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Efficacy of Dexamethasone 0.1mg/Kg when Combined with 0.15% Ropivacaine for Caudal Analgesia in Children undergoing Infraumbilical Surgeries

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Abstract

Introduction: Recent research has focused on the addition of the glucocorticoid dexamethasone as an adjuvant to local anesthetics in regional anesthesia.[8] Although the exact mechanism of action is unknown, preliminary studies suggest its addition can impressively prolong the duration of analgesia with minimal adverse effects.

Methodology: 60 children between the age group 1-5 years of ASA-PS I and II posted for elective infraumbilical surgeries were randomly grouped into two equal groups using shuffled sealed opaque envelope technique. Pre anesthetic evaluation was done and informed consent was obtained from the parents after explaining about the procedure and the drugs being used.

Results: The number of rescue analgesics required by patients receiving only ropivacaine in their caudal block was compared to in patients receiving Dexamethasone as adjuvant with ropivacaine and was found to be statistically highly significant with a p value of 0.001.

Conclusion: The mean pain scores at different time intervals in between 2 groups were compared using Independent t test and was found to be statistically highly significant with a p value of <0.0001.

Keywords: Dexamethasone; Ropivacaine; Caudal analgesia.

Introduction

The alleviation of pain has been the focus of continuing human effort over centuries. Pain is a protective mechanism designed to alert the body to potentially injurious stimuli. The International Association for Study of Pain (IASP) defines pain as an "unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage".[1]

However it has been recognized for some time that the management of acute pain, especially post operative pain, has been consistently and systematically inadequate. Children are special in this regard as this complex phenomenon and the importance of pain relief is often underestimated in them.

Considering the facts that biology of pain, development of pain perception in infancy, assessment of pain, behavioral and psychological aspects of pain and pharmacology of analgesics are unique to this age group, the approach to a paediatric patient and the modalities to reduce pain should also be specialized. Under treatment of post–operative pain may trigger biochemical and physiologic stress response and cause impairments

in pulmonary, cardiovascular, neuroendocrinal, gastrointestinal, immunological, and metabolic function seven in the children and newborns.[2]

Assessment of pain is the most important and critical component of pain management. Assessing pain in children is a difficult task, mainly because so far no single reliable method of assessing and measuring child's pain is available.[3]

Regional anaesthetic techniques decrease the requirement of inhaled anaesthetics, opioids, attenuate the stress response to surgery, facilitate smooth recovery and provide good immediate postoperative analgesia with less systemic analgesic requirements.[4]

Caudal analgesia is a safe and reliable technique, easy to perform and has been found to be very effective in children, especially in infra-umbilical surgeries when combined with general anaesthesia.[5] It is one of the most popular, reliable and safe techniques in pediatric anaesthesia that can be used for intra and postoperative analgesia. It is a relatively simple technique with a good success rate.[4]

The main disadvantage of caudal analgesia is the duration of action after a single injection which is limited by the duration of action of the local anesthetics used. Placement of a catheter has an inherent risk of infection. Prolongation of caudal analgesia using a single-shot technique has been achieved by the addition of various adjuvants such as opioids, ketamine, neostigmine, midazolam and α2 agonists. Many of these adjuvants have side effects like respiratory depression, vomiting, pruritus etc.[5]

Recent research has focused on the addition of the glucocorticoid dexamethasone as an adjuvant to local anesthetics in regional anesthesia. Although the exact mechanism of action is unknown, preliminary studies suggest its addition can impressively prolong the duration of analgesia with minimal adverse effects.[6]

Various studies using dexamethasone along with ropivacaine for caudal analgesia in children for infra umblical surgeries have been done. Majority of the studies used 0.2% of Ropivacaine along with 0.1mg/kg of dexamethasone.The volume used of ropivacaine was 1ml/kg when 0.2% ropivacaine was used and 1.5ml/kgwhen 0.15% ropivacaine was used 11. Only one study has found out that reducing both the concentration (0.15%ropivacaine) and volume (1ml/kg) along with dexamethasone (0.1mg/kg) has found to be effective in prolonging postoperative analgesia.[5]

Hence the present study is to find out the lower volume (1ml/kg) and lower concentration (0.15%) of ropivacaine along with dexamethasone in prolonging the post operative analgesia in children undergoing infraumbilical surgeries.

Methodology

60 children between the age group 1–5 years of ASA-PS I and II posted for elective infraumbilical surgeries were randomly grouped into two equal groups using shuffled sealed opaque envelope technique. Pre anesthetic evaluation was done and informed consent was obtained from the parents after explaining about the procedure and the drugs being used.The two groups were Group R (control group) and Group D (study group).Group R received 1 ml/kg of 0.15% ropivacaine with normal saline (1ml) and Group D received 1 ml/kg of 0.15% ropivacaine with dexamethasone 0.1 mg/kg in saline to make a total volume 1ml in the caudal epidural space.

All the children were premedicated with syrup midazolam 0.5 mg/kg 1 hr before surgery, the patients were then shifted to the operation room. Routine preinduction monitors were instituted which included pulse oximetry, electrocardiogram and noninvasive blood pressure monitoring . The baseline values were recorded and documented. Venous access (I.V) would have been secured by the paediatric surgeon in the ward which is routinely done in our hospital. Anaesthesia was induced with injection thiopentone 5 mg/kg and intubation aided by administering injection atracuriumbesylate 0.5 mg/kg after ensuring adequate chest rise with mask ventilation. Endotracheal (ET) intubation was done as per standard protocol of our hospital with appropriate size ET tube, position confirmed, and ET tube secured in place, Anaesthesia was maintained with 33% O_2: 67% N_2O mixture and sevoflurane 1–2%.

Preparation of The Drug and Blinding

The drug as per the allocated group was prepared by an anesthesiologist who was not involved in administering caudal block and data collection for the study. The caudal block was performed by another anesthesiologist who was blinded to the drug that was injected and also was the observer. 3ml of 0.2% ropivacaine (Ropin 0.2% (2mg/ml) Neon laboratories ltd, preservatives free) was added with 1ml of normal saline to make 0.15%

ropivacaine. If a child of 13kg total volume of 16ml (12ml of 0.2%ropivacaine+4ml NS) of 0.15% ropivacaine was prepared and 13 ml of that will be taken for the study and 1 ml of either saline or 0.1mg/kg of dexamethasone (Dexona 4mg/ml Zydus Cadilla, contains methyl paraben 0.85mg and propyl paraben 0.15mg as preservatives) saline was added. Syringe containing either equal volume of 0.15%ropivacaine with normal saline or 0.15% ropivacaine with dexamethasone were prepared and given to the investigator who was blinded to the identity of drugs .

After intubation, patients were placed in lateral decubitus position and a single dose caudal block was performed under sterile conditions using 22G, 2.5cm blunt tipped and short beveled needle and a standard "give away"(piercing sacrococcygeal) technique after identification of the caudal space. The drug was given as per allocated group. Group R received 1 ml/kg of 0.15% ropivacaine with normal saline (1ml) and Group D received 1 ml/kg of 0.15% ropivacaine with dexamethasone 0.1 mg/kg in saline to make a total volume 1ml. Children were turned to supine posture immediately after the administration of caudal analgesia.

The surgical incision was made after 10 min of caudal placement. The caudal block was considered to have failed if the patient had an increase in heart rate, had an increase in mean arterial pressure, or both of more than 15% compared with baseline during the surgery. In such instances, the patient was to be withdrawn from the study and treated with 1–2 μg /kg of fentanyl.

The recorded parameters were documented every 5 minutes intraoperatively till awakening. The duration of surgery was noted down.

Neuromuscular blocking drugs blockade was reversed with neostigmine (0.05 mg/kg) and glycopyrollate (0.01 mg/kg).

After extubation, pain score was assessed using FLACC scale.

Results

Table 1: Mean age (in years) in each of the groups.

Group	N	Mean (years)	Standard deviation	P value
R	30	3.2	1.4	0.2
D	30	2.8	1.3	

The mean age of the two groups were compared using Anova tests and found to be insignificant with a p value of 0.20. Group R and D had a mean age of 3.2 and 2.8 years respectively.(Table 1)

Table 2: Sex distribution in both the groups.

Sex	Group		Total
	R	D	
Male	23	27	50
Female	7	3	10
Total	30	30	60

The sex distribution between 2 groups were compared using Pearson Chisquare test. There was no significant difference between the 2 groups with a p value of 0.16.(Table 2)

Table 3: Mean weight in kilograms in the two groups.

Group	N	Mean weight (kgs)	Standard deviation	P value
R	30	11.2	2.8	0.2
D	**30**	**12.2**	**3.1**	

The mean weight in Group R was 11.2 kgs, and in Group D was 12.2 kgs. The mean weight of the patients were compared using Anova test and found that there was no statistical significance difference between 2 groups with a p value of 0.20. (Table 3)

Table 4: Number of rescue analgesics in each group.

Number of rescue analgesics	Group R	Group D	P value
0	0 (0%)	3 (10%)	0.001
1	8 (26.7%)	18 (60%)	
2	15 (50%)	9 (30%)	
3	7 (23.3%)	0(0%)	

The number of rescue analgesics required by patients receiving only ropivacaine in their caudal block was compared to inpatients receiving Dexamethasoneas adjuvant with ropivacaine and was found to be statistically highly significant with a p value of 0.001. (Table 4)

Table 5: Mean pain scores at different time intervals in the two groups.

	Group			
	D		R	
	Mean	Standard Deviation	Mean	Standard Deviation
FLACC PAINSCORE At emergence	.0	.0	.0	.0
FLACC PAINSCORE 30min	.0	.0	.0	.2
FLACC PAINSCORE 1hr	.0	.0	1.0	.7
FLACC PAINSCORE 2hr	.5	.5	1.7	.7
FLACC PAINSCORE 3hr	1.1	.7	2.7	1.0
FLACC PAINSCORE 4hr	1.7	.7	1.7	1.6
FLACC PAINSCORE 6hr	2.1	.9	1.1	1.6
FLACC PAINSCORE 7hr	1.8	1.4	.8	1.0

FLACC PAINSCORE 9hr	1.4	1.7	1.7	1.1
FLACC PAINSCORE 12hr	.8	1.3	1.6	1.2
FLACC PAINSCORE 15hr	.6	1.0	1.4	1.0
FLACC PAINSCORE 20hr	.8	.9	1.4	.9
FLACC PAINSCORE 24hr	.8	.8	1.6	.9

The mean pain scores at different time intervals in between 2 groups were compare dusing Independent t test and was found to be statistically highly significant with a p value of<0.0001. (Table 5)

Discussion

The total duration of analgesia was defined as the time from administration of caudal anaesthesia till the time the pain score was more than 3.

In our study, patients in Group R who received caudal block with 0.15% ropivacaine alone had a mean duration of analgesia was 234.17±61.37 mins. The minimum duration of analgesia was 120 minutes and the maximum duration of analgesia observed was 960 minutes.

Patients in Group D received 0.15% ropivacaine with 0.1 mg/kg dexamethasone had a mean duration of analgesia of 447.13±96.26 mins. The minimum duration of analgesia was 300 minutes and maximum was 24 hours, beyond which monitoring was not done.

The difference between the duration of analgesia was statistically highly significant between the two groups, with a p value of< 0.0001.

Similar observations were made by many of the authors using dexamethasone as an adjuvant for caudal analgesia like:

In a study by Kim Lee et al, the number of subjects who remained pain free up to 48 h after operation was significantly greater in the group who received Dexamethasone (0.1 mg/kg) in caudal block [19 of 38 (50%)] as compared to patients in the control group who received 0.15% ropivacaine alone[four of 37 (10.8%); P<0.001. Time to first oral analgesic administration after surgery was also significantly longer in Group D than in Group C (P=0.014).[7]

Girgis et al demonstrated the analgesic efficacy of dexamethasone (0.2 mg/kg) added to bupivacaine (1ml/kg 0.25%) in caudal blocks. The duration of analgesia was± 3.5hrs with dexamethasone vs. 7.1 ± 3.2 hrs with plain bupivacaine. (P<0.001, statistically significant).[8]

Yousef et al observed that addition of magnesium or dexamethasone to caudal ropivacaine significantly prolonged analgesia duration to 8 hours (5–11 hours) and 12 hours (8–16 hours), respectively compared with 4 hours (3–5 hours) with the use of ropivacaine alone. The time to first analgesic dose was significantly longer in groups with Magnesium and Dexamethasone (500 ± 190 and 730 ± 260 min) respectively compared with Ropivacaine alone (260 ± 65 min).[9]

In a study by Naghipour et al, the duration of analgesia was significantly longer in the group receiving dexamethasone in the epidural space (372 ± 58.1) than with plain bupivacaine (234.6 ±24.3 min).[10]

Pain score was assessed using the FLACC scoring system. A pain score of more than three was considered significant at which point a rescue analgesic was given.

Pain scores were assessed every thirty minutes for the first two hours, then every hour till the 6th hour, following which the pain score was assessed every two hours uptil 24 hours. This assessment was done by a person who was blinded to which drug was given in the caudal block. In our study, none of the patients in either of the two groups had any pain for the first 1.5 hours. The earliest onset of pain score of more than 3 was at 120 minutes in a patient who received plain ropivacaine, and 300 minutes in a patient who received ropivacaine with dexamethasone.

Overall, the mean pain scores were found to be lower in subjects who received dexamethasone as a caudal additive as compared to patients who received local anesthetic alone. Rectal paracetamol suppository 30 mg/kg was the rescue analgesic given to patients when their pain score was >3 as measured by FLACC scale. The number of rescue analgesics required by patients receiving only ropivacaine in their caudal block was compared to in patients receiving Dexamethasone as adjuvant with ropivacaine and was found to be statistically highly significant with a p value of 0.001.

There were patients who required no dose of rescue analgesia at all in the group with Dexamethasone as compared to ropivacaine alone (3/30 patients 10% in group D as compared to none in group R).

Similar observations were made by many of the authors using dexamethasone as an adjuvant for caudal analgesia like:

Naghipour et al showed in their study that pain score and rescue analgesia use were less in the Dexamethasone group than the control group (37.1+/– 19.7 mg v.s. 73.1+/– 17.6 mg, respectively; p=0.001).[7]

In a study by Kim Lee et al, the number of subjects who received oral analgesic was significantly lower in Group D (28.9%) than in Group C (54.1%) P=0.027.[11]

Dexamethasone with local anaesthetic has been shown to prolong peripheral nerve block in animalsand humans.

It has been found to be superior than other adjuvants in terms of duration of analgesia, requirement of rescue analgesia, and lesser motor block.

Conclusion

The mean duration of analgesia between 2 groups were compared using Independent t test. The mean duration of analgesia was 234.17±61.37 mins in Group R and 447.13 ±96.26 mins in Group D with a p value <0.0001 which was statistically highly significant. The number of rescue analgesics required by patients receiving only ropivacaine in their caudal block was compared to inpatients receiving Dexamethasone as adjuvant with ropivacaine and was found to be statistically highly significant with a p value of 0.001. The mean pain scores at different time intervals in between 2 groups were compared using Independent t test and was found to be statistically highly significant with a p value of <0.0001.

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