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COMPARISON OF COMBINATION OF ISOBARIC LEVOBUPIVACAINE AND HYPERBARIC LEVOBUPIVACAINE VERSUS HYPERBARIC LEVOBUPIVACAINE IN SPINAL ANAESTHESIA FOR INGUINAL HERNIA SURGERY TO DETERMINE THE ONSET OF BLOCK: A RANDOMIZED CONTROL TRIAL

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ABSTRACT

Introduction: Spinal anaesthesia is the preferred regional technique for inguinal hernia surgeries due to its rapid onset, reliable sensory and motor blockade, and favorable safety profile. Levobupivacaine, available in both isobaric and hyperbaric formulations, is widely used, but the optimal combination for achieving faster onset of block remains unclear. This study aimed to compare the onset of sensory and motor blockade between a combination of isobaric and hyperbaric levobupivacaine versus hyperbaric levobupivacaine alone in patients undergoing inguinal hernia repair.

Methodology- This randomized controlled trial was conducted over 18 months in 100 patients. Patients were randomly assigned to receive either a combination of isobaric (0.4 mL) and hyperbaric (2.6 mL) levobupivacaine (Group A) or hyperbaric levobupivacaine alone (3 mL, Group B) via intrathecal injection at L3–L4. Sensory block was assessed by loss of pinprick sensation to T8, and motor block was evaluated using the Modified Bromage Scale. Hemodynamic parameters and adverse effects were monitored perioperatively, and the onset, maximum level, duration, and regression of sensory and motor block were recorded.

Result- Primary outcome (sensory onset to T8) 5.57 ± 0.99 minutes (Group A) vs 4.15 ± 0.77 minutes (Group B); $p < 0.001$. Motor onset (time to Bromage 3) 7.69 ± 1.47 minutes (Group A) vs 5.87 ± 1.01 minutes (Group B); $p < 0.001$. Group B provided faster onset and longer duration of sensory and motor block, while Group A demonstrated better hemodynamic stability.

Conclusion- The combination of isobaric and hyperbaric levobupivacaine offers a more controlled block with lower hypotension incidence, making it preferable when haemodynamic stability and early recovery are priorities.

KEYWORDS: Isobaric, hyperbaric, levobupivacaine, surgery, hernia, inguinal

INTRODUCTION

Spinal anaesthesia, also referred to as subarachnoid block, is a widely accepted regional anaesthetic technique for infra-umbilical surgeries, including inguinal hernia repair. It is favoured due to its rapid onset, dense sensory and motor blockade, reduced perioperative stress response, minimal airway manipulation, and high patient satisfaction when compared with general anaesthesia [1]. Inguinal hernia surgeries are frequently performed under spinal anaesthesia as they are of moderate duration and require a reliable block with stable intraoperative conditions and rapid postoperative recovery [2]. Among intrathecally administered local anaesthetic agents, bupivacaine has traditionally been the most commonly used drug because of its long duration of action and ability to produce profound sensory and motor blockade; however, as a racemic mixture of R (+) and S (–) enantiomers, the R (+) isomer has been associated with increased cardiotoxicity and central nervous system toxicity, particularly in cases of inadvertent intravascular injection or high spinal block [3]. These safety concerns have led to the development and increasing clinical use of safer single-enantiomer alternatives such as levobupivacaine, the pure S (–) enantiomer of bupivacaine, which has demonstrated a superior safety profile with reduced cardiotoxic and neurotoxic effects [4]. The lower affinity of levobupivacaine for myocardial sodium channels and its faster plasma protein binding further contribute to its reduced potential for adverse cardiovascular events, while several clinical studies have shown that it provides anaesthetic efficacy comparable to bupivacaine with the added advantage of improved hemodynamic stability [5].

Baricity plays a critical role in determining the spread, onset, and extent of intrathecal local anaesthetic solutions. Hyperbaric solutions, which are denser than cerebrospinal fluid (CSF), are influenced by gravity and patient positioning, resulting in faster cephalad spread and quicker onset of sensory blockade [6]. Hyperbaric bupivacaine has long been the standard intrathecal agent due to its predictable spread and rapid onset. However, rapid sympathetic blockade following hyperbaric drug administration has been associated with hypotension and bradycardia [7]. In contrast, isobaric solutions such as plain levobupivacaine exhibit minimal gravitational spread and tend to produce a more uniform and predictable block that is less dependent on patient positioning [8]. Owing to its density being close to that of cerebrospinal fluid, isobaric levobupivacaine is associated with a slower onset of sensory and motor blockade but offers improved hemodynamic stability and a reduced incidence of sudden high spinal block [9]. Several randomized trials have reported a delayed onset of sensory and motor block with isobaric levobupivacaine compared with hyperbaric bupivacaine; however, the quality of surgical anaesthesia remains comparable, with fewer cardiovascular side effects observed [10].

Despite these advantages, the slower onset may be undesirable in clinical situations where rapid establishment of anaesthesia is required, such as high-volume operating theatres or short-duration procedures like inguinal hernia repair. In such settings, hyperbaric levobupivacaine, prepared by the addition of dextrose to isobaric levobupivacaine, has been shown to achieve faster onset and higher sensory levels, although it may still be associated with hemodynamic instability due to rapid sympathetic blockade [11].

Recent studies comparing hyperbaric and isobaric forms of levobupivacaine have demonstrated that hyperbaric preparations achieve faster onset of sensory and motor block, higher dermatomal spread, and earlier attainment of surgical anaesthesia, while isobaric preparations are associated with more stable hemodynamics and earlier motor recovery [12]. The concept of combining isobaric and hyperbaric levobupivacaine intrathecally aims to integrate the advantages of both baricities. Administering a small dose of isobaric levobupivacaine followed by hyperbaric levobupivacaine may allow early neural exposure while moderating the rate of cephalad spread, potentially achieving faster onset without excessive sympathetic blockade. This strategy may be particularly beneficial in surgeries such as inguinal hernia repair, where adequate sensory block to T8 is required without compromising cardiovascular stability [13]. Existing evidence from inguinal hernia surgeries suggests that levobupivacaine provides equivalent intraoperative anaesthetic quality with earlier postoperative mobilization and reduced hypotension compared to hyperbaric bupivacaine [14] . However, the optimal method of administration to balance onset time and hemodynamic stability remains an area of ongoing research. Although multiple randomized controlled trials have compared levobupivacaine with bupivacaine and ropivacaine, as well as isobaric versus hyperbaric formulations, there is limited literature evaluating the combined intrathecal administration of isobaric and hyperbaric levobupivacaine in a single spinal injection protocol. Therefore, this study aims to compare the anesthetic efficacy, in terms of the onset of block, between a combination of isobaric levobupivacaine and hyperbaric levobupivacaine versus hyperbaric levobupivacaine alone in patients undergoing elective inguinal hernia surgeries.

MATERIALS AND METHODS

The study was conducted in the Department of Anaesthesiology at SRM Medical College Hospital and Research Institute, Kattankulathur, Tamil Nadu for a period of 18 months from June 2024 to November 2025, following approval from the Institutional Ethics Committee (SRMIEC-STO724-1755). Patients aged between 18 and 60 years, belonging to American Society of Anesthesiologists (ASA) Physical Status I and II, those scheduled for elective inguinal hernia surgery were included in the study. Patients having infection at the site of spinal injection, patients with deformities in spine or anatomical abnormalities of the spine, patients with known allergy or hypersensitivity to local anesthetic drugs, patients with neuromuscular diseases or seizure disorders, patients with coagulation abnormalities or bleeding disorders, Obesity with body mass index greater than 29 kg/m^2, and patients refusing to provide consent for participation were excluded. 100 patients were randomized , with 50 in each group. Figure 1 shows the flowchart of the progression of participants through the trial according to the Consolidated Standards of Reporting Trials (CONSORT). Eligible patients were enrolled in the study following written informed consent. A detailed pre-anesthetic evaluation was performed for all participants, including history taking, physical examination, and review of laboratory investigations.

On the day of surgery, patients were shifted to the operation theatre, and standard monitors including electrocardiography, non-invasive blood pressure, and pulse oximetry were attached. Baseline vital parameters were recorded. Patients were positioned in the sitting position. Under strict aseptic precautions, lumbar puncture was performed at the L3–L4 intervertebral space using a midline approach with a 25-gauge Quincke spinal needle, with the bevel oriented upwards. After confirmation of free flow of cerebrospinal fluid, Group A patients received 0.4 mL of isobaric levobupivacaine intrathecally, followed immediately by 2.6 mL of hyperbaric levobupivacaine, administered using separate syringes. Group B patients received 3 mL of hyperbaric levobupivacaine intrathecally. Following drug administration, patients were positioned supine, and assessments were carried out as per protocol.

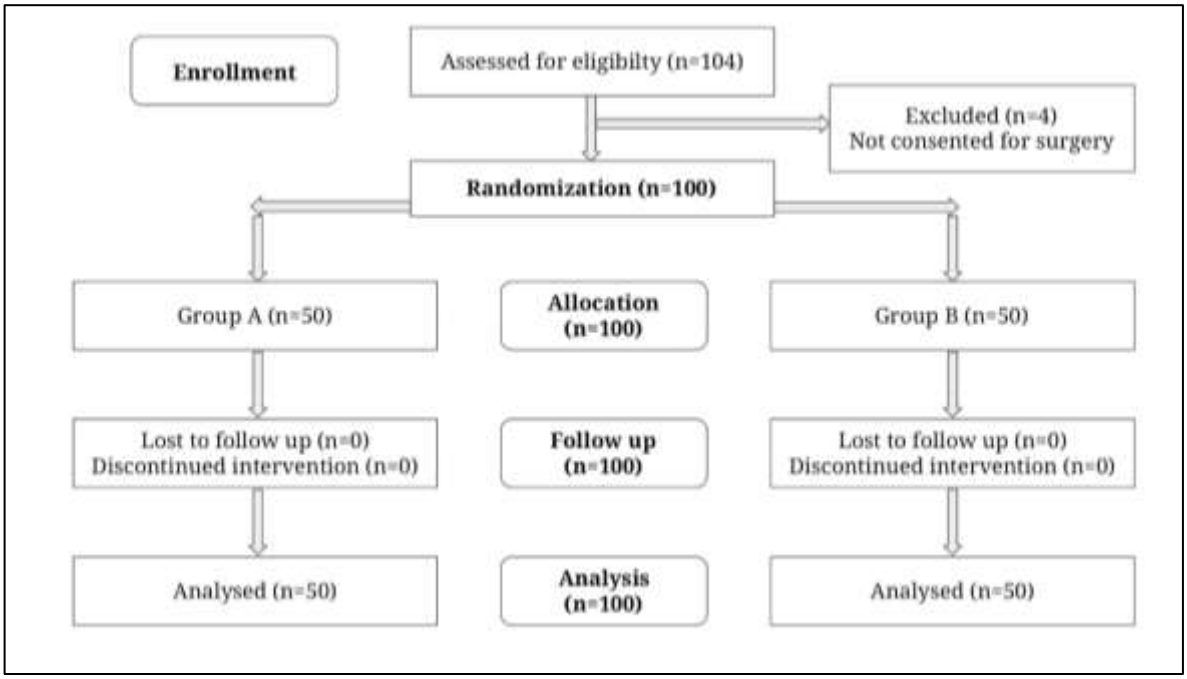

Figure 1 : CONSORT FLOWCHART

Sensory block was assessed using loss of pinprick sensation along the mid-clavicular line bilaterally. Sensory assessment was performed at one-minute intervals starting at 2 minutes after intrathecal injection until a sensory level of T8 was achieved. The maximum sensory level was assessed at 20 minutes. Time to two-segment regression was recorded as the time taken for recovery of sensory level to 2 dermatomal segments below the highest level. The duration of sensory block was recorded postoperatively as the time taken to return to S2. Motor block was assessed using the Modified Bromage Scale. Assessment was performed at one-minute intervals starting at 2 minutes after intrathecal injection until a Bromage score of 3 was achieved. Maximum Bromage score was noted at 10 minutes. The duration of motor block was recorded as the time taken to return to Bromage score 0. Baseline haemodynamic parameters including heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and oxygen saturation were recorded. The same parameters were recorded every two minutes for the first 20 minutes following intrathecal injection and subsequently every 20 minutes until the end of surgery.

Post spinal hypotension was identified as fall in MAP less than 20% from the baseline. This was treated with 250 ml of Ringer lactate IV fluid bolus, if unsettled, was followed by Inj. Ephedrine 6mg IV Stat. Bradycardia was identified as less than 20% from the baseline which was treated with Inj. Atropine 0.6mg IV. The occurrence of vomiting, and shivering was documented. Vomiting was treated with Inj. Ondansetron 4mg IV. If any side effect of shivering occurred, it was treated with Inj. Tramadol 1mg/kg body weight slow IV. Emergency drugs and resuscitation equipment were readily available to manage further adverse events.

All collected data was analyzed using SPSS Version 26.0. Continuous variables were expressed as mean and standard deviation. Normally distributed continuous variables were compared using the independent samples t-test, while non-normally distributed variables were analysed using the Mann-Whitney U test. Categorical variables were expressed as frequency and percentage. Categorical variables were compared using the Chi-square test or Fisher's exact test. Hemodynamic parameters recorded at numerous time points (baseline to 120 minutes) were analysed using two-way mixed repeated measures ANOVA (Group × Time), followed by post-hoc independent t-tests at individual time points. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Table 1 presents the comparison of demographic parameters between the two groups. All baseline characteristics including age, weight, height and BMI were statistically comparable, with negligible to small effect sizes, and all 95% confidence intervals crossing zero, confirming successful randomization.

Table 1: Comparison of Demographic parameters

Parameter	Group A		Group B		p - value
	Mean	SD	Mean	SD	
Age (yrs)	42.20	10.72	42.44	12.54	0.877
Weight (kg)	62.41	7.66	64.48	8.46	0.204

Height (cm)	164.10	6.29	163.45	6.94	0.621
BMI (kg/m2)	23.34	3.90	24.21	3.38	0.237
*Statistically significant ($p < 0.05$)					

Table 2 : Summary of Block Characteristics

	Parameter	Group A		Group B		p - value
		Mean	SD	Mean	SD	
Sensory block	Onset	5.57	0.99	4.15	0.77	<0.001*
	Duration	171.30	25.64	183.44	23.06	0.014*
Motor block	Onset	7.69	1.47	5.87	1.01	<0.001*
	Duration	139.80	16.92	154.80	18.00	<0.001*
Time to 2-segment regression		76.90	10.77	85.16	10.59	<0.001*
*Statistically significant ($p < 0.05$)						

Table 2 summarizes the key block characteristics comparing both study groups. Group B (hyperbaric levobupivacaine alone) demonstrated faster onset and longer duration of block compared to Group A (combination technique).

Table 3: Comparison of Side Effects

Side effects	Group A (n)	Group A (%)	Group B (n)	Group B (%)	P - value
Vomiting	4	8.0	11	22.0	0.091
Shivering	3	6.0	6	12.0	0.487
*Statistically significant ($p < 0.05$)					

Table 3 compares the incidence of side effects between the two groups. Vomiting and shivering showed numerically higher incidence in Group B but did not have statistical significance.

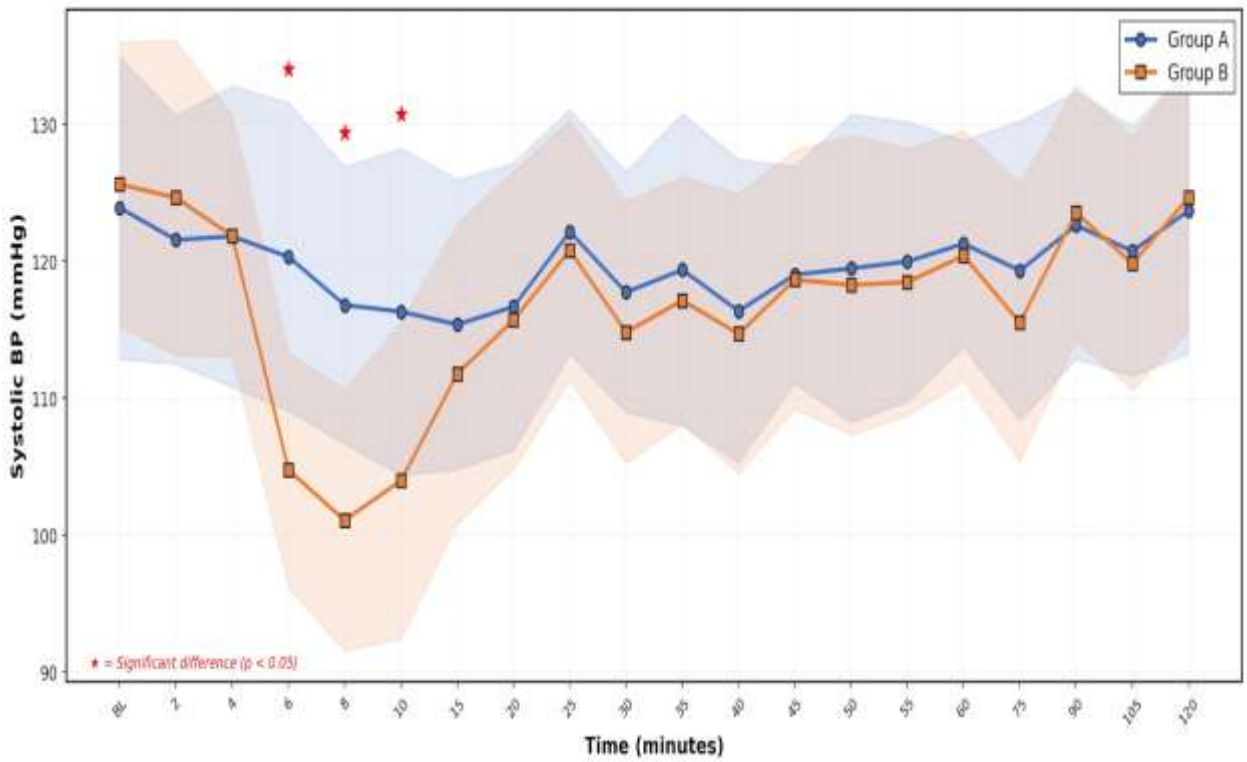

Figure 2 : Comparison of intraoperative Systolic Blood Pressure (SBP) variations between Group A and Group B.

There was significant difference ($p < 0.05$) in systolic blood pressure between both groups. Group B showed a dramatic SBP drop at 6 min (104.8 ± 8.6 mmHg), 8 min (101.1 ± 9.5 mmHg) and 10 min (104.0 ± 11.6) with large effect sizes ($d > 1.5$), while Group A maintained stable values above 116 mmHg. (Figure 2)

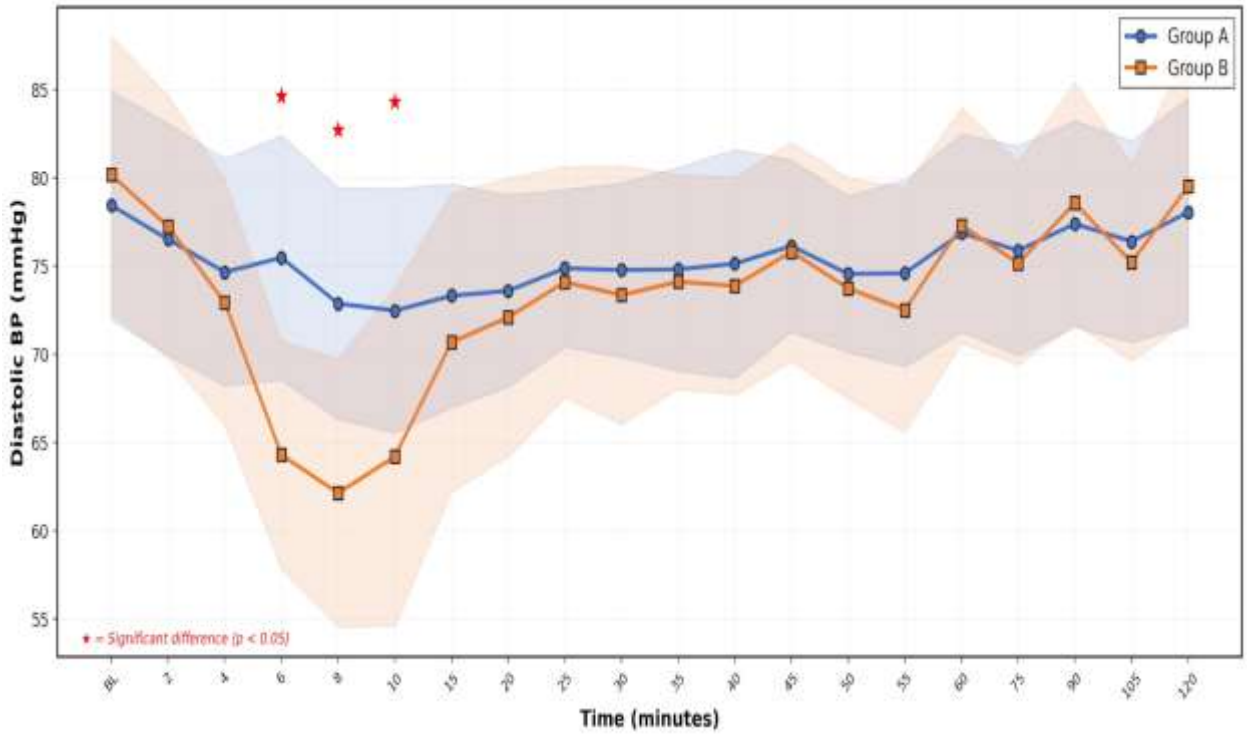

Figure 3 : Comparison of intraoperative Diastolic Blood Pressure (DBP) variations between Group A and Group B.

A statistically significant difference in diastolic blood pressure was observed between the two groups. In Group B, there was a marked reduction in DBP at 6 minutes (64.3 ± 6.5 mmHg), 8 minutes (62.1 ± 7.6 mmHg), and 10 minutes (64.2 ± 9.6 mmHg), with the effect persisting at several intermediate timepoints before normalizing by 120 minutes. (Figure 3)

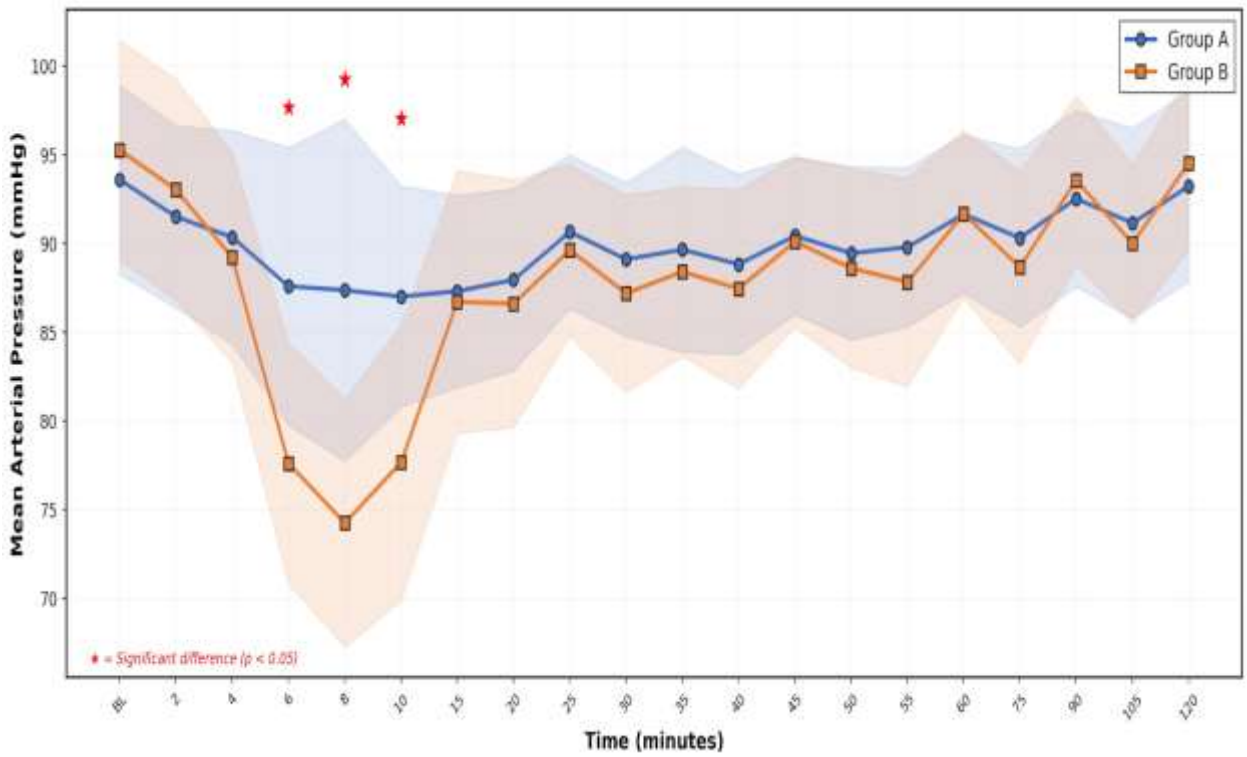

Figure 4 : Comparison of intraoperative Mean Arterial Pressure (MAP) variations between Group A and Group B.

A significant difference in mean arterial pressure was noted between the two groups ($p < 0.05$). Group B exhibited a marked decline in MAP at 6 minutes (77.6 ± 6.8 mmHg), 8 minutes (74.3 ± 7.0 mmHg), and 10 minutes (77.7 ± 7.8 mmHg), reflecting the intense sympatholytic effect.

DISCUSSION

This randomized controlled study demonstrates that intrathecal hyperbaric levobupivacaine alone produces a significantly faster onset of sensory block to the T8 dermatome and earlier attainment of complete motor blockade, along with a longer duration of both sensory and motor block, when compared with a combination of isobaric and hyperbaric levobupivacaine in patients undergoing elective inguinal hernia surgery. In contrast, the combined technique showed better hemodynamic stability.

The demographic characteristics of the two study groups were comparable with respect to age, sex distribution, body mass index, height, weight, and ASA physical status, indicating adequate randomization and minimizing confounding influences. The predominance of middle-aged male patients reflects the typical demographic profile of patients undergoing elective inguinal hernia repair and is comparable to that reported by Sen et al [16]. Demographic comparability is essential in spinal anesthesia studies, as patient-related factors such as age, body habitus, vertebral anatomy, and cerebrospinal fluid dynamics can influence intrathecal drug spread. Greene and Mitchell et al. have previously shown that patient characteristics along with solution baricity play a role in determining spinal block behavior [8,9]. The absence of statistically significant demographic differences in the present study strengthens internal validity and supports the conclusion that observed differences in block characteristics are primarily related to the anesthetic technique used.

With regard to spinal block characteristics, hyperbaric levobupivacaine alone resulted in a significantly faster onset of sensory block and earlier achievement of complete motor blockade. This can be attributed to its higher density relative to cerebrospinal fluid, resulting in gravity-dependent cephalad spread and earlier neural exposure. These findings are consistent with classical descriptions by Greene and further supported by Mitchell et al., who demonstrated the influence of baricity on block onset and spread [8,9]. The present results closely parallel those of the study by Madhanmohan et al., who reported earlier sensory onset and higher dermatomal levels with hyperbaric levobupivacaine compared with isobaric formulations [17]. Similar findings have been reported by Sanansilp et al., who observed faster sensory and motor onset with hyperbaric levobupivacaine, as well as by Kabir et al., who demonstrated rapid and reliable block characteristics with hyperbaric levobupivacaine in adult patients [11,18]. In addition to faster onset, hyperbaric levobupivacaine alone produced a significantly longer duration of sensory and motor block, suggesting prolonged intrathecal action and sustained neural blockade. These findings are consistent with those reported by Sanansilp et al., who also observed longer block duration with hyperbaric formulations compared with isobaric solutions [11]. In contrast, the combination of isobaric and hyperbaric levobupivacaine resulted in a relatively shorter duration of both sensory and motor block, which may facilitate earlier postoperative mobilization and recovery in elective procedures such as inguinal hernia surgery. The time to two-segment regression did not differ significantly between groups, indicating that early regression characteristics may be less

influenced by baricity compared to block onset and total duration. This suggests that while hyperbaric levobupivacaine enhances the onset and prolongs block duration, the combination technique provides a more balanced block profile.

Hemodynamic effects remain an important concern during spinal anesthesia. In the present study, the incidence of hypotension was significantly higher in patients receiving hyperbaric levobupivacaine alone, likely due to more extensive and rapid sympathetic blockade resulting from higher cephalad spread of the anesthetic solution. Carpenter et al. previously identified the extent and rapidity of sympathetic blockade as important predictors of bradycardia and hypotension following spinal anesthesia [7]. Although Singh et al. reported minimal hemodynamic disturbances with intrathecal levobupivacaine in inguinal hernia surgery, the influence of baricity was not specifically evaluated in their study [2]. Verma et al., however, demonstrated greater cardiovascular stability with controlled or lower-baricity levobupivacaine techniques, findings comparable to the reduced incidence of bradycardia observed with the combined isobaric–hyperbaric technique in the present study [19]. These findings suggest that deliberate modulation of intrathecal baricity may improve hemodynamic stability without compromising the adequacy of surgical anesthesia.

Limitations

The trial was conducted in a single surgical context-elective inguinal hernia repair-which may limit extrapolation to other procedures requiring different sensory levels or durations. The exact dosing strategy and volume dynamics inherent to combining isobaric and hyperbaric preparations may vary across institutions, potentially affecting reproducibility unless the technique is clearly standardised. These limitations indicate that while the conclusions are supported within this trial setting, broader confirmation across different patient populations and perioperative contexts would enhance external validity.

CONCLUSION

The present study demonstrates that while Hyperbaric Levobupivacaine provides a faster onset and longer duration of spinal anaesthesia, it is associated with significant early hemodynamic instability, particularly hypotension. In contrast, a combination of Isobaric and Hyperbaric Levobupivacaine offers a more controlled block with better cardiovascular stability and earlier recovery. Therefore, combination of both drugs in spinal anaesthesia may be a safer and more balanced choice.

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