A Prospective Randomized Comparative Study Of Intrathecal Isobaric 1% Chloroprocaine 40MG Versus 0.5% Hyperbaric Bupivacaine 12.5 MG IN Patients Undergoing Short Duration Infra Umbilical Surgeries

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Abstract
AIM: To determine the efficacy of intrathecal 1% Chloroprocaine 40mg compared to intrathecal 0.5% Hyperbaric Bupivacaine 12.5mg in short duration infraumbilical surgeries.

Study Design: Prospective Randomized comparative study. After obtaining Institutional scientific and ethical clearance and written informed consent, 70 patients posted for elective infraumbilical surgeries at Apollo Main hospital Chennai were allocated into two groups by computer generated block randomization. Group C received 4ml of 1% Chloroprocaine and Group B received 2.5ml of 0.5% Bupivacaine heavy.

Materials and Methods: Under standard anaesthetic protocols, intrathecal Chloroprocaine or Bupivacaine administered and following parameters compare the time meeting discharge criteria from Post anaesthesia care unit, the Complete regression of blockade, Time to void and Time to Ambulate between two groups, the time for readiness of surgery (onset of sensory blockade ≥ T10, Bromage score ≤ 2), hemodynamic changes between two groups, and Time requirement of analgesic in the post anaesthesia care unit were compared.

Statistical analysis used: Data were entered in MS-Excel and analysed. Descriptive statistics were represented with percentages, Mean with SD. Chi-square test, Independent t-test were calculated. P<0.05 was considered as statistically significant.

Results: Mean time for eligibility to discharge from hospital between groups were statistically significant with group C having less mean time (245±22 min) as compared to group B (375±19 min).

Conclusion: When compared to 12.5mg of Hyperbaric Bupivacaine 0.5%, intrathecal administration of 40 mg of local anaesthetic 1% Chloroprocaine resulted in a faster recovery from anaesthesia and a shorter time for first rescue analgesic, earlier voiding and unassisted ambulation, favoring earlier discharge from the post anaesthesia care unit. As a result, 40mg of 1% 2-chloroprocaine can be used effectively for short-term lower abdominal and lower limb surgeries.

Keywords: Chloroprocaine, bupivacaine, fast track ambulatory surgery, infraumbilical surgeries

I. Introduction
Ambulatory surgery, also known as day care or fast track surgery, describes the practice of admitting carefully selected and prepared patients on the day of surgery for a planned, non-emergency surgical operation and discharging patients within 24 hours of a procedure. Day care surgery has a large advantage for patients, including obtaining a low risk of hospital infections, a lower expense, and a shorter inpatient stay. The drugs best for spinal anaesthesia in a day care surgery provide faster action, known duration, much less occurrence of the Transient neurological symptoms and minimal systemic effect on body. Chloroprocaine, an amino ester-based local anesthetic, at doses of 30 mg to 50 mg, categorized by a shorter onset and duration of action with an action similar to lidocaine, has shown dural block characteristics same to those of 2% lignocaine, with a very less frequency of the (TNS)-transient neurological symptoms. This study is a comparison of the 2% chloroprocaine and hyperbaric bupivacaine a commonly used intrathecal drug. The primary outcome criteria compare the time meeting discharge criteria from Post anaesthesia care unit - the Complete regression of blockade, Time to void and Time to Ambulate between two groups, secondary were the time for readiness of surgery (onset of sensory blockade ≥ T10, Bromage score ≤ 2), hemodynamic changes between two groups and Time requirement of analgesic in the post anaesthesia care was compared.
II. MATERIAL AND METHODS

After receiving institutional ethical approval and informed consent in writing patients posted for infraumbilical surgeries electively in Apollo Main hospitals chennai, Tamilnadu were included for study. Study was done between February 2021 to February 2022.

2.1 Sample size estimation
With Jessica et al ambulation (simulated discharge) in 2(CP) Chloroprocaine (40 mg) group was 113±14 min and in Bupivacaine (7.5 mg) 191±30 minutes. Keeping this as our background information, with two tail distribution, effect size of 0.7, level of significant at 5%, power of 80% and allocation ratio of 1:1, the required sample size is 35 cases in each group. The total sample required were 70 cases. This size of sample calculation is done using G*Power 3.1.9.2 software.

2.2 Randomization and inclusion exclusion criteria
All the 70 patients has been split into two 1) Group C(chloroprocaine), 2) Group B (Bupivacaine)
Block Randomization:
Block randomization technique will be adopted. Using the random generator software, the sequences will be generated. 35 blocks with block size of 2 will be generated with the sequence. Each block will consist of two sequences either Group C or Group B. All these generated blocks will be put into a concealed envelope and the blocks will be randomly selected by the person who is not a part of the study. According to the selected blocks with the sequence the treatment will be proceeded according to the order. Patient ASA I & II age 18 to 70 years undergoing electively scheduled infraumbilical surgery around 60 mins duration were integrated in the study. The patients with any coagulation abnormality, any neuro disease, sepsis, obesity, pregnant and were excluded.

2.3 Study design: Prospective Randomized comparative study.

III. Methodology

After confirming a 6-hour preoperative fasting status and a brief preoperative review assessment, patients were brought to the operating room identity is confirmed. Standard ASA monitors were fitted and baseline vitals were collected. Preloading with 10ml/kg of 0.9 percent NS normal saline was done once the I.V line was secured. Patients were positioned in a sitting position for spinal anaesthesia, which was administered under strict aseptic conditions. Group C received 4ml of 40mg of 1% chloroprocaine, whereas for Group B 12.5mg (2.5 ml) 0.5% percent Bupivacaine Hyperbaric was administered. The patients were placed in supine immediately and the sensory blockade is evaluated using pin prick examination and Motor blockade using modified Bromage score. Hypotension (>30% from baseline range) was corrected with ephedrine. Bradycardia was corrected with atropine. Post operative parameters assessed were time for motor and sensory regression, time of first analgesic requirement, time to ambulation and time to voiding urine. The patients from PACU has been discharged after modified Aldrete score of ≥ 9 is achieved.

3.1 STATISTICS ANALYSIS:
Data were collected by MS-Excel and interpreted in SPSS.V22. Statistical analysis was done by Comparison of Continuous variable by independent sample ‘t test’. Comparison of categorial variable done by CHI SQUARE or FISCHER’S EXACT TEST or NON PARAMETRIC MANNER WHITNEY U TEST based on number of observations. ‘p’ value, ‘p’ > 0.05 was not significant; values of ‘p’ < 0.05 is significant.
IV. RESULTS

All participants in both groups underwent successful spinal anaesthesia, and no conversion to Intravenous anaesthesia was required to complete the surgery. The average time to achieve motor blockade was faster in the Chloroprocaine group (4.00 ± 1.00 minutes) than in the Bupivacaine group (4.00 ± 2.00 minutes). Hemodynamic parameters during surgery was almost same between both the groups. No incidents of hypotension which required vasopressors and bradycardia in either of the group for the dosing which is used. The average time for motor Reversal to bromage score 4 was shorter in Chloroprocaine group (75 ± 12 minutes) as compared to Bupivacaine (152 ± 11 minutes). The average time to end anaesthesia, i.e. regression of the sensory blockade to the S2 level is relatively shorter in the Chloroprocaine group (111 ± 9) than in the Bupivacaine group (210.5 ± 16 minutes). The time for the first rescue analgesic in the Chloroprocaine group mean (138 ± 14 minutes) was shorter than in the Bupivacaine group (294.5 ± 16 minutes). The time for postoperative ambulation was shorter with chloroprocaine mean (175 ± 20 minutes) than with bupivacaine mean (375 ± 19 minutes). The average time to void in Chloroprocaine group is 245 ± 20 earlier than bupivacaine group B (323.5 ± 26 min). The Chloroprocaine group had a 78-100 minute advantage in this outcome due to faster regression of the block. Thus, both groups had comparable onsets of motor block and sensory blockade, but B Group had a longer motor block duration, sensory blockade, total duration of analgesia, and ambulation.

1- COMPARISON OF PROFILE BETWEEN BUPIVACAINE AND CHLOROPROCAINE

Table 1 - Gender Distribution.

<table>
<thead>
<tr>
<th>Gender</th>
<th>Group B</th>
<th>Group C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency</td>
<td>Percentage</td>
</tr>
<tr>
<td>Female</td>
<td>5</td>
<td>14.3</td>
</tr>
<tr>
<td>Male</td>
<td>30</td>
<td>85.7</td>
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</table>

AGE DISTRIBUTION

MEAN AGE:

Table 2 - Age comparison

<table>
<thead>
<tr>
<th>AGE</th>
<th>GROUP</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
<td>48.83</td>
<td>13.261</td>
<td>2.242</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>47.29</td>
<td>13.562</td>
<td>2.292</td>
</tr>
</tbody>
</table>

BOX PLOT REPRESENTS MEAN AGE OF TWO GROUPS.

ASA DISTRIBUTION:

Table 3 – ASA Distribution

<table>
<thead>
<tr>
<th>ASA</th>
<th>Group B</th>
<th>Group C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency</td>
<td>Percentage</td>
</tr>
<tr>
<td>1</td>
<td>14</td>
<td>40.0</td>
</tr>
<tr>
<td>2</td>
<td>21</td>
<td>60.0</td>
</tr>
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</table>

ECG DISTRIBUTION

Table 4 – ECG Distribution

<table>
<thead>
<tr>
<th>ECG</th>
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<th>Group C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency</td>
<td>Percentage</td>
</tr>
</tbody>
</table>
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**WEIGHT - DISTRIBUTION**

<table>
<thead>
<tr>
<th>GROUP</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>WEIGHT B</td>
<td>73.89</td>
<td>9.854</td>
<td>1.666</td>
</tr>
<tr>
<td>C</td>
<td>72.97</td>
<td>8.863</td>
<td>1.498</td>
</tr>
</tbody>
</table>

**SECONDARY OBJECTIVE VARIABLES**

Intraoperative parameters variables

**MOTOR AND SENSORY BLOCKADE VARIABLES**

<table>
<thead>
<tr>
<th>VARIABLE</th>
<th>MEDIAN</th>
<th>IQR</th>
<th>P VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOTOR BLOCK BROMAGE SCORE≤2</td>
<td>4.00</td>
<td>2</td>
<td>0.042*</td>
</tr>
<tr>
<td>SENSORY BLOCK LEVEL (COLD TOUCH) ≥ T10</td>
<td>7.00</td>
<td>1</td>
<td>0.145</td>
</tr>
</tbody>
</table>

There is considerable difference in motor blockade bromage score among B and C group. p<0.0.

**INTRAOPERATIVE HEMODYNAMIC PARAMETERS**

**HEART RATE VARIABLES**

Independent t test for Heart rate:

![Figure2–Graphical analysis of Heart Rate.](image)
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Figure 3 – Systolic Blood Pressure Graphical diagram

POSTOPERATIVE PARAMETERS

<table>
<thead>
<tr>
<th>Variable</th>
<th>Median</th>
<th>IQR</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOTOR REVERSAL (Bromage score 4)</td>
<td>Group B</td>
<td>152</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>Group C</td>
<td>75</td>
<td>12</td>
</tr>
<tr>
<td>SENSORY REGRESSION TO L1</td>
<td>Group B</td>
<td>180</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Group C</td>
<td>95</td>
<td>11</td>
</tr>
<tr>
<td>COMPLETE REGRESSION OF BLOCK TO S2</td>
<td>Group B</td>
<td>210.5</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>Group C</td>
<td>111</td>
<td>9</td>
</tr>
<tr>
<td>FIRST ANALGESIC REQUIREMENT</td>
<td>Group B</td>
<td>294.5</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>Group C</td>
<td>138</td>
<td>14</td>
</tr>
<tr>
<td>TIME TO VOID</td>
<td>Group B</td>
<td>323.5</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td>Group C</td>
<td>245</td>
<td>20</td>
</tr>
<tr>
<td>TIME TO AMBULATE</td>
<td>Group B</td>
<td>375</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>Group C</td>
<td>175</td>
<td>20</td>
</tr>
</tbody>
</table>

There is significant difference in all the variable between B and C.

V. DISCUSSION

The study included seventy ASA 1-2 patients of all genders, aged 18 to 80 years, who undergone electively planned surgery procedures that was estimated to take about 60 minutes from the moment of subarachnoid block. Group C had received 40mg of 1% 2chloroprocaine(2-CP) in a 4ml solution, while Group B had received 12.5mg of hyperbaric 0.5 % percent Bupivacaine in 2.5ml solution. The very aim of this study was to evaluate Chloroprocaine versus bupivacaine for spinal anaesthesia in an fast track surgery setting. Our main funding came from the fact that intrathecal anaesthesia with Chloroprocaine can give a adequate surgical block while allowing for an earlier discharge from the hospital than spinal bupivacaine. This benefit comes from a faster motor blockade and sensory blockade regression, allowing the patient to ambulate and urinate more quickly.

Because the lowest dosing of each medication was thought to be clinically effective, the Bupivacaine and 2-(CP)Chloroprocaine doses used in our study are considered pharmacologically equivalent. Kopacz determined that a dosing of 40 mg to 60 mg of (CP) 2-chloroprocaine provided dependable motor blockade and sensory blockade for short surgical procedures1. Casati et al discovered that 40mg of(CP)chloroprocaine was the best dose for intrathecal anaesthesia because lower doses ended in insufficient anaesthesia duration and higher doses only resulting in a longer time for blockade recovery20. Sell et al. confirmed the same results21. The spinal Hyperbaric Bupivacaine median dose is 12.5mg Hyperbaric bupivacaine is selected because of predictable drug spread, Vishal Uppal,FRCA et al. In their meta-analysis study, both hyperbaric and isobaric bupivacaine provided

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effective anaesthesia with no differences in failure rate or side effects. The hyperbaric formulation enables a relatively rapid onset and duration of motor and sensory block. In terms of sensory and motor blockade, the isobaric preparation has a slower onset and lasts longer. Ban Leong Sng ³⁸ supports with these studies so that Hyperbaric bupivacaine 12.5 mg were selected to compare with Chloroprocaine.

Efficacy variables of spinal block
All participants in both groups underwent successful spinal anaesthesia, and no intravenous general anaesthesia was required to completion of the surgery. This is consistent with the results of research on low dose Bupivacaine and 2 -CP Chloroprocaine undertaken by Neilson Get al³¹, Rosenberg et al³⁸

Onset of motor and sensory blockade: The average time required to achieve motor blockade was faster in the 2-(CP) Chloroprocaine group (4.00 ± 1.00minutes) than in the Bupivacaine group (4.00±2.00minutes). This is consistent with the findings of wulf H et al¹⁴, Vandenbroucke F et al¹⁶, and Vermeulen et al¹⁷s multicenter trial. The mean time difference between intrathecal block and sensory blockade at T10 dermatome level was the same in the 2-Chloroprocaine and Bupivacpine groups. Chloroprocaine has a shorter latency of action than Bupivacaine, which is consistent with the findings of wulf H et al¹⁵, Vandenbroucke F et al¹⁶, and Vermeulen K et al¹⁷.

Sensory blockade regression to S2: The average time to end anaesthesia, i.e. recovery of sensory blockade to S2 level, was relatively short in the 2Chloroprocaine group (111± 9) than in the Bupivacaine group (210.5 ± 16 minutes). This supports the findings of Vandenbroucke F et al¹⁶, Vermeulen K et al¹⁷, and in their studies linking the regression characteristics of Group B-Bupivacaine and Group C - 2-CP Chloroprocaine.

Time of rescue analgesic and unassisted ambulation: The time for the first rescue analgesic in the Chloroprocaine group mean (138±14 minutes) was shorter than in the Bupivacaine group (294.±16 minutes). This is consistent with the findings of wulf H et al¹⁵, Vandenbroucke F et al¹⁶, and Vermeulen K et al¹⁷. It is worth notable that patients in the Chloroprocaine group C reported occurrence of pain in the post anaesthesia care room.

As a rescue analgesic, they were given Inj.paracetamol. This may not always be a drawback of 1% Chloroprocaine administration. Because their spinal anaesthesia regressed more quickly, patients in the 2-Chloroprocaine group had experienced the most pain occurrence in the post anaesthesia recovery room. As a result, patients in the Chloroprocaine group received nonopioid analgesics relatively early. The time for postoperative mobilization was shorter with chloroprocaine mean(175±20 minutes) than with bupivacaine (375±19 minutes), demonstrating chloroprocaine's superiority in day care settings. This is consistent with the findings of wulf H et al¹⁵, Vandenbroucke F et al¹⁶, and Vermeulen K et al¹⁷.

Time to void – The average time to void in Chloroprocaine group is 245±20 earlier than bupivacaine group. B 323.5± 26 similar to Vandenbroucke F et al³⁸ results. Despite good block regression and successful mobilization many of the bupivacaine patients had experienced a significant delay from their first voiding attempt and subsequent successful completion. The delaying could be the need for the sensory blockade to be re各家 to at least the S3 dermatomal level in order to restore normal bladder detrusor activity. The most beneficial outcome is the time for sensory blockade regression to S2, as the Chloroprocaine was 2-time faster than bupivacaine. The time to eligibility for post anaesthesia care unit discharge, the primary outcome of this study, was monitored from the time intrathecal anaesthesia was administered to the time that the patient met all of the discharge eligibility criteria.

Time to attain discharge eligibility: The Chloroprocaine group had a 78-100 minute advantage in this outcome due to faster block regression, which resulted in earlier mobilisation and voiding which were comparable with the findings of C. Camponovo etal³⁴, Jessica etal³⁹. We compared anawin, a type of bupivacaine with good anaesthetic properties, to chloroprocaine. The volume, dose, concentration, and baricity of the medication all influence the onset of sensory block. Thus, both groups had comparable onsets of motor block and sensory blockade, but group-B duration of motor blockade is longer, and longer sensory blockade, total duration of analgesia, and ambulation.

Side effects: There had been no instances of TNS-transient neurological symptoms in either group, according to the follow-up. This is consistent with the findings of Kopacz DJ et al, in their research study.

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comparing the spinal 2-Chloroprocaine and 2% lignocaine4. Pollock JE et al. reported similar results in their analytical study which had been done retrospective study44. In a study comparing Bupivacaine and Chloroprocaine, Marie-Andre'e Lacasse established one potential case of transient neurological symptom in each of the group45. These findings are similar to those of C. Camponovo et al46, Jessica et al49, who discovered that the anaesthetic properties of both groups were similar except for chloroprocaine's quick anaesthetic turnaround.

VI. Conclusion

When compared to 12.5mg of Hyperbaric Bupivacaine 0.5%, administration of 40mg of local anaesthetic, 1% 2-Chloroprocaine in intrathecal space resulted in a faster recovery from spinal anaesthesia and a shorter time needed for first rescue analgesia, earlier voiding and unassisted mobilization or ambulation, favoring earlier discharge from the post anaesthesia care unit. As a result, 40mg of 1% chloroprocaine( 2 - CP) can be used effectively for short duration infraumbilical surgeries.

7. Source of the Funding- Nil

8. Conflict of Interest

The author declares that there is no conflict of interest.

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