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Original Research Article

A Comparative Study of Spinal Anesthesia with Hyperbaric Ropivacaine and Hyperbaric Ropivacaine plus Fentanyl in Endoscopic Urological Surgery

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Abstract:
Background: Ropivacaine has different sensory and motor blockade with motor function recovering earlier then sensory function. The aims of this study was to evaluate the sensory and motor block characteristics of commercially available 0.75% hyperbaric ropivacaine and effect of fentanyl on block characteristics, postoperative analgesia and side effects when used as adjuvant intrathecaly.
Methods: This prospective, randomized, controlled and double blinded study was conducted on sixty patients of ASA grade I-III, aged 18 to 60 years, of either gender undergoing urological surgery under spinal anaesthesia. All patients were randomized in two groups of 30 patients each: Group R received hyperbaric ropivacaine (0.75%) 2.5 ml with 0.9% normal saline 0.5ml and Group F received hyperbaric ropivacaine (0.75%) 2.5 ml with fentanyl 25 µg (0.5 ml). Sensory and motor block characteristics, postoperative analgesic drug requirement, hemodynamic parameters and incidence of side effects were assessed.
Results: The onset time of sensory block and motor block, time to complete motor block and duration of motor block were comparable in both the groups. The mean time to reach maximum height of sensory block in group F was significantly earlier than in group R ($p = 0.003$), whereas two segment regression time was significantly earlier in group R (83.70±21.22) as compared to group F (109.13±43) $p=0.003$. The time of first requirement of rescue analgesia (min) was found to be significantly prolonged in Group F as compared to Group R (280±55.15 vs215.1±63.4); $p=0.0001$.
Conclusion: Fentanyl when used as an adjuvant with hyperbaric ropivacaine seems to prolong the duration of sensory block and postoperative analgesia without affecting hemodynamics and motor block.
Keywords: Fentanyl, Hyperbaric Ropivacaine, Spinal Anaesthesia.

Introduction

Spinal anaesthesia (S/A) is commonly used mode of anaesthesia for endoscopic urological surgeries. S/A decreases the "stress response" of surgery, reduces intraoperative blood loss, decreases the incidence of postoperative thromboembolic events, and decreases the morbidity in high-risk surgical patients.[1] Ropivacaine is an amide local anesthetic drug which has less neurotoxicity and cardiotoxicity as compared to bupivacaine and has rapid recovery of motor block. [2] Various studies shows intrathecal plain ropivacaine produced variable extent of sensory block and less reliable for surgery above L1 dermatome so many patients required general anaesthesia to complete the surgery. [3,4,5] Hyperbaric solution can be made with glucose 50 mg/ml, with faster onset of block, greater reliability, and has a greater degree of motor sensory differentiation, which could be useful when motor blockade is undesirable but making a hyperbaric solution may have sterility related problems and exact density or baricity of hyperbaric ropivacaine could not estimate.[6,7,8] Recently sterile hyperbaric ropivacaine is commercially available (Ropin Heavy, Neon) which could be used as intrathecally for surgery of intermediate duration as well as for ambulatory surgery. Intrathecal use of opioids with local anesthetics have become a common practice in spinal anesthesia. The addition of fentanyl (10-25 µg) intrathecally to ropivacaine has shown to improve the quality of intra-operative and postoperative analgesia without compromising its benefits such as early mobilization and early voiding.[9] So this study is planned to evaluate the sensory and motor block characteristics of commercially available 0.75% hyperbaric ropivacaine and effect of intrathecal fentanyl as an adjuvant on block characteristics, prolongation of postoperative analgesia and side effects in patients undergoing elective endoscopic urological surgery under spinal anaesthesia.

Material and Methods

After approval from institutional research and ethical committee (GU/HREC/EC/2022/2005) and informed patient consent this prospective, randomized, controlled and double blinded study was conducted on sixty patients admitted in urology department. Patients belonging to ASA grade 1-III, age between 18 to 60 years, of either gender undergoing elective urological surgery under spinal anaesthesia were included in the study. Patients who refuse for spinal anaesthesia, has history of allergy to study drug, coagulopathy, local infection at the site of the block, spinal deformity and complete block failure.

Total sixty patients were included and randomly divided in two groups of 30 patients each by randomization using a computer generated random number tables and received study drugs: Group R: hyperbaric ropivacaine (0.75%) 2.5 ml with 0.5ml normal saline (0.9%) and Group F: hyperbaric ropivacaine (0.75%) 2.5 ml with fentanyl 25 µg (0.5 ml).

Pre-anaesthetic check-up of all patients were done and explained about the procedure in detail. Patients were kept fasting for 8 hours. In the operation theatre, baseline hemodynamic parameters as heart rate(HR),systolic blood pressure(SBP),diastolic blood pressure(DBP),mean arterial blood pressure(MAP),respiratory rate(RR) and oxygen saturation(SPO2) were recorded and ringer's lactate solution 10 ml/kg over 10 min through an 18 G peripheral intravenous cannula was given.

Spinal anaesthesia was given with study drug as per group allocation in sitting position at the level of L3-L4, or L4-L5 interspace using a 25G Quincke's spinal needle. After administration of intrathecal drug patient was placed supine and no head tilt was given to patient

Heart rate, systolic blood pressure, diastolic blood pressure, respiratory rate and SPO2 was recorded every 2 min until 20 min and then 25, 30, 45, 60, 90, 120 min then at 6h, 12h, 18h, 24h. Hypotension was defined as systolic blood pressure reduced by 30% from baseline or SBP < 90 mm Hg and was treated with IV bolus fluids and vasopressor (6mg ephedrine intravenously). Heart rate<60 beats/min was considered as bradycardia and managed with 0.6mg atropine intravenously.

Sensory block assessment was done by loss of pinprick sensation bilaterally in mid-clavicular line using a 24 G hypodermic needle every 2 min till 20 min then every 5 min till 30 min and then every 30 min till complete recovery of sensory block. Surgery was allowed on achievement of T10 sensory blockade. Motor block characteristics assessment was done by using modified Bromage score.(0: no motor Loss; 1: inability to flex the hip; 2: inability to flex the knee and 3: inability to flex the ankle joint) every 2 min till 20 min then every 5 min till 30 min and then every 30 min till complete recovery of motor block.

Data recording

Demographic data regarding age, sex, weight, height, ASA grading and duration of surgery were recorded. Onset of sensory block was assessed as time taken from spinal injection to loss of pinprick sensation at T10 dermatome. Highest level of sensory block, time to reach highest level of sensory block, two segment regression time, duration of effective analgesia: (Time from intrathecal injection to the first analgesic requirement) were recorded.

Motor block characteristic as onset of motor block which is defined as the time taken from end of injection to the loss of motor power (Bromage score 1), time to reach complete motor block (Bromage score 3) and duration of motor block (the time taken from establishment of motor block to complete recovery from motor block).

If patient complains of pain during surgery inj. fentanyl 50 µg intravenously was administered (partial failure). If patients still complains of pain, general anaesthesia was provided (complete failure) and considered as dropout. Requirement of number and doses of analgesics in case of partial block was recorded.

Postoperative pain was assessed using visual analogue scale (VAS) between 0 and 10 (0=no pain and10=most severe pain) at 2h, 6h, 12h, 18h, 24h and tramadol 100 mg intravenously was given on VAS >3. Time of first requirement of analgesic drug, total number and doses of rescue analgesic drug required postoperatively were recorded. Side effects like nausea, vomiting, pruritis, respiratory depression, hypothermia, shivering were recorded.

Statistical analysis: To detect a 20% difference in duration of sensory block between the compared groups with a standard deviation of 25% with 80%

power and 5% alpha error (two sided); a sample size of 25 per group is required. So total 60 patients were taken including dropout for study.

Statistical analysis was performed by IBM SPSS statistics for windows, version 16.0. Data was presented as mean and standard deviation. Student t-test was used for quantitative data while chi – square test was used for qualitative data and $p<0.05$ was considered statistically significant.

Results:

This study was conducted on 60 patients undergoing endoscopic urological surgery and divided into two groups with 30 patients in each group (figure 1). All patients in both the groups achieved desired level of sensory block and did not required any supplement analgesia intraoperatively. The demographic data regarding age, weight, height, sex, ASA grade and duration of surgery were comparable in both the groups ($p>0.05$) (Table 1).

The mean onset time of sensory block in group F was found to be less than in group R but statistically non-significant ($p = 0.4338$). The maximum sensory block height was comparable in both the groups. The time to reach maximum height of sensory block in group F was significantly earlier than in group R ($p =0.003$), whereas two segment regression time was significantly earlier in group R (83.70±21.22) as compared to group F (109.13±43) $p=0.003$. The onset time of motor block and time to complete motor block was found to be less in group F but statistically non-significant. The duration of motor block was found to be comparable in both groups: Group F (127.4±36.51) vs Group R (117.1±28.53); $p=0.2467$. (Table 2).

Visual analogue score (VAS) postoperatively was found to be significantly higher in Group R as compared to Group F at 4h, 6h and 12h; $p<0.05$ (figure 2).The time of first requirement of rescue analgesia (min) was found to be significantly prolonged in Group F as compared to Group R; $p=0.0001$. The number of doses and total dose of rescue analgesia required in 24 hours was significantly more in Group R vs Group F, $p= 0.0373$ (Table 3). The various hemodynamic parameters (HR, SBP, DBP and MAP) at different time intervals were found to comparable in both the groups ($p>0.05$).

Incidence of hypotension was 16.67% in group R while 13.33% in group F which was statistically non-significant. Four patients had shivering in group R and two patients had shivering in group F. No patients in any group had respiratory depression, nausea vomiting, and pruritis (Table 4). The RSS scores at 30 min and 60 min was found to be significantly higher in group F as compared to group R while no significant difference was found in RSS at 90 and 120 min in both groups.

Table 1: Comparison of demographic data in both groups (Mean ±SD)

Patient characteristics		Group R (n=30)	Group F (n=30)	P value
Age (years)		42.56±13.56	45.32±15.92	0.4727
Sex	Male	23(83.33%)	25 (90%)	0.4167
	Female	7(16.6%)	5 (10%)	
Weight (Kg)		55.7±7.31	58.93±7.362	0.0935
Height(cm)		162.4±5.67	163.83±4.423	0.2806
ASA grade	I	11	12	0.07
	II	18	17	
	III	1	1	
Duration of surgery (min)		40.6±13.31	44.43±14.524	0.2913

p>0.05=Non significant

Table 2: Comparison of sensory and motor block characteristics in both groups (Mean ±SD)

Characteristics	Group R(n=30)	Group F (n=30)	P value
Onset of sensory block (min) T10 dermatome	4.23±2.4	3.8±1.78	0.4338
Maximum sensory block height (thoracic dermatome) – Median	T6	T6	0.1206
Time to reach maximum sensory block (min)	12.86±3.13	10.93±1.6	0.003*
Two segment regression time (min)	83.70±21.22	109.13±43	0.005*
Onset of motor block (min) Bromage grade 1	3.5±1.63	3.03±1.45	0.242
Time to complete motor block(min) Bromage grade 3	13.86±9.55	12.2±3.57	0.376
Duration of motor block(min)	117.1±28.53	127.4±36.51	0.2467

p>0.05= Non significant, p<0.05 =significant (denoted by *), p≤0.001=highly significant (denoted by **)

Table 3: Comparison of post-operative requirement of rescue analgesia in both groups (Mean ±SD)

Variable	Group R(n=30)	Group F(n=30)	P value
Time to first rescue analgesia(min)	215.1±63.4	280±55.15	0.0001**
Number of doses (in 24 h)	1.84±0.54	1.52±0.62	0.0373*
Total dose (mg) in 24 h	184 ±54.56	152±62.49	0.0373*

p<0.05 = significant (denoted by *), p≤0.001=highly significant (denoted by **)

Table 4: Comparison of incidence of intraoperative and postoperative adverse effects in both groups.

Adverse effects	Group R(n=30)		Group F(n=30)		P value
	Number of patients	%	Number of patients	%	
Hypotension	5	16.67 %	4	13.33 %	0.7176
Bradycardia	3	10 %	5	16.67 %	0.4475
Respiratory depression	0	0	0	0	-
Nausea and vomiting	0	0	0	0	-
Pruritis	0	0	0	0	-
Shivering	4	13.33 %	2	6.67 %	0.3894

p>0.05 = Non significant

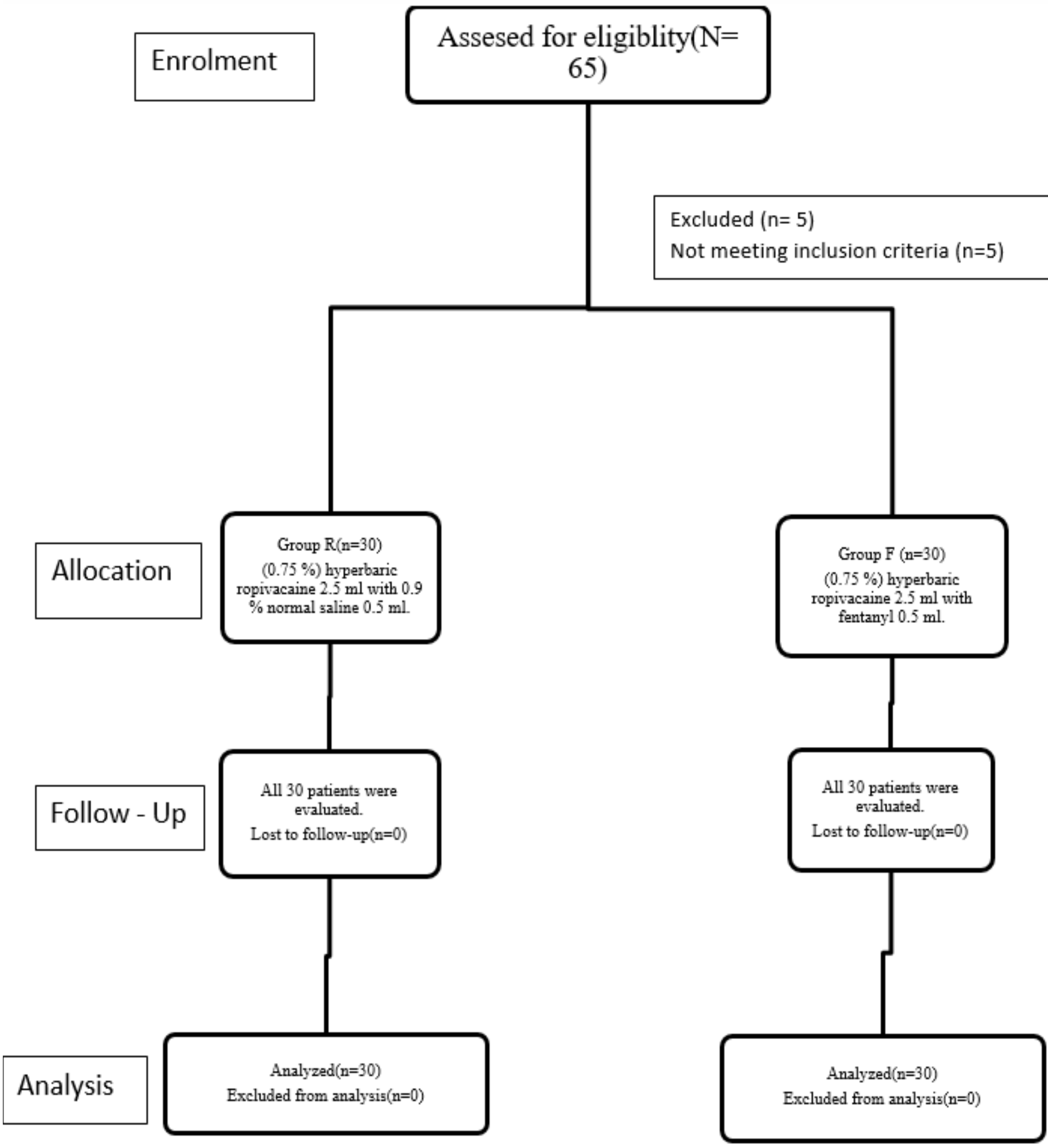

Figure 1: Consort Flow Diagram showing allocation of patients at different stages of study

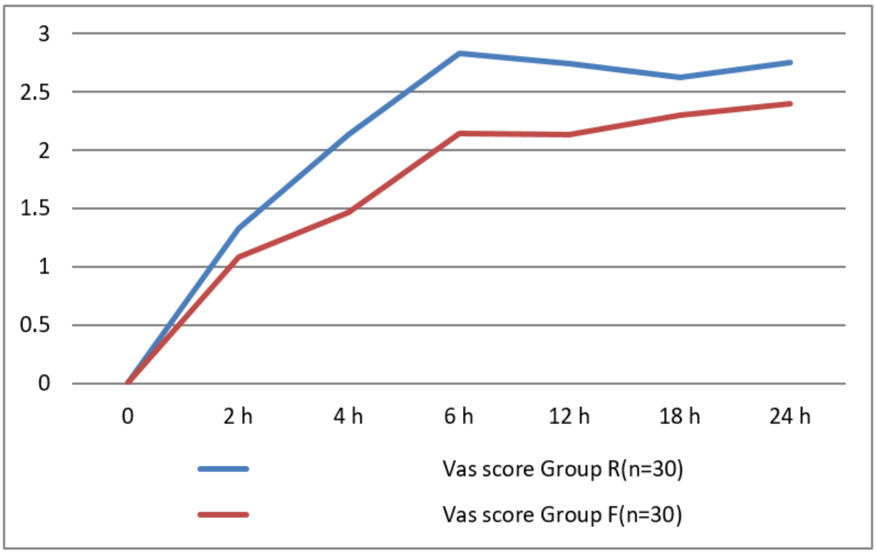

Figure 2: Comparison of post- operative visual analogue score (VAS score) in both groups

Discussion

Spinal anaesthesia (SA) is most commonly used technique for endoscopic urological surgeries. Bupivacaine has a longer duration of motor block while ropivacaine is a newer amide local anaesthetic drug and may be a good choice for ambulatory anaesthesia compared to bupivacaine. Ropivacaine has no effect on the spinal cord blood flow and doesn't induce neurotoxic effects after intrathecal administration in dogs and rabbits. [10,11]

Hemodynamic effects can also be minimized by using ropivacaine 0.75% a pure S (-) enantiomer which has reduced lipophilicity and decreased potential for central and cardiovascular toxicity when compared to other local anesthetics.[12] Moreover, this provides minimum motor block and allows faster recovery and mobilization of the patient so that it can be used for ambulatory surgeries with rapid recovery, and early discharge. Kallio H et al found that ropivacaine 15 mg had a faster recovery of motor block, while sensory block duration was similar to bupivacaine 10 mg. [13]

Various studies have found that intrathecal injection of isobaric ropivacaine produced a sensory block of variable extent due to inadequate distribution of block however hyperbaric ropivacaine produces more predictable and reliable sensory and motor block, with faster onset than a plain solution. Fettes et al found that hyperbaric ropivacaine 15 mg produces predictable and reliable spinal anaesthesia for various surgical procedures of short duration. They added 0.4 ml of 50% dextrose to 2 ml of 0.75% ropivacaine to make the hyperbaric solution and improve the success rate. [14] However these hyperbaric solution may have sterility related problems and exact density or baricity of hyperbaric ropivacaine could not estimate. Recently sterile hyperbaric ropivacaine (0.75%) 4 ml is commercially available (Ropin Heavy, Neon) which contain 7.5 mg ropivacaine hydrochloride and dextrose 80 mg in one ml solution. Intrathecal opioids are added to local anesthetics which provide synergistic effect by acting on opioid receptors in spinal cord and reduce the dose of both the drugs therefore decreasing the likelihood of side effects related to each other. Fentanyl is short acting liphophilic opioid and stimulates μ1 and μ 2 receptors. [15] It increases the afferent sensory blockade and reduces the dose of local anaesthetic drug without intensifying the motor block or prolonging recovery. Fentanyl provides good quality of intraoperative analgesia, hemodynamics stability, excellent quality of postoperative analgesia and minimal side effects. [16] Endoscopic urological surgeries are short and intermediate duration type surgeries and required less motor block as compared to open abdominal surgeries. Therefore this study was planned to evaluate the effect of intrathecal fentanyl on sensory and motor block characteristics of hyperbaric ropivacaine.

The mean onset time of sensory block (T10 dermatome) and maximum sensory level in both the group was found to be comparable in this study. However time to reach maximum height of sensory block was less in fentanyl group (group F) than in ropivacaine group (group R) ($p = 0.003$), whereas two segment regression time was significantly less in group R (83.70±21.22) as compared to group F (109.13±43) $p=0.003$. Bathari R et al found that addition of fentanyl (30 µg) prolonged the duration of sensory block while no significant prolongation of motor block which was similar to our study. [17] Yegin A et al also found that intrathecal fentanyl added to hyperbaric ropivacaine for TURP surgery prolonged the sensory block duration. [18] Murali CH et al found increased duration of two dermatomal regression of sensory blockade and total duration of sensory blockade in fentanyl group which was similar to our study. [19] Similarly Seetharam KR et al and Sanli et al also found prolonged regression time in fentanyl group.[20,21] Lee SC et al did not find any significant difference in block characteristics, postoperative pain score, requirement of analgesics, and adverse effects associated with the block between hyperbaric ropivacaine alone and hyperbaric ropivacaine with additional fentanyl which was contradictory to our results. This might be due to different type of surgery and use of intravenous dexmedetomidine. [22]

The mean onset time of motor block and time to complete motor block was found comparable in both the groups. The duration of motor block was found to be comparable in both groups; p=0.2467. Murali CH et al did not find any significant difference in onset time for complete motor block and duration of motor block between ropivacaine and ropivacaine with fentanyl group.[19] Similarly Seetharam KR et al and Sanli et al, boztug et al also proved that fentanyl do not change the motor block characteristics of ropivacaine when used as adjuvant in spinal anaesthesia. [20,21,23]

The time of first requirement of rescue analgesia (min) was found to be significantly prolonged in Group F as compared to Group R; p=0.0001. The number of doses and total dose of rescue analgesia required in 24 hours was significantly more in Group R as compared to Group F, p= 0.0373.

Murali CH et al showed that time for first requirement of analgesia was significantly prolonged in fentanyl group which was similar to our study**.** [19] They also found that total analgesic requirement also decreased in fentanyl group. Chung et al also found that 10 µg fentanyl when used intrathecally with 18 mg hyperbaric ropivacaine improved intraoperative spinal anaesthesia for caesarean section and increased the postoperative analgesia [24]. Similarly Seetharam KR et al and Sanli et al, boztug et al and Layek et al also found that time for first requirement of analgesic drug requirement was found prolonged in fentanyl group as compared to ropivacaine alone in spinal anaesthesia. [20,21,23,25]

The various hemodynamic parameters (HR, SBP, DBP and MAP) at different time intervals were found to comparable in both the groups (p>0.05).

Incidence of hypotension was found 16.67 % in ropivacaine group and 13.33 % in fentanyl group which was statistically non-significant. Also the incidence of bradycardia and shivering were found to be comparable in both the groups. No patients in any group had respiratory depression, nausea vomiting, and pruritis. Similarly, Bathari R et al and Murali CH et al did not find any significant difference between two groups. [17,19] The RSS scores at 30 min and 60 min was found to be significantly higher in group F as compared to group R while no significant difference was found in RSS at 90 and 120 min in both groups. Similarly Jain N et al and Bindra et al also found that addition of fentanyl intrathecally with local anaesthetic has more sedation upto 60 min but did not have any significant after 60 min. [26,27]

Limitation: Intrathecal opioids may cause urinary retention but we did not compare the voiding time because all patients were catheterized postoperatively in urological surgeries.

Conclusion

Intrathecal hyperbaric ropivacaine (recently commercially available) is safe and has advantage to induce less motor blockade, early recovery and mobilization than bupivacaine in endoscopic urological surgery. The addition of fentanyl to hyperbaric ropivacaine prolongs the duration of sensory block and postoperative analgesia without affecting hemodynamics and motor block.

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