IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 19, Issue 12 Ser.6 (December. 2020), PP 19-25
www.iosrjournals.org

Comparison of Analgesic Efficacy of Caudal Dexmedetomidine Versus Caudal Tramadol With Ropivacaine In Pediatric Urogenital Surgeries- A Prospective, Randomized, Comparative Study.

Dr.T.A Senthamizh[1], Dr.P.Krishnaprasad[2],
Dr.M.Santhi sree[3],Dr.B.Sowbhagyalakshmi[4]

1st Author-Postgraduate,Department of anaesthesia,RangarayaMedicalCollege,Kakinada
2.Corresponding Author-Associate Professor, Department of Anaesthesia, RMC,Kakinada.
3rd Author- Associate Professor, Department of Anaesthesia, RMC,Kakinada
4th Author- -- HOD and Professor, Department of Anaesthesia, RMC,Kakinada

Abstract
BACKGROUND AND AIM: Caudal epidural analgesia is a simple and safe technique practised in children undergoing infraumbilical surgeries but has a shorter duration of action after a single shot injection. The aim of this study is to compare the analgesic efficacy of dexmedetomidine and tramadol co-administered with 0.25% ropivacaine caudally in pediatric patients undergoing urogenital surgeries.
OBJECTIVES: The primary objective is to compare the efficacy of dexmedetomidine and tramadol in prolonging the duration of analgesia.The secondary objectives include measurement of duration of motor block, sedation score, emergence time and adverse effects.
METHODOLOGY: After obtaining approval from institutional ethics committee and informed consent, 60 children aged between 1-8 years belonging to ASA class I and II, scheduled for elective urogenital surgeries under general anaesthesia were randomly divided into 2 groups of 30 each.Group RD: received 0.25% ropivacaine 1 ml/kg with dexmedetomidine 2 mcg/kg.Group RT: received 0.25% ropivacaine 1ml/kg with tramadol 2 mg/kg.Children with infection at the injection site, history of drug allergies, bleeding/ coagulation disorders, history of developmental delay or neurological problems were excluded from the study.
RESULTS: The mean duration of analgesia was 674.2±78.38 in group RT and 750.29± 71.29 in group RD (p= 0.0002). The mean sedation score and the mean emergence time were also statistically significant between the two groups. The hemodynamic parameters and side effects were statistically insignificant between both the groups.
CONCLUSION: caudal dexmedetomidine with ropivacaine prolonged the duration of analgesia compared to caudal tramadol with ropivacaine.

Key Words*: Caudal, analgesia, ropivacaine, tramadol, dexmedetomidine, emergence time.*

Date of Submission: 29-11-2020 Date of Acceptance: 14-12-2020

I. Introduction:

Caudal epidural is one of the simple and safe regional techniques used commonly to provide post operative pain relief in pediatric patients undergoing infra-umbilical surgeries as it reduces the requirement of inhaled and intravenous (IV) anesthetic agents, attenuate the stress response to surgery, facilitate a rapid, smooth recovery, and provide good immediate postoperative analgesia.[1]The main disadvantage of caudal single shot injection is the shorter duration of action even with the use of long actinglocal anaesthetics like bupivacaine or ropivacaine.[2] For continuous infusion, use of a caudal catheter is usually not preferred due to high risk of catheter contamination from faecal soiling.[3] To prolong the duration of post operative analgesia various additives such as tramadol, fentanyl, dexmedetomidine, ketamine have been added to the local anaesthetics. Ropivacaine, the S-enantiomer of the amide local anaesthetic, is suitable for day-care surgery in children as it produces less motor blockade, cardiovascular and neurological toxicity.[4]Tramadol, a synthetic 4-phenyl-piperidine analogue of codeine, is a racemic mixture of two enantiomers, both of which contribute to the analgesic activity through different mechanisms enhancing inhibitory effects on pain transmission in the spinal cord. The complementary and synergistic actions of the two enantiomers enhances the analgesic efficacy and tolerability profile of the two. Tramadol has a striking lack of respiratory depressant effect despite having analgesic potency approximately equal to that of pethidine.[5] Dexmedetomidine, a stereoisomer of

medetomidine, is a highly selective α2-adrenergic receptor agonist with eight times more specificity for α2 adrenoceptors than clonidine. It has sympatholytic, analgesic and sedative effects and is free from side effects except for manageable hypotension and bradycardia.[6]The aim of this study is to compare the analgesic efficacy of caudal dexmedetomidine with ropivacaine and caudal tramadol with ropivacaine.

II. Materials And Method:

This is a prospective, randomised comparative study done between May to October 2020, in GGH, Kakinada. After obtaining ethical committee approval and written informed consent from parents, 60 children aged between 2-8 years belonging to ASA class I and II, scheduled for elective urogenital surgeries under general anaesthesia were randomly divided into 2 groups of 30 each. Group RT received 0.25% ropivacaine 1ml/kg with tramadol 2mg/kg making the volume to 0.5ml. Group RD received 0.25% ropivacaine 1 ml/kg with dexmedetomidine 2 mcg/kg making the volume to 0.5ml.

EXCLUSION CRITERIA: patients having infection at the injection site, drug allergies, bleeding/ coagulation disorders, history of developmental delay or neurological deficits were excluded from the study.

Randomisation was done using computer generated randomization technique. On arrival of the patient in the operation theatre standard ASA monitors were connected and all baseline vitalsrecorded. Premedication was done with injection midazolam 0.05mg/kg IV and injection glycopyrrolate 0.01mg/kg IV, preoxygenation was done using 100% oxygen for 3 minutes and the child was induced with inhalational agent sevoflurane by increasing the concentration upto 8 volume percentage with 100% oxygen. Tracheal intubation with appropriate size endotracheal tube was facilitated after administration of Atracurium besylate 0.5mg/kg IV. Anaesthesia was maintained using 60% Nitrous oxide with oxygen and sevoflurane 0.2- 0.6%. After induction of general anesthesia each child was turned to left lateral position; overlying skin cleaned and draped.The sacral hiatus was identified andSingle-dose caudal epidural injection was performed using a 25-gauge needle by loss of resistance technique.After negative aspiration of blood or cerebrospinal fluid, caudal medication was givenas per the group assigned.The inhaled concentration of sevoflurane was adjusted to achieve haemodynamic changes within 20% of the baseline values. No other analgesics, sedatives or narcotics were used intraoperatively.Hemodynamic parameters were monitored before and after pre-medication, induction, caudal block, after incision and thereafter every 10 minutes until the end of surgery and then every hour till 24 hours postoperatively. At the end of surgery, all anaesthetic drugs were discontinued. Total time of surgery was recorded. Any side effects such as breath holding/apnoea, hypotension, involuntary movements, nausea and vomiting were noted. Hypotension (fall in blood pressure > 20% from baseline) and bradycardia (fall in heart rate > 20% from baseline) was treated with fluid bolus, mephentermine and atropine respectively. The primary outcome was the duration of analgesia, defined as the time period between administration of block until the FLACC score reached ≥4. Secondary outcomes were the duration of the motor block, post-operative sedation by Ramsay sedation score, and emergence time.

FLACC SCALE

categories	scoring		
	0	1	2
face	no particular expression or smile; disinterested	occasional grimace or frown, withdrawn	frequent to constant frown, clenched jaw, quivering chin
legs	no 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 crying (awake or asleep)	moans or whimpers, occasional complaint	crying steadily, screams or sobs, frequent complaints
consolability	content, relaxed	reassured by occasional touching, hugging, or talking to, distractable	difficult to console or comfort

Patient's pain intensity was assessed using FLACC score hourly till 6 h, every 3 h till 12 h and every 6 h till 24 h until the first dose of rescue analgesia was given. Rescue analgesia was with paracetamol suppository 15 mg/kg, given when the FLACC score was ≥4. The number of doses of rescue medication required and the time to first administration of rescue medication were also noted. Motor block was assessed in the PACU on awakening by using a modified Bromage scale.Level of sedation was assessed by Ramsay sedation scale at 15 min, 30 min, and 60 min after extubation and hourly until the Ramsay sedation score became 1 in all patients.Emergence time is the time from the end of surgery to opening of eyes on calling.Anaesthetic emergence was considered as delayed if the time elapsed from the end of surgery to exiting the operating theatre was greater than 20 minutes. Adverse effects such as nausea, vomiting, hypotension, bradycardia, respiratory

depression and urinary retention were monitored for 24 h and treated accordingly. Any increase in HR or mean arterial pressure (MAP) more than 20% of the pre-incision values was considered as caudal block failure. Failure of the caudal block was not reported in any patient.

RAMSAY SEDATION SCALE

SCORE	LEVEL OF SEDATION
1	anxious, agitated, restless or both
2	co operative, oriented and tranquil
3	responds to commands only
4	exhibits brisk response to light tactile stimuli or loud auditory stimulus
5	exhibits sluggish response to light tactile stimuli or loud auditory stimulus
6	exhibits no response

MODIFIED BROMAGE SCALE
0 = flexion of knees and feet
1= flexion of knees
2 = little movement of feet only
3 = no movement of knees or feet.
The data were presented as mean ± S.D.Student's t-test was used for numerical values and Chi-square test used for categorical values. The value $P < 0.05$ wasconsidered statisticallysignificant. Statistical Package for Social Sciences (SPSS) version 20.0 for windows was used for statistical analysis.

III. Results

TABLE 1: DEMOGRAPHIC TRENDS AND DURATION OF SURGERY

The demographic variables and duration of surgery were comparable between both the groups (Table -1)

PARAMETERS	GROUP RT	GROUP RD	P VALUE
AGE (in years)	4.45±2.10	4.65±2.05	0.71
SEX	male -20 female -10	male- 17 female -13	0.728
WEIGHT (in kgs)	14.86±2.72	15.70±2.21	0.194
DURATION OF SURGERY (in mins)	34±8.0	34±8.2	1

TABLE 2: COMPARISON OF MEAN TIME TO RESCUE ANALGESIA AND MEAN EMERGENCE TIME

PARAMETERS	GROUP RT	GROUP RD	P VALUE
Mean time to rescue analgesia (in mins)	690±32.2	884±92.4	<0.0001
Mean emergence time (in mins)	4.0±1.4	4.9±1.9	0.0411

Mean time to first rescue analgesic was 884±92.4 in group RD which was significantly longer than Group RT 690±32.2 (p= <0.0001). The mean emergence time of Group RD was longer than group RT (p= 0.0411). (Table-1)(Fig-1)(Fig-2)

FIGURE 1: COMPARISON OF MEAN TIME TO RESCUE ANALGESIA

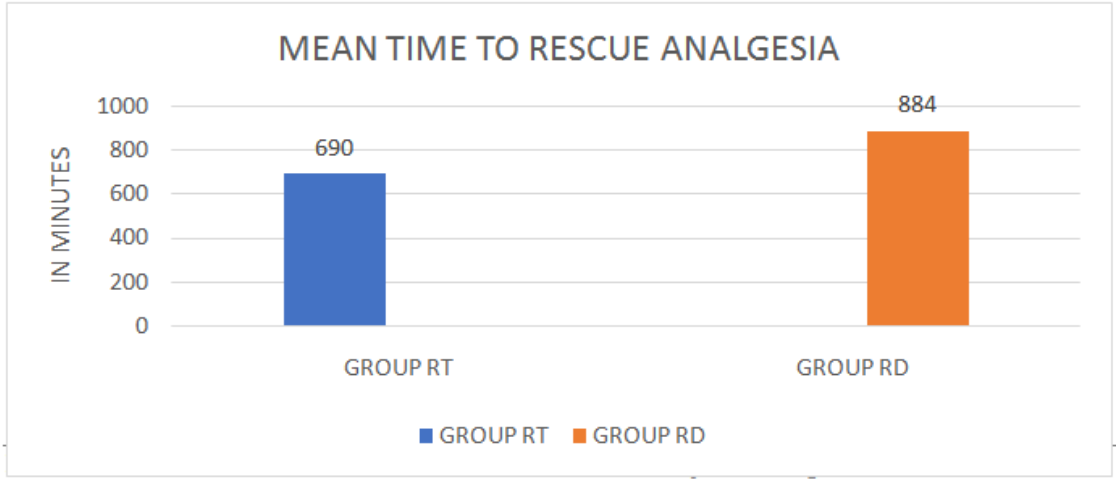


FIGURE 2: COMPARISON OF MEAN EMERGENCE TIME

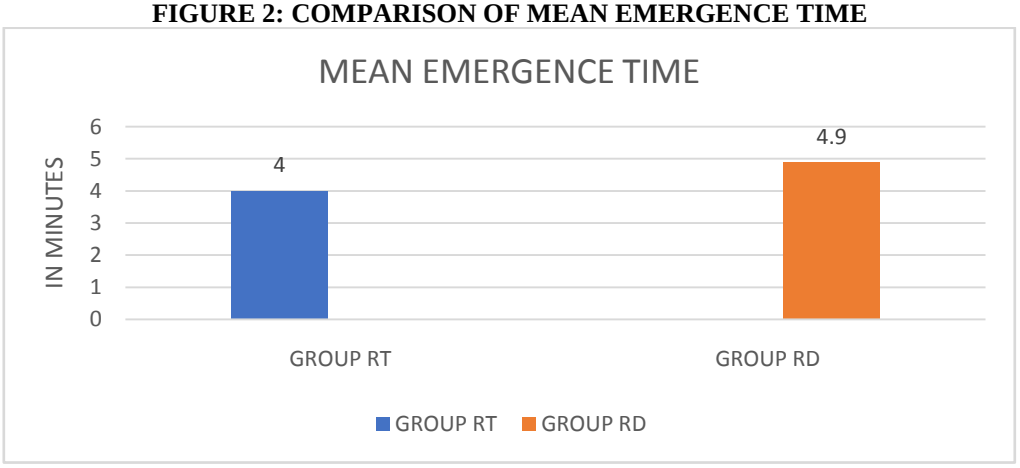


TABLE 3: COMPARISON OF DURATION OF ANALGESIA, MOTOR BLOCK, SEDATION

PARAMETERS	GROUP RT	GROUP RD	P VALUE
Duration of analgesia (in mins)	674.2±78.38	750.29±71.21	0.0002
Duration of motor block (in mins)	413.32±74.16	462.42±80.18	0.0168
Duration of sedation (in mins)	418.13±50.33	532.28±64.12	<0.0001

Duration of analgesia in group RD was 750.29±71.21 which was significantly longer than group RT 674.2±78.38 (p= 0.0002). similarly duration of motor block(p value= 0.0168)and duration of sedation (p value= <0.0001) was longer in group RD compared to group RT. (Tab-3) (Fig-3) (Fig-4)

FIGURE 3: COMPARISON OF DURATION OF ANALGESIA

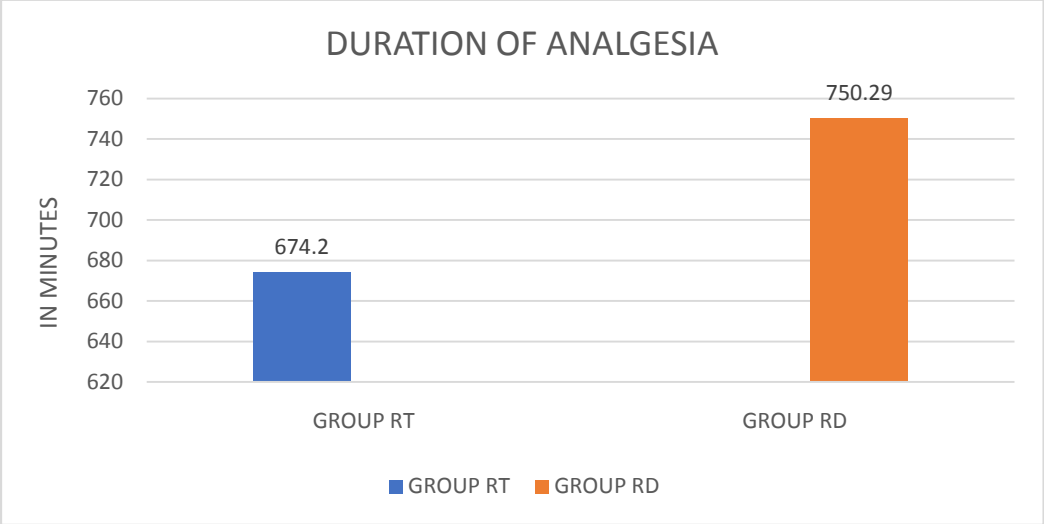


FIGURE 4: COMPARISON OF DURATION OF MOTOR BLOCK AND SEDATION

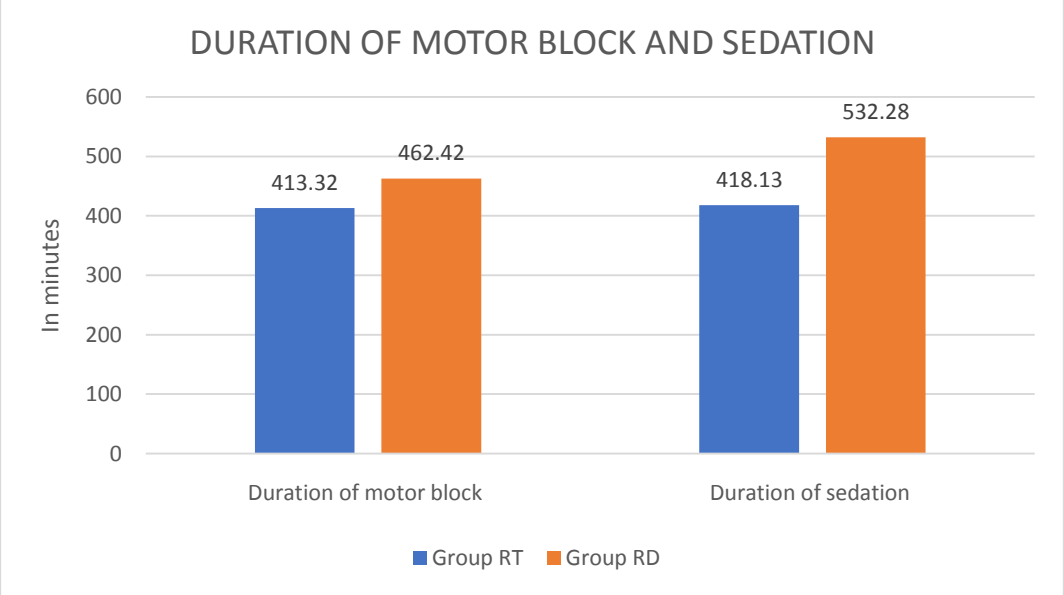
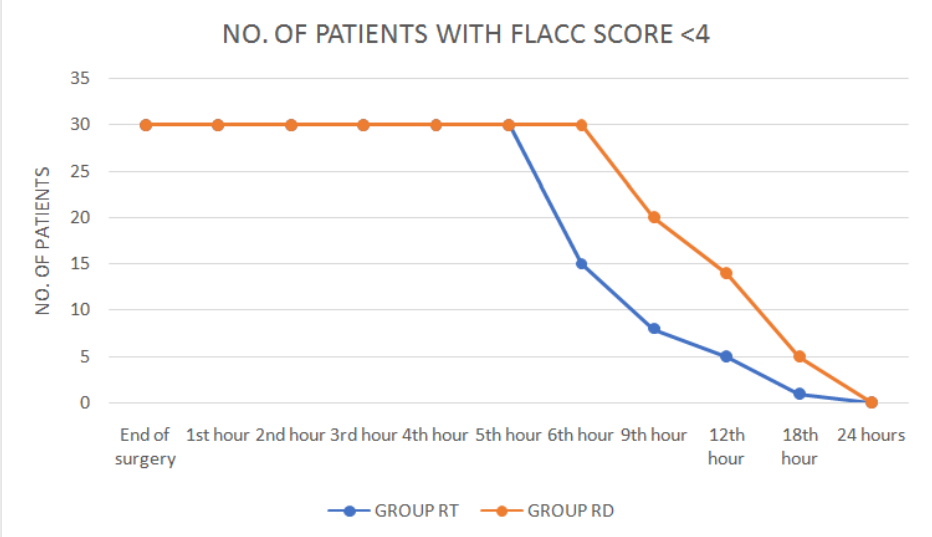


FIGURE 5: NUMBER OF PATIENTS WITH FLACC SCORE <4



During the first 5 h after surgery, all patients in both groups had adequate analgesia (FLACC score <4) and then the number of patients with adequate analgesia declined rapidly in Group RT compared to Group RD and the difference was statistically significant. (Fig-5)

There was no significant difference in the pre, intra and post operative hemodynamic parameters between the two groups. No child had respiratory depression in the post-operative period. There was no significant difference between the two groups in the incidence of side effects such as shivering, post-operative nausea and vomiting and hypotension.

IV. Discussion

Adequate postoperative analgesia allows the patients to breathe and move freely to enhance early restoration of function. Various methods have evolved for providing postoperative analgesia in children.[7] Among them, caudalblock is the safest and most reliable technique.

Ropivacaine, has a wider margin of safety, less motor blockade, less cardiovascular or neurological toxicity and similar duration of analgesia compared to bupivacaine.It can be safely used for regional anaesthesia and analgesia in the ambulatory setting in paediatrics.

Tramadol, a centrally acting synthetic analgesic with low affinity for opioid receptors, appears to modify the transmission of pain impulses by the inhibition of monoamine reuptake. Krishnadas A et al, showed that addition of tramadol to ropivacaine in caudal epidural block significantly prolonged the duration of analgesia.[8]

Dexmedetomidine enhances the effects of local anaesthetics without increasing the incidence of side effects. Dexmedetomidine in comparison to other sedatives has minimal respiratory effects in adults and children which make it a good adjuvant. Sedation caused by dexmedetomidine can be easily reversed with slight stimulation and do not cause respiratory depression even at high doses.

In this study we observed that the duration of analgesia (FLACC <4) without the need of rescue analgesic was significantly longer in the group receiving ropivacaine-dexmedetomidine mixture than the group receiving ropivacaine with tramadol.

Our results are consistent with those reported by Vijay G anand et al, who studied the effects of dexmedetomidine added to caudal ropivacaine in pediatric patients undergoing lower abdominal surgeries and concluded that addition of dexmedetomidine significantly increased the duration of analgesia compared to ropivacaine alone.[9]Similarly El-Hennawy et al, administered dexmedetomidine and clonidine, both in a dose of 2 μg/kg as adjuvant with 0.25% bupivacaine caudally and found that the duration of analgesia was significantly higher in the group receiving bupivacaine–dexmedetomidine mixture or bupivacaine–clonidine mixture than the group receiving bupivacaine alone.[10]

Our results are also similar to those reported by Deming xu et al, who studied the effects of dexmedetomidine added to ropivacaine for caudal anaesthesia in patients undergoing hemorrhoidectomy and observed that Dexmedetomidine as an adjuvant to ropivacaine prolonged the duration of caudal block and improved postoperative analgesia without significant side effects.[11]

Ropivacaine- dexmedetomidine group required significantly less number of rescue analgesics compared with ropivacaine- tramadol group which is similar to a study conducted on the effect of dexmedetomidine on bupivacaine in the caudal block in pediatric patients by Saadawy I et al.[12]

In our study, the level of sedation was significantly reduced in Group RT. Our results are consistent with those reported by Jarineshin et al, who concluded that there was improved sedation and pain scores when dexmedetomidine was added as an intrathecal adjuvant. [13]

The pre, intra- and post-operative hemodynamic variables were comparable between both the groups.

Post-operative side effects like vomiting, shivering, hypotension were statistically insignificant between the two groups.

V. Conclusion

Caudal ropivacaine 0.25% with dexmedetomidine 2 μg/kg prolonged duration of analgesia and reduced the requirement for rescue analgesic compared to caudal ropivacaine 0.25% with tramadol 2 mg/kg. Thus, it can be concluded that dexmedetomidine can be safely added as an alternative to tramadol with caudal ropivacaine for pediatric urogenital surgeries.

References

[1]. Silvani P, Camporesi A, Agostino MR, Salvo I. Caudal anesthesia in pediatrics: An update. Minerva Anestesiol2006;72:453-9.
[2]. Verghese ST, Hannallah RS. Postoperative pain management in children. Anesthesiol Clin North America 2005;23:163-84.
[3]. Dobereiner EF, Cox RG, Ewen A, Lardner DR. Evidence-based clinical update: Which local anesthetic drug for pediatric caudal block provides optimal efficacy with the fewest side effects? Can J Anaesth2010;57:1102-10.
[4]. Doctor TP, Dalwadi DB, Abraham L, Shah N, Chadha IA, Shah BJ. Comparison of ropivacaine and bupivacaine with fentanyl for caudal epidural in pediatric surgery. Anesth Essays Res 2013;7:212-5.

[5]. Yildiz TS, Ozdamar D, Bagus F, Solak M, Toker K. Levobupivacaine-tramadol combination for caudal block in children: A randomized, double-blinded, prospective study. PaediatrAnaesth2010;20:524-9.
[6]. Wu HH, Wang HT, Jin JJ, Cui GB, Zhou KC, Chen Y, et al. Does dexmedetomidine as a neuraxial adjuvant facilitate better anesthesia and analgesia? A systematic review and meta-analysis. PLoS One 2014;9:e93114.
[7]. Lloyd-Thomas AR. Pain management in paediatric patients. Br J Anesth1990;64:85-104
[8]. Krishnadas A, Suvarna K, Hema VR, Taznim M. A comparison of ropivacaine, ropivacaine with tramadol and ropivacaine with midazolam for post-operative caudal epidural analgesia. Indian J Anaesth2016;60:827-32.
[9]. Anand VG, Kannan M, Thavamani A, Bridgit MJ. Effects of dexmedetomidine added to caudal ropivacaine in paediatric lower abdominal surgeries. Indian J Anaesth2011;55:340-6.
[10]. El-Hennawy AM, Abd-Elwahab AM, Abd-Elmaksoud AM, El-Ozairy HS, Boulis SR. Addition of clonidine or dexmedetomidine to bupivacaine prolongs caudal analgesia in children. Br J Anaesth2009;103:268-74.
[11]. Xu D, Xiu M, Zhang X, et al. Effect of dexmedetomidine added to ropivicaine for caudal anesthesia in patients undergoing hemorrhoidectomy: A prospective randomized controlled trial. *Medicine (Baltimore)*. 2018;97(34):e11731. doi:10.1097/MD.0000000000011731
[12]. Saadawy I, Boker A, Elshahawy MA, Almazrooa A, Melibary S, Abdellatif AA, et al. Effect of dexmedetomidine on the characteristics of bupivacaine in a caudal block in pediatrics. Acta AnaesthesiolScand2009;53:251-6.
[13]. Jarineshin H, Fekrat F, Kargar Kermanshah A. Treatment of postoperative pain in pediatric operations: Comparing the efficiency of bupivacaine, bupivacaine-dexmedetomidine and bupivacaine-fentanyl for caudal block. Anesth Pain Med 2016;6:e39495.

Dr.P.Krishnaprasad, et. al. "Comparison of Analgesic Efficacy of Caudal Dexmedetomidine Versus Caudal Tramadol With Ropivacaine In Pediatric Urogenital Surgeries- A Prospective, Randomized, Comparative Study." *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*, 19(12), 2020, pp. 19-25.