Original Article

A DOSE-RESPONSE STUDY COMPARING TWO DOSAGES OF HYPOBARIC BUPIVACAINE (WITH FENTANYL 25 MCG) FOR UNILATERAL SPINAL AN ANAESTHESIA IN HIP FRACTURE SURGERY. A RANDOMIZED DOUBLE BLIND PROSPECTIVE COMPARATIVE STUDY OF 5 MG VERSUS 7.5 MG.

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Abstract

Hip joint fractures are associated with perioperative hypotension and myocardial ischemia. These patients have significant rates of coronary artery disease. This study compares the time it takes for hypobaric bupivacaine (5 mg) and bupivacaine (7.5 mg) to stop the movement of muscles during surgery for a hip fracture with bromage.ULSA or another anesthetic was used if unilateral spinal anaesthesia failed recuperation. The Aldrete and Bromage Scales were modified to aid recovery. S2 sensory block and a bromage score of 0 prompted admission. The ward recorded post-operative analgesia, rescue, and side symptoms such as nausea, vomiting, pruritus, headache, urine retention, etc. Postoperative rescue analgesia was paracetamol (1 g i.v) if the VAS was more than 4. No postoperative nausea, vomiting, or urine retention Unilateral spinal anaesthesia with 5 mg of hypobaric Bupivacaine is as effective as 7.5 mg but has fewer side effects and more stable blood pressure. Low-dose Bupivacaine-induced unilateral spinal anaesthesia helps stabilize hemodynamics.

KEYWORDS: Hypobaric Bupivacaine, Hip joint fractures, Bromage Scales.

INTRODUCTION

Individuals with hip joint fractures are more likely to experience episodes of hypotension and myocardial ischemia during the perioperative period. This is due to the fact that there is a high incidence of coronary artery disease in these patients.[1] General anaesthesia offers superior intraoperative hemodynamic stability; however, regional anaesthesia has been shown in a number of published studies to be the superior choice.[2,3,4] of these studies has been conducted. As a matter of fact, subarachnoid block, which is another name for spinal anaesthesia, can also provide hemodynamic stability by lowering sympathetic block while the patient is in an appropriate condition for surgery.

The most commonly used medicine in the process of spinal anaesthesia is hyperbaric bupivacaine 0.5%. However. Patients who are in the lateral decubitus posture will have an anesthetic effect on the dependent side if

a hyperbaric local anesthetic is provided to them, whereas the converse will occur if a hypobaric solution is used.

Therefore, the purpose of this study is to evaluate and contrast the efficacy as well as the consequences, including the hemodynamic stability, of two dosages of hypobaric bupivacaine in unilateral spinal anaesthesia (7.5 mg versus 5 mg).

AIM

This study compares the time it takes for hypobaric bupivacaine (5 mg) and bupivacaine (7.5 mg) to stop the movement of muscles during surgery for a hip fracture with bromage.

SOURCE OF SAMPLE

The study was done at the "supposed to be a university" Krishna Institute of Medical Sciences in Karad, in the Department of Anesthesiology. The study was approved by the ethics committee.

INCLUSIONCRITERIA

1. The ASA's physical state I-II.

2. People aged 60 to 80 years old.

EXCLUSION CRITERIA

1. A blood pressure reading of less than 90 millimeters of mercury in the systolic position.

2. Patients suffering from cardiovascular disease.

3. A list of conditions that should never be treated using spinal anaesthesia

STUDY DESIGN:

A Randomized Double-Blind Prospective Comparison Study was carried out.

STUDY DURATION

The patient was advised of the treatment and its risks. Every patient in the study gave their verbal and written consent. From November 1, 2021 until April 2022, the research was conducted.

SAMPLE SIZE

To detect a difference in median sensory and motor analgesia onset and duration, Mohd Kahloul et al. recommend a 95% confidence interval (α) and 90% power. We examined 5 mg and 7.5 mg hypobaric bupivacaine for unilateral spinal anaesthesia during hip fracture surgery. We studied 50 patients.

STUDY POPULATION

The study population was 60–80-year-old men and women with hip fractures and a physical status grade of I or II.

ADDITIONAL RESOURCE & SOURCE:

a) The Staff, which includes Surgeons and Anesthesiologists

b) Resources in the form of money: the research was carried out without any outside financial aid.

STUDY GROUPS:

Group A - Fifty patients with an ASA physical status of I or II received one millilitre of isobaric bupivacaine 0.5% (5 mg), 1.5 milliliters of injectable water, and 25 micrograms of fentanyl (Group B5). This solution's Pycnometer density is 0.9994 gm/ml. Hypobaric because the mean CSF density68 is 1.00059 +/- 0.00020 (SD).

50 ASA Physical Status I and II patients received 0.5% isobaric bupivacaine (7.5 mg), 1 ml of injectable water, and 25 g of fentanyl in a 1.5 ml syringe in Group B-7.5. Its Pycnometer density was 1.00050 gm/ml. This solution is hypobaric if the average CSF density is 1.00059 +/- 0.00020 SD.

STUDY VARIABLE

1. TimerequiredforBromage3afterspinal,
2. Timerequiredforbromagescoretoreturn0aftergivingspinalanesthesiaand.
3. Firstpostoperativeanalgesicrequesttime.

MATERIAL & METHOD

METHOD OF COLLECTION OF DATA

The patient gave written informed consent. Hip-fracture surgery patients were randomly allocated into two groups (Group B5 and Group B7.5). Every patient received 0.5 mg of oral alprazolam the night before surgery. Patients were given 150 mg of ranitidine two hours before surgery and told to fast for eight hours.

PROTOCOL FOR INTRA THE CALAN AESTHESIA:

The patient's heart rate, blood pressure, and mean arterial pressure were baselined before surgery. Intravenous testing began with 10 ml/kg/hour Ringer's lactate solution through a 20-gauge cannula. All patients got 4 L/min of facemask oxygen. Non-invasive blood pressure monitoring, pulse oximetry, and electrocardiograms monitored patients before, during, and after the procedure. A 5-ml syringe held eachdrug. Femoral blocks were performed with 10 ml of 2% lignocaine after premedication with 0.05 mg/kg midazolam. The patients were then placed in a lateral decubitus position with the leg to be operated on above them on a neutral table. After painting and draping, 1-2 mL of 2% lignocaine was subcutaneously injected into L3-L4 (or L4-L5) areas under aseptic conditions. A 25-gauge, 89-q Quincke's spinal needle identified the subarachnoid area.

Group B5 received 1 ml of 0.5% isobaric bupivacaine (5 mg), 1.5 ml of injectable water, and 25 g of fentanyl. This solution was 0.9994 g/mL by pycnometer. Based on the mean CSF density68 of 1.00059 +/- SD 0.00020

and Group B7.5, 1.5 ml of 0.5% isobaric bupivacaine (7.5 mg), 1 ml of injection water, and 25 g of fentanyl were given. This solution was 1.00050 g/mL by pycnometer. Hypobaric, this solution has a mean CSF density68 of 1.00059 +/- SD 0.00020. Group B5 received 1 ml of 0.5% isobaric bupivacaine (5 mg), 1.5 ml injectable water, and 25 g of fentanyl. Its Pycnometer density was 0.9994 gm/ml. If the mean CSF density68 is 1.00059 +/- SD 0.00020, this solution is hypobaric. Group B7.5 received 1.5 ml of 0.5% isobaric bupivacaine (7.5 mg), 1 ml of injectable water, and 25 g of fentanyl. Pycnometer measurements gave this solution 1.00050 gm/ml density. This hypobaric solution has a mean CSF density68 of 1.00059 +/- SD 0.00020.

RESCUE PLAN

If unilateral spinal anaesthesia failed, ULSA or another anesthetic was used. Post-surgery recuperation. Patients recovered using Modified Aldrete Scoring and the Modified Bromage Scale. After sensory block regressed to S2 and bromage score returned to 0, patients were admitted. The ward recorded post-operative analgesia duration, rescue analgesic time, and side symptoms such as nausea, vomiting, pruritus, headache, urine retention, and others. Paracetamol (1 g i.v) was given as the first rescue analgesic in the postoperative period if the VAS was greater than 4. No patients had post-operative nausea, vomiting, or urine retention.

DATA COLLECTION AND INTERPRETATION:

1. HR and BP readings from the monitor
2. Information necessary for pre-operative planning was taken from the patient's medical records.
3. The operative record sheet was used to collect data from the intra-operative period.
4. Information about how patients did after surgery was gathered from clinical assessments of patients and medical records from the ward.
5. All of the data was collected in a way that had already been decided, and it was analyzed using well-known statistical methods.

LABORATORY INVESTIGATIONS:

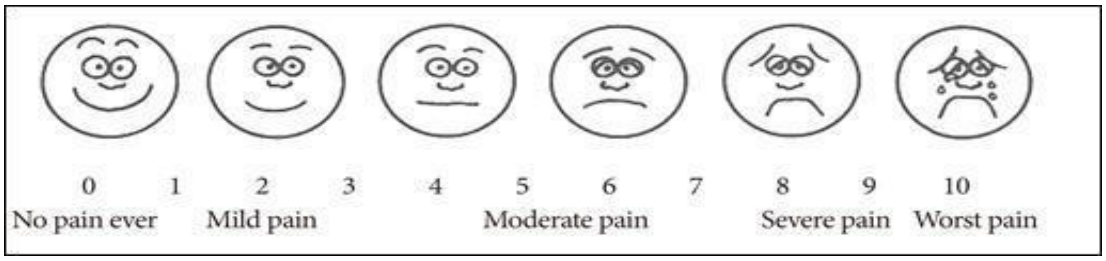
1. Routine hematological tests such as hemoglobin percentage, total leukocyte count, differential leukocyte count, and platelet count.
2. RBS,
3. Blood urea, creatinine,
4. An X-ray of the chest (PA view),
5. ECGs for all leads

STUDY TOOLS

1. Patientinformationandconsentform.
2. PatientPACsheet,O.P.Dticketandperioperativeanestheticnote.
3. VisualAnalogScale.
4. ModifiedBromageScore
5. ModifiedAldreteScore
6. Standardanaesthesiaequipmentandmonitors.

7. Proformafortabulationofdata.

Figure 1: Visualanalogscale (VAS)



MODIFIED BROMAGE SCALE

0= No Block

1= Inability to raise extended leg.

2=Inability toflex knee.

3= Inabilitytoflexankleandfoot.

Figure 2: ModifiedAldrete Score(MAS)

Criteria	Point value
Oxygenation	
SpO2 > 92% on room air	2
SpO2 > 90% on oxygen	1
SpO2 < 90% on oxygen	0
Respiration	
Breathes deeply and coughs freely	2
Dyspnoeic, shallow or limited breathing	1
Apnoea	0
Circulation	
Blood pressure ±20 mmHg of normal	2
Blood pressure ±20−50 mmHg of normal	1
Blood pressure more than ±50 mmHg of normal	0
Consciousness	
Fully awake	2
Aousable on calling	1
Not responsive	0
Activity	
Moves all extremities	2
Moves two extremities	1
No movement	0

STATISTICAL ANALYSIS PLAN:

Data was summarized using the mean or median, depending on data distribution, and standard deviation or inter-quartile range. Summarized categorical data by counts and percentages. Means, medians, and frequencies

or percentages were used for quantitative and qualitative observations. Unpaired t-tests and median tests were used by students to compare numerical variables between groups. Heart rate and mean arterial pressure changed with repeated-measures analysis of variance. Comparing categorical variables between groups required a chi-squared or Fisher's exact test. 0.05 meant something.

RESULT

The median time to Bromage 3 for both Group B5 and Group B7.5 is summarized in Table 7 and Graph 4. Group B5 had a substantially longer mean time to Bromage 3 than Group B2 (12.52 1.63 vs. 15.3 1.66 minutes; p 0.05). The average time gap between the two groups was 2.78 minutes (95% CI: -2.13%, -3.43%).

Table 1: Comparisionof Time toBromage3 inMinutes.

	Group	N	Mean ± SD	P Value
TIME TO BROMAGE 3	Group B5	50	15.3±1.66	0.000 Significant
	Group B7.5	50	12.52±1.63	

Graph 1: ComparisionofTimetoBromage3 inMinutes.

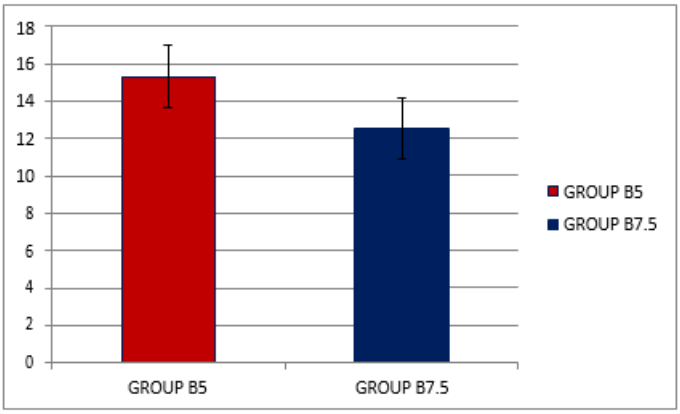
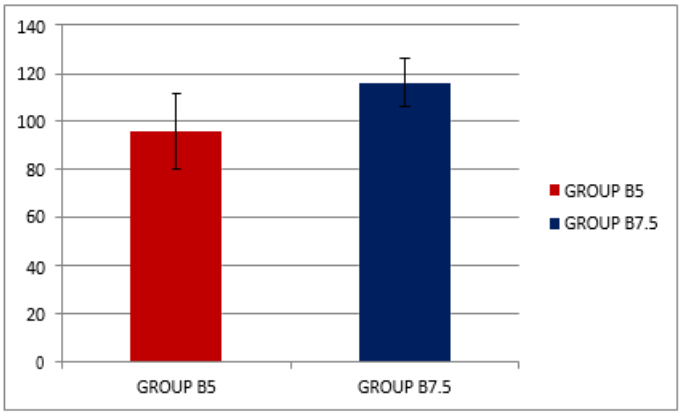


Table 1 and Graph 1 summaries the median time for Group B5 and Group B7.5 to return to Bromage 0. The average time to return to Bromage 0 in Group B5 was 81.8 14.24 minutes, compared to 104.10 minutes in Group A. This is a statistically significant difference (p 0.05). The median time gap between the two groups was 22 minutes (95% CI, 17–27).

Table 2: Comparision ofTimeto ReturntoBromage0in Minutes.

	Group	N	Mean +/-SD	P value
Time to return to Bromage 0	Group B5	50	81.8 +/- 14.24	0.000 Significant
	Group B7.5	50	104 +/- 10.10	

Graph 2: Comparision ofTimetoS2Regressioninminutes.

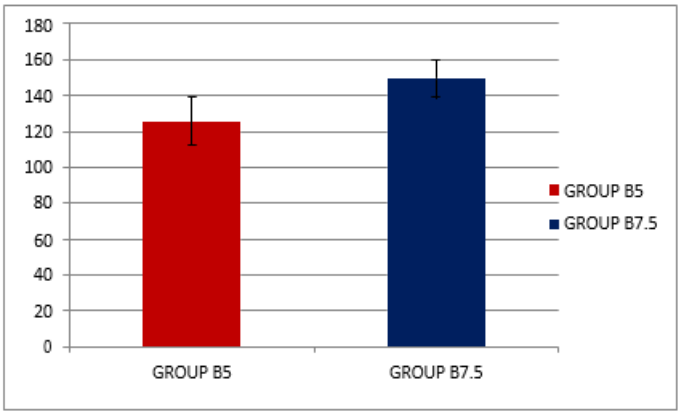


The median time until the first postoperative analgesic was administered, in hours, for patients in Group B5 and Group B7.5 is shown in Table 11 and Graph 8, respectively. The mean time to the first post-op analgesic was significantly shorter in Group B5 (125.6 13.42 min vs. 149.48 10.66 min; p 0.05). The average time gap between the two groups was 23.88 minutes (95% CI: -19.07 to 28.68).

Table 3: ComparisionofTimetoadministrationof1strescueanalgesicin Minutes.

	Group	N	Mean ± SD	P Value
Time of administration of 1st rescue analgesic	Group B5	50	125.6±13.42	0.000 Significant
	Group B7.5	50	149.48±10.66	

Graph 3: ComparisionofTimetoadministrationof1strescueanalgesicin Minutes.



DISCUSSION

Kaya et al. conducted another significant analysis of 7.5 mg of Bupivacaine's efficacy. Fifty patients had orthopaedic work done on their lower extremities. It compared two groups: those who received hyperbaric bupivacaine and those who received hypobaric bupivacaine. Hemodynamic stability was maintained, and both groups experienced rapid recovery from sensory and motor blockade. The hypobaric Bupivacaine group, on the other hand, was more likely to experience bilateralization.[5] While our study did deliver hypobaric Bupivacaine with Fentanyl, the incidence of hypotension episodes was higher in Group B7.5 and lower in Group B5 than in the current study.

Kiran et al. divided 40 patients into two groups to study the effects of hyperbaric Bupivacaine administered via unilateral spinal anesthesia: those who received 3 mg and those who received 4 mg prior to undergoing outpatient knee arthroscopy. An effective dose for knee arthroscopy was reported to be 3 mg. The 5 mg dose we used in our research of hip-area fractures was sufficient for unilateral spinal anaesthesia.[6]

CONCLUSION

Unilateral spinal anaesthesia with 5 mg hypobaric Bupivacaine is as effective as 7.5 mg but has fewer side effects and more stable blood pressure. Low-dose Bupivacaine unilateral spinal anaesthesia helps stabilize hemodynamics.

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