A Comparative, Cross Sectional, Observational Study to Assess the Post Operative Analgesic Efficacy of Bupivacaine VS Levobupivacaine in Illioinguinal / Illiohypogastric Nerve Block for Paediatric Patients Undergoing Inguinal Surgeries

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ABSTRACT

Introduction: Bupivacaine is the most commonly used local anaesthetic pediatric regional blocks. Levobupivacaine, a pure S- enantiomer of bupivacaine, is a long acting local anaesthetic that has a safer pharmacological profile with less cardiac and neurotoxic adverse effects. The present study compared the quality, efficacy, duration of post operative analgesia and adverse effects with Levobupivacaine versus Bupivacaine when used in illioinguinal / illiohypogastric nerve block for pediatric patients undergoing inguinal surgeries.

Material and Methods: A comparative, cross sectional, analytical and observational study was done using a convenient sampling method, 60 paediatric ASA I and II patients undergoing elective inguinal surgeries were divided into 2 groups of 30 each. In L group, illioinguinal / illiohypogastric nerve block was given with 0.25% Levobupivacaine while in B group, 0.25% Bupivacaine was used. In both the groups the total volume of the drug was kept at 0.4ml/kg and the total dose of drug was not more than 2mg/kg.

Results: Patients in Levbupivacaine Group had clinically lower OPS scores and hence better analgesia throughout the observation period as well as significantly prolonged duration of analgesia than Bupivacaine group. The mean duration of analgesia with Bupivacaine was 230 ± 41.19 minutes while with Levobupivacaine it was 344 ± 62.9 minutes as assessed by Broadmans OPS score. All patients were haemodynamically stable during the postoperative period. There was no incidence of bradycardia, respiratory depression, convulsions, hypotension, nausea, vomiting and urinary retention in any patient from both the groups.

Conclusion: Both Levobupivacaine and Bupivacaine provide safe and effective analgesia when given in illioinguinal-illiohypogastric nerve block in pediatric patients for inguinal surgeries Levobupivacaine provides prolonged and better quality post operative analgesia as compared to bupivacaine. Illioinguinal and illiohypgastric nerve block is a simple, safe and easy to perform technique which is devoid of complications of central neuraxial blockade and ideal in day care settings.

Keywords: Illioinguinal-illiohypogastric nerve block, Levobupicaine, Bupivacaine, postoperative analgesia

INTRODUCTION

Regional anaesthesia is popular in paediatric patients as it decreases the intra operative requirement for general anaesthetics and opioids thereby reducing respiratory depression, stress hormone responses and improves postoperative analgesia with shortened recovery.[1-3] Surgical site specific regional techniques such as Illioinguinal/ Illiohypogastric nerve block specifically and peripherally target the location of surgery. These are advantageous as they are not associated with the undesirable side effects of central neuraxial blocks such as urinary retention, hypotension and muscle weakness.[4]

A recent study has shown that as many as 80% of postoperative patients suffer from some degree of untreated or under treated pain.[5] Under treatment of postoperative pain in children and newborns is known to trigger biochemical and physiologic stress response which causes impairments in pulmonary, cardiovascular, neuroendocrinal, gastrointestinal, immunological, metabolic functions and leads to long term psychological effects such as post traumatic stress disorder.[6] An effective pain therapy to block or modify myriad physiologic responses to stress is an essential component of modern pediatric anaesthesia.

Peadiatric regional anaesthesia is beneficial for providing perioperative analgesia. It decreases intra operative requirement of anaesthetics and opoid analgesics thereby reducing respiratory depression and achieving early recovery.[1-3] Techniques that specifically and peripherally target location of the surgery minimize the undesirable side effects of central neuraxial blocks such as urinary retention, hypotension and motor weakness in unaffected areas are increasingly popular.[4]

Majority of work load in a pediatric surgical unit of a public hospital is inguinal surgeries for hernia, hydrocele and orchidopexy surgeries. An ideal technique of post operative analgesia for these procedures should be simple to perform and without side effects such as sedation, respiratory depression, urinary retention or motor block.

Illioinguinal/ Illiohypogastric nerve block is widely used to provide perioperative analgesia in children undergoing inguinal region surgeries.[7,8] The quality and level of block is dependent on the dose, volume and concentration of local anaesthetic used. Bupivacaine is the most common local anaesthetic for illioinguinal/illiohypogastric nerve block in majority of pediatric patients.

Levobupivacaine a pure S- enantiomer of bupivacaine is a long acting local anaesthetic of safer pharmacological profile with less cardiac and neurotoxic adverse effects.[9] The decreased

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toxicity of levobupivacaine is attributed to its faster protein binding rate.

The present study was designed to compare the efficacy and duration of action of levobupivacaine in providing post operative analgesia and compare it with bupivacaine in pediatric patients when used for illioinguinal/illiohypogastric nerve block in inguinal surgeries.

MATERIAL AND METHODS

This randomized, prospective, observer blind study was carried out over a period from July 2014 to July 2015 after obtaining approval from hospital ethics committee and written, informed consent.

A total of 60 ASA class I and II paediatric patients between the age group of 1-7 years undergoing elective inguinal surgery were included in this prospective observational study after obtaining approval from hospital ethics committee. We excluded patients whose parents refused to give consent, patients with haemorrhagic disorder, neurological disorder, uncontrolled convulsions, infection at the injection site, deformity of Vertebral column, haemodynamic instability and hypersensitivity to local anaesthetics.

By convenience sampling method, these were divided into 2 groups of 30 patients each. Group L (levobupivacaine only) received Illioinguinal and illiohypogastric nerve block with 0.25% Levobupivacaine, a total volume of 0.4ml/kg (total dose not more than 2mg/kg). Group B (Bupivacaine only) received Illioinguinal and illiohypogastric nerve block with 0.25% Bupivacaine, a total volume of 0.4 ml/kg (total dose not more than 2mg/kg).

All patients were assessed the previous day, a detailed history and thorough systemic examination was carried out. Parents and patients were explained about the anaesthesia procedure and drugs, and all their queries were answered.

All the patients were investigated for Complete blood count, Chest X-ray, Urine routine and microscopic and bleeding plus clotting time. On the day of surgery, the Anesthesia trolley and difficult airway cart and crash cart was kept ready. In the immediate Preoperative period informed valid consent was confirmed. NBM status was as per the ASA guidelines.

Standard monitoring included pulse oxymeter, NIBP, Cardio scope, Capnometer and temperature. In our hospital children are given IV antibiotics preoperatively in the ward, thus children came to the operating theatre with an IV line in situ. A dextrose saline drip was started and IV fluids were administered as per Holiday Segar formula. Patients were preoygenated with 100% oxygen. All patients received a standard endotracheal anaesthesia with IV Glycopyrolate 0.004 mg/kg + Midazolam-0.03 mg/kg + Fentanyl – 2 mcg/kg iv followed by Thiopentone sodium- 5 mg/kg and Atracurium 0.5 mg/kg as muscle relaxant. Airway was secured using appropriate sized LMA or ETT. Anaesthesia was maintained with O2 + Air (50:50) with an Inhalation agent (Sevoflurane or Desflurane) and intermittent doses of Atracurium.

Illioinguinal nerve block was given after induction of anaesthesia under aspetic precautions using 22G hypodermic needle by anatomical landmark technique. Appropriate drug was injected as per the group the patient was assigned to. All drugs were diluted in 0.9% saline. IV Fentanyl 1mcg/kg was repeated hourly if surgery was prolonged. IV Paracetamol (10mg/kg) was given 20 minutes before end of surgery in all children. At the end of surgery, the inhalational agent was switched off and patient was allowed to awaken. Patient was reversed and extubated after confirming complete recovery.

Patients were monitored for 6 hrs or till fit to be discharged from recovery room to ward for the following parameters 1st one hour every 15 minutes and next 5 hours every ½ hour.

1. Haemodynamic parameters
2. Broadman's objective pain/discomfort scale(OPS)
3. Sedation score
4. The duration of analgesia

If two consecutive measurements at interval of 15 minutes yielded OPS score >8, the child was given iv Tramadol 1mg/kg as rescue analgesia repeated after ½ hour if necessary.

STATISTICAL ANALYSIS

The results were evaluated statistically using unpaired 't' test for intragroup comparison and chi square test for non parametric data and complications.

RESULTS

A total of sixty six patients were studied with thirty patients in each group. Both groups were comparable with regards to age, sex, weight and baseline haemodynamic parameters.

There were 22 male (73.33%) and 8 female (26.67%) patients in Group L and 25 male (83.33%) and 5 female (16.67%) patients in group B. The mean age (years) in group L and group B was 3.49 ± 1.63 and 3.82 ± 1.45 respectively. The mean body weight (Kg) of patients was 13.68± 3.84 Kg in group L and 15.20 ± 3.77 Kg in group II. The pre operative baseline heart rate in group L was 105.77± 10.51 beats per minute and in group B was 104 ± 9.70 beats per minute. The mean baseline systolic blood pressure (SBP) was 100.67± 7.98 mmHg in group L and 104.40 ± 6.02 mmHg in group B. The mean baseline diastolic blood pressure (DBP) was 60 ± 5.03 mmHg in group L and 60± 4.61 in group B.

Duration of Analgesia: Duration of analgesia in both the groups was assessed by Broadman OPS scoring. The mean duration of analgesia in group L was 344 ± 62.90 minutes and 230 ± 41.19 in group B. The mean duration of analgesia was statistically significantly prolonged in group L than in group B (p value 2.05E-8, Mann Whitney test) as shown in Figure-1, Table 1 which shows that levobupivacaine has longer duration of action as compared to bupivacaine.

Pain Scores: Pain assessment in the postoperative period was assessed by Broadman's Objective Pain Score (OPS). It gives a cumulative score of 5-15.

Objective Pain Score (OPS):			
Variable	**Score 1**	**Score 2**	**Score 3**
Crying	None	Consolable	Not consolable
Motor restlessness	None	Restless	Thrashing
Position of torso	Normal	Mildly uncomfortable	Restless
Posture of legs	Normal	Flexed	Holds injuiry site
Facial expressions	Asleep/ Calm	Hurts little bit	Grimacing

The mean OPS in various patients in the two groups at different times in the postoperative period (recovery room) are shown in Figure-2. The OPS observed between the two groups was statistically comparable for the first 45 minutes postoperatively. After 45 minutes the OPS in the bupivacine group was higher than the OPS noted in the levobupivacaine group and remained higher throughout the observation period. This difference was statistically significant. This indicates that levobupivacaine provides better analgesia as compared to plain bupivacaine.

DISCUSSION

Effective pain control is essential for optimal care of paediatric surgical patients as post operative pain is very distressing to a child as well as parents. Children need special consideration while planning postoperative analgesia, due to their physical and psychological immaturity.

Majority of work in pediatric surgical unit in a public hospital is inguinal surgeries for hernia, hydrocele and orchidopexy. Various modalities of providing pain relief are available for these surgeries. An ideal technique of post operative analgesia should be simple to perform, and without side effects such as sedation, respiratory depression, urinary retention or motor block.

Regional analgesic techniques are devoid of side effects associated with systemic analgesics or opioids and allow for early feeding, mobilization, early recovery and discharge from PACU. Caudal epidural block is frequently used for analgesia after lower abdominal surgeries in children, however it may be associated with motor block, urinary retention and rarely cauda equina syndrome. There are also chances of dural puncture and intravascular injection.

Pheripheral nerve blocks target only the nerve innervating the surgical field; it requires less volume of local anaesthetic and has a very low or no chance of systemic toxicity. There is no chance of dural puncture or urinary retention. For inguinal surgeries in children, the ilioinguinal iliohypogastric nerve block has been found to be simple and safer alternative providing postoperative analgesia.[10-13]

Levobupivacaine, an isomer of bupivacaine is associated with prolonged sensory block and lesser motor blockade as compared to Bupivacaine. The toxicity by levobupivacaine occurs at much higher doses than bupivacaine and has been successfully resuscitated in maximum number of patients. Thus levobupivacaine has greater safety profile than bupivacaine. Many studies have proven the safety and efficacy of Levobupivacaine in peripheral nerve blocks for postoperative analgesia in paediatric patients.[12,14]

Considering all the above we chose to compare the post operative analgesic effects of Levobupivacaine versus bupivacaine when administered in illioinguinal/illiohypogastric nerve block in pediatric patients undergoing inguinal surgeries. This was a prospective observational study and was done after the approval from hospital ethics committee and after obtaining informed consent from the parents.

The volume and concentration of levobupivacaine was chosen after literature search. A study was done by Disma N, Tuo P, Pellegrino S, Astuto M on 3 concentrations of levobupivacaine for ilioinguinal / iliohypogastric nerve block in ambulatory

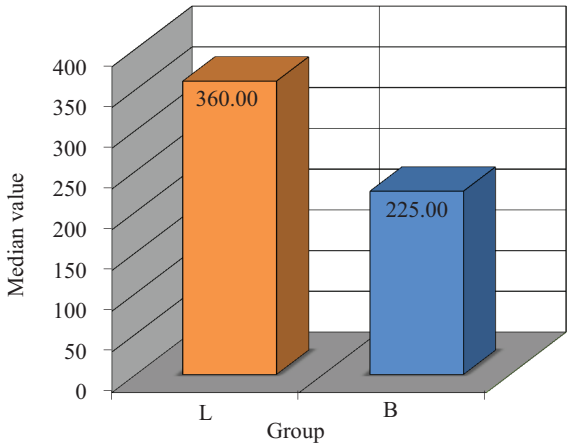

Figure-1: Duration of analgesia (min) in Group L and Group B

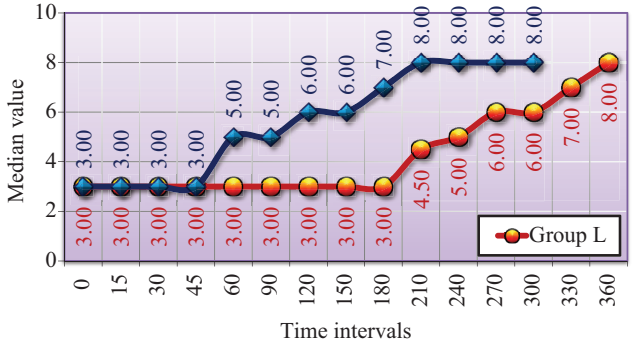

Figure-2: OPS at different intervals

pediatric surgery. They used 0.125%, 0.25%, 0.375% levobupivacaine in 60 pediatric patients in illioinguinal and illiohypogastric nerve block. They concluded that Illioinguinal and illiohypogastric nerve block using 0.4 mL $kg^{(-1)}$ of 0.25% levobupivacaine provided satisfactory postoperative pain relief after inguinal herniorraphy.[15]

60 ASA grade I and II children aged 1 to 7 years undergoing elective inguinal surgery were divided into 2 groups of 30 each and were given illioinguinal and illiohypogastric nerve block; Group L with 0.25% levobupivacaine (0.4ml/kg) and Group B with 0.25% bupivacaine (0.4ml/kg).

A standard anaesthesia protocol was maintained in all patients. Under anaesthesia, Illioinguinal and illiohypogastric nerve block was performed by a single puncture landmark based technique under all aseptic precautions. A qualified anaesthesiologist with at least 3 years experience performed all the blocks. All patients received IV paracetamol (10 mg/kg) 20 minutes before end of surgery. Patients were shifted to recovery room in the arms of mother. Thus monitoring started after the patient was calm and asleep.

Children from both groups Group L and Group B were comparable with respect to age, sex, height, weight, ASA class and surgical procedure to be performed. The male patients outnumbered the female patients in both groups. All patients belonged to ASA class I and herniotomy was the most common surgery performed in all patients.

We used Broadman's Objective Pain Score for assessing the effectiveness of post operative analgesia which was developed by Broadman and Hannallah and combines the psychological and behavioural parameters and has demonstrated both reliability

and validity in pain assessment. This was simplified for by Wilson and Doyle by replacing blood pressure measurement with observation of body language or posture. This scoring system is easy to use, validated, widely used in children and gives an objective evaluation of pain.

Most of the children were calm post extubation but some children from both the groups were agitated at the time of shifting from OT to recovery room which could have been due to emergence from sevoflurane, lifting the child from the operating table and shifting to recovery room, fear, cold temperature, hunger etc. Thus the actual monitoring for pain score started once the children were settled in recovery room in arms of mother.

The duration of analgesia in our study was taken from the time the child was settled in recovery room in arms of mother to the time of rescue analgesia i.e. 2 consecutive OPS pain score ≥ 8 at 15 minute interval. The average duration of analgesia in group B was 230 ± 41.19 minutes (Figure 1, Table 1) while average duration of analgesia in group L was 344 ± 62.9 minutes. This difference was statistically significant between two groups (p value of 2.05E-08). This shows that levobupivacaine provides prolonged duration of analgesia as compared to bupivacaine.

Various studies describe the average duration of analgesia produced by bupivacaine to be between 25 minutes to 244.9 minutes in regional nerve block.[16-18] Duration of analgesia as mentioned by E Tiereny and G Lewis is 160 ± 135 minutes in femoral nerve block, by Raafat S Hannallah etal is 219 ± 25.9 minutes for caudal bupivacaine and 184 ± 14.8 for illioinguinal and illiohypogastric nerve block, by Yifen ding and Paul F White was 126 ± 30 min in illioinguinal and illiohypogastric nerve block. This variability of duration in various studies may be due to the difference in duration of surgery performed, different choice of regional nerve block used, time for performance of block, bupivacaine dose, concentration and volume of bupivacaine, calculation of analgesia time and method of pain scoring. In our study, duration of analgesia for illioinguinal and illihypogastric nerve block with bupivacaine (0.25%) 0.4 ml/kg was 230 ± 41.19 minutes.

OPS Score at different intervals: The OPS score was 3 in all patients from both the groups at the beginning of the observation period. This was because of analgesia provided by the drugs used in the illioinguinal and illihypogastric nerve block, in the background of calm environment and proximity to mother or the

Group	N	Mean Duration of analgesia (OPS) (min)	Std. Deviation	t value	p value
Group L	30	344 ± 62.9	62.90	-5.608	2.05E-8
Group B	30	230.00	41.19	Difference is significant	

Table-1: Duration of Analgesia

OPS at- ^	Group	Mean	SD	Median	IQR	Z-value	
OPS-0 min	L	3.00	0.00	3.00	0.00	0.000	1.000
	B	3.00	0.00	3.00	0.00	Difference is not significant	
OPS-15 min	L	3.00	0.00	3.00	0.00	0.000	1.000
	B	3.00	0.00	3.00	0.00	Difference is not significant	
OPS-30 min	L	3.00	0.00	3.00	0.00	0.000	1.000
	B	3.00	0.00	3.00	0.00	Difference is not significant	
OPS-45 min	L	3.20	0.55	3.00	0.00	-2.534	0.011
	B	3.80	1.00	3.00	2.00	Difference is significant	
OPS-60 min	L	3.20	0.48	3.00	0.00	-6.202	5.57E-10
	B	4.73	0.64	5.00	0.00	Difference is significant	
OPS-90 min	L	3.40	0.86	3.00	0.00	-5.608	2.05E-08
	B	5.13	0.73	5.00	1.00	Difference is significant	
OPS-120 min	L	3.57	1.04	3.00	1.00	-5.692	1.25E-08
	B	5.70	0.79	6.00	1.00	Difference is significant	
OPS-150 min	L	3.83	1.32	3.00	2.00	-5.697	1.22E-08
	B	6.37	0.89	6.00	1.00	Difference is significant	
OPS-180 min	L	4.23	1.50	3.00	3.00	-5.581	2.39E-08
	B	6.89	0.99	7.00	0.00	Difference is significant	
OPS-210 min	L	4.47	1.57	4.50	3.00	-5.681	1.34E-08
	B	7.40	0.82	8.00	1.00	Difference is significant	
OPS-240 min	L	5.63	1.35	5.00	2.00	-4.309	1.64E-05
	B	7.60	0.63	8.00	1.00	Difference is significant	
OPS-270 min	L	6.00	1.07	6.00	2.00	-3.279	1.04E-03
	B	7.83	0.41	8.00	0.25	Difference is significant	
OPS-300 min	L	6.54	0.66	6.00	1.00	-2.768	5.64E-03
	B	8.00	0.00	8.00	0.00	Difference is significant	
OPS-330 min	L	7.32	0.48	7.00	1.00	Data missing in one group. Test not applicable	
	B						
OPS-360 min	L	8.00	0.00	8.00	0.00	Data missing in one group. Test not applicable	
	B						
# Ordinal data. Hence Mann-Whitney test applied.							

Table-2: Comparison of OPS at various time intervals between Group L and Group B cases

tender loving care by parents and staff. The OPS score remained at 3 till 45 minutes in both the groups (Figure 2, Table 2).

After 45 minutes, the mean OPS score started increasing in Group B with the average of 4.73 at 60 min, 5.13 at 90 min, 5.70 at 120 min, 6.37 at 150 min, 6.89 at 180 min, 7.40 at 210 min, 7.60 at 240 min, 7.83 at 270 min, 8 at 300 min. This increase in OPS score continued throughout the observation period from 45 min to 300 min due to waning effect of the analgesia by the drug. Thus most patients of group B received rescue analgesia in this time period in the recovery room itself. Thus the average duration of analgesia in group B was 230 ± 41.19 minutes.

The mean OPS score in group L remained at 3 for 160 min. At 180 min, average OPS score was 4.23, 4.47 at 210 min, 5.63 at 240 min, 6.00 at 270 min, 6.54 at 300 min, 7.32 at 330 min. This difference in the mean OPS between the Bupivacaine group and Levobupivacaine group was statically significant throughout the observation period after the first 45 minutes. This shows that Levobupivacaine provided more effective analgesia than Bupivacaine during the first 6 hours.

During shifting the patient to ward, OPS score increased to 8 in group L patients which can attributed to handling, shifting and resultant anxiety and wearing off of local anaesthetic effect. Thus most of the patients in group L received rescue analgesia at the time period when children getting shifted to the ward or some time later in the ward. The average duration of analgesia in group L patients was 344 ± 62.90 minutes.

It was also found that Levobupivacaine provides better and prolonged sensory blockade than bupivacaine as reflected in our study by the mean OPS scores between two groups.

Haemodynamic Parameters: Hemodynamic parameters were monitored in both groups for 360 minutes or till patient was shifted out of PACU. There was no statistically significant difference in the mean post operative heart rate or the mean baseline systolic and diastolic blood pressure between two groups throughout the observation period indicating that both bupivacaine and levobupivacaine have no effect on heart rate when used in ilioinguinal iliohypogastric nerve block.

We monitored for complications such as bradycardia, respiratory depression, convulsions, hypotension, nausea, vomiting and urinary retention. We did not have any incidence of these complications in any patient from either group.

CONCLUSION

Both Bupivacaine and Levobupivacaine provide effective analgesia without any adverse events when given in ilioinguinal iliohypogastic nerve block for pediatric inguinal surgeries. Levobupivacaine provides statistically longer and better analgesia as compared to Bupivacaine.

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