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Research Article

THE EFFICACY OF INTRATHECAL CHLOROPROCAINE AND ROPIVACAINE IN PERINEAL SURGERIES

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A R T I C L E I N F O

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A B S T R A C T

Purpose: To evaluate the analgesic efficacy of intrathecal chloroprocaine and ropivacaine in perineal surgeries.
Methods: A prospective, randomized, double-blinded study was conducted with 60 patients belonging to American Society of Anesthesiologists (ASA) I and II grades, ages 18-60 years of either gender, posted for elective perineal surgeries under spinal anesthesia. The drugs used were 4ml of 0.5% Ropivacaine or 4ml of 1% Chloroprocaine. The primary objectives noted down were VAS scores, duration of analgesia, and post-operative analgesic requirements.
Results: The VAS scores in the postoperative period were considerably lower in the Ropivacaine group. Patients who received Ropivacaine had a substantially longer duration of analgesia (234.37 ± 12.91 minutes). The Ropivacaine group received fewer rescue analgesias postoperatively, resulting in better postoperative analgesia.
Conclusion: Ropivacaine was found to have a prolonged analgesia duration with lower VAS scores and fewer postoperative analgesic conditions. Hence, it is more effective and superior to chloroprocaine.

INTRODUCTION

Neuraxial blockade became the most frequently employed technique for lower extremity and perineal surgeries, with the advantage of providing better postoperative analgesia conditions, effective pain control, and thereby reducing perioperative complications like nausea, vomiting, prolonged post-operative stay in the hospital, delayed recovery, and airway handling encountered with general anaesthesia [1]. However, lower doses of amide-linked long-acting local anaesthetics like bupivacaine and lidocaine are associated with long hospital stay and less consistency in block effectiveness onset and spread. Still, the search for ideal local anaesthetics for short surgical procedures is ongoing [2]. In recent years, preservative-free chloroprocaine seems to be a better alternative and has been gaining popularity [3]. However, in 1980, chloroprocaine was withdrawn from the market because of neurotoxicity [4,5]. In 2004, an advanced formulation of chloroprocaine was introduced into clinical practice, which was preservative free and no longer associated with any incidence of neurotoxicity [6,7]. Ropivacaine is the first single pure enantiomer specific compound with a reduced risk of cardiotoxicity and neurotoxicity, as well as high sensory motor dissociation stability, making it a viable and preferable alternative [8]. Because of its lower lipid solubility, it has a delayed onset of sensory block and a shorter period of motor blockade as compared to bupivacaine which makes it a recommended and quicker alternative for PACU discharge times [9]. Ropivacaine is the new and upcoming drug well known for its cardiostable properties whereas on the other hand we have preservative-free chloroprocaine resurgence in the market. Hence, to test the better modality amongst the two drugs for perineal surgeries the present study has been conducted.

MATERIALS & METHODS

A prospective, randomized, double-blind study was conducted with 60 patients belonging to ASA I and II grades, aged between 18-60 years of either gender, posted for elective perineal surgeries under spinal anaesthesia at the Department of Anaesthesiology, Dr. D. Y. Patil Medical College, Hospital and Research Center, Chinchwad, Maharashtra, between August 2019 to September 2021. At least 14 participants are required a 80% chances of detecting, as significant at 5% level the decrease in primary out come measure from 3.5 in the C group to 2.5 in the R group. Prior to commencement of the study, written informed consent was obtained in the patient's own understandable language. Sample size was calculated based on the standard deviation (0.50, 0.42) and difference between the groups (0.73) from a previous study, using WINPEPI (version 11.65) at 5% significance level and 80% power. The sample size required was 14 [10]. Considering the

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dropouts in each group, the final sample size calculated was 60 (30 in each group).(Figure1).

Consort diagram

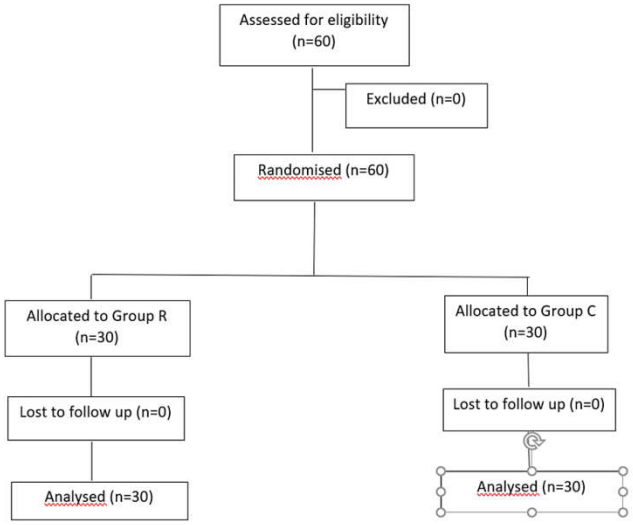

Figure 1 Consort diagram showing details of the study setting

The inclusion criteria were: written informed consent, ASA grade I or II patients, aged between 18-60 years of either gender, patients undergoing perineal surgeries like perineal abscess, hemorrhoids, anal fissure , bladder stones, supra pubic cystostomy, dilatation and evacuation, dilatation and curettage under spinal anaesthesia, hemodynamically stable patients with all routine investigations within normal limits and controlled hypertension, diabetes mellitus, bronchial asthma were included in this study. Patients with significant neurological, cardiac, respiratory, metabolic, renal, hepatic, or coagulation abnormalities, patients contraindicated for spinal anaesthesia, with known allergies, patients scheduled for emergency procedures and procedures expected to last for more than 60 minutes were excluded from the study. Patients were divided into two groups of 30 patients each, Group R (administered with 4ml of 0.5% isobaric Ropivacaine hydrochloride (20mg)) and Group C (administered with 4ml of 1% isobaric Chloroprocaine (40mg)) according to a computer-generated random number table after applying already mentioned stringent inclusion and exclusion criteria in the pre-operative period. For both the group participants, anaesthesia was administered intrathecally. To ensure double blindness of the study, intrathecal drugs were prepared by another anaesthesiologist who was not involved in the administration of anaesthesia and patient care. The monitoring and data collection was done by another doctor who was not involved in drug administration. The non-participating anaesthesiologist was involved in each step of the study. The study was approved by the institutional ethical committee (I.E.S.C./242/2019).

All patients were thoroughly evaluated pre-operatively, including a detailed history (including a history of ischemic heart disease, hypertension, bronchial asthma, and allergy to any of the drugs used). General, physical, and systemic examinations were conducted. The routine laboratory investigations, like complete blood count(CBC), renal function tests(RFTs), random blood sugar(RBS), chest x-ray(CXR), and electrocardiogram(ECG) were done prior to surgery. All the patients were kept nil per oral (NPO) for a period of at least 6 hours prior to the surgery to avoid the risk of aspiration and other anaesthesia-related complications. Pre-induction vital parameters such as pulse rate (PR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), SpO2, respiratory rate, and ECG were recorded. Preloading with an infusion of ringer lactate (RL) at the rate of 10-15 ml/kg was started. Under all aseptic precautions, in the sitting position, spinal anaesthesia was given with a 26G Quincke's spinal needle in the L3-L4 inter-vertebral space after confirming free flow of CSF and, depending upon the groups, respective drugs were injected intrathecally, i.e., Group R was given 4ml of 0.5% isobaric Ropivacaine hydrochloride and Group C was given 4ml of 1% isobaric Chloroprocaine by random allocation. The patient was placed in the supine position immediately after the injection and vital parameters were recorded. Adequate sensory and motor blockades were checked. Modified Bromage Scale was used to measure accuracy. Intraoperatively, pulse rate, mean arterial pressure, and SPO2 were measured. The quality of postoperative analgesia was assessed with the help of the Visual Analogue Scale (VAS). VAS scores were observed at 30 minutes, 1, 2, 3, 4, 5, and 6 hours. Subsequent rescue analgesia (Inj. Tramadol 100mg IV) was given if the patient had a pain score of 4 or more than 4, along with inj ondansetron 4mg IV to avoid nausea and vomiting. The duration of analgesia is measured from the time of subarachnoid block to the time when the patient requires the first rescue analgesia.

Statistical analysis

The data obtained was collected, compiled, and tabulated. The graphs and tables were prepared using Microsoft Word and Excel and analysed using IBM SPSS version 23. Continuous variables were assessed using mean and standard deviation, while categorical variables were assessed using frequency and percentages. The Kolmogorov-Smirnov test was used to determine the normality of the variables. For quantitative data, the "Student's t test" was used to determine whether there were any statistically significant differences between the means of two independent groups P value< 0.05 was considered as significant at 95 % confidence interval.

RESULTS

Demographic details of the participants are shown in table 1.The VAS scores of both the groups at various times have been compared in figure 2. It was found to be similar for both the groups at 30 minutes, 1, 5, and 6 hours. It was lower for group R at 2, 3, and 4 hours compared to group C implying that group R patients received better post-operative analgesia. A comparison between the time to first rescue analgesia i.e, the total duration of analgesia in both groups was represented in Table 2. The duration of analgesia was 123.13 ± 7.80 min for group C and that in group R was 234.37 ± 12.91 min, which was statistically significant . When compared to group C, group R received analgesia for a longer period of time, which indicates that Ropivacaine is a better analgesic compound. The post analgesic requirements of both groups were compared in figure 3. Patients in group R (n = 23) were relieved with only one dose of rescue analgesia, and 2 doses of rescue analgesia were given to 7 patients, whereas patients in group C (n = 28) were given 2 doses of rescue analgesia and only 2 patients were managed with one rescue analgesia dose. These findings suggest that ropivacaine is a better postoperative analgesic.

Table 1 Demographic details of the participants

Variables	Group C (N= 30)	Group R (N= 30)	p-value
Mean Age ± SD	42.63 ± 10.31	42.73 ± 10.33	0.970
Mean BMI ± SD	22.67 ± 2.76	21.92 ± 2.01	0.237
Gender			
Male (%)	17 (56.7%)	13 (34.3%)	0.302
Female (%)	13 (43.3%)	17 (56.7%)	

(SD: Standard deviation; R: 4ml of 0.5% isobaric Ropivacaine hydrochloride; C 4ml of 1% isobaric Chloroprocaine)

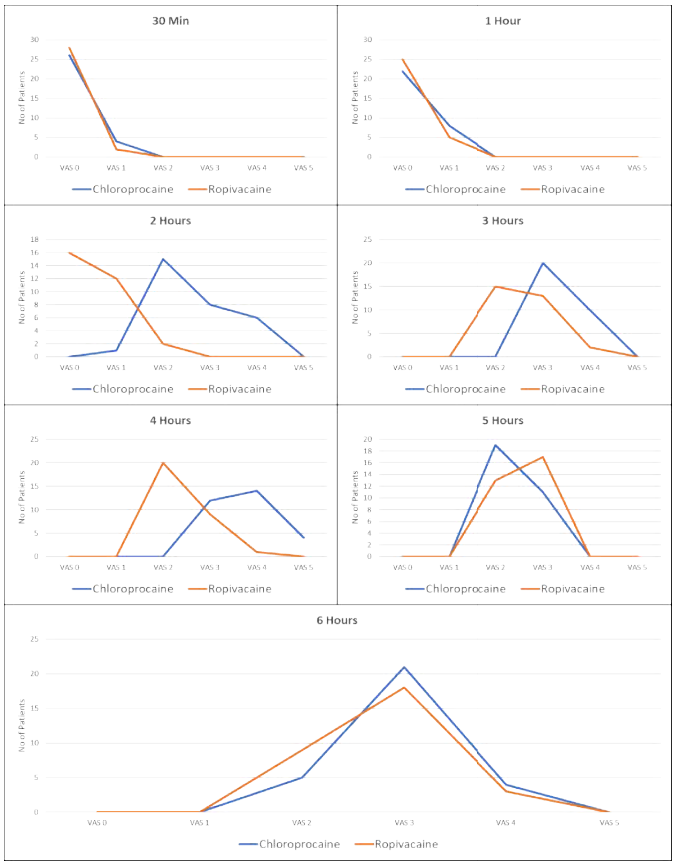

Figure 2 Comparison of VAS scores in group C and group R at various timepoints

Table 2 Comparison of time to first rescue analgesia in both the groups

Variables	Group C	Group R	p-value
Time to first rescue analgesia ± SD	123.13 ± 7.80	234.37 ± 12.91	0.000*

(SD: Standard deviation; R: 4ml of 0.5% isobaric Ropivacaine hydrochloride; C 4ml of 1% isobaric Chloroprocaine)

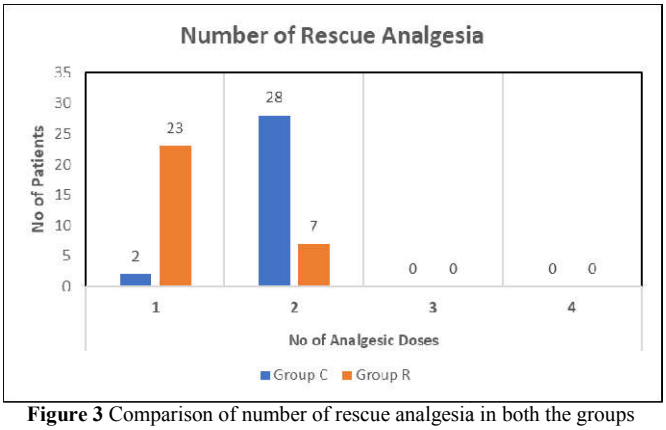

Figure 3 Comparison of number of rescue analgesia in both the groups

DISCUSSION

As compared to hyperbaric drugs, the use of isobaric drugs such as chloroprocaine and ropivacaine provides the additional benefit of not changing the height of the block and so maintaining better hemodynamic stability. For benign proctological illnesses such as haemorrhoids, anal fissures, and other ambulatory surgeries, preservative-free chloroprocaine and ropivacaine are better and more reliable alternatives. Chloroprocaine is a quick-acting amino-ester local anaesthetic with few adverse effects and a short action time. Ropivacaine is a long-acting amide local anaesthetic agent. It is the S (-) enantiomer of ropivacaine that has a lower lipid solubility than bupivacaine, which accounts for its lower penetration into myelinated motor fibres and thus less motor blockade, as well as greater sensory-motor differentiation [11]. On the basis of VAS scores, duration of analgesia, and post-operative analgesic requirements, we compared the analgesic efficacy of intrathecal isobaric chloroprocaine and ropivacaine in patients receiving perineal surgeries. As compared to chloroprocaine, the VAS scores of the ropivacaine group were significantly lower in the 2nd, 3rd, and 4th hour time intervals. Since chloroprocaine is metabolized quickly in the system, it provides a faster offset of the action of sensory blockade, resulting in a short-duration and low-potency analgesic quality and a higher VAS score. This finding suggests that ropavacaine may be a better post-operative analgesic agent. The duration of anaesthesia was long in the ropivacaine group as compared to the chloroprocaine group. It was 234.37 minutes for the R group, whereas it was 123.13 minutes for the C group, which shows statistical significance. This pattern is consistent with previous studies in which the authors discovered longer anaesthesic duration for ropivacaine [12-14]. Other studies also found that ropivacaine had a significantly longer duration of analgesia than chloroprocaine, but the duration was shorter than our reported duration [15,16]. In other studies, the duration of analgesia was reported to be similar to our study. That is an agreement with our study where similar analgesic duration has been reported [17, 18]. The study linked by another group, on the other hand, reported a longer duration of analgesia for ropivacaine [3, 19]. The number of rescue analgesic doses was significantly lower in the Ropivacaine group than in the Chloroprocaine group, which was consistent with the previous findings [3, 20]. 23 patients in ropivacaine group required only one dose of rescue analgesia, whereas only two patients in the chloroprocaine group were managed with one dose of recue analgesia, rest 28 patients were given two doses of rescue analgesia. Inadequate analgesia in the postoperative period might result in a wide range of inimical effects involving multiple systems. Hence, adequate limitation of nociceptive triggers to the central nervous system and optimal and tailored perioperative analgesia lead to the reduction of the incidence of adverse effects on a large scale, thereby enhancing postoperative recovery [21]. It has the added advantage of minimal postoperative nausea and vomiting, shortened recovery time, reduced postoperative stay, no airway handling, and better hemodynamic stability than general anaesthesia. It efficiently curbs the surgical stress response at the site of incision, thereby giving the patient a pain free post operative period and thus reducing the morbidity and mortality of any surgery. Hence, Ropivacaine emerges as a potential alternative and is more efficacious than chloroprocaine.

Limitation of the study states that the present study is single centred. The study deals with only ASA Grade I and II patients were included with no significant uncontrolled comorbidities. Patients posted for emergency procedures were not included in the study. Prolonged surgeries lasting for more than 60 minutes were also excluded from the study.

CONCLUSIONS

The analgesic effectiveness of the isobaric medicines ropivacaine and chloroprocaine in spinal anaesthesia for voluntary perineal operations was examined in this study. The time to first rescue analgesia or total duration of analgesia was prolonged, as well as the total number of rescue analgesic doses, or the analgesic requirements were lower in patients administered Ropivacaine. As compared to chloroprocaine, VAS scores in the Ropivacaine group were significantly lower. In conclusion, ropivacaine was found to have better analgesic efficacy than chlorprocaine in individuals undergoing perineal surgeries under spinal anaesthesia.

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