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2-Chloroprocaine Versus Bupivacaine in Spinal Anaesthesia: A Randomized Controlled Study

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ABSTRACT

Introduction: To cope with the increasing day care surgeries, a fast-acting, predictable anesthesia and time-efficient discharge is becoming the need of anesthesiologists. Spinal anesthesia has become popular nowadays in the day care settings due to the advent of new pencil point spinal needles. The study aims to compare 1% 2-Chloroprocaine with 0.5% Bupivacaine in spinal anesthesia with respect to the recovery from anesthesia and time taken to attain discharge readiness criterion.
Methods: Around 100 patients belonging to ASA I and ASA II categories between the age group 18-60 years undergoing surgery with an expected duration of < 60 minutes were selected. Using double-blinded randomization technique, the participants were equally divided into two groups and were given either 1% 2-Chloroprocaine or 0.5% Bupivacaine. The time taken for onset and regression of sensory as well as motor block was noted.
Results: The achievement of the target sensory block was faster with 2-Chloroprocaine (137.20 ± 23.21 mins) than with 0.5% Bupivacaine (270.00 ± 34.10). The mean time to achieve unassisted ambulation in the 2-Chloroprocaine group (179.72 ± 17.30 mins) was less than the Bupivacaine group (256.52 ± 21.98 mins). The discharge readiness criteria were also attained earlier in the 2-CP group (195.98 ± 15.69 mins) than the Bupivacaine group (304.74 ± 16.99 mins). The incidence of postoperative Nausea and Vomiting was seen in 2% of the patients in both groups.
Conclusion: 2-Chlorprocaine is a faster acting drug when compared to Bupivacaine and it helps in faster recovery of the patients undergoing daycare surgeries.

Keywords: [2-Chloroprocainae, Bupivacaine, day care surgeries, recovery, spinal anesthesia.]

INTRODUCTION

Ambulatory surgery or Daycare surgery is defined as "The practice of admitting, on the day of surgery, of carefully selected and prepared patients for a planned, non-emergency surgical procedure and their discharge within 24 hours of that surgery".[1] The increase in ambulatory surgical procedures has driven anesthesiologists to provide predictable anesthesia and time-efficient discharge of patients.[2] This has been made possible due to recent advances in anesthetic and surgical practices. Daycare anesthesia can several advantages for patients like a shortened hospital stay, minimum psychological disturbances, cost reduction, less risk of nosocomial infections and venous thromboembolism.

The safety of anesthesia for daycare surgeries has increased due to the development of anesthesia, in terms of improved technology, the discovery of

better anesthetic agents, acute pain management, advances in monitoring, training, evaluation of patients, and the evolution of perioperative care.[3] Although general anesthesia was commonly used in ambulatory settings, the emphasis on regional anesthesia is increasing these days.

As compared to general anesthesia, regional anesthetic techniques provide good analgesia with minimum sedation, nausea, vomiting, and cognitive dysfunction. It is rapid acting, cheaper, and has fewer side effects including a five-fold reduction in postoperative nausea and vomiting as compared to general anesthesia.[4] Spinal anesthesia is a safe and reliable technique for surgical procedures on the lower abdomen and lower limbs.[5] It has a more predictable offset as compared to peripheral nerve blocks.[6] However, the use of regional anesthesia in ambulatory settings is limited by various factors like delayed ambulation, risk of urinary retention, and pain after block regression.[7] An ideal anesthetic for spinal anesthesia in daycare surgery would provide a rapid onset of action, adequate potency and predictable duration of action and should cause decreased neurotoxicity and systemic side effects.[8] The development of new small gauge pencil-point spinal needles are responsible for the success of out-patient spinal anesthesia with very low rates (0-2%) of postdural puncture headache (PDPH).[5]

Bupivacaine is one of the most common local anesthetic used in spinal anesthesia with a low incidence of transient neurologic symptoms (TNS) (0-1%).[9] To adapt long-acting Bupivacaine to daycare setting, smaller dose are used, but the results are varied as the duration of the block remains prolonged and smaller doses sometimes provides insufficient anesthesia.[10] Moreover, it delays the time to discharge in patients due to urinary retention.[11] 2-Chloroprocaine (CP) is an amino ester local anesthetic, first introduced in 1951 when Foldes FF and McNall PG described its use in spinal anesthesia.[12] In the early 1980s due to inadvertent intrathecal injection of the sodium bisulfite containing CP, several reports of neurological deficits were reported and this neurotoxicity was experimentally attributed to the preservative sodium bisulfite. [13,14]. About two decades later, this drug was reintroduced. Since then, several studies have been done using Intrathecal preservative-free 2-Chloroprocaine in volunteers and patients successfully without any untoward events hence establishing its safety.[8,15-18]

The present study was undertaken to compare 1% 2-Chloroprocaine and 0.5% Bupivacaine in infra-umbilical surgeries lasting <60 minutes with respect to the recovery from anesthesia and time taken to attain discharge readiness criteria.

MATERIALS & METHODS

A Randomized Control Trial was done among 100 patients to compare the efficacy of 2-Chloroprocaine and 0.5% Bupivacaine from October 2017 to October 2018. The participants were recruited from the outpatient department of a tertiary care institute of north India after obtaining ethical clearance from the institutional ethical committee (IEC/2018/648)

The participants were randomly allocated into two groups using the lottery method to avoid selection bias. The patients aged 18-60 years; of either sex; belonging to American society of Anesthesiologists (ASA) grade I/II, having sound thinking and no language/communication barriers who were scheduled for the lower abdomen, perineal and gynecological surgeries and lower limb surgeries with an expected duration of surgery <60 mins were included in our study. The patients with contraindication to spinal anesthesia, pregnant women, those having body mass index (BMI) ≥36 kg/m^2, and patients with failed spinal anesthesia requiring general anesthesia were excluded from the study.

A preanesthetic check-up of patients was done a day before the surgery. A detailed history, thorough general physical and systemic examination, was done followed by reviewing the routine investigations like

hemogram, renal function tests, serum electrolytes, liver function tests, blood sugar (F), PTI, urine routine examination, electrocardiogram (ECG), and chest X-ray (PA view). Informed written consent was taken from each patient and the patient was kept fasting for a minimum of 6 hours before the scheduled surgery. Tablet Alprazolam 0.25 mg and Tablet Ranitidine150 mg were given at bedtime, a night before the surgery. The intravenous line was secured with a 20 G cannula and Ringer Lactate infusion was started at the rate of 10ml/kg, 20 minutes before surgery.

In the operation theatre, the basic monitors Non-Invasive Blood Pressure (NIBP), ECG and pulse oximeter(sPO2) were attached and baseline parameters were noted. Using all aseptic precautions, in the sitting position, L_3 -L_4 interspace was identified. The skin and interspinous ligament were infiltrated with 2 ml of 2% lignocaine. Lumbar puncture was performed in a sitting position through a midline approach using 26 G Quincke's spinal needle. On ensuring the free cerebrospinal fluid (CSF) flow, intrathecal Bupivacaine 0.5% 7.5 mg (Group B) or 2-Chloroprocaine 1% 40mg (Group C) was administered slowly. After giving the spinal injection, patients were placed in the supine position. Heart rate, NIBP and SpO_2 were recorded just after administering spinal anesthesia, at an interval of 3 mins, 5 mins, and then every 5 mins for the first 30 mins; thereafter every 10 mins until the end of surgery.

The sensory level was assessed by using the loss of pinprick sensation using a blunt 25G hypodermic needle in a caudal to cephalad direction in the mid-clavicular line bilaterally. The point C_5- C_6 dermatome was used as an unblocked reference point. Taking the time of intrathecal injection as zero, time was calculated. The sensory block was evaluated every minute until the level of T_{10} was reached and then every 3 mins till maximum level of the sensory block was reached (the same level of sensory block for three consecutive observations). The checking of sensory level was then suspended during the surgery. The motor block was assessed and scored as per the modified Bromage scale.[19] (Table 1)

The motor block was assessed every minute till the score of Bromage 3 was reached and the time to reach Bromage 2 and Bromage 3 were recorded. Readiness to surgery was defined as loss of pinprick sensation at $\geq T_{10}$, with a modified Bromage score ≥ 2. After surgical anesthesia was achieved, the patient was handed over to the surgeon.

If the patient complained of pain during surgery, supplemental analgesia with 100 µg of fentanyl i.v. was administered. If analgesia was still not adequate, General anesthesia was provided excluding the patients from the study and counting the number of conversions to general anesthesia. Clinically relevant hypotension (decrease in systolic arterial pressure $\geq$ 30% from baseline) was initially treated with a rapid i.v infusion of 200 ml of Ringer Lactate solution. If this was not effective 3mg ephedrine i.v increments were administered. Occurrence of clinically relevant bradycardia (defined as heart rate reduction $\leq$ 50 bpm) was treated with increments of 0.3mg Atropine i.v .Oxygen was supplemented to each patient and monitoring of SpO_2 was done throughout the procedure.

Postoperatively, the monitoring of the vitals of the patient (HR, BP, SpO_2) and sensory and motor block levels was done after every 10 minutes for 60 minutes in post-anesthesia recovery area (PACU). Intravenous Paracetamol infusion(1gm) was given to those when the patients complained of pain. The incidence of nausea and vomiting was also noted and treated with injection Ondansetron 4 mg i.v. Patients were transferred to the post-operative ward after they fulfilled the following criteria: a minimum of 60 minutes stay in the PACU, stable vital signs, signs of regression of the motor block (Bromage 0-2), no analgesia within the previous 20 minutes and normal consciousness. The post-operative monitoring of the vitals of the patient, sensory and motor levels was continued in

the post-operative ward also. As the patients started feeling light touch on their legs, they were asked to ambulate without assistance. Once the patients started walking, attempt to void urine was encouraged.

Discharge from the hospital was suggested when the patient attained all the following criteria (discharge readiness criterion): complete regression of the block height (sensory level to S_2), ability to walk, ability to void (>200 ml), stable vital signs, no nausea, pain controlled with oral medications (last dose given at least one hour before discharge), and ability to tolerate liquids by mouth. The time to eligibility for discharge from the hospital was measured from the time spinal anesthesia was administered till the time patient attained the discharge readiness criteria.

The following data was recorded for the current study:

For sensory block: time to reach T_{10} level, peak block height and time to reach peak block, and time for complete regression to S_2 from peak block.

For motor block: the time taken to reach the score of 2, 3 and 0 was recorded. The Bromage score at the end of surgery was also noted.

In addition, duration of surgery, time to ambulate, time to void and time to reach eligibility for discharge criteria was also recorded.

Any occurrence of TNS, PDPH and back pain was assessed 24 hours and 7 days after surgery using a standardized telephone call questionnaire asking patients in yes or no about paresthesias or dysesthesias in lower limbs or buttocks, headache and pain in the back.

TABLE 1: MODIFIED BROMAGE SCALE

Grade	Limb movement
0	able to move hip, knee and ankle
1	able to move knee and ankle but not hip
2	able to move ankle only but not hip and knee
3	not able to move

STATISTICAL ANALYSIS

The data hence obtained was entered in Microsoft Excel 2016 and was analyzed using SPSS v 24.0. The continuous data was checked for its normality using Shapiro Wilks test. Univariate analysis was done to describe the data as frequencies, mean ± SD and median and interquartile range. Independent t-test was used to compare the means between two groups. All p-values reported were two-tailed and a p-value of <0.05 was considered statistically significant unless specified otherwise.

RESULTS

A total of 137 patients were assessed for eligibility, 29 patients were excluded as they did not meet the inclusion criterion, 8 patients didn't give consent to participate in the study. A total of 100 patients who participated in the study were randomly allocated into two groups. Both groups contained 50 patients. (FIGURE 1) 39(78%) patients in the 2-CP group were males and 11(22%) patients were females and 34(68) patients in the Bupivacaine group were males and 16 (32%) were females. There was no block failure, none of the patients required conversion to general anesthesia and no patient were lost during the follow-up. The patients were similar in terms of baseline demographics and the duration of surgery (TABLE 2)

The time of onset of sensory block and Time to reach Bromage 2 and Bromage 3 were comparable in both the groups. The highest level of sensory block (T7) and the time to reach the highest sensory block in both groups was comparable which was 14.56±4.08 minutes in the 2-CP group while 15.54±3.91 minutes in the Bupivacaine group.

The patients of both groups remained comparable hemodynamically. (FIGURE 2)

However, 2-Chloroprocaine showed a faster regression. The mean time taken to reach sensory regression to S_2 dermatome in the 2-CP group was about 51% of that of the Bupivacaine group (137.20 ± 23.21mins vs 270.00 ± 34.10 mins with a difference of

132.8 mins; p<0.05) (TABLE 3) The regression of motor block to Bromage 0 was 61% faster in 2-CP group than Bupivacaine group (79.40 ± 10.95 mins Vs 129.80 ± 17.31 mins; with a difference of 50.4 mins; p<0.05) (TABLE 3). The mean time taken to unassisted ambulation in 2-CP group was also quite less when compared to the Bupivacaine group (179.72 ± 17.30 mins Vs 256.52 ± 21.98 mins; with a difference of 76.8 mins; p<0.05). (TABLE 3) The patients in 2-CP group also micturated earlier than the Bupivacaine group (195.98 ± 15.69 mins Vs 304.74 ± 16.99 mins; with a difference of 108.8 mins; p<0.05). (TABLE 3)

Postoperative Nausea and Vomiting were experienced by 2% of patients (n=1) receiving 2-CP and 4% of patients (n=2) receiving Bupivacaine. The mean time taken to attain the discharge readiness criterion was less in 2-CP group than Bupivacaine group (195.98 ± 15.69 mins Vs 304.74 ± 16.99 mins; with a difference of 108.8 mins; p<0.05). PDPH was experienced by 2% patients (n=1) in 2-CP group and 4% patients (n=2) in Bupivacaine group (p>0.05). 32% patients (n=16) in 2-CP and 28% (n=14) in Bupivacaine group complained of

Backpain (p>0.05). No patient in any group complained of TNS.

TABLE 2: DEMOGRAPHIC DATA OF THE PATIENTS IN BOTH STUDY GROUPS

PARAMETER	2-Chloroprocaine (Mean ± SD) (n=50)	Bupivacaine (Mean ± SD) (n=50)	F statistics, P value
Age (yrs)	43.64 ± 13.62	41.84±12.54	F= 1.17, p=0.354
Height (cms)	169.52 ± 8.01	160.46 ± 3.62	F= 1.53, p= 0.15
Weight (kgs)	69.34 ± 8.73	65.90 ± 7.32	F= 1.17, p=0.33
Duration of surgery (mins)	47.90 ± 10.50	51.40 ± 8.80	F= 1.87, p= 0.14

TABLE 3: RECOVERY CHARACTERISTICS OF THE PATIENTS IN BOTH GROUPS.

PARAMETER	2-Chloroprocaine (n=50)	Bupivacaine (n=50)	F statistics, P value
Time to reach Bromage 3 (mins)	5.88 ± 1.71	8.80 ± 2.54	F=0.88, p=0.56
Time to reach-T10 (mins)	4.08 ± 1.10	6.14 ± 1.73	F=1.45, p=0.20
Peak sensory level	T7	T7	-
Time to reach peak sensory level	14.56 ± 4.08	15.54 ±3.91	F=0.97, p=0.50
Time to reach S2 dermatome (mins)	137.20 ± 23.21	270.00 ± 34.10	F=2.19, p=0.03*
Time to reach Bromage 0 (mins)	79.40 ± 10.95	129.80 ± 17.31	F=3.23, p=0.008*
Time to ambulate (mins)	179.72 ± 17.30	256.52 ± 21.98	F=2.73, p=0.02*
Time to micturate (mins)	195.98 ± 15.69	304.74 ± 16.99	F=8.88, p=0.00*
Time to discharge readiness (mins)	195.98 ± 15.69	304.74 ± 16.99	F=8.88, p=0.0*

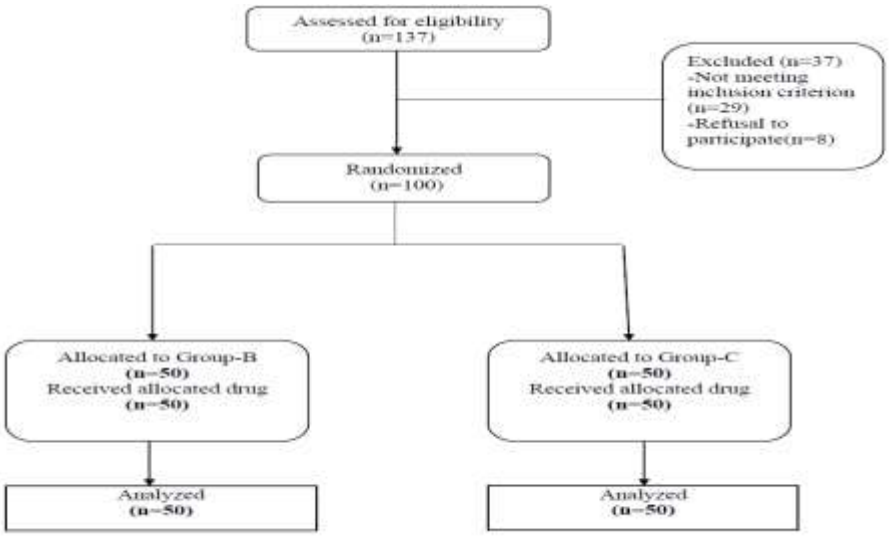

FIGURE 1: CONSORT DIAGRAM

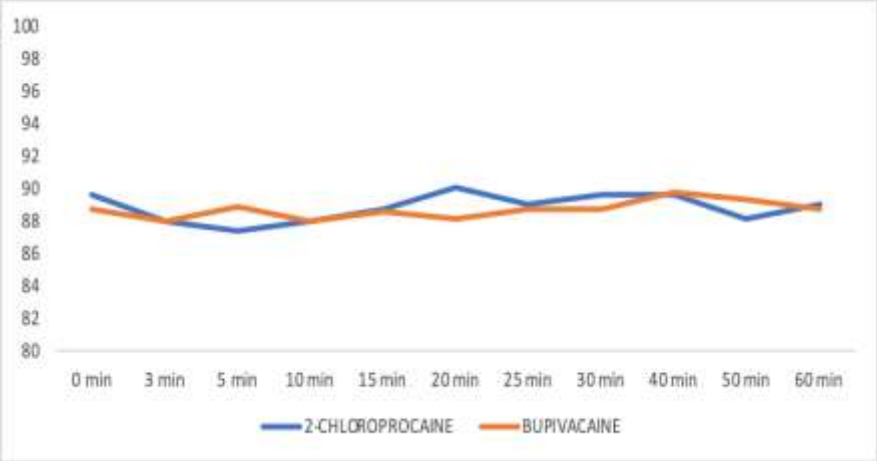

FIGURE 2: FIGURE SHOWING THE INTRA-OPERATIVE COMPARISON OF THE MEAN BLOOD PRESSURE OF THE PATIENTS IN TWO GROUPS AT DIFFERENT TIME INTERVALS.

DISCUSSION

The primary outcome of this study was to compare 2-CP and Bupivacaine with respect to time to attain eligibility for discharge. The mean time taken to attain the discharge readiness criterion in 2-Chloroprocaine group was 108.8 mins less than in Bupivacaine group. This can be explained due to the faster sensory and motor block regression and also a low incidence of urinary retention and postoperative nausea and vomiting with the use of 2-CP. Lacasse et al. used the equivalent doses of the drugs and found that the time to eligibility for discharge was 76 mins earlier in 2-CP group than Bupivacaine group($p<0.05$).[20] Tandan et al. in their study used the same doses and found that the patients in the 2-CP group attained eligibility to discharge 95 mins earlier than the Bupivacaine group ($p<0.05$).[21]

The regression of the sensory block was checked postoperatively and the time taken for regression of the sensory blockade to S_2 dermatome was noted by eliciting the anal reflex or by the ankle reflex (whichever is feasible). The mean time taken to reach sensory regression to S_2 dermatome in the 2-CP group was about half (51%) of that of Bupivacaine group. Lacasse MA et al. found that time taken for complete regression to S_2 dermatome with 2-CP was even less than half of Bupivacaine group(44%).[20] Yoos et al. found a difference of 78 mins between the 2-CP group and Bupivacaine group for complete regression of sensory block which was 1.7 times faster.[15] Our results were also in accordance with Tandan et al. who also found a faster sensory block regression with 2-CP than Bupivacaine.[21] However, our data cannot be directly compared to that of Lacasse et al. and Yoos et al. as they checked the sensory block using loss of cold sensation to ice and loss of pinprick sensation using dermatome tester respectively while we used the loss of sensation to pinprick with a blunt 25 G needle. Although pain and cold sensations both are transmitted via the same nerve fibers, there is a subtle distinction.

Postoperatively, the resolution of the motor blockade was monitored by asking the patient to move his lower limbs and the time taken to reach Bromage 0 was noted. The mean time taken for regression of motor block to Bromage 0 was 61% faster in the 2-CP group than the Bupivacaine group. Lacasse et al. found that the difference in time taken to reach Bromage 0 was 43 mins respectively in favor of 2-CP[20]. The faster offset of the block by 2-Chloroprocaine can be explained by its rapid plasma metabolization and shorter t1/2.

The mean time taken for unassisted ambulation in the 2-CP group was less than compared to the Bupivacaine group with a difference of 76.8 mins and the time to independent micturition (>200 ml) in the 2-CP group was 64% of that of the Bupivacaine group. Our results were in

accordance with that of Lacasse et al[20] and Yoos et al[15]. These studies demonstrated earlier micturition in the 2-CP group. Inability to void delayed the discharge in 18% of the patients after spinal anaesthesia.[22] A significant difference in the time to micturate was found between the two groups in favor of 2-CP favoring its early recovery. The Bupivacaine group showed a greater incidence of urinary retention even in patients who had achieved a good motor block regression. This may be explained that the micturition reflex returns in most patients on regression of the block to S3.[23] Also there was a great incidence of delayed voiding in the patients undergoing anorectal surgeries. It can be due to various factors including increased fluid administration and post-operative pain.[24].

PONV was experienced by 2% of patients in 2-CP and 4% patients in patients in the Bupivacaine group in accordance to the studies of Lacasse et al. and Casati et al.[20,25]

The median highest peak block achieved in both groups was T7 in our study inspite of using the different volumes of the study drugs i.e. 4 ml of 2-Chloroprocaine and 1.5 ml of Bupivacaine. It was also noted that the difference between the two groups in time to achieve peak sensory block was statistically insignificant. The different volume of drugs was used in an attempt to use the equivalent doses of the drugs. Nielsen et al had suggested that rather than the volume of the drug administered, total milligram dose of the local anesthetic has more influence on the cephalad spread of spinal blockade.[26]

CONCLUSION

The study conducted demonstrated that intrathecal 2-CP produced satisfactory block for surgeries lasting <60 minutes with a similar time of onset of sensory and motor block when compared to Bupivacaine. It has a better recovery profile with sooner sensory and motor recovery. The time to void, ambulate and time to attain discharge readiness was also shorter as compared to hyperbaric Bupivacaine. Hence, 2-Chloroprocaine is a better choice drug for spinal anesthesia as compared to Bupivacaine in ambulatory settings in infra-umbilical surgeries of duration <60 minutes.

Conflict of Interest: None

Ethical Approval: Approved

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