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COMPARISON OF ANALGESIC EFFECT OF DEXMEDETOMIDINE AND FENTANYL AS ADJUVANTS TO CAUDAL ROPIVACAINE IN PAEDIATRIC INFRAUMBILICAL AND LOWER LIMB SURGERIES : AN INTERVENTIONAL STUDY

Anaesthesiology

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ABSTRACT

Background And Objectives: Management of post-operative pain in children can be challenging as it leads to decreased feeding, increased crying and distress amongst the parents. Caudal epidural analgesia is one of the most commonly performed regional techniques in paediatric age group, useful in providing prolonged duration of post-operative analgesia. It is commonly administered in children undergoing infra-umbilical and lower limb surgeries. Additives are being used in combination with local anaesthetics for an increased duration of analgesia. This study was conducted to know the effect of dexmedetomidine and fentanyl as adjuvants to local anaesthetic namely ropivacaine administered in single shot caudal block with respect to post-operative analgesia, and evaluated for hemodynamic parameters and other side effects. **Methods:** An interventional study was conducted on 100 children of 2-8 years age group belonging ASA I and II undergoing elective infra-umbilical and lower limb surgeries under General Anaesthesia [GA]. After institutional ethical committee clearance and taking parental informed, written and valid consent, patients were randomly allocated into 2 groups, Group RD [ropivacaine-dexmedetomidine, n=50] receiving 1ml/kg of 0.2% ropivacaine with 1mcg/kg dexmedetomidine and Group RF [ropivacaine-fentanyl, n=50] receiving 1ml/kg of 0.2% ropivacaine with 1mcg/kg fentanyl after induction of GA with inj. Propofol 2mg/kg IV. I-gel of appropriate size is inserted following induction. Caudal block was performed with either drug combination. Intra-operative monitoring included a precordial stethoscope, pulse-oximetry, NIBP recorded at 0, 5, 15, 30, 45 60, 120 and 180 minutes after administration of caudal block and ECG. The time of caudal block and duration of surgery was noted. Post-operative analgesia was assessed by the Wong-Baker pain rating scale and Face Legs Activity Cry Consolability [FLACC] pain scale. The assessment was done for a period of 24 hours after caudal block. **Results:** The groups were similar in age, gender and weight. The hemodynamic parameters like heart rate, systolic and diastolic blood pressure showed significant decrease in RD group as compared to RF group after administering caudal block. The mean duration of analgesia in RD group [11.6±1.7 hours] was significantly longer [p <0.001] than RF group [7.4±1.5 hours]. The pain score in the two groups were similar up to three hours after administering caudal block but was higher in group RF at the end of fourth, eighth and twelfth hours. There was no difference in the incidence of side effects like vomiting, bradycardia, hypotension, respiratory depression in either of the groups. **Conclusion:** Caudal administration of dexmedetomidine [1mcg/kg] with 0.2% ropivacaine resulted in superior and longer duration of analgesia as compared to fentanyl [1mcg/kg] with 0.2% ropivacaine without the incidence of side effects with stable hemodynamics.

KEYWORDS

INTRODUCTION:

Pain is perhaps the most feared symptom of a disease that a man is always trying to alleviate and conquer for ages. Children are special in this regard because in them it is a very complex phenomenon. An effective pain therapy to block or modify the myriad physiologic responses to stress has become an essential component of modern paediatric anaesthesia and surgical practice.[3] The Declaration of Montreal [September 2010] states that "Access to Pain Management is a Fundamental Right", it is estimated that 80% of the global population is affected by insufficient pain management, and this is a serious problem in over 150 countries.[1] The World Health Organization [WHO] analgesic ladder provides a strong foundation for the treatment of pain.[2]

Pain, as described by the International Association for the Study of Pain, is an unpleasant sensory and emotional experience associated with actual or potential tissue damage. Acute pain in children involves a combination of physiologic, psychological, behavioural, developmental and situational factors.[11]

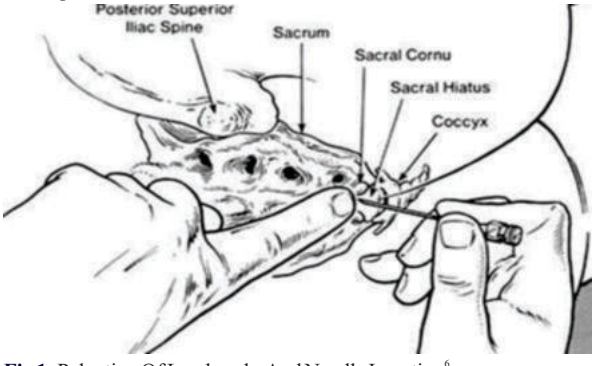

Fig 1: Palpation Of Landmarks And Needle Insertion[6]

Caudal anaesthesia is one of the most used-popular regional blocks in children. Although it is a versatile block, one of the major limitations of the single-injection technique is the relatively short duration of postoperative analgesia. The most frequently used method to further prolong postoperative analgesia following caudal block is to add different adjunct drugs to the local anaesthetics solution.[4] Caudal block can be used as a sole method for surgical anaesthesia, or in combination with general anaesthesia to provide good postoperative analgesia. When used as an adjunct to general anaesthesia, it helps spare volatile anaesthetic agents and neuromuscular blockers and provides excellent analgesia approach to caudal block can either be landmark or ultrasound guided.[5]

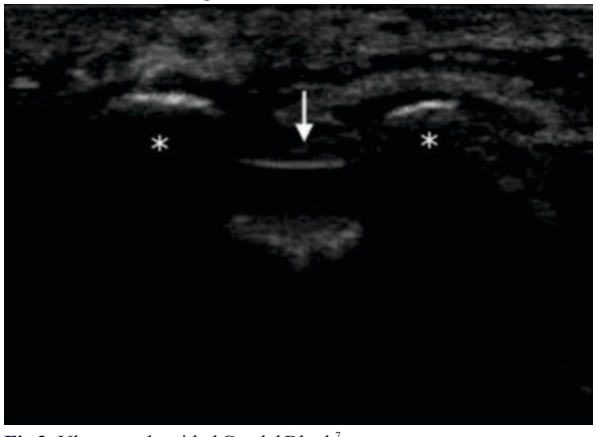

Fig 2: Ultrasound-guided Caudal Block[7]

Concentrations of solution adequate to block sensory fibres are bupivacaine, ropivacaine and levobupivacaine 0.2%, etodicaine 1%, mepivacaine 1%, chlorprocaine 2%, lidocaine 1%, prilocaine 1%.

Increased concentration will increase the degree of motor block and probably will improve the speed of onset.[6] Ropivacaine is long acting amide local anaesthetic agent first synthesised in the year 1957. It is a pure S[-] enantiomer, unlike bupivacaine which is a racemic mixture. It was developed to reduce potential toxicity and improve relative sensory and motor block profiles.[8]

Both clonidine and dexmedetomidine belong to same α_2 agonists group, but the difference is that latter has 1600 times' greater affinity for α_2A receptors. These drugs interact with local anaesthetics by an increase in potassium conductance in isolated neurons, thus intensifying local anaesthetic conduction block, second by causing local vasoconstriction, thus decreasing local anaesthetic spread. This effect is mediated by drug action on postsynaptic α_2 receptors; spinal α_2 adrenergic agonists may also induce analgesia by activating spinal cholinergic neurons resulting acetylcholine release. It is given at a dose of 1 mcg/kg. The most frequently observed adverse effects include hypotension, hypertension, bradycardia, dry mouth and nausea.[9]

Epidural and intrathecal administration of fentanyl are long-established routes for intraoperative anaesthesia and postoperative analgesia. Mechanism of analgesia of epidural opioids include movement across the meninges into the cerebrospinal fluid [CSF] and then into the opioid receptor or other nonspecific binding site in the spinal cord. vascular absorption in the epidural or spinal vascular system and uptake into epidural fat. The dosage of fentanyl used for repeated single bolus administration varies 1-3 mg/kg and up to 5mg/kg. [10] Adverse effects of intrathecal fentanyl include nausea and vomiting, pruritus, respiratory depression, muscle rigidity, urinary retention.[10]

Some of the complications associated with caudal block are absent or patchy block, accidental intravenous injection, intraosseous injection, dural puncture, urinary retention, excessive spread and infections.[6]

METHODS-

Approval for this interventional study was obtained from the institutional ethical committee.

The present study was conducted on patients aged between 2-8 years of American Society of Anaesthesiologists [ASA] physical status 1 and 2 of either sex, posted for infra-umbilical and lower limb elective surgeries under general anaesthesia at GADAG INSTITUTE OF MEDICAL SCIENCES, GADAG from March 2021 -September 2022.

A total number of 100 patients satisfying the inclusion criteria were enrolled in the study after taking parental informed, written and valid consent and were divided into 2 groups of 50 each by simple random sampling by lottery method.

Group RD [n=50]: patients receiving caudal epidural ropivacaine 0.2% 1ml/kg body weight with dexmedetomidine 1mcg/kg body weight.

Group RF [n=30]: patients receiving caudal epidural ropivacaine 0.2% 1mL/kg body weight with fentanyl 1mcg/kg body weight.

Inclusion Criteria:

- Age 2-8 years.
- ASA grade: 1 and 2.
- Undergoing infra-umbilical and lower limb elective surgeries.
- Informed, written and valid consent by parents or guardians of patients.

Exclusion Criteria:

- Infection at the site of injection.
- Coagulation disorder.
- Anatomical abnormalities of the spine.
- Documented allergy to local anaesthetics.
- Active CNS diseases.

Patients were induced with oxygen, nitrous oxide [50:50] and sevoflurane using Jackson Rees modification of Ayre's 'T' piece and an IV line was secured if previously not placed. An infusion of Ringer Lactate was started and fluid was administered according to the calculated requirements. Injection glycopyrrolate 0.004mg/kg IV, inj. Midazolam 0.05mg/kg IV and inj. Propofol 2mg/kg IV was given. After adequate depth of anaesthesia was achieved, an appropriate-sized I-gel by weight was inserted and the patient was ventilated using the Jackson Rees circuit.

The patient was gently placed in the Sim's position [left lateral], and vitals were recorded. Under strict aseptic conditions epidural drug was injected after confirming the needlepoint being to be in epidural space by the "whoosh" test. No analgesia was given by any route pre-operatively or intra- operatively. Anaesthesia was maintained with oxygen, nitrous oxide and sevoflurane [0.5-2%] and ventilated by Jackson Rees circuit throughout the surgery.

Intra-operative monitoring included a precordial stethoscope, pulse-oximetry, NIBP recorded at 0, 5, 15, 30, 45 60, 120 and 180 minutes after administration of caudal block and ECG. The time of caudal block and duration of surgery was noted.

At the beginning of skin closure, all anaesthetic agents were discontinued and 100% oxygen was administered. I-gel was removed once the vitals were stable with spontaneous ventilation and the patient was awake. Patients were then shifted to the Surgical Intensive Care Unit [SICU] and monitored.

Duration of analgesia of the drug is defined as the time interval between the administration of caudal block and the first requirement of supplementary analgesia for the patient. Post-operative analgesia is assessed by the Wong-Baker pain rating scale and Face Legs Activity Cry Consolability [FLACC] pain scale. The assessment was done for a period of 24 hours after caudal block. If the pain score was 4 for two consecutive intervals of 10 minutes, then supplementary analgesia with syrup Paracetamol [15mg/kg] was given and the time of the end of analgesia was noted.

Fig 3: Wong-baker Faces Pain Rating Scale

	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 complaints	Crying steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging or "talking to". Distractable	Difficult to console or comfort

Fig 4: FLACC PAIN SCALE

Statistical Analysis:

The data collected was entered in the MS Excel master sheet. Data was tabulated and analyzed using software OpenEpi version 3.01 and Statistical Package for Social Sciences [SPSS] version 22. Categorical data have been presented as numbers and percentages [%] and quantitative data in terms of mean and standard deviation. Categorical variables have been analysed using Pearson's chi-square test and Fisher exact tests [when the expected count of 20% of cells is less than 5]. Ordinal data was analysed using Mann-Whitney U test. Quantitative variables have been analysed using Student T test, ANOVA and repeated measures ANOVA. A p value of <0.05 has been considered as statistically significant.

RESULTS AND DISCUSSION-

Following are the observations of this study.

A. Demographic Parameters

Table-1: Distribution Based On Age And Weight

Parameter/ study group	Mean	Std. Deviation	p-value
Age (in years)			
RD	4.8	1.5	0.104
RF	5.3	1.7	
Weight (in kg)			
RD	12.9	2.7	0.420
RF	13.2	2.8	

Group RD has 50 patients with mean age of 4.8 1.5 years and mean weight of 12.9 2.7 kg. Group RF has 50 patients with mean age of 5.3 1.7 years and mean weight of 13.2 2.8 kg. The p value of the two groups for age comparison is 0.104 and for weight is 0.420 hence the two groups are comparable in terms of age and weight.

Table-2: Distribution Based On Gender

Gender	Study group		Total
	RD	RF	
Female	11	13	24
	22.0%	26.0%	24.0%
Male	39	37	76
	78.0%	74.0%	76.0%
Total	50	50	100
	100.0%	100.0%	100.0%
p-value	0.640		

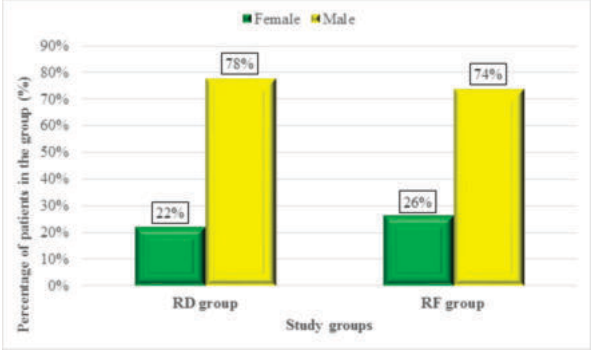

Chart- 1: Distribution Based On Gender

It is evident that both groups are comparable with respect to gender distribution. Group RD has 39[78%] male and 11[22%] female patients. Group RF has 37[74%] male and 13[26%] female patients. The p value is 0.64 which is statistically insignificant as shown in table 5 and chart 1.

A study done by Elfawal SM et al[12],Swapnadeep Sengupta et al[13] Bharati N et al[20] all had similar demographic parameters as our study.

B. CONCENTRATION AND DOSAGE OF DRUG

G. Luz et al[23] compared the efficacy of 0.1% and 0.2% ropivacaine with 0.2% bupivacaine for single shot caudal anaesthesia in children. Ropivacaine 0.1% was not sufficient for perioperative pain relief. Analgesic efficacy of ropivacaine 0.2% was similar to that of bupivacaine 0.2%. In the early postoperative period, both ropivacaine concentrations caused less intense and shorter motor block than does bupivacaine. Farad Imani et al[21] and Sandhya Kalappa et al[25] used 0.2% ropivacaine 1ml/kg for paediatric caudal analgesia for patients undergoing lower abdominal and lumbo-sacral surgeries respectively.

Khaled R. Al-zaben et al[18] compared the efficacy of caudal bupivacaine alone and bupivacaine with two doses of dexmedetomidine for postoperative analgesia in paediatric patients undergoing infraumbilical surgeries. They found that 1mg/kg dose of caudal dexmedetomidine achieved comparable prolongation of postoperative analgesia to 2 mg/kg dose, with shorter duration of postoperative sedation and lower incidence of other side effects like bradycardia, hypotension and urinary retention. Park SJ et al[11], Goyal V et al[9], also used dexmedetomidine in the dose of 1mg/kg as an adjuvant to ropivacaine and bupivacaine respectively in caudal analgesia in children.

Desai DJ et al[24] compared two different doses of fentanyl- 0.5mg/kg and 1mg/kg with 0.25% bupivacaine and found that both doses of fentanyl with bupivacaine 0.25% when administered caudally provided satisfactory surgical anaesthesia without any hemodynamic disturbances with prolonged duration of analgesia with fentanyl 1mg/kg as compared to 0.5mg/kg without any major postoperative complications. Park SJ et al[11], Nasr DA Abdelhamid HM et al[19], and Elfawal et al[12] also used fentanyl as an adjuvant to caudal epidural analgesia in the dose of 1mg/kg.

In our study we chose 0.2% ropivacaine which provides better quality of analgesia with less incidence of hemodynamic instability, 1mg/kg of dexmedetomidine which prolongs postoperative analgesia with reduced incidence of side effects like bradycardia and hypotension and 1mg/kg of fentanyl which prolongs the duration of postoperative analgesia with minimal side effects.

C. HEMODYNAMIC PARAMETERS

Table- 3: Comparison Of Heart Rate Between Study Groups

Parameter/ study group	Mean	Std. Deviation	p-value
Baseline heart rate (beats/ minute)			
RD	127.2	9.2	0.325
RF	125.5	7.4	
Heart rate at 0 min (beats/ minute)			
RD	114.4	7.8	0.514
RF	113.5	6.8	
Heart rate at 5 min (beats/ minute)			
RD	113.8	6.8	0.024
RF	110.5	7.8	
Heart rate at 15 min (beats/ minute)			
RD	112.8	10.0	0.012
RF	108.0	8.7	
Heart rate at 30 min (beats/ minute)			
RD	109.6	8.7	0.027
RF	105.9	7.9	
Heart rate at 45 min (beats/ minute)			
RD	106.4	10.1	0.883
RF	106.2	7.2	
Heart rate at 60 min (beats/ minute)			
RD	105.7	10.0	0.592
RF	106.7	6.9	
Heart rate at 120 min (beats/ minute)			
RD	108.5	9.5	0.489
RF	107.4	7.0	
Heart rate at 180 min (beats/ minute)			
RD	107.6	10.5	0.752
RF	107.0	7.5	

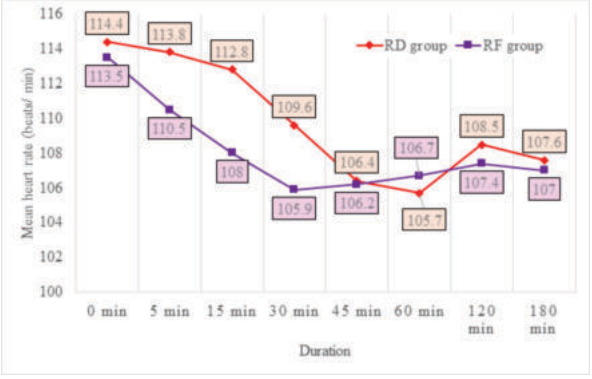

Chart- 2: Comparison Of Heart Rate Between Study Groups

The mean baseline heart rate was similar in both the groups. The mean baseline heart rate was 127.2±9.2 beats/minute in group RD and 125.5 ±7.4 beats/minute in group RF. The initial decline might be attributed to decrease in anxiety of the children after the induction of general anaesthesia. Further on commencement of caudal block, there was a decrease in the heart rate in both the groups. The mean heart rate at 180 minutes after administration of caudal block was 107.6±10.5 beats/minute in group RD and 107.0±7.5 beats/minute in group RF. There was a statistically significant difference in heart rate between the two groups at 5 minutes, 15 minutes and 30 minutes after caudal block administration. Dexmedetomidine group showed a greater decrease in heart rate as compared to fentanyl group. However, clinically

significant decrease in heart rate that required treatment was not observed. This is similar to the findings obtained by Khaled Al-Zaben et al[18] and by Dalia Abdelhamid et al[19] also showed statistically significant decrease in heart rate in dexmedetomidine group [p <0.05] as compared to fentanyl group.

Table- 4: Comparison Of SBP Between Study Groups

Parameter/ study group	Mean	Std. Deviation	p-value
Baseline systolic BP (mm of Hg)			
RD	106.4	7.1	0.309
RF	105.1	5.9	
Systolic BP at 0 min (mm of Hg)			
RD	102.8	6.3	0.583
RF	103.5	6.4	
Systolic BP at 5 min (mm of Hg)			
RD	100.6	5.5	0.072
RF	102.8	6.8	
Systolic BP at 15 min (mm of Hg)			
RD	98.7	5.8	0.010
RF	102.2	7.4	
Systolic BP at 30 min (mm of Hg)			
RD	97.4	8.2	0.002
RF	102.7	9.0	
Systolic BP at 45 min (mm of Hg)			
RD	97.7	6.2	0.004
RF	102.2	8.6	
Systolic BP at 60 min (mm of Hg)			
RD	98.9	5.7	0.013
RF	102.5	8.2	
Systolic BP at 120 min (mm of Hg)			
RD	99.2	5.9	<0.001
RF	104.3	7.8	
Systolic BP at 180 min (mm of Hg)			
RD	99.0	6.2	0.001
RF	103.4	7.1	

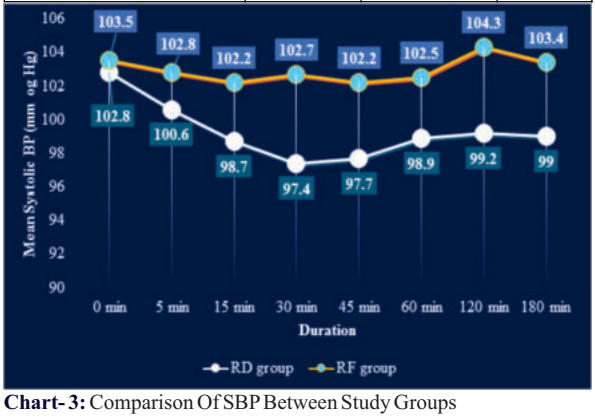

Chart- 3: Comparison Of SBP Between Study Groups

Table- 5: Comparison Of DBP Between Study Groups

Parameter/ study group	Mean	Std. Deviation	p-value
Baseline diastolic BP (mm of Hg)			
RD	60.5	3.3	0.193
RF	61.6	5.0	
Diastolic BP at 0 min (mm of Hg)			
RD	59.7	3.4	0.458
RF	60.3	4.3	
Diastolic BP at 5 min (mm of Hg)			
RD	56.5	3.4	0.001
RF	59.2	4.2	
Diastolic BP at 15 min (mm of Hg)			
RD	54.9	3.8	0.001
RF	57.7	4.6	
Diastolic BP at 30 min (mm of Hg)			
RD	53.5	4.1	0.001
RF	56.6	5.0	
Diastolic BP at 45 min (mm of Hg)			
RD	52.8	4.2	<0.001
RF	57.2	4.6	
Diastolic BP at 60 min (mm of Hg)			
RD	53.7	3.0	<0.001
RF	58.8	3.9	
Diastolic BP at 120 min (mm of Hg)			
RD	55.2	3.4	<0.001
RF	60.5	3.6	
Diastolic BP at 180 min (mm of Hg)			
RD	56.6	3.0	<0.001
RF	61.8	2.6	

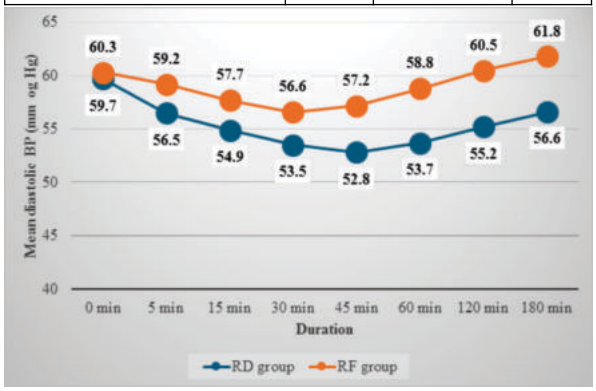

Chart- 4: Comparison Of DBP Between Study Groups

The mean baseline blood pressure, SBP and DBP were similar in both the groups. Mean baseline SBP and DBP in RD group was 106.4±7.1 mmHg and 60.5±3.3 mmHg and in group RF was 105.1 mmHg and 61.6 mmHg. The initial decline can be attributed to drugs used in general anaesthesia. After the administration of caudal block there was a statistically significant difference in SBP and DBP values between the two groups at all time points. The mean SBP and DBP at 180 minutes in group RD was 99.0 mmHg and 56.6 mmHg, in group RF was 103.4 mmHg and 61.8 mmHg. At the end of 180 minutes, group RD showed a significant reduction in mean SBP and mean DBP values. However, there was no clinically significant reduction in blood pressures that required treatment.

This is in concordance to the study done by Dalia Abdelhamid et al[19], Khaled Al-Zaben et al[18] and Deming Xu et al[22] and Farnad Imani et al[21] who found that the mean SBP and DBP were lower in dexmedetomidine group at each observation time point [p< 0.05].

Tejinderpal Kaur et al[15] conducted a study to evaluate the effects of fentanyl as an adjuvant to ropivacaine had comparable hemodynamic parameters at all time intervals throughout the study. The results obtained in our study is in concordance with the above study as we did not observe any changes in blood pressure in fentanyl group.

C. POST-OPERATIVE ANALGESIA

Table- 6: Wong Baker's Pain Scale At Different Time Intervals

TIME INTERVAL [hours]	RD	RF	P Value
1	0	0	-
2	0	0	-
3	0	0	-
4	0	14 (28%)	<0.001
8	9 (18%)	32 (64%)	<0.001
12	37 (74%)	4 (8%)	<0.001
16	4 (8%)		-
24			-

Table- 7: FLACC Pain Scale At Different Time Intervals

TIME INTERVAL hours]	RD	RF	P VALUE
1	0	0	-
2	0	0	-
3	0	0	-
4	0	11 (22%)	<0.001
8	11 (22%)	36 (72%)	<0.001
12	34 (68%)	3 (6%)	<0.001
16	5 (10%)		-
24			-

Table- 8: Duration Of Analgesia Among Study Groups

Duration of analgesia (in hours)	Mean	Std. Deviation	p-value
RD	11.6	1.7	<0.001
RF	7.4	1.5	

The mean duration of analgesia was 11.6 1.7 hours in RD group and 7.4 1.5 hours in group RF. The difference in the mean duration of Analgesia was statistically significant [p <0.001] which is shown in table 14 and chart 5.

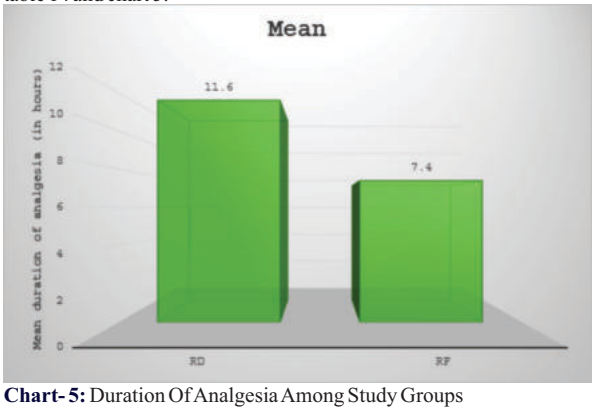

Chart- 5: Duration Of Analgesia Among Study Groups

There was no incidence of pain in both the drug groups, i.e, pain score of 4 at the end of first, second and third hours of giving caudal block. At the end of fourth hour, none of the patients in RD group and 14 [28%] patients in RF group had pain scores of 4 which was highly significant [p<0.001]. By the end of eighth hour, 11 [22%] patients in RD group and 32 [64%] patients in RF group had pain scores of 4 which was highly significant [p<0.001]. 92% of patients in RF group had received rescue analgesia by the end of eighth hour. By the end of twelfth hour, 37 [74%] of patients in RD group had pain scores of 4 and the remaining 4 [8%] patients of RF group had pain score of 4 RD group showed statistically significant [p< 0.001] lower pain scores in fourth, eighth and twelfth post-operative hours. This is in concordance with a study conducted by Dalia Abdelhamid et al[19] found that patients who received dexmedetomidine had lower pain scores during the first eight hours of giving caudal block.

The duration of analgesia was significantly prolonged in dexmedetomidine group 11.6 1.7 hours as compared to fentanyl group 7.4 1.5 hours in our study. This is similar to the study done by Swapnadeep sengupta et al[13], Solanki NM et al[14] who studied fentanyl and found the mean duration of post-operative analgesia to be 4.7-7 hours which is similar to our study.

Manoj Kamal et al[16] and Vijay Anand et al[17] compared the efficacy of dexmedetomidine as an adjuvant to ropivacaine in paediatric caudal epidural block. The mean duration of analgesia in dexmedetomidine group was 12.5 hours and 14.5 hours respectively. The results obtained in the above studies are in concordance with our study.

D. SIDE EFFECTS

Table- 9: Incidence Of Side Effects Between Study Groups

Complications	Study group		Total
	RD	RF	
None	43	46	89
	86.0%	92.0%	89.0%
Vomiting	7	4	11
	14.0%	8.0%	11.0%
Total	50	50	100
	100.0%	100.0%	100.0%
p-value	0.338		

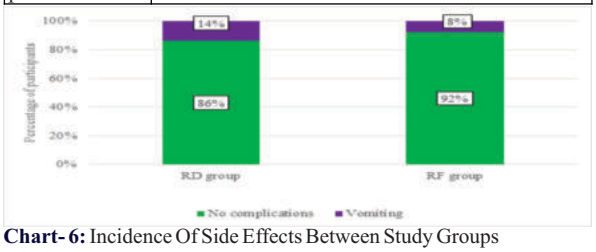

Chart- 6: Incidence Of Side Effects Between Study Groups

The incidence of vomiting was 7 [14%] in group RD and 4 [8%] in group RF. There was no incidence of hypotension, bradycardia and respiratory depression in both the groups as shown in table 15 and chart 6.

In our study, 7 patients in group RD and 4 patients in group RF had an episode of vomiting which was treated with inj. Ondansetron 0.1mg/kg IV. The incidence of vomiting was comparable in both the groups, 14% in RD and 8% in RF group [p =0.338].

Other side effects like hypotension, bradycardia, respiratory depression which are expected to be seen by epidural dexmedetomidine and fentanyl did not occur in our study.

Limitations Of The Study:

1. Post-operative sedation score was not done in our study which is the common side effect of alpha agonists.

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