Original Article

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Comparison of Different Dosage of Intrathecal Morphine as an Adjuvant to Hyperbaric Ropivacaine in Lower Limb Orthopaedic Surgeries: A Double-blinded Randomised Controlled Study

Anaesthesia Section

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ABSTRACT

Introduction: Spinal anaesthesia with hyperbaric bupivacaine is the cornerstone of lower limb surgeries. With introduction of commercially prepared hyperbaric ropivacaine, its use has increased considerably as an effective alternate.

Aim: To evaluate the analgesic and blockade characteristics of different dosages of morphine when used intrathecally as an adjuvant with hyperbaric ropivacaine in lower limb orthopaedic surgeries.

Materials and Methods: The present double-blinded randomised controlled study was conducted on 114 patients undergoing lower limb orthopaedic surgery under spinal blockade, Patients were divided into three groups. Group R received 3 mL of 0.75% hyperbaric ropivacaine, Group RM1 received 3 mL of hyperbaric ropivacaine with 100 µg morphine, and Group RM2 received 3 mL of 0.75% hyperbaric ropivacaine with 200 µg morphine, respectively. The onset and duration of sensorimotor blockade, duration of analgesia, visual analogue scale for pain and incidence of adverse effects were compared in three groups. Analysis of Variance (ANOVA) test was used for quantitative data while Chi-square test was used for qualitative data.

Results: Demographic data was comparable in all the groups. Group RM2 has significantly prolonged postoperative analgesia {11.59±0.60 hours ($p<0.001$)}. Analgesic requirement was lower in groups RM1 (1.58±0.37) and RM2 (1.26±0.45) as compared to Group R (1.58±0.50) ($p<0.001$). A statistically significant difference was observed between the total duration of sensory blockade in Group R (201.95±7.12 min), Group RM1 (232.21±7.48 min) and Group RM2 (467±21.04 min) ($p<0.001$). The duration of motor blockade was also increased in Group RM2 (424±25.78 min).

Conclusion: Addition of 200 µg morphine to hyperbaric ropivacaine provides haemodynamically stable anaesthesia with prolonged duration of analgesia and sensory blockade. This dosage does not have any additional adverse effects.

Keywords: Analgesia, Local anaesthesia, Lower extremity, Opioid, Spinal anaesthesia

INTRODUCTION

Spinal anaesthesia is a frequently used anaesthetic procedure for abdominal and lower limb surgeries. It is simple, reliable and offers a high success rate. Analgesia offered by spinal anaesthesia is usually limited to <3 hours with the use of long acting local anaesthetic such as bupivacaine or ropivacaine. Hence, the role of adjuvant is of paramount importance in providing analgesia without prolonging the motor effects in the postoperative period [1,2]. Ropivacaine has been used for central neuraxial blockade for a few decades but the recent availability of commercial hyperbaric preparation has created new scopes for use and research. Due to high pKa and low lipid solubility, ropivacaine offers a comparatively safer drug profile as compared to bupivacaine with reduced cardiac toxicity. But ropivacaine is less potent than bupivacaine, hence necessitating the need of adjuvants for improved efficacy [3]. Opioids are considered best adjuvants for intrathecal use along with local anaesthetics, with morphine being adjudged as the most effective due to its potent and prolonged effect [4]. Many authors have researched use of opioids with hyperbaric bupivacaine and isobaric ropivacaine but advent of hyperbaric solution of ropivacaine provided the opportunity of finding solutions with minimal side-effects while providing better outcome for the patients [5].

The present study was conducted to compare the analgesic and blockade characteristics of different dosages of morphine (100 µg and 200 µg) when used intrathecally as an adjuvant with hyperbaric ropivacaine (0.75%) in lower limb orthopaedic surgeries. The primary objective was to compare the duration of analgesia after administration of spinal anaesthesia in between the groups. Secondary objectives of the study included comparison of sensorimotor blockade characteristics, effect on haemodynamic parameters and incidence of side-effects in all three groups.

MATERIALS AND METHODS

The present double-blinded randomised controlled study was conducted in the Department of Anaesthesiology from September 2022 to January 2024, after approval from the institutional ethical committee (BPSGMCW/RC844/IEC/22) and enrollment in a trial registry (CTRI/2023/04/052091). The procedures were conducted as per ethical standards set by Helsinki Declaration-2013.

Sample size calculation: On the basis of the study conducted by Kamath SS et al., considering a superior clinical study with parallel design, sample size was calculated to be 38.13 in each group with difference in means for duration of analgesia of 20.83±4.99 hrs between 0.5% hyperbaric bupivacaine and 0.5% hyperbaric bupivacaine with morphine, type I error (α)=0.05, type II error (β)=0.20, power of study at 80% and confidence limit at 95% [6]. Considering 10% dropout rate total sample size required was 114 (i.e., 38 in each group).

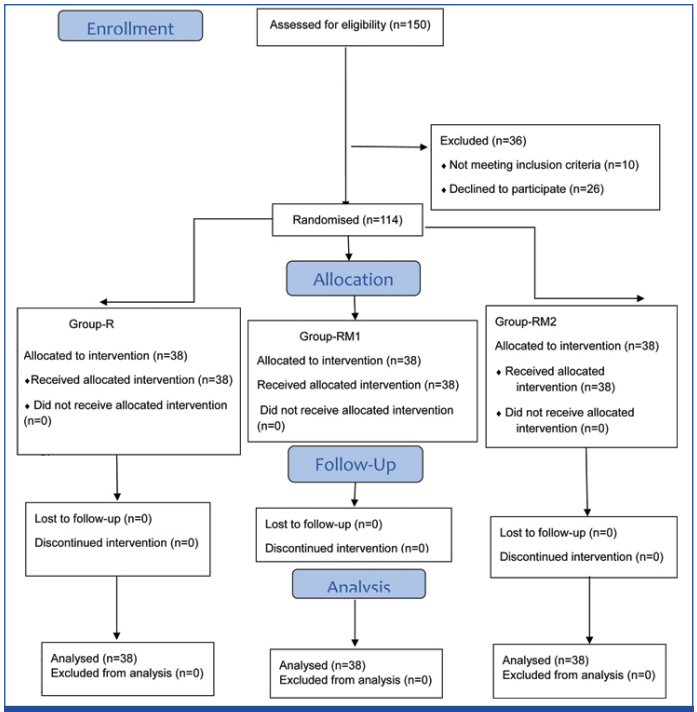
$$m=\frac{2\sigma^2\{z_{1-\alpha}+z_{1-\beta}\}^2}{(\mu_T-\mu_S-\delta)^2}\ m=\frac{2(4.99)^2(1.96+0.84)^2}{(24.2-21)^2}=38.13 \text{ per group.}$$

σ: Standard deviation (4.99); α: Significance level (1.96 at 95%); 1-β: Power (0.84 at 80%) μ_T: Mean of the test treatment; μ_S: Mean of the standard treatment; $\mu_T - \mu_S$: Expected mean difference (24.2); δ: Superiority limit of the difference in means=(21).

Inclusion and Exclusion criteria: Patients between age 18-65 years of age, belonging to American Society of Anaesthesiologists Physical Status (ASA PS) I/II and undergoing elective lower limb orthopaedic surgical procedures under spinal anaesthesia were included in the study. Exclusion criteria comprised of contraindication to spinal anaesthesia, history of allergy to morphine or ropivacaine, patients with history of any cardiac disease, coagulopathy or any respiratory disorder, patients with severe psychiatric disorder such as depression, dementia or drugs which could interfere with the comprehension of the study and patients not willing to participate in the study.

Study Procedure

With the help of computerised random numbers, patients were randomised into three groups of 38 each. Patients in Group R were administered 3 mL 0.75% Inj. hyperbaric ropivacaine intrathecally, while patients in Group RM1 and Group RM2 received 3 mL 0.75% Inj. hyperbaric ropivacaine along with 100 µg and 200 µg morphine, respectively [Table/Fig-1] [6,7]. ASA fasting guidelines were followed in all the patients. In the operating room, standard ASA monitoring {Electrocardiogram (ECG), Pulse Oximetry (SpO_2) and Non-Invasive Blood Pressure (NIBP)} was applied, and baseline haemodynamic parameters {Heart Rate (HR) and mean arterial pressure} were recorded. Under all aseptic conditions, spinal anaesthesia was administered by an Anaesthesiologist who did not participate in observation or collection of data. The patient as well as the investigators was blinded to the administered drug. Completion of the spinal anaesthesia procedure was taken as time zero of spinal anaesthesia. Using a pin prick along the mid axillary line, sensory level was monitored bilaterally, every minute for the initial five minutes, followed by every two minutes for 15 minutes. The motor blockade was assessed using the Bromage scale, and the time taken from completion of the spinal procedure to development of grade 3 motor blockade was also recorded. Regression of sensory block was defined as the time taken for the sensory block to regress up to two segments of the dermatome from the highest level achieved. The duration of motor block was assessed by recording the time elapsed from the maximum to the lowest Bromage scale. The surgical incision was made only after the onset of sensory blockade, i.e., the time taken from completion of the spinal procedure to the loss of pin-prick sensation up to the T10 dermatome level. HR, mean arterial pressure, oxygen saturation and ECG were recorded every five minutes during intraoperative period. The plane of sedation was assessed as per the Ramsay sedation score. Patient was observed perioperatively for side-effects like hypotension, bradycardia, nausea, vomiting, pruritus and respiratory depression. Hypotension (decrease in MAP ≥ 20% from baseline value) was initially treated with a fluid bolus of 200 mL crystalloid followed by Inj. Mephentermine 6 mg intravenous bolus, if required. Bradycardia (HR <50 beats/min) was treated with Injection atropine 0.6 mg intravenously. Nausea/vomiting were treated with Injection ondansetron 0.1 mg/kg intravenously. Intolerable pruritus not corrected with Inj. ondansetron or respiratory rate <8/min was treated with Inj. naloxone (0.1-0.2 mg i.v. bolus, to be repeated every 3-4 min) while oxygen supplementation was initiated at 4-6 L/minute via oxygen flow mask if SpO_2 decreased to 92%. Side-effects and adverse events were monitored up to 36 hours postoperatively. Postoperatively, pain was assessed using the Visual Analogue Score (VAS). Inj. Paracetamol 15 mg/kg max. up to 1 gm intravenously was the drug of choice for analgesia. Inj.



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) diagram.

Tramadol 1-2 mg/kg in slow i.v. infusion in 100 mL 0.9% normal saline was earmarked as a rescue analgesic. Duration of analgesia was calculated as the time from administration of spinal anaesthesia till demand for analgesia. The Likert satisfaction score (1-3) was used to note the patient satisfaction score.

STATISTICAL ANALYSIS

The data was recorded in a Microsoft Excel spreadsheet. Analysis was done using IBM Statistical Package for Social Sciences (SPSS) (SPSS Inc., IBM Corporation, NY, USA) Statistics Version 25 (trial) for Windows software program. Descriptive statistics included computation of percentages, means and standard deviations. The data were checked for normality before statistical analysis using the Kolmogorov-Smirnov test. For quantitative data, ANOVA test was applied. Chi-square test was used for comparison of qualitative data. Level of significance was set at p≤0.05.

RESULTS

Demographic characteristics were comparable in all the groups [Table/Fig-2].

Variables	Group R (n=38)	Group RM1 (n=38)	Group RM2 (n=38)	p-value
Age (years)	52.63±15.69#	38.11±12.32#	43.61±15.85#	0.06
Weight (Kg)	66.39±7.28#	67.26±9.47#	65.66±11.42#	0.76
Height (feet)	5.56±0.18#	5.52±0.19#	5.49±0.26#	0.43
Gender (Male/Female)	27/11	28/10	26/12	0.88
ASA PS I/II	28/10	22/16	18/20	0.06

[Table/Fig-2]: Demographic parameters N=114.
#Values are expressed as Mean±Standard deviation

The mean duration of analgesia in Group RM2 was significantly more than Group RM1 and Group R (p<0.001). This resulted in significant reduction of total analgesic requirement in the Group RM2 [Table/Fig-3].

No difference was observed in the onset of sensory blockade between the three groups (p=0.12). A statistically significant difference was observed between the total duration of sensory blockade with Group RM2 having maximum duration (p<0.001) [Table/Fig-3]. Postoperatively the mean VAS score in Group RM2 was statistically lower (p<0.05) [Table/Fig-4].

Variables	Group R (n=38)	Group RM1 (n=38)	Group RM2 (n=38)	p-value
Onset of sensory block (minutes)	3.45±0.18#	3.28±0.63#	3.29±0.27#	0.12
Onset of motor block (minutes)	7.22±0.59#	6.33±1.05#	6.95±0.65#	<0.001*
Duration of sensory block (minutes)	201.95±7.12#	232.21±7.48#	467.00±21.04#	<0.001*
Duration of motor block (minutes)	205.63±6.69#	226.87±8.46#	424.00±25.78#	<0.001*
Duration of analgesia (hours)	3.58±0.57#	5.43±1.52#	11.59±0.60#	<0.001*
No. of rescue dosages	1.58±0.50#	1.58±0.37#	1.26±0.45#	<0.001*
Duration of surgery (minutes)	126.60±5.16	130.13±14.45	135.00±45.54	0.45

[Table/Fig-3]: Sensorimotor characteristics of spinal anaesthesia and surgical duration N=114.
#Values are expressed as Mean±Standard Deviation: *Significant value

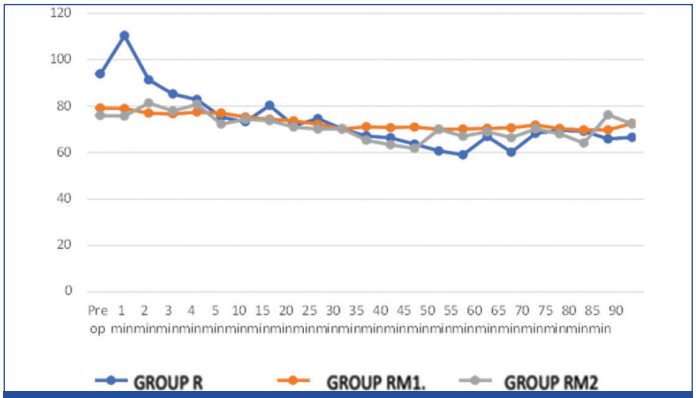
Time (hour)	Group R (n=38)	Group RM1 (n=38)	Group RM2 (n=38)	p-value
1 hour	3.63±0.79	0.00±0.00	0.00±0.00	0.001*
2 hour	3.66±0.75	0.00±0.00	0.00±0.00	0.001*
4 hour	3.63±0.79	0.00±0.00	0.00±0.00	0.001*
6 hour	3.66±0.75	0.79±0.88	0.00±0.00	0.001*
8 hour	3.79±0.78	1.53±0.76	0.00±0.00	0.001*
12 hour	3.79±0.78	1.97±0.79	0.29±0.84	0.001*
18 hour	3.84±0.75	3.53±0.80	1.45±0.92	0.001*
24 hour	3.79±0.78	4.32±0.78	1.53±0.69	0.001*
36 hour	3.74±0.80	5.18±0.93	1.24±0.54	0.001*

[Table/Fig-4]: Comparison of VAS score across the study groups.
*Significant

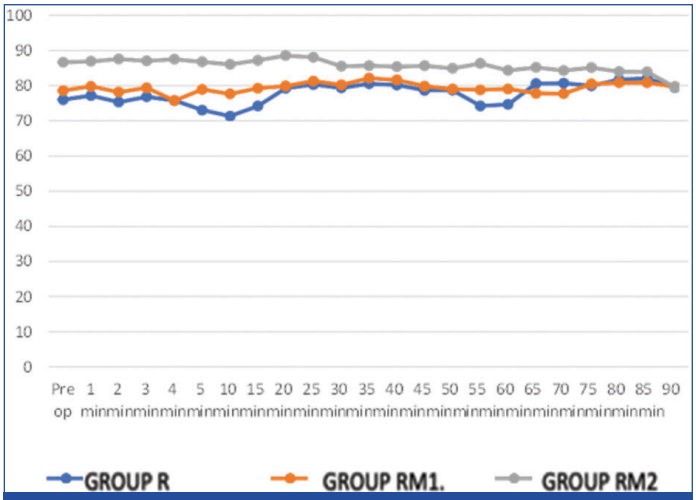
During the intraoperative period, haemodynamic parameters were comparable across the groups [Table/Fig-5,6]. Except pruritus in Group RM2, none of the side-effects were observed to be statistically significant [Table/Fig-7]. Patient satisfaction was significantly more in Group RM2 [Table/Fig-8]. No sedation was observed in any of the patients and SpO_2 was comparable across all the groups during periods of monitoring [Table/Fig-9].

DISCUSSION

In the present study, it was observed that the addition of 200 µg morphine to 0.75% hyperbaric ropivacaine in spinal anaesthesia prolonged the duration of analgesia, improved pain scores, decreased the requirement of rescue analgesia in the postoperative period without increasing the side-effects over a lower dosage, i.e., 100 µg. The patient satisfaction was also comparatively better. Morphine did not affect the onset of sensory blockade, but there was a variable effect on the onset of motor block.



[Table/Fig-5]: Trend line diagram for the comparison of mean Heart Rate (HR) across the study groups.



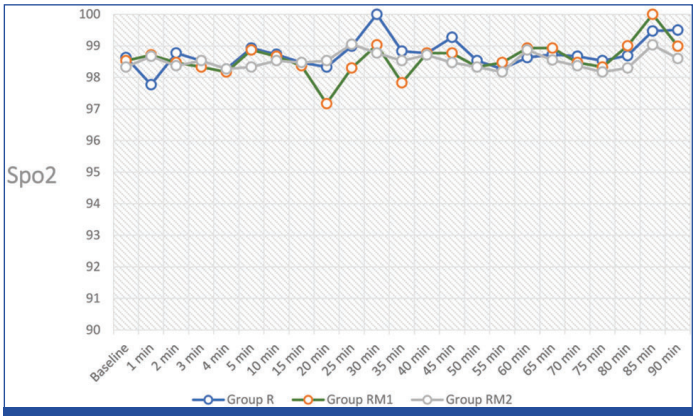
[Table/Fig-6]: Trend line diagram for the comparison of mean arterial blood pressure across the study groups.

Side-effects	Group R (n=38)	Group RM1 (n=38)	Group RM2 (n=38)	p-value
Hypotension	2	1	3	0.059
Pruritus	0	1	3	0.043*
Urinary retention	0	0	0	1.000

[Table/Fig-7]: Comparison of side-effects across the study groups N=114.
*Significant

Likert score	Group R (n=38)	Group RM1 (n=38)	Group RM2 (n=38)	p-value
Very satisfied	0	16	23	0.001*
Satisfied	20	18	15	0.27
Neither satisfied Nor dissatisfied	18	4	0	0.001*

[Table/Fig-8]: Patient satisfaction score N=114.
*Significant



[Table/Fig-9]: Trend line diagram for the comparison of oxygen saturation across the study groups.

The recent introduction of commercial preparation of 0.75% hyperbaric ropivacaine provided a good alternative to 0.5% hyperbaric bupivacaine for intrathecal administration [7]. Previously, isobaric or manually prepared solutions of hyperbaric ropivacaine were used, which produced variable results, but hyperbaric solutions have consistently produced better results than isobaric solutions. Addition of glucose to ropivacaine increases the baricity relative to CSF, producing denser and reliable spinal anaesthesia with faster onset and recovery similar to bupivacaine [8,9].

The addition of morphine significantly increased the duration of postoperative analgesia. The difference in the duration of analgesia across the groups was statistically significant (p<0.001). In the present study, it was observed that 200 µg morphine along with hyperbaric ropivacaine provides much better anaesthesia and prolonged analgesia with good haemodynamic stability. The mean duration of

analgesia in patients receiving 200 µg morphine was almost eight hours longer than in patients without any adjunct and six hours longer than in patients receiving 100 µg morphine. The difference in the duration of analgesia across the group was statistically significant (p<0.001). The addition of morphine significantly increased the duration of postoperative analgesia, similarly to when used with bupivacaine during spinal anaesthesia [10]. Though Gehling MHG et al., observed comparable analgesia with similar doses [11], this study observed a significant increase in the duration with 200 µg in concordance with observations made by Kaczocha M et al., [12]. Direct intrathecal administration of morphine increases the drug availability at local receptors, producing a significant analgesic effect through direct and indirect action at the spinal cord. The advantage of intrathecal morphine over intravenous morphine is that it passes the first-pass metabolism and the blood brain barrier by working directly at the dorsal horn of the spinal cord hence it can achieve an analgesic effect at a lower dose and with potentially fewer systemic side-effects. It produces an extensive and prolonged duration of analgesia up to 18-24 hours, depending on the dosage, with higher doses usually associated with more side-effects. The present study used comparatively lower doses for evaluation than higher doses, as up to 300 µg morphine has been associated with minimal side-effects and comparable analgesic action as observed in previous studies [7].

The total analgesic requirement was also significantly lower in the patients receiving 200 µg morphine as an adjunct due to denser analgesia for longer durations. Foadi N et al., made similar observations with decreased requirement of systemic opioids in patients receiving intrathecal morphine [13]. The VAS scores were also lower in Group RM2. Similar findings were observed by Cole PJ et al., who found that VAS scores were continuously lower in the group receiving morphine when compared with the placebo [14]. The use of morphine intrathecally showed adequate analgesia with long-lasting effect due to its hydrophilicity, decreased systemic absorption, cephalad spread in the cerebrospinal fluid and slow rate of clearance from the opioid receptors. Therefore, it provided increased duration of analgesia even though the onset time was slow.

In the current study, there was no significant difference between the onset of sensory blockade among all three groups, but the duration of sensory blockade was again prolonged in the Group RM2 as compared to the other two groups. The addition of 200 µg morphine in hyperbaric ropivacaine enhanced its efficacy in terms of good sensory block, with favourable recovery, making it a reliable local anaesthetic adjuvant for prolonged surgeries. The mean duration of motor blockade in patients receiving 200 µg morphine was significantly longer than in the other two groups.

Patients receiving 200 µg morphine as an intrathecal adjuvant were comparably haemodynamically stable as compared to other groups. Similarly previous studies have made the same observations that morphine has minimal effect on haemodynamic variables such as HR and MAP [15].

Opioids are the most established analgesic for postoperative pain control but have side-effects such as respiratory depression, vomiting, nausea, urinary retention and pruritus. In this study, side-effects increased in a dependent manner, with the highest being in Group RM2. Though few patients responded well to counselling in case of pruritus in groups receiving morphine, at least four patients required intervention for pruritus (Inj. ondansetron 0.1 mg/kg) .Neither respiratory depression nor sedation was observed in any of the groups during the whole perioperative period. This is in concurrence with the meta-analysis conducted by Gonvers E et al., who made similar observations regarding the side-effects of morphine when used intrathecally [16]. Qi X et al., found no episodes of pruritus and hypotension when 150 µg morphine was compared with dexmedetomidine intrathecally along with hyperbaric bupivacaine [17], which is in contrast to this study, as reported incidence of pruritus in such patients is 69% [18]. Patients in Group RM2 had the best satisfaction across the groups. Patients receiving plain ropivacaine were equivocal about their satisfaction. Previously Kara I et al., have also made similar observations where prolonged analgesia had been a key factor for better satisfaction [19]. Huang JY et al., have also made observations that intrathecal morphine is itself associated with better patient satisfaction than other regional anaesthesia techniques, even if administered alone [20].

Limitation(s)

The limitation of present study was a comparatively small sample size. The ideal dosage of morphine as an adjuvant with ropivacaine could not be determined owing to this small sample size. Another limitation was that the study population was limited to orthopaedic surgeries only. Further research may be needed to validate a few results, such as the effect on motor blockade. Also, VAS for analgesia and Likert scales for patient satisfaction are too unidimensional to assess overall analgesia and patient satisfaction, respectively. Detailed questionnaires like Quality of Recovery (QOR) 40/15 scores will make much better tools for assessment in the future.

CONCLUSION(S)

The present study compared the effect of two different doses of morphine (100 and 200 µg) with a placebo intervention and observed that addition of 200 µg morphine to hyperbaric ropivacaine produced haemodynamically stable anaesthesia with prolonged duration of analgesia and sensory blockade while avoiding the increase in motor duration. Patients receiving morphine as an intrathecal adjuvant experienced better analgesia, required lower number of analgesic dosages and were most satisfied with the intervention. Though lower dosage of morphine can also be used but 200 µg morphine provides reliable anaesthesia and sustained analgesia with minimal increase in side-effects.

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