Original Article

Comparison of addition of either dexamethasone or dexmedetomidine to caudal ropivacaine for Post-Operative analgesia after Paediatric Circumcision: A Randomized Controlled Study

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Abstract

Background: Over recent years, there are lots of advancements in providing adequate postoperative analgesia for pediatric patients who are undergoing infra-umbilical surgeries. Of which, the caudal block is a type of neuraxial block that is simple, easy to administer with more reliability, thus providing a very effective pain–free period. This study aimed to compare the efficacy of Ropivacaine with dexmedetomidine and dexamethasone in pediatric circumcision surgeries.

Materials and Methods: The prospective, randomized, double-blinded study included 60 children (30 children in each group, assigned by computer-generated randomization code). In Group I: 0.25% Ropivacaine 0.5 ml/kg + Dexmedetomidine 1mcg/kg. Group II: 0.25% Ropivacaine 0.5 ml/kg + Dexamethasone 0.1 mg/kg.

Results: FLACC score was used to assess the postoperative analgesia. The mean duration of postoperative analgesia was 478.04±61.22min in Dexmedetomidine group and 530.07±134.04 min in Dexamethasone group which was statistically significant. The sedation score was better with Dexmedetomidine Group compared to Group Dexamethasone.

Conclusion: Our study proved that caudal administration of 0.25% Ropivacaine with Dexamethasone (0.1 mg/kg) resulted in a longer duration (530.07 minutes) of action compared with 0.25% Ropivacaine with Dexmedetomidine (1 mcg/ kg) and the sedation was better with Dexmedetomidine when compared to dexamethasone, without any other significant differences in the hemodynamic parameters and the incidence of adverse events.

Keywords: Caudal, Analgesia, Postoperative, Ropivacaine, Dexamethasone, Dexmedetomidine

Article Summary: Submitted: 05-July-2021 **Revised:** 25-August-2021 **Accepted:** 02-September-2021 **Published:** 30-September-2021

Quick Response Code:

Web Site

http://ijmsnr.com/

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Introduction

The pain perception in children is a complex phenomenon which involves behavioral, psychological, physiological and developmental factors [1]. Pediatric anesthesia has evolved over-time in making surgical procedures much safer, lesser anesthesia-induced neurotoxicity, and much longer postoperative analgesia. In pediatric surgeries, the caudal epidural an anesthetic technique is one of the safe, reliable & easy to administer technique. Therefore, it is used for postoperative analgesia in below-umbilical surgeries [2]. The most frequently used method to further prolong its action is to add adjuvant drugs to the local anesthetic solution [3].

A highly potent and selective glucocorticoid is dexamethasone which has been used as an adjuvant to local anesthetics in different nerve blocks. The variable effect includes onset, prolonged duration of analgesia, and motor block [4]. And Dexmedetomidine, highly selective α2-adrenergic receptor (α2 -AR) agonist [5] is known to be associated with sedation and analgesia sparing effects, perioperative sympatholysis, cardiovascular stabilizing effects, reduced delirium and agitation and maintenance of respiratory function. Ropivacaine is a local anesthetic that is structurally similar to bupivacaine. It has less cardiovascular side effects, motor blockade and neurotoxicity. These effects have made Ropivacaine a better option over Bupivacaine [6]. Hence in this randomized comparative study, we compared caudal dexmedetomidine and dexamethasone with Ropivacaine for postoperative analgesia in pediatric circumcision.

How to cite this article: Gnanasekaran S, Thirupathi MR, Kulasekar A. Comparison of addition of either dexamethasone or dexmedetomidine to caudal ropivacaine for Post-Operative analgesia after Paediatric Circumcision: A Randomized Controlled Study. Int J Med Sci and Nurs Res 2021;1(1):3–7.

Materials and Methods:

Methodology: This randomized control study was conducted in the Department of Anesthesiology & Critical Care, in a tertiary care Hospital and Research Institute at Chennai, Tamil Nadu among children scheduled for circumcision. The sample needed for this study was calculated based on a previous observation made by Choudhary S et al., [7] The required sample size for this study was calculated as 30 subjects for each of groups at alpha error (α) = 0.05 and statistical power = 80%. All the 60 Children was randomly divided into two groups (30 children in each group) using a computer-generated randomization code. The inclusion criteria were children aged 1-8 years, weighing 10-25 Kilograms and grade I – II based on the American Society of Anesthesiologists (ASA) [8]. Children with neurological disorder, local infection at the caudal site, history of allergy to local anesthetics, Sacral or vertebral abnormalities, and bleeding diathesis was excluded from the study. Patients in each group have received caudal anesthesia as follows: All the 60 Children was randomly divided into two groups (30 children in each group) using a computer-generated randomization code. Group I received 0.25 % Ropivacaine 0.5 ml/ kg + Dexmedetomidine 1mcg/kg in normal saline (1ml) and Group II received 0.25% Ropivacaine 0. 5 ml/kg + Dexamethasone 0.1mg/kg in normal saline (1ml) with maximum volume of 25 ml (Armitage formula) in both the groups.

The data was collected for this study was between November 2016 – October 2018. The study was approved by the Institutional Human Ethics Committee (64/IHEC/9-16) Informed written consent was obtained from the parents of all study participants and only those who were willing to sign the informed consent was included in this study. The risks and benefits involved in the study and voluntary nature of participation was explained to the participant's parents through participant information sheet before obtaining written consent.

Procedure:

On the day of surgery, pre-medication in the form of Midazolam nasal spray (0.3mg/kg) was administered and Glycopyrrolate injection (0.004 mg/kg) was administered if IV access was secured already. Standard monitoring including electrocardiogram (ECG), non-invasive blood pressure (NIBP) measurement, heart rate, pulse oximetry and capnography was applied. All patients were induced with inhalational agent sevoflurane (1-6%) with 50% nitrous oxide in oxygen. If the IV access has not been established prior, it was established and secured under aseptic precautions after induction. In the left lateral position, a caudal block was performed using 22G or 24G 1½ hypodermic needle under complete aseptic precaution. After confirmation and negative aspiration for blood and cerebrospinal fluid, the study drug was given in the epidural space. [9]

Postoperative sedation was assessed by using Ramsay sedation score and Postoperative pain was assessed by using the FLACC score, the Motor blockade was assessed by a Motor block scale. [10 – 12] To eliminate any kind of bias in the study, the anesthesiologist performing the caudal block was different from the person conducting the study and both were blinded to the identity of the drug used (double-blinding). [13] The time of caudal block was noted and the time of incision was 10 minutes after administration of caudal block.

Statistical Analysis:

Data collected and complied by Microsoft Excel 2010 and was analyzed by SPSS 20.0 version software. Descriptive statistics was reported as mean and standard deviation for continuous variables and frequency and proportions for categorical variable. An independent t-test was used to find statistical significance between the groups. [14] A two-sided p-value was taken as statistically significant.

Results:

The common presentation of the age group in our study participants was between 1 – 3 years for both the groups which are about 66.7% and 40% in Dexmedetomidine and dexamethasone group respectively. The mean weight of the study participants was 14.31±3.88 kgs in the Dexmedetomidine group and 14.93±4.06 kgs in the dexamethasone group as shown in **Table–1a** and **Table–1b.**

Table 1a: Demographic variables of study participants

Age- Group	Dexmedetomidine		Dexamethasone	
	No.	Percentage	No.	Percentage
1-3 years	20	66.7	12	40
3-5 years	3	10	9	30
>5 years	7	23.3	9	30
Mean ± SD	3.65 ± 2.19		4.27 ± 2.23	
t-value	-0. 879			
p-value	0.380			

Table: 1b Demographic variables of study participants

Variable	Dexmedetomidine Mean ± SD	Dexamethasone Mean ± SD	t-value	p-value
Weight	14.31 ± 3.88	14.93 ± 4.06	-0. 601	0.550

The mean HR (Heart Rate) in Dexmedetomidine and Dexamethasone. There was a significant ($p<0.05$) difference between the two groups only at 0 minutes (after premedication). Other timeline distribution shows no significant ($p>0.05$) improvement in mean scores between the two groups as shown in **Table – 2**.

Table: 2 Comparison of mean Heart Rate in Dexmedetomidine and Dexamethasone: at Baseline, 0 min (after premedication), 15, 20, 60, 90, 120, 150 & 180 min.

Heart rate	Dexmedetomidine	Dexamethasone	p value
Baseline	131.03 ± 20.03	123.23 ± 15.71	0.101
0 min	135.86± 15.63	126.90± 16.40	**0.030**
1 min	137.38± 16.05	135.57± 13.28	0.638
5 min	129.62 ± 15.41	127.20± 12.05	0.500
10 min	127.66 ± 14 93	123.53± 11.69	0.240
Intra OP 0 min	136.31 ± 12.96	133.23± 12.56	0.350
Intra OP 15 min	125.34 ± 13.33	123.20± 11.94	0.510
Intra OP 20 min	95.62 ± 56.06	82.10 ± 59.55	0.370
Post-op 1 hr	129.72 ± 12.03	128.13± 11.61	0.600
Post-op 2 hr	125.83± 12.64	123.07± 11.91	0.390
Post-op 3 hr	122.00± 12.98	117.97± 11.53	0.210
Post-op 4 hr	118.90± 13.21	114.80± 11.44	0.200

Bolded p – values< 0.05 Significant

Table 3: Comparison of FLACC score, duration of analgesia, sedation score and motor block at various time interval in Dexmedetomidine and Dexamethasone

Variables	Dexmedetomidine Mean ± SD	Dexamethasone Mean ± SD	t value	p value
FLACC score at one hour	1.97 ± 1. 08	1.10 ± 0.75	3.561	**0.010**
Duration of Analgesia	286. 90 ± 102.15	530. 07 ± 134.04	-7.817	**0.001**
Sedation score at POP first hour	3.00 ± 0. 98	1.70 ± 1. 08	4.850	**0.001**
Sedation score at POP second hour	0.80 ± 0.80	0.13 ± 0.34	4.160	**0.001**
Motor block at first hour	0.17 ± 0. 37	0.10 ± 0.30	0.750	0.450

Bolded p – values< 0.05 Significant

The FLACC score was comparatively less in the dexamethasone group and was statistically significant ($p<0.05$). The duration of analgesia was more in the dexamethasone group and showed statistical significance ($p<0.05$).

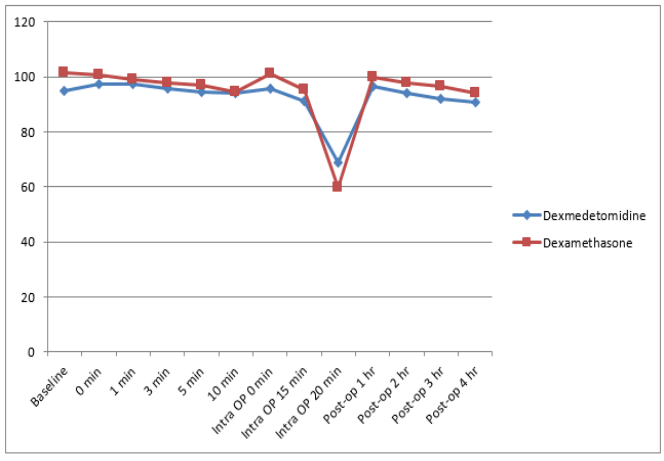
The sedation score of the study participants was significantly lower in the dexamethasone group at postoperative 1hr and 2hr respectively. The sedation score of the study participants was significantly lower in the dexamethasone group at postoperative 1hr and 2hr respectively. The motor block score in the study participants was similar in the Dexmedetomidine group and the dexamethasone group as shown in **Table-3.**

Discussion:

In our study, patients undergoing surgery in both groups was in similar demographic profile. The common presentation of the age group in our study participants was between 1 – 3 years for both the groups. The mean weight of the study participants was 14.31±3.88 kgs in the Dexmedetomidine group and 14.93±4.06 kgs in the dexamethasone group which was almost the same. Participants receiving dexmedetomidine and dexamethasone was also compared for the differences in their heart rate, systolic blood pressure, diastolic blood pressure. In this study we noticed that there was a statistically significant difference ($p<0.05$) in heart rate between the groups only at 0 minutes that is after premedication with midazolam nasal spray. [15] The heart rate in the intra-operative period of 0, 15, and 20 minutes in the dexmedetomidine group and dexamethasone group did not show significant difference between them. Similarly, no difference was noticed in the heart rate across both the groups in the postoperative period with $p>0.05$.

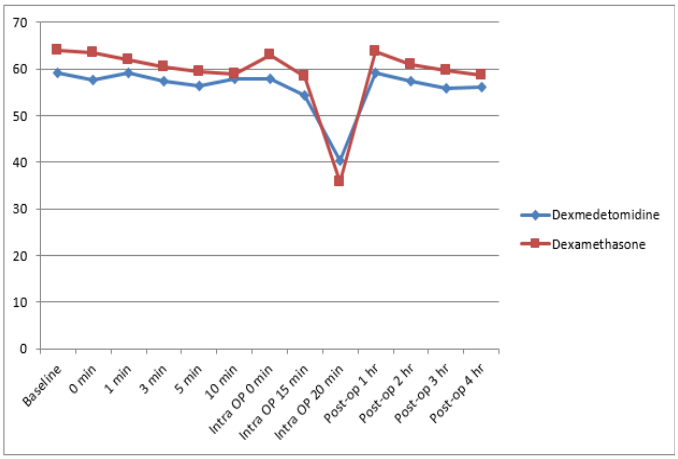
The systolic blood pressure at various time frames was observed at intra-operative and post-operative periods across the dexmedetomidine group and dexamethasone group. Results showed that there was a statistically significant ($p<0.05$) higher difference in mean systolic blood pressure in the dexamethasone group at baseline, intra-operative period 0 min & 15min, and post-operatively at 3hrs as shown in **Figure-1.**

Figure: 1 Comparison of mean SBP in Dexmedetomidine and Dexamethasone: at Baseline, After Premedication o min, 15, 30, 60, 90, 120, 150 & 180 min



Comparison of mean diastolic blood pressure in dexmedetomidine and dexamethasone group showed at baseline, after premedication, at 0 min, 15, 20, 60, 90, 120, 150 and 180 mins was done as shown in **Figure-2.**

Figure: 2 Comparison of mean DBP in Dexmedetomidine and Dexamethasone: at Baseline, After Premedication o min, 15, 20, 60, 90, 120, 150 & 180 min



The statistically significant higher difference in mean scores among dexamethasone group at baseline, intra-operative 0 min & 15 min, and post-operatively at 1 hr and 3hrs respectively.

When pain scores (FLACC) was compared between two groups, it was observed that in the dexamethasone group (1.10±0.75), the FLACC score was found to be significantly less ($p<0.001$) as compared to Dexmedetomidine (1.97±1.08). This infers that postoperative pain was less in the dexamethasone group and was statistically significant. The motor block score in the study participants was similar in the Dexmedetomidine group and the dexamethasone group. Kim EM et al. [16] in their study found that FLACC scores was almost comparable between the groups and there was no difference seen in motor block scores among the study participants which agreed with our study findings.

The mean duration of analgesia in the dexamethasone group was significantly more than the dexmedetomidine group that is 530.07 ± 134.04 minutes and 478.04±61.22 minutes ($p < 0.0001$), respectively. Choudhary S et al., [7] revealed the same findings in his study with a mean duration of analgesia in Group A as 248.4±54.1 minutes and Group B as 478.05±104.57 minutes with $p = 0.001$ where Group 'A' received 0.2% ropivacaine caudally and Group 'B' received a bolus of 0.2% ropivacaine with dexamethasone 0.1 mg/kg. Whereas many studies like Isaac GA et al., [17] found that Caudal dexmedetomidine 1 µg/kg with 0. 25% of ropivacaine for a pediatric patient undergoing infra-umbilical surgeries achieved postoperative pain relief up to 8 hours and the required dose of rescue analgesia was less with minimal adverse effects. Also, Takrouri MS et al., [18] found that dexmedetomidine, when compared with conventional sedatives and opiates was found to be associated with both sedative and analgesic sparing effects, minimal respiratory depression, reduced delirium and agitation, and desirable cardiovascular effects. Similarly, Gurbet A et al., [19] found that dexmedetomidine intra-operatively provides effective postoperative analgesia, and reduces postoperative morphine requirements without increasing the incidence of adverse effects.

It was also found that the sedation score of the study participants was significantly lower in the dexamethasone group at postoperative 1st hr and 2nd hr ($p<0.001$). This shows that patients in the dexmedetomidine group was more sedated than the dexamethasone group. Similarly, a study conducted by Bharti N et al., [20] noticed that patients receiving dexmedetomidine was more sedated as compared to the other groups ($p<0.01$) which correlates with our study.

Conclusion:

It is evident from our study that patients in the dexamethasone group had less postoperative pain and the duration of analgesia was more compared to that of dexmedetomidine. Hence dexamethasone is a good adjuvant for post-op analgesia.

Limitations of this study:

1. This study has included only small number of patients. It needs larger sample size to investigate the true effectiveness of adjuvants added in caudal block.

2. Since few of the patients belonged to pre-verbal age group, the assessment of pain was observer biased.

Acknowledgement: The authors thank the parents of the participants, members of the Department of Anesthesia, Operation Theatre Services and the Staff Nurses for co-operating throughout the study period.

Authors Contributions: SG, MRT, AK: Conception and design, Acquisition of Data. SG, MRT: Analysis and Interpretation of data, all authors. SG, MRT, AK: Drafting the article, revising it for Intellectual content, all authors; approval of final version of submitted manuscript.

Here, SG-Smyrna Gnanasekaran, MRT-Mohana Rangam Thirupathi, and AK-Ashok Kulasekar.

Source of funding: We didn't get any types of financial support from our parent institution and any other financial organization.

Conflict of Interest: The authors declare no conflict of interest, financial or otherwise.

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