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Comparative study of Intrathcal 1% 2 Chloroprocaine with intrathecal 1% 2 Chloroprocaine and fentanyl for infraumblical short surgical procedures under subarachoid block

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Abstract

Successfully used for spinal anesthesia without complications. The short duration of action of 2 CP (40 min.) make it an ideal local anesthetist for infraumbilical short surgical procedures but the early postoperative pain may be undesirable.

To avoid post operative pain Intrathecal fentanyl has been used to enhance the spinal analgesic effect with 2 chloroprocaine .This study aims to compare the effect of adding intrathecal fentanyl to 2-chloroprocaine with regard to spinal anesthesia characteristics.

Materials and Methods: Sixty ASA physical status I and II patients posted for various short duration lower limb surgeries under spinal anaesthesia were divided into two groups to receive 1% Chloroprocaine 35 mg (Group C) and 1% Chloroprocaine 35 mg with 25mcg fentanyl (Group F) via intrathecal injection. Sensory and motor block characteristics, time to ambulation, hemodynamic parameters, and side effects were recorded.

Results: There was no difference in terms of demographic data and duration of surgery.The onset of sensory block was significantly faster in group F when compared to group C

($p < 0.05$).The mean time for regression to L1 was significantly longer in group C (Figure 3)

The mean time for complete regression to S 2 was significantly longer in group F (2chlorprocaine with fentanyl)which was 50.75 ± 5.25 minutes compared to group C 48.52 ± 4.72 minutes. The time to reach the modified Bromage score of 0 in group F was longer, 76.25 minutes, when compared to group C, 70.20 minutes

Conclusions: The addition of fentanyl facilitates prolong postoperative analgesia without delay in discharge from the hospital and no hemodynamic compromise and other adverse effects barring pruritus. Addition of fentanyl is a

better choice for infraumbilical surgery in comparison to Chloroprocaine alone.

Keywords: Chloroprocaine, Fentanyl, Spinal Anaesthesia, Infraumbilical Surgery

Introduction

Due to advancement of anesthesia and surgical techniques number of day care surgery is increased.With this search for better local anesthestic agent is also increased. [1].The choice of anesthesia for day care surgery is based on the type of surgery, duration of surgery, patient medical history and possible perioperative complications.

Spinal anesthesia is a most commonly used anesthesia modality for patients undergoing surgeries including lower limb, urological, abdominal, perianal and gynecological surgeries. Previously, general anesthesia was preferred over spinal anesthesia due to lack of ideal spinal anesthetic drugs for day care surgery and wide availability of rapid and short-acting drugs for general anesthesia like propofol and remifentanil.[2, 3] In recent decades, increased availability of safe and short-acting local anesthetic drugs, neuraxial anesthesia became a good option for short duration surgeries.**4**

Most commonly used local anesthetic for spinal anesthesia in day care is bupivacaine, a long-acting amino amide local anesthetic that can be associated with prolonged block effects [5]as well as unpredictable anesthetic effects, long duration of action, and hemodynamic instability when given in higher doses [6]

Shorter-acting local amino amides such as lidocaine and mepivacaine are being used, but there have been repeated reports of transient neurologic symptoms (TNSs) by multiple groups [7,8]and side effects that are both undesirable and avoidable for these specific medications.

IN 1952 an amino-ester local anesthetic agent Chloroprocaine was established in clinical use . Initially, it was used for epidurals in obstetric patients. In the 1980s there were several reports suggestive persistent neurological deficit following large volumes of intrathecal injection of chloroprocaine.[9,10] Studies showed that preservative, sodium bisulfite was responsible for the neurotoxicity of chloroprocaine[11,12] After these reports, its use was abandoned.

Subsequently, the pH of the solution has been adjusted and a preservative free formulation was reintroduced into clinical use in 2005.[13] This new formulation has been safely used for spinal anesthesia in healthy volunteers and in patients without complications.[14,15]

The duration of action of 2-chloroprocaine was found to be 40 minutes, which is ideal for short-duration surgeries. But the occurrence of early postoperative pain may be undesirable. Adjuvants when added to neuraxial local anesthetics should ideally prolong the duration of intraoperative and postoperative analgesia.[16]

The Intrathecal opioids enhance sensory block without prolonging motor and sympathetic block [17,18] .Among them, Fentanyl has a rapid onset of action, binds strongly to plasma proteins, and potentiates the afferent sensory blockade. That's why we decide to study Efficacy of Fentanyl as adjuvant to 2 Chlorprocaine.

The aim of this study was to evaluate and compare the efficacy of 1% 2 Chloroprocaine 3.5 ml (35 mg) with 1% 2 Chloroprocaine 3.5 (35 mg) plus Fentanyl 25 mcg, with respect to onset of sensory and motor block, duration of sensory and motor block, , time to unassisted ambulation, postoperative analgesia, hemodynamic parameters, and side effects and complications of the drugs in spinal anesthesia.

Material and Methods

This observational study was planned to compare 1% 2chlorprocaine [3.5ml] with 1% 2 Chlorprocaine [3.5ml]

plus fentanyl 25 mcg in subarachnoid block in 60 patient between age group 18-55 years. of either sex belonging to ASA grade I and II for elective short duration (less than 60 min.)infraumblical surgery under spinal anesthesia.

Patients with ASA grade more than II, patient refusal, hypersensitivity to drugs under study, and patients with contraindications to spinal anesthesia were excluded from the study. Selected patients received study drugs.

Day before surgery all the patients were evaluated and they were kept nil by mouth for a minimum period of 6 hours before the surgical procedure. As the patient come in the operation theatre, a large bore intravenous cannula was inserted, and the crystalloid infusion was started. All ASA standard monitors were connected, and baseline parameters were recorded. Spinal anesthesia was performed in the patient with a sitting position with all aseptic precautions, after infiltration of 1 ml of 1% of lidocaine, lumbar puncture was done with a 25-gauge Quincke needle in L3-4 or L4-5 interspaces. After clear and free cerebrospinal fluid flow, patients received either 3.5 ml (35 mg) of 1 % Chloroprocaine with 0.5ml normal saline(GROUP C) or 3.5 ml (35 mg) of 1%Chloroprocaine with 25mcg(0.5 ml) Fentanyl (GROUP F). After the completion of spinal injection, the patients were immediately placed supine.

The patients were assess and evaluated by an independent anesthetist for sensory and motor blockades every three minutes for 20 min, then every 15 min until complete regression of sensory and motor blocks. During surgery, the patient's blood pressure (systolic, diastolic, and mean), heart rate, and oxygen saturation were recorded.

Sensory block was evaluated by assessing the peak level dermatome (assessed by loss of pinprick sensation starting at the L1 dermatome and graded according to Gromley and Hill 1996: Normal sensation-0, Blunted sensation-1, No sensation-2 with grade 2 being considered as the onset of the sensory block) using 23G hypodermic needle.[19]

The sensory block characteristics such as onset of the block (sensory block at L1), peak block height, time to reach peak block height, time to reach readiness for surgery (sensory block ≥ T10), time for regression of two segments, time for regression to L1, and time for complete regression to S2 were recorded.

Assessment of motor block was done using a modified Bromage scale [20]

Modified Bromage scale

Score 0: No motor block

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

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

Score 3: Complete motor block

The motor block characteristics like time to reach modified Bromage score of 3, modified Bromage score at the end of the surgery, and time to reach modified Bromage score of 0 were recorded. Additional data such as duration of surgery, duration of stay in the Post Anesthesia Care Unit, time to ambulateand time of first postoperative analgesic requirement were recorded. Pain was assessed using a numerical rating scale (NRS) score. It is a 0 to 10 pain rating scale, score 0 is considered as no pain and score > 4 considered as a need for rescue analgesia. Time for first rescue analgesia was recorded and injection paracetamol 1gm IV was given as rescue analgesia.

A modified Aldrete score was used for discharge criteria from PACU, and Patients were discharged from PACU after achieving a modified Aldrete score ≥ 9 and were shifted to the ward. Time to void and unassisted ambulation were noted.

Side effects like hypotension (blood pressure < 20 % of baseline),Bradycardia,respiratory depression nausea/vomiting,pruritus were treated accordingly, documented and statistically analyzed.

Statistical Analysis To determine the association between the groups, the Student's t-test was used for comparing two groups. A comparison of qualitative variables was analyzed by the chisquare test. A P-value of 0.05 will be taken as the level of significance. Data were presented as mean +/- S.D. Data were entered in Microsoft Excel, and Data analysis was performed using windows MEDCALC software on a personal computer.

Observations and Results

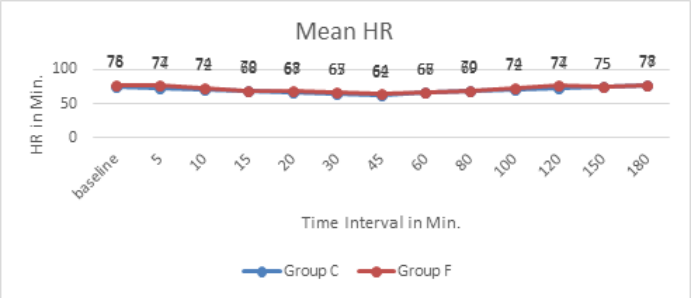
Sixty patients of ASA Grade 1 & 2 were assessed for eligibility, prepared for surgery and none of the patients required conversion to general anesthesia. There was no significant difference between two Groups Group C and Group F in respect to demographic profile and duration of surgery. (Table -1). Data represented as mean + SD S= Significant(p< 0.05)., NS= Non-Significant

Table 1: Demographic characteristics and duration of surgery

Patient variable	Group C(n=30)	Group F(n=30)	P value (S/NS)
Age (Yrs)	35±8.50	36±10.00	NS
Sex M /F	24/6	26/4	NS
Height in cm	160 ± 5.53	158 ±4.95	NS
Weight (Kgs)	65 ±5.53	67 ±12.00	NS
Duration of Surgery	38+/-8.5	36 +/- 10.05	NS

There is no significant difference in patient age, gender & ASA classification in two groups.(Table 1)

Figure 1: Mean heart Rate (HR) at different Time Intervals



Heart rate changes were comparable between the groups [Figure 1]

There was no statistically significant difference in two groups In mean MAP throughout the Study period [Figure 2].

Figure 2: Mean Arterial Pressure (MAP) at different Time Intervals

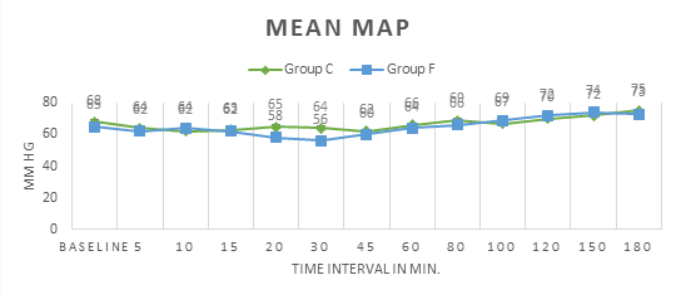
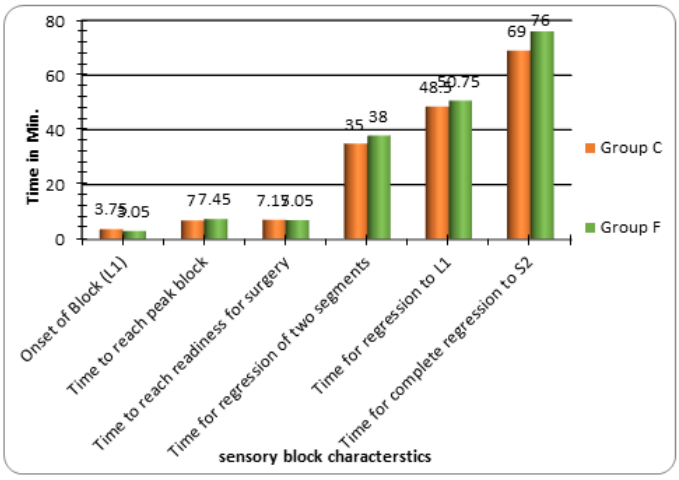


Figure 3: Sensory block Characterstics

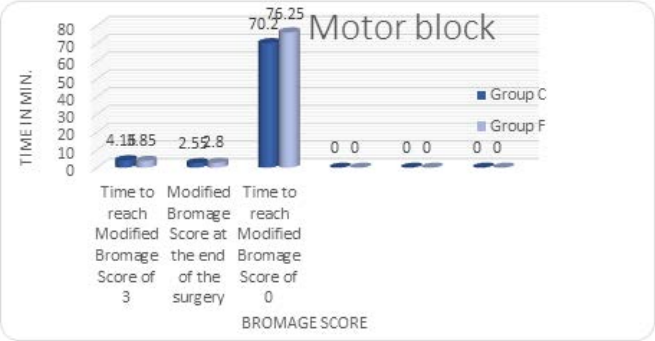


The onset of sensory block was significantly faster in group F when compared to group C (p< 0.05).The mean

time for regression to L1 was significantly longer in group C (Figure 3)

The mean time for complete regression to S 2 was significantly longer in group F (2 chlorprocaine with fentanyl)which was 50.75 ± 5.25 minutes compared to group C 48.52 ± 4.72 minutes.

Figure 4: Motor block characteristics



The time to reach the modified Bromage score of 0 in group F was longer, 76.25 minutes, when compared to group C, 70.20 minutes.Figure 2

Table 2 : Postoperative observations n side effects

	Group C	Group F	P value S/NS
Duration of stay in the post-anesthesia care unit (min)	0.20±14.40	36.62 ±8.20	NS
Time for first rescue analgesia (min)	220.50± 75.55	380.80±90.78	<0.001
Time for unassisted ambulation (min)	75.05±15.75	80.85 ±13.35	NS
Hypotension (No. of patients)	2	3	NS
Bradycardia	2	1	NS
Itching	0	2	NS
Nausea /vomiting	0	1	NS

Discussion

Recent trends for day care anesthesia is use of low dose local anesthetic providing segmental block with adjuvants such as opioids.

The most commonly used combination to enhance and increase the duration of sensory analgesia without intensifying the motor blockade or prolonging recovery from spinal anesthesia opioids like fentanyl added to local anesthetics.[21]

Fentanyl, a short-acting lipophilic opioid stimulates μ_1 and μ_2 receptors, it potentiates the afferent sensory blockade and facilitates reduction in the dose of local anesthetics 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. [22]

Kopacz DJ et al compared different doses of chloroprocaine to find the correct dose of chloroprocaine for ambulatory surgery, and concluded that 40 mg is the ideal dose for surgical procedures of short duration. Chloroprocaine 20-30mg can be used for ultra-short procedures but it is associated with less motor block, and 10 mg is ineffective for surgical procedures.From references of Various studies We compared a chloroprocaine 35 mg a short-acting local anesthetic agent, using fentanyl as an adjuvant to both the groups for short surgical procedures.[23]

Demographic profile

In our study, both the groups were comparable with respect to age, sex, height, weight and duration, and type of surgery. No patients had to be excluded from the study.

Changes in HR and MAP were similar and non significant in both the groups in our study, and similarly, other clinical studies have found no difference in the hemodynamic profile between Chlorprocaine and chlorprocaine Fentanyl group.

Sensory Block Characteristics

The time of onset of block to L1 was faster in group F(3.05 min.) in which intrathecal 25 mcg of Fentanyl was added to Chlorprocaine 35 mg and it was statistically significant. Fentanyl, due to its lipophilic nature, has a rapid onset of the sensory block when administered intrathecally .Results of this study is similar to study done by Attri et al[24],Madhusudhana Rao [25]they find Group F (fentanyl) has a faster onset of the sensory block when compared to group C (3min vs. 5min), which can be attributed to the addition of Fentanyl.

The sensory block characteristics like onset of block, time to reach peak block, and time to reach readiness [Fig. 3] for surgery were similar between the groups.

The time to reach peak block(7 vs 7.4 min.) was similar in both groups in our study and was slightly faster than Camponovo C *et al.*(8 minutes) where a higher dose of intrathecal 50 mg of 2- chloroprocaine was administered as compared to our study 35 mg.[15]

In our study, the two-segment regression where intrathecal Fentanyl was added was slightly prolonged, 35+/-4.75 minutes in group C and 38.75 ±7.25 minutes in group B with *P* value of 0.077 but was statistically not significant.Our results are similar to study of Vath and colleagues found that the time for two-segment regression when 20 mcg intrathecal Inj. fentanyl was added to 40 mg 2-chloroprocaine.[26]

The mean time for regression to L1 was significantly longer in group F which was 50.75 ± 5.25 minutes compared to group C 48.52 ± 4.72 minutes with a statistically significant *P* value of < 0.05. Time for complete regression to S2 was similar between the two groups 69+/- 16.35 & 76+/- 10.76 min.Group C & GroupF respectively. Similar results observed in study of Jayprakash S,Vinayak et al [27]and contradictory to results of Vijay Mathur, T. Mansuri,in there study they compare chlorprocaine 40 mg with 20 mcg fentanyl with Bupivacaine with fentanyl 20 mcg. [28]

The addition of opioids like fentanyl to spinal local anesthetic agent prolongs sensory blockade while minimally affecting the motor blockade.

In group C, the time to reach the modified Bromage score of 3 was 4.16 ± 1.50 minutes and the modified Bromage score at the end of the surgery was 2.55± 0.90. In group F,the time to reach the modified Bromage score of 3 was 3.85± 1.25 minutes and the modified Bromage score at the end of the surgery was 2.80± 0.51. The time to reach the modified Bromage score of 0 in group F was longer,76.25 ± 10.15 minutes, when compared to group C,70.20 ± 18.85 minutes.

The duration of motor block(Group C- 75.05 min vs. Group F-80.85 min) and time to unassisted ambulation in our study was shorter when compared to the study done by Madhusudhana Rao[25] Vath et al[26]who compared Chloroprocaine with Chloroprocaine and Fentanyl which might be because of the lower concentration (1% vs. 2%) and lower dose of Chloroprocaine (35 vs. 40 mg)used in our study.

The time to void urine was similar in both the group. None of the patients in both groups required catheterization for urinary retention.

Studies done by Madhusudhana Rao [25],Vijay Mathur et[28] al reported that the addition of 25mcg Fentanyl to local anesthetics improves quality and prolongs postoperative analgesia without prolonging the time to void. Contarary to our study , prolongation of time of voiding by addition of intrathecal opioid found by Vath *et al.*[26] when they added fentanyl intrathecally to 2-chloroprocaine.

Time for first administration of rescue analgesic (220.50 ± 75.55 min and 380.80 ± 90.78 min in Group C and Group

F, respectively, $P < 0.001$) were statistically prolonged in Group F.

The incidence of hypotension,bradycardia, nausea, and vomiting was similar in both the groups C&F ($p > 0.05$); no statistical difference exists in comparison. The incidence of pruritus was higher and statistically significant in group F when compared to group C.Although None of the patient required any medication for pruritis.

The addition of fentanyl facilitates prolong postoperative analgesia without delay in discharge from the hospital and no hemodynamic compromise and other adverse effects barring pruritus.

The quality of the surgical condition was similar in both the groups, as none of the patients complaining of pain intra-operatively.

Conclusion

Both the study groups are effective in providing surgical anaesthesia and haemodynamic stability, but group F offered an advantage of rapid onset of sensory and motor block , postoperative analgesia with early ambulation. This makes the combination of 1% 2 Chloroprocaine (35 mg) with Fentanyl (25 mcg) a better choice for short duration infraumbilical surgeries under spinal anesthesia.

Limitations of study are we compared chloroprocaine and fentanyl on their safe as well as known optimal doses for short surgical procedure. However, a larger study with large sample size needs to be conducted to establish the perfect dose.

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Ethical approval: The study was approved by the Institutional Ethics Committee GMC Bhopal

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