Section: Anaesthesia

Original Research Article

COMPARISON OF INTRATHECAL ISOBARIC CHLOROPROCAINE 1% AND 0.5% BUPIVACAINE HEAVY IN PATIENTS UNDERGOING DAY CARE SURGERIES –A PROSPECTIVE RANDOMISED DOUBLE BLIND STUDY

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Received : 20/07/2023
Received in revised form : 22/08/2023
Accepted : 05/09/2023

Keywords:
Intrathecal isobaric chloroprocaine 1%, 0.5% bupivacaine heavy, day care surgeries.

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DOI: 10.47009/jamp.2023.5.5.52

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2023; 5(5); 259-264

Abstract

Background: Spinal anesthesia is a safe and well-established technique for lower abdominal surgeries. Spinal anesthesia with chloroprocaine appears to be safe, reliable, and effective for short procedures with few complications. The aim of our study was to compare intrathecal chloroprocaine isobaric 1% with intrathecal bupivacaine heavy 0.5% for day care surgeries. **Materials and Methods:** This prospective randomized double blind study was conducted in Dept of Anaesthesiology in a Tertiary Care Hospital from 2017 to 2019. 60 ASA Grade I and Grade II patients who met inclusion and exclusion criteria who were undergoing short duration day care surgeries were selected. **Result:** The onset time of sensory and motor blockade with 1% chloroprocaine is lesser than that of 0.5% bupivacaine when used intrathecally. The two segment sensory regression time and motor recovery are faster with 1% chloroprocaine in comparison with 0.5% bupivacaine which was statistically significant. Ambulation time and urine voiding time were clinically and statistically lesser in chloroprocaine group compared to bupivacaine group. Hemodynamic stability though clinically insignificant, was better with chloroprocaine. **Conclusion:** Post-operative two segment regression time, urine voiding time and ambulation timewas significantly shorter in chloroprocaine group than bupivacaine group in patients undergoing day care surgeries.

INTRODUCTION

Sub arachnoid block is a type of central neuraxial block and also a form of regional anaesthesia involving injection of local anaesthetic agent along with permitted additives into sub arachnoid space.[1] Conventionally it is called spinal anaesthesia

Spinal anaesthesia is used to provide surgical anaesthesia for all procedures carried out on the lower part of the body. Indications being surgery on the lower limbs, perineum, pelvis, genitals, most urological procedures and orthopaedic lower limb procedures.[2]SAB is the most convenient anaesthetic technique that offers reduced stress response and improved pain relief.[3]

Bupivacaine is an amide type local anaesthetic agent which has longer duration of action. When it is used intrathecal, the duration of action ranges from 120 - 150 minutes with an onset time of 5 - 10 minutes. The post- operative recovery time for complete regression of motor blockade is more than 240 minutes which is not suitable for day care surgeries.

Chloroprocaine is a short acting local anaesthetic agent which is suitable and safe to be used in day care surgeries. It is an ester type local anaesthetic agent with shortest duration of action. After spinal administration of preservative free chloroprocaine, the motor blockade lasts for approximately 40 minutes with onset time of 3 to 5 minutes and time for ambulation is 90 minutes.

Since day care surgeries are quite popular in present time, we would like to compare chloroprocaine as the intrathecal local anaesthetic agent in comparison with that of bupivacaine and check for post-operative two segment regression time and ambulation time of both the drugs. Thus we take up this study whether 1% chloroprocaine will be suitable for day care surgeries in preference to bupivacaine.

ISSN(O): 2687-5365; ISSN(P): 2753-6556

MATERIALS AND METHODS

This prospective randomized double blind study was conducted in Department Of Anaesthesiology in a Tertiary Care Hospital from 2017 to 2019. After obtaining the approval from institutional review board and the ethical committee, 60 ASA Grade I and Grade II patients who met inclusion and exclusion criteria who were undergoing short duration day care surgeries were selected.

Sample Size Determination

The sample size was calculated with 5% level of significance and 80% power, the size varied from 14 to 36. To strengthen the power of the study the required sample size is rounded to 60; 30 for chloroprocaine group and 30 for bupivacaine group.

Sampling Technique

The patients will be randomly allocated into either chloroprocaine group (Group A) and bupivacaine group (Group B) using a sealed envelope technique which will be opened just before shifting the patient to the operation theatre.

GROUP A: Patients received 35 mg of preservative free, isobaric 1% chloroprocaine hydrochloride intrathecally (3.5 mL).

GROUP B: Patients received 1.5 ml of 0.5% bupivacaine heavy intrathecally.

Inclusion Criteria

- Age group 18 – 70 years
- ASA grade I, II of either sex
- Patients with BMI 20-35 kg/m2
- Patients undergoing elective surgery of short duration (≤60 min) day care surgeries.

Exclusion Criteria

- Patient refusal for the study
- Patients receiving anticoagulants or with coagulation disorders.
- Patients with infection at the site of administration of spinal anaesthesia
- Patients allergic to local anaesthetic agents
- Pregnant or lactating mothers

Materials Required

- A sterilized spinal set with 26 Gauge Quincke spinal needle
- Preservative free isobaric chloroprocaine 1% ampoule
- 0.5% heavy bupivacaine ampoule

Procedure

On the day before surgery, a thorough pre-anaesthetic Evaluation was done. Routine investigations such as complete blood count, random blood sugar were done. Electrocardiography was carried out in patients above 40yrs of age. An informed written consent was taken during pre-operative visit. Patients were advised fasting for 6hrs before surgery. During pre-operative visit, Bromagescalewas explained to the patients for intraoperative and postoperative motor block assessment.

The operating room is prepared beginning with the machine check protocol, all necessary drugs needed for the study and also emergency drugs needed for resuscitation were kept ready. Routine premedication which includes tablet Ranitidine 150 mg per oral and tablet Alprazolam 0.5 mg per oral were given the previous night and morning of surgery.

Once the patient was taken into the operation theatre patient identity was confirmed using WHO surgical safety checklist. Continuous monitoring of patients with pulse oximetry, non-invasive blood pressure measurement, and electrocardiography were done. Baseline vital parameters were noted. An 18G IV access was obtained and an IVnormal saline solution was started.

Drug Preparation and Blinding

Under all aseptic precautions, in sitting position parts were painted and draped. Injection 2% lidocaine 2-3 ml was injected into selected space lumbar (L) L3-4/L4-5 for local infiltration.

Subarachnoid block was performed using 26G Quincke spinal needle.The patients in Group A were administered 3.5 ml of 1% chloroprocaine isobaric. The patients in Group B were administered 1.5 ml of 0.5% bupivacaine heavy. These drugs were prepared and administered by an anaesthesiologist who was not involved in monitoring.The time at which injection is completed will be considered as zero time of study and all measurements will be recorded from this point. The level of sensory blockade achieved by the end of 5 minutes can be assessed by needle prick method and the time taken to achieve T10 level will be noted down. Motor blockade was assessed by modified Bromage Scale. The time taken to reach modified Bromage 3 was recorded. Thereafter the patient was observed for hemodynamic changes every 2.5 minutes for the first 15 minutes and 5 minutes until the end of surgery and thereafter for every 15 minutes till two segment regression of the block is achieved in post anaesthesia care unit.

All the patients were monitored in the post anaesthesia care unit until two segment regression is achieved and also regression of motor blockade i.e. Bromage scale 1.

Duration of the sensory blockade and motor blockade was considered from the time of intrathecal drug administration upto two segment regression of the block was achieved.

ISSN(O): 2687-5365; ISSN(P): 2753-6556

Figure 1: Chloroprocaine

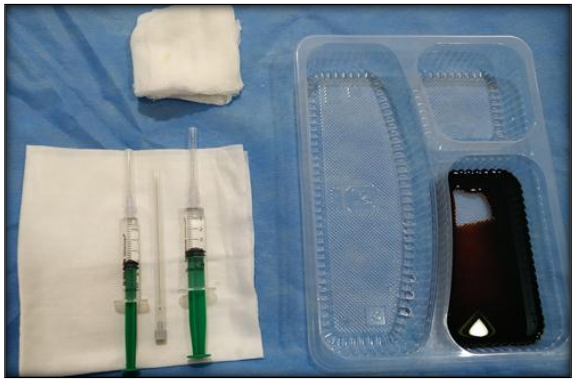

Figure 2: Spinal tray

The motor block was assessed using the modified Bromage scale

Immediate postoperative period: Patients were transferred to PACU. Need for rescue analgesia, regression of sensory and motor block, heart rate, blood pressure, oxygen saturation was monitored.

Rescue analgesics consists of injection Paracetamol 15mg/kg IV. If patient still complained of pain, injection Tramadol 1mg/kg IV was given. Injection Ondansetron 4 mg IV was given for patients who complained of nausea and vomiting.

Patients were discharged from the post anesthesia care unit (PACU) when they had attained all of the following criteria: a minimum 60-minute stay, stable vital signs, regression of the motor block (Bromage scale 0 to 2), no analgesia within the previous 20 min, and modified Aldrete score of >=9.

After discharge from the PACU, the patients were transferred to the wards where the nurses responsible for patient care were to undertake further management. The patients were offered clear liquids just over 2 hours after their arrival in the wards, and once they could tolerate liquids by mouth and feel a light touch to their legs, they will be asked to ambulate without assistance and success at walking were followed by an attempt to void if they were not catheterised.

Statistical Analysis: Qualitative data represented in the form of frequency and percentage. Association between variables was done with Chi Square test. Quantitative data represented using mean & Standard Unpaired t test was used to compare the mean difference between groups. A P value of <0.05 was considered statistically significant. IBM SPSS Version 22 for windows was used to do statistical analysis.

RESULTS

Both the groups were comparable with respect to age, height, weight, ASA grade, type of surgery and duration of surgery.

The independent 't' test result shows that there is a significant difference in mean of time to peak T10 sensory level (min) between the two groups. The group with chloroprocaine was taking less time to achieve T10 sensory level than group with bupivacaine (P<0.000).

The independent 't' test result shows that there is a significant difference in mean of time to reach motor Bromage 3(min) between the groups and the group with chloroprocaine takes less time time than group with bupivacaine (P<0.000).

The independent 't' test result shows that there is a significant difference in mean of time for two segment sensory regression (min) between the groups. The group with chloroprocaine (Group A) takes less time when compared to the group with bupivacaine (GroupB) (P< 0.000).

The independent 't' test result shows that there is a significant difference in mean of return to Bromage 0 (min) between the groups. The group with Chloroprocaine takes less time for regression to Bromage 0 than group with bupivacaine (P<0.000). [Table 1]

The results show that there is a significant difference in motor (Bromage scale) between the groups at 5,10, 45, 60,75, 90 minutes. [Table 2]

Heart rate noted in bupivacaine group was less compared to chloroprocaine group which was statistically significant after 45 minutes of administration of drug which was clinically not significant.

The mean (SD) systolic blood pressure at baseline between the two groups was not statistically significant and hence were comparable.

The SBP in chloroprocaine group reduced from 127±5.46 to 120.7±16.3 mm of Hg at the end of 10 minutes.

The SBP in bupivacaine group reduced from 129±2.27 to 111.8±19.6 mm of Hg at the end of 10 minutes of administration of drug.

Systolic blood pressure was measured in both the groups for the next 120 minutes and was found to be

ISSN(O): 2687-5365; ISSN(P): 2753-6556

significantly reduced in bupivacaine group when compared to that of chloroprocaine group.

The diastolic blood pressure in the chloroprocaine group reduced from 77± 7.6 mm of Hg to 68± 6.0 mm of Hg after 10 minute of administration of the drug.

The diastolic blood pressure in bupivacaine group reduced from 76.7±5.1 to 62.9±11.1 mm of Hg at the end of 10 minutes of sub-arachnoid block.

Diastolic blood pressure was measured for the next 120 minutes in both the groups and was found to be statistically significant where the diastolic pressure reduced less in chloroprocaine group than bupivacaine group.

The Mean blood pressure at baseline and at 5 minutes between the two groups was not statistically significant but at 1, 3, 10, 15, 20, 30 minutes and 15minutes interval thereafter upto 120 minutes was statistically significant. [Table 3]

The unpaired 't' test result shows that there is significant difference in mean of time to micturition (min) between the groups (P<0.000). [Table 4]

Table 1: Comparison of weight (in kg), height (in cm) and BMI between the two groups

Parameters	Group-A	Group-B	Unpaired t Test P Value	Significance
Height (in cm)	161.4 ± 5.72	162.47 ± 5.8	0.476	NS
Weight (in kg)	60.03 ± 6.72	61.83 ± 7.44	0.329	NS
BMI	23.07 ± 2.56	23.55 ±3.52	0.545	NS

Table 2: Comparison of motor blockade (BROMAGE SCALE) between the two groups

Modified Bromage scale	Group-A	Group-B	Unpaired t Test P Value	Significance
On arrival	0	0		
At SAB	0	0		
1 min	1	1		
3 Min	2.03 ± 0.18	1.96 ± 0.18	.163	NS
5 Min	2.5 ± 0.51	2.17 ± 0.38	.006	HS
10 Min	3.0 ±00	2.8 ± 0.41	.009	HS
15 Min	3.0± 00	3.0± 00		
20 Min	3.0± 00	3.0± 00		
30 Min	3.0± 00	3.0± 00		
45 Min	2.33 ± 0.48	3.0 ± 00	.000	HS
60 Min	1.6 ± 0.5	3.0 ± 00	.000	HS
75 Min	0.8 ±0.55	3.0 ± 00	.000	HS
90 Min	0.067 ±0.25	3.0± 00	.000	HS
105 Min	0	3.0± 00		
120 Min	0	3.0± 00		
HS = Highly Significant				

Table 3: Comparison of mean heart rate (beats per minute) between the two groups (unpaired t-Test)

HR	Group-A	Group-B	Unpaired t Test P Value	Significance
Base line	83.0 ± 13.7	79.6 ± 14.2	0.343	NS
At SAB	80.6 ±12.8	78.2 ± 11.7	.451	NS
1 min	79.1 ±12.5	80.6 ±10.2	.613	NS
3 Min	79.4 ± 12.1	79.8 ± 12.2	.890	NS
5 Min	77.4 ± 12.0	75.9 ± 9.2	.588	NS
10 Min	77.0 ± 12.2	73.8 ± 9.1	.177	NS
15 Min	77.0 ± 12.2	73.8 ± 9.4	0.27	NS
20 Min	76.9 ± 11.7	72.1 ± 11.2	0.114	NS
30 Min	76.4 ± 11.7	71.3 ± 11.7	0.098	NS
45 Min	76.9 ±12.2	69.2 ± 11.3	.017	S
60 Min	77.6 ± 11.3	67.7 ± 12.4	.002	HS
75 Min	79.1 ± 11.2	75.6 ±13.0	.277	NS
90 Min	79.0 ± 10.2	73.0 ± 11.8	.038	S
105 Min	78.6 ± 10.4	74.9 ± 13.1	0.239	NS
120 Min	78.1 ± 9.8	73.5 ± 12.6	0.123	NS
HS = Highly Significant				

Table 4: Urine voiding time between the two groups

Urine voiding time (in minutes)			
Group-A	**Group-B**	**Unpaired t Test P Value**	**Significance**
156.0 ± 10.2	251.6 ± 13.3	0.000	HS

Table 5: Ambulatory time between the two groups

Ambulatory time (in minutes)			
Group-A	**Group-B**	**Unpaired t Test P Value**	**Significance**
103.6 ± 13.3	266.7 ± 15.2	0.000	HS

ISSN(O): 2687-5365; ISSN(P): 2753-6556

The unpaired 't' test result shows that there is significant difference in mean of time to ambulation (min) between the two groups (P<0.000).

DISCUSSION

Both groups were comparable and there was no statistically significant difference with regards to mean age, weight, height, duration and type of surgery.

In our study, mean time for onset of sensory block in chloroprocaine group was 3.7 ± 1.15 and bupivacaine group was 5.60±1.75.

The mean time for onset of motor blockade in group chloroprocaine was 5.75 ± 1.4 minutes and group bupivacaine was 7.97 ± 1.9 minutes.

There was statistically significant difference with regard to onset of sensory and motor blockade between the two groups. However clinically the difference was insignificant. C Camponovo et al,[4] conducted a study in 130 patients undergoing lower abdominal or lower limb surgeries and concluded that the time of onset of motor and sensory blockade in chloroprocaine group was faster than bupivacaine group with a difference of 1 minute which was clinically not significant. This study coincides with that of our study.

Jessica R. Yoos et al5 conducted a double-blind, randomized, crossover, volunteer study to compare 40 mg of 2-chloroprocaine with small-dose (7.5 mg) bupivacaine and concluded that there was no significant difference in time to peak sensory and motor blockade between the two drugs. This observation differs from our study but the difference maybe because they conducted the study on human volunteers with sample size of 4 in each group. Hence the result may not be convincing.

These patients were assessed for the post-operative two segment regression time and it was observed that patients who received intrathecal chloroprocaine had two segment sensory regression in 45.27 ± 4.79 minutes when compared to intrathecal bupivacaine which was 109.97 ± 18.96 minutes and it was statistically and clinically significant. In the study conducted by C Camponovo et al,[4] in 130 patients undergoing lower abdominal or lower limb surgeries and concluded that the time for two segment sensory regression from highest sensory level in chloroprocaine group was faster in comparison with bupivacaine group which was statistically significant. This matches with our study.

Yoos and Kopacz5conducted a volunteer study and concluded that two segment sensory regression was significantly shorter for chloroprocaine (40 mg) group which was 45 ± 20 minutes in comparison with bupivacaine (7.5 mg) which was 74 ± 20 minutes. Our result correlates with above mentioned study.

The mean duration of motor block (time for complete motor recovery) in group chloroprocaine was 81.63 ± 7.09 minutes and in group bupivacaine was 191.43 ± 29.46 minutes. This was statistically significant with P<0.000

C Camponovo et al,[4] in the year 2014 conducted a study in 130 patients undergoing lower limb or abdominal surgeries between 50 mg chloroprocaine 1% and 10 mg plain bupivacaine 0.5% where they concluded that the mean time for complete motor recovery in chloroprocaine group was 100 minutes and that of bupivacaine was 210 minutes which was statistically significant. This correlates with our study mentioned above.

An Teunkens et al,[6] in the year 2016 conducted a randomized controlled clinical trial and included 99 patients scheduled for diagnostic knee arthroscopy where the patients received 40 mg of 1% preservative free plain 2-chloroprocaineintrathecally; patients in the lidocaine group received 40 mg of 1% plain lidocaine,whereas patients in the bupivacaine group received 7.5 mg of 0.5 % plain bupivacaine as intrathecal anaesthetic and concluded that the median time for complete motor recovery was 88.8 minutes in chloroprocaine group , 109.8 minutes in lidocaine group and 195 minutes in bupivacaine group. This was statistically significant and their results regarding complete motor recovery are similar to our results as far as chloroprocaine and bupivacaine are concerned.

Yoos and Kopacz,[5] in the year 2005 conducted a volunteer study and concluded that the mean time for complete motor recovery was 81±15 min for chloroprocaine group (40 mg) and 138±24 minutes in bupivacaine (7.5 mg) group which was statistically significant. This correlates with our study.

Not many studies have compared the hemodynamic changes between the groups. In the present study, heart rate noted in bupivacaine group was less compared to chloroprocaine group which was statistically significant after 45 minutes of administration of the drug. But none of the patient in either group required pharmacological treatment as it was clinically not significant.

The mean (SD) systolic blood pressure at baseline between the two groups was not statistically significant and hence were comparable.

The SBP in chloroprocaine group reduced from 127±5.46 to 120.7±16.3 minutes at the end of 10 minutes.

The SBP in bupivacaine group reduced from 129±2.27 to 111.8±19.6 minutes at the end of 10 minutes of administration of drug.

Systolic blood pressure was measured in both the groups for the next 120 minutes and was found to be significantly reduced in bupivacaine group when compared to that of chloroprocaine group.

The diastolic blood pressure in the chloroprocaine group reduced from 77± 7.6 to 68± 6.0 mm of Hg after 10 minute of administration of the drug.

ISSN(O): 2687-5365; ISSN(P): 2753-6556

The diastolic blood pressure in bupivacaine group reduced from 76.7±5.1 to 62.9±11.1 mm of Hg at the end of 10 minutes of sub-arachnoid block.
Diastolic blood pressure was measured for the next 120 minutes in both the groups and was found to be statistically significant where the diastolic pressure reduced less in chloroprocaine group than bupivacaine group.
Though these hemodynamic changes were found to be statistically significant, but clinically they were not significant and pharmacologically did not require any intervention.
In our study the time taken for unsupported ambulation in chloroprocaine group was 103.6±13.3 minutes and that of bupivacaine group was 266.7±15.2 minutes which was statistically and clinically highly significant.
An Teunkens et al6 in the year 2016 conducted a randomized controlled clinical trial included 99 patients scheduled for diagnostic knee arthroscopy where the patients received 40 mg of preservative free plain 2- chloroprocaineintrathecally , patients in bupivacaine group received 7.5 mg of 0.5% plain bupivacaine as intrathecal anaesthetic and concluded that the median time for unassisted ambulation in chloroprocaine group was 192 (168 – 228) minutes and in bupivacaine group was 282 (234 – 342) minutes which was statistically significant. These results were in agreement to our study.
C. Camponovo et al4 conducted a study in 130 patients undergoing lower abdominal or lower limb procedures between 1% 2-chloroprocaine (50 mg) and bupivacaine 0.5% (10 mg) and concluded that the mean time for unassisted ambulation for chloroprocaine group was 142.5 minutes and that of bupivacaine group was 290.5 minutes which was statistically significant. Once again this matches the results of our study.
However the dose of chloroprocaine used in this study was 50 mg but in our study the dose of chloroprocaine used was 35 mg. Hence the time for unassisted ambulation in our study was slightly lesser i.e.103.6±13.3 minutes when compared to the above study.
The time taken for post operative urine voiding time in our study was 156.0±10.2 minutes in chloroprocaine group and that of bupivacaine group was 251.6± 13.3 minutes which was statistically and clinically highly significant.
Yoos and Kopacz,[5] in the year 2005 conducted a volunteer study and concluded that the mean time for post operative urine voiding time was 103±12 min for chloroprocaine group (40 mg) and 156±23 minutes in bupivacaine (7.5 mg) group which was statistically significant. This study matches with our study mentioned above.
However there are not many studies conducted comparing postoperative urine voiding time between chloroprocaine 1% and bupivacaine 0.5%.

CONCLUSION

Hence we conclude that 1% preservative free chloroprocaine is a better alternative compared to 0.5% bupivacaine for day care sub arachnoid blocks for the surgeries lasting lesser than 60 minutes.

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ISSN(O): 2687-5365; ISSN(P): 2753-6556