January 2016; 3(1) ISSN: ISSN: 2349-5340

Impact Factor (PIF): 2.672

### HAEMODYNAMIC CHANGES IN ELDERLY PATIENTS AFTER SPINAL ANAESTHESIA – HYPERBARIC BUPIVACAINE VS ISOBARIC BUPIVACAINE

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#### Abstract

#### Keywords:

Elderly patients, spinal anaesthesia, bupivacaine, haemodynamic changes.

Haemodynamic changes were compared in two groups of elderly patients after spinal anaesthesia. Control group received hyperbaric bupivacaine 0.5% and study group received isobaric bupivacaine 0.25%. Systolic blood pressure, mean blood pressure and heart rate were compared. The difference in drop in blood pressure between both groups was found to be statistically not significant even though the mean fall in blood pressure was slightly less in the study group. The change in heart rate was similar in the control group and the study group. So hyperbaric bupivacaine and isobaric bupivacaine caused similar haemodynamic changes in both the groups.

#### Aim

To compare the haemodynamic changes of hyperbaric 0.50% bupivacaine and isobaric 0.25% as spinal anaesthetic agents in elderly patients by comparing the following characteristics

- 1) Systolic blood pressure
- 2) Mean blood pressure
- 3) Heart rate

#### Introduction

In order to keep the study environment uniform, we choose the patients undergoing urological procedures such as Transurethral Resection of Prostate (TURP), Transurethral Resection of Bladder Tumour (TURBT), Bladder Neck Incision (BNI) or Endoscopic Internal Urethrotomy (EIU). The majority of patients coming for these procedures are of the older age group<sup>2</sup>. Also the ideal anaesthesia for patients undergoing such urological procedures is spinal anaesthesia<sup>1</sup>.

In this randomised controlled double-blind study, adult patients in the 41-80 age group were randomly assigned to either 0.50% or 0.25% Bupivacaine group. The haemodynamic changes were assessed.

A pilot study was undertaken with 20 patients to assess the feasibility of the study, prior to performing the present study. During the pilot study, no untoward effects were noted. The duration and level of analgesia and the intensity of motor blockade were found to be adequate. All aspects of the study were found to be practically manageable and acceptable. The data of the pilot study was analysed. The proportion of the values between case and study group were found to be 20% and 30% respectively. A difference of 20% between case and study groups was kept to estimate the sample size. Thus a sample size of 70 patients was estimated with 35 patients in each group.

#### **Review of literature**

The conventional approach to intrathecal anaesthesia is to use a sufficient dose of local anaesthetic to be effective in all the patients and to produce a level of block assured of outlasting the duration of surgery. Sometimes this produces a block, which is more than what is required.

January 2016; 3(1)

ISSN: ISSN: 2349-5340

Impact Factor (PIF): 2.672

For minimal haemodynamic consequences and faster recovery and discharge, it would be optimal to limit the spread of spinal anaesthesia only to the area, which is necessary for surgery.

Studies have been done with reduced concentration of local anaesthetics to produce a sufficiently effective block with decreased side effects. The resulting reduction in local anaesthetics confers a rapid recovery, fewer side effects, noticeably less haemodynamic instability and less motor blockade.

The baricity of spinal anaesthetic agent is a main predictor of the upper level of the block. With isobaric solutions, the maximal level of spinal analgesia is minimally affected by age. On the contrary, with hyperbaric solutions, older patients attain a faster onset of motor block and a higher level of sensory block<sup>3</sup>.

In the elderly patients during regional anaesthesia, the problems which need significant attention are hypotension, hypothermia and increased sensitivity to local anaesthetic agents. During spinal anaesthesia, there is sympathetic blockade which results in vasodilatation and a reduction in systemic vascular resistance. This leads to decreased venous return and ultimately hypotension. Old age and high level of spinal anaesthesia are the important causative factors for hypotension<sup>4</sup>.

Due to old age, there are degenerative changes in the autonomic nervous system, structural and functional changes in the vascular system and decreased cardiac reserves. All these lead to hypotension. Since the elderly patients have limited cardiac reserve, marked hypotension can be harmful to them. In elderly patients, preloading with fluids before spinal anaesthesia did not prevent spinal induced hypotension<sup>5</sup>.

The effective treatment for hypotension after spinal anaesthesia in elderly patients is the administration of fluids and vasopressors during initial ten minutes<sup>6</sup>.

At the old age there are small but significant increases in maximum spread, rate of onset of motor block and cardiovascular instability, regardless of the anaesthetic agent used<sup>7,8,9,10,11</sup>.

Spinal anaesthesia produces sympathectomy, which in turn induces haemodynamic changes. The level of sympathetic block is determined by the upper level of spinal anaesthesia. The magnitude of change in cardiovascular parameters is as per the extent of sympathetic blockade. Hypotension and bradycardia are the most common side effects seen with sympathetic blockade<sup>12</sup>.

#### **Materials and Methods**

A randomized double-blind study was conducted on seventy patients coming for elective surgery. A pilot study was conducted in twenty patients to get an estimate of the effects of 0.50% hyperbaric bupivacaine and 0.25% isobaric bupivacaine. These data were used for the calculation of the sample size for the main study. A sample size of thirty-five patients was required in each group.

#### 1) Inclusion criteria:

Age: Adults between the ages of 41 and 80 years were included in the study.

Physical status: All the patients in the study came under ASA grade 1,2 or 3.

Type of surgery: Patients undergoing elective urological procedures like Transurethral resection of prostate, Transurethral resection of bladder tumour, Endoscopic internal urethrotomy and Bladder neck incision were included

#### 2) Exclusion criteria:

Adults above 80 years of age were excluded because of the anticipation of hypotension in a group, which is at a high risk of ischemic heart disease. Patients with anomalies of the spinal column like kyphosis or scoliosis were excluded from the study.

#### 3) Pre operative preparation:

The anaesthetist assessed the patients on the day before surgery. The procedure was explained and informed consent obtained. In addition to the regular physical examination, measurements of patient's height, weight and the distance between occipital protuberance and coccyx were made. On the day of operation, all patients received a premedication of diazepam (0.2 mg/kg) orally, approximately 60 to 90 minutes before the surgery.

#### 4) Randomisation:

The patients were randomly allocated into two groups, using the randomisation table. Each group consisted of 35 patients.

Group A received 2.5-ml of 0.50% hyperbaric bupivacaine in 8% dextrose.

Group B received 5.0 ml of 0.25% bupivacaine, the study drug.

The patients were blinded to the group allocation. Also a different anaesthetist did the assessment. Thus the study was randomized and double blinded.

January 2016; 3(1) ISSN: ISSN: 2349-5340 Impact Factor (PIF): 2.672

Procedure

An intravenous line was started with a #18 G or #16 G cannula. The patient was preloaded with crystalloid up to 10 ml / kg body weight, to prevent the possible hypotension. Monitoring composed of a continuous electrocardiograph monitor, pulse oximetry and a non-invasive blood pressure.

#### **Technique**

All the bupivacaine ampoules and distilled water used in our study were autoclaved.

Group A patients were given 2.5 ml of hyperbaric bupivacaine i.e., 0.50 % bupivacaine in 8% dextrose.

Group B patients were given 5 ml of the study drug prepared by mixing 2.5 ml of 0.50% bupivacaine in 8% dextrose with 2.5 ml of distilled water.

The patients were positioned in the lateral position. The neck, hips and knees were flexed to facilitate easy identification of the interspinous spaces.

The patients' back were cleaned with Povidone iodine solution. Lumbar puncture was carried out at the L<sub>3-4</sub> interspace using #25 G disposable Quincke- Babcock spinal needle under strict aseptic conditions. Once the needle tip was in the subarachnoid space, the syringe containing the drug was attached to the spinal needle and cerebrospinal fluid aspirated to ascertain the correct position. Local anaesthetic solution was injected over 20-25 seconds without barbotage. Immediately after the injection, the patients were returned to the supine position. Fifteen minutes later, the patients were positioned in the lithotomy position.

#### Assessment of the patient and recordings

Baseline heart rate, blood pressure and arterial oxygen saturation were recorded before the start of spinal anaesthesia and immediately after injection of the drug, every minute for the first five minutes and every 5 minutes for the first half-hour. Thereafter they were recorded at 15 minutes intervals until the patient left the recovery room.

If the systolic blood pressure dropped below 25% of the highest recorded pre-spinal blood pressure, intravenous fluid was administered rapidly and if this did not bring up the systolic blood pressure, incremental doses of Mephentermine sulphate were given.

A heart rate less than 50 per minute was treated with incremental doses of intra venous atropine.

- 4. The level of spinal anaesthesia was tested from the time of injection of the local anaesthetic along with other parameters until complete regression of the block. The level of sensory block was tested by eliciting the loss of pinprick sensation using a hypodermic needle. The onset, intensity and duration of sensory block were recorded. The onset of sensory block was taken as the time of achievement of block to T<sub>12</sub> from the time of injection of the drug. Checking whether the largest segment (S<sub>1</sub>) was blocked tested the intensity of block. The duration of sensory block was taken as the time from onset of block until regression of the block three segments below the highest level of block.
- 5. The motor block was assessed using the Bromage scale<sup>13</sup>.

No block (0%) - Full flexion of knees and feet possible, (no paralysis).

Partial block (33%) - Just able to flex knees, still full flexion of feet possible,

(unable to raise extended leg).

Almost complete (66%) - Unable to flex knees. Still flexion of feet possible,

(unable to flex knees).

Complete block (100%) - Unable to move legs or feet, (unable to flex ankle).

The onset of motor block was taken as the time of achieving 33% block from the time of injection. The duration of motor block was taken as the time from the onset of 33% block until the reappearance of 33% of the motor

- 6. A list of drugs used and the volume of intra venous fluids administered during the procedure was recorded.
- 7. The patients were discharged from the recovery room after complete regression of the block. They were followed up for the next 24 hours and checked for the manifestations of any of the complications of spinal anaesthesia like headache, backache and nerve deficits.

#### Statistical methods

The data obtained from the patients was entered in EXCEL and statistical analysis was done using SPSSPC+ software. Comparison of the different variables between the two groups was done by Students t- test and Chisquare test.

January 2016; 3(1)

ISSN: ISSN: 2349-5340

Impact Factor (PIF): 2.672

#### **Results**

The study was conducted on 70 patients. Patients were randomly allocated into two groups i.e., Group A and Group B. Each group had 35 patients.

Group A patients received 2.5-ml of 0.50% hyperbaric bupivacaine.

Group B patients received 5 ml of 0.25% isobaric bupivacaine.

The variables of the two groups were compared by Students t-test and Chi-square test.

The p-value <0.05 was considered as significant.

The p-value >0.05 was considered as non-significant.

#### Demographic data

The demographic data are shown as below. There is no significant difference in the distribution of age, sex, height, weight and spinal column length between both the groups.

Table 1. Demographic data

Variables		Control group		Study group		n voluo
		Mean	SD	Mean	SD	p - value
Age (Years)		60.51	7.18	59.03	9.85	0.473
Sex	Male	33		35		0.4976
	Female	2		0		
Height (cms)		165.97	6.10	165.63	4.87	0.796
Weight (kgs)		60.86	10.29	56.91	10.43	0.116
Spinal column length (cms)		71.51	4.19	71.06	3.88	0.637

#### **DISTRIBUTION OF SURGERIES:**

The distribution of surgeries between both groups is shown as below.

Table 2. Distribution of surgeries

Surgeries	Control group	Study group	
TURP	18	24	
TURT	10	6	
EIU	4	5	
BNI	3	0	

(p = 0.17414)

There is no significant difference in the distribution of surgeries between both groups.

There are 42 Transurethral resection of prostate, 16 Transurethral resection of tumour, 9 Endoscopic internal urethrotomy and 3 Bladder neck incision. The Transurethral resection of prostate is distributed between control and study groups as 18 and 24 respectively. The Transurethral resection of tumour is distributed between control and study groups as 10 and 6 respectively. The Endoscopic internal urethrotomy is distributed between control and study groups as 4 and 5 respectively. Only the control group has 3 Bladder neck incision and the study group has none. The p-value is 0.17414. There is no significant difference in the distribution of surgeries between both the groups.

#### Fall in blood pressure

The degree of fall in systolic blood pressure in both groups is shown as below.

January 2016; 3(1)

ISSN: ISSN: 2349-5340

Impact Factor (PIF): 2.672

Table 3. Fall in blood pressure

Fall in blood pressure		Control		Study		n voluo
		Mean	SD	Mean	SD	p - value
Systolic blood pressure	Fall in percentage	25.49	12.960	25.05	9.370	0.869
	After 15 minutes	-27.14	21.283	-25.74	16.903	0.762
	After 30 minutes	-27.26	23.082	-26.89	13.549	0.935
	After 60 minutes	-25.54	22.014	-22.31	17.524	0.500
Mean blood pressure	Fall in percentage	24.26	12.237	22.99	9.344	0.630
	After 15 minutes	-20.23	12.845	-17.26	11.299	0.308
	After 30 minutes	-19.14	14.679	-18.26	10.216	0.771
	After 60 minutes	-16.83	13.452	-14.83	11.693	0.509

The degree of fall in systolic blood pressure is  $25.4926\% \pm 12.960$  and  $25.0454\% \pm 9.370$  for control and study groups respectively. The p-value is 0.869. Thus, the degree of fall in systolic blood pressure was not statistically significant.

The degree of fall in mean blood pressure is  $24.2597\% \pm 12.237$  and  $22.9991\% \pm 9.344$  for control and study groups respectively. The p- value is 0.630. Thus, the degree of fall in mean blood pressure was not statistically significant.

There is no significant difference in the drop in systolic blood pressure after 15 minutes in both groups. The drop in systolic blood pressure after 15 minutes from the time of subarachnoid injection is - 27.1429 mm Hg  $\pm$  21.283 in the control group and -25.7429 mm Hg  $\pm$  16.903 in the study group. The p-value is 0.762. This is statistically not significant.

There is no significant difference in the drop in systolic blood pressure after 30 minutes in both groups. The drop in systolic blood pressure after 30 minutes from the time of subarachnoid injection is - 27.2571 mm Hg  $\pm$  23.082 in the control group and -26.8857 mm Hg  $\pm$  13.549 in the study group. The p-value is 0.935. Statistically this is not significant.

The drop in systolic blood pressure after 60 minutes from the time of subarachnoid injection is -25.5429 mm Hg  $\pm$  22.014 in the control group and -22.3143 mm Hg  $\pm$  17.524 in the study group. The p-value is 0.500. This is statistically not significant.

There is no significant difference in the fall in Mean blood pressure after 15 minutes in both groups. The drop in mean blood pressure after 15 minutes from the time of subarachnoid injection is -20.2286 mm Hg  $\pm$  12.845 in the control group and -17.2571 mm Hg  $\pm$  11.299 in the study group. The p-value is 0.308. Statistically this is not significant.

There is no difference in the drop in Mean blood pressure after 30 minutes in both groups. The drop in mean blood pressure after 30 minutes from the time of subarachnoid injection is -19.1429 mm Hg  $\pm$  14.679 in the control group and -18.2571 mm Hg  $\pm$  10.216 in the study group. The p-value is 0.771. This is statistically not significant.

The drop in mean blood pressure after 60 minutes from the time of subarachnoid injection is -16.8286 mm Hg  $\pm$  13.452 in the control group and -14.8286 mm Hg  $\pm$  11.693 in the study group. The p-value is 0.509. Statistically this is not significant.

January 2016; 3(1) ISSN: ISSN: 2349-5340

Impact Factor (PIF): 2.672

#### Vasopressors

#### Table 4. Vasopressors

VASOPRESSORS	Control	Study	z- value	
Required	11	8	0.75	
Not required	24	27	0.75	

In our study, 11 patients in the control group and 8 patients in the study group required vasopressors and 24 patients in the control group and 27 patients in the study group did not require vasopressors. The z - value is 0.75, which is not statistically significant. A z-value greater than 1.96 is statistically significant.

#### Bradycardia

The incidence of bradycardia in both groups is shown as below.

Table 5. Bradycardia

Variables	Control	Study	p - value
Bradycardia	15	11	0.32244

There is no significant difference in the incidence of bradycardia between both groups. 15 patients in the control group and 11 patients in the study group had bradycardia. The p-value is 0.32244.

#### Shivering

The incidence of shivering in both groups is shown as below.

Table 6. Shivering

Variables	Control	Study	p - value
Shivering	23	19	0.32911

There is no significant difference in the incidence of shivering between both groups. 23 patients in the control group and 19 patients in the study group had shivering. The p-value is 0.32911.

Both hyperbaric bupivacaine and isobaric bupivacaine provided excellent analgesia in all the 70 patients. Both the drugs provided adequate sensory and motor block in all patients. Hence, none of the patients in both groups needed supplementary general anaesthesia.

### **Post-operative complications**

Post operatively all the patients in both the groups were followed till the day of discharge. None of the patients in both the groups had headache or neurological deficits

Patients in both groups were satisfied with respect to anaesthesia. None of the patients had pain intraoperatively. Apart from the routine physiological responses, no unusual effects were noted. Patients were happy with the duration of analgesia also.

Surgeons found no difference in the surgical environment in both groups since analgesia was adequate.

#### **Discussion**

This study was done to compare the effects of isobaric bupivacaine with that of hyperbaric bupivacaine in elderly patients undergoing endoscopic urological procedures under spinal anaesthesia. Haemodynamic changes were compared.

Transurethral resection of prostate, Transurethral resection of tumour, Bladder neck incision and Endoscopic internal urethrotomy are common urological surgeries. Many of the patients coming for these procedures belong 
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January 2016; 3(1) ISSN: ISSN: 2349-5340 Impact Factor (PIF): 2.672

to old age group<sup>2</sup>. Several of these patients have other systemic diseases such as coronary arterial disease, cardiac dysfunction and diabetes mellitus<sup>14</sup>. In this group haemodynamic stability is a desired feature during anaesthesia<sup>15</sup>.

Many studies have been done with reduced concentration of isobaric bupivacaine<sup>8</sup>. In these studies, an effective anaesthesia with minimal haemodynamic instability could be achieved with isobaric bupivacaine as compared to hyperbaric bupivacaine<sup>16,17,18</sup>.

Hyperbaric bupivacaine produces an extensive block compared to isobaric bupivacaine. In addition, the greater the age the more cephalad will be the level of blockade<sup>6,7,8,9,10</sup>. All these factors can lead to haemodynamic instability in the form of profound hypotension and bradycardia. This can be avoided by using a lower concentration of bupivacaine<sup>3,5,8</sup>. Our aim in this randomized study was to see if changing the baricity of bupivacaine without changing the mass produced less haemodynamic instability. If we could establish the superiority of isobaric bupivacaine, the practice of using hyperbaric bupivacaine could be changed to isobaric bupivacaine.

A major clinical advantage of isobaric spinal anaesthetics is that position of the patient during and after injection has no effect on the distribution of the anaesthetic and thus no effect on the levels of anaesthesia  $^{19}$ . Injection can be made with the patient in any position and the patient can then be placed in the operative position without affecting the level of anaesthesia  $^{20}$ . Isobaric spinals are particularly useful when levels of anaesthesia to  $T_{10}$  or below are required.

Lower concentration of bupivacaine when given in the form of isobaric bupivacaine results in lesser cephalad spread of the drug<sup>4,21</sup>. Thus haemodynamic stability the major desired feature in the old age group can be achieved.

Since our patients were all in the older age group with potential cardiovascular problems, we felt it would be a good idea to test bupivacaine as a spinal anaesthetic agent in a lesser concentration but keeping the baricity as isobaric. We modified the standard hyperbaric bupivacaine 0.50% in 8% dextrose by adding equal volume of distilled water so as to achieve isobaricity with a concentration of 0.25%. However, the mass of bupivacaine in both groups was kept at 12.5 mgms in order to prevent the failure of acquisition of adequate level of analgesia and the intensity of motor blockade. The control group received 2.5 ml of 0.50% hyperbaric bupivacaine in 8% dextrose and the study group was given 5 ml of 0.25% isobaric bupivacaine.

The spinal anaesthetic technique was standardised with respect to posture, technique of lumbar puncture, speed of injection and absence of barbotage.

The outcome of our study is as below.

Both hyperbaric bupivacaine and isobaric bupivacaine provided excellent analgesia in all the 70 patients. Both the drugs provided adequate sensory and motor block in all patients.

The distribution of sex, age, weight, height, spinal column length and surgeries was comparable in both groups.

**Fall in blood pressure:** A drop in systolic, diastolic and mean blood pressure was noted in both the groups and the drop was comparable in the two groups. However in other studies 16,17,18,22, the incidence and degree of hypotension was more with hyperbaric bupivacaine.

In our study, the difference in drop in blood pressure between both groups was found to be statistically not significant even though the mean fall in blood pressure was slightly less in the study group.

**Vasopressors required:** In our study, 11 patients in the control group and 8 patients in the study group required vasopressors. The z - value is 0.75, which is not statistically significant. Thus almost similar number of patients in the control group and the study group needed vasopressors. Thus the incidence and degree of post-spinal hypotension was same in both the groups. However, in other studies  $^{11,16,17,18}$ , the hypotension was more with hyperbaric bupivacaine group and hence many patients required vasopressors.

**Change in heart rate:** The change in heart rate after subarachnoid injection was similar in the control group and the study group. This is due to the similar level of sympathetic blockade produced in both the groups.

**Shivering:** In the control and the study group, the difference in the incidence of shivering was statistically not significant. This is because the degree of vasodilatation produced was similar in both the groups due the same level of sympathetic blockade.

**Supplementation:** Both hyperbaric bupivacaine and isobaric bupivacaine provided excellent analgesia in all the 70 patients. Both the drugs provided adequate sensory and motor block in all patients. Hence, none of the patients in both groups needed supplementary general anaesthesia.

Post operatively all the patients in both the groups were followed till the day of discharge. None of the patients in either group had headache. Use of only 25-G spinal needle in all the patients can be attributed for this outcome. None of the patients in both the groups had any neurological deficit.

January 2016; 3(1) ISSN: ISSN: 2349-5340 Impact Factor (PIF): 2.672

In both the groups, surgeons were happy with the surgical environment. In addition, patients were satisfied with anaesthesia in both the groups.

In summary, hyperbaric bupivacaine and isobaric bupivacaine produced identical haemodynamic changes in both the groups.

#### Conclusion

Isobaric bupivacaine is as good as hyperbaric bupivacaine in producing adequate motor and sensory block when the mass of bupivacaine was kept constant, for urological procedures such as Transurethral Resection of Prostate, Transurethral Resection of Bladder Tumour, Bladder Neck Incision or Endoscopic Internal Urethrotomy.

In elderly patients, isobaric bupivacaine does not produce more favourable haemodynamic changes than hyperbaric bupivacaine if the mass of bupivacaine is same. None of the patients in both the groups had any untoward complications. Surgeons were happy with the surgical environment and patients were satisfied with anaesthesia in both the groups.

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January 2016; 3(1)

ISSN: ISSN: 2349-5340

Impact Factor (PIF): 2.672

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