Original Article

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To Compare the Efficacy Of 1% Chloroprocaine Alone And 1% Chloroprocaine with Fentanyl in Infraumbilical Surgical Operations Performed Under Spinal Anaesthesia

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Abstract

Background: Spinal anaesthesia is a dependable and secure method for performing surgery on the lower abdomen, perianal area, and lower limbs. The recent availability of short-acting local anaesthetic drugs, such as preservative-free 1% chloroprocaine, has sparked fresh interest in using this approach for short and ultra-short operations. Opioids remain the most often used additives in local anaesthetics to enhance the pain-relieving effects. **Aim:** To compare the efficacy of 1% chloroprocaine alone and 1% chloroprocaine with fentanyl in infraumbilical surgical operations performed under spinal anaesthesia. **Subjects and Methods:** A total of 120 patients, aged between 20 and 70 years, of either gender, with ASA grade I and II, weighing between 38 and 68 kg, and with a height between 150 and 170 cm, were scheduled for elective infraumbilical surgery lasting less than 60 minutes. The patients were randomly assigned to two groups using the envelope technique. Group C received 3.0 mL of 1% Chloroprocaine mixed with 0.5 mL of normal saline, whereas Group CF received a 3 mL of 1% Chloroprocaine mixed with 25 µg of fentanyl (0.5 mL). During the surgical procedure, intravenous (i.v.) access was established and patients were administered a preload of 10 mL/kg of Ringer lactate over a period of 15 minutes. All standard monitors, such as noninvasive blood pressure, pulse oximetry, and three-lead electrocardiogram, were attached. **Results:** In group CF, the average time it took to achieve motor block was 8.88±1.06 minutes, which was sooner compared to group C, where it took 11.36±1.27 minutes (P=0.001). In our investigation, the average time it took for the sensory block to start at the T10 dermatomal level was shorter in the group that received 1% Chloroprocaine with Fentanyl (6.66±0.48 minutes) compared to the group that received just 1% Chloroprocaine (9.24±0.58 minutes) (P = 0.001). The highest sensory level dermatome in 36 individuals in Group C was seen between T6 and T9, while in Group CF, this was observed in 50 patients. 24 patients in Group C achieved the highest levels of T10-T12, compared to 10 patients in Group CF. The average length of sensory block was significantly longer in group CF compared to group C (94.58±3.97 min vs 82.28±3.61 min, p = 0.001). The Visual Analogue Scale (VAS) at the time of first pain relief was 4.08±0.87 in Group C and 3.11±0.81 in Group CF (p=0.001). In Group C, the time for initial mobilisation was 124.39±3.61 minutes, but in Group CF it was 162.25±3.87 minutes (p=0.001). **Conclusion:** Our findings indicate that the use of 2-Chloroprocaine leads to prompt alleviation of sensory and motor blockage, as well as early mobilisation and release for procedures lasting less than 60 minutes. Our research indicates that incorporating intrathecal Fentanyl as a supplementary agent to 2 - Chloroprocaine in the correct dosage is a superior option.

Keywords: Chloroprocaine, Fentanyl, Spinal anaesthesia.

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Introduction

Spinal anaesthesia is a dependable and secure method for performing surgery on the lower abdomen, perianal area, and lower limbs. It has several benefits compared to general anaesthesia, since it mitigates the surgical stress response, decreases intraoperative blood loss, and delivers analgesia during the early post-operative period. Nevertheless, the use of this technique for ambulatory procedures may be restricted due to factors such as delayed ability to walk, potential for urine retention, and post-block regression discomfort. The problem has been alleviated by using short-acting local anaesthetics such as 1% chloroprocaine. Camponovo conducted a comparison between spinal anaesthesia with 1% chloroprocaine and general anaesthesia for outpatient operations. The study concluded that, when the appropriate local anaesthetics are used, spinal anaesthesia is more appropriate for ultra-short outpatient treatments.[1]Currently, a favourable post-operative result is only deemed favourable if it is linked to a reduced duration of hospitalisation. Chloroprocaine enables a swifter recuperation from anaesthesia in comparison to other short-acting local anaesthetics. Lacasse et al. demonstrated that the duration of unsupported walking and the period at which patients were

deemed eligible for hospital release were dramatically reduced when chloroprocaine was used instead of bupivacaine.[2] Adjuvants, such as opioids, are often used with intrathecal local anaesthetics to enhance the effectiveness and duration of spinal blocking, as well as to extend post-operative pain relief.[3] Fentanyl is the predominant opioid used in sub-arachnoid block.[4]

2-Chloroprocaine, an ester local anaesthetic with ultra-short duration of action, was first developed in 1952 by FOLDES and MCNALL for the purpose of spinal anaesthesia. During the early 1980s, the compound 2-Chloroprocaine was developed and used with 0.2% sodium bisulfite as an antioxidant. Several studies in literature have shown that the primary cause of transitory neurological impairment is a combination of low pH (<3) and sodium bisulfite in the anaesthetic preparation. Free from preservatives 2-Chloroprocaine, when administered in spinal anaesthesia, offers sufficient duration and intensity of surgical anaesthesia for short operations. It has the advantage of speedier resolution of the anaesthetic effect, allowing patients to regain mobility and be discharged from the hospital sooner. Additionally, there is no evidence of Transient Neurological Symptoms associated with its usage. Incorporating intrathecal opioids into spinal anaesthesia extends the duration of sensory blockage without causing a delay in motor recovery.[5,6] The objective of our study was to compare the effectiveness of intrathecal administration of 1% Chloroprocaine and 1% Chloroprocaine with Fentanyl in patients undergoing short duration surgery below the umbilicus. We assessed the onset and duration of the block, duration of pain relief, hemodynamic parameters, Visual Analogue Scale (VAS) score at the time of first rescue analgesia, time of mobilisation, and any side effects.

Subjects and Methods

Following the acquisition of clearance from the hospital ethics committee and getting written informed consent from the participant, a prospective randomised double-blind research was conducted at the Department of Anaesthesiology. A total of 120 patients, aged between 20 and 70 years, of either gender, with ASA grade I and II, weighing between 38 and 68 kg, and with a height between 150 and 170 cm, were scheduled for elective infraumbilical surgery lasting less than 60 minutes. The research excluded patients who refused treatment, were uncooperative, had an infection at the spinal site, had coagulopathy, severe hypovolemia, were pregnant or lactating, had allergies or intolerance to local anaesthetic, or had a history of systemic illness.

Prior to surgery, patients had a comprehensive evaluation including general, physical, and systemic examinations. All necessary regular and specialised investigations were conducted in accordance with the hospital's policy. The patients were randomly assigned to two groups using the envelope technique. Group C received 3.0 mL of 1% Chloroprocaine mixed with 0.5 mL of normal saline, whereas Group CF received a 3mL of 1% Chloroprocaine mixed with 25 µg of fentanyl (0.5 mL). During the surgical procedure, intravenous (i.v.) access was established and patients were administered a preload of 10 mL/kg of Ringer lactate over a period of 15 minutes. All standard monitors, such as noninvasive blood pressure, pulse oximetry, and three-lead electrocardiogram, were attached. The initial heart rate, systolic blood pressure, diastolic blood pressure, and average arterial pressure were recorded. The lumbar puncture procedure was performed with strict aseptic measures. The patient was positioned on their left side, and the puncture was made in the L2-L3 interspace using a 23G Quincke spinal needle via a midline approach. The SAB was administered upon confirmation of unobstructed cerebrospinal fluid flow. The study medication was then injected, and the patient was then positioned in a supine posture for the duration of the trial. The following parameters were observed and recorded for data collection: The time it took for the sensory level of the block to reach T10 (in minutes) was determined by evaluating the lack of pinprick feeling using a 23 gauge hypodermic needle after administering the research medication.

The onset of motor blockage was evaluated using the Modified Bromage scale. 0 indicates the absence of motor block, 1 indicates the ability to bend the knee with the hip blocked, 2 indicates the ability to dorsiflex the foot with both the hip and knee blocked, and 3 indicates a full motor block with all three joints (hip, knee, and ankle) blocked. The highest degree of dermatome was evaluated with a 23 gauge hypodermic needle after the achievement of a full sensory block. The patients were evaluated for the length of time that the motor block (Bromage 0) lasted, the duration of the sensory block, the duration of pain relief, and the moment at which the first movement occurred. These were considered as the clinical endpoints. The duration of analgesia, which is the time from the start of pain relief following spinal anaesthesia until the beginning of pain, was documented. Three-fourths Hemodynamic parameters, such as pulse rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure, were measured at certain time intervals (S3, S5, S10, S15, S30, S60, S90, S120 minutes) after the administration of the study medication. During the surgical procedure, if there was a decrease in MAP below 20% of the initial value, it was addressed by administering a bolus dose of an injectable medication. Administer Mephenteramine intravenously at a dosage of 6mg. A patient with a heart rate of less than 60 beats per minute was treated with an injection. Administer intravenous injection of atropine sulphate at a dosage range of 0.3-0.6mg. The cumulative dose of bolus medications was recorded. The assessment of postoperative pain was conducted using a VAS which is a horizontal scale of 10 cm in length. The scale is marked with gradations, where 0 represents the absence of pain and 10 represents the most severe pain possible. Pain scores over 3 were addressed by administering rescue analgesia via injection. Administer Tramadol intravenously at a dosage of 2mg per kilogramme of body weight, diluted in 100 millilitres of normal saline solution, for the purpose of alleviating postoperative pain. All adverse reactions or complications resulting from the medicine or procedure were documented, including low blood pressure, high blood pressure, slow heart rate, fast heart rate, postoperative nausea and vomiting (PONV), itching, shivering, and Transient Neurological Symptoms (TNS).

Statistical Analysis

The statistical analysis was conducted using SPSS software Version 25.0. The results were reported as the mean value

together with the standard deviation for normally distributed data using the chi-square test. This analysis was conducted for age and different time lengths. An unpaired t-test and a paired t-test were used to compare the means of two groups, based on whether the distribution was parametric or non-parametric, respectively. The significance level will be set at a confidence level of 95%, with a p-value threshold of less than 0.05.

Results

The fundamental characteristics of the patients were similar among the groups in terms of age, height, weight, and length of operation, as shown in Table 1 and 2. In group CF, the average time it took to achieve motor block was 8.88±1.06 minutes, which was sooner compared to group C, where it took 11.36±1.27 minutes (P=0.001). In our investigation, the average time it took for the sensory block to start at the T10 dermatomal level was shorter in the group that received 1% Chloroprocaine with Fentanyl (6.66±0.48 minutes) compared to the group that received just 1% Chloroprocaine (9.24±0.58 minutes) (P = 0.001). The highest sensory level dermatome in 36 individuals in Group C was seen between T6 and T9, while in Group CF, this was observed in 50 patients. 24 patients in Group C achieved the highest levels of T10-T12, compared to 10 patients in Group CF. This difference is statistically significant, with a P value of 0.001, indicating a strong relationship between the two groups. In group CF, the average length of motor block was significantly longer compared to group C (84.58±3.69 min vs 73.39±2.89 min, P = 0.001). The average length of sensory block was significantly longer in group CF compared to group C (94.58±3.97 min vs 82.28±3.61 min, p = 0.001). The average duration of pain relief was significantly longer in group CF compared to group C (133.37±4.87 min vs 89.57±4.15 min, p= 0.001). There was no statistically significant difference in HR (heart rate), SBP (systolic blood pressure), DBP (diastolic blood pressure), and MAP (mean arterial pressure) between the two groups over the whole perioperative period. The Visual Analogue Scale (VAS) at the time of first pain relief was 4.08±0.87 in Group C and 3.11±0.81 in Group CF (p=0.001). In Group C, the time for initial mobilisation was 124.39±3.61 minutes, but in Group CF it was 162.25±3.87 minutes (p=0.001) [Table 3]. The incidence of adverse effects was lower in both groups. Only 3 (5%) patients reported shivering in Group C, while 4 (6.67%) patients reported pruritis in Group CF. The occurrence of hypotension, bradycardia, nausea, and vomiting was comparable in both groups C and F, indicating no significant statistical disparity between them.

Table 1: Age and gender of the participants

Gender and age	Group C =60		Group CF=60		P value
	Number	Percentage	Number	Percentage	
Gender					0.14
Male	42	70	45	75	
Female	18	30	15	25	
Age					0.34
Below 30	12	20	14	23.33	
30-40	28	46.67	30	50	
40-50	8	13.33	7	11.67	
50-60	7	11.67	6	10	
Above 60	5	8.33	3	5	
Age (years)	37.85	3.85	36.78	2.87	

Table 2: Duration of surgery

	Group C =60		Group CF=60		P value
	Mean	SD	Mean	SD	
Weight (kgs)	58.14	3.74	60.71	4.25	0.14
Height (cm)	159.99	2.58	160.28	2.74	0.27
Duration of Surgery(Min)	35.41	2.85	35.89	2.96	0.33

Table 3: Clinical parameter of the participants

Clinical parameter	Group C =60		Group CF =60		p value
	Mean	SD	Mean	SD	
Time for onset of sensory block upto T10 (min)	9.24	0.58	6.66	0.48	0.001
Time for onset of motor block (Bromage 3)	11.36	1.27	8.88	1.06	0.001
Peak level dermatome T6-T9 T10-T12	36 24		50 10		0.001
Duration of motor block (Min)	73.39	2.89	84.58	3.69	0.001
Duration of sensory block (Min)	82.28	3.61	94.58	3.97	0.001
Duration of analgesia(min)	89.57	4.15	133.37	4.87	0.001
VAS Score at the time of first rescue analgesia	4.08	0.87	3.11	0.81	0.001
Time of first mobilization (Min)	124.37	3.61	162.25	3.87	0.001

Table 4: Side effects in both groups

Side effects	Group C =60		Group CF=60		P value
	Number	Percentage	Number	Percentage	
Hypotension	3	5	2	3.33	0.15
Bradycardia	3	5	2	3.33	0.24
Nausea/ Vomiting	3	5	2	3.33	0.18
shivering	3	5	0	0	0.11
Pruritis	0	0	4	6.67	0.13

Discussion

Chloroprocaine is a brief-acting local anaesthetic that facilitates rapid restoration of sensory and motor function. The abbreviated period of action is a result of the very low affinity for proteins and the rapid breakdown by pseudocholinesterase. In the past, there were several worries about the safe use of chloroprocaine and its possible neurotoxicity, which was attributed to the inclusion of preservatives. Nevertheless, research has shown that the use of chloroprocaine without preservatives yields prompt and dependable numbing of both sensory and motor functions. This effect may be achieved with dosages ranging from 30 to 60 mg, making it suitable for short

surgical operations conducted under sub-arachnoid block. Notably, no noteworthy problems have been seen in relation to this approach. The use of adjuvants in intrathecal local anaesthetics enhances the effectiveness and duration of spinal blockade, as well as extending the length of post-operative pain relief.[7]

We have used a 1% Chloroprocaine solution that is free from preservatives, and it has been reintroduced into clinical practice. 2-Chloroprocaine facilitates prompt alleviation of sensory and motor blockage, allowing for swift mobilisation and thus leading to an expedited hospital release. While 2-Chloroprocaine has the benefit of a brief duration and early discharge, its use in unpleasant procedures is limited due to the early onset of postoperative pain.[8] Various adjuvants, such as Clonidine, Fentanyl, Epinephrine, Buprenorphine, and Dextrose, have been used in spinal anaesthesia with 2-Chloroprocaine.

Research has shown that intrathecal opioids may significantly improve pain relief when combined with lower-than-optimal dosages of local anesthetics.[9]Fentanyl is an opioid that activates the μ-receptors and has a high affinity for lipids. Fentanyl acts intrathecally by binding to opioid receptors in the dorsal horn of the spinal cord, resulting in an upward extension of sensory block. Our research found that patients in both groups had similar characteristics, including age, weight, height, sex distribution, and length of operation, with no statistically significant differences (P>0.05). The demographic data in the studies conducted by Vath JS et al,[9] were similar. Spinal anaesthesia was effective in all individuals from both groups, and there was no need for general anaesthesia to be administered during the procedure. The average time it took for the sensory block to start at the T10 dermatomal level was shorter in the group that received 1% Chloroprocaine with Fentanly (6.66±0.48 minutes) compared to the group that received just 1% Chloroprocaine (9.24±0.58 minutes) (P = 0.001). In their research, Vath JS et al,[9] examined the effects of adding Fentanyl to 2-Chloroprocaine. They found a very significant difference (p=0.005) in the time it took to reach the highest degree of anaesthesia in the dermatome (T8 versus T5) when Fentanyl was added.

In the CF group, the average time it took to achieve motor block was 8.88±1.06 minutes, which was sooner compared to the C group where it took 11.36±1.27 minutes (P=0.001). The findings of this research align with those of Srivastava et al,[10] indicating that group F had a more rapid start of motor block compared to group N. The highest sensory level dermatome in 36 individuals in Group C was seen between T6 and T9, while in Group CF, this was observed in 50 patients. 24 patients in Group C achieved the highest level of T10-T12, but only 10 patients in Group CF reached this level. The statistical analysis showed a very significant difference between the two groups, with a p-value of 0.001, indicating a strong relationship. Vath JS et al,[9] administered Fentanyl (20 μg) in combination with 2-Chloroprocaine (40 mg). They found that the maximal degree of anaesthesia was detected at dermatome T5 (T3-T7) when Fentanyl was used, compared to dermatome T9 (T4-L1) when Fentanyl was not used (p<0.01).

The investigation revealed that the average length of motor block was significantly longer in group CF compared to group C (84.58±3.69 min vs 73.39±2.89 min, P = 0.001). Our findings align with those of Vath JS et al,[9]and Davis BR et al,[11] The investigation revealed that the average length of sensory block was significantly longer in group CF compared to group C (94.58±3.97 min vs 82.28±3.61 min, P = 0.001). Our findings align with many previous studies, including those conducted by Vath JS et al,[9] Davis BR et al,[11] The research found that the average duration of pain relief was longer in group CF compared to group C, and this difference was statistically significant (133.37±4.87 min vs 89.57±4.15 min, p= 0.001). Our research found no statistically significant difference (p>0.05) in hemodynamic parameters (PR, SBP, DBP, and MAP) across groups at different time intervals. During our investigation, we measured the Visual Analogue Scale (VAS) scores at the time when the first rescue analgesia was administered. The VAS scores were found to be 4.08±0.87 in Group C and 3.11±0.81 in Group CF. The difference between the two groups was statistically significant (p=0.001). There were no instances of VAS (Vasovagal Syncope) detected at TRA1 when Fentanyl and 2-Chloroprocaine were administered simultaneously, according to the researchers. Our research also found that the duration it took for initial mobilisation was 124.39±3.61 minutes in Group C and 162.25±3.87 minutes in Group CF (p=0.001). The findings of the research conducted by Vath JS et al,[9] and Davis BR et al,[11] are consistent with our own investigation.

In the current investigation, minimal side effects or complications were noted in both groups throughout the study duration, with the exception of three patients in Group C (5%) who reported experiencing shivering. These individuals were administered a 40mg intravenous tramadol injection. Additionally, four patients in Group CF (6.67%) reported mild pruritus, which did not require any treatment. Neither group had any instances of temporary neurological symptoms. These findings align with the results reported by Kouri ME et al,[12]Davis BR et al,[11]and Vath JS et al.[9] The limitations of our research lie in our failure to compare 2-CP with other local anaesthetics often used for spinal anaesthesia. According to the literature, it is recommended to provide a dosage of 30-60 mg of 2-CP for operations lasting 60 minutes or less. A dose of 10 mg is believed to have no effect. Therefore, we conducted a comparison of the minimal dose necessary for each agent to establish spinal anaesthesia. We lacked a contingency plan for an epidural catheter to provide anaesthesia in the event of a protracted procedure. Therefore, if the surgical process had been extended, the pregnant women may have been subjected to the hazards of general anaesthesia.

Conclusion

Our findings indicate that the use of 2-Chloroprocaine leads to prompt alleviation of sensory and motor blockage, as well as early mobilisation and release for procedures lasting less than 60 minutes. Our research indicates that incorporating intrathecal Fentanyl as a supplementary agent to 2 - Chloroprocaine in the correct dosage is a superior option. This combination offers a quicker onset, prolongs the duration of pain relief, maintains stable blood pressure, and does not result in any significant complications. Therefore, it may be concluded that 2-Chloroprocaine is efficacious for outpatient procedures performed with spinal anaesthesia, and the inclusion of Fentanyl enhances the overall quality of the anaesthesia.

References

1. Camponovo C. Spinal 1% 2-chloroprocaine versus general anesthesia for ultra-short outpatient procedures: A retrospective analysis. Acta Biomed. 2014;85(3):265-8. PMID 25567463.
2. Lacasse MA, Roy JD, Forget J, Vandenbroucke F, Seal RF, Beaulieu D, et al. Comparison of bupivacaine and 2-chloroprocaine for spinal anesthesia for outpatient surgery: A double-blind randomized trial. Can J Anaesth. 2011;58(4):384-91. doi: 10.1007/s12630-010-9450-x, PMID 21203878.
3. Hindle A. Intrathecal opioids in the management of acute postoperative pain. Continuing Education in Anaesthesia Critical Care & Pain. 2008;8(3):81-5. doi: 10.1093/bjaceaccp/mkn016.
4. Vampugalla P, Vundi V, Kumar K, Kambar C, Mahalakshmi P, Pisipati R. A comparative study of intrathecal ropivacaine with fentanyl and L-bupivacaine with fentanyl in lower abdominal and lower limb surgeries. Int J Basic Clin Pharmacol. 2015; 4:1147-55. doi: 10.18203/2319-2003.ijbcp20151349.
5. Choudhary D, Sethi P, Chouhan DS, Karnawat R, Saran A, Chouhan RS. A comparative study of intrathecal low dose bupivacaine with fentanyl and low dose levobupivacaine with fentanyl in transurethral resection of prostate: randomized, double blind, prospective study. Indian J Clin Anaesth. 2017; 4:165-9.
6. Zhang Y, Bao Y, Li L, Shi D. The effect of different doses of chloroprocaine on saddle anesthesia in perianal surgery. Acta Cir Bras. 2014;29(1):66-70. doi: 10.1590/S0102-86502014000100010, PMID 24474180.
7. Brull R, MacFarlane AJR, Chan VWS: chap 56. Spinal, epidural, and caudal anesthesia. In: Miller RD, editor. Miller's anesthesia. 8th ed. Amsterdam: Elsevier Saunders; 2015. p. 1684.
8. Goldblum E, Atchabahian A. The use of 2-chloroprocaine for spinal anaesthesia. Acta Anaesthesiol Scand. 2013;57(5):545-52. doi: 10.1111/aas.12071, PMID 23320599.
9. Vath JS, Kopacz DJ. Spinal 2-chloroprocaine: the effect of added fentanyl. Anesth Analg. 2004;98(1):89-94. doi: 10.1213/01.ANE.0000093360. 02058.ED, PMID 14693593.
10. Srivastava U, Kumar A, Saxena S, Saxena R, Gandhi NK, Praveen Salar P. Spinal anaesthesia with lignocaine and fentanyl. Ind J Anaesthesiol. 2004; 48:121-3.
11. Davis BR, Kopacz DJ. Spinal 2-chloroprocaine: the effect of added clonidine. Anesth Analg. Feb 2005;100(2):559-65. doi: 10.1213/01.ANE.0000143381.30409.62, PMID 15673894.
12. Kouri ME, Kopacz DJ. Spinal 2-chloroprocaine: a comparison with lidocaine in volunteers. Anesth Analg. Jan 2004;98(1):75-80. doi: 10.1213/01.ANE.0000093228.61443. EE, PMID 14693590.

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