

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

Aim: To compare the bupivacaine heavy and 2-chloroprocaine for saddle block in perianal day care surgeries.

Methods: This observational study conducted in the Department of Anesthesiology & Critical Care Patna Medical College & Hospital, Patna, Bihar, India, for 12 months. 80 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 58 years undergoing elective perianal day care surgeries < 60 mins duration were included in the study.

Results: 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 (238.42± 18.86 min) compared to group B (341.75±16.66 min). The mean time for length of stay in PACU was less in group A (62.25±6.88 min) as compared to group B (75.26±8.66 min) with p value of <0.001. Mean time taken to ambulate was statistically significant with group A having less mean time (182.52±20.36 min) compared to group B (266.78±19.69 min) with p value of < 0.001. The time taken to void was statistically significant with group A having less mean time (216.89±29.66 min) compared to group B (308.25±20.45 min), with p value of <0.001.

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.

Keywords: PACU., bupivacaine heavy

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Introduction

The incidence of perianal surgery varies among institutions, accounting for up to 10% of general surgical procedures. The procedure is suitable to perform on a day-case basis with spinal anaesthesia. However, prolonged sensory and motor block and urinary retention can cause a delay in discharge [1,2]. It was widely used in Anglo-Saxon countries until the 1960s, especially in obstetrics, before being replaced by more flexible epidural anaesthesia [3]. Saddle block provides anaesthesia of the perineum, tip of the coccyx, medial and bottom of the buttocks and posteromedial part of the thighs covering an area that for a rider would correspond to that in contact with a saddle. Such anaesthesia is obtained by injecting a small dose of hyperbaric local anaesthetic (LA) in a patient maintained in sitting position for a few minutes to facilitate preferential impregnation of sacral roots (S1 to S5) responsible for innervation of perineum, external genitalia and anus. The saddle block causes a parasympathetic blockade at the bladder level which may result in bladder and rectal atony which is advantageous because of sphincteric relaxation for the operator.

Proctologic surgery is one of main indications of saddle block. The anaesthesia it provides is particularly suitable for this very painful surgery that additionally requires a fully relaxed sphincter. A slightly extended block decreases, as much as possible, the risk of acute retention of urine, a common complication after this surgery. Spinal puncture is performed in a monitored patient in the sitting position. The needle is inserted in the lower lumbar region, i.e. the interspinous space L4-15 or L5-S1. Using a Whitacre® type pencil needle of 25 or 27 Gauge reduces the incidence of headache after puncture of the dura mater. The distal eyelet of this needle needs to be directed downward or caudally. With clear CSF flow, the hyperbaric solution of LA is injected as slowly as possible, without air bubbles, to deliver as

much local anaesthetic as possible to sacral territory. To “fix” the block without extension, the patient is kept in a sitting position for at least ten minutes. However, with lower the doses of LA, the patient should remain longer in the sitting position. The baricity of the LA solution and the position of the patient after the injection affect the caudal or cephalic diffusion of anaesthesia [4] so hyperbaric anaesthesia is used to insure a caudad block. When sitting is difficult for a patient due to painful lesions, sedation with low doses of opioids may be useful.

Material and Methods

This observational study conducted in the Department of Anesthesiology & Critical Care, Patna Medical College & Hospital, Patna, Bihar, India, for 12 months. We included 40 patients in each group.

Methodology

Total 80 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 58 years undergoing elective perianal day care surgeries <60 mins duration was included in the study. The patients with bleeding/coagulation disorders, existing neurological disease, sepsis, pregnancy and obese patients (BMI > 30kg/m²) were excluded.

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 6-10 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.

Statistical analysis

Data were entered in MS-Excel and analyzed in SPSS V 21.0. 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.

Results

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

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 (238.42 ± 18.86 min) compared to group B (341.75 ± 16.66 min). The mean time for length of stay in PACU was less in group A (62.25 ± 6.88 min) as compared to group B (75.26 ± 8.66 min) with p value of < 0.001 . Mean time taken to ambulate was statistically significant with group A having less mean time (182.52 ± 20.36 min) compared to group B (266.78 ± 19.69 min), with p value of < 0.001 . The time taken to void was statistically significant with group A having less mean time (216.89 ± 29.66 min) compared to group B (308.25 ± 20.45 min), with p value of < 0.001 .

Table 1: Clinical data

	Group A	Group B	P value
Eligibility to discharge from the hospital	238.42 \pm 18.86	341.75 \pm 16.66	<0.001
Length of stay in PACU (MIN)	62.25 \pm 6.88	75.26 \pm 8.66	<0.001
Time to ambulate(min)	182.52 \pm 20.36	266.77 \pm 20.69	<0.001
Time to void urine (min)	216.89 \pm 19.66	308.24 \pm 21.45	<0.001

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

Table 2: Complications

Parameter	Group A	Group B
No complications	30	35
Bradycardia	2	0
Hypotension	0	2
Headache	2	4
PONV	6	0
Backache	2	2

Discussion

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. 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 (238.42±20.86 min) compared to group B

(341.75±16.66 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 [20] 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.

The mean time for length of stay in PACU was less in group A (62.25±6.88 min) as compared to group B (75.26±8.66 min) with p value of <0.001. However, in the study conducted by Lacasse MA et al [20] mean duration of stay in PACU was 67±16 min in chloroprocaine group and 68±14 which was statistically insignificant with p=0.66.

±The time taken to void was statistically significant with group A having less mean time (216.89±29.66 min) compared to group B (308.25±20.45 min), with p value of <0.001. In the study conducted by Lacasse MA et al [20] 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 chloroprocaine group was lesser (177.46 ± 33.41 min) than bupivacaine group (277.56 ± 43.31 min) which was similar to our study.

Mean time taken to ambulate was statistically significant with group A having less mean time (181.52 ± 21.36 min) compared to group B (265.78 ± 20.69 min), with p value of < 0.001 . In a review study by Ghisi D, Bonarelli S concluded that 1% 2-chloroprocaine showed faster unassisted ambulation and discharge from hospital. In the study conducted by Lacasse MA et al [20]. 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.

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.

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