RESEARCH PAPER

A Prospective Randomized Study Comparing Intrathecal Isobaric Ropivacaine-Fentanyl with Intrathecal Isobaric Bupivacaine-Fentanyl in Patients Undergoing Elective Endoscopic Urological Procedures

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ABSTRACT

Background:
Spinal anaesthesia is widely used for elective urological procedures. Isobaric solution may provide a better controlled block spread, better haemodynamic stability and less extensive motor and sensory blockade. Isobaric Ropivacaine offers a predictable shorter motor blockade and potentially earlier mobilisation compared to bupivacaine.

Aim:
To compare the clinical efficacy and block characteristics of intrathecal isobaric 0.5% ropivacaine-fentanyl with intrathecal isobaric 0.5% bupivacaine-fentanyl in elective endoscopic urological procedures.

Materials and Methods:

A prospective, single-blinded study included 100 ASA physical status I or II patients aged >18 years undergoing elective endoscopic urological procedures. Patients were randomized into two groups (n=50 each) to receive intrathecal 0.5% isobaric ropivacaine with fentanyl (RF group) or bupivacaine-fentanyl (BF group). Sensory and motor block characteristics, duration of analgesia, postoperative pain scores, haemodynamic parameters, and complications were assessed. Data were analysed using SPSS version 25. A p-value <0.05 was considered statistically significant.

Results:
The RF group demonstrated a significantly faster onset of sensory and motor blockade and significantly shorter durations of sensory and motor blockade compared with the BF group. The mean duration until the first rescue analgesic was 152.67 ± 15.46 minutes in the RF group compared with 184.39 ± 17.93 minutes in the BF group. Postoperative pain scores were comparable at 1 and 6 hours, while significant differences were observed at selected intermediate time points. Complications were more frequent in the BF group.

Conclusion:
Intrathecal 0.5% isobaric ropivacaine-fentanyl provided effective spinal anaesthesia with faster onset and shorter sensory and motor blockade than bupivacaine-fentanyl. Its shorter duration of blockade may be advantageous for elective and day-care urological procedures where early recovery and mobilisation are desirable.

Keywords: Spinal Anaesthesia, Ropivacaine, Bupivacaine, Fentanyl, Urological Procedures

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Introduction

Endoscopic urological procedures are common and often performed as minimally invasive interventions to diagnosis and treat various urinary tract disorders. Although these procedures are minimally invasive, the need for adequate anaesthesia is essential to provide satisfactory analgesia, suitable sensory and motor block, patient immobility and maintain them haemodynamically stable. Spinal anaesthesia is commonly used because of its effectiveness in providing regional anaesthesia for infraumbilical surgical procedure thereby avoiding airway instrumentation and preserving spontaneous respiration. [1,2]

Bupivacaine is a popular choice for spinal anaesthesia due to its consistency, reliability and give a strong blockade both sensory and motor as well as its relatively long-lasting action. However, one drawback of using isobaric bupivacaine may slow down the patient's recovery and mobilisation postoperatively. The characteristics of spinal anaesthesia are affected by several factors like type of drug and dosage of the local anaesthetics, baricity, injection site and general condition of the patient. [3,4] The use of local anaesthetic isobaric solutions may give a more even distribution of block and avoid some of the unevenness in cephalad spread associate with hyperbaric solutions, potentially supporting to greater haemodynamic stability and limited motor and sensory blockade. [3,4]

Ropivacaine is a S-enantiomer which long-acting amino-amide local anaesthetic. The pharmacological properties of Ropivacaine are different from bupivacaine especially related to lipid solubility. since their effects on sensory and motor nerve fibres also differs, intrathecal isobaric ropivacaine has been used as an alternative to isobaric bupivacaine, pertaining to achieving good surgical anaesthesia and reducing the duration of motor blockade therby facilitating earlier postoperative recovery.[5,6] Studies comparing anaesthesia have shown differences in how long sensory blockade and motor blockade last, between Ropivacaine and bupivacaine. However, these differences are depends on the dose, formulation and nature of the surgical population.[5,7]

Adding opioids to local anaesthetics is a well-known approach to make spinal anaesthesia and pain relief after surgery better. Fentanyl a lipophilic μ-opioid receptor agonist has been used as an intrathecal adjuvant because of its effectiveness even with smaller doses of local anaesthetic. [8] Studies done on evaluating the combinations of fentanyl with ropivacaine or bupivacaine have therefore focused the adequacy of surgical anaesthesia, onset and regression of sensory and motor blockade and postoperative pain managements. [9]

Evidence that compares these two combinations shows a trade-off. Isobaric Ropivacaine–fentanyl may give a motor block with short duration and faster recovery while isobaric bupivacaine–fentanyl may give a longer sensory block and longer analgesia after surgery. [9–11] Importantly studies that involve urological surgery have shown that isobaric ropivacaine–fentanyl can give adequate spinal anaesthesia with shorter duration of motor block than isobaric bupivacaine–fentanyl. [12]

However, the exact benefits of the two regimens in endoscopic urological procedures are still important especially when we want good surgical anaesthesia and quick recovery after surgery. This study compared effectiveness of intrathecal isobaric bupivacaine -fentanyl and intrathecal isobaric ropivacaine-fentanyl in patients undergoing, postoperative analgesia, haemodynamic stability and complications in elective endoscopic urological procedures.

Materials and Methods

Study design and setting

This prospective, single-blinded, randomized controlled trial was conducted over 18-months from November 2022 to May 2024 elective endoscopic urological procedures at Government General Hospital (GGH), Kakinada, a tertiary care hospital. (Reg. No. IEC/RMC/2022/857/29/11/2022).

Study population

Adult patients undergoing elective endoscopic urological surgery were selected and screened for eligibility. Adults aged >18 years, of either sex, American Society of Anesthesiologists (ASA) of physical status I or II and BMI <30 kg/m² were listed. Patients who provided written informed consent were included in the study.

Sample size

A total of 100 patients (50 each group) were included, with 80% power, a 5% significance level, and a 5% dropout allowance. The sample size was determined with an alpha level of 0.05 and 80% power, allowing a 5% margin for dropouts. The final sample comprised 50 patients in each treatment group.

Randomization and blinding

After informed consent, patients were randomized equally into two groups using computer-generated random numbers. Data were collected using a pretested proforma. Since the study was single-blinded, with the anaesthesiology postgraduate responsible for data collection being unaware of the group allocation. This approach was used to minimize observer bias in assessment of study outcomes.

Intervention

Patients were allocated to one of the following groups: RF group, BF group.

The total intrathecal volume administered was 2.5 ml in both the groups. RF group received 2 ml of 0.5% isobaric ropivacaine and 0.5 ml of 25 µg fentanyl while BF group received 2 ml of 0.5% isobaric bupivacaine and 0.5 ml of 25 µg fentanyl.

Preoperative assessment

During the preoperative assessment, a detailed medical history and a thorough physical examination were performed. Routine investigations, including haemoglobin, blood sugar, renal function parameters and electrocardiography, were obtained. The purpose of the study, study procedures and possible complications were explained to participants in the native language, following which written informed consent was obtained.

Assessment of spinal block

Spinal anaesthesia efficacy was assessed by the onset and duration of sensory and motor blockade, using the Bromage scale of 2 for Motor block was assessed. Both groups achieved a mean maximum sensory level of **T7**.

Haemodynamic monitoring

Heart rate, blood pressure parameters (systolic & diastolic), mean arterial pressure and peripheral oxygen saturation were monitored at baseline and at predefined intraoperative and postoperative intervals. The recorded intervals included baseline, 5, 10, 15, 20, 25 and 30 minutes, followed by 1, 1.5 and 2 hours.

Postoperative assessment

The time to the first rescue analgesia was compared between the two groups. Postoperative pain was assessed using the visual analogue scale (VAS) at 1- 6 hours after surgery. The number of supplemental analgesic requirements was also recorded as a secondary outcome. Patients were monitored for adverse events and complications associated with spinal anaesthesia. The complications recorded included bradycardia, hypotension, nausea and vomiting.

Ethical considerations

The study was approved Institutional Ethics Committee of Government General Hospital, Kakinada, and written informed consent was obtained from all participants.

Statistical analysis

Data were analysed using IBM SPSS, version 25.0. Quantitative variables were expressed as mean ± standard deviation (SD), and compared using the independent-samples t-test, while categorical variables were expressed as frequencies and proportions. The independent-samples *t*-test was used for comparison of continuous variables between the two groups, while the chi-square test was used for categorical variables. Age, weight and time were compared using the independent-samples *t*-test, and sex distribution was compared using the chi-square test. A p-value <0.05 was considered statistically significant. For categorical complications were analysed using chi-square test. while time to first rescue analgesia and VAS scores were compared using the independent-samples t-test.

Results

A total of 100 patients undergoing elective endoscopic urologic procedures were equally allocated into two groups. The mean age of the participants was 31.36 ± 6.93 in RF group and 41.36 ± 7.52 in BF group.

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Table 1. Baseline characteristics of study participants

Characteristic	RF (n=50)	BF (n=50)	P value
Age, years, mean ± SD	31.36 ± 6.93	41.36 ± 7.52	**<0.001**
Male, n (%)	41 (82)	43 (86)	0.585
Female, n (%)	9 (18)	7 (14)	
ASA I, n (%)	39 (78)	42 (84)	0.44
ASA II, n (%)	11 (22)	8 (16)	
Weight, kg, mean ± SD	58.27 ± 10.69	56.91 ± 10.84	0.52
Height, cm, mean ± SD	163.77 ± 11.67	164.39 ± 12.75	0.80

Majority of them were male patients, i.e, 82%, 86% in the RF group and BF group respectively, rest the females. According to American Society of Anesthesiologists, physical status was comparable. In the RF group, 39 (78%) patients were ASA I and 11 (22%) were ASA II, whereas 42 (84%) and 8 (16%), respectively, in the BF group ($p = 0.44$)

Table 2. Comparison of efficacy of spinal anaesthesia between the groups

Efficacy parameter	RF (n=50)	BF (n=50)	P value
Onset of sensory block, min	4.38 ± 1.26	5.67 ± 3.99	**0.038**
Onset of motor block, min	5.31 ± 1.64	6.91 ± 2.84	**<0.001**
Duration of sensory block, min	154.27 ± 21.34	196.34 ± 18.22	**<0.001**
Duration of motor block, min	179.66 ±	201.61 ±	**<0.001**

	20.94	20.69	
Duration of surgery, min	48.36 ± 4.37	49.34 ± 3.64	0.22
Time to first rescue analgesia, min	152.67 ± 15.46	184.39 ± 17.93	**<0.001**

The mean onset time of sensory block was significantly shorter in the RF group than in the BF group (4.38 ± 1.26 minutes vs. 5.67 ± 3.99 minutes; $p = 0.038$). Similarly, the onset of motor block was significantly faster with ropivacaine-fentanyl (5.31 ± 1.64 vs. 6.91 ± 2.84 minutes; $p < 0.001$). The duration of sensory block was significantly shorter in the RF group compared with the BF group (154.27 ± 21.34 vs. 196.34 ± 18.22 minutes; $p < 0.001$). Similarly, the duration of motor block was significantly shorter with ropivacaine-fentanyl (179.66 ± 20.94 vs. 201.61 ± 20.69 minutes; $p < 0.001$). The mean duration of surgery was comparable between the two groups (48.36 ± 4.37 vs. 49.34 ± 3.64 minutes; $p = 0.22$).

The time to first rescue analgesia was significantly shorter in the RF group than in the BF group (152.67 ± 15.46 minutes vs. 184.39 ± 17.93 minutes; $p < 0.001$), indicating a shorter duration of postoperative analgesia with ropivacaine-fentanyl. This ropivacaine-fentanyl demonstrated a faster onset and shorter duration of sensory and motor blockade, while bupivacaine-fentanyl provided more prolonged postoperative analgesia.

Table 3. Postoperative pain and adverse events

Outcome	RF (n=50)	BF (n=50)	P value
VAS score, mean ± SD			
1 hour	0.31 ± 0.18	0.34 ± 0.13	0.34
2 hours	0.39 ± 0.61	1.89 ± 0.28	**<0.001**
3 hours	3.56 ± 1.51	3.21 ± 2.69	0.119
4 hours	1.83 ± 1.07	1.21 ± 0.87	**0.002**
5 hours	1.89 ± 0.87	1.34 ± 0.91	**0.003**
6 hours	2.97 ± 0.99	2.86 ± 0.91	0.56
Complications, n (%)			
Bradycardia	0	3	**0.037***
Hypotension	1	4	
Nausea/vomiting	3	3	

Postoperative pain scores and adverse events show at 1 hour, the mean VAS scores were comparable between the RF and BF groups (0.31 ± 0.18 minutes vs. 0.34 ± 0.13 minutes; $p = 0.34$). At 2 hours, the RF group had a significantly lower mean VAS score than the BF group (0.39 ± 0.61 vs. 1.89 ± 0.28; $P < 0.001$). At 3 hours, the difference was not statistically significant (3.56 ± 1.51 vs. 3.21 ± 2.69; $P = 0.119$). At 4 and 5 hours, the mean VAS scores differed significantly between the groups (1.83 ± 1.07 vs. 1.21 ± 0.87, $P = 0.002$ and 1.89 ± 0.87 vs. 1.34 ± 0.91, $P = 0.003$, respectively). At 6 hours, the pain scores were again comparable (2.97 ± 0.99 vs. 2.86 ± 0.91; $P = 0.56$).

Regarding complications, bradycardia was not observed in the RF group but occurred in 3 patients in the BF group, while hypotension occurred in 1 and 4 patients, respectively. Nausea/vomiting occurred in 3 patients in each group. The overall distribution of complications was statistically significantly different between the two groups with a greater occurrence of adverse events in the BF group.

Heart rate, systolic and diastolic blood pressure, mean arterial pressure and oxygen saturation were comparable between the groups at baseline and during the study, with no statistically significant.

Discussion

The present RCT compared the intrathecal isobaric 0.5% ropivacaine with fentanyl (RF) and intrathecal isobaric 0.5% bupivacaine with fentanyl (BF) in patients undergoing elective endoscopic urological procedures.

The mean onset of sensory blockade was significantly faster in the RF group than in the BF group. The maximum sensory level was comparable between the groups, with T7 as the average level in both groups. This finding indicates that although the onset differed, both regimens provided a comparable cephalad spread of sensory anaesthesia adequate for the surgical procedures. The onset observed with RF was faster, consistent with the study done by Kulkarni et al., with same significant shorter duration of sensory block with ropivacaine, with onset at 4.13 ± 1.32 minutes with ropivacaine compared with 4.57 ± 1.46 minutes with bupivacaine. [13] The research done by Ganvit et al. also reported that the concentration, formulation and dose of the local anaesthetic used can affect the effect and result of it.[14] However, Atabekoğlu and Bozkırlı found no such significance in the onset and maximum sensory level of the block between isobaric ropivacaine and bupivacaine in elderly patients undergoing transurethral resection.[15] A significant difference in the onset of motor blockade was observed, with RF producing motor

block earlier than BF. Seetharam and Bhat also reported similar findings with a mean motor block onset of approximately 5.2 minutes with ropivacaine-fentanyl. [11,16] Varu et al. also observed a shorter duration of motor blockade in lower abdominal and lower limb surgery with ropivacaine compared with bupivacaine-fentanyl.[17] Despite the shorter block duration, BF gave longer analgesia as shown by the longer time until the first rescue analgesic was needed. Also, Layek et al., in a study of orthopaedic surgery patients found that bupivacaine-fentanyl gave longer pain relief than ropivacaine-fentanyl. [9]

Although the readings of Heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure and SpO_2 recorded were lower and relatively stable in the RF group, these differences were not statistically significant. This was consistent with study by Koltka et al., who found similar haemodynamic profiles.[18] Alternatively, Athar et al. reported that levobupivacaine caused more low blood pressure than ropivacaine. [19] These results support that both ropivacaine-fentanyl and bupivacaine-fentanyl can keep haemodynamics stable during spinal anaesthesia. Singh et al. Also found heart rate and blood pressure between the ropivacaine-fentanyl and bupivacaine-fentanyl groups.[20]

Overall, a higher frequency of complications was observed in the BF group and the difference was statistically significant. The complications involved bradycardia, hypotension and nausea/vomiting. However, only a small number events warrants the interpretation with caution.

Conclusion

In the present study, intrathecal 0.5% isobaric ropivacaine with fentanyl provided effective spinal anaesthesia, with a faster onset and shorter sensory and motor blockade than 0.5% isobaric bupivacaine with fentanyl. Although bupivacaine-fentanyl combination produced a significantly longer duration of analgesia, sensory block and motor block, the shorter duration of blockade with ropivacaine may be particularly beneficial in day-care urological procedures, where early recovery and mobilization are desirable. The ropivacaine-fentanyl regimen also demonstrated comparable haemodynamic stability, with fewer perioperative adverse effects. Overall, intrathecal isobaric ropivacaine-fentanyl appears to be a useful alternative to bupivacaine-fentanyl for elective endoscopic urological procedures, particularly when a shorter block and faster postoperative recovery are preferred.

Limitations

The single-centre design and small sample size (100 patients) may limit the generalizability of the findings. The inclusion of only ASA I and II patients with BMI <30 kg/m² and therefore the results may not be directly applicable to patients with significant comorbidities or obesity. The study was also single-blinded, which may introduce the possibility of assessment bias. In addition, the study focused on elective endoscopic urological procedures, and the findings may not be applicable to other types of surgeries or emergency procedures. Long-term postoperative outcomes and patient satisfaction were not assessed.

Recommendations

Larger, multicentric randomized controlled trials involving a broader range of patients and urological procedures are recommended to strengthen the evidence and improve the generalizability of the findings. Future studies could include patients with different ASA grades, varying BMI, and significant comorbidities. Further research comparing different doses and concentrations of intrathecal ropivacaine and bupivacaine, with or without intrathecal adjuvants, may help identify the optimal regimen for specific surgical procedures. Studies evaluating early ambulation, time to discharge, patient satisfaction, functional recovery, and cost-effectiveness would also help determine the practical advantages of ropivacaine-fentanyl, particularly in the setting of day-care urological surgery.

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