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Original Research Article

A Study of Caudal Epidural Dexmedetomidine with Tramadol as an Adjuvant to Ropivacaine 0.25% for Postoperative Analgesia in Children Undergoing Infraumbilical Surgeries

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Abstract:

Background and Objectives: Good pain control after surgery is important to prevent negative outcomes of postoperative pain. Many different modalities to treat the paediatric postoperative pain. The main objective of the current study is to compare the caudal epidural dexmedetomidine with tramadol as an adjuvant to ropivacaine 0.25% for postoperative analgesia in children undergoing infraumbilical surgeries

Material and Method: The study was conducted in 60 paediatric patients randomly allocated in two groups each having 30 patients. All patients underwent pre anaesthetic check-up the day before surgery and all routine investigations like CBC, RBS, and Urine, if needed s. creatinine were advised. Patients were kept NBM for at least 6 hours for solid food and 2 hours for clear fluid. Child was taken in OT after psychological reassurance. All standard monitors (ECG, NIBP, and SpO2) were applied under Sevoflurane inhalation. An intravenous cannula was secured and crystalloid like DNS solution was started. General anaesthesia was given.

Results: This prospective double blind study was carried out in 60 ASA I-II paediatric patient undergoing infra umbilical surgeries for postoperative analgesia in a two years. Patient in our study were demographically comparable in both groups. We have selected only infra-umbilical surgeries. Most of the surgeries were hypospadias repair and open ureteric reimplant in both groups. The type of surgery done in both group were comparable which are not statistically significant. In our study, we also used Dexmedetomidine $(1\mu g/kg)$ as an additive to ropivacaine as caudal analgesia. Duration of analgesia in-group RD was 14.57±2.45hrs, which was longer than tramadol group.

Conclusion: Thus we can conclude that addition of Dexmedetomidine $(1\mu G/kg)$ with Ropivacaine in caudal block significantly prolong the duration of postoperative analgesia as compared to Tramadol (2mg/kg) for children undergoing infraumbilical surgeries and reduces the postoperative analgesic.

Keywords: Epidural, Dexmedetomidine, Tramadol, Ropivacaine, Postoperative, Analgesia.

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Introduction

"Pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage."[1].

Postoperative pain refers to the occurrence of pain after operation all over the body, including joint and muscle, head and limbs, accompanied by restlessness, insomnia, sweating or lack of sweating, fatigue, poor appetite or even dysfunction of the limbs [2].

Caudal anaesthesia is a commonly used regional anaesthetic technique in paediatrics that can be useful in providing perioperative and postoperative analgesia. Prolongation of caudal analgesia could be accomplished using a caudal catheter or by the addition of various adjuvants such as Epinephrine and clonidine can help to prolong the blockade, Opioids such as morphine and fentanyl are options but there can be side effects and Tramadol has centrally acting analgesic effect via opioid receptors. alpha-2 agonist such as Dexmedetomidine having major advantage of it is eightfold greater affinity for α2A receptors which is sedative. responsible for the hypnotics, sympatholytic and analgesic properties without respiratory depressant effect. Clinicians perform

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caudal epidural techniques by accessing the epidural space via sacral hiatus. Landmark based technique is the most common technique for carrying out a caudal epidural block [3].

Aims and Objectives

Study was conducted in 60 children with ASA physical status I & II for assessment of postoperative pain in infra umbilical urological surgeries. The aim of the study was to compare the efficacy of Tramadol and dexmedetomidine as an additive to Ropivacaine through caudal epidural route for postoperative analgesia.

Material and Methods

The study was conducted in 60 paediatric patients randomly allocated in two groups each having 30 patients. Institutional ethical committee approval and parental written informed consent were taken.

Inclusion Criteria:

- n = 60 (Group RT: Tramadol, Group RD: Dexmedetomidine)
- ASA grade I or II
- Age: 2-8 years
- Surgery: Infra umbilical urogenital surgeries

Exclusion Criteria:

- Children with congenital anomaly
- Parents refusal
- Mental retardation
- Neuromuscular/ spinal diseases
- Sacral anomalies
- Coagulation abnormality
- Allergic to drugs
- Local infection at site of caudal injection

Drugs and Equipment:

- BD precision needle i.e. hypodermic needle 22G (1.5 inch)
- 10 ml & 5ml syringe
- Sterile towels for draping
- Sponge holding forceps
- Cotton swabs
- Inj Ropivacaine 0.25% (1ml/kg)
- Inj Tramadol (2mg/kg) volume: 1ml
- Inj Dexmedetomidine (1µg/kg) volume: 1ml

All patients underwent pre anaesthetic check-up the day before surgery and all routine investigations like CBC, RBS, and Urine, if needed s. creatinine were advised. Patients were kept NBM for at least 6 hours for solid food and 2 hours for clear fluid.

Child was taken in OT after psychological reassurance. All standard monitors (ECG, NIBP, and SpO2) were applied under Sevoflurane inhalation. An intravenous cannula was secured and crystalloid like DNS solution was started. General anaesthesia was given.

General anaesthesia:

Premedication: inj. Glycopyrrolate 0.004mg/kg

Inj. Fentanyl $2\mu g/kg$ Preoxygenation: 100% O2 for 3 minutes Induction: inj. Thiopentone 5-7mg/kg, Inj. Succinylcholine 1.5mg/kg, Endotracheal tube of appropriate size was inserted. Maintenance: O₂+ N₂O + Sevoflurane+ Atracurium. After Induction, patients were put in lateral position with knee and hip joints of both legs flexed.

Technique:

Under full aseptic precautions, sacral cornue was palpated & sacral hiatus was identified. 22 G hypodermic needle was inserted in the midline in between the two sacral cornue through the sacral hiatus at an angle of 45° with the skin & directed cranially to penetrate the sacrococcygeal membrane. The penetration of sacrococcygeal membrane was felt as "loss of resistance" or as "give in sensation".

Then the needle was depressed i.e. the angle reduced. The needle was advanced into the sacral canal. The space is confirmed by "Whoosh test". After negative aspiration for blood & CSF, Inj Ropivacaine 0.25% (1ml/kg) Maximum Total 20 with Inj Tramadol (2mg/kg) ml or Inj Dexmedetomidine $(1\mu g/kg)$ in 1.0 ml volume was given according to random allocation of the patients in Group RT or Group RD respectively by the doctors blinded to the drug. Surgery was started in supine position. Haemodynamic monitoring (HR, BP, and SPO2) was done intraoperatively. Thermoregulation was maintained during surgery. Fluid was given according to holliday segar formula.

After completion of surgery, Patients were extubated after adequate muscle tone and good respiratory effort. Patients were observed for 24 hours postoperatively in recovery room.

All vital parameter were observed. We have chosen FLACC (Face, Legs, Activity, Cry, Consol ability) score. It is a measurement used to assess pain for children between the age of 2 month to 8 year and individuals that are unable to communicate their pain.

The score in a range of 0-10 with 0 representing no pain. The score has five criteria, which are each assigned a score of 0,1 or 2. Pain intensity was assessed at the end of Surgery, 1, 2, 4 and then every 4 hours for 24 hours after surgery. If the FLACC Score was 4 or more, paracetamol suppository (15 mg/kg) was given as a rescue analgesic and duration of caudal analgesia was noted. Total dose of paracetamol suppository required during 24 hours was also noted. Sedation was assessed by Modified Ramsay

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Sedation score in recovery room. Motor block was assessed by Modified bromage scale.

Parameters observed were:

- Vitals –HR / BP/ SPO2.
- Quality and duration of analgesia by FLACC score.
- Duration of sedation by Modified Ramsay"s sedation score.
- Motor block was assessed by Modified bromage scale.
- Time of 1st dose of paracetamol suppository i.e. duration of caudal analgesia.
- Total doses of paracetamol suppository in 1st 24 hrs.

• Any side effects observed (nausea/vomiting/bradycardia) and treated.

Results:

This prospective double blind study was carried out in 60 ASA I-II pediatric patient undergoing infra umbilical surgeries for postoperative analgesia in a year 2018-2020.

All collected data are entered into SPSS V20. Continuous data are expressed as mean±SD form. Continuous data follows parametric and Non-Parametric data both. Independent t test and Mann Whitney test have been used carrying out significant P-value.

Table 1: Demographic Data			
Demographic Data	Group Rd (Mean±SD)	Group RT (Mean±SD)	P- Value
Age (Year)	3.57±1.41	3.53±1.43	0.914 (Ns)
Sex: M/F	28/2	26/4	0.3939 (N S)
Weight (Kg)	12.13±2.32	12.13±2.14	1 (Ns)
Duration of Surgery (Min)	138±57.71	145.33±63.23	0.641 (Ns)

Table 2: Surgery			
Surgery	Group RD	Group RT	P- Value
Circumcision	3(10%)	5(16.67%)	0.451(NS)
Hypospadias repair	10(33.33%)	7(23.33%)	0.394(NS)
Vesicostomy closure	1(3.33%)	2(6.67%)	0.556(NS)
OPEN CLT	5(16.67%)	3(10%)	0.451(NS)
Open Ureteric Reimplant	6(20%)	9(30%)	0.375(NS)
Orchidopexy	3(10%)	3(10%)	1.00(NS)
Meatoplasty	1(3.33%)	0	0.318(NS)
Vesicostomy	1(3.33%)	1(3.33%)	1.00(NS)

Intraoperative Hemodynamic parameters

Table 3: Pulse Rate (Per Minute)

Time(Minute)	Group RD (Mean±SD)	Group RT(Mean±SD)	P- Value
0	140.6±5.40	141.87±5.66	0.486(NS)
15	138.6±5.44	138.6±5.12	1(NS)
30	130.73±4.69	132.67±4.71	0.104(NS)
60	120.8±3.75	121.93±4.75	0.369(NS)
120	114.67±5.64	116.87±5.18	0.121(NS)
180	114±4.91	116±4.22	1(NS)

Table 4: Systolic and Diastolic Blood Pressure (mm of Hg)

Time(Minute)	Group RD SYT. & DIA	Group RT SYT. & DIA	P-Value
	(Mean±SD)	(Mean±SD)	
0	101±2.55	102±2.33	0.118(NS)
	62±2.19	63±2.06	0.07(NS)
15	100±2.24	101±2.62	0.117(NS)
	61±1.96	62±1.92	0.05(NS)
30	99±2.16	100±2.06	0.07(NS)
	60±2.10	60±1.85	1(NS)
60	99±1.78	99±1.64	1(NS)
	59±1.25	59±1.53	1(NS)
120	99±1.78	99±1.64	1(NS)
	59±1.26	59±1.53	1(NS)
180	98±2.64	99±2.91	0.16(NS)
	58±0.08	59±2.15	0.07(NS)

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	Table 5. Mean blood i ressure (min of fig)			
Time(Minute)	Group RD (Mean±SD)	Group RT (Mean±SD)	P-Value	
0	75±2.26	76±2.08	0.079(Ns)	
15	74±1.96	75±2.05	0.05(Ns)	
30	73±1.96	73±1.83	1(Ns)	
60	72±1.26	72±1.48	1(Ns)	
120	72±1.26	72±1.48	1(Ns)	
180	71±2.21	72±2.27	0.08(Ns)	

Table 5: Mean Blood Pressure (mm of Hg)

Postoperative Hemodynamic Parameters

Table 6: Pulse Rate (per minute)

Time(Hour)	Group RD (Mean±SD)	Group RT (Mean±SD)	P Value
0	123.73±11.46	126.87±10.90	0.28(NS)
1	122±11.90	125.4±10.36	0.24(NS)
2	121.53±11.52	123.8±10.37	0.42(NS)
4	120.27±11.60	122.47±10.49	0.57(NS)
8	118.53±11.24	121.33±10.47	0.32(NS)
12	116.8±11.15	120.07±10.61	0.24(NS)
16	116.2±11.50	118.73±10.58	0.37(NS)
20	114.6±11.10	117.13±10.30	0.36(NS)
24	113.13 ± 11.18	115.8±10.18	0.47(NS)

Table 7: Blood Pressure (mm of Hg)

Time (Hour)	Group RD SYT. &	· · · · · · · · · · · · · · · · · · ·	P- Value
× • •	DIA (Mean±SD)	(Mean±SD)	
0	103±2.84	104±3.35	0.217(NS)
	63±3.35	64±3.03	0.23(NS)
1	102±2.38	103±2.83	0.145(NS)
	62±3.11	63±3.35	0.23(NS)
2	101±1.87	102±2.38	0.07(NS)
	61±2.14	62±3.11	0.152(NS)
4	100±2.04	101±1.87	0.05(NS)
	60±2.38	61±2.14	0.09(NS)
8	99±2.04	100±2.04	0.06(NS)
	59±1.63	60±2.38	0.06(NS)
12	99±1.79	99±2.04	1(NS)
	59±1.67	59±1.63	1(NS)
16	99±1.71	99±1.79	1(NS)
	59±1.85	59±1.67	1(NS)
20	98±2.01	99±2.00	0.05(NS)
	58±1.89	59±2.03	0.05(NS)
24	99±2.14	100±3.40	0.178(NS)
	59±2.23	59±3.06	1(NS)

Table 8: FLACC Score				
Time (Hour)	Group RD (Mean±SD)	Group RT (Mean±SD)	P- Value	
0	1.23±0.73	1.8 ± 0.48	0.0007*	
1	1.67±0.79	2.13±0.34	0.004*	
2	2.17±0.64	2.5±0.50	0.029*	
4	2.23±0.62	2.67±0.47	0.003*	
8	2.2±0.6	3.57±0.67	0.0001*	
12	2.4±0.55	3.27±0.51	0.0001*	
16	2.8±0.6	3.17±0.57	0.017*	
20	3±0.93	3.17±0.37	0.35(NS)	
24	3±0.73	3.1±0.37	0.50(NS)	

Table 9: Modified Ramsay Sedation Score			
Time (Hour)	Group RD (Mean±SD)	Group RT (Mean±SD)	P- Value
0	2.9±0.47	1.97±0.55	0.0001*
1	2.73±0.51	1.73±0.44	0.0001*
2	2.57±0.50	1.53±0.50	0.0001*
4	1.83±0.37	1.3±0.46	0.0001*
8	1.47±0.50	1.3±0.46	0.0086*

Table 10: Modified Bromage Scale			
Time (Minute)	Group RD (Mean±SD)	Group RT (Mean±SD)	P-Value
0 Minute	2.1±0.76	1.93±0.69	0.36(Ns)
60 Minute	1.4±0.51	1.3±0.47	0.18(Ns)
120 Minute	1	1	1(Ns)

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Table 11: Rescue Analgesic Cons	umption

Tuble III Research Analysis Consumption				
	Group RD (Mean±SD)	Group RT(Mean±SD)	P- Value	
Duration Of Analgesia(Hours)	14.57±2.45	10.93±1.77	0.0001*	
No. of Doses Of PCM Suppo. In 24 Hrs	1.43±0.50	2.5±0.62	0.0001*	

Discussion

Postoperative pain can result in an uncooperative and restless child. Hence, it is preferable to prevent the onset of pain rather than to relieve its existence. [4] Postoperative analgesia provides not only pain relief but also inhibits trauma induced nociceptive impulses to blunt autonomic reflexes. [5] Caudal block is one of the most popular and commonly used regional anaesthesia procedures in paediatric patients for most surgeries below the umbilicus.

Assessment of pain can be done by various scoring systems. In neonates, infants, and toddlers, it is often difficult to assess pain as crying, a common sign is seen in other non-painful conditions as well. CRIES postoperative pain scale, and FLACC scale show behavioural and physiologic parameters to assess pain. [6]

We have chosen FLACC (Face, Legs, Activity, Cry, Consol ability) score. Ropivacaine, the Senantiomer of the amide local anaesthetic, is suitable for day-care surgery in children as it produces differential neural blockade, with less motor blockade, cardiovascular and neurological toxicity.

Surhan ozercinar et al 2015 compared the postoperative analgesic efficacy of Ropivacaine 0.175% and bupivacaine 0.175% injected caudally into infants for lower abdominal surgery and conclude that both provided effective and similar postoperative pain relief in infant. [7] B. locatelli at el 2004 compared the effect of levobupivacaine 0.25%, ropivacaine 0.25% and bupivacaine 0.25% by the caudal route in children and concluded that caudal levobupivacaine provide reliable analgesic efficacy during sub umbilical surgery in children, which was comparable with ropivacaine and bupivacaine using similar amounts of local anaesthetics, bupivacaine produced a higher incidence of residual motor block and longer

analgesic block than ropivacaine and levobupivacaine. [8]

Like Clonidine, Dexmedetomidine also enhances the effect of local anaesthetics without increasing the incidence of side effects. It is highly selective α^2 adrenoceptors agonist that has sedative and analgesic properties which helps in immediate recovery. Here In our study we used caudal tramadol (2mg/kg) and Dexmedetomidine (1µg/kg) as an adjuvant to Ropivacaine 0.25% (1ml/kg) for postoperative analgesia. The addition of Tramadol as an additive to Ropivacaine in caudal block prolongs duration of postoperative analgesia with minimum side effects.

In our study, duration of analgesia was 10.93 ± 1.77 hrs in-group RT. There were other studies, which supported that caudal addition of Tramadol to local anaesthetic prolongs the duration of postoperative analgesia. A.C Senel et al 2001[9] found that duration of analgesia in-group Tramadol with Bupivacaine longer (13.5 ± 2.2 hrs) than ours (10.93 ± 1.77 hrs). Locusceruleus of the brain stem is the principal site for the sedative action and spinal cord is the principal site for the analgesic action, both acting through α 2A-AR.It produce cooperative sedation, i.e., patients remain awake, calm, and are able to communicate their needs [10].

Haemodynamic parameter: In our study, Haemodynamic parameter (pulse, B.P, Spo2) was comparable in both groups, which were not statistically significant.

Motor block: There was no motor block observed in both the groups of our study.

Post-operative complication: In-group RT, 2 patients had c/o nausea only but it did not require any treatment while in RD group no patient had any nausea or vomiting.

Conclusion

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No statistically significant hemodynamic difference was observed between two groups. Postoperative pain score (FLACC score) was higher in group RT as compared to group RD. Duration of caudal analgesia was higher in group RD as compared to group RT. Postoperative sedation score (Modified Ramsay Sedation Score) was higher in group RD as compared to group RT in initial postoperative period. Requirement of total no. of doses of Paracetamol suppository were higher in-group RT as compared to group RD. Thus we can conclude that addition of Dexmedetomidine $(1\mu G/kg)$ with Ropivacaine in caudal block significantly prolong the duration of postoperative analgesia as compared to Tramadol (2mg/kg) for children undergoing infraumbilical surgeries and reduces the postoperative analgesic requirement in first 24 hours with better quality of sleep in immediate postoperative period.

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