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EVALUATION OF EFFECT OF COMBINATION OF INTRAVENOUS DEXAMETHASONE AND CAUDAL ROPIVACAINE ON DURATION OF POST OPERATIVE ANALGESIA IN PAEDIATRIC PATIENTS

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ABSTRACT
Aims : To study the effect of combination of intravenous Dexamethasone and caudal Ropivacaine on duration of post-operative analgesia, perioperative hemodynamic parameters and complications. Methods: 50 patients of ASA I & II scheduled for infraumbilical surgery were included in double blind randomized comparison of 25 patients in each group. Group A patients were given Inj. Ropivacaine (1ml/kg of 0.2% concentration) in caudal block with i.v. Dexamethasone (0.5 mg/ kg) and group B patients were given Inj. Ropivacaine (1ml/kg of 0.2% concentration) in caudal block with i.v. saline (0.125 ml/ kg). We recorded duration of post-operative analgesia, hemodynamic changes and side effects in both groups. Results: Mean duration of Post-operative analgesia is more in group A (602.6 ± 21.0 mins) compared to group B (411.4 ± 15.5 mins). And mean FLACC score at 8 hours was lower in group A as compared to group B. Conclusion: Intravenous Dexamethasone with caudal Ropivacaine significantly prolongs the duration of post-operative analgesia without significant sedation

INTRODUCTION

Pain is a common postoperative symptom impairing the quality of postoperative recovery, delaying discharge from Post-anaesthesia care unit (PACU) or surgical centre. Inadequate pain relief during childhood may have long term negative effects including harmful neuroendocrine responses, disrupted eating and sleep cycles and increased pain perception during subsequent painful experiences. Various multimodal techniques for paediatric pain relief have been designed [5]. These involve regional anaesthesia with systemic analgesics, out of which the most commonly used regional block in paediatrics is caudal epidural block [1]. Caudal analgesia is more popular because of its simple technique, predictable level of blockade and high success rate, excellent postoperative analgesia with smooth recovery for various surgeries, for example, lower abdominal, urologic and lower limb operations. It reduces analgesic requirement and facilitates early discharge. Caudal block is a useful alternative/supplement to general anaesthesia and total I.V. anaesthesia as it provides effective post-operative analgesia. Clinically adequate doses of Ropivacaine appear to be associated with a lower incidence & grade of motor block & quicker regression of motor block which encourages early mobilization. Ropivacaine also provides a better safety profile than other local anaesthetics regarding CNS & cardiac toxicity [4]. Hence Ropivacaine is an ideal drug for infraumbilical surgeries as it will not come in way of the surgeon's assessment of motor system in the

immediate postoperative period as well as causes significant decrease in postoperative pain leading to early mobilization. Various additives e.g. Ketamine, Neostigmine, Clonidine, Dexmedetomedine, Dexamethasone, Ephedrine and opioids have been used to prolong the duration of analgesia provided by single injection [16]. However, their use has been limited by adverse effects in children. Continuing research is being carried out in an attempt to find relatively safer drugs associated with minimal side effects. Dexamethasone apart from being an antiemetic for postoperative nausea and vomiting, also has analgesic and anti-inflammatory properties [3]. Several studies have shown that Dexamethasone prolongs the analgesic effect of regional anesthesia by inhibiting phospholipase and COX II, thus blocking the synthesis of prostaglandins [2]. Considering the above facts, we have designed a randomised prospective controlled study using Ropivacaine alone and with intravenous Dexamethasone along with caudal epidural block in order to assess duration of postoperative analgesia, heamodynamic changes, side effects and degree of sedation.

MATERIALS AND METHODS

It was a prospective randomized clinical study. This study was carried out to evaluate the effect of combination of intravenous Dexamethasone and caudal Ropivacaine on duration of post-operative analgesia. The study consisted of 50 patinets of either sex between the ages 1 to 6 years of ASA risk I & II posted for infraumbilical surgery. Randomized was done by envelope technique and the patients were allocated to two groups as follows-

Group A: Inj. Ropivacaine (1ml/kg of 0.2% concentration) in caudal block with i.v. Dexamethasone (0.5 mg/ kg) (Test group)
Group B: Inj. Ropivacaine (1ml/kg of 0.2% concentration) in caudal block with i.v. saline (0.125 ml/ kg) (Control Group)

Pre operative evaluation was carried out a day before the surgery. A thorough history was taken from parents and a detailed examination carried out. Patients were subjected to routine and relevant investigations like Random blood sugar, CBC, renal and liver function tests, Chest X Ray. The procedure was explained to the parents and written informed consent was taken. On arrival to the operation theatre, IV access was established with 22G cannula and all patients were given isolyte-P. Standard Monitors were applied and baseline pulse rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), SpO2 and EtCO2 were recorded. All patients were pre-medicated with Inj. Glycopyrrolate 0.04mg/kg IV. The patient was pre oxygenated for 3 mins using 100% oxygen with JR circuit. Induction of anaesthesia was carried out using inhalational induction agent sevoflurane with O2. Airway was secured using an appropriate size supra-glottic airway device (I- gel or LMA). After induction patients were placed in the lateral decubitus position, and a single dose caudal block was performed under aseptic and antiseptic conditions using a 23G hypodermic needle and standard loss of resistance technique. The drug Ropivacaine (1 ml/kg of formulation 2mg/ml i.e. 0.2% Ropivacaine) was given in caudal block after negative aspiration for blood and cerebrospinal fluid in all patients.

Just after giving caudal block, iv drug was given according to groups
Test group: iv Dexamethasone (0.5 mg/kg)
Control group: iv Saline (0.125 ml/kg)

Anaesthesia was maintained using oxygen, nitrous oxide and sevoflurane. Haemodynamic parameters (heart rate, ECG, blood pressure), respiratory rate and SpO2 were recorded before induction, after induction and then immediately after caudal anaesthesia, and every 10 minutes during surgery.

After completion of surgery, airway device was removed after full recovery from general anesthesia. Pulse, blood pressure, sedation score, FLACC score were recorded postoperatively at 0 minute, 1, 2, 4, 8, 12, 24 hours.

Postoperative analgesia was assessed using FLACC pain scale and sedation was assessed by sedation score. Children who have a pain score of more than 4 were administered Acetaminophen 15 mg/kg suppository. Time of first micturition and time of administration of rescue analgesia was also noted. Patients were assessed for 24 hours postoperatively.

Duration of anaesthesia, defined as time from induction of anaesthesia to the time of removal of airway device; duration of surgery; and Duration of post-operative analgesia defined as time from single shot caudal injection of drug to the FLACC pain score of more than 4 were also noted.

Statistically, all data were presented as mean ± S.D. for comparison between two groups and compared using unpaired student t- test. P values <0.05 was interpreted as clinically significant.

SEDATION SCORE:
0. Eyes open spontaneously
1. Eyes open in response to verbal command
2. Eyes open in response to physical stimulation
3. Unarousable

FLACC PAIN SCORE:

	0	1	2
Face	No expression or smile	Occasional grimace or frown, Withdrawn, uninterested	Frequent to constant quivering chin, clenched jaw
Legs	Normal position or relaxed	Uneasy, restless, tensed	Kicking or legs drawn up
Activity	Lying quietly normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, jerky
Cry	No cry (awake or asleep)	Moans or whimper, occasional complaint	Crying, steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging or being talked to, distractible	Difficult to console or comfort

OBSERVATION AND RESULTS:

There was no statistically significant difference between two groups with respect to age, sex, weight, ASA status (Table 1); Type of surgery (Table 2) and Duration Of Surgery And Anesthesia (Table 3)

Table 1. Demographic Data

	Group A	Group B	p value
Age (yrs) (Mean ± S.D.)	3.2 ± 1.6	3 ± 1.6	0.66
Weight (kg) (Mean ± S.D.)	10.92 ± 2.9	11.04 ± 3.4	0.58
Gender (M:F)	24:1	24:1	

Table 2. Type of Surgery

S.No.	Type of surgery	Group A (no. of patients)	Group B (no. of patients)
1	Hypospadias repair	9	8
2	Herniotomy for inguinal hernia	6	5
3	Herniotomy for hydrocele	4	6
4	Orchidopexy	1	2
5	Circumcision	3	2
6	Stoma closure	1	1

Table 3. Duration of Surgery and Anaesthesia

	Group A	Group B	p value
Duration of Surgery (min) (Mean ± S.D.)	58 ± 24.6	55.8 ± 26.28	0.76
Duration of Anesthesia (min) (Mean ± S.D.)	71.2 ± 23.99	69.4 ± 26.4	0.8

Table 4. Mean Duration of Post-Operative Analgesia

	Group A	Group B	p value
Duration of analgesia (min) (Mean ± S.D.)	602.6 ± 21.0	411.4 ± 15.5	0.0001

As seen in table 4, Mean duration of post-operative analgesia was significantly prolonged by giving iv Dexamethasone along with caudal Ropivacaine (test group) in comparison to caudal Ropivacaine alone (control group).

Table 5. Post-Operative Mean FLACC Score

Time	Group A (Score)	Group B (Score)	p value
1 hour	0.4 ± 0.5	0.4 ± 0.5	1
2 hours	0.8 ± 0.57	0.64 ± 0.49	0.29
4 hours	1.4 ± 0.5	1.52 ± 0.52	0.41
8 hours	2.56 ± 0.58	3.88 ± 0.33	0.0001
12 hours	4 ± 0	4 ± 0	1

As seen in table 5, there is no statistically significant difference in mean FLACC score at postoperative 1 hour, 2 hours and 4 hours between the two groups ($p>0.05$). However, statistically significant difference was seen in mean FLACC score at 8 hours which was lower in test group as compared to control group.

Table 6. Post-Operative Mean Sedation Score

Time	Group A (Score)	Group B (Score)	p value
1 hour	1.08 ± 0.2	1.04 ± 0.2	0.48
2 hours	0.2 ± 0.4	0.24 ± 0.4	0.72
4 hours	0.12 ± 0.33	0.16 ± 0.37	0.68
8 hour	0	0	1
12 hours	0	0	1

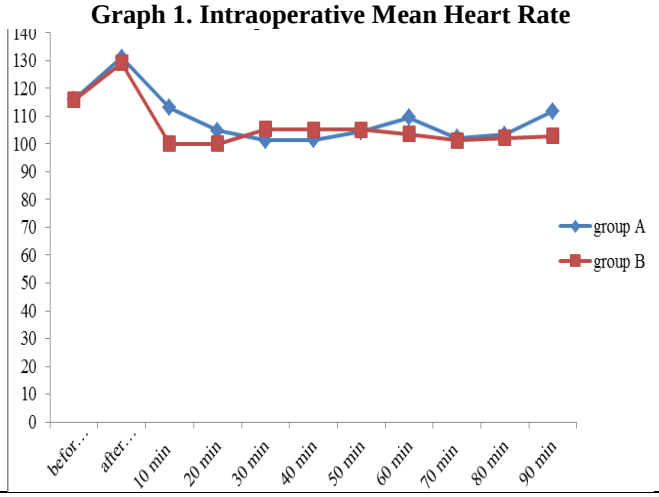
Table 6 shows that there is statistically insignificant difference between postoperative mean sedation score between the two groups ($p > 0.05$).

Table 7. Post-Operative Complications

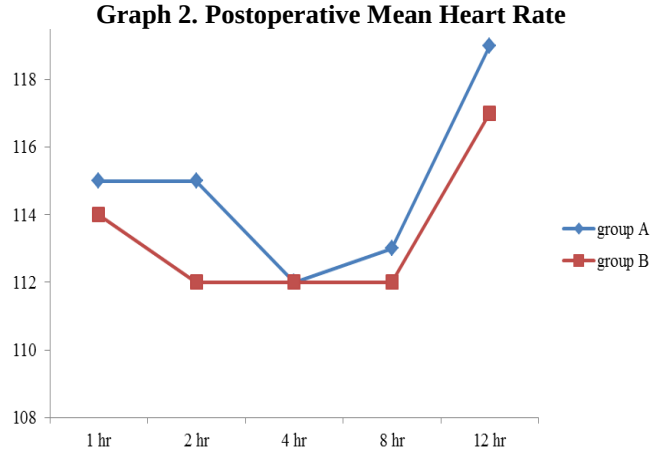
S. No.	Complications	Group A (No. of patients)	Group B (No. of patients)
1	Nausea	0	2
2	Vomiting	1	1
3	Bradycardia	0	0
4	Hypotension	0	0
5	Respiratory depression	0	0

Table 7 shows that there was higher incidence of nausea and vomiting in group B as compared to group A but difference was not statistically significant ($p = 0.23$). No episodes of respiratory depression, hypotension or bradycardia were observed in any of two groups.

Graph 1. Intraoperative Mean Heart Rate



Graph 2. Postoperative Mean Heart Rate



DISCUSSION

"Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage." Children with significant postoperative pain may demonstrate anxiety, fright, insomnia which often exacerbate their pain perception rendering the postoperative recovery period an unpleasant and traumatic experience. Other deleterious consequences of pain include sleep disturbance, nausea, vomiting, prolonged hospital stay and parental dissatisfaction [5]. Regional anaesthesia not only provides an extended pain free period but also reduces the stress responses of surgery. Caudal block has been found to be an excellent and safe technique for providing postoperative analgesia in paediatric population with a high success rate [4]. We designed a randomized, prospective and double blind case control study to examine the effect of a single i.v. dose of Dexamethasone in combination with caudal block on postoperative analgesia in children.

Fifty children, aged 1- 6 yrs, ASA I and II, undergoing infra-umbilical surgeries under general anaesthesia were randomly assigned one of the two groups of 25 patients each. Caudal epidural was given in all patients with inj. Ropivacaine (1 ml/kg of formulation 2mg/ml i.e. 0.2% Ropivacaine) after giving general anaesthesia. Just after giving caudal block, iv drug was given according to groups: Test group: iv Dexamethasone (0.5 mg/kg) and Control group: iv saline (0.125 ml/kg). Patients in our study were demographically similar in both

the groups (Table 1). There were no statistically significant variations regarding age, body weight and gender.

All patients had infraumbilical surgical procedures like inguinal hernia, hypospadias, orchidopexy. Duration of surgery was also similar in both the groups and statistically not significant (Table 2)

Ropivacaine, the N- propyl homologue of bupivacaine is a long acting amide local anesthetic. Compared with bupivacaine, which is a racemic mixture, Ropivacaine is the pure S –enantiomer. Ropivacaine has several properties which may be useful in paediatric practice, namely the potential to produce differential neural blockade with less motor block, and reduced cardiovascular and neurological toxicity.

Herbert Koning et al concluded in their study that Ropivacaine 0.25% is well tolerated, provides effective analgesia associated with less side effects as compared to 0.5%.. We used a volume of 1 ml/kg of 0.2% Ropivacaine in our study.

Analgesic duration of single shot caudal Ropivacaine is 4- 6 hours. However the single shot of caudal block provides analgesia for a limited period of time. To increase this duration, various methods have been utilized. The use of catheter technique did not gain popularity because of risk of infections, dislocation of catheter and unpredictable effect. Various additives have been tried successfully till now to increase the duration of caudal block including epinephrine, clonidine, dexmedetomidine, neostigmine, ketamine, morphine, tramadol and fentanyl. However they do have their share of undesirable side effects.

M Santhi Sree, B Sowbhagya Laxshmi et al demonstrated in their study that adding Dexamethasone significantly increases the analgesic duration of caudal block with ropivacane and reduces pain scores and analgesic consumption for post-operative 48 hrs [24]. Steroids have a powerful anti-inflammatory action and have demonstrated reduced pain and swelling after oral surgery, spinal surgery, and laparoscopic surgery. Systemic administration of steroids has been found to suppress tissue levels of bradykinin and the release of neuropeptides from nerve endings, both of which can enhance nociception in inflamed tissue. They also inhibit other mediators of inflammatory hyperalgesia, for example, tumour necrosis factor-a, interleukin-17b, and interleukin-6 [11].

M. Desmet et al compared the duration of analgesia between iv and perineural Dexamethasone with 0.5 % Ropivacaine in single shot interscalene block [25]. Because absorption in the systemic circulation and gene transcription is time consuming, one could argue that clinically relevant anti-inflammatory effects of steroids, would come too late after perineural administration with short acting local anaesthetics. So instead of adding Dexamethasone to local anesthetic drug, we gave Dexamethasone by i.v. route.

Steward DL et al focused on the effects of systemic Dexamethasone on nausea, vomiting, and pain after tonsillectomy demonstrated that the dose of i.v. Dexamethasone leading to pain reduction was 0.5–1.0 mg/ kg, and 0.4 mg / kg of systemic Dexamethasone produced only an antiemetic effect without analgesic effects [30]. Therefore, we chose a single dose of 0.5 mg/ kg Dexamethasone for children that weighed 20 kg and a maximum dose of 10 mg.

Dexamethasone unlike other intravenous adjuncts or additives to caudal block does not cause problems like prolonged sedation, vomiting or urinary retention, rather Dexamethasone has antiemetic properties and is used for prevention of postoperative nausea and vomiting. Dexamethasone may exert an antiemetic action via prostaglandin antagonism, serotonin inhibition in the gut, and release of endorphins. In addition, the cost of Dexamethasone is relatively low, which makes routine use reasonable. Dexamethasone in high doses or in continuous use can produce side effects like hyperglycemia and adrenocortical suppression but single dose upto 0.5 mg/kg used in our study is not likely to produce such harmful effects. Maillefert et al found that a much larger dose of epidural Dexamethasone (15 mg) may induce transient adrenal suppression.

We chose the FLACC score to evaluate post-operative pain as it is easy to use, is validated and gives an objective evaluation.

Duration of caudal analgesia means time from injection of caudal to first dose of rescue analgesic i.e. FLACC > 3. FLACC score was 4 or more, rescue analgesic in form acetaminophen suppositories 15 mg/kg was given in both the groups.

The results in our study were comparable to those of Hong et al who showed that the mean duration of analgesia after caudal block reaches up to 646 minutes if intravenous Dexamethasone is administered to the patients as compared to 430 minutes when Ropivacaine is used alone [23]. Bangesh L. R.8et al also found significant difference in duration of analgesia when iv Dexamethasone is used along with caudal Ropivacaine when compared to caudal Ropivacaine alone (621.6 min vd 402.4 min). In our study, duration of caudal analgesia using plain Ropivacaine (group B) was 411.4 ± 15.5 (Mean ± SD), which was increased by i.v Dexamethasone to 602.6 ± 21.0 (Mean ± SD) ($p< 0.05$, significant).

We found that there was no statistically significant difference in mean FLACC score at postoperative 1 hour, 2 and 4 hours between the two groups ($p>0.05$). However, statistically significant difference was seen in mean FLACC score at 8 hours which was lower 3.88 + 0.33 in test group as compared to control group. 2.56 ± 0.58. Hong et al also demonstrated that pain scores using CHEOPS and FLACC assessed at the PACU were significantly lower in the Dexamethasone group than in the control group [20].

No significant difference with respect to mean heart rate & systolic arterial pressure were noted during perioperative period between the groups ($p>0.05$). No

patient required drug therapy to treat hypotension or bradycardia.

Hong et al found no significant differences in the incidence of adverse effects including vomiting (7.7% vs 10.5%), sedation (25.6% vs 31.6%), and shivering (2.6% vs 0%) [20]. Karim Girgis found no relevant side effects like prolongation of motor block or increase in sedation score with the use of Dexamethasone as an additive during a caudal block [21]. In our study, mean sedation score at 1 hour was 1.08 ± 0.2 vs 1.04 ± 0.2 in test group and control group which was statistically insignificant (p> 0.68). This shows that unlike opioids, Dexamethasone provides no sedation when used as adjunct to caudal Ropivacaine. Incidence of nausea and vomiting in postoperative period was slightly higher in control group as compared to test group (12% vs 4%) showing additional antiemetic effect of Dexamethasone.

CONCLUSION

To conclude the study, we observed that

- Intravenous Dexamethasone with caudal Ropivacaine significantly prolongs the duration of post-operative analgesia without significant sedation.
- Dexamethasone having antiemetic action decreases the incidence of postoperative nausea and vomiting.
- Dexamethasone does not produce significant hemodynamic fluctuations or any other adverse effect.
- Hence we conclude that an i.v. Dexamethasone (0.5 mg/ kg) in combination with a caudal block with Ropivacaine prolongs the duration of postoperative analgesia pediatric patients undergoing infraumbilical surgeries without any adverse effect.

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CONFLICT OF INTEREST:

The authors declare that they have no conflict of interest.

STATEMENT OF HUMAN AND ANIMAL RIGHTS

All procedures performed in human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed by any of the authors.

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