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A comparative study of intrathecal 2-chloroprocaine with fentanyl versus 2-chloroprocaine alone in patients undergoing infraumbilical surgeries

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Abstract
Background: Spinal anesthesia with 2-Chloroprocaine produces blocks with rapid onset, higher level of sensory blockade and early voiding and ambulation. The addition of fentanyl prolongs sensory blockade. The aim of this study is to evaluate efficacy of fentanyl adjunct to intrathecal 2-Chloroprocaine in terms blockade characteristics.
Methods: A prospective randomised controlled study conducted in 50 ASA I and II patients in the age group 18-60years, posted for elective infraumbilical surgeries. They randomised into 2 groups of 25 patients each. Group CF (n=25) received intrathecal 3.0 ml of 1% 2-CP with 20 mcg Fentanyl and Group CS (n=25) received intrathecal 3.0 ml of 1% 2-CP with 0.4ml Normal Saline. Hemodynamic parameters, onset and duration of sensory and motor blockade, time for highest sensory and motor blockade, time for rescue analgesic and time for ambulation were recorded.
Results: Demographic data were comparable between the 2 groups. Group CF showed faster onset and prolonged sensory and motor blocks compared to Group CS. No side effects were noted in both the groups.
Conclusion: Addition of Fentanyl to Intrathecal 2-chloroprocaine decreases the onset time for sensory and motor blockade, prolongs postoperative analgesia, prolongs sensory and motor block and prolongs ambulation. Hence it may be proposed for day care surgeries.

Keywords: Intrathecal chloroprocaine, fentanyl, infraumbilical surgeries, ambulatory surgery

1. Introduction
Spinal anaesthesia results from injecting local anaesthetic agent directly into the intrathecal space and is most commonly used for surgery to the lower abdomen, pelvic organs, and lower limbs, and for cesarean deliveries [1]. Bupivacaine is usually the drug for spinal anaesthesia procedures, having a lasting effect of 4 to 5.5 hours. But some of its characteristics may limit its use for short duration ambulatory surgery, including delayed ambulation, risk of urinary retention [2]. Usage of Lidocaine was associated with symptoms of transient neurologic syndrome [3, 14].
2-Chloroprocaine is an amino-ester local anesthetic with a very short half-life [4]. Spinal anesthesia performed with preservative-free 2-Chloroprocaine produces blocks with rapid onset, increased potency in comparison with Procaine, and no evidence of toxicity [5]. In comparison with Bupivacaine, Lidocaine and Procaine 2-Chloroprocaine showed quicker onset of action, higher level of sensory blockade and early voiding and ambulation [6, 7, 8]. Hence 2-Chloroprocaine can be a better alternative for short duration ambulatory surgery. When compared with lidocaine, the time to ambulation and time to discharge were significantly shorter with 2-Chloroprocaine [13].
To improve the quality of spinal anesthesia opioid agents are added as adjuncts [9]. The addition of intrathecal Fentanyl prolonged sensory blockade while only minimally extending the time to ambulation, void, and discharge [10].
The aim of this study is to evaluate efficacy of Fentanyl adjunct to intrathecal 2-Chloroprocaine in terms of duration of spinal anesthesia, duration and level of sensory or motor blockade, in adult patients undergoing lower abdomen and lower limb surgeries.

2. Objectives of the study
1. To evaluate and compare the onset and duration of motor block and sensory block.

2. To evaluate and compare the hemodynamic changes.
3. To evaluate the safety profile of the drug.

3. Methodology

It is Prospective randomized comparative study in the patients age group of 18 to 60 years undergoing infraumbilical surgeries at Victoria Hospital attached to Bangalore medical college and Research institute in the Study period November 2017 to May 2019.

After obtaining clearance and approval from Institutional Ethical Committee, 50 patients fulfilling inclusion criteria who were willing to give informed consent were included in the study. The study was conducted in 50 patients over a period of 18 months. They were randomly divided into two groups of 25 patients each by using the computer-generated randomization table (http://www.randomizer.org).

Group CF (n=25): Intrathecal 3.0 ml of 1% 2-CP with 0.4 ml of 20 mcg Fentanyl

Group CS (n=25): Intrathecal 3.0 ml of 1% 2-CP with 0.4ml Normal Saline

All patients were kept nil per orally for 8 hours. Tab Ranitidine 150mg and Tab. Alprazolam 0.5mg was given night before the day of surgery. On arrival to the operation room, intravenous access was secured and patients were preloaded with 10ml/kg of Ringer Lactate over 15minutes. Non-Invasive Blood Pressure, Pulse Oximetry and three lead Electrocardiogram was connected. The baseline Systolic, Diastolic and Mean Arterial blood pressures (SBP, DBP, and MAP), Heart Rate (HR) and Oxygen Saturation (SpO2) were recorded.

Under strict aseptic precautions Subarachnoid Block was performed using 26 G Quincke Babcock spinal needle in the L3– L4 space with patient in lateral position. The loaded drug was injected over 10-15 seconds. The time at which injection was completed was considered zero time of the study and all measurements were recorded from this point. Following Subarachnoid Block, patients were made to lie supine. Sensory testing was assessed by loss of pinprick sensation to 23 G sterile hypodermic needle for onset and dermatomal levels was tested every 1 minute for the first 5 min, then at 5-min intervals for next 60 minutes and at every 10 minutes intervals until complete resolution of sensory anesthesia. Time of onset, highest level of sensory block and duration of sensory block was recorded. Duration of sensory block was defined as the time taken from onset of sensory blockade to sensory regression to S1.

Motor block was assessed by using a Modified Bromage Scale, every 1 minute for the first 5 min, then at 5-min intervals for next 60 minutes and at every 10 minutes intervals until complete resolution of motor anesthesia. Time of onset, highest level of motor block and duration of motor block was recorded. Time to gain back the motor function of lower limb defined as time to reach Modified Bromage scale 0. Hemodynamic variables were recorded every minute for first five minutes, at 5 minutes for first 60 minutes after the administration of subarachnoid block and every 10 minutes thereafter up to 120 minutes after the block.

After the surgery, patients were shifted to the PACU where they will remain until there was complete recovery of sensory and motor blockade. The incidence of any adverse effects such as hypotension, bradycardia, shivering, nausea, vomiting, pruritus, and respiratory depression and ECG changes was recorded. Time to gain back the motor function of lower limb defined as time to reach modified Bromage 0 was noted. Time to complete sensory regression i.e perception of pinprick sensation at the sole of foot and time to mobilize are recorded.

3.1 Modified Bromage Scale

0 - No motor block

1 - Inability to raise extended leg; able to move knees and feet

2 - Inability to raise extended leg and move knee; able to move feet

3 - Complete block of motor limb

3.2 Statistical software: The statistical software SPSS 25.0 (2017) for windows, was used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

4. Results

Following the data collection, statistical analysis was done as described above. The results were as follows;

The study participants of two study groups were comparable in terms of age, height and weight.

Table 1: Mean time for sensory onset

Time taken for sensory onset in min	Group CF	Group CS	P value
Mean ±SD	5.30±0.87	6.60±0.75	<0.005
Minimum	3	5	
Maximum	6	9	

The mean time of onset for sensory blockade in group CS (control group) was 6.60±0.75 mins and in group CF (fentanyl group) was 5.30 ±0.87 mins. There was a statistically highly significant difference between group CS and group CF (p<0.001).

Table 2: Mean time for highest level of sensory block

Time taken to reach highest sensory level (min)	Group CF	Group CS	P value
Mean ±SD	8.32±0.66	9.25±0.99	0.211
Minimum	6	6	
Maximum	10	11	

The mean time taken for attaining the highest level of sensory blockade was 9.25±0.99 mins in group CS (control group) and 8.32±0.66 mins in group CF (fentanyl group). There was no statistically significant difference between group CF and group CS (p>0.05)

Table 3: Mean time for two segment regression of sensory block

Duration of two segment sensory regression in mins	Group CF	Group CS	P value
Mean±SD	56.83±11.78	46.36±9.87	<0.001
Minimum	45	35	
Maximum	75	60	

The mean time taken for regression of sensory block by two segments was 46.36± 9.87 mins in group CS (control group) and 56.83 ± 11.78 mins in group CF (fentanyl group). There was a statistically highly significant difference between group CS and group CF (p<0.001)

Table 4: Mean duration of sensory block

Duration of sensory block in mins	Group CF	Group CS	P value
Mean±SD	112.33±11.29	91.51±12.66	<0.005
Minimum	90	80	
Maximum	130	110	

The mean duration of sensory block was 91.51±12.66 mins in group CS (control group) and 112.33±11.29mins in group CF (fentanyl group). There was a statistically significant difference between group CS and group CF (<0.005).

Table 5: Time taken for onset of motor blockade

Time taken for Motor block onset in mins	Group CF	Group CS	P value
Mean ±SD	11.53±0.78	12.37±0.89	<0.005
Minimum	8	9	
Maximum	15	15	

The mean time taken for the onset of motor blockade was 12.37±0.89 mins in group CS (control group) and 11.53±0.78 mins in group CF (fentanyl group). There was a statistically highly significant difference between group CS and group CF (p<0.005).

Table 6: Mean duration of motor blockade

Duration of motor block in mins	Group CS	Group CF	P value
Mean ±SD	55.1±7.33	68.2±10.56	<0.001
Minimum	45	55	
Maximum	75	100	

The mean duration of motor blockade was 55.1±7.33 mins in group CS (control group) and 68.2±10.56 mins in group CF (fentanyl group). There was a statistically highly significant difference between group CS and group CF (p<0.001)

Table 7: Mean Time for ambulation

Time for Ambulation in mins	Group CS	Group CF	P value
Mean ±SD	92.3±10.01	105.53±11.37	<0.05
Minimum	75	90	
Maximum	120	150	

The mean time for ambulation was 92.3±10.01 mins in group CS (control group) and 105.53±11.37 mins in group CF (fentanyl group). There was a statistically highly significant difference between group CS and group CF (p<0.005)

Table 8: Side effects

Side Effects	Group CF	Group CS
Nausea	0	0
Vomiting	0	0
Bradycardia	1 (4%)	2 (8%)
Hypotension	1 (4%)	1 (4%)
Respiratory Depression	0	0

In Group CF incident of bradycardia was 1 and 2 in Group CS. It was not statistically significant (p=0.382). All the patients who developed bradycardia were treated by single dose of Injecion 0.6 mg of atropine.

5. Discussion

In our study, onset of sensory block at T10 was the time taken from deposition of study drug till the patient feels loss of temperature sensation to cold swab at T 10 level. The mean time for the onset of sensory block at T10 level was 5.30±0.87 min in Group CF as compared to 6.60±0.75min in Group CS. There was statistically significant difference in the onset of sensory block at T10 between the two groups (p<0.05).

In our study maximum level of sensory block in Group CS was T6 (T6 – T10) (median – T8) and in Group CF it was T4 (T4 – T8) (Median T6). Time for highest sensory block was defined as the time taken from deposition of the study drug to the maximum level of sensory blockade attained. The mean time required to achieve highest level of T6 in Group CF was 8.32±0.66min and in Group CS for T4 was 9.25±0.99 min with a p value of 0.211 which is not statistically significant. Yoos and Kopacz [2] (2006) showed maximum level of sensory block in Group 2-CP 40 mg was T7 (T3–T10). Our study was consistent with this study in Group CS. Vath and Kopacz [10] (2004) compared intrathecal injection of 40 mg 2% 2-CP with intrathecal injection of 40 mg 2% 2-CP and 20µg fentanyl in eight healthy volunteers and demonstrated that mean time required to achieve highest level of T6 in Group CF was 21±11 min and in Group CS for T4 was 17±6 min. Our study results were comparable with Yoos *et al*. and Vath and Kopacz *et al*. study. 2-chloroprocaine provides adequate spinal anesthesia for lower abdominal and lower limb outpatient procedures lasting less than 40 minutes with faster recovery from anesthesia and eligibility for home discharge in comparison with 10 mg of plain 0.5% bupivacaine [15].

In our study, two dermatome regression time was defined as the time in minutes taken for two segment regression from maximum level achieved, with loss of temperature sensation to cold swab. The mean time required for the regression of sensory level by two dermatomes in Group CF was 56.83±11.78min and in Group CS it was 46.36±9.87 min with a p value of <0.001 which is statistically significant. Lacasse [8] *et al*. (2011) showed two dermatome regression time with 40 mg 2-CP of 50±18 min. Our study was consistent with this study in time for two segment regression of sensory blockade in Group CS. Vath and Kopacz [10] (2004) compared intrathecal injection of 40 mg 2% 2-CP with intrathecal injection of 40 mg 2% 2-CP and 20µg fentanyl in eight healthy volunteers and demonstrated that mean time required to achieve the regression of sensory level by two dermatomes in Group CF was 48±8 min and in Group CS it was 45±16 min with a p value of <0.02.

Mean duration of sensory block was defined the time taken from the onset of sensory block to the regression of sensory block to S1. The mean duration of sensory block in Group CF was 112.33±11.29 min and in Group CS it was 91.51±12.66 min with a p value of <0.05 which is statistically significant. Cassati *et al*. [7] (2006) showed Mean duration of sensory block with 40 mg 2-CP of 85 (46–141) min. Our study was consistent with this study in time for Mean duration of sensory block in Group CS. Vath and Kopacz [10] (2004) compared intrathecal injection of 40 mg 2% 2-CP with intrathecal injection of 40 mg 2% 2-CP and 20µg fentanyl in eight healthy volunteers and demonstrated that mean duration of sensory block in Group CF was 107±7 min and in Group CS it was 95±9 min with a p value of <0.02.

In our study, the mean duration of motor block in Group CF was 68.2±10.56min and in Group CS was 55.1±7.33 min with a p value of <0.001. Hence, there was a statistically significant difference between the 2 groups. Gonter and Kopacz [5] (2005) showed Mean duration of motor block with 30 mg 2-CP of 54±23 min. Our study was consistent with this study in time for Mean duration of motor block in Group CS. Vath and Kopacz [10] (2004) compared intrathecal injection of 40 mg 2% 2-CP with intrathecal injection of 40 mg 2% 2-CP and 20µg fentanyl in eight healthy volunteers and demonstrated that, the mean duration of motor block in Group CF was 81±16min and in Group CS was 67±13 min with a p value of <0.02.

The Mean duration for ambulation in Group CS was 92.3±10.01 min and in Group CF it was 105.53±11.37 min with a p value of <0.05. Hence, there was a statistically significant difference between the 2 groups. Warren and Kopacz [12] (2007) showed mean duration for ambulation with 40 mg 2-CP of 96±7 min. Our study was consistent with this study in time for ambulation in Group CS. Vath and Kopacz [11] (2004) compared intrathecal injection of 40 mg 2% 2-CP with intrathecal injection of 40 mg 2% 2-CP and 20µg fentanyl in eight healthy volunteers and demonstrated that, the mean duration for ambulation in Group CF was 104±7min and in Group CS was 95±9 min with a p value of <0.02.

6. Conclusion

This study concluded that intrathecal fentanyl in the dose of 20 µg along with 3 ml (30mg) isobaric 1% 2-Chloroprocaine, in patients undergoing elective infraumbilical surgeries, decreases the onset time for sensory and motor blockade, produces higher level of sensory blockade, produces prolonged sensory and motor blockade, produces prolonged postoperative analgesia, produces prolonged ambulation, produces no significant Haemodynamic changes. It was not associated with side effects like transient neurological symptoms. This makes it a suitable combination for outpatient anesthesia and can be proposed for day care surgeries.

7. References

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