

Comparative study between isobaric levobupivacaine and isobaric chlorprocaine in patients undergoing ambulatory surgeries under spinal anesthesia

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Abstract

Background: With development of safer local anesthetic agents and advances in minimally invasive surgical techniques, the performance of day care surgeries are increasing in prevalence. Many local anesthetic drugs with varying concentrations and physical properties are used in spinal anesthesia to achieve early recovery, mobilization with minimal adverse effects. In the present study we are comparing the efficacy of Isobaric 0.5% Levobupivacaine with isobaric 1% 2-chlorprocaine in patients undergoing ambulatory surgeries under spinal anesthesia. **Material and Methods:** Sixty patients aged 18 to 60 years belonging to ASA physical status I-II, scheduled for various elective ambulatory surgeries under spinal anesthesia were randomized into two groups. Group A patients received 3ml of 0.5% Levobupivacaine and Group B received 4ml of 1% chlorprocaine. The time of onset, duration of sensory and motor block, hemodynamic changes and adverse effects were studied. **Results:** The time of onset of sensory block and motor block was significantly shorter ($p < 0.001$) in Group B compared to Group A. Similarly, the duration of sensory and motor block in Group B was shorter ($p < 0.001$). Intraoperative hemodynamic parameters including heart rate, systolic blood pressure and diastolic blood pressure were comparable in both groups. **Conclusion:** Intrathecal isobaric 1% 2- chlorprocaine has a shorter onset and duration of both Sensory and motor blockade compared to Isobaric 0.5% Levobupivacaine thereby, enabling early recovery and ambulation **Keywords:** Isobaric, Chlorprocaine, Levobupivacaine, Ambulatory surgeries.

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INTRODUCTION

Ambulatory or outpatient surgical procedures often involve less invasive techniques with minimal dissection and short operating times, which facilitate early recovery, mobilization and discharge of the patients. The anesthetic

goals of such procedures aim at providing early recovery from anesthesia with favorable onset, optimum duration, safe emergence and minimal systemic adverse effects.^{1,2} The choice of anesthetic technique is very important in providing safe perioperative care for ambulatory surgeries.³ Although general anesthesia is commonly preferred² spinal anesthesia offers many advantages such as avoiding airway related complications, reduced incidence of PONV and aspiration. better postoperative pain control and decreased stress response which favor early ambulation.³ however, spinal anesthesia is associated with prolonged motor blockade, urinary retention. Several local anesthetic agents are developed to mitigate these issues. Chlorprocaine an amino ester type of local anaesthetic with the shortest duration of action amongst all of the local anaesthetic.^{4,5,6} was used in the 1980s.^{7,5} However, neurotoxicity after intrathecal injection was

reported due to the combination of low pH and presence of sodium bisulphate as preservative.^{8,5} The alteration in pH and development of preservative free solution has lead to the reintroduction of the drug.⁸ Bupivacaine is routinely used local anesthetic in spinal anesthesia due to its longer duration of action, using smaller doses of the drug can lead to inadequate anaesthesia and urinary retention making it unsuitable for ambulatory surgeries. Levobupivacaine, an amino amide single S-enantiomer of Bupivacaine has recently been introduced and is not only known to have reduced cardiovascular and neurological toxic profile compared to Bupivacaine⁹ but, also exhibits differential block characteristics by sparing motor blockade at low concentration.^{10,11} The appropriate selection of drug is crucial in outcome of ambulatory surgery , hence the purpose of this clinical study is to compare the isobaric preparations of amide local anesthetic 0.5%Levobupivacaine and the ester 1% 2-Chlorprocaine in patients undergoing ambulatory surgeries under spinal anesthesia.

MATERIAL AND METHODS

This randomized clinical study was conducted for a period of six months from November 2020 to April 2021 in a tertiary healthcare centre. Sixty patients aged between 18 to 60 years of either sex, undergoing elective ambulatory surgeries were recruited in this study Patients belonging to ASA physical status I and II were included in the study. Patients who refused consent, patients with allergy to study drugs, coagulopathy, spinal abnormalities, neurological

deficits were excluded from the study. Study participants were randomly divided into two groups of 30 each by computer generated tables. Group A received 3ml of isobaric 0.5% Levobupivacaine and Group B received 4ml of isobaric 1% 2-chloroprocaine. All patients underwent thorough pre anesthetic evaluation, informed consent was obtained and advised overnight fasting. Routine investigations such as complete blood count, Random blood sugar, Serum creatinine, blood grouping and typing, Chest X-ray, Electrocardiography were carried out. In the preoperative holding area, a wide bore i.v. access was secured and patients were preloaded with ringer lactate 10ml/kg half an hour before induction of anaesthesia. Anaesthetic techniques was standardised for all patients. Inside the operation theatre, Standard monitoring devices pulse oximeter, ECG, non-invasive BP were connected. Patients were positioned in right lateral decubitus position and under strict aseptic precautions, L3-L4 space was identified. Local infiltration of 2ml of 2% lignocaine was injected in L3- L4 space using 25G Quincke spinal needle, study drugs were injected after confirming free flow of CSF. Patients were immediately placed in supine position and the following parameters were studied. Sensory blockade was assessed by pin prick in mid axillary line every minute till T10 block occurs, following which it was assessed at 10-minute intervals for next one hour. Surgery was allowed to start once T10 dermatome was blocked. Cases with failed spinal after 30 minutes were labeled as block failure and excluded from final analysis. Motor blockade was assessed using Modified Bromage scale.¹²

Degree	Evidence
0	Full leg movement, full flexion of knees and ankles
1	Inability to raise extended legs, just able to flex knees, full ankle flexion
2	Inability to flex knees, some flexion of ankles possible
3	No movement possible (unable to move legs or feet)

Motor block onset was taken as the time to reach modified Bromage score 3 and total duration of motor block was noted as the time for return to modified Bromage score 0. Time for first rescue was noted and treated with Inj. Diclofenac 75mg added to 100ml of normal saline. Hemodynamic parameters HR, BP and SpO2 were monitored throughout the surgery. Hypotension was defined as decrease in systolic BP by 20% from baseline values or a systolic less than 90mm of Hg and was treated with incremental intravenous boluses of mephentermine 5mg and a bolus administration of 250ml of Ringer Lactate solution over 10mins. Bradycardia was defined as decrease in heart rate less than 50 beats per minute and treated with intravenous atropine

0.6mg. Statistical software SPSS 15.0 and MedCalc 9.0.1 was used for the analysis of the data and Microsoft word and Excel is used to generate graphs and tables. continuous measurements of descriptive data is presented as Mean ± SD and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. Student t test is used to find the significance of study parameters on continuous scale . Chi-square and Fischer’s test has been used to find the significance of study parameters on categorical scale between the groups. P value of less than 0.05 was considered statistically significant.

RESULTS

Demographic data included Age, weight, height and no statistical significance was observed ASA physical status distribution and duration of surgery are as described in Table 1.

Table 1: Comparison of Demographic data, ASA physical status distribution and duration of surgery

Baseline characteristics	Group BC	Group LC	P value
Age (years)	42.35±10.37	43.15±10.27	0.765
Weight (kg)	66.40±6.34	65.30±5.74	0.484
Height (cm)	164.30±7.10	166.10±6.80	0.320
Gender: Male:Female (percentage)	80.5% : 19.5%	81.5% : 18.5%	0.858
ASA I : ASA II (percentage)	78% : 22%	76.5% : 23.5%	0.736
Duration of Surgery (min)	108.40±21.67	113.75±22.32	0.350

The mean time of onset of sensory block of Group A was 5.07±1.14 minutes compared to 3.35±0.82 minutes of Group B that received intrathecal Chlorprocaine with P<0.001 which was highly statistically significant. Similar results were seen with the onset of motor block in Group A of 6.93±0.72 and 4.77±0.69 minutes in group B (P<0.001). Group B had significant shorter duration of sensory (115.68±11.97 min) as well as motor block (93.22±20.42) compared to Group A of 173.35±6.55 min and 130.78±15.44 minutes. As shown in Table 2

Table 1: Block characteristics between the study groups

Block characteristics	Group A	Group B	P value
Onset of Sensory block (min)	5.07±1.14	3.35±0.82	P<0.001 t=6.70, DF=58
Onset of Motor block (min)	6.93±0.72	4.77±0.69	P<0.001 t=11.86, DF=58
Duration of Motor (min)	130.78±15.44	93.22±20.42	P<0.001 t=8.03, DF=58
Duration of Sensory (min)	173.35±6.55	115.68±11.97	P<0.001 t=23.14, DF=58

Hemodynamic parameters showed the mean heart rate in the Intra-operative period was 76.30 ±5.17 bpm in Group A and 72.50 ± 7.04 bpm in Group B as shown in Figure 1. the mean systolic BP in the Intra-operative period was 118.41 ± 5.17 mm of Hg in group A and 122.11 ± 4.01 mm of Hg in group B and was comparable (Figure 2) the mean diastolic BP in the pre-operative phase was 78.42±6.15 mm of Hg in group A and 80.04±5.11 mm of Hg in group B (Figure 3) all the measures hemodynamic parameters were comparable and statistically not significant with P > 0.05.

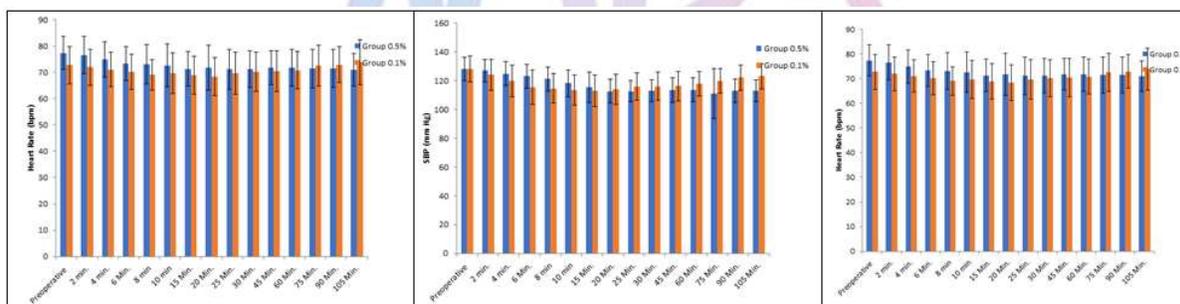


Figure 1

Figure 2

Figure 3

Figure 2: Intraoperative heart rate between the study groups (beats per minute); **Figure 2:** Intra operative Systolic blood pressure (mm Hg); **Figure 3:** Intraoperative diastolic blood pressure (mm Hg)

Table 3 shows the distribution of various elective ambulatory surgeries which included gynecological, urological, orthopedics and general surgeries

Table 1: Distribution of ambulatory surgeries between the groups (percentage)

Surgery	Group A	Group B	P value
	%	%	
Gynecology:Dilatation and curettage	26.0	28.0	Not significant
Gynecology:Cervical polypectomy	17.0	24.0	Not significant
Urology: Uretroscopy	14.0	9.5	Not significant
Urology: Cystoscopy	10.0	11.0	Not significant
Orthopedics: implant removal	6.5	10.0	Not significant
Orthopedics: tendon repair	10.0	7.5	Not significant
Surgery: Hemorrhoids	10.0	6.5	Not significant
Surgery:Lateral sphincterotomy	6.5	3.5	Not significant

DISCUSSION

The anesthetic requirements for day care surgical procedures differ from the routine conventional elective surgeries. There are several challenges in the process of deciding the appropriate anesthetic technique and the choice of drugs, which is primarily aimed at early ambulation and discharge of the patient without compromising patient safety or the quality of anesthesia. The decision of general anesthesia compared to regional anesthesia can affect outcome of the surgery, Although general anesthesia is commonly preferred for outpatient procedures^{13,14} Spinal anesthesia offers many benefits. In a systematic review conducted by Malchow *et al.*¹⁵ who prospectively analyzed a total of 13,897 regional anesthetic techniques performed on 10,338 patients revealed, excellent patient satisfaction, low incidence of postoperative nausea and vomiting (PONV) and minimal postoperative pain. Similarly, In 2020, Capdevilla *et al.*¹⁶ conducted a prospective, multicentre observational cohort study on 592 patients from 33 hospitals to determine patients choice between spinal and general anesthesia revealed patients being apprehensive towards general anesthesia and reported high degree of satisfaction with spinal anesthesia. However, the presence of prolonged motor block and urinary retention is very common especially with long acting local anesthetics to mitigate this issue several drugs are studied¹⁷. Usage of Lignocaine is limited due to the high incidence of transient neurological symptoms.^{16,9} The incidence of urinary retention after 60 mg Prilocaine in a day-case setting was described as high as 23%¹⁸ Bupivacaine is a common local anesthetic being used in spinal anesthesia but, due to its longer duration of action its role as the drug for day care surgeries have been limited^{19,20} We chose Isobaric levobupivacaine, an s isomer of Bupivacaine with less cardiovascular and neurotoxicity as well as exhibits early motor recovery^{21 22}, which is favorable to ambulatory surgeries and compared its efficacy with with a short acting ester local anesthetic Chlorprocaine. Literature review by Ghisi D *et al.*⁸ compared three doses of chlorprocaine being 30mg, 40mg and 50mg. as a result of inadequate analgesia 33% of patients in the 30mg group required intraoperative analgesic supplementation. It was found that dose ranging between 30-60 mg of chlorprocaine was adequate for short duration surgeries Various gynecological, urological, orthopedic and general surgical procedures were performed in our study. [Table 3]. The onset of sensory block in Chlorprocaine group was 3.35±0.82 min and the onset of motor block 4.77±0.69 min, which was significantly shorter (p<0.001) than the levobupivacaine group. However, similar randomized control trials showed different block characteristics. Bhaskar *et al.*¹¹ who compared intrathecal 1%

chlorprocaine and 0.5% levobupivacaine on patients undergoing perianal surgeries reported no significant difference in onset of motor block with P=0.302. Sinha *et al.*²³ who compared 1% chlorprocaine with 0.05% levobupivacaine in seventy patients undergoing lower limb and lower abdominal surgeries, also noted Levobupivacaine group achieving a higher dermatomal blockade compared to Chlorprocaine similar findings were reported by Yoos *et al.*²⁴ who compared chlorprocaine with low dose bupivacaine, however no such observations were made in our study, the median height of sensory block was between T6 and T8 dermatomes in both the groups. The duration of sensory and motor block in chlorprocaine group was significantly shorter with p<0.001 these findings were comparable with similar to similar studies.^{11, 23} The hemodynamic parameters including heart rate, systolic blood pressure and diastolic blood pressure was comparable and was not statistically significant. Hypotension was seen in Five patients from Group A and four patients from Group B Three patients receiving 1% 2 chlorprocaine had bradycardia and injection atropine 0.6mg was given. no other major adverse effects were seen.

CONCLUSION

Findings of our clinical trial suggest Isobaric 1% 2-chlorprocaine to be an ideal drug for ambulatory surgeries under spinal anesthesia when compared to intrathecal 0.5% isobaric Levobupivacaine. 2- chlorprocaine is associated with shorter onset and duration of both Sensory and motor blockade with hemodynamic parameters compared to levobupivacaine, thereby enabling faster recovery from spinal anesthesia, allowing early ambulation and discharge.

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