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A Prospective Randomized Study to Compare the Effectiveness of High Versus Low Doses of Intrathecal Hyperbaric Bupivacaine given at Different Time Intervals for Inguinal Hernia Surgeries

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Abstract

Background: Spinal anaesthesia is the most common neuraxial regional block used in surgical procedures providing favourable conditions for lower abdominal surgeries like inguinal hernia repair. The aim of the study is to compare effectiveness of high versus low doses of intrathecal hyperbaric bupivacaine given at different time intervals for inguinal hernia surgeries. **Material and Methods:** The study was carried out on 90 patients which were randomized in 3 groups of 30 patients each. Group H1 received 10 mg of 0.5% bupivacaine heavy in 2 ml volume intrathecally in sitting position and remained in this position for 1 minute before turning them to supine. Group H2 received similar doses of heavy bupivacaine as H1 but remained in this position for 2 minutes before turning them to supine. Group L0 was given 5 mg of 0.5% bupivacaine heavy diluted to 2 ml volume intrathecally in sitting position and made to lie supine immediately. Onset and duration of sensory and motor block together with haemodynamic parameters and any associated complications/side effects were assessed. **Results:** On comparing the heart rate between Group L0 and Group H1/H2 statistically significant difference was observed from 5 to 30 minutes ($p<0.05$). Similar results were obtained while comparing systolic blood pressure between Group L0 and Group H1/H2 from 5 to 30 minutes ($p<0.05$). However, no significant results were observed on comparing Group H1 and H2 for heart rate and systolic blood pressure at any time interval. Intergroup comparison of Group L0, H1 and H2 revealed statistically significant results in onset/duration of sensory/motor block ($p<0.05$). **Conclusion:** The present study revealed that at 1 & 2 minutes sitting position after injecting hyperbaric bupivacaine intrathecally 10 mg in inguinal hernia surgeries results in more haemodynamic stability compared with immediately lying down.

Keywords: Bupivacaine, Inguinal Hernia, Spinal anaesthesia.

INTRODUCTION

Inguinal hernia surgery is the most common lower abdominal surgery performed worldwide under regional or general anaesthesia that depends on patient's preference, cost and early recovery and surgeon's choice.[1] However, the type of anaesthesia used may vary from one patient to another.[2] In this regard, the most common type of anaesthesia is neuraxial blockade, which creates favourable conditions by injecting small amount local anaesthetic agent intrathecally for lower abdominal procedures such as inguinal hernia repair and desired effect is achieved.[3]

Low dose spinal anaesthesia has been proven in providing faster onset of anaesthesia together with decreased chances of haemodynamic complications.[4] It also reduces the rate of pneumonia and respiratory failure in

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chronic lung disease patients in comparison to general anaesthesia. Even in elderly patients, the occurrence of hypotensive episode reduces after using low dose spinal that has detrimental effect and can lead to cardiovascular collapse in these patients.[4]

El-Hakeem suggested that patient's position during or after spinal anaesthesia may affect the incidence of hypotension.[5] Spinal anaesthesia can be performed with patient in sitting or lying down position. It is technically easier to insert needle in sitting position. Lying the patient immediately down after anaesthesia will force local anaesthetic towards head and increase thoracic dermatome blockade and thus will increase the incidence of hypotension.

Extensive medline search revealed that most of the studies were conducted on caesarean section or elderly patients. There were no studies conducted on patients posted for inguinal hernia repair. Therefore, the present study was planned to compare the effectiveness of high versus low doses of intrathecal hyperbaric bupivacaine given at different time intervals for inguinal hernia surgeries. The Null hypothesis (H0) of our study is that higher doses of intrathecal hyperbaric bupivacaine at different time intervals is equally effective in providing haemodynamic stability as low doses of intrathecal bupivacaine. However, alternative hypothesis suggests that high doses of intrathecal hyperbaric bupivacaine at different time intervals is more effective in providing haemodynamic stability as low dose of bupivacaine.

METHODOLOGY

After getting written informed consent and clearance from institutional ethical committee, the present study was planned in the Department of Anaesthesiology, Teerthanker Mahaveer Medical College and Research Centre, Moradabad from July 2021 to June 2022. The present study is also registered under Clinical Trial Registry of India (CTRI:2021/11/037984 dated 11/12/2021). Patients aged between 18 to 65 years and American society of anaesthesiologists physical status I and II were included in the study. Exclusion criteria were patient refusal for procedure, patient with neurological diseases, spine abnormalities, renal, hepatic, cardiac and pulmonary diseases, raised intracranial pressure, bleeding diathesis, on anticoagulant therapy, infection at the local site and allergic reaction to local anaesthetics.

Patients were instructed nil per oral from midnight prior to surgery. In preoperative room 20G intravenous cannula was secured and Ringer lactate at the rate of 10ml/kg was infused. Inside operation theatre, all standard monitors for oxygen saturation, blood pressure and ECG were attached and vitals were noted as per standard protocol.

A total of 90 patients were recruited in the study and divided into 3 equal groups. Randomisation was performed using chit and box method and all patients were allocated in three different groups;

Group H1 (30 patients) received 10 mg of bupivacaine heavy 0.5% in 2 ml volume intrathecally, and the patient was held in the sitting position for 1 minute before lying down.

Group H2 (30 patients) received 10 mg of bupivacaine heavy 0.5% in 2 ml volume intrathecally, and the patient was held in the sitting position for 2 minutes before lying down.

Group L0 (30 patients) was given 5 mg of bupivacaine heavy 0.5% in 2 ml volume intrathecally before being forced to lie down in supine posture.

In the sitting position, after taking all aseptic precautions spinal anaesthesia was administered using 25G Quincke's needle in L4-L5 space and then patient. After adequate loss of sensation till T10, surgery was started. Once the patient is made supine, the patient's haemodynamic parameters (heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure) was monitored at baseline and at each 5 minute intervals for first thirty minutes of procedure and further at every 10 minutes till the completion of surgery. The patients was further observed for the onset/duration of loss of sensation by pin-prick method and motor blockade 5 minutes after intrathecal injection. The motor blockade was assessed using Modified Bromage scale as below;

Modified Bromage Scale[4]

0	No motor block	No block(0%)
1	Can flex knee, move foot but cannot raise leg	Partial(33%)
2	Cannot move foot only	Almost complete (66%)
3	Cannot move foot or knee	Complete(100%)

Hypotensive episode was managed with intravenous Injection Mephentermine 6 mg in case if there was 30% fall from the baseline value. Bradycardia (HR<50 beats per minute) was treated with 0.5 mg of atropine

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intravenously. Nausea/Vomiting, shivering, pruritis, respiratory depression and any other complications was also observed and managed conservatively if occured.

Statistical analysis and sample size

The sample size was calculated as 27 patients per group using 80% power to detect a difference between the group proportions of 40% in the incidence of hypotension,[6] and significance level of the test was targeted at 0.05. In the present study, total of 30 patients were enrolled to compensate any missing data. The data was compiled using Microsoft Excel 2016 and analysed using the standard SPSS software package version 21 (Chicago, IL, USA). Presentation of data was done as mean ±standard deviation and Students t-test or Chi-Square/Fischer test were used for quantitative or qualitative data respectively. Value of P<0.05 was considered as statistically significant.

RESULTS

The present study enrolled 90 patients and all had successfully completed the study(fig.1). On comparing mean age among group L0, H1, H2, no significant difference was observed statistically (p>0.05) (Table1). On comparing BMI among group L0, H1, H2(21.47±1.31, 21.80±1.45, 21.82±1.43) (Table 1) no significant results were observed. On comparing ASA physical status among group L0, H1, H2(9/20±8.48, 14/15±1.41, 11/19±5.65) no significant results was observed [Table 1].

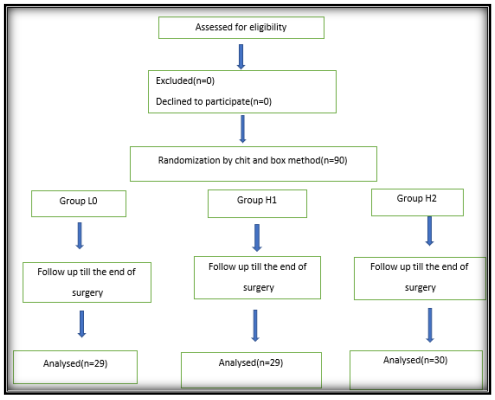

Figure 1: Consort flow diagram

Table 1: ?.

Variables	Group L0	Group H1	Group H2	P-value in between group L0 and H1	P-value in between group L0 and H2	P-value in between group H1 and H2
Age (years)	42±31.11	43±31.11	42.5±31.81	0.90	0.95	0.95
Weight (Kg)	54.5±16.26	56.5±13.43	56.5±13.43	0.60	0.60	1.00
Height (cm)	161±15.55	161±15.55	161±15.55	1.00	1.00	1.00
BMI (Kg/m^2)	21.47±1.31	21.80±1.45	21.82±1.43	0.35	0.32	0.95
ASA grade(I/II)	9/21±8.48	14/15±1.41	11/19±5.65	0.77	0.77	0.77

Table 2: Comparison of Mean Heart Rate among group L0, H1, H2.

HR (beats/minute)	Group L0	Group H1	Group H2	p-value in between group L0 and H1	p-value in between group L0 and H2	p-value in between group H1 and H2
At baseline	72.9±7.4	72.80±3.6	74.76±5.1	0.89	0.14	0.10
At 5 minutes	81.90±5.6	76±3.77	77.97±8.21	0.00	0.04	0.23
At 10 minutes	83.27±5.79	79±3.77	79.07±9.65	0.00	0.04	0.97
At 15 minutes	84.40±8.08	82.80±3.72	80.20±8.86	0.02	0.04	0.26
At 20 minutes	85.13±6.99	87.8±4.02	81.31±9.06	0.04	0.01	0.06
At 25 minutes	89.07±6.27	88.2±4.79	82.57±5.04	0.02	0.00	0.20
At 30 minutes	89.57±9.87	89.67±3.50	83.17±4.22	0.01	0.01	0.24

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At 40 minutes	82.47±12.5	86±4.21	81.13±6.01	0.14	0.60	0.10
At 50 minutes	80.49±11.50	85.23±7.26	79.57±7.41	0.05	0.74	0.12

The Mean Heart Rate among Groups L0, H1 and H2 at baseline was 72.9±7.42, 72.80±3.6 and 74.76±5.1 respectively (p=0.72) (Table2). On comparing mean Heart Rate in between Group L0 and H1 was 81.70±5.66 and 76±3.77 (p=0.00) & Group L0 and H2 was 81.90±5.6 and 77.97±8.21 (p=0.04) respectively at 5 minutes interval and were found to be significant [Table 2]. On comparing mean Heart Rate between group L0 and H1 & L0 and H2 at 10,15,20,25,30 minutes significant results were observed (p<0.05). However, there was no significant difference observed at 40,50 minutes of surgery(p>0.05).

Table 3: Comparison of Mean Systolic Blood Pressure among group L0, H1, H2.

SBP (mm of Hg)	Group L0	Group H1	Group H2	p-value in between group L0 and H1	p-value in between group L0 and H2	p-value in between group H1 and H2
At baseline	121.56±3.29	119.63±4.81	118.93±5.95	0.07	0.38	0.62
At 5 minutes	120.57±7.90	114.8±6.02	115±6.47	0.00	0.00	0.90
At 10 minutes	119.33±9.43	113.43±4.68	113.47±5.24	0.00	0.00	0.97
At 15 minutes	118.9±7.98	111.23±6.25	112.17±5.80	0.00	0.00	0.55
At 20 minutes	114.7±8.48	108.96±6.94	112.3±6.97	0.02	0.03	0.19
At 25 minutes	113.17±8.50	108.6±6.95	109.3±6.91	0.02	0.02	0.69
At 30 minutes	112.73±8.25	106.83±7.13	106.13±6.78	0.00	0.001	0.69
At 40 minutes	117.5±6.12	116.50±7.91	118.16±5.34	0.22	0.65	0.34
At 50 minutes	118.86±6.74	119.43±6.59	119.50±5.99	0.743	0.372	0.60

Mean Systolic Blood Pressure among Groups L0, H1 and H2 at Baseline was 121.56±3.29,119.63±4.81,118.93±5.95 respectively and was found to be insignificant (p-value=0.09) [Table 3]. On comparing mean Systolic Blood Pressure in between Group L0 and H1 was120.57±7.90 and 114.8±6.02 (p=0.00) & Group L0 and H2 was 120.57±7.90 and 115±6.47 (p=0.00) at 5 minutes and was found to be significant (Table 3). On comparing Systolic Blood Pressure between group L0 and H1 & L0 and H2 at 10,15,20,25,30 minutes significant results were observed (p<0.05). However, the results were found to be statistically insignificant at 40,50 minutes of surgery(p>0.05).

Table 4: Comparison of Mean Diastolic Blood Pressure among group L0, H1, H2.

DBP (mm of Hg)	Group L0	Group H1	Group H2	p-value in between group L0 and H1	p-value in between group L0 and H2	p-value in between group H1 and H2
At baseline	78.98±7.12	79.33±6.33	77.86±5.92	0.83	0.52	0.35
At 5 minutes	75.53±3.89	78.47±7.12	75.77±5.61	0.05	0.85	0.10
At 10 minutes	73.1±5.09	77.2±7.70	73.43±5.34	0.18	0.80	0.13
At 15 minutes	72.43±5.08	76.47±6.52	73.17±5.3	0.11	0.58	0.17
At 20	71.33±6.11	75.5±4.80	72.8±5.3	0.05	0.32	0.06

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minutes						
At 25 minutes	72.6±5.81	74.87±4.69	73.23±5.41	0.42	0.66	0.39
At 30 minutes	70.67±6.56	73.27±6.11	74.53±6.20	0.11	0.42	0.42
At 40 minutes	72.77±5.11	76.23±6.45	77.53±6.34	0.07	0.10	0.43
At 50 minutes	74.9±3.14	78.43±8.41	78.1±6.14	0.07	0.09	0.86

The Mean Diastolic Blood Pressure among Groups L0, H1, H2 at Baseline was 78.98±7.12, 79.33±6.33, 77.86±5.92 respectively and was found to be insignificant (p-value=0.66) [Table 4]. On comparing mean Diastolic Blood Pressure in between Group L0 and H1 was 75.53±3.89 and 78.47±7.12 (p=0.05) & Group L0 and H2 was 75.53±3.89 and 75.77±5.61(p=0.85) at 5 minutes interval that was found to be insignificant (Table 4). On comparing Diastolic Blood Pressure between group L0 and H1 & L0 and H2 at 10,15,20,25,30,40,50 minutes significant results were observed (p>0.05).

Table 5: Comparison of Mean Arterial Pressure among group L0, H1, H2.

MAP (mm of Hg)	Group L0	Group H1	Group H2	p-value in between group L0 and H1	p-value in between group L0 and H2	p-value in between group H1 and H2
At baseline	93.16±5.27	92.76±3.96	91.55±4.59	0.74	0.21	0.27
At 5 minutes	88.81±9.4	90.57±5.27	88.23 ±4.48	0.37	0.98	0.17
At 10 minutes	88.51±4.8	89.28±5.27	86.73±4.09	0.56	0.14	0.05
At 15 minutes	87.92±4.43	88.0±5.35	86.17±3.9	0.91	0.11	0.12
At 20 minutes	86.12±4.43	89.05±5.35	86.17±3.93	0.25	0.87	0.36
At 25 minutes	87.92±4.43	87.03±5.35	86.74±3.93	0.55	0.43	0.16
At 30 minutes	84.68±5.19	82.45±4.60	85.06±5.1	0.85	0.77	0.63
At 40 minutes	87.68±4.20	89.66±4.50	91.07±5.02	0.58	0.65	0.34
At 50 minutes	89.94±3.2	90.43±5.9	90.13±4.8	0.51	0.66	0.80

The Mean MAP among Groups L0, H1, H2 at Baseline was 93.16±5.27, 92.76±3.96, 91.55±4.59 respectively and was found to be insignificant (p-value=0.37) [Table 5]. On comparing Mean MAP in between Group L0 and H1 was 88.81±9.4 and 90.57±5.27 (p=0.37) & Group L0 and H2 was 88.81±9.4 and 88.23 ±4.48 (p=0.98) at 5 minutes and was found to be statistically non-significant (Table 5). On comparing Mean MAP between group L0 and H1 & L0 and H2 at 10,15,20,25,30,40,50 minutes no significant results were observed (p>0.05).

Table 6: Comparison of Mean of Onset and Duration of sensory and motor block among group L0, H1, H2.

	Group L0	Group H1	Group H2	p-value in between group L0 and H1	p-value in between group L0 and H2	p-value in between group H1 and H2
Onset of sensory block	2.66±0.39	2.89±0.4	3.28±0.45	0.03	0.00	0.00
Duration of sensory block	81.54±4.63	95.9±2.03	97.90±2.03	0.00	0.00	0.00
Onset of motor block	3.83±0.63	5.88±0.96	5.80±0.83	0.00	0.00	0.73

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Duration of motor block	87.12±2.06	95.99±1.34	97.99±1.34	0.00	0.00	0.00

The Mean Sensory block onset among Group L0, H1, H2 were 2.66±0.39, 2.89±0.40, 3.28±0.45 respectively and was found to be significant (p=0.00) (Table 6). Mean duration of sensory block among group L0, H1, H2 were 81.54±4.63, 95.9±2.03, 97.90±2.03 respectively and was found to be significant(p=0.001) (Table 6). The Mean Motor block onset among Group L0, H1, H2 were 3.83±0.63, 5.88±0.96, 5.80±0.83 respectively and was found to be significant (p=0.00) (Table 6). Mean duration of sensory block among group L0, H1, H2 were 87.12±2.06, 95.99±1.34, 97.99±1.34 respectively and was found to be significant (p=0.00) [Table 6].

Table 7: Comparison of group L0, H1 and H2 with respect to Complication wise.

Complication/Adverse Reactions	Group L0	Group H1	Group H2
Nausea/vomiting	2	2	2
Shivering	0	0	0
Pruritis	0	0	0
Respiratory Depression	0	0	0
Any other	0	0	0

[Table 7] representation frequency distribution of cases of present complication in group L0, H1 and H2. For Shivering, Pruritis, Respiratory Depression and Any other ware not found Complication in patients and nausea/vomiting ware found 2 cases in each group L0, H1 and H2.

DISCUSSION

Hypotension is one of the most dreaded complications of spinal anaesthesia in patients undergoing cesarean section. There are numerous studies that are conducted to reduce the incidence of complications. Patient's position after intrathecal injection plays a pivotal role.

The current study emphasized on assessment of effectiveness of injecting heavy bupivacaine into subarachnoid space for inguinal hernia surgeries. This study primarily focused on to compare the effectiveness of high versus low doses of intrathecal hyperbaric bupivacaine, a widely used anaesthetic agent under both local and spinal anaesthesia for neuraxial anaesthesia as a route to inguinal hernia surgeries. Further, it evaluated the effectiveness of intrathecal hyperbaric bupivacaine for inguinal hernia surgeries employed in the participants segregated in three different groups specifically group L0, H1 and H2 as mentioned in the materials method section, at different time intervals.

In the same way, mean SBP was not significantly different across the dosage group in the baseline and assessment at 40, 50 Minutes. SBP found to be significantly different across dosage groups over the intraoperative time period of 5 –30 minutes of surgery. When group H1 and group H2 were compared to group L0, the results were consistent, and there was no discernible change in SBP among the group of patients at any of SBP recording time intervals.

Rucklidge et al,[6] used 2.5 cc of hyperbaric bupivacaine plus 10 g of sufentanil to compare the effects of left lateral, Oxford, and sitting positions for the induction of CSE in caesarean section. When compared to the lateral and Oxford position groups, the sitting group used less ephedrine and had a slower onset of anaesthesia. According to the findings, the Oxford position had no advantage over the sitting or left lateral positions.

Studies comparing sitting position to left or right lateral positions yielded disparate results. Patel et al,[7] discovered that injecting 10 mg of hyperbaric bupivacaine in the sitting position versus the left lateral position did not provide adequate analgesia for caesarean section, whereas Inglis et al,[8] discovered no significant difference in the maximum sensory block level or degree of motor block.[8] In the latter study, patients in the lateral group required more ephedrine in the first 10 minutes after spinal anaesthesia.

Unlike the previous studies, Coppejans et al. discovered that spinal anaesthesia with 6 mg of hyperbaric bupivacaine plus 3.3 g of sufentanil resulted in less severe hypotension and lower ephedrine supplementation in patients in the sitting versus right lateral position.[9] Ortiz-Gomez et al. also investigated the sitting, left, and right lateral decubitus positions during spinal anaesthesia induction using hyperbaric bupivacaine plus 20 g fentanyl. Although the incidence of hypotension and vasopressor requirements did not differ significantly, the sitting position was recommended because it was easier to administer the anaesthetic and was more comfortable for the patients.[10]

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Another study by Wang et al. found that patients who remained in the left lateral position after spinal anaesthesia in caesarean section had a lower incidence of hypotension and ephedrine requirements than patients who shifted to a left-tilt supine posture.[11] Furthermore, Hallworth et al. investigated the effects of baricity and posture on spinal anaesthesia for caesarean section, finding that the incidence of hypotension and ephedrine use increased with decreasing baricity, with the highest incidence of hypotension reported in patients who received hyperbaric bupivacaine in the sitting position.[12]

The effect of delayed supine positioning after spinal anaesthesia induction in the sitting position has also been studied in the literature. El-Hakeem et al. discovered in 2011 that sitting up for 5 minutes rather than immediately lying down reduced sensory block height, ephedrine and fluid requirements, and some adverse effects such as nausea and vomiting, while having no effect on SBP [5].

In similar studies, Kohler et al,[13] and Gori et al,[14] discovered that sitting up for 3 and 2 minutes, respectively, had no effect on the incidence of maternal hypotension or the required ephedrine dose when compared to immediately lying down. The disparities between these studies and the current research could be attributed to the varying doses and baricities of bupivacaine, which is used for spinal anaesthesia. In addition, the use of isobaric bupivacaine in the Gori et al. study versus hyperbaric bupivacaine in the current study, as well as the higher dose of bupivacaine used by Kohler et al., could explain the conflicting results.

CONCLUSION

The current study found that patient positioning is an important factor that influences the frequency of hypotension and the onset of sensory block during spinal anaesthesia for inguinal hernia repair surgery. According to the findings, keeping participants seated for 1 or 2 minutes after spinal anaesthesia, rather than immediately lying down, may reduce the frequency of hypotension.

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