Original Article

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Spinal Anaesthesia for Ambulatory Perianal Surgeries: A Comparison between Short Acting and Long Acting Local Anaesthetics

Anaesthesia Section

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ABSTRACT

Introduction: Chloroprocaine (ester group) is a preservative-free local anaesthetic which is available as isobaric solution. It is being recently popularised in spinal anaesthesia for its shorter duration of action which plays a significant role in the early ambulation and voiding functions, which is the primary essence in ambulatory surgery. Intrathecal Bupivacaine is the most commonly used drug for its block characteristics, taking into account not only the fast initiation of sensory and motor blockade but also faster sensory and motor regression.

Aim: To compare the block characteristics between 1% Chloroprocaine and 0.5% Bupivacaine in patients undergoing perianal surgeries under spinal anaesthesia.

Materials and Methods: This randomised, interventional double blinded study was carried out in Chettinad Hospital and Research Institute, Kelambakkam, Chennai, Tamil Nadu, India, from April 2020 to August 2021. The patients were split into two groups of 34 each. Group 1: Patients received 30 mg of 1% Chloroprocaine intrathecally. Group 2: Patients received 10 mg of 0.5% Bupivacaine intrathecally. In both the groups the onset, duration of both sensory and motor blocks, intraoperative haemodynamic, two segment regression time, time to ambulation and micturition, the time to eligibility for discharge from hospital was evaluated. Independent sample t-test, Chi-square test and Fisher's-Exact test were employed to compare the distribution of qualitative variables between the groups.

Results: Total of 68 participants 31 (45.6%) males and 37 (54.4%) females), 34 in each group 1 and group 2 were analysed. Both groups contained maximum patients in >45 years age group, 12 (35.2%) in each group. Demographic and anthropometric parameters of patients in both the groups were comparable. Mean time of ambulation after spinal anaesthesia in the Group 1 was 137.65±9.15 minutes and in Group 2 was 193.38±8.14 minutes (p-value <0.05). Mean time taken to return of voiding function the Group 1 was 157.06±16.05 minutes and in Group 2 was 213.53±10.26 minutes (p-value <0.05). Mean time taken for Post-Anaesthetic Discharge Scoring System (PADSS) score >9 in Group 1 was significantly less (165.29±13.59 minutes) than Group 2 (219.41±9.52 minutes). Mean time duration for request of first rescue analgesic in Group 1 was significantly faster (104.71±8.69 minutes) than Group 2 (157.79±8.81 minutes). There was no significant difference in haemodynamic changes between the study groups.

Conclusion: Chloroprocaine has proved to be better than Bupivacaine. It has proven to provide adequate surgical anaesthesia, it leads to early regression of motor and sensory blocks, faster un-assisted ambulation and micturition. Time to rescue analgesia was earlier in the Group 1 when compared to Group 2.

Keywords: Bupivacaine, Chloroprocaine, Day care surgeries, Subarachnoid block

INTRODUCTION

The incidence of perianal surgeries varies among institutions, accounting for more than 5% of General surgical procedures. Commonly done perianal surgeries like lateral sphincterotomy, haemorrhoidectomy, fistulectomy are of short duration (less than one hour) [1]. However, in terms of effective recovery and airway management, regional anaesthesia has massive benefits over general anaesthesia. Frequent post-operative negative impacts of general anaesthesia, such as post-operative nausea and vomiting, giddiness might be mitigated by confining the anaesthetised region to the surgical field [2]. Because it delivers a stable anaesthetic action with a quick onset of effect, spinal anaesthesia is an appropriate anaesthetic choice for ambulatory procedures of the infraumbilical region [3].

Duration of spinal anaesthesia with 15-20 mg of hyperbaric Bupivacaine ranges from 90 to 200 min [4]. In order to reduce the duration of surgical anaesthesia for day care surgeries lower dose of 10 mg of 0.5% hyperbaric Bupivacaine is routinely used. However, a few of their properties, such as delayed ambulation and the likelihood of retention of urine, may restrict it being used for ambulatory surgery [5]. The perfect anaesthetic should have a rapid onset as well as offset of its action in order to enable rapid patient discharge with the least number of adverse effects possible. Therefore, in the ambulatory context, determining the correct local anaesthetic for spinal anaesthesia is essential [6].

Chloroprocaine (ester group) preservative free local anaesthetic with a very short half-life, available as isobaric solution has been recently used in spinal anaesthesia for its shorter duration of action. This drug was first made available in 1952 and has since been widely used for spinal anaesthesia. It wasn't until 1956 that sodium bisulfite was put into commercial chloroprocaine formulation as a preservative [7]. For obstetric patients, the medication was administered as an epidural anaesthetic. Several instances of neurologic impairments linked to inadvertent intrathecal injections of high volumes of chloroprocaine during labour analgesia were described in the 1980s [8].

Considering this and the paucity of studies in the Indian set-up, intrathecal 1% preservative free chloroprocaine has been used in this study for short duration perianal surgeries lasting less than one hour. These preservatives resemble para-aminobenzoic acid. Because of this, allergic reactions may be due to preservative stimulation of antibody formation rather than a response to the local anaesthetic [9].

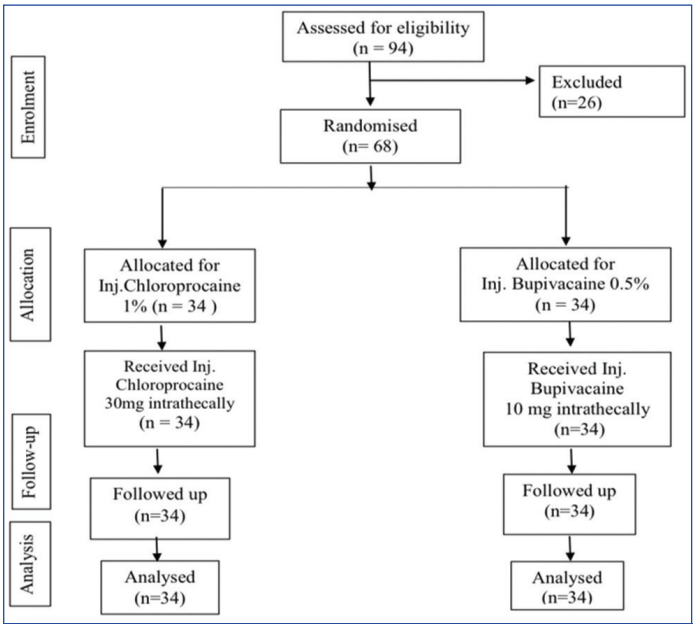
The purpose of this study was to evaluate the efficacy of 1% Chloroprocaine 30 mg over 0.5% hyperbaric Bupivacaine 10 mg intrathecally in perianal surgeries. The primary outcome measures

were the time taken to reach eligibility for discharge from Post Anaesthesia Care Unit (PACU). The secondary outcomes were the block characteristics (onset and regression of sensory and motor block), the haemodynamic changes and the time taken to request of first rescue analgesic.

MATERIALS AND METHODS

It was a, randomised, interventional double blinded study carried out at Chettinad Hospital and Research Institute in Kelambakkam, Chennai, Tamil Nadu, India, from April 2020 to August 2021, under the Department of Anaesthesiology. The Institutional Human Ethical Committee reviewed and approved the study- IHEC No: 009/IHEC /Feb.2020, dated 22-03-2020, CTRI/2021/07/034845. Prior to enrolment all study participants were explained the risks and benefits associated with the study in a language they understand, following which an informed written consent was obtained. Anonymity was maintained with regards to information of study participant.

The enrolled 68 participants were randomly allocated into two groups (34 patients in each group) using a computer-generated randomisation code. Group 1 (n=34): Patients received 30 mg of 1% Chloroprocaine (3 mL) intrathecally. Group 2 (n=34): Patients received 10 mg of 0.5% Bupivacaine (2 mL) intrathecally [Table/Fig-1].



[Table/Fig-1]: Consort flowchart.

Inclusion criteria: American Society of Anaesthesiology (ASA) Grade-I and ASA Grade-II, age 18-65 years, Body Mass Index (BMI) of the patient <35, both elective and emergency surgeries, duration of surgery < 60 minutes.

Exclusion criteria: Coagulopathy and other bleeding disorder, increased intracranial pressure, patient allergic/sensitive to local anaesthetic agents, pregnant and lactating patients, patients with peripheral neuropathy were excluded from the study.

Study Procedure

All patients underwent routine pre-operative assessment in the pre-anaesthetic assessment clinic and were assessed again the day before surgery. Those who fulfilled the eligibility criteria were enrolled, after explaining the study and the risks associated with the interventions in the language they understood.

The patients were advised fasting of six hours for a light meal, two hours for clear liquids prior to surgery and pre-medicated with Tablet Ranitidine 150 mg the night before surgery and 6 am on the day of surgery. On arrival, in the pre-anaesthetic room, one hour prior to wheeling inside the operation theatre, all patients were encouraged to void the bladder, the consent forms were re-checked, an 18 Gauge (G) intravenous (i.v.) access secured and the patients were pre-loaded with 500 mL of ringer lactate solution.

Once the patient was shifted inside the operating room, routine monitors for haemodynamic monitoring (3-lead Electrocardiogram (ECG) monitoring, heart rate, blood pressure, oxygen saturation) were attached and baseline vital signs were recorded. The appropriate study drug according to the randomised code was pre-loaded and kept in a sterile syringe by anaesthesiologist not involved in the study.

All patients were made to sit, with arms hugging a pillow, their neck flexed and both legs stretched out on the operation table. Their lumbar region was painted with antiseptic solution and draped. The intervertebral space to which the drug to be given was identified and 1-2 mL of 2% lignocaine local anaesthetic was infiltrated in the skin and subcutaneous tissue and after that subarachnoid block was performed with 26 G Quincke needle using median approach. After the lumbar puncture, the continuous flow of cerebrospinal fluid was ascertained.

Each of the 68 patients was given the study drug intrathecally over 10-15 seconds. The patients were placed in supine position immediately after the injection, and this time was defined as 'zero'. The patients were placed in supine position for a minimum of at least three minutes before any positional change. All patients were given a hot air forced convective warmer blanket with a temperature of 40ºC. Thereafter, investigator assessed all of the following parameters. An anaesthesiologist who was not involved in the trial prepared pre-filled marked syringes with the study drug. The composition of the injections and the group allocation were unknown to the anaesthesiologist who performed the intervention and recorded the observations.

Level of sensory blockade was assessed by loss of cold sensation, using cotton swab dipped in cold saline.

The grading used for sensory blockade-

- Grade-0: Normal Sensation to cold cotton swab.
- Grade-1: Dull sensation to cold cotton swab.
- Grade-2: Sensation felt.

Time taken for onset of sensory block (level L1), time taken for sensory block to level T10 and maximum level of sensory blockade and time taken for it are duly noted. Level of motor blockade was assessed using Modified Bromage score. Time taken to onset of complete motor block (score 1) was duly noted.

All haemodynamic parameters such as heart rate, blood pressure {Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP)}, SpO_2, were monitored every three minutes for first 15 minutes and then every five minutes for first one hour and then every 15 minutes for 90 minutes. In the event of failed subarachnoid block or inadequate anaesthesia duration during procedure, the patient will be given general anaesthesia and excluded from the study group. Any hypotension due to spinal anaesthesia was managed with intravenous fluids or injection Ephedrine as needed.

Patients were put in lithotomy position and surgery started and duration of surgery was noted. Postoperatively, patients were shifted to PACU for further monitoring. Time taken to request of first rescue analgesic was noted. Patients were asked to rate their pain using a 100 mm Visual Analogue Scale (VAS) till they reported a VAS >3 and the patient was given rescue analgesic (Inj. Paracetamol 1 g intravenously). Time taken to un-assisted ambulation was noted. Time to spontaneous voiding of urine was noted. Patients were observed in the PACU till micturition.

Patients were started on liquids and soft solid diet from 180 minutes from starting of anaesthesia, provided there was no contraindication to start oral diet on a surgical aspect. Common side effects like

nausea, bradycardia, vomiting, hypotension, shivering, urticaria, if any, were noted. Postoperatively, eligibility to discharge from hospital was calculated based on Post Anaesthesia Discharge Scoring System (PADSS) [10]. A score >9 is fit for discharge. PADSS has been modified to ensure a higher level of safety, thus the "vital signs" criteria must never score lower than two, and none of the other five criteria must ever be equal to 0, even if the total score reaches nine.

Degree of sensory regression, motor regression was recorded every five minutes till one hour and every 15 minutes till four hours. Time for two-segment sensory regression, complete sensory regression to level S2 and complete motor regression (score 6) were noted.

STATISTICAL ANALYSIS

Independent sample t-test was used in order to compare two means. Chi-square test and Fisher's-Exact test was employed to compare the distribution of qualitative variables between the groups. In case if one characteristic is measured multiple times along the timeline, two way Repeated Measures Analysis Of Variance (RMANOVA) was used as inferential statistic. All tests were two tailed and results were considered statistically significant if the p-value is <0.05. Continuous variables were expressed as mean and standard deviation. Description of categorical variables were expressed as frequency and proportion. The data were entered using Microsoft Office Excel 2010 and analysed using Statistical Package for Social Sciences (SPSS) software version 24.0.

RESULTS

Demographic and anthropometric parameters of patients in both the groups were comparable. In both the groups' females were more than males [Table/Fig-2]. Mean time of ambulation after spinal anaesthesia in the Group 1 was 137.65±9.15 minutes and in Group 2 was 193.38±8.14 minutes (p-value <0.05). Mean time taken to return of voiding function the Group 1 was 157.06±16.05 minutes and in Group 2 was 213.53±10.26 minutes (p-value <0.05).

Mean time taken for PADSS score >9 was found to be significantly low in Group 1 when compared to Group 2 [Table/Fig-3].

Demographic characteristics	Group 1 (N=34) n (%)	Group 2 (N=34) n (%)	Total	p-value
Age category (years)				
18 to 25	4 (11.76%)	4 (11.76%)	8	0.712
>25 to 35	7 (20.59%)	9 (26.47%)	16	
>35 to 45	11 (32.35%)	9 (26.47%)	20	
>45	12 (35.29%)	12 (35.29%)	24	
Sex distribution				
Male	15 (44.1%)	16 (47.1%)	31 (45.6%)	0.06
Female	19 (55.9%)	18 (52.9%)	37 (54.4%)	1
Body mass index (kg/m²)	28.56±3.75	29.06±3.24		0.559
ASA grading				
ASA PS 1	20 (58.8%)	19 (55.9%)	39 (57.4%)	1
ASA PS 2	14 (41.2%)	15 (44.1%)	29 (42.6%)	1

[Table/Fig-2]: Demographic characteristics.

Group	Mean time taken (minutes)	t-value, p-value
Group 1	165.29±13.59	1.68 **0.001**
Group 2	219.41±9.52	

[Table/Fig-3]: Time taken for Post-Anaesthetic Discharge Scoring System (PADSS) score >9.
p-value is significant

Onset of sensory block among the Group 1 was longer than that of the Bupivacaine Group 2. Mean time to attain Sensory level T10 among the Group 1 was faster than that of the Group 2 [Table/Fig-4].

Parameters assessment of sensory block	Group	Mean time of sensory block (mins)±Standard deviation	p-value
Time to onset of Sensory block in mins	Group 1	1.47±0.51	0.332
	Group 2	1.35±0.48	
Time to sensory level (T10) in mins	Group 1	3.62±0.95	0.261
	Group 2	3.85±0.74	
Time to reach the Maximum level of sensory block	Group 1	6.68±1.17	0.546
	Group 2	6.53±0.79	

[Table/Fig-4]: Time to onset of sensory block, time to Sensory level (T10) and time to reach the maximum level of sensory block.

Mean time to attain complete motor block among the Group 1 was faster than that of the Group 2, though not statistically significant [Table/Fig-5].

Mean time for two-segment regression from peak block and time for sensory regression to level S2 among the Group 1 was significantly faster than that of the Group 2 [Table/Fig-6].

Group	Mean time to attain complete motor block (mins)±Standard deviation	p-value
Group 1	5.76±0.92	0.387
Group 2	5.94±0.74	

[Table/Fig-5]: Time to attain complete motor block (Modified Bromage score 1).

Sensory regression	Group	Mean time in mins±Standard deviation	p-value
Time for two segment regression	Group 1	42.35±4.96	**0.001**
	Group 2	69.12±10.48	
Time for sensory regression to level S2	Group 1	92.21±10.53	**0.001**
	Group 2	136.76±8.87	

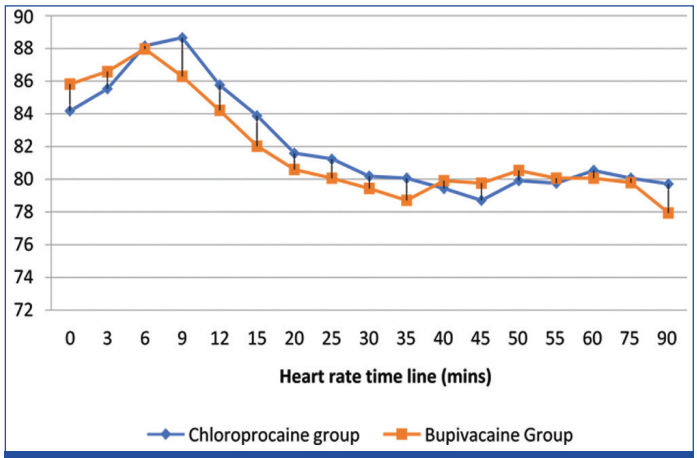
[Table/Fig-6]: Time for two segment regression and time for Sensory regression to level S2.
p-values are significant

The mean duration of motor block was significantly low in Group 1 when compared to Group 2 [Table/Fig-7].

Mean heart rate of study participants both the groups showed a declining trend. The change in heart rate in both the groups was found to be similar over the surgical process [Table/Fig-8].

Group	Mean time for motor block regression in mins±Standard deviation	t-value, p-value
Group 1	108.09±9.61	0.54 **0.001**
Group 2	159.09±9.87	

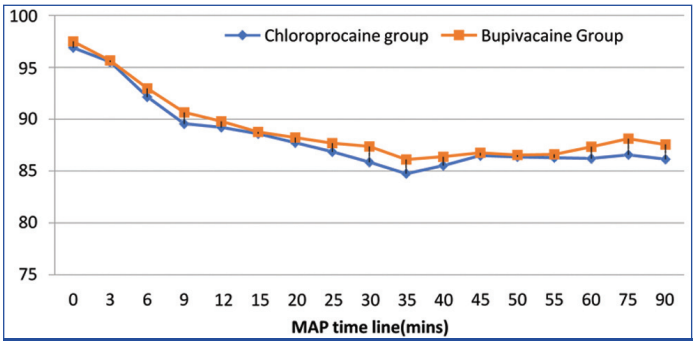
[Table/Fig-7]: Time for motor block regression (Modified Bromage score 6).



[Table/Fig-8]: Line diagram showing heart rates over the period of surgical process.

MAP of study participants both the groups showed a declining trend. The change in MAP in both the groups was found to be similar over the surgical process [Table/Fig-9].

Mean time duration to request of first rescue analgesic was significantly lesser in Group 1 when compared to Group 2 [Table/Fig-10].



[Table/Fig-9]: Line diagram showing Mean Arterial pressure (MAP) over the period of surgical process.

Group	Mean time to request of first rescue analgesic (VAS >3) in mins±Standard deviation	t-value, p-value
Group 1	104.71±8.69	0.04 **0.001**
Group 2	157.79±8.81	

[Table/Fig-10]: Time to request of first rescue analgesic (VAS >3).

In this study the only complication reported was shivering. Other complications like nausea, bradycardia, vomiting, hypotension and urticaria were not reported in both the group.

DISCUSSION

The present randomised interventional double-blinded study carried out with an aim to evaluate the block characteristics between 1% Chloroprocaine versus 0.5% hyperbaric Bupivacaine in spinal anaesthesia for short duration perianal surgeries. Outcome of the study Chloroprocaine for perianal surgeries of short duration resulted in an adequate surgical anaesthesia and at the same time quicker recovery from anaesthesia and early hospital discharge when compared with 10 mg of hyperbaric 0.5% Bupivacaine. Few previous studies also discuss the comparative toxicities and side effects, useful for deciding the anaesthetic agents [11-13]. Mean time of ambulation after spinal anaesthesia in the Chloroprocaine group was faster than the Bupivacaine group. This was similar to the study done by Gys B et. al. Their study also concluded faster motor and sensory regression as compared to prilocaine. [14].

Lacasse MA et al., who studied the effect of 30 mg chloroprocaine and 10 mg Bupivacaine in healthy volunteers and found that mean time to ambulation was 225+56 minutes and 265+65 in respective groups and stated mean time to ambulation was earlier in chloroprocaine group. This proves that patients who were given Chloroprocaine can be ambulated early than Bupivacaine group patients [15].

Mean time taken to return of voiding function the Chloroprocaine group was faster than Bupivacaine group This was similar to the study done by Smith KN et al., who found the mean time to micturition in 30 mg Chloroprocaine group was 167+47 minutes and Prabhakar A et. al., found that 10 mg Bupivacaine in spinal had mean time to micturition of 241+14 minutes [4,5]. Lacasse MA et al., stated that mean time of voiding after spinal anaesthesia was earlier in Chloroprocaine group than Bupivacaine similar which was analogous with our study [15].

Rescue analgesic: The mean time duration to request for first rescue analgesic was found to be low in Chloroprocaine Group when compared to Bupivacaine group. Patients required analgesics earlier in Chloroprocaine Group. This was similar to study conducted by Lacasse MA et al., who stated patients in 30 mg Chloroprocaine group experienced more pain, earlier in PACU and required rescue analgesic faster than Bupivacaine group as the level regressed faster [15]. The association of anaesthetists from various countries all together explained the skin antisepsis for central neuraxial blockade, in their previous literature [16].

PADSS scoring: The mean time taken for PADSS score >9 was found to be low in Chloroprocaine Group when compared to Bupivacaine group This was similar to the results of Lacasse MA et al., Campbell JP et. al. and Camponov C et. al. who stated that readiness to home discharge was earlier with chloroprocaine group when compared to Bupivacaine group [15-17]. In this study the only complication reported was shivering.. Other complications like nausea, bradycardia, vomiting, hypotension and urticaria were not reported in both the group. In contrast to various other previous studies depicting toxicities in their literature [8,9,16].

Limitation(s)

One of the limitations of this study is that Chloroprocaine is an ultra short acting drug so even though blinded we can predict the drug given to each patient by the time taken for the regression of block. The selection and information bias due to the above limitation was avoided by randomisation and collecting data under supervision of guide. An additional limitation of this study was determining the precision of the sensory level of the block within two dermatomal levels. This was reduced by having the same blinded observer responsible for collecting data all the time during the entire study.

CONCLUSION(S)

Intrathecal administration of 30 mg of 1% 2-Chloroprocaine for perianal surgeries of short duration resulted in an adequate surgical anaesthesia and at the same time quicker recovery from anaesthesia and early hospital discharge when compared with 10 mg of hyperbaric 0.5% Bupivacaine. So, it can be effectively used for ambulatory perianal surgeries of shorter duration.

Declaration

This research was a thesis project done in Chettinad Hospital and Research Institute, Chennai.

1. Dr. Navin Gandhi, was the principal investigator of this study.
2. Dr. Mohana Sundaram had the chief role in manuscript preparation, visualisation and data presentation.
3. Dr. Ashok Kulasekhar was the guide for this study. He provided resources and helped with study conception and data curation
4. Dr. S Anand was the co-guide for this study and helped in methodology and formal analysis of the study.
5. Dr. Arun Kumar supervised the overall study and helped in computation.

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