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Original Research Article

A comparative study of bupivacaine heavy and 2-chloroprocaine for saddle block in perianal day care surgeries: A prospective randomized double blind clinical trial

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ABSTRACT

Aims: To compare the clinical efficacy of 1% 2-chloroprocaine and 0.5% bupivacaine heavy for saddle block in patients undergoing perianal day care surgeries.
Settings and Design: After obtaining Institutional ethical clearance and written informed consent, 80 patients posted for elective perianal surgeries at SNMC and HSK Hospital were allocated into two groups by computer generated random numbers (1:1 ratio). Group A received 2ml of 1% 2-Chloroprocaine and Group B received 2ml of 0.5% Bupivacaine heavy. Double-blinding was done where neither the patient nor the investigator knew about the drug.
Materials and Methods: In the OT standard anesthetic protocols were employed. Saddle block was given with bupivacaine heavy and 2-chloroprocaine and the following parameters, time to eligibility for discharge from hospital, length of stay in PACU, time to ambulate and void urine and any other complications were noted.
Statistical analysis used: Data were entered in MS-Excel and analysed in SPSS V22. Descriptive statistics were represented with percentages, Mean with SD. Chi-square test, Independent t-test were calculated. P<0.05 was considered as statistically significant.
Results: Mean time for eligibility to discharge from hospital between groups were statistically significant with group A having less mean time (235.8+22.8 min) as compared to group B(337.1+16.4 min).
Conclusion: Saddle block with 2-Chloroprocaine in perianal day care surgeries provides adequate duration and depth of surgical anesthesia with the advantages of faster block resolution and earlier hospital discharge.

1. Introduction

Ambulatory day care surgical procedures has increased worldwide. Spinal anaesthesia is safe and reliable technique for surgery of lower abdomen and limbs.[1] However, some of its characteristics like delayed ambulation, risk of urinary retention and pain after block regression may limit its use for ambulatory surgeries. Saddle block provides a reliable but is a restricted block with good surgical conditions and hence is optimal for perianal surgeries.

The ideal anesthetic should have minimal side effects with rapid onset and offset of its own effect for early patient discharge.[2,3] 2-Chloroprocaine is an amino-ester local anesthetic and has very short half-life. Bupivacaine heavy is a long acting amide local anaesthetic agent with comparatively slower onset of action and longer duration. In this study we have compared the clinical efficacy of 2-chloroprocaine and bupivacaine heavy. The primary outcome criteria was time to eligibility for discharge from hospital and secondary outcome criteria were length of stay in PACU, time to ambulate, void urine and any other complications.

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2. Materials and Methods

After obtaining Institutional ethical clearance and written informed consent, patients posted for elective perianal daycare surgeries at S Nijalingappa Medical College and HSK Hospital, Bagalkot, Karnataka were included in the study. The study was conducted from December 2017 to June 2019.

2.1. Sample size calculation

Sample size was calculated using OPEN-EPI software version 2.3.1 at 95% confidence level, 80% power of the study. According to study conducted by Lacasse MA et al[4] on elective ambulatory surgeries of short duration (<60 min), the time to eligibility for discharge from hospital was considered. Sample size was calculated as 34 in each group. To overcome the patient drop out we included 40 in each group.

2.2. Randomization and blinding

Eighty patients were divided randomly into two groups, Group A and Group B by computer generated random numbers at 1:1 ratio. Group A received 2ml of 1% 2-Chloroprocaine, group B received 2ml of 0.5% Bupivacaine heavy. Double blinding was done where neither the patient nor the investigator knew about the drug.

The patients of ASA physical status grade I and II aged between 18 to 65 years undergoing elective perianal day care surgeries < 60 mins duration were included in the study. The patients with bleeding/coagulation disorders, existing neurological disease, sepsis, pregnancy and obese patients (BMI> 30kg/m^2) were excluded.

3. Methodology

After pre-anaesthetic evaluation, all patients received tablet Ranitidine 150 mg orally in the night and were kept nil by mouth for 8 hours for solids and 2 hours for clear liquids. On the day of surgery, in the OT standard monitors like pulse oximetry, NIBP and ECG were connected and baseline readings were recorded. IV line was secured with 20G iv cannula and coloaded with ringer lactate solution at the rate of 15ml / kg.

Under aseptic precautions, spinal anaesthesia was given at L3- L4 or L4-5 interspace using 25 G Quincke spinal needle with patient in sitting position. The patients were placed in supine after 7-10 minutes to achieve adequate saddle block. The sensory level of the block is assessed in a caudal to cephalad direction by using pin prick examination. The occurrence of clinically relevant hypotension (>20% from baseline values) was treated with ephedrine. Clinically relevant bradycardia was treated with atropine.

The patients were discharged from PACU after achieving modified Aldrete score of ≥ 9 and from hospital after achieving Post Anesthesia Discharge Score system of ≥ 9.[5] Time to ambulate and void urine were also noted. Patients were contacted over phone, 24 hr and 7 days following surgery for assessing potential complications. A standardized questionnaire was used to check for the presence of headache, nausea, vomiting and backache.

3.1. Statistical analysis

Data were entered in MS-Excel and analyzed in SPSS V22. Descriptive statistics were represented with percentages, Mean with SD. Chi-square test, Independent t-test were applied to find significance. P<0.05 was considered as statistically significant.

4. Results

All the surgical procedures were done under saddle block. There was no difference between the two groups in terms of demographic criteria (Table 1).

The mean time for eligibility to discharge from hospital between groups were statistically significant with p value <0.001.Group A had less mean time (235.8±22.8 min) compared to group B(337.1±16.4 min). The mean time for length of stay in PACU was less in group A(63.0±8.0 min) as compared to group B (73.7+8.8 min) with p value of <0.001. Mean time taken to ambulate was statistically significant with group A having less mean time (178.7±24.4 min) compared to group B (267.3±19.3 min),with p value of < 0.001. The time taken to void was statistically significant with group A having less mean time (211.6±28.6 min) compared to group B (305.2±20.6 min), with p value of <0.001.

Table 1: Demographic data

	Group A	Group B	P Value
Age	44.5±16.9	44.6±14.9	0.98
Gender (Male/Female)	25/15	24/16	0.82
Weight	60.9±8.5	64.4±7.6	0.06

Table 2: Clinical data

	Group A	Group B	P value
Eligibility to discharge from hospital (min)	235.8±22.8	337.2±16.4	<0.001
Length of stay in PACU(min)	63.0±8.0	73.7±8.8	<0.001
Time to ambulate(min)	178.7±24.4	267.3±19.3	<0.001
Time to void urine(min)	211.6±28.6	305.2±20.6	<0.001

The complications in our study like bradycardia, hypotension, headache, PONV and backache were comparable between the two groups.

Table 3: Complications in our study

	Group A	Group B
No complications	30	32
Bradycardia	2	0
Hypotension	0	2
Headache	2	4
PONV	5	0
Backache	1	2
P=0.07		

5. Discussion

In the modern world, ambulatory surgeries are gaining popularity due to various advantages. Due to early recovery and short hospital stay it reduces the economical burden on patient and health care system. To provide good intraoperative anesthesia and analgesia along with minimal side effects and early recovery, optimal dosage and concentration of local anesthetic is crucial in ambulatory settings.

Saddle block is advantageous in terms of usage of small dose of local anesthetic, simplicity to perform and offers rapid onset of action, reliable surgical analgesia with good muscle relaxation.

In the study conducted by Liu SS[6] et al showed that long acting anesthetics such as bupivacaine can be administered for outpatient surgeries but optimum dose is needed. Bupivacaine heavy is a long acting amide local anaesthetic agent with comparatively slower onset of action and longer duration.

2-chloroprocaine is an amino-ester local anesthetic with a short half-life. Since 1952 it has been successfully used for spinal anesthesia.[7] Many reports of neurotoxicity were reported following the use of large doses of 2-chloroprocaine and hence was withdrawn from commercial use.[8–10] The combination of low PH (<3) and an antioxidant, sodium bisulfite, may have been responsible for the neurotoxicity.[11–14] Thereafter a preservative free formulation was reintroduced in which the pH of the solution has been adjusted. This new formulation has been safely used for spinal anesthesia in healthy volunteers and in patients without complications.[15–18]

In this study we compared 1% 2-chloroprocaine with bupivacaine for saddle anesthesia in perianal day care surgeries.

5.1. Time for eligibility to discharge from hospital

There is a significant difference between two groups with group A having less mean time (235.8+22.8 min) compared to group B (337.1+16.4 min).

Yoos JR and Kopacz DJ[19] conducted double blind, randomized crossover study on 8 healthy volunteers concluded time to simulated discharge (including time to complete block regression, ambulation, and spontaneous voiding) was significantly longer with bupivacaine(191±30 min) as compared to 2-Chloroprocaine (113±14min). In the study conducted by Lacasse MA et al[4] conducted on 106 patients undergoing outpatient surgery under spinal anesthesia, mean time to hospital discharge was 277±87 min for chloroprocaine group as compared to 353±99 for bupivacaine group.

5.2. Time taken to discharge from PACU

Mean time for length of stay in PACU was less in group A (63.0±8.0 min) as compared to group B (73.7+8.8 min). However in the study conducted by Lacasse MA et al[4] mean duration of stay in PACU was 67±16 min in chloroprocaine group and 68±14 which was statistically insignificant with p=0.66.

5.3. Time taken to void

There is a significant difference between two groups with group A having less mean time (211.6+28.6 min) compared to group B (305.2+20.6 min).

In the study conducted by Lacasse MA et al[4] conducted on 106 patients undergoing outpatient surgery under spinal anesthesia, mean time to micturition in the chloroprocaine group was 271±96 min and in bupivacaine group was 338±99 min. Their results were consistent with our study. Mathur V et al[5] conducted a study on 100 patients undergoing ambulatory urology surgery under spinal anesthesia. According to their study time to first void in chloroproacine group was lesser (177.46±33.41 min) than bupivacaine group (277.56±43.31 min) which was similar to our study.

5.4. Time to ambulate

There is a significant difference between two groups with group A having less mean time (178.7±24.4 min) compared to group B (267.3±19.3 min).

In a review study by Ghisi D, Bonarelli S[20] concluded that 1% 2-chloroprocaine showed faster unassisted ambulation and discharge from hospital. In the study conducted by Lacasse MA et al[4] conducted on 106 patients undergoing outpatient surgery under spinal anesthesia, mean time to ambulate was lesser in chloroprocaine group(225±56 min) as compared to bupivacaine group(265±65 min), the results being similar to our study.

The complications in our study like bradycardia, hypotension, headache, PONV and backache were comparable between the two groups.

6. Conclusion

In conclusion saddle block with 2-Chloroprocaine provides satisfactory surgical anesthesia for perianal surgeries when

compared to low dose hyperbaric Bupivacaine with earlier hospital discharge and shorter PACU stay and time to ambulation and micturition.

7. Source of Funding

None.

8. Conflict of Interest

The author declares no conflict of interest.

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