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A COMPARATIVE STUDY BETWEEN 0.5% BUPIVACAINE (HEAVY) AND 2-CHLOROPROCAINE (PRESERVATIVE FREE) FOR SPINAL ANAESTHESIA IN ELECTIVE SHORT SURGICAL PROCEDURES

Anaesthesiology

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ABSTRACT

Background: Spinal anaesthesia is the preferred anaesthetic technique in lower abdominal surgeries but in case of short surgeries (< 60 min), appropriate choice of local anaesthetic is of prime importance to prevent problems like prolonged motor block, delayed ambulation and delayed micturition postoperatively. Preservative free 2-Chloroprocaine has recently come up as a good alternative as compared to commonly used local anaesthetics.

Aim: The aim of this study was to compare the efficacy between 1% 2-Chloroprocaine and 0.5% Bupivacaine (heavy) in terms of early block resolution and early ambulation.

Material And Methods: This prospective, randomised, double blinded, comparative study was conducted in the Department of Anaesthesiology, North Bengal Medical College and Hospital. One hundred and ten (110) patients of ASA physical status I or II and age of 18-60 yrs undergoing lower abdominal surgeries under spinal anaesthesia were chosen and randomly divided into two groups, Group A and Group B. Group A received 40 mg (4ml) of intrathecal 1% preservative free 2-Chloroprocaine and Group B received 12 mg (2.4ml) of intrathecal 0.5% Bupivacaine (heavy). After administration of intrathecal drugs, vital parameters were monitored and any intraoperative complications recorded. Onset and height of sensory block were monitored by pinprick method and degree of motor block was monitored by modified Bromage Scale – (0-3). Time to reach readiness for surgery, duration of sensory block and motor block, time to ambulation and micturition, any supplementation required and any complications were recorded. The data were analysed using appropriate statistical tests.

Results: The patients in Group A had a lower duration of motor block in comparision to those in Group B [81 ± 11 min vs 142 ± 29 min (P<0.001)]. The duration of sensory block was also significantly lower in Group A as compared to Group B [100 ± 14 min vs 188 ± 39 min (P<0.001)]. Also patients in Group A had lower time to ambulation than those in Group B[142 ± 24 min vs 280 ± 51 min (P<0.001)] as well as lower time to micturition as compared to those in Group B[204 ± 37 min vs 365 ± 57 min (P<0.001)].

Conclusion: For spinal anaesthesia in lower abdominal short surgical procedures, intrathecal 2-Chloroprocaine produces a satisfactory surgical block and is a better drug in comparison to hyperbaric bupivacaine with respect to faster block resolution and ambulation.

KEYWORDS

spinal anaesthesia, 2-chloroprocaine, hyperbaric bupivacaine, block resolution, ambulation

INTRODUCTION

Spinal anaesthesia is a commonly employed anaesthetic technique for lower abdomen and lower limb surgeries[1]. Some of its characteristics may confine its use in short surgeries (duration less than 60 min), including delayed ambulation, risk of urinary retention, and pain after block regression[2]. Therefore, to choose the correct local anaesthetic for spinal anaesthesia is crucial in short surgical procedures. The ideal anaesthetic drug should allow rapid onset as well as offset of its action for fast patient discharge with the least amount of side effects[3]. Although trials have been conducted to adapt small doses of hyperbaric bupivacaine, a long-acting local anaesthetic, to the short surgical procedures, however, the duration of the block remains prolonged with these smaller doses[4]. Also, urinary retention (or an increased interval to first voiding) is frequently seen with higher doses of bupivacaine, which cause delay in hospital discharge for patients[5]. Even though an amino-ester local anaesthetic, 2-chloroprocaine (2-CP) was mainly used for obstetrical epidurals, it was reported to be safe and reliable for spinal anaesthesia only since 1952[6].

It was found to be a potentially favourable option for spinal anaesthesia in short outpatient procedures because of its short half life[6,7]. Due to presence of an antioxidant preservative namely, Sodium bisulfite, in Chloroprocaine solution, many cases of neurotoxicity were reported two decades ago[7-9]. Thereafter, studies have been conducted using preservative-free 2-CP for spinal anaesthesia in healthy volunteers as well as in patients[10-14]. Previous researches with intrathecal preservative free 2-CP had been confined particularly to evaluation of block characteristics and dose comparisons in patients undergoing short surgeries, mainly day care procedures[15]. So, the purpose of this study is to compare the efficacy between 0.5% Bupivacaine (heavy) and 2-Chloroprocaine (preservative free) for spinal anaesthesia in elective short surgical procedures (less than 60 min) regarding early block resolution and early ambulation.

MATERIALS & METHODS

Based on the study by M.A Lacasse et al[16], considering a mean difference in time of ambulation of 40 min as primary outcome, a superiority margin of 30 min, an alpha error of 0.05 and power 80%, the calculated sample size was 49 in each group. Considering a dropout rate of 5%, the final total sample size was taken to be 115. 3 patients did not meet the exclusion criteria and 2 patients declined to participate. So, a total of 110 patients(n=55 in each group) were enrolled in this randomised double-blind comparative study which was conducted under the department of anaesthesiology in North Bengal Medical College and Hospital within the time period of May 2019 to April 2020 after receiving approval from the Institutional Ethics Committee and taking informed consent from each patient. Patients included in the study were of age group 18-60 yrs and posted for elective lower abdominal surgical procedures of short duration (<60 min). The following surgeries were included: Urologic surgeries (Ureteroscopic Lithotripsy, Optical Internal Urethrotomy), General surgeries (Circumcision, Hydrocelectomy, Haemorrohoidectomy), and Gynaecologic surgeries (ligation surgeries). The exclusion criteria included patient refusal, pregnancy, history of allergy to any medications used in the study or any contraindication to spinal anaesthesia.

Pre-Anaesthetic Checkup was done for all the patients before posting for their respective elective surgery and the standard fasting guidelines were followed by each of them prior to the procedures. When the patient arrived in the pre-operative room, he or she was randomly selected according to a computer generation randomised list and assigned to either Group A, containing patients (n=55) who received spinal anaesthesia with preservative free 2- chloroprocaine or Group B, containing patients (n=55) who received spinal anaesthesia with 0.5% Bupivacaine (Heavy).

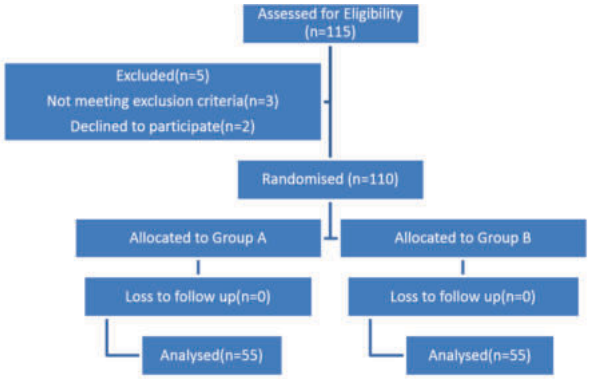

Figure 1: Consort Diagram

After arrival in the operating room standard monitoring was used throughout the procedure, including non-invasive arterial blood pressure, electrocardiogram and pulse oximetry. Baseline data was recorded. Spinal anaesthesia was performed under sterile conditions after local infiltration of the skin with 2% lignocaine. The subarachnoid space was entered at the L3-L4 intervertebral space via the midline approach using a 25G Quincke spinal needle with the patient in the sitting position. Patients in Group A received an intrathecal injection of 40 mg (4 mL) of preservative free formulation of 1% 2-Chloroprocaine and patients in Group B received 12 mg (2.4 mL) of 0.5% hyperbaric bupivacaine.

The loss of pin prick sensation was used to test the sensory level of the block in a caudal to cephalad orientation, with the C5-C6 dermatome serving as an unblocked reference point. The modified Bromage scale was used to analyse the motor block (Figure 2).

Modified Bromage Scale	
Activity	**Score**
Able to lift legs against gravity	0
Able to flex knee but unable to flex legs	1
Able to move feet but unable to flex knee	2
Unable to move any joints	3

Figure 2: Modified Bromage Scale

From the time of administration of spinal drugs, an independent blinded observer monitored the sensory block every 1-minute interval in the midline. Loss of pin prick feeling >T10 was used to determine surgical readiness. Similarly, from the time of intrathecal drug administration until the block advanced to grade 3 on the Modified Bromage Scale, the progression of the motor block was examined every 1-minute interval. If the patient complained of pain, supplementation with Fentanyl 25-30mcg iv was administered. If the patient still felt pain, general anaesthesia was provided and the protocol was stopped. A fall in mean arterial pressure (MAP) < 65 mmHg was considered as hypotension and was treated with IV fluids and iv vasopressors eg. Inj Mephentermine in incremental doses. Pulse rates <50 bpm was regarded as clinically relevant bradycardia and treated with Inj Atropine(0.6mg) iv. Side effects like nausea, vomiting was noted and treated with iv ondensetron(4mg) if needed. Other side effects like shivering if occurred, was treated with Inj Tramadol 50mg iv.

During surgery, evaluation of sensory and motor block was suspended till the end of procedure keeping in view the short procedure(<60min) and the inconvenience created to the surgeon due to multiple interference with the procedure. After the completion of the surgical procedure, sensory block was checked using the loss of pin prick feeling every 10 minutes for 60 minutes and every 15 minutes until sensory block regressed to the L1 dermatome. Duration of sensory block was defined as time taken from administration of spinal anaesthesia to regression to L1 dermatome. Similarly, regression of motor block was also assessed after end of procedure every 10 min for 60 min and then every 15 min interval till block regressed to Grade 0 according to Modified Bromage scale. Duration of motor block was defined as time taken from administration of spinal anaesthesia to regression of motor block to Grade 0 as per Modified Bromage Scale.

After that, patients were asked if they could feel a mild touch on their legs. If they were capable, then they were asked to ambulate with assistance. If they could ambulate with assistance they were asked to ambulate without assistance. Time to ambulation was defined as time taken from administration of spinal anaesthesia to ambulation without assistance. After successful walking patients attempted to void urine. Time to micturition was calculated from time of administration of the spinal anaesthetic to the time of voiding urine.

The following data were recorded: Time to reach readiness for surgery, incidence of hypotensive episodes and bradycardia, duration of sensory block, duration of motor block, time to ambulation, time to micturition, any other supplementation required and any other complications (nausea, vomiting, shivering, anaphylaxis etc).

After completion of data collection, the proforma were unblinded and tabulated into a SPSS sheet for statistical comparison. The data were analysed using Statistical Package for Social Sciences version 23.0 for Windows [IBM Corp. Released 2015. IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.]

All continuous data were presented in the tables as mean ± Standard deviation(SD). Discrete categorical data were presented as absolute values (%) or relative number of patients, as appropriate. Comparisons for each demographic and clinical variable among the two groups were performed by independent sample T test for normally distributed variables and Pearson Chi-Square test for categorical variables. The level of significance was set as $p < 0.05$.

RESULTS

Both groups were comparable in terms of demographic parameters and type and duration of surgeries (Table 1,2). The time required to achieve readiness for surgery was also comparable in both the groups (Table 3). However, regression characteristics showed a different profile between the two groups. Regression of the sensory block to L1level was significantly faster in the Group A than in Group B (100 min vs 180 min; P <0.001). Similarly, the duration of the motor block was significantly shorter in the Group A (81 min vs 142 min; P<0.001) (Table 3). Similarly, the time to ambulation and micturition were all significantly shorter in the Group A than the Group B [142 min vs 280 min and 204 min vs 365 min respectively] (Table 3). No patient required General Anaesthesia but some patients required analgesic supplement with Fentanyl which was also comparable in both the groups (Table 3).

Table 1: Demographic Parameters And Duration Of Surgery

VARIABLES	Group A (n = 55) [Mean ± SD]	GROUP B (n = 55) [Mean ± SD]	p value
Age(yrs.)	35.96 ± 10.21	35.8 ± 9.87	0.932
Sex (M/F)	30/25(54.5/45.5)	28/27(50.9/49.1)	0.702
Weight (Kgs)	60.92 ± 6.81	60.29 ± 6.90	0.628
Height(cm)	166.34 ± 10.461	165.90 ± 9.47	0.819
BMI(Kg/m2)	22.00 ± 1.37	21.87 ± 1.38	0.615
ASA(I/II)	25/30(45.5/54.5)	28/27(50.9/49.1)	0.567
Duration of surgery(min)	42.15 ± 3.91	42.16 ± 3.98	0.981

Table 2: Types Of Surgery

Types of surgery	Group A (n = 55)	Group B (n = 55)	p value
Urological surgeries	27 (49.1%)	27 (49.1%)	0.964
General surgeries	11 (20%)	12 (21.8%)	
Gynaecological surgeries	17 (30.9%)	16 (29.1%)	

Table 3: Block Characterictics

Variable	Group A (n = 55)	Group B (n = 55)	P value
Time to reach readiness for surgery (min)	4.25 ± 1.26	4.0 ± 1.03	0.251
Duration of motor block (min)	81.47 ± 11.9	142.36 ± 29.32	< 0.001
Duration of sensory block (min)	100.65 ± 14.5	180.54 ± 39.6	< 0.001
Time to ambulation (min)	142.94 ± 24.49	280.43 ± 51.10	< 0.001
Time to micturition (min)	204.25 ± 37.16	365.92 ± 57.19	< 0.001
Requirement of supplement	6 (10.9%)	4 (7.3%)	0.507

During surgery, the incidence of intraoperative complications like

hypotension, bradycardia, nausea, vomiting, shivering were comparable between the two groups (Table 4).

Table 4: Intraoperative Complications

Complications	Group A (n = 55)	Group B (n = 55)	p value
Incidence of Hypotension	5 (9.1%)	8 (14.5%)	0.376
Incidence of Bradycardia	4 (7.3%)	3 (5.5%)	0.696
Incidence of Nausea	12 (21.8%)	15 (27.3%)	0.506
Incidence of Vomiting	8 (14.5%)	8 (14.5%)	1.000
Incidence of Shivering	7 (12.7%)	6 (10.9%)	0.768

DISCUSSION

Most of the studies available have studied 2-chloroprocaine in day care surgeries. M. A Lacasse et al [16] studied 106 patients and compared 7.5 mg of 0.75% Bupivacaine (heavy) and 40 mg of 2% Chloroprocaine in an elective ambulatory setting. Kopacz [17] concluded that a dose of 40 to 60 mg has a reliable sensory block and motor block. In a clinical study by Casati et al [18] 40 mg of Chloroprocaine was shown to be the most ideal dose because lowering this dose resulted in insufficient duration of anaesthesia, and a higher dose only resulted in an increased time for block recovery. Studies aimed at using low doses (<10 mg) of bupivacaine for bilateral spinal anaesthesia were seen to have an unacceptably high rate of failure[19]. Liu et al [20] compared various doses (3.25mg, 7.5 mg and 11.25 mg) of bupivacaine for ambulatory surgeries of short duration. Taking into consideration of the above references, in this study we have compared 40 mg of 1% Chloroprocaine i.e., 4ml (Group A) and 12mg of 0.5% Bupivacaine i.e., 2.4 ml (Group B) in elective short surgical procedures of less than 60 min in 110 indoor patients to look for the better drug with respect to faster block resolution and early ambulation. A higher range dose for bupivacaine was taken in this study because we expected a higher mean duration of surgery (but less than 60 min) since we compared the drugs in elective short surgeries in indoor setting while the above studies were done in day care setting. Our primary aim was to ensure early ambulation in patients undergoing short surgeries in indoor settings. Once the surgery is over, it is unnecessary and not desirable for the patient to have motor paralysis post operatively. So early resolution of block and early ambulation are beneficial for the patient even in indoor setting.

In our study, both the groups were comparable regarding time to reach readiness of surgery. Our study had a faster readiness for surgery as compared to the study conducted by M.A. Lacasse et al[16] which is desirable and beneficial. However, the data of M. A Lacasse et al[16] cannot be compared directly to ours as they used a different method to evaluate the sensory block. In our study, the level of sensory block was assessed using lack of sensation to pinprick with a blunt needle, whereas M.A Lacasse et al[16] utilized loss of cold sensation to ice. Although the same nerve fibres conduct pain and cold sensation, there is a delicate difference. Pinprick sensation is transmitted by the A delta fibres, while cold sensation is carried by both the A delta fibres and the C fibres[21]. Due to differences in evaluation of sensory block, M.A. Lacasse et al[16] showed that the Chloroprocaine Group had almost 2 times faster regression of sensory block to L1 dermatome than Bupivacaine whereas our study showed a 1.8 times faster regression. In a volunteer study of eight patients comparing spinal 2-CP and bupivacaine, Yoos et al[22] demonstrated a 1.7 times faster regression of the sensory block with 2-Chloroprocaine which correlates with our study because they used similar method to evaluate sensory block as our study.

Group A had significantly lower duration of motor block than Group B. The difference in the mean values in both the groups in our study (81 min vs 142min) as compared to the study conducted by Yoos et al[22] (59 min vs 80 min) is most probably because they undertook the endpoint of motor block as Bromage = 1 while in our study, the endpoint was Bromage = 0. Our data was almost consistent with the study done by M.A Lacasse[16] (76 min vs 119 min) except for the mean duration of motor block in Bupivacaine group which is slightly higher in our study probably because we used a lower concentration and higher dose of bupivacaine.

In our study, Patients in Group A ambulated almost 2 times faster than those in Group B. Also, Group A had significantly lower time to micturition as compared to Group B. Urinary retention was particularly seen in the bupivacaine group. This delay may be explained by the fact that for gaining normal detrusor function regression of sensory blockade to S3 dermatome is essential.[16]

Intraoperative complications and intraoperative requirement of analgesic supplements were similar in both groups.

This study had few limitations. One of them was that the patients couldn't be followed after discharge to record any late complications if any. Also, another limitation was we didn't consider opiods as adjuvants to the local anaesthetics which is very common in most indoor settings. Therefore in future, further studies can be conducted to evaluate the effect of different adjuvants with 2-Chloroprocaine in short surgical procedures.

CONCLUSION

Therefore, from this study we conclude that 2-Chloroprocaine (preservative free) is more efficacious in comparison to hyperbaric bupivacaine with respect to faster block resolution and ambulation for spinal anaesthesia in elective short surgeries.

Conflicts Of Interest

There were no conflicts of interest regarding this research work.

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