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A Prospective Comparative Study of the Efficacy of Standard Dose Bupivacaine vs. Low Dose Bupivacaine with Fentanyl for Hip Arthroplasty in Elderly Females in a Tertiary Care Hospital in South India

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Abstract
Neuraxial anaesthesia particularly spinal anaesthesia is the most popular form of anaesthesia for surgical repair of hip in the elderly because of its excellent operating conditions. But the associated high incidence of bradycardia and hypotension may be deleterious for them.
Aims: *To compare standard dose of bupivacaine with fentanyl vs. low dose bupivacaine with fentanyl for surgical repair of hip in elderly females with regard to its hemodynamic stability and adequacy for the procedure.*
Methods and Materials: *After ethical committee approval and informed consent from patients a prospective observational study was performed on elderly females posted for elective or emergency surgical repair of hip fracture under spinal anaesthesia. This study was done among two comparable groups of ASA status I-IV and age 65 yrs and above. Low dose (Group A) received 1 ml of 0.5 % bupivacaine with25 µg fentanyl and Standard dose (Group B) received 2 ml of 0.5% bupivacaine with 25 µg fentanyl.*
Statistical software: *MS Excel, SPSS version 22 (IBM SPSS Statistics, Somers NY, USA) was used to analyze data.*
Results: *Low dose spinal provides adequate duration of analgesia. Significant difference in mean blood pressure (BP) between 2 groups (P=0.001).Dose of vasopressors required to maintain BPin low dose (* $\mathbf{3.2 \pm 3.1\ mg}$ *) vs. (13.6 ± 7.4 mg)in standard dose group. Onset of sensory block delayed in low dose group.*
Conclusions: *This study shows that low dose spinal anaesthesia provides adequate anaesthesia for surgical repair of hip fracture in elderly females with excellent hemodynamic stability.*

Introduction

Elderly patients are at increased risk of osteoporosis and hence incidence of fracture particularly hip fractures are very common, more so in females. Over the age of 60 years, females were 2.3 times more likely to sustain a fracture than males (95% CI 2.1 to 2.4).[1] Neuraxial anaesthesia particularly spinal anaesthesia is the most common choice of anaesthesia for hip repair surgery but it is associated with risk of severe and

prolonged hypotension due to rapid extension of sympathetic block. This can be deleterious in elderly who have multiple comorbid conditions. Vasopressors and crystalloids are the mainstay in the management of hypotension. Another option is to limit the dose of local anaesthetic but that may not provide acceptable duration of analgesia. This can be overcome by use of additives like opioids along with hyperbaric bupivacaine which together have a synergistic effect.[2] Intrathecal fentanyl does not cause any further depression of efferent sympathetic activity, and hence it is possible to improve the quality of sensory blockade with much lower doses of local anaesthetic.[3] Our study aims to find out whether a single shot low dose local anaesthetic will provide acceptable anaesthesia for hip arthroplasty with minimal incidence of hypotension and we have compared efficacy of low dose spinal anaesthesia using 1 ml bupivacaine with 25 µg fentanyl vs standard dose of 2 ml bupivacaine with 25 µg fentanyl .

Materials and Methods

After getting approval from the Institutional Ethics Committee we studied 100 elderly females over the age of 65 years undergoing hip arthroplasty, elective or emergency, American Society of Anaesthesiologists (ASA) status I-IV from November 2017 to February 2018. A thorough pre-anaesthetic evaluation was done and informed consent was obtained from all the patients. Inclusion criteria included age more than 65 years, height between 145-155 cm and patients who had been given minimal analgesia and sedation for positioning. Patients who were given bolus dose of propofol for sedation or those given peripheral nerve blocks to aid in positioning were excluded from the study. The primary objective was whether the low dose was adequate for the procedure and secondary objective was comparison of haemodynamic stability between the two groups. Patients were kept nil per oral for 8 H prior to surgery. Upon arrival in operating room Electrocardiogram, Blood pressure monitor and pulse oximeter were connected and basal heart rate and blood pressure (BP) were recorded. Under local anaesthesia intravenous access with 18 gauge cannula in forearm was obtained and intravenous fluid 0.9% normal saline was started. As this was an observational study, the dose of subarachnoid block was decided by the attending anaesthesiologist and the outcome was assessed by the investigators who were blinded to the drug dosage and they entered the operation theatre only after patient was given anaesthesia and made supine. The subarachnoid block was done by an experienced anaesthesiologist using a 25gauge Quincke needle under all aseptic precautions. Patients were positioned in sitting posture for the procedure as it was more comfortable to patients. In those for whom they planned a low dose spinal anaesthesia they inserted an epidural catheter in L2-L3 space in case of an unanticipated delay in completion of surgery and thereafter spinal anaesthesia (1 ml of 0.5% bupivacaine and 25 µg fentanyl) was performed in L3-4 space. For patients being given standard dose of 2 ml of bupivacaine and 25 µg fentanyl, spinal anaesthesia was performed in L3-4 space. All patients given low dose spinal anaesthesia (1 ml of 0.5% bupivacaine and 25 µg fentanyl) were placed in low dose group (Group A) and those given standard drug dose (2ml of bupivacaine and 25 µg fentanyl) were placed in standard dose group (Group B). The patient and the statistician who computed the results were blinded to the drug composition. Immediately after performing the block the patients were placed in supine position. Systolic blood pressure and heart rate were recorded two minutes after giving spinal anaesthesia and thereafter every 5 min for 30 min and thereafter every 15 min till completion of surgery. For study purpose BP recordings till two hours or for the duration of surgery whichever was later was taken. Sensory block levels were checked on the bilateralmid thoracic line with a blunt needle from the time of spinal injection to the time of attainment of maximum block level. Hypotension (Systolic Blood Pressure decrease more than 30%) was treated with mephenteramine

bolus and bradycardia (less than 55) was treated with atropine. Sensory block was checked by loss of pinprick sensation. When sensory level reached T 10 level and a Bromage scale of 2 or 3 was achieved surgery was allowed to proceed. Data related to surgical time, hemodynamic stability in terms of change in blood pressure and heart rate, need for vasopressors, maximum level of sensory block and time taken to achieve that were recorded. Since motor block was not a study objective we have not recorded the onset and duration of motor block. Sample size calculation was done using Master software developed by Christian Medical College, Vellore. Taking the level of significance as 5% and power of 95% sample size was found to be 47 patients which was rounded to 50 per arm. Data was entered into Microsoft excel data sheet and analyzed using SPSS 22 version software. Categorical data was represented in the form of frequencies and proportions. Chi-square test was used as test of significance for qualitative data. Continuous data was represented as mean and standard deviation. Independent t test was used as test of significance to identify the mean difference between two quantitative variables. Paired t testis the test of significance for paired data such as before and after surgery for quantitative and qualitative data respectively. p value (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

Statistical software

MS Excel**,** SPSS version 22 **(**IBM SPSS Statistics, Somers NY, USA) was used to analyze data.

Results

The baseline demographic characteristics (Age, ASA grade) of the two groups of patients were comparable (Table 1). In Group A two patients had to be supplemented with epidural as the surgery time went beyond 150 min and in one patient spinal anaesthesia failed to act and surgery was done under epidural anaesthesia. These three patients were excluded from the study. In Group B two patients were given repeat spinal block as there was complete failure to act and two were given epidural block as there was partial analgesia and a repeat spinal was not deemed to be safe. These four patients were excluded from the study. So a total of seven patients were excluded from the study. The mean time taken to reach T10 sensory block was significantly prolonged in Group A (5.6 ± 1.2min) compared with Group B(3.8 ± 0.8 min)(P=0.001) (Table 2) Peak sensory levels showed a significant difference with majority of patients in Group B (41.3%) reaching T2 levels whereas none of the patients in Group A reached this level. Majority of patients (36.2%) in Group A reached T4 level. (P=0.001) (Table 3) There was no significant difference in mean BP between two groups at baseline but there was significant difference in mean BP between two groups at all the intervals from 2 min to 120 min (P=0.001) Mean BP was higher in Group A compared to Group B at all the intervals. (Table 4) There was no significant difference in mean heart rate between two groups at baseline and other intervals of follow up. Mean duration of surgery in Group A was 94.4 ± 16 min and in Group B was 92.6 ± 14.6 min. There was no significant difference in mean duration of surgery between two groups. (P=0.583)(Table 5)Mean vasopressor received by Group A was 3.2 ± 3.1 mg vs 13.6 ± 7.4 mg in Group B. There was significant difference in the amount of vasopressor used in two groups. (P=0.001)(Table 6)

Table 1: Age and ASA distribution of subjects in two groups

		Group A N =47	Group B N=46	
Age		72.1± 6.7	73.5 ± 8.2	P=0.347
ASA	1	4 (8.5 %)	2 (4.3 %)	χ 2 =5.815 df =3 P= 0.121
	2	14 (29.8 %)	22 (47.8 %)	
	3	26 (55.3%)	16 (34.8%)	
	4	3 (6.4 %)	6 (13 %)	

Table 2: Time of onset of sensory block

		Time of onset		P value
		Mean	SD	
Group	A	5.6	1.2	<0.001*
	B	3.8	0.8	

Table 3: Maximum level of sensor block---- comparison between two groups

		Group			
		A		B	
		Count	%	Count	%
Level	T2	0	0.0%	19	41.3%
	T4	17	36.2%	16	34.8%
	T6	15	31.9%	8	17.4%
	T8	15	31.9%	3	6.5%

$\chi 2 = 29.15$, df = 3, p <0.001*

Table 4: BP comparison between two groups at different time intervals

BP	Group				P value
	A		B		
	Mean	SD	Mean	SD	
PreOp	153.7	18.1	150.5	12.4	0.332
2 min	146.4	16.8	130.4	24.8	<0.001*
5 min	134.6	24.0	99.8	18.1	<0.001*
10 min	136.8	18.2	103.1	13.3	<0.001*
15 min	138.3	17.5	108.7	13.6	<0.001*
20 min	137.5	16.4	111.7	13.0	<0.001*
25 min	137.3	16.8	113.5	10.1	<0.001*
30 min	135.0	15.6	113.4	8.6	<0.001*
45 min	132.2	13.8	109.1	9.1	<0.001*
60 min	129.9	14.5	109.5	9.3	<0.001*
75 min	129.9	15.0	111.5	9.6	<0.001*
90 min	130.3	14.4	111.7	8.7	<0.001*
105 min	130.4	14.1	112.3	9.0	<0.001*
120 min	128.6	20.6	112.3	8.4	<0.001*

Table 5: Surgery time comparison between two groups

		Surgery time		P value
		Mean	SD	
Group	A	94.4	16.0	0.583
	B	92.6	14.6	

Table 6: Vasopressor received by subjects--- comparison between two groups

		Group			
		A		B	
		Count	%	Count	%
Vasopressor (mg)	0	6	46.2%	1	3.3%
	6	7	53.8%	8	26.7%
	12	0	0.0%	10	33.3%
	18	0	0.0%	5	16.7%
	24	0	0.0%	5	16.7%
	30	0	0.0%	1	3.3%
	Mean ± SD	3.2 ± 3.1		13.6 ± 7.4	

$\chi 2 = 21.23$, df = 5, p = 0.001*

Discussion

Elderly patients undergoing hip fracture repair constitute a high risk group with considerable mortality and morbidity and most often a protracted postoperative stay. The East Anglian hip fracture audit revealed a median hospital stay of 20 days and hospital mortality of 5-24%.[4]In view of age, frailty and perceived high cardiovascular risk in this patient population it is likely that many remain under resuscitated before, during and after the surgery as clinicians fear that giving excessive fluids will precipitate left ventricular failure. They are also likely to have a reduced intravascular volume in the perioperative period probably due to decreased fluid intake as a result of immobility and associated dementia. Neuraxial anaesthesia particularly spinal anaesthesia is the most common choice of anaesthesia for hip repair surgery in the elderly because of its many advantages like speed, reduced blood loss and protection against thromboembolic complications. A recent systemic review on 141 trials including 9559 patients reported that overall mortality and number of myocardial infarction were reduced by one third in patients who were allocated to neuraxial block.[5] This strongly supports use of regional anaesthesia for fracture repair in elderly. But hypotension associated with spinal block may be deleterious to them. A study done by Charlson ME et al.[6] in patients with hypertension and diabetes mellitus undergoing noncardiac surgery reported ischemic complications in 19% of patients who had intra operative decrease in mean arterial pressure greater than 20 mm Hg lasting 5min-59 min or more. Elderly patients have multiple co morbid conditions which places them in the high risk group. Bone cement implantation during bipolar hemiarthroplasty may cause prominent hemodynamic changes in the very elderly. A study done by Hye Jin Park et al.[7] found that to maintain hemodynamic stability after cement insertion the requirement of ephedrine was higher in the very old age group (≥85 years) than old age group (65-84 years) (13.52±7.76 vs

8.65±6.38, P=0.001) This superadded hypotension due to bone cementing makes it imperative to limit the hypotension caused by spinal block especially in the very elderly. Haemodynamic effects of spinal anaesthesia are mostly studied observing arterial pressure and heart rate. Mainstay of treatment of hypotension is increasing fluid infusion and using vasopressors. However if fluids are not judiciously given, the high incidence of cardiac problems in these patients predispose them to increased incidence of pulmonary oedema. Another option is to reduce the dose of local anaesthetic. A large retrospective study done on 1131 patients for proximal femoral fracture repair observed correlation between volume of 0.5% hyperbaric bupivacaine and fall in systolic blood pressure and concluded that those receiving bupivacaine less than or equal to 1.5 ml were less likely to experience absolute or relative hypotension.[8] Though limiting the dose of local anaesthetic can decrease hypotension it may not provide adequate surgical anaesthesia. Addition of opioids like fentanyl can overcome this problem. Mohammed Qamarul Hoda et al.[9]in their study concluded that low dose of 6 mg bupivacaine with 20 µg fentanyl provided adequate anaesthesia for surgical repair of hip.In their study they found that mean ephedrine usage was much lower in low dose group. This is in accordance with our result and the vasopressor use in our study in standard group is 13.6±7.4 mg and in low dose group is3.2 ± 3.1 mg.In our study BP of two patients of standard dose group was not controlled even after giving 24 mg mephenteramine and they had to be stabilised with phenylephrine infusion. In another study done with low dose spinal bupivacaine with fentanyl none of the patients developed hypotension or bradycardia.[10] Ben David etal.[11] studied two groups of elderly patients ≥70 years coming for repair of hip fracture. They found that only one patient in low dose group required ephedrine, a single dose of 5mg whereas nine out of ten patients in the other group required vasopressor support. They studied only 20 patients and their study was discontinued at this number of patients because with even this small number there was significant difference between the two groups and they felt that they could not justify a higher dose spinal anaesthetic. Gupta et al.[10] noted the duration of effective analgesia(time from the onset of adequate analgesia to the first postoperative analgesia request) to be 221.67±26.92min . Though we did not look for the total duration of spinal block we observed the patient for 2 hours from the time of spinal injection or till the completion of surgery whichever was later and none of our patients complained of pain during the study period except for two patients whose surgery got prolonged beyond 150 min. Adequacy of spinal sensory block was assessed using verbal patient feedback or physical signs of discomfort during surgery and in postoperative period. After the attainment of maximum sensory block, height block was not routinely measured and therefore we cannot comment on block regression. Mean surgical time was nearly 90 min and none of the patients complained of pain during the procedure. Two patients in low dose group complained of pain when the surgery time took more than 150min and had to be supplemented with epidural. Duration of motor block in the study done by Kumar et al.[12] was recorded as 98.167±5.796min. Probably because our surgical time was around 90 min none of our surgeons complained of inadequate muscle relaxation .We have not studied the duration of motor block as it was not our study objective. In our study the low dose group took longer time (5.6 ± 1.2 min) to achieve adequate sensory level of T_{10} and it is in accordance with other studies.[13,14] The reduced volume of the drug may be the reason for delay in achieving adequate sensory level. In our study the highest sensory level achieved with low dose was T4. This differs from other study where highest level achieved was T7.[14] 41.3% patients in standard group reached T2 level in our study. Clinical studies have shown that the characteristics of neural block after administration of subarachnoid bupivacaine changes with

increasing age.[15] In particular the level of analgesia extends approximately three to four segments higher in the elderly compared to young adult population. In our study population which comprised only of elderly females with a height of about 145-155 cm the addition of fentanyl to standard dose group also might have resulted in a higher level of sensory block. Also since the spinal was given in a sitting position the speed with which patient was made supine may also have influenced the level as spill over can occur into the higher dermatomal segments. Studies done with low dose bupivacaine and 25 µg fentanyl have provided adequate anaesthesia with stable haemodynamics for transurethral resection of prostate and percutaneous nephrolithotomy and lower abdominal surgeries [16,17,18]since these surgeries also need a level of T10 it further supports our results that an adequate level of spinal block can be achieved with a low dose. The use of sub anaesthetic doses of local anaesthetic is supported by the study done by Labbene et al. [19] Block duration vs. age needs further study. One should be cautious in extrapolating the results of this study to younger patients either in terms of adequacy of the dose orin terms of duration of surgical anaesthesia for surgical repair of hip. Neither can one extrapolate these findings to other surgeries for which a higher cephalad level of block may be required.

Conclusion

This study shows that low dose spinal anaesthesia provides adequate anaesthesia for surgical repair of hip fracture in elderly females. In prolonged surgeries combined spinal epidural technique utilising low dose spinal bupivacaine with fentanyl may be a better option because it provides excellent haemodynamic stability with the flexibility to prolong anaesthesia.

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