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ORIGINAL RESEARCH REGIONAL ANESTHESIA

A randomized prospective comparative study between intrathecal chloroprocaine 1% and ropivacaine 0.5% for short duration surgery

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ABSTRACT

Background and Objectives: Spinal anesthesia (SA) has recently seen a rapid surge in is popularity due to its edge over general anesthesia, being easier, cost-effective, lack of addictive drugs, reduced analgesic demand in the post anesthesia care unit, less nausea and vomiting within 24 h postoperatively, and a shorter hospital stay. Research continues regarding the best and the safest drug to be used for SA. We compared chloroprocaine 1% and ropivacaine 0.5% for SA in short duration surgery.

Methodology: A total of 70 patient were enrolled and subdivided into two groups; Group R (35 patients), to receive 4 ml of 0.5 % ropivacaine (20 mg) and Group C (35 patients), to receive 4 ml of 1% chloroprocaine (40 mg). Hemodynamic parameters and block characteristics were compared between the two groups.

Conclusion: This study shows that chloroprocaine 1% and ropivacaine 0.5% are equally effective in spinal anesthesia. However, chloroprocaine 1% is better suitable for shorter duration surgeries.

Key words: Chloroprocaine; Ropivacaine; Hemodynamics; Block Characteristics

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1. INTRODUCTION

Spinal anesthesia (SA) is a well-established meritorious technique in anesthesia practice. By virtue of its localized action on central nerves, it provides favorable conditions such as reduced catecholamine surge, less intraoperative blood loss and low risk of developing DVT. The drive to pursue our study was the swift shift to day care surgeries with persuasion to adapt our anesthetic medication to the ambulatory environment thus promoting the search for short acting local anesthetic (LA) for the same.[1–4]

The length of the proposed surgery influences the selection of the LA. There are some potential limitations of the use of long-acting LAs, like extensive sensory, motor and sympathetic block, with all associated complications and side effects. Hence, a need was felt to search a short acting LA which offers a balance between adequate anesthesia and the above-mentioned limitations. In this context, chloroprocaine was reintroduced as a short-acting drug with shorter half-life and a greater recovery profile when compared to other short-acting drugs.[5, 6]

Ropivacaine, an S- enantiomer of racemic bupivacaine has a differential neural block with motor power preservation with lower concentration. In the absence of well-established results, lower doses of longer acting

LAs are being used for short duration surgery leading to variable outcomes.[7]

Extensive literature research has shown that till date no study has been conducted between 1% isobaric chloroprocaine versus isobaric ropivacaine 0.5%.

We compared chloroprocaine 1% and ropivacaine 0.5% in short duration surgeries to assess and compare the primary objective of block characteristics and secondary objective of hemodynamics and discharge time in both groups, and to test null hypothesis that there is no significant difference between the two drugs in term of hemodynamic block characteristic and discharge criteria.

2. METHODOLOGY

A prospective randomized control trial was conducted, after obtaining approval by the institutional ethical committee (No. TMU/IEC/20-21/069), in Teerthankar Mahaveer Medical College, Moradabad (India), to compare the efficacy of chloroprocaine 1% and 0.5% ropivacaine during August 2020 to May 2022.

In this study 78 patients were screened, out of which 70 patients met the inclusion criteria of ASA grading I or II, age 18–65 y, with a BMI between 18.5–24.9 kg/m^2 undergoing short duration surgery, e.g., less than 70 min. Exclusion criteria were refusal to informed consent, pregnant females, patients with coagulopathy, infection at injection site, and failed spinal anesthesia. The patients were further divided into two groups of 35 each, using computer generated randomization method representing Group R (ropivacaine group) and Group C (chloroprocaine group).

Primary objective was to observe and analyze block characteristics; e.g., onset of sensory block to T10, time to two segment regression, time to Bromage scale 3, and the peak height of sensory block; the secondary objective of the study was to compare hemodynamic parameters (heart rate, systolic BP, diastolic BP, mean arterial pressure, oxygen saturation, respiratory rate) and the time to discharge.

Anesthetic evaluation prior to surgery was done and standard investigations were ordered. Patients were instructed about the use of numerical rating scale (NRS) preoperatively. Informed and written consent for anesthesia was taken and all patients were fasted on the night before surgery for a minimum duration of 8 h. Intravenous lines were secured with 20G cannula and Ringer's lactate was infused 30 min prior to the surgery. Standard monitor was attached to the patient, and baseline hemodynamic parameters were recorded.

Under aseptic precautions, skin at spinal site (L3−L4) was infiltrated with 2 ml of lignocaine 1%. In sitting position, subarachnoid block was performed using a 25G Quincke needle via midline approach. On confirmation of CSF flow Group C received 4 ml (40 mg) of 1%

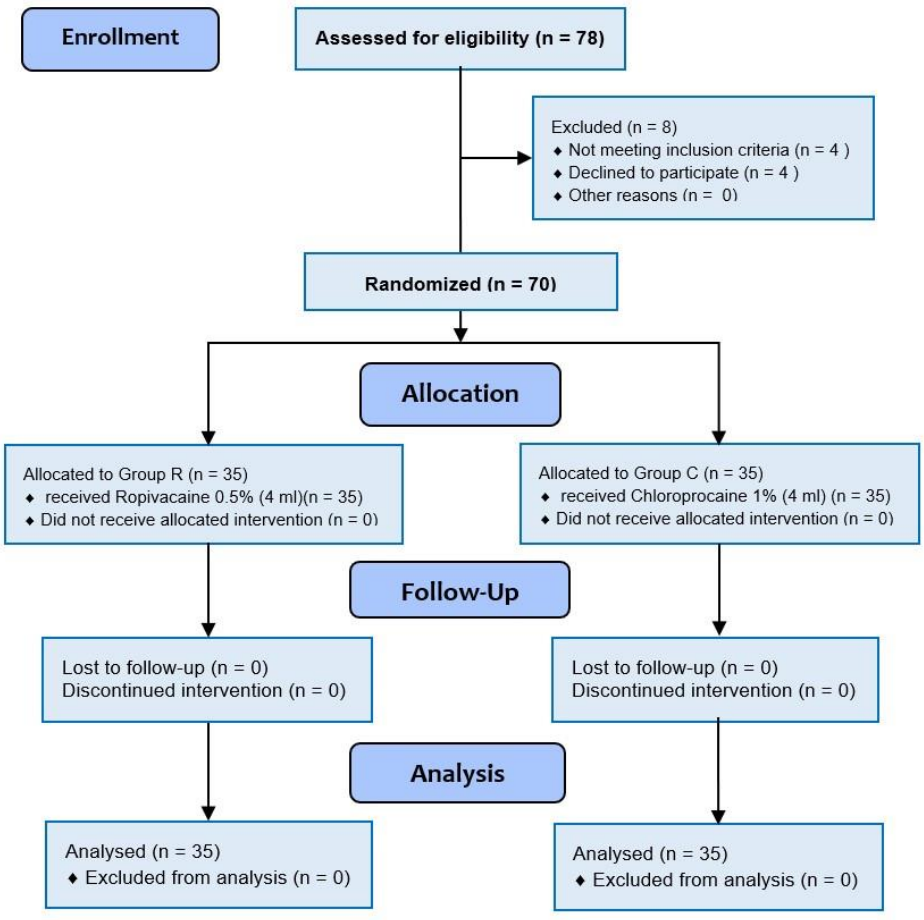

Figure 1: CONSORT Flow Diagram

Table 1: Comparative demographic parameters and duration of surgery

Variables	(Group C) Mean ± SD	(Group R) Mean ± SD	P value
Age (y)	41.49 ± 11.434	38.31 ± 12.854	0.278
Weight (kg)	64.60 ± 7.289	69.40 ± 7.58	0.835
Duration of surgery (min)	47.90 ± 10.50	51.40 ± 8.80	0.14

Data presented as mean ± SD; P < 0.05 is significant

isobaric chloroprocaine and Group R received 4 ml (20 mg) of isobaric 0.5% ropivacaine. The drug under evaluation was drawn up by a member of the staff who was no longer the part of the study. Thus, it was a double blinded study in which neither patient nor the observer/analyzer was aware of the drug injected. After repositioning the patient to supine position, vital signs were evaluated every 3 min for 30 min and after that every 5 min till the surgery was completed. Loss of sensation to pinprick with blunt (25G) hypodermic needle in a caudo-cephalic direction in the mid clavicular line was checked bilaterally (T2 taken as reference point) every 2 min till T10, and then every 2 min till the highest level was achieved. Motor block was assessed as per the Modified Bromage Scale using the same time intervals till Bromage 0 was achieved. The point of adequate anesthesia was taken as loss of pinprick sensation at >T10, with modified Bromage score >3, at which point surgery was started. Sensory and motor blocks were evaluated every 15 min intraoperatively/ postoperatively till regression to S1 and Bromage 0 was achieved.

Time to rescue analgesia was taken when NRS > 4 and tramadol 1 mg/kg IV was given for the same.

Discharge from the post anesthesia care unit (PACU) was done by assessing and assuring full consciousness, no PONV, pain controlled on oral analgesics, the vital signs (within 20% of pre-operative values), return of normal sensation (normal peri-anal sensation S4-S5), muscle strength (plantar flexion of foot, proprioception in big toe) and restoration of sympathetic nervous function (ability to void).[8]

Table 2: Comparative heart rates in two groups

Time (min)	Group C	Group R	P value
0	80.29 ± 6.26	80.26 ± 6.38	0.985
3	84.09 ± 8.38	84.11 ± 8.32	0.989
6	86.74 ± 9.57	86.83 ± 9.47	0.970
9	91.34 ± 14.78	85.74 ± 9.07	0.060
12	90.11 ± 23.40	84.63 ± 9.43	0.203
15	79.91 ± 7.78	79.91 ± 7.83	1.000
18	74.37 ± 8.00	74.46 ± 7.99	0.964
21	73.26 ± 9.77	73.03 ± 9.79	0.922
24	73.23 ± 8.91	73.23 ± 8.86	1.000
27	73.91 ± 8.55	73.89 ± 8.54	0.989
30	72.74 ± 8.23	72.74 ± 8.26	1.000
35	72.86 ± 9.15	72.86 ± 9.12	1.000
40	73.06 ± 6.66	73.06 ± 6.64	1.000
45	71.71 ± 7.93	71.71 ± 7.89	1.000
50	74.11 ± 8.62	74.00 ± 8.68	0.956
55	72.69 ± 9.11	72.74 ± 9.12	0.979
60	72.57 ± 9.08	72.63 ± 9.11	0.979

Data presented as mean ± SD; P < 0.05 is significant

Statistical Analysis

G Power for Windows (Dusseldorf, Germany) was used to calculate sample size, taking difference between two independent means (two groups). With an alpha error of 0.05 value, effect size of 0.7 and power of study at 0.85 using one tailed test, the minimum estimated sample size in each group was 30. This number was increased to 35 in each group. Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) for Windows version 23.0 (IBM Corp, New York, USA). P ≤ 0.05 was considered statistically significant.

SPSS version 22 and MS Excel were used to evaluate the data (IBM SPSS Statistics, Somers NY, USA). Frequencies and percentages were used to depict categorical statistics. As a measure of relevance for qualitative data, the chi-square test was employed. Mean and standard deviation were used to depict continuous statistics. For quantifiable data, the independent t-test was put to use to evaluate if there was any significant mean difference among the groups. After taking account all the guidelines for statistical tests into, a P ≤ 0.05 was said to be significant statistically (i.e., the chance that the outcome is accurate). The study's quantifiable factors were all evenly spaced out.

3. RESULTS

A total of 70 patients were enrolled in this trial, with 35 patients each in two groups. The demographic data and surgical time in Groups C and R were comparable and without statistically significant differences (Table 1). The hemodynamic parameters e.g., heart rate, mean arterial pressure and oxygen saturation were monitored, and no statistically significant differences were found between the two groups (Table 2 and 3).

Sensory block start time till the level of T10 was with significant difference as it was early in Group C (2.34

Table 3: Comparative mean arterial blood pressures in two groups

Time (min)	Group C	Group R	P value
0	96.07 ± 5.87	94.19 ± 7.28	0.240
3	93.25 ± 6.18	93.65 ± 6.81	0.798
6	92.40 ± 8.22	90.73 ± 5.47	0.321
9	90.70 ± 4.34	88.95 ± 5.14	0.128
12	91.77 ± 4.63	91.90 ± 4.67	0.912
15	92.80 ± 4.92	91.50 ± 4.88	0.272
18	93.09 ± 5.36	92.88 ± 4.64	0.862
21	91.60 ± 6.07	91.33 ± 4.51	0.835
24	90.52 ± 5.76	88.97 ± 6.37	0.288
27	92.34 ± 5.77	92.04 ± 5.28	0.818
30	92.55 ± 6.13	91.56 ± 5.34	0.474
35	92.39 ± 5.85	92.38 ± 5.78	0.995
40	91.64 ± 5.99	91.39 ± 5.90	0.864
45	92.57 ± 7.06	92.57 ± 6.90	1.000
50	93.09 ± 5.28	93.13 ± 5.20	0.970
55	94.34 ± 5.77	94.46 ± 5.72	0.934
60	93.81 ± 5.11	94.00 ± 5.10	0.876

Data presented as mean ± SD; P < 0.05 is significant

min ± 0.48) P < 0.000 as compared to Group R (5.49 min ± 0.5) P < 0.000. Sensory block duration was observed to be more in Group R (181.34 min ± 8.68) than Group C (61.1 min ± 4.92) P < 0.000 which was statistically significant. Two-segment regression time was found to be significantly different between Groups C and R, with Group C being early compared to Group R (37.8 min ± 1.43 vs. 89.83 ± 1.29 min; P = 0.000) (Table 4).

The peak height of sensory block was observed to go till T4 in Group R; whereas in Group C the peak height was achieved till T6 P < 0.004 which was significant.

The motor block onset time was late in Group R in comparison to Group C ((7.55 ± 0.52 vs. 4.41 ± 0.49 min; P < 0.05) and the duration of motor block was less in group chloroprocaine as compared to Group R (55.2 ± 4.09 vs. 163.54 ± 10.79 min; P < 0.000) which was significant (Table 4).

With a significant P < 0.05, Group C accomplished all of the discharge criteria earlier than Group R, including the ability to void, normal perineal sensation, plantar flexion of the foot, and proprioception of the big toe. The time of request of first analgesia was shorter for the Group C as compared to Group R (P < 0.05 which was significant).

The complications / side effects, e.g., pruritus, hypotension, nausea/vomiting were equivalent in the two groups, the differences were statistically not significant (P > 0.05)

Table 4: Comparison of the block characteristics in two groups

Block parameters	Group C Mean ± SD	Group R Mean ± SD	P Value
Onset of sensory block [T10]	2.34 ± 0.482	5.49 ± 0.507	.000
Duration of sensory block	61.11 ± 4.92	181.34 ± 8.6	.000
Two segment regression time [S1 Dermatome]	37.89 ± 1.43	89.83 ± 1.29	.000
Onset of motor block [Bromage scale 3]	4.41 ± 0.492	7.55 ± 0.525	.000
Duration of motor block	55.29 ± 4.09	163.54 ± 10.79	.000
Time of request of first rescue analgesia (min)	80.33 ± 5.23	156 ± 2.44	.004

Data presented as mean ± SD; P < 0.05 is significant

4. DISCUSSION

The pursuit for encouraging ambulatory surgeries has led to extensive research on LAs maintaining equilibrium between adequate anesthesia and early recovery.

LAs are known for their differential neural blockade properties along with differing duration of action as well as efficacies. Till date no study has been conducted between chloroprocaine and ropivacaine for short duration surgeries analyzing and comparing their block characteristics and discharge criteria.

In terms of the demographic profile and hemodynamic parameters (HR, SBP, DBP, MAP, SpO_2, RR) this research has produced statistically non-significant results. Krishna et al. conducted a study which showed similar results for chloroprocaine with respect to demographic profile and hemodynamic parameters.[9] MAP initially decrease in the two groups which stabilized within 10 min and was statistically insignificant.

In the present research, the sensory block start times till T10 level in Group C and R came around 2.34 ± 0.482 min and 5.49 ± 0.50 min respectively, that was statistically significant (P < 0.043). Bhaskara et al. showed onset of chloroprocaine as 2.27 ± 0.52 min,[1] and Bhaskara et al. observed 4.8 ± 0.74 min as ropivacaine's onset time till T10 providing supporting evidence.[10] On contrary the same researchers showed sensory response onset analysis for both the drugs as statistically

Table 5: Comparative side effects in two groups

Side effects	Group C	Group R	P value
Bradycardia	1	2	0.723
Hypotension	1	2	0.48
Pruritus	4	2	0.82
PONV	1	3	0.437

insignificant (P > 0.05). Chloroprocaine group took longer to act, perhaps because of lesser dose used (30 mg) in comparison to our study (40 mg) (Figure I). Peak height achieved in Group C was T8 (51.4%) whereas in Group R was T6 (48.6%)

which was significantly more (P < 0.05). Our results are supported by studies conducted by Bhaskar et al.[10] and Bhati K et al. [11.] None of the patients in Group C achieved T4 where as 22.9% patients achieved T4 in Group R in our present study.

Bhaskara et al. showed different peak sensory block height (T8) in patients receiving ropivacaine, which was T6 in Group R in the present study. This difference might be present as Bhaskara et al. used a lower dose of ropivacaine (7.5 mg) as compared to our present study which used 4 ml of ropivacaine 0.5% (20 mg).[10]

The duration of two segment regression to S2 in Group C was 37.89 ± 1.43 min, considerably less than Group R's time of 89.83 ± 1.29 min (Table 2). The results were supported by Bhati K et al. and Gupta DA et al.[11,12] The cessation of sensory block in Group C was observed in 61.11 ± 4.92 min which was significantly lesser than Group R 181.34 ± 8.68 min (P = 0.000). Previous literature seconded our results as Gupta DA et al. (chloroprocaine 74.4 ± 10.96 min) and McNamee DA et al. (ropivacaine 180 min ± 5.62 min) produced similar duration of block.[12,13]

Bhaskara et al.[10] showed different duration of sensory block (163 ± 14.82 min) in patients receiving ropivacaine which is significantly less than what was observed in Group R in the present study. This difference might be present as they used a lower dose of ropivacaine (7.5 mg) compared to our present study which used 20 mg of ropivacaine (Table 2).

Bromage Scale 3 was achieved in Group C in 4.40 ± 1.30 min, whereas in Group R in 7.55 ± 0.52 min. Similar findings for onset of motor block were observed by Bhaskara et al[1] and by Bhaskara et al.[1,10] The mean difference considered to be statistically significant.

The return of Bromage from 3 to Bromage 0 was observed in 55.29 ± 4.09 min in Group C similar to that observed by Bhaskara et al., whereas in Group R was 163.54 min ± 10.79 min, alike to study by Bhaskara et al.[1,10] The mean time of motor block offset was significantly different in both the groups.

Time to first rescue analgesia in Group C was significantly earlier in comparison to Group R, as shown by Bhaskara et al.[1]

Criteria for discharge from post anesthesia care unit like ability to void, return of perineal sensations, plantar flexion of the foot and proprioception at big toe were all achieved early in Group C in comparison to Group R and is supported by research conducted by Bhaskar et al.[1]

Side effects observed were manageable and statistically not significant in patients and ranged from hypotension and bradycardia due to expected sympathetic blockade, to pruritus and nausea and vomiting.

The strength of our study was that double blinding (in terms of volume of drug) was possible in contrast to study by Bhaskar et al. Moreover, the strength of the drugs used was also equivalent to each other thus decreasing the bias. The study was conducted in a variety of short duration surgeries increasing the credibility in contrast to Bhaskar et al., who conducted only in limited surgeries.

5. LIMITATIONS

During the course of the study, the following limitations were noticed. As speculated observer bias was seen because of shorter duration of action of chloroprocaine, thus multiple observers were employed. We didn't use any adjuvant in our drugs, which could lead to entirely different results, thus further studies for the same will be required. Due to differential neural block, motor and sensory effects plus conditions of surgery could differ, thus patient satisfaction and surgeon satisfaction score should have been done, which is an added limitation to our study.

6. CONCLUSION

This research suggests that chloroprocaine 1% and ropivacaine 0.5% are clinically identical and equally effective for surgical anesthesia. Chloroprocaine 1% is more suitable in surgeries of shorter duration and thus enhances the patient turn-over time and thus economical usage of resources. However, ropivacaine proves to be more suitable in longer duration procedures, and provides better postoperative analgesia.

7. Data availability

The numerical data generated during this research is available with the authors.

8. Acknowledgement

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9. Conflict of interest

The study utilized the hospital resources only, and no external or industry funding was involved.

10. Authors' contribution

All authors took part in Concept, conduct the study, data collection, data analysis. manuscript writing, editing and correction, and final approval

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