

A PROSPECTIVE STUDY OF INTRATHECAL CHLOROPROCAINE FOR PERIANAL- DAYCARE SURGERIES

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Received : 20/05/2022
Received in revised form : 31/07/2022
Accepted : 08/08/2022

Keywords:
Spinal Anesthetics,
Chloroprocaine, Perianal Surgeries,
Motor Block

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DOI: 10.47009/jamp.2022.4.3.30

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm,
2022; 4 (3); 130-135



Abstract

Background: With increasing focus on outpatient care, there has been an increased demand for short-acting spinal anesthetics, facilitating early recovery and mobilization of the patient. **Aim:** To study the effect of intrathecal chloroprocaine in day care perianal surgeries and to study the onset, duration of motor and sensory block, Micturition time, Ambulation time and side effects of Chloroprocaine. **Materials and Methods:** A Prospective interventional study was conducted among 100 patients who were posted for perianal surgeries in department of Anaesthesiology. **Result:** The mean age of the patients was 44.05 ± 9.64 yrs with male: female gender ratio of 1.38:1: There was statistical significant decrease (p<0.05) in vital parameters immediately (5 min) after injection and after 5 min there was no statistical significant difference (p>0.05) in vital parameters when compared to baseline value. There was no statistical significant difference in vital parameters postoperatively till full recovery of patient. At the end of 4 hr after surgery the mean Bromage score was 0 in all the patients. There was statistical significant decrease in Bromage score postoperatively till full recovery of patient. In the present study 2% patients had post dural puncture headache and 4% patients had Nausea and vomiting. **Conclusion:** Chloroprocaine 40mg provided rapid-onset spinal anaesthesia that was well tolerated by the patients and the duration of motor block lasted about 60-90min in almost all the patients, which is suitable for perianal surgeries.

INTRODUCTION

Most Anorectal surgeries were performed in a hospital environment, and involved a stay in the hospital that could last for several nights as the patient recovered. Over time, it became evident that most Anorectal procedures did not require such an elaborate recovery, and could instead be performed in an ambulatory fashion. Currently, it is estimated that as many as 90% of anorectal procedures may be candidates for ambulatory surgery.^[1]

Anorectal pathology amenable to ambulatory surgery includes anal fissures, warts, fistulas, hemorrhoids, pilonidal cysts, abscesses, and small neoplasms, among others.^[2]

Ambulatory anorectal surgery is an appealing approach for patients and physicians due to its increased efficiency and decreased surgical costs. This coincides with a high degree of patient

satisfaction in spite of challenges such as decreased contact time with the medical staff. Ambulatory anorectal surgery can be successful for all parties involved with proper patient selection, the use of evidence-based perioperative care, effective postoperative pain control, patient education, and follow-up.^[1]

International association of ambulatory surgery defines day care surgery as “operation or procedure, an office or outpatient operation procedure, where the patient is discharged on the same working day”. The boundaries of day care surgery are redefined exponentially with time. The rapidly changing financial situation in the world has led to the increase in the incidence of ambulatory surgery. The advances in surgery, anaesthesia and pain management have allowed huge expansion of this modality of care with a consequent reduction in the need for hospitalization. Even though data are not

available for India, there is huge potential in view of a massive population of 1.2 billion and recent huge expansion in the private sector has created an opportunity for expansion in day care surgery India.^[2]

The advantages of day care surgeries are minimal psychological disturbances for the patient, especially children, economical with reduced requirement of nursing and medical supervision and hospital services allowing more number of patients to be treated and finally consequent reduction in the risk of hospital acquired infection and venous thromboembolism. Safety rapid recovery and minimal post-operative problems are essential in selecting surgical procedures and anaesthesia techniques for day care surgeries. The choice of anaesthesia techniques can affect post operative morbidity at home.^[3]

Spinal anesthesia is a safe and reliable technique for surgery of the lower abdomen and lower limbs. Nevertheless, some of its characteristics may limit its use for ambulatory surgery, including delayed ambulation, risk of urinary retention, and pain after block regression. The choice of the correct local anesthetic for spinal anesthesia is therefore crucial in the ambulatory setting: the ideal anesthetic should allow rapid onset and offset of its own effect for fast patient discharge with minimal side effects. In the past, the lack of the ideal spinal local anesthetic and the availability of fast-acting drugs such as remifentanyl and propofol have made general anesthesia the preferred choice for short outpatient procedures.^[3]

To investigate the most suitable anesthetic technique for day surgery, Liu et al published a meta-analysis in 2005 comparing regional and general anesthesia, including more than 1,300 patients. Regional anaesthesia reduced pain scores and pain medication request in the post-anaesthesia care unit. However, neither central neuraxial block nor peripheral nerve blocks decreased the overall ambulatory surgery unit time and both required longer induction time versus general anesthesia.^[4]

Although low doses of long-acting local anesthetics such as bupivacaine, ropivacaine, and levobupivacaine are usually administered intrathecally, they are associated with significant risk of delays in hospital discharge and less reliability of block efficacy, onset, and spread. Preservative free Chloroprocaine (CP) is a short-acting aminoester local anaesthetic which was reintroduced had low incidences of side effects. Few studies had reported that the fast onset and the short duration of action make spinal anesthesia with chloroprocaine advantageous in day care surgery. So, the present study was conducted to observe the efficacy of intrathecal chloroprocaine for perianal day care surgeries.

MATERIALS AND METHODS

The study was designed as Prospective interventional study was carried out over a period of 12 months from December 2018 to November 2019. After Institutional ethics committee approval & Department approval the present study was conducted at Department of Anaesthesiology, Government General Hospital, Nizamabad, Telangana. 100 Patients of both genders aged between 18 and 60 yrs of physical status ASA grade 1 and 2 who were electively posted for perianal surgeries were included in the study.

As per the study conducted by Lacasse MA et al,^[5] the SD for motor block using 40 mg chloroprocaine was 25 Taking confidence interval 95%, and absolute error 5%, using standard formula

Sample size $n = 4SD/L^2$

$$n = 4 \times (25) \times (25) / 5 \times 5$$

$$n = 100 \text{ Subjects.}$$

So, the final sample size of the study was 100 patients

Inclusion Criteria

Patients aged between 18yrs and 60 yrs OF Physical status ASA grade 1 and ASA grade 2, Scheduled for peri anal procedures such as Peri anal abscess, Haemorrhoidectomy, Fistula & Fisture in ano.

Exclusion Criteria

Patient who are allergic to local anaesthetic and study drugs, Infection at the site, Local site anatomical abnormality, Patients with coagulation abnormalities, peripheral neuropathy/traumatic injury to nerve, Head injury, psychiatric disorder, severe cardiac, pulmonary, renal and endocrine disorder.

The study protocol, informed consent form and case report form were submitted and clearance obtained from ethical committee of Government General Hospital, Nizamabad, Telangana.

Written informed consent was taken from each participant of the study. Illiterate individuals gave their fingerprint (left thumb impression) instead of signature in the presence of an appropriate witness. Scientific committee of our institution has reviewed the protocol and approved the study. After getting clearance from preoperative assessment clinic (PAC), all patients included in the study were premeditated with tablet ranitidine 150mg and tablet alprazolam 0.5 mg orally at night before surgery and they were kept nil orally for 6 hrs before surgery. After arriving to operating room, intravenous line of 18/20 gauge cannula was secured and an infusion of Ringer's lactate was started as per calculation of perioperative fluid replacement therapy. The patients were monitored for heart rate, noninvasive measurements of Systolic blood pressure (SBP), Diastolic blood pressure (DBP), Mean arterial blood pressure (MAP) at an interval of 5 min, continuous electrocardiographic (ECG) monitoring, and

haemoglobin oxygen saturation (SPO2) throughout the perioperative period. Study medication was prepared in 5ml syringe with 40 mg Chloroprocaine. Patient were placed in sitting position Intrathecal block under aseptic conditions performed at L3-L4 or L4-L5 space with 25G QUINCKE spinal needle. Immediately after completion of the block, patients were made to lie in the supine position.

variables were observed as Sensory blockade -onset & duration, Motor blockade- onset & duration, Maximum of level of sensory block, Two segment regression time, Micturition time, Ambulation time and Side effects All the parameters were recorded as per the proforma and statistically analysed.

Data collected was entered into MS-Excel 2013 spreadsheet. The collected data was analyzed using IBM statistical package for social sciences (IBM SPSS) version 23 software (trial version). Continuous variables was reported as mean \pm standard deviation (SD) while categorical variables was expressed as absolute values and percentages. Linear regression analysis was applied to find significance between vital parameters after induction of anaesthesia and $P < 0.05$ at 95% CI was considered as statistically significant.

RESULTS

Table 1: Demographic details in present study

Age Group	Number of Patients	%
≤ 30 yrs	11	11%
31 – 40 yrs	21	21%
41 – 50 yrs	49	49%
51 – 60 yrs	19	19%
Total	100	100 %
MEAN AGE = 44.05 ± 9.64 yrs		
Gender		
Male	58	58%
Female	42	42%
Height		
< 160 cm	26	26%
160 – 170 cm	44	44%
> 170 cm	30	30%
Weight in kgs		
< 60 kgs	23	23%
60 – 70 kgs	71	71%
> 70 kgs	6	6%
BMI		
< 18.5	1	1%
18.5 – 22.9	54	54%
23 – 24.9	36	36%
> 25	9	9%
ASA grading		
1	44	44%
2	56	56%
Duration Of Surgery		
≤ 30 min	12	12%
31 – 45 min	44	44%
> 45 min	44	44%

Among 100 patients, majority (49%) belong to 41 – 50 yrs. The mean of the study was 44.05 ± 9.64 yrs. 58% were male and 42% were female. The male: female gender ratio was 1.38:1. The mean height of the study population was 165.21 ± 8.13 cm, with majority (44%) were in the range of 160 – 170 cm.

The mean weight of the study population was 64.18 ± 5.77 kgs, with majority (71%) were between 60–70 kgs. The mean BMI of the study population was 22.72 ± 1.87 kg/Sq.mt, with majority (54%) were $18.5 – 22.9$ kg/Sq.mt.

Among the study population 56% belong to ASA grade 2 and 44% belong to ASA grade 1. The mean duration of surgery was 43.02 ± 9.63 mins. In 44% of cases the duration of surgery was between 31 – 45 min and >45 min.

Table 2: Onset of sensory and motor block in present study

Onset of Sensory Block	Number of Patients	%
≤ 60 Sec	19	19%
61 – 90 Sec	58	58%
> 90 Sec	23	23%
Total	100	100 %
Onset of Sensory Block = 81.10 ± 19.57 Secs		
Onset of Motor Block		
≥ 120 Sec	19	19%
120 – 180 Sec	64	64%
> 180 Sec	17	17%
Total	100	100 %
Onset of Motor Block = 160.30 ± 32.23 Secs		

The mean duration for onset of sensory block was 81.10 ± 19.57 secs. In 58% of cases the onset of sensory block was 61 – 90 sec. The mean duration for onset of motor block was 160.30 ± 32.23 secs. In 64% of cases the onset of motor block was 120 – 180 sec.

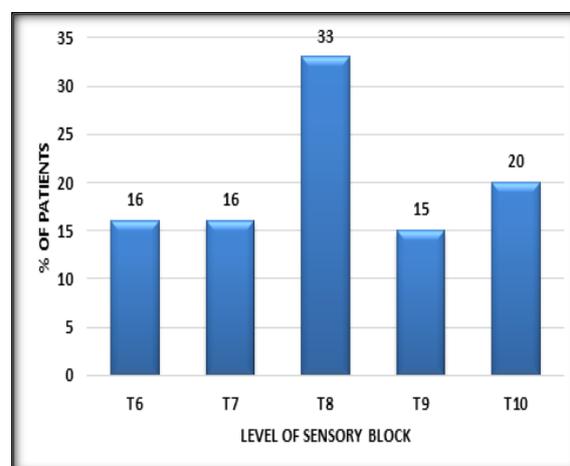


Figure 1: Bar graph showing level of sensory block

In 33% of cases, the maximum level of sensory block was upto T8 level. In 20%, it was upto T10 level and in 16% cases it was upto T6 and T7 level each.

Table 3: Distribution of patients based on tsrt(two segment regression time)

TSRT	Number of patients	%
≤ 45 min	4	4%
45 – 60 min	60	60%
> 60 min	36	36%
Total	100	100 %
Mean duration of TSRT = 58.28 ± 9.38 mins		

The mean duration for two segmental regression time was 58.28 ± 9.38 mins and in majority 60% it was between 45 – 60 min.

Table 4: Distribution of patients based on duration of sensory block and motor block

DSB	Number of patients	%
≤ 90 min	29	29%
90 – 120 min	43	43%
> 120 min	28	28%
Total	100	100 %
Mean duration of SB = 107.72 ± 22.96 mins		
DMB	Number of patients	%
≤ 60 min	8	8%
60 – 90 min	45	45%
> 90 min	47	47%
Total	100	100 %
Mean duration of MB = 87.29 ± 20.11 mins		

The mean duration of sensory block was 107.72 ± 22.96 mins and in majority 43 % it was between 90

– 120 min. The mean duration of motor block was 87.29 ± 20.11 mins and in majority 47% it was > 90 min.

Table 5: Distribution of patients based on micturition time

Micturition time	Number of patients	%
≤ 180 min	58	58%
> 180 min	42	42%
Total	100	100 %
Mean micturition time = 177.42 ± 37.91 mins		
Ambulation time	Number of patients	%
≤ 150 min	51	51%
> 150 min	49	49%
Total	100	100 %
Mean duration of ambulation time = 154.19 ± 32.45 mins		

The mean micturition time was 177.42 ± 37.91 mins and in majority 58% it was < 180 min. The mean ambulation time was 154.19 ± 32.45 mins and in majority 51% it was < 150 min.

Table 6: Postop monitoring of vitals and bromage score

	Post-operative monitoring till full recovery				P-value
	First reading	Post op 2hr	Post op 3hr	Post op 4hr	
PR	77.05 ± 4.35	76.56 ± 4.26	76.87 ± 4.43	76.89 ± 4.35	> 0.05
RR	17.15 ± 1.34	17.16 ± 1.49	16.94 ± 1.39	17.08 ± 1.44	> 0.05
Spo2	99.10 ± 0.78	98.96 ± 0.80	98.93 ± 0.81	98.90 ± 0.80	> 0.05
SBP	109.96 ± 11.6	111.27 ± 11.3	110.31 ± 11.1	110.39 ± 11.2	> 0.05
DBP	79.27 ± 6.27	78.63 ± 6.24	78.80 ± 7.04	78.59 ± 6.68	> 0.05
Bromage score (0-1-2-3)	1.82 ± 0.76	0.72 ± 0.66	0.16 ± 0.37	0	< 0.05

There was no statistically significant difference in vital parameters postoperatively till full recovery of patient. The mean Bromage score in first reading after surgery was 1.82 ± 0.76 and at Post op 2hr was 0.72 ± 0.66 . At the end of 4 hr after surgery the mean Bromage score was 0 in all the patients. There was statistically significant decrease in Bromage score postoperatively till full recovery of patient.

Table 7: Postop complications among patients

Post op complications	Number of patients	%
Nausea and vomiting	2	4%
Headache	1	2%
Total	3	6%

In the postoperative period before discharge 4% patients had nausea and vomiting and 2% patients had complaints of headache.

DISCUSSION

There is a high prevalence of Perianal diseases like haemorrhoids, fistula and anal fissures and their current treatment trends are towards ambulatory surgery. The characteristics of an ideal spinal anesthetic agent in day care setting would include a rapid onset of a reliable block providing adequate surgical anesthesia of appropriate duration, rapid recovery of sensory and motor block and minimal side-effects.

Among 100 patients in our study, majority (49%) belong to 41 – 50 yrs of age. The mean age of our study was 44.05 ± 9.64 yrs. In a study conducted by

Bhaskara et al,^[6] the mean age was 31.77 yrs and in studies conducted by Kouri et al,^[7] and Yoos et al,^[8] the mean age of the study was 35 and 37 years respectively which was low when compared to the present study. Lacasee et al,^[5] had reported the mean age of 53 years. The difference in mean age in various studies was due to different demographic settings and different surgical conditions for surgery.

Among 100 patients in our study, 58% were male and 42% were female. The male: female gender ratio was 1.38:1. Similar study on perianal surgeries by Patel PK et al,^[9] had reported 53% male and 47% female which was similar to the present study. However Lacasee et al,^[5] had reported 45% male and 55% female in their study and this was due to inclusion of gynaecological procedures along with perianal surgeries in their study.

The mean height of the study population in our study was 165.21 ± 8.13 cm, with majority (44%) were between 160 – 170 cm. Lacasee et al,^[5] and Patel PK et al,^[9] had reported that the mean height of 165 cm and 165.3cm respectively which was similar to the present study.

The mean weight of our study population was 64.18 ± 5.77 kgs, with majority (71%) were between 60-70 kgs. Similar study conducted by Bhaskara et al,^[6] had reported the mean weight of patients 65.87 kgs which was similar to the present study. Lacasee et al,^[5] had reported that the mean weight of 77 kgs which was high when compared to the present study maybe due to different demographic settings.

Among our study population 56% belong to ASA grade 2 and 44% belong to ASA grade 1. Khare A et al,^[10] study had reported that 82.2% belong to ASA grade 1 and 17.8% belong to grade 2 and the difference when compared to the present study was due to inclusion of not only perianal but also orthopaedic and gynaecological procedures.

In a study conducted by Bojaraaj et al,^[11] on perianal surgeries, 66% of the study population belong to ASA grade 2 and 34% belong to ASA grade 1 and the difference when compared to the present study maybe due to low sample in Bojaraaj study.

The mean duration of surgery in our study was 43.02 ± 9.63 mins. In majority (44%) of cases the duration of surgery was between 31 – 45 min and >45min. In a study conducted by Bhaskara et al,^[6] the mean duration of surgery was 27.83 min and Lacasee et al,^[5] had reported the mean duration of surgery of 20 min which was low when compared to the present study may be due inclusion of different lower abdominal surgical procedures. In a study conducted by Patel PK et al,^[9] the mean duration of surgery was 46 min which was similar to the present study due to the use of similar dose of chloroprocaine.

The mean duration for onset of sensory block was 81.10 ± 19.57 secs and in majority (58%) the onset of sensory block was 61 – 90 sec. The mean duration for onset of motor block was 160.30 ± 32.23 secs and in 64% of cases it was 120 – 180 sec. In a study conducted by Bhaskara et al,^[6] the mean duration of onset of sensory block was 4.7 min and motor block was 5.4 min which was high when compared to the present study due to different dosage. Khare A et al,^[10] conducted a study using 40 mg chloroprocaine and reported the mean onset of sensory block was 1.8 min and motor block was 3.7 min which was similar to the present study. In a study conducted by Bojaraaj et al,^[11] on perianal surgeries the mean onset of sensory block was 150 sec and motor block was 5.8 min and the difference may be due to different study settings.

In our study in 33% of cases, the maximum level of sensory block was upto T8 level. In 20%, it was upto T10 level and in 16% cases it was upto T6 and T7 level each, in 15% it was upto T9. In kouri et al,^[7] and Yoos et al, study the peak height of sensory block was T8 and T7 respectively. Lacasee et al,^[5] study had reported the peak height of sensory block at T7 level. In a study conducted by Bhaskara et al,^[6] the maximum level of sensory block was upto T8 level whereas in the present study it was upto T6 level, This difference may be due to different dosage and different demographic parameters.

In our study, the mean duration for two segmental regression time was 58.28 ± 9.38 mins and in majority (60%) it was between 45 – 60 min. In a study conducted by Bhaskara et al,^[6] the mean duration of two segmental regression time was 76.87 ± 12.47 mins which was high when compared to the present study may be due to addition of fentanyl to chloroprocaine.

In Kouri et al,^[7] study, the two segmental regression time was 46 min which was less than the present study and this was due to the fact that Kouri et al, study was crossover study with lidocaine. In Yoos et al,^[6] and Lacasee et al,^[5] studies two segmental regression time was 45 min & 50 min respectively which was similar to the present study. Forster et al,^[3] had also reported similar mean two segmental regression time of 60 min to the present study due to similar dose of chloroprocaine.

The mean duration of sensory block in our study was 107.72 ± 22.96 mins and in majority (43 %) it was between 90 – 120 min. In Kouri et al,^[7] study the mean duration of sensory block was 103 min and in Yoos et al., study it was 113 min respectively which was similar to the present study due to the use of similar dose of chloroprocaine. Lacasee et al,^[5] had reported the mean duration of sensory block of 146 min which was high when compared to the present study maybe due to different study settings. In a study conducted by Bhaskara et al,^[11] the mean duration of sensory block was 94.72 ± 5.32 mins which was similar to the present study. Forster et al,^[3] had also reported the mean duration of sensory block of 105 min similar to the present study due to the use of similar dose of chloroprocaine.

The mean duration of motor block in our study was 87.29 ± 20.11 mins and in majority (47%) it was > 90 min. In Kouri et al,^[7] study the mean duration of motor block was 79 min and In Yoos et al,^[8] study it was 81 min respectively which was similar to the present study due to use of same dosage of chloroprocaine. Lacasee et al,^[5] had reported the mean duration of motor block of 76 min. In a study conducted by Bhaskara et al,^[6] the mean duration of motor block was 81.46 ± 10.54 mins which was similar to the present study as the study was done among perianal surgeries only. Forster et al,^[3] had reported the mean duration of motor block of 75 min and the low duration is due to the fact that the study was conducted among knee surgeries.

The mean micturition time in our study was 177.42 ± 37.91 mins and in majority (58%) it was < 180 min. In a study conducted by Bhaskara et al,^[6] the mean duration of micturition time was 172 ± 27.06 mins which was similar to the present study. In Kouri et al study the mean micturition time was 104 min and in Yoos et al,^[8] study it was 103 min respectively which was less than the present study, as kouri et al,^[7] study was a crossover study with lidocaine. Forster et al,^[3] had reported the mean micturition time of 204 min which was high when compared to the present study, and this difference might be due to different study settings.

The mean ambulation time in our study was 154.19 ± 32.45 mins and in majority 51% it was < 150 min. In a study conducted by Bhaskara et al,^[6] the mean duration of ambulation time was 163 ± 16.3 mins which was similar to the present study. In Kouri et al,^[7] study, the mean ambulation time was 104 min and in Yoos et al,^[8] study it was 103 min respectively which was less than the present study,

as Kouri et al, was a crossover study with lidocaine and Yoos et al, study was conducted with the addition of fentanyl to chloroprocaine. Lacasee et al,^[5] had reported the mean ambulation time of 225 min which was high when compared to the present study as the study included all types of lower abdominal surgeries. Forster et al had reported high mean ambulation time which was 318 min as the study was conducted among knee arthroscopic surgeries which requires more ambulatory time.

There was statistical significant decrease in vital parameters immediately (5 min) after injection and after 5 min there was no statistical significant difference in vital parameters when compared to baseline value. Bhaskara et al,^[6] study also reported similar range of vital parameters. Lacasee et al,^[5] had also reported haemodynamic stability in most of the cases with use of 40 mg chloroprocaine. There was no statistical significant difference in vital parameters postoperatively till full recovery of patient which was similar to Bhaskara et al,^[6] study. The mean Bromage score in first reading after surgery was 1.82 ± 0.76 and at Post op 2hr was 0.72 ± 0.66 . At the end of 4 hr after surgery the mean Bromage score was 0 in all the patients. There was statistical significant decrease in Bromage score postoperatively till full recovery of patient. In a study conducted by Siddaiah J et al,^[12] the modified Bromage score at the end of the surgery was 2.69 ± 0.76 which was high when compared to the present study. This difference might have existed because of the inclusion of gynaecological and orthopaedic procedures along with perianal surgeries in the study.

In our study, 4% patients had nausea and vomiting and 2% patients had complaints of headache in the postoperative period before discharge. Lacasee et al,^[5] study had reported Transient neurologic symptoms in 2% patients, Postdural puncture headache in 2% patients. Bhaskara et al,^[11] study had reported nil postoperative complications with the use of chloroprocaine in perianal surgeries. In line with our observations, Forster et al,^[3] study had reported 5% patients had post-operative nausea and vomiting. The smaller number of postoperative complications with the use of 40mg chloroprocaine indicates that it was safe and effective drug for anesthesia in perianal surgeries.

Limitations of the Study

The main limitation of the study was that we did not compare with other local anaesthetic drugs. Single dose of chloroprocaine was used for study in all the patients and the use of different doses was not evaluated

CONCLUSION

Day- care anesthesia and surgeries are undergoing a phase of evolution from the traditional methods. The availability of reliable and short-acting local

anesthetics has recently renewed interest in spinal technique for outpatient surgery, offering an alternative to general anesthesia.

Chloroprocaine (preservative free) 40mg provides rapid-onset spinal anaesthesia that was well tolerated (e.g., good haemodynamic stability) among patients. The anesthesia lasted about 60-90min in almost all the patients, which is suitable for perianal surgeries. Recovery, after surgery was also faster with chloroprocaine 40 mg with almost nil complications in the postoperative period.

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