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A CLINICAL COMPARATIVE STUDY OF TWO DIFFERENT DOSES,35MG AND 45MG OF 1% CHLOROPROCAINE IN PATIENTS UNDERGOING LOWER ABDOMINAL, PERINEAL AND LOWER LIMB SURGERIES UNDER SPINAL ANESTHESIA

Anaesthesiology

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ABSTRACT

Background: The introduction of short-acting local anesthetic agents such as chloroprocaine permits rapid onset of spinal anesthesia for short-duration day-care surgery, offering the advantage of early home discharge. Our study is to compare two different doses, 35mg and 45mg of 1% 2-chloroprocaine in patients undergoing lower abdominal, perineal, and lower limb surgeries under spinal anesthesia. **Methods:** A prospective randomized controlled study with 100 patients belonging to ASA I and ASA II patients scheduled for elective lower abdominal, lower limb, and perianal surgeries were selected randomly and divided into two groups of 50 each. Group A received 1% chloroprocaine 35mg intrathecally and Group B received 45mg intrathecally. Onset and duration of sensory blockade, Onset, and duration of motor blockade, the highest level of sensory blockade, time for two-segment regression, quality of intraoperative analgesia, hemodynamic parameters, side effects or complications if any were studied **Results:** The mean time of onset of peak sensory level was 6.74+/- 1.367 and 5.20+/- 1.212 for 2-chloroprocaine 35mg and 45mg respectively. The duration of sensory block achieved with 35mg chloroprocaine was 74.34 +/- 2.639 min and 103.54+/- 5.292 min in the 45mg group. The duration in motor blockade was proportional to the volume of drug injected and was found to be 75.96+/-3.29 min and 95.56+/- 3.92 min in groups A and B respectively. All the patients in both groups achieved a complete degree of motor blockade. The highest level of sensory block achieved in both groups was T6. The time for two-segment regression of sensory block was found to be 44.32+/-2.706 min and 54.16+/- 3.119 min with 35mg and 45mg chloroprocaine respectively. No significant hemodynamic alteration or complications were noticed. **Conclusion:** 2-CP can be used as an excellent drug for spinal anesthesia in ambulatory surgeries. The duration of spinal anesthesia, time to resolution of spinal block, and time to recovery of ambulation were dose-related. The dose of 1% 2-chloroprocaine can be titrated according to the desired level and duration of sensory and motor blockade.

KEYWORDS

Spinal anesthesia, 2-chloroprocaine, intrathecal, ambulatory surgery

INTRODUCTION

Spinal anesthesia was first introduced into clinical practice by Karl August Bier in 1898 by injecting cocaine into the cerebrospinal fluid of a patient1. Spinal anesthesia is defined as 'the regional anesthesia obtained by blocking nerves in the subarachnoid space' and is a popular and common technique worldwide. The advantages of an awake patient, simple to perform, rapid onset of action, minimal drug cost, minimal stress response, relatively fewer side effects, and rapid patient turnover have made this the method choice of anesthesia for many surgical procedures.

In the last few years, the number of surgical procedures based on an ambulatory basis has increased throughout the world.2. Some of the characteristics of currently used local anesthetics may limit their use for ambulatory surgery, including risk of urinary retention, delayed ambulation, and prolonged hospital stay.3. Therefore, the choice of the correct local anesthetic for spinal anesthesia is crucial in the ambulatory setting. In the last few years, the number of surgical procedures based on an ambulatory basis has increased throughout the world.2. Some of the characteristics of currently used local anesthetics may limit their use for ambulatory surgery, including risk of urinary retention, delayed ambulation, and prolonged hospital stay.3. Therefore, the choice of the correct local anesthetic for spinal anesthesia is crucial in the ambulatory setting.

The recent introduction of short-acting local anesthetic agents such as chloroprocaine permits rapid onset of spinal anesthesia for short-duration day-care surgery and provides an early recovery profile, offering the advantage of early home discharge.4.

This study is designed to compare the two doses of 1 % chloroprocaine- 35mg and 45 mg- on duration and recovery of sensory and motor block, quality of analgesia, its effects on hemodynamics, and side effects.

METHODOLOGY

This was a prospective randomized comparative clinical study conducted on 100 adult patients of American Society Of Anesthesiologists (ASA) physical status I & II in the age group of 18 years to 60 years, of either sex, posted for elective lower limb, lower abdominal and perineal surgeries under spinal anesthesia after taking informed consent, over 24 months in a tertiary care center. After approval from the hospital's ethical committee, a comparative study was carried out on 100 adult patients. Patients were randomly divided on an alternative basis into two groups of 50 each- group A: 1% chloroprocaine 35mg and group B: 1% chloroprocaine 45mg. The inclusion criteria for the study were male/female adolescent patients scheduled for surgical procedures of lower abdominal, perineal, and lower limb surgery under spinal anesthesia, age 18-60 years, ASA physical status I & II, Body Mass Index (BMI) between 18 and 32 kg/m2, Patients giving valid informed consent, ability to comprehend the full nature and purpose of the study, including possible risks and side effects, ability to co-operate and comply with the requirements of the entire study. The exclusion criteria were patient refusal, pregnancy, contraindications to spinal anesthesia, history of neuromuscular diseases to the lower extremities, ASA physical status III-V, allergy: ascertained or presumptive hypersensitivity to the active principle and/or formulations ingredients, diseases: ascertained psychiatric and neurological diseases, drug: history of drug abuse, therapeutic use of opioids, bleeding coagulopathy. Pre-anesthetic checkup was carried out with a detailed history, general physical examination, and systemic examination. Airway assessment and spinal column examination were done. The following laboratory examinations were done - hemoglobin, urine analysis, blood sugar, blood urea, serum creatinine, coagulation profile, blood grouping and Rh typing, electrocardiogram, and chest x-ray.

Preoperatively, the patient's informed written consent was taken. Nil per oral status was confirmed. The procedure of subarachnoid block was explained and the patient was informed to communicate to the anesthesiologists about perception of pain or discomfort during the surgery. The patient was shifted to the operation table, intravenous(IV) access was obtained on the forearm with an 18 gauge cannula and a lactated ringer's solution of 10 ml/kg was infused intravenously before the block. The monitors that were connected to the patient included noninvasive bp, and oxygen saturation using a pulse oximeter. Baseline pulse rate, blood pressure, respiratory rate, and spo2 were recorded. Under strict aseptic precautions, lumbar puncture was performed in the left lateral or sitting position by midline approach by using a disposable Quincke's spinal needle (23 G) at L3-L4 intervertebral space. The study drug was administered over 30 seconds. After the spinal block, pulse rate, respiratory rate, and noninvasive blood pressure were measured at 0,5,10,15,20,25,30,45, 60,90,120,180 min. Patients were monitored continuously using non-invasive blood pressure, pulse oximeter, and electrocardiogram. After

giving spinal anesthesia, oxygen (4l/min) by facemask was given. Fluid therapy was maintained with lactated ringer's solution (10ml/kg/hr). Hypotension was defined as a 20% decrease in blood pressure from baseline values and was treated with intravenous fluids and incremental IV boluses of ephedrine 5 mg. Bradycardia was defined pulse rate of less than 60bpm and treated with IV Atropine 0.6mg.

The onset of sensory block was tested by pin-prick method using a hypodermic needle. The time of onset was taken from the time of injection of the drug into subarachnoid space to loss of pinprick sensation. The highest level of sensory block and the time required to achieve it were noted. The time for two dermatomal segments regression of sensory level was noted. The duration of sensory blockade was taken as time from onset to time of the return of pinprick sensation to the s1 (heel) dermatomal area. The requirement of any supplemental analgesics intraoperatively was noted. Motor blockade was assessed by the Bromage scale*. The time interval between the injection of the drug into subarachnoid space, to the patient's inability to lift the straight extended leg was taken as onset time. The duration of the motor block was taken from the time of injection to the complete regression of the motor block. The quality of intraoperative analgesia was assessed on a four-point modified Belzarena scale. Postoperatively, monitoring of vital signs was continued every 30 minutes until the time of regression of sensory block to L1 dermatome. Side effects like sedation, nausea, vomiting urinary retention were monitored in the recovery room and then shifted to the ward. A neurological examination was done to rule out any neurological deficits at discharge.

Statistical Methods

The demographic data were analyzed using either the student's t-test or the chi-square test. Quantitative data was analyzed by student's t-test and qualitative data was analyzed by chi-square test. Mann Whitney U test has been used to find the significance between two groups for parameters on the non-interval scale. All values were expressed as mean ± standard deviation. $P < 0.05$ was considered statistically significant. The statistical software namely sas 9.2, spss 15.0, Stata 10.1, medcalc 9.0.1, and systat 12.0 were used for the analysis of the data and Microsoft Word and Excel were used to generate graphs, tables, etc

RESULTS AND OBSERVATION

The mean age of the patient in group A was 31.16+/- 7.56 and in group B was 32.66+/- 7.91. In Group A there were 39 males and 11 females and in Group B, there were 36 males and 14 females. The mean height of the patients in group A was 6.35+/- 0.45 feet and in group B was 5.59+/- 0.28 feet. The mean weight of the patients in group A was 63.14+/- 6.10 kg and in group B was 59.84+/- 5.94 kg (ABLE-1) There was no statistically significant difference between the two groups with regards to age, sex, height, and weight (p >0.05) and the samples were age, sex, height, and weight-matched.

Table 1: General Characteristic Of Study Population

		GROUP A	GROUP B
AGE		31.16	32.66
HEIGHT(Ft)		6.35	5.59
WEIGHT(Kg)		63.14	59.84
GENDER	MALE	39	36
	FEMALE	11	14

The mean onset of sensory block for group A is 6.74 +/- 1.367 minutes and that of group B is 5.20 +/- 1.212 minutes with a p-value of <0.05, which is statistically significant. The highest sensory blockade levels achieved in groups A and B were T6.

The time for two-segment regression of sensory block was 44.32 +/- 2.706 minutes in group A and in group B, it was 54.16+/- 3.119 minutes, which is statistically significant(TABLE 2). In group A, the mean time taken for complete sensory recovery was 74.34+/-2.639 minutes, and in group B it was 103.54 +/-5.292 minutes with a p-value of <0.05. The mean onset of the duration of motor blockade for group A was 10.18 +/- 1.987 minutes and for group B it was 8.68 +/- 1.096 minutes with a p-value of <0.05, which is statistically significant. A complete degree of motor blockade was seen in all patients of both groups. This was clinically and statistically not significant. In group A, the mean duration for motor blockade was 75.96+/-3.29 minutes, and in group B it was 95.56 +/-3.92minutes with p p-value of <0.05 which is statistically significant. Two out of the 50 patients in group A felt discomfort in the surgery requiring sedation and 1 patient, who underwent appendicectomy had pain over the surgical site, which was tolerable with additional analgesics. All patients in group B had adequate quality of intraoperative analgesia without any requirement of analgesics. Nausea was seen in 1 patient in both groups A and B. Hypotension was seen in a patient in group A and 3 patients in group b. No case of allergy or respiratory depression was seen in both groups. There was no clinical or statistical significance in the incidence of side effects in both groups.

Table 2: Study Findings

		Group A	Group B	P Value
Onset Of Sensory Block		6.74 min	5.20 min	<0.05
Maximum Level Of Sensory Block	T6	3	32	>0.05
	T8	14	13	
	T10	33	5	
Time To 2-segment Regression		44.32 min	54.16 min	<0.05
Time To Complete Sensory Regression		74.34min	103.54 min	<0.05
Onset Of Motor Block		10.18min	8.68 min	<0.05
Duration Of Motor Block		75.96	95.56	<0.05
Degree Of Motor Blockade (bromage Scale)		Grade 3	Grade 3	

DISCUSSION

Spinal anesthesia is a reliable and commonly employed anesthetic technique for the lower abdominal, perianal, and lower limbs. The technique is simple, inexpensive, and easy to administer technique.5. Nevertheless, some of its characteristics may limit its use for ambulatory surgery including delayed ambulation, risk of urinary retention, and pain after the block regression. Therefore, the correct local anesthetic for spinal anesthesia is crucial in ambulatory settings. Chloroprocaine is an amino ester local anesthetic with a very short half-life.

In our study, a major proportion of the patients were middle-aged in both groups. The mean weight and height in both groups were also identical. These parameters were kept identical in both groups to avoid variations in the intraoperative and postoperative outcomes of the patients. The subarachnoid block was administered under all aseptic precautions. 1% chloroprocaine solution was injected according to the doses, already mentioned above. The onset of sensory block was assessed using the pinprick method at the highest dermatome level in both groups. The time of onset of peak sensory level was shorter in the 45mg group. The faster onset of action can be interpreted as the volume of drug used; as the volume of a drug is inversely proportional to the onset of action of the drug in the subarachnoid block. The time required for the onset of a complete motor blockade was studied using the modified Bromage scale. The mean values observed in the study were 10.18 +/-1.987 minutes in group A and 8.68 +/-1.096 minutes in group B. All the patients in our study achieved a complete degree of motor blockade. The above observation was per the study done by Cassati et al6 who compared 3 different doses of chloroprocaine 30mg,40mg, and 50mg in spinal anesthesia and found that the onset of sensory and motor blockade is dose-related. The result of our study was comparable with a study done by Yoos and Kopacz7, in which they obtained the onset of the complete motor blockade at 10 minutes for 40mg chloroprocaine. Regarding the highest level of sensory block achieved, in both groups, it was T6, with 6% of patients in group A and 64% of group B patients achieving it. 66% of patients in group A achieved a sensory block level of T10. More patients achieving the highest sensory level with chloroprocaine 45 mg can be attributed to the increased amount of volume of drug administered in the subarachnoid space. This observation was comparable to the study done by Yoos and Kopacz7, in which they achieved a level of T6 and T9 with 40 mg and 30 mg of chloroprocaine respectively. The above observations help to prove that the dose of local anesthetic drug injected into the subarachnoid space; is one of the key factors determining the level of sensory blockade. The other factors that influence the level of the block are age, height, and position of the patient, the site of injection, the direction of the spinal needle, the rate of injection, barbotage, the CSF volume, and the baricity of the solution8,9.

The time for two-segment regression of sensory block was found to be 44.32+/-2.706 min and 54.16+/- 3.119 min in group A and group B respectively. This was comparable to the study conducted by Forster et

al4 in which the time for two-segment regression for chloroprocaine 40mg was 52 min(45-60 min). Another study done by Gonter and Kopacz10 comparing the effect of chloroprocaine and procaine in spinal anesthesia found that the time for two-segment regression of chloroprocaine 30mg was 37+/-16 min. In our study, the duration of sensory block in group A was 74.34 +/- 2.639 min, and in group, B was 103.54+/- 5.292 min. The duration of the motor blockade was proportional to the volume of the drug injected. In our study, it was found to be 75.96+/-3.29 min and 95.56+/- 3.92 min in group A and group B respectively. The above findings are in relationship with the study done by Casati et al6 in which he compares the three different doses of chloroprocaine in spinal anesthesia and found out that spinal block resolution and time to recovery of ambulation results were dose-related. Another study done by Sell et al11 tested four different doses of spinal chloroprocaine (35, 40, 45, and 50 mg) in a cohort of 64 patients scheduled for elective lower extremity procedures. The regression of sensory block and time to discharge was faster in the lower dose groups (35 and 40 mg), although the higher level blocked and time to complete block regression were comparable in all four groups.

The quality of intraoperative analgesia was satisfactory in all patients in group B, but 1 patient who underwent appendicectomy in group A required additional analgesics for pain relief over the surgical site towards the end of surgery. This may be due to the early regression of sensory block in this patient. The above findings were from the study conducted by Casati et al.6, in which they found that 33% of patients undergoing procedures lasting between 45 and 60 minutes with low-dose chloroprocaine required intraoperative analgesic supplementation as a result of insufficient analgesia. They concluded that the spinal block resolution was dose-related.

In our study hypotension occurred in 2% of patients in Group A and 6% of patients in Group B and was managed by intravenous ephedrine boluses. The hemodynamic parameters like respiratory rate, pulse rate, and systolic and diastolic blood pressure were comparable between the two groups, and no significant hemodynamic alteration was seen in the two groups. This study correlates with Vaghadi et al12, Lacasse et al13, and Sell et al11 studies. Incidence of nausea and vomiting were seen and were comparable with both study groups. They responded to IV ondansetron 4mg, oxygenation, and restoration of blood pressure. No incidence of transient neurologic symptoms or allergic reactions was seen.

CONCLUSION

We concluded from our study that 1% 2-chloroprocaine provides adequate spinal anesthesia when administered intrathecally. The duration of spinal anesthesia, time to resolution of spinal block, and time to recovery of ambulation were dose-related. Chloroprocaine can be used as an excellent drug for spinal anesthesia in ambulatory surgeries of the lower limb, lower abdominal, and perineal region. The dose of 1% 2-chloroprocaine can be titrated according to the level and duration of sensory and motor blockade desired, using the minimum amount of drug necessary.

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