pain in pediatric inguinal herniorrhaphy and observed that in children, bupivacaine infiltration group and the group who received caudal bupivacaine produce better analgesia than the third group who received suppository acetaminophen. They concluded that bupivacaine infiltration is better than a caudal block because of its simplicity, lower incidence of complications, and reduced failure rates. In our study diclofenac was used instead of acetaminophen. As suppository alone did not produce effective analgesia local wound infiltration was administered to the suppository group in our study.

Gupta et al.[14] studied postoperative analgesia in children undergoing infraumbilical surgeries. They concluded that rectal diclofenac in combination with caudal block provides good postoperative

analgesia in early as well as later in the postoperative period, in comparison to caudal block alone which provides analgesia only in early postoperative period or rectal diclofenac alone which does not provide good analgesia in the early or immediate postoperative period. As diclofenac suppository alone did not produce effective analgesia in postoperative period local wound infiltration was given in the suppository group in our study.

William and Splinter, Juan Bass, Lydia Komocar, et al.[15] compared the analgesic efficacy, adverse effects and the cost associated with supplementation of local infiltration with either intravenous ketorolac or caudal analgesia in children having an inguinal hernia repair. They concluded that, supplementation of intraoperatively administered local anesthesia with ketorolac results in a small improvement in pain, a lower incidence in vomiting and a more notable decrease in the time to micturition than a caudal block. These findings are consistent with our present study. However, the nonsteroidal antiinflammatory drug used here was intravenous ketorolac instead of diclofenac suppository used in our study.

Machotta et al.[16] compared between instillation of bupivacaine versus caudal analgesia for postoperative analgesia following inguinal herniotomy in children. They concluded that instillation of Bupivacaine into a wound provides postoperative pain relief following hernia repair, which is as effective as that provided by a postoperative caudal block which is consistent with the result of our study. We added rectal diclofenac suppository to the local infiltration group in our study.

Borkar Dave et al.[17] compared the analgesic efficacy of caudal block against diclofenac suppository with local anesthetic infiltration in children undergoing laparoscopy. They found that the analgesic efficacy of diclofenac suppository combined with local anesthetic infiltration at port sites were comparable to caudal block. Given the necessarily invasive nature of caudal block, they suggested the combined use of diclofenac suppository with local anesthetic infiltration at port sites as a useful and more economical alternative for analgesia following pediatric laparoscopy. Although these observations were for laproscopy, their conclusions are consistent with that of ours.

Gavrilovska et al.[18] compared the analgesic effects of caudal block with local wound infiltration in pediatric patients after inguinal hernia repair. The two groups did not differ in terms of patient characteristic data, surgical profile and hemodynamic changes as in our study. The duration of analgesia and time for first rescue analgesic are comparable between both groups. There were significant differences in incidence of adverse effects in caudal and local group including vomiting and urinary retention.

The results of this study are consistent with those of our study.

Conclusion

We conclude that both caudal block and local infiltration with rectal diclofenac suppository are equally effective for postoperative analgesia in below umbilical surgeries. As administration of caudal block is more time consuming and requires expertise, a less invasive and comparatively easier method of analgesia provided by diclofenac suppository and local wound infiltration of bupivacaine can also be used as an alternative for effective postoperative analgesia in children.

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