Original Research Article

Comparision of 1% chloroprocaine and 1% chloroprocaine with fentanyl in infraumbilical surgical procedures under spinal anaesthesia

Swati Jhania[1], Satyendra Singh Yadav[2], Shakti Singhal[3], Dilip Kothari[4]

[1]Post Graduate Resident 3rd Year, Department of Anaesthesiology, Gajra Raja Medical College, Gwalior, Madhya Pradesh, India
[2]Associate professor, Department of Anaesthesiology, Gajra Raja Medical College, Gwalior, Madhya Pradesh, India
[3]Assistant Professor, Department of Anaesthesiology, Gajra Raja Medical College, Gwalior, Madhya Pradesh, India
[4]Prof. & HOD, Department of Anaesthesiology, Gajra Raja Medical College, Gwalior, Madhya Pradesh, India

Received: 30-11-2021 / Revised: 21-12-2021 / Accepted: 02-01-2022

ABSTRACT

Background: In the ambulatory setting, day by day there is an increase in the use of spinal anaesthesia. Antioxidant- and preservative-free form of 2-chloroprocaine (1%) has been re-emerged as a short-acting local anesthetic for use in spinal anesthesia.In this study,we evaluate the efficacy of 1% Chloroprocaine and 1 % Chloroprocaine with Fentanyl in spinal anaesthesia and any untoward side effects and complications associated with the study drugs and technique. **Material and Methods:** For this prospective, ramdomizes ,comparative study we recruited a total of 100 adult patient for infraumblical surgeries under spinal anaesthesia were randomly divided into two groups (n=50 each).Group C (n=50) received 30 mg 1% chloroprocaine with 0.5ml normal saline and Group CF (n=50) received 30 mg 1% chloroprocaine with 25mcg Fentanyl (0.5ml). **Result:** Faster Onset of sensory and motor blockade was seen in the group CF duration of spinal anesthesia and sensory and motor block duration is prolonged in group CF.($p<0.001$) Duration ofanalgesia was significantly prolonged in the group CF when compared to group C(87.5±11 vs132.5±4.9min $p<0.001$) hemodynamic parameter insignificant with less side effect in both group. **Conclusion:** The addition of Fentanyl to intrathecal 1% chloroprocaine will increase the duration and quality of both sensory and motor blockade in spinal anaesthesia as compared to 1% chloroprocaine alone.

Key words: Adjuvant, Fentanyl, Chlorprocaine, Infraumblical surgery.
Study design: Prospective, Randomised, Double Blind Observational Study.

Introduction

In the ambulatory setting, day by day there's a rise in the use of spinal anaesthesia. Being a simple and quick procedure, Spinal anaesthesia is always a better option for short procedure also.[1] It has become possible to minimize the adverse effects of anesthesia on the recovery process, with the handiness of fast, short acting anesthetic, analgesic, sympatholytic and muscle relaxant drugs, as well as better monitoring devices. An ideal anesthetic agent for spinal anesthesia in day care surgery patients should have rapid onset of action, predictable duration of action , adequate potency, less neurotoxicity and systemic untoward effects[2].

However, some of the characteristic of spinal anaesthesia may limit it's use for ambulatory surgery including delayed ambulation due to motor blockade, risk of urinary retention and severe pain after block regression. The choice of correct local anaesthetic for spinal anaesthesia is therefore crucial in the ambulatory surgery[3].

Corresponding author
Dr. Shakti Singhal
Assistant Professor, Department of Anaesthesiology,
Gajra Raja Medical College, Gwalior, Madhya Pradesh, India.
Email: shaktiksinghal@gmail.com

2-Chloroprocaine an ultra short acting ester local anaesthetic with agent was first introduced in 1952 by FOLDES and MCNALL[4] for the use in spinal anaesthesia. In early 1980's the formulation of 2-Chloroprocaine was used with 0.2% sodium bisulfite as an antioxidant. There are many study in literature which suggested that a combination of low pH (<3) and sodium bisulfite in the anesthetic preparation were the main cause of transient neurological deficit.[5] Preservative free 2-Chloroprocaine when used in spinal anaesthesia provides adequate period and depth of surgical anaesthesia for brief procedures with the benefits of faster block resolution and earlier ambulation and hospital discharge while no sign of Transient Neurological Symptoms[6].
The addition of intrathecal opioids to spinal anesthesia prolongs sensory blockade without prolonging motor recovery[789]
Thus, aim of our study was to compare the efficacy of intrathecal 1% Chloroprocaine and 1% Chloropocaine with Fentanyl in patient undergoing infraumblical short duration surgery in term of onset and duration of block, duration of analgesia, hemodynamic parameters, VAS at the time of first rescue analgesia, time of mobilization and side effects.

Material and Methods

After obtaining approval from the hospital ethics committee and written informed consent taken from participent to perform a prospective randomised double blind study, carried out in the Department of Anaesthesiology, G.R. Medical College and J.A Group of Hospitals, Gwalior (M.P.) Total of 100 patient were taken age 20-60 years of either sex of ASA grade I and II having

weight 40-70 kg and height between 150 -170 cms scheduled for elective infraumblical surgery less than 60 minutes. Any patient refusal, uncooperative, infection at spinal site,Coagulopathy, Severe hypovoluemia,Pregnant and lactating women, allergic or intolerance to local anaesthetic and any history of systemic disease were excluded from study.

Patients were examined a day before surgery to do complete general, physical and systemic examination. All the required routine and special investigation as per hospital protocol were carried out. Patients were randomized into two groups using envelope method; Group C – 3.0 mL of 1% Chloroprocaine with 0.5ml normal saline and Group CF – mL of 1% Chloroprocaine with 25 µg fentanyl (0.5ml).In the operation theater, intravenous (i.v.) access was secured and patients were preloaded with 10 mL/kg of Ringer lactate over 15 min. All routine monitor were connected like noninvasive blood pressure, pulse oximetry, and three-lead electrocardiogram. The baseline heart rate, systolic, diastolic, and mean arterial pressure, were recorded. Under all aseptic precautions, Lumbar puncture was done in left lateral decubitus position at the L2-L3interspace via midline approach using 23G Quincke spinal needle. Subarachnoid block (SAB) was performed after ensuring free flow of CSF, the study drug was injected and then patient was put in supine position for the remaining of the study period. Following parameter were observed and recorded for data collection:

1. Time for onset of sensory level of the block upto T10 (in min) was assessed by loss of pinprick sensation with 23 gauge hypodermic needle after injection of the study drug.

2. Evaluation of motor blockade onset was assessed by the Modified Bromage scale.

0 = no motor block
1 = able to bend the knee (hip blocked)
2 = able to dorsiflex the foot (hip and knee blocked)
3 = complete motor block (hip, knee and ankle blocked).

3. Highest level dermatome was assessed by 23 gauge hypodermic needle after obtaining complete sensory block.

4. Patients were assessed for duration of motor block (Bromage 0) ,duration of sensory block, duration of analgesia and time of first moblilization were defined as clinically end points.

5. Duration of analgesia defined as from onset of analgesia after spinal anaesthesia to onset of pain was recorded.

¾ Assessment of haemodynamic parameter including PR, SBP, DBP and MAP were recorded at S3, S5, S10, S15, S30, S60, S90, S120 minutes after injection of study drug. During surgery, any fall in MAP below 20% of baseline value was treated with bolus dose of inj. Mephenteramine 6mg i.v. PR <60 beats /min was treated with inj. Atropine sulphate 0.3-0.6mg i.v. Total dosage of bolus drugs were recorded.

7. Postoperative pain was assessed by Visual analogic score scale consisting of a 10 cm horizontal scale with gradations marked as 0 means no pain at all and 10 means worst pain imaginable.VAS score >3 was managed with rescue analgesia with inj. Tramadol 2mg/kg i.v.in 100ml normal saline to relieve postoperative pain.

8. Any side effect or complication due to the drug or technique were noted including hypotension, hypertension, bradycardia, tachycardia, postoperative nausea vomiting (PONV), pruritus, shivering and Transient Neurological Symptoms (TNS) were recorded.

Statistical Analysis

The statistical analysis was performed using SPSS software(Version 20). Data were presented as mean with Standard deviation for normaldistribution/scale data using chi square (age and various time durations). Unpaired 't' test and Paired 't' test were used to compare the means following parametric and non-parametric distribution respectively between both group. Significance level will be 95% confidence level ($p<0.05$).

Results

Spinal anaesthesia was successfully obtained in all the patients. The demographic profile of patients was comparable between the groups in terms of age, height, weight, and duration of surgery was found to be similar [Table 1]. Mean time of onset of sensory block at T10 and sensory block were faster with addition fentanyl(group CF)($p<0.05$).Higher no. of patients had accomplished T6-T9 level of dermatome block in group CF as compared to Group C.The mean duration of motor block was prolonged in group CF in comparison to group C (83.7±4.9 min versus 72.1±4.9 min , $p < 0.001$).The mean duration of sensory block was prolonged in group CF in comparison to group C, with the difference being statistically significant (93.6±5.0 min versus 81.7±4.9 min, $p < 0.001$). The mean duration of analgesia was prolonged in group CF compared to group C, with the difference being statistically significant (132.5±4.9 min versus 87.5±11 min, $p< 0.001$) .The difference in HR, SBP, DBP and MAP was not statistically significant in both the groups throughout the perioperative period. VAS at the time of first recue analgesia(Mean±SD) 4.1±0.8 and 3.0±0.7 in Group C and Group CF respectively ($p<0.001$) . The time for first mobilization (Mean ±SD) were 122.1±7.4 minutes and 161±6.1 minutes in Group C and Group CF respectively ($p<0.001$) [Table 2].Adverse effect were less in both the group only 2(4%) patient complaint of shivering in Group C and 3(6%) patient complaint of pruritis in Group CF.

Table 1: **Demographic data an duration of surgery**

Demographic parameter	Group C (n=50) (Mean±SD)	Group CF (n=50) (Mean±SD)	p value
Age (years)	36.8±9.9	35.8±9.6	0.618 (NS)
Weight (in kgs)	57.8±6	59.1±5.5	0.247(NS)
Height (in cm)	159.7±5.8	160.2±5	0.617(NS)
Male:Female	36:14	39:11	0.488(NS)
Durationof Surgery(Min)	34.2±6.5	34.9±6.6	0.626(NS)

Statistically significant=P<0.05(S) ; Statistically insignificant= P>0.05(NS)

Table 2: Comparison of spinal block characteristics in two groups

Clinical parameter	Group C (n=50) (Mean±SD)	Group CF (n=50) (Mean±SD)	p value
Time for onset of sensory block upto T10 (min)	9±0.8	6.5±0.5	0.000(HS)
Time for onset of motor block (Bromage 3)	11.1±0.9	8.5±0.8	0.000(HS)
Peak level dermatome T6-T9 T10-T12	 28 22	 43 7	 0.000(HS)
Duration of motor block (Min)	72.1±4.9	83.7±4.9	0.000(HS)
Duration of sensory block (Min)	81.7±4.9	93.6±5.0	0.000(HS)
Duration of analgesia(min)	87.5±11	132.5±4.9	0.000(HS)
VAS Score at the time of first rescue analgesia	4.1±0.8	3.0±0.7	0.000(HS)
Time of first mobilization (Min)	122.1±7.4	161±6.1	0.000(HS)

Statistically significant=P<0.05(S); Statistically highly significant= P<0.001(HS)

Discussion

Regional anaesthesia like subarachnoid block (SAB) provides adequate analgesia with minimal side effects including postoperative nausea and vomiting (PONV) and respiratory depression.[10]

We have used preservative free 1% Chloroprocaine which is reintroduced in clinical practice. 2-Chloroprocaine provides early resolution of sensory and motor blockade with early mobilization resulting in early hospital discharge. Although short duration and early discharge is the advantage with 2-Chloroprocaine but early onset of postoperative pain limits its use in painful surgeries.[11]

Many adjuvants have been used with 2-Chloroprocaine in SAB like Clonidine, Fentanyl, Epinephrine, Buprenorphine and Dextrose.

Studies have shown that intrathecal opioids can greatly enhance analgesia of subtherapeutic doses of local anesthetics[6].Fentanyl is a lipophilic μ-receptor agonist opioid. Intrathecally, Fentanyl exerts its effect by combining with opioid receptors in dorsal horn of spinal cord and it provides cephalad extend of sensorial block.

In our study, patients in both the groups are comparable (p>0.05) with regards to age, weight, height, sex distribution and duration of surgery. In Vath JS et al[6]and Siddaiah et al[12]study demographic data were comparable.

Spinal anaesthesia was successful in all participants of both the groups, and general anaesthesia was not required in any case to complete the surgery.

In our study mean onset of sensory block at T10 dermatomal level was shorter in 1% Chloroprocaine with Fentanly group(6.5±0.5 minutes) than the 1% Chloroprocaine group(9±0.8 minutes) respectively (p value <0.001). Vath JS et al[6] conducted study with 2-Chloroprocaine and Fentanyl observed highly significant difference (p=0.005) in time to achieve peak level dermatome (T8 vs T5) by addition of Fentanyl.

The mean time to attain motor block was earlier in group CF(8.5±0.8 minutes) than the group C (11.1±0.9 minutes) respectively (p<0.000).This is similar to the results obtained in the study done by Srivastava et al[13]group F showed fast onset of motor block than group N.

The peak sensory level dermatome in 28 patients in Group C had peak level between T6- T9 in comparison to 43 patients in Group CF. Peak level of T10- T12 were attained by 22 patients in Group C in contrast to 7 patients in Group CF with p value of 0.000 that is statistically highly significant difference association exist between groups. Vath JS et al[6] used Fentanyl (20 µg) along with 2-Chloroprocaine (40 mg) in which they observed peak level dermatome with Fentanyl T5 (T3-T7) and without Fentanyl T9 (T4-L1) (p<0.01).

In the study we observed duration of motor block (mean ±SD) was to be 72.1±4.9 minutes and 83.7±4.9 minutes in Group C and Group CF respectively (p =0.00). Our finding are similar to that of Vath JS et al[6]andDavis BR et al[14]

In the study we observed duration of sensory block (mean ±SD) was to be 81.7±4.9 minutes and 93.6±5.0 minutes in Group C and Group CF respectively (p =0.000). Our finding are similar to many other researchincludingVath JS et al[6],Davis BR et al[14],Singariya et al[15]and Bhaskara et al[16]

In our study, duration of analgesia (Mean±SD) was found to be 87.5±11 min and 132.5±4.9 min in Group C and Group CF respectively (p=0.00). Results of our study are similar to those of Singariya et al[15] who conducted a study with 2-Chlorprocaine and Fentanyl found highly significant difference (p<0.0001) in duration of analgesia with addition of Fentanyl.

In our study hemodynamic parameters (PR, SBP, DBP and MAP) showed statistically insignificant difference (p>0.05) when compared between groups at various time intervals. Singariya et al[15]alsoobserved statistically insignificant difference in HR and BP in both group.

In our study, we observed VAS (Mean±SD) 4.1±0.8 and 3.0±0.7 in Group C and Group CF respectively (p=0.000) at the time of first recue analgesia. No researchers observed VAS at TRA1 with Fentanyl and 2-Chloroprocaine together.

In our study we also observed that time for first mobilization (Mean ±SD) were 122.1±7.4 minutes and 161±6.1 minutes in Group C and Group CF respectively (p=0.00). The observation in study done by Vath JS et al[6]andDavis BR et al[14]is similar to our study.

In present study not much side effects or complication were observed in both groups during the study period except two patient complaint of shivering in Group C (4%) they were treated by 40mg iv tramadol injection and 3 patient complaint of pruritis in Group CF(6%) which was mild no treatment was needed .There were no cases of transient neurological symptom in either group.This is similar to the results obtained by Kouri ME et al[17],Davis BR et al[14]andVath JS et al[6].

The limitations of our study are that we did not compared 2-CP with other local anesthetic used for spinal anaesthesia. Literature suggests a dose ranging between 30-60 mg of 2-CP for procedures lasting 60 min or less, while 10 mg is considered as no-effect dose thus we tried comparing minimum dose of each drug required to achieve spinal anesthesia. We did not have a back-up of an epidural catheter to provide anaesthesia in case the surgery got

prolonged. Hence, if the surgical procedure had got prolonged, the parturients might have got exposed to the risks of general anaesthesia (GA).

Conclusion

According to the results, 2-Chloroprocaine provides early resolution of sensory and motor blockade, and also early mobilization and discharge for procedure less than 60 min. Our study suggest addition of intrathecal Fentanyl as an adjuvant to 2-Chloroprocaine in appropriate dose is a better choice as it provide faster onset, increases the duration of analgesia and hemodynamic stability, with no major complication. Thus we can say that 2-Chloroprocaine is effective for daycare surgeries under spinal anaesthesia while addition of Fentanyl improves quality of anaesthesia.

References

1. Chakravorty N, Jain R.K , Chakravorty D, Agrawal R.C. Spinal anaesthesia in the ambulatory setting - A Review. Indian J. Anaesth 2003; 47(3):167-173
2. Shetty A, Raveendra US. Anaesthesia for day care surgery. NUJHS Vol.5, No.2, June 2015, ISSN 2249-7110.
3. 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(2):315-319.
4. Foldes FF, McNall PG. 2-Chloroprocaine: a new local anesthetic agent. Anesthesiology 1952;13:287-96.
5. Reisner LS, Hochman BN, Plumer MH. Persistent neurologic deficit and Adhesive arachnoiditis following intrathecal 2-chloroprocaine. AnesthAnalg 198059(6);452-454
6. Vath JS, Kopacz DJ. Spinal 2- Chloroprocaine: The effect of added Fentanyl. Anesth Analg 2004; 98:89-94.
7. Liu S, Chui AA, Carpenter RL, Mulroy MF, Allen HW, Neal JN and Pollock JE. Fentanyl prolongs lidocaine spinal anaesthesia without prolonging recovery.Anesth Analg 1995; 80:730-4.
8. Chilvers CR, Vaghadia H, Mitchell GWE, Merrick PM. Small dose hypobaric lidocaine - Fentanyl spinal anaesthesia for short duration outpatient Laproscopy. Anesth Analg 1997; 84:65-70.
9. David BB, Solomon E, Levin H, Admoni H, Goldik Z. Intrathecal Fentanyl with small dose dilute Bupivacaine: better anaesthesia without prolonging recovery. Anesth Analg 1997; 85:560-5.
10. Brull R, MacFarlane AJR, Chan VWS. Spinal, epidural, and caudal anesthesia. In: Miller RD, ed. *Miller's Anesthesia*. 8th ed. Philadelphia, PA: Elsevier Saunders; 2015:chap 56, 1684.
11. Goldblum E, Atchabahian A. The use of 2-chloroprocaine for spinal anaesthesia Acta Anaesthesiol Scand. 2013;57:545–52
12. Siddaiah J, Pujari VS, Madalu AS, Bevinaguddaiah Y, Parate LH. A comparative study on the effect of addition of intrathecal buprenorphine to 2-Chloroprocaine spinal anesthesia in short duration surgeries. J Anaesthesiol Clin Pharmacol. 2019;35(4):533-539.
13. Srivastava U, Kumar A, Saxena S, Saxena R, Gandhi NK, Praveen Salar P. Spinal anaesthesia with lignocaine and Fentanyl. Ind J Anaesthesiol 2004; 48:121–123.
14. Davis, Brad R. MD; Kopacz, Dan J. MD Spinal 2-Chloroprocaine: The Effect of Added Clonidine, Anesthesia & Analgesia: February 2005; 100(2):559-565.
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;65:102-7.
16. 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.
17. Kouri, Mary E. MD; Kopacz, Dan J. MD Spinal 2-Chloroprocaine: A Comparison with Lidocaine in Volunteers, Anesthesia & Analgesia: January 2004; 98(1):75-80.

Conflict of Interest: Nil
Source of support: Nil