

A Randomised Controlled Study Comparing Intrathecal Hyperbaric Bupivacaine And Isobaric Bupivacaine In Common Urological Procedures

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I. Introduction:

For thousands of years, pain relief could be secured only at the expense of central nervous system depression as with the use of mandragora, wine and opium ancient china, mandragora and poppy in ancient Egypt, Rome and Greece, and atropine, opium, cocaine and hallucinogens by the Incas and ancient Peruvians.

Subarachnoid block is defined as the temporary interruption of transmission of nerve impulses produced by the injection of local anaesthetic agents into the subarachnoid space. Subarachnoid block is one of the oldest forms of regional block and is still a very commonly used one in our country. When given to properly selected patients, subarachnoid block gives a clear advantage which is difficult to duplicate with general anaesthesia for surgical procedures below the level of the umbilicus.

Advantages-

Easy, Cheap, Highly reliable, Rapidity of onset, Safe

II. Aim And Objectives

The aim of this study is to compare the hemodynamic effect and recovery between intrathecal isobaric bupivacaine-fentanyl mixture and hyperbaric bupivacaine-fentanyl mixture in common urological procedures based on the following objectives:

- 1 Systolic and diastolic blood pressures at regular time intervals
- 2 Heart rate at regular time intervals
- 3 Respiratory rate at regular time intervals
- 4 Onset of sensory and motor block
- 5 Duration of sensory and motor block

III. Patients And Methods

Patient selection

Inclusion criteria

- 1 Patients aged between 18 and 60 years of both genders.
- 2 Patients belonging to ASA physical status 1 and 2
- 3 Patients undergoing elective surgeries below the umbilical level under spinal anaesthesia.

Exclusion criteria

Patient with any one of the following will be excluded from this study

- 1 Patient refusal
- 2 Contraindication to spinal anaesthesia inclusive of spinal cord deformities, bleeding disorder, local infection at injection site and any pre-existing neurological disorders.
- 3 Surgeries lasting more than 3 hours.

After the conduct of subarachnoid block the following parameters will be evaluated-

Time of onset of sensory block will be assessed as the time interval between completion of injection of local anaesthetic solution to onset of complete loss of sensation to pinprick in the anterior axillary line bilaterally. Duration of sensory block - assessed by two segment regression time and is defined as time interval from injection of local anaesthetic solution until maximum sensory level of sensory block has decreased by two segments.

Motor Block assessed by-

Modified Bromage scale (by Breen et al)

STATISTICAL METHOD-

Student unpaired "T" test ANOVA with repeated measurement will be used.

IV. Observations And Results

100 patients of either sex and between 18-60 years age participated in this study. Each group had 50 patients each enrolled (Group I: n=50 and Group II: n=50).

Group I received 3ml of isobaric bupivacaine and 25µg fentanyl mixture.

Group II received 3 ml of hyperbaric bupivacaine and 25µg fentanyl mixture.

Statistical analysis was done using the SPSS 11.5 software. The tests used for statistical analysis were the student's unpaired 't' test and the χ^2 test. Patients were randomized using block randomization to group I and group II.

Demographics

Demographic characteristics were similar in both groups, as shown in table 1.

Table 1: Demographic information^a

	Group I (n=50)	Group II (n=50)
Age (yr)	41.92 ±9.3	40.18 ±9.3
Height (cm)	169.4±5.56	170.18±4.48
Weight (kg)	63.74±7.9	64.86±7.62
Sex (M:F)	46:4	45:5

a – values are reported as mean ± standard deviation

The mean age for the group I was 41.92; while that for group II was 40.18. The average height (in centimeters) in both groups were 169.4±5.56 and 170.18±4.48. With regard to the weight (in kilogram) the values were 63.74±7.9 and 64.86±7.62. Group I consisted of 46 males and 4 females; whereas group II had 45 males and 5 females.

V. Systolic Blood Pressure

Table 2: Comparison of mean systolic blood pressure

Time (min)	GROUP 1 (mmHg) N=50		GROUP 2 (mmHg) N=50	
	Mean	Standard deviation	Mean	Standard deviation
Baseline	136.42	17.32	128.9	19.01
5	130.52	15.26	109.32	15.01
10	127.18	18.87	102.94	16.16
15	126.44	15.23	108.8	14.98
20	124.72	15.08	111.18	13.14
30	121.32	18.34	110.6	12.08
45	123.86	15.65	112.2	11.04
60	123.5	14.42	114.06	12.41

VI. Diastolic Blood Pressure

Table 3: Comparison of mean diastolic blood pressure

Time (min)	GROUP 1 (mmHg) N=50		GROUP 2 (mmHg) N=50	
	Mean	Standard deviation	Mean	Standard deviation
Baseline	79.96	7.15	78.34	9.15
5	75.80	8.40	69.12	8.51
10	76.36	12.61	66.00	9.10
15	75.68	8.16	68.96	7.52
20	72.16	9.80	70.38	8.98
30	72.96	10.27	70.90	6.97
45	72.76	8.96	70.68	8.03
60	75.04	8.09	73.06	5.51

VII. Heart Rate

Table 4: Comparison of mean heart rate

Time (min)	GROUP 1 N=50		GROUP 2 N=50	
	Mean	Standard deviation	Mean	Standard deviation
Baseline	77.00	14.64	75.06	12.46
5	73.70	14.49	72.40	12.71
10	69.95	14.65	70.63	12.53
15	69.06	14.13	70.81	11.72
20	67.74	12.43	69.82	11.20
30	67.40	10.73	68.74	11.13
45	67.00	10.69	68.92	11.64
60	67.42	10.91	69.56	10.63

VIII. Respiratory Rate

Table 5: Comparison of mean respiratory rate

Time (min)	GROUP 1 N=50		GROUP 2 N=50	
	Mean	Standard deviation	Mean	Standard deviation
Baseline	17.24	1.64	17.08	1.22
5	17.24	1.98	17.12	1.33
10	17.22	2.32	17.08	1.39
15	17.54	2.43	17.24	1.66
20	17.40	2.25	16.98	1.37
30	17.10	2.59	16.92	1.15
45	17.02	1.78	17.20	1.48
60	17.04	1.85	17.36	1.45

IX. Discussion

Subarachnoid block is one of the most popular techniques in our country, which has the disadvantages of sympathetic and motor block, resulting in hypotension, bradycardia and immobility. It has been a dream to produce sensory block without its accompanied complications and a major step in this path is the use of intrathecal opioids, but they are not adequate anesthetics for surgery. So local anesthetics combined with opioids are the appropriate choice. Fentanyl, a phenyl piperidine derivative and a synthetic opioid, is 100 times more potent than morphine and being more potent than morphine and being more lipophilic, has less tendency to cause late respiratory depression and hence, is more suitable especially in our country which has few monitoring facilities and a greater demand on them. There are numerous benefits of using opioids with local anesthetics for spinal vs systemic opioids in the perioperative period:

- Superior analgesia with shorter time to ambulation
- Fewer pulmonary complications
- Earlier return of bowel function
- Earlier hospital discharge rates

A decreased stress response As plain solutions are in fact, slightly hypobaric (specific gravity 1.004 at 20°C and 0.998 at 37°C) compared to CSF (specific gravity 1.0063-1.0075 at 25°C), it was found that the sitting position would result in a greater cephalad spread.²⁰ Under controlled clinical conditions, for example, Axelsson et al⁸ found that decreasing the volume injected to 2.0 ml significantly decreased the level of anesthesia to T10-11 level, but that a further decrease in volume to 1.5ml was not associated with a further decrease in level of anesthesia. They compared 1.5ml, 2ml, 3ml and 4ml instilled intrathecally in 40 patients undergoing urological surgery under spinal anaesthesia. Increasing the volume injected in this study was not associated with an increase in level of anesthesia⁸. With increasing volume there was an increase in the duration of analgesia and time to complete motor block of lower limbs decreased (3ml – 14mins). Time to maximum cephalad spread took about 15-18 minutes in all groups. 2-3 segment recession was on an average between 1.5-2 hours and the rate of regression was similar in all groups (while using 3ml the rate of regression was 101 ± 15.4 minutes to reach a T₁₀ level). Based on this study we took 3ml as standard volume of bupivacaine in our study. Though we added 25µg of fentanyl to the mixture we did not find considerable difference in the results as compared to previous

studies. The duration of sensory block in our study had a mean of 2.1378(hrs) which was comparable to the above results.

Meanwhile in our study, the statistical analysis showed differences between mean systolic blood pressure as well as diastolic blood pressure were significant from 5min interval onwards ($p < 0.05$) between the two study groups. While isobaric bupivacaine showed hardly any drop in blood pressure, systolic blood pressure dropped after 5 minutes with a P value < 0.001 and diastolic blood pressure also dropped upto 15 minutes duration in the hyperbaric group ($P < 0.001$). The differences in heart rate and respiratory rates were not statistically significant. The onset of sensory and motor block in group I was delayed as compared to group II. In group I the mean onset time for sensory block was 4.7837 ± 2.93 (mins) while in group II it was 1.0580 ± 0.312 (mins) with a p value < 0.001 . The mean onset time for motor block in group I was 5.5449 ± 2.79 (mins) while in group II it was 1.2354 ± 0.193 (mins) with a p value < 0.001 . The duration of sensory and motor block were also less in group I with mean values of 2.1378 ± 0.644 (hrs) and 2.8418 ± 0.464 (hrs) as compared to group II having 3.0952 ± 0.268 (hrs) and 3.3664 ± 0.238 (hrs) respectively. Here also the p value was statistically significant.

X. Conclusion

Based on this present study, we can conclude that both hyperbaric bupivacaine-fentanyl mixture and isobaric bupivacaine-fentanyl mixture provides effective subarachnoid block for urological procedures with the following underlying conclusions outlined:

- The isobaric bupivacaine-fentanyl mixture has shown to have better “rock-steady” hemodynamic stability with least changes in systolic and diastolic blood pressures after spinal anesthesia.
- The mean onset time of both sensory and motor block is significantly delayed with the use of isobaric bupivacaine-fentanyl mixture.
- Due to the delayed onset time of the isobaric bupivacaine-fentanyl mixture, sedation supplementation was required in a majority of the patients.
- The duration of both sensory and motor block is lesser in the isobaric-fentanyl mixture group as compared to the hyperbaric-fentanyl mixture group thereby enabling quicker recovery from anesthesia possible in urological procedures.
- Isobaric bupivacaine showed to have best results for surgeries below the umbilical (T_{10}) level.
- Post-operative shivering was not observed with the use of isobaric mixture unlike the 22% cases observed after the use of the hyperbaric mixture.

Hence, the isobaric bupivacaine-fentanyl mixture can be used in spinal anesthesia for urological procedures providing an effective subarachnoid block with minimal incidence of hemodynamic instability

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