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TO COMPARE THE EFFICACY OF ANALGESIA PRODUCED BY THE ADDITION OF FENTANYL TO1%2- CHLOROPROCAINE VERSUS 0.5% ROPIVACAINE IN SPINAL ANAESTHESIA FOR AMBULATORY SURGERIES - RANDOMIZED DOUBLE-BLINDED CONTROLLED STUDY.

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ABSTRACT **Introduction:** Short surgical procedures warrant the use of a lower dose of local anaesthetics. We compare the combination of 2-chloroprocaine (CP) + fentanyl and ropivacaine+ fentanyl spinally for early micturition and ambulation. Our aim was to assess the duration of the motor blockade. As CP has a shorter half-life it would show a significantly shorter block regression time. **Methodology:** Randomized double-blinded study involving 82 patients posted for short-duration surgeries (<90 mins) was carried out. Randomization was done using the chit method, 41 chits each with C and R written on it, for ropivacaine and 2-CP were used: Group C - 1%2- CP (30mg) with 12.5mcg fentanyl and Group R - 0.5% Ropivacaine (15mg) with 12.5mcg fentanyl. The assessor and patient were blinded. Onset, time of regression and duration of sensory and motor blockade, intraoperative haemodynamic parameters, time of first rescue analgesia, time of micturition and time of ambulation was assessed. **Statistical analysis** – chi-square test, independent t-test, p-value <0.05 Result: CP shows a faster recovery of early ambulation and micturition, without side effects. Fentanyl improves duration without interfering in micturition/ambulation **Conclusion:** CP provides adequate duration and depth of surgical anaesthesia for the short procedure with faster block regression and early ambulation compared to ropivacaine. The addition of fentanyl improves the quality of the block without interfering with the postoperative outcomes.

KEYWORDS : comparison, chloroprocaine+fentanyl, ropivacaine+fentanyl, ambulation, analgesia

INTRODUCTION

Ambulatory anaesthesia is in practice since 1842[1]. The incidence of ambulatory surgeries has increased due to advancements in anaesthesia techniques, such as regional anaesthesia with shorter-acting drugs with minimal side effects[1,2]. Ambulatory anaesthesia allows for faster recovery from anaesthesia and rapid ambulation and return to daily activities. In ambulatory surgeries, selecting the right anaesthetic methods is crucial. In this setting, rapid action and anaesthesia recovery allows early ambulation and micturition, as well as good postoperative analgesia with low risk of nausea and vomiting[2]. Spinal anaesthesia is a reliable and secure method for lower-extremity procedures. However, local anaesthetics that are generally employed have several disadvantages, such as delayed ambulation, the possibility of urine retention, and pain following block regression, which may restrict its usage for ambulatory surgery[3]. Short-acting local anaesthetics are currently available, which has renewed interest in this technique for short-duration surgeries[4].

1% 2-Chloroprocaine (CP) is an amino ester local anaesthetic with a very short half-life. Up until 1980, the drug was administered as an epidural anaesthetic for obstetric patients, but it was discontinued due to severe transient neurological symptoms (TNS) effects after accidental administration of a high dose of the drug[5]. Sodium bisulfite preservative was blamed for TNS, now it has been reintroduced as an isobaric preservative-free preparation of 1% 2 chloroprocaine with lesser side effects[6].

Ropivacaine, a pure S enantiomer of ropivacaine, is a long-acting amide local anaesthetic. It is less likely to cause cardiotoxicity and neurotoxicity than bupivacaine, making it a safer alternative[7].

Ropivacaine provides a similar sensory block similar to bupivacaine at equivalent doses, but the duration of the motor block is shorter[7].

To enhance the antinociceptive impact of local anaesthetics, opioids are used as an adjuvant in regional anaesthesia. A pure agonist Fentanyl has a quicker action, prolongs the duration of sensory blocked, and shortens the requirement for rescue analgesics[8].

Our aim was to study and compare the Efficacy of analgesia produced by addition of fentanyl to1%2- chloroprocaine versus 0.5% Ropivacaine in spinal anaesthesia for Ambulatory surgeries - Randomized double-blinded controlled study to study effects on haemodynamics and sedation / respiratory depression other side effects, and to study time of micturition and ambulation.

MATERIALS AND METHODS

Our study was conducted after being approved by the Institutional ethics committee (REF.BVDUMC/IEC/78) and registration with the Central trial registry of India (CTRI REG No -CTRI/2021/08/035513) in a tertiary care centre. Patients were enrolled between August 2021 to August 2022 after obtaining written informed consent from patients. This randomized double blinded comparative study includes 82 adult patients belonging to American Society of Anaesthesiologists (ASA) of class I /ll, in the age group18-55yrs scheduled to undergo short-duration surgeries under the subarachnoid block (SAB) with a duration of surgery <90 mins were included in our study.

Exclusion criteria - Patients Refusal, infection on the spinal region, Patients with a history of severe cardiovascular disease, steroid use, renal or hepatic dysfunction mental retardation, known sensitivity to the drug to be used, Patients on anticoagulant therapy, coagulation disorder.

There is a high prevalence of short procedures like haemorrhoids, fistulectomies, any short perianal surgeries, lower limb cellulitis or abscess incision and drainage, dilation and curettage, DJ stenting, and short urological procedures, and many others, their current treatment practices are focused toward ambulatory settings Patients were randomized using the chit method into groups, Group C and Group R. All 82 chits were prepared with R and C written on 41 chits each. Each patient received the drug according to the chit. The observer and patient were blinded.

Detailed pre-aesthetic check-up of all the patients posted for surgery has been carried out a day prior to surgery. All the patients were kept nil by mouth for more than 6 hours prior to surgery. Written informed consent was taken prior to surgery On the day of surgery, patients were brought to the operation theatre, the intravenous line was secured with a 20-gauge Angiocath, Standard monitoring was done baseline pulse rate, blood pressure, ECG, and oxygen saturation(spo2) were noted. Initial parameters of the patient were recorded, All the patients were preloaded with Ringer lactate 10ml/kg before giving spinal anaesthesia. All the fluids and drugs were stored and administered at room temperature. Under all aseptic precautions, the drug was loaded by Person who was not involved in the study and the assessor, and the patient were blinded, whether the drug was 1%2-chloroprocaine with Fentanyl or 0.5% Ropivacaine with fentanyl, Subarachnoid block was given in sitting position using 27G Quincke's spinal needle at the level of L3-4 or L4-5 inter Space via the midline approach.

Patients in group C received an intrathecal injection of 1% 2-chloroprocaine (3 ml) with 12.5 µ g fentanyl (0.25ml) and patients in group R received an intrathecal injection of 0.5% Ropivacaine (3 ml) with fentanyl 12.5 microgram (0.25 ml). After the subarachnoid block patient was placed in the supine position.

The following parameters were used to find out.
a) Onset of peak Sensory analgesia was checked using a pin prick in a caudal to cephalad direction in the mid-axillary line for every 2 mins till desired level was achieved, and the maximum level of dermatome(T_8) time was recorded,

b) Onset of peak motor block was done using a modified Bromage scale. Modified Bromage scores was recorded till the bromage score 0 time was noted with complete motor block.

c) Throughout surgery hemodynamic parameters monitored. Systolic blood pressure, Diastolic blood pressure and mean arterial pressure were recorded.

d) Time for two-segment regression, complete sensory and motor block regression, Visual Analogue Score (VAS) and Ramsay sedation score were assessed. The pain was assessed using a VAS score. It is a 0 to 10 pain rating scale, a score of 0 is considered as no pain and a score > 4 is considered as a need for rescue analgesia.

e) Time for first rescue analgesia was recorded in both groups and injection of paracetamol 1gm IV was given as rescue analgesia.

f) The patient was shifted to, the ward from PACU when the modified Aldrete score would be ≥ 9. In the ward time of ambulation, that stands without support and walking and time of voiding of urine were noted. Side effects were enquired regarding headache, vomiting, (PDPH) weakness and numbness in lower limbs or any other symptoms on the telephone up to 5 days after discharging the patients.

STATISTICALANALYSIS

The data on categorical variables are shown as n (% of cases) and the data on continuous variables are presented as mean and standard deviation (SD). The inter-group statistical comparison of the distribution of categorical variables is tested using the Chi-Square test or Fisher's exact probability test if more than 20% of cells have an expected frequency of less than 5. The inter-group statistical comparison of means of normally distributed continuous variables is done using an independent sample t-test. The underlying normality assumption was tested before subjecting the study variables to a t-test. In the entire study, the p-values less than 0.05 are considered statistically significant**.** The entire data is statistically analysed using Statistical Package for Social Sciences (SPSS version 22.0, IBM Corporation, USA) for MS Windows

RESULTS

The demographic profile of patients was comparable between the groups in terms of age, gender, sample size and ASA grade, and was found to be similar to table nu I. Duration of surgery was longer with the ropivacaine group by 5 mins (group C- 54.76 +/- 8.39 and group R 61.51+/-8.75) with a p-value 0.001 which is statically significant clinically not significant.

The mean time of onset of maximum sensory block in both the groups was comparable and short (4.98+/-0.67 mins) in Group C as compared to Group R (6.10+/-0.77 mins), mode and the median of the maximum upper level of sensory block was at T_8 in both the groups as given in table no I.

There was a significant difference between groups in meantime to the onset of the maximum sensory block and time of onset of maximum motor block (group C 4.34+/-0.93 and group R 5.20+/-0.89) with p valve (<0.003) and shorter with chloroprocaine group, quality of motor block and analgesia was adequate, and there was no statistically significant difference between the groups.

Time for regression of sensory level to L_1(Group C-56.85+/-3.63 Group R -82.68+/-10.00 with p-value 0.001) was significantly shorter with chloroprocaine, the duration of motor blockade (76.88+/-3.96 min in Group C and108+/-14.11 Group R Respectively with p-value,0.001) was significantly longer with ropivacaine Group. The time of the end of the sensory block was shorter in the chloroprocaine group (85.58+/-4.32) than in the ropivacaine group (118+/-14.04) with a significant p-value less than 0.001 as shown in table no 1.

Time for the first administration of rescue analgesic (Group C 71.95+/-8.05 min and Group R100.98+/-17.44 min, with p-value <0.001) were statistically shorter in Group C. The time of voiding in Group R (207.78+/-38.36) and Group C (157.98+/-38.59) p-value (0.001) was significantly delayed in group R (Table no I). None of the patients required catheterization in the groups as given in table no 1.

All patients in both groups were calm and cooperative and no undue sedation (sedation score>3) was observed intraoperatively, no patients required supplemental analgesia intraoperatively, and patients with the Chloroprocaine group had significantly early ambulation time (225.90+/-53.85) than Ropivacaine group (298.68+/-31.32).

Figure I
Inter group distribution of mean heart rate in patients.

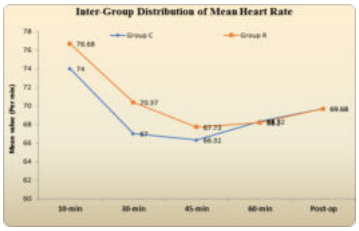
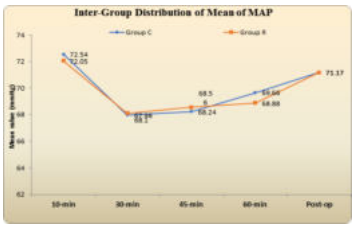


Figure II
Inter group distribution of mean of MAP in patients.



Heart rate changes were comparable between the groups both the groups had an initial moderate fall in MAP in keeping with sympathetic blockade produced by the spinal anaesthesia MAP stabilized after 20 mins as shown in figure I and II.

Table I Comparison of subarachnoid blockade characteristics in two groups of patients studied

Parameters	Group C	Group R	P Value
Time Maximum sensory block	4.98+/- 0.67	6.10+/-0.77	0.001
Time of maximum motor block	4.34+/-0.93	5.20+/-0.89	0.003
Time of regression of sensory block till L1	56.85+/-3.63	82.68+/-10.00	0.001
Time of complete regression of sensory block	90.58+/-4.32	120+/-14.40	0.002
Time of end of motor block	76.88+/-3.96	108+/-14.11	0.001
Time of first rescue analgesia	71.95+/-8.05	100.98+/-17.44	0.001
Time of micturition	157.98+/-38.59	207.78+/-38.36	0.001
Time of ambulation	225.90+/-53.85	298.68+/-31.32	0.001

Table II
Side Effects in two groups of patients studied Intraoperative period and post operative side effects

Parameters	Group C	Group R	P value
Intraoperative			
Bradycardia (<,60 bpm)	0	0	1
Hypotension	0	0	1
RSS (n) 41 each	2	2	1
Nausea (n) 41 each	0	1	0.49
Postoperative			
PONV (n) 41 each	0	6	0.109

VAS (>4) 41 each	15	1	0.001
RSS (n)41 each	2	2	0.999
Aldrete score(n) 41 each	>9	>9	1
Postoperative urinary retention (n) 41 each	0	0	1

There was no statistically significant difference in the two groups throughout the intraoperative and postoperative period, and there was no significant decrease in heart rate and hypotension in none of the patients. the most commonly occurring adverse effect was postoperative Nausea experienced in (14%) and vomiting (2.4%) patients in Group R as compared to Group C (0%). Patients in Group R had nausea/vomiting as compared to none in Group C as given in table no II.

DISCUSSION

Spinal anaesthesia is a safe and reliable technique for lower limb surgeries. Short-acting drugs like CP which have been reintroduced recently after being initially abandoned due to its side effects (Neurotoxicity) and are being increasingly used for early ambulation. Studies have shown that the use of opioids as adjuvant intrathecally can greatly enhance analgesia of subtherapeutic doses of local anaesthetics[8,9].

Chloroprocaine, an amino ester local anaesthetic with a shorter half-life and quicker blockage regression, Numerous studies were conducted to determine the optimal dosage of 2 CP in order to ensure adequate drug efficacy and fast regression of block in the ambulatory setting[10]. In 2022, Pallath NM et al. conducted a study on the effectiveness of various doses of 1% 2CP in spinal anaesthesia below umbilical surgeries. They came to the conclusion that 30 mg and 40 mg of 2 chloroprocaine had comparable pharmacological and clinical profiles, both groups had adequate levels of block for the required duration of action, and both groups could be used in procedures that did not require longer durations of sensory and motor block[11].

Gautier et al study comparing 8 mg bupivacaine with intrathecal ropivacaine (dose ranging from 8 mg to 15 mg) in 150 patients revealed that only 5% of patients had inadequate action with 15 mg of dose isobaric ropivacaine in lower limb surgeries. In our study, used 15 mg (3ml) of 0.5 per cent ropivacaine with 12.5 mcg of fentanyl as the minimum dose necessary for adequate action[12].

In our study, the age, sex, and ASA grading of the two groups were comparable. No patients had to be denied participation in our trial. Similar results were observed in research by Soumya et al. In our study, ropivacaine group's surgical duration was statistically 6 minutes longer than chloroprocaine group's, a difference that is not clinically significant. Changes in Heartrate and Mean arterial pressure were similar and there was no Bradycardia (decrease in HR 20% baseline) and hypotension (20% decrease from baseline). In a study done by Arvind Khare et al[13].

Since CP has a higher pKa than lignocaine and bupivacaine, it acts more quickly during spinal anaesthesia. In our study, the maximal sensory block and time to the onset of action were faster in the chloroprocaine group (4.98+/-0.67) than in the ropivacaine group (6.10+/-0.77), with a significant p-value (0.001). A study by Camponovo et al. revealed a similar result, with chloroprocaine showing a quicker start to sensory activity and maximum block (8.5 vs14 min)[14].

In our study, time to maximum motor blockade (Group C – 4.34 +/- 0.93 mins Group R-5.20+/-0.80 mins) was shorter in chloroprocaine group with a significant p-value (0.003), and the duration of motor blockade (Group C – 76.88+/-3.96 mins Group R 108+/-14.11 mins p-value 0.001) was significantly longer with ropivacaine group. Similarly, the onset of motor block (5 vs 6 mins) was better in chloroprocaine than bupivacaine in a study done by Camponovo et al and regression of motor blockade was shorter with chloroprocaine than bupivacaine (76 vs 118 mins) in a study done by LaCasse et al [14,15] CP is rapidly metabolized by pseudocholinesterase, so it has a shorter duration of action and low systemic toxicity. In our study, time of regression of sensory level to L1(Group C 56.85+/-3.63 mins and Group R 82.68+/-10.00 mins; p-value 0.001) was significantly shorter with chloroprocaine. Time to end of sensory block was shorter in the CP group (Group C – 85.58+/-4.32 Group R 118+/-14.40, p-value 0.001) Similar findings were seen in the study by Lacasse et al, in which time of regression was (CP- 82+/-24, bupivacaine 160+/-62)[15]

Time for the first administration of rescue analgesia was earlier in Chloroprocaine group as compared to ropivacaine group (group C - 71.95+/-8.05 mins Group R - 100.98+/-17.44 mins) with p-value (0.001) and Time to micturition was significantly delayed with ropivacaine than chloroprocaine (Group C -157.98+/-38.59 mins Group R 207.78+/-38.36 mins) with significant p-value. This finding was similar to the study of Bhaskar et al (CP-172+/-27.06 mins and Ropivacaine -261+/-35.12 mins)

Time of ambulation was shorter in chloroprocaine group as compared to ropivacaine group (Group C 225.90+/-53.85 mins Group R 298.68+/-31.32 with p-value 0.001) these findings were similar to the study conducted by B Bhaskar et al chloroprocaine had early ambulation.[16]

The addition of an adjuvant like fentanyl to Local anaesthetics not only prolongs the duration of the sensory blockade but also provides good postoperative analgesia as found in the study conducted by Seetharam et al was consistent with our study finding.

Compared to chloroprocaine, ropivacaine had a higher incidence of delayed urine voiding, but none required urinary catheterization. In a study by Bhaskar et al, there was no incidence of urine retention, and time to void was shown to be substantially different between ropivacaine and chloroprocaine. This finding is comparable to that of our study[16].

LIMITATIONS

1. Although it is known ropivacaine has a longer duration of analgesia than CP. Because of the non-availability of a short-acting drug, we were forced to use Ropivacaine.
2. We could have restricted only to daycare surgeries but that would have been not possibly conclusive.

CONCLUSION

1% 2-chloroprocaine provides adequate duration and depth of surgical anaesthesia for short surgical procedures with faster recovery of motor function.

It also achieves early voiding and early ambulation as compared to 0.5% ropivacaine.

The addition of fentanyl improves the quality of intraoperative block without interfering with the post-operative outcomes inclusive of adequate hemodynamic stability.

As a part of its early regression of sensory block, there is also an early requirement of fifirst rescue analgesia with CP compared to Ropivacaine.

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