

CLINICAL EVALUATION OF EFFICACY AND SAFETY OF DEXMETOMETEDINE AS AN ADJUNCT TO CAUDAL ROPIVACAINE IN PEDIATRIC INFRAUMBILICAL SURGERIES

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ABSTRACT: BACKGROUND: Caudal epidural is one of the most popular reliable & safe technique mainly used for intra and post-op analgesia in pediatric patients undergoing infra umbilical surgeries. To prolong the duration of analgesia various adjuvants like epinephrine, opioids, ketamine, midazolam, tramadol, clonidine, were added to local anesthetic. The aim of this study was to evaluate the clinical efficacy and safety of CAUDAL administration of plain Ropivacaine 0.2% (1milligram/kilogram body weight) with and without dexmedetomidine (2 microgram/kilogram body weight) in children undergoing infraumbilical surgeries; in terms of quality of surgical anesthesia and the duration of post-operative analgesia. **METHOD:** After approval from the institutional ethics committee and written informed consent of the parents, 60 children of (age 1-10 years) ASA gr. I and II undergoing elective lower abdominal and urogenital surgeries, were randomly divided into two groups of 30 each. After careful pre-anesthetic examination, children were kept fasting for an appropriate period prior to surgery. All patients received Injection Glycopyrrolate- 0.01 milligram /kilogram body weight, Injection midazolam- 0.1 milligram /kilogram body weight, Injection ketamine - 1 milligram /kilogram body weight, intravenously, just prior to caudal block. Caudal block was performed under all aseptic precautions. No surgical stimulus was allowed for the next 10 minutes i.e. the onset time for sensory block to occur, after which surgery was performed under the residual effect of ketamine and caudal block only. Patients were randomly allocated to receive Injection Ropivacaine 0.2% (1 milliliter/kilogram body weight; Group R) +1millilitre Normal saline or Injection Ropivacaine 0.2% (1millilitre/kilogram body weight) +Injection dexmedetomidine (2 microgram/kilogram body weight; Group RD) in Normal saline 1 milliliter. Hemodynamic parameters were observed before, during and after the surgical procedure. Quality of surgical anesthesia & requirement of supplemental midazolam/ketamine were also noted. Duration of Post-operative analgesia, pain scores, level of sedation and side effects if any were looked for and duly recorded. All the results were tabulated and analyzed statistically. The variables in the two groups were compared using the non-parametric tests. For all statistical analyses, the level of significance was $P < 0.05$. **RESULT:** The Mean duration of analgesia was 6.65 ± 0.25 hours in Group R compared with 12.68 ± 0.36 hours in Group RD, with a P value of < 0.05 . Quality of surgical anesthesia in Group R was excellent in 20 patients as compared to 24 patients in Group RD. 12 children in group RD and 4 children in group R did not require any additional pain medication during the study period; which was statistically significant. The peri-operative hemodynamics were stable among both the groups, although patients in RD group showed lesser degree of tachycardia as compared to pre op values, but it was statistically insignificant. **CONCLUSION:** A single caudal injection of dexmedetomidine (2 microgram/kilogram body weight) added to 0.2% ropivacaine (1

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millilitre/kilogram body weight) offers good quality of surgical anesthesia with significant postoperative pain relief that resulted in a better quality of sleep and a prolonged duration of arousable sedation.

KEYWORDS: Caudal, Dexmedetomidine, ropivacaine, pediatric analgesia.

INTRODUCTION: Caudal block is a well-accepted technique and proved to be a good alternative to general anesthesia in pediatric infra-umbilical surgeries. It provides excellent analgesia intraoperatively as well as during postoperative period. Usage of single local anesthetic agent via caudal route provides shorter duration of block¹ and requires often supplemental anesthetics. In order to decrease intra and postoperative analgesic requirements after single shot caudal epidural blockade, various additives, such as morphine, fentanyl, clonidine and ketamine, with local anesthetics have been investigated.²

Caudal analgesia could reduce the amount of inhaled and intravenous (IV) anesthetic administration, attenuate the stress response to surgery, facilitate a rapid, smooth recovery, and provide good immediate postoperative analgesia.³

Ropivacaine, a long-acting amide local anesthetic related structurally to bupivacaine, has been used for pediatric caudal anesthesia. It provides pain relief with less motor blockade and is less cardiotoxic than bupivacaine, which makes it a more suitable agent for caudal epidural analgesia, especially following day care surgery.⁴

Dexmedetomidine has become of the frequently used drugs in anesthetic armamentarium, along with routine anesthetic drugs, due to its hemodynamic, sedative, anxiolytic, analgesic, neuroprotective and anesthetic sparing effects.⁵

Dexmedetomidine is a potent and highly selective α_2 -adrenoreceptor agonist. A major advantage of dexmedetomidine is its higher selectivity compared with clonidine for α_{2A} receptors which is responsible for the hypnotic and analgesic effects.⁶ In contrast to other agents, the sedation and analgesia produced by dexmedetomidine are achieved without significant respiratory or hemodynamic compromise.

Recent studies suggested that caudal administration of dexmedetomidine could prolong postoperative pain relief in children,^{6,7} but the perioperative effects of caudal dexmedetomidine have not been adequately examined.

The aim of this study was to evaluate the clinical efficacy and safety of caudal administration of plain Ropivacaine 0.2% (1miligram/kilogram body weight) with and without dexmedetomedine (2 microgram/kilogram body weight) in children undergoing infraumbilical surgeries; in terms of quality of surgical anesthesia and the duration of post-operative analgesia. To observe the side effects if any.

MATERIAL AND METHODS: After taking the institute ethics committee approval, 60 children of American Society of Anesthesiologist (ASA) physical status I and II of either sex in the age range of 1 to 10 years scheduled for elective Infraumbilical surgical procedures were selected for this study. Exclusion criteria included: Infection at site of injection, deformity of spine at the site of injection, systemic infection, patients with history of bleeding diathesis ASA grade III or IV, pre-existing neurological, hepatic or renal disease and any known allergic diathesis.

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During the preoperative visit, all patients were evaluated and assessed. The study protocol was explained to the parents and written informed consent was taken from them and the patients were kept fasting for an appropriate period prior to surgery.

It was a Double blinded study. The anesthesiologist administering anesthesia and doing data collection were blinded to the drug administered.

The drugs were prepared and coded by anesthesiologists who were not involved in patient management or data collection.

In the operation theatre after connecting the patient to the monitors, an intravenous line was established. Patients were hydrated with a multiple electrolytes infusion 6 ml kg / hr. all patients received following drugs just prior to caudal block:

Injection Glycopyrrolate- 0.01 mg/kg,

Inj midazolam- 0.1 mg/kg,

Injection ketamine- 1 mg/kg.

Patients were randomly allocated to one of the two groups of 30 patients each.

GROUP R (n=30): Caudal 0.2% Ropivacaine (1 ml/kg) +1 ml Normal saline

GROUP RD (n=30): Caudal 0.2% Ropivacaine (1 ml /kg) with Dexmedetomidine (1 micg/kg) + 1 ml Normal saline.

Caudal block was performed with child positioned in left lateral position, under all aseptic precautions, using 23 G hypodermic needle, after negative aspiration.

No surgical stimulus was allowed for the next 10 mins i.e. the onset time for sensory block to occur, after which surgery was performed under the residual effect of ketamine and caudal block only.

If a child responded to the incision with an increase in or heart rate (>10beats/min), blood pressure (>10mmHg) was considered as inadequate block. These patients were received supplemental doses of ketamine + midazolam. For anesthesia and quality of surgical anesthesia is scored as poor.

H.R. and B.P. were recorded pre operatively; immediately after pre-medication.(H.R and BP reading after receiving premedication considered as base line value); 5 mins after administration of caudal block and there after every 10 mins till completion of surgery. Pulse oximetry and ECG recorded continuously. Quality of surgical anesthesia & requirement of supplemental Midazolam / ketamine were also noted.

Quality of Surgical Anesthesia was Assessed and Managed as Follows:

1. **Excellent:** if no response to surgical stimulus.
2. **Good:** if patient showing sad facial expressions & moving upper half of body, but is allowing surgery without pain/cry; & requires supplemental Inj. midazolam for sleep.
3. **Poor:** not allowing surgery at all & requires supplemental dose of Inj.ketamine and midazolam for anaesthesia.

Pin prick method was used to assess the level of sensory anesthesia and the Bromage Scale for assessing the degree of motor blockade. Post-operatively the following parameters were recorded: Vital parameters: H.R.; B.P.; R.R.SP_O₂

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Level of Sedation: A 4-point patient sedation score (PSS) ⁸ was assigned as follows:

1. Asleep, not arousable by verbal contact;
2. Asleep, arousable by verbal contact;
3. Drowsy/not sleeping;
4. Alert/aware.

The PSS was used to quantify sedation and to help to identify side effects, such as respiratory depression from excess sedation.

Pain Assessed by Modified Pain Score⁹

Table: 1: After discharge from recovery room, patients were monitored every 2 hours until the administration of first rescue analgesic, the maximum time being 24 hours.

CRITERIA	FINDING	POINTS
Crying	none	0
	consolable	1
	Not consolable	2
Movement	none	0
	restless	1
	thrashing	2
Agitation	Asleep; calm	0
	mild	1
	hysterical	2
Posture	normal	0
	flexed	1
	Holds injury site	2
Verbal	Asleep; no complaint	0
	Complains but cannot localize	1
	Can localize	2

Table 1: Pain Assessed by Modified Pain Score^[9]

If pain score > 4, patient was given syrup Paracetamol (15 mg/kg) as rescue analgesic. The time in minutes from the caudal block to the time when rescue analgesic was first administered was considered duration of analgesia.

All the above assessments were made at 30 min interval for 1st hr, At 1 hrly interval for next 6 hrs At 8th, 12th, 24th hour., Side effects if any, were duly recorded.

After completion of the study, the data was analyzed statistically. Data was described as mean \pm SD and percentages. The intergroup comparisons for the metric data was done by Student's 't' test, whereas non-metric data was analyzed by Mann-Whitney 'U' test. And p values <0.05 considered statistically significant.

RESULTS: Sixty patients selected for this study were randomly divided into two groups of 30 patients each.

DEMOGRAPHIC PROFILE: for all patients in terms of age, sex, weight and duration of surgery were similar and comparable. (Table 2)

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In this study, hemodynamic effects with regards to pulse rate and systolic blood pressure showed a benign profile and no clinically relevant change was observed in these variables at various stages.

Although patients in RD group showed reduction in the heart rate, but the magnitude of hemodynamic changes between groups did not reach statistically significant values. (Figure -1)

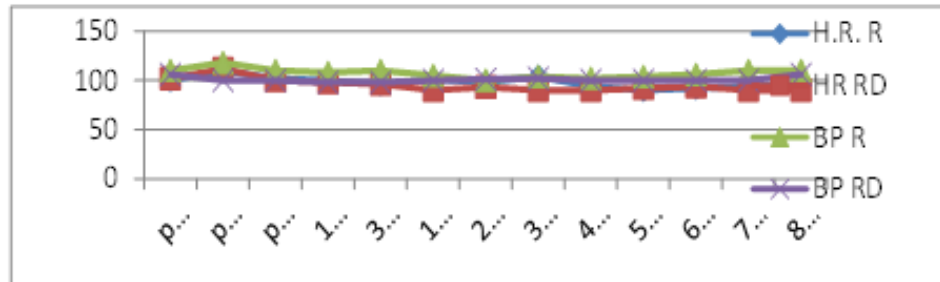


Figure 1: Showing HR & B.P

Spo2 remained unchanged in all patients throughout the study period within and between groups.

	Group R	Group RD
AGE (yrs)	6.2± 0.6	5.8±0.56
SEX	All male	All male
WEIGHT(kg)	11± 5.4	11.65±5.7
DURATION OF S _x (min)	58±10.30	56± 08.45

Table 2: Demographic Characteristics of the Studied Patients

	GROUP R	GROUP RD
EXCELLENT	20	24
GOOD	6	5
POOR	4	1

Table 3: Quality of Surgical Anaesthesia

CHARACTERISTIC	GROUP R	GROUP RD	P value
Mean sedation score	2.94 ± 0.54	3.58± 0.45	> 0.05
Duration of analgesia (Hrs)	6.65±0.25	12.68 ± 0.36	< 0.05
Mean OPS	3.72±0.42	2.76 ±0.50	> 0.05
Total analgesic dose	172 ± 80	96±72	< 0.05

Table 4: Showing Drug Characteristics

SIDE EFFECT	GROUP R	GROUP RD
Nausea/vomiting	2	1
Urinary retention	0	0
Resp. depression	0	0
miscellaneous	none	None

Table 5: Side Effects

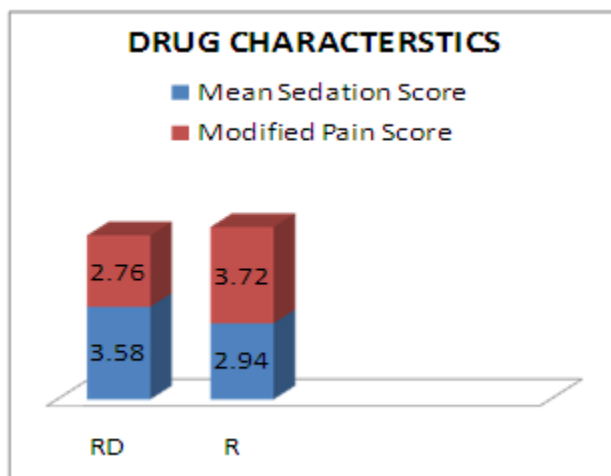


Figure 2: Showing Mean Sedation Score & Modified pain score

In this study, we have seen that addition of 2 mcg/kg dexmedetomidine to caudal ropivacaine provided excellent intra operative analgesia, prolongs the post-operative analgesia (12.68 ± 0.36 hours) as compare to Ropivacaine alone. 6.65 ± 0.25 Hours which is statistically significant.

(Table 3) and patients in Group RD were required less analgesics.

There was no significant prolongation of motor blockade with addition of dexmedetomidine.

The Quality of sleep was better in Group RD.

12 children in group RD and 4 children in group R did not require any additional pain medication during the study period; which was statistically significant.

No significant side effects were noticed in both groups, (Table 5). Except one patient in Group R had fever after 2 hrs. in postoperative period and treated with Injection Paracetamol.

DISCUSSION: Principal aim: To evaluate the efficacy of caudal dexmedetomidine 2 mcg / kg with a 0.2% solution of Ropivacaine. This study was undertaken to assess the efficacy and safety dexmedetomidine with Ropivacaine in pediatric patients undergoing lower abdominal. The duration of study was 24 hours, to assess the maximum duration of analgesia provided by dexmedetomidine and local anesthetic Ropivacaine combination.

Results of this study shows that caudal administration of dexmedetomidine 2 mcg / kg when added to ropivacaine 0.2% results in, good quality of intra & post-operative analgesia, lesser pain score with prolonged duration of postoperative analgesia without undue side effects.

Going through various literatures, we came across some related articles to our study. The past decade has witnessed many advances in the understanding and treatment of pain in children. The use of adjuncts can effectively help in reduction of the dose and an increase in duration of the local anesthetic agents. The results of this study show the excellent quality of surgical anesthesia in maximum number of patients in both the group.

The better intraoperative analgesia observed in Group BD is most probably caused by the central nervous system effects of dexmedetomidine and possibly a synergic or additive action with IV ketamine. This is in correspondence with the study of Q. Xiang, et al.¹⁰

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The duration of post-operative analgesia in RD group significantly higher 12.68 ± 0.36 hrs as compared to group R 6.65 ± 0.25 Hrs (Ropivacaine alone). p value 0.05.

α_2 Adrenergic receptor agonists could prolong the duration of action of local anesthetics and improve the quality of analgesia.^{6,7} by causing local vasoconstriction and increasing the potassium conductance in Ad and C fibres.¹¹

Similar to our study Vijay G Anand et al¹² administered Caudal dexmedetomidine $2 \mu\text{g}/\text{kg}$ with 0.25% ropivacaine $1 \text{ ml}/\text{kg}$ for pediatric lower abdominal surgeries achieved significant postoperative pain relief up to 15 hours. Our results are similar to the study of El-Hennawy et al⁶, M.Neogi¹³ & others; they found postoperative analgesia lasting for 16 hrs (14 - 18) & 15.26 ± 0.86 respectively with dexmedetomidine. El-Hennawy et al⁶ administered dexmedetomidine and clonidine both in a dose of $2 \mu\text{g kg}^{-1}$ as adjuvant with 0.25% bupivacaine caudally. They found duration of analgesia was significantly higher in the group receiving bupivacaine dexmedetomidine mixture.

Neogi et al.¹³ compared clonidine $1 \mu\text{g}/\text{kg}$ and dexmedetomidine $1 \mu\text{g}/\text{kg}$ as adjuncts to ropivacaine 0.25% for caudal analgesia in pediatric patients and concluded that addition of both clonidine and dexmedetomidine with ropivacaine administered caudally significantly increases the duration of analgesia. The mean duration of analgesia was 6.32 ± 0.46 hours in ropivacaine group, and 15.26 ± 0.86 hours in dexmedetomidine group. The patients stayed hemodynamically stable and there were no undue side effects.

Hemodynamic Stability: Bradycardia and hypotension are considered to be the most prominent adverse effects of α_2 -adrenoreceptor agonists, but appear to be less pronounced in children than in adults.^{7,8} These problems could also be readily managed with volume expansion, sympathomimetic drugs, or both.⁷

The results of our observations show that in addition to prolonged post-op analgesia, dexmedetomidine has a favorable safety profile and stable hemodynamics, which are in concordance with the reports published by several other authors.^{6, 12-19}

The sympatholytic effect of dexmedetomidine decreases heart rate and mean arterial reasure by reducing noradrenaline release.²⁰

In this study reduction in Heart rate is observed in RD group but it did not reach statistically significant values.

Similar results were observed by Saadway et al.⁷ decrease in H.R & mean BP within 25-30 in. of caudal dexmedetomidine administration. However it does not reach statistically significant value. No significant respiratory depression was reported in this study, and none of the children had an pO_2 value of $<95\%$. This confirms previous studies as α_2 agonists have no clinical respiratory depressant effect.¹⁴ Saadawy et al.⁷ compared caudal bupivacaine 0.25% administered with dexmedetomidine $1 \mu\text{g}/\text{kg}$ and caudal bupivacaine alone and showed that the incidence of agitation following sevoflurane anesthesia was significantly lower with dexmedetomidine ($P < 0.05$).

The duration of analgesia was significantly longer with dexmedetomidine administration ($P < 0.001$). No statistically significant difference in hemodynamics was found between both the groups. Dexmedetomidine produced better quality of sleep and a prolonged duration of sedation ($P < 0.05$). Dexmedetomidine possess anxiolytic, sedative, sympatholytic and analgesic properties without respiratory depressants effect.²¹

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SEDATION: Dexmedetomidine produces a unique form of sedation, (caused by the stimulation of the α_2 adrenoceptor in the locus coeruleus.¹¹ in which patients become responsive as well as calm and cooperative when aroused, and then back to sleep when not stimulated.

Although rapid recovery without residual sedation is a major objective in out-patient adult surgery, a certain degree of sedation after pediatric surgery might represent a desired effect by the parents. A calm and sedated child during the early post-operative period could decrease the parent's anxiety.²²

Results from the current study indicate that supplementation of caudal Ropivacaine with dexmedetomidine could provide more satisfying levels of postoperative sedation than Ropivacaine alone.

The difference between mean sedation scores of both the groups was statistically significant. In this study No episodes of clinically significant postoperative complications such as PONV, respiratory depression, urinary retention, pruritus, were observed.

The findings of our study were Similar to Vijay G Anand et al¹³ & Saadawy et al.⁷

The duration of sedation was prolonged in group BD compared with group B (210±72 vs. 24±72 min) (P<0.05). Increased duration of sedation, helps in decreasing the parent's anxiety because the child remains calm and sedated. Saadawy et al.⁷

Vijay G Anand et al¹³ administered Caudal dexmedetomidine 2 µg/kg with 0.25% ropivacaine 1 ml/kg for pediatric lower abdominal surgeries achieved significant postoperative pain relief up to 15 hours, which resulted in a better quality of sleep and a prolonged duration of arousable sedation without any supplemental analgesic and the hemodynamics too were stable. No episodes of clinically significant postoperative complications were observed.

One major difference between the above studies and this study was that, in all these patients general anaesthesia were given in conjunction with caudal analgesia, with use of volatile anaesthetic gases or muscle relaxant.

Whereas in our study, we use minimal dose of ketamine which was given prior to caudal block to make the patient co-operative; patients were on spontaneous respiration throughout, without use of any volatile anaesthetic gases.

This probably decreased the incidence of side effects and complications associated with general anaesthesia and helped in earlier post-operative mobilization of our patient.

Brenner, S. C. et al²³ investigated 512 infants and children. In their study Caudal block was performed with ropivacaine 1 ml kg⁻¹ (0.2% or 0.35%). after Premedication with midazolam, sedation was induced with i. v. nalbuphine 0.1 mg kg⁻¹ and propofol 1 mg kg⁻¹, and maintained with propofol 5 mg kg⁻¹ h⁻¹ in children, if necessary. They concluded that Caudal block under sedation is a safe and effective procedure for pediatric subumbilical surgery. With low incidence of adverse events.

Q. Xiang et al¹⁰ They conducted randomized, double-blinded clinical trial, with aim to examine whether supplementation of caudal bupivacaine with dexmedetomidine can eliminate the responses to hernial sac traction & to study the perioperative effects of dexmedetomidine in pediatric patients. They concluded that the addition of dexmedetomidine to caudal bupivacaine could reduce the response to hernial sac traction, and prolong the duration of postoperative analgesia in children undergoing inguinal hernia repair.

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CONCLUSION: We conclude that dexmedetomidine is a better adjuvant to single shot caudal anesthesia for pediatric infraumbilical surgeries. Caudal block under sedation is a safe and effective procedure offers good quality of surgical anesthesia with significant postoperative pain relief that resulted in a better quality of sleep and a prolonged duration of arousable sedation without undue side effects.

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