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A Comparative Study between Chloroprocaine and Chloroprocaine with Fentanyl in Diagnostic Knee Arthroscopies under Spinal Anesthesia

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Abstract: ***Background: Spinal anesthesia is a reliable and safe technique for Diagnostic knee arthroscopies. Preservative-free, 1% chloroprocaine, has re-emerged for use in spinal anesthesia. Due to its short duration of action, Chloroprocaine has earlier regression of sensory block and shorter time to request for the first rescue analgesia. Opioids, when combined with local anesthetics intrathecally prolong the duration of analgesia without prolonging motor block and time to void. We compared intrathecal use of 1% Chloroprocaine (35 mg) with 1% Chloroprocaine (35 mg) plus Fentanyl (25mcg) in terms of onset and duration of sensory, motor block, duration of analgesia, time to unassisted ambulation, time to return of voiding function, hemodynamic parameters and side effects. Methodology:60 patients of age group 18-60 years of either sex, belonging to ASA physical status 1 and 2 undergoing diagnostic knee arthroscopies were randomly divided into two groups, 1% Chloroprocaine with normal salineGroup C (n=30) and 1%Chloroprocaine with Fentanyl Group F (n=30). Each group received intrathecally either 35mg (3.5ml) of 1% Chloroprocaine with 0.5mlnormal saline or 35mg (3.5ml) of 1% Chloroprocaine with 0.5ml Fentanyl (25mcg). For statistical analysis, unpaired-t-test and chi-square tests were used. Results: The onset of sensory block was earlier in group F when compared to group C (group C-5min vs. group F-3min). Peak block height was higher in group F (T6) when compared to group C(T8). The onset of motor block, duration of motor block, time to unassisted ambulation, and time to void were similar between the groups (p > 0.05). Duration of sensory block (85min vs. 65 min) and time to first rescue analgesia (115min vs. 85 min) was prolonged in group F when compared to group C respectively. Hemodynamic parameters (HR and BP) and side effects like nausea and vomiting were comparable between the groups. Pruritus was significantly high in group F (33%) when compared to group C(0%). Conclusion: Both Chloroprocaine and Chloroprocaine with Fentanyl provided satisfactory anesthesia. The addition of Fentanyl to Chloroprocaine resulted in the early onset of sensory block and prolonged analgesia when compared to Chloroprocaine alone. This makes the combination of 1%Chloroprocaine (35 mg) with Fentanyl (25 mcg) a better choice for arthroscopic knee surgeries under spinal anesthesia.***

Keywords: 1% Chloroprocaine, Fentanyl, outpatient surgery, spinal anesthesia, duration of analgesia

1. Introduction

The number of ambulatory surgeries is on the rise due to its advantages like lack of dependency on the availability of hospital beds, greater flexibility, reduced nosocomial infections, lower procedural costs, and recovery in a familiar environment[1,2,3].

An ideal anesthetic for spinal anesthesia in daycare surgery patients would provide fast onset of action, adequate potency, predictable duration, and decreased neural toxicity and systemic adverse effects. Bupivacaine, which is most commonly used, can result in the unpredictable duration of the block, even with smaller doses, and can result in delays in discharge.

In 1952 an amino-ester local anesthetic chloroprocaine was first introduced as a short-acting spinal anesthetic. Several case reports of neurological deficits were observed in the early 1980s after inadvertent intrathecal 2-chloroprocaine injections intended for epidural delivery[4]. The antioxidant sodium bisulfite in the acidic environment was thought to be the culprit in these cases[5]. So, the drug was no longer used for spinal anesthesia after that.

In recent years, Chloroprocaine was once again available in a preservative-free form for use in subarachnoid space. It has a faster onset of action, short duration of action, predictable block height, and time to complete regression. Several studies such as Camponovo et al[6] study, Forster et al[7] study demonstrated the safe use of preservative-free intrathecal 1% chloroprocaine in spinal anesthesia. However, the major drawback of Chloroprocaine is a shorter duration of analgesia due to its short duration of action.

Intrathecal opioids enhance sensory block without prolonging motor and sympathetic block[8,9]. Among them, Fentanyl has a rapid onset of action, binds strongly to plasma proteins, and potentiates the afferent sensory blockade. The aim of this study was to evaluate and compare theefficacy of 1% Chloroprocaine (35 mg) with 1% Chloroprocaine (35 mg) plus Fentanyl 25 mcg, with respect to onset of sensory block, onset of motor block, duration of sensory and motor block, postoperative analgesia, time to unassisted ambulation, time to void, hemodynamic parameters, and side effects and complications of the drugs in spinal anesthesia.

2. Materials and Methodology

After obtaining approval from the local ethics committee and procuring a written informed consent, 60 patients were randomized into two groups.

Patients between aged 18 years and 60 years of ASA status I or II, weighing between 40-90 kg, scheduled to undergo

elective diagnostic knee arthroscopy lasting for <45 minutes, under subarachnoid block were included.

Patients with ASA status greater than II, patient refusal, hypersensitivity to drugs under study, and patients with contraindications to spinal anesthesia were excluded from the study. The study population was divided randomly into two groups, Group Cand GroupF.

The day before surgery, a thorough pre-anesthetic evaluation of the patient was done, and they were kept nil by mouth for a minimum period of 6 hours before the surgical procedure.

After the arrival of the patient in the operation theatre, an intravenous cannula 20 G was inserted, and the crystalloid infusion was started. All ASA standard monitors were connected, and baseline parameters were recorded. Under all aseptic precautions, spinal anesthesia was performed in the patient with a sitting position at L3-L4 subarachnoid space using 25 G spinal needle. 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 independent blinded observer evaluated the sensory and motor blocks every 1 min until readiness for surgery and, every 20 min after the end of surgery in PACU until resolution of the motor block to Bromage score 0 and regression of sensory block to S2 dermatome.

Sensory block was evaluated by assessing the peak level dermatome (assessed by loss of pinprick sensation starting at the L2 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. The onset of sensory block was the time from intrathecal injection to the time taken to achieve the T10 dermatome level. The peak level of sensory block and time to achieve the peak sensory level were noted.Duration of sensory block (was the time taken to regress sensory block up to S2 dermatome in the heel) was also noted.

Motor block was assessed by using the modified Bromage scale (no motor block = 0; hip blocked = 1; hip and knee blocked = 2; hip, knee, and ankle blocked = 3). The onset of motor block(time to injection of a local anesthetic to modified Bromage scale of 2) and duration of motor block(time to regression of modified Bromage scale to 0) were noted. If the level of anesthesia was inadequate, the regimen was switched to general anesthesia and excluded from the study.

Intraoperatively, hemodynamic parameters (BP, HR, spO2) were charted every 5 minutes for the first 30 minutes and then even 15 minutes until the end of surgery. Side effects likehypotension (blood pressure <30% from the baseline), bradycardia (heart rate< 20 % of baseline), nausea/vomiting,pruritus were treated accordingly, documented and statistically analyzed.

At the completion of the surgery, the duration of surgery was noted, and the patient was shifted to the PACU where vital parameters, duration of sensory and motor blockade, and any side effects of the drugs were observed for 12 hours.

The pain was assessed by the visual analog scale (VAS) postoperatively, in which patients were asked to grade their severity of pain (0 was minimal or no pain, 10 was the worst pain ever felt). Rescue analgesia in the form of intravenous tramadol 2 mg/kg was given if VAS ≥ 3. The time for the first request of rescue analgesia (duration of analgesia) was recorded. Time to unassisted ambulation was noted. Time to return of voiding function was noted.

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 chi-square 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.

3. Observations and Results

Sixty patients were assessed for eligibility, and none of the patients required conversion to general anesthesia. There was no significant difference in demographic profile and duration of surgery in both Group C and Group F (Table -1).

Table 1: Demographic characteristics and duration of surgery

Patient variable	Chloroprocaine Group C(n=30)	Chloroprocaine with Fentanyl Group F(n=30)	P value (S/NS)
Age (yrs)	39.08 ± 11.8	37.6 ± 12	0.63(NS)
Sex(Male/Female)	25/5	24/6	
Weight (Kgs)	51.24± 9	52.6 ± 8.2	0.612(NS)
Height(Ft)	5.4 ± 0.5	5.3 ± 0.4	0.39(NS)
Duration of Surgery	32± 8	30 ± 7	0.30(NS)

Data represented as mean ± SD
S= Significant, NS= Non-Significant

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

The peak block height was higher in group F (T6 vs. T8) when compared to group C. Regression of sensory block to S2 level and the time to first demand of analgesia (duration of analgesia) in the postoperative period was significantly longer in Group F as compared to group C ($p< 0.05$).(Table-2). (Figure -1)

Table 2: Sensory block characteristics

Variable	Group C (n=30)	Group F(n=30)	P Value (S/NS)
Onset of sensory block(min)	5 ± 1.2	3 ± 1.5	<0.0001(S)
Peak block height	T8	T6	<0.05(S)
Duration of sensory block(min)	65± 15.6	85 ± 21.8	0.0001(S)
Time to first rescue analgesic (min)	85± 16.2	115± 20.5	0.0001(S)

Data represented as mean ± SD

S= Significant, NS= Non-Significant

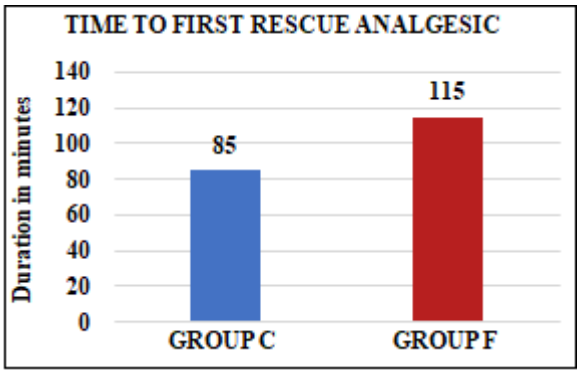

Figure 1: Comparison of time to request for first rescue analgesia between groups

The time to onset of motor block, duration of motor block, time to unassisted ambulation, and time to void weresimilar in both the groups (p> 0.05).(Table-3)

Table 3: Motor characteristics and time to void

Variable	Group C (n=30)	Group F (n=30)	P-Value (S/NS)
The onset of motor block (min)	6± 2.8	5 ± 1.8	0.1(NS)
Duration of motor block(min)	55 ± 12.6	59 ± 14.5	0.25(NS)
Time to unassisted ambulation (min)	90± 18.4	95± 20.5	0.32(NS)
Time to void (min)	104± 22.8	107± 25.4	0.63(NS)

Data represented as mean ± SD
S= Significant, NS= Non-Significant

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. (Table-4)

Table 4: Incidence of side effects with the drugs administered

Variable	Group C (n=30)	Group F (n=30)	P-value (S/NS)
Hypotension, n (%)	3(10%)	4(13%)	0.7(NS)
Bradycardia, n (%)	1(3%)	2(6%)	0.5(NS)
Nausea/ Vomiting, n (%)	2(6%)	4(13%)	0.3(NS)
Pruritus, n (%)	0(0%)	10(33%)	0.0006(S)

Data represented as numbers and percentages.
S= Significant, NS= Non- Significant

4. Discussion

In this study, the addition of 25 mcg Fentanyl to intrathecal 1% Chloroprocaine not only speeded up the onset and increased the duration of the sensory block but also prolonged the postoperative analgesia without affecting the recovery of motor block,time to unassisted ambulation and time to void.

Group F 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. Fentanyl, due to its lipophilic nature, has a rapid onset of the sensory block when administered intrathecally[10].

Our findings coincide with the study done by Uma Srivastava et al[11] who has compared Lignocaine (group N) with Lignocaine and Fentanyl (group F) (group N-5.4 min vs. group F -3.6 min) and cherug et al[12], which showed that the addition of Fentanyl to local anesthetic resulted in the early onset of the sensory block.

The peak block height was higher in group F (T6) when compared to group C (T8). The difference in the level of sensory block in both groups can be explained by the difference in the baricity of the injected solutions. Opioids are hypobaric, and when added to hypobaric local anesthetic will make the mixture more hypobaric, thus altering the density of the resulting solution, which affects the direction and extent of spread in the spinal block. Similar findings were observed in the study done by Attri et al[13] which showed that levobupivacaine with Fentanyl (T6) had higher peak sensory block when compared to levobupivacaine (T8) alone.

No statistically significant difference exists between the groups on the onset of motor block.

In the present study, the mean duration of sensory block (85min vs. 65 min) and time to first rescue analgesia (115min vs. 85min) was prolonged in group F when compared to group C respectively. This can be attributed to the addition of Fentanyl in group F. The findings of prolongation of sensory block and postoperative analgesia are consistent with experimental[8] as well as clinical synergistic interaction[14] between spinal opioids and local anesthetics. Opioids appear to produce analgesia by inhibition of synaptic transmission in nociceptive afferent pathways via A-delta and type C fibers by opening presynaptic K+ channels to inhibit transmitter release and thus reduce Ca++ influx. Similar findings of prolongation of sensory block and time to request for first rescue analgesia(duration of analgesia) have been reported in the studies done by Uma Srivastava et al[11]and Attri et al[13]on the addition of Fentanyl to Lignocaine and Levobupivacaine respectively.

In the present study, the duration of motor block (group C- 55 min vs. group F- 59 min) and time to unassisted ambulation (group C- 90 min vs. group F- 95 min) was similar in both the groups and no significant difference is present between the groups on the comparison(<0.05). Similar findings have been reported in the study done by Uma Srivastava et al[11], where they found that there is no prolongation of the motor block on the addition of Fentanyl to Lignocaine.

The duration of motor block and time to unassisted ambulation in our study was shorter when compared to the study done by Vath et al[15]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.

In the present study, the average duration of time to void was similar in both the groups. Studies reported that the addition of 25mcg Fentanyl to local anesthetics improves

anesthesia quality and prolongs postoperative analgesia without prolonging the time to void. These findings have been supported by the results of the study done by Uma Srivastava et al[11], where they reported that there is no prolongation of time to void on the addition of Fentanyl to Lignocaine.

The overall incidence of side effects was similar in both the groups except the pruritis, which was present in 33% of patients of group F and none in group C (P=0.0006). Pruritus has been observed in other studies combining Fentanyl with local anesthetics for spinal anesthesia[14], and our results are consistent with these findings. However,it resolved spontaneously without any treatment.

Our study was limited by a few factors. We did not follow up the patients beyond the period of their discharge from the hospital through follow up phone calls to evaluate any neurologic toxicity or other adverse effects.

5. Conclusion

Both Chloroprocaine and Chloroprocaine with Fentanyl provided satisfactory anesthesia. The addition of Fentanyl to Chloroprocaine resulted in the early onset of sensory block and prolonged analgesia when compared to Chloroprocaine alone. This makes the combination of 1%Chloroprocaine (35 mg) with Fentanyl (25 mcg) a better choice for arthroscopic knee surgeries under spinal anesthesia.

6. Conflict of interest

There is no conflict of interest.

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