Original Research Article

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Evaluation Safety and Efficacy of Chloroprocaine V/S Chloroprocaine With 20µg Fentanyl in Subarachnoid Block in Participants Undergoing Lower Limb Ambulatory Surgery

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Abstract

Aims: To Investigate the efficacy and safety profile of the Fentanyl when added to Chloroprocaine for outpatient spinal anaesthesia in terms of quality and duration of sensory and motor blockade and effective analgesia. *Settings and Design:* prospective, randomized, double blind study *Methods and Material:* After institutional review board approval and informed written consent from patients,100 participants, aged 18 to 60 years, of ASA Physical status I, II or III scheduled for lower limb ambulatory surgery under subarachnoid block, were randomly divided into two groups (n = 50 each); Group C received 4.0ml (40 mg) 1% isobaric Chloroprocaine + 0.4ml Normal Saline (0.9%) and Group F received 4.0ml (40mg) 1% isobaric Chloroprocaine + 0.4ml Fentanyl (20µg). Degree of sensory and motor block, postoperative analgesia (VAS score), time of 1st rescue analgesia (effective analgesia), time of ambulation, voiding of spontaneous urine, hemodynamic variables and side effects were evaluated and compared. At VAS ≥ 4, rescue analgesic Inj. Diclofenac Sodium I.V. was given. *Results:* Participants in Group F had prolonged onset (3.91 ± 1.09 min), peak (7.54 ± 1.30 min) and duration (110.74 ± 9.78 min) of sensory block than group C (3.02 ± 0.97 min), (6.53 ± 1.34 min), (104.64 ± 10.83 min) respectively. Motor characteristics were comparable in both groups with onset, peak and duration respectively in group C was (4.01 ± 1.42 min),(7.48 ± 1.89 min) and(79.6 ± 8.42 min) and in group F was (4.52 ± 0.83 min), (9.05 ± 0.52 min),(90.76 ± 5.59 min). Duration of analgesia was longer in Group F (148.36 ± 2.84 min) than in Group C (145.12 ± 2.78 min). Time of ambulation was early in group C (110.62 ± 5.25) than group F (115.42 ± 5.8 9min). Voiding of spontaneous urine was early in group C (112.8 ± 4.69) than group F (115.76 ± 5.92 min). Incidence of side effects was comparable in both groups.

Keywords: Subarachnoid Block; Fentanyl; isobaric Chloroprocaine; Lower-limb Ambulatory Surgery.

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Introduction

Ambulatory surgery as a day care procedure, continues to gain popularity day by day in today's era as it cuts down the total cost, decreases the hospital stay, better patient satisfaction because of their early return to daily routine.[1] So, for this purpose the interest in available and emerging local anaesthetic drugs for outpatient spinal anaesthesia is being increases.[1] The properties for ideal anaesthetic agent for ambulatory surgery includes,

1. Rapid onset
2. Adequate potency
3. Predictable duration

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4. Decreased neurotoxicity and other systemic side effects.

When going through literature, procaine having high failure rate is unreliable for outpatient spinal anaesthesia.[1] Though lignocaine was a popular among all as it matched ideal characteristics for ambulatory surgery, increasing incidence of transient neurologic syndrome (TNS) has decreased the drug use.[1] Bupivacaine has been studied in smaller doses but results in unpredictable duration of block, which can lead to delay in discharge and that's why not suitable for ambulatory procedures.[2]

Spinal anaesthesia performed with preservative free 2-chloroprocaine produced blocks with rapid onset, relatively increased potency than procaine, no evidence of toxicity.[3] In early 1980, due to reports of neurologic deficits from 2-chloroprocaine after accidental intrathecal injection, 2-chloroprocaine was discontinued from market for intrathecal use.[4] In 2003, 2-chloroprocaine was once again available in preservative free and anti-oxidant free form and this has regenerated the interest in its use for outpatient spinal anaesthesia.[4]

A combination of intrathecal opioids with local anaesthetics permits reduction in the dosage of both components, minimizing the side effects of the local anaesthetic (motor blockade) and the opioid[5] (i.e. urinary retention, itching and delayed respiratory depression in the case of morphine). An important benefit to their spinal use is that, because of their rapid clearance, these agents at analgesic spinal doses can produce effect at blood levels that are similar to those producing effects after systemic administration.[6]

So, this study was aimed to investigate the efficacy and safety profile of the Fentanyl when added to 2-chloroprocaine for outpatient spinal anaesthesia in terms of quality and duration of sensory and motor blockade as well as effective analgesia.

Materials and Methods

After approval from the Institutional Review Board and informed written consent from all the patients, this prospective, randomized, double blind study was carried out in the Department of Anaesthesiology, Govt. Medical College and Sir T. Hospital, Bhavnagar, Gujarat. We enrolled 100 patients, aged 18–60 yr and ASA Class I, II and III, who underwent spinal anaesthesia for lower limb ambulatory surgery with duration of surgery 30-45 min. Written informed consent was obtained from all patients before randomization. Patients were not admitted to the study if any of the following criteria were present: Patients with psychiatric disorder, spinal cord and peripheral nerve diseases, drug/alcohol abuse, un-cooperative patients, pregnant lady and lactating mother. After proper preoperative evaluation like history, clinical examination, routine baseline investigations and electrocardiogram (ECG) patient shifted in pre-anaesthetic room were Heart rate (HR), noninvasive blood pressure (NIBP), peripheral arterial oxygen saturation (SpO_2) measured. Patients were randomly allocated in the two groups by computer generated random number sequence in sealed envelopes. Patient was asked to pick one envelope in pre-anaesthetic room. One member from the team except from principle Investigator (PI), asked to open the envelope and filled up the drug as per group assigned to patient. PI was responsible for performing the procedure (SAB)

Group C (n = 50): received 4.0ml (40 mg) 1% chloroprocaine + 0.4ml NS (0.9%)

Group F (n = 50): received 4.0 ml (40 mg) 1% chloroprocaine + 0.4ml Fentanyl (20µg)

18G intravenous venous (IV) cannula inserted and pre-medicated with Inj. Ondansetron 0.08mg/kg iv 15 minutes prior to procedure. In the operation theater: Preloading was done with Inj. Ringer Lactate 10 ml/kg. Under strict aseptic and antiseptic precaution subarachnoid block was performed with study drug in left lateral position, using midline approach with 25G spinal needle in L3 – L4 intervertebral space. After the block, patient was turned supine. The time of injection was noted as time "0". The sensory block was assessed by skin sensation to pinprick with 23G needle. The motor block was assessed according to Modified Bromage Scale. After the completion of surgery: Patients were shifted to PACU where sensory and motor blockade were assessed till regression of blockade. Time of analgesia request were noted with 'Visual Analog Scale' (VAS) Inj. Diclofenac Sodium (1.5mg/kg) intravenous was given at VAS ≥ 4.

Statistical analysis

Sample size calculation done with alpha and beta error. Data will be presented as Mean ± Standard Deviation (SD) or numbers. Comparison between two groups will be done using Mann-Whitney test (for non-parametric data) or unpaired Student's t-test (for parametric data). p value < 0.05 is considered statistically significant.

Results

In Demographic data Patients characteristics in terms of age, gender, weight and height were comparable among both the groups. (p > 0.05). There is statistically significant difference in mean time for onset, peak and duration of sensory block in two groups (p < 0.001). There was earlier onset and peak of sensory block (Fig. 1) achieved in group C than in group F. Duration of sensory block (Fig. 2) was prolonged in group F. On comparison, between group C and group F, there is statistically significant difference in onset, peak and Duration of motor block (Fig. 3, Fig. 4) among two group, earlier in group C rather than group F. Addition of 20µg of Fentanyl to chloroprocaine (Group F) produced statistically significant prolonged duration of effective analgesia (Fig. 5) than chloroprocaine group. Mean time for Ambulation (Fig. 6) was comparable in both the groups. (p > 0.05) HR was comparable in both the groups. (p > 0.05) Mean Arterial Blood Pressure was comparable in both the groups at different time points (p > 0.05) 15 participants in group C, while 10 participants in group F developed hypotension. 2 participant developed bradycardia in group F. 2 participants in group C experienced nausea and vomiting, which was statistically not significant. 1 participant developed sheivering in group F and 3 participants developed pruritus and it does not required any treatment (Fig. 7).

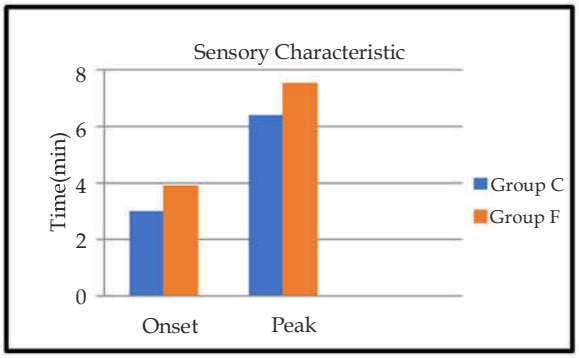

Fig. 1: Onset and Peak of Sensory Block Characteristic

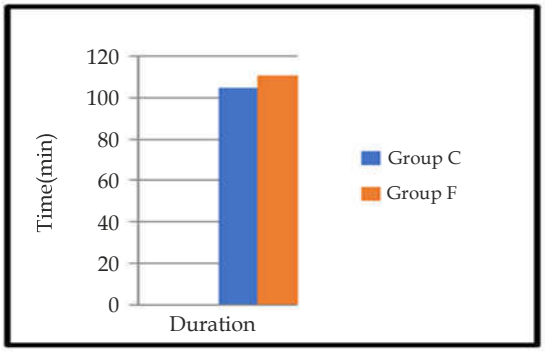

Fig. 2: Duration of sensory block

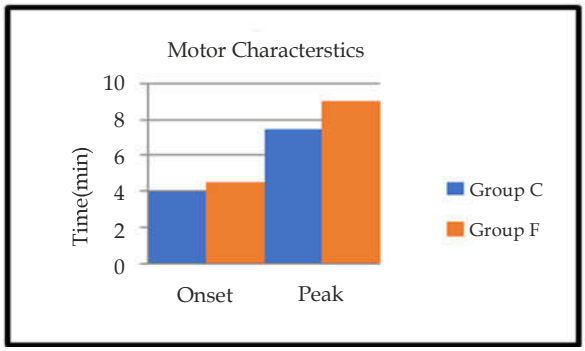

Fig. 3: Motor Characterstics

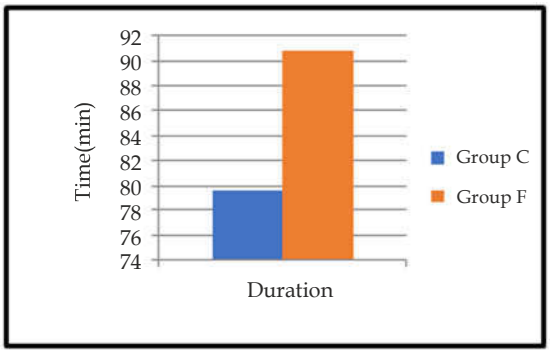

Fig. 4: Duration of motor block

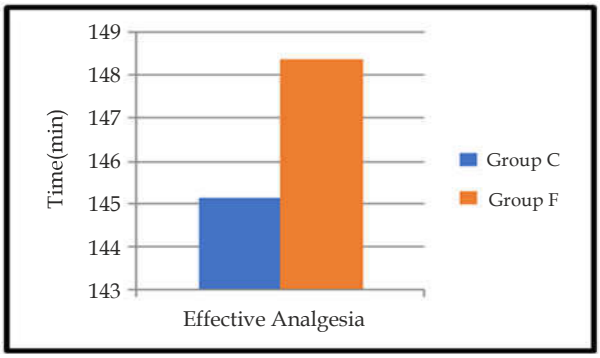

Fig. 5: Duration of Effective Analgesia

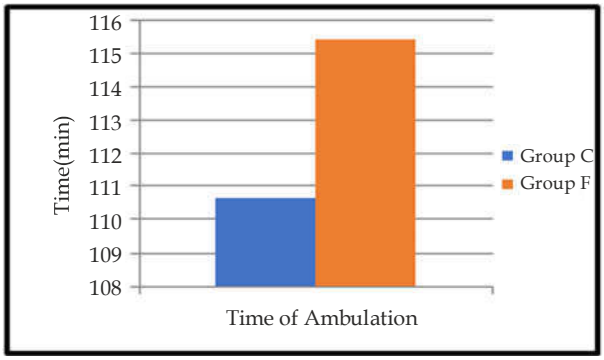

Fig. 6: Mean time for Ambulation

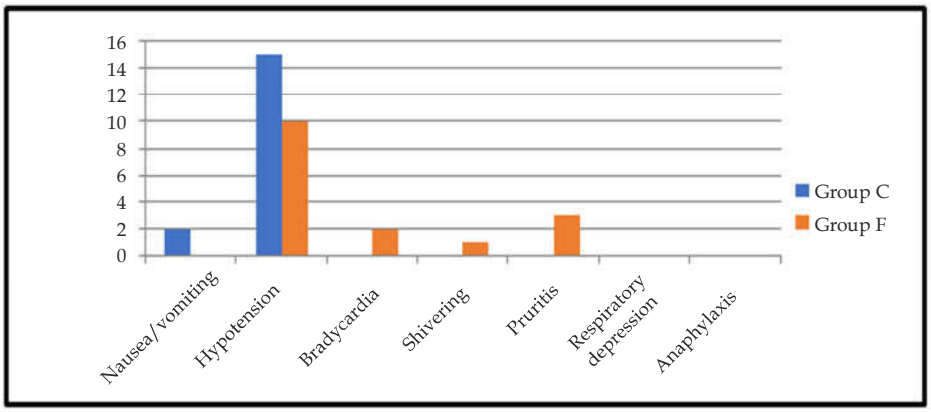

Fig. 7: Side-effects

Discussion

Chloroprocaine is an ideal agent which can be used as an ambulatory surgery.[1] The use of opioids As an adjuvant with local anaesthetics in subarachnoid block has been associated with improved blockade quality and reduced analgesic requirement in postoperative period.[1] In this study, result showed that there was early time of onset and peak of sensory blockade with Chloroprocaine group and there was prolong duration of sensory blockade with fentanyl group. Past studies showed that peak of sensory blockade with saline or fentanyl was contrast to our study and total duration of sensory blockade was comparable to our study.[1] In this study, the mean time of onset, peak and duration of motor blockade were statistically significant in both the groups. Past studies showed that Chloroprocaine with saline or fentanyl , duration of motor blockade was comparable to our study.[1,7] In this study, the duration of effective analgesia was comparable in both the group, prolong analgesia seen with fentanyl group. Past studies showed that Chloroprocaine with saline or fentanyl suggested that there was prolong effective analgesia seen with fentanyl group.[1] In this study, time of ambulation was comparable among both the groups. Past studies showed that when Lidocaine, Bupivacaine and Chloroprocaine compared, there was early ambulation with Chloroprocaine.[5] In this study, side-effects observed were nausea, vomiting, hypotension, bradycardia and shivering, were treated accordingly. Past studies showed that Chloroprocaine with saline or fentanyl suggested that there was only pruritus noted with fentanyl group.[1]

Conclusion

Addition of 20µg Fentanyl as an adjuvant with 1% isobaric Chloroprocaine, in subarachnoid block for lower limb ambulatory surgery, has prolongs sensory block without influencing motor blockade; improves postoperative analgesia with less requirement of rescue analgesic, with minimal side effects. It has no effect on time of ambulation, so it is recommended for day care surgery.

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