

Original Article

COMPARISON OF 0.75% HYPERBARIC ROPIVACAINE WITH FENTANYL AND 0.75% HYPERBARIC ROPIVACAINE WITH DEXMEDETOMIDINE FOR SPINAL ANAESTHESIA IN ELECTIVE LOWER LIMB SURGERIES

SIMRIT KAUR, KETHAVATH SOUMITH, TANVEER SINGH KUNDRA*, TEJINDERPAL KAUR GREWAL, MOHAMMED SHAMNAD, TRIPAT KAUR BINDRA

Department of Anaesthesiology and Intensive Care, Government Medical College and Rajindra Hospital, Patiala, Punjab, India

*Corresponding author: Tanveer Singh Kundra; Email: tvskundra@yahoo.co.in

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ABSTRACT

Objective: Spinal anaesthesia is a preferred technique for lower limb surgeries due to its reliability and safety. Adjuvants like fentanyl and dexmedetomidine are commonly added to local anaesthetics to enhance block characteristics. To compare the sensory and motor block characteristics, haemodynamic profile, sedation, duration of analgesia, and complications of intrathecal 0.75% hyperbaric ropivacaine with fentanyl versus dexmedetomidine in elective lower limb surgeries.

Methods: After institutional ethics committee approval, 60 ASA I-II patients aged 18–60 y scheduled for elective lower limb surgeries were randomised into two groups (n=30 each). Group I received 2 ml of 0.75% hyperbaric ropivacaine+25 µg fentanyl, and Group ii received 2 ml of 0.75% hyperbaric ropivacaine+10 µg dexmedetomidine intrathecally. Onset and duration of sensory and motor block, haemodynamics, sedation (Ramsay score), postoperative pain (VAS), and side effects were recorded. Data were analysed using Student's t-test and chi-square test; p<0.05 was considered significant.

Results: Onset of sensory (Group I: 2.76±0.08 min vs Group ii: 2.72±0.08 min; p=0.134) and motor block (Group i: 1.58±0.40 min vs Group ii: 1.38±0.37 min; p=0.053) was comparable. Duration of sensory block (Group I: 275.10±16.46 min vs Group ii: 310.13±14.94 min; p<0.001), motor block (Group I: 113.77±13.01 min vs Group ii: 124.30±6.91 min; p<0.001), and analgesia (Group I: 226.40±18.09 min vs Group ii: 280.60±13.90 min; p<0.001) was significantly longer in Group ii. Haemodynamic parameters and sedation scores remained stable and comparable. Incidence of side effects was similar.

Conclusion: Intrathecal dexmedetomidine as an adjuvant to 0.75% hyperbaric ropivacaine provides significantly longer sensory and motor blockade and postoperative analgesia compared to fentanyl, with similar haemodynamic stability and side-effect profile.

Keywords: Dexmedetomidine, Fentanyl, Hyperbaric ropivacaine, Spinal anaesthesia

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INTRODUCTION

Spinal anaesthesia is widely preferred for elective lower limb surgeries due to its rapid onset, effective sensory and motor blockade, reduced blood loss, and avoidance of airway manipulation [1]. It provides excellent intraoperative conditions along with early detection of complications and better postoperative analgesia when compared to general anaesthesia. Ropivacaine is a long-acting amide local anaesthetic structurally related to bupivacaine, with a favourable safety profile owing to reduced cardiotoxicity and neurotoxicity [2]. Compared to bupivacaine, ropivacaine produces differential blockade with relatively shorter motor block, making it suitable for procedures where early mobilisation is desirable [3]. However, its shorter duration of action may limit postoperative analgesia when used alone intrathecally.

To enhance the quality and prolong the duration of spinal anaesthesia, various intrathecal adjuvants have been studied. Opioids such as fentanyl act synergistically with local anaesthetics by binding to spinal opioid receptors, improving analgesia without significantly affecting motor function [4]. Dexmedetomidine, a highly selective α_2 -adrenergic agonist, has emerged as an effective intrathecal adjuvant by prolonging sensory and motor blockade and providing extended postoperative analgesia through inhibition of nociceptive neurotransmission [5].

Although several studies have evaluated fentanyl and dexmedetomidine as intrathecal adjuvants, limited data are available comparing these two drugs when used with 0.75% hyperbaric ropivacaine for spinal anaesthesia in elective lower limb surgeries [6]. The present study was undertaken to compare the efficacy and safety of intrathecal fentanyl and dexmedetomidine as adjuvants to hyperbaric ropivacaine [7].

MATERIALS AND METHODS

Study design and ethical approval

This prospective, randomized, comparative study was conducted after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all patients prior to enrolment.

Sample size

Sample size was calculated to compare the means of two independent groups (onset of sensory block) using the standard formula for a two-sample t-test assuming equal variances and group sizes: $n = [2 \sigma^2 (z_{\{1-\alpha/2\}} + z_{\{1-\beta\}})^2] / \delta^2$, where σ is the pooled standard deviation, δ is the expected mean difference, $z_{\{1-\alpha/2\}}$ is the critical value for the two-tailed significance level, and $z_{\{1-\beta\}}$ is the critical value for power.

From pilot study data, the pooled standard deviation (σ) was estimated as 0.61, and the clinically relevant difference in means (δ) was 0.53. With a two-tailed significance level (α) of 0.05 ($z_{\{1-\alpha/2\}} = 1.96$) and desired power of 90% ($1-\beta = 0.90$, $z_{\{1-\beta\}} = 1.282$), the calculated sample size was approximately 28 per group. To provide a margin for potential dropouts, violations of assumptions, and to enhance study power, a sample size of 30 patients per group (total n = 60) was selected.

Study population

Adult patients of both sex, aged 18 to 60 y, belonging to American Society of Anaesthesiologists (ASA) physical status I and II, scheduled for elective lower limb surgeries under spinal anaesthesia were included in the study.

Inclusion criteria

- ASA physical status I and II
- Age – years
- Patients scheduled for elective lower limb surgeries
- Patients willing to participate and provide informed consent

Exclusion criteria

- Patient refusal
- Allergy to study drugs
- Coagulation abnormalities
- Infection at the site of spinal injection
- Neurological disorders
- Significant cardiac, respiratory, hepatic, or renal disease
- Spine deformity

Patients were randomly allocated into two groups using a computer-generated random number table:

- Group I (n=30): 2 ml 0.75% hyperbaric ropivacaine+0.5 ml (25 µg) fentanyl
- Group II (n=30): 2 ml 0.75% hyperbaric ropivacaine+0.5 ml (10 µg) dexmedetomidine

Anaesthetic technique

Under strict aseptic precautions, spinal anaesthesia was administered in the sitting position or lateral position at the L3–L4 or L4–L5 intervertebral space using a 23G Quincke spinal needle. After confirmation of free flow of cerebrospinal fluid, the study drug was injected intrathecally according to group allocation. Patients were immediately placed in the supine position. Supplemental oxygen was administered via face mask, and standard monitoring was continued throughout the procedure.

Assessment parameters**Sensory block**

The onset of sensory block was assessed by loss of pinprick sensation along the midclavicular line. Maximum sensory level

achieved and time to reach it was recorded. Duration of sensory block was defined as time from onset to regression to the S1 dermatome.

Motor block

Motor blockade was assessed using the modified Bromage scale. Time to onset of motor block and duration of motor block were recorded.

Haemodynamic parameters

Heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and oxygen saturation were recorded at regular intervals intraoperatively and postoperatively.

Postoperative analgesia

Pain was assessed using the Visual Analogue Scale (VAS). Duration of postoperative analgesia was defined as the time from intrathecal injection to first request for rescue analgesia.

Adverse effects

Patients were monitored for adverse effects such as hypotension, bradycardia, nausea, vomiting, pruritus, respiratory depression, and sedation.

STATISTICAL ANALYSIS

Data were compiled and analysed using appropriate statistical software. Continuous variables were expressed as mean±standard deviation, and categorical variables as numbers and percentages. Student's t-test and Chi-square test were used as applicable. A p-value <0.05 was considered statistically significant.

RESULTS

Both groups were comparable with respect to age, gender, weight, ASA status, and duration of surgery (p>0.05).

Onset of sensory and motor block was similar between groups. Duration of sensory block, motor block, and postoperative analgesia was significantly prolonged in Group II (p<0.001). Haemodynamic parameters remained stable throughout the study period with no significant inter-group differences. Sedation scores were comparable (Ramsay score 2 in all patients). Incidence of hypotension, bradycardia, pruritus, and other side effects was similar and statistically non-significant.

Table 1: Sensory block

Variables	Groups	N	Mean	Std. deviation	Std. error mean	95% lower CI	95% upper CI	t-test	p value
Onset of SB (min)	Group I	30	2.76	0.08	0.01	-0.07	0.07	1.520	0.134 (NS)
	Group II	30	2.72	0.08	0.01				
Duration of sensory block (min)	Group I	30	275.10	16.46	3.01	-14.94	3.01	10.017	0.001(HS)
	Group II	30	310.13	14.94	2.73				

Table 2: Duration of analgesia

Duration of analgesia (mins)	Group I		Group II	
	Patients	Percentage	Patients	Percentage
≤180 min	1	3.33%	0	0%
181-240 min	24	80%	0	0%
241-300 min	5	16.67%	28	93.33%
>300 min	0	0%	2	6.67%
Total	30	100%	30	100%
Mean±SD	226.40±18.09		280.60±13.90	
Median	225.00		280.00	
Range	180-265		260-315	
t-test	13.010			
p value	0.001 (HS)			

Table 3: Modified bromage scale

Time intervals (min)	Groups	N	Mean	Std. deviation	Std. error mean	95% lower CI	95% upper CI	t-test	p value
5 min	Group I	30	3.00	0.66	0.12	-1.359	-0.775	0.850	0.399 (NS)
	Group II	30	2.83	0.87	0.15				
10 min	Group I	30	1.66	0.65	0.12	-0.568	0.034	1.774	0.147 (NS)
	Group II	30	1.43	0.50	0.09				
15 min	Group I	30	1.13	0.25	0.05	-0.223	0.090	0.851	0.398 (NS)
	Group II	30	1.07	0.35	0.06				
20 min	Group I	30	1.00	0.00	0.00	---	---	---	---
	Group II	30	1.00	0.00	0.00				
25 min	Group I	30	1.00	0.00	0.00	---	---	---	---
	Group II	30	1.00	0.00	0.00				
30 min	Group I	30	1.00	0.00	0.00	---	---	---	---
	Group II	30	1.00	0.00	0.00				

Table 4: Complications

Complications		Group I		Group II		χ^2	p value
		Patients	Percentage	Patients	Percentage		
Hypotension	Yes	4	13.33%	6	20%	0.48	0.488 (NS)
	No	26	86.67%	24	80%		
Bradycardia	Yes	5	16.67%	8	26.67%	0.88	0.347 (NS)
	No	25	83.33%	22	73.33%		
Pruritus	Yes	3	10%	2	6.67%	0.22	0.640 (NS)
	No	27	90%	28	93.33%		
Urinary Retention	Yes	0	0%	0	0%	--	--
	No	30	100%	30	100%		
Headache	Yes	0	0%	0	0%	--	--
	No	30	100%	30	100%		
Respiratory Depression	Yes	0	0%	0	0%	--	--
	No	30	100%	30	100%		

DISCUSSION

Spinal anaesthesia is the technique of choice for lower limb surgeries due to its rapid onset, reliable blockade, and favourable safety profile. This study compared fentanyl and dexmedetomidine as intrathecal adjuvants to 0.75% hyperbaric ropivacaine with respect to block characteristics, haemodynamic stability, postoperative analgesia, and adverse effects. Both groups were comparable with respect to demographic variables such as age, gender, and body weight, ensuring uniform baseline characteristics. Similar observations have been reported by Gupta *et al.*, Kanazi *et al.*, and Shashikala *et al.* [1-3], indicating appropriate randomisation and comparability between study groups. The onset of sensory and motor block was similar in both groups, suggesting that either adjuvant does not significantly affect onset characteristics of hyperbaric ropivacaine [8, 9].

Baseline haemodynamic parameters, including heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, oxygen saturation, and respiratory rate, were comparable between the two groups [10]. Intraoperatively, haemodynamic parameters remained stable in both groups. Although the incidence of bradycardia and hypotension was slightly higher in the dexmedetomidine group, the difference was statistically non-significant. These findings are consistent with those reported by Al-Ghanem *et al.*, Shashikala *et al.*, Sun *et al.*, Bayer *et al.*, and Farokhmehr *et al.* [3-9], who also observed comparable haemodynamic stability with fentanyl and dexmedetomidine as intrathecal adjuvants [11].

Oxygen saturation and respiratory rate remained normal throughout the perioperative period in both groups, with no episodes of respiratory depression or hypoxia, consistent with earlier studies by Nallam SR *et al.* [17], Ravipati *et al.* [6], Kumar *et al.* [8].

The onset of sensory block and motor blockade was rapid and comparable between the two groups, with no statistically significant difference. Similar findings have been reported by Kiran *et al.*, Sun *et al.*, Agarwal A *et al.*, Chaudary *et al.* [13-20].

A key finding was the significantly prolonged duration of sensory and motor blockade in the dexmedetomidine group.

Dexmedetomidine prolongs spinal anaesthesia by inhibiting nociceptive neurotransmission and hyperpolarising spinal interneurons. These findings are consistent with previous studies reporting superior block prolongation with α_2 -agonists compared to opioids.

The duration of analgesia was significantly longer in the dexmedetomidine group, indicating superior postoperative pain control compared to fentanyl. These findings are in concordance with previous studies and meta-analyses by Sun *et al.*, Ravipati *et al.*, Farokhmehr *et al.* [6, 7], Kiran *et al.*, and Patel *et al.* [13, 14]. Which reported prolonged analgesia with intrathecal dexmedetomidine. Despite the known sympatholytic effects of dexmedetomidine, no clinically significant bradycardia or hypotension was observed, likely due to the low intrathecal dose used.

Modified Bromage scores were comparable between the two groups, indicating similar intensity of motor blockade. Sedation assessed using the Ramsay Sedation Score showed that none of the patients required additional intraoperative sedation, suggesting adequate patient comfort and surgeon satisfaction. These findings are consistent with those reported by Nallam *et al.* [17] and Agarwal *et al.* [18].

Postoperative pain assessed using the Visual Analogue Scale showed low and comparable scores in both groups, with rescue analgesia administered as required. Similar findings have been reported by and Agarwal *et al.* [18]. Chaudhary *et al.* [20]. Further supporting the analgesic efficacy of both adjuvants.

In summary, dexmedetomidine as an intrathecal adjuvant to hyperbaric ropivacaine provided a longer duration of sensory block, motor block, and analgesia compared to fentanyl, without significant haemodynamic or respiratory compromise.

LIMITATIONS

- Single-centre study
- Limited sample size
- Long-term outcomes were not assessed

CONCLUSION

Dexmedetomidine and fentanyl are effective adjuvants to 0.75% hyperbaric ropivacaine in subarachnoid block for lower limb surgeries. Dexmedetomidine offers comparable analgesia, longer sensory and motor blockade, stable hemodynamics, and enhanced patient comfort, making it ideal for lower limb surgeries. Fentanyl, with rapid onset and moderate duration, suits short daycare procedures. The choice of adjuvant should align with surgical and postoperative needs. Further studies are needed for dose optimization, broader patient groups, and long-term patient outcomes.

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AUTHORS CONTRIBUTIONS

All authors have contributed equally

CONFLICT OF INTERESTS

Declared none

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