

Comparative study of spinal anaesthesia with bupivacaine versus 2 Chloroprocaine at a tertiary hospital

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Abstract

Background: Spinal anesthesia is a time tested, safe and reliable anesthetic technique for surgery of the lower abdomen and lower limbs. It is easy to administer, has rapid onset of action, low risk of infection and low failure rates. Present study was done to know efficacy and the readiness for discharge between 2 local anesthetics Bupivacaine and 2-Chloroprocaine, used for spinal anesthesia. **Material and Methods:** Present study was hospital based prospective randomized double-blind study conducted in patients of 18-60 years age, ASA grade 1 and 2, scheduled for elective ambulatory surgeries (for perineal surgery like haemorrhoidectomy, fistula in ano, rectal biopsy etc. or gynaecological procedure like check curettage, hysteroscopy etc.) of short duration (<60min). 60 patients were randomized by computer assisted table into 2 groups as Group B (receiving 10 mg 0.5% Bupivacaine Hydrochloride) and Group C (receiving 40 mg 1% 2- chloroprocaine) as drug for spinal anaesthesia. **Results:** There was no significant statistical difference in mean age, gender and ASA grade distribution amongst two groups. Difference in group B and C for mean time for onset of sensory block, mean time for onset of motor block, mean time to achieve maximum sensory block, mean duration of sensory block, mean duration of sensory block was statistically significant and favourable findings were noted in chloroprocaine group. The mean length of stay in group C was 1.20 ± 0.32 days and group B was 1.83 ± 0.41 days. There was significant difference in length of stay in two groups. ($p < 0.05$) The mean time to ambulation in group C was 225.23 ± 56.11 and group B was 265.18 ± 58.23 minutes. There was significant difference in time to ambulation in two groups. ($p < 0.05$) This shows that Group C patients get early ambulated with early discharge compared to Group B. **Conclusion:** Intrathecal 2% 2-Chloroprocaine has early and satisfactory onset of sensory and motor block, desired level of spinal block, satisfactory duration of sensory and motor block, haemodynamically more stable, with advantages of early ambulation and early discharge from the hospitals as compared to intrathecal Bupivacaine.

Keywords: Intrathecal, 2-Chloroprocaine, Bupivacaine, spinal anesthesia, short duration surgeries

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INTRODUCTION

Spinal anesthesia is a time tested, safe and reliable

anesthetic technique for surgery of the lower abdomen and lower limbs. It is easy to administer, has rapid onset of action, low risk of infection and low failure rates. An ideal spinal anesthetic for short duration surgeries should allow rapid onset and faster offset of its own effect for early patient discharge with minimal side effects.^{1,2} But, no local anesthetic can provide a block with rapid onset, predictable duration, good effectiveness and reliability, fast recovery, and lack of side effects.³ Attempts have been made to adapt hyperbaric bupivacaine, a long-acting local anesthetic, to the ambulatory setting by using smaller doses. However, the duration of the block remains prolonged with these smaller doses, and they may provide insufficient anesthesia.⁴ Urinary retention is frequently encountered

with bupivacaine, which delays the time until discharge for ambulatory patients.⁵ Then, 2-chloroprocaine exists in a preservative-free formulation and has been used in patients worldwide, without any neurotoxicity.^{6,7} The major advantage of 2-chloroprocaine is its shorter duration of action, adequate duration and density of block for short duration surgery; permitting a faster recovery from anesthesia and also permitting a faster discharge from hospital.^{8,9} Present study was done to know efficacy and the readiness for discharge between 2 local anesthetics Bupivacaine and 2-Chloroprocaine, used for spinal anesthesia.

MATERIAL AND METHODS

Present study was hospital based prospective randomized double-blind study conducted in Department of Anaesthesiology, Vilasrao Deshmukh Government Medical College, Latur, India. Study duration was of 18 months (1st January 2019 to 30th June 2020). Study was approved by institutional ethical committee.

Inclusion criteria: Patients of 18-60 years age, ASA grade 1 and 2, scheduled for elective ambulatory surgeries (for perineal surgery like haemorrhoidectomy, fistula in ano, rectal biopsy etc. or gynaecological procedure like check curettage, hysteroscopy etc.) of short duration (<60min), willing to participate in study.

Exclusion criteria: Patients with ASA grade 3 and 4. Patients allergic to or intolerance to chloroprocaine or Bupivacaine. Patients with contraindication to spinal anaesthesia (INR>1.3, Platelets <75000, use of anticoagulant drugs). Patients with neurological disease (multiple sclerosis, symptomatic lumbar herniated disc, spinal stenosis). Patients with fluids restriction (cardiac and renal insufficiency). 60 patients were randomized by computer assisted table into 2 groups of 30 subjects. Group B (bupivacaine) (n=30) receiving 10 mg 0.5% Bupivacaine Hydrochloride.

Group C (2-chloroprocaine) (n=30) receiving 40 mg 1% 2-

chloroprocaine

Preanesthetic checkup was done one day prior to the surgery. Patients were evaluated for any systemic diseases and laboratory investigations recorded. The procedure of spinal anaesthesia was explained to the patients and written consent was obtained.

All patients were fasted for at least six hours before the procedure. Once the patient was shifted to OT, IV access was secured with an 18G cannula and approximately 10ml/kg of crystalloids was infused. Monitors ECG, NIBP and Spo2 probe was connected. Baseline Heart rate, SBP, DBP, and Spo2 was measured. Patient was then put into sitting position and under aseptic precautions painting and draping was done. Then using a 25gauge Quincke Babcock spinal needle L3-L4 space was pierced using midline approach, free flow of cerebrospinal fluid was examined. According to their randomization, patient received an intrathecal injection of either 0.5% bupivacaine or a preservative and bisulfite-free formulation of 2% 2-CP. Oxygen 5 L/min was administered using a facemask. Evaluated the sensory and motor blocks every three minutes for 15 min, then every five minutes for 45 min, and then every ten minutes for 60 min, and finally every 15 min until the sensory block had regressed to the S2 dermatome. During surgery, the patient’s blood pressure (systolic and diastolic), electrocardiogram, and pulse oximetry was recorded. Readiness for surgery was defined as loss of cold sensation >T10.

Statistical analysis was done using descriptive statistics. Data was collected and compiled using Microsoft Excel, analysed using SPSS 23.0 version. Frequency, percentage, means and standard deviations (SD) was calculated for the continuous variables, while ratios and proportions were calculated for the categorical variables. Difference of proportions between qualitative variables were tested using chi-square test or Fisher exact test as applicable. P value less than 0.5 was considered as statistically significant.

RESULTS

There was no significant statistical difference in mean age, gender and ASA grade distribution amongst two groups

Table 1: Demographic profile

Characteristics	Group C (n=30) (%)	Group B (n=30) (%)	P Value
Mean age (years)	38.53 ±13.88	38.96 ±11.41	0.783
Gender			
Male	23	21	0.71
Female	07	09	
ASA			
I	18	21	0.42
II	12	09	

Vital characteristics such as heart rate, systolic blood pressure, diastolic blood pressure, O2 saturation, mean arterial pressure were measured at baseline, at 0,3,5,10,15,20,25,30,45,60, 90,120,150,180 and 240 minutes after spinal anaesthesia, and difference between Group C and Group B was statistically non-significant The mean time for onset of sensory block was found to be 4.13 ±1.32 seconds in group C while 4.57 ±1.46 seconds in group B. The difference in mean

time for onset of sensory block was statistically significant. The mean time for onset of motor block was found to be 5.13 ± 0.58 seconds in group C while 5.63 ± 0.92 seconds in group B. The difference in mean time for onset of motor block was statistically significant. ($P < 0.5$) The mean time to achieve maximum sensory block was found to be 12.03 ± 3.12 minutes in group C while 13.19 ± 3.41 minutes in group B. The difference in mean to achieve maximum sensory block was statistically significant. ($P < 0.05$) The mean duration of sensory block was found to be 153.03 ± 19.19 minutes in group C while 194.16 ± 21.43 minutes in group B. The difference in mean duration of sensory block was statistically highly significant. ($P < 0.0001$) The mean duration of motor block was found to be 169.26 ± 19.38 minutes in group C while 197.18 ± 21.78 minutes in group B. The difference in mean duration of motor block was statistically highly significant. ($P < 0.0001$)

Table 2: Anaesthesia characteristics

Parameters	Group C	Group B	P value	
Onset of Sensory block (sec)	4.13 ± 1.32	4.57 ± 1.46	0.02	Significant
Onset of motor block (sec)	5.13 ± 0.58	5.63 ± 0.92	0.02	Significant
Time to achieve maximum sensory block (minutes)	12.03 ± 3.12	13.19 ± 3.41	0.01	Significant
Duration of sensory block (minutes)	153.03 ± 19.19	194.16 ± 21.43	< 0.0001	Highly Significant
Duration of motor block (min)	169.26 ± 19.38	197.18 ± 21.78	< 0.0001	Highly Significant

Out of total 60 patients, it was observed that maximum level of sensory block reached was T6; 16 (53.33%) and 14 (46.67%) patients among Group C and Group B respectively. There was no difference in level of sensory block when two groups were compared statistically. ($p > 0.05$).

Table 3: Maximum level of sensory block :

Level	Group C	Group B	P value
T4	08	06	$X^2=1.44$;
T6	16	14	DF=3;
T8	05	08	$P=0.69^*$
T10	01	02	

($P > 0.05$ Statistically Not Significant)

Out of total 60 patients, it was observed that maximum intensity of motor block was Bromage 3; 28 (93.33%) and 30 (96.67%) patients among Group R and Group B respectively. There was statistically no significant difference in intensity of motor blockade when two groups were compared. ($p > 0.05$)

Table 4: Intensity of motor blockade:

Intensity	Group C	Group B	P value
Bromage 1	00	00	$X^2=1.07$; DF=2;
Bromage 2	02	0	$P=0.31^*$
Bromage 3	28	30	

($P > 0.05$ Statistically Not Significant)

Out of total 60 patients, there were 5 (8.33%) patients with back pain. 2 from group C (6.67%) and 3 from group B (10%). There was no difference when two groups were compared statistically for complications. ($p > 0.05$)

Table 5: Complications

Complication	Group C (n=30)	Group B (n=30)	Total
Headache	01	01	02
Transient neurologic symptoms	01	01	02
Back Pain	02	03	05

The mean length of stay in group C was 1.20 ± 0.32 days and group B was 1.83 ± 0.41 days. There was significant difference in length of stay in two groups. ($p < 0.05$) The mean time to ambulation in group C was 225.23 ± 56.11 and group B was 265.18 ± 58.23 minutes. There was significant difference in time to ambulation in two groups. ($p < 0.05$) This shows that Group C patients get early ambulated with early discharge compared to Group B.

Table 6: Hospital stay among various groups

Stay	Group C (n=30)	Group B (n=30)	P value
Length of stay	1.20 ± 0.32	1.83 ± 0.41	< 0.05 (S)
Time to ambulation (min)	225.23 ± 56.11	265.18 ± 58.23	< 0.05 (S)

DISCUSSION

Relief of pain during surgery and postoperative period is one of the mainstays of balanced anaesthesia. Spinal anaesthesia remains one of the basic techniques in modern anaesthesia despite variable popularity over many years since its introduction into clinical practice. Various drugs have been tried in subarachnoid block along with local anaesthetics with the aim of improving the quality of intra operative and postoperative pain relief. Spinal anaesthesia has been widely used for urologic operations because it permits early recognition of symptoms caused by over hydration, transurethral resection syndrome, and bladder perforation. Bupivacaine is a long-acting local anesthetic, to the ambulatory setting by using smaller doses. However, the duration of the block remains prolonged with these smaller doses, and they may provide insufficient anaesthesia. The major advantage of 2-chloroprocaine is its shorter duration of action, adequate duration and density of block for short duration surgery; permitting a faster recovery from anaesthesia and also permitting a faster discharge from hospital. Demographic characters (age, sex, ASA grading) were comparable in all two groups. There was no statistically significant difference ($p > 0.05$) amongst them. Similar findings were noted by Marie Andre'e Lacasse *et al.*,¹⁰ Ben Gys *et al.*,¹¹ and C Camponovo *et al.*,¹² In a study done by Ben Gys *et al.*,¹¹ observed statistically significant difference in the onset time of sensory block in both groups, which was 10.8 min in the C group and 11.1 min in B group. Similar findings were noted in present study while C Camponovo *et al.*,¹² observed no statistically significant difference in the onset time of sensory block in both groups. This was contrast to present study. In our study, the mean time for onset of motor block was found to be 5.13 ± 0.58 seconds in group C while 5.63 ± 0.92 seconds in group B. The difference in mean time for onset of motor block was statistically significant. ($P < 0.05$). C Camponovo *et al.*,¹² study showed Group C showed faster onsets of motor block (5 vs. 6 min), than Group B with statistically significant difference. In An Teunkens *et al.*,¹³ study chloroprocaine group had a significantly shorter time for onset of motor block compared to bupivacaine group. The mean duration of sensory block was found to be 153.03 ± 19.19 minutes in group C while 194.16 ± 21.43 minutes in group B. The difference in mean duration of sensory block was statistically highly significant. ($P < 0.0001$) Similarly, in Ben Gys *et al.*,¹¹ study observed the median duration of sensory block at the T₁₀ dermatome was significantly longer in B group (5.3 hours) compared with (2.8 hours) in the C group. ($p < 0.05$) In a study by Marie-Andre'e Lacasse.,¹⁰ reported that duration of sensory block in the 2-CP group was less than half that of the bupivacaine group (146 min vs 329 min, respectively, a difference of 185 min;

$P < 0.001$) C Camponovo *et al.*,¹² study showed Group C showed faster resolution of sensory (105 vs. 225 min) blocks with statistically significant difference. In An Teunkens *et al.*,¹³ study chloroprocaine group had a significantly shorter time until recovery from sensory block (median, 2.6 hours) than patients in the bupivacaine group (6.1 hours; $P < 0.0001$). The mean duration of motor block was found to be 169.26 ± 19.38 minutes in group C while 197.18 ± 21.78 minutes in group B. The difference in mean duration of motor block was statistically highly significant. ($P < 0.0001$) C Camponovo *et al.*,¹² study showed Group C showed faster onsets of motor block (5 vs. 6 min), maximum sensory block level (8.5 vs. 14 min), resolution of sensory (105 vs. 225 min) and motor (100 vs. 210 min) blocks. Yoos *et al.*,⁹ observed time to complete motor block regression was significantly longer with Bupivacaine compared to chloroprocaine group. In a study by Marie-Andre'e Lacasse.,¹⁰ reported that the duration of the motor block was significantly shorter in the 2-CP group. In the study, out of total 60 patients, there were 5 (8.33%) patients with back pain. There was no difference when two groups were compared statistically for complications. ($p > 0.05$) Similar findings were seen in a study done by Marie-Andre'e Lacasse *et al.*,¹⁰ and Ben Gys *et al.*,¹¹ In study done by Marie-Andre'e Lacasse *et al.*,¹⁰ they observed that in terms of discharge criteria, the time to ambulation, micturition, and eligibility for discharge were all significantly shorter in the 2-CP group. Yoos *et al.*,⁹ designed double-blind, randomized, crossover, volunteer study to compare 40 mg of 2-CP with small-dose (7.5 mg) bupivacaine observed time to simulated discharge was significantly longer with bupivacaine.

CONCLUSION

Intrathecal 2% 2-Chloroprocaine has early and satisfactory onset of sensory and motor block, desired level of spinal block, satisfactory duration of sensory and motor block, haemodynamically more stable, with advantages of early ambulation and early discharge from the hospitals as compared to intrathecal Bupivacaine. Considering all of the above advantages, the 2% 2-Chloroprocaine is recommended for spinal anaesthesia in patients posted for short or ultra-short duration procedures.

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