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# Comparison of 2-Chloroprocaine and 2-Chloroprocaine with Buprenorphine Given Intrathecally in Short Duration Surgeries: A Randomised Controlled Study

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**ABSTRACT**

**Background and aims:**

Spinal anesthesia is a simple and one of the most frequently done procedure in surgical field due to it's predictable post operative outcome, minimal monitoring requirement and maintenance of hemodynamic stability. The present study was done to compare the addition of Buprenorphine as an adjunct to Chloroprocaine and comparing it's feasibility for day care surgeries against plain Chloroprocaine.

**Methods:**

70 adults planned for lower limb surgeries of duration less than 60 minutes were randomly divided into two groups, Group B- 4mL of 1% Chloroprocaine plus 0.15ml Buprenorphine (45mcg) and Group C- 4ml of 1% Chloroprocaine plus 0.15ml normal saline intrathecally. Hemodynamic changes, time of onset, offset, time of void and time of request of first analgesia was noted in both the groups.

**Results:**

The mean time of onset of analgesia and anaesthesia was comparable in both the groups. The time of request of first analgesia was two times in the group receiving Buprenorphine as adjunct. There was no prolongation in voiding time.

**Conclusion:**

Addition of Buprenorphine in low doses highly enhances the period of pain free post operative duration promoting early discharge from the hospital.

**KEYWORDS:** Ambulatory surgery, neuraxial block, spinal anaesthesia, chloroprocaine, Buprenoprphine, post-operative analgesia, anaesthsia, analgesia

## INTRODUCTION

Spinal anesthesia is the most common neuraxial block used in a surgical setting. It provides excellent surgical conditions for lower abdominal & lower limb procedures. The advantage of spinal anaesthesia is a predictable post operative course and limited need for monitoring. Some limitations with spinal anaesthesia are late locomotion, chances of urinary retention and pain once block regresses.[1]

Chloroprocaine has a very fast onset, short duration of action, faster resolution leading to lesser side effects. [2]
Ideal adjuvant should decrease the time of onset of action of the LA drug and also decrease its dosage along with providing hemodynamic stability, optimal sedation, and minimum adverse effects.

There is dearth of literature on the use of adjuvant with intrathecal 2-chloroprocaine; when Fentanyl was added it was observed that it lengthens the regression to L1 dermatome and tourniquet time while minimally lengthening duration of block.[3]

Though 2-Chloroprocaine has been advocated as the local anesthetic of choice for spinal anaesthesia in short duration surgeries, there have been limited studies with use of adjuvant especially low dose Buprenorphine to enhance postoperative comfort and hence facilitates early recovery.[4] Therefore, we plan to conduct a prospective, randomized study to study the effect of intrathecal Buprenorphine as adjuvant to 2-Chloroprocaine in consenting healthy patients after their approval for participating in the study.

## MATERIAL AND METHODS

After obtaining approval from institutional ethical committee, a double blinded randomized controlled study was conducted in Rohilkhand medical college and hospital, Bareilly. The study was registered in CTRI with CTRI number-CTRI/2021/07/035270. A thorough, well informed and written consent was taken from all patients prior to the procedure and patients of ASA grade I and II posted for lower limb surgery between the age group of 18-60 years who were

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randomly divided into two groups using computer generated randomization technique. Group B received 4ml of 1% Chloroprocaine (40mg) plus 0.15 mL Buprenoprhine (45mcg) intrathecal, whereas the other group, Group C received 4ml of 1% Chloroprocaine (40mg) plus 0.15 mL normal saline intrathecally. Patients who had refused to consent, had any contraindications to spinal anaesthesia, were obese, and had any neuropathy, patients receiving opioids for chronic analgesic therapy and patients allergic or intolerant to local anesthetics were excluded from our study.

Thorough pre-anesthetic check-up was done one day prior to the surgery and written informed consent for participation in the study was taken. The patients were randomly divided into two groups: Group B and C. Drugs were prepared by anesthetists who were not involved in observation. Patients were explained about the procedure of spinal anaesthesia. They were kept nil per oral for 6 hrs & Tab Ranitidine 150mg and Tab Alprazolam 0.25mg was given orally, the night before surgery. Patients were instructed to void before being taken into the operating room.

On the day of surgery, intravenous line was secured and I.V. fluid Ringer Lactate was started at 15ml/kg 30 min before surgery. Monitor was attached and baseline readings were taken.

Patients were pre-medicated with Inj. Ranitidine 50mg iv, Inj. Ondansetron 4mg iv, and heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, arterial oxygen saturation were monitored and noted.

Spinal anaesthesia was administered to the patient in L2-L3 interspaces with patient sitting using a midline approach using 25G Quincke spinal needle. According to randomization, patient received either preservative free & bisulfite free formulation of 45mcg Buprenorphine with isobaric 1% Chloroprocaine 40mg or isobaric 1% Chloroprocaine 40mg plus 0.15mL of normal saline as per group allocated.

The patient was evaluated for sensory and motor block, for every 2 minutes for first 20 minutes, then every 3 minutes for next 30 minutes, then every 5 minutes for 40 minutes, and then every 10 minutes for 60 minutes and finally every 15 minutes until the sensory block had regressed to S1 dermatome. The patients were administered Inj. Midazolam 1mg IV after spinal anaesthesia was given. During the surgery the patient's pulse, Systolic Blood pressure, Diastolic Blood pressure, Mean Arterial Pressure, arterial oxygen saturation were recorded every 3 minutes for 30 minutes and then every 5 minutes until completion of the surgery.

The sensory level of the block was observed from caudal to cephalad direction, using loss to pin prick sensation. The motor block was observed using the Modified Bromage Scale.
Readiness for incision was assessed as loss of pin prick sensation ≥ T10 with modified Bromage ≥2. Modified Bromage scale:
Grade 0 - Absence of movement
Grade 1 - Trembling of the muscle group
Grade 2 - Ability to move against gravity but not against resistance
Grade 3 - Strength reduced but able to move against resistance
Grade 4 - Full strength of shoulder muscles

Modified Aldrete score was assessed every 30 minutes postoperatively till modified Aldrete score was>/ 9 and the time was noted. NRS score was assessed every 30 minutes postoperatively till NRS< 4 where rescue analgesic IV Paracetamol 1g was administered. If the patient complaint of pain at any pointing time, the NRS scale was noted, rescue analgesic given and time to rescue analgesic was recorded.

**MODIFIED ALDRETE SCORE**

| PARAMETER | DESCRIPTION OF PATIENTS | SCORE |
|---|---|---|
| Activity level | Moves all extremities voluntarily/ on command.<br>Moves 2 extremities.<br>Cannot move extremities | 2<br>1<br>0 |
| Respiration | Breathes deeply & coughs freely<br>Is dyspneic, with shallow, limited breathing<br>Is apneic | 2<br>1<br>0 |
| Circulation (Systolic blood pressure) | Is 20mmHg >preanesthetic level | 2 |

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| | | |
|---|---|---|
| | Is 20-50mmHg >preanesthetic level<br>Is 50mmHg >preanesthetic level | <br>1<br>0 |
| Consciousness | Is fully awake<br>Is arousable on calling<br>Is not responding | 2<br>1<br>0 |
| Oxygen saturation as determined by pulse oximetry spO2 | spO2 level >90% when breathing room air<br>Requires supplemental oxygen to maintain level >90%<br>spO2 level <90% with oxygen supplementation | 2<br>1<br>0 |

**STATISTICS**

Statistical data analysis was done using SPSS version 23.0 using independent t- test to determine mean significant difference between the two variables and $p<0.05$ is considered statistically significant. Continuous variables were expressed as mean ±standard deviation.

**RESULTS**

Spinal block was successfully achieved in all the patients and all patients enrolled for the study completed the study. Demographic variables like age, gender and duration of surgery were comparable in both the groups. Onset of sensory block in group B was 4.83 ±0.82 minutes and in group C was 5.29 ±1.38 minutes.Mean onset (motor block) of patients in group B was 5.43 ±0.85 and in group C was 6.43 ±1.22.

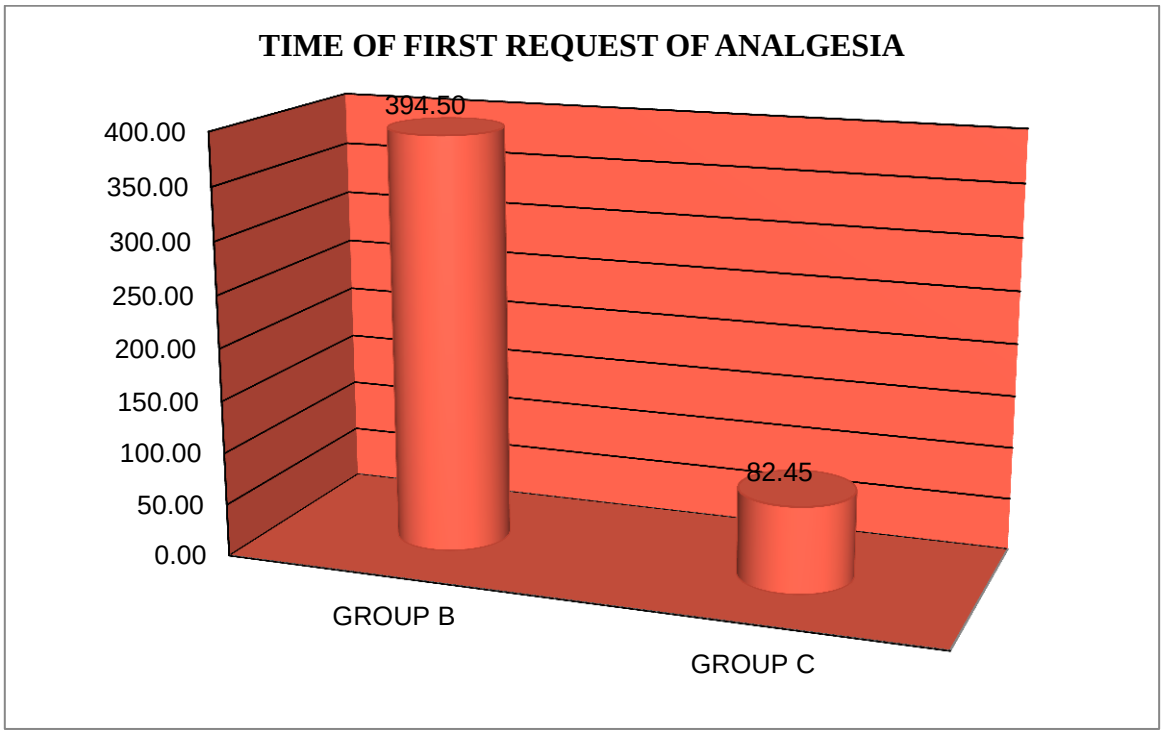
The duration of sensory block of patients in group-B was 56.71 ±9.01and in group-C was 54.54 ±7.92. The difference in mean duration of sensory block was statistically significant in both groups.

The duration of motor block of patients in group-B was 48.49 ±11.57 and in group-C was 47.94 ±9.2. The difference in mean duration of motor block was statistically significant in both groups.

The hemodynamic parameters in both groups were comparable.

The mean voiding time (in minutes) in group-B was 118.4 ±16.62 and in group-C was 114.8 ±12.66.

The mean time of first request of analgesia in group B was 250.2 ±5.83 minutes and in group C it is 110.4 ±10.17 minutes. The time of rescue analgesia was approximately 5 times more in the Group B than in the group C. It was statistically significant.



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**DISCUSSION**

Spinal neuraxial block is the most commonly used regional anaesthesia for lower abdominal and lower limb surgeries. A faster recovery for the patients not only benefits the patients but also reduces the burden from the already overburdened health care services in our country.[1]

Preservative free 1% Chloroprocaine has been used safely for subarachnoid block in large numbers of lower abdomen and lower limb surgeries of short duration.[2] Buprenorphine has also been extensively used as an adjuvant with other local anesthetics (LA) in subarachnoid blocks. It has been seen to improve the duration and potency of sensory and motor block. [4]

Various dose ranges have been studied of Chloroprocaine ranging from 30-60mg showing the minimal effective dose for a surgery of 40-60 minutes was 30mg and doses more than 60mcg leads to delayed voiding time.[6]

Siddaiah *et al* in their randomized study found the time of onset of sensory block was slightly faster in the group receiving 60mcg Buprenorphine as adjunct to 40mg Chloroprocaine, while the motor block characteristics were comparable in both the groups suggesting that Buprenorphine has no effect on the motor blockade, time to reach peak block height was similar in both the groups, time of duration of sensory block was longer in the group with Buprenorphine as adjunct than in the group receiving plain Chloroprocaine while the duration of motor block in both their groups to be not varying significantly, the first postoperative request of analgesia was more than two times longer after addition of 60mcg of Buprenorphine to 2-Chloroprocaine.[7]

Mishra *et al* conducted their study on 63 patients divided into three groups, one receiving plain chloroprocaine 30mg, second with addition of 25mcg fentanyl and third where 60mcg buprenorphine was added to chloroprocaine for spinal anesthesia for perianal surgeries. They found that the time of onset on sensory block was fastest in fentanyl group at 3.1 minutes followed by buprenorphine group at 3.2 minutes on an average. while addition of adjunct did not alter the onset time of motor block, the duration of sensory block was longest in the group receiving Buprenorphine as adjunct , duration of motor block to be slightly less in buprenorphine group but not significant.[8]

In the present study we found that mean time of onset of sensory analgesia was comparable in both the groups. The mean time taken to achieve highest level of sensory analgesia was not significant but slightly more in group of patients who received Chloroprocaine with Buprenorphine. The mean time of onset and duration of motor blockade was not affected by addition of Buprenorphine. The mean time of request of rescue analgesia i.e. the first analgesia in the post operative period was two times more in the group which received Buprenorphine as adjunct. There was no prolongation of voiding time in the Buprenorphine group. There were two incidents of vomiting in the Buprenorphine group.

**CONCLUSION**

Buprenorphine was found to be an excellent adjuvant to Chloroprocaine in increasing the pain free period post-operatively without affecting the duration of motor blockade and time of ambulation.

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