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Comparison of 0.5% hyperbaric bupivacaine versus 1% chloroprocaine in spinal anaesthesia in day care surgeries

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***Abstract*---**Background: An increasing number of day-care surgical patients are challenging the presently used methods of anesthesia. Reliable surgical anesthesia should be fast, with rapid recovery and minimal side effects. To produce reliable spinal anesthesia with a reasonable recovery time it is essential to understand the factors affecting the spread of spinal block and to choose the optimal drug and adequate dose for special surgical procedures. Bupivacaine may provide prolonged postoperative analgesia and has a lower incidence of TNS. A new formulation 2-Chloroprocaine is characterized by both a very fast onset (5-10minutes) and a quick 13-14 recovery time (70-150minutes). Methods: 40 ASA I/II patients were evaluated for time for ambulation, onset, and duration of sensory blockade, after randomly allocating them into two groups namely Group C(Chloroprocaine) and Group B (Bupivacaine). Results: The time to the first ambulation after spinal anaesthesia was shorter in the Group C(Chloroprocaine) (183.11±14.17min) as compared with Group B(bupivacaine) (274.63±18.21 min) in respect of day-care surgeries. Thus ,the onset and shorter duration of sensory block was observed in Group C as compared to Group B respectively ($p<0.05$). Similarly, time to ambulate was found to be shorter in Group C as compared to Group B respectively ($p<0.05$). Demographic parameters (Age, Weight, Height, ASA, Duration of surgery) were comparable in both groups. Conclusion: we concluded that 1% 2-chloroprocaine showed faster recovery from anesthesia and thus prompter eligibility for home discharge than the control, suggesting its suitability for the ambulatory setting.

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***Keywords*---**spinal anesthesia, 2-chloroprocaine, 0.5% bupivacaine, daycare surgeries, TNS.

Introduction

Day-care surgery has become an immensely popular modality of treatment throughout the globe. It refers to the practise of admitting and preparing selected patients on the day of surgery, planning for a nonemergency surgical procedure, and their discharge within 24 hours of that surgery [1]. Ambulatory anaesthesia offers various advantages, like reduced risk of nosocomial infections, cost reduction, and a short duration of hospital stay [2]. Spinal anaesthesia is the most convenient anaesthetic technique and is commonly used in surgeries below the umbilicus [3]. Its advantages over general anaesthesia are reduced stress response, rapidity in onset, post-operative pain relief, shorter hospital stay, and cost-effectiveness [4]. It is generally performed by using local anaesthetic drugs at different doses and baricity with or without additional adjuvant. The ideal anaesthetic for spinal anaesthesia in an ambulatory surgery patient would provide a rapid onset of action, adequate potency, predictable (short) duration, and a low incidence of transient neurological symptoms (TNS) and systemic side effects. [5]

Hyperbaric bupivacaine is the most widely used drug for spinal anaesthesia as it showed faster recovery than the plain solutions and with higher or comparable cephalad spread owing to the rapid dissociation of molecules over the lumbar curve to the lowest level of the thoracic kyphosis when the patient is allowed to resume the supine position. This more cephalad spread of local anaesthetic might result in a dilution of molecules in the CSF and thus a lower “mg per segment” concentration. The time necessary to absorb the local anaesthetic molecules is shorter because of a lower concentration which might explain faster block regression of a hyperbaric substance than a plain local anaesthetic. However the major disadvantage was prolonged motor block and insufficient analgesia along with retention of urine post operatively which lengthen the patient stay in hospital.[6]

In 1952 an amino-ester local anesthetic 2-chloroprocaine was first introduced as short acting spinal anesthetic as compared to lignocaine with less systemic toxicity. Several case reports of neurological deficits were observed in the early 1980s after inadvertent intrathecal 2-chloroprocaine injections intended for epidural delivery. The antioxidant sodium bisulfite in acidic environment was thought to be the culprit in these cases. Hence thereafter this drug was no longer used for spinal anesthesia.[7]

In recent years, 2-chloroprocaine was once again available in a preservative-free and antioxidant-free form for use in subarachnoid space. It has faster onset of action, short duration of action, predictable block height and time to complete regression. Several studies reported in literature by Lacasse et al [8] , Forster et al [9] demonstrated the safe use of preservative free intrathecal 2-chloroprocaine in spinal anesthesia but still its usage is limited. Very little literature is available comparing 2-chloroprocaine's effectiveness with

hyperbaric bupivacaine in day care procedures. So, we planned a randomised prospective, double-blind control study to compare the effectiveness of 1% chloroprocaine over hyperbaric 0.5% isobaric bupivacaine for spinal anaesthesia.

Methods

A prospective comparative study was conducted for a period of 1 year from November 2019 to November 2020 in the Department of Anaesthesia of JNMC and AVBRH, Wardha, Maharashtra, after ethical committee clearance was obtained on 19/12/2019. ref No DMIMS(DU)/IEC/Dec-2019/1576 along with the written consent. Assuming the average duration of sensory block of 35.33 minutes and SD of 4.30(with reference to the study done by Kalra P et al [1] keeping power at 80% and confidence interval at 95%, a sample size of 18 samples in each group would be required to detect a minimum difference of 20% in the mean duration of motor block. So, considering the probable dropouts, the total sample size was kept at 40 i.e. 20 samples in each group.

Adult Patients between ages 18 to 60 years, with an American Society of Anaesthesiologists (ASA) grade I or II, weighing between 40-80 kg, scheduled to undergo surgical cases requiring Spinal Anesthesia. i.e. Deep Vein Thrombosis surgery, Hydrocele surgery, Anal fissure and Anal dilatation surgery under subarachnoid block and willing to consent for the study were included. Exclusion criteria included patients with contraindications to spinal anaesthesia, known or ascertained hypersensitivity to local anaesthetics (medications used in the trial), patients with bleeding disorders, cardiopulmonary disorders, hepatic, renal disease patients and ASA Class III and above.

All patients posted for elective lower limb surgeries were assessed preoperatively and baseline heart rate and blood pressure were noted. After clinical evaluation, patients were shifted to OT and multipara monitors like ECG, SPO_2, non-invasive blood pressure (NIBP) were connected to the patients. 18 G IV cannula was secured, and infusion of Ringer's lactate had begun at the pace of 80 ml / hr. All baseline parameters were noted. Emergency medications and equipment for GA were kept prepared. The drug was prepared in a 5ml syringe in equal volume. Patients were randomly divided into two groups by computer-generated simple randomization.

Group C (n=20) received 4 ml (40 mg) of 1 % 2-chloroprocaine
Group B (n=20) received 3 ml (15 mg) of 0.5% hyperbaric bupivacaine
Under all aseptic precautions spinal anesthesia was performed by a blinded investigator on the patient in a sitting position at L3-L4 subarachnoid space using Quinkes spinal needle of size 25 G. After clear and free cerebrospinal fluid flow, patients received either 4 ml (40 mg) of 1 % 2-chloroprocaine or 3 ml (15 mg) of 0.5% hyperbaric bupivacaine according to their study groups. No adjuvant medication was added to both local anesthetics.

After the administration of the spinal injection, the patient was placed in a supine position with a 15° head down tilt immediately to achieve the level of a block of T5-T6. The same observer evaluated the sensory (with 25g hypodermic needle) and motor blocks (as per modified Bromage score) every five minutes for 15

minutes, then every ten minutes for 45 minutes, and then every fifteen minutes for 60 minutes, and until the sensory block regressed to the S2 dermatome. During surgery, the patient's blood pressure (systolic, diastolic, and mean arterial pressure), electrocardiogram, and pulse oximetry were recorded. Vitals were checked every 5 minutes for 30 minutes and after that every 10 minutes till the end of the surgery. The sensory block was assessed by pinprick test bilaterally in mid-clavicular line by using a 25G hypodermic needle. The level of sensory block was assessed every two minutes till the highest level of the block was achieved. The highest level of sensory block achieved was noted and the time taken to achieve the highest level of sensory block was also noted.

If the patient complains of pain, fentanyl 25 to 100 mcg IV was given. If additional sedation needed, midazolam 0.025 to 0.05 mg /kg IV was given. The total dose of any given medication was recorded. If the patient continues to experience pain, general anesthesia was administered and the protocol was stopped. Intraoperatively, hemodynamic parameters (BP, HR, SPO2) were observed until the end of surgery. Side effects like hypotension (blood pressure < 20 % of baseline), and nausea/vomiting were documented.

After the surgery, the duration of surgery was noted and the patients were shifted to the post-anesthesia recovery room. After discharge from the recovery room, the patients were transferred to the day care surgical unit where the nurses responsible for the patient care supervised further management. The patient was allowed to take liquid just over an hour after they arrived in the daycare unit, and once they can tolerate liquids by mouth and feel a light touch on their legs. The following clinical criteria as described by Pflug was used to determine the time when ambulation may safely be permitted for patients who have had a subarachnoid block:

1. Return of pin-prick sensation in the peri-anal area (sacral 4-5)
2. Plantar flexion of the foot (while supine) at pre-anesthetic levels of strength
3. Return of proprioception in the big toe.

Then patients were asked to ambulate without assistance. This time was taken as the time of ambulation.

Statistical Analysis

It was performed using SPSS (SPSS, Inc., Chicago, IL, USA) software packages. Values of normal distribution are expressed as means ± SD and others as medians (ranges). Normal distribution was tested with Kolmogorov-Smirnov test. Quantitative values of normal distribution values were presented as mean and standard deviation and futher were compared by students t-test. Homogeneity of variance was tested with Levene's test. Nonparametric rank values were analyzed with chi –square tests. $P > 0.05$ was considered significant.

Results

For Group C, the mean age was 42.16±5.69 years, mean weight was 66.31±19.92 kg, and mean height was 168.42±7.01cm. The corresponding values of these

parameters for Group B were 43.81±5.34 years, 65.3±10.27kg, and 166.98±6.84cm. The categorization as per the American Society of Anaesthesiologists' physical status (I/II) was 17/3 and 18/2 for Group C and B respectively. The variations between the groups in respect of all the above demographic parameters were not statistically significant (p>0.05). The mean duration of surgery was 48.54±9.24min in patients of Group C and 51.22±8.25min in patients of Group B. The difference in the mean duration of surgery between the two groups was comparable (P>0.05).Table 1

Table 1: Demographic characteristics among the study groups

Variables	Group C (N=20)	Group B (N=20)	p-value
Age (in years)	42.16±5.69	43.81±5.34	0.47
Gender;M/F (Male:Female)	11/9 (1.2:1)	10/10 (1:1)	0.79 [c]
ASA Grade; I/II	17/3	18/2	0.86
Weight (in kg)	66.31±9.92	65.302±10.27	0.68
Height (in cm)	168.42±7.01	166.98±6.84	0.41
Duration of Surgery (in min)	48.54±9.24	51.22±8.25	0.52
[C]= compared using chi square test			

The time to the first ambulation after spinal anesthesia was also shorter in the chloroprocaine group (183.11±14.17min) as compared with the bupivacaine group (274.63±18.21 min). When the time to the first ambulation was compared between groups C and B using the t-test, it was found to be statistically significant at p<0.05 (Table 2).

Table 2: Comparison of time to first ambulation (minutes) among the study groups

Group	Mean	SD	p-value
Group C	183.11	14.17	<0.01*
Group B	274.63	18.21	

*: statistically significant

The onset of sensory block (min) and time to reach peak sensory block (minutes) was comparable among both the groups at p<0.05. Time for complete regression to S2 (total duration of the sensory block) was significantly higher in group B as compared to group C (table 3). No adverse event was reported among the groups. Table 3,Figure 1.

Table 3: Comparison of sensory blockade characteristics among the study groups

Variables	Group C (N=20)	Group B (N=20)	p-value
The onset of sensory block (min)	2.41±0.34	2.34±0.26	0.76
Time to reach peak sensory block (minutes)	16.54±2.89	17.16±2.45	0.64
Time for complete regression to	148.41±17.58	251.30±18.87	<0.01*

s2(total duration of the sensory block)			

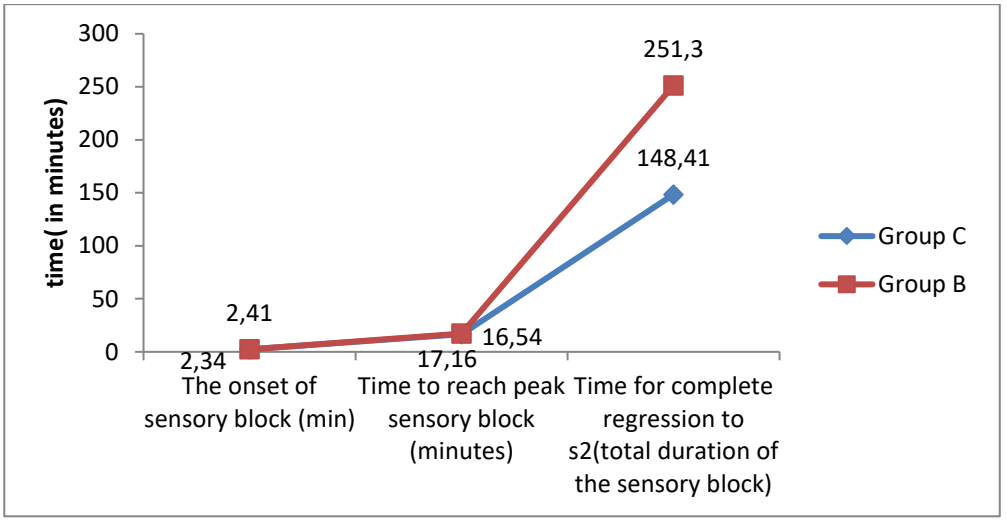

Figure 1 Comparison of sensory blockade characteristics among the study groups

Hypotension and bradycardia were more observed in Group C than Group B. Postdural headache and transient neurological symptoms were not observed in any patients

Table 4: Adverse effects

Adverse effects	Group B (n =20)	Group C (n = 20)	p-value
Hypotension (≥30% baseline)	0	4 (20%)	0.002
Bradycardia (< 50 beats/min)	0	1 (5%)	0.078
Nausea	2(10%)	3 (13%)	0.748
Vomiting	1(5%)	2 (10%)	0.238

Discussion

The aim of our study was to compare intrathecal 1% 2-Chloroprocaine 4 mL (40 mg) with 0.5% hyperbaric bupivacaine 3ml(15 mg) in day care surgeries. Amino-ester local anaesthetic 2 Chloroprocaine has an early onset and short duration of action. Several case reports of Neurological toxicity was noted in 1980, due to inadvertent intrathecal 2-chloroprocaine injections intended for epidural delivery which was attributed to its preservative sodium 1% bisulfite, 1% 2-chloroprocaine, preservative free is available as 10 mg/ml solution nowadays, which is approved for intrathecal use. [7,8] The present study demonstrates that spinal anaesthesia performed with 40 mg of 1% 2-chloroprocaine (group C) provides adequate spinal anesthesia for daycare surgeries, with faster recovery

from anesthesia and eligibility for home discharge in comparison with 15 mg of 0.5% hyperbaric bupivacaine (group B). Concerning, the recovery and the effects of spinal anesthesia after chloroprocaine cease more rapidly than after bupivacaine (148.41 vs. 251.30 min), these results are in accordance with a camponavo et al [9] study comparing 7.5 mg of 0.75% bupivacaine with 40 mg of 2-chloroprocaine.

The average time to ambulation was shorter (142.5 vs. 290.5min) in the chloroprocaine group as was the average time to complete regression of sensory block (105 vs. 225 min). Similar results were also reported by Kalra et al[1] and C. Camponovo et al.[10] In a similar study by Lacasse et al [8] where spinal anaesthesia was achieved with 2% preservative-free 2-chloroprocaine 40mg or 0.75%, hyperbaric bupivacaine 7.5 mg, time to ambulation was 225±56 minutes vs 265±65 minutes (P-value=0.001).

No adverse event was reported among the groups. This is in accordance with the study reporting a 'zero' incidence with 2-chloroprocaine in over 4000 patients compared with 17–33% using lidocaine or 1% using bupivacaine [10-12]. Despite the fact that this study wasn't designed to measure health care costs in our rural area setup, our results could be significant when considered from a cost savings perspective. As health care costs are determined, in part, by the length of hospital stay, achieving faster discharge from hospital through the utilization of 2-Choloroprocaine for spinal anaesthesia could provide potential cost savings without compromising the quality of patient care .

Conclusion

Thus we concluded that 1% 2-chloroprocaine showed faster recovery from anesthesia and thus prompter eligibility for home discharge than the control, suggesting its suitability for the ambulatory setting. Future work may confirm our predication that choosing 2-Choloroprocaine for spinal anaesthesia in an ambulatory surgery setting may free up the post anaesthesia acre units and ambulatory surgical unit resources with a corresponding decrease in total perioperative costs.

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