Original Research Article

Comparative study of intrathecal low dose hyperbaric bupivacaine 7.5mg and 12.5mg hyperbaric bupivacaine using fentanyl as an adjuvant in elderly patients undergoing lower limb and abdominal surgeries

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Abstract

Background: Spinal anaesthesia for lower limb surgeries is routinely used. It provides both analgesia and muscle relaxation, has rapid onset of action. However, many geriatric patients have coexisting cardiac or pulmonary diseases, it's very important to limit the distribution of the block to prevent the possible hemodynamic and pulmonary adverse effects by using very small doses of local anesthetics. Many adjuvants have been used to prolong the duration of spinal anaesthesia. **Aim:** The aim of this study is to compare intrathecal low dose bupivacaine (7.5mg) + fentanyl (25µg) and 12.5mg bupivacaine + fentanyl in elderly patients undergoing lower limb and abdominal surgeries. **Material and methods:** Prospective, randomized, comparative study. After obtaining the Institutional ethics committee clearance and informed consent, a total of 80 elderly patients with ASA grade II-III scheduled for elective lower limb and abdominal surgeries were recruited in this study. Study was carried out at Dept, of Anaesthesiology, Krishna institute of medical sciences, Secunderabad. **Results:** Onset of sensory blockade, onset of motor blockade, time for two segment regression of sensory blockade, duration of motor blockade, duration of analgesia were studied. These parameters were tested every 2minutes until complete motor and sensory levels were achieved. Hemodynamic parameters like HR,SBP,DBP,MAP were studied in both the groups, and were recorded every 5 min for first 30 min, then every 15 min till the end of surgery . Demographic variables age, sex, ASA grade, weight, height were all comparable between the two groups. Basline HR, MAP, SPO2 were also comparable between the two groups. Time for onset of sensory blockade(group A- 4.17 ± 0.446 & group B – 3.5 ± 0.599 (p value 0. 001) Onset of motor blockade (group A- 5.28±0.504 & group B - 4.36±0.476 (p value 0.001).Duration of motor blockade (group A- 116.4±7.669 & group B-232.82±13.311 p value 0.001), In group B, there was significant delay in two segment regression of sensory blockade (group A- 81.05± 5.905 & group B – 129.75± 15.890 p value 0.001) and also longer duration of analgesia was seen (group A- 177.83± 13.7 & group B - 228.80± 14.576 p value 0.001). **Conclusion:** Based on the above observations, we conclude that low dose bupivacaine(7.5mg) with fentanyl is as good as 12.5mg bupivacaine with fentanyl in elderly patients undergoing lower limb and abdominal procedures as it provides profound analgesia, good muscle relaxation, good patient and surgeon satisfaction and better hemodynamic profile.

Keywords: Spinal anaesthesia**,** Bupivacaine, Fentanyl, HR, MAP, SPO2, lower limb,

Introduction

Spinal Anesthesia is a popular and common anesthesia procedure practiced worldwide. It was first performed by August Bier more than a century ago by injection of cocaine into CSF of a patient. Spinal anesthesia is the gold standard for abdominal /lower limb surgeries in geriatric patient population.

During the peri-operative period, it provides effective sensory and motor blockade and involves use of a small volume of drug, having virtually minimal systemic pharmacologic effects, and yet produce profound sensory analgesia. Epidural anaesthesia necessitates the use of a large mass of local anaesthetic that produces pharmacologically active systemic blood levels. These may have side effects and complications, not seen with spinal anaesthesia[1].

As the average life span has been recently increased due to an advancement of medical service quality and the rise of attention on health conditions, the aging population started to rapidly increase.

Normally, sensory block levels are approximately 3–4 dermatomes higher in those of older age than in young adults[2,3].The sympathetic block level is generally 1–4 segments higher than the analgesia level[4,5]. Thus, in elderly patients, high sympathetic block is frequent during spinal block, which may explain frequent cardiovascular side effects, compared to young adults. Most of the elderly patients, having a coexisting cardiovascular, pulmonary or some other co-morbid conditions, it is important to restrict the block level in these patients.

Selective spinal anesthesia (SSA) is defined as "the practice of employing minimal doses of intrathecal agents so that only the nerve roots supplying a specific area and only the modality that is required to be anesthetized are affected[6]. Thus, SSA is more appropriate in elderly patients[7]. Additionally, rapid recovery with spared motor function is a tremendous boost to patient satisfaction.

In the past, lignocaine was widely used intrathecally in clinical practice due to its properties like rapid onset of action and good diffusability. In spite of this, its action was not sufficiently long, so as to provide pain relief in the post operative period and it was also implicated in producing neurotoxicity[8,9]. Then,A.F.Ekanstam and his colleagues synthesized Bupivacaine in 1957 at Sweden[10]. It was used clinically by Telivuo in 1963. Bupivacaine was the first local anaesthetic that combined the properties of an acceptable onset, long duration of action and low incidence of transient radicular irritations with spinal bupivacaine[11].

0.5% Heavy bupivacaine is most commonly used local anesthetic for spinal anesthesia, However, effectiveness of sole bupivacaine is controversial. Addition of opioids like fentanyl intrathecally, prolongs the duration of sensory block induced by local anaesthetics without prolonging motor recovery[12] and also reduces the dose requirement of local anaesthetic, yet still provide excellent analgesia for surgical procedures[13]. But, intrathecal fentanyl in dosage of 50 micrograms or higher can cause respiratory depression in the elderly**[14]**.

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Intrathecally administered fentanyl or sufentanil can rapidly be diffused into the spinal cord and bound to opioid μ receptor due to their lipophilic essentials[15].When they are given with even low dose bupivacaine, the anesthetic quality of spinal block is enhanced as well[13,15,16].

The purpose of the present study is to compare the effectiveness of low dose Intrathecal hyperbaric bupivacaine 7.5mg verses 12.5 mg added to fentanyl 25 µg, for lower limb and abdominal surgeries in geriatric patient population.

Aims & objectives

To compare intrathecal low dose bupivacaine(7.5mg) + fentanyl (25µg) and 12.5mg bupivacaine + fentanyl(25µg) in elderly patients undergoing lower limb and abdominal surgeries

With regards to,

- Onset of sensory blockade in minutes.
- Maximum height of sensory blockade.
- Onset and duration of motor blockade in minutes.
- Time to 2- segment regression.
- Assessment of analgesia- duration of analgesia,
- VAS score, time to first pain medication.
- Hemodynamic changes like heart rate and blood pressure.
- Side effects/complications.

Materials and methods

Methodology

After institutional ethics committee approval and obtaining written informed consent from all patients, 80 ASA (American Society of Anesthesiologists Physical Status) grade II- III patients, aged 60 to 75yrs, scheduled for elective lower limb, abdominal and urological surgeries were enrolled in this comparative study conducted at Department of Anaesthesia in Krishna Institute of Medical Sciences, Secunderabad.

The patients were randomly allocated into two study groups according to a list of random numbers obtained from the random number table.

Group A received an intrathecal injection of 0.5% hyperbaric bupivacaine 7.5mg with 25 µg fentanyl= 2ml total volume.

Group B received 0.5% hyperbaric bupivacaine 12.5 mg with 25 µg fentanyl=3ml total volume.

Anaesthesia Technique

A thorough pre-operative evaluation was done one day prior to surgery. On the day of surgery, a quick examination was carried out and laboratory investigations recorded. Then patient was shifted to operating room. Standard monitoring devices like NIBP, Pulse oximeter and ECG were attached, and venous access was secured, if not already present. Pre-operative vitals of the patient were recorded.

Before starting anesthesia, procedure of spinal anesthesia and methods of sensory and motor assessment was explained to the patients. All patients were started on IV lactated Ringer's solution.

Inj Ondansetron 0.1 mg/kg was given to all patients as premedication. The procedure of spinal puncture was performed through midline approach at L3-L4 interspace (L4-L5 in case of failure) with a 25G quincke needle in the sitting position. After checking the free flow of cerebrospinal fluid, drug was administered over 10 sec with gentle aspiration. The direction of the needle aperture was kept cranial during the injection. All patients were immediately placed in a supine position following the injection. Oxygen was administered via Hudson mask if required.

Parameters evaluated

1. The **sensory block levels** and the **time** to achieve till T10 were assessed bilaterally on the midclavicular line using an alcohol swab and pinprick (26 G hypodermic needle) every 2 minutes until the peak level was reached, then every 30min until the end of the procedure. Postoperatively every hour till complete regression of block. When the peak sensory and cold blocks were obtained, the loss of touch sense to light finger touch was assessed.
2. **Maximum height of block achieved (peak level)** and time to achieve the same, defined as the interval from intrathecal administration to the maximum height achieved in terms of dermatomes where patient is unable to perceive pinprick sensation were recorded.
3. **The motor block** was evaluated using the modified Bromage scale .
   0: No motor block
   1: Inability to raise extended leg; able to move knees and feet
   2: Inability to raise extended leg and move knee; able to move feet
   3: Complete block of motor limb
   Assessment of motor block was done every 2min until grade 3 bromage scale achieved, at the beginning of the surgery, end of the surgery and post operatively every hour until grade 0 of bromage scale.
4. **Time to 2 segment regression** is defined as the interval from the maximum height of block till the point of regression of the sensory block of 2 segments when the patient starts perceiving pinprick sensation.
5. **Time to complete recovery of motor block** is defined as the interval from intrathecal administration to the point of complete resolution of the motor block i.e. to the point where the Bromage score will be back to grade 0 and patient starts to move his legs and feet freely.

At the end of surgery, surgeons satisfaction is assessed in the ease of operation with respect to muscle relaxation.

Haemodynamic changes

a) **Pulse Rate (PR)** – Bradycardia was defined as heart rate (HR) below 50 bpm and was treated with 0.3-0.6 mg of iv Atropine and supplemental Oxygen with a Hudson mask.

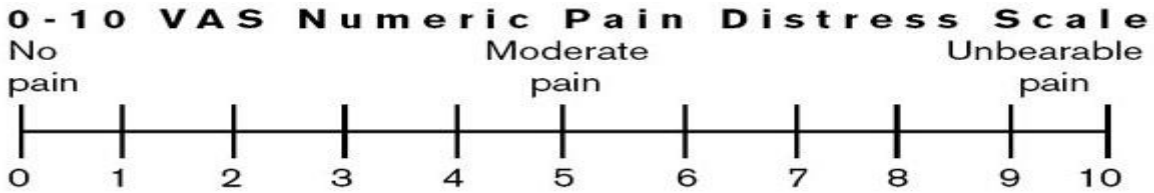
b) **MAP---** Hypotension was defined as a MAP decrease of > 20% or SBP < 90 mmHg alone. It was treated with incremental iv doses of 6 mg of injection Mephentermine.

c) **SpO2-**was recorded. Oxygen was delivered if SpO2 was less than 95%.

d) **Respiratory depression** (RR<8 or SpO_2 <95%) was treated with O_2 supplementation or respiratory support if required.

Analgesia

a. **Duration of analgesia (min):** It was noted as time interval from intrathecal injection to complaint of pain by the patient (min).
b. **First post-operative analgesia & VAS Scale criteria:** Visual analog score (VAS) was utilized for administration of first post-operative analgesia. VAS criteria of ≥ 6, was used to administer analgesia in the form of Inj. Diclofenac Sodium 1.5 mg/ kg intravenous infusion.



Side effects

The incidence of adverse effects such as nausea, vomiting, pruritus, respiratory depression and hypotension were recorded.

Statistical analysis

The data obtained is coded and entered into SPSS version 20. The categorical data expressed as rates, ratios and proportions and Quantitative data expressed in mean and standard deviation (SD).

The data analysed using independent sample't' test and Mann Whitney U tests. A probability value (p) of < 0.050 is considered as statistically significant.

Results

Table 1: Age Distribution among Study Groups

	Group	N	Mean	Std. Deviation	P Value
Age	A	40	66.98	3.840	0.953
	B	40	66.93	3.710	

p-value > 0.05 , which is statistically insignificant , so our study was comparable in age.

Table 2: Sex Distribution in Both Study Groups

		Sex		Total	P Value
		Female	Male		
Group	Group A	19	21	40	0.366 Not significant
	Group B	15	25	40	
Total		34	46	80	

P value >0.05, which is statistically insignificant so our study was comparable for sex distribution among both the groups.

Table 3:Height Distribution among Study Groups

	Group	N	Mean	Std. Deviation	P Value
height(cms)	A	40	162.33	6.010	0.766
	B	40	161.98	4.329	

p-value >0.05 , which is statistically insignificant, so our study was comparable in height distribution .

Table 4:Weight Distribution among Study Groups

	Group	N	Mean	Std. Deviation	P Value
weight(kgs)	A	40	63.63	4.533	0.750
	B	40	63.95	4.557	

p-value >0.05 , which is statistically insignificant, so our study was comparable in weight distribution.

Table 5: ASA distribution among Study Groups

		ASA		Total	P value
		II	III		
Group	A	18	22	40	0.822 Not significant.
	B	17	23	40	
Total		35	45	80	

P value >0.05, which is statistically insignificant, so our study was comparable in ASA distribution.

Table 6: Pre operative heart rate in both the groups

		N	Mean	Std. Deviation	P value
pre op HR	Group A	40	78.55	8.376	0.562*
	Group B	40	79.95	6.034	

Since p is >0.05, pre op HR profile was not significantly different in both the groups.

Table 7:Pre operative map in both groups

		N	Mean	Std. Deviation	P Value
Pre –op MAP	Group A	40	86.95	6.740	0.654*
	Group B	40	87.67	7.553	

Since p is >0.05, pre op MAP profile was not significantly different in both the groups.

Table 8: Pre Operative SPO_2 In Both Groups

		N	Mean	Std. Deviation	P Value
SPO2	Low Dose	40	98.55	1.518	0.420
	Conventional Dose	40	98.30	1.224	

Since p is >0.05, pre op SPO_2 profile was not significantly different in both the groups.

Table 9:Time in minutes for onset of sensory block to T_{10}

	Mean + SD	p-value
Group A	4.17±.446	0.001
Group B	3.50±.599	

Time taken for onset of sensory blockade to T10 is longer in group A(7.5mg bupivacaine +25mcg fentanyl) and is statistically significant as p value <0.05.

Table 10:Time taken for maximum sensory block level

	Mean ± SD	p-value
Group A	6.35±1.231	0.001
Group B	4.50±.641	

Time taken for maximum sensory blockade is longer in group A(7.5mg bupivacaine +25mcg fentanyl) and is statistically significant as p value <0.05

Table 11:Maximum Height of Block

Group	maximum Height	Frequency	Percent
GROUP A	T10	25	62.5
	T6	5	12.5
	T8	10	25
	Total	40	100.0
GROUP B	T10	5	12.5
	T5	2	5.0
	T6	25	62.5
	T8	8	20
	Total	40	100.0

Majority (62.5%) of participants who received low dose achieved maximum height of up to T10 whereas majority of participants receiving 12.5mg dosage achieved maximum height of up to T5.

Table 12: Onset of motor block in minutes

	Mean ±SD	p-value
Group A	5.28+0.504	<0.001
Group B	4.36+0.476	

Mean time for Onset of Motor Blockade is higher (5±0.5) with low dose spinal anaesthesia when compared to 12.5mg dose (4±0.5) and this difference is statistically significant.

Table 13: Modified Bromage grade at the start of surgery

		Motor block grade at the start of surgery		Total
		TWO	THREE	
Group	A	25	15	40
	B	0	40	40
Total		25	55	80

Out of 80 study participants, Modified bromage grade-III at the start of surgery constitute 55 in number of which 15 were administered with low dose spinal anesthesia, 40 with 12.5mg dose spinal anesthesia.
Modified bromage grade-II at the start of surgery constitute 25 of which 25 were administered with low dose spinal nnesthesia and 0 with 12.5mg dose spinal anesthesia.

Table 14: Modified Bromage grade at the end of surgery

		Motor block grade at the end of surgery			Total
		ZERO	TWO	THREE	
Group	Low Dose	1	24	15	40
	Conventional Dose	0	0	40	40
Total		1	24	55	80

Out of 80 study participants, Modified bromage grade–III at the end of surgery constitute 55 in number of which 15patients were administered with low dose spinal anesthesia, 40 with 12.5mg dose spinal anesthesia .
Modified bromage grade-II at the end of surgery, constitute 24 patients of which 24 were administered with low dose spinal anesthesia and 0 with 12.5mg dose spinal anesthesia .
Modified bromage grade-O at the End of surgery, constitute 01 of which 01 were administered with low dose spinal anesthesia and 0 with 12.5mg dose spinal anesthesia .

Table 15:Time taken for 2-segment regression in minutes

	Mean±SD	p-value
Group A	81.05±5.905	0.001
Group B	129.75±15.890	

Time taken for 2-segment regression was longer in group B, and is statistically significant, as p value <0.05.

Table 16:Time to complete recovery to bromage 0 in minutes

	Mean±SD	p-value
Group A	116.40±7.669	0.001
Group B	232.82±13.311	

Time taken for complete recovery to bromage 0 was longer in group B ,and is statistically significant, as p value<0.05
There is Statistically Significant difference between the means of, Time to two segment Regression and time taken for complete recovery from anesthesia in relation to dosage of Spinal Anesthesia.

Table 17:Duration of analgesia in minutes

	Mean±SD	p-value
Group A	177.83±13.700	0.001
Group B	228.80±14.576	

Mean time taken for post-op analgesia is 178±14 seconds with low dose spinal anesthesia while it is 229±15 seconds with 12.5mg dose Spinal Anesthesia. There is statistically significant difference between time taken for Post-Op Analgesia between the two groups.

Table 18:Heart Rate at Different time Intervals:

		N	Mean	Std. Deviation	P value
pre op HR	GROUP A	40	78.55	8.376	0.562*
	GROUP B	40	79.95	6.034	
After spinal HR5 Min	GROUP A	40	78.25	8.880	0.001
	GROUP B	40	70.48	9.323	(V. Significant)
HR 10 Min	GROUP A	40	77.90	7.792	0.001
	GROUP B	40	67.75	10.374	(V. Significant)
HR 15 Min	GROUP A	40	76.45	8.718	0.001
	GROUP B	40	65.25	10.921	(V. Significant)
HR 20Min	GROUP A	40	74.98	9.691	0.001
	GROUP B	40	65.28	10.013	(V. Significant)
HR 25Min	GROUP A	38	73.79	9.754	0.001
	GROUP B	40	65.10	11.010	(V. Significant)
HR 30Min	GROUP A	25	75.92	7.686	0.001
	GROUP B	26	66.15	8.889	(V. Significant)
HR 45Min	GROUP A	19	73.74	10.439	0.029
	GROUP B	17	67.06	6.329	(Significant)
HR 60Min	GROUP A	15	71.93	10.250	0.084 *
	GROUP B	10	65.10	7.534	
HR 90Min	GROUP A	9	77.67	4.770	0.007
	GROUP B	4	69.50	1.000	(V. Significant)

* Not Significant.

Table 18 shows the HR at different time intervals in both the groups. Inter-group statistical analysis of HR at different time intervals both shows statistically significant difference of (Mean ± SD) of HR at 5 min to 45 min intervals among both groups. ($p<0.05$)

The mean heart rate at preoperative level is similar in both low dose and 12.5mg doses later there is a steady decrease of heart rate at 5, 10, 15 ,20, 25, 30 and 45 minutes in the 12.5mg dose when compared to the low dose which is statistically significant. Low dose is hemodynamically more stable than the 12.5mg dose.

Table 19: Mean Arterial Pressure at Different Time Intervals

		N	Mean	Std. Deviation	P Value
MAP	Low Dose	40	86.95	6.740	0.654*
	Conventional Dose	40	87.67	7.553	
MAP 5	Low Dose	40	85.20	6.760	0.001
	Conventional Dose	40	77.90	8.961	(V. Significant)
MAP 10	Low Dose	40	85.63	6.319	0.001
	Conventional Dose	40	76.05	9.860	(V. Significant)
MAP 15min	Low Dose	40	83.90	6.122	0.001
	Conventional Dose	40	75.55	8.964	(V. Significant)
MAP 20	Low Dose	40	83.80	5.703	0.001
	Conventional Dose	40	75.10	9.405	(V. Significant)
MAP 25	Low Dose	38	83.24	4.863	0.001
	Conventional Dose	40	74.40	8.427	(V. Significant)
MAP 30	Low Dose	25	84.28	4.551	0.001
	Conventional Dose	26	74.88	7.207	(V. Significant)
MAP 45	Low Dose	19	80.89	6.064	0.036
	Conventional Dose	17	75.59	8.419	(V. Significant)
MAP 60	Low Dose	15	81.00	6.118	0.003
	Conventional Dose	10	71.30	8.744	(V. Significant)
MAP 90	Low Dose	9	79.00	5.268	0.135 *
	Conventional Dose	4	72.50	9.539	

* Not significant.

Table 19 shows the MAP at different time intervals in both the groups. Inter-group statistical analysis of MAP at different time intervals show statistically significant difference of (Mean ± SD) of MAP at between 5 min to 60 min intervals among both groups ($p<0.05$).

Pre operatively the mean arterial pressure is similar in the both the groups .The mean arterial pressure is low in 12.5mg dose than low dose anaesthesia at all the time intervals starting from 5 minutes to 60 minutes . The mean arterial pressure is better controlled with low dose anaesthesia than 12.5mg dose which is statistically significant.

Table 20: SPO2 values at Different time intervals

		N	Mean	Std. Deviation	P Value
SPO2	GROUP A	40	98.55	1.518	0.420
	GROUP B	40	98.30	1.224	

SPO2 5	GROUP A	40	99.90	.496	.006 *
	GROUP B	40	99.48	.816	
SPO 10	GROUP A	40	99.90	.304	.002*
	GROUP B	40	99.35	1.027	
SPO2 15 min	GROUP A	40	98.83	5.987	.549
	GROUP B	40	99.40	.810	
SPO2 20	GROUP A	40	99.48	.679	.171
	GROUP B	40	99.23	.920	
SPO2 25	GROUP A	38	99.53	.725	.888
	GROUP B	40	99.50	.906	
SPO2 30	GROUP A	25	100.00	.000	.332
	GROUP B	26	99.92	.392	
SPO2 45	GROUP A	19	100.00	.000	-------
	GROUP B	17	100.00	.000	
SPO2 60	GROUP A	15	100.00	.000	-------
	GROUP B	10	100.00	.000	
SPO2 90	GROUP A	10	100.00	.000	-------
	GROUP B	4	100.00	.000	

Table 20 shows the SPO_2 at different time intervals in both the groups. Inter-group statistical analysis of SPO_2 at different time intervals show statistically significant difference (Mean ± SD) of SPO_2 between 5 min to 10 min intervals among both groups ($p<0.05$).
Oxygen saturation levels were maintained at adequate levels at all the time intervals by 12.5mg and the low dose anesthetic groups.

Table 21: Incidence of bradycardia

		Bradycardia		Total	P value
		NO	YES		
Group	GROUP A	39	1	40	<0.001 Significant
	GROUP B	22	18	40	
Total		61	19	80	

Out of 80 study participants, 19 had Bradycardia of which 1 was administered with Low dose Spinal Anesthesia and remaining 18 with 12.5mg dose Spinal Anesthesia.
61 didn't had any Bradycardia of which 39 were administered with Low dose Spinal Anesthesia and 22 with12.5mg dose Spinal Anesthesia.
There is statistically significant association between presence of Bradycardia and type of dose in spinal anesthesia.

Table 22: Incidence of hypotension

		Hypotension		Total	P VALUE
		NO	YES		
Group	GROUP A	36	4	40	0.048 Significant
	GROUP B	28	12	40	
Total		64	16	80	

Out of 80 study participants, 16 patients had hypotension of which 4 were administered with Low dose Spinal anesthesia and remaining 12 with 12.5mg dose Spinal Anesthesia.
64 patients didn't had any hypotension of which 36 patients were administered with low dose Spinal Anesthesia and 28 with 12.5mg dose Spinal Anesthesia.
There is statistically significance association between incidence of hypotension and type of dose in spinal anesthesia.

Table 23: Incidence of nausea and vomiting

		Nausea, Vomiting		Total	P Value
		No	Yes		
Group	GROUP A	39	1	40	0.305 Not .Significant
	GROUP B	37	3	40	
Total		76	4	80	

Out of 80 study participants, 4 patients had Nausea, Vomiting of which 01 was administered with low dose spinal anesthesia and remaining 03 with 12.5mg dose spinal anesthesia.
76patients didn't had any Nausea, Vomiting of which 39 were administered with low dose spinal anesthesia and 37 with 12.5mg dose spinal anesthesia.
There is no statistical significance association between Presence of Nausea, Vomiting and type of dose in spinal anesthesia.

Table 24: Presence of pruritus

		Pruritis		Total	P Value
		No	Yes		
Group	GROUP A	37	3	40	0.104 Not .Significant
	GROUP B	32	8	40	
Total		69	11	80	

Out of 80 study participants, 11patients had pruritis of which 03 patients were administered with low dose spinal anesthesia and remaining 08 patients with 12.5mg spinal anesthesia
69 patients didn't had any pruritis of which 37 patients were administered low dose spinal anesthesia and 32 patients with 12.5mg spinal anesthesia
There is no statistical significant association between presence of pruritis and type of dose in spinal anesthesia.

Table 25: VAS scores

	Group	N	Mean	Std. Deviation	P value
1hr	GROUP B	40	2.10	1.057	
	GROUP A	40	3.03	1.230	<0.001
3hr	GROUP B	40	3.75	1.032	
	GROUP A	40	6.25	.742	<0.001
5hr	GROUP B	40	4.58	.844	
	GROUP A	40	7.50	.987	<0.001

Mean VAS score at 1hr with12.5mg dose spinal anesthesia is 2±1 and with low dose spinal anesthesia is 3±1.
Mean VAS at 3hrs with with12.5mg dose spinal anesthesia is 4±1 and with low dose spinal anesthesia is 6±1.
Mean VAS at 5hrs with with12.5mg dose spinal anesthesia is 5±1 and with low dose spinal anesthesia is 8±1.
There is Statistically significant association between VAS score and type of dose in spinal anesthesia.

Table 26:Drug Intervention

Drug Intervention	Group-A	Group B
Mephenteramine 6mg	2	7
Mephenteramine 6mg + Atropine 0.6 mg	0	3
Mephenteramine 12 mg + Atropine 0.6 mg	0	1
Atropine 0.6 mg	1	14
Not used	37	15

Table 27:Surgeon satisfaction

		GROUP A	GROUP B	Total
surgeon satisfaction	No	3	0	3
	yes	37	40	77
Total		40	40	80

		GROUP A	GROUP B	Total	P Value
surgeon satisfaction	yes	37	40	77	> 0.05

Z test for differences in proportion was used. (Exact p value =0.076).The Surgeon satisfaction was similar in both low dose(7.5mg) and 12.5mg dose of Anaesthesia.

Discussion

Regional anesthesia is commonly employed for lower limb and abdominal procedures and is also better choice. The technique is simple, rapid onset & is reliable. The risk of aspiration or mishaps of airway and polypharmacy associated with general anaesthesia are avoided by this technique.

Bupivacaine is routinely used for most of the lower limb and abdominal procedures because of its high potency and minimal neurological symptoms. As endoscopic urological procedures are short procedures and also to limit the block in elderly, low dose of intrathecal L.A is sufficient, addition of fentanyl gives a reliable block[13,17] and also decreases the analgesics in early postoperative period.

Work has been done to find the most effective dose which can provide optimal peri-operative and post-operative analgesia, while minimizing the hemodynamic instability.

A total of 80 patients with ASA grade II and III, who were planned for elective lower limb and abdominal surgeries were selected. The study was a prospective, randomized study. The patients were distributed randomly into 2 groups with 40 patients in each group.

Group A received an intrathecal injection with 7.5 mg (1.5 ml) of 0.5 % Hyperbaric Bupivacaine + 25 mcg (0.5 ml) Fentanyl.

Group B received an intrathecal injection with 12.5 mg (2.5 ml) of 0.5 % Hyperbaric Bupivacaine + 25mcg (0.5 ml) fentanyl.

Demographic profile

Our study showed that both the groups are comparable with respect to Age, Sex, Height, Weight, ASA grade as the p-value >0.005.

D Fernandez-Galinski et.al assessed the risks and benefits of the administration of fentanyl

during spinal anesthesia in the elderly. Forty patients (70-83 yr) undergoing knee or hip replacement were studied. Groups were comparable regarding demographic data and are not significant (p>0.05)[18].

Sachi Mehta et.al compared hemodynamic and sensory effects of low dose bupivacaine-fentanyl in spinal anaesthesia versus conventional dose of bupivacaine in 60 elderly patients undergoing surgical repair of lower limb fractures.The demographic data (age, weight, sex & ASA grading) were comparable and statistically non significant[18].

Preoperative Vitals

Preoperative vitals include Heart rate, MAP, SpO2. These values were comparable among the two groups and had no clinical or statistically significant difference (p>0.05).

Onset of sensory and motor blockade

The onset time of sensory blockade to T10 (mean ± SD) was found to be 4.17 ± 0.446 min and 3.5 ± 0.599 min in group A and group B respectively.

The onset time of complete motor blockade (mean ± SD) was 5.28 ± 0.504 min in group A, 4.36 ± 0.476 min in group B.

There was a significant difference ($p < 0.05$) seen with regards to onset of sensory and motor block between the groups with earlier onset in group B when compared to group A. The results of the present study are comparable with following studies.

Sachi Mehta et al[19] evaluated two different doses group A (Bupivacaine-15mg,3ml) & group B (Bupivacaine-10mg, 2ml + 25 mcg [1ml]fentanyl)in 60 patients undergoing elective lower lower limb orthopedic surgeries. The time of onset of adequate level of sensory block (T10) was longer for group B (128 +/- 8.3sec) than group A (95 +/- 10.32sec) and was statistically significant. Addition of fentanyl reduces the pH of hyperbaric bupivacaine. This may be reason for delay in onset of adequate block. In my study both groups had fentanyl but onset is longer in group A because of usage of low dose of bupivacaine.

Highest level of sensory blockade

In the present study the maximum sensory level achieved by group A is T10 and by group B is T5. Time to achieve maximum sensory blockade in group A is 6.35+/- 1.231 min and group B is 4.5+/- 0.641min. There was statistically significant difference between both groups with regard to maximum height achieved ($p<0.05$).This study shows that low dose bupivacaine 7.5mg with 25mcg fentanyl, do not affect the cephalic extension of sensory blockade. The results are comparable with the following studies.

Akan B et al[20] studied 60 patients undergoing elective TURP under spinal anesthesia were randomized into three groups.Group A -10mg of 0.5% levobupivacaine ,GroupB-0.5%levobupivacaine with 25mcg fentanyl, group C -0.5%levobupivacaine with 25mcg sufentanil.

Time to 2 segment regression of sensory block and motor block to bromage grade 0(min)

Time to 2-segment regression and time to achieve Bromage scale 0 were taken to assess the duration of sensory and motor block respectively. We found that group A achieved earlier regression of sensory block than group B (81.05 ± 5.905 vs 129.75 ± 15.890) and also earlier regression of motor block compared to group B (116.4 ± 7.669 vs 232.82±13.311). In other words, 12.5mg bupivacaine +25mcg fentanyl prolongs the duration of both sensory and motor block compared to 7.5mg bupivacaine +25mcg fentanyl when given intrathecally ($p<0.05$). The results of the present study are comparable with following studies:

Kristiina S. Kuusniemi et.al[21], evaluated the effect of 25 mcg of fentanyl added to bupivacaine on sensory and motor block in 80 men undergoing urologic surgery. They were randomized into the following four groups: Group I, bupivacaine 10 mg; Group II, bupivacaine 10 mg + fentanyl 25 mcg; Group III, bupivacaine 7.5 mg + fentanyl 25 mcg; Group IV, bupivacaine 5 mg + fentanyl 25 mcg. The degree of motor block was more profound in Group II compared with Group I at the end of operation. In Group IV, there was no motor block at the end of operation in any of the patients. The addition of 25 mcg of fentanyl to 5 mg of bupivacaine resulted in short-acting motor block. When 25 mcg of fentanyl was added to 10 mg of bupivacaine, it increased the intensity and duration of motor block.

Time to first post-operative analgesic requirement(duration of analgesia)

Patients were assessed using VAS score and rescue analgesia was provided only when the VAS score is more than or equal to 6. The time to first post-operative analgesic requirement (min) was found to be 177.83 ± 13.7 min in group A, 228.80± 14.576 min in group B. Group B significantly prolongs the time required for the demand of rescue analgesia when compared to 7.5mg dose because of more sensory blockade which was provided with 0.15mg/kg of Inj. Diclofenac I.V. infusion ($p< 0.05$).

Haemodynamic parameters

Heart rate

Preoperative vitals were recorded and were comparable between the two groups.

We compared intergroup heart rate, and there was a statistically significant difference between heart rate from 5 min to 45 mins ($p< 0.05$). There was a fall in heart rate from baseline and the fall was found more with 12.5mg bupivacaine group.

Mean arterial pressure (MAP)

During the inter group comparison, there is statistically significant difference between MAP from 5min - 60min post spinal anaesthesia ($p< 0.05$). Fall in MAP was found more with 12.5mg bupivacaine group in our study. The results of the present study are comparable with following studies.

A Kararmaz et.al[22], evaluated the effect of low-dose bupivacaine plus fentanyl administered intrathecally in elderly patients undergoing transurethral prostatectomy. Patients were randomly assigned to one of two groups. Group F received plain bupivacaine 4 mg with 25 µg of fentanyl and sterile water to a total of 1.5 ml, and Group B received only 0.5% plain bupivacaine 7.5 mg for spinal anesthesia. They concluded that intrathecal bupivacaine 4 mg combined with fentanyl 25 mcg is associated with a lower incidence of hypotension and shivering than a conventional dose of bupivacaine (7.5 mg). In my study 7.5mg bupivacaine produced less hemodynamic changes compared to 12.5mg bupivacaine. This is similar to study conducted by **Ben David et,al[16].**

Recommendations

Fentanyl as an adjuvant to hyperbaric Bupivacaine is recommended to be used for elective lower limb and abdominal surgeries as it enhances the duration of sensory block without affecting motor blockade and also prolongs the duration of analgesia compared to the conventional method of using plain hyperbaric Bupivacaine. Since, we found stable hemodynamics and lesser side effect profile with 7.5mg bupivacaine+fentanyl, we recommend the use of low dose(7.5mg) bupivacaine + fentanyl in elderly patients.

Limitations

1. As we excluded the ASA grade I and ASA IV patients, sensory and motor block characteristics is still a questionable parameter in such grade.
2. There is no control group in this study to compare data from the conventional methods. This study was performed to compare only two doses of bupivacaine + fentanyl with each other.
3. My study mainly included elderly patients undergoing elective surgeries, so sensory and motor characteristics in young patients and in emergency surgeries is still a questionable parameter in such cases.

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