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STUDY OF USE OF INTRATHECAL HYPERBARIC BUPIVACAINE (2.5MG) WITH FENTANYL FOR LOWER LIMB SURGERIES IN HIGH-RISK GERIATRIC PATIENTS

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ABSTRACT

Background & Aims: In geriatric population spinal anesthesia is associated with a high incidence of hemodynamic fluctuations. Synergism between intrathecal opioids and low dose local anaesthetics have been used to achieve reliable spinal anesthesia with minimal hypotension. A single armed prospective study was conducted with an aim to establish a safe regime of intrathecal anaesthesia with opioid for ASA III and IV geriatric patients scheduled for lower limb surgery. **Materials and Methods**: After obtaining IEC approval and registering the study for CTRI CTRI/2022/07/044344 a total of 30 ASA grade III and IV geriatric patients, of either sex undergoing lower limb surgery under spinal anesthesia were enrolled. Patients received 0.5ml of hyperbaric 0.5% bupivacaine and 25mcg of fentanyl intrathecally. Statistical analysis was carried out using the chi-squared test or Fisher's exact test, ANOVA, the Kruskal-Wallis test, Wilcoxon-Mann-Whitney U Test, Pearson's Correlation and Spearman Correlation. **Results:** All patients had satisfactory anesthesia. Out of 30 patients only 4 required (single episode) vasopressor support and other 4 had PONV. None of the patients required conversion to general anesthesia. Sensory level variability noted, which is statistically significant p value 0.0017 (<0.05), indicating variability based on patient characteristics. **Conclusion:** A dose of 2.5mghyperbaric bupivacaine with fentanyl provides optimal spinal anesthesia for short duration lower limb surgical intervention in high-risk geriatric patient, avoiding hemodynamic fluctuations and ensuring a stable perioperative and postoperative period.

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INTRODUCTION

Aging is characterised by a steady loss of functional reserve in all organ systems. As people age, they become more sensitive to the effects of anaesthetic medications, necessitating less prescription and prolonging the duration of the therapeutic impact. [1,2]

Due to the interactions with the ageing heart and vascular, hemodynamic reactions to intravenous anaesthetics may be exacerbated.[3,4] The results of a Cochrane systematic review of studies for lower limb procedures in geriatric patients demonstrate that neuraxial anaesthesia is a widely used method to prevent pulmonary compromise (atelectasis, pneumonia, and prolonged mechanical ventilation), reduce surgical stress (tachycardia and hypertension), and provide superior postoperative pain management.[3,4]

The concept of lowering the dose of local anesthetic (LA) and adding lipophilic opioids has gained popularity in place of the traditional method of spinal anaesthesia (SA) as a result of the findings from numerous studies.[3]

It is widely known that intrathecal (IT) opioids and LA have an antinociceptive synergism. This idea offers more potent and effective analgesia and could extend the effectiveness and duration of surgical analgesia without causing accompanying motor blockage[3,5].

While neuraxial opioids are safer and preferable to parenteral opioids, neuraxial anaesthesia reduces the risk of frequent postoperative side-effects encountered with general anaesthesia, such as POCD, fatigue, disorientation, pain, and gastrointestinal dysfunction.[3]

Higher ASA grade indicates significant preoperative comorbidity, when coupled with old age present a management challenge to the clinicians and demand timely aggressive approach for a favourable outcome.[3,5]

Here we aimed to study our *primary outcome* to establish a safe regime for neuraxial anesthesia in high risk geriatric patients.

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Also, *a secondary outcome that is* estimation the dermatomal level achieved, hemodynamic stability analysis of adverse effects and recovery.

MATERIAL & METHODS

A single arm interventional study was conducted after obtaining institutional ethical clearance Registration number- ECR/83/Inst/GOA/2013/RR-20 and CTRI registration CTRI/2022/07/044344.

30 patients of physical status ASA classes III and IV of either sex ≥65 years undergoing lower limb surgeries where the duration of surgery was ≤ 60 mins was included in the study. Uncooperative patient/inability to communicate effectively, patients with allergy to the drugs involved in the study, or difficult airway with impending obstruction, or any history of drug or alcohol abuse, and patients on long-term opioids or sedative medication and contraindication to central neuraxial blockade were excluded from this study.

The sample size of the study determined by considering the alpha error of 0.05 and power of study 80% was calculated to be 30. [(6)]

Informed consent was obtained from all the patients after explaining the procedure .The pre anesthetic check-up included general physical and systemic examination was done. Routine blood investigations which included complete blood count (haemoglobin, total count, differential count, platelet count), Prothrombin time and international normalized ratio (in patients who were started on anticoagulants for cardiac condition),renal function tests with serum electrolytes electrocardiogram and thorax radiograph was done .patients were kept fasting 6 hours fasting prior to the surgery . Standard monitoring including non-invasive arterial blood pressure, ECG, heart rate (HR), and oxygen saturation (SpO2) was conducted.

In preoperative anaesthesia room, intravenous access was secured with 20G cannula. Intraoperatively fluids were titrated based on the patient profile and the blood loss. Baseline blood pressure, pulse rate, respiratory rate, and SpO2 was recorded.
Under strict aseptic precautions, lumbar puncture was performed using 25G spinal needle in sitting position. After obtaining a clear and free flow of cerebrospinal fluid, 0.5ml of hyperbaric 0.5% bupivacaine and 25mcg of fentanyl was injected. All the patients received supplemental oxygen at the rate of 4 L.min-1 via Hudson mask.

The assessment of sensory block by a pinprick was performed at every minute until the maximum level was achieved (the level which will not change in between two readings taken 5 min apart.). The time required for a sensory block to reach T12 dermatome level was considered as the sensory onset. The time required for two-segment regression from the highest level achieved was considered as the duration of anaesthesia.

Motor block was assessed using a modified Bromage scale every 5 min before incision and then after completion of surgery. The time for the motor block to the Bromage scale of 2 was considered as the motor onset, and also be considered the point where surgery was allowed to start. The time to achieve one grade lower motor regression was noted.

Vitals were recorded initially every 5 minutes for the first 20 min and then every 10 minutes till the end of surgery. During surgery, any bradycardia that occurred was treated with injection atropine 1mg and if hypotension occurred then it was treated with injection ephedrine 6 mg intravenously. Total doses of atropine and vasopressors were recorded. Pain intensity was measured using Visual Analog Score every 4 and at 8^{th} hour postoperatively, between 0 and 10 (0=no pain, 10= worst pain).

The duration of spinal analgesia is defined as the time from intrathecal injection until pain score ≤4. When VAS >4 and inadequate motor blockade general anesthesia was to be considered.

Complications such as nausea, vomiting, bradycardia, hypotension, and pruritus was noted and treated accordingly. General Anesthesia was strategized in cases of failure of neuraxial anesthetic technique or insufficient anesthesia.

RESULTS

Statistical Analysis

The continuous variable (quantitative data) was expressed as mean and standard deviation. The categorical variables (qualitative data) were presented in frequency and percentage. Statistical analysis was carried out using the Chi-squared test or Fisher's exact test, repeated measures ANOVA, the Kruskal-Wallis test, Wilcoxon-Mann-Whitney U Test, Pearson's Correlation and Spearman Correlation.

RESULTS

The mean Age (Years) was 73.30 ± 6.19. 27 (90.0%) of the participants were ASA Grade: III. 3 (10.0%) of the participants were ASA Grade: IV. Out of 30 patients 13 patients were hypertensive and diabetic with past history of IHD and Met score of 4, 4 patients were with chronic obstructive pulmonary disease and were on inhalational steroids and beta agonist, 5 patients were having chronic afibrillation while 8 patients were having diabetes mellitus with nephropathy. Above demographic data of the patient had no statistical significance. (Table 1, 2)

Table 1 Summary of Demographic details and Surgery

Basic Details	Mean |Frequency (%)
Age	
60-69 Years	11 (36.7%)
70-79 Years	14 (46.7%)
80-89 Years	5 (16.7%)
Gender	
Male	18 (60.0%)
Female	12 (40.0%)
ASA Grade	
III	27 (90.0%)
IV	3 (10.0%)
Type of Surgery	
Hip Hemiarthroplasty (Bipolar)	13(43.3%)
DHS(Dynamic Hip Screw)	11(36.7%)
Lateral malleolus plating	6(20%)

Table 2 Comorbid conditions

Comorbidities	Number of patients
Ischemic heart disease with diabetes mellitus and hypertension	13(43.3%)
Chronic atrial fibrillation	4(13.3)
COPD	5(16.7)
Diabetes Mellitus	8(26.7)

ANOVA was used to explore whether the Heart Rate (BPM), systolic blood pressure, diastolic blood pressure and mean arterial pressure changed significantly over time. The mean Heart Rate (BPM) decreased from a maximum of 79.20 at the Induction timepoint to a minimum of 66.13 at the 30 Minutes timepoint, and then increased to 68.27 at the 45 Minutes timepoint. This change was statistically significant (Repeated Measures ANOVA: F = 6.8, p = <0.001). The mean Systolic BP (mmHg) decreased from a maximum of 143.37 at the Induction timepoint to a minimum of 116.40 at the 15 Minutes timepoint, and then increased to 121.97 at the 45 Minutes timepoint. This change was statistically significant (Repeated Measures ANOVA: F = 4.0, p = 0.002). The mean MAP (mmHg) decreased from a maximum of 103.17 at the Induction timepoint to a minimum of 85.13 at the 15 Minutes timepoint, and then increased to 88.53 at the 45 Minutes timepoint. This change was statistically significant (Repeated Measures ANOVA: F = 2.5, p = 0.035). Changes in diastolic blood pressure over time was not statistically significant. (Table 3)

Table 3 Hemodynamic Data

Timepoint	Heart Rate (BPM)			Repeated Measures ANOVA	
	Mean (SD)	Median (IQR)	Range	F	P Value
Induction	79.20 (11.07)	80.00 (17.00)	55.00 - 100.00	6.8	<0.001
5 Minutes	71.23 (9.37)	72.50 (13.50)	52.00 - 90.00		
10 Minutes	67.07 (3.30)	67.50 (6.00)	60.00 - 74.00		
15 Minutes	66.90 (3.10)	67.50 (6.00)	60.00 - 72.00		
30 Minutes	66.13 (4.46)	65.00 (6.25)	60.00 - 78.00		
45 Minutes	68.27 (6.80)	68.00 (9.75)	58.00 - 86.00		
Timepoint	**Systolic BP (mmHg)**			**Repeated Measures ANOVA**	
	Mean (SD)	**Median (IQR)**	**Range**	**F**	**P Value**
Induction	143.37 (9.22)	145.00 (12.00)	122.00 - 160.00	4.0	0.002
5 Minutes	126.67 (12.23)	129.00 (12.00)	90.00 - 144.00		
10 Minutes	117.87 (12.84)	116.50 (19.75)	90.00 - 140.00		
15 Minutes	116.40 (12.38)	114.00 (13.00)	100.00 - 150.00		
30 Minutes	117.70 (10.64)	118.00 (13.00)	100.00 - 140.00		
45 Minutes	121.97 (9.23)	121.00 (12.75)	102.00 - 141.00		
Timepoint	**Diastolic BP (mmHg)**			**Repeated Measures ANOVA**	
	Mean (SD)	**Median (IQR)**	**Range**	**F**	**P Value**
Induction	83.03 (7.77)	85.00 (7.75)	60.00 - 96.00	1.5	0.178
5 Minutes	75.03 (8.83)	76.00 (10.00)	46.00 - 90.00		
10 Minutes	69.50 (8.37)	70.00 (11.50)	40.00 - 84.00		
15 Minutes	69.37 (8.43)	68.00 (8.00)	52.00 - 96.00		
30 Minutes	70.07 (7.22)	67.50 (12.00)	60.00 - 90.00		
45 Minutes	71.97 (7.62)	72.00 (9.00)	60.00 - 92.00		
Timepoint	**MAP (mmHg)**			**Repeated Measures ANOVA**	
	Mean (SD)	**Median (IQR)**	**Range**	**F**	**P Value**
Induction	103.17 (6.87)	103.50 (7.75)	88.00 - 113.00	2.5	0.035
5 Minutes	91.83 (9.60)	93.50 (11.75)	61.00 - 107.00		
10 Minutes	85.70 (8.99)	86.00 (12.00)	57.00 - 99.00		
15 Minutes	85.13 (8.94)	84.50 (7.50)	68.00 - 114.00		
30 Minutes	85.97 (7.35)	85.00 (8.00)	73.00 - 107.00		
45 Minutes	88.53 (7.19)	87.50 (7.00)	75.00 - 108.00		

(Repeated Measures p value <0.05(statistically significant))

The mean Time For B3(Complete block of motor limb) (Minutes) was 12.93 ± 3.77.3 (10.0%) of the participants had Sensory blockade at the Level: T6 , 8 (26.7%) of the participants had Level: T8. 13 (43.3%) of the participants had Level: T10 while 6 (20.0%) participants had Level: T12. The mean Time taken to achieve modified bromage of B1(inability to raise extended limb but able to move knees and feet) was 91.87 ± 24.90.

There was a significant difference between the patients who achieved various level of dermatomal sensory blockade in terms of Time taken to achieve modified bromage score of B1 ($\chi 2$ = 11.450, p = 0.010), with the median Time for B1 being highest in the Level: T6 group (116.67min (30.55).

Non-parametric tests (Kruskal Wallis Test) were used to make group comparisons. (Table 4)

Table 4 Neuraxial blockade characteristics (sensory and motor)

Sensory blockade	Frequency and Percentage
T6	3(10%)
T8	8(26.7%)
T10	13(43.3%)
T12	6(20.0)
Time taken for Modified bromage scale	
Bromage 3	12.93 (±3.77) minutes
Bromage 1(duration of block)	91.87 (±24.90) minutes
Complications	
Hypotension (<90mmHg) with use of ephedrine (single episode)	4(13.3%)
PONV	4 (13.3%)
Bradycardia (use of atropine)	0

33.3% of the participants who achieved a sensory level of T6 and 37.5% of the participant who achieved T8 were administered ephedrine 6mg only once throughout the surgery. (In view of hypotension where systolic blood pressure dropped below 90 mmHg.

Fisher's exact test was used to explore the association between 'Level' and 'Ephedrine Used'. There was a significant difference between the various groups in terms of distribution of Ephedrine Used ($\chi 2$ = 8.005, p = 0.028). (Table 4) only 4 patients reported post operative nausea and vomiting, none of the patients had bradycardia or pruritis.

DISCUSSION

This study demonstrates that the use of 2.5 mg bupivacaine (0.5ml) with 25 micrograms fentanyl (0.5ml) provides hemodynamic stability, no episodes of severe hypotension and successful anesthesia for lower limb trauma surgeries in the high-risk geriatric population.

In geriatric population choice of anesthesia for lower limb surgeries can vary from general anesthesia to regional anesthesia including central neuraxial blockade (single shot spinal to combined epidural spinal) or peripheral nerve block. It is tailored based on the preoperative condition of the patients. Defining and implementing optimal perioperative care for older adults is of great importance[7,8].

According to a meta-analysis by Messina et al, baricity is the only potential confounding factor that affected the incidence of hypotension following spinal anaesthesia, supporting the idea that Spinal Anesthesia with lowered doses of LA (localAnesthetic) lowers hypotensive episodes regardless of other patient or SA-related characteristics. In comparison to the high-dose ofLA [mean 10.5 mg (2.4)], the low dose of [mean 6.5 mg (1.9)] anaesthetic was linked to a lower incidence of hypotension[9].

Intrathecal opioids increase the analgesic effects of subtherapeutic local anaesthetic doses and enable the successful induction of spinal anaesthesia with otherwise insufficient doses of local anaesthetic. [10,11].

The study done by Kumar S et al, showed that adding low-dose sufentanyl to a local anaesthetic dose allowed it to be safely and considerably reduced by 40%, preventing hemodynamic fluctuation and ensuring a stable perioperative and postoperative phase in the geriatric population. Also, the time that sensory analgesia lasts is extended, and the need for an epidural top-up after surgery is lessened[(12)]. According to a dose discovery trial, bupivacaine 4 mg + fentanyl 20 mcg was the medication combination that worked best for senior individuals undergoing quick transurethral operations[(13).] Another study found that using a low-dose bupivacaine + fentanyl spinal anaesthetic (four mg of bupivacaine plus 20 micrograms of fentanyl) for older patients undergoing surgical hip fracture repair results in effective anaesthesia and only minor hypotension[(14).]

There are very few studies done in ASA III and IV geriatric patients to compare our findings with respect to the patient profile. In randomised control trial conducted by Rabab et al., where 0.5 ml of isobaric bupivacaine in increments via intrathecal catheter along with 25 mcg of bupivacaine vs SD (single dose) of 1.5 ml of 0.5% isobaric bupivacaine and 0.5 ml of fentanyl (25 mcg) showed lower incidence of hypotension in the former group with only two patients requiring top up of 0.5 percent bupivacaine[(6)]**.**

These findings are comparable to our study where only 4 out of 30 patients had a single episode of hypotension where systolic blood pressure was recorded below 90 mmHg.

The variability in the cerebrospinal fluid volume in the elderly and a wide range of sensory block heights observed in the studies would also play a role in differential blockade observed in our study[(9)].

In our study 10.0% of the participants had Sensory blockade at the Level: T6, 26.7% had Level T8, 43.3% Level T10 while 20.0% participants had Level: T12.

A Case report in 95 year old high risk geriatric patient, by Namba et al had a similar finding of achieving dermatomal sensory level T10 with 1.5 mg of bupivacaine, supporting our findings[(15)]. Regarding Single shot spinal SA with local anaesthetics, iso or hypobaric drugs produced longer duration of motor and sensory blockade compared with the hyperbaric ones[(16).]

Study done by Jasinki et al. suggested that among the opioid adjuvants, baricity measurements revealed that pure fentanyl solution is highly hypobaric. Further this feature of fentanyl influenced the density and baricity of Local anesthetic - Adjuvant mixtures measured in the study causing a reduced density of the final mixture above 0.0006 g/mL; however, in all cases, hyperbaric solutions remained the same while isobaric solution turned hypobaric on addition of fentanyl[(17).]

In our study we were able to achieve a higher sensory dermatomal level (T6-T12) with low dose of 2.5 mg of hyperbaric bupivacaine (that is 0.5ml of 0.5% (H) bupivacaine) and fentanyl 25 mcg (0.5ml), probably due to changes in the baricity of the drug on premixing with opioid .We conducted an in vitro experiment to support our finding that addition of fentanyl in (0.5ml)to 0.5 ml of hyperbaric 0.5% bupivacaine causes change in the density of the drug mixture ,based on a similar experimental study by Sharma J et al[(18)].

To 1 ml of CSF, we added methylene blue labelled 1 ml of 0.5% hyperbaric bupivacaine in sample A and in sample B we added methylene blue labelled 0.5 ml of fentanyl and 0.5ml of 0.5% hyperbaric bupivacaine. Observations were made over time intervals 0,5 min and 30 min. Denser spread more at the base noted in sample A while sample B has an even spread of the drug, suggesting changes in the density of the drug on addiction of fentanyl in hyperbaric solution in equal amounts. *(refer figures below)*

With varied degrees of efficacy, a variety of opioid adjuvants have been employed, including morphine, fentanyl, sufentanyl, hydromorphone, buprenorphine, and tramadol. However, due to their negative side effects, particularly when used for neuraxial purposes, such as respiratory depression, nausea, vomiting, and itching, their usage has been restricted. One of the most popular classes of local anaesthetic adjuvants are alpha 2 adrenoreceptor antagonists, such as clonidine and dexmedetomidine. Other medications with varying degrees of success include neostigmine, midazolam, ketamine, and anti-inflammatory drugs including parecoxib and lornoxicam[(19)].

The most widely used intrathecal lipophilic opioid, fentanyl has a quick onset (10–20 min), a short duration of action (4-6 h), and limited cephalic spread when given as a single dose of 10–30 mcg. These characteristics reduce the possibility of delayed respiratory depression and encourage the use of intrathecal fentanyl in ambulatory anaesthesia, where it is crucial to provide increased analgesia without a lengthy hospital stay. Morphine's sluggish onset (30–60 min), dose-related duration of analgesia (13–33 h), and side-effect profile, particularly the delayed onset respiratory depression, make it unsuitable for ambulatory surgery [(9,20).]

Research have been conducted to determine if the distribution and hemodynamic stability of fentanyl and bupivacaine administered sequentially at rapid rate or slow rate or premixed vary at all. It has been noticed that rapid administration of sequential intrathecal fentanyl and bupivacaine had a quicker onset and prolonged duration of action as compared to the contrary[(21)].

Study done to assess whether premixed is better than sequential suggested that when fentanyl is administered first, followed by hyperbaric bupivacaine, sensory and motor block develops sooner and lasts longer. This also improves haemodynamic stability and reduces the requirement for rescue analgesia within 24 hours **(22).** In our study we sequentially administered fentanyl followed by bupivacaine .

Randomized controlled trials conducted to compare the effects of dexmedetomidine and fentanyl as adjuvants to LAs for intrathecal injection, reported that compared to fentanyl, dexmedetomidine as LA adjuvant in spinal anesthesia prolonged the duration of spinal anesthesia, improved postoperative analgesia, reduced the incidence of pruritus, and did not increase the incidence of hypotension and bradycardia [(23,24)]**.**

Pruritis was noted only in one patient and was not statistically significant .Motor blockade was inadequate (bromage of 2 at end of 15 minutes) only in one participant and was statistically insignificant. None of the patients had intraoperative shivering. This finding is supported by the fact established by Crowley et al that intrathecal fentanyl reduces the incidence of intraoperative shivering [(25).]

Other methods used to reduce perioperative hypotension include peripheral nerve block for hip surgeries such as ultrasound guided fascia iliaca compartment block [(26)].

Psoas compartment -sciatic nerve block, unilateral spinal anesthesia, combined epidural spinal [(27, 28, 29, 30)]

Limitations

Current study was conducted on a small sample size with no comparative group. Furthermore, study on the variability based on stature of the patient was not assessed. There is future scope for this study to compare it with combined epidural spinal and various adjuvant for the single shot spinal anesthesia.

CONCLUSION

From this study we conclude that use of 2.5 mg bupivacaine (0.5ml) with 25 micrograms (0.5ml) fentanyl provides hemodynamic stability, no episodes of severe hypotension and successful anesthesia for lower limb trauma surgeries in the high-risk geriatric population. This regimen is apt only for surgeries lasting for less than or equal to 60 minutes as although sensory blockade persists adequate motor blockade is not present for surgical manipulation thereafter.

Figure Legends

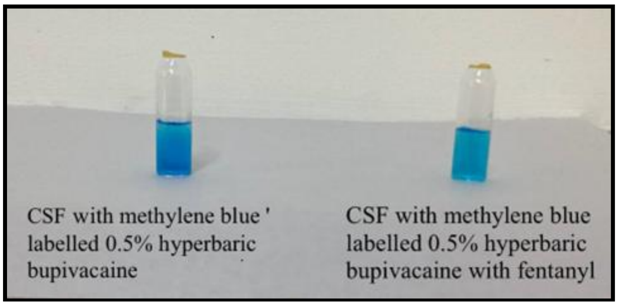

Fig 1 Study of changes in density of the local anesthetic on mixing with fentanyl *(refer discussion for detailed description)*

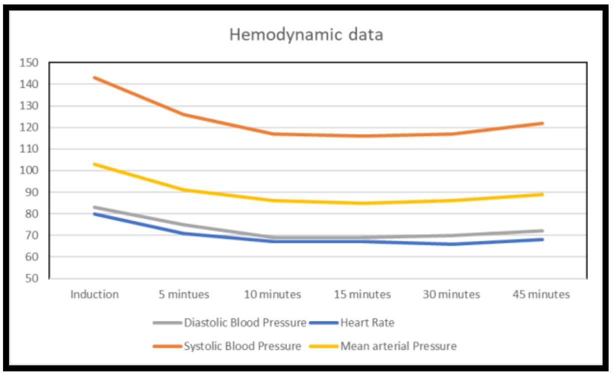

Figure 2 Hemodynamic trend over time since induction

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Conflicts of interest (if present, give details)**:** None

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