ORIGINAL ARTICLE ASIAN JOURNAL OF MEDICAL SCIENCES

Comparison of 2 doses of 1% 2-chloroprocaine as spinal anesthetic for perineal and lower-limb surgeries

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Submission: 20-09-2023 Revision: 28-11-2023 Publication: 01-01-2024

ABSTRACT

Background: Spinal anesthesia is a commonly employed anesthetic technique for infraumbilical surgeries. Some of its properties may limit its use for ambulatory surgery. For outpatient surgery, lignocaine was anesthetic of choice for years, but its use has been associated with significant risk. Short-acting local anesthetic may therefore represent a valid alternative in this setting. **Aims and Objectives:** We compare the duration of action of sensory and motor block with 40 mg and 50 mg preservative-free 1% 2-chloroprocaine (2-CP), as a subarachnoid block. **Materials and Methods:** Patients posted for surgery were randomized to two groups A and B with 64 patients in each group to whom, 40 mg and 50 mg preservative-free 1% 2-CP was administered as spinal anesthesia, respectively. After completion of spinal injection onset time, evolution of sensory and motor block and vitals were studied. **Results:** The median onset time was 4 min for both 40 mg and 50 mg 1% 2-CP. The duration of sensory block with 40 mg 2-CP was 117 (74–168) and with 50 mg 2-CP was 148 (116–176) min. The duration of motor block with 40 mg 2-CP was 104 (60–150) and with 50 mg 2-CP was 134 (106–158) min. In terms of hemodynamic parameters and adverse effects, there was no statistically significant difference found between both groups. **Conclusion:** Our study revealed that 40 mg of 1% 2-CP produces a satisfactory surgical block for procedures lasting <90 min. When compared with 1% 2-CP 50 mg, it resulted in comparable onset of action, with significantly faster regression of the block, shorter time to ambulation.

Key words: 2 chloroprocaine; Spinal anesthesia; Ambulatory surgery

Access this article online

Website: http://nepjol.info/index.php/AJMS

DOI: 10.3126/ajms.v15i1.58685

E-ISSN: 2091-0576

P-ISSN: 2467-9100

INTRODUCTION

Spinal anesthesia is one of the most popular techniques for both elective and emergency surgical procedures, particularly cesarean sections, lower abdominal surgeries, orthopedic lower-limb surgeries, and urological surgeries just to name a few.[1]

The advantages of subarachnoid block are limited by its short duration of action and side effects such as hypotension and bradycardia, due to sympathetic blockade. The choice of correct local anesthetic (LA) for spinal anesthesia is therefore crucial in ambulatory settings.[2] In the past, two LAs were mainly used for intrathecal injection; for inpatient surgery, bupivacaine was used, which is long-acting LA; and for outpatient surgery, 5% hyperbaric lignocaine was anesthetic of choice for years; it is a short acting LA[1] but its use has been associated with a significant risk of transient neurological symptoms (TNS), and therefore, it is no more used.[3,4]

This made this study more important. Short-acting LA may therefore represent a valid alternative in this setting.[5-7]

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The recently re-introduction of intrathecal articaine, chloroprocaine (CP), and prilocaine may offer a solution in ambulatory settings, with a slightly faster profile for CP.[8]

1% isobaric 2-CP introduced recently was successful as day-care spinal anesthetic drug, as the action of it wears of completely within 2–3 h, so that the patient can go home by walking.[5,9] The recommended dose is 50 mg for the adult and is available as 1% solution, 5 mL ampoule,[8] which when used produces good analgesia, muscle relaxation, and quick in onset, wears of within 2–3 h. However, the disadvantage is profound hypotension. To overcome this, we can reduce the dose to 40 mg. The present study is undertaken to know whether 40 mg of 1% CP will produce the same desired effects with less hypotension. We compared the duration of sensory and motor block with 40 mg and 50 mg preservative-free 2-CP, in the subarachnoid block.

Aims and objectives

- To compare the duration of sensory and motor block with 40 mg and 50 mg preservative free 2- CP, in subarachnoid block.
- To study hemodynamic changes of drug till regression of block.

MATERIALS AND METHODS

This quasi-experimental study was conducted in Yenepoya Medical College Hospital Mangalore, Karnataka, India, from October 2017 to October 2019. This study was conducted after Institutional Ethical Committee clearance (YUEC/388/2017). Study allotment was done as per consolidated standards of reporting trials flow diagram (Figure 1).

Sample size

The formula used to calculate the sample size based on Casati et al.[10] was:

$$N = \frac{(r+1)(Z_{\alpha/2} + Z_{1-\beta})^2 \sigma^2}{rd^2}$$

Zα is 1.96 for 5% level of significance.
Z1-β=1-β% power with β% of type II error (0.84 at 80% power).
r=n1/n2 is the ratio of sample size required for 2 groups.

σ and d are the pooled standard deviation and difference of means of 2 groups.

Therefore, to calculate the sample size, a power analysis (0.05 and 0.80) showed that 64 patients per study group were needed.

128 patients were randomly allocated by closed envelope method into two groups of 64 each in which:

Group A receives 40 mg preservative-free 2-CP.

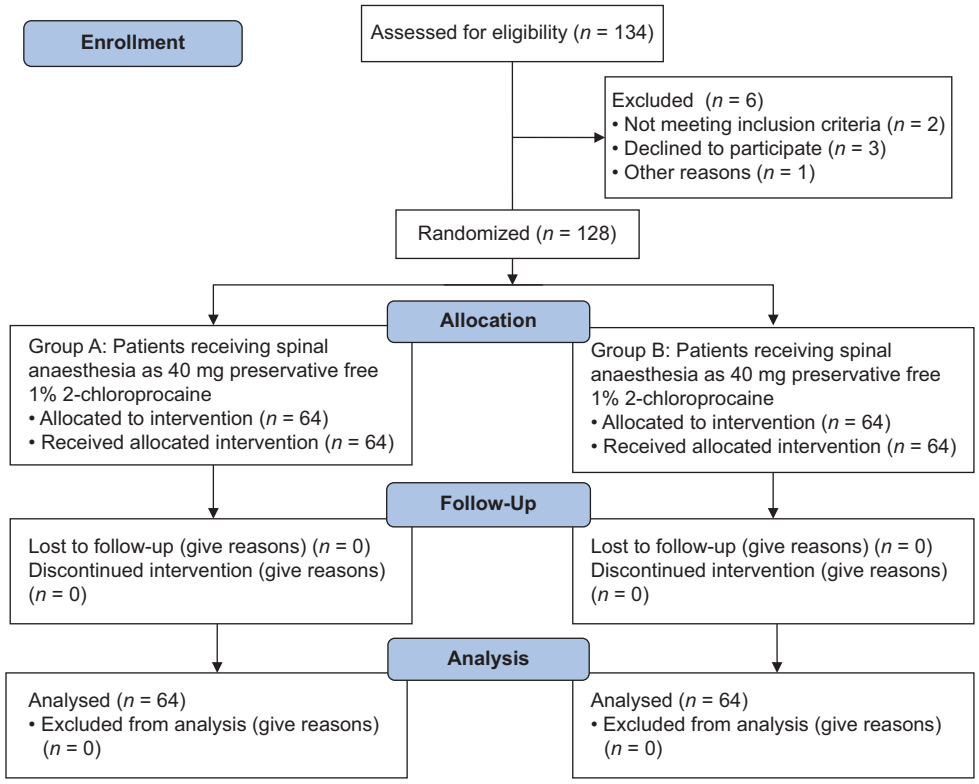

Figure 1: Consolidated standards of reporting trials flow diagram

Group B receives 50 mg preservative-free 2-CP.

Methods

Inclusion criteria

- Patients undergoing perineal and lower-limb surgeries under spinal anesthesia
- American Society of Anesthesiology (ASA) Grades 1 and 2 patients
- Both males and females between age 20 and 60 years
- Duration of surgery <1 h.

Exclusion criteria

- Known allergy to LAs
- Patients having absolute contraindication for spinal anesthesia such as raised intracranial pressure, severe hypovolemic, bleeding diathesis, and local infection
- Patients not willing for the study
- Disturbance of autonomic function
- Pregnant patients
- Obese patients body mass index (BMI) >30
- Height <145 cm.

Source of data

Patients were admitted for perineal and lower abdominal procedures in a Medical College hospital, where spinal anesthesia is the routine procedure preferred.

After informed consent, patients belonging to ASA Grades 1 and 2, aged between 20 and 60 years, scheduled for elective perineal and lower-limb procedures under spinal anesthesia were selected by simple randomized sampling.

Written informed consent was taken from the patient after explaining the procedure to the patient in their own language. Pre-anesthetic check-up was done with necessary investigations. Patients were enquired about previous drug allergies.

Routine pre-medications were given: Tablet ranitidine 150 mg HS and in the morning of surgery and tablet alprazolam 0.25 mg, a night before the day of surgery. Intraoperative 18 gauge IV line was secured.

Both group patients were preloaded with 10 mL/kg of ringer's lactate solution over 10–20 min period.

Routine monitors were connected such as non-invasive blood pressure, pulse oximeter, and electrocardiogram. Baseline readings of heart rate, blood pressure, and oxygen saturation were recorded.

Standard premedication was given (intravenous [IV] injection fentanyl 1 mcg/kg body weight).

Spinal anesthesia was performed at L2-L3 or L3-L4 interspaces with patient in the left lateral position using midline approach. Tuffier's line as landmark, using 25-gauge Quincke's spinal needle, dura was pierced. The presence of cerebrospinal fluid was noted and drug was given according to group. Supplemental oxygen was given at 4 L/min.

After spinal injection, patients were turned back to the supine position, and all patients were evaluated for sensory and motor blocks every 3 min until readiness to surgery, then every 5 min until maximum level of sensory block reached. Further assessment was performed every 15 min for the first 60 min and every 10 min until ambulation. Simultaneously, systolic and diastolic blood pressure, mean arterial values, heart rate, and saturation were also recorded.

The level of sensory block was assessed using the loss of pinprick sensation (26-gauge hypodermic needle). Whereas motor block was assessed using modified Bromage scale.

After desired surgical anesthesia is achieved, the procedure began. If patient complained of pain during surgery, supplement analgesia with 1 mcg/kg fentanyl IV was planned to be administered. If this will not be adequate to complete surgery, general anesthesia was planned to be provided.

Clinically relevant hypotension (decrease in systolic arterial blood pressure ≥30% from baseline[11]) was initially treated with 250 mL of Ringer's lactate rapid IV infusion over 10 min. When this was not being effective, 6 mg ephedrine was administered.

The occurrence of clinically relevant bradycardia (heart rate <45 bpm) was treated with 1 mL, 0.6 mg atropine IV injection.

The time from the end of spinal injection to the readiness to surgery (on set time), maximum level of block, time of complete regression of sensory and motor block (duration of action), time of unassisted ambulation, and vitals were recorded.

Parameters

Baseline systolic and diastolic blood pressure, mean arterial pressure, heart rate, and saturation were recorded.

Assessment of sensory blockade tested by pin-prick test using hypodermic needle and the time of onset, highest level of sensory blockade, and duration of sensory block were noted.

Assessment of motor blockade tested by modified Bromage scale, time of onset, degree of motor block

duration of motor block were also recorded through modified Bromage scale.

Statistical analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) for Windows version 16.0 software, SPSS. Data are expressed in terms of mean±SD. Categorical data are expressed as count of percentage. Student's *t*-test is used to compare between two groups.

RESULTS

The characteristics of two groups were comparable in terms of age, gender, surgical procedure and ASA grade as shown in Table 1. In Chi - Square test it showed that on comparison of the peak sensory level between the two groups, the peak sensory level attained was statistically significant with a p value of 0.040. In group A 48 patients attained peak sensory level of T10 , 5 patients attained T12, 9 patients attained T9 and 2 patients attained T8 level. T10 (T8 - T12)

In group B 45 patients attained peak sensory level of T10 , 15 patients attained T9, 4 patients attained T8 level whereas no patient attained T12 level. T10 (T8 - T11) as shown in Table 2.

Table 3 shows that on comparison of the peak motor block between the two groups the peak motor block attained was statistically significant with a p value of 0.014 . In group A 59 patients attained peak motor block 2 score of modified Bromage scale and 5 patients attained score 1. In group B 49 patients attained peak motor block 2 score of modified Bromage scale and 15 patients attained score 1.

In Independent t test it showed that on comparison of the time taken to attain peak sensory level between the two groups the peak sensory level attained in both groups was not statistically significant with a p value of 0.067. In group A mean time taken to attain peak sensory level was 4.305(3-6) mins and Group B its 4.600 (3-7) mins. (Table 4)

Table 1: Demographic characteristic of patients

S. No.	Patient characteristics	Group A (n=60)	Group B (n=60)
1.	Age		
	20–30	16 (25%)	16 (25%)
	31–40	15 (23.4%)	14 (21.9%)
	41–50	16 (25%)	16 (25%)
	51–60	17 (26.6%)	18 (28.1%)
2.	Sex		
	Male	31 (48.4%)	33 (75%)
	Female	48 (51.6%)	16 (25%)
3.	Surgical procedure		
	General surgery	12	23
	Orthopedics	11	15
	Obstetrics and gynecology	21	5
	Urology	20	21
4.	ASA grade		
	ASA 1	15	16
	ASA 2	49	48

ASA: American Society of Anesthesiology

Table 2: Comparison of peak sensory level between the two groups peak sensory levels

Group	Groups	Peak sensory levels			
		T10	T12	T8	T9
Group A	40 mg	48 75.4%	5 7.7%	2 3.1%	9 13.8%
Group B	50 mg	45 69.8%	0 0.0%	4 6.3%	15 23.8%

Table 3: Comparison of peak motor level between the two groups peak sensory levels

Group	Groups	Peak motor levels				
		1	2	3	4	5
Group A	40 mg	5 (7.8%)	59 (92.2%)	0	0	0
Group B	50 mg	15 (23.4%)	49 (76.6%)	0	0	0

DISCUSSION

A prospective, randomized, quasi-experimental study entitled "comparison of 2 doses of 1% 2-CP as spinal anesthetic for perineal and lower-limb surgeries" was undertaken in Yenepoya Medical College, Mangalore. After informed consent, 124 patients of ASA Class I and II posted for perineal and lower-limb surgeries were grouped randomly into two groups – Group A received 40 mg 1% 2-CP and Group B received 50 mg 1% 2-CP.

In the present study, the patients studied in both groups did not vary much with respect to age and sex (Table 1). Majority of the patients were middle aged in both groups, ranging between 22 and 55 years. Based on the sex ratio, males were slightly more than females with a percentage of 61.7%.

- Peak sensory block level:
  Peak sensory block dermatome level attained in the present study with group 40 mg 1% 2-CP was T10 (T8-T12) and with 50 mg was T10 (T8-T10). Casati et al.[10] have similar findings with 40 mg 1% 2-CP T9 (T12-T6) and T9 (T12-T7) with 50 mg 2-CP (Table 2).
- Time required to attain peak sensory level:
  As the onset of action of drug depends on pKa, CP has greater pKa greater than lignocaine and bupivacaine, therefore, it has a lesser time to attain peak sensory

Table 4: Comparison of time taken for action and recovery of the drug

Time taken for action and recovery of the drug group statistics					
Time taken	**A 40 mg**		**B 50 mg**		**P value**
	Mean	**Standard deviation**	**Mean**	**Standard deviation**	
To attain peak sensory level	4.305	0.9993	4.600	0.7958	0.067
To complete sensory block regression	117.48	17.554	148.83	15.509	<0.001
Complete motor block regression	104.78	16.306	134.97	14.204	<0.001
Time of ambulation	134.95	15.337	166.98	16.904	<0.001

Table 5: Comparison of parameter

S. No.	Variables	Present study	Casati et al., study[10]	Vaghadia study[3]	Lacasse study[4]
1.	Sample size	128	45	40	106
2.	Comparison with	2-CP 40 mg	2-CP 30 mg	2-CP 40 mg+12.5 mcg fentanyl	2-CP 40 mg
		2-CP 50 mg	40 mg 50 mg	Lignocaine 35 mg+ 12.5 mcg fentanyl	Bupivacaine 7.5 mg
3.	Peal sensory block level (dermatome level)	2-CP 40 mg T10(T8-12)	30 mg T9 (T12–4)	2-CP 40 mg T8 (L2-T1)	2-CP 40 mg T7 (T1-T10)
		2-CP 50 mg 50 mg T10 (T8–10)	40 mg T9 (T12–6) 50 mg T9 (T12–7)		
4.	Time required to attain peak sensory level (in min)	40 mg 4 (3–6) 50 mg 4 (3–7)	30 mg 8 (3–25) 40 mg 7 (3–26) 50 mg 6 (3–20)	NA	NA
5.	Duration of block a. Motor	40 mg 104 (60–150)	NA	117±36	76±25
		50 mg 134 (106–158)	30 mg 60 (41–98)		
	b. Sensory	40 mg 117 (74–168)	40 mg 85 (46–141)	155±55	105 (105/65)
		50 mg 148 (116–179)	50 mg 97 (60–169)		
6.	Time of ambulation (in min)	40 mg 134 (100–184)	30 mg 85 (45–123)	NA	225±56
		50 mg 166 (119–198)	40 mg 180 (72–281) 50 mg 185 (90–355)		

level. There is also low systemic toxicity due to rapid metabolism by pseudocholinesterase.[12] The present study demonstrated 4 (3–6) min time, required to attain peak sensory level with 40 mg 2-CP and 4 (3–7) min with 50 mg 2-CP (Table 4). In Casati et al.[10] study, 7 (3–26) min was the time required to attain peak sensory level with 40 mg 1% 2-CP and 6 (3–20) min with 50 mg drug (Table 5).

- Duration of block:
  Duration of motor block with the present study is 104 (60–150) min (Table 4), which is comparable with Vaghadia et al.[3] study (177±36 min) and Lacasse et al.[4] study (76±25 min) (Table 5).
  The present study showed duration of sensory block of 117 (74–168) min with 40 mg 1% 2-CP, which is comparable with Vaghadia et al.[3] study of 155±55 min and Lacasse et al.[4] study of 105±65 min (Table 4).
- Time of ambulation (Table 4):
  In the present study, time of ambulation was 134 (100–184) with 40 mg 1% 2-CP, which is comparable with Casati et al.[10] study 108 (72–281) min as time of ambulation and Lacasse et al.[4] study with 225±56 min (Table 5).
- Adverse effects:
  The present study resulted in side effects like bradycardia one in both groups, requiring treatment with 0.6 mg injection atropine, hypotension three in each group requiring fluid boluses and 6 mg injection ephedrine, and nausea one in each group. The incidence of shivering was one with 40 mg 2-CP group and 3 with 50 mg 2-CP group and injection site pain was reported by one patient of 50 mg 2-CP group. In Casati et al.[10] study, one patient belonging to 30 mg 1% 2-CP group developed vomiting and five patients suffered from bradycardia requiring, treatment with injection 0.6 mg Atropine. In Vaghadia et al.,[3] one patient developed Cauda equnia syndrome, recovered completely after some weeks. In Lacasse et al.[4] study, one patient suffered from post-dural puncture headache, one patient developed TNS, and 45% patients complained of backpain after 2-CP.

Limitations of the study

- The present study was not a double-blind study. If double-blind technique was used for the study, it would have been a more definite and a better study
- ASA 3 and 4 patients were not included in the present study
- Obese patients with BMI >30 were not included in the study
- Pediatric and geriatric patients were not included in the study.

CONCLUSION

Our study revealed that 40 mg of 1% 2-CP produces a satisfactory surgical block for procedure lasting <90 min. When compared with 1% 2-CP 50 mg, it resulted in comparable onset of action, with significantly faster regression of the block, shorter time to ambulation and lesser side effects.

ACKNOWLEDGMENT

The author would like to thank department of anesthesiology, yenepoya medical college hospital and each participant who contributed to this study.

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Authors Contribution:
PK- Definition of intellectual content, Literature survey, Prepared first draft of manuscript, implementation of study protocol, data collection, data analysis, manuscript preparation and submission of article; **HV-** Concept, design, clinical protocol, manuscript preparation, editing, and manuscript revision; **HV-** Design of study, statistical Analysis and Interpretation; **PK-** Review Manuscript; **RSR-** Review Manuscript; **SP-** Literature survey and preparation of Figures; **JSZ-** Coordination and Manuscript revision.

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Source of Support: Nil, **Conflicts of Interest:** None declared.