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Original Research Article

A Comparative Study between Chlorprocaine and Bupivacaine for Spinal Anaesthesia in Short Duration Obstetric and Gynaecological Procedures

Sujeet Baban Kolhe[1], Kirti Arvind Kundalwal[2], Prajakta Madhukar Tayade[3], Nanasaheb Khandu Bhangare[4]

[1,2,3]Department of Anaesthesiology, BJGMC and Sassoon General Hospitals, Pune, Maharashtra, India
[4]Department of Pharmacology, Bharatratna Atal Bihari Vajpayee Medical College and Hospital, Pune, Maharashtra, India

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Corresponding Author: Dr. Nanasaheb Khandu Bhangare
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Abstract:

Background: Spinal anaesthesia is a commonly performed anaesthetic technique. An ideal spinal anaesthetic drug/ drugs for short-duration surgeries should have rapid onset of action and faster offset/ regression of spinal block so as to early discharge and minimal postoperative side effects. In addition, adequate postoperative pain control is one of the most important factor in determining safe discharge after surgery. Hence the present study was done at our tertiary care centre to compare the duration of sensory and motor blockade and complications of chlorprocaine with that of bupivacaine for spinal anaesthesia in obstetric gynaecological procedures.

Aims and Objectives: To compare the action of intrathecal hyperbaric 0.5% bupivacaine and 1% isobaric chlorprocaine for spinal anaesthesia in short duration obstetric and gynaecological procedures less than 1 hour. The primary objectives were to compare the onset and duration of sensory block, motor block and the voiding time. The secondary objectives were to compare the hemodynamic effects. (systolic BP, diastolic BP and heart rate).

Methods: A hospital based double blind, prospective, randomized study was undertaken on 90 patients to compare the efficacy of intrathecal hyperbaric 0.5% bupivacaine and 1% isobaric chlorprocaine for spinal anaesthesia in short duration obstetric and gynaecological procedures less than 1 hour.

Results: The mean duration of motor block was significantly lower for chlorprocaine (107.60±15.48 mins vs 63.81±7.52 mins) ($p<0.05$). The mean duration of sensory block was significantly less for chlorprocaine (161.61±7.49 mins vs. 81.32±10.06 mins; $p<0.05$). The time taken for ambulation was significantly more for bupivacaine (263.04±29.08 mins vs. 225.44±29.48 mins; $p<0.05$). The time taken for voiding of urine was significantly more for bupivacaine (336.13±19.76 mins vs. 276.49±23.99 mins; $p<0.05$).

Conclusion: Chlorprocaine provides satisfactory surgical block, has significantly faster regression of block, earlier ambulation, and voiding, and hence facilitates the faster discharge of the patient from the hospital as compared to intrathecal bupivacaine following spinal anaesthesia in short duration obstetric and gynaecological procedures.

Keywords: Chlorprocaine, Bupivacaine, Spinal Anaesthesia, obstetric and Gynaecological procedures, Sensory block, Motor Block, Voiding time, Ambulation time.

Introduction

Spinal anaesthesia is a commonly performed anaesthetic technique. The most common complication associated with the spinal anaesthesia is hypotension with an incidence of 25%-80%. [4] Nausea and vomiting constitutes a most common anaesthesia related undesirable event. Its reported incidence varies between 20-80%. [5] It may at times lead to serious complications like Mallory Weiss syndrome and esophageal rupture. [6]

Spinal anaesthesia is a time tested, safe, and reliable anaesthetic technique for surgery of the lower abdomen and lower limbs. An ideal spinal anaesthetic drug / drugs for short-duration surgeries should have rapid onset of action and faster offset/ regression of spinal block so as to early discharge and minimal postoperative side effects. [1,2] In addition, adequate postoperative pain control is one of the most important factor in determining safe discharge after surgery. [3]

Bupivacaine is the most commonly used drug for spinal anaesthesia. [7] Bupivacaine hydrochloride (HCL) is an aminoacyl LA. Hyperbaric bupivacaine

(HB): a formulation with density heavier than CSF. HB is made dense by the addition of glucose (80 mg/mL) to isobaric or plain bupivacaine. Duration of action of intrathecal hyperbaric bupivacaine is 130-230 minutes depending on, patient related factors (age, Height, CSF volume, pregnancy), position of the patient.[8] Chlorprocaine is an ester class local anesthetic and is indicated for neuraxial anesthesia (caudal, epidural, and spinal) and peripheral nerve blocks and obstetric anesthesia (pudendal and paracervical blocks). The most common application for chlorprocaine is the obstetric setting, where it is used to provide fast onset epidural anesthesia when urgent or emergent cesarean delivery is indicated. [9,10] Large doses of chlorprocaine can be administered in this setting because of the low potential for maternal and fetal toxicity. [11]

Chlorprocaine causes reversible nerve conduction blockade by decreasing nerve membrane permeability to sodium. [12] Chlorprocaine has a pKa greater than lidocaine, ropivacaine, bupivacaine, and mepivacaine, yet it can provide faster onset epidural anesthesia.Chlorprocaine has the lowest protein binding of all clinically used local anesthetics and is amongst the shortest in duration of action. [13]

This study aims to compare 0.5% hyperbaric bupivacaine with 1% isobaric chlorprocaine in short duration obstetric and gynaecological procedures in terms of sensory and motor action, voiding time, time to ambulation.

The primary objectives were to compare the onset and duration of sensory block, motor block and the voiding time. The secondary objectives were to compare the hemodynamic effects. (systolic BP, diastolic BP and heart rate).

Methods

It was a prospective randomized double blind study. After obtaining ethical committee clearance and written informed consent from each patient, 90 patients between the age group of 18-50 years and ASA status 1 and 2, undergoing short duration obstetric and gynaecological procedures were studied. The study was conducted in a tertiary care hospital. Sample size was calculated from a pilot study of 20 patients receiving spinal anaesthesia for short duration Obstetric and gynaecological procedures, mean time to total regression of motor block was 119min with standard deviation of 93. Considering 95% of confidence level and 80% of power of study to achieve 60 min of effect size, minimum of 37 patients was required per group. Considering dropout, the study was conducted with 45 patients per group.

The data was analysed using SPSS version 20.0. Comparison of quantitative data measured between group category (Group A and B) was done using unpaired t-test and p-value < 0.05 was considered statistically significant.

Inclusion criteria

- Dilatation and evacuation
- Dilatation & Curettage
- MTP
- Cervical biopsy
- Cervical encirclage
- Hysteroscopy

Exclusion criteria:

- History of asthma, HT, IHD or DM
- Severe renal, pulmonary or hepatic, Cardiac disorders
- Raised intracranial pressure.
- Drug allergy to present drug.
- Bleeding disorders
- Infection at spinal site.
- Patient refusal
- Spine abnormalities

The procedure was carried out in the morning with patient fasting over night for at least 8 hours. On arrival in the operation theatre, the intravenous line was inserted using 20G cannula. The multipara monitor was connected to the patient, Monitoring of Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Heart rate (HR), Electrocardiogram (ECG) and hemoglobin oxygen saturation (SpO2) were observed and recorded prior to induction and throughout the procedure.

After starting intravenous line, all patients received pre-anaesthetic medications with Inj. Ondansetron 4 mg IV just before the start of the procedure. All patients received Inj. Midazolam 0.03 mg/kg iv for anxiolysis. All the patients were preloaded with fluid with 10ml/kg of crystalloid solution.

Spinal Anaesthesia was induced with either3ml of 0.5% hyperbaric bupivacaine or 3 ml 1% isobaric chlorprocaine. Anaesthesia level up to level T10 was achieved.

Spinal anaesthesia was given in sitting position. Vital parameters were recorded again and level of the action of the drug was checked. All the patients were ventilated with oxygen using venturi mask. All operative procedures were performed by highly experience surgeons.

All patients were monitored and Pulse, Blood Pressure, Modified Bromage Scale, number of analgesic doses required and side effects if any were recorded in all patients at regular interval postoperatively. The loss of pinprick feeling was used to determine sensory block. The Modified Bromage Scale was used to assess motor block. Patients who had no effect or had an insufficient spinal anesthetic effect were given general anesthesia and were removed from the research. The

loss of pinprick feeling at T12 with a Modified Bromage score of 2 was considered the commencement of surgical anesthesia. Sensory and motor block progression was tracked every 3 min for the first 15 min, and then every 5 min for the next 15 min, then every 15 min for the next 30 min until the sensory block had regressed to the S2 dermatome.

Depth of sensory, motor action, post op voiding time and complications if any were noted.

Block failure was defined as the inability to achieve a sensory block at T12 within 30 min of spinal injection. The patient's BP (both systolic and diastolic), ECG, and pulse oximeter values were all taken and noted during the operation. Hypotension was defined as a drop in SBP/MAP of more than 25% from baseline and was treated with IV fluid and if necessary with IV mephentermine 6 mg. If necessary, the vasopressor medication was repeated, and total dose was recorded. Patients were given 0.6 mg IV atropine if their HR dropped below 50 beats/min and this treatment was repeated if necessary. The amount of time taken to ambulate (walk without assistance) and void urine was recorded.

The results were analysed statistically using appropriate tests.

Results

Demographic parameters Age and ASA grading of the patients were not significant according to chi square test ($p>0.05$). Also hemodynamic parameters (Systolic Blood Pressure, Diastolic Blood Pressure, Heart rate) were also not significant according to unpaired t-test.

The mean onset time of sensory block (Table:1) was significantly faster in Group B compared to Group A as per Student t-test (4.76±0.30 mins vs. 3.37 ± 0.18 mins; $p<0.05$).

Table 1: Comparison of Onset Time of Sensory Block in both groups

	Group A		Group B		p Value
	Mean	**SD**	**Mean**	**SD**	
Onset Time of Sensory Block (mins)	4.76	0.30	3.37	0.18	**<0.05**(< 0.0001)

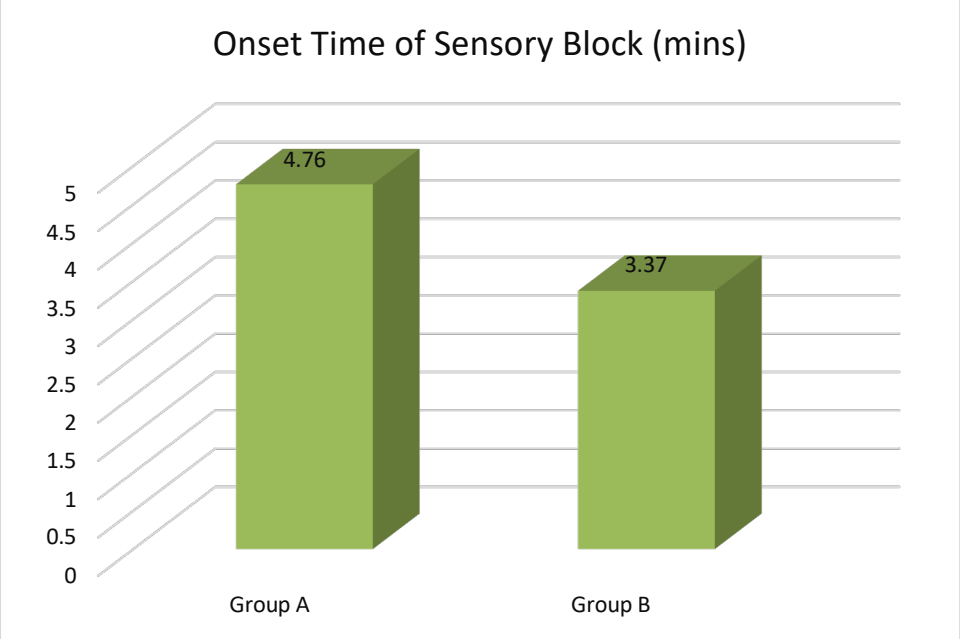

Figure 1:

The onset time of motor block (Table: 2) was significantly faster in Group B compared to Group A as per Student t-test (6.27±0.65 mins vs. 4.92±0.64 mins; **p<0.05**).

Table 2: Comparison of Onset Time of Motor Block in both groups

	Group A		Group B		p Value
	Mean	**SD**	**Mean**	**SD**	
Onset Time of Motor Block (mins)	6.27	0.65	4.92	0.64	**<0.05**(< 0.0001)

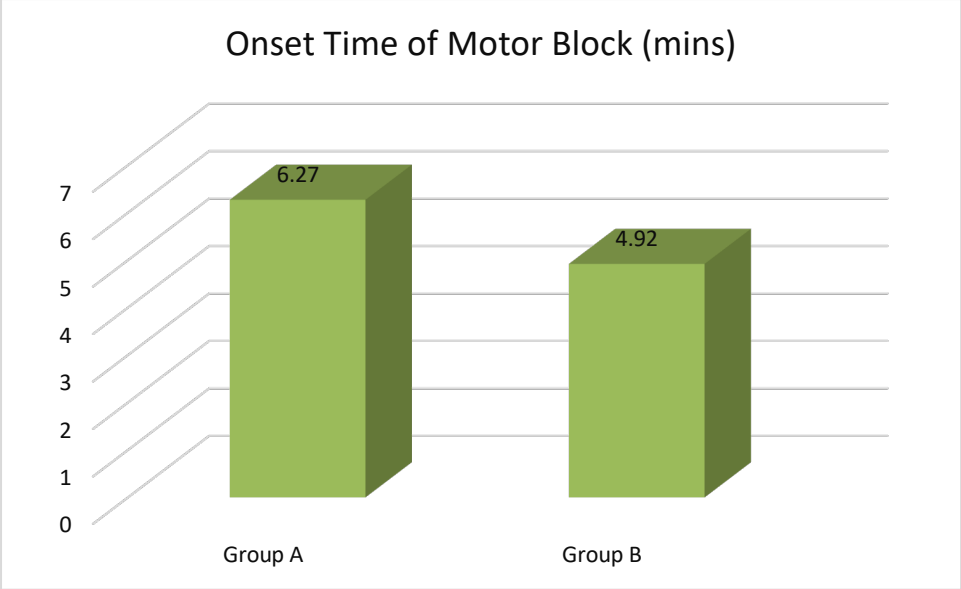

Figure 2:

The mean duration of motor block (Table: 3) was significantly lower in Group A as compared to Group B (107.60±15.48 mins vs 63.81±7.52 mins) as per Student t-test (**p<0.05**).

Table 3: Comparison of Duration of Motor Block in both groups

Parameter	Group A		Group B		p Value
	Mean	SD	Mean	SD	
Duration of Motor Block (mins)	107.60	15.48	63.81	7.52	**<0.05**(< 0.0001)

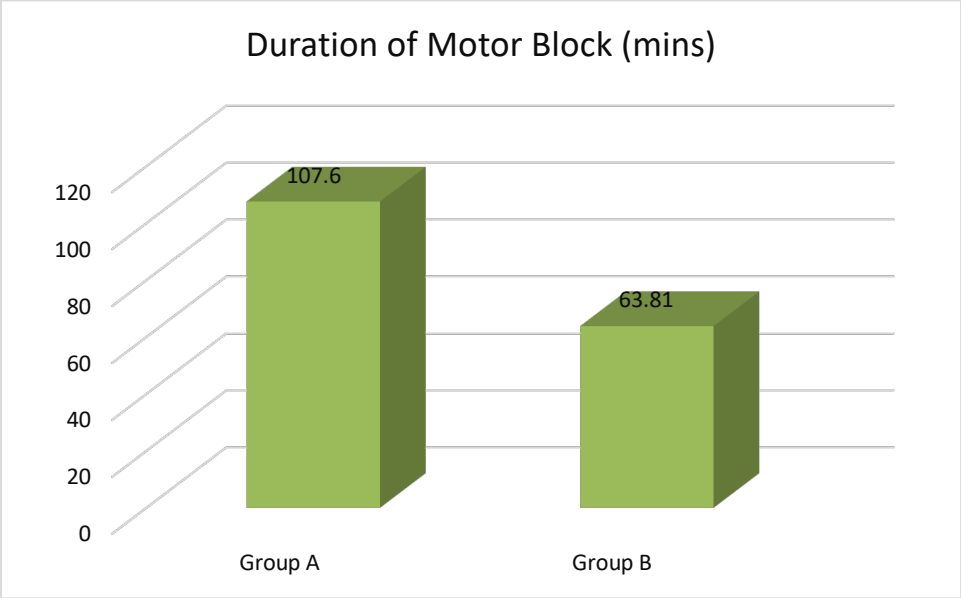

Figure 3:

The mean duration of sensory block (Table:4) was significantly longer in Group A as compared to Group B as per Student t-test (161.61±7.49 mins vs. 81.32±10.06 mins; **p<0.05**).

Table 4: Comparison of Duration of Sensory Block in both groups

	Group A		Group B		p Value
	Mean	SD	Mean	SD	
Duration of Sensory Block (mins)	161.61	7.49	81.32	10.06	**<0.05**(< 0.0001)

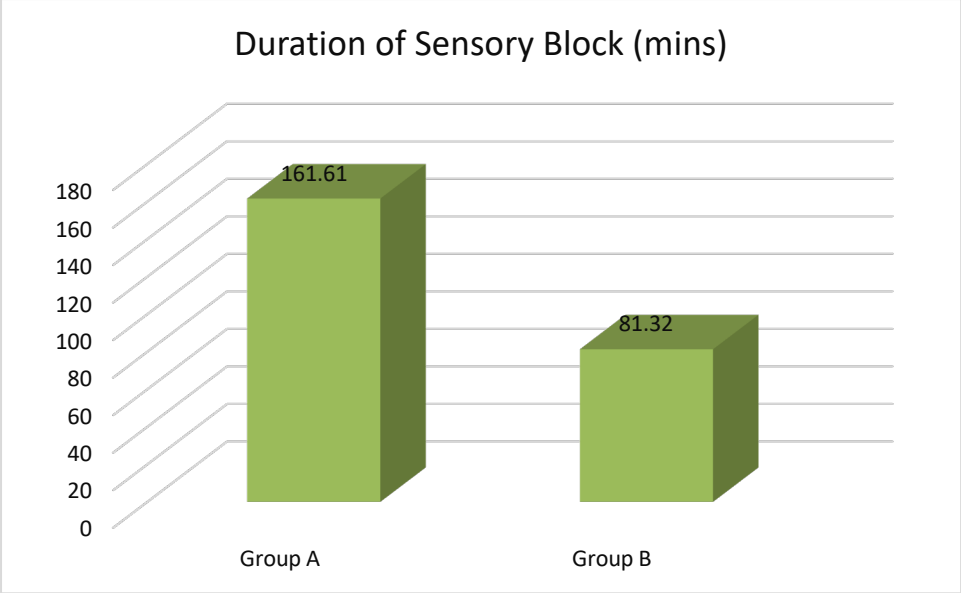

Figure 4:

The time taken for ambulation (Table: 5) was significantly more in Group A compared to Group B as per Student t-test (263.04±29.08 mins vs. 225.44±29.48 mins; **p<0.05**).

Table5: Comparison of Time Duration taken for Ambulation in both groups

	Group A		Group B		p Value
	Mean	SD	Mean	SD	
Time taken for Ambulation (mins)	263.04	29.08	225.44	29.48	**<0.05**(< 0.0001)

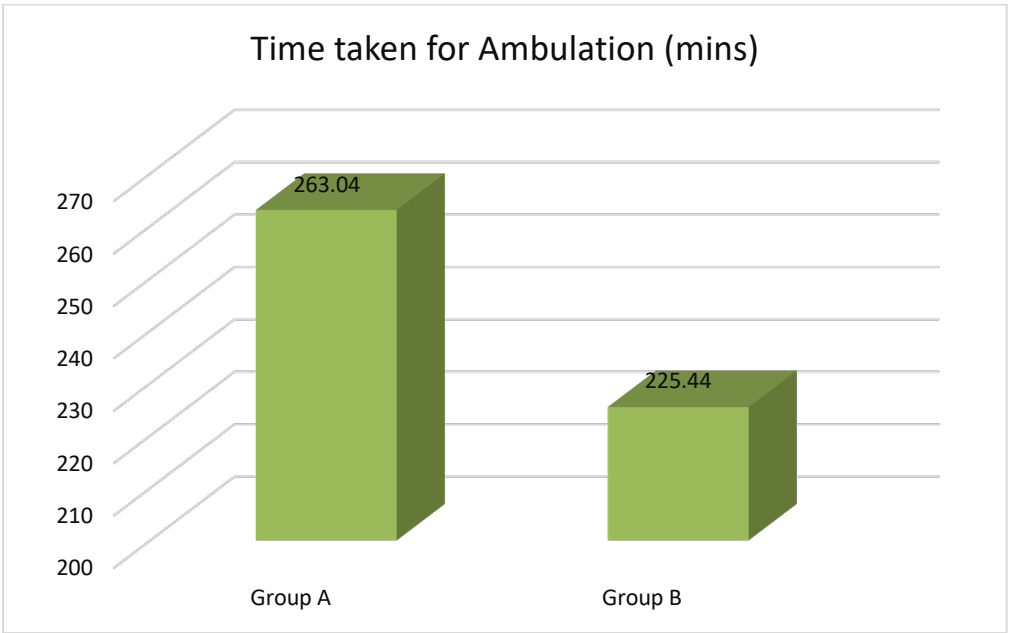

Figure 5:

The time taken for voiding of urine (Table: 6) was significantly more in Group A compared to Group B as per Student t-test (336.13±19.76 mins vs. 276.49±23.99 mins; **p<0.05**).

Table6: Comparison of Time Duration taken for Voiding of Urine in both groups

	Group A		Group B		p Value
	Mean	SD	Mean	SD	
Time taken for Voiding of urine (mins)	336.13	19.76	276.49	23.99	**<0.05**(< 0.0001)

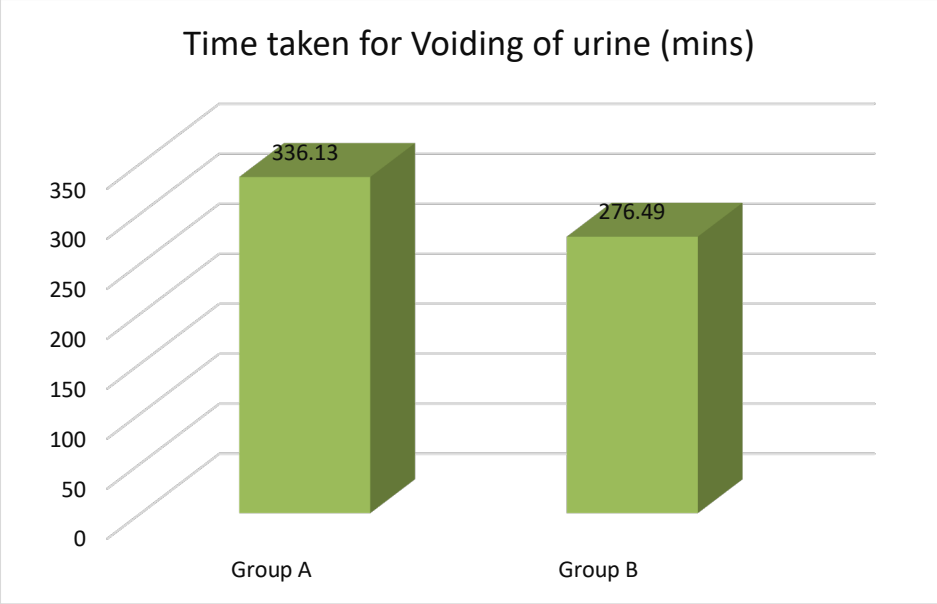

Figure 6:

There was no significant difference with respect to intraoperative and post-operative complications. (Table 7 and 8)

Table 7: Distribution of patients according to Intra-Operative Complications in both groups

Intra-operative complications	Group A		Group B		p Value
	N	%	N	%	
Hypotension	4	8.8%	3	6.6%	>0.05 (0.2290)
Bradycardia	3	6.6%	2	4.4%	
Nausea\Vomiting	2	4.4%	2	4.4%	
Shivering	1	2.2%	2	4.4%	

Table 8: Distribution of patients according to Post-Operative Complications in both groups

Post-operative complications	Group A		Group B		p Value
	N	%	N	%	
Hypotension	5	11.1%	4	8.8%	>0.05 (0.3288)
Bradycardia	3	6.6%	4	8.8%	
Nausea\Vomiting	3	6.6%	2	4.4%	
Delayed respiratory depression	2	4.4%	1	2.2%	

Discussion

It was observed in the present study that the mean onset time of sensory block was significantly faster in Group B compared to Group A as per Student t-test (4.76±0.30 mins vs. 3.37 ± 0.18 mins; **p<0.05**). This is comparable to the studies of Lacasse MA et al [14] in ambulatory surgeries, Ghisi D et al [15] in lower limb sureries and Thomas Set al [16] in gynaecological surgeries.

It was observed in our study that the onset time of motor block was significantly faster in Group B compared to Group A as per Student t-test (6.27±0.65 mins vs. 4.92±0.64 mins; **p<0.05**). Thomas Set al [16] noted similar observations in their study. Thomas Set al [16] randomized single-blinded study In the 2CP and bupivacaine groups, the meantime for onset of motor block was 4.92 and 6.27 min, respectively, which was statistically significant and motor onset was considerably faster in the 2CP group and resolution of motor blockade was 1.7 times faster in the 2CP group than in the bupivacaine group.

In the present study, the mean duration of motor block was significantly lower in Group A as compared to Group B (107.60±15.48 mins vs 63.81±7.52 mins) as per Student t-test (p<0.05). This is concordant to the studies of Lacasse MA et al [14] and Thomas S et al [16].

Lacasse MA et al [14] study found duration of the motor block was significantly shorter in the 2-CP group. Successful spinal anesthesia was attained in all patients, which was defined as the ability to complete the surgery without the need for general anesthesia. In our study, the mean duration of sensory block was significantly longer in Group A as compared to Group B as per Student t-test

(161.61±7.49 mins vs. 81.32±10.06 mins; p<0.05). Similar findings were observed by Thomas S et al [16], Lacasse MA et al14, Ghisi D et al15 and Mathur V et al [17].

Thomas S et al [16] randomized single-blinded study showed in the 2CP and bupivacaine groups, the meantime to ambulate was 225.44 min and 263.04 min, respectively and the finding revealed a statistically significant increase in ambulation time in the bupivacaine group. Time taken for ambulation was delayed significantly in the bupivacaine group, i.e., 263.04 ± 29.08 min compared to the 2CP group, i.e., 225.44 ± 29.48 min, which was a delay of almost 38 min.

Lacasse MA et al [14] study showed regression of the block to L1 was almost 50% faster in the 2-CP group than in the bupivacaine group (82 min vs 160 min, respectively, a difference of 79 min). The time for complete regression to S2 in the 2-CP group was less than half that of the bupivacaine group (146 min vs 329 min, respectively, a difference of 185 min. However, in terms of discharge criteria, the time to ambulation, micturition and eligibility for discharge were all significantly shorter in the 2-CP group.

In the present study, the time taken for voiding of urine was significantly more in Group A compared to Group B as per Student t-test (336.13±19.76 mins vs. 276.49±23.99 mins; **p<0.05**). Delayed discharge due to urinary retention was particularly problematic in the bupivacaine group. This is similar to the studies of Ghisi D et al [15], Thomas S et al [16], Mims SC et al [18], Herndon CL et al [19], Mathur V et al [20] and Lacasse MA et al [14].

Thomas S et al [16] randomized single-blinded study showed average time it took to void urine was 276.49 min in the 2CP and bupivacaine groups; the time was 336.13 min and 336.13 min, respectively and time taken for voiding of urine was significantly longer in the bupivacaine group.

Lacasse MA et al [14] study comparing 2-CP with bupivacaine for spinal anesthesia in an elective ambulatory setting showed average time to discharge readiness was 277 min in the 2-CP group and 353 min in the bupivacaine group, a difference of 76min (40 to 112 min).

In our study, in Group A, 4 (8.8%) and 3 (6.6%) patients had hypotension and bradycardia respectively while 2 (4.4%) and 1 (2.2%) patient had Nausea\Vomiting and shivering respectively. In Group B, 3 (6.6%) patients had hypotension while 2 (4.4%) patients each had bradycardia and Nausea\Vomiting. 2 (4.4%) patient had shivering. There was no significant difference between the groups as per Chi square test (p>0.05). Lacasse MA et al [14] noted similar observations in their study.

Conclusion

Chlorprocaine provides satisfactory surgical block, has significantly faster regression of block, earlier ambulation, and voiding, and hence facilitates the faster discharge of the patient from the hospital as compared to intrathecal bupivacaine following spinal anaesthesia in short duration obstetric and gynaecological procedures. Chlorprocaine may represent a safe and viable option for mobilizing and discharging patients rapidly procedures.

References

1. Chung F, Ritchie E, Su J. Postoperative pain in ambulatory surgery. Anesth Analg.1997;85:808-816.
2. Förster JG, Rosenberg PH. Revival of old local anesthetics for spinal anesthesia in ambulatory surgery. Curr Opin Anaesthesiol. 2011; 24:633-637.
3. Fanelli A, Ghisi D, Allegri M. Is spinal anesthesia a suitable technique for ultra-short outpatient procedures? Acta Biomed. 2013; 84:76-80.
4. Raghu K, Kumar S, Rajaram G et al. Effect of Ondansetron in the prevention of spinal anaesthesia induced hypotension. J Sci Soc. 2018; 45:125-128.
5. Kaufmann MA, Rosov C, Schnieper P et al. Prophylactic antiemetic therapy with patient controlled analgesia: a double blind,placebo-controlled comparison of droperidol,metoclopromide and tropisetron. Anaesth Analg.1994;78:988-994.
6. Gan TJ, Hetreed MC. Double blind comparison of ondansetron,droperidol and saline in the prevention of post-operative nausea and vomiting. Br Jr of Anaesthesia.1994;72:544-547
7. Morgan GE Jr., Mikhail MS, Murray MJ et al. Clinical Anaesthesiology, Lange, New York, NY, USA, 4th edition, 2002.
8. Brull R, Macfarlane AJR, Chan VWS. Spinal, Epidural and Caudal Anesthesia. Miller's Anesthesia. 8th edition 2015; 8:1965-2000.
9. Datta S, Corke BC, Alper MH et al. Epidural anesthesia for cesarean section: a comparison of bupivacaine, chlorprocaine, and etidocaine. Anesthesiology. 1980;52(1):48-51.
10. Gaiser RR, Cheek TG, Gutsche BB. Epidural lidocaine versus 2-chlorprocaine for fetal distress requiring urgent cesarean section. Int J ObstetAnesth. 1994;3(4):208-210.
11. Kuhnert BR, Kuhnert PM, Philipson EH et al. The half-life of 2-chlorprocaine. AnesthAnalg. 1986;65(3):273-278.
12. Butterworth JF, Strichartz GR. Molecular mechanisms of local anesthesia: a review. Anesthesiology. 1990;72(4):711-734.
13. Covino BG. Pharmacology of local anaesthetic agents. Br J Anaesth. 1986;58(7):701-716.
14. Lacasse MA, Roy JD, Forget J et al. Comparison of bupivacaine and 2-chlorprocaine for

spinal anesthesia for outpatient surgery: a double-blind randomized trial. Can J Anaesth. 2011;58(4):384-391.
15. Ghisi D, Boschetto G, Spinelli AM et al. Spinal anaesthesia with Chlorprocaine HCl 1% for elective lower limb procedures of short duration: a prospective, randomised, observer-blind study in adult patients. BMC Anesthesiol. 2021; 21:58.
16. Thomas S, Pawar DB, Ruparel DH et al. Randomized controlled study comparing 2-chlorprocaine and bupivacaine for spinal anesthesia in gynecological surgeries. Anesth Essays Res. 2022; 16:12-16.
17. Mathur V, Mansuri T, Goyal VK et al. Spinal anaesthesia for ambulatory urology surgery: A comparison of chlorprocaine with fentanyl and bupivacaine with fentanyl. Indian J ClinAnaesth. 2020;7(2):313-318.
18. Mims SC, Zanolli NC, Fuller M et al. Intrathecal bupivacaine versus chlorprocaine for transvaginal cervical cerclage placement: a retrospective cohort study, International Journal of Obstetric Anesthesia. 2022; 50:103276.
19. Herndon CL, Martinez R, Sarpong NO et al. Spinal Anesthesia Using Chlorprocaine is Safe, Effective, and Facilitates Earlier Discharge in Selected Fast-track Total Hip Arthroplasty, Arthroplasty Today.2020;6(3):305-308.
20. Mathur V, Mansuri T, Goyal VK et al. Spinal anaesthesia for ambulatory urology surgery: A comparison of chlorprocaine with fentanyl and bupivacaine with fentanyl. Indian J ClinAnaesth. 2020;7(2):313-318.