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Original Research Article

Comparison of Dexmedetomidine and Nalbuphine as Additive to Ropivacaine for Spinal Anaesthesia in routine Gynaecological Surgeries

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Abstract

Background: Spinal anaesthesia is widely used for gynaecological surgeries, and adjuvants are often added to improve the quality and duration of analgesia. Dexmedetomidine and nalbuphine have emerged as promising intrathecal adjuvants; however, comparative data with ropivacaine remain limited. The study aimed to compare the efficacy and safety of dexmedetomidine versus nalbuphine as an additive to ropivacaine for spinal anaesthesia in routine gynaecological surgeries, and to assess intraoperative alertness and rescue medication requirement.

Materials and Methods: This prospective, randomized, single-blinded interventional study included 150 patients (ASA I–II) undergoing gynecological surgeries, allocated equally into two groups. Group A received intrathecal ropivacaine with nalbuphine (5 mg), while Group B received ropivacaine with dexmedetomidine (50 µg). Sensory and motor block characteristics, Bromage score, MOAA/S score, rescue analgesia, and adverse drug reactions were assessed. Statistical analysis was performed using SPSS, with $p<0.05$ considered significant.

Results: Baseline characteristics were comparable between groups. The onset of sensory block (2.56 ± 0.50 vs 4.88 ± 1.47 min) and motor block (2.72 ± 0.83 vs 5.40 ± 1.05 min) was significantly faster in Group A ($p=0.0001$). Bromage scores were higher in Group A up to 4 hours ($p=0.0001$). Rescue analgesia requirement was significantly lower in Group A (28.0% vs 61.3%, $p=0.0001$). Hemodynamic parameters were stable in both groups. Adverse drug reactions were more frequent in Group B, particularly nausea and vomiting (18.7% vs 0%). Sedation levels remained unchanged in both groups.

Conclusion: Nalbuphine is a superior adjuvant to ropivacaine compared to dexmedetomidine, providing faster onset, better analgesia, and a more favorable safety profile.

Keywords: Ropivacaine, Nalbuphine, Dexmedetomidine, Spinal Anesthesia, Gynecological Surgeries.

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Introduction

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, and remains a highly subjective phenomenon influenced by individual perception and prior experiences [1]. Effective pain control is a cornerstone of perioperative care, as inadequately managed postoperative pain can adversely affect multiple organ systems including

cardiovascular, respiratory, gastrointestinal, neuroendocrine, and musculoskeletal systems [2]. It may lead to complications such as hypoxemia, increased myocardial oxygen demand, delayed gastrointestinal recovery, metabolic disturbances, reduced mobility, and psychological distress, thereby prolonging hospital stay and impairing recovery [3]. Hence, optimal pain management is essential to improve both physiological outcomes and patient satisfaction [4].

Spinal anaesthesia is widely employed for lower abdominal and gynaecological surgeries owing to its simplicity, cost-effectiveness, and reliability [5]. Commonly used local anaesthetics include bupivacaine, levobupivacaine, prilocaine, and ropivacaine [6]. Among these, ropivacaine, a long-acting amide local anaesthetic and a pure S(−) enantiomer, has gained popularity due to its lower cardiotoxicity and neurotoxicity compared to bupivacaine [7]. It also exhibits differential sensory-motor blockade due to its lower lipid solubility, resulting in reduced motor blockade with adequate sensory anaesthesia [8]. However, despite its favorable safety profile, ropivacaine is associated with a relatively shorter duration of action when used intrathecally, necessitating the use of adjuvants to prolong analgesia [9].

To enhance the duration and quality of spinal anaesthesia, various intrathecal adjuvants such as opioids (fentanyl, tramadol), benzodiazepines (midazolam), and α2-agonists (clonidine) have been explored [10]. However, these agents have limitations including side effects and variable efficacy. Recently, dexmedetomidine and nalbuphine have emerged as promising alternatives. Nalbuphine, a mixed κ-agonist and μ-antagonist opioid, provides effective analgesia with minimal respiratory depression, stable hemodynamic, and fewer opioid-related side effects such as pruritus and excessive sedation [11]. Dexmedetomidine, a highly selective α2-adrenergic agonist, offers superior analgesia, sedation, and hemodynamic stability, and has been increasingly studied as a neuraxial adjuvant with encouraging results [12].

Although both dexmedetomidine and nalbuphine have demonstrated efficacy as intrathecal adjuvants, comparative data, particularly in the context of routine gynaecological surgeries, remain limited in the Indian population [13-15]. Given their distinct pharmacological profiles and potential advantages, a direct comparison is essential to determine the more effective and safer additive to ropivacaine in spinal anaesthesia.

Therefore, this study aimed to compare the efficacy of dexmedetomidine versus nalbuphine as an additive to ropivacaine for spinal anaesthesia during routine gynaecological surgeries; to assess intraoperative patient alertness; to evaluate the requirement of rescue medications; and to compare the incidence of adverse drug reactions between the two groups.

Materials and Methods

This prospective, randomized, single-blinded interventional study was conducted in the Department of Pharmacology in collaboration with the Departments of Anaesthesiology & Critical Care and Obstetrics & Gynaecology at SCB Medical College & Hospital, Cuttack, over a period from November 2018 to October 2020. The study was carried out in accordance with the International Council for Harmonisation–Good Clinical Practice (ICH-GCP) guidelines and the Declaration of Helsinki. Written informed consent was obtained from all participants after explaining the study procedure in their vernacular language.

A total of 150 female patients aged between 35–55 years, belonging to the American Society of Anaesthesiologists (ASA) physical status I and II, and scheduled for routine gynaecological surgeries were enrolled in the study. Patients with local infection at the puncture site, spinal deformities, coagulation disorders, known allergy to study drugs, or morbid obesity (BMI ≥35 kg/m²) were excluded. Eligible patients were randomly allocated into two groups (n=75 each) using a simple randomization technique. Group A received intrathecal 2.5 ml ropivacaine with 5 mg nalbuphine (0.5 ml), while Group B received 2.5 ml ropivacaine with 50 μg dexmedetomidine (0.5 ml). Study drugs were prepared under sterile precautions and coded to maintain blinding.

All patients underwent thorough preoperative evaluation including baseline investigations such as haemoglobin, blood glucose, renal function tests, urine analysis, and electrocardiogram. Standard pre-anaesthetic assessment was performed, and patients were kept nil per oral for 6 hours prior to surgery. Premedication with oral diazepam 5 mg was administered 2 hours before surgery. In the operating room, standard monitoring including heart rate, blood pressure, respiratory rate, oxygen saturation, and ECG was instituted. Baseline parameters were recorded prior to administration of spinal anaesthesia and monitored at predefined intervals intraoperatively and postoperatively.

Efficacy was assessed in terms of onset and duration of sensory and motor blockade, degree of motor block using the Bromage scale, intraoperative alertness using the Modified Observer's Assessment of Alertness/Sedation (MOAA/S) scale, and requirement of rescue medications. Safety was evaluated by recording adverse drug reactions (ADRs), which were analyzed using the WHO–UMC causality assessment scale and Hartwig and Siegel severity

scale. Data were recorded at baseline, intraoperatively, and at multiple postoperative intervals (0, 2, 4, 6, 8, and 12 hours).

Statistical analysis was performed using SPSS version 26.0, with continuous variables expressed as mean ± standard deviation and categorical variables as percentages. Student's t-test and Chi-square test were applied as appropriate, and a p-value <0.05 was considered statistically significant.

Results

A total of 224 patients were screened for eligibility, of which 74 were excluded based on predefined criteria. The remaining 150 patients were enrolled and randomized in a 1:1 ratio into two equal groups of 75 each. Group A received intrathecal ropivacaine with nalbuphine (R+N), while Group B received intrathecal ropivacaine with dexmedetomidine (R+D) during routine gynecological surgical procedures. All randomized patients were included in the final analysis. Baseline demographic characteristics were comparable between the two groups. The mean age was 42.33 ± 11.52 years in Group A and 39.61 ± 11.90 years in Group B (p=0.167). Similarly, mean weight (58.92 ± 6.64 kg vs 60.96 ± 9.40 kg), height (1.55 ± 0.02 m vs 1.56 ± 0.04 m), and BMI (24.40 ± 2.79 kg/m² vs 25.05 ± 4.00 kg/m²) were comparable (p>0.05). Most patients belonged to the normal BMI category (64.0% in Group A vs 48.0% in Group B) and upper lower socioeconomic class (62.7% vs 66.7%), with no statistically significant differences (p=0.5631) (Table 1).

Table 1: Baseline Demographic Characteristics

Parameter		Group A	Group B	p-value
Age (years)	**Mean ± SD**	42.33 ± 11.52	39.61 ± 11.90	0.167
Weight (kg)	**Mean ± SD**	58.92 ± 6.64	60.96 ± 9.40	0.127
Height (m)	**Mean ± SD**	1.55 ± 0.02	1.56 ± 0.04	0.320
BMI (kg/m²)	**Underweight**	1 (1.3%)	2 (2.7%)	0.261
	Normal	48 (64.0%)	36 (48.0%)	
	Overweight	21 (28.0%)	31 (41.3%)	
	Obese	5 (6.7%)	6 (8.0%)	
	Mean ± SD	24.40 ± 2.79	25.05 ± 4.00	
Socioeconomic Status (Kuppuswamy Classification)	**Upper (I)**	0 (0%)	0 (0%)	0.5631
	Upper Middle (II)	0 (0%)	0 (0%)	
	Lower Middle (III)	3 (4.0%)	5 (6.7%)	
	Upper Lower (IV)	47 (62.7%)	50 (66.7%)	
	Lower (V)	25 (33.3%)	20 (26.7%)	

The distribution of surgical procedures was broadly similar between groups.

VH-PFR was the most common procedure, performed in 37.3% of patients in Group A and 24.0% in Group B, followed by TAH-BSO (21.3% in both groups). Laparotomy was more frequent in Group B (13.3% vs 4.0%), while D&C was more common in Group A (10.7% vs 5.3%).

Other procedures such as myomectomy, cervical biopsy, and tubal recanalization were performed in smaller proportions, with no major imbalance overall (Table 2).

Table 2: Type of Surgical Procedures

Procedure	Group A (n=75)	Group B (n=75)
VH-PFR	28 (37.3%)	18 (24.0%)
TAH-BSO	16 (21.3%)	16 (21.3%)
Laparotomy	3 (4.0%)	10 (13.3%)
LAVH	2 (2.7%)	3 (4.0%)
NDVH	0 (0%)	3 (4.0%)
Cervical Biopsy	2 (2.7%)	4 (5.3%)
Myomectomy	3 (4.0%)	5 (6.7%)
Tubal Recanalization	1 (1.3%)	3 (4.0%)
D & C	8 (10.7%)	4 (5.3%)
Others (Vaginoplasty, Cystectomy, EUA dilatation, TLH, D & E, DHL, Hysteroscopic Removal, ECC)	10 (13.3%)	11 (14.7%)

Hemodynamic parameters showed comparable trends with some significant differences at specific time points. Heart rate was similar at baseline (82.36 ± 9.66 vs 82.03 ± 15.17 bpm; p=0.873) and at 10 minutes, but was significantly lower in Group B at 45 minutes (74.69 ± 13.42 vs 79.11 ± 8.99 bpm; p=0.019). Baseline SBP (135.92 vs 124.47 mmHg; p=0.021), DBP (80.63 vs 76.84 mmHg;

p=0.002), and MAP (98.98 vs 94.34 mmHg; p=0.002) were significantly higher in Group B. However, values became comparable at 10 minutes, while DBP remained significantly lower in Group B at 45 minutes (70.73 vs 75.48 mmHg; p=0.000) (Table 3).

Table 3: Hemodynamic Parameters

Parameter	Time	Group A	Group B	p-value
Heart Rate	**Baseline**	82.36 ± 9.66	82.03 ± 15.17	0.873
	10 minutes	80.12 ± 9.35	76.99 ± 15.95	0.144
	45 minutes	79.11 ± 8.99	74.69 ± 13.42	0.019
SBP	**Baseline**	124.47 ± 19.33	135.92 ± 14.02	0.021
	10 minutes	119.56 ± 18.05	119.99 ± 16.27	0.879
	45 minutes	116.07 ± 15.29	115.53 ± 15.59	0.833
DBP	**Baseline**	76.84 ± 5.22	80.63 ± 9.19	0.002
	10 minutes	75.15 ± 5.62	74.12 ± 8.24	0.374
	45 minutes	75.48 ± 5.91	70.73 ± 7.35	0.000
MAP	**Baseline**	94.34 ± 8.75	98.98 ± 9.21	0.002
	10 minutes	89.71 ± 8.44	89.29 ± 9.61	0.774
	45 minutes	89.38 ± 8.27	85.71 ± 9.16	0.11

The onset of sensory and motor block was significantly faster in Group A. The time to reach T6 sensory level was 2.56 ± 0.50 minutes in Group A compared to 4.88 ± 1.47 minutes in Group B, and time to achieve Bromage score 3 was 2.72 ± 0.83 minutes versus 5.40 ± 1.05 minutes respectively, both showing highly significant differences (p=0.0001) (Table 4).

Table 4: Onset of Sensory and Motor Block

Parameter	Group A	Group B	p-value
Time to reach T6 (min)	2.56 ± 0.50	4.88 ± 1.47	0.0001
Time to Bromage 3 (min)	2.72 ± 0.83	5.40 ± 1.05	0.0001

Motor block was more intense and prolonged in Group A. At 0 hours, the Bromage score was higher in Group A (2.4 ± 0.75 vs 2.04 ± 0.25), and this difference persisted at 2 hours (2.83 ± 0.38 vs 0.93 ± 0.86) and 4 hours (1.79 ± 0.64 vs 0.47 ± 0.68), all statistically significant (p=0.0001). Complete recovery (score 0) was observed in both groups by 6 hours (Table 5).

Table 5: Bromage Score (Motor Block)

Time	Group A	Group B	p-value
0 hours	2.4 ± 0.75	2.04 ± 0.25	0.0001
2 hours	2.83 ± 0.38	0.93 ± 0.86	0.0001
4 hours	1.79 ± 0.64	0.47 ± 0.68	0.0001
6 hours	0	0	-
8 hours	0	0	-
12 hours	0	0	-

Sedation levels remained unchanged in both groups throughout the study period. All patients maintained a MOAA/S score of 5 at all-time points (0 to 12 hours), indicating full alertness with no difference between the groups (Table 6).

Table 6: MOAA/S Sedation Score

Time	Group A	Group B
0 hours	5	5
2 hours	5	5
4 hours	5	5
6 hours	5	5
8 hours	5	5
12 hours	5	5

Rescue medication requirement was significantly higher in Group B, with 46 patients (61.3%) requiring additional analgesia compared to 21 patients (28.0%) in Group A (p=0.0001). This reflects superior and longer-lasting analgesic efficacy in Group A (Table 7).

Table 7: Rescue Medication Requirement

Parameter	Group A (n=75)	Group B (n=75)	p-value
Required	21 (28.0%)	46 (61.3%)	0.0001
Not required	54 (72.0%)	29 (38.7%)	

Adverse drug reactions were more frequent in Group B. Nausea and vomiting occurred in 18.7% of patients in Group B compared to none in Group A (p=0.0001).

Hypotension (22.7% vs 9.3%) and bradycardia (14.7% vs 13.3%) were comparable between groups. WHO-UMC causality assessment showed probable reactions in 35.7% of Group B patients versus none in Group A (p=0.0043), while all reactions in Group A were classified as possible.

Similarly, mild reactions were observed only in Group B (35.7%), whereas all reactions in Group A were moderate, indicating a relatively better safety profile in Group A (Table 8).

Table 8: Adverse Drug Reactions, Causality and Severity Assessment

Parameter	Category	Group A (n=75)	Group B (n=75)	p-value
Adverse Drug Reactions	**Nausea & Vomiting**	0 (0%)	14 (18.7%)	0.0001
	Hypotension	7 (9.3%)	17 (22.7%)	0.260
	Bradycardia	10 (13.3%)	11 (14.7%)	0.815
	Pruritus	0 (0%)	1 (1.3%)	0.319
WHO-UMC Causality	**Probable**	0 (0%)	15 (35.7%)	0.0043
	Possible	17 (100%)	27 (64.3%)	
Hartwig & Siegel Severity	**Mild**	0 (0%)	15 (35.7%)	0.0043
	Moderate	17 (100%)	27 (64.3%)	

Discussion

The present study demonstrated that both dexmedetomidine and nalbuphine are effective adjuvants to ropivacaine for spinal anaesthesia; however, nalbuphine showed a comparatively faster onset and better early block characteristics. The onset of sensory block (2.56 ± 0.50 min vs 4.88 ± 1.47 min) and motor block (2.72 ± 0.83 min vs 5.40 ± 1.05 min) was significantly faster in the nalbuphine group, which was further supported by higher Bromage scores in the initial hours. Hemodynamic parameters remained largely stable in both groups, although a greater decline in heart rate and diastolic blood pressure was observed in the dexmedetomidine group at later time points. These findings indicate that while both agents are clinically useful, nalbuphine provides a quicker onset with comparable hemodynamic stability. In contrast to the present findings, studies such as those by Mahendru et al and Shaikh et al have reported superior efficacy of dexmedetomidine in terms of prolonged analgesia, better intraoperative conditions, and stable hemodynamic when used as an adjuvant to bupivacaine [16,17].

Similarly, Kiran et al and Makhni et al observed earlier onset and prolonged duration of block with dexmedetomidine compared to local anaesthetic alone or other adjuvants [18,19]. The discrepancy with the present study may be attributed to differences in the local anaesthetic used (ropivacaine vs bupivacaine), drug dosages, and surgical population, as ropivacaine is known to have a different pharmacodynamic profile with shorter duration and differential sensory-motor blockade. Interestingly, the findings of the present study align more closely with those of Murthy et al, who reported comparable efficacy between nalbuphine and dexmedetomidine as adjuvants to ropivacaine [20]. However, in our study, nalbuphine demonstrated a clear advantage in terms of faster onset and reduced requirement of rescue analgesia (28.0% vs 61.3%). In contrast, Bhalavat et al reported prolonged sensory and motor blockade with dexmedetomidine compared to nalbuphine when used with bupivacaine, which is again contrary to the present findings [21]. This variation could be explained by the difference in physicochemical properties between ropivacaine and bupivacaine, influencing drug spread and receptor interaction at the spinal level. With respect to safety, both drugs were well tolerated, with no serious adverse events reported. However, adverse drug reactions were more frequent in the dexmedetomidine group (43 vs 17 events), particularly nausea and vomiting (18.7% vs 0%). Hypotension and bradycardia were comparable between groups. Causality and severity assessments indicated that most reactions were possible and moderate in nature, with a higher proportion of probable and mild reactions in the dexmedetomidine group. These findings suggest that nalbuphine may offer a more favourable safety profile, especially in terms of reduced incidence of postoperative nausea and vomiting, while maintaining adequate analgesic efficacy.

Conclusion

Both dexmedetomidine and nalbuphine are effective adjuvants to ropivacaine for spinal

anaesthesia in routine gynaecological surgeries; however, nalbuphine demonstrated a comparatively faster onset of sensory and motor block, better early motor blockade characteristics, reduced requirement of rescue analgesia, and a more favourable safety profile with fewer adverse drug reactions, particularly nausea and vomiting.

While dexmedetomidine provided adequate anaesthesia with stable hemodynamic, it was associated with higher incidence of adverse effects and delayed onset.

Therefore, nalbuphine may be considered a preferable additive to ropivacaine in this clinical setting. Nevertheless, further large-scale studies with longer follow-up and comparison with other standard adjuvants are recommended to validate these findings.

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