



Anaesthesiology

A COMPARISON OF INTRATHECAL ISOBARIC ROPIVACAINE - FENTANYL AND HYPERBARIC BUPIVACAINE - FENTANYL FOR UROLOGICAL SURGERIES

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ABSTRACT **Background :** To compare the sensory & motor block characteristics in patients undergoing urological surgeries when isobaric 0.75% ropivacaine or hyperbaric 0.5% bupivacaine were used in spinal anaesthesia .

Methodology : Sixty ASA grade I & II patients of either sex in the age group of 18 to 70 years undergoing urological surgery were randomly divided into two equal groups. In group R , patients received 18.75 mg of ropivacaine & in group B , patients received 15mg of bupivacaine . Injection fentanyl 25 µgm was added as an adjuvant to both these groups . Parameters observed were onset & duration of sensory & motor blockade, degree of motor block & intraoperative hemodynamic stability.

Results : There was statistically significant difference in onset of sensory block between the two groups. Patients in group R showed faster onset of sensory block (4.13±1.32 min) compared to group B (4.57±1.46 min). The duration of sensory block was prolonged in group B (194.16 ±21.43 min) as compared to group R (153.03 ±19.19 min) , the difference being statistically highly significant (P <0.001). The onset of motor block was faster in group R (5.13 ±0.58 minutes) than group B (5.63 ±0.92 minutes) with statistically significant difference (p=0.02). The duration of motor blockade was significantly prolonged in bupivacaine group (197.18 ±21.78 min) compared to ropivacaine group(169.26 ±19.38 min), P<0.001. Intensity of motor blockade was similar in both the groups.

There was no significant difference in the comparison of heart rate & blood pressure between the two groups.

Conclusion : Intrathecal 0.75% isobaric ropivacaine with fentanyl might be a good alternative to 0.5% hyperbaric bupivacaine with fentanyl in urological surgery in terms of faster onset of sensory & motor blockade, faster regression of sensory and shorter duration of motor blockade with intraoperative hemodynamic stability.

KEYWORDS : Bupivacaine, Fentanyl, Ropivacaine , Spinal anaesthesia

INTRODUCTION

Spinal anesthesia is a widely used technique that offers many advantages over general anaesthesia like reduced stress response, improved post-operative pain relief , early ambulation & maintenance of post operative cognitive functions in elderly.¹

Traditionally, bupivacaine has emerged as long acting local anaesthetic drug used for subarachnoid block however , it has some undesirable side effects such as cardiotoxicity & prolonged motor paralysis thus delaying discharge. Ropivacaine, an amide local anaesthetic, has been introduced recently and used successfully in epidural to provide post operative analgesia & in spinal it has been used for day care procedures as it provides adequate sensory block with early motor recovery. It has an improved safety profile over bupivacaine with a reduced central nervous system and cardio toxic potential².

Local anesthetics with adjuvants have proven many benefits in recent years by enhancing the sensory blockade without altering the degree of sympathetic blockade ensuring better hemodynamic stability.³

Various drugs such as morphine, pethidine, , ketamine, buprenorphine, fentanyl, and many others have been used intrathecally.

Fentanyl a synthetic opioid and a strong agonist at μ receptors., is preferred because of its rapid onset and short duration of action with lesser incidence of respiratory depression when used as an adjuvant in spinal anaesthesia. The addition of fentanyl to ropivacaine for spinal anaesthesia has been shown to prolong the duration of analgesia in the early postoperative period.⁴ However there are limited studies comparing 0.75% isobaric ropivacaine fentanyl with hyperbaric 0.5% bupivacaine fentanyl for urological procedure.

This study was undertaken to compare the safety & efficacy of isobaric 0.75% ropivacaine & hyperbaric 0.5% bupivacaine with Fentanyl.

MATERIALS AND METHODS

After obtaining approval from the hospital ethical committee, this prospective, double blind, randomized study was conducted at the tertiary care hospital over a period of two years. Sixty patients of American society of Anaesthesiologists physical status-I and II, aged between 18 to 70 years, scheduled for elective endoscopic urological procedure of less than two hour duration under spinal anaesthesia were included in study. Pregnant females, lactating mothers, and patients having allergy to study drugs were excluded from the study.

The study population was randomly divided into two groups using sealed envelope method.

Group R received 2.5 ml of 0.75 % isobaric ropivacaine & Group B received 2.5 ml of 0.5% hyperbaric bupivacaine. Inj fentanyl 25g added as an adjuvant to both the study drugs.

After explaining the procedure & obtaining written consent from patients, intravenous line secured & baseline parameters like heart rate (HR), blood pressure (NIBP), Oxygen saturation (SPO2) and ECG were noted. Under all aseptic precautions Spinal anaesthesia was administered in sitting position in L3-L4 interspace with 23G quincke needle and the study drug was injected as per allotted group. One anaesthetist administered the drug intrathecally while another anaesthetist who was blind to the drug administered recorded the findings making the study double blind.

Onset of Sensory block was tested by pin prick method in mid-axillary line every 5min till peak sensory level i.e. two consecutive reading at the same dermatomal level is achieved. Thereafter sensory block was tested every 30 mins till the block regression to L1 level. The time from spinal injection (T-0) to time taken to achieve T10 level was taken as onset of sensory block. The time from intrathecal injection (T-0) to regression to L1 was taken as duration of sensory block. Motor block was tested using modified Bromage score every 5 min.till grade 3

motor block was achieved. Motor block was tested in post operative period every 30 mins till complete recovery (Bromage score 0) achieved.

Onset & duration of motor block was taken as time from intrathecal injection (T-0) to obtaining a motor block of Bromage score 2 & recovery to bromage score 0 respectively.

Surgery was allowed after achieving sensory block up to T10 and grade 2 motor block. Failure to achieve the required block in 20 mins was considered as failure of block and general Anaesthesia was given.

After spinal anaesthesia was administered, pulse rate and mean blood pressure were recorded every 5min for the first 20 mins then every 15 mins till the regression of level to L1. Fall of mean arterial pressure by more than 25% of base line was taken as hypotension and treated with inj. mephenteramine 6 mg intravenously. Fall in pulse rate to less than 50/min was taken as bradycardia and treated with injection atropine 0.6mg IV. Incidence of side effects like nausea, vomiting, and pruritus were noted.

Statistical Analysis

Setting the α error at 0.05 and β error at 0.8, the minimum sample size required was 17 in each group. Considering the drop-outs, we included 30 patients in each group.

All statistical analysis was made using SPSS 20 for Windows (Statistical Package for Social Science) -The qualitative data was represented in the form of frequency and percentage and Chi Square test was used for checking the significance between two groups. The quantitative data was expressed in mean & standard deviation and unpaired t-test was used for checking significance between two groups. p value < 0.05 was considered Statistically significant & less than 0.001 as highly significant. P>0.05 was regarded as non signify

RESULTS

Demographic data was comparable in both the groups. -The two groups were comparable regarding age, sex, ASA grading and surgical duration.(p<0.05)

Table 1: Demographic profile of both the groups

Characteristics	Group R (n=30) (%)	Group B (n=30) (%)	P Value
Mean age (years)	38.53 ±13.88	38.96 ±11.41	0.783
Sex	Male	23	0.71
	Female	07	
ASA	I	12	0.42
	II	09	
	III	09	

P>0.05 statistically non significant

Patients in group R showed faster onset of sensory block (4.13±1.32 min) compared to group B (4.57±1.46 min), the difference being statistically significant (p<0.02). In group R, 16 patients had (53.33%) maximum level of sensory block was T6 which was comparable to group B where 14 patients (46.67%) had level of T 6. Nearly 8 patients (26.66 %) had maximum level of sensory block at T4 in group R as compared to 6 patients (20%) in group B.

The mean duration of sensory block found in group R was 153.03 ±19.19 minutes while 194.16 ±21.43 minutes in group B, the difference being statistically highly significant (P <0.001). The mean time for onset of motor block was faster in group R (5.13 ±0.58 minutes) than group B (5.63 ±0.92 minutes). The difference was being statistically significant (p=0.02) The mean duration of motor blockade was 169.26±19.38 minutes in group R while 197.18 ±21.78 minutes in group B with P<0.001 suggesting significantly shorter duration of motor blockade in group R.

Table 2 : Comparison of sensory & motor block characteristics

Parameters	Group R	Group B	P value
Onset of Sensory block (min.)	4.13 ±1.32	4.57 ±1.46	0.02
Duration of sensory block (min.)	153.03 ±19.19	194.16 ±21.43	<0.001
Onset of motor block (min.)	5.13 ±0.58	5.63 ±0.92	0.02
Duration of motor block (min.)	169.26 ±19.38	197.18 ±21.78	<0.001

Out of 30 patients in each group, 28 (93.33%) patients in group R had grade 3 motor blockade compared to 30 (96.67%) patients in Group B which was statistically not significant (p>0.05)

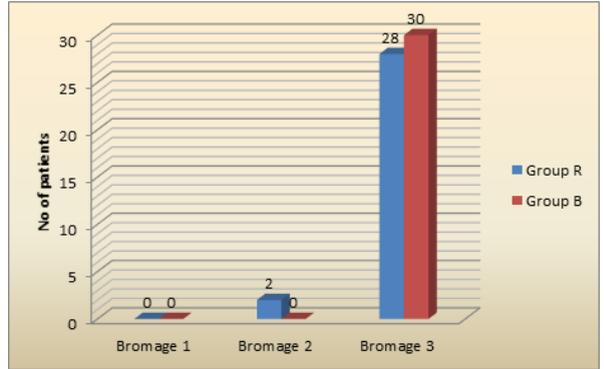


Figure 1: Intensity of motor block:

The mean intra operative heart rates of patients from group R and group B at different time intervals showed no statistical significance. (P>0.05)

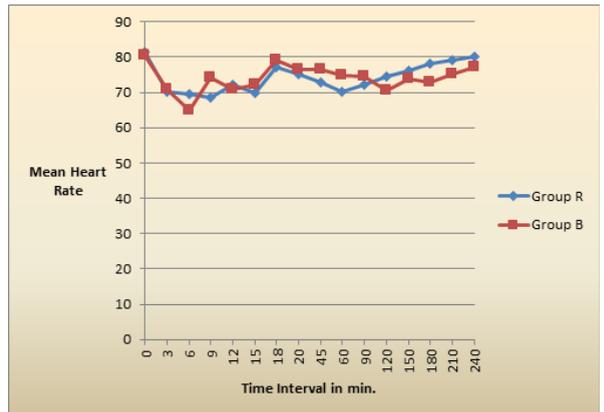


Figure 2: Mean heart rate at different intervals

The intraoperative mean arterial blood pressure of patients from Group R and Group B at different time intervals showed no statistical significance. (Fig 2)

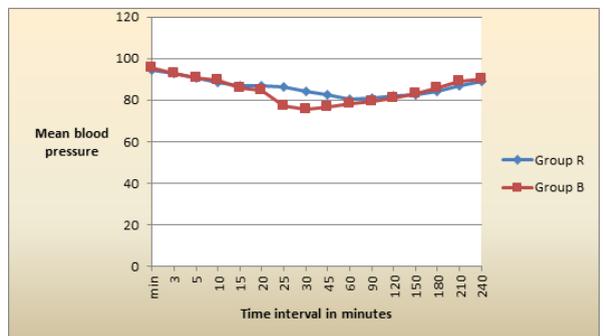


Figure 3: Mean arterial blood pressure at different intervals

In our study, one patient had bradycardia and two patients had hypotension in Group B having no statistically significant difference when compared with patients in group R.

Complication	Group R	Group B	Total
Bradycardia	00	01	01
Hypotension	00	02	02
Pruritis	00	00	00
Nausea	00	00	00

DISCUSSION

Spinal anaesthesia is the preferred anaesthesia technique for most of the urological surgeries. Bupivacaine a long-acting local anesthetic widely used in practice, however its certain features like prolonged motor block, cardiotoxicity has made ropivacaine a safer choice.⁵ Ropivacaine, a pure S(-) enantiomer of bupivacaine, developed for the purpose of reducing potential toxicity and improving relative sensory and motor block profiles.¹⁸The addition of fentanyl to spinal

anaesthesia reduces dose of local anaesthetic, improves quality & duration of sensory block, providing postoperative analgesia without affecting motor function.⁴

Our study population consisted of 60 patients posted for urological surgeries which were divided into two groups of 30 each.

In our study, mean time for onset of sensory block in group R was (4.13 ±1.32) min and in group B was (4.57 ±1.46) min. This difference was statistically significant (P<0.05).

According to Ganvit J *et al*¹ sensory onset time using 20 g fentanyl when added to 13 mg of 0.5% isobaric bupivacaine was 1.6 min when compared with 19.5 mg of 0.75% isobaric ropivacaine which was 1.58 min. They observed no statistical significant difference in the onset time of sensory block in both the groups (p=0.977). This result may be because of use of isobaric drugs.

Atabekoglu S *et al*² conducted a study in patients undergoing transurethral resection of prostate by using 22.5 mg of isobaric 0.75% ropivacaine & 15 mg of 0.5% isobaric bupivacaine. Their observation was similar with our study in terms of onset of sensory block which was 4.572.57 mins in group R & 4.772.56 mins in group B even though there was no statistical significant difference. Addition of intrathecal fentanyl in our study might have resulted in early onset of sensory block.

In our study, maximum level of sensory block was T4 (n=8) in group R & (n=6) in group B. Median level of sensory block was T6 (T4-T10) in group R and same T6 level (T4-T10) Group B respectively. There was no significant difference in maximum level of sensory block when two groups were compared statistically (p>0.05). Our study correlates with the study conducted by Layek. A *et al*³ who used 3ml 0.5% isobaric ropivacaine + 25g Fentanyl & compared with 3ml 0.5% isobaric bupivacaine + 25g fentanyl. In patients undergoing elective infra umbilical orthopaedic surgeries where they found that maximum level of sensory block in Group R was T6 (T4-T9) and Group B was T6 (T4-T10) with no statistical significant difference.

Hari. K *et al*⁴ reported maximum level of sensory block in ropivacaine group as T7 (T4-T11) & T6 (T5-T11) in bupivacaine group. This small difference may be due to not adding fentanyl in their study.

Duration of sensory blockade was defined as the time taken from completion of injection of drug till the regression of sensory level to L1. In our study, mean duration of sensory block in group R was 153.03 ±19.19 minutes while in group B was 194.16 ±21.43 minutes. The mean difference in duration of sensory block was statistically highly significant. (P<0.001)

Our results correlate with the results obtained by Varu. S *et al* (2009)^{9a} Layek. A (2011)³ *et al* where they compared 0.5% isobaric ropivacaine with 0.5% isobaric bupivacaine. Varun *et al* observed that sensory block regression to S2 was faster in 0.5% isobaric ropivacaine group than 0.5% isobaric bupivacaine group with statistically significant difference (p=0.025).

Layek *et al*³ found that two segment regression was 85 min vs. 120 min in group R & B respectively with highly significant difference of P value <0.001

Erturk. E *et al*¹⁰ conducted a study in patients undergoing major orthopaedic surgery in geriatric patients under spinal anaesthesia. Group B received 8 mg 0.5% hyperbaric bupivacaine + 20g fentanyl & Group R received 12mg 1% plain ropivacaine + 20g fentanyl + 1.4 ml 10% dextrose in equal volume.

They observed that duration of sensory block in Group B was 14520 min, Group R was 91 10 min. Even with hyperbaric ropivacaine, duration of sensory block was shorter with statistically significant difference of p value p<0.05.

Onset of motor blockade was defined as the time taken from the completion of injection of the study drug till the patient developed motor block of Bromage score 2. In our study, the mean time taken for the onset of motor blockade was 5.13 ±0.58 minutes in group R and 5.63 ±0.92 minutes in group B, the difference being statistically significant (p< 0.05). A study conducted by Varu *et al*⁹ found that

mean time taken to achieve maximum grade of motor block was 4.06±1.62 min in ropivacaine group which was shorter than our ropivacaine group. The reason might be due to 3 ml of ropivacaine used in their study.

Murali C *et al*¹¹ & Kaushik *et al*¹² observed similar results like in our study where they found onset of motor block in Group RF was 5.12 0.6 min & 5.21.1 min respectively with similar doses of isobaric 0.75% ropivacaine & fentanyl. Bhatia *et al* reported onset of motor block of 4.91.4 min in ropivacaine & fentanyl group which is almost similar to our study.

Out of total 60 patients, it was observed that maximum degree of motor blockade of Bromage score 3 in 28 (93.33%) patients in ropivacaine and 30 (100%) patients in bupivacaine group. There was no statistically significant difference in degree of motor blockade when two groups were compared.

Layek. A *et al*³ & Ganvit J *et al*¹ observed no statistical significant difference in the intensity of motor block even with isobaric 0.5% ropivacaine & 0.5% bupivacaine. The duration of motor block in group R was 169.26±19.38 mins compared to 197.18 ±21.78 mins in group B. The difference was statistically highly significant (p<0.001). Our findings are similar with the observations done by Tiwari *et al*¹³ (group B 323.03 39.70 min. and group R 224.63 24.10 min) & Ganvit J *et al*¹ (group RF 233.5 48.06 min & group BF 279.6 46.5 min) with longer duration of motor block in their study than our study. This could be related to more dose of bupivacaine and ropivacaine used in their study.

Results obtained from the study done by Erturk. E *et al*¹⁰ were similar to our study showing longer duration of motor blockade in bupivacaine group than ropivacaine group which was 162 48 min & 115 25 min. respectively. Their shorter duration of action as compared to our results might be due to lower volume of drug used.

In our study no patients had pruritus or nausea in any one of the group. Incidence of bradycardia & hypotension was 3.33 % & 6.67 % respectively in bupivacaine group at 5min, 30 & 45 min respectively. No patients had such incidences in ropivacaine group.

CONCLUSION

From the present study, it can be concluded that Intrathecal 0.75% isobaric Ropivacaine with fentanyl is a good alternative to 0.5% hyperbaric bupivacaine with fentanyl in urological surgeries as it shows faster regression of sensory and motor block with excellent intensity of motor blockade & intraoperative hemodynamic stability.

REFERENCES

1. Dr Bipin J. Ganvit, Parimal H Patel, Dr Hitesh R. Ahir, Comparison of of intrathecal ropivacaine with fentanyl and bupivacaine with fentanyl for urological surgery, IJSR-International journal of scientific research, ISSN No 2277-8179
2. Boztug N, Bigat Z, Ertok E, Erman M. Intrathecal ropivacaine versus ropivacaine plus fentanyl for out-patient arthroscopic knee surgery. J Int Med Res 2005;33:365-71.
3. Gautier PE, De Kock M, Van Steenberghe A, Poth N, Lahaye-Goffart B, Fanard L, *et al*. Intrathecal ropivacaine for ambulatory surgery. Anesthesiology 1999;91:1239-45.
4. Saad A Sheta, Essam A Eid, Ashraf A Moussa, Spinal ropivacaine in fast-track TURP, Alexandria journal of anaesthesia and intensive care AJAIC-Vol. 8 s.
5. Mudita Bhatia, Alaka Purohit, Mohit Pareek, Pradeep Charan, comparison of 0.75% isobaric ropivacaine alone and 0.75% ropivacaine with fentanyl as adjuvant in spinal anaesthesia for orthopaedic lower limb surgeries, Journal of medical science and clinical research Vol. 05 Issue 06 June 2017.
6. Serap Atabekoglu, Comparison of clinical effects of intrathecal ropivacaine and bupivacaine in geriatric patients undergoing trans urethral resection. Arastirma research article, Gazi Medical Journal, 2007;CILT 18;SAYI4: 182-185
7. Amitava Layek, Souvik Maitra, Nitish K Gozi, Sulagna Bhattacharjee, Sugata Pal, Suvadeep Sen, Avijit Hazra, Comparison between intrathecal isobaric ropivacaine - fentanyl and bupivacaine - fentanyl in elective infra umbilical orthopaedic surgery: randomized controlled study, Journal of anesthesiology clinical pharmacology, October - December 2015, Vol.31, Issue 4.
8. K Hari Prasad, A comparative evaluation of hyperbaric ropivacaine Vs hyperbaric bupivacaine in lower abdominal surgeries, International journal of Recent trends in science and technology, August 2014, 12(1): 210-214.
9. Sangeeta Varu, Mridul Srivastava, Indubala Maurya, Rakesh Garg, Vipin Dhama, Yogesh Kumar Manik, A clinical prospective, randomized study to compare intrathecal isobaric bupivacaine-fentanyl and isobaric ropivacaine - fentanyl for lower abdominal and lower limb surgeries, Anesthesia, pain and intensive care, Vol. 16(3) Sep - Dec 2012.
10. Engin Erturk, Cigdem Tutuncu, Ahmet Eroglu, Merih Gokben, Clinical comparison of 12mg ropivacaine and 8 mg bupivacaine, both with 20 g fentanyl, in spinal anaesthesia for major orthopaedic surgery in geriatric patients, Medical principles and practice 2010, 19, 142-147.
11. Murali C.H., Laxmi Narsaiah G, Effects of fentanyl on isobaric ropivacaine in subarachnoid anaesthesia for lower abdominal and lower extremity surgery. International journal of research in medical sciences, July 2016, Vol. 4, Issue 7, ISSN 2320-6012.
12. Kaushik Rao Seetharam, Gayathri Bhat, Effects of isobaric ropivacaine with or without fentanyl in sub archnoid blockade: Prospective double blind, randomized study, Anesthesia: Essays and researches Res 2015;9:173-7
13. Dr Bupendra Tiwari, Dr Shriphal Meena, Haemodynamic comparison of intrathecal

hyperbaric 0.5% bupivacaine 2ml (10mg) with isobaric 0.75% ropivacaine 2ml (15mg) with fentanyl 20µg as adjuvant in geriatric patients undergoing major lower limb orthopedic surgery, International journal of science and research, ISSN: 2319-7064, Vol. 6 Issue 4 April 2017