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Original Research Article

Efficacy of isobaric 1% chloroprocaine intrathecal for patients undergoing infraumbilical short surgical procedures

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ABSTRACT

Background: The selection of an ideal anesthetic agent for spinal anesthesia is critical in an ambulatory setting. While lignocaine is associated with transient neurological symptoms (TNS), bupivacaine has a prolonged duration of action. This study aimed to evaluate chloroprocaine for its potential benefits in early ambulation and discharge.

Objectives: To assess the time required for micturition, ambulation, sensory and motor block characteristics, and the time taken for 2-segment regression, as well as to document complications such as hypotension, bradycardia, nausea, and vomiting.

Materials and Methods: Following Institutional Ethics Committee (IEC) approval, this observational study involved 100 ASA I and II patients undergoing surgeries under subarachnoid block. Informed consent was obtained from all participants. All patients received 30 mg of 1% chloroprocaine intrathecally while in a sitting position. The primary endpoints were the time taken for micturition and ambulation, while secondary endpoints included sensory and motor block characteristics, time taken for 2-segment regression, and incidence of complications.

Results: The average time for unassisted ambulation was 130 ± 12.57 minutes, while the time for micturition was 152.59 ± 13.57 minutes. The onset of sensory block was 8.36 ± 1.48 minutes, and motor onset occurred at 10.10 ± 1.2 minutes. The duration of sensory block was 100 ± 12.12 minutes, and motor block lasted 105.93 ± 14.01 minutes. No instances of bradycardia or hypotension were observed in any patient.

Conclusion: Chloroprocaine (30 mg) provided faster recovery from anesthesia, demonstrating its suitability for short outpatient surgical procedures, particularly regarding ambulation and early discharge from the hospital.

1. Introduction

Subarachnoid block (spinal anesthesia) is widely recognized as a preferred technique for infra-umbilical surgical procedures due to its simplicity and rapid onset of both sensory and motor blockade, which is essential for effective anesthesia in such surgeries.[1] While regional anesthesia is commonly used for ambulatory surgeries, spinal anesthesia has traditionally been less popular in outpatient settings, primarily due to the lack of short-acting local anesthetics and concerns about post-dural puncture headache (PDPH). The incidence of PDPH, however, has been significantly reduced with the introduction of thinner gauge spinal

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needles.

Lidocaine, once the most frequently used short-acting local anesthetic, was gradually replaced by low-dose bupivacaine due to concerns over transient neurological symptoms (TNS) associated with lidocaine use.[2] However, low-dose bupivacaine is often inadequate for outpatient surgeries, as it may provide unpredictable durations of anesthesia. Recently, preservative-free chloroprocaine has emerged as a promising alternative for spinal anesthesia in day-care surgeries. Chloroprocaine, a local anesthetic from the ester class, offers the advantage of rapid onset and a shorter duration of action, allowing for early ambulation and hospital discharge with minimal postoperative side effects.[3,4]

Clinical studies indicate that chloroprocaine, in doses ranging from 30mg to 60mg, provides effective spinal blockade with very low incidences of TNS (around 0.6%).[5] Its shorter duration of action, compared to bupivacaine, minimizes postoperative complications and facilitates quicker recovery. Consequently, chloroprocaine has gained popularity as a substitute for longer-acting anesthetics, such as lidocaine and bupivacaine, in ambulatory surgeries.[6] Hence the study was conducted with the objectives to assess the efficacy intrathecal 1% plain chloroprocaine with respect to time required for micturition, ambulation sensory and motor block characteristics with time taken for 2 segment Regression Complications like hypotension, bradycardia, nausea and vomiting.

2. Materials and Methods

The present study was conducted in the Department of Anaesthesiology at JSS Medical College and Hospital, Mysuru, spanning from November 2018 to October 2019. This observational study included 100 patients classified under the American Society of Anaesthesiologists (ASA) physical status class I and II, who were scheduled for infraumbilical short surgical procedures under subarachnoid block. The study protocol was approved by the Institutional Ethical Committee (JSS/MC/PG/4623/2018-19). Informed consent was obtained from all patients prior to their participation in the study. Sample Size was estimated Based on previous study,[7] sample size was calculated using the formula

$N = Z^2 P Q / d^2$

= 1.96 x 1.96 x 0.07 [33]x 0.93/ 0.05 x 0.05 = 100

N – Sample size, Z – standard score, P – prevalence, Q – (1-p) and d – precision limit

A total of 103 patients were recruited for the study to account for possible dropouts, and three patients were excluded, resulting in a final sample size of 100 participants. The sampling technique employed was purposive sampling, with the study population consisting of patients between the ages of 20 and 49 years, with a height range of 150 to 170 cm and a Body Mass Index (BMI) of less than 28 kg/m^2. Exclusion criteria included patients with a basal heart rate of less than 60 beats per minute, refusal to participate, local infections, known allergies to local anesthetics, bleeding disorders, spinal deformities, cardiac diseases, pregnancy, and those in hypovolemic shock.

The anesthetic agent used in the study was 1% chloroprocaine (Chlorquik®), manufactured by Neon Laboratories. A 25-gauge Quincke spinal needle was employed for administering the spinal anesthesia. The methodology of the study commenced with securing ethical approval, followed by informed consent from the selected patients. All patients underwent a thorough pre-anesthetic evaluation on the day before surgery, during which they were also informed about the Nil per Oral (NPO) guidelines, which included a six-hour fasting period for solid foods and a two-hour fasting period for clear liquids prior to the procedure.

On the day of surgery, an 18-gauge intravenous cannula was inserted into each patient before administering spinal anesthesia. The patients were connected to multiparameter monitoring devices to record their baseline parameters, including electrocardiogram (ECG), non-invasive blood pressure (NIBP), and pulse oximetry readings. Spinal anesthesia was administered to the patients in a sitting position using the 25-gauge Quincke spinal needle, through which 30 mg (3 ml) of 1% isobaric chloroprocaine was injected intrathecally. After the administration of anesthesia, the patients were repositioned in a supine posture.

The efficacy of the sensory block was assessed using a pin-prick test with a blunt 26-gauge needle, and the endpoints of the sensory block were carefully documented. Statistical analysis was conducted using SPSS software version 21.0. Descriptive statistics, such as mean, standard deviation, median, and interquartile range (Q1–Q3), were used to summarize the collected data. Proportions were calculated for relevant variables. Inferential statistics were applied through one-way repeated measures ANOVA to determine statistical significance in differences across time intervals. A p-value of less than 0.05 was set as the threshold for statistical significance.

3. Results

In the present study, the mean age of the subjects was 42 ± 12.70 years. A majority of the study population were male (52%), while females comprised 48%. The mean weight of the subjects was 67.85 ± 17.21 kg, and the mean height was 165.80 ± 9.23 cm. Regarding ASA grade, 60% of the subjects were classified as ASA grade 1, while 40% were in ASA grade 2.

The mean time for micturition was 152.59 ± 13.75 minutes, with a median time of 150 minutes. The interquartile range (IQR) for micturition was between 140.00 (Q1) and 160.00 (Q3), with a minimum of 130 minutes and a maximum of 190 minutes. The mean time for

Table 1: Time for micturition and unassisted ambulation

	Mean	SD	Median	Q1	Q3	Min	Max
Time For Micturition	152.59	13.75	150.00	140.00	160.00	130.00	190.00
Time for Unassisted Ambulation	130.35	12.57	130.00	123.50	140.00	100.00	180.00

Table 2: Distribution of study subjects based on duration of sensory block

	Mean	SD	Min	Max
Duration of Sensory Block	100	12.12	88	130
Time of 2 segment regression of sensory block	98.86	11.98	78.00	130.00
Motor Onset (Minutes)	10.10	1.77	6.00	16.00
Duration of motor block	105.93	14.01	67.00	135.00

unassisted ambulation was 130.35 ± 12.57 minutes, with a median of 130 minutes. The IQR for unassisted ambulation was between 123.50 (Q1) and 140.00 (Q3), with a minimum time of 100 minutes and a maximum time of 180 minutes (Table 1).

The mean duration of sensory block was 100 ± 12.12 minutes, with a minimum of 88 minutes and a maximum of 130 minutes. The mean time for two-segment regression of the sensory block was 98.86 ± 11.98 minutes, with a range of 78.00 to 130.00 minutes. The mean motor onset was 10.10 ± 1.77 minutes, with a range of 6.00 to 16.00 minutes. The duration of the motor block lasted for a mean of 105.93 ± 14.01 minutes, with a range of 67.00 to 135.00 minutes (Table 2).

4. Discussion

Ambulatory surgery is becoming increasingly common worldwide due to its many advantages, such as shorter hospital stays, reduced financial burden for both patients and hospitals, early mobility, better safety profiles, and fewer complications. The availability of shorter-acting drugs and necessary equipment has made ambulatory anaesthesia safer, with better patient satisfaction. The most commonly used anaesthesia technique for ambulatory surgeries is regional anaesthesia. However, spinal anaesthesia is less popular in these settings because of the unavailability of short-acting local anaesthetics and the risk of Post-Dural Puncture Headache (PDPH). Using thinner gauge spinal needles has helped reduce the incidence of PDPH.

The ideal local anaesthetic for ambulatory anaesthesia should be safe and of a short duration, which does not delay postoperative discharge. Lidocaine, once the most commonly used short-acting local anaesthetic, was replaced by low-dose bupivacaine for outpatient infraumbilical short surgeries because lidocaine was associated with transient neurological symptoms. However, low-dose bupivacaine often results in inadequate surgical anaesthesia and unpredictable duration.

Recently, preservative-free Chloroprocaine has emerged as an alternative agent for spinal anesthesia in daycare surgeries. Chloroprocaine, an ester-type local anesthetic, has a faster onset and shorter duration of action. Foldes and McNall in 1952, reported 214 cases of subarachnoid block using chloroprocaine, with or without epinephrine, in doses between 82.5 mg and 100 mg. They found that sensory action lasted 82 ± 2.8 minutes with 2% plain Chloroprocaine and 121 ± 3 minutes with the addition of epinephrine.[8] Despite its effectiveness, chloroprocaine did not gain widespread use as a spinal drug, likely due to the success of lignocaine. In the 1980s, instances of transient neurological symptoms were observed, which were believed to be associated with the administration of larger volumes of chloroprocaine epidurally.

A study conducted by Kouri and Kopacz et al compared chloroprocaine with lidocaine in eight volunteers in a randomized crossover trial. Seven of the eight subjects experienced transient neurological symptoms with lidocaine, while none experienced such symptoms with chloroprocaine.[9] This finding demonstrated that chloroprocaine was safe for intrathecal administration and, because of its short duration of action, was a suitable local anesthetic for spinal anesthesia in infraumbilical ambulatory surgeries.

Chloroprocaine 1% was introduced in India in 2018,[10] but few studies have evaluated its efficacy as a spinal anesthetic in ambulatory surgeries in the country. This study aimed to assess the effect of 1% intrathecal chloroprocaine among 100 patients undergoing short surgical procedures, focusing on the onset and duration of sensorimotor action, time for ambulation, and time for voiding urine.

To determine the least effective dosage for subarachnoid block, Kopacz evaluated 10 mg and 20 mg doses of chloroprocaine. The 10 mg dose was found to be ineffective for subarachnoid block, and while the 20 mg dose produced a good level of sensory anesthesia, it did not provide a strong motor block in all patients. Therefore, it was concluded that a dose greater than 20 mg may be required for a dense block.[11] In our study, all patients received a uniform dose of 30 mg (3 ml) preservative-free chloroprocaine in a sitting position using a 25G Quincke spinal needle.

The mean time to unassisted ambulation after the intrathecal injection of chloroprocaine in this study was 130.35 ± 12.57 minutes. A study by Gerhardt et al. found a mean time of 118 ± 20 minutes, which is comparable to our findings.[12] Similarly, Camponovo et al. reported a mean time of 142.5 minutes for unassisted ambulation, which aligns with our results.[13]

The time for sensory onset, defined as the time from completion of the drug administration in the subarachnoid space to the development of a sensory block at the T10 level, was 8.36 ± 1.48 minutes in this study. The sensory onset was determined by the loss of pinprick sensation at the T10 level. The time to achieve the maximum sensory block (T10 level) in this study was 14.17 ± 2.81 minutes. Lacasse et al. reported a similar result, with chloroprocaine reaching its maximum sensory level in approximately 15 minutes.[14]

The duration of the sensory block in our study was 100 ± 12.12 minutes. A study conducted by Suryanayana et al. found that the mean time for a two-segment regression was 46.36 ± 9.87 minutes, which is shorter than the duration found in this study.[15]

The mean time to onset of motor block in this study was 10.10 ± 1.77 minutes. Capdevilla et al. reported a comparable mean onset time of 8.8 ± 4.8 minutes in their study.[16] The mean duration of motor blockade in this study was 105.93 ± 14.01 minutes. Bhaskara et al. found a shorter duration of 81 minutes in their study.[17]

The mean modified Bromage score at the end of surgery in this study was 2.3 ± 0.36, which is comparable to the findings of Siddiah et al., who reported a Bromage score of 2.76 ± 0.76 at the end of surgery.[18]

M Sugumar et al. found that patients who received 1% chloroprocaine had a similar recovery profile, with faster return of sensory and motor functions compared to those administered 0.5% bupivacaine. In their study, chloroprocaine patients experienced shorter times to ambulation and discharge, which is consistent with the present study's findings, showing an advantage in the use of chloroprocaine for rapid recovery and reduced hospital stay.[19] Moreover, Ravi and Krishna et al., observed that isobaric chloroprocaine provided faster onset and recovery times in ambulatory urological procedures compared to general anesthesia, highlighting its efficacy in facilitating early ambulation, similar to the 130.35-minute mean time reported in this study.[20]

Jain et al. also compared 1% chloroprocaine with hyperbaric 0.5% bupivacaine in cesarean sections, finding that chloroprocaine had a faster onset of sensory and motor block, as well as quicker recovery, which is comparable to the 10.10 ± 1.77 minutes motor onset and 105.93 ± 14.01 minutes motor block duration in this study.[21] Prakash et al. compared 1% chloroprocaine with 0.5% ropivacaine for short-duration surgeries and found that chloroprocaine provided faster sensory regression, allowing for earlier discharge, which is consistent with the present study's finding of a mean sensory block duration of 100 ± 12.12 minutes. These studies affirm that chloroprocaine is advantageous for short-duration procedures due to its rapid recovery profile, making it suitable for ambulatory surgeries.[22]

5. Limitations

The present study, while providing valuable insights into the efficacy of 1% chloroprocaine for infraumbilical short surgical procedures, has several limitations. The study was restricted to ASA I and II patients, excluding those with higher surgical risks, limiting the generalizability of the findings to a broader patient population. Additionally, the study did not include a comparison with other short-acting anesthetic agents, such as lidocaine, which would provide a more comprehensive understanding of chloroprocaine's relative effectiveness. Lastly, the study primarily focused on the immediate postoperative outcomes, without long-term follow-up to assess delayed complications or recovery experiences beyond the hospital setting, such as residual pain or long-term neurological effects. These factors warrant consideration in future research.

6. Future Research

Further research could explore chloroprocaine's efficacy in specific populations, such as elderly patients or those with comorbidities, to ascertain whether its efficacy and safety profile holds true across a broader demographic. Additionally, studies comparing the use of adjuncts to prolong its duration or enhance postoperative analgesia could expand its clinical utility.

7. Conclusion

Intrathecal 1% chloroprocaine is a promising alternative for day-care surgeries, providing faster regression of sensory and motor block, which enables early ambulation due to its shorter duration of action.

8. Recommendations

The study demonstrated that intrathecal administration of 1% chloroprocaine is a highly effective anesthetic for infra-umbilical short surgical procedures, offering several advantages in ambulatory settings. The findings confirmed chloroprocaine's rapid onset of sensory and motor blockade, as well as its short duration of action, facilitating early ambulation and discharge additionally, chloroprocaine was associated with a low incidence of postoperative complications and side effects, such as hypotension, bradycardia, nausea, and vomiting. These results support chloroprocaine as a suitable alternative to longer-acting anesthetics like bupivacaine and lidocaine,

especially for day-care surgeries where rapid recovery and minimal side effects are crucial.

9. Source of Funding

None.

10. Conflict of Interest

None.

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