Archives of Anesthesiology and Critical Care (Winter 2023); 9(1): 27-33.

Available online at http://aacc.tums.ac.ir

Research Article

Comparison of Duration of Postoperative Analgesia after Caudal Block with or without Intravenous Dexamethasone in Paediatric Day Care Infraumbilical Surgeries under General Anaesthesia

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ARTICLE INFO

Article history:
Received 13 April 2022
Revised 04 May 2022
Accepted 18 May 2022

Keywords:
Analgesia;
Dexamethasone;
Pain;
Bupivacaine

ABSTRACT

Background: Pain is defined as a subject's conscious perception of modulated nociceptive impulses that generate an unpleasant experience associated with actual or potential tissue damage. General anaesthesia, when combined with regional anaesthesia provides effective perioperative analgesia. Aim of the study was to study the effect of intravenous dexamethasone on duration of post-operative analgesia when given along with intra operative caudal block in paediatric day care infra umbilical surgeries under general anesthesia.

Methods: Sixty paediatric patients, American Society of Anesthesiologist's class I and II, patients were randomly divided in to two groups. In Group D - 30 paediatric patients who were given intravenous dexamethasone in a dose of 0.2 mg/kg iv in 5 ml normal saline along with caudal block with 0.75ml/kg of 0.25% bupivacaine. Group S - 30 paediatric patients who were given 5 ml of normal saline intravenously along with caudal block with 0.75ml/kg of 0.25% bupivacaine. Primary objective of the study was to determine the duration of post-operative analgesia.

Results: The demographic data were comparable in both groups. There were no significant difference of mean (SD) Heart Rate and Mean arterial pressure (mmHg) at baseline, post-operative 1st hour, post-operative 2nd hour, post-operative 3rd hour, post-operative 4th hour (p value >0.05). Time for rescue analgesia (minutes) to be given was more in group D when compared to group S (190.67 ± 41.76 versus 181.17± 37.97) however it was not statistically significant. Total duration of analgesia(minutes), i.e., including both intra-operative and post-operative period was more in group D when compared to group S (266.83 ± 37.69 versus 255.73 ± 42.83). However, there was no significant difference between them. (p value=0.188).

Conclusion: We conclude that a single bolus dose of intravenous dexamethasone (0.2 mg/kg) given along with caudal block with 0.75 ml/kg of 0.25% bupivacaine did not prolong the duration of postoperative analgesia in paediatric patients.

Pain is defined as a subject's conscious perception of modulated nociceptive impulses that generate an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage [1]. Although pain is often regarded as an inevitable consequence of surgery, its control is very important to improve both clinical outcome and patient comfort. Postoperative pain should be managed and treated as early and as effectively as possible to reduce suffering and to promote healing and rehabilitation so that patients can return to their routine life as soon as possible [2-3].

Postoperative pain in paediatric cases is often difficult to interpret and is usually underestimated. Anaesthesia and

The authors declare no conflicts of interest.

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surgery are unpleasant environments for children. Separation from caregivers, hunger, fear of strange places and perioperative pain can cause further stress and result in indistinct behavioural and physiological changes. Thus, children continue to be undertreated for pain due to difficulty in assessment or apprehension regarding cardio respiratory depression.

With day care surgery having become established in most parts of the world, the goal of postoperative pain relief after day care surgery is to provide analgesia but with minimal side effects, so that the patient can be discharged on the same day [4-5]. In paediatrics, day care surgery includes procedures like orchidopexy, circumcision, hernia repair, tonsillectomy, etc. These minor surgeries cause significant pain in children and in current times, a multimodal approach to analgesia is used, which includes psychological support, mild analgesics like paracetamol to NSAIDs and local and regional anaesthesia so as to provide opioid free analgesia and reduce opioid related adverse effects [6].

Regional nerve blocks have been used as an effective technique to manage intraoperative and postoperative pain. General anaesthesia, when combined with regional anaesthesia provides effective post-operative analgesia and reduces intraoperative requirement of analgesics and results in quicker recovery. The most widely used regional anaesthesia technique in paediatric practice for infraumbilical surgery is the caudal epidural block.

Historically, Campbell in 1933 carried out a series of caudal block in 114 patients successfully and since then, it has been widely used in children [8]. Over time it has become a technique of great interest, from premature infants and new-borns until 8-10 years of age. It is safe, easy to administer and provides effective postoperative analgesia. It also reduces the intraoperative requirement of inhalational and intravenous analgesics and reduces the neuro-humoral response to surgery [7].

Main disadvantage of the single shot caudal block technique using only local anesthetic drug is its short duration of action. Bupivacaine is a long-acting local anesthetic which is regularly used for caudal anesthesia. It has an onset of action of 15-20 minutes and normally acts for a duration of 180-350 minutes [9]. In a significant section of patients, despite good initial analgesia from caudal blockade with local anesthetic, moderate to severe pain develops as the block resolves. To overcome this disadvantage, various drugs such as opioids, ketamine, clonidine and dexmedetomidine have been used as additives along with local anesthetics. Many of them, however, have reported adverse effects such as nausea, vomiting, respiratory depression, sedation, undesirable hemodynamic effects and neurotoxicity [10-11].

Dexamethasone is a corticosteroid with anti-inflammatory effect, which is free from these side effects. It has been shown to be effective in prolonging the duration of action of bupivacaine and ropivacaine when given as an adjuvant along with it [12-15]. Even when used by the intravenous route, dexamethasone has been documented to prolong analgesia after caudal bupivacaine. It has been shown to significantly reduce the intensity of pain and decrease analgesic requirement in the postoperative period. Also, it has the advantage of reducing nausea, vomiting, fever, morbidity and delayed feeding in children [16].

Various studies have used dexamethasone intravenously in doses of 0.5mg/kg and have demonstrated its efficacy in augmenting analgesia provided by caudal block. Some studies have also been done at a lower dose of 0.25 mg/kg with positive results.

0.5mg/kg is a very high dose of dexamethasone and can be associated with side effects such as hyperglycemia, cortisol suppression and delayed wound healing. We decided to conduct this study to assess if this lower dose of dexamethasone (0.2mg/kg) augments analgesia provided by caudal block in paediatric day care infraumbilical surgeries performed under general anaesthesia.

We hypothesise that Intravenous dexamethasone alters the duration of post-operative analgesia when given along with intra operative caudal block in paediatric day care infra umbilical surgeries under general anaesthesia. Aim of the study was to study the effect of intravenous dexamethasone on duration of post-operative analgesia when given along with intra operative caudal block in paediatric day care infra umbilical surgeries under general anesthesia.

Methods

This prospective Randomised Comparative Study was conducted after approval from institutional ethics committee and registration with clinical trial registry of India (CTRI/2020/07/026307) between 1st November 2019 to 31st March, 2021. Sixty pediatric patients, ASA class I and II, age between 2 to 7 years of either sex, posted for elective infra umbilical surgeries were included in this study. Patients with any allergy to local anaesthetic drugs, Coagulopathy and bleeding disorder, Local site infection, preexisting neuromuscular disorders, Congenital anomalies of lower back, Mental retardation and delayed development were excluded.

The sample size calculation was based on a study conducted by JY Hong, et al, 17 observed that mean level of time to first acetaminophen in control group was 430 ± 205 minutes and in dexamethasone was 646 ± 149 minutes.26 Taking these values as reference, the minimum required sample size with 99% power of study and 5% level of significance was 26 patients in each study group. Total sample size was rounded off to 60 (30 patients per group).

Formula for comparing mean of two groups:

$$N \geq \frac{2\,(\text{standard deviation})2*(Z\alpha + Z\beta)2}{(\text{Mean difference})2}$$

Where Zα is value of Z at two side alpha error of 5% and Zβ is value of Z at power of 99% and mean difference is difference in mean values of two groups.
Pooled standard deviation=Sqrt(S1)2+(S2)2/2)
where S1 is the standard deviation of the first group.
and S2 is the standard deviation of the other group.
Calculations:
Pooled standard deviation=sqrt(205)2+(149)2)/2) =179.201

$$N \geq \frac{2(179.201)2 *(1.96 + 2.33)2}{(216)2}$$

≥25.335=26(approx.)

Written informed consent was taken from all the patients. After careful pre-anaesthetic examination and investigation, patients meeting the inclusion criteria were taken for the study. 60 patients were randomly divided into two group of 30 patients each by computer generated random number. Group D- 30 paediatric patients who were given intravenous dexamethasone in a dose of 0.2 mg/kg iv in 5 ml normal saline along with caudal block with 0.75ml/kg of 0.25% bupivacaine. Group S- 30 paediatric patients who were given 5 ml of normal saline intravenously along with caudal block with 0.75ml/kg of 0.25% bupivacaine.

The children were fasted 6 hours for solids and 2 hours for clear liquids before surgery. In the operation theatre, baseline values of heart rate, blood pressure and SpO2 were measured. Patients were induced with inhalation of sevoflurane, oxygen and nitrous oxide. Appropriately sized cannula was put, and Ringer Lactate was started at a calculated rate. Inj. fentanyl 2µg/kg was given and Proseal laryngeal mask airway of an appropriate size was inserted, and patient was maintained on sevoflurane, oxygen and nitrous oxide. Study drug was given to the patient diluted in 5 ml of normal saline. Patient was then turned to the lateral position and using landmark technique, caudal epidural block was given.

After the block was given, patient was turned supine. Surgery was allowed to start 10 minutes after the block was given. Intraoperatively, heart rate, blood pressure and SpO2 were monitored every 15 minutes for the first hour and every 30 minutes for the second hour of surgery. At the end of surgery, sevoflurane was discontinued. When the child was completely awake, the Proseal laryngeal mask airway was removed, and the patient was then shifted to the PACU for observation.

After excluding other causes, if there was an increase in heart rate or mean arterial pressure (>20% over baseline) after incision, it was considered to be failure of caudal analgesia and the patients were excluded from the study.

Patients were monitored for post-operatively for hemodynamic changes and oxygen saturation was monitored. Analgesia was assessed by FLACC scale hourly. Rescue analgesia was given with intravenous paracetamol 15 mg/kg when FLACC score was ≥ 4, marking the end of study.

Parental satisfaction with analgesia and patient comfort was noted by using the Likert scale at the end of study.

Primary objective of the study was to determine the duration of post-operative analgesia. Secondary objectives of the study were to assess the incidence of post-operative nausea and vomiting (PONV).

In statistical analysis Categorical variables were presented in the form of number and percentage (%). On the other hand, the quantitative data were presented as the means ± SD and as median with 25th and 75th percentiles (interquartile range). The data normality was checked by using Kolmogorov-Smirnov test. The cases in which the data was not normal, we used nonparametric tests. The following statistical tests were applied for the results: The comparison of the variables which were quantitative and not normally distributed in nature were analyzed using Mann-Whitney Test and Independent t test was used for comparison of normally distributed data between two groups. The comparison of the variables which were qualitative in nature were analyzed using Chi-Square test. If any cell had an expected value of less than 5 then Fisher's exact test was used. Kaplan Meier survival analysis curve with log rank test was used to compare time of requirement of rescue analgesia between group D and S. The data entry was done in the Microsoft EXCEL spreadsheet and the final analysis was done with the use of Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, version 21.0. For statistical significance, p value of less than 0.05 was considered statistically significant.

Results

60 pediatric patients were included in the study. Mean age of patients in group D was 4.53 ± 1.87 and in group S was 5.17 ± 1.7. No significant difference was seen in the demographic parameters in both groups in terms of age, height, weight, body mass index between group D and S. (p> 0.05) Distribution of gender was comparable between group D and S. There were 20 male and 10 female patients in each group. The mean(SD) duration of surgery (minutes) in group D was 74.57 ± 51.52 minutes and group S was 76.17 ± 51.89. no significant difference between the groups. (p=0.354) (Table1). Hernia repair was the most performed surgery in both groups. The types of procedure performed in both groups were comparable and there was no significant difference between them. Other cases include marsupialization of mucus retention cyst, cystoscopy, and anorectoplasty.

Minimum and maximum values for heart rate (per minute) were 76 and 132 in Group S and 84 and 126 in Group D respectively. However, they were comparable in both the groups and no significant difference was seen at baseline (p value=0.305), post-operative 1st hour (p value=0.319), post-operative 2nd hour (p value=0.186), post-operative 3rd hour (p value=0.48), post-operative

4th hour (p value=0.34) between group D and S. No significant difference was seen in Mean arterial pressure (mmHg) at baseline (P value=0.111), post-operative 1st hour (p value=0.321), post-operative 2nd hour (p value=0.691), post-operative 3rd hour (p value=0.853), post-operative 4th hour (0.522) and the results were comparable. No significant difference was seen in SpO2 at different time intervals with no signs of hypoxia. It was maintained 100 % at all times.

6.67% of patients in both groups required rescue analgesia after 1st post-operative hour. 33.33% of patients in group S in contrast to 20% in group D had to be given rescue analgesia between 2nd and 3rd hour. 73.33% of patients in group D had their effect of analgesia lasting beyond 3 hours when compared to 60% in group S. So, although the results were not statistically significant. Time for rescue analgesia (minutes) to be given was more in group D when compared to group S (190.67 ± 41.76 versus 181.17 ± 37.97) however it was not statistically significant. Total duration of analgesia (minutes), i.e., including both intra-operative and post-operative period was more in group D when compared to group S (266.83 ± 37.69 versus 255.73 ± 42.83). However, there was no significant difference between them. (p value=0.188). (Table 2)

Kaplan Meier analysis showed no significant difference in time of requirement of rescue analgesia (minutes) between the two groups (p value=0.556) with a mean duration of rescue analgesia as 181.167 in group S and 190.667 in group D (Figure 1).

All 60 patients had successful caudal block in our study and FLACC score was 0 at baseline in both groups. Rescue analgesia was given when FLACC score was 4. It was higher at all times in group S when compared to Group D, i.e., 0.37 ± 0.61 versus 0.67 ± 1.15 at post-operative 1st hour, 1.33 ± 1.21 versus 1.93 ± 1.14 at 2nd post-operative hour, 2.6 ± 1.35 versus 3.24 ± 0.54 at 3rd post-operative hour and 4 ± 0 versus 4 ± 0 at 4th post-operative hour. However, it was not statistically significant at any point of time.

Nearly 80% of guardian were satisfied with the analgesia given to their patient in both groups. Distribution of Likert scale was comparable between group D and S. (Excellent: - 26.67% vs 23.33% respectively, Good: - 53.33% vs 66.67% respectively, Fair: - 16.67% vs 3.33% respectively, Poor: - 3.33% vs 6.67% respectively) (p value=0.366). (Table 3)

All patients were observed for side effects including PONV, bradycardia, pruritus and hypotension in both groups. One patient in group D developed pruritus post operatively, while one patient in group S developed PONV. However, it was not statistically significant.

Table 1- Comparison of demographic characteristics

Demographic characteristics	Group D(n=30)	Group S(n=30)	P value
Age(years)			
Mean ± SD	4.53 ± 1.87	5.17 ± 1.7	0.18†
Gender			
Female	10 (33.33%)	10 (33.33%)	1§
Male	20 (66.67%)	20 (66.67%)	
Height(cm)			
Mean ± SD	100 ± 12.77	103.03 ± 11.68	0.374†
Weight(kg)			
Mean ± SD	16.27 ± 3.95	16.93 ± 3.51	0.492*
Body mass index(kg/m²)			
Mean ± SD	16.17 ± 2.33	15.95 ± 2.42	0.647†
Duration of surgery(minutes)			
Mean ± SD	74.57 ± 51.52	76.17 ± 51.89	0.354†

* Independent t test, † Mann Whitney test, § Chi square test

Table 2- Comparison of number of patients against time for rescue analgesia

Time for rescue analgesia(minutes)	Group D(n=30)	Group S(n=30)	P value
>1 to 2 hours	2 (6.67%)	2 (6.67%)	1‡
>2 to 3 hours	6 (20%)	10 (33.33%)	0.32 §
>3 hours	22 (73.33%)	18 (60%)	0.26 §
Mean ± SD	190.67 ± 41.76	181.17 ± 37.97	0.166†
Total duration of analgesia(minutes)			
Mean ± SD	266.83 ± 37.69	255.73 ± 42.83	0.188†

† Mann Whitney test, ‡ Fisher's exact test, § Chi square test

Figure 1- Kaplan Meier survival analysis curve to compare time of requirement of rescue analgesia

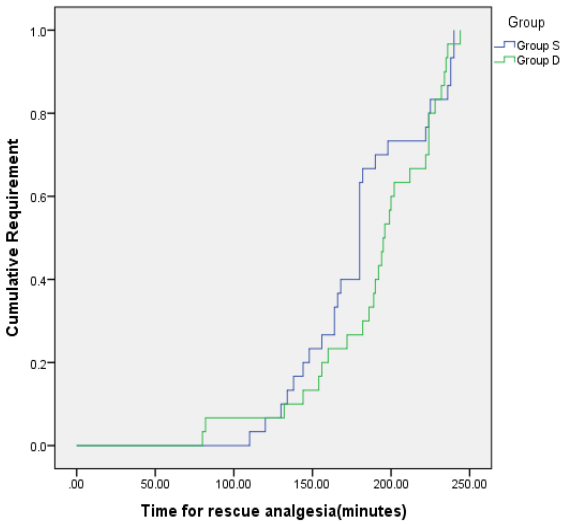

Table 3- Comparison of FLACC score and Likert scale

FLACC score	Group D	Group S	P value
At baseline			
Mean ± SD	0 ± 0	0 ± 0	1†
Post-operative 1st hour			
Mean ± SD	0.37 ± 0.61	0.67 ± 1.15	0.54†
Post-operative 2nd hour			
Mean ± SD	1.33 ± 1.21	1.93 ± 1.14	0.055†
Post-operative 3rd hour			
Mean ± SD	2.6 ± 1.35	3.24 ± 0.54	0.212†
Post-operative 4th hour			
Mean ± SD	4 ± 0	4 ± 0	1†
Likert scale			
Excellent	8 (26.67%)	7 (23.33%)	0.366‡
Good	16 (53.33%)	20 (66.67%)	
Fair	5 (16.67%)	1 (3.33%)	
Poor	1 (3.33%)	2 (6.67%)	
Total	30 (100%)	30 (100%)	

† Mann Whitney test

Discussion

Dexamethasone is a synthetic adrenocorticosteroid with glucocorticoid activity that exerts its analgesic action due to its strong anti-inflammatory property. It also reduces prostaglandin synthesis from the inflamed site which is responsible for pain [18]. Even though dexamethasone has been frequently used as an additive along with local anesthetic drugs for prolonging the action of caudal anesthesia, Various studies have used intravenous dexamethasone as a part of multimodal analgesia to relieve pain, however, there has been no standardization of the dose to be used, especially in children [17,19].

Patients in both groups were comparable in terms of age, weight, height and body mass index ($p > 0.05$). In our study, distribution of gender was also comparable between group D and S. Studies conducted by Hong JY et al in 2010 and Arbi MS et al in 2015 also had similar demographic characteristics [17,20].

There are very few studies where a similar dose of dexamethasone was used intravenously and its impact on duration of analgesia along with caudal block studied in paediatric patients.

Shifaat F et al did a similar study in 2019, where they used dexamethasone in a dose of 0.25mg/kg intravenously and found that it prolonged the duration of analgesia of caudal block after infraumbilical surgeries. The difference in their results could be due to the use of a slightly higher dose (0.25mg/kg vs 0.2mg/kg) and due

to assessment of pain using a different scoring system (VAS) to evaluate pain in children [21].

Salami OF et al in 2017 have also used low dose of intravenous dexamethasone (0.25 mg/kg) in children along with caudal block to study the influence of IV dexamethasone on postoperative analgesic requirement after caudal block. Their results are contradictory to our findings. They concluded that low dose intravenous dexamethasone along with caudal bupivacaine prolonged pain free duration, reduced the post-operative pain scores and analgesic consumptions in children undergoing day care unilateral inguinal herniotomy. The difference in results seen in their study could be because of a slightly higher dose of dexamethasone used in their study. Their population characteristics and ethnicity were also different. Further, they have used a higher volume of local anesthetic (0.25% bupivacaine) 1ml/kg in comparison to 0.75 ml/kg used in our study. That could have contributed to the longer duration of analgesia seen in all patients in their study [22].

Dongare DH et al 2017 also found that low dose of systemically given dexamethasone is ineffective in augmenting the effect of caudal anesthesia in children. However, they used an even lower dose of dexamethasone (0.1mg/kg) [23].

Studies conducted by J Y Hong et al in 2010, Arbi MS et al in 2015 and Srinivasan B et al in 2016 have concluded that intravenous dexamethasone prolongs the duration of caudal analgesia. However, all these studies have used dexamethasone in a dose of 0.5 mg/kg which is a higher dose than we have used in our study and that would explain the observed difference in results [17,20,24].

In our study, all patients in both groups had a FLACC score more than 4 by the end of four hours. No significant difference was seen in FLACC score at any study interval. Mean duration of analgesia was 190.67 ± 41.76 minutes in group D and 181.17 ± 37.97 minutes in group S. Kaplan Meier analysis done for the study showed no significant difference in time of requirement of rescue analgesia between the group D and S (p value=0.556). FLACC has also been used by Nadeem A et al for pain assessment in their study [25].

Distribution of Likert scale was comparable between group D and S and nearly 80% of parents in both groups were well satisfied with the mode of analgesia used. Hong et al also used Likert scale for assessment of parent satisfaction and concluded that 79.5% guardian in control group and 97.4% guardian in dexamethasone group were satisfied [17].

In our study, one patient in group D complained of pruritus and one in group S developed PONV. These side effects were also studied in the study by Arbi MS et al 2015 and Dongare DH et al 2017 and they did not find any statistical difference in side-effects in the two groups [20,23].

Limitations to our study was that it ended after first rescue analgesia and dose of total post-operative analgesia was not monitored for next 24-48 hours. Follow up for longer period would have highlighted the analgesic effect of dexamethasone once the effect of caudal block had worn off. Another limitation was that we did not do laboratory testing to check for hyperglycemia or adrenal suppression that may occur in these patients on administration of dexamethasone. Although every effort was made to keep NPO under check, hunger may have affected FLACC scoring in some way. Anxiety may have played a role. Also, we did not use multiple doses of dexamethasone. That would have brought clarity regarding the ideal dose for analgesia.

Conclusion

We conclude that a single bolus dose of intravenous dexamethasone (0.2 mg/kg) given along with caudal block with 0.75 ml/kg of 0.25% bupivacaine did not prolong the duration of postoperative analgesia in paediatric patients.

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