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0.25%LEVOBUPIVACAINE VERSUS 0.25% ROPIVACAINE FOR CAUDAL EPIDURAL ANALGESIA IN PEADIATRIC PATIENTS- COMPARISON OF RECOVERY FROM MOTOR BLOCKADE AND POST OPERATIVE ANALGESIA

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ABSTRACT

Introduction: Caudal block is one of the most commonly performed regional blocks in children. Many new local anaesthetics were tried in caudal. We made a comparison between the effectiveness of (0.25%) of ropivacaine and levobupivacaine in children undergoing minor subumbilical surgery

Aim: The aim of the present study was to compare equal concentrations (0.25%) of ropivacaine and levobupivacaine in children undergoing minor infraumbilical surgeries.

Methodology: The Prospective, randomized, double-blinded comparative study was conducted in 60 children belonging to ASA 1 and 2,of either sex, aged between 1-10 years undergoing elective surgery in the Paediatric surgery department in Stanley medical College..Following induction of anesthesia, patients (1–10 years) were randomized in a double-blind manner to receive a caudal block with either ropivacaine 0.25% (group R, 30) or levobupivacaine 0.25% (group L, 30), total volume 1 milligram per kg bodyweight. Post operative Motor blockade (Motor power scale)and Analgesia (modified Hannallah Pain Scale) were assessed at predetermined time points during the first 24-postoperative hours.

Results: The groups were comparable for age, sex, weight, height, vital signs, duration and type of surgery. The duration of postoperative pain relief between the groups is not statistically significant ($p > 0.05$).The time for full motor recovery were similar in both ropivacaine and levobupivacaine group.

Conclusion: Our study concluded that both ropivacaine and levobupivacaine are equally effective for Caudal block in children undergoing infra umbilical surgery.

KEYWORDS : Caudal analgesia, Infraumblical surgeries,Ropivacaine,Levobupivacaine

INTRODUCTION

Regional anesthesia techniques have become routine interventions in children and infants.[1] The most preferred pediatric regional anesthesia techniques are caudal and lumbar epidural blocks, and ilioinguinal, iliohypogastric and penile nerve blocks.[2]

Levobupivacaine has been successfully used in providing epidural anesthesia and analgesia for surgical procedures with relatively longer post op analgesia and reduced motor blockade. Equipotent doses of levobupivacaine and ropivacaine provide comparable post-operative pain relief and recovery of sensory and motor function.[13]We compared the effectiveness of levobupivacaine and ropivacaine in caudal block in peadiatric patients.

AIM AND OBJECTIVES

To compare the incidence of PostoperativeAnalgesia and motor blockade following use of similar concentrations (0.25 %) of ropivacaine and levobupivacaine for Caudal block in children undergoing infra umbilical surgery.

MATERIALS AND METHODS:

STUDY POPULATION :

After obtaining the ethical committee approval, 60 patients of either sex in the age range of 1 to 10 years posted for elective infra-umbilical surgical procedures were selected for this study as per the listed out inclusion and exclusion criteria.

INCLUSION CRITERIA

American Society of Anaesthesiologist (ASA) physical status I and II

Exclusion criteria

- Infection at site of injection
- Deformity of spine
- Respiratory or Cardiovascular disease
- Known history of bleeding diathesis
- ASA grade III or IV

I) Sample size:

Before the study, the number of subjects required in each group was determined using a power calculation (G power) with data obtained from a pilot study. The expected mean duration of analgesia for Ropivacaine and Levobupivacaine was 316± 14 min and 324± 21min respectively.'G power' calculation indicated that a total sample of 28 patients in each group would be required to have large effect (d=0.80) with 90% power using t-test with α =0.05 and β=0.2[21]. We therefore recruited 30 subjects in each group.

ii) Study design:

Prospective, Randomized, Double blinded Comparative Study.

Clearance from the Institutional Ethical Committee, and written Informed Consent from each parent obtained. After standard fasting times and premedication(Oral midazolam 0.4mg kg^{-1} given 40 min before the procedure) patient was shifted to operation theatre.Standard monitors like Pulse Oximeter(Spo_2), NIBP, ECG, HR were connected. After recording Baseline parameters, intravenous access secured with 22G cannula, the childrenweregiven Inj.Atropine 20 $mcgkg^{-1}$ i.v. Preoxygenated with 100% O2 and induced with Inj. ketamine 2mg kg^{-1} i.v.

Immediately following induction of anesthesia the patients were randomizedusing the sealed envelope technique (based on computer generated random numbers), to receive caudal block with either(Group R)ropivacaine 0.25% or (Group L)levo bupivacaine 0.25% of volume 1 milligram per kilogram bodyweight. The study drug was prepared in a separate room by a doctor who did not take any further part in the study. Thus, the anesthesiologist performing the block and taking care of the anesthetic was blinded to the drug administered as was the research assistant performing the postoperative assessments.

The patient was positioned in left lateral and under full aseptic precautions, a sterile 22-G needle was introduced in Caudal epidural space. After confirming the position of the needle with whoosh test, the allocated drug was given slowly over 60 seconds.Then the patient was turned to Supine position, anesthesia was maintained with sevoflurane (1-2%) in oxygen 5 L/min connected via Jackson rees circuit.

The block was considered successful if there were no hemodynamic changes to the skin incision. After completion of the surgical procedure, children were shifted to the post op ward for observation for 24 hours. Post-operatively, severity of pain was assessed every 1 hr for first 6 hrs, then 2ndhourly for following 18 hrs using modified Hannallah Objective Pain Scale. Patients with pain score is ≥ 4 were given paracetamol suppositories 20 mg kg^{-1} as rescue analgesia.The time of administration offirst rescue analgesic drug was noted. At the

same time points, motor blockade was assessed using Motor power scale.

Analysis

- The statistical analysis was carried out using statistical software SPSS 19.0.The Categorical variables were expressed as Frequency and percentage.The Quantity variables were expressed as mean and standard deviation. Descriptive statistics were used to evaluate baseline characteristics.The group comparison for the categorical variables was analyzed using Chi square test and for quantity variables were analyzed using Student independent 'T' Test.Post op Analgesia was compared using Kruskal-Wallis test.Motor blockade between the groups were compared by Mann-Whitney U test. Friedman test was used to see the difference in the Motor Power Scale over different time intervals in a particular group.
- The P<0.05 was considered as statistically significant.

Results: Physical Characteristics:

The patients were comparable in both groups regarding age, sex, weight and height.

Clinical Data

Intra Op Heart rate, Systolic blood pressure, Diastolic blood pressure and mean arterial pressure were recorded during procedure and analyzed.

Intra Op - Heart Rate

Basal heart rate was comparable between the groups. The mean basal heart rate varied from 122.68±6.52 per minute in Levobupivacaine 0.25% and 121.80±7.58 per minute in Ropivacaine 0.25%. With progression of time after administration of premedication, there was no significant change in Mean Heart Rate during the surgical procedure between Levobupivacaine 0.25% and Ropivacaine 0.25%.Basal Mean arterial pressure was comparable between the groups. The mean basal mean arterial pressure in Levobupivacaine 0.25% was 73.82±2.16 mmHg and in Ropivacaine 0.25% it was 73.96±2.44 mmHg. There was no significant change in Mean arterial pressure groups During the 24-h observation period Pain scores were almost identical for the two groups. During the earlier periods of observation i.e. 6 hour, 8 hour and 10 hours shows significant difference in both groups and later period in 16 hour and 22 hours shows a significant difference (p<0.05)in the pain score among two groups. Overall there was no significant difference among Levobupivacaine 0.25% and Ropivacaine 0.25% in the Mean Pain Score readings taken over the 24 hour. The mean time for duration of Post op analgesia was 332.47 and 313.56 min in levobupivacaine and ropivacaine groups, respectively and there was no significant difference among the groups (p>0.05). Motor Power Scale was comparable between the groups with median. Beginning of the observational Period median Motor power scale was identical in two groups (p>0.05). With progression of time the median Motor Power Scale observed in both groups were similar but it had statistically significant change (Levobupivacaine 0.25% chi square = 142, p = 0.000: Ropivacaine 0.25%; chi square = 274, p = 0.000). The mean time for full motor recovery were similar in both ropivacaine and levobupivacaine group. In group R (Ropivacaine : 182.50 $\pm$ 13.59 min) and in group L (Levobupivacaine : 183.48 $\pm$ 17.96 min) with p=0.162 (p > 0.05), but this difference is not statistically significant. (p> 0.05)

DISCUSSION

Caudal anesthesia plays a major role in providing good pain relief in below umbilical surgeries. Various studies showed that the effect of analgesia might vary between patients, which depend on the type of the surgery, patient's age, type and volume of the local anesthetic agent.

In a study by G Ivani and colleagues,they compared commercially available concentrationsof ropivacaine (0.25%), levo-bupivacaine(0.25%) and racemic bupivacaine (0.25%). They foundno major differences between the drugs with regard to the quality of postoperative analgesia but the use of ropivacaine was associated with significantly lessearly postoperative motor blockade compared with racemic bupivacaine. Although not significant, a similar trend for less motor blockade was also observed when ropivacaine was compared with levobupivacaine.[10]These results were similar to the results of our study.

Astuto and colleagues did not observe motor blockade after surgery using ropivacaine 0.25% or levobupivacaine 0.25%.[11] However, in a study by Locatelli and colleagues found more than half of their patients receiving levobupivacaine 0.25% and ropivacaine 0.25% presented with some degree of motor block at wake-up.[12]

Ivani and colleagues found a significant difference in residual motor block 1 hr after operation between 0.2% ropivacaine and bupivacaine 0.25%. No significant differences were noted between levobupivacaine 0.25% and bupivacaine 0.25% or between levobupivacaine 0.25% and 0.20% ropivacaine. One obvious explanation for this result is that the dose of ropivacaine administered was 20% less than the dose of levobupivacaine.[27]

Our results showed that, when using the same doses, ropivacaine and levobupivacaine produced almost the same residual motor blockade. Patients receiving levobupivacaine or ropivacaine had similar duration of motor blockade and post op analgesia

Two studies have compared the efficacy of levobupivacaine 0.25% with bupivacaine 0.25% or with ropivacaine 0.25% by the caudal route in children. In a randomized double-blind controlled study, caudal injection of levobupivacaine 0.25%, 1mg kg^{-1} was compared with ropivacaine 0.2% and bupivacaine 0.25%. Levobupivacaine, ropivacaine and bupivacaine presented comparable onset time and analgesia during and after surgery.[10] When compared with caudal ropivacaine 0.25%, caudal levobupivacaine 0.25% provided similar anaesthetic and analgesic block.[11]Our results showed that, when using the same doses, ropivacaine and levobupivacaine produced almost the same residual motor blockade. Patients receiving levobupivacaine or ropivacaine had similar duration of motor blockade and post op analgesia.

Praveen P et al have concluded that levobupivacaine 0.25% and ropivacaine 0.25% have similar recovery from imotor blockade and postoperative analgesia, which is comparable with our study.

The evidence regarding residual motor block is less clear. Astuto and colleagues did not observe motor blockade after surgery using ropivacaine 0.25% or levobupivacaine 0.25%.[10]However, Locatelli and colleagues found more than half of their patients receiving levobupivacaine 0.25% and ropivacaine 0.25% presented with some degree of motor block at wake-up.[11]Our results showed that, when using the same doses, ropivacaine and levobupivacaine produced almost the same duration of residual motor blockade.

CONCLUSION

Our study concluded that both ropivacaine and levobupivacaine are equally effective for Caudal block in children undergoing infra umbilical surgery.

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Conflict Of Interest: nil

TABLES

TABLE 1: Mean Arterial Pressure

	Levobupivacaine 0.25%		Ropivacaine 0.25%		P value
	N	Mean +SD	N	Mean +SD	
MAP Base	30	73.69 + 2.11	30	73.95 + 2.46	0.783
0 min	30	72.88 + 2.12	30	72.67 + 2.17	0.837
3 min	30	71.96 + 2.14	30	72.05+ 1.91	0.486
5 min	30	71.06 + 1.41	30	70.96 + 1.83	0.463
10 min	30	70.55 + 1.12	30	70.78 + 1.28	0.331
15 min	30	70.93 + 0.95	30	71.09 + 1.08	0.542
20 min	28	71.84 + 1.30	28	72.26 + 1.44	0.282
25 min	22	71.86 + 1.35	19	72.05 + 1.72	0.548
30 min	19	72.56 + 1.31	16	71.84 + 1.49	0.024
35 min	12	72.66 + 1.12	11	72.85 + 1.70	0.868
40 min	3	73.88 + 1.89	4	74.16 + 0.78	0.726
45 min	3	73.90 + 2.92	3	74.89 + 0.98	0.626
50 min	1	74.00	1	73.20	1.000

Table 2:Pain Scores

Time (Hrs)	Levobupivacaine 0.25%	Ropivacaine 0.25%	P value
1	.00	.00	0.196
2	.00	.00	0.296
3	0.37 + 0.46	0.43 + 0.52	0.423
4	0.78 + 0.38	1.12 + 0.61	0.008
5	1.80 + 0.41	1.77 + 0.43	0.759
6	1.88 + 0.20	2.24 + 0.52	0.003
8	2.84 + 0.42	3.12 + 0.36	0.022
10	3.00 + 0.28	3.52 + 0.57	0.000
12	3.35 + 0.52	3.30 + 0.70	0.097
14	3.18 + 0.64	3.22 + 0.35	0.124
16	3.11 + 0.39	3.52 + 0.48	0.000
18	3.34 + 0.54	3.30 + 0.44	0.814
20	3.38 + 0.61	3.23 + 0.39	0.046
22	3.56 + 0.52	3.21 + 0.43	0.004
24	3.65 + 0.78	3.64 + 0.44	0.826

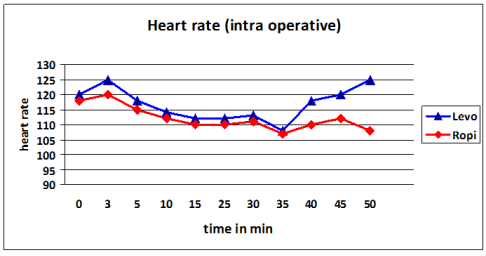

Figure1

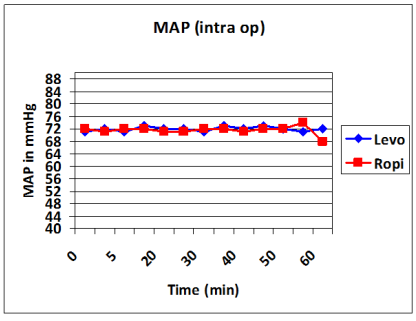

Figure.2

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