

## A Comparative Clinical Evaluation of Isobaric Levobupivacaine versus Hyperbaric Bupivacaine for Spinal Anaesthesia in Lower Extremity Surgeries

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### Abstract

**Aims and Objective:** The present study compares the clinical efficacy of intrathecal 0.5% isobaric levobupivacaine with routinely used intrathecal 0.5% hyperbaric bupivacaine for spinal anaesthesia in lower extremity surgeries. **Material and Methods:** A prospective, randomized, double blind study at a Tertiary care hospital included one hundred ASA grades I & II patients of either sex in the age range of 20-60 years underwent lower extremity surgeries were divided into two groups. They received 0.5% isobaric levobupivacaine (group L) or 0.5% hyperbaric bupivacaine (group B), both intrathecally in a 3.25 ml total volume for spinal anaesthesia. Parameters observed were onset & duration of sensory and motor block, quality of surgical anaesthesia, hemodynamic parameters, perioperative complications of the patients. **Results:** Group L had comparable onset of sensory block as compared to group B, [p > 0.05]. The motor onset was significantly delayed in group L as compared to group B, [p < 0.05]. The duration of sensory block and motor block was significantly longer in group L as compared to group B, [p < 0.05]. The 0.5% isobaric levobupivacaine required significantly longer time to achieve T10 dermatome level and Modified Bromage Scale III as compared to 0.5% hyperbaric Bupivacaine, [p < 0.05]. The hemodynamic stability was better in group L as compared to group B. **Conclusion:** 0.5% isobaric levobupivacaine provides satisfactory anaesthesia, with better hemodynamic stability, longer duration of sensory and motor block and minimal perioperative complications comparable to routinely used 3.25 ml of 0.5% hyperbaric bupivacaine. Thus it can be used as a safer alternative to 3.25 ml of 0.5% hyperbaric bupivacaine in spinal anaesthesia for elective lower extremity surgeries requiring duration up to 3 hours. **Keywords:** Isobaric Levobupivacaine, hyperbaric Bupivacaine, efficacy, lower extremity surgeries, spinal anaesthesia.

### 1. Introduction

Spinal anaesthesia is widely used for lower limb, lower abdominal and lower

extremity surgeries providing a fast onset and effective sensory and motor blockade. It has been the mainstay for regional anaesthesia in

developing countries, especially in India. Various local anesthetics have been injected into the intrathecal space to achieve intrathecal blockade, starting with cocaine way back in 1898 [1]. Bupivacaine is available as racemic mixture of its enantiomers, dextrobupivacaine, and levobupivacaine. In the past few years, its pure S-enantiomers ropivacaine and levobupivacaine have been introduced into clinical practice [2-5], because of their lower toxic effects for cardiovascular and central nervous system. The clinical profile of spinal bupivacaine and levobupivacaine has been evaluated in volunteers and clinical studies and found to be effective in patients undergoing lower abdomen surgery, day care gynecology procedures, inguinal hernia repair, and lower limb procedures [6-17].

In our country, levobupivacaine is available in preservative free isobaric form (LevoAnawin™) in two concentrations (5 mg/ml = 0.5% and 2.5 mg/ml = 0.25%) packaged in 4 and 10 ml ampoules. Hyperbaric bupivacaine in 8% glucose is often used. Plain, or glucose-free, bupivacaine has been frequently referred to as “isobaric” in the literature, even after Blomqvist and Nilsson [18] demonstrated its hypobaricity. Hyperbaric solutions may cause sudden cardiac arrest after spinal anesthesia because of the extension of the sympathetic block [19, 20]. Hyperbaric solutions may cause hypotension or bradycardia after mobilization, isobaric solutions are favored with respect to their less sensitive to position issues properties [21].

In 1957, Ekenstam and his colleagues synthesized bupivacaine hydrochloride [22] which was clinically introduced in 1963 [23]. Bupivacaine rapidly gained popularity for

surgeries of longer duration. Although it has slow onset of action, it produces good muscle relaxation, prolonged sensory and motor blockade. Duration and quality of motor and sensory blockade is dose dependant [24]. But increasing the doses of this hyperbaric bupivacaine leads to increased cephalad spread of drug which accounts for more incidences of hypotension, bradycardia and in some cases, respiratory difficulty and cardio-respiratory arrest. Prolonged motor weakness associated with use of bupivacaine is also a limiting factor for its use especially when used for surgeries of short duration as it delays the ambulation. It is also associated with side effects including cardiovascular and central nervous system toxicity. In cases of inadvertent intravascular injection of bupivacaine, it was often fatal and responded poorly to conventional resuscitation methods [25].

Levobupivacaine is the relatively new amino amide local anaesthetic agent that was introduced in the market in 1999 [26]. It is a single S-isomer of bupivacaine with low toxicity profile with no change in anaesthetic and analgesic characteristics. It has reduced cardiovascular and central nervous system toxicity compared to racemic bupivacaine, and adverse events following accidental intravascular injection are easier to treat. Thus making it a less toxic substitute for bupivacaine [27].

Many studies were carried out comparing the bupivacaine and levobupivacaine. But due to the unavailability of hyperbaric formulation of levobupivacaine, the authors compared the two drugs either by changing baricity of bupivacaine or levobupivacaine. This could potentially reduce the safety of spinal injection. Moreover, the

final density of the anaesthetic solution may be less predictable than that of the commercially available specific hyperbaric formulations [28].

Opas Vanna *et al.*, in 2006 studied isobaric levobupivacaine versus hyperbaric bupivacaine (available market preparations) and showed that isobaric levobupivacaine has more sustained sensory and motor blockade than hyperbaric bupivacaine in transurethral endoscopic surgeries [29].

Neon Laboratories has recently introduced a preparation of 0.5% isobaric levobupivacaine (4 ml ampoule) for intrathecal use in the market. Though isobaric levobupivacaine is used for lower abdominal surgeries, after reviewing the literature, very less data is available comparing it with intrathecal hyperbaric bupivacaine that too very less in lower extremity surgeries. The plain levobupivacaine has been shown to be truly isobaric with respect to CSF of pregnant women. Because of its significantly decreased cardiovascular and central nervous system toxicity, levobupivacaine seems to be an attractive alternative to bupivacaine [30].

As isobaric levobupivacaine formulation is now made available in our hospital, this study was carried out to know clinical efficacy of isobaric levobupivacaine for spinal anaesthesia in lower extremity surgeries. The results were compared with routinely used standard technique with 0.5% hyperbaric bupivacaine.

## 2. Materials and Methods

The prospective, randomized double blind study included total 100 patients belonging to ASA grade I & II of either sex with the age, weight and height between 20-60 years, 45-75 kgs and 150-175 cms respectively. Before starting the study ethical approval was

obtained from the Hospital Ethical Committee. The present study was conducted in the department of anaesthesiology at tertiary care hospital during the period from Nov 2012 to Oct 2014. A detailed pre-anaesthetic evaluation including relevant laboratory investigations was done and a written informed consent was obtained from all the patients after explaining the procedure. All of the patients undergoing elective lower extremity surgery requiring sensory level up to T10 and duration up to 2 hours were selected for the study. Exclusion criteria included patient's refusal to participate in the study, patients with contraindications to spinal anaesthesia, patient having history of hypersensitivity to amide type local anaesthetics, ASA grade III and IV, Uncontrolled hypotension or hypertension of any cause, pregnant patient. 100 selected patients were divided into two equal groups of 50 patients each using the sealed envelope technique. Group B: In this group patients were given 0.5% hyperbaric bupivacaine 3.25 ml (16.25mg) intrathecally. Group L: In this group patients were given 0.5% isobaric levobupivacaine 3.25 ml (16.25mg) intrathecally. A detailed history and a thorough general and systemic examination and all relevant investigations were done for all the patients undergoing lower extremity surgery. Pre-operative explanation of the procedure was done to gain the confidence of the patients and written consent was taken. Patients were kept NBM for 6 hours prior to the procedure. Patients were evaluated for vital parameters like pulse rate, respiratory rate, oxygen saturation (SpO<sub>2</sub>), blood pressure and ECG changes in pre-operative room. Patients were preloaded with 10 ml/kg of Ringers lactate solution. All the patients were

given injection ranitidine 50 mg as premedication. Under all aseptic precautions, subarachnoid block was given with Quinke type 23 gauge spinal needles at L2-L3 or L3-L4. After obtaining continuous clear and free flow of cerebrospinal fluid, 3.25 ml of either bupivacaine or levobupivacaine was injected according to the group allotment, at the rate of 0.2 ml per second into the subarachnoid space. Sensory block assessment was done by observing onset, duration and level using pinprick test. Motor block was assessed at every 30 seconds from '0' hour as per the Modified Bromage Scale.

“MODIFIED BROMAGE SCALE” (MBS)

- Grade 0 : No motor blockade
- Grade I : Inability to raise extended legs but able to flex knee and ankle
- Grade II : Inability to flex hip and knee but able to flex ankle
- Grade III : Complete motor blockade of hip, knee and ankle

In motor block assessment was done by observing MBS grade achieved by patient; Time to achieve motor block MBS III, onset and duration of motor block. Overall quality of anaesthesia was evaluated in perspective of patient and anaesthesia provider. Each one was questioned about quality of anaesthesia using a 3 or 4 point scale. In the intra-operative period, patients were closely monitored for pulse rate, respiratory rate, SpO<sub>2</sub>, blood pressure and blood loss. Any side effects such as nausea, vomiting, pain, shivering, pruritus, sedation, respiratory discomfort were noted and treated with appropriate drugs. For postoperative complications, patients were visited daily in the ward till their discharge to enquire about the postoperative complications like urinary retention, postdural puncture headache,

backache and neurological symptoms. Data were collected, tabulated, coded then analyzed using Statistical software STATA version 13.1. The results were considered statistically significant when P-value was < 0.05. Finally the results in the two groups were compared to draw the conclusion.

### Statistical Analysis

Continuous variables (age, weight, height, onset and duration of sensory and motor block, maximum sensory level, pulse rate, systolic blood pressure and SPO<sub>2</sub> variations) were presented as mean  $\pm$  SD. Categorical variables (sex, grades, complications) were presented in actual numbers and percentage. Categorical variables were compared by Pearson's chi-square test. For small numbers, Fisher's exact test was applied. Hemodynamic parameters were compared at different time point in each group by performing one-way repeated measure ANOVA. Changes in hemodynamic parameters were compared between two groups at different time point from baseline by performing unpaired t test for normalized data and Mann-Whitney test was used for non-normalized data.

### 3. Observations and Results

100 patients has been selected for the study, equally divided into group B and group L. Out of which 13 (26%) females and 37 (74%) males whereas 17 (34%) females and 33 (66%) males have been enrolled in group B and group L respectively. The mean duration of surgery in group B was  $106.6 \pm 12.99$  minutes and that of in group L was  $108.6 \pm 14.17$  minutes. The two groups were comparable statistically with regard to the duration of surgery and demographic profile was shown in (table 1). Characteristics of patient's age, weight and height showed no statistically significant

differences between these two groups ( $P > 0.05$ ).

### **Sensory and Motor Blockade**

The group L had comparable onset of sensory block ( $206.8 \pm 17.54$  seconds) as compared to group B ( $213.6 \pm 20.57$  seconds), [ $p > 0.05$ ]. The time required to achieve T10 dermatome level was significantly higher in group L ( $15.42 \pm 1.79$ ) than in group B ( $10.4 \pm 2.94$ ), when both the groups were compared ( $p < 0.05$ ). Maximum sensory level was significantly less cephalic spread and takes longer time in group L (T6-T8,  $22.68 \pm 2.03$  min.) as compared to group B (T4-T7,  $18.92 \pm 2.74$  min.), [ $p < 0.05$ ]. The mean duration of sensory block was more in group L ( $226.4 \pm 24.64$ ) as compared to that in group B ( $170.4 \pm 26.72$ ), which was statistically significant, ( $p < 0.0001$ ). The mean time for onset of motor block in group L ( $303.3 \pm 21.37$ ) was significantly higher than that in group B ( $249.2 \pm 34.92$ ), ( $p < 0.0001$ ), while the duration of motor block was more prolonged in group L ( $201.4 \pm 24.90$ ) than that in group B ( $187.6 \pm 21.14$ ) which was statistically significant. ( $P < 0.05$ ). (Table 2).

When the two groups were compared, the time required to achieve MBS III in group L ( $11.79 \pm 1.35$  minutes) was found to be higher than in group B ( $10.87 \pm 2.23$  minutes), ( $p < 0.05$ ). Group L produced Modified Bromage Scale III in 98% patients which were comparable to 94% patients in group B, [ $p > 0.05$ ]. (Table 3).

### **Hemodynamic Changes**

The significantly less decrease in systolic blood pressure and pulse rate in group L which is compared to group B [ $p < 0.05$ ] i.e. group L is more stable hemodynamically. There was no significant difference in baseline pulse rate, systolic blood pressure and SpO<sub>2</sub>

between two groups, P-value  $> 0.05$  (Table 4). The changes in mean pulse rate and systolic blood pressure in both the groups was compared at various time intervals and showed statistically significant differences between the two groups, ( $p$  value  $< 0.0001$ ). (fig.1 and 2)

### **Quality of surgical anaesthesia**

The 0.5% isobaric levobupivacaine provided excellent quality of anaesthesia, as stated by anaesthesia provider, in 78% of patients which was comparable to 70% of patients in 0.5% hyperbaric bupivacaine group, [ $P > 0.05$ ]. (Table 5)

### **Perioperative complications**

The group L as well as group B did not produce any respiratory difficulty or hypoxia. Group L had significantly less incidence of intra operative hypotension and bradycardia as compared to group B, [ $p < 0.05$ ]. Incidence of intra operative nausea, vomiting and shivering was negligible with both the groups, [ $p > 0.05$ ]. There were no post operative complications in both the groups (Table 6 and fig. 3).

These observations showed that 3.25 ml of 0.5% isobaric levobupivacaine when used in spinal anaesthesia for lower extremity surgeries provides satisfactory surgical conditions with better hemodynamic stability and minimal perioperative complications.

## **4. Discussion**

The present study was conducted with the objective to evaluate isobaric levobupivacaine versus hyperbaric bupivacaine for spinal anaesthesia in lower extremity surgeries. In this study, isobaric levobupivacaine provides longer duration of sensory and motor block required for lower extremity surgeries were achieved in group L, and it was observed that the hemodynamic



stability with isobaric levobupivacaine was better maintained. Levobupivacaine is increasingly popular in replacement of bupivacaine because of its equipotency with lower cardiovascular and central nervous system side effects. This study demonstrates that isobaric levobupivacaine, the pure S (-) enantiomer of racemic bupivacaine, is an effective and safer alternative local anesthetic to hyperbaric bupivacaine for spinal application.

Clinical utilization of levobupivacaine has been studied for epidural anaesthesia, peripheral blockades and local procedures, but more has to be known about its intrathecal administration. Previous literature showed no significant differences between levobupivacaine and racemic bupivacaine with regard to onset time, the duration and the spread of sensory and motor blockades, as well as to their hemodynamic effects [31, 32].

As isobaric 0.5% levobupivacaine was recently introduced by Neon laboratories in the Indian market, present study was carried out to provide further observations about this new local anaesthetic by comparing the clinical and anaesthetic properties of bupivacaine and levobupivacaine in spinal anaesthesia for lower extremity surgery. Due to the isobaric nature of levobupivacaine, some authors of previous studies made the study by either adding dextrose to the solution to make it hyperbaric or compared it with solutions of bupivacaine by making it isobaric with addition of normal saline [31, 32, 33]. But the addition could potentially reduce the safety of spinal injection and also the final density of anaesthetic solution may be less predictable than that of commercially available specific hyperbaric formulations [28].

The present results are in concordance with previous studies. In this study it was observed that the time taken by isobaric levobupivacaine to produce the onset of sensory block was similar to the time taken by hyperbaric bupivacaine. When the two groups were compared with respect to the time to reach T10 dermatome level, it was observed that isobaric levobupivacaine takes more time to reach T10 dermatome level than hyperbaric bupivacaine which was statistically significant ( $p < 0.05$ ). The delay in the time to reach T10 dermatome level can be attributed to the isobaric nature of levobupivacaine. Thus, the levobupivacaine requires more time to achieve the maximum sensory block as compared to hyperbaric bupivacaine which was statistically significant. No previous studies are available comparing hyperbaric bupivacaine and isobaric levobupivacaine in terms of time required to achieve maximum sensory level to substantiate this finding. When the two groups in the present study were compared with respect to duration of sensory block, isobaric levobupivacaine provided significantly longer duration of anaesthesia than hyperbaric bupivacaine. This makes it a better alternative to bupivacaine for long duration surgeries.

Furthermore the present study correlates with the previous studies. On comparing the two groups in the present study, it was observed that isobaric levobupivacaine requires more time to achieve modified Bromage scale III as compared to hyperbaric bupivacaine which was statistically significant. While with respect to duration of motor block, isobaric levobupivacaine produced longer duration of motor block than hyperbaric bupivacaine. The difference may be explained by the greater vasoconstrictive

properties of levobupivacaine than bupivacaine.

In addition, the fall in pulse rate and systolic blood pressure from the baseline was significantly more with hyperbaric bupivacaine than that with isobaric levobupivacaine ( $p < 0.0001$ ). There are other studies mentioning that there is no difference between systolic blood pressures of patients receiving the two drugs, but the formulation they used was comparable in baricity either both drugs were isobaric or hyperbaric [30,32]. The quality of anaesthesia graded by anaesthesia provider was comparable in both the groups. All the surgeries were completed before recovery from the block and no patient required supplementation because of regression of block.

Although it was observed that hyperbaric bupivacaine had higher incidence of hypotension than isobaric levobupivacaine which was significant statistically. More cephalic spread of the block and rapid increase in block level explains the higher incidence of significant hypotension with bupivacaine. While block level and incidence of hypotension was not related in the levobupivacaine group. And also, observed that hyperbaric bupivacaine had higher incidence of significant bradycardia than isobaric levobupivacaine but it was not statistically significant ( $p > 0.05$ ). On comparing two groups, it was higher cephalic spread of sensory block up to T4 explains the higher incidence of bradycardia with bupivacaine which was not there with levobupivacaine.

None of the patients from either groups developed respiratory difficulty or fall in SPO<sub>2</sub> below 90% throughout the surgery. The overall incidence of intraoperative

complications like nausea/vomiting and shivering was minimal in both the groups and was not significant statistically. Out of 12 patients, 6 patients in bupivacaine group who complained of nausea/vomiting also had significant hypotension after spinal anaesthesia and higher level of sensory block. None of the patients from both the groups had postdural puncture headache or neurological complaints postoperatively.

## 5. Conclusion

The present study concludes that 3.25 ml of 0.5% isobaric levobupivacaine when used in spinal anaesthesia for lower extremity surgeries provides satisfactory anaesthesia comparable to routinely used 3.25 ml of 0.5% hyperbaric bupivacaine, with better hemodynamic stability, longer duration of sensory and motor block and minimal perioperative complications. The only limitation is delayed onset of block.

Hence, the study suggests that 3.25 ml of 0.5% isobaric levobupivacaine can be used as a safer alternative to 3.25 ml of 0.5% hyperbaric bupivacaine in spinal anaesthesia for elective lower extremity surgeries requiring duration up to 3 hours.

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**Table 1. Demographic data and duration of surgery**

Variable	Group B		Group L		P Value
	Range	Mean $\pm$ SD	Range	Mean $\pm$ SD	
Age (yrs)	21-60	37.20 $\pm$ 7.70	21-60	37.0 $\pm$ 7.66	0.8651, NS
Weight (kgs)	50-80	60.94 $\pm$ 6.23	50-80	60.34 $\pm$ 6.39	0.6357, NS
Height (Cms)	150-175	165.36 $\pm$ 4.86	150-175	165.14 $\pm$ 4.87	0.8217, NS
Duration of surgery (Min)	75-120	106.6 $\pm$ 12.99	75-120	108.6 $\pm$ 14.17	>0.05, NS

Above data indicates that the study groups i.e. group B and group L are statistically comparable with regard to age, weight, height and duration of surgery of the patients ( $p > 0.05$ ).

**Table 2. Data showing Sensory and Motor Blockade**

Variable	Group B		Group L		P Value
	Range	Mean $\pm$ SD	Range	Mean $\pm$ SD	
Time for onset of sensory block (Sec)	180-250	213.6 $\pm$ 20.57	180-240	206.8 $\pm$ 17.54	0.0785,NS
Time to reach T10 (Min)	4-18	10.4 $\pm$ 2.94	10-20	15.42 $\pm$ 1.79	<0.0001,HS
Time required for MSL (Min)	15-26	18.92 $\pm$ 2.74	18-30	22.68 $\pm$ 2.03	<0.0001,HS
Duration of sensory block (Min)	121-240	170.4 $\pm$ 26.72	181-300	226.4 $\pm$ 24.64	<0.0001,HS
Time for onset of motor block (Sec)	181-330	249.2 $\pm$ 34.92	241-360	303.3 $\pm$ 21.37	<0.0001,HS
Duration of motor block (Min)	150-240	187.6 $\pm$ 21.14	150-270	201.4 $\pm$ 24.90	0.0036, HS

Data are Mean (range and SD). NS: no significant; HS: Highly significant; MSL: Maximum sensory level

**Table 3. Time to achieve Modified Bromage Scale III (MBS)**

Time to achieve MBS III (Min)	Group B	Group L
8-10	25 (50%)	6 (12%)
11-13	11 (22%)	29 (58%)
14-16	11 (22%)	4 (8%)
Total	47	49
Mean $\pm$ SD	10.87 $\pm$ 2.23	11.79 $\pm$ 1.35
p Value	0.017, S	

**Table 4. Comparison of Baseline\_Vital Parameters (Pulse rate,Systolic BP (mmHg))**

Vital parameters	Group B	Group L	P-value
	Mean $\pm$ SD (n=50)	Mean $\pm$ SD (n=50)	
Pulse rate (min)	78.64 $\pm$ 11.59	75.20 $\pm$ 7.42	p <0.0001
Systolic BP (mmHg)	117.12 $\pm$ 8.7	117.84 $\pm$ 6.52	p < 0.005

**Table 5. Quality of anaesthesia (anaesthesia provider)**

Quality of anaesthesia	Group B	Group L
E (Excellent)	35 (70%)	39 (78%)
S (Satisfactory)	15 (30%)	11 (22%)
N (Non-Satisfactory)	-	-
Total	50	50
p-value	0.758, NS	

**Table 6. Data showing Perioperative complications**

Complications		No. of Patients (%)		p-value
		Group B	Group L	
Intra operative	Nausea/Vomiting (N/V)	12 (24%)	3 (6%)	0.031, S
	Hypotension (HT)	14 (28%)	2 (4%)	0.012, S
	Bradycardia (BR)	12 (24%)	4 (8%)	0.618, NS
	Respiratory Difficulty	-	-	-
	Shivering (SH)	6 (12%)	2 (4%)	0.618, NS
Post operative	Nausea/Vomiting	-	-	-
	Urinary Retention	-	-	-
	Postdural Puncture Headache	-	-	-
	Backache	-	-	-
	Neurological Symptoms	-	-	-

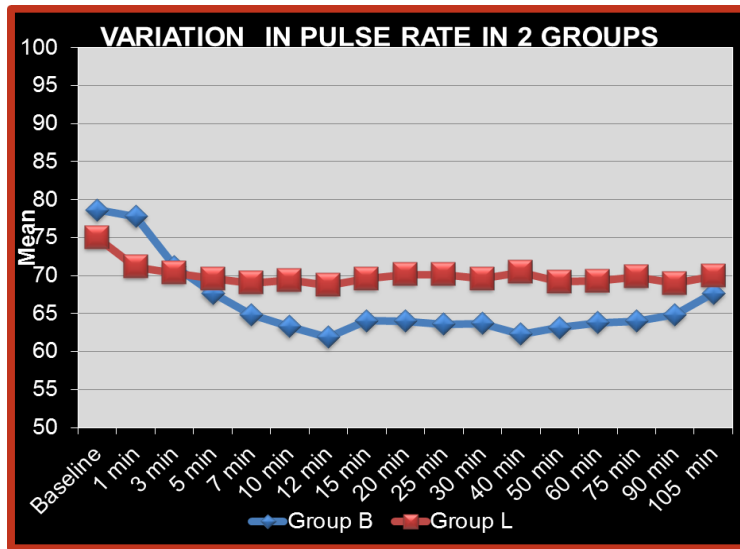


Fig. 1 Graphical representation of variation in pulse rate in two groups

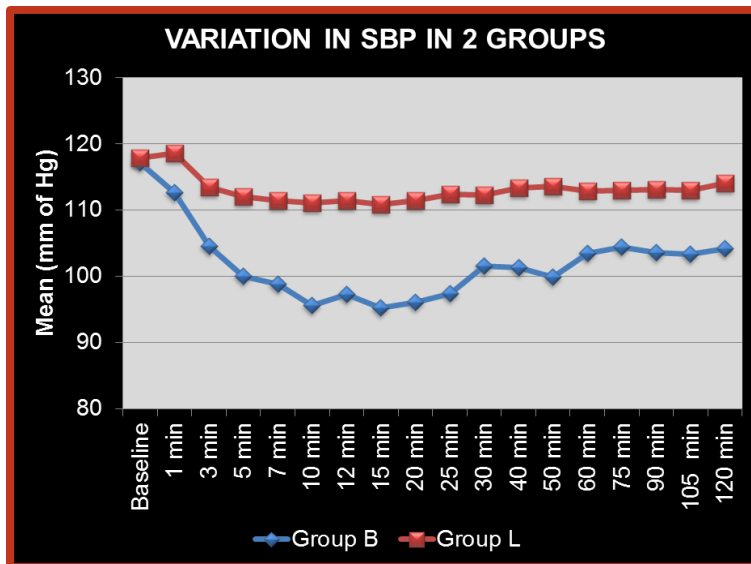


Fig. 2 Graphical representation of variation in SBP in two groups

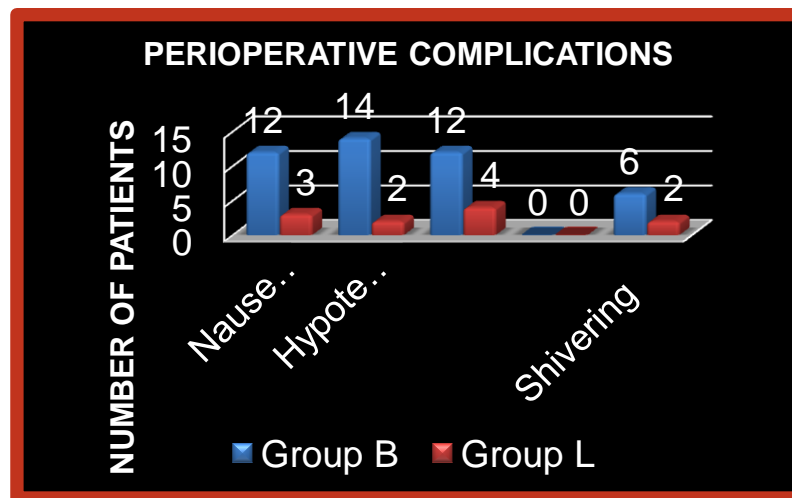


Fig. 3 Graphical representation of preoperative complication