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Original Research Article

Comparing intrathecal 1% 2-chloroprocaine and 0.5% bupivacaine for patients undergoing saddle block in daycare surgeries with respect to recovery and home readiness: A prospective double blind randomised study

Krishna K[1], Shivakumar G[1], Archana BN[1], Vansuma S R Gowda[1,*], Somsundar R G[1]

[1] *Dept. of Anaesthesiology, Mandya Institute of Medical Sciences, Mandya, Karnataka, India*

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ABSTRACT

Background: Preservative free 2-chloroprocaine seems to be a better alternative to lidocaine and bupivacaine for day care procedures, because of its short duration of action. This study was designed to compare 2-chlorprocaine with low dose bupivacaine for saddle block in elective perineal surgeries on day care basis in terms of recovery and home readiness.

Aims: To compare 1% 2- chloroprocaine with 0.5% bupivacaine with respect to time taken to obtain discharge criteria from post-anaesthesia care unit (PACU) to post-operative ward, from hospital to home and time taken for ambulation and micturition.

Setting and Design: This is a prospective, randomized, double blind, parallel group clinical study, conducted on ASA class I and II patients undergoing elective perineal surgeries on daycare basis in MIMS teaching hospital, Mandya.

Materials and Methods: After obtaining approval from institutional ethical committee, a total of 100 patients were enrolled in this study. Saddle anaesthesia was achieved with 7.5 mg 0.5% hyperbaric bupivacaine (Group B, n = 49) or 1% 2- chloroprocaine 40 mg (Group C, n = 50). After completion of surgery, patients were monitored in PACU and postoperative ward using modified Aldrete's score and PADSS. After discharging, patients were contacted at 24 hours and followed up for 7 days via telephone to assess potential complications of saddle block.

Statistical Analysis: Data analysis was done using IBM SPSS version 20. Chi-square test, Fisher's exact test and independent t-test were used to compare the variables. P value of <0.05 is considered statistically significant.

Results: Mean time required to attain discharge eligibility from hospital in Group B was 296.24 min and Group C was 213.3 min with a difference of 83 mins ($P < 0.001$). Mean duration of time spent in PACU in Group B was 105.18 min and Group C was 27.22 min ($P < 0.001$). Time to unassisted ambulation and micturition was also significantly lower in Group C. None of the patient in both study groups required additional analgesia in the intraoperative period. However, 26% patients in Group C experienced more pain in the post-operative period compared to Group B (4%) ($P = 0.04$).

Conclusion: Chloroprocaine provides satisfactory anaesthesia with advantage of faster regression of block, early ambulation and micturition, and thus early discharge from the hospital.

1. Introduction

In recent years, more number of surgical procedures are performed on day care basis. In North America alone

* *Corresponding author.*
E-mail address: suvidya.s.r.gowda@gmail.com (V. S. R. Gowda).

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between 50% and 70% of the cases are currently performed as outpatient procedures.[1] India being highly populated with acute shortage of health care facility and adequate availability of surgeons, the day care surgeries can play a better role.

Spinal anaesthesia is safe and reliable technique for lower abdomen and lower limb surgeries, and makes daycare surgery accessible to some patients in whom the risk of general anaesthesia are excessive. The ideal anaesthetic in this setting, should allow rapid onset and offset of sensory and motor blockade with lesser side effects and by the end of the day patient should be ready for home discharge.

Lidocaine was anaesthetic of choice for years in the context of out-patient procedures. But it's use has declined due to significant risk of transient neurological symptoms (TNS).[2–6] Until recently, bupivacaine was the most obvious alternative, being devoid of TNS, but causing unacceptable delays in home discharge, because of prolonged duration of block and urinary retention if used in standard doses.[7] Attempts have been made to use smaller doses of bupivacaine, but has resulted in either delay in hospital discharge or insufficient anaesthesia.[8]

Other shorter acting local anaesthetics like articaine, prilocaine and chloroprocaine are reintroduced into the ambulatory anaesthesia from past few years to hasten the recovery and home discharge, while ensuring the safety.

Chloroprocaine (2-CP) is an amino-ester local anaesthetic with short duration of action. The new pH adjusted and preservative free formulation have been made available for intrathecal use and has been studied extensively both in healthy volunteers and patients. Preservative free and pH adjusted 2-CP is found to be safe for intrathecal administration. The spinal 2-CP provides adequate duration and density of block for day care surgery with faster regression, early ambulation and voiding.[9]

Hence, we decided to design a study to compare 1% 2-CP with low dose bupivacaine for saddle block in elective perineal surgeries on day care basis in terms of recovery and home readiness. Our primary objectives were, time spent in post-anaesthesia care unit (PACU) and the time taken for obtaining discharge criteria from hospital to home. Time taken for unassisted ambulation and micturition was our secondary objective. We hypothesized that 1% 2-CP provide spinal anaesthesia with shorter recovery profile and early discharge from hospital than bupivacaine.

2. Materials and Methods

After receiving approval from institutional ethics committee, a total of 100 patients aged ≥18 years and ≤ 60 years, belongs to American society of anaesthesiologist (ASA) class I or II, posted for elective perineal surgery of duration ≤ 60 minutes were included in our study and patients who have contraindications for spinal anaesthesia, allergy to local anaesthetic drugs and patients with atypical or deficient plasma cholinesterase were excluded from this study.

Each patient was evaluated pre-operatively and written informed consent was obtained. Patients were explained about Visual analogue scale (VAS) score during the pre-anaesthetic evaluation. Patients were randomized into two groups (Group B and Group C) of 50 each based on allocation sequence by computer generated random number tables. Group B patients received intrathecal injection of 0.5% hyperbaric bupivacaine 7.5 mg and Group C patients received intrathecal injection of preservative free 1% 2-chlorprocaine 40 mg.

On arrival in the operating room, intravenous line was secured with 18G intravenous cannula and patients were preloaded with lactated ringer's solution at 15ml/kg. Basal vitals like heart rate, blood pressure, and saturation were recorded using non-invasive blood pressure (NIBP), ECG and pulse oximeter. After ensuring asepsis, saddle block (spinal anaesthesia) was performed by placing patient in sitting position using 25G or 23G Quincke's spinal needle with midline approach at L3-L4 or L4-L5. After ensuring adequate flow of cerebrospinal fluid and negative aspiration of blood, one of the study drugs was administered intrathecally with bevel of the needle being directed caudal.

All patients were made to remain in sitting position for 10 min and later positioned according to the need of surgery. After confirming adequate saddle blockade patients were allowed to undergo surgery. Motor block was assessed using modified Bromage scale at the beginning of procedure. Patients were assessed for peak block height every 5 minutes for 30 minutes after administration of the drug using pin prick technique and time duration was recorded. Once patient has achieved peak block height, we would assess patient for sensory regression every 15 minutes until complete sensory regression. The time from injection of drug to complete sensory regression was taken as duration of sensory block.

Patient's vitals like heart rate, blood pressure, saturation were monitored continuously throughout the surgery and complications like hypotension and bradycardia, was treated accordingly using mephenteramine and atropine respectively. For patients, who experience mild to moderate pain during surgery, additional analgesia was given with injection fentanyl (0.5 to 1 mcg/kg) and the total dosage received was recorded. In case of severe pain and inadequate motor block, patient were given general anaesthesia for surgery and such cases were considered block failure and excluded from the study. Intravenous diclofenac infusion 75mg was given prophylactically at the end of surgery. Patients were shifted to PACU for further management. They were assessed every 5 minutes for readiness to be discharged from PACU to the ward using Modified Aldrete's scoring system.[10] Once patients achieve a score of 10,

patients were discharged from PACU and the time duration of stay in PACU was noted.

After getting shifted from PACU to post-operative ward, patients were assessed every 30 minutes for home readiness using modified post-anaesthesia discharge scoring system (PADSS),[11] and for pain using VAS score. All patients were assessed for complications like headache, shivering, postoperative nausea and vomiting during their stay in post-operative ward. Patients, who can ambulate without assistance and have passed urine with modified PADSS score 10 were discharged from hospital.

After discharging, patients were contacted at 24 hours and followed up for 7 days by telephone to assess potential complications of spinal anaesthesia such as headache, paraesthesia or dysesthesia in lower limbs, lower back pain, nausea, vomiting, and difficulty in voiding.

2.1. Statistical analysis

Sample size was calculated based on a previous study, where mean time for discharge eligibility was taken as one of the variable. Considering the dropout rate and better validation of the results, 50 patients were chosen for each group.

Data collected was entered in excel sheet and analysed using SPSS software. Descriptive data like ASA class, type of surgery, gender, requirement of additional analgesia, postoperative complications were compared using chi-square test or Fisher's exact test (when expected values in any of the cells of a contingency table were < 5). Independent t- test was used to compare the other variables, including primary outcome (length of stay in PACU and time to eligibility for discharge) and secondary outcome (time to unassisted ambulation, time to unassisted micturition, duration of sensory and motor block). Statistical analysis was performed using IBM SPSS version 20 for windows. Continuous variables are represented as mean ± standard deviation. Categorical data are presented as number of cases recorded (percent). Any P value of < 0.05 is considered statistically significant.

3. Results

A total of 100 patients undergoing elective perineal surgery on daycare basis were evaluated during the period between May 2019 to April 2020. One patient was excluded from the study due to block failure.

Demographic variables were comparable between two study groups. There were no significant differences between the study groups regarding age, sex, body mass index (BMI) and ASA class. Both the study groups were comparable in terms type and duration of surgical procedures. (Table 1)

Haemodynamic parameters namely heart rate, systolic and diastolic blood pressure, and oxygen saturation were monitored throughout the intraoperative period, PACU stay and postoperative period. There was no statistically significant difference between Group C and Group B with respect to heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP) and oxygen saturation (SPO_2). (Figures 2 and 3)

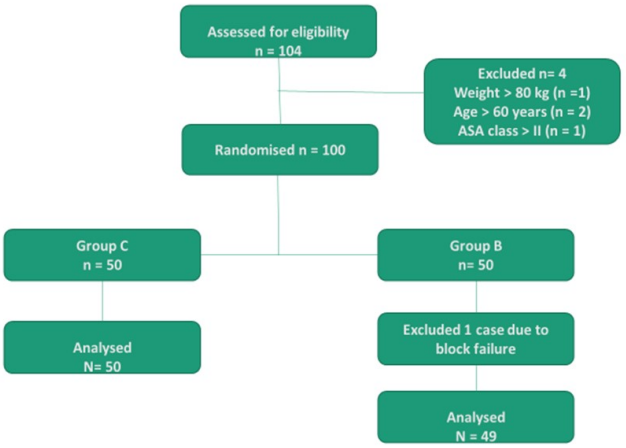

Fig. 1: The consort flow chart of the study

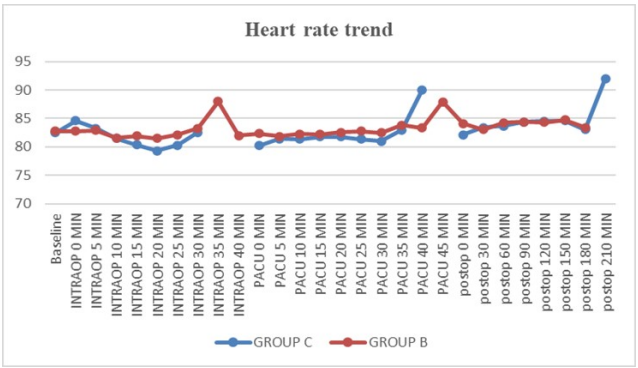

Fig. 2: Heart rate trend in intraoperative period, PACU and postoperative period

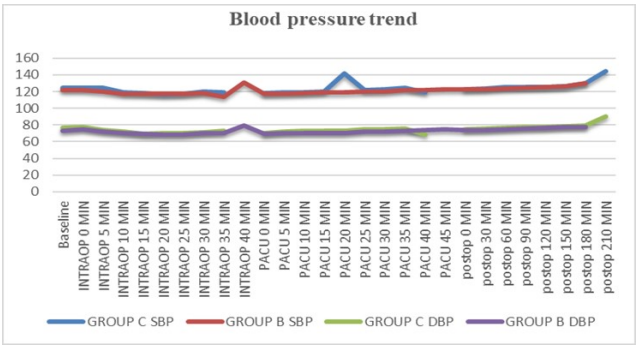

Fig. 3: Blood pressure during intraoperative period, PACU and postoperative period

Table 1: Comparison of demographic variables, type and length of surgery between two groups

Basic variables	Group C (n = 50) Mean ± SD	Group B (n = 49) Mean ± SD	P value
Age in years	38.2 ± 12.1	35.59 ± 9.46	0.235
BMI Kg/m^2	22 ± 0.98	22.3 ± 0.73	0.258
Sex (male/female)	27/23	24/25	0.617
ASA physical status (I/II)	33/17	35/14	0.560
Type of surgery			
Gynaecological procedure	4	5	0.772
Perianal procedures	46	44	
Duration of surgery in min	17.6 ± 2.4	18.43 ± 3.4	0.155

Values are presented as mean ± SD, P < 0.05 significant, SD = Standard deviation, ASA = American society of anaesthesiologists

Table 2: Clinical data including primary and secondary outcome and block characteristics

Parameters	Group C (n = 50) Mean ± SD	Group B (n= 49) Mean ± SD	P value
Time spent in PACU (min)	27.22 ±4.66	105.18 ±8.9	<0.001
Time to eligibility for discharge from hospital (min)	213.3 ±21.4	296.26 ±20.2	<0.001
Time to unassisted ambulation (min)	144.5± 13.4	243 ± 20	<0.001
Time to micturition (min)	204.3 ±21.5	289.4 ± 21.5	<0.001
Peak block height	T_8 (range T_2 -T_{10})	T_{11} (rangeT_8- L_1)	
Time to peak block height (min)	14.68 ±1.31	19.92 ± 2.34	<0.001
Duration of sensory block in (min)	73.8 ±5.77	177.33 ±10.12	<0.001
Duration of motor block in (min)	56.86 ±2.39	136.61 ±8.31	<0.001
Requirement of additional analgesia in the intra-operative period	None	None	-
Requirement of additional analgesia in postoperative period	13 (26%)	2 (4%)	0.04.
Postoperative complications (PONV)	4 (2%)	1 (0.5%)	0.362

Values are presented as mean ± SD and proportions, P < 0.05 significant, SD = Standard deviation

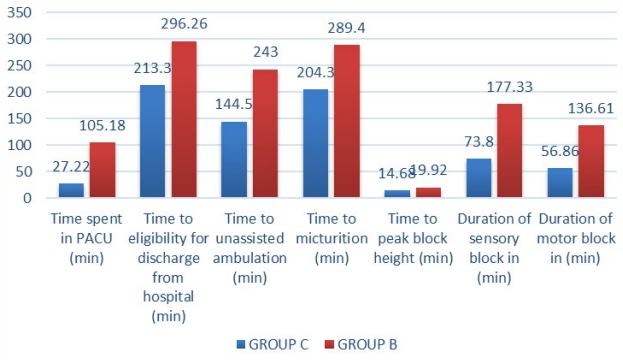

Fig. 4: Bar graph depicting difference between two groups with respect to primary and secondary outcome, block characteristics

Mean duration of time spent in PACU in Group C was significantly shorter when compared to Group B (27.22 ± 4.66 vs 105.18 ± 8.988, P <0.001). Mean time required to attain discharge eligibility from hospital in Group C was significantly shorter compared to Group B (213.3 ± 21.372 vs 296.24 ± 20.264, P <0.001).(Table 2, Figure 4) Mean time for unassisted ambulation and micturition in Group C was significantly shorter compared to Group B (144.48 ± 13.37 min vs 243.04 ± 19.99 min, P < 0.001, 204.28 ± 21.47 vs 289.37 ± 21.46 P< 0.001). (Table 2 , Figure 4)

The block onset characters were comparable between two study groups. The peak block height in Group C was T_8 (range T_2 -T_{10}) and it was T_{11} in Group B (range T_8 - L_1). Duration of sensory and motor block and time to attain peak block height were significantly shorter in GROUP C compared to Group B. (Table 2, Figure 4)

None of the patients in both study groups required additional analgesia or sedatives in the intraoperative period. However, 26% patients in Group C experienced more pain in the post-operative period compared to Group B (4%), and it is found to be statistically significant as the P- value is 0.04.(Table 2, Figure 4) One patient in Group B, while 4 patients in Group C experienced nausea and vomiting which was statistically insignificant as the P value was 0.362.(Table 2, Figure 4) There were no incidence of other postoperative complications such as shivering, hypotension, bradycardia or bleeding. Incidences of back pain recorded during the follow-up phone calls were similar between two groups. Two patients in each study group complained of back pain within first week of the procedure. There were

no incidences of complications such as post-dural puncture headache and TNS.

4. Discussion

Several studies have been conducted to know the block characteristics and recovery profile of 2-CP when compared to bupivacaine. The present study is an attempt to compare 2-CP with bupivacaine in terms of recovery and home readiness, in patients receiving saddle block for perineal surgeries on day care basis. Our main finding is that spinal anaesthesia with 2-CP can provide a satisfactory surgical block while permitting an earlier discharge from hospital than spinal bupivacaine due to more rapid regression of the sensory and motor block with early unassisted ambulation and faster voiding.

The doses of 2-CP and bupivacaine used in this study are considered clinically equivalent, because the minimum dose chosen for each medication was believed to be clinically efficacious. Ben-David et al. showed that spinal hyperbaric bupivacaine 7.5 mg provide satisfactory anaesthesia and rapid resolution of block for ambulatory arthroscopic knee surgery, but further lowering of dose or dilution resulted in block failure. Kopacz DJ et al. showed in their study that spinal 2-CP 40 and 60 mg provide rapid and reliable sensory and motor block. They also concluded that 20 mg and 30 mg can produce adequate sensory anaesthesia for brief surgical procedures with less motor block and some sacral sparing.[12] Hence, we decided to use a minimum effective dose of 40 mg 2-CP in our study.

The finding which shows significant advantage is the duration of sensory block. It is considered from time of injection to regression of sensory block to S2, and it was 2.4 times faster in 2-CP as compared to bupivacaine. This finding is supported by results of other studies by Marie-Andrée Lacasse et al. In their study, they demonstrated that the time for sensory regression to S2 was 2.3 times faster in 2-CP compared to bupivacaine.[13] However, the data of Marie-Andrée Lacasse et al. cannot be compared directly to our study as they used different method to evaluate the sensory block. They used loss of cold sensation to ice to assess the sensory level. In our study, the level of sensory block was assessed using needle pin prick method. Pin-prick sensation is conducted by the A-delta fibres, while cold sensation is transmitted by both A-delta fibres and the C-fibres.

One of the primary outcome of this study was time taken to obtain discharge criteria from PACU to postoperative ward. It was measured from the time of admission to post anaesthesia care unit to the moment patient attained modified Aldrete's score of 10. With respect to this outcome, a significant difference of 78 min was observed in favour of Group C due to faster regression of the block. Manjulata Tandan et al., demonstrated no significant difference in length of stay in PACU between two study groups.[14] But, our study is different from their study, as patients were discharged from PACU after attaining a modified Aldrete's score of 10. Manjulata Tandan et al., considered following criteria to discharge patients from PACU: a minimum of 60-min stay, stable vital signs, signs of regression of the motor block (Bromage 0 to 2), no analgesia within the previous 20 min, and normal consciousness. In our study, all the patients were kept in PACU until patient achieves a modified Aldrete's score of 10 and modified Bromage score of 0.

The moment patients achieve modified Aldrete's score of 10, they were shifted to post-operative ward. It is noteworthy to mention that more patients in Group C (26%) experienced pain in the post-operative period. Consequently, these patients were treated with parenteral analgesics. Patients with mild pain in both the groups were treated with oral nonsteroidal anti-inflammatory drugs.

Four patients in Group C and one patient in Group B experienced nausea and vomiting, and they were treated with antiemetic medications. There were no complications such as bleeding from the operative site, hypotension, bradycardia and shivering in the PACU and postoperative period.

Another primary objective of our study was time taken for obtaining discharge criteria from hospital to home. This was measured from the time of administration of study drug to the moment patient attained all of the discharge criteria. As with this outcome, a significant difference of 83 min observed between two groups. GROUP C patients attained home discharge eligibility earlier compared to GROUP B, due to faster regression of the block, resulting in early ambulation and voiding. This findings were comparable to results of previous studies conducted by J. R Yoos, et al., and Marie-Andrée Lacasse et al. Study conducted by Marie-Andrée Lacasse et al., showed that the average time to discharge readiness was 277 min in the GROUP C and 353 min in the GROUP B, with a difference of 76 min.

Times to ambulation and micturition were significantly lower in the Group C. A statistically significant difference of 99 min and 85 min observed between 2 groups with regard to unassisted ambulation and voiding respectively. Urinary retention resulting in delayed discharge was particularly problematic in GROUP B patients. Even after good block regression and successful ambulation, many patients in Group B experienced a longer delay between first urge to micturate and their eventual successful complete micturition. This can be explained by the need for regression of sensory block to at least S3 dermatome in order to obtain normal detrusor function. Breebart et al. also demonstrated a longer interval to first voiding in case of spinal anaesthesia with long acting local anaesthetics such as bupivacaine compared with short acting agents.[15]

After discharge, all patients were followed up at 24 hours and on 7^{th} day via telephone. There were 2 cases of back

pain in each group after first 24 hours of spinal anaesthesia. Backpain was not associated with any dysesthesia or radiation of pain to the buttock or leg, hence TNS was ruled out. There were no incidence of TNS, post-dural puncture headache, postoperative nausea vomiting (PONV).

We acknowledge that there are few limitations with regard to our study. One of the limitations of our study is that it was not perfectly blinded. Because the block in GROUP C regressed earlier and faster, the blinded observer could guess to which group patient had been assigned. Though this limitation was recognised before starting the study, we could not find a better alternative to the protocol. Another drawback of our study was that, the drug volume could not be matched with each other. We used 4 ml of 2-CP in Group C in contrast to 1.5 ml in Group B. There is a possibility that, this could lead to changes in block characteristics and also this volume discrepancy can introduce bias with respect to administration of analgesics. All patients in both groups were kept in PACU until they achieve a modified Aldrete's score of 10. This was done to standardise the duration of stay in PACU. But this could lead unnecessary utilization of post-anaesthesia care unit facility and man power. Another limitation of study is that cost analysis was not done. Our study could be criticized for not using opioid additives for intrathecal administration, as it is a common clinical practice these days. In this study intrathecal opioids were not used to reduce the possible confounding factors.

5. Conclusion

In this study, we found out that saddle 2-chloroprocaine 40 mg provides satisfactory anaesthesia for perineal surgeries lasting less than 1 hour. Spinal 2-chloroprocaine when compared with bupivacaine resulted in faster regression of block, early ambulation and micturition, and thus early discharge from the hospital.

6. Financial Support and Sponsorship

Nil.

7. Conflicts of interest

There are no conflicts of interest.

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Author biography

Krishna K, Associate Professor https://orcid.org/0000-0003-4154-9705

Shivakumar G, Professor and HOD https://orcid.org/0000-0003-4154-9705

Archana BN, Assistant Professor https://orcid.org/0000-0002-5790-7573

Vansuma S R Gowda, Senior Resident https://orcid.org/0000-0003-4154-9705

Somsundar R G, Assistant Professor https://orcid.org/0000-0003-4154-9705

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