

## **A Comparative Evaluation between 4 ml Intrathecal 1% 2 Chloroprocaine and Intrathecal 0.5% Levobupivacaine for Infraumbilical Short Surgical Procedures under Subarachnoid Block: A Clinical Study**

**Sonam Shrivastava<sup>1</sup>, Jitendra Kushwaha<sup>2</sup>, Urmila Keshari<sup>3</sup>, Rajkumar Ahirwal<sup>4</sup>**

<sup>1</sup>Post Graduate Student, MD Anesthesia, Department of Anaesthesiology, Gandhi Medical College Bhopal, MP, India

<sup>2</sup>Senior Resident, Department of Anaesthesiology, Gandhi Medical College, Bhopal, MP, India

<sup>3</sup>Professor, Department of Anaesthesiology, Gandhi Medical College, Bhopal, MP, India

<sup>4</sup>Associate Professor, Department of Anaesthesiology, Gandhi Medical College, Bhopal, MP, India

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Corresponding author: Dr. Rajkumar Ahirwal

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### **Abstract**

**Aim:** This study aims to assess the anaesthetic effects of intrathecal 1%, 2-chloroprocaine versus intrathecal 0.5%, levo bupivacaine in infraumbilical short surgical procedures.

**Material and Methodology:** After obtaining approval from the Institutional Ethics Committee and written informed consent from patient, the present prospective randomised double blind study entitled was carried out on 60 patients (ASA grade I and II ) age of 18-45 years of either sex scheduled for infraumbilical surgeries. The selected patients were randomly divided into two equal groups of 30 patients. GROUP CP patients received 40 mg 1% chloroprocaine and GROUP LB patients received 30 mg 0.5% levobupivacaine. The parameters assessed were duration of sensory & motor blockade, perioperative hemodynamic effects and duration of post operative analgesia.

**Results:** In our study, we observed that, the mean onset time of sensory block was early in CP group ( 3.75±1.5 min in CP and 4.25±0.75 min in LB) but was not significant. The time for two segment regression of sensory block was 49.22±6.52 min versus 78.97±6.17 min in group CP group and LB group respectively with significant p value. It was significantly shorter in group CP. The time for complete regression to S2 in CP group was 112.15±33.45 min and in group LB 252.16±31.43 min which was statistically significant. Onset of motor block was shorter in CP group 4.75±0.55 min than LB group 5.80±0.65 min. Duration of motor block was observed and found that it was shorter in CP group, 108.91±5.15 min versus 222.12±16.60 min in LB group. Duration of analgesia was 118±2.18 min versus 214±4.20 min in group CP and LB respectively with significant p value. Hemodynamic parameters were stable in both the groups.

**Conclusion:** According to the results obtained from the present study it is concluded that chloroprocaine intrathecally in dose of 30 mg provides adequate duration & Surgical anaesthesia for infra-umbilical surgeries with the advantage of earlier onset and faster regression of spinal block, resulting in earlier hospital discharge with stable hemodynamics as compared to 0.5% Levobupivacaine 30 mg.

**Keywords:** Levobupivacaine, chlorprocaine, Subarachnoid block, Motor block, Sensory block.

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## Introduction

Regional anaesthesia techniques provide an excellent means for managing intra-operative and post operative pain relief in the lower abdominal and lowerlimb surgeries . [1]

Spinal anaesthesia is one of the most commonly used Regional Anesthesia anaesthetic technique for surgery of the lower abdomen and lower limbs.' Single injection spinal anaesthesia with local anaesthetic shows a reliable anaesthetic profile, ease of administration, cheaper and minimal side effects including postoperative nausea and vomiting. Spinal anaesthesia requires a small volume of local anaesthetic that is almost devoid of systemic pharmacologic effect to produce rapid, profound, reversible sensory analgesia. [2] It is very secure and reliable technique for the procedures of infraumbilical region. However, some of the features of spinal anaesthesia may restrict its use for ambulatory surgery including delayed mobilisation due to motor blockade, risk of urinary retention and severe pain after block regression. [3]

The choice of correct local anaesthetic for spinal anaesthesia is therefore very important in the ambulatory surgery. An ideal local anaesthetic would provide fast onset of action, appropriate surgical anaesthesia of adequate duration, early recovery of sensory and motor block, early ambulation, decreased neurotoxicity and systemic side effects. [4]

With discovery of amide local anaesthetics revolution has been seen. Since 1949 Lignocaine Lidocaine has been the anaesthetic of choice for years. However, its use has been associated with greater risk of transient neurological symptoms[TNS] and most anaesthesiologist have therefore stopped its use. [5]

Procaine is a short acting ester local anaesthetic agent having infrequent incidence of TNS but associated with high incidence of clinical block failure and prolonged discharge due to nausea and vomiting, so it is not suitable for daycare surgery. [6,7]

Bupivacaine is very popular and greatly used long acting local regional anaesthetic, which like all amides anaesthetics has been associated with cardiac toxicity when used in higher concentration or when accidentally administered intra vascularly. It is a highly protein bound long acting local

anaesthetic agent with slow onset having prolonged motor and sensory blockade, delayed anaesthetic recovery, urinary retention frequently leading to the delay in hospital discharge. Hence it is not suitable for daycare surgery. [8]

The levorotatory isomer[ S ] of Bupivacaine that is levobupivacaine shown to have a very safe pharmacological profile with much less cardiac and neurotoxic adverse effects. The decreased toxicity of levo bupivacaine is attributed to its faster protein binding rate.

The pure S(-) enantiomers of bupivacaine that is levo bupivacaine were thus introduced into the clinical anaesthesia practice. [9]

Levo bupivacain is the local anaesthetic drug belonging to amino ester group. It is S-enantiomer of bupivacaine. It provides late resolution of block, late ambulation, prolonged urinary retention and delayed patient discharge. It has been seen that ,the clinical anaesthetic effect of the levobupivacaine is indistinguishable from that of bupivacaine in individual patients however the safety profile of levo bupivacaine confers the advantage over its racemic parent [9,10]

Foldes and McNall(1952) [11] had first introduced Chlorprocaine a ultrashort acting ester local anaesthetic for the use in spinal anaesthesia. It is rapidly metabolised by pseudocholine esterase an enzyme responsible for its very short half-life. Chlorprocaine when used in spinal anaesthesia provides appropriate duration and adequate depth of surgical anaesthesia for short procedures with the advantages of faster block resolution and earlier ambulation and hospital discharge. [12]

Since 1952 Chlorprocaine has been used for spinal anaesthesia. Sodium bisulfite was then added as an antioxidant in 1956. [13]

In 1980 several reports of neurological deficit in patients receiving accidentally high dose of intrathecal chlorprocaine during epidural labour analgesia. Spinal injection was initially linked to neurological injuries. However subsequently, it was determined that these injuries were due to either the preservative or accidental injection of epidural dose [14] Wang et al [15] & Gissen *et al* [16] determined that the combination of antioxidant sodium bisulfite and low pH was the cause of persistent neurologic deficit. Recently antioxidant and preservative free chlorprocaine available for intrathecal use. [17]

The present study was designed to compare the effect of intrathecal 1% 2-chlorprocain 4 ml(40 mg) versus intrathecal 0.5% levo bupivacaine 3 ml(30mg) in infraumbilical short surgical procedures.

### Aims and Objectives

This study will be conducted in patients scheduled for infraumbilical short surgical procedures done under spinal anaesthesia with following aims and objectives:

- To evaluate the efficacy of 1% 2-Chlorprocaine[40 mg] in spinal anaesthesia.

- To evaluate the efficacy of 0.5% Levobupivacaine[30mg] in spinal anaesthesia.
- To observe the haemodynamic changes associated with drug in spinal anaesthesia
- To observe any side effect and complication associated with the study drug and technique.

### Materials and Methods

After obtaining approval from the Institutional Ethics Committee and written informed consent from patient, the present prospective randomised double blind study entitled was carried out on 60 patients (ASA grade I and II ) age of 20-50 years of either sex scheduled for infraumbilical surgeries in the Department of Anaesthesiology, Gandhi Medical College and Hamidia Hospital, Bhopal (M.P.).

### Inclusion criteria

1. Consent to participate in study.
2. Age 18-45 years of either sex of ASA grade I and II.
3. Weight 40-70 kg.
4. Patient scheduled for elective infraumbilical surgery less than 60 minutes.

### Exclusion criteria

1. Patient's refusal.
2. Uncooperative patient.
3. Infection at the site of injection.
4. Coagulopathy or bleeding diathesis.
5. Neurologic disease (multiple sclerosis, symptomatic lumbar herniated disc, spinal stenosis).

### Methodology

**Preanaesthetic assessment:** All the patients were examined a day before surgery to do complete general, physical and systemic examination. All the required routine and special investigations as per protocol including complete blood count, random blood sugar, blood urea, serum creatinine,

E.C.G. (above 30 years of age) and Chest x ray (above 30 year of age) as per hospital protocol were carried out. The purpose and protocol of the study were explained to patients and informed written consent was obtained.

### Grouping:

GROUP CP (n=30) 40 mg 1% chloroprocaine

GROUP LB (n=30) 30 mg 0.5% levobupivacaine

### Preparation of patient:

- All patients were kept nil orally for atleast 6 hours before the procedure.
- Upon arrival of the patient in the operation theatre, intravenous access with 18 G cannula was inserted into the patient's forearm.
- All routine monitors including Pulse oximeter, NIBP and E.C.G were connected, and observations were recorded by multipara monitor.
- Preloading was done with approximately 10 ml/kg of lactated ringer solution. The patient was premedicated with 0.1mg/kg ondansetron and 0.1 mg/kg of midazolam.
- All the baseline (BO) vitals parameters including pulse rate (PR), Non — invasive Systolic blood pressure (SBP), Diastolic blood pressure (DBP), MAP and Spo2 were recorded preoperatively.

### Material

- An autoclaved tray consisting of adequate cotton swabs with swab holding forcep.
- Antiseptic solutions and drapes.
- Disposable 25G spinal needle.
- Disposable 5cc syringe, 2cc syringe and 22G hypodermic needle.

### Methods

Under all aseptic precautions, Lumbar puncture was done in sitting position at the

L3-L4 interspace via midline approach using 23G Quincke spinal needle. Subarachnoid block (SAB) was performed after ensuring free flow of CSF, the study drug was injected and then patient was put in supine position immediately for the remaining of the study period.

### Parameters of study

1. Time for onset of sensory block
2. Time for onset of motor block
3. Peak level dermatome
4. Duration of motor block
5. Duration of Analgesia
6. Assessment of Haemodynamic parameters (PR, SBP, DBP & MAP) & Spo2
7. VAS Score at different time interval for first rescue analgesic (TRAI)
8. Observation & recording of side effects & complication of the study drugs and technique.

#### 1. Time For Onset Of Sensory Block Up to T6

Time for onset of sensory level of the block upto T6 (in min) was assessed by loss of pinprick sensation with 23 gauge hypodermic needle after injection of the study drug.

#### 2. Time For Onset of Motor Block (Bromage 3)

Evaluation of motor blockade was assessed by the Bromage scale [18]

0 no motor block

1 able to bend the knee (hip blocked)

2 able to dorsiflex the foot (hip and knee blocked)

3 complete motor block (hip, knee and ankle blocked).

Time for onset of motor block (Bromage 3) in minutes was recorded after injection of the study drug.

#### 3. Peak Level Dermatome

Highest level dermatome was assessed by 23 gauge hypodermic needle after obtaining complete sensory block.

#### 4. Duration Of Motor Block (Bromage 0)

Postoperatively all patients were transferred to the postanesthesia care unit (PACU) where patients were assessed for duration of motor block (Bromage 0), duration of analgesia and time of first mobilization were defined as clinically end points.

#### 5. Duration of Analgesia

Duration of analgesia defined as from onset of analgesia after spinal anaesthesia to onset of pain was recorded.

#### 6. Assessment of Haemodynamic Parameters

Haemodynamic parameters including PR, SBP, DBP, MAP and Spo<sub>2</sub> were recorded at S3, S5, S10, S15, S30, S60, S90, S120, S150 and S180 minutes after injection of study drug. During surgery, any fall in MAP below 20% of baseline value was treated with bolus dose of inj. Mephenteramine 0.12 mg/kg i.v. PR <60 beats /min was treated with inj. Atropine sulphate 0.01mg/kg i.v. Total dosage of bolus drugs were recorded.

#### 7. Vas Score at Different Time Interval for First

##### Rescue Analgesic (Tra1) [19]

Postoperative pain was assessed by Visual analogic score scale consisting of a 10 cm horizontal scale with gradations marked as 0' means no pain at all and 10 means worst pain imaginable.

0 No pain

1-3 Mild pain

4-6 moderate pain

7-10 Severe pain

VAS score was noted at time for first rescue analgesic (TRA I).

VAS score >3 was managed with rescue analgesia with inj. Tramadol 2 mg/kg i.v.in 100 ml normal saline to relieve postoperative pain.

#### 8. Observation and Recording of Side Effects and Complication of The Study Drugs and Technique

Any side effect or complication due to the drug or technique were noted including hypotension, bradycardia, postoperative nausea vomiting (PONV), urine retention, TNS & shivering were recorded.

#### Statistical Analysis

After compilation of data, it was analysed statistically by SPSS software version 20.0. Statistical tests used were Student t-test (paired and unpaired) and Chi square test. Significance level will be 95% confidence level (p<0.05). Data was described as a frequency (Percentage) distribution as well as in Mean±SD. Data was presented through suitable statistical graphs.

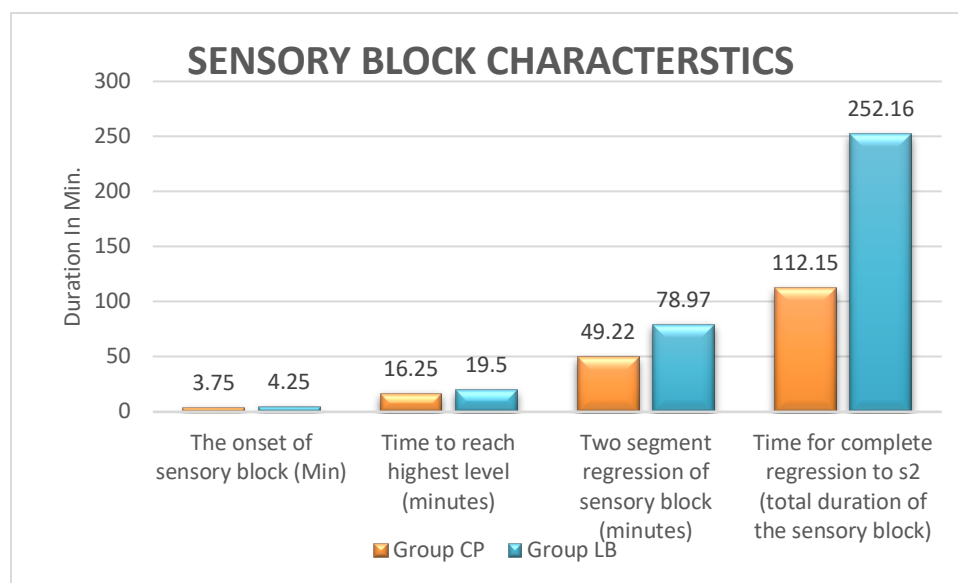
#### Observation & Results

This study is conducted to assess and compare the onset, level and regression of sensory and motor block, postoperative ambulation, intra-operative and post-operative analgesic effect, hemodynamic stability and side effects if any after giving 1% 2-chloroprocaine (40 mg) vs 0.5% hyperbaric bupivacaine (30 mg) in spinal anaesthesia in an ambulatory setting

**Table 1: Demographic Profile & Duration of Surgery**

	Group CP( n =30)	Group LB(n = 30)	P value
Age (Years)	33±8.85	34±9.92	0.634
Weight(kg)	56±4.31	57±4.96	0.335
Mean duration of Surgery(Min.)	25.33±3.30	28.25±4.5	0.821(NS)

Demographic profile of patients in both groups are comparable. Age, weight, duration of surgery are non-significant when compare statistically.



**Graph 1: Sensory Block Characteristics**

Graph 1: Shows Sensory block Characteristics;

Onset of sensory block (min)  $3.75 \pm 1.5$ ,  $4.25 \pm 0.75$  ( $p < 0.800$ ) in Grp CP, Grp LB respectively, Time to achieve highest level (min)  $16.25 \pm 2.2$ ,  $19.50 \pm 1.25$ , Time for two segment regression (min)  $49.22 \pm 6.52$ ,  $78.97 \pm 6.17$ , Duration of sensory block (min)  $112.15 \pm 33.45$ ,  $252.16 \pm 31.43$  ( $p < 0.001$ ) Statistically significant.

Table 2: Motor blockade characteristics, duration of analgesia [Mean ± SD]. Group A Group B P-value The onset of motor block(minutes.)  $3.87 \pm 0.75$ ,  $6.12 \pm 0.65$  3/rescue analgesia) (minutes)  $114.31 \pm 2.15$ ,  $224.66 \pm 12.05$   $< 0.0001(S)$ .

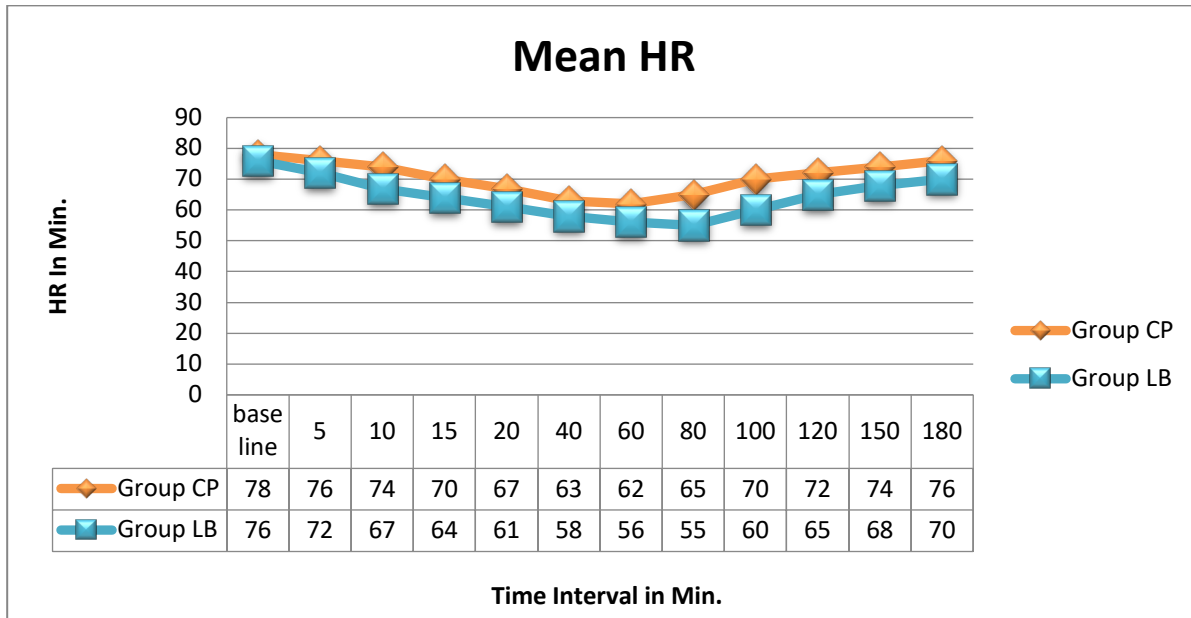
**Table 2: Motor Block Characteristics**

	Group CP	Group LB	P-value
The onset of motor block(mins.)	$4.75 \pm 0.55$	$5.80 \pm 0.65$	$< 0.0001(S)$
Total duration of motor block (mins)	$108.91 \pm 5.15$	$222.12 \pm 16.60$	$< 0.0001(S)$
Duration of analgesia (VAS score > 3/rescue analgesia) (mins)	$118 \pm 2.18$	$214 \pm 4.20$	$< 0.0001(S)$
Time for Unassisted Ambulation (min.)	$144 \pm 3.8$	$246 \pm 5.10$	$< 0.0001(S)$

Table 2: Motor blockade characteristics, includes

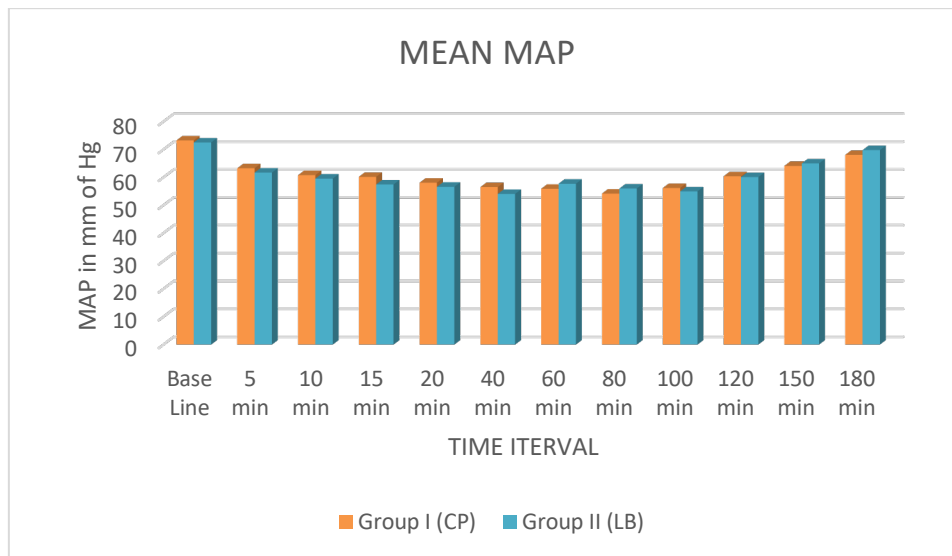
The onset of motor block(minutes.)  $4.75 \pm 0.55$ ,  $5.80 \pm 0.65$ , Total duration of motor block (min)  $108.91 \pm 5.15$ ,  $222.12 \pm 16.60$ ,

Duration of analgesia (VAS score >3 /Rescue analgesia) (minutes)  $118 \pm 2.18, 214 \pm 4.20 < 0.0001(S)$   
 Time for Unassisted Ambulation (min.)  $144 \pm 3.8, 246 \pm 5.10$ . (statistically significant)



**Graph 2: Mean Heart Rate**

Baseline Hemodynamic parameters Heart Rate & BP are comparable in both the groups, after spinal block there is gradual reduction in HR & MAP till 20 min. (statistically non-significant, Figure 2 & 3).



**Graph 3: Mean Map**

Hemodynamically (HR, BP, SPO2) both the groups are comparable throughout study period. Bradycardia & hypotension is observed in Group LB manage with bolus IV fluids. (Table 4)

**Table 4: Comparison of Side Effect**

Side Effect	Group CP	Group LB
TNS	0	0
Bradycardia	1	2
Hypotension	0	2
Nausea /Vomiting	1	1
Respiratory /Depression	0	0
Urinary Retention	0	0
Shivering	1	2

The most commonly occurring adverse effect TNS, was not observed with this new Chlorprocaine preparation.

## Discussion

Spinal anesthesia is a preferred technique for infraumbilical surgeries due to various advantages like rapid onset and offset, inexpensive and easy technique.

Chlorprocaine is an amino-ester and Levobupivacaine is an amino –amide group of local anesthetics. As the duration of anesthetic action of local anesthetics is dose dependent, a dose of 30 and 60 mg of chlorprocaine used for surgical procedures lasting 60 mins or less and a dose of 10 mg has no effect as in study Gebhardt et [20] but in study Casati *et al* [21] concluded that chlorprocaine 30 mg had insufficient duration of spinal blockade. Minimum levobupivacaine dose 10 mg in cesarean section by study Parpaglioni *et al* [22]. In this study we aim to compare intrathecal 1% 2-chlorprocaine 40 mg with 0.5% levobupivacaine 30mg in infraumbilical surgeries.

The demographic profile between the two groups were comparable and did not show any significant statistical difference ( $p > 0.05$ ). Mean age was  $33 \pm 8.85$  years in CP group and  $34 \pm 9.92$  year in LB group. Mean weight was  $56 \pm 4.31$  kg in CP group and  $57 \pm 4.96$  kg in LB group and mean duration of surgery was  $25.33 \pm 3.30$  mins in CP group and  $28.25 \pm 4.5$  mins in LB group.

Sensory blockade characteristics ; onset, time to reach highest level ,two segment regression and time for complete regression to S2 were compared . In our study ,the mean onset time of sensory block was early in CP group(  $3.75 \pm 1.5$  mins in CP and  $4.25 \pm 0.75$  mins in LB) but was not significant  $P = 0.800$  similar results obtained in the study Lacasse *et al* [23] with 2% chlorprocaine 40mg with bupivacaine showed chlorprocaine had early onset  $6 \pm 4$  mins but was also not statistically significant. In the study Bhaskara *et al* [24] showed Chlorprocaine had faster onset of sensory blockade  $2.26 \pm 0.52$  min than levobupivacaine  $3.36 \pm 0.49$  min and was statistically significant.

Time to reach highest level of sensory block T6 with chlorprocaine was  $16.25 \pm 2.2$  mins and with levobupivacaine was  $19.50 \pm 1.25$  mins which was not statistically significant  $p = > 0.05$ . In study Veena charath *et al*. [25] found similar results with chlorprocaine  $4.40 \pm 1.45$  and with levobupivacaine  $8.10 \pm 0.83$ , maximum sensory level achieved was T4. The study by del rio vellosillo *et al* [26] on chlorprocaine and on levobupivacaine had similar results.

The time for two segment regression of sensory block was  $49.22 \pm 6.52$  min versus  $78.97 \pm 6.17$  min in group CP group and LB group respectively with significant p value



<0.0001. It was significant shorter in group CP. Our results coincide with the study Rachit sinha *et al* [27] In group A with chlorprocaine was  $43.06 \pm 8.75$  min and group B with levobupivacaine was  $119.31 \pm 34.87$  min and was statistically significant. The study by Bhaskara *et al* [24] sensory regression in chlorprocaine group was shortest  $59.0 \pm 8.75$  and longest in levobupivacaine group  $126 \pm 20.11$  min  $p < 0.0001$ .

The time for complete regression to S2 in CP group was  $112.15 \pm 33.45$  mins and in group LB  $252.16 \pm 31.43$  mins which was statistically significant  $p < 0.0001$ . Levobupivacaine was associated with higher duration  $153 \pm 20.4$  min & in study Yoos, Kopacz *et al* [28] found that the time for regression of sensory block with 2 Chlorprocaine was 1.7 times faster than bupivacaine.

Motor block characteristics was observed ; onset and total duration of motor block. In our study, we observed that onset of motor block was shorter in CP group  $4.75 \pm 0.55$  mins than LB group  $5.80 \pm 0.65$  mins which was statistically significant  $p < 0.0001$ . In study Bhaskara *et al* [24]; onset of motor block was not statistically significant between the group chlorprocaine  $1.43 \pm 0.5$  min and levobupivacaine  $1.57 \pm 0.50$  mins; but in study Rachit sinha *et al* [27]; Onset of motor block was statistically significantly less in chlorprocaine group  $7.40 \pm 1.5$  than levobupivacaine group  $10.91 \pm 3.47$ , as found in our study.

Duration of motor block was observed and found that it was shorter in CP group,  $108.91 \pm 5.15$  min versus  $222.12 \pm 16.60$  min in LB group and was statistically significant,  $p < 0.0001$ . The study done by Lacasse *et al* [23] with 2% chlorprocaine 40mg with bupivacaine found shorter duration of motor blockade in chlorprocaine group  $76 \pm 25$  min versus bupivacaine  $119 \pm 93$  mins and in study

done with levobupivacaine Singh A *et al* [29] found that duration of motor block with levobupivacaine was shorter  $185.9 \pm 20.3$  mins than bupivacaine  $196.4 \pm 21.2$  mins and was not statistically significant.

Duration of analgesia was  $118 \pm 2.18$  min versus  $214 \pm 4.20$  min in group CP and LB respectively with significant  $p$  value  $< 0.0001$ . Similar results found in study Bhaskara *et al* [24] ; analgesic supplementation was required within a short period of time in group chlorprocaine  $85.33 \pm 5.07$  mins than group levobupivacaine  $156 \pm 24.44$  mins.

Time for unassisted ambulation was  $144 \pm 3.8$  mins in group CP and  $246 \pm 5.10$  mins in LB group which was statistically significant  $p < 0.0001$ ; when compared with other studies, Casati *et al* [21]; the time for unassisted ambulation was 85 min and in study Onur Oet *et al* [30]; time for unassisted ambulation in levobupivacaine group was 265 mins.

### Hemodynamic parameters

Heart rate, MAP changes were comparable between the groups Grp CP, Grp LB [Figure 2,3], Moderate fall in MAP is observed in both the Groups. ( expected sympathetic blockade produced by the spinal anesthesia), although the MAP stabilized after 30 min. There was no statistically significant difference in two groups throughout the postoperative period. Results of this study are coincides with the study of Bhaskara *et al* 2020[24]

**Side Effects:** Hypotension/ bradycardia occurred in 2 (6.6%) patients in Group LB, Only one patient in Group CP had bradycardia, Although it settled with IV fluid. One patient of both the Groups had nausea/vomiting. 1 patient of each group had shivering. [24]

### Conclusion

Chloroprocaine intrathecally in dose of 30 mg provides adequate duration & Surgical anesthesia for infra-umbilical surgeries with the advantage of earlier onset and faster regression of spinal block resulting in earlier hospital discharge with stable hemodynamics as compared to 0.5% Levo-bupivacaine 30 mg.

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