Original Article

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Efficacy of Intrathecal 0.5% Hyperbaric Ropivacaine for Day Care Gynaecological Procedures: An Interventional Study from a Tertiary Care Centre, Telangana, India

Anaesthesia Section

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ABSTRACT

Introduction: Although various beneficial effects of intrathecal local anaesthetics have been proven, their use is limited by dose-dependent adverse effects. Ropivacaine, a local anaesthetic, has been demonstrated to provide safe and reliable spinal anaesthesia of the required duration, with a relatively shorter duration of motor block that encourages earlier mobilisation in patients.

Aim: To examine the efficacy of a hyperbaric solution of ropivacaine for spinal anaesthesia in minor gynaecological surgeries in a day care setting.

Materials and Methods: This was an interventional study involving 60 subjects undergoing day care gynaecological surgery. The subjects were between 18 and 65 years old. Basic vital signs were recorded. All patients were preloaded with 15 mL/kg of Ringer's lactate 15 minutes before surgery. Lumbar puncture was performed at the L3-L4 space. Patients received 3 mL of 0.5% hyperbaric ropivacaine (2 mL of 0.75% ropivacaine combined with 1 mL of 5% dextrose). Variations in vital signs were recorded during all phases of surgery. The onset and total duration of sensory and motor blockade, variations in vital signs at preoperative and postoperative phases, side-effects, time for ambulation and time for rescue analgesics were assessed. The values were expressed as means, frequencies and percentages. IBM Statistical Package for the Social Sciences (SPSS) Statistics version 29.0 was used to analyse all the data.

Results: The onset of sensory blockade to reach T10 occurred in 214.90 seconds, while the onset of motor blockade occurred in 205.13 seconds. The sensory blockade persisted for 366.17 minutes, whereas the motor blockade continued for 153.57 minutes. Significant changes were observed from the preoperative period to 60 minutes in the mean values of Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), and Mean Arterial Pressure (MAP) (p-value <0.05), while there was no change in Heart Rate (HR) and Oxygen Saturation (SpO_2).

Conclusion: Day care surgery can be performed effectively with spinal anaesthesia using intrathecal ropivacaine. The more reliable and effective anaesthesia provided by intrathecal ropivacaine improves the expediency for anaesthetists.

Keywords: Ambulation, Day care surgeries, Motor block, Sensory block, Spinal anaesthesia

INTRODUCTION

Day care surgeries place a high demand on anaesthetic techniques. Spinal anaesthesia is a better choice of anaesthetic technique for various day care surgeries compared to general anaesthesia, which was used earlier [1]. The main advantage of using spinal anaesthesia in day care surgeries is the consistency of drug spread and the appropriate duration of the block [2]. Although the beneficial effects of intrathecal local anaesthetics have been proven, their use is limited by dose-dependent adverse effects [3].

Earlier, a 5% hyperbaric lignocaine was the drug of choice for intrathecal anaesthesia. However, its use was associated with transient radicular irritation [4-8]. Subsequently, 0.5% hyperbaric bupivacaine has been widely used for spinal anaesthesia. It provides a longer duration and an intense motor block, which is usually not necessary for lower-limb and perineal surgeries. The longer duration of action, along with urinary retention, makes it unsuitable for day care anaesthesia [9]. Therefore, it became necessary to find a newer local anaesthetic agent that could be used for spinal anaesthesia in day care surgeries and could avoid the potential cardiotoxicity associated with bupivacaine.

Ropivacaine, a newer amino acid amide local anaesthetic with a longer duration of action, is a hydrochloride monohydrate salt of 1-propyl-2', 6'-pipecoloxylidide [10]. It was synthesised by Ekenstam almost 50 years ago, simultaneously with bupivacaine, and was launched in 1996. It is the first clinically introduced pure S (-)-enantiomeric local anaesthetic. Ropivacaine has been demonstrated to provide safe and reliable spinal anaesthesia of the required duration, with a relatively shorter duration of motor block, encouraging earlier mobilisation of patients [11,12].

Ropivacaine 0.5% (in 5% glucose) provides reliable spinal anaesthesia of shorter duration and with less hypotension [13]. In contrast, bupivacaine may lead to spinal anaesthesia-induced hypotension, as well as associated intraoperative nausea and vomiting. Hypotension has several associated consequences like renal injury, postoperative troponin elevation and mortality [14,15]. Studies show that ropivacaine is less cardiotoxic than bupivacaine, potentially resulting in an improved cardiovascular profile with less hypotension [16-19]. In contrast, a previous meta-analysis showed no difference in the incidence of hypotension between intrathecal ropivacaine and bupivacaine in the obstetric setting [20]. However, studies examining the non obstetric setting have found mixed results [21-23]. Moreover, there are only a few data comparing the actions of plain and hyperbaric solutions of this drug [24]. Hence, the current study was designed to examine the efficacy of the hyperbaric solution of ropivacaine for spinal anaesthesia in minor gynaecological surgeries in a day care setting.

MATERIALS AND METHODS

The study was an interventional study conducted at Osmania General Hospital, Hyderabad, Telangana, India, between May 2022 and April 2023. A total of 60 subjects who were undergoing day care gynaecological surgery were involved in the study. A convenient

and feasible number of subjects was included in the study. The study was approved by the Institutional Ethical Committee (IEC) of Osmania Medical College, Hyderabad (Regd. No. 20102001036D). Written informed consent was obtained from all the patients.

Inclusion criteria: Subjects aged between 18 and 65 years with American Society of Anaesthesiologists (ASA) physical status grades I and II were included in the study.

Exclusion criteria: Patients with a history of coagulopathies, cardiac, hepatic, renal, respiratory, neurological and endocrine disorders, patients on medications that may modify pain perception, and patients with infections at the site of the block were excluded from the study.

Data collection: A preanaesthetic check-up was conducted one day prior to the surgery. Patients were evaluated for any systemic diseases. Routine laboratory investigations such as complete blood count, blood sugar, bleeding time/clotting time, renal function tests, electrolytes, urinalysis, chest X-ray and Electrocardiogram (ECG) were recorded. The Body Mass Index (BMI) of all the patients was noted. A BMI between 18.5 to 24.9 kg/m^2 was considered normal [25]. The procedure of Subarachnoid Block (SAB) was explained to the patients, and written consent was obtained. The patients were educated about the use of the visual analogue scale. The patients' preparation included overnight fasting. Rantac 150 mg and Alprazolam 0.5 mg tablets were administered at bedtime.

Patients were then shifted to the Operating Room (OR) table and baseline vitals such as body temperature, pulse rate, respiratory rate and blood pressure were recorded. Intravenous access was obtained on the forearm with an 18G i.v. cannula, and all patients were preloaded with 15 mL/kg of Ringer's lactate 15 minutes before anaesthesia. Under strict aseptic conditions, a lumbar puncture was performed at the L3-L4 space using a 23G or 25G Quincke spinal needle. Patients received 3 mL of 0.5% hyperbaric ropivacaine (5 mg/mL) in 5% dextrose [26].

Variations in heart rate, blood pressure, MAP and SpO_2 were noted during the preoperative, intraoperative and postoperative phases.

Sensory and motor blockade: The onset and duration of sensory and motor blockade were noted. The time of onset of the sensory block, time to achieve T10 level sensory block and peak sensory block were recorded using the pin prick method. The time of onset of Bromage 3 motor block was noted, and motor block was assessed using the Modified Bromage scale. Paracetamol injection 1 g (slow i.v.) was the first rescue analgesic drug and Tramadol injection 100 mg (slow i.v.) was the second rescue analgesic used after the regression of sensory block.

STATISTICAL ANALYSIS

Descriptive statistics were used to analyse the data. The values were expressed as means, frequencies and percentages. A one-way repeated measures Analysis of Variance (ANOVA) was performed to determine the differences in the haemodynamic parameters from preoperative to 60 minutes post-operation. IBM SPSS Statistics version 29.0 was used to analyse all the data.

RESULTS

A total of 60 patients were analysed in this open-label study, who were aged between 18 and 65 years, with a mean age of 43.25±8.2 years. More than 50% of the patients were between 41 and 50 years old. Thirty-four patients were classified as ASA grade I and 26 were classified as grade II [Table/Fig-1]. A BMI above the normal level was noted in 15 (25%) patients. Thirty-eight (63%) patients underwent dilation and curettage procedures. [Table/Fig-2] presents the mean values of the onset and total duration of sensory and motor blockade. The onset of motor blockade took less time than the onset of sensory blockade to reach T10. The sensory blockade persisted for a longer duration than the motor blockade. [Table/Fig-3] presents the variations that occurred in the characteristics from the preoperative period up to 60 minutes of the surgical procedure (administration of Ropivacaine). Significant changes can be seen in SBP, DBP and MAP from the preoperative period to 60 minutes (p-value <0.05), whereas no changes were observed in HR and SpO_2. Most of the patients did not experience any side-effects. The main side-effects observed during the study period were nausea, vomiting and headache [Table/Fig-4].

Characteristics	n (%)
Age group (years)	
21-30	8 (13.33)
31-40	8 (13.33)
41-50	31 (51.67)
51-60	13 (21.67)
American Society of Anaesthesiologists (ASA) grade	
I	34 (56.67)
II	26 (43.33)

[Table/Fig-1]: Demographic characteristics.

Spinal characteristic	Onset (in seconds) (Mean±SD)	Duration (in minutes) (Mean±SD)
Sensory blockade (to reach T10)	214.90±33.68	366.17±19.65
Motor blockade	205.13±21.16	153.57±16.91

[Table/Fig-2]: Time of onset and duration of sensory and motor blockade.

Variables	Time of measurement (Mean±SD)						
	Preoperative	5 minutes	15 minutes	30 minutes	60 minutes	F	p-value
HR	77.13± 9.92	80.17± 9.73	79.68± 9.45	79.50± 9.51	80.43± 9.00	1.14	0.33
SBP	122.20± 9.76	116.67± 10.7	111.70± 8.59	114.15± 8.48	113.30± 8.42	11.79	<0.0001
DBP	77.72± 6.26	75.42± 6.01	72.83± 5.77	72.15± 5.76	72.60± 6.04	9.44	<0.0001
MAP	92.48± 5.96	89.16± 5.60	85.86± 5.30	86.05± 4.66	87.81± 12.79	17.54	<0.0001
SpO_2	98.9± 0.71	98.75± 0.67	98.9± 0.61	98.9± 0.82	98.87± 1.15	0.6	0.66

[Table/Fig-3]: Variations in the characteristics at different phases.
F, P: one-way repeated measures ANOVA.
HR: Heart rate; SBP: Systolic blood pressure; DBP: Diastolic blood pressure; MAP: Mean arterial pressure; SpO_2: Oxygen saturation

Side-effect	n (%)
Nausea	7 (11.7)
Vomiting	4 (6.7)
Headache	2 (3.3)
None	47 (78.3)

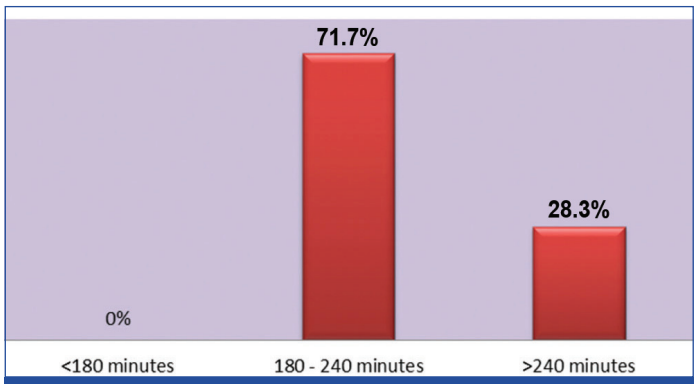
[Table/Fig-4]: Side-effects observed in the patients.

Most of the patients ambulated after four hours of surgery, with only a few ambulating between three to four hours [Table/Fig-5]. The mean time for ambulation was 258.8 minutes. Rescue analgesia

Time of ambulation (Hours)	n (%)
1-2	0
2-3	0
3-4	7 (11.7)
4-5	51 (85)
>5	2 (3.3)

[Table/Fig-5]: Ambulation time of patients.

was required by 43 (71.7%) patients between 180 and 240 minutes after surgery. After 240 minutes, 17 (28.3%) patients required rescue analgesia, and no patients required it within 180 minutes [Table/Fig-6].



[Table/Fig-6]: Time for rescue analgesia.

DISCUSSION

Ambulatory surgery has evolved considerably over the past two decades and has gained wider acceptance [27]. Spinal anaesthesia using long-acting local anaesthetic agents is associated with a delayed return of bladder function, urinary retention and an inability to ambulate due to motor weakness [28,29]. In the present study, ropivacaine was used to evaluate its efficacy in ambulatory surgery. Evidence from previous studies suggests that the addition of dextrose to ropivacaine increases the density of the block and provides a predictable and consistently high sensory block with increased speed of onset and recovery [26,30]. The major advantage of ropivacaine is its shorter duration of motor block compared to bupivacaine, which reduces the psychological discomfort associated with prolonged immobility. Additionally, ropivacaine is less cardiotoxic than bupivacaine. These advantages make ropivacaine a better alternative to bupivacaine in day care surgeries [16-19].

1. **Onset of sensory block at T10:** A hyperbaric solution of ropivacaine can produce a more reliable block than a plain one. In present study the mean time for the onset of sensory block at T10 was 214.9 seconds. The findings of the present study are also similar to those of a study conducted by Kallio et al., in which 56 patients undergoing surgery for lower extremities received intrathecally either 1.5 mL of ropivacaine at 10 mg/mL (-1) and 0.5 mL of glucose at 300 mg/mL (-1) (HYP) or 2 mL of ropivacaine at 7.5 mg/mL (-1) (PL). They found that the time for the onset of sensory block at T10 was five minutes with hyperbaric ropivacaine [31]. Similar results were found by Fettes et al., where the median time for the onset of sensory block at T10 was 10 minutes with plain ropivacaine and five minutes with hyperbaric ropivacaine [24]. On the other hand, a study that compared the effects of ropivacaine, bupivacaine and levobupivacaine found no significant differences between the groups regarding the mean time for the onset of sensory block at T10 [22].

2. **Duration of sensory blockade (Regression of sensory block to S1):** The duration of sensory blockage can be more consistent with hyperbaric ropivacaine. In the present study, the mean duration of sensory blockade was 366.17 minutes, which was compatible with a study by Dwivedi et al., in which the median duration of sensory block from the injection of the anaesthetic to complete recovery (regression to the S1 dermatome) was 300 minutes (290-312 min) [32]. However, another study reported that levobupivacaine had a statistically significant longer duration of sensory blockade compared to ropivacaine [33].

3. **Time for onset of motor block:** In comparison with plain ropivacaine, intrathecal hyperbaric ropivacaine can produce a faster onset of motor block. The mean onset for motor blockade in present study was 205.13 seconds. This was in agreement with a study conducted by Chung et al., in which the mean onset of motor blockade was 188.7 seconds [34]. A previous study compared plain ropivacaine with hyperbaric ropivacaine and found that the onset of motor block is faster in the hyperbaric group [24]. This was further confirmed by another study that recommended ropivacaine for a quicker block onset compared to levobupivacaine [35].

4. **Duration of motor blockade:** Intrathecal hyperbaric ropivacaine can produce a more consistent duration of motor blockade compared to the plain form. The mean duration of motor blockade in our study is 153.57 minutes. In a study by Dwivedi et al., the mean duration of complete motor block was 139.89 minutes [32]. The study conducted by Whiteside et al., confirmed present study results that ropivacaine at 5 mg/mL with glucose at 50 mg/mL had a less potent effect on motor nerves in both degree and duration compared to hyperbaric bupivacaine (90 minutes versus 180 minutes), which was in accordance with present study [13]. A meta-analysis also concluded that intrathecal ropivacaine can result in a reduced duration of motor block compared to intrathecal bupivacaine [20].

5. **Haemodynamic parameters:** The present study demonstrated stable HR, SBP, DBP and MAP (all within the normal range) throughout the 60-minute observation period in all patients. There was a slight increase in the mean pulse rate. Hypotension was not alarming in any of the cases and there were no instances of clinically severe hypotension observed in the study. In a study by Bansal et al., similar observations were made, wherein no significant haemodynamic changes were reported [36]. Fettes et al., found that cardiovascular changes were unremarkable throughout their study [24].

6. **Time for ambulation:** The present study demonstrated that the mean time for ambulation was consistent with the study conducted by Whiteside et al., which found that patients receiving ropivacaine were mobilised sooner (ropivacaine mean: 253.5 minutes; bupivacaine mean: 331 minutes) and passed urine sooner (ropivacaine mean: 276 minutes; bupivacaine mean: 340.5 minutes) than those receiving bupivacaine [13].

Limitation(s)

The primary limitation of the study was that there was only one group and all participants received the same intervention without a comparison group receiving an alternative treatment. Another significant limitation was that the study was conducted at a single tertiary care centre. Future research could compare intrathecal 0.5% hyperbaric ropivacaine with other local anaesthetics. Conducting a study at multiple centres would provide a broader perspective and enhance the external validity of the findings, making them more applicable to various clinical environments.

CONCLUSION(S)

Day care surgery can be performed effectively with spinal anaesthesia using intrathecal ropivacaine. Since intrathecal ropivacaine provides anaesthesia that is more reliable and effective, the options available to anaesthetists have increased. Ropivacaine is a good choice for achieving better and more desired nerve blockade. The rapid onset of both sensory and motor blockade, adequate surgical anaesthesia and analgesia, better haemodynamic stability and a lesser incidence of post-discharge nausea and vomiting (PONV), along with early patient mobilisation, suggest that 15 mg of 0.5% hyperbaric ropivacaine, when injected intrathecally, is sufficient to produce anaesthesia for day care gynaecological surgeries.

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