



## Original Research Article

## Randomized controlled study comparing the efficacy of neuraxial blockade by using intrathecal administration of 0.5% hyperbaric bupivacaine 15mg and fentanyl 25mcg - in a single syringe versus separate syringe techniques in inguinal hernia surgeries

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## ABSTRACT

**Introduction:** Adjuvants premixed with local anaesthetic solution can alter the density of the hyperbaric solution affecting the spread of block. Administering local anaesthetic and adjuvant in a separate syringe may minimize these changes with respect to densities. Hence we aimed to compare the efficacy of the drugs when administered sequentially and as a mixture.

**Objective:** To compare the efficacy of neuraxial blockade with pre-mixed fentanyl and 0.5% hyperbaric bupivacaine and sequential administration of fentanyl and 0.5% hyperbaric bupivacaine.

**Materials and Methods:** After obtaining the institutional ethics committee approval, patients were randomly allocated into Group M = received spinal anesthesia using 15mg of 0.5% bupivacaine heavy and 25mcg fentanyl premixed in the same syringe. Group S = received spinal anesthesia sequentially. Drugs were injected through 25 gauge quincke's needle in sitting position, inserted at L3-L4 space. Onset of block, hemodynamics, duration of analgesia and complications were monitored.

**Results:** Group S had slower onset and slow progression of the block with more time taken to regression of the block compared to the group. Incidence of hypotension, bradycardia was less in group S compared to group M.

**Conclusion:** We conclude that administering adjuvants to local anaesthesia sequentially is better than mixing them in a single syringe in terms of surgical anaesthesia, hemodynamic stability and post operative pain relief.

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## 1. Introduction

The concept of neuraxial blockade has undergone numerous modifications over the years with respect to local anaesthetic drugs used, additive agents, the needle tips and their sizes. Local anaesthetics in neuraxial blockade act at the spinal cord level and block the motor and sensory system. It is the accompanying sympathetic nervous system blockade that causes unwanted physiological alterations. The addition of adjuvants is primarily aimed avoiding these side effects by bringing down the volume of local anaesthetic administered.

They also help in prolonging the duration of analgesia. Theoretically, mixing local anaesthetics with an adjuvant may alter the baricity of the former which may make the spread of the drug unpredictable. Hence we aimed at administering 0.5% hyperbaric bupivacaine 15mg and inj.fentanyl 25mcg in subarachnoid block, either as a premixed syringe or as sequential syringes. The primary aim was to study the onset of sensory and motor blockade, while the secondary aim was to compare the duration of analgesia and motor blockade, hemodynamic changes and the average ephedrine consumption between the groups.

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## 2. Materials and Methods

The study was a randomized double blinded control trial involving 100 patients with 50 in each group. Institutional ethics Committee approval and informed written consent was obtained. Patients aged from 20-70 years of ASA grade I-II undergoing open hernioplasty were randomly allocated to one of the groups on the basis of a computer generated random table. Patients with contraindication for spinal anaesthesia and height less than 150 cms and more than 180 cms were excluded. Intravenous access was secured with 18G cannula in all patients. Pulse-oximeter, NIBP, ECG was connected and baseline values were noted. Group M included the patients receiving spinal anaesthesia using 15mg of 0.5% hyperbaric bupivacaine and 25mcg of fentanyl premixed in the same syringe. Group S included the patients receiving spinal anaesthesia without premixing using two different syringes, the first one is 25mcg of fentanyl and second is 15mg of 0.5% hyperbaric bupivacaine without barbotage. All medications were prepared before the insertion of spinal needle. An anaesthesiologist not involved in the study performed the subarachnoid block and administered the drug. Spinal anaesthesia was performed in sitting position with a 25G Quincke's needle at L<sub>3</sub>-L<sub>4</sub> interspace and then the patient was asked to lie down. Timing between the first and second doses was kept as low as possible to prevent the loss of CSF through the spinal needle during the administration of the drugs in Group S. The observer then entered the operation theatre to monitor the parameters.

The surgery was started after the attainment of sensory blockade of T<sub>6</sub> level and motor blockade of grade 3 as per the modified Bromage scale. The maximum level of sensory blockade was checked at 30th minute after performing spinal anaesthesia and documented. Hypotension was defined as greater than 20% fall in the mean arterial pressure (MAP) and was managed by inj. Ephedrine in 6 mg intravenous boluses. A drop in pulse rate greater than 20% of the baseline was recorded as bradycardia. Inj. Atropine 0.6 mg was administered intravenously when the pulse rate fell below 40 beats per minute. Failure of spinal anaesthesia was managed by general anaesthesia with controlled ventilation. Pain relief was assessed by visual analog scale and rescue analgesia was given if VAS is  $\geq 4$  and the time of rescue analgesia was noted in all the patients. All the spinal anaesthesia related side effects like nausea, vomiting and shivering was documented and treated symptomatically.

Descriptive statistics was done for all data and were reported in terms of mean values and percentages. Normality of the data was confirmed using Shapiro-Wilk test. Continuous variables were analysed with the unpaired t test. Categorical variables were analysed with the Chi-Square Test and Fisher Exact Test. Statistical significance was taken as  $p < 0.05$ . The data was analysed using SPSS

version 16 and Microsoft Excel 2007.

## 3. Results

The demographic variables were comparable in the study (Table 1). The groups were similar in the onset of motor blockade as all the patients attained Modified Bromage scale of 3 at 5 minutes. Group S took  $12.6 \pm 1.929$  minutes to attain T<sub>6</sub> level of sensory anaesthesia in comparison to Group M which attained the same level at  $5.82 \pm 1.892$  minutes ( $p < 0.001$ ). After 30 minutes of drug administration, 39 patients in Group M attained T<sub>4</sub> level of sensory anaesthesia and 2 patients progressed to T<sub>2</sub> level. In contrast, 36 patients in Group S showed T<sub>6</sub> level, 11 attained T<sub>4</sub> level and only one patient had T<sub>2</sub> level of sensory anaesthesia ( $p < 0.001$ ) (Table 2). The groups also showed a significant difference with respect to the duration of motor blockade (Group M =  $177.50 \pm 8.70$  minutes, Group S =  $185.83 \pm 7.17$  minutes ( $p < 0.001$ )) and duration of analgesia (Group M =  $200.50 \pm 11.08$  minutes, Group S =  $210.94 \pm 10.03$  minutes ( $p < 0.001$ )) (Table 2). Unpaired t test revealed no significant association between the hemodynamics of the groups up to 40 minutes but statistically significant fall in systolic and diastolic pressures was seen in Group M during the intra operative period between 45 minutes to 2 hours (Figures 1 and 2). Group M consumed more ephedrine than Group S and the difference was statistically significant (Table 3). A similar trend was obtained in the heart rate in Group M compared to Group S (Figure 3).

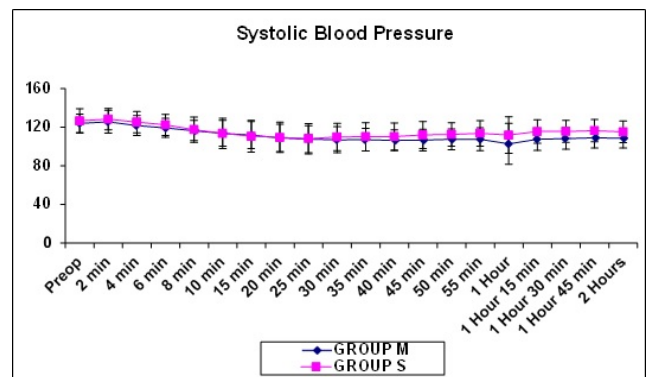


Fig. 1: Comparison of systolic blood pressure

## 4. Discussion

Spinal anaesthesia remains the gold standard technique for surgeries performed below the level of umbilicus. Numerous additives have been added to the local anaesthetic solution to provide a better surgical anaesthesia in view of better hemodynamic stability and outcome. One such additive used is fentanyl which is a lipophilic opioid.

**Table 1:** Demography

	Group M	Group S	P value
Age in years (Mean ±SD)	50.34±12.67	45.94±10	0.060(student t test)
Gender	41	36	0.399(chi square test)
Male			
Female	9	12	
Weight in kgs	64.90±9.55	65±7.85	0.936(student t test)
Height in cms	169.60±4.89	170.52±3.58	0.292(student t test)
ASA 1	24	21	0.673(fisher exact test)
ASA 2	26	27	
ASA 3	0	0	

**Table 2:** Comparison of motor and sensory blockade

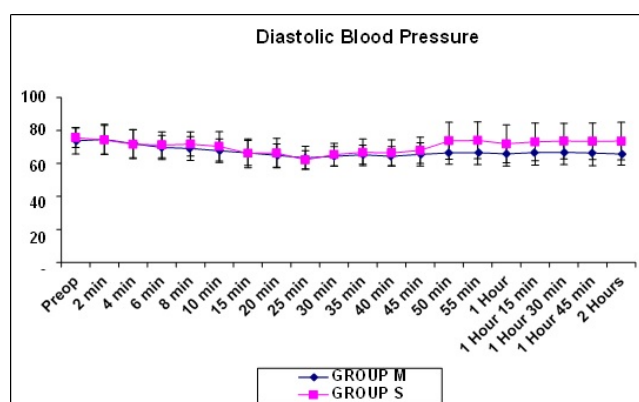
	Group M	Group S	P value
Time taken to attained T6 level of anaesthesia	5.82±1.892	12.6±1.929	0.001(student t test)
Level of anaesthesia attained at 30 mins	2	1	0.001( Fisher exact test)
T2			
T4	39	11	
T6	9	36	

**Table 3:** Comparison of colloids

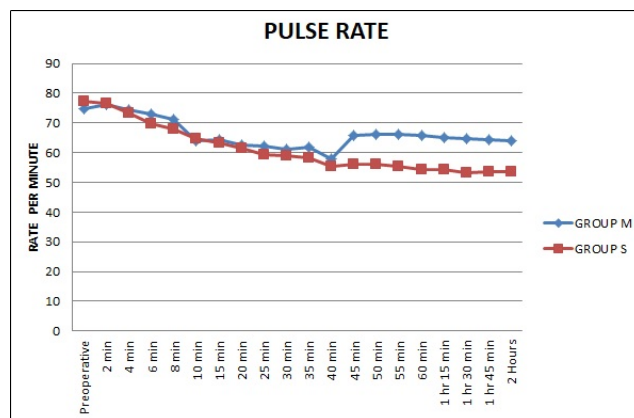
Fluids - Colloids	Group M	%	Group S	%
No	50	100	48	100
Yes	0	0	0	0
Total	50	100	48	100
	P value		1.00	

**Table 4:** Complications

	Group M	Group S
Nausea	2(2.5%)	2(2.5%)
vomiting	1(2%)	1(2%)
hypotension	6(12%)	7(14%)
shivering	4(8%)	5(10%)



**Fig. 2:** Comparison of diastolic blood pressure



**Fig. 3:** Comparison of pulse rate

Hence a study was framed to analyze the efficacy of two drugs, hyperbaric bupivacaine and fentanyl which were

administered sequentially and as a mixture for inguinal hernia patients subjected to open hernioplasty under spinal anaesthesia.

In our study we found that in group S, injecting the drugs sequentially attained the sensory anaesthetic level of T<sub>6</sub> slower when compared to group M (Table 2). Comparison of segmental progression of sensory blockade 30 minutes after administration of spinal anaesthesia was higher in group M (39 patients attained higher than T<sub>6</sub> level) compared to group S (11 patients). This observation is comparable with the results of the study conducted by Keera et al.<sup>1</sup> The maintenance of hyperbaricity of bupivacaine in Group S prevents the rapid spread of the drug as well as the higher ascent noted in Group M. We attained a motor blockade of score 3 in modified Bromage scale in all the patients in both the groups within 5 minutes of administration of spinal anaesthesia. These results are comparable with the study performed by Bansal et al.<sup>2</sup> We had restricted the assessment of motor block to the attainment of modified Bromage score of 3. Further analysis of the effect of the differences in the drug administration techniques on the motor activity of the abdominal wall and intercostal muscles was not done and this is a limitation in our study.

Hypotension and bradycardia are the commonest adverse effects of spinal anaesthesia caused by the response of sympathetic nerve fibres. The alteration is because of decreased preload and cardiac volume leading to bradycardia and decrease in blood pressure. In our study we found that the incidence of hypotension was less in group S compared to group M (fig 1,2). The reason for the delayed onset of hypotension is unclear. Though group M attained T<sub>6</sub> level at approximately 6 minutes there were no incidences of early hypotension. Probably the pre-hydration before spinal anaesthesia could have alleviated this early hypotension. The exact reason for this late onset of hypotension could not be elucidated.<sup>3</sup> Helmi et al and Martin et al too observed a similar pattern in their studies where hyperbaric and isobaric bupivacaine in spinal anaesthesia was compared. They concluded that isobaric bupivacaine produced rapid onset of hypotension compared to hyperbaric bupivacaine.<sup>4,5</sup> Although hypotension was recorded in both the groups, significant hypotension which required treatment with Inj. Ephedrine was observed more in group M than in group S (Table 3) and these results co-related with the earlier studies.<sup>6</sup> The incidence of bradycardia was also more pronounced in group M compared to group S (fig 3). The higher levels of sympathetic blockade produced in the former group causes this bradycardia.<sup>7</sup> However none of the patients in the groups had a pulse rate less than 40 per minute requiring intravenous inj. Atropine.

When a hyperbaric drug is given, its movement in intrathecal space is influenced by gravity and the lumbar curvature of the patient's spine. Isobaric solutions, being less viscous, move easily in subarachnoid space and are

not influenced by gravity. When hyperbaric bupivacaine is administered separately in group S, the baricity of the drug is not altered, leading to intense blockade. This could be the reason for dense blockade and delayed time of motor and sensory recovery. Baricity of the intrathecal medications was studied by Cesur et al., who compared 10 mg of hyperbaric bupivacaine in one group and another group receiving 5 mg of plain bupivacaine and 5 mg of hyperbaric bupivacaine in sequential syringes and they found that the latter had better hemodynamic stability and prolonged sensory blockade than the former.<sup>8</sup> Numerous studies have proved the efficacy and safety of fentanyl as an adjuvant in subarachnoid block.<sup>9,10</sup> Administration of fentanyl separately ahead of hyperbaric bupivacaine in Group S doesn't alter the pharmacological properties of the drug, allowing it to act on higher spinal and supraspinal levels leading to delayed onset of pain and increase in the duration of motor and sensory blockade compared to group M. This observation in our study is similar to the findings in various identical studies.<sup>11,12</sup>

## 5. Conclusion

We conclude that administering the local anaesthetic solution and adjuvant sequentially in separate syringes is better than mixing them in a single syringe in terms of surgical anaesthesia, hemodynamic stability and post-operative pain relief.

## 6. Source of Funding

None.

## 7. Conflict of Interest

None.

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