Original Article ISSN (O):2395-2822; ISSN (P):2395-2814

Comparative Study of 0.5% Bupivacaine and 0.75% Ropivacaine in Spinal Anaesthesia in Patients Undergoing Transurethral Resection of Prostate.

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Received: August 2017
Accepted: August 2017

ABSTRACT

Background: Ropivacaine is a relatively recent local anaesthetic agent. Its decreased lipophilicity is associated with decreased incidence of central nervous system toxicity and cardiotoxicity. This study was aimed to evaluate safety,efficacy, effects on haemodynamics and complications of spinal anaesthesia using 0.5% hyperbaric Bupivacaine and 0.75% isobaric Ropivacaine in patients undergoing transurethral resection of prostate. Aim: To study safety, efficacy, effects on haemodynamics and complications of spinal anaesthesia using 0.5% hyperbaric Bupivacaine and 0.75% isobaric Ropivacaine in patients undergoing transurethral resection of prostate. **Methods:** Ninety patients were included in our case control study and they were randomly divided into two groups, Group A and B. Group A received 3 ml of 0.5% of hyperbaric bupivacaine and group B received 3ml of 0.75% isobaric ropivacaine. The parameters like demographic characteristics, duration of surgery, onset of sensory and motor blockade, haemodynamic stability and complications were compared in both the groups. **Results:** There was a significantly less time required for sensory as well as motor blockade in Group B than in group A. Patients in group B was found to be haemodynamically more stable with less incidence of hypotension. Moreover incidence of complications during and after surgery was less in Group B as compared to Group A. **Conclusion**: 0.75% isobaric Ropivacaine is a better choice for spinal anaesthesia in elderly patients undergoing transurethral resection of prostate as compared to 0.5% hyperbaric Bupivacaine.

Keywords: Bupivacaine, Ropivacaine, Spinal Anesthesia, Haemodynamic Stability, Complications.

INTRODUCTION

Benign prostatic hyperplasia is benign enlargement of prostate seen very commonly in elderly men. It starts occurring after 40 years of age and it is said that 10% men in their 30s, 20% of men in their 40s, 60% in their 60s and almost 80% to 90% men suffers from BPH in their 70s and 80s.[1] With the increase in medical facilities and increase in life expectancy one of the most rapidly growing age group is going to be elderly people (>60 years). This increase in population of elderly is going to be reflected in increase in the overall burden of BPH cases worldwide.[2]

Common clinical features seen in patients with benign prostatic hyperplasia include urinary frequency, urgency and hesitancy.[3]

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Urinary outflow obstruction and post void residual urine may contribute to frequent occurrence of urinary tract infections in these patients.[4] The diagnosis is done by digital per rectal examination, ultrasonography and in selected cases endoscopy of lower urinary tract. In cases with mild signs and symptoms pharmacological management consisting of alpha-1–receptor blockers, alpha-adrenergic receptor blockers and anticholinergics can be tried. In patients with severe signs and symptoms, BPH complicated by repeated urinary tract infections and those not responding to pharmacological management surgery is recommended.[5]

Most common surgeries for BPH include transurethral resection of prostate and freyer's prostatectomy.[6] Since benign prostatic hyperplasia is mostly seen in elderly people who may also have co-morbidities like diabetes, hypertension and coronary artery disease regional anesthesia has an obvious advantage over general anesthesia.[7] Regional anesthesia is obviously associated with less risk of deep venous thrombosis, early recognition of deterioration of haemo-dynamics and early recovery. Hence subarachnoid block is a preferred type of anesthesia in these patients.[8]

Bupivacaine and Ropivacaine are the two most common local anesthetic agents used in patients posted for transurethral reaction of prostate under regional anesthesia.[9] We conducted this study to compare these twoaminoamide drugs for regional anesthesia for TURP.

MATERIALS AND METHODS

This was a prospective randomized comparative study conducted in a tertiary care hospital situated in an urban area. The duration of the study was 2 years. After taking written informed consent 90 patients of aged above 40 years of age undergoing TURP were included in this study.

Inclusion Criteria

- Patient diagnosed with BPH.
- ASA I/II
- Age more than 40 years
- BMI < 30

Exclusion Criteria

- Patients who refused to give the consent.
- ASA III or more.
- Patients in whom spinal anesthesia is contraindicated (Local infection, coagulopathy, allergic to drugs etc).
- Patients who required to be converted to general anesthesia due to any reason.

Taking into consideration previous studies with an alpha error of 0.05 and a power of 80% the minimum sample size should be 30 patients per group so we included 45 patients in each group. Detailed history was taken in all the patients with an emphasis on symptoms like urinary urgency and hesitancy, episodes of burning micturition, presence of any comorbid medical condition like diabetes, hypertension, asthma or any other significant medical illness. History of any surgery in the past was also noted down. A through clinical examination was done.

Anesthetic procedure and protocol

In the operating room I.V access was done with 18 gauge cannula and patients were preloaded with normal saline at a rate of 6 ml/kg/hr. Standard monitors were attached to record heart rate (HR), non-invasive blood pressure (BP), electrocardiography and oxygen saturation (SpO2). The study population was allocated randomly into Group A and Group B of 45 patients each. Preloading with 6 ml/kg of normal saline was done in all the patients. Under all aseptic precautions subarachnoid block was given in the sitting position in L3-L4 space by midline approach using 25 gauge Quincke's spinal needle. The subarachnoid space was confirmed by free flow of CSF with absence of blood. Group A patients received 3ml of 0.5% bupivacaine (Hyperbaric) and Group B received 3ml of Ropivacaine (isobaric).O2 inhalation by nasal prongs was given to all the patients. After the patient achieved satisfactory sensory level, patient was given lithotomy position. No analgesia was needed during the procedure. Onset of sensory and motor blockade (injection of drug to Bromate scale 3), Duration of sensory and motor block, heart rate, blood pressure, oxygen saturation, Duration of the surgery and incidence of complications like hypotension, bradycardia, vomiting etc were noted in all the patients.

Statistics

Data were analyzed by SPSS 16.0 version. The data was presented as mean and standard deviation. Chi-square test and student 't' tests were used for difference in the demographic data. Hemodynamic variables were analyzed using paired't' test. For statistical comparisons P value less than 0.05 was taken as significant.

RESULTS

This study was a prospective, randomized double blind case control study in which 90 patients with ASA I and II undergoing TURP for benign prostatic hyperplasia were studied as per inclusion criteria. Patients were excluded if they had any factor of exclusion criteria. Patients were divided into 2 groups Group A: Bupivacaine (3ml of 0.5% hyperbaric bupivacaine was given to patients belonging to this group) and Group B (3ml of 0.75% isobaric Ropivacaine was given to patients belonging to this group).

Demographic Data:

Out of the studied cases Group A had a mean age of 64.39 years and group B had a mean age of 65.46 years. In group A 42.22% patients belonged to ASA I and 57.77% patients belonged to ASA II. The percentage of patients with ASA I and ASA II was 62.22% and 37.77% respectively in group B [Table 1].

Table 1: Demographic data in studied cases.

Parameters	Group A	Group B
No of cases	45	45
Mean Age	64.39	65.46
ASA I II	 19 (42.22%) 26 (57.77%)	 28 (62.22%) 17 (37.77%)

Comparison of mean duration of the surgeries showed that the mean duration of the surgery was 92 +/- 18.72 minutes in group A while this duration was 80 +/-20.34 minutes in Group B. The test of significance applied showed that p value was 'not significant' [Table 2].

Table 2: Mean duration of the surgery in the studied cases.

N= 45	N=45
Group A	92 +/- 18.72 Min
Group B	80 +/-20.34 Min
P Value	0.2926
P value	Not Significant

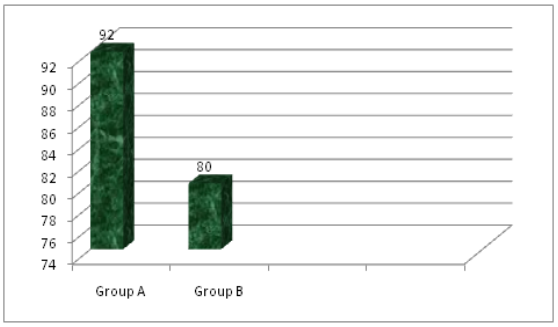

Figure 1: Mean duration of the surgery (in Minutes)

The study of the mean time for onset of sensory blockade revealed that the sensory blockade was significantly faster with Group A (5.21+/-1.21) than Group B (9.10 +/- 1.50 min). The difference was found to be statistically significant (P<0.001).

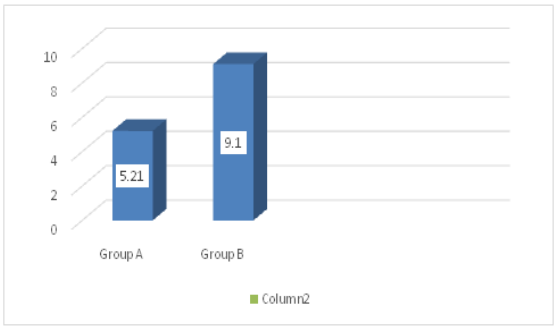

Figure 2: Onset of sensory blockade in the studied cases.

The study of the mean time for onset of sensory blockade revealed that the sensory blockade was significantly faster with Group A (8.25+/-1.30) than Group B (11.50 +/- 1.75 min). The difference was found to be statistically significant (P<0.001).

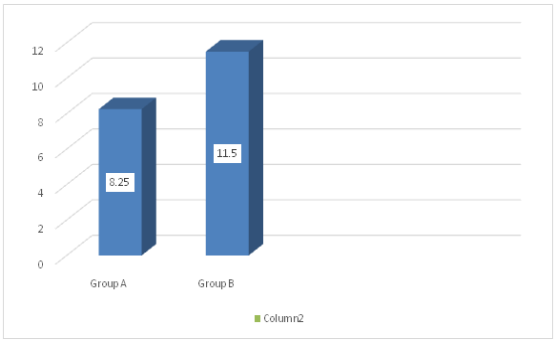

Figure 3: Onset of motor blockade in the studied cases.

The analysis of highest segmental level of sensory blockade achieved by these 2 levels revealed that Out of 45 patients in Group A 20 patients had block up to T10 level, 15 patients had block upto the level of T8 , 8 patients had highest segmental block up to T6 and remaining 2 patients showed segmental block up to the level of T4. In group B the highest segmental level was seen up to T10, T8, T6 and T4 levels in 36, 8, 1 and 0 patients respectively.

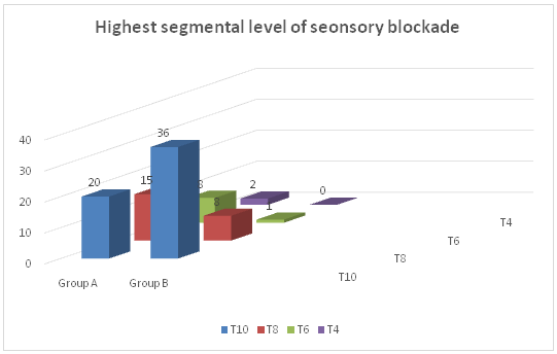

Figure 4: Highest Segmental level of sensory blockade.

Comparison of duration of the sensory blockade in the studied cases revealed that the the mean duration of the sensory blockade was 108.75 +/- 22.50 minutes in group A and 96.35 +/- 15.25 minutes. The difference was found to be statistically significant.

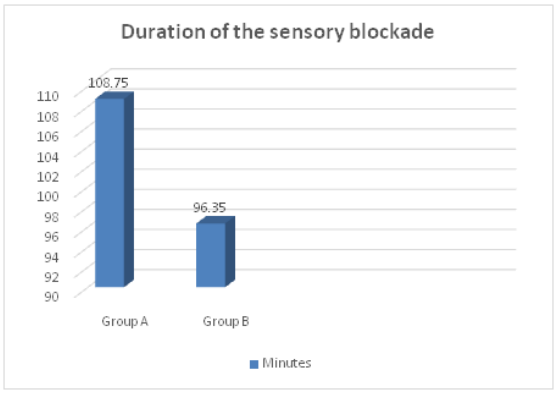

Figure 5: Duration of the sensory blockade in the studied cases.

Comparison of duration of the motor blockade in the studied cases revealed that the mean duration of the motor blockade was 148.35 +/- 32.25 minutes in group A and 116.35 +/- 18.26 minutes. The difference was found to be statistically significant.

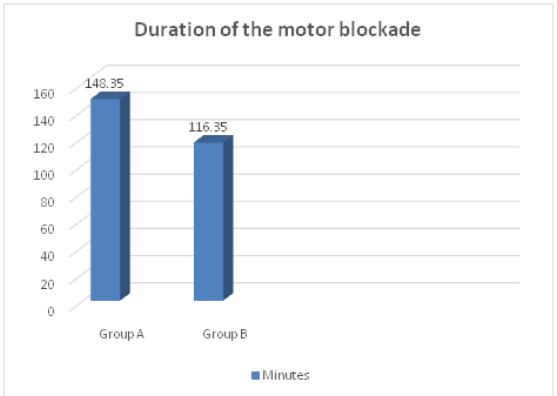

Figure 6: Duration of the motor blockade in the studied cases.

The comparison in the changes in the heart rate during surgery was analyzed in both the groups. The mean heart rate before induction was 80.26 +/- 11.50 minutes in group A as compared to group B in which

the mean heart rate before induction was 76 .34 +/- 10.80. The difference was statistically 'not significant'. After induction the heart rate was higher in group A as compared to group B till 20 minutes of the surgery and the difference was found to be statistically significant. During rest of the surgery the heart rate was comparable in the 2 groups.

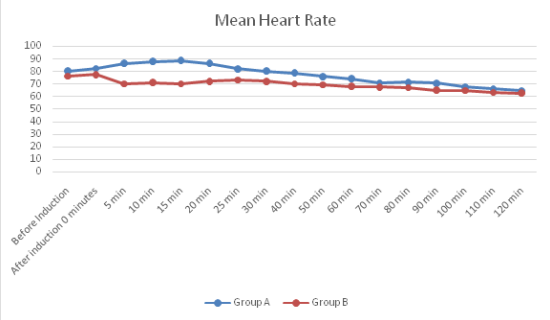

Figure 7: Mean Heart Rate in the studied cases

Comparison in mean systolic blood pressures during the surgery was tabulated and studied in both the groups. Mean systolic blood pressure before induction was 135.12 +/- 12.36 in group A while it was 132 +/- 11.31 in group B. After induction till 50 minutes of the surgery mean systolic blood pressure in group A was lesser than group B. In the rest of the study the systolic blood pressure was comparable.

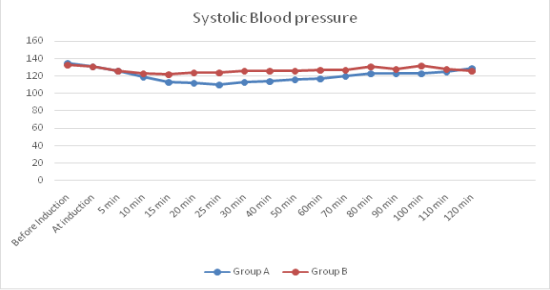

Figure 8: Systolic blood pressure in the studied cases

Comparison in mean diastolic blood pressures during the surgery was tabulated and studied in both the groups. Mean diastolic blood pressure before induction was 81.20 +/- 8.12. in group A while it was 80.26 +/- 8.22 in group B. After induction till 60 minutes of the surgery mean diastolic blood pressure in group A was lesser than group B. In the rest of the study the diastolic blood pressure was comparable.

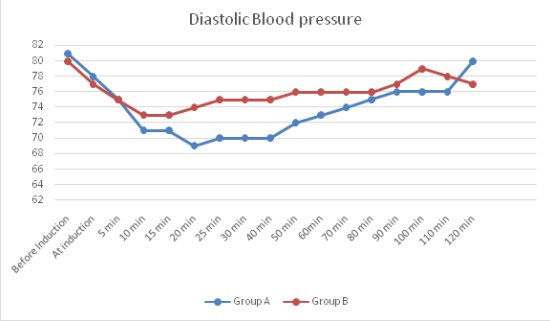

Figure 9: Diastolic blood pressure in the studied cases

The analysis of mean arterial pressure in both the groups just before induction and during the surgery revealed that there was no statistically significant difference in the mean arterial pressures of both the groups during most of the surgery period.

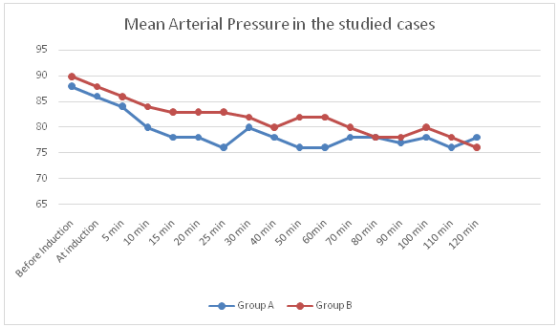

Figure 10: Mean arterial pressure in the studied cases.

Just before induction and during the surgery SPO2 levels were maintained in both the groups and there was no statistically significant difference in SPO2 of both the groups.

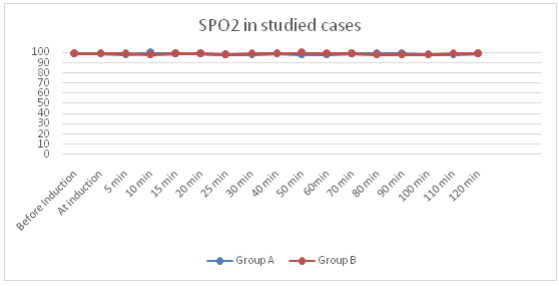

Figure 10: SPO2 in the studied cases

The most common complication seen in group A was nausea and vomiting which was seen in 4 (8.89%) patients followed by hypotension (17.78%) and shivering (13.33%). In group B the most common complication seen were hypotension, pruritus and shivering (6.67% each). The overall complication rate was more in group A than in group B.

Table 3: Complications during and after surgery in both the groups.

N=45	Group A	Group B
Hypotension	8	3
Bradycardia	3	0
Nausea/Vomiting	4	2
Pruritis	5	3
Shivering	6	3
Urinsryretension	5	2

DISCUSSION

The purpose of this study was to compare these two aminoamide drugs in spinalanaesthesia for transurethral resection of prostate in patients with benign prostatic hyperplasia meeting the criteria of the study.

Benign prostatic hyperplasia is a common problem in elderly population. The most common surgical intervention done in patients who respond poorly to pharmacological treatment is transurethral resection of prostate. The procedure has advantage of being minimally invasive and except in some cases which gets complicated short hospital stay and early mobilisation is a rule. Since BPH is usually seen in elderly patients who are expected to have other co-morbid medical conditions like diabetes, hypertension and coronary artery disease spinal anaesthesia is considered as anaesthesia of choice in these patients. Low-dose anaesthetic agents via spinal anaesthesia is the preferred anaesthesia given in these patients during TURP.[10]

Bupivacaine and Ropivacaine are the twoamidoamide group of drugs commonly used for spinal anaesthesia in these patients. Ropivacaine is relatively new drug introduced in 1996 owing to its reduced toxicity over myocardium and central nervous system. Scott DA et all concluded in their study that Ropivacaine exhibits less cardiotoxicity and causes less motor block than bupivacaine when used in equipotent doses. They further showed that Ropivacaine is potentially well suited for epidural infusion for postoperative analgesia. Their study proved that Ropivacaine has a higher therapeutic index than bupivacaine making it a relatively safe drug than bupivacaine. In our study we got similar findings as complications were observed more frequently with the use of Bupivacaine than Ropivacaine.[11]

From an Indian perspective it is important to know that Ropivacaine is one of the new addition to the drugs used for anaesthesia and many studies have been conducted on its efficacy and safety in comparison with other anaesthetic drugs. Sonal Bhat et al conducted a prospective randomized clinical study was conducted to study the efficacy and safety of Ropivacaine with Bupivacaine intrathecally for lower abdominal and lower limb surgeries and concluded that “use of Ropivacaine for intrathecal anaesthesia in the lower abdominal and lower limb surgeries provided an adequate level of block for the surgery with faster onset of sensory and motor blockade, lesser duration of motor blockade with good analgesia and stable haemodynamics” again confirming the high safety profile of Ropivacaine over Bupivacaine.[12]

The mean duration of the surgery was not significantly different statistically in Bupivacaine and Ropivacaine group. This was similar to the results found in various study conducted by Malinovsky JM metal and swathi et al.[13,14]

Study of sensory and motor blockade seen in both the groups showed that the onset of sensory blockade was significantly faster with Ropivacaine group than the bupivacaine group and onset of motor blockade was statistically significantly earlier in Ropivacaine group than the bupivacaine group. These findings shows Ropivacaine to be faster acting than bupivacaine as far as onset of sensory and motor blockade are concerned. These findings were similar to the studies conducted by Soni et al and McNamee DA.[15,16]

The study of differences in haemodynamic parameters of the patients showed that the parameters like heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressures were more in group B during initial 25-30 minutes post induction. Group B had more haemodynamic stability than group A confirming the higher safety profile and less incidence of hypotension in group B. These findings were similar to the studies conducted by Barisanker H and Udelsmann A.[17,18]

Finally the complications occurred during surgery in group B were less than group A. The difference was statistically significant. Safety profile of Ropivacaine was found to be better than the bupivacaine. These findings were consistent with the findings of studies conducted by Eryilmaz NC and Kallio H.[19, 20]

CONCLUSION

From the present study we conclude that 0.75% Ropivacaine is a better alternative to 0.5% Bupivacaine in TURP surgeries because of its safety profile and low risk of cardiovascular complications. The recovery with 0.75% Ropivacaine is faster than with 0.5% Bupivacaine making it a suitable alternative for day care surgeries.

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How to cite this article: Yennawar SD, Memon NY, Nandanwakar NK. Comparative Study of 0.5% Bupivacaine and 0.75% Ropivacaine in Spinal Anaesthesia in Patients Undergoing Transurethral Resection of Prostate. Ann. Int. Med. Den. Res. 2017; 3(5):AN12-AN17.

Source of Support: Nil, **Conflict of Interest:** None declared