ORIGINAL ARTICLE

Efficacy of spinal ropivacaine versus ropivacaine with fentanyl in transurethral resection operations

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ABSTRACT

Background: The low-dose ropivacaine provides differential spinal block to reduce adverse hemodynamic effects in elderly patients. Addition of intrathecal fentanyl with ropivacaine may enhance analgesia and early postoperative mobility. The present study was performed to evaluate the efficacy of intrathecal ropivacaine alone and in combination with fentanyl in transurethral resection operation. **Methods:** Sixty male patients aged >50 years of ASA I-III scheduled for elective transurethral resection were included in a prospective, randomized, double-blinded study and they were divided in two groups of 30 each. Group A (n = 30) received intrathecal injection of ropivacaine 2 ml (0.75%) and Group B (n = 30) ropivacaine 1.8 ml (0.75%) with fentanyl 10 µg. The characteristics of onset and regression of sensory and motor blockade, hemodynamic stability, and side effects were observed. Student's *t* test (for parametric data) and Mann-Whitney U test (for non-parametric data) were used for statistical analyses. **Results:** There were no significant differences between the two groups for patient demographic data, intraoperative hemodynamic parameters, side effects, and satisfaction to patients and surgeon. The highest level of sensory block was at T10 in group A and T9 in group B ($P = 0.001$). Duration of motor block was longer in group B being 210.51 ± 61.25 min than in group A being 286.25 ± 55.65 min ($P < 0.001$). **Conclusion:** The addition of fentanyl to ropivacaine may offer the advantage of shorter duration of complete motor block, hemodynamic stability, and without any increase in the frequency of major side effects.

Key words: *Analgesics, fentany, ropivacaine, spinal anesthesia*

INTRODUCTION

Spinal anesthesia is widely used for transurethral resections because it allows early recognition of symptoms caused by overhydration, transurethral resection of prostate (TURP) syndrome, and bladder perforation. Many patients undergoing TURP or transurethral resection of bladder tumor (TURBT) have coexisting pulmonary or cardiac disease.[1] By reducing the dose of local anesthetic used, side effects can be decreased. However, a low dose of local anesthetic cannot provide an adequate level of sensory block. Ropivacaine is a new amide-type long-acting, pure S-enantionmer, local anesthetic, and analgesic. Ropivacaine has similar efficacy but an enhanced safety profile when compared to bupivacaine, a major advantage in regional anesthesia.[2,3] Addition of intrathecal opioids to low-dose local anesthetics enhances analgesia and intensifies motor and sensory blockade.[4,5]

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Ropivacaine may be a proper alternate local anesthetic for spinal anesthesia in elderly patients with coexisting systemic disease for TURP operations. By adding fentanyl to ropivacaine, side effects can be reduced. In this study, we aimed to investigate the characteristics and side effects of spinal blocks achieved by ropivacaine and ropivacaine with fentanyl for TURP-BT operations.

METHODS

After obtaining ethics committee approval of our Institution and patients' informed consent, 60 males, aged >50 years, ASA I-III patients scheduled for elective TURP or TURBT operations were included in a prospective, randomized, double-blinded study. Patients with uncontrolled hypertension, diabetes, chronic obstructive pulmonary disease (COPD), infection at the injection site, disorders of coagulation, ischemic heart disease (IHD), history of headache, reluctance to the procedure, neurologic disease, or hypersensitivity to amide local anesthetics or fentanyl were excluded.

No premedication was given. Patients were randomly assigned into two equal groups for spinal anesthesia according to numbers inserted in sealed envelopes. After routine monitoring, infusion of 20 ml/kg of Ringer's Lactate fluid was done. The baseline hemodynamic values were recorded and then spinal anesthesia was performed with the patient in the left lateral position, using a 26-G Quincke needle at the L3-4 interspace and a midline approach. In group A (n = 30), 2 ml of 0.75% ropivacaine and in group B (n = 30), 1.8 ml of 0.75% ropivacaine with fentanyl citrate 10 μg (0.20 ml) were administered via intrathecal injection. The direction of the needle aperture was cranial during the injection. After free flow of cerebrospinal fluid was verified, anesthetic solution was given in 15 second without barbotage or aspiration. Immediately after the injection, the patients were placed in the supine position. Heart rate (HR), mean arterial blood pressures (MAP), and oxygen saturation (SpO_2) were recorded every 2 min for 15 min after intrathecal injection and every 5 min thereafter. A 20% decrease from baseline SAP or SAP <90 mmHg was treated with incremental intra venous (iv) boluses of ephedrine 5 mg and bradycardia (HR <45) was treated with iv atropine 0.5 mg. Supplementary oxygen 4 L/min was given via a nasal cannulae if SpO_2 was less than 93% with the patient breathing ambient air sensory and motor block were assessed every 2 min for 15 min after intrathecal injection and every 5 min thereafter until the sensory block regressed to S1. Anesthesia was considered adequate for surgery if pain sensation as assessed by the pinprick test was lost at the T10 level. Patients were then placed in the lithotomy position and operation started.

The time to achieve sensory block of T10, highest level of sensory block, the time to two-segment regression of sensory block, and the time to regression of sensory block to S1 were recorded. Motor block was assessed using the Bromage scale (0 = no motor block, 1= inability to raise extended legs, 2 = inability to flex knees, and 3 = inability to flex ankle joints). Onset time of motor block, maximum motor block (Bromage score), duration of motor block (the time from intrathecal injection to the regression of motor block to Bromage score = 0), and duration of complete motor block (the time from intrathecal injection to the regression of the block to a Bromage score of <3) were also recorded. Complete motor block was defined as a Bromage score of 3. Volume of glycine used, duration of surgery, and patient and surgeon satisfaction were recorded at the end of the operation. Patients were interviewed regarding their opinion of the anesthetic procedure. Likewise, the surgeon was asked to estimate the operating conditions on a scale of excellent, good, fair, and poor. Patients were observed until the level of sensory block was S1 and the Bromage score was 0. Adverse effects such as hypotension, bradycardia, nausea, vomiting, shivering, sedation, respiratory depression, and pruritus were recorded. Metoclopramide 10 mg IV was used to treat nausea and vomiting and paracetamol 1 gram IV was given during infusion lasting 15 min when the patient complained of pain in the postoperative period. The patients were discharged from the recovery room after the motor blockade was completely resolved, had stable vital signs, no nausea, vomiting, severe pain, and bleeding. Our primary endpoint was the difference in the duration of motor block between the two groups. Other endpoints included were the difference between the two groups, in the characteristics of sensory blockade, operating conditions, hemodynamic stability, and side effects.

Statistics analysis

The data was analyzed using SPSS 15.0 statistical software. A sample size of 30 patients per group was required, which was determination on the basis of α risk of 0.05 and β risk of 0.10. Descriptive statistics were quoted as mean ±SD, median (range), number (incidence) as appropriate. Student's *t* test (for parametric data) and Mann-Whitney U test (for non-parametric data) were used for statistical analyses. The incidences of side effects and satisfactions were analyzed using Fisher's exact test and chi-square test. The paired *t*-test was used to investigate hemodynamic changes over time in each group. Statistical significance was set at the $P < 0.05$ level.

RESULTS

There were no significant differences between the two groups in demographic data, ASA classification, type, and duration of operation or volume of glycine used ($P > 0.05$) [Table 1]. Time taken to onset of sensory blockade at level T10 was 4.50 ± 1.62 in group A and 5.32 ± 1.50 in group B, there was no significant difference between the groups. The highest level of sensory blockade was T10 (T8-T10) in group A and T9 (T6-T10) in group B, there was significantly difference ($P < 0.001$) [Table 2]. In the time taken for two-segment regression and regression of sensory block to S1 there was no significant difference (105.35 ± 12.30 and 276.25 ± 61.53 in group A, respectively and 106.10 ± 10.42 and 287.22 ± 65.10 in group B, respectively) [Table 2]. Onset time of motor block, maximum motor block, and duration of complete motor block were similar in both groups ($P > 0.05$). On the other hand, duration of motor block was longer in group B than group A (<0.001) [Table 2]. Visual analog scale (VAS) score was higher in group A compared to group B and there was a significant difference ($P < 0.05$) [Table 2].

Patients were hemodynamically stable (heart rate, mean arterial pressure, and SpO_2) in both groups, there was no significant difference [Figures 1-3]. No patient required supplemental oxygen, analgesia, or anxiolysis intraoperatively. There were no significant differences between the two groups with respect to side effects [Table 3].

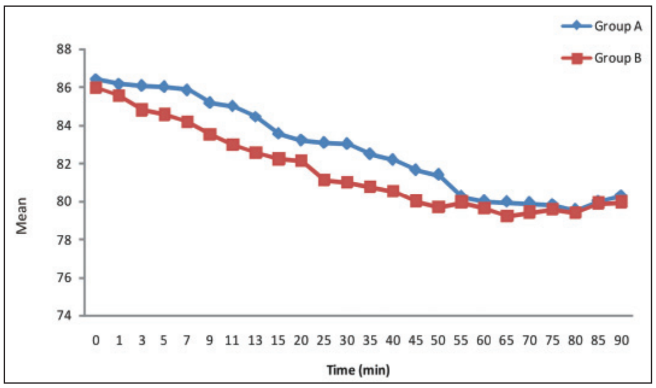

Figure 1: Heart rate (beat/min)

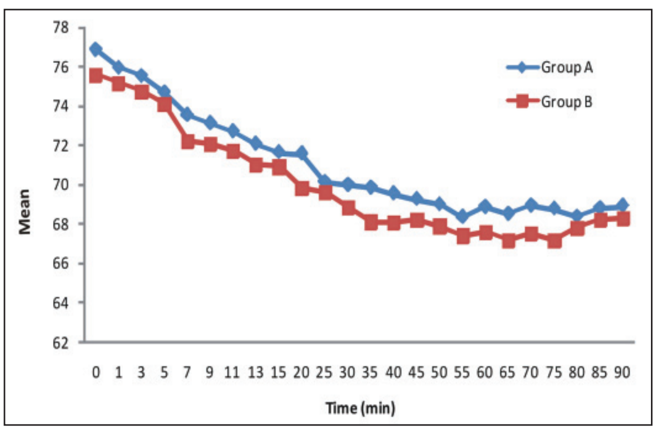

Figure 2: Mean arterial blood pressure

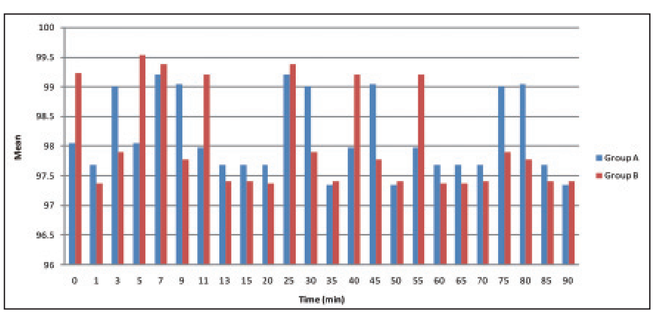

Figure 3: SpO_2

Table 1: Demographic and perioperative data

	Group A	Group B	*P*-Value
Age (yr)	65.20±6.23	68.10±7.50	NS
Weight (kg)	68.15±10.61	70.92±10.22	NS
Height (cm)	160.52±7.24	165.75 ±5.73	NS
ASA Grade (I/II/III)	12/13/5	14/12/4	NS
Type of operation			
TUR-prostate/ bladder tumor	22/8	23/7	NS
Duration of operation (min)	68.00±15.82	65.25±20.50	NS
Volume of glycine (L)	14.25±7.60	15.50±6.36	NS

NS=Non Significant (*P*>0.05), Data are means±standard deviation or number of patients, A=Ropivacaine, B=Ropivacaine plus fentanyl

Table 2: Characteristics of spinal anesthesia in two groups

	Group A	Group B	*P*-Value
Sensory block			
Onset sensory level: T10 (min)	4.50±1.62	5.32±1.50	>0.05
Highest level of sensory blockade (dermatome)	T10 (T8-T10)	T9 (T6-T10)	<0.001**
Time to two segment regression (min)	105.35±12.30	106.10±10.42	>0.05
Time to regression to S1 (min)	276.25±61.53	287.22±65.10	>0.05
Motor block			
Onset time of Bromage 1 (min)	3.90±1.39	3.50±1.17	>0.05
Maximum motor block (n) (Bromage Score 3/2)	29/1	28/2	>0.05
Duration of motor block (min)	286.25±55.65	210.51±61.25	<0.001**
Duration of complete motor block (min)	162.35± 38.17	143.50±37.19	>0.05
Pain assessment			
Visual analog scale (VAS)	1.5±1.18	0.8±0.94	<0.05*

Data are means±standard deviation, median (range) or number of patients, A=Ropivacaine; B=Ropivacaine plus fentanyl, *=*P*<0.05, **=*P*<0.001: A significant differences between the two groups

Table 3: Side effects in groups A and B

	Group A		Group B		*P*-Value
	N	%	n	%	
Hypotension	1	3.33	0	0	0.10
Bradycardia	0	0	0	0	—
Nausea	0	0	1	3.33	0.10
Vomiting	0	0	0	0	—
Shivering	0	0	0	0	—
Sedation	0	0	2	6.66	0.106
Respiratory	0	0	0	0	—
depression	0	0	0	0	—
Pruritus	0	0	0	0	—

A=Ropivacaine; B=Ropivacaine plus fentanyl

DISCUSSION

This prospective double-blinded randomized study has ropivacaine and fentanyl, which provides pain relief and hemodynamic stability. Addition of 15 μg fentany in plane ropivacaine (10 mg) for spinal anesthesia provides similar sensory blockade but short duration of motor block, compared with plain bupivacaine with fentanyl.[6] Reduction in dose of ropivacaine with less motor blockade was achieved with addition of fentanyl.[7] It has been proved that combination of opioids to local anesthetics has a synergistic action.[1,8] For TUR surgery, a blockade up to the level of T10 is necessary for irrigation of bladder however the onset and stabilization of block was similar.[9] The effect of ropivacaine plane and combination of fentanyl indicate similar onset and sensory blockade.[10] McNamee *et al* observed that onset, intensity, level, and duration have no significant difference in alone and combination.[11,12] Luck *et al* was reported that there was no significant difference in mean time to onset and mean time to maximum spread. Total duration of sensory block, regression of sensory block, and motor recovery were faster in the plane ropivacaine group at T10 and more rapid and shorter times to independent mobilization in the plane ropivacaine group.[13] Intrathecal fentanyl (25 μg) with hyperbaric ropivacaine (18 mg) prolongs the analgesic effect compared with hyperbaric ropivacaine.[10]

In our study, the highest sensory blockade achieved and duration of motor blockade were higher in significantly group B. There was no significant difference in time taken to T10, two segment regression, sensory regression to S1, onset time of Bromage 1, maximum motor blockade, and duration of complete motor blockade. The analgesic effect was prolong in group B as compared to group A.

Kaohsiung *et al.* reported that the two dose of plane ropivacaine (26.25 mg and 33.75 mg) produce no significant hemodynamic changes and similar efficacy and safety.[9] There was no significant difference in hemodynamic changes in between hyperbaric ropivacaine (10 mg and 15 mg) with fentanyl (20 μg).[11] In our study, there were no significant difference in hemodynamic changes in both groups.

Till now, a combination of bupivacaine with fentany was taken as standard for intrathecal block. Presently, ropivacaine has been introduced in our country which has less neuro and cardio-toxic effects. Therefore, it is safer and provides faster motor regression thereby indicating earlier postoperative mobility with pain relief.

CONCLUSION

Both regimes are effective, and the addition of fentanyl to ropivacaine may offer the advantage of shorter duration of complete motor block, hemodynamic stability, and prolong post operative analgesia. Hence, it can be used as an alternative to pure ropivacaine in spinal anesthesia for transurethral resections.

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