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Original Research Article

Comparative Study between the Efficacy of Single Dose Caudal Bupivacaine and Levobupivacaine for Post Operative Analgesia after Infraumbilical Surgeries in Children

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Abstract

Background: Among all postoperative pain management techniques in paediatric population caudal epidural block has emerged as a safe, effective and preferred technique for postoperative analgesia. Caudal block is easy to perform in children and is associated with fewer complications. In addition, newer agents having lesser cardiotoxicity and motor block have made it more safer.

Objectives: Our present study was conducted to compare the postoperative analgesic efficacy of two local anaesthetic agents- Bupivacaine and Levobupivacaine used in caudal route for infra-umbilical surgeries of less than 90 min duration in children.

After ethical committee clearance this study was carried out at VIMS, RKMSP, Kolkata.

60 children aged between 1 year to 5 years of ASA physical status I posted for infraumbilical surgeries were included in the study. Children were divided into two equal groups based on the local anaesthetic agent used. After inducing the patient caudal anaesthesia was administered. Group B received Bupivacaine 0.25% 1ml/kg and group L received Levobupivacaine 0.25% 1ml/kg via caudal route. Postoperative pain assessment was done using children and infants postoperative pain scale (CHIPPS). Duration of postoperative analgesia was recorded by noting the time of first rescue analgesic. Residual motor blockade was recorded in terms of modified Bromage scale. Changes in hemodynamic parameters like systolic blood pressure (SBP), mean arterial pressure (MAP), heart rate (HR), and SpO_2 were monitored intraoperatively. Any adverse effect in each of the groups was also taken into account.

Observed data were analyzed with the help of Statistical Package for Social Sciences software (SPSS version 20).

Results: According to demographic characteristics two groups was comparable (median age group B=37.17±12.4 vs group L=36.90±14.14, p=0.938, male 25/30 in group B vs 24/30 in group L, female 5/30 in group B vs 6/30 in group L, p=0.739, mean body weight of group B=14.63±2.01 kg and group L=14.27±2.78 kg, p=0.560).

The 2 groups were comparable in pre-operative, intraoperative and post operative haemodynamic parameters i.e. HR, SBP and MAP, the difference being statistically insignificant i.e. $p > 0.05$.

CHIPPS scores was significantly lower at 60 min (p=0.024), 120 min (p<0.001), 180 min (p<0.001) and 240 min (p=0.002) in groupB than group L. There was increase in the mean CHIPPS scores with time starting from the first measurement within the groups.
Duration of postoperative analgesia was significantly higher in group B (334±22.34 min for group B vs 284.7±16.11minutes for group L, p<0.001).
Residual motor blockade recorded in terms of Bromage score was observed to be significantly higher at wake up (p=0.001), 30min (p=0.005) and 60min (p<0.001) in group B than group L.
No group showed significant number of side effects.
Conclusion: From our study it can be concluded that in children caudal administration with bupivacaine provide prolonged postoperative analgesia and motor blockade than levobupivacaine and none causes any hemodynamic instability or side effects. Further large RCTs are needed to establish these present findings.
Keywords: Caudal Block, Bupivacaine, Levobupivacaine.

Introduction

The International Association for study of Pain (IASP) defines pain as "an unpleasant sensory & emotional experience associated with actual or potential tissue damage or described in term of such damage". Surgical trauma generates increased amount of catecholamines and catabolic hormones are liberated in the body along with decreased secretion of anabolic hormones. As a result, tachycardia, raised blood pressure, increased cardiac workload leads to increased myocardial oxygen consumption, and other systemic consequences [1]. Thus pain, if poorly managed in perioperative period can lead to adverse physiological effects contributing to significant morbidity and mortality resulting in increase in the incidence of chronic postoperative pain syndrome. Because aggressive treatment of acute post-operative pain is beneficial, pain has been declared as the 'fifth vital sign [2].

Previously there were common misconceptions that neonates and infants are physiologically unable to perceive pain. On the other hand, all children are at excessive risk of respiratory depression after the administration of opioids, therefore less usage of opioids were warranted and children gets exposed to pain or painful procedures. But researchers of the past three decades have established that the intensity of pain perception in children is no less than adults [3]. Pain is treated less aggressively in paediatric population due to difficulty in proper identification & assessment of pain, as one has to depend completely on their parents or caregivers for their wellbeing. There is difficulty in differentiating crying or restlessness due to pain or hunger or fear [3,4]. Round the clock analgesics increase likelihood of excessive sedation and respiratory depression leading to desaturation [5]. Hence, they are prone to get significantly less medication regardless the intensity of pain. Lack of routine assessment of pain also interferes with effective acute pain management [5].

Utilisation of post-operative pain relief in paediatric population has improved dramatically over recent years. Acute post-operative pain in paediatric patients can be managed by multimodal approach. Drugs include Paracetamol, Nonsteroidal anti-inflammatory drugs (NSAIDS), Opioids and neuraxial or regional local anaesthetics agents like Bupivacaine/Ropivacaine. Pre-emptive analgesia is defined as a treatment that is initiated before surgery in order to prevent the establishment of central sensitization evoked

by the incisional and inflammatory injuries occurring during surgery and in the early postoperative period [6].

Caudal epidural can be used for infraumbilical surgery in children which provides pain control both in intra and postoperative period. Caudal block is a simple and safe techniques in paediatric surgery with high success rate [7]. Caudal block along with general anaesthesia usually decrease the requirment of inhaled and intravenous anaesthetic agents, decrease the stress response of surgery with rapid and smooth recovery and also low incidence of postoperative vomiting along with good postoperative analgesia [8]. Caudal block provides sensory analgesia, motor block and sympathetic block depending on the dose of local anaesthetics. Complications rate is about 1 case per 1000 procedures, and usually minor [9].

Bupivacaine is an amino amide group of local anaesthetic. Bupivacaine is a racemic mixture of R (-) and S (-) enantiomers, of which R (-) enantiomer is linked with the cardiotoxicity [10]. This led to the quest for search of longer acting drugs with a wide margin of safety. Hence the S (-) enantiomers were isolated, of which Levobupivacaine has been recently introduced in the Indian market. Pharmacological studies demonstrated less degree of depressant effects on myocardium. Reports of toxicity with levobupivacaine are less and occasional toxic symptoms are usually reversible with minimal treatment. In practice of anaesthesia and analgesia, levobupivacaine and bupivacaine produce comparable surgical sensory block with similar adverse side effects [11]. This present study was intended to compare the effect of equal doses of caudal levobupivacaine and bupivacaine in terms of obtaining prolonged post-operative analgesia with less residual motor block in paediatric patients undergoing infra umbilical surgeries.

Aim

To compare the quality of postoperative analgesia with caudal bupivacaine versus levobupivacaine in paediatric patients undergoing infraumbilical surgeries.

Objectives

1. To study and compare duration of postoperative analgesia after single dose of caudal racemic bupivacaine and levobupivacaine by noting down the time of first dose of rescue analgesia.
2. To note the duration of motor block in both the groups.
3. To study and compare changes of hemodynamic parameters.
4. To note any adverse effect of the drugs used in both the groups.

Material and Methods

The study was conducted at Vivekananda Institute of Medical Sciences & Ramakrishna Mission Seva Pratishthan. After taking clearance from institutional ethical committee & scientific committee, sixty children of either sex, aged between 1year to 5 years of (ASA) I status, posted for infraumbilical surgeries were included in the study. After taking consent from the parents of the children they were divided into two equal groups for the study.

1. Group (B) received Bupivacaine 0.25% 1ml/kg
2. Group (L) received Levobupivacaine 0.25% 1ml/kg

At the beginning we induced the patients with conventional method and after securing airway caudal anaesthesia was administered with either of the study drugs.

Changes in hemodynamic parameters like systolic blood pressure (SBP), mean arterial pressure (MAP), heart rate (HR), and SpO_2 were monitored intraoperatively. Postoperative pain assessment was done using children and infants postoperative pain scale (CHIPPS). Time of first dose of rescue analgesic was recorded & duration of postoperative analgesia noted. Duration of motor blockade in terms of modified Bromage scale was also noted.

Study area

Vivekananda Institute of Medical Sciences, Kolkata, West Bengal

Study population

Paediatric patients of age group 1 to 5 years of either sex, ASA physical status I scheduled for elective infraumbilical surgeries including inguinal herniotomy, Lap/Open orchidopexy, urethroplasty, other orthopaedic surgeries in lower limbs with expected duration of less than 90 minutes will be included in this study.

Study design

A prospective, double blind, randomized comparative study. The study was prospective as all the parameters were noted after the administration of study drugs. Also, the study was perfectly blinded as neither the patients nor the observers who performed the procedure and assessed the study parameters were aware about the drug given to the patients.

Methods of randomization

Randomization was done by using a computer generated random number table. All patients were randomly allocated in two groups (Group B and L) with 30 patients in each group.

Group B (n=30): Received 0.25% Bupivacaine 1ml/kg body weight.

Group L (n=30): Received 0.25% Levobupivacaine 1ml/kg body weight.

Sample size

Sample size have been calculated using the formula $n > 2(Z_\alpha + Z_{1-\beta})^2 \times p*q/d^2$, where $p = (p_1 + p_2)/2$, $q = 1-p$, and d is p_1-p_2 Now assuming p value <0.05 to be significant and considering effect to be two sided, we get $Z_\alpha = 1.96$; assuming power of study to be 80% we get $Z_{1-\beta} = 0.84$. taking p_1 and p_2 as the percentage of expected incidence of no residual motor block in the 2 groups as 48% and 12% respectively, using the above formula we get n = 21 in each group. However, depending upon the available patients finally we have taken 30 patients in each group.

Study period

1.5 years from June 2016 to December 2017.

Inclusion criteria:

1. Paediatric patients of ASA I.
2. Paediatric patients aged between 1yr to 5yrs of either sex.
3. Patients scheduled for elective infra umbilical surgeries. the procedures include inguinal hernia repair, orchidopexy, hypospadias correction, urethroplasty, any orthopaedic surgeries in lower limbs with an anticipated duration of less than 90 minutes.

Exclusion criteria:

1. Children of parents who are not willing to give consent for participation of their child in the study
2. Children with known allergy to amide local anesthetics, cardiac disorder and Blood Clotting Disorders.

Methodology

Preparation of Patients

Preoperative checkup done and Procedure explained. All patients were given syr. Midazolam 0.25mg/kg body weight, 30 minutes prior to the expected time of surgery. Baseline hemodynamic parameters were noted at this time. At OT ASA standard monitoring tools attached. General anesthesia was induced as par protocol.Caudal block was then performed under strict aseptic condition by experienced in paediatric anaesthesia.

Patient kept in left lateral position. After proper asepsis approximate position of sacral hiatus was identified. With 22G or 23G hypodermic needle the puncture was done between two sacral cornu. The needle is oriented 45° to the sacrum. With the advancing needle decrease in resistance was appreciated. The needle is advanced until bone (i.e., the dorsal aspect of the ventral plate of the sacrum) is contacted and then is slightly withdrawn,

and needle is redirected so that the angle of insertion relative to the skin surface is decreased. During redirection of the needle, loss of resistance confirms entry into the epidural space. The needle is left open for 10-20 seconds to detect blood or CSF in case of any accidental venous or dural puncture.

A syringe with the total dose of study drug was then attached to the hub of the needle. Then after proper negative aspiration the study drugs was injected in small increments. If any swelling of the overlying skin was noted, or if there was resistant to injection, then the needle was withdrawn and reinserted. The puncture point was covered with antiseptic dressing. The end point was noted as 0 min. Monitoring of the vital signs was continued throughout the procedure at scheduled interval.

Patients were randomly allocated into two groups using computer generated random numbers. Group B received Inj. Bupivacaine 0.25% 1ml/kg and group L received Inj. Levobupivacaine 0.25% 1ml/kg. The performing anesthesiologist was unaware of the drug he/she administered.

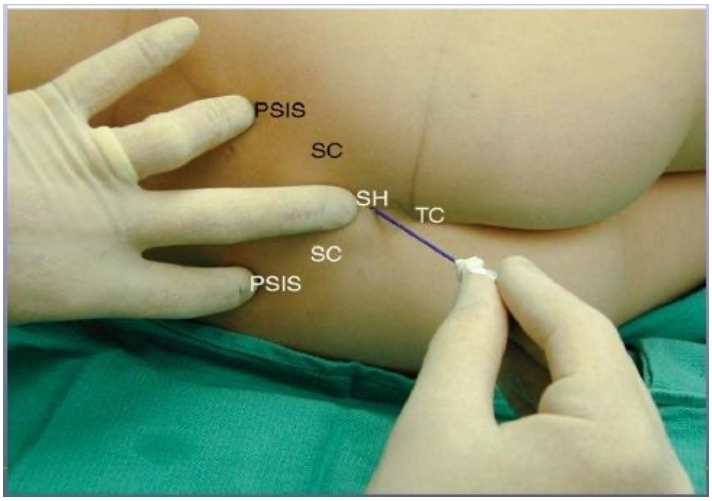

Figure 1
PSIS – Posterior Supirior Iliac Spine
SC – Sacral Cornu
SH – Sacral Hiatus
TC – tip of coccyx

Intraoperative management and data collection

- Anesthesia was maintained using O_2: N_2O=2:3 ratio and Sevoflurane of 0.2-1MAC using positive pressure ventilation.
- The hemodynamic data were continuously monitored during intraoperative period. Heart rate, SBP, MAP, SpO_2 were recorded 0min, 5min,10min, 15min, 20min, 30min, 45min, 60min and 90min after completion of the procedure.
- At the end of surgery child was reversed from general anesthesia and patient extubated.
- CHIPPS score, Bromage score, HR, SBP, MAP, SpO_2 were recorded at the time of wake up.

Postoperative management and data collection

- Patients monitored postoperatively in post anaesthesia care area with monitoring of HR, SBP, MAP, SpO_2, CHIPPS score and Bromage score before sending to ward.
- In the paediatric ward the degree of pain was assessed by CHIPPS scale hourly till score was ≥4 or first requirement of rescue analgesic.

- The motor blockade was assessed by Bromage scale till it is 0.
- HR, SBP, MAP, CHIPPS score and Bromage score were recorded 30min, 60min after wake up and then hourly.
- Inj. Paracetamol was administered intravenously as rescue analgesic at dose 15mg/kg body weight once pain score ≥4. Time of requirement of 1st rescue analgesic was noted.

Table 1: Children and Infants' Postoperative Pain Scale (CHIPPS)

Item	Score 0	Score 1	Score 2
Crying	None	Moaning	Screaming
Facial expression	Relaxed smiling	Wry mouth	Grimacing
Posture of the trunk	Neutral	Variable	Rear up
Posture of the legs	Neutral	Kicking	Tightened
Motor restlessness	None	Moderate	Restless

Total score indicates how the baby should be managed according to the scale

- 0 - 3 No requirement for treating pain,
- 4 - 10 Progressively greater need for analges

Table 2: Bromage scale (motor block scale)

Leg movements	Score
No motor block, able to stand unassisted or complete flexion of ankle, knee and thigh flexion in non-walking child or at wake-up evaluation	0
Unable to stand unassisted or partial knee flexion, with complete thigh flexion in non-walking child or at wake-up evaluation.	1
Unable to flex the knee but can flex the ankle	2
No movement or complete motor blockade in a fully awake child	3

Statistical Methods

The parents of the patients were unaware of which of the study drugs the patients received. Group of anaesthetists who administered the caudal block were unaware of the group of drug they were administering.

The same group of anaesthetists who were experienced in paediatric anaesthesia performed the preoperative checkup, conducted the anesthetic procedures and monitored the patients intraoperatively as well as postoperatively. They performed the observations, measurements and scoring to exclude any inter observer variability.

Categorical variables are expressed as Number of patients and percentage of patients and compared across the groups using Pearson's Chi Square test for Independence of Attributes/ Fisher's Exact Test as appropriate.

Continuous variables are expressed as Mean ± Standard Deviation and compared across the 2 groups using unpaired t test.

The statistical software SPSS version 20 has been used for the analysis.

An alpha level of 5% has been taken, i.e. if any p value is less than 0.05 it has been considered as significant. All the results were considered statistically significant at $P < 0.05$.

Results

Sixty children of age group 1-5 years of ASA I posted for infra umbilical surgeries were included in the study. The study was undertaken to evaluate the postoperative analgesic efficacy of single dose caudal bupivacaine in comparison with same amount of caudal levobupivacaine.

Group B (n=30) received caudal 0.25% bupivacaine 1ml/kg body weight and Group L (n=30) received caudal 0.25% levobupivacaine 1ml/kg body weight.

Table 1: Demographic Data

Parameters		Group L	Group B	P Value	Significance
Age (Month)		36.9 ± 14.14	37.17 ± 12.4	.938	Ns
Sex	M	6(20)	5(16.67)	.739	Ns
	F	24(80)	25(83.33)		
Weight (Kg)		14.27 ± 2.78	14.63 ± 2.01	.560	Ns

Table-1 shows:

A) Median age distribution between two groups was almost equal and statistically not significant.

B) Majority of the subjects are male in both the groups. The difference of gender distribution between two groups was not statistically significant.

C) The body weights of children in two groups were approximately equal. Difference between the mean body weights between two groups was not statistically significant.

Table 2: Distribution of different types of surgery in Group B and Group L.

		Group		Total		
		B	L		p Value	Significance
Surgery	Circumcision	5(16.67)	3(10)	8(13.33)	0.961	Not Significant
	Hernia	6(20)	8(26.67)	14(23.33)		
	Hydrocele	3(10)	2(6.67)	5(8.33)		
	Orchidopexy	7(23.33)	7(23.33)	14(23.33)		
	Ortho	5(16.67)	5(16.67)	10(16.67)		
	Urethroplasty	4(13.33)	5(16.67)	9(15)		

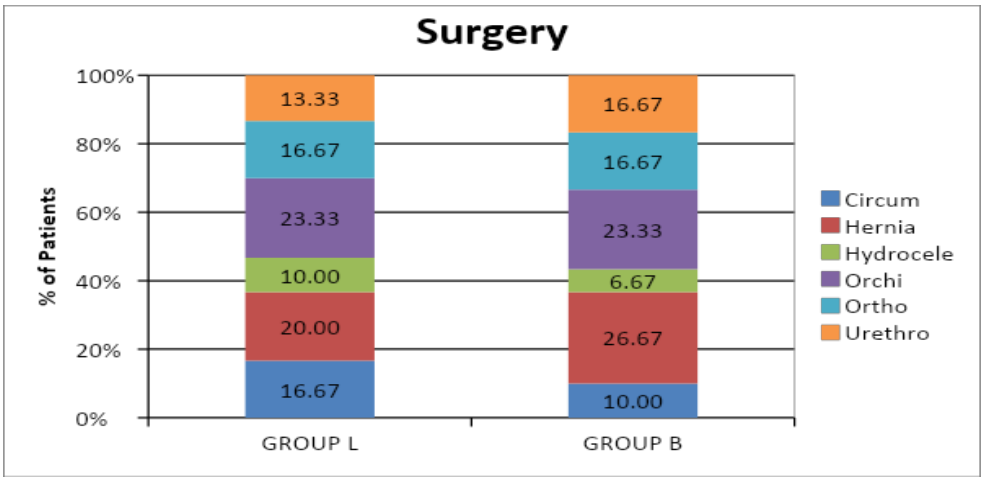

Figure 1: Types Of Surgeries Performed In Two Groups

Table 3: Difference between mean duration of surgery

	Group		p Value	Significance
	Group L	Group B		
	Mean ± Std. Deviation	Mean ± Std. Deviation		
Duration (min)	54.4 ± 18.91	54.73 ± 19.96	0.947	Not Significant

In each group the difference between mean duration of surgery is not statistically significant. Heamodynamic parameters such as perioperative heart rate, systolic blood pressure, diastolic blood pressure, mean blood pressure was comparable in both group and p-value is not statistically significant.

Table 4: Post Operative Pain Scoring

	Group			
	Group L	Group B		
	Mean ± Std. Deviation	Mean ± Std. Deviation	p Value	Significance
CHIPPS wake up	0.1 ± 0.31	0.07 ± 0.25	0.647	Not Significant
CHIPPS 30 min	0.93 ± 0.25	0.9 ± 0.31	0.647	Not Significant
CHIPPS 60 min	1.83 ± 0.38	1.57 ± 0.5	0.024	Significant
CHIPPS 120 min	2.6 ± 0.5	2.03 ± 0.56	<0.001	Significant
CHIPPS 180 min	2.87 ± 0.43	2.33 ± 0.48	<0.001	Significant
CHIPPS 240 min	3.6 ± 0.67	3.03 ± 0.67	0.002	Significant
CHIPPS 300 min	4.38 ± 0.51	4.09 ± 0.6	0.139	Not Significant
CHIPPS 360 min		5 ± 0	NA	NA

Table-4 Children & Infants Postoperative Pain Scale (CHIPPS) score in postoperative periods.

From the above chart it is noted that CHIPPS score after 60 TO 240 minitues following caudal anaesthesia were lower in Group B than Group L and this difference is statistically significant.

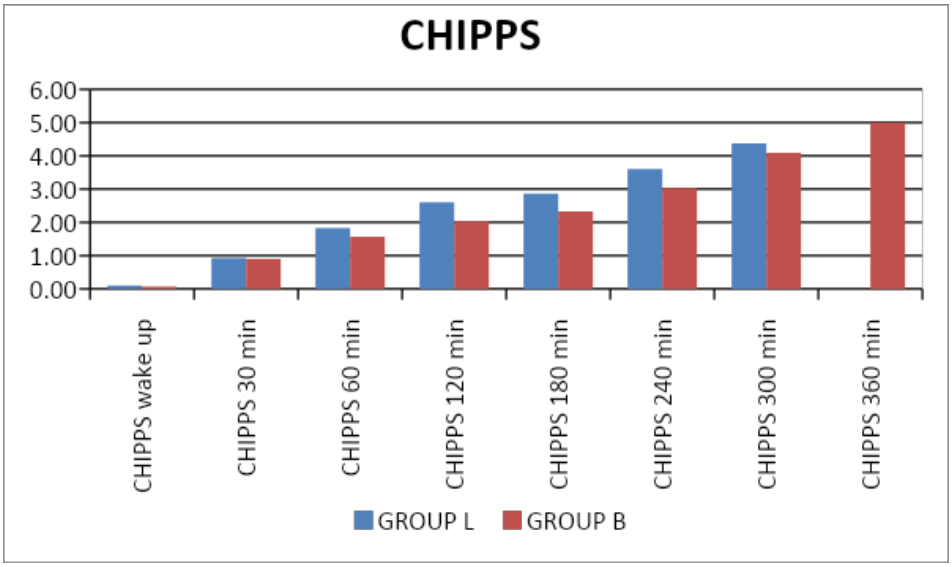

Figure 2: Mean Chipps Score In Two Groups

Table 5: Total Duration Of Analgesia

	Group		p Value	Significance
	Group L	Group B		
	Mean ± Std. Deviation	Mean ± Std. Deviation		
Duration of analgesia	284.7 ± 16.11	334 ± 22.34	<0.001	Significant

Total duration of analgesia was noted to be higher in Group B than Group L with difference being statistically significant

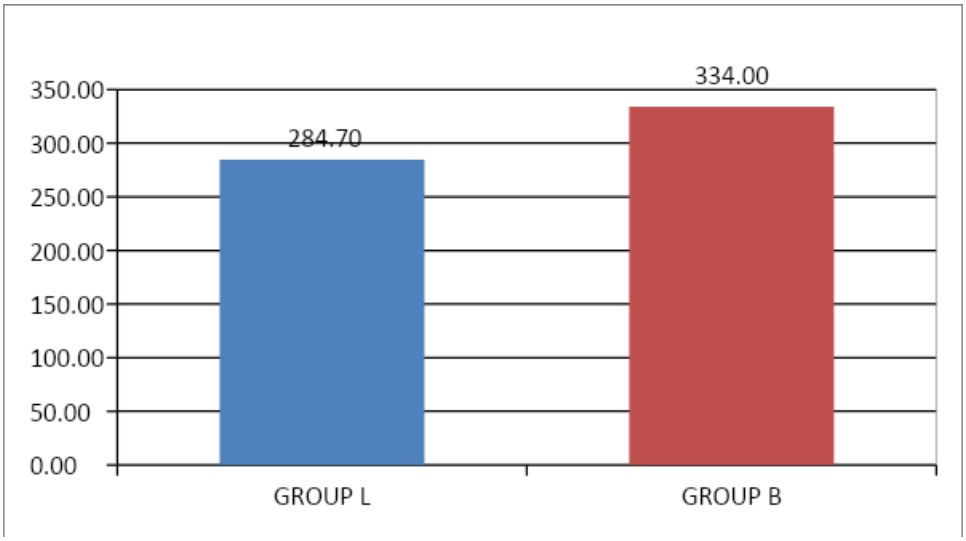

Figure 3: Comparison Of Duration Of Analgesia In Two Groups

Table 6: Distribution of postoperative Bromage Score at fixed time intervals

	Group		p-Value	Significance
	Group L	Group B		
	Mean ± Std. Deviation	Mean ± Std. Deviation		
BROMAGE wake up	2.53 ± 0.68	2.97 ± 0.18	0.001	Significant
BROMAGE 30 min	2.4 ± 0.67	2.83 ± 0.46	0.005	Significant
BROMAGE 60 min	1.47 ± 0.68	2.17 ± 0.59	<0.001	Significant
BROMAGE 120 min	0.3 ± 0.6	0.33 ± 0.61	0.831	Not Significant
BROMAGE 180 min	0.13 ± 0.35	0.2 ± 0.48	0.542	Not Significant
BROMAGE 240 min		0.07 ± 0.25	0.155	Not Significant
BROMAGE 300 min			NA	NA
BROMAGE 360 min			NA	NA

Postop Bromage Score was noted to be higher in Group B than Group L with difference being statistically significant at wake up, 30min and 60min.

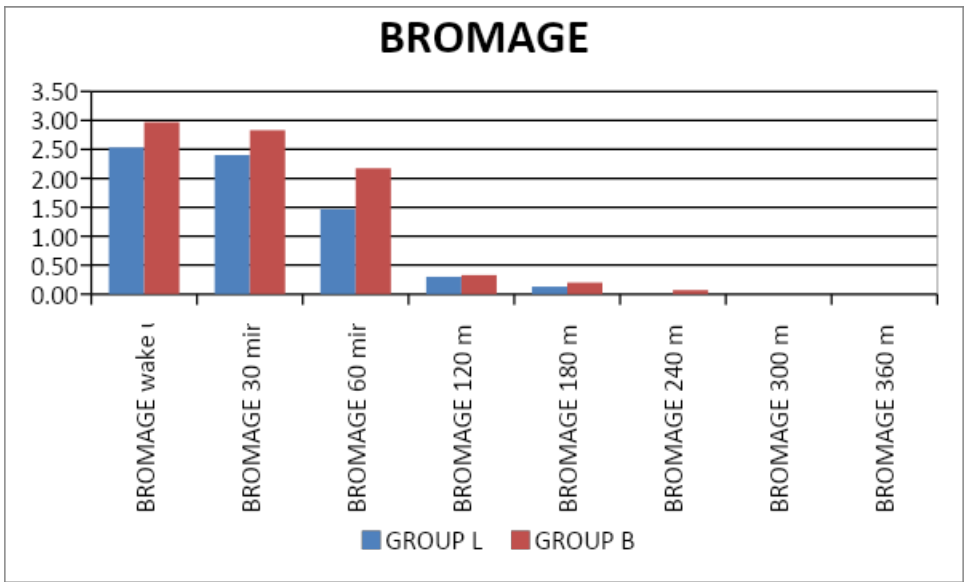

Figure 4: Postop Bromage Score In Two Groups

Table 7: Complications observed in two groups.

		Group		Total	p-Value	Significance
		Group B	Group L			
Complications	Nausea vomiting	2(6.67)	2(6.67)	4(6.67)	1.000	Not Significant
	Retention of Urine	2(6.67)	2(6.67)	4(6.67)		
	None	26(86.67)	26(86.67)	52(86.67)		
Total		30(100)	30(100)	60(100)		

Very less number of children had nausea and vomiting, few had retention of urine. No other complications noted

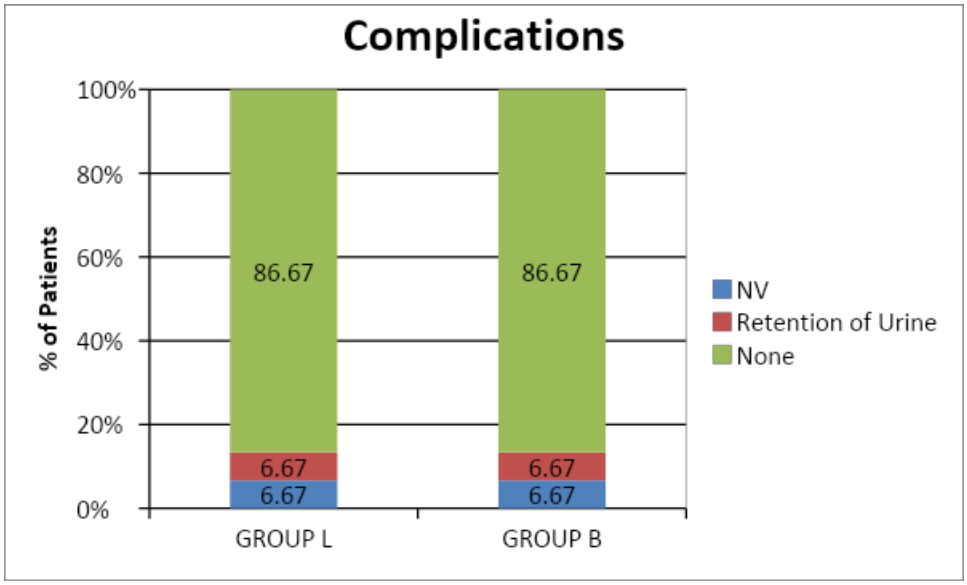

Figure 5: Different Side Effects Observed In Two Groups

Discussion

Pain is a unpleasant sensations experienced by human beings. Pain causes subjective distress and increases sympathetic tone and release endogenous catecholamines having several negative implications on the haemodynamic status and postoperative recovery. All the children have well developed pain pathways and they are also vulnerable to adverse side effects of pain.

We can use various medicines and regional anaesthesia techniques to control postoperative pain. Regional anaesthesia has changrd postoperative pain management in pediatric populations. Caudal epidural is one of the most commonly used techniques in paediatrics anaesthesia. Caudal anaesthesia is easy to administer, safe and very well tolerated.This also reduces intraoperative anaesthetic agent consumption.

Newer generation local anaesthetic agents with less cardiotoxicity has also increased the use of regional anaesthesia technique in paediatric age group.Most commonly used local anaesthetic agent bupivacaine can cause cardiac and central nervous system toxicity. Drugs like levobupivacaine, Ropivacaine are now more frequently used due to lesser cardiotoxicity/motor blockade similar degree of analgesia with equipotent dose of bupivacaine.

The present study was designed to determine & compare the duration of analgesia and post-operative motor blockade with single dose caudal 0.25% Bupivacaine with 0.25% Levobupivacaine in infraumbilical surgeries in children. This randomized, prospective, double blind study was conducted between June 2016 to December 2017 at Vivekananda Institute of Medical Sciences (VIMS), Ramkrishna Mission Seva pratishthan (RKMSP)

Sixty children of both sex aged between 1-5 years of ASA physical status I were included in the study & divided into two equal groups. Group B (n=30) received inj. Bupivacaine (0.25%) 1ml/kg caudally and group L received inj. Levobupivacaine (0.25%), 1ml/kg caudally. Caudal block administered after induction of general anaesthesia with endotracheal intubation. Anaesthesia was maintained with O_2, NO_2 and sevoflurane.

Postoperative pain was assessed by CHIPPS scale and duration of analgesia was obtained by noting the time of first rescue analgesia. Postoperative motor blockade was assessed by Bromage score. Along with that various perioperative events are also noted and documented.

In our study the demographic data like age, weight was comparable in the groups and the difference were statistically insignificant (Table 1). Therefore, the influence of those parameters, if any, on the study were similar in both the groups. The sex distribution was almost similar in the two groups and the difference was not statistically significant (Table 1). So, the influence of sex, if any, on the study was similar.

The mean duration of surgery and distribution of patients according to surgery were almost similar in both groups without any statistical significance (Tables 3 and 2). Therefore, their influence on the study were also same in both the groups. Z. Kaya *et al* [12] observed in their study that there was no significant difference in terms of mean heart rates between the two groups ($p>0.05$). However, when the comparison was done within the groups, there was a significant decrease observed within the first 30 min ($p<0.05$). Also, no significant difference was observed between the two groups in terms of mean blood pressure ($p>0.05$). However, when the comparison was done within the groups, there was a significant increase in MBP (compared to the first measurement of MBP) at 45^{th} min, 60^{th} min and 90^{th} min within the bupivacaine group ($p<0.001$).

Uma Soujanya.S *et al* [13] observed in their study that there was no significant difference in terms of hemodynamic variables like heart rate, SpO_2 and mean arterial pressure among the groups. However, when the comparison was done within the groups, maximum fall in MBP and heart rate was noted at 30 min in all the 3 groups.

Our study, have similar findings to Z. Kaya *et al* [12] and Uma Soujanya.S *et al* [13] where we have found that the 2 groups were comparable in HR intra-operatively at fixed time intervals, the difference being statistically insignificant ($p>0.05$). However, in contrast to these studies, we have found that the 2 groups were comparable in HR intra-operatively at fixed time intervals, the difference being statistically insignificant i.e. $p>0.05$. In group B, the maximum decrease in HR was seen at 60 min (115.12 ± 14.56) and in group L it was noted at 60 min (112.5 ± 11.98) too (Table 4). The groups were also comparable in MAP and SBP at fixed time intervals, the difference being statistically insignificant. In group B, the maximum decrease in SBP and MAP were seen at 90 min (91 ± 1.41 and 73.5 ± 2.12 respectively). And in group L the maximum decrease in SBP was at 20 min (94.3 ± 6.16) and the maximum decrease in MAP was at 45 min (73.56 ± 7.58) (Table 5 and 6).

In our study, in the post-operative period, the 2 groups were comparable regarding changes in HR, SBP, MAP and SpO_2 at fixed time interval. The differences were statistically insignificant i.e. $p>0.05$ (Table 11, 12,13 and 14). In post-operative period maximum drop in HR in both the groups were observed at 30 min which was (115.33 ± 12.07) in case of group B and (120.1 ± 13.55) in case of group L (Table 11).

Z. Kaya *et al* [12] observed in their study that group B had a significantly lower mean CHIPPS scores at 15^{th} ($p=0.005$), 30^{th} ($p<0.01$) and 90^{th} ($p=0.018$) min than group L. There was a statistically significant decrease in the mean CHIPPS scores with time starting from the first measurement within groups ($p<0.001$).

B. Locatelli *et al* [14] noted in their study that there were no significant differences in the number of patients receiving rescue analgesia, as guided by CHIPPS scores. Rescue analgesia was administered to 7 patients in the bupivacaine group, 5 patients in the levobupivacaine group and to 5 patients in the ropivacaine group ($p=0.75$) which is statistically not significant.

C Breschan *et al* [15] observed that postoperative pain scoring evaluated with CHIPPS score showed no statistical difference between groups

Our study, has similar finding to Z. Kaya *et al* [12] where we observed that group B had a significantly lower mean CHIPPS scores than group L. However, in contrast to the study of Z. Kaya *et al*, group B had a significantly lower CHIPPS scores at 60 min ($p=0.024$), 120 min ($p<0.001$), 180 min ($p<0.001$) and 240 min ($p=0.002$) than group L. There was increase in the mean CHIPPS scores with time starting from the first measurement within the groups.

P. A. Jadhav *et al* [16] observed in their study that in the levobupivacaine group 9 out of 30 and in the bupivacaine group 21 out of 30 patients had a significant motor blockade at wake up and the difference was statistically significant ($p=0.004$). None of the patients in the levobupivacaine group exhibited motor blockade at 180min post caudal whereas 3 patients still had modified bromage of >1 ($p=0.236$).

Uma Soujanya.S *et al* [14] observed in their study that residual motor blockade was prolonged in bupivacaine than levobupivacaine and ropivacaine group.

Z Kaya *et al* [12] observed in their study that there was no significant difference in Bromage scores between two groups.

B. Locatelli *et al* [13] observed in their study that bupivacaine produced a significant

incidence of residual motor block at wake up compared to levobupivacaine or ropivacaine ($p<0.01$). They also observed that three hours after caudal injection of local anaesthetic, patient receiving levobupivacaine 0.25% had significantly less residual motor blockade than patients receiving bupivacaine 0.25% ($p=0.04$).

In our study, we observed that group B had a significantly higher mean Bromage scores at wake up ($p=0.001$), 30min ($p=0.005$) and 60min ($p<0.001$) postoperatively than group L. Decreasing trend in Bromage score with time starting from the first measurement is noted in both the groups. Similar findings were observed in the studies by P. A. Jadhav *et al* [16] Uma Soujanya.S *et al* [13] and B. Locatelli [14] Whereas Z Kaya *et al* [12] observed no significant difference in Bromage scores between the two groups.

Uma Soujanya.S *et al* [13] observed that duration of analgesia was higher in bupivacaine (302.17±47.23) group compared to levobupivacaine (273.5±48.53) and ropivacaine (255±41.89) groups ($p=0.001$). C Breschan *et al* [15] observed in their study that median postoperative analgesia was 5.75 h (SEMed: ± 0.65) in Group L, 5.7 h (SEMed: ± 0.8) in Group R and 5.35 h (SEMed: ± 1.3) in Group B the difference being statistically nonsignificant.

B. Locatelli *et al* [14] noted in their study that the mean time from caudal injection to the first administration of analgesic medication was 2.45h in the bupivacaine group, 1.7 h in the levobupivacaine group and 1.6h in the ropivacaine group ($p=0.03$). In our study duration of analgesia in group B is noted to be 334 ± 22.34 min which is significantly higher ($p<0.001$) than group L in which duration of analgesia is found to be 284.7 ± 16.11 min. These findings were similar to the findings of Uma Soujanya.S *et al* [13] and C Breschan *et al* [15].

Minor complications like nausea, vomiting and retention of urine are observed in few patients in both the groups which was not significant ($p=1.0$). Major complications like hypotension, bradycardia, respiratory depression were not observed in any of the patients. These findings were in accordance to the findings noted by P. A. Jadhav *et al* [16]. Uma Soujanya.S *et al* [13] B. Locatelli *et al* [14].

Summary

Among all postoperative pain management techniques in paediatric population, regional anaesthesia, in particular caudal epidural block has emerged as a safe, effective and preferred technique for postoperative analgesia. Caudal block is easy to perform in children and is associated with fewer complications. In addition, newer local anesthetic agents have lesser cardiotoxicity and motor block. With these backgrounds our present study was conducted to compare the postoperative analgesic efficacy of two local anaesthetic agents- bupivacaine and levobupivacaine used by caudal route in infra-umbilical surgeries of less than 90 min duration in children.

This study was carried out at VIMS, RKMSP, Kolkata after obtaining clearance from institutional ethical committee & scientific committee during the period of July 2016 to December 2017.

60 children aged between 1 year to 5 years of ASA physical status I posted for infraumbilical surgeries in this study were divided into two equal groups based on the type of local anaesthetic agent used. After administering general anaesthesia ,caudal block was administered with either of the study drugs. Group B received Bupivacaine 0.25% 1ml/kg and group L received Levobupivacaine 0.25% 1ml/kg via caudal route. Postoperative pain assessment was done using children and infants postoperative pain scale (CHIPPS). Duration of postoperative analgesia was recorded by noting the time of first rescue analgesic. Residual motor blockade was recorded in terms of modified Bromage scale. Changes in hemodynamic parameters like

systolic blood pressure (SBP), mean arterial pressure (MAP), heart rate (HR), and SpO_2 were monitored intraoperatively. Any adverse effect in each of the groups was also taken into account. Observed data were analyzed with the help of Statistical Package for Social Sciences software (SPSS version 20).

The two groups were comparable in terms of the demographic characteristics (median age group B=37.17±12.4 vs group L=36.90±14.14, p=0.938, male 25/30 in group B vs 24/30 in group L, female 5/30 in group B vs 6/30 in group L, p=0.739, mean body weight of group B=14.63±2.01 kg and group L=14.27±2.78 kg, p=0.560).

The 2 groups were comparable in pre-operative baseline haemodynamic parameters i.e. HR, SBP and MAP, the difference being statistically insignificant i.e. $p > 0.05$ and the study groups were also comparable in the intraoperative and postoperative period regarding the changes in HR, SBP and MAP, the differences being statistically insignificant i.e. $p > 0.05$.

CHIPPS scores was significantly lower at 60 min (p=0.024), 120 min (p<0.001), 180 min (p<0.001) and 240 min (p=0.002) in groupB than group L. There was increase in the mean CHIPPS scores with time starting from the first measurement within the groups. Duration of postoperative analgesia was significantly higher in group B (334±22.34 min for group B vs 284.7±16.11minutes for group L, p<0.001).

Residual motor blockade recorded in terms of Bromage score was observed to be significantly higher at wake up (p=0.001), 30min (p=0.005) and 60min (p<0.001) in group B than group L. No group showed significant number of side effects.

Conclusion

From our study it can be concluded that in children caudal administration of bupivacaine provide prolonged postoperative analgesia and motor blockade than levobupivacaine and none causes any hemodynamic instability or side effects. Further large RCTs are needed to establish these present findings.

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