



Original Research Article

Spinal anaesthesia for ambulatory urology surgery: A comparison of chloroprocaine with fentanyl and bupivacaine with fentanyl

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ABSTRACT

Background: Spinal anesthesia is an attractive choice for ambulatory surgery of the lower abdomen and lower limbs but it requires a local anesthetic agent of short duration with minimal side effects. We compare the effect of intrathecal chloroprocaine with fentanyl to bupivacaine with fentanyl in ambulatory urology surgery.

Materials and Methods: Hundred patients aged 18 – 60 years undergoing ambulatory urology surgery randomly divided into two groups of 50 each. Group A received 40 mg of 1% chloroprocaine with 20mcg fentanyl and group B received 7.5 mg of 0.5% bupivacaine and 20mcg fentanyl. Sensory and motor block characteristics, time to ambulation, void and time for ready to discharge from hospital were recorded.

Results: There was no difference in terms of demographic data and duration of surgery. Peak sensory block level was T5 in group A and T4 in group B. The mean time to reach the peak block level was similar in both groups ($P=0.228$). Time to two-segment regression and regression to the S2 segment were shorter in group A ($P<0.001$). Regression of motor block was faster in group A, compared to group B ($P<0.001$). The length of stay in PACU was similar in both the groups ($P=0.729$). Time to ambulation, time for first void and time for ready to discharge from hospital were significantly shorter in group A compared to group B ($P < 0.001$).

Conclusions: Chloroprocaine and fentanyl is a better choice for ambulatory urology surgery in comparison to low dose bupivacaine and fentanyl.

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1. Introduction

In the current era of modern anesthesia, the focus is changing towards ambulatory surgery. With the advancement of anesthesia and surgical techniques and the availability of rapid and short-acting anesthetic agents, the number of ambulatory surgeries has increased significantly.¹

The choice of anesthesia for ambulatory surgery is based on the type of surgery, duration of surgery, patient medical history and possible perioperative complications. Spinal anesthesia is a well-known 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 ambulatory surgery and wide availability of rapid and short-acting drugs for general anesthesia like propofol and remifentanyl.^{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

The selection of an ideal local anesthetic agent for spinal anesthesia holds the utmost importance in ambulatory surgery. In previous studies, several local anesthetic agents were used in different doses and concentrations, which were titrated to meet the requirement of short duration of anesthesia and early recovery.

Lidocaine is a short-acting local anesthetic agent and was extensively used for ambulatory surgeries but its use has been abandoned because many reports describe

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“transient neurological symptoms” (TNS) with its use.⁵ Bupivacaine can be administered intrathecally for outpatient surgeries, but several reports suggest that bupivacaine use in ambulatory surgery leads to delay in hospital discharge due to prolonged motor blockade, urinary retention, and delay in ambulation.⁶

Chloroprocaine is an amino-ester local anesthetic agent. Its clinical use was established in 1952. 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.^{7,8} Studies showed that preservative, sodium bisulfite was responsible for the neurotoxicity of chloroprocaine.^{9,10} After these reports, its use was abandoned. New formulations of preservative-free chloroprocaine were introduced. These modifications reestablished its safety and efficacy and it has been successfully used without neural deficit.^{11,12}

Post-operative pain is a major concern with short-acting local anesthetic agents. The synergistic analgesic effect of opioids with the local anesthetic agent is well known, the addition of intrathecal opioids like fentanyl prolongs the duration of sensory blockade without increasing the duration of the motor blockade.^{13,14} The advantage of this effect is the longer duration of analgesia with a decreased need for rescue analgesics.

In this study, we compared the effect of short-acting local anesthetic agent, chloroprocaine to low dose bupivacaine for ambulatory urology surgery, and in an attempt to prolong the duration of analgesia, we added intrathecal fentanyl, as an adjuvant with both the local anesthetic agents.

2. Materials and Methods

This prospective, randomized, double-blind and comparative study was conducted in Mahatma Gandhi Medical College and Hospital, Jaipur, after receiving approval from the institutional ethical committee (reference number MGMCH/IEC/JPR/2018/05). A written and informed consent was obtained from all the patients.

A total of 100 patients of American Society of Anaesthesiology (ASA) physical status grade I and II, aged between 18 – 60 years undergoing ambulatory urology surgery were enrolled for this study.

Exclusion criteria for this study were patient refusal, patient with coagulation disorders, any contraindications to neuraxial anesthesia, known allergy to study drug and patients with cardiac and renal insufficiency.

2.1. Randomization and blinding

A total of hundred patients were randomly divided into two groups of 50 each with the help of a computer-generated table of random numbers, an unblinded anaesthesiologist linked each number with the study drugs, either chloropro-

caine and fentanyl or bupivacaine and fentanyl. Both the patient and the observer were blinded. The blinded observer enrolled all the patients and allotted a number according to their enrolment order. Spinal anesthesia was performed by an unblinded anaesthesiologist. The same blinded observer collected the data.

2.2. Study protocol

All patients received oral alprazolam 0.5 mg night before surgery and fasted for six hours. In the operating room, standard five lead ECG, non-invasive blood pressure (NIBP) and pulse oximetry (SpO₂) were attached and baseline parameters were noted. Intravenous access was secured using a 20G cannula on the dorsum of the hand.

Under all aseptic precautions, subarachnoid block was given after local infiltration of skin with 2% lignocaine using 25G Quincke's spinal needle at the level of L3-4 or L4-5 inter-space via the midline approach in sitting position. Patients in group A received an intrathecal injection of 1% chloroprocaine 40 mg with 20 µg fentanyl (4.4 ml) and patients in group B received an intrathecal injection of 0.5% hyperbaric bupivacaine 7.5 mg with 20 µg fentanyl (1.9 ml). After subarachnoid block patients were placed supine and evaluated for sensory and motor block characteristics. Sensory block was checked using an ice pack in a caudal to cephalad direction in mid-axillary line every 3 minutes for 15 min, then every 5 minutes until the completion of surgery.

Assessment of motor block was done using a modified Bromage scale

2.3. 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

Peak sensory block level, time to reach peak sensory block level, time for two-segment regression and duration of motor block were recorded.

After completion of surgery patients were shifted in post anesthesia care unit (PACU). NIBP, heart rate, and SpO₂ were recorded and patients were assessed for sensory and motor block characteristics. Sensory and motor block was assessed every 15 minutes for 60 min and then every 30 minutes until complete regression.

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 ambulatory surgery unit. Time to void and unassisted ambulation were noted.

In the ambulatory surgery unit, time for unassisted ambulation and time for the first void were recorded. The primary outcome of our study was time to ready for discharge from hospital. Patients were discharged from the hospital according to the PADS (Post Anaesthesia Discharge Score) system. It includes six parameters; vital signs, ambulation, Post Operative Nausea Vomiting (PONV), pain, surgical bleeding, and voiding. Patients who score PADS ≥ 9 considered as ready for discharge from hospital and time was recorded.

Patients were telephonically contacted and asked about post dural puncture headache (PDPH) and numbness or weakness in lower limbs.

2.4. Sample size calculation

Our primary outcome was time for ready to discharge from the hospital. The sample size was calculated using G*Power version 3.1.9.4 package program based on a study by Lacasse MA et al. Assuming an α error of 0.01 and power of 90%, 47 patients were needed in each group. To overcome the patient's dropout we included 50 patients in each group.

2.5. Statistical analysis

Statistical analysis was performed with the SPSS, version 21 for Windows statistical software package. The Categorical variables were presented as numbers and were compared among groups using the Chi-square test. The quantitative variables were presented as mean and standard deviation and were compared by student t-test. Results are considered to be significant if the P-value was less than 0.05.

3. Results

All the surgical procedures were done under spinal anesthesia. There was no difference between the two groups in terms of demographics and duration of surgery [Table 1].

The highest sensory block level achieved was T4 and T5 in group B and group A respectively. The maximum number of patients achieved T8 level in both the groups (26% and 28% in group A and group B respectively), and no statistically significant difference observed between groups [Figure 1].

Statistical analysis reveals that the time for ready to discharge from hospital was significantly earlier in group A compared to group B, as the P-value was highly significant ($P < 0.001$).

The mean time to reach peak block level was similar in both groups. Time for two-segment regression and time

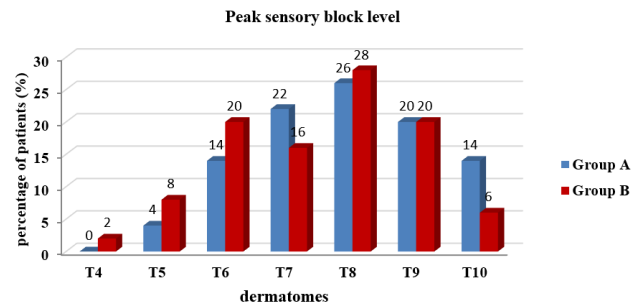


Fig. 1: Peak sensory block level

Group A: chloroprocaine with fentanyl (blue), group B: bupivacaine with fentanyl (red).

for regression to the S2 segment were shorter in group A compared to group B. Regression of motor block was also faster in group A, compared to group B. The time for first rescue analgesia was significantly earlier in group A than group B. Duration of stay in PACU was similar in both groups. Time to ambulation and void were shorter in group A, compared to group B [Table 2].

3.1. Side effects

The incidence of hypotension, bradycardia, PONV, pruritus, and PDPH were similar in both groups. [Figure 2]

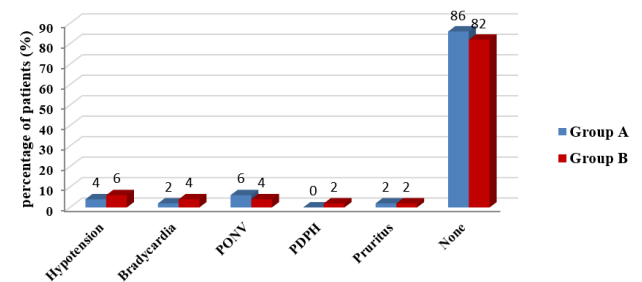


Fig. 2: Side effects

Group A: chloroprocaine with fentanyl (blue), group B: bupivacaine with fentanyl (red)

3.2. Mean arterial pressure and Heart rate

The difference in mean arterial pressure (MAP) at different time intervals was comparable between groups. There is a slight decrease in systolic blood pressure at 5 to 15 min intervals, but it was not significant between group A and group B ($P > 0.05$). [Figure 3]

Statistical analysis reveals no significant difference in mean heart rate between group A and group B at different time intervals ($P > 0.05$). [Figure 4].

Table 1: Demographic data and duration of surgery

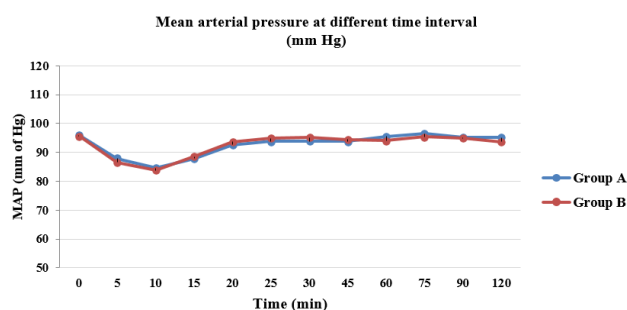
	Group A	Group B	P-value
Age (Years)	38.82±10.52	40.14±11.77	0.555
Height (cm)	168.88 ±4.85	169.50 ±4.49	0.507
Weight (kg)	65.59 ±7.90	66.24 ±5.79	0.638
Gender (Male: Female)	44:6	44:8	0.773
ASA grade			
I	41(82.00%)	39(78%)	0.803
II	9(18.00%)	11(22%)	
Duration of Surgery (minutes)	35.98±9.17	34.44±9.30	0.406

Group A: chloroprocaine with fentanyl, group B: bupivacaine with fentanyl

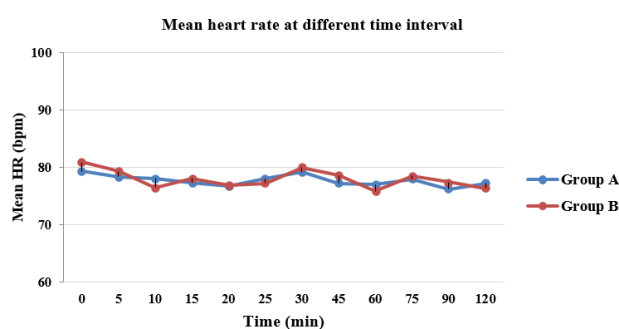
Table 2: Clinical characteristics

	Group A (Mean ± SD)	Group B (Mean ± SD)	P-value
Time for ready to discharge from hospital (min)	202.64±32.59	304.78 ±42.90	< 0.001 (S)
Time to reach peak block level (min)	17.20 ±5.74	18.54 ±5.30	0.228 (NS)
Time for two-segment regression (min)	47.18 ±9.96	74.12 ±11.91	< 0.001 (S)
Time for regression to S2 (min)	146.80 ±14.15	202.40 ±31.57	< 0.001 (S)
Duration of motor block (min)	77.36 ±11.39	127.90 ±15.83	< 0.001 (S)
Duration of stay in the post-anesthesia care unit (min)	46.92±9.10	47.62 ±11.03	0.729 (NS)
Time for first rescue analgesia (min)	133.14±12.04	242.20±31.38	< 0.001 (S)
Time for unassisted ambulation (min)	153.18±24.48	246.44 ±33.35	< 0.001 (S)
Time for first void (min)	177.46±33.41	277.56 ±43.31	< 0.001 (S)

Group A: chloroprocaine with fentanyl, group B: bupivacaine with fentanyl

**Fig. 3:** Mean arterial pressure (MAP) at different time intervals

Group A: chloroprocaine with fentanyl (blue), group B: bupivacaine with fentanyl (red)

**Fig. 4:** Mean heart rate (HR) at different time intervals

Group A: Chloroprocaine with fentanyl (blue), group B: bupivacaine with fentanyl (red)

4. Discussion

Outpatient surgery is gaining popularity in the modern world due to its various advantages. In developing countries like India, where the health care cost and hospital bed occupancy are major concerns, same-day hospital discharge reduces the burden on the healthcare system, and patient satisfaction is also higher due to early recovery and short hospital stays.

To provide good intraoperative anesthesia and analgesia along with minimal side effects and early recovery, optimal

dosage and concentration of local anesthetic agent is needed. We compared a small dose of local anesthesia agent, bupivacaine, with a short-acting local anesthetic agent, chloroprocaine and using fentanyl as an adjuvant to both the groups for ambulatory urology surgeries.

In previously available studies, Liu SS et al have shown that long-acting local anesthetic agents, such as bupivacaine, can be administered for outpatient surgery, but the optimum dose is needed.⁶ Many authors concluded in their studies, that bupivacaine 7.5 mg is the optimal dose for ambulatory

surgeries, a higher dose is associated with the delay in ambulation and void, leads to a longer stay in hospital and low dose does not provide adequate anesthesia and increases the number of intraoperative analgesics.^{15,16}

The increasing trend of using chloroprocaine in ambulatory surgery is due to its short duration of action. In an attempt to find the correct dose of chloroprocaine for ambulatory surgery, Kopacz DJ et al compared different doses of chloroprocaine 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.¹⁷

The addition of opioids like fentanyl to spinal local anesthetic agent prolongs sensory blockade while minimally affecting the motor blockade. Vath JS et al demonstrated that the addition of 20µg fentanyl to 40 mg chloroprocaine prolongs the regression to L1, (78 min with fentanyl and 53 min without fentanyl), whereas minimally affect the duration of motor block (104 min with fentanyl and 95 min without fentanyl).¹⁸ 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.

In our study, spinal bupivacaine-fentanyl combination is used as a control drug of proven efficacy to compare with chloroprocaine and fentanyl for ambulatory urology surgery. We observed that the quality of the surgical condition was similar in both the groups, as none of the patients complaining of pain intra-operatively.

Similar to our study, Lacasse MA et al found that the mean peak block level was T7, and the mean time to reach peak block level was 15 min and 18 min in chloroprocaine and bupivacaine group respectively ($P = 0.15$).¹⁹ Campnovo C et al, compared 1% chloroprocaine 50 mg, to 0.5% bupivacaine 10 mg and found that the time to reach maximum sensory block level was faster in chloroprocaine group compared to bupivacaine group (5 min vs 6 min and 8.5 vs 14 min respectively),²⁰ however in our study time to reach peak block level was similar in both the groups, it may be due to lower dose used in our study.

In our study the regression of sensory and motor block was faster in group A, compared to group B. Our observations coincide with the study of Campnovo C et al, they found that the regression of sensory and motor block was rapid with chloroprocaine, as the complete regression of sensory block was significantly shorter in chloroprocaine group than bupivacaine group (105 min vs 225 min respectively). The duration of motor block was 100 min vs 210 min in chloroprocaine and bupivacaine group respectively ($P < 0.001$).²⁰

Other researchers also demonstrated similar findings, Teunkens A et al, conducted a study and compare spinal 2-

chloroprocaine, bupivacaine, and lidocaine, they evaluated that the mean time to complete regression of sensory block was minimum in chloroprocaine group (2.6 hours), then lidocaine group (3.1 hours) or bupivacaine group (6.1 hours), and motor block recovery was also faster in chloroprocaine group, compared to other two groups.²¹

We observed no difference in length of stay in PACU between groups. Lacasse MA et al also observed that the length of stay in PACU was comparable between groups ($P = 0.66$).¹⁹ However, Palamara C et al found that the duration of stay in PACU was significantly shorter in the chloroprocaine group than the bupivacaine group (47 ± 24 min vs 61 ± 34 min, $P = 0.04$).²²

In our study, the requirement of rescue analgesia was early in the chloroprocaine group compared to bupivacaine. Similar observations were found by Campnovo C and colleagues, they also observed that the earlier requirement of rescue analgesics in chloroprocaine group than the bupivacaine group (120 min vs 290 min in chloroprocaine and bupivacaine group, respectively).²⁰ In comparison to our study, the duration of motor block was longer, but the duration of sensory block and the duration analgesia was shorter in their study (in chloroprocaine group). This prolonged sensory block and analgesic effect in our study might be explained by the additive effect of fentanyl while faster recovery from motor block may be attributed to lower doses of local anesthetics used in our study.

As a result of above observations, it is beneficial to use lower concentration and lower doses of local anesthetic agent in ambulatory surgery to produce adequate surgical anesthesia and analgesia, further addition of opioids like fentanyl prolongs the duration of sensory block and postoperative analgesia without significant increase in the duration of motor blockade.

We found that the time for unassisted ambulation was significantly earlier in group A than group B. Many authors found similar results as the earlier ambulation in chloroprocaine group.^{19,20}

Urinary retention is a major concern in ambulatory surgery under spinal anesthesia. Further urological procedures increase the risk of urinary retention. We observed that the time for the first void was significantly shorter in group A ($P < 0.001$). In a recent retrospective study, conducted by Palamara C et al compared chloroprocaine and bupivacaine in ambulatory urology surgery and observed similar results as the earlier return of voiding function with chloroprocaine group as compared to bupivacaine group in urology surgery.²² Our observations also coincide with Lacasse MA et al, as they found an earlier return of voiding function in the chloroprocaine group.^{19,21}

Time for ready to discharge from hospital was our primary outcome, and we observed significantly earlier discharge in group A compared to group B. there was a significant difference of 102.14 min between groups. Early

ambulation, void, and minimum side effects, all contribute to short hospital stay after ambulatory urology surgery.

Our observations coincide with many studies comparing chloroprocaine to other local anesthetic agents, as all the authors found earlier unassisted ambulation and void, leads to early home readiness with chloroprocaine spinal anaesthesia.^{19–21}

There was no significant difference observed among groups in regards to mean arterial pressure and heart rate. Three patients in the bupivacaine group and two patients in chloroprocaine groups had hypotension, which was treated with boluses of IV fluid and injection ephedrine.

Side effects like hypotension, bradycardia, PONV, PDPH, and pruritus were comparable in both the groups. The use of fentanyl as an adjuvant to local anesthetic agents may be associated with pruritus. In our study, only one patient in each group complained of pruritus, but it was mild and resolved spontaneously without medication. One patient in the bupivacaine group complained of PDPH and treated with analgesic and hydration. We used preservative-free chloroprocaine, and we found that none of our patients complained of TNS.

5. Conclusion

In this study, the use of 1% chloroprocaine 40 mg and fentanyl 20 μ g proves the superiority of this combination over 0.5% hyperbaric bupivacaine 7.5 mg and fentanyl 20 μ g in ambulatory urology surgery. Chloroprocaine fulfills all the criteria for an ideal agent for ambulatory surgeries, and we can recommend its use as a routine in anesthesia practice.

Future conjectures with titrated doses of chloroprocaine will confirm that the use of intrathecal chloroprocaine in ambulatory surgery may bypass the PACU and can lead to a decrease in total perioperative cost.

6. Conflicts of Interest

The authors declare no conflicts of interest.

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