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"A COMPARISON OF BUPIVACAINE AND 2-CHLOROPROCAINE FOR SPINAL ANAESTHESIA IN SHORT DAY CARE PROCEDURE"

Anaesthesiology

Upasna Deep* MD Anaesthesia, Department of Anaesthesiology, Christian Medical College and Hospital, Ludhiana, India *Corresponding Author

Dootika Liddle MD Anaesthesia, Department of Anaesthesiology, Christian Medical College and Hospital, Ludhiana, India

Narjeet K Osahan MD Anaesthesia, Department of Anaesthesiology, Christian Medical College and Hospital, Ludhiana, India

Shaveta Mala DA Anaesthesia, Department of Anaesthesiology, Government Multi Speciality Hospital Sector-16, Chandigarh, India

ABSTRACT

Background: Spinal anaesthesia is a reliable technique for lower limb day care surgeries. Preservative free 2-chloroprocaine is an amino-ester local anesthetic with a very short half life. It may be a suitable alternative drug for ambulatory surgeries. **Aims:** To compare intrathecal 0.5% bupivacaine and 1% of 2-chloroprocaine in terms of onset of action, duration of action, and their hemodynamic stability. **Methods and Material:** Seventy patients, aged 20-60 years belonging to physical status American Society of Anaesthesiologists (ASA) I and II, undergoing surgery under spinal anaesthesia were included in this study. They were randomly allocated into Group A - Injection Bupivacaine 7.5 mg dose and Group B- Injection 2-Chloroprocaine 30 mg dose. Patients heart rate, systolic and diastolic blood pressure were recorded intra and post operatively. The primary outcome was onset and duration of sensory and motor blockade. The secondary outcomes were time taken for spontaneous voiding and unassisted ambulation. **Statistical analysis used:** Chi square test was used to find the association of categorical variables. The P value <0.05 was considered significant. Regression models were performed to assess association between the variables **Results:** 2-Chloroprocaine showed a faster resolution of sensory blockade (60 to 90 minutes) compared to bupivacaine (100-120 minutes). The mean time taken for full return of motor function post operatively by chloroprocaine was 63.86 minutes compared to bupivacaine 111 minutes (P value<0.0001). **Conclusions:** Injection2-chloroprocaine has shorter duration of action resulting in faster regression of sensory and motor blockade. It is a useful alternative to low dose of bupivacaine in short day care procedures.

KEYWORDS

2-chloroprocaine; bupivacaine; spinal anaesthesia; ambulatory surgeries

INTRODUCTION:

Day care surgeries are becoming popular due to reduced health costs and excellent safety profile.[1]Spinal anaesthesia is one of the most desired modes of delivering anaesthesia due to its simple technique and avoidance of complications of general anaesthesia. It not only decreases intraoperative blood loss but also blunts the stress response to surgery thereby reducing morbidity and mortality.[2]

Bupivacaine is a commonly used intrathecal local anaesthetic but adverse effects like cardiac arrhythmias, heart block and even cardiac arrest has been seen with higher doses.[3] 2-chloroprocaine is an amide ester anesthetic with a very short half- life. It originally contained a preservative sodium metabisuphite, responsible for sacral neurological dysfunction.[4]Gissen et al demonstrated in the 1980s that liberation of preservative sulphur dioxide from 2-chloroprocaine avoided neurological injury.[5] Therefore, a chloroprocaine solution devoid of preservative was made available for intrathecal use commercially. We aim to compare the efficacy of 2- chloroprocaine and bupivavaine for spinal anaesthesia in short day care surgeries.

MATERIALS AND METHODS:

This prospective, randomized, observational study was conducted after approval by the Institutional Ethics Committee with registration number ECR/120/Inst/PB/2013 issued under Rule 122DD. After obtaining informed written consent, 70 patients in the age group from 20-60 years belonging to physical status ASA I and II who were planned for an outpatient surgery under a subarachnoid block between December 2017 and May 2019 were included in this study. Exclusion criteria included patient with any contraindications to spinal anaesthesia, spinal deformities, coagulative disorder, neurological disease or hemodynamically unstable patients.

All patients were hospitalized on the day of surgery. A routine pre anaesthetic check up of all patients was conducted. Patients were kept nil per oral for atleast six hours prior to surgery. The patients were allocated into two groups using randomization scheme by computer generated random number system using the website www.randomization.com Patients in Group A were given bupivacaine 7.5 mg and in Group B chloroprocaine 30 mg dose for spinal anaesthesia.

After shifting the patients on the operating table their heart rate, non invasive systolic and diastolic blood pressure, respiratory rate, electrocardiography and oxygen saturation were recorded. A 20 gauge intravenous (iv) cannula was secured and iv fluid was started.

Under strict aseptic precautions, lumbar puncture was performed in lateral position at the level of L3-4 intervertebral space using 25 gauge spinal needle after infiltrating the skin with 0.5-1 ml of injection 2 % lidocaine. After obtaining free flow of cerebrospinal fluid, the study drug was injected intrathecally. After administering the drug, spinal needle was taken out and patient were turned in the position appropriate for the surgery.

Heart rate, non invasive systolic and diastolic blood pressure, respiratory rate and oxygen saturation were recorded at two minutes interval for first 20 minutes from the time of injection of spinal solution and then every ten minutes for the complete period of surgery. The level of sensory block was determined by pinprick test every two minutes till the level has been established. Motor block of the lower extremities was measured according to the Modified Bromage Score (MBS) every two minutes till achievement of MBS 3. Patients with inadequate block requiring general anaesthesia were excluded from the study.

Side effects like hypotension (blood pressure <20% from base line), bradycardia (heart rate < 20 % of baseline), nausea/vomiting were recorded. Post operatively patients were shifted to the recovery room where the vital parameters ,time taken for full regression from sensory and motor block and time taken by patients for self voiding and ambulation was observed. Duration of sensory blockade was noted by assessing the level of sensory block after every 30 minutes until the time of regression to S2 dermatome. Motor block was assessed and graded at the end of surgery and then at 30 minutes interval using the Modified Bromage Score. Time until full return of lower extremity motor function was noted. The pain assessment was done using Visual Analogue Scale (VAS).

Statistical analysis:

The data was summarized using frequency of distribution and descriptive analysis. Chi square test was used to find the association of categorical variables. The *P* value <0.05 was considered significant.

Regression models were performed to assess association between the variables. Statistical analysis was performed using SPSS (Statistical Packages for Social Sciences version 21.0. Armonk, NY: IBM corp.)

RESULTS:

Seventy patients were enrolled in this study. Thirty five were assigned to the group A (bupivacaine), while thirty five were assigned to the group B(2-chloroprocaine) . There were no dropouts. The two groups were comparable in terms of demographic profile.

Table 1: Demographic profile of patients

Parameters	Group A (n=35)	Group B(n=35)	P value
Age (years)	45.8 13.8	43.5 14.4	0.5
Sex (male/female)	20/15	22/13	0.6
Height (cms)	153.51 4.37	155.63 3.20	0.06
Weight (kg)	66.29 10.78	66.31 7.79	0.9
ASA (I/II)	22/13	23/12	0.8

*ASA (American Society of Anaesthesiology). Data is expressed as Mean SD

The maximum upper level of sensory blockade attained in both the groups was T8 which was achieved faster in chloroprocaine group(5.26 minutes with SD of 1.15) compared to bupivacaine group (5.89 minutes in with a SD of 1.13) P value=0.03. There was no significant difference between the two groups in terms of time to attain bromage score of 3.

Intraoperatively, the mean heart rate in group A varied form 81.82 12.11 beats per minute(bpm) to 88.60 11.00 bpm and in group B, the mean heart rate varied from 82.30 5.68 bpm to 90.00 5.42 bpm (Fig 1). The difference in both the groups with regard to trend of change in pulse rate over time was statistically not significant, P value= 0.4.

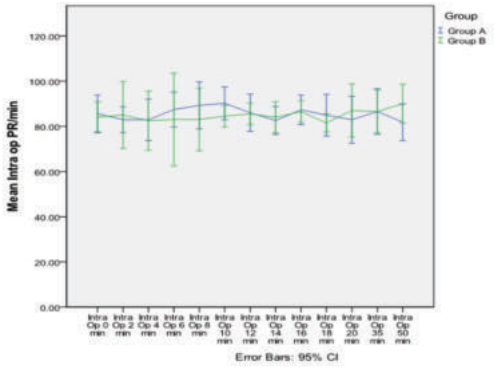

Fig 1: Intraoperative Pulse Rate (beats per minute) of patients in both groups

The incidence of intraoperative hypotension was significantly higher in bupivacaine group (40%) than chloroprocaine group (5.7%) P value=0.001 (Fig 2).

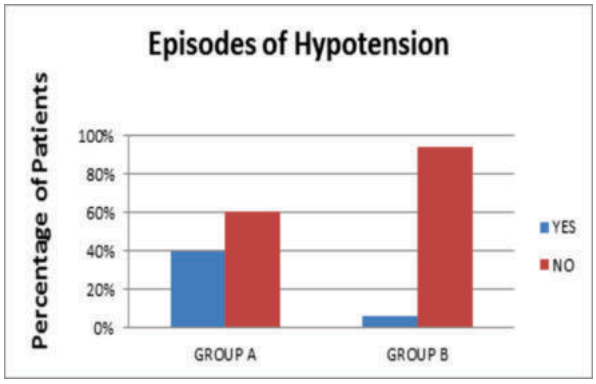

Fig 2: Distribution of patients having intraoperative hypotension

Post operatively at 60 minutes,full regression from sensory block was seen in 80% of patients in group chloroprocaine compared to group bupivacaine where 62.9% of patients showed sensory block regression only upto T12. P value <0.0001 (Fig 3).

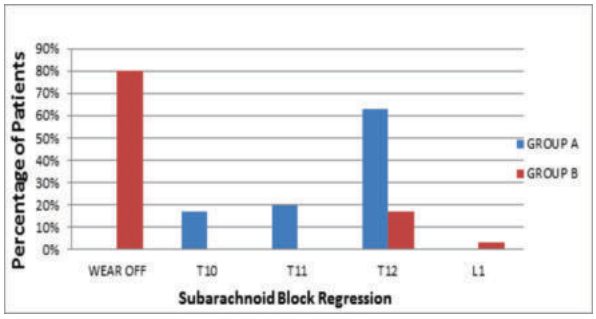

Fig 3: Sensory blockade regression post operative at 60 minutes both groups

The motor block regression was also seen faster in chloroprocaine group (Fig 4). Post operatively at 90 minutes Bromage scale 0 was seen in 42.9% patients in Group A compared to 83.3% in Group B. P value 0.014.

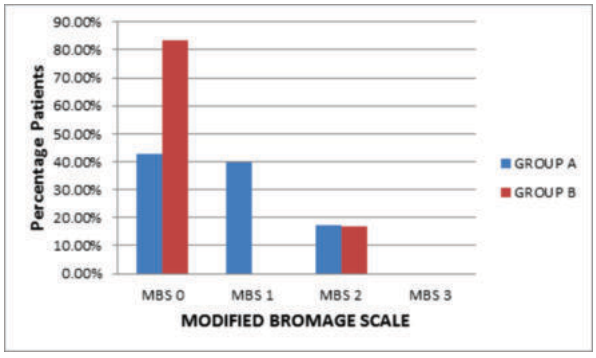

Fig 4: Motor blockade regression by assessing Modified Bromage Scale post operative at 90 minutes both groups.

The difference in post operative VAS score, time taken for spontaneous voiding and unassisted ambulation was statistically significant between the two groups. (Table 2)

Table 2: Time taken for spontaneous voiding, unassisted ambulation, Visual Analogue Scale

Post-op block characteristics	Group A (n=35)	Group B (n=35)	P value
Time taken for spontaneous voiding (mins)	136.43 18.82	85.60 20.06	<0.0001
Time taken for unassisted ambulation (mins)	150.86 22.41	107.14 16.19	<0.0001
Visual analogue scale at 120 minutes post op	3.20 0.96	4.40 1.01	<0.0001

Data is expressed as Mean SD

DISCUSSION:

Recent advances in anaesthetic and surgical techniques along with escalating health care costs have resulted in an ever increasing number of surgical procedures being performed on day care basis. A short acting local anaesthetic may be a very good alternative in this setting. An ideal anaesthetic for spinal anaesthesia in ambulatory surgery patients would provide rapid onset of action, adequate potency, predictable duration, and low neurotoxicity and systemic side effects.

Chloroprocaine was introduced in 1952 in order to replace lidocaine.[6] The drug was still questionable due to evidences of neurotoxicity due to the preservative sodium metabisulphite added to its preparation. All preservatives and antioxidants have now been removed from currently available preparations of CP.[7]

The first study of the use of chloroprocaine in a clinical setting was published by Palas. In this study 2-chloroprocaine 30 mg and 40 mg was successfully used for short surgical procedures under subarachnoid block in 500 patients without any complications.[8]

In our study, the demographic data such as age, weight, gender and height were comparable between the two groups and did not show any significant statistical difference. We found incidence of intraoperative

hypotension was significantly more with bupivcaine (40 %) compared to chloroprocaine (5.7%). Ankit et al also had studied the intraoperative hemodynamic perturbations with both the drugs. They found that incidence of intraoperative hypotension was much less with chloroprocaine (3.3%) compared to bupivacaine (10%).[9]

We found a statistically significant difference in the time taken for onset of sensory blockade in our study, (p =0.03). The mean time taken by bupivacaine was 5.89 minutes whereas it was 5.26 minutes by chloroprocaine. The maximum level of sensory blockade attained in both the groups was T8. Lacasse et al compared bupivacaine 7.5 mg with 2% chloroprocaine40 mg and both the drugs showed a mean of 6 minutes to reach maximum block height of T10.[10] Their findings do not correlate to our study .This could be attributed to difference in positioning after spinal or demographic profile of patients (Height).

On comparing the motor blockade, Modified Bromage score 3 (maximum motor blockade) was attained by mean time of 7.11 minutes by bupivacaine and by 7.03 minutes by chloroprocaine. It was comparable in both the groups. Ankit et alalso observed that time taken to Bromage score 3 by bupivacaine and chloroprocaine was comparable.[9]Their findings endorse our observations.

The post operative pain must be assessed and reassessed frequently and documented on the bedside chart of the patient. In our study post operatively, at 120 minutes we found a VAS score of 4-5 in chloroprocaine group and 2-3 in bupivacaine group. Ben et al compared 2 chloroprocaine and bupivacaine for ambulatory abdominal wall herniorrhaphy. Their study showed a VAS score of 4-6 in chloroprocaine group and 0-3 in bupivacaine group post operatively.[11] Thus our findings correlate to their findings.

Chloroprocaine showed a faster recovery from motor block favouring early ambulation and discharge from hospital. We found that in group A, 85.7% of the cases showed complete motor block regression by 120 minutes whereas in group B 83% of them showed complete block regression by 90 minutes. Sell et al concluded in their study that for 35 mg of chloroprocaine, the time taken until 90% of recovery of bromage score post operatively was 90-120 minutes.[12] This was similar to our observation.

We also noticed a faster resolution of sensory blockade in group B which took 60 to 90 minutes compared to group A which showed resolution of sensory blockade by 100-120 minutes. Yoos and Kopaczalso concluded resolution of sensory block by 113-120 minutes in chloroprocaine group and 190-220 minutes in bupivacaine group.[13] Our findings correlate to their observations.

We also observed that patients in group A took a longer time to ambulate which was 150.86 minutes with a standard deviation of 22.41 as compared to group B, in which the mean time taken to ambulate was 107.14 minutes with a standard deviation of 16.19. This difference was statistically significant. Camponovo et al concluded with similar findings that patients were able to ambulate after surgery after approximately 142.5 minutes in chloroprocaine group as compared to 290 minutes in bupivacaine group .[14]

The mean time taken for spontaneous micturation was significantly shorter in group B, which was 86.60 minutes with a standard deviation of 18.82 whereas in group A it was 136.43 with a standard deviation of 20.06 which concurs with the study conducted by Lacasse et al where a faster onset of micturation post op by 200 minutes in chloroprocaine group was compared to 219 minutes by bupivacaine group.[10]

There were no cases of incomplete block requiring supplemental analgesia. No cases of TNS were observed in our study.

Thus our principal findings were that spinal anaesthesia with 2-chloroprocaine can provide a satisfactory surgical block while permitting an earlier discharge from hospital than spinal bupivacaine. This advantage is due to a more rapid regression of the sensory and motor block, which helps patient ambulate and void faster.

CONCLUSION:

We conclude from our study that 1% 2-chloroprocaine has a faster onset of sensory blockade, it also displays a faster recovery from sensory and motor blockade, early ambulation, early voiding and henceforth early discharge as compared to 0.5% bupivacaine. Therefore intrathecal 2-chloroprocaine is proposed to be a better drug for spinal anaesthesia for short day care surgeries.

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