COMPARISON OF HYPERBARIC BUPIVACAINE IN CONVENTIONAL DOSE TO ISOBARIC LEVOBUPIVACAINE USED FOR INFRA UMBILICAL SURGERIES

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ABSTRACT

Background: For spinal anaesthesia, levobupivacaine is considered an effective alternative anesthetic agent to conventional bupivacaine owing to the faster recovery profile and lower probability of cardiovascular toxicity.

Aim: To comparatively assess the analgesic and hemodynamic features of conventional dose of hyperbaric bupivacaine to isobaric levobupivacaine used for infra umbilical surgeries.

Methods: Thepresent clinical study included 120 subjects from ASA I and ASA II categories presented for elective infra umbilical surgeries and were randomly divided into 2 groups of 60 subjects each. Group, I subjects was given 0.5% hyperbaric bupivacaine at the dose of 3ml, and Group II was given 0.5% isobaric levobupivacaine at the dose of 3ml. Hemodynamic parameters including SpO2, NIBP, and heart rates were assessed every 15 minutes till 2 hours postoperative. Side effects including nausea and vomiting, bradycardia, and hypotension were also evaluated.

Results: Sensory block onset was slower in the levobupivacaine group and sensory block levels were comparable. For levobupivacaine, analgesia duration was significantly lower. With levobupivacaine, shorter motor blockade duration and slower motor blockade onset were seen. Complete motor blockade was seen in all subjects. Concerning hemodynamic parameters, lesser incidence of bradycardia and hypotension and high cardiovascular stability

was observed. No incidence of PDPH, shivering, nausea, or vomiting was seen in any subject.

Conclusion: The present study concludes that significantly similar effects concerning analgesia duration are seen with Bupivacaine as with levobupivacaine. However, Bupivacaine showed better cardiovascular stability making Levobupivacaine use successful for lower abdominal surgeries.

Keywords: Abdominal surgeries, anaesthesia, Bupivacaine, cardiovascular stability,levobupivacaine

INTRODUCTION

In modern anaesthesia practice, regional anaesthesia plays a crucial role. In recent times, spinal anaesthesia has gained popularity owing to enhanced skills and advanced equipment use. Spinal anaesthesia has advantages in cases with difficult airways and is a safe and easy technique for effective anaesthesia.[1] Also, spinal anaesthesia provides good muscle relaxation and excellent analgesia. Spinal anaesthesia provides a good hold over stress and cardiovascular responses is cost-effective, has less hospital stay, and has good postoperative pain control.[2]

For lower abdominal pain of short duration and inguinal hernia surgeries, spinal anaesthesia has been a popular anaesthesia modality. Hyperbaric racemic bupivacaine is routinely used in spinal anaesthesiaowing to its property of combined sensory and motor blockade and its long duration of action.[3]However; some drawbacks are associated with hyperbaric racemic bupivacaine use for spinal anaesthesia. Bupivacaine has a high probability of causing bradycardia and hypotension after the intrathecal injection. Also, there is catastrophic cardiac toxicity with bupivacaine owing to its high affinity for cardiac myocytes.[4]

For lower limb or lower abdominal surgeries, the subarachnoid block is a gold standard as well as the choice of anaesthesia technique in comparison to epidural or general anaesthesia. It is attributed to the fact that there are associated chances of lack of reliability with the block with epidural anaesthesia and high associated chances of aspiration syndrome.[5] In the current times, 0.5% of the hyperbaric bupivacaine hydrochloride is used widely and extensively owing to its longer duration of blocks for both sensory and motor blockade. However, 0.5% of the hyperbaric bupivacaine hydrochloride has a high risk for central nervous and cardiac toxicity in cases where the inadvertent injection is given intravenously.[6]

Levobupivacaine is a local anesthetic agent coming under the amide type of local anesthetic which is an S-enantiomer of bupivacaine and shares a similar clinical profile as bupivacaine. It is also reported that decreased degree of toxicity is associated with a faster protein binding rate. Previous literature data have reported lesser central nervous and cardiovascular toxicity compared to bupivacaine. Equal clinical efficacy has been shown for levobupivacaine and bupivacaine when used in brachial plexus or epidural anaesthesia. However, the literature data available is scarce concerning the use of levobupivacaine in spinal anaesthesia.[7] Hence, the present clinical study was done tocomparatively assess the analgesic and hemodynamic features of conventional dose of hyperbaric bupivacaine to isobaric levobupivacaine used for infra umbilical surgeries.

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MATERIALS AND METHODS

The present prospective randomized clinical study in which study population was comprised of subjects from the Department of General Surgery of the Institute. The study included 120 subjects from both genders undergoing elective limb/ lower abdominal surgery using a subarachnoid block at the institute.

The inclusion criteria for the study were subjects in the age range of 18-50 years, having ASA grade I or II, having a height of more than 150 cm, undergoing elective surgeries, and being willing to participate in the study. The exclusion criteria were subjects with a history of severe headache and migraine, failure to achieve desired motor or sensory blockade, neurological deficit, undergoing emergency surgeries, increased intracranial pressure, coagulation abnormalities, bleeding disorders, infection at the site of needle insertion, and having spine deformities. After the detailed study design was explained to all the participants, informed consent was taken in both verbal and written format.

After the final inclusion of the study participants, detailed history was recorded for all the participants followed by a clinical examination. The pre-anaesthetic evaluation was done 1-day before the surgery. All the subjects were assessed for any existing systemic disease followed by laboratory investigations. A night before the surgery, subjects were advised to fast overnight and were given Alprazolam 0.5mg and Ranitidine 150 mg as premedications. One liter of Ringer's Lactate solution was infused intravenously as preload.

Included 120 subjects were randomly divided into 2 groups of 60 subjects each where Group I subjects were given 0.5% hyperbaric bupivacaine in the dose of 3ml intrathecally and Group II was given 0.5% isobaric levobupivacaine in the dose of 3ml intrathecally.

The subjects were then taken for surgery. All subjects were monitored for SpO2 (percentage oxygen saturation), NIBP (non-invasive blood pressure), and HR (heart rate) during the surgery. Spinal anaesthesia was given under strict aseptic and sterile conditions keeping the subject in a lateral position. 3ml of the anaesthetic agent was given in 30 seconds. The subject was then gently placed into a supine position and was assessed every 5 minutes till sensory blockade was spread maximally and then every 15 minutes for the whole surgery duration.

Subjects were taken as hypotensive when their mean arterial pressure dropped to <25% from the baseline and was given a 6ml intravenous Ephedrine injection based on the response. 0.02mg/kg intravenous atropine injection was given as a bolus in cases with a heart rate of fewer than 60 beats per minute. During the intraoperative period, duration of both motor and sensory block, onset and offset time for the motor blockade, onset time for maximum motor block, maximal motor block level, onset time for highest sensory block level, and the highest level of sensory block was assessed for all the subjects. The complications assessed were shivering, vomiting, and nausea along with the treatment provided. Analgesia quality was evaluated at the end of the surgery based on the description by the subjects as poor when the subject had Moderate to severe pain that required additional analgesics, as good when the subject had mild pain/discomfort, no need for additional analgesics, and excellent when the subject had no pain or discomfort.

All the subjects were assessed postoperatively for 2 hours and every 6^{th} hour to assess the pain intensity, pain quality, and pain duration. The subjects were followed for 3-4 days postoperative and were assessed for post-dural puncture headache (PDPH) development.

The data gathered were statistically analyzed using logistic regression and multivariate statistical techniques. The data were presented in tabulated and descriptive format. SPSS version 22.0, 2013, Armonk, NY: IBM Corp and chi-square and Man-Whitney U test. The data were expressed as mean and standard deviations and as percentages and numbers with a 5% significance level.

RESULTS

The present clinical study was done to comparatively assess the analgesic and hemodynamic features of conventional doses of hyperbaric bupivacaine to isobaric levobupivacaine used for infra umbilical surgeries. The study included 120 subjects who were randomly divided into 2 groups of 60 subjects each where Group I subjects were given 0.5% hyperbaric bupivacaine in a dose of 3ml intrathecally and Group II was given 0.5% isobaric levobupivacaine in a dose of 3ml intrathecally. The demographic data of the study subjects are listed in Table 1. The mean age of the study subjects in group I was 41.95±12.27 years and for the group, II was 41.95±11.13 years. The majority of the study subjects were in the age range of 31-0 years with 46.6% (n=28) and 36.6% (n=22) subjects from groups I and II respectively followed by <20 years age range with 30% (n=18) subjects from Group I and 20% (n=12) subjects from group II. There were 30% (18) females and 70% (n=42) males in both the study groups. The BMI for group I subjects was 20.03±1.96 kg/m2 and for the group, II was 20.43±2.47 kg/m2. The mean weight was 54.55±7.46 kg for Group I subjects was 54.55±7.46 kgs and55.25±8.83 kgs for Group II subjects. The mean height for Group I subjects was 164.55±5.24 cm and 164.01±5.24 cm for Group II subjects. These results show that baseline demographics were comparable for the two study groups.

Concerning the type of infra umbilical surgery done in the study participants, the most common procedure done was TURP (transurethral resection of the prostate) in 11.66% (n=14) study subjects followed by mesh repair in 8.33% (n=10) study subjects and ORIF (open reduction and internal fixation) with DHS (dynamic hip screw) and Trendelenburg procedure in 6.66% (n=8) subjects each. Excision, lithotripsy, lithotripsy with stenting, mesh repair, ORIF with IM (intramedullary) nail, and ORIF with plates and screws were done in 5% (n=6) subjects each. Below knee amputation, CRIF (closed reduction and internal fixation) with IM nail, Debridement with disarticulation, Meatoplasty, ORIF with bone grafts, ORIF with TBW (tension bends and wires), and SSG (split skin grafting)was done in 3.33% (n=4) study subjects each. Other surgeries done were ORIF with K wire and screws, high inguinal orchidectomy, lateral sphincterotomy, Jaboulays procedure, hemorrhoidectomy, and AMP (Austin Moore's Prosthesis) hemiarthroplasty were each done in 1.66% (n=2), study participants, as shown in Table 2.

On assessing the anaesthesia parameters with bupivacaine and levobupivacaine, it was seen that the mean onset time for the sensory block was significantly more with levobupivacaine at 168.88±7.63 minutes compared to 31.15±6.13 minutes with bupivacaine (Group I). This was statistically significant with $p<0.001$. The maximum level of sensory block was at T8 for all the 100% (n=60) subjects of both Group I and Group II. For no subject, the sensory block level was T10 or T6. The maximum duration of the sensory block was significantly higher for Group II with 190.35±9.35 minutes compared to Group I with 182.69±20.27 minutes with $p<0.05$. However, the duration of motor block was significantly higher with Group I

(bupivacaine), 218.52±19.15 minutes compared to 149.02±3.79 minutes for levobupivacaine with $p<0.05$ as depicted in Table 3.

For the complications in the two groups of study subjects, no complication was reported with Levobupivacaine study subjects, whereas 36.6% (n=22) subjects given bupivacaine (group I) reported complications. Among thesecomplications, bradycardia was seen in 23.3% (n=14) subjects, hypotension in 10% (n=6) subjects of Group II, and B/H (bradycardia/hypotension) in subjects of group II (Table 4).

DISCUSSION

The study assessed 120 subjects were randomly divided into 2 groups of 60 subjects each where Group I subjects were given 0.5% hyperbaric bupivacaine in a dose of 3ml intrathecally and Group II was given 0.5% isobaric levobupivacaine in a dose of 3ml intrathecally. The demographic data of the study subjects are listed in Table 1. The mean age of the study subjects in group I was 41.95±12.27 years and for the group, II was 41.95±11.13 years. The majority of the study subjects were in the age range of 31-0 years with 46.6% (n=28) and 36.6% (n=22) subjects from groups I and II respectively followed by <20 years age range with 30% (n=18) subjects from Group I and 20% (n=12) subjects from group II. There were 30% (18) females and 70% (n=42) males in both the study groups. The BMI for group I subjects was 20.03±1.96 kg/m2 and for the group, II was 20.43±2.47 kg/m2. The mean weight was 54.55±7.46 kg for Group I subjects was 54.55±7.46 kgs and 55.25±8.83 kgs for Group II subjects. The mean height for Group I subjects was 164.55±5.24 cm and 164.01±5.24 cm for Group II subjects. These results show that baseline demographics were comparable for the two study groups. These demographic characteristics were similar to HakanErbay R et al[8] in 2010 and Gozaydin[9] in 2014 where authors assessed subjects with similar demographics as of the present study.

Type of infra umbilical surgery done in the study participants, a most common procedure done was TURP (transurethral resection of the prostate) in 11.66% (n=14) study subjects followed by mesh repair in 8.33% (n=10) study subjects and ORIF (open reduction and internal fixation) with DHS (dynamic hip screw) and Trendelenburg procedure in 6.66% (n=8) subjects each. Excision, lithotripsy, lithotripsy with stenting, mesh repair, ORIF with IM (intramedullary) nail, and ORIF with plates and screws were done in 5% (n=6) subjects each. Below knee amputation, CRIF (closed reduction and internal fixation) with IM nail, Debridement with disarticulation, Meatoplasty, ORIF with bone grafts, ORIF with TBW (tension bends and wires), and SSG (split skin grafting) was done in 3.33% (n=4) study subjects each. Other surgeries done were ORIF with K wire and screws, high inguinal orchidectomy, lateral sphincterotomy, Jaboulays procedure, hemorrhoidectomy, and AMP (Austin Moore's Prosthesis) hemiarthroplasty were each done in 1.66% (n=2) study participants. These results were comparable to the studies of KokkiM et al[10] in 2016 and Sahin AS et al[11] in 2014 where authors reported TURP, mesh repair, and ORIF as the most common infraumbilical surgeries done in their studies.

Concerning the anaesthesia parameters with bupivacaine and levobupivacaine, it was seen that the mean onset time for the sensory block was significantly more with levobupivacaine at 168.88±7.63 minutes compared to 31.15±6.13 minutes with bupivacaine (Group I). This was statistically significant with $p<0.001$. The maximum level of sensory block was at T8 for all

the 100% (n=60) subjects of both Group I and Group II. For no subject, the sensory block level was T10 or T6. The maximum duration of the sensory block was significantly higher for Group II with 190.35±9.35 minutes compared to Group I with 182.69±20.27 minutes with $p<0.05$. However, the duration of motor block was significantly higher with Group I (bupivacaine), 218.52±19.15 minutes compared to 149.02±3.79 minutes for levobupivacaine with $p<0.05$. These findings were consistent with the studies of GulerG et al[12] in 2012 and Erdil F et al[13] in 2009 where authors reported similar anesthetic parameters as in the study subjects.

The complications in the two groups of study subjects showed that no complication was reported with Levobupivacaine in study subjects, whereas 36.6% (n=22) of subjects given bupivacaine (group I) reported complications. Among these complications, bradycardia was seen in 23.3% (n=14) subjects, hypotension in 10% (n=6) subjects of Group II, and B/H (bradycardia/hypotension) in subjects of group II. These complications were in agreement with the previous studies of Cuvas O et al[14] in 2009 and MantouvolauM et al[15] in 2008 where similar complications were seen with bupivacaine as an anesthetic agent.

CONCLUSION

Considering its limitations, the present study concludes thatsignificantly similar effects concerning analgesia duration are seen with Bupivacaine as with levobupivacaine. However, Bupivacaine showed better cardiovascular stability making Levobupivacaine use successful for lower abdominal surgeries. The limitations of this study were smaller considered population, cross-section design, and biased related to the geographic location warranting further long-term studies planned longitudinally.

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TABLES

Characteristics	**Group I (Bupivacaine)**		**Group II (Levobupivacaine)**	
	Percentage (%)	**Number (n=60)**	**Percentage (%)**	**Number (n=60)**
Mean age (years)	41.95±12.27		41.95±11.13	
Age range (years)				
<20	30	18	20	12
21-30	6.66	4	26.6	16
31-40	46.6	28	36.6	22
41-50	16.6	10	16.6	10
Gender				
Females	30	18	30	18
Males	70	42	70	42
BMI (kg/m2)	20.03±1.96		20.43±2.47	

Weight (kg)	54.55±7.46	55.25±8.83
Height (cm)	164.55±5.24	164.01±5.24

Table 1: Demographic data of the study participants

Type of Surgery	**%**	**n=120**
ORIF with K wire and screws		
High inguinal Orchidectomy	1.66	2
Lateral Sphincterotomy	1.66	2
Jaboulays procedure	1.66	2
Hemorrhoidectomy	1.66	2
AMP	1.66	2
Ureteroscopy with lithotripsy	3.33	4
SSG	3.33	4
ORIF with TBW	3.33	4
ORIF with plate and screws	5	6
ORIF with bone grafts	3.33	4
Meatoplasty	3.33	4
Debridement with disarticulation	3.33	4
CRIF with IM nailing	3.33	4
Below knee amputation	3.33	4
ORIF with IM nailing	5	6
Mesh repair	5	6
Lithotripsy with stenting	5	6
Lithotripsy	5	6
Excision	5	6
Trendelenburg procedure	6.66	8
ORIF with DHS	6.66	8
Mesh repair	8.33	10
TURP	11.66	14

Table 2: Type of infra umbilical surgeries done in study subjects

Anaesthesia Parameters	**Group I Bupivacaine**	**Group IILevobupivacaine**	**p-value**
Sensory block (onset time)	31.15±6.13	168.88±7.63	**<0.001**
Sensory block (maximum level) n (%)			
T10	0	0	
T8	60 (100)	60 (100)	
T6	0	0	
Maximumsensory block duration	182.69±20.27	190.35±9.35	**<0.05**
Motor block duration	218.52±19.15	149.02±3.79	**<0.05**

Table 3: Comparison of onset and duration of motor and sensory blocks in two groups of study subjects

Complications	Group I (Bupivacaine)	Group IILevobupivacaine	p-value
Complications reported			
No	38 (63.3)	60 (100)	<**0.001**
Yes	22 (36.6)	0	
B/H	3.33 (2)		
Hypotension	6 (10)	0	
Bradycardia	14 (23.3)	0	

Table 4: Complications reported in two groups of study subjects