Original Article

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

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Abstract

General and regional anaesthesia are possible for hip joint fractures, but subarachnoid block (spinal anaesthesia) is most usual. This study compares the sensory block onset and duration of hypobaric bupivacaine (5 mg and 7.5 mg) in unilateral spinal anaesthesia for hip fracture surgery.ULSA or another anesthetic was given if unilateral spinal anaesthesia failed. Recuperation. Modified Aldrete and Bromage Scales helped patients recover. Patients were admitted after S2 sensory block and bromage score restored to 0. The ward recorded post-operative analgesia, rescue, and side effects such nausea, vomiting, pruritus, headache, urine retention, and others. If the VAS was greater than 4, paracetamol (1 g i.v) was given as the initial rescue analgesic postoperatively. Post-operative nausea, vomiting, and urine retention were absent. Unilateral spinal anaesthesia with 5 mg of hypobaric Bupivacaine is just as effective as 7.5 mg, but has fewer side effects and more stable blood pressure. Unilateral spinal anaesthesia can give hemodynamic stability due to a lower sympathetic block with low Bupivacaine dosages.

Keywords: Hypobaric Bupivacaine,Fentanyl 25 Mcg, Subarachnoid block,Hip Fracture Surgery.

Introduction

Elderly people get hip fractures frequently. Due to its safety, convenience, predictability, and lower cost than general anaesthesia, subarachnoid block is the anesthetic of choice for these fractures. Hyperbaric bupivacaine 0.5% is the most common spinal anesthetic. Low doses of local anesthetics and unilateral spinal anaesthesia help maintain hemodynamic stability during surgery, improving the prognosis. This study compared hypobaric bupivacaine (7.5 mg versus 5 mg) in unilateral spinal anaesthesia for efficacy, effects, and hemodynamic stability.

Subarachnoid block (spinal anaesthesia) is the most common method for hip joint fractures, but general and other regional anaesthesia methods are conceivable. Elderly adults have lower cardiovascular compensation, which increases the frequency and severity of hypotension owing to sympathetic block in spinal anaesthesia.[1,2,3]

Henceforth, our study compares the efficacy and hemodynamic stability of two hypobaric bupivacaine dosages (7.5 mg vs. 5 mg) in unilateral spinal anaesthesia.

AIM

This study compares the sensory block onset and duration of hypobaric bupivacaine (5 mg and 7.5 mg) in unilateral spinal anaesthesia for hip fracture surgery.

SOURCE OF SAMPLE

The Krishna Institute of Medical Sciences ("deemed to be a university"), Karad, Department of Anesthesiology, did the study with ethics committee approval.

INCLUSION CRITERIA

1. Physical status I-II of the ASA.

2. People between 60 and 80 years old.

EXCLUSION CRITERIA

1. Systolicbloodpressurelessthan90mm ofhg.
2. Patientswithcardiacdisease
3. Conditionsinwhichspinalanesthesiacontraindicated

STUDY DESIGN:

Randomized Double-Blind Prospective Comparative Study.

STUDY DURATION

The patient was informed of both the treatment itself and any potential issues that could arise from it. Every patient who participated in the study gave their verbal and written consent to participate. The research was carried out over the course of a period of one year and six months, beginning on November 1, 2021 to April 2022.

SAMPLE SIZE

According to (Mohd Kahloul et al.), we need a 95% confidence interval (α) and 90% power to detect a difference between the median onset and duration of sensory and motor analgesia. We compared 5 mg and 7.5 mg of hypobaric bupivacaine for use in unilateral spinal anaesthesia during hip fracture surgery. We used a total of 50 patients in the study.

STUDY POPULATION

Men and women between the ages of 60 and 80 with fractures around the hip joint and an American Society of Anesthesiology physical status grade of I or II were chosen as the study population.

ADDITIONAL RESOURCE & SOURCE:

a) Personnel: anesthesiologists and surgeons

b) Financial resources: the study was conducted without financial assistance.

STUDY GROUPS:

Group A - One millilitre of isobaric bupivacaine 0.5% (= 5 mg Bupivacaine), one and a half milliliters of water for injection, and 25 micrograms of fentanyl were administered to fifty patients with an ASA physical status of I or II (Group B5). This solution has a density of 0.9994 gm/ml as determined by the Pycnometer technique. In light of the fact that the mean CSF density68 is 1.00059 +/- 0.00020 (Standard Deviation), this answer is hypobaric.

Group B- 7.5 consisted of 50 ASA Physical Status I and II patients who were given 0.5% isobaric bupivacaine (7.5 mg Bupivacaine), 1 ml of water for injection, and 25 g of fentanyl in a 1.5 ml syringe. After subjecting it to the Pycnometer test, we found that its density was 1.00050 gm/ml. This solution is also hypobaric if the average CSF density is taken to be 1.00059 +/- 0.00020 SD.

STUDY VARIABLE

- Heart rate
- Bloodpressure
- TimerequiredtoachieveT10level.
- S2regressiontime.

Material & Method

METHODOFCOLLECTIONOFDATA

The patient provided their written, informed consent. Patients receiving surgery for a fracture around the hip joint were randomly divided into two groups (Group B5 and Group B7.5). Every patient was given 0.5 mg of oral alprazolam the night before surgery. Patients were instructed to abstain from eating and drinking for eight hours prior to surgery and were given 150 mg of ranitidine orally two hours prior to the procedure.

PROTOCOLFORINTRATHECALANAESTHESIA:

The patient's heart rate, blood pressure, and mean arterial pressure were taken as a baseline upon entrance to the operating room. A 20-gauge cannula was used for the intravenous assessment, and a starting volume of 10 ml/kg/hour of Ringer's lactate solution was administered. All patients received facemask delivery of supplemental oxygen at a rate of 4 L/min. Before, during, and after the procedure, patients were monitored using non-invasive blood pressure monitors, continuous pulse oximetry, and electrocardiograms. Each set of medications came in a 5-ml syringe.

After premedication with 0.05 mg/kg of midazolam, 10 ml of lignocaine 2% was used to accomplish a femoral block. The patients were then put in a lateral decubitus position, with the leg to be operated on above them, while the table remained in a neutral position. Then, after painting and draping, L3-L4 (or L4-L5 spaces) were infiltrated subcutaneously with 1-2 mL of 2% lignocaine under strict aseptic conditions. The subarachnoid space was subsequently identified using a 25-gauge, 89-q Quincke's spinal needle.

Group B5 was administered 1 ml of 0.5% isobaric bupivacaine (equal to 5 mg of bupivacaine), 1.5 ml of water for injection, and 25 g of fentanyl. According to pycnometer measurements, the density of this solution was 0.9994 g/mL. This solution is hypobaric; 1.5 ml of 0.5% isobaric bupivacaine (equal to 7.5 mg of bupivacaine), 1 ml of water for injection, and 25 g of fentanyl were administered based on the mean CSF density68 of 1.00059 +/- SD 0.00020 and Group B7.5. According to pycnometer measurements, the density of this solution was 1.00050 g/mL. This solution is also hypobaric, with a mean CSF density68 of 1.00059 +/- SD 0.00020.

Group B5 received 1 ml of 0.5% isobaric bupivacaine (= 5 mg Bupivacaine), 1.5 ml of injectable water, and 25 g of Fentanyl. Using the Pycnometer method, the density of this solution was 0.9994 gm/ml. This solution is hypobaric if the mean CSF density68 is 1.00059 +/- SD 0.00020 & Group B7.5 was given 1.5 ml of 0.5% isobaric bupivacaine (= 7.5 mg Bupivacaine), 1 ml of injectable water, and 25 g of Fentanyl. The density of this solution was determined to be 1.00050 gm/ml using the Pycnometer method. With a mean CSF density68 of 1.00059 +/- SD 0.00020, this solution is also hypobaric.

RESCUE PLAN

If unilateral spinal anaesthesia failed, ULSA or another anesthetic was tried. Patients went to recovery after surgery. In recovery, patients were assessed using Modified Aldrete Scoring and modified bromage scale. Patients were moved to ward after sensory block regressed to S2 and bromage score reverted to 0.

The duration of post-operative analgesia, the time of administering the first rescue analgesic, and the incidence of side effects (nausea, vomiting, pruritus, headache, urine retention, and so on) were all recorded in the ward. When the Visual analogue score (VAS) was greater than 4, paracetamol (1g i.v) was delivered as the first dose of rescue analgesic in the postoperative period, and this dose was repeated when the VAS score was greater than 4. None of the patients experienced post-operative nausea, vomiting, or urine retention.

DATACOLLECTIONANDINTERPRETATION:

1. HR&BPfrommonitor
2. Pre-operativedatawascollectedfromthepatient'smedicalfile.
3. Intra-operativedatawascollectedfromoperativerecordsheet.
4. Post-operative data was collected from clinical examinations of patientsandmedical recordsinthe ward.
5. All data was collected in a predetermined format and analyzed using established statistical procedures.

LABORATORYINVESTIGATIONS:

1. RoutinehematologicalinvestigationslikeHb%,TLC,DLC,plateletcount.
2. RBS,
3. Bloodurea,creatinine,
4. ChestX-ray(PAview),
5. ECGalllead

STUDY TOOLS

1. Patientinformationandconsentform.

2. PatientPACsheet,O.P.Dticketandperioperativeanestheticnote.

3. VisualAnalogScale.

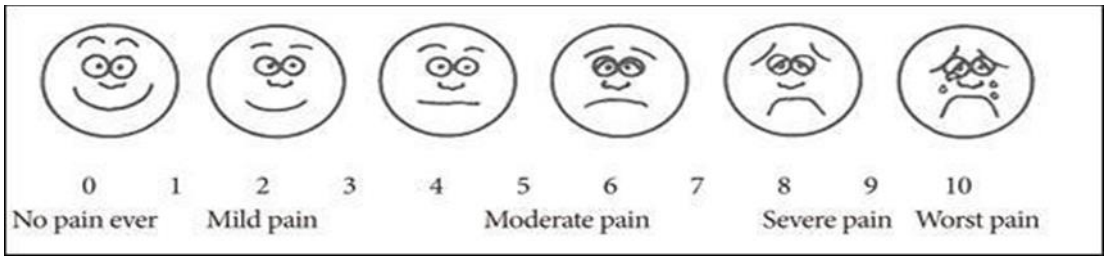
4. ModifiedBromageScore

5. ModifiedAldreteScore

6. Standardanaesthesiaequipmentandmonitors.

7. Proformafortabulationofdata.

Figure 1: Visualanalogscale (VAS)



MODIFIEDBROMAGE 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:

The mean or median, depending on data distribution, and standard deviation or inter-quartile range were used to summaries data. Counts and percentages summarized categorical data. Quantitative and qualitative observations had means, medians, and frequencies or percentages. To compare numerical variables between groups, students used an unpaired t-test and the median test. Repeated-measures analysis of variance detected changes in heart rate and mean arterial pressure. A chi-squared or Fisher's exact test was used to compare categorical variables between groups. 0.05 was significant.

ADDITIONALRESOURCESANDSOURCE:

a) Humanresources: Anesthesiologists&surgeons.

b) Financialresources: Nofinancialhelpwastakenforconductofthestudy.

ETHICAL CLEARENCE

The Krishna Institute of Medical Sciences is "deemed to be a university," and the Karad Institutional Ethics Committee approved the project. The study subject was advised of confidentiality, anonymity, and freedom to withdraw, and informed permission was obtained before data collection.

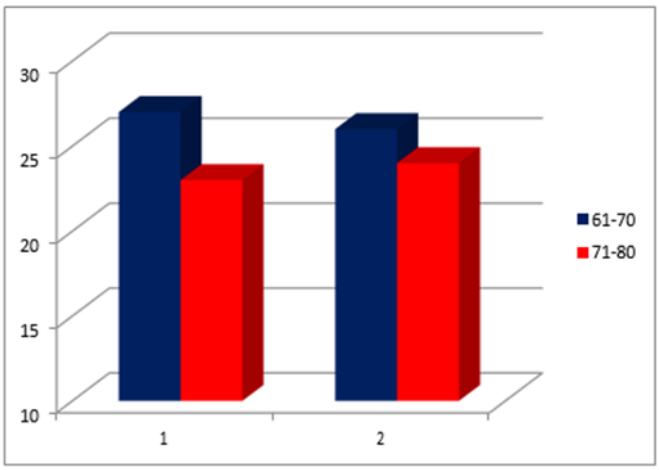
Result

Table 1 and Graph 1 show the age distribution of Group B5 and B7.5 patients. 70.92 +/- 4.33 in Group B5 and 70.56 +/- 4.62 in Group B7.5; p value > 0.05 (extremes range from 62 to 80 years in both groups).

Table 1: ComparisonofAge(Yrs)Distribution

AGE	GROUP B5	GROUP B7.5
61-70 YRS	27	26
71-80 YRS	23	24

Graph 1: ComparisonofAge(Yrs) Distribution

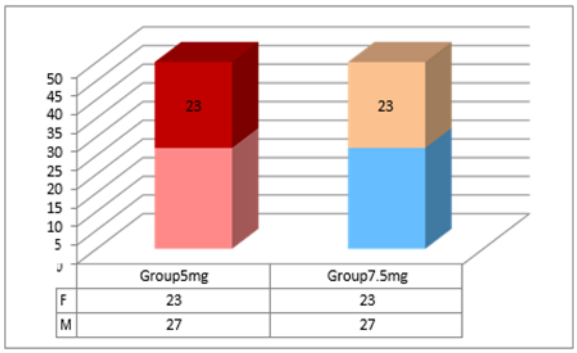


The following table 2 and bar graph 2 break down the patients in Groups B5 and B7.5 by gender. In both groups, the male-to-female ratio was 1.17.

Table 2: ComparisonofGenderDistribution(M/F)inbothgroups.

Gender	Group B5	Group B7.5
Male	27	27
Female	23	23

Graph 2 : comparisonofGenderdistribution(M/F)inbothgroups

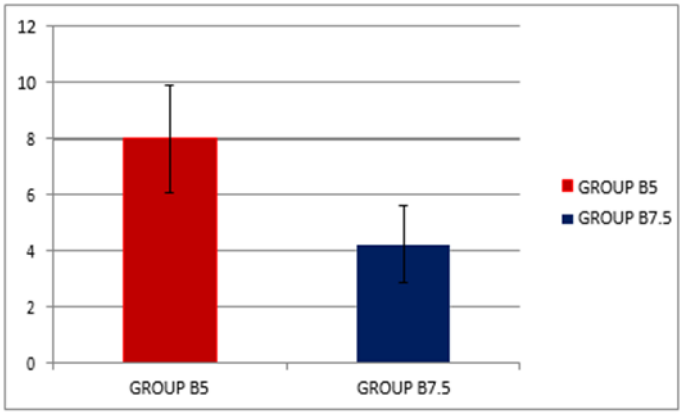


The median time until T10 sensory block occurs in Group B5 and Group B7.5 is listed in Table 6 and depicted in Graph 3. Group B5 had a substantially longer average onset time of sensory block at T10 (8 1.92 min vs. 4 1.34 min; p 0.05). Four minutes was the average time gap between the two groups (95% CI: 3.34, 4.66).

Table 3: comparisonof TimetoSensoryonsetatT10inMinutes.

	Group	N	Mean +/- SD	P Value
Time to Sensory Onset at T10	Group B5	50	8 +/- 1.92	0.000 Significant
	Group B7.5	50	4 +/- 1.34	

Graph 3: Comparisionof TimetoSensoryonset atT10in Minutes

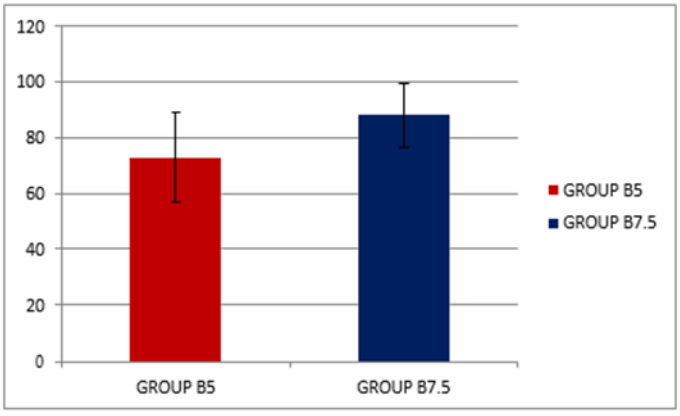


The average time for Group B5 and Group B7.5 to experience regression of sensory block after two segments is shown in Table 8 and as a bar chart in Graph 5. Group B5 had a considerably shorter median time to regression of sensory block over two segments (72.8 ± 15.91 min vs. 88.42± 0.51 min; p = 0.05). The mean time gap between the two groups was 15.2 minutes (95% CI: 9.70–20.69).

Table 4: ComparisionofTimeTo2SegmentRegressioninminutes.

	Group	N	Mean ± SD	P Value
TIME TO 2 SEGMENT REGRESSION	Group B5	50	72.8±15.91	0.000
	Group B7.5	50	88±11.42	Significant

Graph 4: ComparisionofTimeTo2SegmentRegressioninminutes.

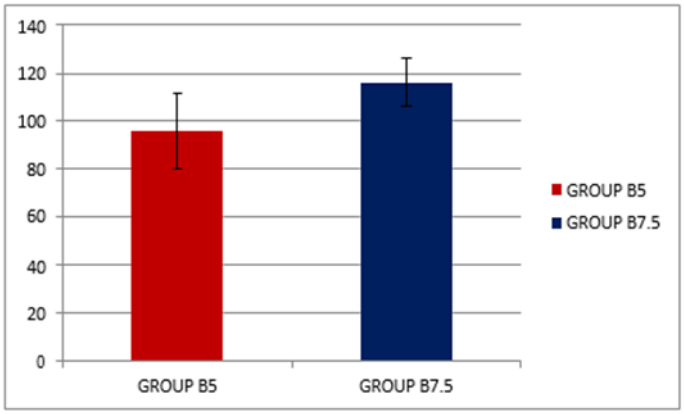


The median time for Group B5 and Group B7 to regress from sensory block to S2 is presented in Table 9 and Graph 6. Group B5 had a considerably shorter average duration for sensory block regression to S2 than Group A (95.8 ± 15.53 minutes vs. 116.2 ± 9.87 minutes; p = 0.05). The average time gap between the two sets of people was 20.4 minutes (95% CI: 15.24, 25.56).

Table 5: ComparisionofTimetoS2Regression inMinutes.

	Group	N	Mean ± SD	P Value
TIME TO S2 REGRESSION	Group B5	50	95.8±15.53	0.000 Significant
	Group B7.5	50	116.2±9.87	

Graph 5:Comparision ofTimetoS2Regressioninminutes



Discussion

Kahloul et al. compared 5 mg and 7.5 mg hypobaric Bupivacaine in unilateral spinal anaesthesia for hip fracture surgery on 108 patients in a prospective, randomized, double-blind trial.Kahloul et al. found that Group B7.5 had a substantially shorter sensory block onset time at T10 (8 ±1.92 min versus 4± 1.34 min; p 0.05). Group 1 had a considerably faster sensory block regression to S2 (91.29 ± 31.55 min versus 112.77 ± 18.77 min). However, Group B5 had a considerably lower mean time of sensory block regression to S2 (95.8± ±15.53 min vs 116.2 ± 9.87 min in Group B 7.5).[4] Nair et al. examined spinal anesthesia-assisted arthroscopic knee surgery. 15 RCTs examined 1248 pts. Five trials with 387 patients compared Bupivacaine dosages and found that 4–5 mg was sufficient. We also found 5 mg Bupivacaine (hypobaric) effective.[5] Minville et al. examined the effects of varying doses of isobaric bupivacaine on 74 patients over 75 who had spinal anaesthesia for hip fracture surgery.[6]Kaya et al. examined the efficacy of 7.5 mg Bupivacaine in another major trial. 50 patients had lower-limb orthopaedic surgery.[7]

Conclusion

Unilateral spinal anaesthesia with 5 mg of hypobaric Bupivacaine is just as effective as 7.5 mg, but has fewer side effects and more stable blood pressure. Unilateral spinal anaesthesia can give hemodynamic stability due to a lower sympathetic block with low Bupivacaine dosages.

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