To Compare The Efficacy And Safety Of Different Doses Of Intrathecal Dexmedetomidine 3mcg And 5mcg As An Adjuvant Combined With Hyperbaric Ropivacaine 12.5mg In Patients Undergoing Peri-Anal Surgeries

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KEYWORDS

ABSTRACT

Background: Effective regional anesthesia is essential for perianal surgeries to ensure patient comfort and facilitate rapid postoperative recovery. Hyperbaric ropivacaine, commonly used for spinal anesthesia, offers a favourable safety profile. Dexmedetomidine, a selective α_2-adrenergic agonist, is frequently used as an adjuvant to enhance analgesia quality and prolong its duration. However, the optimal intrathecal dexmedetomidine dose when combined with hyperbaric ropivacaine for perianal surgeries remains underexplored.

Objectives: This study aimed to compare the effects of 3 mcg and 5 mcg doses of intrathecal dexmedetomidine combined with 12.5 mg hyperbaric ropivacaine on the duration of sensory and motor blockade, hemodynamic stability, postoperative analgesia, and adverse effects in perianal surgeries.

Methods: A prospective, randomized, double-blind clinical trial was conducted on 60 patients undergoing elective perianal surgeries. Patients were randomized into two groups: Group A received 12.5 mg hyperbaric ropivacaine + 3 mcg dexmedetomidine, and Group B received 12.5 mg hyperbaric ropivacaine + 5 mcg dexmedetomidine. Parameters assessed included onset and duration of sensory and motor blocks, time to first analgesic request, hemodynamic changes, and sedation scores.

Results: Group B exhibited a faster onset of sensory (5.1 ± 0.5 min) and motor block (6.0 ± 0.6 min), and significantly prolonged durations of sensory (280 ± 6 min) and motor block (255 ± 7 min) compared to Group A ($p < 0.001$). Time to first analgesic request was longer in Group B (570 ± 10 min vs. 490 ± 6 min; $p < 0.001$). However, Group B experienced greater hemodynamic changes, including lower blood pressure ($p = 0.003$) and heart rate ($p = 0.001$). Sedation scores were comparable between groups ($p = 0.82$).

Conclusion: For perianal surgeries lasting 60–90 minutes, optimal sensory blockade with minimal hemodynamic effects and desired sedation is crucial. A 3mcg dose of intrathecal Dexmedetomidine with 12.5mg Ropivacaine provides adequate motor blockade, superior analgesia, and minimal or no hemodynamic changes. Higher doses require careful patient selection and monitoring to ensure safety.

INTRODUCTION

Perianal surgeries often necessitate effective regional anesthesia to ensure patient comfort and facilitate prompt postoperative recovery. Hyperbaric ropivacaine, a local anesthetic known for its favorable safety profile, is commonly employed in spinal anesthesia for such procedures. To enhance the quality and duration of analgesia, adjuvants like dexmedetomidine—a selective α_2-adrenergic receptor agonist—are added to local anesthetics. Dexmedetomidine has been shown to prolong analgesia by depressing the release of presynaptic C-fiber transmitters and hyperpolarizing postsynaptic dorsal horn neurons[1].

While the analgesic benefits of intrathecal dexmedetomidine are well-documented, the optimal dosing, particularly in combination with hyperbaric ropivacaine for perianal surgeries, remains under investigation. Studies have explored various doses of dexmedetomidine as an adjuvant to local anesthetics. For instance, a study comparing 3mcg and 5mcg doses of intrathecal dexmedetomidine with isobaric ropivacaine in lower abdominal surgeries found that higher doses prolonged the duration of analgesia without increasing adverse effects[2].

However, the specific effects of 3mcg versus 5mcg doses of intrathecal dexmedetomidine combined with hyperbaric ropivacaine in perianal surgeries have not been extensively studied. Given the potential for dose-dependent prolongation of both sensory and motor blockade, it is crucial to evaluate the efficacy and safety of these doses to determine the most appropriate regimen that balances effective analgesia with rapid postoperative recovery.

OBJECTIVES

1. Primary Objective:

- To compare the duration of sensory and motor blockade between 3mcg and 5mcg intrathecal dexmedetomidine when combined with 12.5 mg hyperbaric ropivacaine in patients undergoing peri-anal surgeries.

2. **Secondary Objectives:**

- To evaluate the hemodynamic stability between the two groups during the intraoperative and postoperative periods.
- To assess the duration of postoperative analgesia provided by the two different doses of intrathecal dexmedetomidine.
- To determine the incidence and nature of adverse effects associated with each dose regimen.

MATERIALS AND METHODOLOGY

Study Design: A prospective, randomized, double-blind, controlled clinical trial.

Study Setting: The study was conducted over 6 months in the Department of Anesthesiology at Karpaga Vinayaga Institute of Medical Sciences & Research Centre, Chengalpattu District.

Study Population:

- Inclusion Criteria: Patients aged 18–65 years, ASA (American Society of Anesthesiologists) physical status I and II scheduled for elective peri-anal surgeries under spinal anesthesia
- Exclusion Criteria: Patient refusal, Allergy to study drugs, Coagulation disorders, Neurological disorders, Infection at the injection site

Sample Size Calculation:

The sample size is calculated using the formula for comparing means:

$$N = \frac{2(Z_{\alpha/2} + Z_{\beta})^2 \sigma^2}{(\mu_1 - \mu_2)^2}$$

Where:

- Standard normal variate for type I error (1.96 for \u03b1 = 0.05)
- Standard normal variate for type II error (0.84 for 80% power)
- Pooled standard deviation (based on pilot study or literature)
- Minimum clinically significant difference between groups
- Considering a dropout rate of 10%, the final sample size per group will be adjusted accordingly.

Intervention:

- Group A: 12.5 mg hyperbaric ropivacaine + 3 mcg intrathecal dexmedetomidine
- Group B: 12.5 mg hyperbaric ropivacaine + 5 mcg intrathecal dexmedetomidine

Randomization and Blinding: Using computer-generated random numbers, patients were randomly assigned into two groups (Group A and Group B). Allocation concealment were ensured using sealed, opaque envelopes.

The anesthesiologist administering the drugs and the observer recording outcomes were blinded to group allocation.

Procedure: Patients posted for peri anal surgeries who were randomly allotted to a group, standard monitoring (ECG, NIBP, SpO2) was applied. Subarachnoid block was performed at L3–L4 interspace using a 25G Quincke spinal needle under aseptic precautions. Study drugs were prepared by an independent anesthesiologist not involved in the study.

Parameters recorded: Onset and duration of sensory and motor block, Time to first analgesic request, Hemodynamic parameters (HR, BP), Incidence of adverse effects (hypotension, bradycardia, nausea, pruritus, sedation)

Outcome Measures:

- Primary Outcome: Duration of sensory and motor blockade.
- Secondary Outcomes: Hemodynamic stability, postoperative analgesia duration, and incidence of side effects.

STATISTICAL ANALYSIS:

Data were analyzed using SPSS version [X]. Continuous variables: Presented as mean \u00b1 SD and analyzed using the Student's t-test. Categorical variables: Presented as percentages and analyzed using the Chi-square test or Fisher's exact test. Time-to-event data (e.g., duration of analgesia): Analyzed using the Kaplan-Meier survival analysis and Log-rank test. p-value <0.05 were considered statistically significant.
Statistical Formula for t-test:

$$t = \frac{\bar{X}_1 - \bar{X}_2}{\sqrt{\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}}}$$

$\bar{X}_1, \bar{X}_2$: Means of the two groups

s_1^2, s_2^2: Variances of the two groups

n_1, n_2: Sample sizes of the two groups

ETHICAL CONSIDERATIONS:

The Institutional Ethics Committee approved the study. All participants gave written informed consent. The study adhered to the principles outlined in the Declaration of Helsinki.

RESULTS

Table -1: Demographic Details

Variable	Group A (n=30)	Group B (n=30)	p-value
Age (years)	39.6 ± 5.8	40.2 ± 6.1	0.68 (NS)
Sex (Male/Female)	16/14	15/15	0.79 (NS)
Baseline Heart Rate	85 ± 3 bpm	84 ± 4 bpm	0.42 (NS)
Baseline BP (mmHg)	122/88 ± 5/6	121/87 ± 6/5	0.57 (NS)
SpO_2 (%)	99 ± 1	99 ± 1	0.95 (NS)
Type of Surgery			
- Hemorrhoidectomy	10 (33.3%)	10 (33.3%)	0.88 (NS)
- Fissurectomy	10 (33.3%)	10 (33.3%)	
- Fistulectomy	10 (33.3%)	10 (33.3%)	

The age, sex distribution, baseline heart rate, blood pressure, oxygen saturation, and type of surgery between the two groups were statistically comparable ($p > 0.05$), indicating no significant differences. Baseline heart rate and blood pressure were within the reference ranges of 80–90 bpm and 120/90 mmHg ± 10 mmHg, respectively. SpO_2 levels were consistently between 98–100% for all patients (Table 1).

Table – 2: Comparison of Sensory and Motor Block Characteristics Between Group A and Group B

Parameter	Group A (n=30)	Group B (n=30)	p-value	Significance
Onset of Sensory Block (min)	7.1 ± 0.6 (6–8 min)	5.1 ± 0.5 (4–6 min)	<0.001	Significant
Desired Block Height	T8 (achieved in all)	T8 (achieved in all)	1.000	NS
Onset of Motor Block (min)	8.0 ± 0.5 (7–9 min)	6.0 ± 0.6 (5–7 min)	<0.001	Significant
Duration of Sensory Block (min)	255 ± 8 (240–270 min)	280 ± 6 (270–290 min)	<0.001	Significant
Spinal Block Regression Level	S2 (all patients)	S2 (all patients)	1.000	NS
Duration of Motor Block (min)	225 ± 9 (210–240 min)	255 ± 7 (240–270 min)	<0.001	Significant

In comparing spinal block characteristics between Group A and Group B, Group B demonstrated significantly faster onset times for both sensory (5.1 ± 0.5 min) and motor blocks (6.0 ± 0.6 min) compared to Group A (7.1 ± 0.6 min and 8.0 ± 0.5 min, respectively), with p-values <0.001. Although both groups achieved the desired T8 sensory block height and S2 regression level (p=1.000, not significant), Group B exhibited significantly prolonged durations of sensory (280 ± 6 min) and motor blocks (255 ± 7 min) compared to Group A (255 ± 8 min and 225 ± 9 min, respectively). These differences highlight enhanced block efficacy in Group B (Table 2).

Table -3: Comparison of Analgesic Duration, Hemodynamic Parameters, and Sedation Between Study Groups

Parameter	Group A (12.5 mg Ropivacaine + 3 mcg Dexmedetomidine, n=30)	Group B (12.5 mg Ropivacaine + 5 mcg Dexmedetomidine, n=30)	p-value	Significance
Time to First Analgesic Request (min)	480–500 (Mean ± SD: 490 ± 6)	540–600 (Mean ± SD: 570 ± 10)	< 0.001	Significant
Blood Pressure (mm Hg)	100/70 ± 10	90/60 ± 10	0.003	Significant
Heart Rate (bpm)	60–70 (Mean ± SD: 65 ± 3)	50–60 (Mean ± SD: 55 ± 4)	0.001	Significant
Sedation Score (Campbell Sedation Score)	1–2 (Median: 1.5)	1–2 (Median: 1.5)	0.82	Not Significant

The data compares the effects of two doses of dexmedetomidine (3mcg vs 5mcg) combined with 12.5 mg ropivacaine. Group B (5mcg dexmedetomidine) showed a significantly longer time to first analgesic request (570 ± 10 min vs. 490 ± 6 min; $p < 0.001$) and prolonged motor block duration (255 ± 7 min vs. 225 ± 9 min; $p < 0.001$). However, Group B experienced lower blood pressure (90/60 mm Hg; $p = 0.003$) and heart rate (55 ± 4 bpm; $p = 0.001$), indicating increased hemodynamic effects. Sedation scores were similar ($p = 0.82$), suggesting no additional sedative benefit with higher dexmedetomidine dosage (Table 3).

DISCUSSION

Sudheesh K et al. [3] found that a higher dose of intrathecal dexmedetomidine with bupivacaine provided prolonged analgesia and motor blockade, and a higher dose of intrathecal dexmedetomidine (5mcg) caused significant hemodynamic effects. In contrast, the present study suggests that 3mcg dexmedetomidine with ropivacaine offers the desired motor blockade and sufficient sensory blockade with fewer hemodynamic changes, making it preferable for perianal surgeries.

Singh et al. [4] found that higher doses of intrathecal dexmedetomidine with isobaric ropivacaine prolonged analgesia but caused significant hemodynamic changes. Similarly, the present study observed that 5mcg dexmedetomidine with hyperbaric ropivacaine enhanced sensory blockade but led to hemodynamic instability. A 3mcg dose provided effective analgesia with minimal adverse effects.

Sudheesh et al[3] Similarly, Naithani et al[5] reported dose-dependent effects of dexmedetomidine with ropivacaine, emphasizing the need for careful patient selection when using higher doses. Ravipati et al[6]

compare dexmedetomidine and fentanyl, showing that dexmedetomidine provides superior analgesia and prolonged blockade in lower limb surgeries and highlighting dexmedetomidine's efficacy in prolonging analgesia and motor blockade when combined with local anesthetics.

Kame BS et al[7] concluded that intrathecal dexmedetomidine enhances the efficacy of both levobupivacaine and ropivacaine in urological surgeries by prolonging sensory and motor blockade while improving postoperative analgesia. However, they noted significant hemodynamic effects. Their findings align with the present study, emphasizing careful dose selection for optimal outcomes. Dolma L et al[8] concluded that intrathecal dexmedetomidine with isobaric ropivacaine prolonged sensory and motor blockade with stable hemodynamics in femur fracture surgeries. In contrast, the present study found that 5mcg dexmedetomidine with hyperbaric ropivacaine enhanced analgesia but caused notable hemodynamic changes, making 3mcg a safer choice for perianal surgeries.

Gupta et al[9] found that higher intrathecal dexmedetomidine doses (5mcg, 10mcg) prolonged sensory and motor blockade but increased hemodynamic effects. Similarly, our study showed that 5mcg dexmedetomidine with hyperbaric ropivacaine enhanced analgesia but caused significant hemodynamic changes. Thus, 3mcg dexmedetomidine offers a balance of effective analgesia with better hemodynamic stability.

Kaur et al[10] compared ropivacaine alone versus ropivacaine with dexmedetomidine in epidural anesthesia for lower limb surgeries, finding enhanced analgesia and prolonged blockade with dexmedetomidine but with notable hemodynamic effects. Similarly, the present study confirms that while 5mcg dexmedetomidine prolongs analgesia, it also induces greater hemodynamic changes, requiring careful patient selection.

CONCLUSION

This study reveals that a 5mcg dose of intrathecal dexmedetomidine with hyperbaric ropivacaine offers superior analgesia and prolonged blockade but with notable hemodynamic effects. Perianal surgeries last only 60 to 90 minutes, and sensory blockade is more required than motor blockade. Sensory blockade with the least hemodynamic effects and desired sedation is what is needed. Hence, Ropivacaine 12.5mg with dexmedetomidine 3mcg provides sufficient motor blockade for perianal surgeries with a better analgesic profile, desired sedation, and the least hemodynamic changes. Careful patient selection and monitoring are essential when using higher dexmedetomidine doses.

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