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Original Article

Comparison of Ropivacaine Alone versus Ropivacaine with Dexamethasone in Caudal Block for Pediatric Post-operative Analgesia

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Abstract

Background: Caudal block is a regional anesthesia technique most commonly used for post-operative analgesia in children undergoing infraumbilical surgeries. The local anesthetics used in caudal block have the shortcoming of less duration of action which can be increased by adding adjuncts. The aim of our study was to compare the duration of post-operative analgesia when 0.2% ropivacaine versus 0.2% ropivacaine with dexamethasone is administered caudally in pediatric patients undergoing infraumbilical surgeries.

Materials and Methods: The study included 80 patients of 1-8 years age group of ASA Status I undergoing infraumbilical surgery allocated randomly into two groups of 40 each in double-blinded manner after ethical committee clearance and parent's/legal guardians consent. After securing airway with laryngeal mask airway under standardized general anesthesia Group R received 0.2% ropivacaine 1 ml/kg and Group RD received 0.2% ropivacaine 1 ml/kg with 0.1 mg/kg dexamethasone for caudal analgesia according to group allocated. Post-operative pain was assessed by objective pain scale and face, legs, activity, cry and consolability behavioral pain assessment scale for 24 h. Motor recovery and side effects were noted. The hemodynamics, duration of post-operative analgesia and number of rescue analgesia needed was noted and analyzed statistically.

Results: Mean duration of analgesia in Group R was 324 ± 55.6 min and in Group RD was 1278 ± 304.4 min with $P = 0.000$. The number of subjects who remained pain-free up to 24 h postsurgery was significantly higher in Group RD than in Group R.

Conclusion: Dexamethasone added to ropivacaine for caudal block has significantly improved analgesic efficacy and increased the duration of post-operative analgesia in children undergoing infraumbilical surgery.

Key words: Caudal, Dexamethasone, Pediatric, Post-operative analgesia, Ropivacaine

INTRODUCTION

The society of pediatric anesthesia on 15th Annual Meeting at New Orleans (2001) defined the alleviation of pain as a basic human right, irrespective of age, medical condition, treatment, primary service response for the patient care, or medical institution.[1] The scope of anesthesiologists has widened these days in pediatric regional analgesia as its use is supported by extensive data from the literature documenting its safety and efficacy. The almost complete absence of hemodynamic effects of regional anesthesia in infants and young children together with realization that anesthesiology includes treatment of all form of pain in all patients have led to renewed interest in pediatric regional anesthesia.[2] In 1998 more than 50 anesthesiologists from all over the world demonstrated that the performance of a block in an anesthetized child is safe, reliable and ethical and that the use of this technique in a sedated child is much safer than its use in an awake and excited baby.[3]

Surgical procedures in children are followed by pain, which may give rise to restlessness, tachycardia, hypertension,

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fear, crying, anxiety, and agitation in children. To negate these physiological and psychological effects of pain and to improve the quality of analgesia, caudal epidural block is a well-known technique[4] and thus caudal anesthesia holds a definite part in anesthesiologist armentarium.

Local anesthetics are drugs that inhibit conduction in peripheral nerves, and these are being used in regional anesthesia. Bupivacaine was the local anesthetic commonly used previously. Ropivacaine is a long-acting local anesthetic which is considered safe in pediatric population because of its property to produce differential neural blockade with less motor block along with reduced cardiovascular and neurological toxicity.[5]

Single shot caudal was preferred and most commonly used technique. However, the disadvantage of single shot caudal is less duration of action of local anesthetic and the need for supplementation of analgesia postoperatively. Epidural catheters were introduced which lost its popularity due to increased incidence of infection and other complications. To overcome these drawback of epidural catheters adjuncts have been added to local anesthetics which prolonged the duration of action of local anesthetics thus providing post-operative analgesia.

Various adjuncts have been introduced initially to increase the duration of action of local anesthetics which includes opioids, epinephrine, ketamine, clonidine, fentanyl, and tramadol. However, these adjuncts have their own side effects such as respiratory depression, nausea, vomiting, pruritis, urinary retention, and tachycardia. Dexamethasone is a glucocorticoid with strong anti-inflammatory effects. Dexamethasone is successfully used as an adjunct in caudal blocks for children to reduce pain without inducing any significant respiratory and hemodynamic effects.[6]

The pain scores are developed for pediatric patients as they cannot express the actual intensity of pain verbally and these pain scores help documentation of pain and its effective management.

The acronym face, legs, activity, cry and consolability (FLACC) facilitates recall of the categories, each of which is scored from 0 to 2 with total scores ranging 0-10 similar to other clinical assessment tools. Inter-rater reliability of the FLACC among two observers was established in 30 children in the postanesthesia care unit (PACU) (r = 0.94). Validity was established by demonstrating an appropriate decrease in FLACC scores after analgesic administration. A high degree of agreement was found between FLACC scores, the PACU nurses global rating of pain, and with objective pain scale (OPS) scores. The reliability and validity of this tool has been established in diverse settings and in different patient populations.[7-10]

Norden *et al.* developed the OPS to monitor pain in children of 8 months to 13 years[11] after surgery. Observational pain scale incorporates 4 pain behaviors (crying, movement, agitation, and verbalization) and blood pressure (BP) change, a physiological measure of pain. Each of these categories was scored from 0 to 2. In our study, we used two pain scales to eliminate underestimation of some categories included in both the scores.

This study was designed to compare the efficacy and duration of post-operative analgesia in pediatric population undergoing infraumbilical surgeries and to find out the effect of ropivacaine alone versus ropivacaine with dexamethasone on duration and quality of pain relief and also side effects after getting approval from Hospital Ethical Committee.

MATERIALS AND METHODS

Subjects

This study was conducted as prospective double-blinded randomized controlled trial conducted on 80 pediatric patients at Guru Nanak Dev Hospital (GNDH) connected to Government Medical College, Amritsar, after obtaining approval from Hospital Ethical Committee. The children in the age group of 1-8 years, ASA Grade I admitted to GNDH undergoing infraumbilical surgery were included in the study after obtaining informed consent from parents/legal guardians. The exclusion criteria included Parent's refusal, developmental delay, mental retardation, Type I diabetes mellitus, suspected coagulopathy, known allergy to local anesthetic or steroid, congenital anomaly of spine, and infection at sacral region. Patients were divided into two groups of 40 each, namely, Group R (ropivacaine alone) and Group RD (ropivacaine with dexamethasone) by a computer-generated randomization method. Sample size was calculated by consulting the statistician after taking into account the parameters such as duration of analgesia, motor blockade, hemodynamic changes, and side effects to get the power of the study >85%.

Anesthesia

Patients were kept fasting for 4-6 h depending on age before surgery. On the day of surgery patients were reassessed in the pre-operative room. Premedication was given orally with syrup midazolam 0.5 mg/kg, 30-45 min before induction. In the operating room monitors to check the heart rate (HR), respiratory rate (RR), noninvasive BP (NIBP), oxygen saturation (SpO_2), and electrocardiogram were attached. After securing intravenous (IV) access

injection glycopyrolate 0.005-0.01 mg/kg and injection ondansetron 0.1 mg/kg were administered. Induction of anesthesia was done with either injection propofol 2-3 mg/kg or halothane/sevoflurane in 100% O_2. Airway was secured with appropriate size of supraglottic airway devices, and anesthesia was maintained with O_2, N_2O and halothane/sevoflurane. Multiparameter monitoring was done.

Caudal Block

Patients positioned in left lateral position. The triangle formed by 2 posterior superior iliac spines with sacral hiatus was identified. The area above was carefully cleaned with antiseptic solution. Under all aseptic precautions, a 22 gauge short beveled needle was introduced into the skin at an angle of 45-50°. Needle was advanced till a click was felt as the sacro coccygeal membrane was pierced. The needle is further advanced in cephalad direction at an angle approaching the long axis of the spinal cord. Position of the needle was tested by "Whoosh" test and after aspiration test to exclude needle in blood vessel drug was given according to the group assigned.

Assessments

The patient was positioned supine, and surgery was allowed to proceed with continuous intraoperative monitoring of SpO_2, HR, NIBP, and RR every 5 min. Postoperatively an observer blinded to the group allocation and procedure observed hemodynamics, pain scores, motor blockade, and side effects were calculated every 15 min till 2 h, then every 2 hourly till 12 h and then at 24th h. OPS (Table 1) and FLACC (Table 2) behavioral pain assessment scale were used for assessment of pain scores. Bromage scale was used for motor block (Bromage 3 [complete]: Unable to move feet/knees; Bromage 2 [almost complete]: Able to move feet only; Bromage 1 [partial]: Just able to move knees; Bromage 0 [none]: Full flexion of knee and feet). Rescue analgesia was administered when OPS and FLACC ≥4. The number of rescue analgesia needed and time for 1st rescue analgesia noted.

Table 1: OPS score

Parameter	Finding	Points
Systolic BP	Increase <20% of pre-operative BP	0
	Increase 20-30% of pre-operative BP	1
	Increase >30% of pre-operative BP	2
Crying	Not crying	0
	Responds to age appropriate nurturing (tender loving care)	1
	Does not respond to nurturing	2
Movements	No movements relaxed	0
	Restless moving about in bed constantly	1
	Thrashing (moving wildly)	2
	Rigid (stiff)	2
Agitation	Asleep or calm	0
	Can be comforted to lessen the agitation (mild)	1
	Cannot be comforted (hysterical)	2
Complaints of pain	Asleep	0
	States no pain	0
	Cannot localize	1
	Localizes pain	2

BP: Blood pressure, OPS: Objective pain scale

Statistical Analysis

All the hemodynamic parameters, pain scores, and side effects were entered in master chart and analyzed statistically using SPSS software. Variables were analyzed using Chi-square test and continuous parameters were analyzed using unpaired *t*-test. A $P < 0.05$ - significant at 5% significance level is considered to be nonsignificant; $P < 0.01$ - significant at 1% significance level and $P < 0.001$ is considered to be highly significant.

RESULTS

A total of 80 subjects of age group 1-8 years were enrolled in the study. Caudal block was successful in all the patients. The demographic data and surgical profiles of the two groups did not differ (Table 3). There was no significant difference in the hemodynamic parameters between the two groups. There was no case of motor blockade after the surgery. Vomiting and retching was noticed in one patient in Group R. No other side effects were noticed. Comparison of OPS and FLACC pain score among Group R and Group RD was analyzed (Table 4). In Group R, the OPS and FLACC pain score reached 4 at 6th h in most of the patients with mean analgesic duration of 324 ± 55.6 min (mean - 5.4 h). In Group RD, the OPS and FLACC score reached 4 at 24th h in most of the patients with mean analgesic duration of 1278 ± 304.4 min (mean - 21.3 h) (Figures 1 and 2). The patients who needed 2nd dose of rescue analgesia were more in Group R (27 patients) as compared to Group RD where no patients needed 2nd dose of rescue analgesia. The mean dose of rescue analgesia needed in Group R was 1.58 ± 0.501 and in Group RD was 1.00 ± 0.000 (Table 5 and Figure 3).

DISCUSSION

Regional anesthetic techniques have gained considerable popularity for use in pediatric patients. The primary advantage of regional supplementation is lowering the anesthetic requirement along with good post-operative analgesia. And also relieving the patient of pain will lead to early ambulation which helps in decreasing morbidity and improving the outcome after surgery.

This study was aimed at evaluating the efficacy of dexamethasone in prolonging the analgesic duration when

Table 2: FLACC score

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

FLACC: Face, legs, activity, cry and consolability

Table 3: Demographic data shown as mean±SD or mean (%)

Data	Group R	Group RD	*P* value
Age (years)	3.88±1.5	3.88±1.3	1.000
Weight (kg)	15.23±3.0	14.90±2.8	0.626
Sex (%)			
Male	33 (82.5)	35 (87.5)	0.531
Female	7 (17.5)	5 (12.5)	
Duration of surgery (min)	36.75 (7.9)	34.75 (8.0)	0.269

SD: Standard deviation

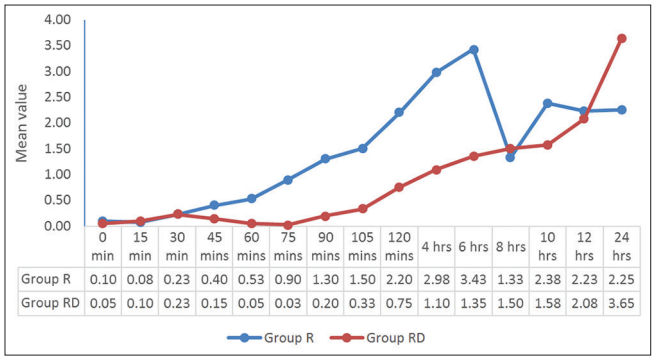

Figure 1: Objective pain scale (mean) during post-operative period in two groups

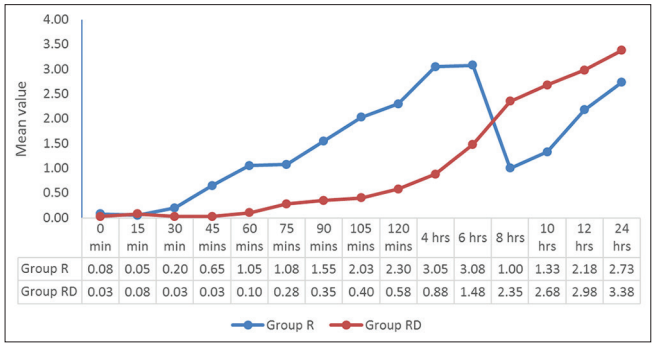

Figure 2: Face, legs, activity, cry and consolability score (mean) during post-operative period in two groups

given along with ropivacine in caudal for pediatric post-operative analgesia.

Pre-emptive analgesia involves the introduction of an analgesic before the onset of noxious stimuli. Pre-emptive analgesia involves the introduction of an analgesic before the onset of noxious stimuli. The effectiveness of preemptive analgesia[12] has been studied by Wulf *et al.*

The age group we selected was 1-8 years old pediatric patients, and the dosage of ropivacaine we used in our study was 1 ml/kg of 0.2% ropivacaine. This dosage has been documented to be safe in this age group by the study done by Wulf *et al.* who evaluated the pharmacokinetics of ropivacaine 0.2% in children after caudal epidural injection.[13]

Circumcision was the most commonly performed surgery followed by herniotomy, hypospadias, and chordae repair. The mean duration of surgery (in minutes) in Group R was 36.75 ± 7.970 min and in Group RD was 34.75 ± 8.082 min. The type of surgeries was selected in such a way that they have approximately equal mean duration to avoid the misinterpretation of early pain if surgery is for longer time.

All the hemodynamic parameters were comparable at all-time intervals throughout the study. The property of ropivacaine to cause less motor blockade has been explained by the fact that ropivacaine is less lipophilic than bupivacaine and so it is less likely to penetrate the large myelinated motor nerve fibers (Aβ). Therefore, it has selective action on pain-transmitting nerve fibers. A study done on comparison of caudal ropivacaine 0.2% with bupivacaine 0.2% in pediatric patients by Kumar *et al.* showed that motor recovery was faster in ropivacaine group with motor power scale of 10.00 ± 0.00 in comparison to 8.80 ± 0.99 in bupivacaine group ($P < 0.01$) at 2 h in post-operative period.[5] A study done by Kim *et al.* compared caudal ropivacaine versus ropivacaine with dexamethasone has also stated that they found no motor blockade in their study.[14] Our study is also in accordance to the literature had no motor blockade in the recovery room. There was one patient in Group R who had retching and vomiting, and no other side effects noted.

A study done by Yousef *et al.* compared enhancement of analgesic duration of ropivacaine using dexamethasone (RD)

Table 4: Pain scores shown as mean±SD and *P* value

Post-operative pain score analysis						
Time	OPS score			FLACC score		
	Group R	Group RD	*P* value	Group R	Group RD	*P* value
0 min	0.10±0.30	0.05±0.22	0.402	0.08±0.26	0.03±0.15	0.311
15 min	0.08±0.26	0.10±0.30	0.697	0.05±0.22	0.08±0.26	0.649
30 min	0.23±0.53	0.23±0.53	1.000	0.20±0.51	0.03±0.15	0.044
45 min	0.40±0.77	0.15±0.53	0.098	0.65±0.77	0.03±0.15	0.000
60 min	0.53±0.90	0.05±0.22	0.002	1.05±0.95	0.10±0.30	0.000
75 min	0.90±0.95	0.03±0.15	0.000	1.08±0.88	0.28±0.45	0.000
90 min	1.30±1.24	0.20±0.56	0.000	1.55±1.19	0.35±0.48	0.000
105 min	1.50±1.34	0.33±0.65	0.000	2.03±1.02	0.40±0.49	0.000
120 min	2.20±1.13	0.75±1.03	0.000	2.30±1.11	0.58±0.71	0.000
4 h	2.98±1.25	1.10±1.12	0.000	3.05±1.13	0.88±0.75	0.000
6 h	3.43±1.43	1.35±1.09	0.000	3.08±1.80	1.48±0.67	0.000
8 h	1.33±1.20	1.50±1.13	0.506	1.00±0.87	2.35±0.62	0.000
10 h	2.38±1.12	1.58±1.08	0.002	1.33±0.85	2.68±0.52	0.000
12 h	2.23±1.38	2.08±1.34	0.625	2.18±1.05	2.98±0.69	0.000
24 h	2.25±1.53	3.65±0.73	0.000	2.73±1.485	3.38±1.19	0.034

FLACC: Face, legs, activity, cry and consolability, OPS: Objective pain scale, SD: Standard deviation

Table 5: Number of rescue analgesia needed

Group	Mean number of rescue analgesia required	*P* value with significance
R	1.58±0.501	0.000 (HS)
RD	1.00±0.000	

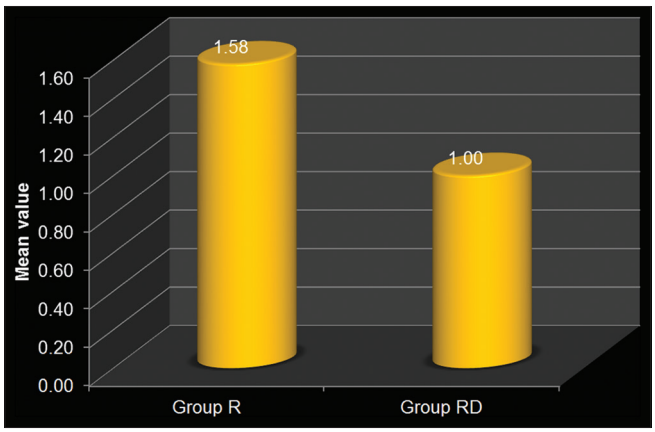

Figure 3: Number of rescue analgesia needed

or magnesium (RM) documented significant difference of Children's Hospital of Eastern Ontario Pain Scale and FLACC score between three groups at 4th h and in Group RD the score of four was attained at 12th h.[15] Kim in his study concluded that the post-operative pain score at 6th and 24th h postsurgery were significantly lower in dexamethasone group.[14] Similarly, our study also showed OPS and FLACC score ≥4 at 4 and 6 h with mean of 5.4 h in Group R and at 12 and 24 h with mean of 21.3 h in Group RD. Thus, the analgesic duration of ropivacaine in our study is 324 ± 55 min. This is in consistent with study Ray *et al.* who has noted the average duration of analgesia as 405 ± 18 min in ropivacaine (0.25%) group[16] and Kumar *et al.* who found that average duration of analgesia in ropivacaine group (0.2%) was 390 ± 35.16 min.[5]

Dexamethasone is a high potency, long-acting glucocorticoid with little mineralocorticoid effect that has been proved useful in post-operative nausea and vomiting. Single dose of dexamethasone has also been proved to have analgesic effects after surgery whether by oral[17] or IV route.[18]

It is demonstrated that the duration of post-operative pain relief was lengthened when dexamethasone is administered as an additive for peripheral nerve blockade.[19] Kopacz *et al.* also have showed in their study that steroids have analgesic effects in neuraxial and peripheral blocks.[20] Thomas and Beevi found that epidural dexamethasone is significantly more effective than IV dexamethasone to reduce post-operative pain and morphine consumption following laparoscopic cholecystectomy.[21]

The action of epidural steroid to decrease pain may be attributed to its property of anti-inflammatory action, edema reduction, and shrinkage of connective tissue.[22] Local steroid application was found to suppress transmission in unmyelinated C fibers but not in myelinated A-β fibers.[23] Steroids act by binding to intracellular nuclear receptors and altering the protein synthesis by gene transcription.[24]

Epidural dexamethasone affects intraspinal prostaglandin formation. Acute noxious stimuli during surgery lead to activation of phospholipase A2 and upregulation of cyclooxygenase 2 (COX 2) in the spinal cord, leading to prostaglandin synthesis and a resultant hyperalgesic state.[25] Inflammatory, metabolic, hormonal and immune response to surgery are activated immediately after surgical incision. Moreover, pre-operative administration of steroids may

reduce these responses due to their anti-inflammatory and immunosuppressive property, by inhibiting both phospholipase A2 and COX 2 enzymes.[26] This was obvious with the reduction of C-reactive protein levels, pain and fatigue score in patients who received pre-operative dexamethasone.[18]

The effect of dexamethasone on spinal cord is due to the presence of transcription factor nuclear factor kappa β (NF-kβ) present throughout the nervous system.[27] Dexamethasone by regulating NF-kβ inhibits central sensitization after surgery and potentiates analgesia of the caudal block.[28,29]

In a study conducted by Mohamed on evaluation of the analgesic effect of caudal dexamethasone combined with bupivacaine the duration of analgesia was significantly longer in the dexamethasone/bupivacaine group, where it was (9.2 ± 0.9 h), when compared with the bupivacaine group (4.8 ± 1.1 h).[30]

Another study conducted by Almajali *et al*. with dexamethasone as an adjunct to bupivacaine came out with the results that mean pain-free period was more significant in group who received bupivacaine along with dexamethasone (272 min) than in group who received only bupivacaine (186 min).[1]

Yousef *et al*. demonstrated that post-operative analgesia persisted for a longer duration in Groups RM (ropivacaine with magnesium) and RD (ropivacaine with dexamethasone), 8 (5-11) h and 12 (8-16) h, respectively compared with 4 (3-5) h in Group R (ropivacaine alone, with a ($P < 0.001$). It was also found that time to first paracetamol was to 260 ± 65 min in ropivacaine group and 730 ± 260 min in ropivacaine with dexamethasone group.[15]

Choudhary *et al*. in their study found that the mean duration of analgesia in ropivacaine with dexamethasone group was significantly more than in ropivacaine group, i.e., 478.046 ± 104.57 min and 248.4 ± 54.1, respectively.[31]

Kim *et al*. conducted study on analgesic efficacy of caudal dexamethasone combined with ropivacaine found that the number of subjects who remained pain free up to 48 h after operation was significantly greater in ropivacaine-dexamethsone group (Group D) (19 of 38) than in ropvacaine group (Group C) (4 of 37). The number of subjects who received oral analgesic was significantly lower in Group D (11 of 38) than in Group C (20 of 37). Time to first oral analgesic administration after surgery was also significantly longer in Group D than in Group C.[14]

In consistent with the literature our study also showed that the mean duration of analgesia in Group R was 324 ± 55.6 min and in Group RD was 1278 ± 304.4 min. The difference in their mean was highly significant with $P < 0.001$ and this is in consistent with the literature.

And also our study has found that the mean dose of rescue analgesia that was needed in Group R was 1.58±0.501 and in Group RD was 1.00 ± 0.000, and the difference between them was statistically significant with $P < 0.001$.

Furthermore, it was found that the number of patients who needed two doses of rescue analgesia in Group R was 23 (57.5%). In Group RD, there were no patients who needed 2nd dose of rescue analgesia. In Group R, there were 17 (42.5%) who needed one dose of rescue analgesia.

CONCLUSION

In our study, we concluded that caudal block with ropivacaine and ropivacaine with dexamethasone combination are safe and effective in providing intraoperative and post-operative analgesia in pediatric patients undergoing infraumbilical surgeries. Addition of dexamethasone to ropivacaine prolongs the duration of analgesia and decreases the need of rescue analgesia in the post-operative period. The maximum duration of analgesia was noted in ropivacaine with dexamethasone group and the total rescue analgesic requirement in the post-operative period was found to be less in this group.

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