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COMPARISON OF CHLOROPROCAINE AND BUPIVACAINE FOR SPINAL ANAESTHESIA AT A TERTIARY CARE HOSPITAL: A DOUBLE BLIND RANDOMIZED CONTROLLED STUDY

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ABSTRACT

Background: Anesthesiologists are facing an increasing demand for a fast-acting, predictable anesthesia and a rapid discharge to address the increase in day care surgery. The introduction of new pencil-point spinal needles has led to the popularity of spinal anesthesia in day care settings. The current study was conducted to compare the recovery from anesthesia and the time required to achieve discharge readiness criterion between 1% 2-Chloroprocaine and 0.5% Bupivacaine in spinal anesthesia.

Materials and Methods: 60 patients between the ages of 18 and 60 who were in the ASA I and ASA II categories and were having lower abdomen, perineal and gynecological surgeries, and lower limb surgeries that was anticipated to take less than 60 minutes were chosen. The subjects were divided evenly into two groups using the double blinded randomization approach, and they were administered either 0.5% buprevacaine or 1% 2-chloroprocaine. The onset and duration of sensory and motor blockage, recovery characteristics, and adverse effects of the two medications were compared.

Results: When compared to Group B (5.76 ± 1.45), Group C's time of sensory block onset was faster (4.12 ± 1.10 minutes). When compared to Group B (7.86 ± 1.86 minutes), Group C's motor block began sooner (5.06 ± 1.71 minutes). When compared to group C (14.12 ± 3.75 minutes), Time to reach peak sensory level-T7 was longer in group B (15.12 ±3.85minutes). When compared to group C (135.18 ± 21.18minutes), group B's Time to reach sensory regression was longer (261.00 ± 32.06 minutes). When compared to group C (78.28 ± 9.96 minutes), group B's Time to reach motor regression was longer (127.54 ± 16.28minutes). When compared to Group C (182.68 ± 16.18 minutes), Group B's time to ambulation was longer (248.64 ± 19.86 minutes). When compared to Group C (194.56 ± 14.78 minutes), Group B's length of stay was longer (298.87 ± 15.86 minutes).

Conclusion: Intrathecal 1% 2-chloroprocaine 40 mg offers sufficient spinal anesthesia duration for outpatient procedures, with the benefit of markedly expedited recovery of sensory and motor functions relative to 0.5% hyperbaric bupivacaine 10 mg. Consequently, we ascertain that 2-chloroprocaine offers spinal anaesthesia with a more expedited recovery profile than bupivacaine, facilitating faster hospital release after day care procedures.

KEYWORDS: 2-Chloroprocaine, Bupivacaine, Spinal Anesthesia.

INTRODUCTION:

The practice of receiving carefully chosen and ready patients on the day of surgery for a planned, non-emergency surgical treatment and sending them home within 24 hours of that surgery is called ambulatory surgery or daycare surgery [1]. The rise in ambulatory surgery has compelled anesthesiologists to provide consistent anesthesia and expedite patient discharge [2].

The major economic benefits of mobile surgery are that it makes the operating room more efficient, lowers personal costs, and lowers the number of services provided. Some clinical benefits are fewer infections after surgery, fewer complications after surgery, and increased mobility [3,4]. The best local anesthetic should start working quickly, relieve muscle blockage quickly and for a known amount of time, manage surgical pain well, have low neurological potential, and cause few systemic side effects [5].

The lack of a perfect spine local anesthetic and the easy access to drugs like remifentanil and propofol made general anesthesia the most popular choice for short treatments lasting about 30 minutes.Finally, lidocaine was chosen as the best anesthetic for years of outpatient treatments [6,7]. However, it is no longer used because it is linked to a high chance of short-term brain effects [8,9].
2-chloroprocaine (2-CP) is an amino-ester local anesthetic (LA) that is accessible without preservatives. It has a fast onset, effective sensory and motor block, a quick recovery period, and little adverse effects [10]. Intrathecal LA combined with adjuvant medications improves the quality and duration of spinal blockade while also extending postoperative analgesia. Using an adjuvant may reduce the quantity of LA and, as a result, the incidence of adverse effects. Similarly to the parturient getting elective LSCS, bupivacaine is the most widely utilized local anaesthetic for spinal anesthesia. Bupivacaine is a long-acting amide local anesthetic that effectively relieves pain while having little impact on motor fibers [11,12]. Its activity lasts between one and a half and two hours. Because of its quick onset and short duration of action, predictable block height, and time to full regression, the antioxidant and preservative-free form of 1% 2chloroprocaine is currently available for use in subarachnoid blocks [13].

The current study was conducted to compare the recovery from anesthesia and the time required to achieve discharge readiness criterion between 1% 2-Chloroprocaine and 0.5% Bupivacaine in spinal anesthesia

MATERIALS AND METHODS:

The present study was a hospital-based prospective randomised double-blind study conducted in the Anaesthesia department at Viswabharathi Medical College & General Hospital, Kurnool for a duration of one year after the study was approved by the ethical committee.

The participants were randomly assigned to two groups using the lottery procedure. The study included patients aged 18-60 years, both sexes, ASA grade I/II, with clear thinking and no language barriers, scheduled for lower abdomen, perineal and gynecological surgeries, and lower limb surgeries with a surgery duration of <60 minutes.
Patients with an ASA rating of 3 or 4, those who are sensitive to or allergic to bupivacaine or chlorprocaine, those who cannot tolerate spinal anesthesia. Patients with neurological conditions (spinal stenosis, multiple sclerosis, and symptomatic lumbar herniated discs). Individuals with restricted fluid intake (renal and cardiac dysfunction) and Pregnant women were excluded from the study.

A preanesthetic evaluation of patients was conducted one day before to the procedure. Informed written agreement was obtained from each patient, and the patient was required to fast for a minimum of 6 hours before to the planned procedure. Alprazolam 0.25 mg and Ranitidine 150 mg tablets were administered at nighttime prior to the procedure. The intravenous line was established using a 20 G cannula, and Ringer's Lactate infusion commenced at a rate of 10 ml/kg, 20 minutes before to operation. In the operating theatre, the fundamental monitors Non-Invasive Blood Pressure (NIBP), ECG, and pulse oximeter (sPO2) were connected, and baseline data were recorded. All aseptic measures were used to identify the L3-L4 interspace while the patient was in a seated posture. Two milliliters of 2% lignocaine were administered to the skin and interspinous ligament. A lumbar puncture was conducted in a seated posture using a midline approach with a 26 G Quincke spinal needle. To ensure unobstructed cerebrospinal fluid (CSF) flow, intrathecal Bupivacaine 0.5% 10 mg (Group B) or 2-Chloroprocaine 1% 40 mg (Group C) was delivered gradually. Following the administration of the spinal injection, patients were positioned supinely. Heart rate, non-invasive blood pressure (NIBP), and oxygen saturation (SpO2) were documented immediately after the administration of spinal anesthetic, at intervals of 3 minutes, 5 minutes, and then every 5 minutes for the first 30 minutes; thereafter, measurements were taken every 10 minutes until the conclusion of the operation.
The sensory level was evaluated by testing the loss of pinprick feeling with a blunt 25G hypodermic needle, applied in a caudal to cephalad manner along the mid-clavicular line bilaterally. The C5-C6 dermatome served as an unobstructed reference point. The timing of intrathecal injection was designated as zero for the purpose of calculation. The sensory block was assessed every minute until T10 was attained, followed by evaluations every three minutes until the maximal level of sensory block was achieved, defined as the same level seen in three consecutive assessments. The assessment of sensory level was subsequently halted throughout the procedure. The motor block was evaluated and rated according to the modified Bromage scale [14]. The motor block was evaluated every minute until a Bromage score of 3 was attained, and the duration to get Bromage scores of 2 and 3 was recorded. Surgical readiness was defined as the absence of pinprick sensation at or below T10, accompanied by a modified Bromage score of 2 or above.

Upon the attainment of surgical anesthesia, the patient was transferred to the surgeon. Oxygen was administered to each patient, and SpO2 levels were monitored continuously throughout the surgery. Postoperatively, the patient's vital signs (heart rate, blood pressure, oxygen saturation) and sensory and motor block levels were monitored every 10 minutes for 60 minutes in the post-anesthesia recovery unit (PACU). Intravenous paracetamol infusion (1 g) was administered to individuals who reported pain. Patients were moved to the post-operative ward upon meeting the following criteria: a minimum of 60 minutes in the PACU, stable vital signs, evidence of motor block regression, no analgesia administered in the preceding 20 minutes, and normal awareness. The post-operative monitoring of the patient's vital signs, as well as sensory and motor levels, was maintained in the post-operative ward. Upon perceiving mild tactile stimulation on their legs, the patients were instructed to ambulate independently. Upon the initiation of ambulation, patients were encouraged to try urination. Hospital discharge was recommended when the patient met all the following criteria: complete regression of block height (sensory level to S2), ambulation capability, ability to void (>200 ml), stable vital signs, absence of nausea, pain managed with oral medications (last dose administered at least one hour prior to discharge), and ability to tolerate oral liquids. The duration of eligibility for hospital release was assessed from the administration of spinal anesthetic until the patient met the criteria for discharge preparedness.

The following data was recorded for the current study:
For sensory block: time to reach T10 level, time to reach peak block, and time for complete regression to S2 from peak block.
For motor block: motor block was evaluated using Bromage score.
Furthermore, the length of operation, time to ambulation, time to void, and time to meet discharge eligibility requirements were also documented. Following surgery, any problems like headaches, backaches, nausea, vomiting, urine retention, or indications of TNS were recorded and managed accordingly.
Statistical Analysis: SPSS 23 was used for the data analysis. The t-test for independent samples was employed for continuous variables. p values lower than 0.05 were regarded as significant.

RESULTS:
A total of 60 patients who participated in the study were randomly allocated into two groups. Both groups contained 30 patients. 18(60%) patients in the 2-CP group were males and 16(53.3%) patients were females and 16(53.3%) patients in the Bupivacaine group were males and 14 (46.7%) were females. ASA grading in Group C was shown to be exhibited with n=30 with Grade ASA-I and n=10 with Grade ASA-II, similarly with that of Group B shown to have n=31 with Grade ASA- I and n=9 in Grade ASA-II respectively as shown in Table 1

Table 1: Demographic characteristics

Variable	Group C (n=30)	Group B (n=30)
Age (Years)	40.43±12.66	41.47±12.36
Gender		
Male	18 (60%)	16 (53.3%)
Female	12 (40%)	14 (46.7%)
ASA		
I	16 (53.3%)	17 (56.7%)
II	14 (46.7%)	13 (43.3%)
Duration of surgery	49.32 ± 9.20	50.46± 9.35

The mean time for the start of sensory block was 4.12 ± 1.10 minutes in group C & 5.76 ± 1.45 minutes in group B. the mean time for the beginning of motor block In group C was 5.06 ± 1.71 minutes & 7.86 ± 1.86 minutes in group B. the mean time to reach the maximal sensory block in group C was 14.12 ± 3.75 minutes, & 15.12 ±3.85 minutes in group B. The time to reach sensory regression in group C was 137.20 ± 23.21minutes &, 270.00 ± 34.10 minutes in group B which was statistically significant. The time to reach motor regression in group C was 79.40 ± 10.95 minutes &, 129.80 ± 17.31minutes in group B which was statistically significant as shown in Table 2

Table 2: Anaesthesia characteristics

Parameter	Group C (n=30)	Group B (n=30)	p value
Time to reach Bromage 3 (mins)	5.06 ± 1.71	7.86 ± 1.86	0.08

Time to reach-T10 (mins)	4.12 ± 1.10	5.76 ± 1.45	0.2
Time to reach peak sensory level-T7 (mins)	14.12 ± 3.75	15.12 ±3.85	0.09
Time to reach sensory regression (mins)	135.18 ± 21.18	261.00 ± 32.06	0.001*
Time to reach motor regression (mins)	78.28 ± 9.96	127.54 ± 16.28	0.002*
Time to ambulate (mins)	182.68 ± 16.18	248.64 ± 19.86	0.001*
Time to micturate (mins)	194.56 ± 14.78	298.87 ± 15.86	0.02*
Time to discharge readiness (mins)	194.56 ± 14.78	298.87 ± 15.86	0.01*

The time to ambulate in Group C was 179.72 ± 17.30 minutes and 256.52 ± 21.98 minutes in Group B. The time to micturate in Group C was 195.98 ± 15.69 minutes and 304.74 ± 16.99 minutes in Group B as shown in Table 3

Table 3: Time to Ambulate, Micturate & discharge

Parameter	Group C (n=30)	Group B (n=30)	p value
Time to ambulate (mins)	182.68 ± 16.18	248.64 ± 19.86	0.001*
Time to micturate (mins)	194.56 ± 14.78	298.87 ± 15.86	0.02*
Time to discharge readiness (mins)	194.56 ± 14.78	298.87 ± 15.86	0.01*

1 patient from group C & 2 patients from group B had back pain. 1 patient from group B & 1 patient from group C had Headache. None of the patient had transient neurologic symptoms as shown in Table 4

Table 4: Complications

Complications	Group C (n=30)	Group B (n=30)
Headache	1 (3.3%)	1 (3.3%)
Transient neurologic symptoms	0	0
Back pain	1 (3.3%)	2 (6.6%)

DISCUSSION:

The study intended to compare 2-CP with bupivacaine for spinal anesthesia in an outpatient surgical context. Our first discovery was that spinal anesthetic with 2-CP may provide an adequate surgical block while facilitating an earlier hospital release compared to spinal bupivacaine. This benefit arises from a more expedited regression of the sensory and motor blockade, facilitating swifter ambulation and urination in patients.

In our study, the onset time of sensory block was 4.12 ± 1.10 minutes in group C and 5.76 ± 1.45 minutes in group B, demonstrating statistical significance. The onset time of motor block was 5.06 ± 1.71 minutes in group C and 7.86 ± 1.86 minutes in group B, also showing statistical significance. Ben Gys et al. reported that the onset of sensory block was 10.8 minutes in group C and 11.1 minutes in group B, revealing a statistically significant difference between the two groups [15]. In the research by Teunkens et al. [16], the chloroprocaine group exhibited a much quicker onset of motor block compared to the bupivacaine group.

The average time to attain peak sensory level-T7 in group C was 14.12 ± 3.75 minutes, but in group B it was 15.12 ± 3.85 minutes, which was statistically significant. Ben Gys and colleagues achieved comparable findings [15].

The average time to achieve motor regression in group C was 78.28 ± 9.96 minutes, but in group B it was 127.54 ± 16.28 minutes, with a statistically significant difference. Camponovo et al. reported that Group C exhibited a more rapid onset of motor block (5 minutes compared to 6 minutes), achieved a greater maximum sensory block level (8.5 minutes against 14 minutes), and had a quicker resolution of both sensory and motor blocks (105 minutes as opposed to 225 minutes) [17].

Our main result was that spinal anesthesia with 2-CP can provide a good surgery block while letting patients leave the hospital earlier than spinal bupivacaine. This benefit comes from the fact that the sense and movement block goes away more quickly, which lets people move around and go to the bathroom more quickly. Yoos et al. [18] Showed that 2-CP helped the sense block go away 1.7 times faster, which is a difference of 78 minutes. Laccases et al. [19] also found that relapse happened 2.3 times faster with chloroprocaine than with bupivacaine.

The time it took for group C (182.68 ± 16.18 minutes) and group B (248.64 ± 19.86 minutes) to get back to walking. The voiding function returned in 194.56 minutes, a little more than 14.78 minutes, in Group C and 298.87 minutes, a little more than 15.86 minutes, in Group B. This difference was statistically significant. So, we saw that the time it took for Group C patients to be able to walk and go to the bathroom again was much shorter. The results we got are the same as those from

Dr. Kannan Bojaarraj et al.'s study [20]. They discovered that the chloroprocaine group had quicker function return than the bupivacaine group ($p<0.05$).

CONCLUSION: Intrathecal 1% 2-chloroprocaine 40 mg offers sufficient spinal anesthesia duration for outpatient procedures, with the benefit of markedly expedited recovery of sensory and motor functions relative to 0.5% hyperbaric bupivacaine 10 mg. Consequently, we ascertain that 2-chloroprocaine offers spinal anaesthesia with a more expedited recovery profile than bupivacaine, facilitating faster hospital release after day care procedures.

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