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Original Research Article

# Evaluation of Anaesthetic Effects of Intrathecal 2-Chloroprocaine with or Without Fentanyl in Perianal Surgery:A Prospective and Randomized Study

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**Conflict of interest: Nil**

## Abstract:

**Introduction:** Spinal anaesthesia is reliable and safe technique for perianal surgeries. 2-Chloroprocaine has a rapid onset and short duration of action and less systemic toxicity. The primary goal of ambulatory anaesthesia is rapid recovery leading to early patient discharge with minimal side effects.

**Aim:** This study was aimed to evaluate the effectiveness of 2-chloroprocainewith or without fentanyl in perianal surgeries in terms of block characteristics as primary objective and to note haemodynamics and any side effects as secondary objective.

**Study design:** A prospective, randomized, double blind interventional study.

**Methods:** Sixty adult patients of 18-60 years, of either sex, ASA grade I or II posted for perianal surgeries under spinal anaesthesia were randomized into two groups of 30 each, in which one group (CF) received1% 2-chloroprocaine 3 ml (30mg) with fentanyl 0.5ml (25mcg) and other group (CS) received 1% 2-chloroprocaine 3ml (30mg) with normal saline 0.5ml.

**Results:** The mean time to peak sensory level in Group CF was 8.20±0.96 min and in Group CS, it was 8.66±0.95 min (P = 0.065).The mean duration of sensory block in Group CF was 96.20±10.30min and in Group CS, it was 90.60±10.92 min (P = 0.045).The mean duration of motor block in Group CF was 90.47±8.67 min and in Group CS, it was 88.43±8.67 min (P= 0.31).The mean duration of analgesia in Group CF was 117.60±11.54 min and in Group CS, it was 111.28±11.66 min (P = 0.039).

**Conclusion:** Addition of fentanyl 25 mcg as an adjuvant to 2-chloroprocaine (30 mg) resulted in marginal but statistically significant prolongation of sensory block duration and time to rescue analgesia in patient undergoing perianal surgery under spinal anaesthesia .

**Keywords:** 2-Chloroprocaine, Fentanyl, Amulatory anaesthesia, Spinal anaesthesia.



## Introduction

Spinal anaesthesia is a reliable and safe technique for perianal surgeries. But this technique have some limitations which is unfavorable for ambulatory surgery, like delayed ambulation, risk of urinary retention, and pain after block regression.[1]. Increasing number of day care surgeries has urged us to modify our anaesthetic drug to suit the early ambulation. The primary goal of ambulatory anaesthesia is rapid recovery leading to early patient discharge with minimal side effects. Although low doses of long-acting local anaesthetics such as bupivacaine, ropivacaine, and levobupivacaine are usually administered intrathecally, they are associated with significant delays in hospital discharge and less reliability of block efficacy, onset, and spread.[2]

Regional anaesthesia reduces pain scores and pain medication request in the post anaesthesia care unit. However, neither central neuraxial block nor peripheral nerve blocks decreased the overall ambulatory surgery unit time and both required longer induction time versus general anaesthesia.[3]

The lack of the ideal spinal local anaesthetic and the availability of fast acting drugs such as a remifentanil and propofol have made general

anaesthesia the preferred choice for short outpatient procedures.[4]

The selection of an ideal local anaesthetic agent for spinal anaesthesia holds the utmost importance in ambulatory surgery. In previous studies, several local anaesthetic agents were used in different doses and concentrations, which were titrated to meet the requirement of short duration of anaesthesia and early recovery.[5]

2-Chloroprocaine (CP) is an aminoester local anaesthetic with a very short half-life. It was abandoned in the 1980s for several reports of neurological deficits in patients. Subsequently it was reintroduced for spinal anaesthesia in a preservative free and antioxidant free form and the pH of the solution was improved. It has been extensively evaluated in clinical practice with a favorable profile in terms of both safety and efficacy.[3][6]

The dose of local anaestetic can be reduced by adding adjuvants to it for spinal anaesthesia. Several drugs have been used as adjuvant and fentanyl an opioid is one of them. The addition of intrathecal fentanyl has been used to prolong sensory blockage without delaying motor recovery. [7,8]

Fentanyl, a short-acting lipophilic opioid stimulates μ1 and μ2 receptors, it potentiates the afferent sensory blockade and facilitates reduction in the dose of local anaesthetics without intensifying the motor block or prolonging recovery, fentanyl provides good quality of intraoperative analgesia, hemodynamic stability, minimal side effects, and excellent quality of postoperative analgesia.[9]

Thus, aim of our study is to evaluate the anaesthetic effect of intrathecal 1% 2-Chloroprocaine in lower dose 30 mg with or without fentanyl in patients undergoing perianal surgery in terms of block characteristics, hemodynamic parameters and side effects.

**Material and methods**

After taking institutional ethical committee clearance and taking informed written consent from the patients for participation this study was done. 60 patients with ASA physical status Grade I and II of either sex in the age group 18-60 years posted for perianal surgeries under spinal anaesthesia were included in this prospective, randomized, double blind interventional study.

**Exclusion criteria:**

- Patient refusal to participate in study.
- Patients having any absolute contraindications for spinal anaesthesia.
- Patients having coagulation abnormalities, platelet count <75,000, INR >1.5, or on anticoagulants.
- Any allergy to local anaesthetic drug.
- Patients having systemic illness (like severe hypovolemia, raised intracranial pressure, neuromuscular diseases, ischemic/valvular/ congenital heart diseases, psychiatric, hematological disorder).
- Pregnant patients.
- Short stature (height <150 cm), with spinal deformity.

The patients were randomly allocated into one of the two groups using computer generated random number table in opaque sealed envelope technique as follows:

Group I (CF) –1% 2-Chloroprocaine 3 ml (30 mg) + Fentanyl 0.5 ml (25 μg)

= Total volume 3.5 ml.

Group II (CS) – 1% 2-Chloroprocaine 3 ml (30 mg) + Normal Saline 0.5 ml =Total volume 3.5 ml.

All patients were advised for fasting as per standard fasting guideline before surgery. One night before surgery tab. Alprazolam 0.25 mg, tab. Ranitidine 150 mg was given. On arrival to operation room standard monitors including pulse oximeter (SpO2), noninvasive blood pressure (NIBP), and electrocardiogram (ECG) were applied and patient's baseline vitals including heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and peripheral oxygen saturation (SpO2) were noted. After securing 20G peripheral I.V. cannula, preloading with 500ml Ringer lactate was done in all cases.

Using strict aseptic technique, Sub-arachnoid Block was performed at L3-L4 interspace with patient in sitting position using a 25-gauge Quincke's spinal needle via midline approach. After getting free flow of cerebrospinal fluid, intrathecal drug was administered as per group allocation and sterile dressing was applied. End of spinal injection was taken as time zero (T0) for all further data recording. Oxygen at a rate of 5 L/min was administered via a Hudson mask.

Sensory block was assessed by pin prick method using a short beveled 24G needle checked bilaterally in mid-clavicular line and no perception to pin prick was considered as sensory block.

Motor block was assessed using Modified Bromage scale

0 = no motor block, able to flex hips/ knees, ankles;

1 = able to move knees and ankle, unable to flex hip i.e. unable to raise extended legs (partial motor block).

2 = able to flex ankles, unable to flex hip/knee

(almost complete motor block).

3 = unable to move any part of the lower limb (complete motor block).

Sensory and motor block was assessed every 2 min after intrathecal injection till maximum sensory level and maximum Modified Bromage score of 2 or 3 is achieved, which is criteria to allow start of surgery. If patient felt pain at surgical site at 15 min and Modified Bromage score was 0 or 1 then the case was declared as failed spinal and was excluded from the study. Time to reach T10 (sensory onset), peak sensory level, time to peak sensory level, maximum Modified Bromage score, time to maximum Modified Bromage score (motor onset) was recorded. Vital parameters including blood pressure (SBP, DBP, and MAP), HR and SpO2 were recorded at every 2 min till 10 min then every 5 min till completion of surgery. Hypotension was defined as fall in MAP of >20% from baseline value and treated with Inj. Mephentermine 6 mg in graded dose till desired effects was achieved. Bradycardia was defined as fall in HR < 60/min and treated with Inj. Atropine 0.3 mg.

Other side effects like nausea, vomiting and shivering were also noted and treated with inj. ondansetron 4 mg and inj. Dexamethasone 8 mg slow IV.

Sensory level and Bromage score were recorded at the end ofsurgery. They were assessed at every 15 minutes till sensory regression to S1 (return of sensation at lateral side of foot), Bromage score return to zero, and was defined as duration of sensory and motor block respectively. Time of first pain was defined as duration of analgesia. Vitals parameters (SBP, DBP, MAP, and HR) were recorded at 15 minute interval in postoperative period. Any occurrence of complications in postoperative period was noted and treated accordingly.

**Results**

**Table1: Comparison of demographic parameters**

| | Group CF | Group CS | P value |
|---|---|---|---|
| **Age(years)[mean±SD]** | 44.6±13.70 | 40.17±12.6 | 0.32 |
| **Gender** | | | |
| **Male** | 29 | 30 | |
| **Female** | 01 | 00 | |
| **Weight(kg)[mean±SD]** | 71.03±3.21 | 69.60±3.95 | 0.102 |
| **Height(cm)[mean±SD]** | 167.13±3.95 | 165.7±6.08 | 0.304 |
| **Duration of surgery(min)** | 29.77±6.60 | 29.47±4.95 | 0.84 |

Both groups were statistically comparable in terms of demographic parameters.

**Table 2: Spinal block parameters**

| | Group CS | Group CF | P Value |
|---|---|---|---|
| Time to t10 (min.) | 7.66±0.75 | 7.93±0.36 | 0.08 |
| Time to peak sensory level(min.) | 8.20±.0.96 | 8.66±0.95 | 0.065 |
| Time to maximum Bromage score(min.) | 7.93±1.85 | 7.80±1.76 | 0.777 |
| Duration of sensory block(min.) | 96.20±10.30 | 90.60±10.92 | 0.045 |
| Duration of motor block (min.) | 90.47±8.67 | 88.43±6.92 | 0.31 |
| Duration of analgesia (min.) | 117.60±11.54 | 111.28±11.66 | 0.039 |

In group CF time to peak sensory level was 8.20±.0.96 min and in group CS, it was 8.66±0.95 min and two groups were statistically comparable regarding Time to peak sensory level (p=0.065).Mean time to maximum bromage score was 7.93±1.85min.

in group CF and 7.80±1.76 in group CS. Two groups were statistically comparable regarding time to maximum Bromage score, (P=0.777).

Total duration of sensory block was 96.20±10.30 min in group CF and 90.60±10.92 min in group CS. This difference was statistically significant in between two groups (P=0.045). Total duration of motor block was 90.47±8.67 min in group CF and 88.43±6.92 min in group CS and two groups were statistically comparable regarding total duration of motor block (P=0.31). Total duration of analgesia was 117.60±11.54 min in group CF and 111.28±11.66 min in group CS. This difference was statistically significant in between the two groups (P=0.039).

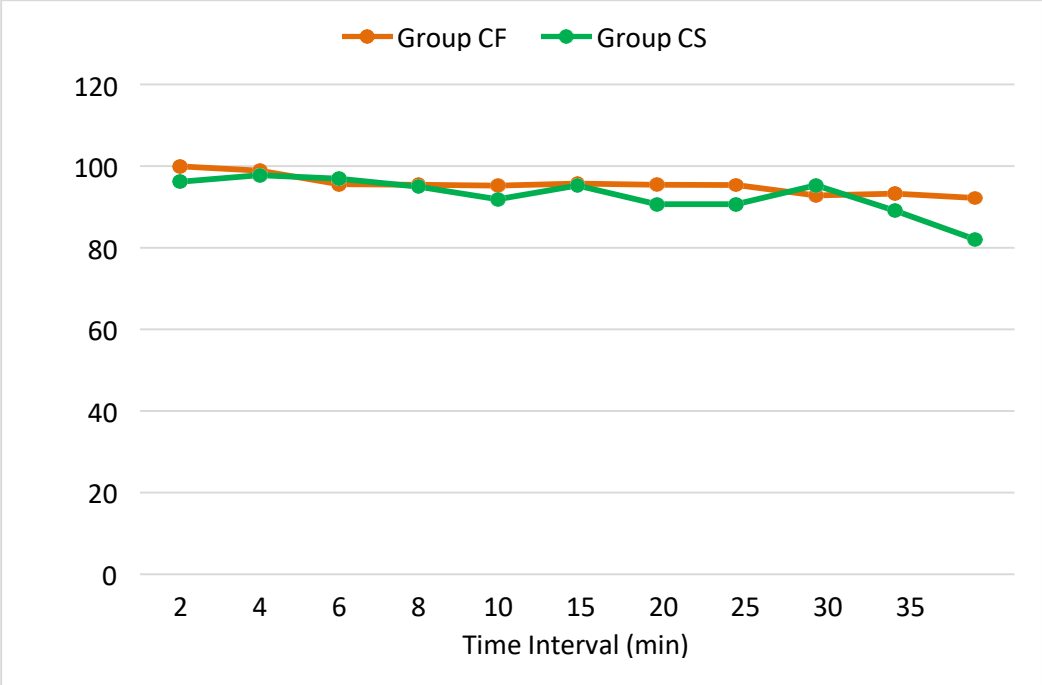


**Figure 1: Comparison of intraoperative mean arterial pressure(mmHg) in two groups**

**Table 3: Intraoperative adverse effects**

| **Comparison of Hypotensive episodes** | | | |
|---|---|---|---|
| **Groups** | **Hypotension** | | **P value** |
| | **Present** | **Absent** | |
| CF | 0(0.0%) | 30(100.0%) | 0.157 |
| CS | 1(3.33%) | 29(96.66%) | |
| **Comparison of Bradycardia** | | | |
| **Groups** | **Bradycardia** | | **P value** |
| | **Present** | **Absent** | |
| CF | 1(3.33%) | 29(96.66%) | 0.276 |
| CS | 2(6.66%) | 28(93.33%) | |
| **Comparison of Nausea Vomiting episodes** | | | |
| **Groups** | **Nausea, Vomiting** | | **P value** |
| | **Present** | **Absent** | |
| CF | 1(3.33%) | 29(96.66%) | 0.276 |
| CS | 2(6.66%) | 28(93.33%) | |
| **Comparison of Shivering** | | | |
| **Groups** | **Shivering** | | **P value** |
| | **Present** | **Absent** | |
| CF | 1(3.33%) | 29(96.66%) | 0.276 |
| CS | 2(6.66%) | 28(93.33%) | |

Both groups were comparable in terms of intraoperative adverse events.

## Discussion

Long acting anaesthetic agents have been used in subarachnoid block to prolong the duration of anaesthesia. Short acting agents such as 2-Chloroprocaine has been recently introduced in India. It provides adequate duration and depth of surgical anaesthesia for short procedures with the advantages of faster block resolution and earlier hospital discharge compared with other long acting local anaesthetics like bupivacaine etc.

In this study, we have evaluated the efficacy of intrathecal isobaric 1% 2-chloroprocaine with or without an opioid Fentanyl as an adjuvant for elective perianal surgeries under spinal anaesthesia.

The aim of our study was to evaluate the effect of lower dose of 1% 2-chloroprocaine (30mg) with or without fentanyl in day care surgeries in terms of duration of sensory and motor block along with analgesia which may contribute to early recovery and ambulation.

**Sensory Block**

In our study, when Fentanyl was used with 2-chloroprocaine as an adjuvant mean time to reach T10 sensory level was lesser than when normal saline was used with 2-chloroprocaine. Onset of Sensory block in terms of both time to T10 and time to peak sensory level was not statistically significant in both Groups (P= 0.08 & 0.06 respectively). Similar conclusion also gave by Nagar et al[10] and Mishra M et al[11] in their studies. But results of, Chatrath V et al [12] and Khare A et al [13] did not support our findings as they found significant difference in mean onset time to sensory block. This might be due to higher doses of 2-chloroprocaine ie 40 and 50 mg used in their studies. sensory block duration was prolonged on addition of fentanyl with 2-chloroprocaine as compared to 2-chloroprocaine alone. The difference was statistically significant (P=0.045) in two groups. Similarly conclusion was drawned by Suryanarayana et al [14], Singariya G et al [15], Khare A et al[13] and Chatrath V et al [12] that addition of fentanyl to 2-chloroprocaine used for spinal anaesthesia increases duration of sensory block which is statistically significant when compared to 2-chloroprocaine alone. Our finding was also supported by, studies done by Bhaskara B et al [8], Vath JS and Kopacz DJ[16]. However the duration was only marginally prolonged which may/may not be clinically relevant.

**Motor block**

In present study, mean Time to onset of motor block and total duration of motor block was statistically insignificant in two groups. Similarly Bhaskar B et al[8] and Nagar et al[10] also found no significant difference in mean time to achieve maximum bromage score between both the groups. Similarly, in study conducted by Singariya G et al [15] , the mean duration of motor block was (70.4±14.44min.) in CF group and (69.8±13.66 min.) in CS group which was also comparable (P=0.33).

This comparable motor effect can be justified by the fact that fentanyl do not have effect on motor blockade. However a few studies also reported prolongation of postoperative motor blockade on addition of fentanyl. study conducted by Nagar et al.[10] is one of them that showed that the mean time to end of motor block was (80.13±10.009 min.) in CF group and (64.80±5.13 min.) in CS group which was statistically significant (P<0.001). Study done by Suryanarayana et al[14] showed similar results (68.2±10.56 min. in CF group and 55.1±7.33 min. in CS group) which was statistically significant (P<0.001).

**Duration of Analgesia**

In our study, duration of analgesia was prolonged when fentanyl used as an adjuvent which was statistically significant (P=0.039).

Similar results were obtained in some other previous studies where total duration of analgesia was increased by adding fentanyl to 2-chloroprocaine. These studies are Suryanarayana et al [14] (the total duration of analgesia was 105.53±11.37 min. in CF group and 92.3±10.01 min. in CS group), Singariya G et al [15] , (the total duration of analgesia was 115±25.24 min. in CF group and 79.59±10.74 min. in CS group), Khare A et al[13], (the total duration of analgesia was 90.48±17.97 min. in C group and 128.80±15.81 min. in CF group and 140±15.42 in group CC ), Bindra TK et al[17], (the total duration of analgesia was 87.35±3.33 min. in A group and 93.05±4.68 min. in B group). This can be explained by the fact that fentanyl stimulate μ1 and μ2 receptors and potentiates the afferent sensory blockade resulting in prolonged duration of postoperative analgesia.

**Hemodynamic Parameters**

In our study, baseline hemodynamic parameters i.e. mean HR, SBP, DBP, MAP and SpO2 were comparable between both groups. There was no significant difference in these hemodynamic parameters intraoperatively at different time intervals between both groups. (P>0.05) Postoperatively also the haemodynamic parameters were comparable among the two groups. (P>0.05) Similar to our results, most of studies i.e. Mishra M [11], Suryanarayana et al [14], Bhaskara B et al [8], Chatrath V et al [12], Singariya G et al [15] and Bindra TK et al[17] did not found any statistically significant difference in hemodynamic parameters intraoperatively and postoperatively. Hemodynamically stability, can be explained by the fact that fentanyl affects only sensory pathway and do not affect autonomic pathways.

**Side Effects**

In our study only 1 (3.33%) patient in CS group encountered hypotensive episode and none in CF group. But this was not found to be statistically significant. (P=0.157)

Among other complications, bradycardia, shivering and nausea vomiting only 1 patient (3.33%) encountered these complications in CF group compared to CS group where 2 patients (6.66%) encountered these complications. But this was not found to be statistically significant (P=0.276). Similarly Singariya G et al [15], Bindra TK et al [17] and Devi V et al [18] also found comparable side effects in both the groups.

**Conclusion**

The present study concludes that the addition of 25 mcg Fentanyl as an adjuvant to 3 ml (30 mg) of isobaric 1% 2-Chloroprocaine administered

intrathecally to patients undergoing perianal surgeries resulted in prolongation of sensory block and duration of analgesia when compared to 2-Chloroprocaine alone.

## References


1. Mulroy MF, Salinas FV, Larkin KL, Polissar NL. Ambulatory surgery patients may be discharged before voiding after short-acting spinal and epidural anesthesia. Anesthesiology. 2002; 97:315–9.
2. Förster JG, Rosenberg PH. Revival of old local anesthetics for spinal anesthesia in ambulatory surgery. Curr Opin Anaesthesiol2011; 24:633-7.
3. Liu S, Chiu AA, Carpenter RL, Mulroy MF, Allen HW, Neal JM et al. Fentanyl prolongs lidocaine spinal anesthesia without prolonging recovery. Anesth Analg. 1995;80(4):730–4.
4. Fanelli A, Ghisi D, Allegri M. Is spinal anaesthesia a suitable technique for ultra-short outpatient procedures Acta Biomed. 2013; 84(1):76-80.
5. Mathur V, Mansuri T, Goyal V K, Jethava D Spinal anaesthesia for ambulatory urology surgery: A comparison of chloroprocaine with fentanyl and bupivacaine with fentanyl. Indian J Clin Anaesth 2020;7(2):313-318.
6. Förster JG, Kallio H, Rosenberg PH, Harilainen A, Sandelin J, Pitkänen MT. Chloroprocaine vs. articaine as spinal anaesthetics for day-case knee arthroscopy. Acta Anaesthesiol Scand. 2011; 55:273–81.
7. David BB, Solomon E, Levin H, Admoni H, Goldik Z. Intrathecal fentanyl with small-dose dilute bupivacaine: better anesthesia without prolonging recovery. Anesth Analg. 1997;85(3):560–5.
8. Bhaskara B, Prabhakar SA, Rangadhamaiah R. Intrathecal 1% 2- Chloroprocaine with Fentanyl in Comparison with Ropivacaine (0.5%) with Fentanyl in Day Care Perianal Surgery: Prospective Randomized Comparative Study. Anesth Essays Res. 2019; 13(3): 471–475.
9. Seetharam KR, Bhat G. Effects of isobaric ropivacaine with or without fentanyl in subarachnoid blockade: A prospective double-blind, randomized study. Anesth Essays Res. 2015; 9:173–7.
10. Nagar A, Khandelwal R, Goyal PK, Pareek S, Bharti DK. Comparing anaesthetic effects of intrathecal 2- Chloroprocaine with or without fentanyl in ambulatory surgeries- A prospective and randomized control study. Indian Journal of Clinical Anaesthesia 2020;7(4):619–624.
11. Mishra M., Marulappa SK, Madhusudhana R Study of 2- Chlorprocaine 1% with Adjuvants Fentanyl and Buprinorphine in Comparison with Plain 2-Chlorprocaine1% for Subarachnoid Blocks in Perianal Surgeries. F IJAA 2018; 5 (10) : 1662-1667
12. Chatrath V, Attri JP, Kaur G. Intrathecal Chloroprocaine Plus Fentanyl and Levobupivacaine Plus Fentanyl in Infraumbilical Surgeries in Adults. International Journal of Scientific Study 2020; 8(3):113-119.
13. Khare A, Jain K, Kanwar M, Thada B, Mathur V, Singh M. A comparative study on the effects of intrathecal chloroprocaine alone and with fentanyl or clonidine for infraumbilical surgeries. Indian Anaesth Forum. 2020; 21:147-52.
14. Suryanarayana, Sagar K, Ramachandraiah R. A comparative study of intrathecal 2-chloroprocaine with fentanyl versus 2-chloroprocaine alone in patients undergoing infraumbilical surgeries. International Journal of Medical Anesthesiology 2020; 3(1): 302-305.
15. Singariya G, Choudhary K, Kamal M, Bihani P, Pahuja H, Saini P. Comparison of analgesic efficacy of intrathecal 1% 2- chloroprocaine with or without fentanyl in elective caesarean section: A prospective, double-blind, randomised study. Indian J Anaesth. 2021;65(2):102-7.
16. Vath JS, Kopacz DJ. Spinal 2-Chloroprocaine: The Effect of Added Fentanyl. Anesthesia & Analgesia 2004; 98(1):89-94.
17. Bindra TK, Chawla D, Kumar A, Kaur G, Kaur A. Comparison of 1% chloroprocaine in sub-arachnoid block with or without fentanyl for enhanced recovery after perianal surgeries. Asian J Pharm Clin Res 2022; 15(7): 131-134.
18. Devi V, Wani M, Gupta H, Anju Jamwal. A comparative study of efficacy of clonidine and fentanyl as adjuvant to intrathecal 2 chloroprocaine in lower limb surgeries: A randomized double blind trial. J Cell Mol Anesth. 2022;7(2):93-100.