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Research Article

A RANDOMISED SINGLE BLIND COMPARATIVE STUDY OF EFFICACY OF INTRATHECAL USE OF CHLOROPROCAINE (1%) WITH ROPIVACAINE (0.5%) FOR INFRAUMBILICAL SURGERIES

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A B S T R A C T

Introduction: The aim of this study is to compare and evaluate the efficacy of aforementioned drugs and determine a suitable drug for infraumbilical surgeries. **Material and method:** Our primary objective was to compare the efficacy of Inj. Chloroprocaine (1%) 4ml + Inj Fentanyl 25µg versus Inj. Ropivacaine (0.5%) 4ml + Inj.Fentanyl 25µg for spinal anaesthesia by using onset, total duration of sensory and motor block.Secondary objectives were to compare effective maintenance of hemodynamic parameters, occurrence of side effects & complications if any Patients were randomly allocated to one of the group **Group C** Inj. Chloroprocaine (1%, preservative free) 4ml + Inj. fentanyl 25µg and **Group R:** Inj. Ropivacaine (0.5%, preservative free) 4ml + Inj. fentanyl 25µg using computer generated list with 50 in each group. **Statistical analysis:** Mean duration of onset of sensory action was 2±1.33 min with Group C, while it was 7.5±2.643 min with Group R ($p<0.001$). Mean duration of onset of motor action was 1.8 ±1.6856 min with group C, while it was 11.6 ± 2.688 min with group R. Mean duration of maximum motor block was 91.4±10.587 minutes with Group C while it was 144.2±9.99 minutes with Group R. Regression of sensory block required 107.6±10.409 minutes and 207.8±12.512 minutes with group C and group R respectively. Drop in mean arterial pressure, systolic blood pressure and diastolic blood pressure was significantly more in Group R as compared to Group C from baseline (0 minute) level till 140 minutes. **Conclusion:** In a study of comparison of Chloroprocaine 1% (without preservative) and Ropivacaine 0.5% for intrathecal administration under spinal anaesthesia lasting for 80 to 100 minutes showed that with overall stability , quicker onset and shorter duration of action,Chloroprocaine 1% recommended for intrathecal use in dose of 4ml with Fentanyl 25µg as an additive for short surgical procedures of infraumbilical surgeries.

INTRODUCTION

Ambulatory anesthesia is the subspecialty of anesthesiology that deals with the preoperative, intraoperative and postoperative anesthetic care of patients undergoing elective, same-day surgical procedures (day care surgery). Ambulatory anesthesia needs to provide quick recovery from anesthesia, leading to an early discharge and rapid resumption of daily activities. Day care procedures are of great benefits to the patient include quick recovery hence short duration of hospital stay ,reduced risk of hospital acquired infections, minimal psychological disturbances, short duration of leave from work place and also decreased financial burden[2].

Local anesthetic chloroprocaine has been developed to meet the need for short acting drug for short duration surgeries[3]. It has been proven to be a reliable drug with good safety profile to support growing need for spinal anesthesia in day care surgery.

Very few clinical studies in literature have compared Chloroprocaine 1% with Ropivacaine 0.5% for intrathecal use. The aim of this study is to compare and evaluate the efficacy of aforementioned drugs and determine a suitable drug for infraumbilical surgeries.

MATERIAL AND METHOD

This was a prospective, randomized, single blind comparative study. It had been conducted in tertiary care centre. After approval from hospital ethical committee, and written informed consent from patients, a randomized controlled

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single blinded study had been conducted on patients undergoing lower limb or lower abdomen and perineal surgeries. Total 100 patients participated in study. Our primary objective was to compare the efficacy of Inj. Chloroprocaine (1%) 4ml + Inj.Fentanyl 25µg versus Inj.Ropivacaine (0.5%) 4ml + Inj. Fentanyl 25µg for spinal anaesthesia by using onset, total duration of sensory and motor block. Secondary objectives were to compare effective maintenance of hemodynamic parameters, occurrence of side effects & complications if any. ASA I to II ,Both male and female between 20yrs to 60 yrs, lower limb or lower abdomen/perineal surgeries and short duration surgeries up to 80-100 minutes were recruited. Patients with refusal, known case of hypersensitivity reactions to local anaesthetics., patients with coagulation disorders or on anticoagulant therapy, local infection ,unstable hemodynamic, severe hypovolemia, sepsis, neurological and musculoskeletal disorders that makes technique difficult were excluded from our study.

Patients were randomly allocated to one of the group **Group C** Inj. Chloroprocaine (1%, preservative free) 4ml + Inj. fentanyl 25µg and **Group R:** Inj.Ropivacaine (0.5%, preservative free) 4ml + Inj. fentanyl 25µg using computer generated list with 50 in each group. An observer anaesthesiologist, not involved in patient care or study protocol, prepared standard solution following standard written instruction. He/she also performed the procedure & was blinded to the study.

A detailed history, complete physical examination was carried out in all patients and routine investigations were done. Before commencement of anaesthesia adequate fasting confirmed. Patients were explained about method of anaesthesia, sensory and motor block assessment methods. Intravenous line secured, and 10 ml/kg crystalloid infused before the initiation of procedure. Monitors were connected to patients like pulse oximeter, 5 leads ECG, noninvasive blood pressure monitor.

All procedures done under all aseptic precautions with patient in sitting position lumber puncture done in L2-3/ L3-4 intervertebral space with 25 G quincke's spinal needle and drugs (Chloroprocaine 1% 4ml with 25µg Fentanyl (Group C) or Ropivacaine 0.5% 4ml with 25 µg fentanyl (Group R)) injected after ensuring clear, free flow of CSF. Heart rate, blood pressure, respiratory rate and oxygen saturation were recorded till the end of procedure with interval of 10 minutes. (Figure 1)

Sensory block assessment was done by loss of pin prick sensation with 26G sterile needle. Time of onset of sensory block was measured from time of intrathecal injection to loss of pin prick sensation at level of anaesthesia achieved. Highest level of sensory block noted. Total duration of block noted as time interval between intrathecal drug administration up to complete recovery from loss of pin prick sensation. Modified Bromage scale was used for assessment of motor block. Time of onset of motor block was noted as time of intrathecal injection up to complete block (modified bromage scale-1). Total duration of block was time from intrathecal injection up to complete recovery from motor blockade (modified bromage scale- 6).

Monitoring and recording of vitals (heart rate, blood pressure, respiratory rate, Oxygen saturation by pulse oximeter) done. Complications also monitored, treated and recorded. Clinically relevant hypotension (defined as a decrease in systolic arterial blood pressure ≥ 20% from baseline values) was initially treated with a rapid IV infusion of 200 mL of Ringer's lactate solution over a 10-min period. If this was not effective, 6 mg ephedrine IV was administered. Occurrence of clinically relevant bradycardia (defined as heart rate reduction 45 bpm) was treated with 0.5 mg atropine IV. Before discharge and in followup patients were evaluated regarding possible side effects like headache (PDPH), back pain, transient neurological symptoms (moderate to severe pain in lower back, buttock, and posterior thighs that appears within 6 to 36 hours after complete recovery from uneventful single shot spinal anaesthesia.), any residual weakness in lower limbs.

Sample Size: Sample size was determined by formula

$$n = \frac{Z^2 pq}{E2}$$

Z is reliability coefficient at 95% confidence interval (1.96); E is Absolute precision = 10%; p is the proportion in the population processing the characteristics of interest, q is the complement of p which is determined by (1-p).

Data analysis was performed by SPSS Version 18.0 software .Qualitative data was analysed by applying chi square test. Unpaired t – test performed for comparison between two group. A p value <0.05 was considered statistically significant

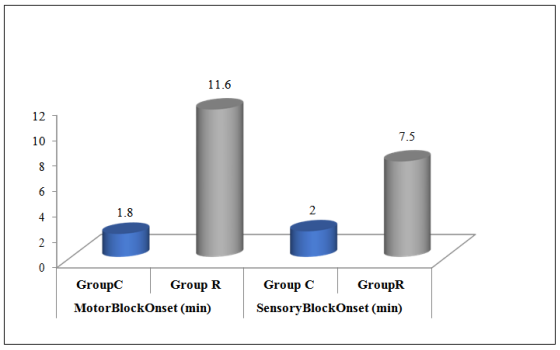
RESULTS

110 patients were screened for eligibility and 100 patients were randomly allocated to two groups, with 50 in each group.

CONSORT:

Consolidated standards of reporting trials (CONSORT) flow of participants Enrollment
Assessed for eligibility (n=110)
Excluded (n=10)(unwilling)
Allocation
Randomised (n=100)
Group C (n=50)
Group R(n=50)
Lost to follow up (n=0)
Lost to follwup(n=0)
Excluded from analysis (n=5)
Excluded from analysis (n=5)

The demographic characteristics and distribution of patients in ASA physical status I and II were comparable among the study groups. Mean duration of onset of sensory action was 2±1.33 min with Group C, while it was 7.5±2.643 min with Group R ($p<0.001$). Mean duration of onset of motor action was 1.8 ±1.6856 min with group C, while it was 11.6 ± 2.688 min with group R. (Graph 1)



Graph 1 Graphs Comparing Onset of both Motor and Sensory Blocks in Both the Groups

Mean duration of maximum motor block was 91.4±10.587 minutes with Group C while it was 144.2±9.99 minutes with Group R. (Fig.1) Regression of sensory block required 107.6±10.409 minutes and 207.8±12.512 minutes with group C and group R respectively.

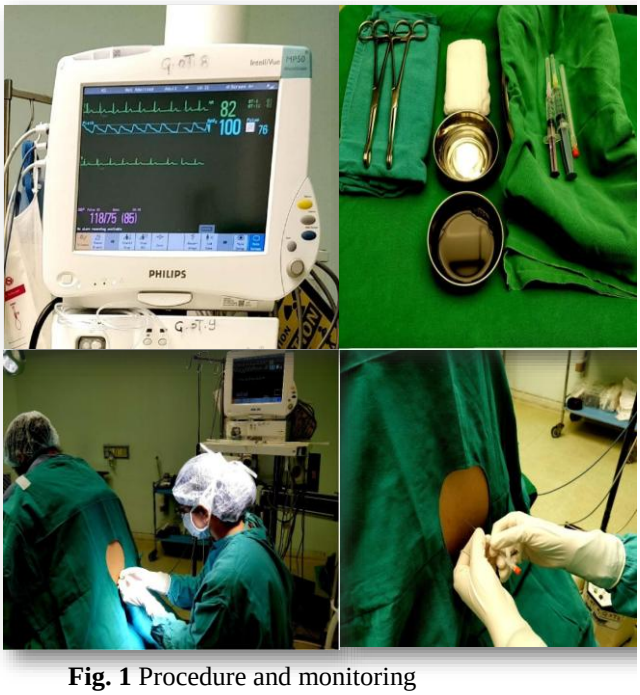
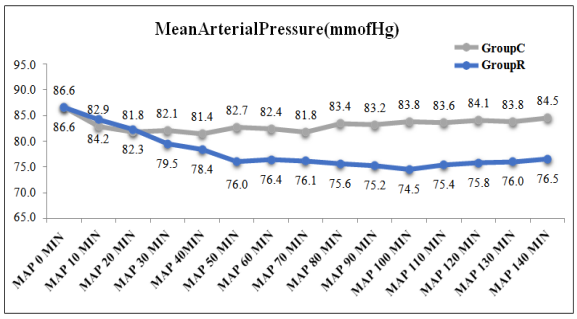


Fig. 1 Procedure and monitoring

Drop in mean arterial pressure, systolic blood pressure and diastolic blood pressure was significantly more in Group R as compared to Group C from baseline (0 minute) level till 140 minutes (deviation from baseline 5.2 in Group C, 11.4 in Group R) ($p<0.001$)(Graph 2).



Graph 2 Graph Depicting Comparision of Map Variation from Baseline in Both the Groups with 10min Observation Interval till 140 Min

5 patients (out of 50) of Group C and 15 patients of group R developed pruritus. Out of total patients who developed pruritus, 25% belongs to group C and 75% belongs to group R. This difference found between pruritus and groups was significant statistically. But none of these patients require d any medications. None of patients included in study developed respiratory depression, hypotension, bradycardia or postoperative sedation or transient neurological symptoms.

DISCUSSION

Over the past decades, general anaesthesia has been predominantly practiced for day care surgeries because of non-availability of short acting drugs for regional anesthesia. There has been an upsurge of interest in recent times in use of spinal anaesthesia for short surgical procedures due to revival of short acting local anaesthetic drugs. Drug used for subarachnoid block should ideally offer quick recovery from motor blockade, allowing early ambulation, minimal side effects and discharge from hospital.

Various drugs and techniques have been studied for intrathecal use in ambulatory anaesthesia like short acting spinal, unilateral spinal selective spinal anaesthesia. But it offers unpredictable spread and block[4]. Drugs like lignocaine, bupivacaine have been tried in past. Because of larger profile of neurological side effects after use of 5% lignocaine, discouraged its use for subarachnoid block[5].

Chloroprocaine had been used in past for neuroaxial block which was with preservatives (sodium metabisulfite), in high concentration (2%-3%), and large volume. Development of neurological side effects following its use leads to decreased popularity. Later on it was found out that, this neurological sequel was due to preservatives used in a drug large volume and high concentration (2%-3%). So with the development of formulation which is preservative free and with reduced concentration (1%), Chloroprocaine regained its popularity. Chloroprocaine 1% has been studied previously and holds promise as a short acting agent offering rapid recovery with minimal side effects.

On the other hand, Ropivacaine has also been proposed and used for day care surgeries because of its short duration of action, efficacy and safety profile as compared to other conventional agents such as bupivacaine. Ropivacaine is structurally related to Bupivacaine. It is a pure S(-)enantiomer, unlike Bupivacaine, which is a racemate, developed for the purpose of reducing potential toxicity and improving relative sensory and motor block profiles.[6] It is developed in various concentration out of which 0.5% has been tried for day care anaesthesia and has adequate action.

In our study we aimed to compare duration of motor blockade, duration of sensory blockade and incidence of complications between preservative free Chloroprocaine 1% and Ropivacaine 0.5%. Kopacz[7] tested 10 and 20 mg of Chloroprocaine 1%. Both doses were found to be inadequate for motor block. Both doses failed to provide sufficient anaesthesia for even short duration surgeries. Hence we used Chloroprocaine 1% of 4ml (50mg) with 25µg of fentanyl in our study, which can be used for surgery of duration up to 80- 100min. Similar to our study Julie S. Vath, MD, and Dan J. Kopacz[8] in 2004, studied effect of added fentanyl to Chloroprocaine. They added 20µg of fentanyl to 40 mg (4ml) of Chloroprocaine 1%. Pallath *et al*[9] found similar clinical and pharmacological profile with 30 mg and 40 mg of choloroprocaine.

Ropivacaine is available in various concentration (0.2%, 0.5%, 0.75%, and 1%). Most commonly 0.5% and 0.75% concentrations are used in spinal anaesthesia. Amitava Layek,*et al*[10], studied effect of Ropivacaine 0.5% with 25 µg of fentanyl in comparison of bupivacaine 0.5% with 25 µg of fentanyl.

In our study,Mean duration of onset of sensory action was 2±1.33 min with 4ml Chloroprocaine 1%+25µg fentanyl, while it was 7.5±2.643 min with 4ml Ropivacaine 0.5%+25µg fentanyl. Similarly, **Vaghadia H**, etal[11], used 40 mg of Chloroprocaine with 12.5 µg of fentanyl to compare its duration with 35 mg of lignocaine with12.5 µg of fentanyl. Onset of action of Chloroprocaine was 4 minutes. **Wahedi W, Nolte H, and Klein P**[12] did a study to find dose of Ropivacaine for intrathecal

use. They compared 0.5% and 0.75% of Ropivacaine with 3ml volume of each. Onset of sensory block to highest point required 12.5 min and 13 min for Ropivacaine 0.5% and Ropivacaine 0.75% respectively.

In a study done by **Camponovo C, Wulf H, *et al,* 13** compared Chloroprocaine 1% and bupivacaine 0.5% for ambulatory surgery. With **50 mg of plain Chloroprocaine 1%** duration of sensory block was 105 min whereas that of 10 mg of bupivacaine was 225 min. In our study, Mean duration of sensory block was 107±10.4 minutes with group C (4ml of Chloroprocaine 1%+25µg fentanyl), while it was 207.8±12.512 minutes with group R (4ml of Ropivacaine 0.5%+25µg fentanyl). **Our study** showed total duration of sensory block was 207.8±12.512 minutes with 4ml of Ropivacaine 0.5% + 25µg of fentanyl. This finding is comparable to studies. **McNamee DA, McClell and AM**[14] did a study in which patients received 3.5ml of Ropivacaine 0.5% (17.5mg). The median duration of sensory block at the T10 dermatome was 3.0 h (range 1.5-4.6 h) and 3.5 h (2.7-5.2 h) in 0.5% bupivacaine group.

Vaghadia H, etal[11], used 40 mg of Chloroprocaine with 12.5 µg of fentanyl to compare its duration with lignocaine. Their results showed total duration of motor block was 117±37 minutes.**Our study** showed total duration of motor block with 40mg of Chloroprocaine 1% with 25µg of fentanyl was 91.4±10.587 minutes. It is comparable with studies mentioned above. **McNamee DA, McClelland AM**[14]did a study in which patients received 3.5 ml of Ropivacaine 0.5% (17.5 mg) and compared with 0.5% bupivacaine. The median duration of complete motor block was 2.1 hrs in Ropivacaine group. **Our study** showed that patients who received 4ml Ropivacaine 0.5% with 25µg of fentanyl, total duration of motor block was 144.2±9.99 minutes.

Julie S. Vath, [8] while studying the effect of added fentanyl to Chloroprocaine 1% and compared 2-Chloroprocaine with or without fentanyl. They found that all patients (n=8) who received fentanyl experienced pruritus ranging from mild to moderate. In our study 5 patients (out of 50) of Group C and 15 patients of group R developed pruritus. Out of total patients who developed pruritus, 25% belongs to group C and 75% belongs to group R. **Amitava Layek**[10], when added 25µg fentanyl to 4ml of Ropivacaine 0.5%, none of the patients experienced any kind of pruritus or respiratory depression in intraoperative period and sedation in the postoperative period.

Postoperative pruritus is known complication of fentanyl when used intravenous or intrathecal. As seen in studies mentioned above and with reference to our study, pruritus is seen with use of fentanyl but it gets completely regressed with regression of block. Reason of more patients developing pruritus in Group R as compared to Group C, it may be correlated with longer duration of block. From our study it is found that Chloroprocaine 1% and Ropivacaine 0.5% both are safe for intrathecal use. For ambulatory surgery Chloroprocaine 1% should be preferred over Ropivacaine 0.5% because of its faster onset and shorter duration of action. Chloroprocaine 1% has faster and quicker onset of both sensory and motor block than Ropiacaine 0.5%.

Duration of sensory and motor block is short with Chloroprocaine 1% than Ropivacaine 0.5%. So faster is the ambulation and early discharge from hospital will be achieved with the use of Chloroprocaine than Ropivacaine. Both drugs provided stable hemodynamics intraoperatively and post operatively. But Chloroprocaine maintains blood pressure and heart rate very well near to baseline value than Ropivacaine. So duration of postoperative observation and discharge will be reduced with Chloroprocaine, hence qualifying one of the ideal property of day care anaesthesia Limitations of our study was it is a single-center study conducted in patients undergoing short procedures; hence further evaluation is required on larger sample sizes and in patients undergoing other surgical procedures.

CONCLUSION

In a study of comparison of Chloroprocaine 1% (without preservative) and Ropivacaine 0.5% for intrathecal administration under spinal anaesthesia lasting for 80 to 100 minutes showed that with overall stability, quicker onset and shorter duration of action, Chloroprocaine 1% recommended for intrathecal use in dose of 4ml with Fentanyl 25µg as an additive for short surgical procedures of infraumbilical surgeries.

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