Original Research Paper

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A COMPARATIVE CLINICAL STUDY OF EFFICACY OF DEXMEDETOMIDINE OR CLONIDINE AS ADJUVANT WITH LEVOBUPIVCAINE FOR POSTOPERATIVE ANALGESIA IN ULTRASOUND GUIDED CAUDAL BLOCK IN CHILDREN UNDERGOING INFRAUMBILICAL SURGERIES.

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ABSTRACT

Background: Postoperative pain is an annoying subjective sensation for both children and their parents. The caudal route is one of the simplest and safest techniques in pediatric surgery, with a high success rate.

Materials and Methods: In this present prospective, Randomized, double-blind study 60 children aged between 1 to 6 years, ASA grade I & II scheduled for elective infraumbilical surgeries that were allocated randomly into two groups. Group LC received 0.75ml/kg levobupivacaine 0.25% with clonidine 1 µg/kg diluted with normal saline and Group LD received 0.75ml/kg levobupivacaine0.25% with dexmedetomidine 1 µg/kg diluted with normal saline. Intraoperative hemodynamic stability was assessed by using HR, MAP, postoperative pain scores were assessed using CHIPPS scale up to 12 hours.

Results: Regarding demographic data, MAP, Sp02, there was no significant difference between both groups (P > 0.05). Regarding HR & RR during preoperative and intraoperative period no significant difference found (p >0.05) but postoperatively 1,6 & 10 hours in HR and 6 & 10 hours in RR statically significant difference were found(p = <0.001.The mean duration of analgesia in Group LC was 350.27±17.20 min and in Group LD was 580±7.22 min which was statistically significant (p<0.001).

Conclusion: We conclude that Dexmedetomidine in doses of 1 µg/kg as an adjuvant to 0.25% levobupivacaine for caudal block in pediatric infraumbilical surgeries provides significant prolonged postoperative analgesia and better quality of sleep without any increase in adverse effects.

KEYWORDS : Caudal block • Levobupivacaine • Dexmedetomidine • Clonidine • Paediatric.

INTRODUCTION:

Postoperative pain is an annoying subjective sensation for both children and their parents, planning for post-surgical analgesia to be done even before induction of anesthesia. Various methods have evolved for providing postoperative pain relief in pediatric patients aiming for a better quality of sleep and prolonging the duration of analgesia.

Regional anesthetic techniques significantly decrease the postoperative pain and systemic analgesic requirement. [1] Caudal anesthesia is an accepted reliable, safe, and commonly performed regional block in pediatric patients because caudal route is one of the simplest and safest techniques with a high success rate.[2] Reliability and ease of performance make caudal block the most popular block. Nowdays Caudal anesthesia was described in the last century by two French physicians **Fernand Cathelin and Jean Anthanase Sicard.**[3] Sicard and Cathelin first described the sacral approach to epidural anesthesia in 1901 but the first published report on the use of caudal anesthesia in children was in 1933 by Campbell.[4]

There were various techniques used for the caudal block including palpation identification, fluoroscopy, and ultrasound-guided. Ultrasound increases the success rate and reduces the risk of complications [5] such as tissue trauma, dural puncture, local anesthesia toxicity, and vascular compromise in whom the anatomy of the sacral hiatus, caudal canal, and the dural sac is variable.

The major drawback of single-shot caudal block injection is the limited duration of analgesia with the use of a long-acting local anesthetic. [6] Epidural catheter placement into the caudal epidural space adds the risk of infection due to fecal contamination [7] and tends to prevent early mobilization. Therefore to increase postoperative analgesia after single-shot caudal epidural block, various additives, such as dexmedetomidine, clonidine, fentanyl, tramadol, ketamine, morphine, midazolam with local anesthetic have been investigated.

Clonidine an α_2-adrenergic agonist produces analgesia without causing significant respiratory depression after caudal administration in children.[8] Using clonidine as an adjuvant enables us to use a lower concentration of the local anesthetic to achieve the same level of analgesia with the advantages of prolonged duration of analgesia, reduced residual motor blockade, and increase the margin of safety.[09][10]

Dexmedetomidine is a potent and highly selective α_2-adrenergic agonist that has been described as a safe and effective additive in many anesthetic applications and analgesic techniques.[11] In contrast to other additive agents, it has sympatholytic analgesic and sedative effects and is remarkably free from side effects except for manageable hypotension and bradycardia.[12]

Thus, this study was designed to compare the relative analgesic efficacy of caudal dexmedetomidine versus clonidine when added with levobupivacaine in pediatric patients posted for infraumbilical surgeries

METHODOLOGY:

The study was conducted after obtaining approval from the ethical committee of Moti Lal Nehru Medical College, Prayagraj. After written informed consent from the patient's parent/guardians. The study was conducted from July 2020 to July 2021. Total of 60 patients, belonging to ASA I and II, in age group 1-6 years, of either gender, who underwent infra umbilical surgery, were enrolled.

INCLUSION CRITERIA:

1] Age between 1-6 year.
2] ASA grade I and II patients.
3] Children of either sex, ideal body weight [weight for age] and height[height for age], scheduled for elective infraumbilical surgeries, and gave written informed consent for the study.

EXCLUSION CRITERIA :

1. Parents' refusal.
2. Patients having age >6 years.
3. Patients belonging to ASA physical status III or >III.
4. History of allergy to any study drugs.
5. History of seizure disorders.
6. Neurological and neuromuscular disorders.
7. Blood dyscrasias.

8. Coagulopathy
9. Anatomical malformation of the spine.
10. Infection at the puncture site.

The study was carried out in 60 pediatric patients who were divided into two groups - group LD and group LC.

GROUP-D: Patients received 0.75ml/kg Levobupivacaine 0.25% with dexmedetomidine 1 µg/kg diluted with normal saline.

GROUP-C: Patients received 0.75ml/kg Levobupivacaine0.25% with clonidine 1 µg/kg diluted with normal saline**.**

All patients kept N.P.O. according to the standard guideline, All the monitors attached including ECG electrode, NIBP, Pulse oximetry, and temperature probe, baseline parameters were observed and recorded. Patients premedicated with inj. Atropine 0.02mg/kg I.V, Inj. Midazolam 0.05mg/kg given just before induction of anaesthesia, and preoxygenated with 100% oxygen for 3 minutes, patients induced with inj. Propofol 2.5mg/kg and then intubated using muscle relaxant Inj. Succinylcholine 2mg/kg with appropriate size E.T.tube. Anaesthesia maintained with mixture of nitrous oxide, oxygen (50:50), isoflurane patients connected with ventilator, for muscle relaxation Inj. Cis-atracurium 0.1mg/kg(loading dose) and 0.02mg/kg (maintenance) I.V. given, after attachment of ventilator patients turned to the left lateral position, with full aseptic precaution anatomical landmarks identified by the linear transducer of 10- 13 MHz probe of ultrasound. A low-frequency linear probe is placed in the transverse plane across the two sacral cornua. The sacral cornua can be visualized as a "frog eye sign". A 22 G caudal needle is inserted into the space between two cornua. A distinct "pop" is felt as the needle tip penetrates the sacrococcygeal ligament. After negative aspiration of blood or CSF caudal medication is given as per the group assigned. Immediately after the caudal block patient turned into a supine position for surgery. No intravenous or per rectal analgesia drugs were given intraoperatively. The time of onset of analgesia was studied with a modified allis clamp by giving a mechanical stimulus every 5 minutes for a total of 15 minutes. The mechanical stimulus stimulates both A and C nerve fibers and detects the pain threshold within the physiological limit without causing tissue damage.[14] A surgical incision is given 15 minutes after the caudal block.

If the patient shows any gross movement after incision or increase in heart rate or mean arterial pressure more than 20% of the baseline value, then it was considered as block failure.

Onset and duration of caudal block calculated from the time of the caudal injection of the study drug till the requirement of rescue analgesia.

After the completion of surgery reversal of muscle relaxation done by inj. Atropine 0.01mg/kg and inj. Neostigmine 0.05mg/kg IV and extubation were done and the patient was shifted to the postoperative anesthesia care unit.

During intraoperatively HR, MAP, Sp02 , RR and Temperature assessed 0,5,10,20,30,45,60,90 minutes intraoperatively and also at immediate postoperative period and then at 1,2,4,6,8,10 and 12 hours after postoperative. Postoperative pain score assessed by using Children's and Infants Postoperative Pain Scale { CHIPPS SCORE } in the less than 6 years of age.

Crying
None-0
Moaning-1
Screaming-2
Facial expression
Relaxed/smiling-0
Wry mouth-1
Grimace[mouth and eyes]-2
Posture of the trunk
Neutral-0
Variable-1
Rear up-2
Posture of the legs
Neutral-0
Kicking-1
Tightened legs-2
Restlessness
None-0
Mode rate-1
Restless-2

If the score >3 **[CHIPPS SCORE]**, rescue analgesia in the form of rectal PCM 20 mg/kg was given.

The **side effect** and **complications** of the study like bradycardia hypotension arrhythmias nausea and vomiting will be noted and treated symptomatically.

OBSERVATIONS & RESULTS

The mean age of the children in the two groups was compared using an Unpaired T-test. Group LC patients had a mean age of 2.72 months and Group LD patients had a mean age of 3.10 months. The difference was insignificant with a *P-value* of 0.253. There was no significant difference between the two groups in terms of weight, sex, type of surgery, and duration of surgery.

Descriptive Summary of Age, Weight, and Duration of Surgery of Cases

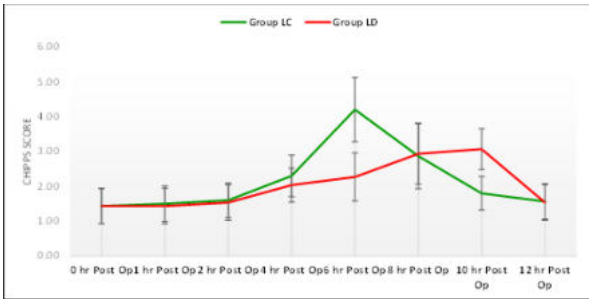
Variable	Group LC		Group LD		Unpaired t test	
	Mean	SD	Mean	SD	t-value	p-value
Age	2.73	1.51	3.10	1.20	-1.04	0.301
Weight	10.92	3.29	11.72	2.92	-1.00	0.323
Duration of Surgery	38.67	10.50	36.33	10.74	0.85	0.398

Intergroup Comparison of Chipps Score:-

CHIPPS SCORE	Group LC		Group LD		Unpaired t test	
	Mean	SD	Mean	SD	t-value	p-value
0 hr Post Op	1.43	0.50	1.43	0.50	0.00	1.000
1 hr Post Op	1.50	0.51	1.43	0.50	-0.51	0.608
2 hr Post Op	1.60	0.50	1.53	0.51	-0.52	0.605
4 hr Post Op	2.30	0.60	2.03	0.49	-1.89	0.063
6 hr Post Op	4.20	0.92	2.27	0.69	9.17	**<0.001**
8 hr Post Op	2.87	0.94	2.93	0.87	0.29	0.776
10 hr Post Op	1.80	0.48	3.07	0.58	-9.15	**<0.001**
12 hr Post Op	1.57	0.50	1.53	0.51	-0.26	0.797

The mean CHIPPS score in group LC was 1.43±0.50 at 0 hr post op which was changed at post op with the maximum value 4.20±0.92 was observed at 6 hr which was > 3 so rescue analgesia given at this time, while finally at 12 hr the mean CHIPPS score was recorded 1.57±0.50. The mean CHIPPS score in group LD was 1.43±0.50 at 0 hr post op which was changed at post op with the maximum value 3.07±0.58 was observed at 10 hr which was > 3 so rescue analgesia given at this time while finally at 12 hr the mean CHIPPS score was recorded 1.53±0.51. The significant differences were observed at 6 hr post op and 10 hr post op ($p<0.001$).

We concluded that rescue analgesia requirement delayed in LD group compared to LC group.



DISCUSSION

The present study compared the effect of dexmedetomidine and clonidine when added to 0.25% levobupivacaine for caudal block in patients undergoing infraumbilical surgeries. In our study total of 60 patients were admitted, age 1-6 years, ASA I & II, allocated in two groups LC & LD, Group LC Patients received 0.75ml/kg Levobupivacaine 0.25% with clonidine 1 µg/kg diluted with normal saline and Group LD Patients received 0.75ml/kg Levobupivacaine 0.25% with dexmedetomidine 1 µg/kg diluted with normal saline.

The patients studied across the group did not vary much with respect to Age, Sex, Weight, ASA grading, Type and duration of surgeries which

was not significant (p=>0.05) as shown in the table, our results were supported by B Sarvesh *et al*(2019)[12] who conducted a study in 60 patients aged 2 -12 years, ASA I & II and concluded that there were no significant differences in the age, sex, weight, ASA status, type, and duration of surgery in intergroup.

These results were supported by Dutt *et al*. who compared the addition of fentanyl or dexmedetomidine to caudal ropivacaine in pediatrics who underwent lower abdominal and lower limb surgeries and concluded that hemodynamics was comparable between the two studied groups. Saadawy *et al*,[13] who studied the effect of dexmedetomidine on bupivacaine characteristics in the caudal block, found no significant changes in the hemodynamics among their groups and prolonged postoperative analgesia with dexmedetomidine compared to bupivacaine alone.

Our supporting study to use of levobupivacaine, Brechan C *et al,* [14] compared three different LAs like 0.2% levobupivacaine, 0.2% bupivacaine, 0.2% ropivacaine assessed by using CHIPPS scale have similar efficacy in all but less systemic toxicity associated with levobupivacaine so we selected levobupivacaine in this study. Arumugam *et al.(2016)* conducted a study in 100 patients to evaluate the effect of clonidine as an adjuvant to levobupivacaine, an S (-) enantiomer of bupivacaine. Group L received 0.5% levobupivacaine (1.5mg/kg) and group LC received 0.5% levobupivacaine (1.5mg/kg) with clonidine (2µg/kg). They concluded that the duration of anesthesia and duration of analgesia was prolonged in group LC (234.5±16.1mins, 412.8±48.3mins) compared to group L (173.56±12.78 min, 269.2±24.2mins) which was statistically significant (p<0.05). So in our study duration of analgesia in LC group is 352.27±30.20 which is near to this study.

CONCLUSION:

We conclude that Dexmedetomidine in doses of 1 µg/kg as an adjuvant to 0.25% Levobupivacaine for caudal block in pediatric patients undergoing infraumbilical surgeries provides significant prolonged postoperative analgesia and better quality of sleep without any increase in adverse effects than clonidine with a similar dose.

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