

“Intrathecal 2-Chlorprocaine and Bupivacaine for Outpatient Surgery: A Prospective, Randomized Double Blind Comparison”

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Abstract:

Background: . comparison of 2 chlorprocaine and bupivacaine in below umbilical surgery, in relation to onset of sensory and motor block, duration of sensory and motor block, time of unassisted ambulation, time of voiding

Materials and Methods: : A total of 60 patients of either sex undergoing below umbilical day care surgery was randomly divided into two groups 30 patients in each. Group CP received 40 mg of 1% 2 chlorprocaine intrathecally. Group B received 7.5 mg of .5% bupivacaine intrathecally. Onset and regression of sensory and motor block observed, time of ambulation, time of voiding, post op analgesia (VAS Score), vitals was assessed at different time intervals.

Results: : We observed significant difference of onset of sensory block in group CP was 2.5 ± 0.73 min and in group B was 3.33 ± 0.84 min. Onset of motor block was 4.00 ± 0.74 min in group CP and 4.90 ± 0.99 min in group B. Time to achieve maximum sensory block level was significantly faster in 2-CP group which was 4.77 ± 0.86 min in 2-CP and 5.33 ± 1.06 min in B group. The duration of motor block was 58.8 ± 5.42 min in group 2-CP and 178.6 ± 34.29 min in group B. Time of ambulation was earlier in group CP as compared to group B. Voiding time in group CP was 173.83 ± 18.27 min and 359.83 ± 28.54 min group B.

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I. Introduction

In the past decade, ambulatory surgery has grown worldwide. An efficient anaesthetic technique in the ambulatory setting has to be able to provide rapid onset and offset of the anaesthetic effect leading to fast patient discharge with minimal side effects.¹ Spinal anaesthesia is a reliable and safe technique for procedures of the below umbilical region. Nevertheless, some of its characteristics may limit its use for ambulatory surgery, including delayed ambulation, risk of urinary retention, and pain after block regression².

For many years, spinal lidocaine has been the local anaesthetic of choice for outpatient surgery because of its profile of fast onset and short duration. However, transient neurological symptoms (TNS), described as back pain with irradiation to the lower extremities, have been reported. As an alternative, attempts have been made to adapt hyperbaric bupivacaine, a long-acting local anaesthetic, to the ambulatory setting by using smaller doses. However, the duration of the block remains prolonged with these smaller doses, and they may provide insufficient anaesthesia. Furthermore, urinary retention (or a prolonged interval to first voiding) is frequently encountered with bupivacaine, which delays the time until discharge for ambulatory patients.³

2-Chlororprocaine (2-CP) is an amino-ester local anaesthetic with a very short half-life and spinal block for ultra-short outpatient procedures. Its pharmacological profile is very similar to lidocaine, as characterized by short latency and short duration but with lower incidence of transient neurological symptoms.¹

with comparison to bupivacaine, 2-chlororprocaine showed faster offset times to end of anaesthesia, unassisted ambulation, and early discharge from hospital. These findings suggests that 2-CP may be a suitable alternative to low doses of long-acting local anaesthetics in ambulatory surgery. Its safety profile also suggests that 2-CP could be a valid substitute for intrathecal short and intermediate-acting local anaesthetics, such as lidocaine and mepivacaine often causes of transient neurological symptoms.⁴

Keeping the above facts in mind, present study was undertaken to compare the 2 chlorprocaine with bupivacaine for spinal anaesthesia in ambulatory surgery below umbilical region to evaluate the efficacy and recovery profile of the study drugs.

II. Material And Method

The present study entitled use of “Intrathecal 2-chlororprocaine and bupivacaine for outpatient surgery: a prospective, randomized, double blind comparison” was carried out in the Department of Anaesthesiology and Critical Care, Government Medical College and Associated Groups of Hospitals, Kota. After hospitals ethical committee’s approval and written informed consent, the present study was conducted on 60 patients aged

18 years to 60 years belonging to ASA grade I & II, scheduled for elective ambulatory surgery of short duration (less than 60 minute) under spinal anaesthesia.

Complete medical history, physical examination including vital signs and airway assessment including mouth opening, mallampati grading, all routine investigations including complete blood count, BT, CT, fasting blood sugar, renal function test, chest X-ray, ECG for all patients were done. Patients were kept fasting for 6-8 hrs pre-operatively.

In this prospective double blinded study 60 patients were randomly divided into two groups of 30 patients each.

Group CP (n=30): Patients were receive 40 mg of preservative free 1% 2-Chlorprocaine intrathecally.

Group B (n=30): Patients were receive 7.5 mg of preservative free 0.5% heavy bupivacaine intrathecally.

On arrival of patients into operation theatre all standerd monitored were attached. An intravenous line was established with 18G cannula to preload the patient with Ringer lactate solution at rate of 10 ml/kg before the initiation of subarachnoid block. Under all aseptic condition, spinal anaesthesia was administrated at the L3-4 interspace via the midline approach using a 25-gauge Quincke needle. After confirmation of free flow of cerebrospinal fluid, drug prepared as per group of patients were be injected slowly over 15 second. Immediately after block patients were asked to lie down. Surgery was started. During surgery, if patient complain of pain, Inj. Fantanyl 25-100ug i.v. was given.

Patients were discharge from the post operative ward when they attained all the following criteria minimum 60 minute stay, stable vital sign, sign of regression of motor block (Bromage scale 0-2) and normal consciousness. From post operative ward patients were discharge to ambulatory surgical ward. An hour after patients were asked to ambulate without assistance.

Sensory block assessment-Onset of sensory blockade was assessed by bilateral pin prick along the midclavicular line using a 26-G hypodermic needle every minute until 15 minute after spinal block and then every 10 minute until regression to T₁₀ dermatome.

Time of onset of sensory blockade was defined as completion of intrathecal injection to the loss of pinprick at dorsum of foot.

Highest level of sensory block and time taken to achieve highest level of sensory block was noted.

Duration of sensory anaesthesia was defined as a time taken from intrathecal injection to regression to S₅ from the peak block height.

Motor block assessment- The motor blockade was assessed by modified bromage scale every 2, 4,6 minute after spinal block:

- a. 0=no power impairment and able to raise straight scale
- b. 1=unable to raise straight leg but able to flex knee
- c. 2=unable to flex knee
- d. 3=unable to flex ankle and foot-no movements

Onset of motor block was defined as a time from intrathecal injection till the patient unable to raised the extended leg (bromage score 1). Time of onset of motor block was noted. Recovery of motor block was defined as the time of placement of spinal block to bromage score to zero. Duration of motor block recorded as intrathecal injection to recovery of bromage score 0.

-Time to unassisted ambulation was recorded.

-Time to first voiding was recorded.

III. Results

In this study, distribution of patients with respect to age, weight were comparable in both groups (p > 0.05 non significant). ASA grade of the patients and the type of surgery performed were non significant in both group.(p > 0.05)

Table 1: Age distribution of study groups

Age groups (years)	Group-CP		Group-B	
	n	%	n	%
10 – 29	4	13.33	5	16.67
30 – 49	14	46.67	15	50.00
50-60	12	40.00	10	33.33
Total	30	100	30	100
Mean± SD(years)	43.40 ± 12.20		42.07 ± 11.07	

Table 2 : Weight distribution

Weight (kg)	Group-CP		Group-B	
	n	%	n	%
41 – 45	2	6.6	3	10%
46 – 50	1	3.3	2	6.6%
51 – 60	9	30	10	33.3%
61 – 70	18	60	15	50%
Mean ±SD(Kg)	61.80±7.46		59.3±7.92	

Table 3: Distribution of study patients according to ASA grade

ASA grade	Group-CP		Group-B	
	n	%	n	%
ASA I	16	53.33	19	63.33
ASA II	14	46.67	11	36.67
Total	30	100	30	100

Table: 4 Onset of sensory block at T 10

Time interval (min)	Group-CP		Group-B	
	n	%	n	%
Mean ± SD(min)	2.5 ± 0.73		3.33 ± 0.84	

Table 4 shows that onset of sensory block at T10 was earlier in group CP (2.5 ± 0.73) than group B (3.33 ± 0.84) and the difference was statistically significant (p<0.001).

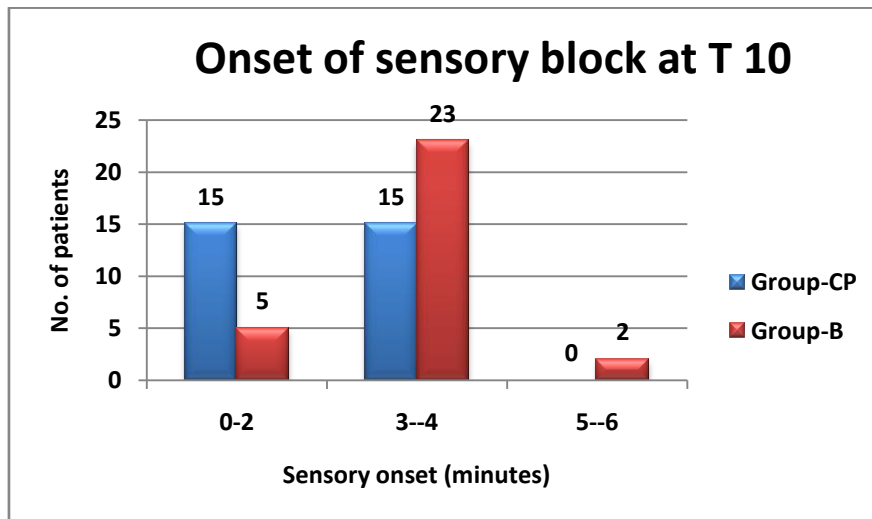


Table : 5 Onset of motor block

Time interval(min)	Group-CP	Group-B
Mean ± SD(min)	4.00 ± 0.74	4.90 ± 0.99

Table 5 shows that onset of complete motor block in group CP was 4.00 ± 0.74 min and in group B it was 4.90 ± 0.99 min. The difference was statistically significant (p<0.001).

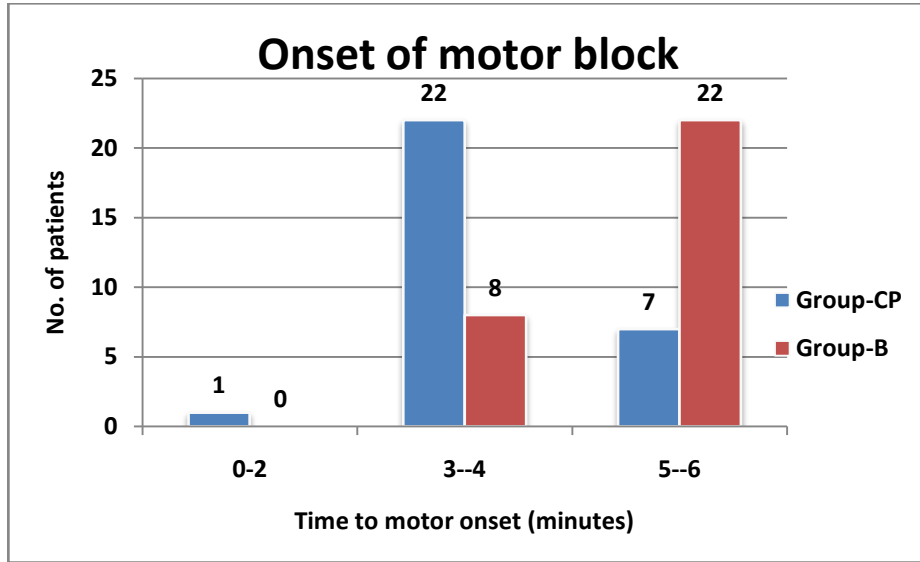


Table :6 Mean time to sensory block regression at S₅ level

Time (min)	Group - CP	Group-B
Mean ± SD	77.73 ± 9.49	214.3 ± 30.37

Table 6 shows that mean time to sensory regression at S₅ was 77.73± 9.49 and 214.3 ± 30.3 min in group CP and group B respectively. The difference was statistically significant (p<0.001).

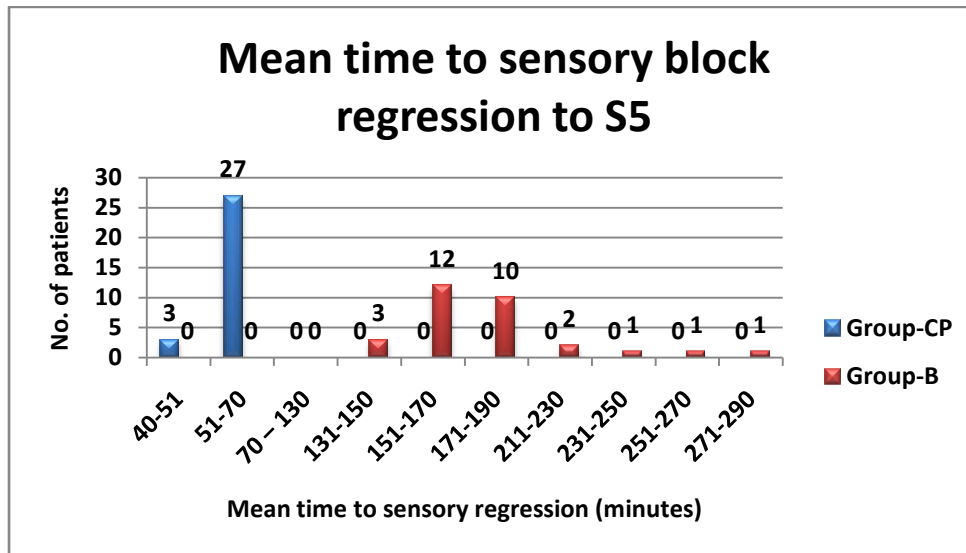


Table :7 Mean time to Motor block regression to bromage 0

Time(min)	Group – CP	Group –B
Mean ± SD	58.8 ± 5.42	178.6 ± 34.29

Table 7 depicts that mean duration of motor block (Mean time to Motor block regression to bromage 0) was 58.8 ± 5.42 min in group CP and in group B 178.6 ± 34.29 min. It was statistically significant (p<0.001)

Table : 8 Time of unassisted ambulation

Time(min)	Group - CP	Group-B
Mean ± SD	172.33 ± 12.98	297.17 ± 37.09

Table 8 shows the mean time of unassisted ambulation of patients. The mean time was 172.33 ± 12.98 min of group CP and 297.17 ± 37.09 min in group B. Ambulation was early in patients of group CP and difference was statistically significant ($p < .001$)

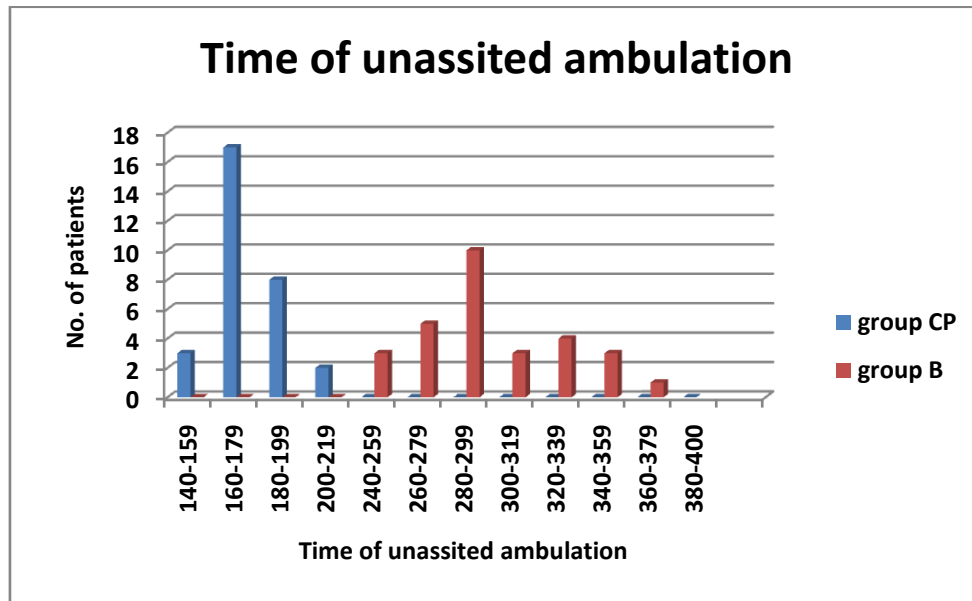
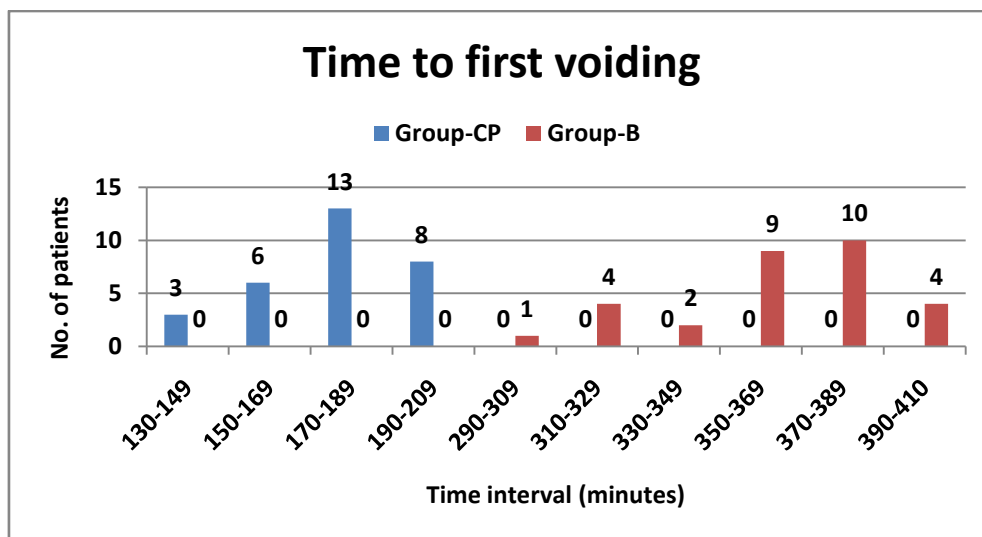


Table :9 Time to first voiding

Time	Group – CP	Group-B
Mean \pm SD(min)	173.83 ± 18.27	359.83 ± 28.54

Table 9 shows that mean time to first voiding was 173.83 ± 18.27 min in group CP and 359.83 ± 28.54 min in group B and difference was statistically significant ($p < .001$)



IV. Discussion

The purpose of this study was to compare 2-Chlorprocaine with bupivacaine for spinal anesthesia in an ambulatory surgery setting. In this prospective double blind randomized study, we found that 40 mg of intrathecal chlorprocaine has shorter duration of motor and sensory block than 7.5 mg bupivacaine, with equal quality of surgical anaesthesia.

Demographic parameter: The demographic data in terms of age, weight, sex distribution was comparable in both groups of the study. The distribution of patients with respect to ASA grading I/II werein group CP & in group B...(p >0.05) respectively which was in significant.

Onset of sensory and motor block: Our study showed significant difference between the two group as regards the onset of sensory loss by Pin-Prick at T 10 which was 2.5 ± 0.73 min in group CP while 3.33 ± 0.84 min in group B. The onset of sensory loss (T10) was faster in group CP than in group B. The difference was statistically significant ($P < 0.05$). These results coincide with the studies done by M. B. Breebaart et al⁵ where the onset was earlier in the CP group as compared to B group. The results are also comparable to those of Marie-Andre'e Lacasse et al³ who used 0.75% hyperbaric bupivacaine 7.5 mg (n = 30) or 2% preservative-free 2-CP 40 mg and found earlier onset of analgesia in chlorprocaine group.

Time to maximum sensory level -

mean time to attain maximum sensory level was 4.77 ± 0.86 min in group CP and 5.33 ± 1.09 min in group B. The difference was statistically significant ($P < 0.05$). These finding suggesting that chlorprocaine reach maximum sensory level early in comparison to bupivacaine .

Our results coincide with the studies done by Yoos and Kopacz et al⁶ in which they found that less time to reach maximum sensory level in chlorprocaine group in comparison with bupivacaine group (15.04 ± 1.44 versus 16.68 ± 0.95 min). Similar results of time to reach maximum sensory level fast by chlorprocaine found by Andrea Casati et al⁷.

Onset of motor block-

In our study onset of complete motor blockade in group CP it appeared 4.00 ± 0.74 min while in group B it appeared in 4.90 ± 0.99 min. It was found that onset of motor block of chlorprocaine was earlier as compared with bupivacaine and the difference was statistically significant ($P < 0.05$)

Duration of motor block-

As depicted in table no. 11 duration of motor block increased with bupivacaine. Mean duration of motor block in group CP was 58.80 ± 5.42 min compared to 178.63 ± 4.29 min in group B. The difference was highly statistically significant ($P < 0.001$).

The results of our study were in accordance with study done by Aaron F. et al⁸ who compared 2 Chlorprocaine 30 mg and procaine 80 mg in spinal anaesthesia. They found that in comparison to procaine, chlorprocaine causes early onset and prolonged duration of motor block . Our result also coincide with studies of Andrea Casati et al⁹, Mary E. Kouri et al¹⁰.

Duration of analgesia-

Duration of analgesia in group CP and group B was 141.63 ± 13.30 min and 278.87 ± 31.95 min respectively (Table 19). Duration of analgesia was significantly longer in group B as compared to group CP ($P < 0.001$).

Results depicts that duration of analgesia was shorter with chlorprocaine due to early regression of sensory block. Similar results of shorter duration of analgesia with chlorprocaine was found Andrea Casati et al⁹ and Ben Gys et al¹⁰.

VAS score- Post-operatively all patients were assessed for 10 point visual analogue scale. When VAS reached ≥ 4 inj fentanyl 100ug i.v. was administered . Total duration of analgesia was longer in group B (278.87 ± 31.95) as compared to group CP (141 ± 13.30). After 60 min VAS score increased in group CP and in group B VAS score was 0 upto 180 min. After 180 min VAS score increased in both group and the difference was statistically insignificant upto 720 min in both group (p-value > 0.05). The results of our study were in accordance with the study done by Ben Gys et al¹⁰.

Time of unassisted ambulation – Post operative time for ambulation was recorded, which was shown in table 20. Patients of group CP was ambulated without support after 172.33 ± 12.98 min and patients of group B was ambulated after 297.17 ± 37.09 which was longer than group CP. Same result of our study were recorded by Lacasse et al¹¹ and Yoos and Kopacz, et al⁶.

Time of voiding- Patients in group CP voided after 173.83 ± 18.27 min which was faster than group B (359.83 ± 28.54). The results of our study were in accordance with study done by Aaron F. et al¹².

V. Conclusion

We concluded that The onset of sensory block and motor block was significantly rapid in 2- CP group in comparison to B group. The time to achieve maximum sensory block level was significantly faster in 2-CP group than group B. The difference was statistically significant in both groups. Duration of motor block was shorter in group CP. There was no significant difference in both groups with regards to haemodynamic stability.

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