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Original research article: A study of comparative evaluation of bupivacaine plain versus bupivacaine with fentanyl in spinal anaesthesia in geriatric patients

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Abstract
Background: The undertaking of complex and major surgical procedures on frail elderly patients with multiple disorders has always been and still remains a controversial and enigmatic issue. At the same time, in an increasingly ageing society, the need for such procedures will extend and the patients will expect a more favorable outcome. Surgery in old age will, therefore, pose an ongoing challenge.
Objectives: The aim of the study is comparative evaluation ofbupivacaine plain versus bupivacaine with fentanyl in spinal anaesthesia in geriatric patients.
Methodology: This prospective study includes60 patients of age 65 year or more than 65 year undergoing hip replacement. The study population was randomly allocated to two groups; Group A(n=30) - 15mg of 0.5% bupivacaine & Group B(n=30) - 10mg of 0.5% bupivacaine and 25µg of fentanyl.
Result: Systolic B.P. decreased in both the groups, maximum fall occurred at 15 to 20 min in both the groups: decreases were more severe in group A than in group B,(P<0.O5).heart rates were better maintained in group B than in group A. thus group B showed better hemodynamic stability. Group B had lesser duration of motor blockage without significantly compromising the duration of sensory block or the operative conditions. None of the patients required intraoperative anesthetic supplementation. 8 patients in group B had pruritus while none of the patients developed respiratory depression.
Conclusion: Spinal anesthesia for elderly patients undergoing lower limb surgeries with 2cc bupivacaine 0.5% and 25 µgfentanyl is a safer and better option, both in terms of maintaining hemodynamic stability and lower incidence of complications without compromising the surgical conditions.

Keywords: Spinal anaesthesia, Drugs: Bupivacaine, Fentanyl, Geriatric patients

1. Introduction

Intrathecal opioids are synergistic with local anaesthetics and intensify the sensory block without increasing the sympathetic block [1].

Elderly surgical patients undergo approximately 20% or more of all surgical procedures in acute care hospitals across the country. The presence of age-related systemic changes and multiple co-morbid conditions often limits their functional capacity and recovery and increase the risk of peri-operative morbidity and mortality. [2]It is universally agreed that the anaesthesia of choice for lower limb surgeries is subarachnoid block. Regional anaesthesia is generally well tolerated by the elderly patients, producing less postoperative confusion and delirium than general anaesthesia. It is also associated with lesser incidence of post-op thromboembolism. However subarachnoid block has got its own inherent complications, especially related to cardiovascular stability [3].

The combination makes it possible to achieve spinal anaesthesia with otherwise inadequate doses of local anaesthetic as intrathecalopoids offer hemodynamic stability. As interathecal morphine is assiciated with higher incidence of side effects, use of newer opioids like fentanyl are combined with local analesthetics which have milder side effects.

Regional anaesthesia is well tolerated by geriatric patients undergoing orthopaedic surgery, producing less postoperative confusion and delirium than general anaesthesia[4]. In the nongeriatric population, the association of fentanyl and local anaesthetics improves the sensory block induced by the spinal administration of local anaesthetics in the intra and postoperative period. The advantages and risks of this procedure have not been fully examined in the elderly[4,5] although Varrassi*et al.*[5]have reported respiratory depression after the administration of 50 µg, of spinal fentanyl.

On the basis, of the routine use of spinal anaesthesia for orthopaedic surgery and the presumed increased "sensitivity" to opioids in the geriatric population, we designed a protocol to evaluate a) the characteristics of the spinal block and incidence of side effects induced by bupivacaine plus fentanyl and b) the consequences of the administration of spinal fentanyl on mental function in the immediate postoperative period.

2. Material and Methods

This prospective study was conducted at B J Medical College and Civil hospital,Ahmedabad,Gujarat from from year 2000-2001.60 patients aged 60 yrs or older, scheduled for total hip replacement under spinal anaesthesia were evaluated.

First group received bupivacaine alone(Group A,n=30) and the second group a combination of bupivacaine and fentanyl(Group B,n=30). Patients satisfying the inclusion criteria were randomly divided into groups of 30 each. Both

the patient and the principle investigator were blinded for the drug, which was
being administered during the period of observation.

Inclusion criteria
- ASA I,II & III
- Age >60 yrs
- Height 155-175
- Patients posted for lower limb surgeries

Exclusion criteria
- History of allergy to local anaesthetics
- Patients with severe cardiac or respiratory disease eg. Cardiac arrhythmia, abnormal cardiac anatomy or congestive cardiac failure,
- Patients with psychiatric illness, mental retardation,
- clinical evidence of significant dehydration
- Hemoglobin concentration less than 8g/dl
- Patients with uncontrolled hypertension, taking medications such as digoxin.

Prior to inclusion in the study, all potential patients underwent a rigorous physical and psychological examination, minimental state examination test [MMSE][6]to exclude those with severe psychiatric disorders, depression and/or dementia which could interfere with the comprehension of the protocol. Patients suitable and willing were visited again the night before surgery and ASA physical status, associated pathologies (unrelated to the surgical problem), adequacy of treatment and drugs consumed were recorded and the information stored in a database (Table I).

Table 1: Pre-operative assessment

Associated Pathology (a)	Drugs (b)	Adequacy of treatment
01Respiratory	01Respiratory	1 Asymptomatic, treated
02Cardiovascular	02 Cardiovascular	2 Symptomatic,treated
03Neurological	03Endocrine	3 No treatment
04Psychiatric	04CNS	4 No symptoms
05Muscle-bone	05Analgesic- anti-inflammatory	
06Endocrine	06 Opthalmological	
07Digestive		
08 Kidney		
09Genitourinary		
10 Neoplasia		
11 Infections		
12 Opthalmological		

Factors (a) and (b) were subdivided into items reflecting common pathologies and drugs
CNS = Central Nervous System

All patients were premedicated with 5 mg of oral diazepam the night before surgery. In the operating room, routine monitoring was used, and the patients received a slow infusion of 500 mL of lactated Ringer's solution over a period of 30 min. With the patient in left lateral position, spinal anaesthesia was administered at L_3-L_4 through a 23 gauge spinal needle. Patients were randomly distributed in two groups who received spinal anaesthesia in a final volume of 3.0 mL: 12.5 mg of hyperbaric bupivacaine plus saline (Group A, n = 30) or the same dose of the local anaesthetic plus 25 μg of fentanyl (Group B, n = 30). The anaesthesiologist who administered the drugs and the patient were blinded as to the combination used. The following variables were recorded: latency and upper level of sensory block (pin prick): onset and degree of motor blockade (Bromage scale, 1-4); intraoperative discomfort with the following scores: 0 no distress; 1 slight (need of a single dose of an anxiolytic drug); 2 moderate (need of two doses); and 3 intense (more than two doses). Intraoperative vitals signs were recorded every 10 minutes. Midazolam at 1 mg increments was used for intraoperative sedation and no other drugs were administered intraoperatively.

During surgery, blood loss, blood replacement, and urine output were recorded. The following side effects were also recorded: respiratory depression (estimated as a decrease in SaO_2 less than 90%), hypotension (when mean arterial pressure (MAP) decreased to less than 20% of baseline values obtained prior to anaesthesia) and nausea, vomiting, and/or itching.

In the recovery room, vital signs were recorded every 20 mins for six hours then hourly upto 12 hours from start of anaesthesia. At the time of analgesia request (TAR), pain intensity was assessed by a visual analog scale graded 1-100 mm (VAS). Duration of motor and sensory blocks were also recorded. The MMSE test was performed at the TAR. Complications like, bradycardia, hypotension, respiratory depression, nausea and vomiting, itching were recorded.

All the observations were recorded and all the results were analysed statistically and compared using the student's 't' test. P-value <0.05 was considered significant.

3. Results

Groups were comparable regarding demographic variables, type and duration of surgery (Table 2). Incidence of associated pathologies/patient was 2.6 and 2.9 for each group with a prevalence of cardiovascular (51% and 59% for Groups A and B), muscle-bone (30% and 11%, p <0.02, x^2 test), and ophthalmological (32% and 30%) disorders. Similarly, the number of drugs taken was 2.3 in each group; in both, the most commonly consumed drugs were analgesic-antiinflammatory (40% and 52%), cardiovascular (36% and 52%). When individual pathologies were evaluated in relation to treatment, 32% and 26% (Groups A and B, respectively) of the disorders did not receive treatment; 16% (Group A) and 22% (Group B) were symptomatic regardless of therapy, and

in 28% (Group A) and 30% (Group B) the medication was appropriate (patients asymptomatic). Regarding preoperative cognitive function, values of MMSE were within normal limits for the geriatric population (25.3 ± 0.7 and 25.8 ± 0.6 for groups A and B, respectively).

Table 2: Patient Characteristics

	GROUP	
	A(n=30)	**B(n=30)**
N	30	30
Age (yrs)	68.80±2.12	66.85±2.48
Weight (kg)	68.9±1.8	69.6±1.8
Height (cm)	148.8±1.8	152.6±1.8
No. pathologies/patient	2.5±0.1	2.4±0.2
No drugs/patient	2.2±0.2	2.1±0.3
Surgery		
Type THR/DHS	12 /8	11/9
Duration (min)	140.75±8.03	141.65±8.54

Table 3: Characteristics of the spinal block

	GROUP		P-value
	A	B	
Sensory			
Latency (min)	13.58±0.73	12.73±0.36	
Level (at surgery)	T-7	T-8	
TAR (min)	191.90±4.01	219.65±7.02	< 0. 0 1
Levelat TAR	L-4	L-4	
Motor			
Latency (min)	5.8±0.41	5.7±0.62	
Duration (min)	160.9±5.5	163.75±2.9	
Discomfort			
Incidence(n)	8	4	
Degree (0-3)	2.25±0.89	1.50±0.58	< 0. 0 5

Table 4: Prevalence of side effects

	GROUP	
	A	B
Prevalence, n (%)		
Hypotension	9 (30%)	15 (50%)
RD	4 (13%)	7 (23%)
Pruritis	-	8 (26%)
Nausea and vomiting	5 (17%)	2 (6%)

There was no statistically significant difference regarding latency of sensory/motor and duration of motor block but there was significant difference in the duration of sensory block and degree of discomfort between two groups (Table 3), the latter was evaluated according to a simple score system graded 0-3 (see Methods). The results show that the block was satisfactory (adequate sensory/ motor block and zero discomfort) in 12 (saline) and 16 patients (fentanyl). The rest of the patients had an acceptable block, but presented different degrees of discomfort; in Group A, four patients had a degree of discomfort of 3, two patients had a degree of discomfort of 2 and another two a degree of 1, while in Group B, two patients had a score of 2, two had a score of 1. None of the patients required the administration of intravenous analgesics prior to completion of surgery.

Table 5: Pain intensity and cognitive function at the time of analgesia request (TAR)

Group	TAR (min)	VAS (mm)	MMSE
A	193.90±4.46	66.50±4.01	25.45±1.23
B	221.65±7.02	34.00±4.47	25.00±1.34
P-value	<0.001	<0.001	>0.05

On arrival to the operating room, MAP, heart rate, and SaO_2 were comparable in both groups. All of these variables showed a significant decrease ($p < 0.001$) after the spinal block was established; the decrease in MAP and heart rate was approximately 20% in both groups. Hypotension was treated with mephenteramine (3 mg boluses) and the slow administration of lactated Ringer's solution. Pre and post-blockade values for SaO_2 were 94.2% ± 1.24% and 93.35% ± 2.01% in Group A, and 93.35% ± 1.46% and 90.90% ± 2.15% in Group B ($p = 0.007$). Thus, fentanyl significantly decreased SaO_2 in these patients. Incidence of side effects was more frequent in Group B. When the effects were analyzed individually, pruritis and respiratory depression were significantly more recurrent in Group B ($p = 0.02$) (Table 4).Pruritis was localized in the upper abdomen, thorax, and face; of the four patients with pruritis, three required the administration of intramuscular droperidol.

Blood loss (740 ± 51 and 810 ± 87 ml, Groups A and B, respectively), blood replacement (252 ± 82 and 335 ± 124 mL, Groups A and B, respectively) and diuresis (345 ± 20 and 310 ± 40 mL, groups A and B, respectively) were comparable in both groups.

In the recovery room, the TAR was significantly increased in group B (Table 5) and, pain intensity at the TAR was significantly lower in Group B when evaluated by VAS ($p = 0.001$). Cognitive function (MMSE test), evaluated in the recovery room at the TAR and again the day before discharge from the hospital, did not show significative differences from pre-operative values.

4. Discussion

The present study shows that, in elderly patients, adding 25 µg of fentanyl to bupivacaine during spinal anaesthesia does not alter the latency of sensory and motor block/duration of motor block but prolongs the duration of sensory block, reduces intraoperative discomfort and decreases the pain intensity in postoperative period. Our findings agree with those of Wang *et al.*[7] Singh *et al.*[8] Dahlgren *et al.*[9]Nigiam*et al.*[10] Singh *et al.*[11]Belzarena*et al.* [12]Bendavid*et al.* [13] as all concluded that fentanyl does not alter onset of sensory or motor block but prolongs duration of sensory block without prolonging recovery of motor block. In addition, we did not find significant differences in the upper sensory level of the block at any time point measured.

Postoperative period is usually associated with less ambulation and therefore chance of stagnation of blood is more. This increases the risk of venous thromboembolism. This risk is even higher among the orthopaedic procedures and elderly. One significant and interesting finding we got was the lesser degree of motor blockade in the combination group when compared to the bupivacaine alone group. The duration of motor blockade was also higher for Group A than Group B. However the surgical conditions were found to be satisfactory in both the groups and none of the patients

required any supplementary anaesthetic interventions during the surgery. Pruritus is considered as the most common side effect of intrathecal opioids. Mulroy*et al.*[14] has noted a reduced incidence of pruritus when fentanyl is combined with bupivacaine than when combined with lignocaine. Pruritus is thought to be mediated through the μ receptors present centrally.Workers havefound ondansetron to be significantly useful for the treatment of this pruritus. In our study 8 among the thirty in the fentanyl group had pruritus. No one from the other group experienced pruritus which is consistent with the above mentioned studies.

The incidence of nausea and vomiting were not seen in any of these groups. Mannulang *et al.* [15] in a double blinded randomized study has reported that intrathecal fentanyl is superior to ondansetron for prevention of peri-operative nausea and vomiting during caesarean section under spinal anaesthesia.

Inspite of the intravenous administration of 500 mL of lactated Ringer's solution, the spinal block induced a comparable decrease in MAP in both groups, supporting the finding that prehydration does not regularly preclude hypotension induced by sympathetic blockade during spinal anaesthesia. The results also show that in geriatric patients, 25 μg of spinal fentanyl do not alter the cardiovascular response to the spinal block.

In the recovery room, duration of sensory block was prolonged in patients receiving fentanyl; also patients receiving fentanyl requested analgesia with lower VAS scores than those in the saline group. This finding could be related to the steep (and coinciding) dissipation of the effects of bupivacaine and probably reflects a residual analgesic effect of fentanyl that surfaced when the sensory block induced by bupivacaine vanished.

Regarding cognitive function evaluated by the MMSE[14], we did not find significant changes in the mental status of our patients, demonstrating that in geriatric nondemented patients, orthopedic surgery under regional anaesthesia does not alter cognitive function.

5. Conclusion

Spinal anesthesia for elderly patients undergoing lower limb surgeries with 2cc bupivacaine 0.5% and 25 μg fentanyl is a safer and better option, both in terms of maintaining hemodynamic stability and lower incidence of complications without compromising the surgical conditions.

6. References

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