Section: Anaesthesia

Original Research Article

TAKING BABY STEPS TOWARDS RE-EMERGENCE OF CHLORPROCAINE AS A PREFERRED LOCAL ANAESTHETIC IN SPINAL ANAESTHESIA FOR AMBULATORY GYNEACOLOGICAL SURGERIES

N Trivikram[1], Chada Sirisha[2], Syed Ali Aasim[3]

[1]Assistant Professor, Department of Anaesthesia, Chalmeda Anand Rao Institue of Medical Sciences, Karimnagar, Telangana, India.
[2]Associate Professor, Department of Anaesthesia, Chalmeda Anand Rao Institue of Medical Sciences, Karimnagar, Telangana, India.
[3]Professor, Department of Anaesthesia, Chalmeda Anand Rao Institue of Medical Sciences, Karimnagar, Telangana, India.

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Corresponding Author:
Dr. Chada Sirisha,
Email: drchadasirisha@gmail.com

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Abstract

Background: Taking baby steps towards re-emergence of chlorprocaine as a preferred local anaesthetic in spinal anaesthesia for ambulatory gynaecological surgeries. **Materials and Methods:** Total of 40 female patients aged 18-45 years with ASA grade I/II, who were scheduled for cerclage or dilatation and curettage or cervical polypectomy between February and August 2021. The patients were randomly split into two groups of 20. Patients in Group BP received 0.5% Hyperbaric Bupivacaine 2ml(10mg), whereas those in Group CP received 1% Isobaric 2-Chlorprocaine 4ml (40mg). **Result:** The length of the onset of paresthesias was 83.5±24.17 seconds in the bupivacaine group and 60.75±17.18 seconds in the chlorprocaine group. The time required to achieve T10 dermatomal level was determined to be 289.75±48.67 seconds in the BP group and 182.5±26.92 seconds in the CP group. The p-value was 0.0000001, indicating that the time required for sensory onset to T10 dermatomal level was quicker in the CP group than in the BP group. **Conclusion:** As a result, it may be concluded that Chlorprocaine was superior than Bupivacaine in spinal anaesthesia for ambulatory gynaecological procedures.

INTRODUCTION

The usage and interest in spinal anaesthesia have been great opportunities during COVID-19 for patients, staff and anaesthetists alike, presenting us with an alternative to the risks of general anaesthesia.[1] International Association of Ambulatory Surgery defines day care surgery as an operation or procedure, in office or outpatient, when the patient is discharged on the same working day.[2] Ambulatory surgeries are defined by the Royal College of Surgeons in Ireland and England as a patient who is admitted for investigation or operation on a planned non-resident basis and who also require facilities for recovery.[3] According to the Modified Aldrete Scoring System for Determining when Patients Are Ready for Discharge from the Postanesthesia Care Unit, an activity level of movement of four limbs is given a high score of.[2] Also Guidelines for Safe Discharge After Ambulatory Surgery include ability to walk without assistance. In post anesthesia Discharge Scoring System (PADSS) for Determining Home-Readiness for activity criterion,[4] patient must be able to ambulate at preoperative level, a steady gait, no dizziness or preoperative level given a high score of.[2] Various studies have compared the efficiency of regional versus general anaesthesia techniques in ambulatory anaesthesia to attain the above scoring and it has been established that regional anaesthesia, in specific, spinal anesthesia with short duration of action is most preferable.[4-8]

This study focuses on most common ambulatory Gynaecological procedures that can be done under spinal anaesthesia such as cerclage, dilatation and curettage, simple benign cervical polypectomies which can be done in a duration of 15-30 minutes. Transvaginal Cerclage is primarily used to prevent preterm birth in cervical insufficiency.[9] Dilatation and curettage is a small procedure done transvaginally for diagnostic or therapeutic purposes.[10,11] Cervical polyps are benign growths, usually protruding from the surface of the cervical canal, commonly occurring during the reproductive years.[12] Conventionally, hyperbaric bupivacaine has been the drug of choice for all the procedures. The intent is to prove that isobaric 1% chlorprocaine an ester local anesthetic, which is a short acting one due to ester hydrolysis metabolism, can be used for spinal anesthesia due to its shorter duration of

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sensory and motor blockade and similar safety profile compared with bupivacaine.[12,13]

Chlorprocaine is an amino ester class local anesthetic 4 having a short duration of action, shorter duration of motor blockade,[13] and apparently having a smaller risk for postanesthestic TNS,[14] has re-emerged as a better agent for ambulatory spinal anesthesia than bupivacaine, which has been the conventional agent of choice for all below umbellical surgeries of long or short duration.[15] This study focuses on the merits and demerits of chlorprocaine versus bupivacaine in cerclages, dilatation and curettage and cervical polypectomies.

MATERIALS AND METHODS

This study was conducted as randomized, double blinded, prospective one on a total of 40 female patients of age groups between 18-45 years of ASA grade I/II, posted for cerclage or dilatation and curettage or cervical polypectomy between February and august 2021 in Chalmeda Anandrao Institute of Medical Sciences, Karimnagar. Patients with absolute contraindications to Spinal Anesthesia or with a known allergy to any of the study drugs, with any spinal deformity, and those having cardiovascular, respiratory, renal, or neurological diseases, diagnosed malignancies were excluded from this study.

After obtaining approval from ethics committee of institutional review board, patient selection was done randomly. Total of 50 patients were selected, but 10 of them dropped out during various phases for inclusion into the study. The procedure was thoroughly explained to the patient and written consent was obtained by an observer A, who was blinded to the drug. The patients were divided to two groups of 20 each randomly. Patients in Group BP were given 0.5% Hyperbaric Bupivacaine 2ml(10mg) and patients in Group CP were given 1% Isobaric 2-Chlorprocaine 4ml(40mg).

The night previous to the surgery, the patients were advised to remain nil per oral for 8 hours and tablet alprazolam 0.5mg per oral was advised at bedtime. The patients were advised to report at a given prescribed time to the day care reception on the day of surgery. An 18gauge cannula was secured and the patients were preloaded with 10-15ml/kg of ringer's lactate. Premedication was done with inj ondansetron 4mg iv and inj midazolam 1mg iv. Patients were shifted to the operation room and basic monitors such as pulse oximeter, non-invasive blood pressure cuff and ECG leads were connected. Baseline readings were noted. Patients was put in left lateral decubitus position and spinal anaesthesia was given with a 23 gauge Quincke needle in L3-L4 interspinous space and after free flow of CSF was seen, an observer B who was blinded to the drug, injects either 40mg of isobaric 1 % 2-Chlorprocaine CP or 10mg of hyperbaric 0.5% Bupivacaine BP.

Patients were questioned regarding the onset of paresthesias and the time was noted. Time taken to achieve T10 level was tested with pin prick sensations. Time taken to achieve motor blockade was assessed with modified bromage scale. Two segment regression time also was assessed. Duration of motor blockade was recorded. The data obtained thus, was statistically calculated using Openepi version 3.01. Graphs and tables were obtained and results were analyzed.

RESULTS

Demographic parameters such as age of patients given bupivacaine (31.5±11.3137085 years) and those given chlorprocaine (25±9.89949494 years) were comparable with a p-value of 0.564, which means it was insignificant [Table 1 and Figure 1].

Onset of paresthesias was assessed by asking the patient for tingling in feet and legs and was measured in seconds after injection of the spinal drug. The duration of onset of paresthesias in bupivacaine group was 83.5±24.17589056 seconds and 60.75±17.18896525 seconds in chlorprocaine group. The p-value was 0.001469, which was significant. It implies that the onset was paresthesias was faster in chlorprocaine group than in bupivacaine group [Table 1 and Figure 2].

Time taken to attain T10 dermatomal level was assessed and it was found to be 289.75±48.67926717 seconds in BP group vs 182.5±26.92582404 seconds in CP group. The p-value was 0.0000001 which was a significant value implying that the time taken for sensory onset to T10 dermatomal level was faster in CP group than in BP group [Table 3 and Figure 3].

Highest dermatome attained in both the groups was assessed. In BP group, 1 out of 20 patients (5%) reached T4, 4 patients (20%) reached T6, 10 patients (50%) reached T8 and 5 patients (25%) reached T10 dermatomal level. Median highest dermatomal level in BP group was T8. Whereas in CP group, 6 out of 20 patients (30%) reached T4, 8 patients (40%) reached T6, 4 patients (20%) reached T8, 2 patients (10%) reached T10 dermatomal level [Table 4 and Figure 4]. Median highest dermatomal level reached in CP group was T6 [Table 5 and Figure 5]. Hence, it can be implied that the height of sensory blockade achieved with chlorprocaine was higher with bupivacaine.

Time taken to attain maximum bromage scale was assessed. It was 244.25±35.51408171 seconds in Bupivacaine group. It was found to be 200±36.41861872 seconds in chlorprocaine group. The p-value was 0.0003905, which was significant, implying that the time taken by the chlorprocaine group to attain maximum motor blockade was significantly faster than bupivacaine group [Table 6 and Figure 6].

Bromage scale was assessed in both the groups. 7 out of 20 cases attained bromage III and 13 out of

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20 attained bromage IV in bupivacaine group, which means 35% attained bromage III and 65% attained bromage IV in Bupivacaine group. In Chlorprocaine group, 9 out of 20 attained bromage III which is 45% and 11 out of 20 attained bromage IV which is 55%. Also the Median Bromage Scale attained in both groups was 4. This shows that the strength of motor blockade was similar in both groups [Table 7 and Figure 7].

Table 1: Age of the patients

AGE BP	31.5±11.3137085	p- value – 0.564
AGE CP	25±9.89949494	

Table 2: Onset of Paresthesia in seconds

BP	83.5±24.17589056	p-value-0.001469
CP	60.75±17.18896525	

Table 3: Time taken to attain T10 Dermatome Level (in seconds)

BP	289.75±48.67926717	p-value-0.0000001
CP	182.5±26.92582404	

Table 4: Time taken to attain T Highest reached (in seconds)

	T4	T6	T8	T10
BP	1 (5%)	4 (20%)	10 (50%)	5 (25%)
CP	6 (30%)	8 (40%)	4 (20%)	2 (10%)

Table 5: Time taken to attain Median T Highest Dermatome (in seconds)

BP	T8
CP	T6

Table 6: Time taken to attain Median T Maximum Bromage Scale (in seconds)

BP	244.25±35.51408171	p-value-0.0003905
CP	200±36.41861872	

Table 7: Bromage Scale Assessment

	Grade III	Grade IV
BP	7(35%)	13(65%)
CP	9(45%)	11(55%)

Table 8: Two Segment Regression Time (in minutes)

BP	63.9±8.6383478	p-value - <0.0000001
CP	45.6±6.03847314	

Table 9: Duration of Motor Block (in minutes)

BP	105.8±11.23247172	p-value – 0.000003281
CP	89.55±7.207269722	

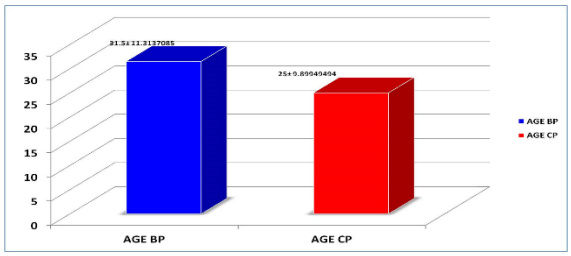

Figure 1: Demographic details

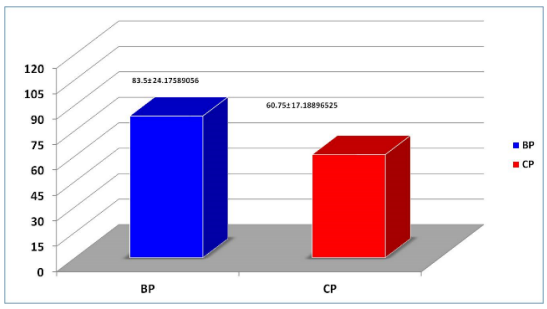

Figure 2: Onset of Paresthesia

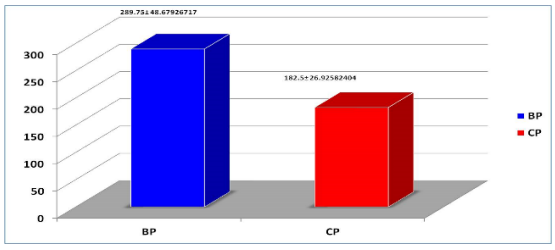

Figure 3: Time taken to attain T10 Dermatome Level (in seconds)

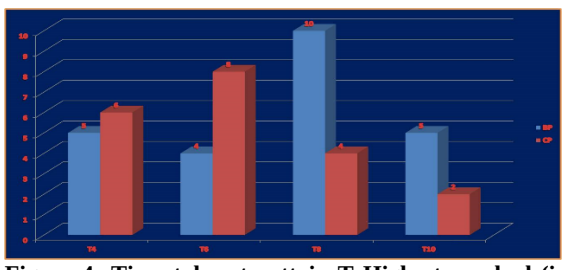

Figure 4: Time taken to attain T Highest reached (in seconds)

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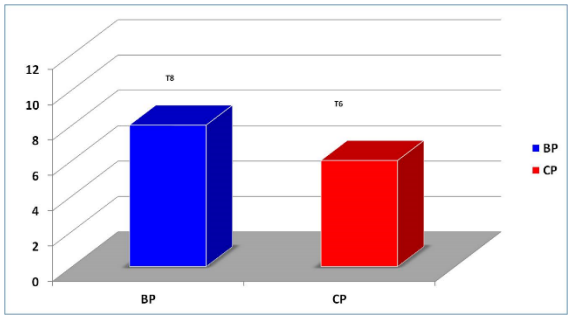

Figure 5: Time taken to attain Median T Highest Dermatome (in seconds)

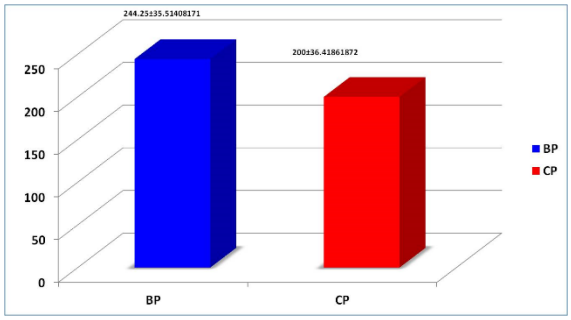

Figure 6: Time taken to attain Median T Maximum Bromage Scale (in seconds)

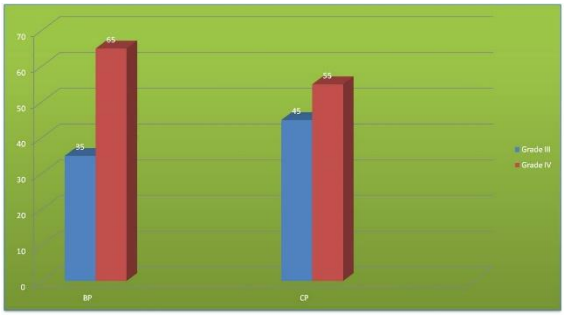

Figure 7: Bromage Scale Assessment

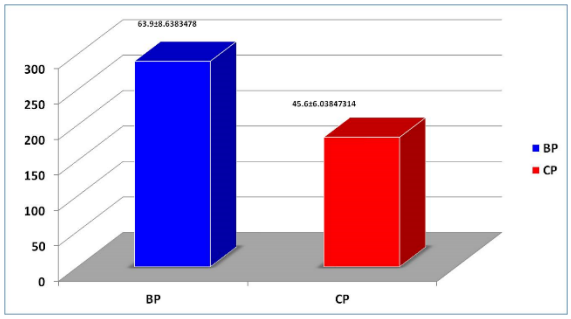

Figure 8: Two Segment Regression Time (in minutes)

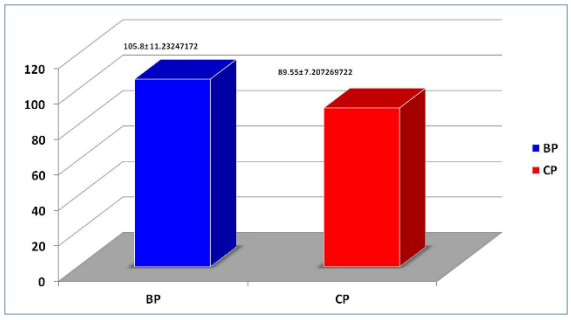

Figure 9: Duration of Motor Block (in minutes)

Two segment regression time was assessed in BP group as 63.9±8.6383478 minutes and 45.6±6.03847314 minutes in CP group with a significant p-value of <0.0000001. The two-segment regression time was faster in CP group than in BP group implying that the duration of sensory anaesthesia was shorter in CP group than in BP group [Table 8 and Figure 8].

Duration of motor blockade was assessed with loss of regression of bromage scale from III/IV to bromage scale I. The duration was 105.8±11.23247172 minutes in bupivacaine group and 89.55±7.207269722 minutes in chlorprocaine group. The p-value was 0.000003281 which was significant [Table 9 and Figure 9]. The duration of motor blockade was shorter in CP group than BP group implying that ambulation of patients was faster in CP group than BP group proving that Isobaric Chlorprocaine was preferable to Hyperbaric Bupivacaine in Ambulatory Gynecological surgeries.

DISCUSSION

This study was conducted on 40 female patients between the age groups of 18-45 years who were posted for cerclages, dilatation and curettage and simple cervical polypectomies. Half of them were given 1% isobaric 2-Chlorprocaine and half of them were given 0.5% hyperbaric Bupivacaine. Onset of paresthesias, onset of sensory block to T10 dermatomal level, and attainment of bromage scale in CP group was similar to BP group. This study mainly focuses on faster sensory regression as seen in two segment regression time and faster motor regression as in bromage scale recovery from III/IV to I of Chlorprocaine as compared to Bupivacaine. This highlights the fact that Chlorprocaine is a better alternative to Bupivacaine in ambulatory surgeries requiring spinal anaesthesia.

The patients chosen for the study were in the age group between 18-45 years which were comparable in both groups. The onset of paresthesias was faster in Chlorprocaine group than in Bupivacaine group as in 60.75±17.18896525 versus 83.5±24.17589056 minutes, by almost more than 20 seconds. p-value was 0.001469, which is a significant one. In a study done by Jain N et al,[20] on 100 parturients, where Group A (n = 50) received intrathecal isobaric 1% 2-CP 5 ml (50 mg) and Group B (n = 50) received intrathecal hyperbaric 0.5% bupivacaine 2 ml (10 mg) in Spinal Anaesthesia, it was found that the onset of sensory blockade was significantly faster in Group A (1.66 ± 0.49 min) compared to Group B (3.00 ± 0.58 min) (P < 0.05) which was similar to the present study. Very few studies are available which have compared the onset of paresthesias between chlorprocaine and bupivacaine.

In this study, the time taken to attain T10 dermatomal level was assessed and compared between both the groups. It was

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289.75±48.67926717 seconds in Bupivacaine group and 182.5±26.92582404 seconds in Chlorprocaine group. The p-value was 0.0000001. It showed that the sensory onset at T10 level in chlorprocaine group was significantly faster than bupivacaine group.

In a study done by Camponovo et al, the maximum sensory block level (8.5 vs. 14 min) was documented when 50mg of 1% plain chlorprocaine was compared with 10mg 0f 0.5% plain bupivacaine. This study differed with the present study in the administered dosage of chlorprocaine being 50mg, while the later used only 40mg and also in the usage of plain bupivacaine, rather than a hyperbaric one as in the present study. Also, the present study showed a faster attainment of T10 level in comparison to the study done by Camponovo et al, who found that the time taken to reach level of T10 was comparable in both the groups16. In another study done by Jain N et al,[17] on 100 parturients, where Group A (n = 50) received intrathecal isobaric 1% 2-CP 5 ml (50 mg) and Group B (n = 50) received intrathecal hyperbaric 0.5% bupivacaine 2 ml (10 mg) in Spinal Anaesthesia, the mean time to achieve the highest level of sensory block was 2.96 ± 0.63 min and 5.08 ± 0.75 min in Group A and Group B, respectively. The mean time to achieve the highest sensory level was significantly shorter in Group A as compared to Group B (P < 0.001). This was in concurrence with the present study which also had similar findings.[17]

T highest dermatomal level attained in both the groups was documented for all the 40 patients. In Bupivacaine group, 1 out of 20 patients (5%) reached T4, 4 patients (20%) reached T6, 10 patients (50%) reached T8 and 5 patients (25%) reached T10 dermatomal level. Median highest dermatomal level in BP group was T8. Whereas in CP group, 6 out of 20 patients (30%) reached T4, 8 patients (40%) reached T6, 4 patients (20%) reached T8, 2 patients (10%) reached T10 dermatomal level. Median highest dermatomal level reached in CP group was T6. Hence, it can be implied that the height of sensory blockade achieved with chlorprocaine was higher with bupivacaine. In a study done by Jain N et al.[17] In Groups A (chlorprocaine) and B (bupivacaine), the median (range) for the highest dermatomal level of sensory block was T4 (T3–T6) and T6 (T4–T6), respectively. The present study also showed that the group of patients administered chlorprocaine attained a higher dermatomal level than compared to that of bupivacaine. Also, in a study done by Yoos JR,[18] Kopacz DJ et al,[19] a retrospective study, Chlorprocaine in a dose of 30 or 40 mg, with or without fentanyl (10-20 μg) was used in ambulatory surgery, it was found that Peak block height in 2-CP was an average T7 (range T3-10) and in bupivacaine it was an average of T9 (range T4-L1). Thus, both the studies had findings in concurrence with the present study.

The parameter taken to assess the loss of sensory blockade was two segment regression time. The time taken by the sensory level to regress by two segments from the T highest was assessed by observer B. In BP group it was 63.9±8.6383478 minutes and 45.6±6.03847314 minutes in CP group with a significant p-value of <0.0000001. Thus, the two segment regression time was faster in CP group than in BP group implying that the duration of sensory anaesthesia was shorter in CP group than in BP group. In a study done by Marie-Andrée Lacasse et al20, where 0.75% hyperbaric bupivacaine 7.5 mg (n = 53) was compared with 2% preservative-free 2-CP 40 mg (n = 53), the average time for complete regression of the sensory block was 146 minutes in the 2-CP group and 329 minutes in the bupivacaine group, a difference of 185 min (95% CI: 159 to 212 min (P < 0.001). In another study done by Camponovo et al,[16] where 50 mg of plain 1% 2-chloroprocaine vs. 10 mg of 0.5% plain bupivacaine was used, resolution of sensory anaesthesia was 105 vs. 225 min in chlorprocaine versus bupivacaine group. In another study by Jain N et al,[17] wherein Group A (n = 50) received 5 ml (50 mg) intrathecal isobaric 1% 2-CP, and Group B (n = 50) received 2 ml (10 mg) intrathecal hyperbaric 0.5% bupivacaine in Spinal Anesthesia, it was found that in Group A, the mean time of two-segment regression was 41.44 ± 5.41 min, while in Group B, it was 70.24 ± 10.38 min, i.e., the mean time was significantly shorter in Group A than in Group B (P < 0.001). The mean duration of sensory block in Groups A and B was 76.74 ± 11.94 min and 168.60 ± 12.41 min, respectively, i. e., it was significantly shorter in Group A than in Group B (P < 0.05). In another study done by David H Kim et al,[21] who conducted a retrospective chart review of all patients from June to December 2016 at their institution who had ambulatory surgeries, when the median chlorprocaine dosage was 44 mg (interquartile range [IQR], 40 to 50) was used, the median duration of sensory block was 156 min (IQR, 128 to 189) whereas in the present study the median for two segment regression time was 43.5 minutes. Unfortunately in the present study, the total time for sensory blockade regression was not documented, hence total duration of sensory anaesthesia also could not be documented. Although, two segment regression time of sensory anaesthesia was considered as an indicative of speed of loss of sensory anaesthesia.

The time taken by the chlorprocaine group (244.25244.25±35.51408171 seconds) to attain maximum motor blockade which was assessed by modified bromage scale was significantly faster (p-value - 0.0003905) than that of bupivacaine group (200±36.41861872 seconds) in the present study. In a study done by Camponovo et al,[16] when 50mg of plain Chlorprocaine was administered in comparison with 10mg of plain bupivacaine, Group Chlorprocaine showed faster onsets of motor block (5 vs. 6 min) compared to Group Bupivacaine. In a

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study done by Jain N et al,[17] comparing 50mg of chlorprocaine with 10mg of bupivacaine, the mean time for onset of motor block was 3.27 ± 0.62 min in Group A and 4.34 ± 0.71 min in Group B. Thus, the mean time for onset of motor block was found to be significantly shorter in Group A than in Group B (P < 0.001). Hence, the findings of the both the studies had the same implications as of the present study.

Bromage scale assessment was done on the patients based on modified bromage scale 19. 7 (35%) out of 20 cases attained bromage III and 13 (65%)out of 20 attained bromage IV in bupivacaine group. In Chlorprocaine group, 9 (45%) out of 20 attained bromage III and 11 (55%) out of 20 attained bromage IV. Also the Median Bromage Scale attained in both groups was 4. This shows that the strength of motor blockade was similar in both groups. There were no previous studies that could assert the findings related to bromage scale assessment in the present study. Thus, this study can be taken as one of those pioneers that proves that the strength of motor blockade attained by chlorprocaine is similar to that of bupivacaine.

The loss of motor blockade was assessed as return of bromage scale of III/IV to Bromage scale I and thus the duration of motor blockade was estimated. Assuming that the preoperative bromage scale is bromage scale I, the time taken to regress to that level is the duration of the motor blockade. In the present study, the duration was 105.8±11.23247172 minutes in bupivacaine group and 89.55±7.207269722 minutes in chlorprocaine group. The p-value was 0.000003281 which was significant. In a study done by C Camponovo et al,[16] where 50 mg of plain 1% 2-chloroprocaine vs. 10 mg of 0.5% plain bupivacaine was used, resolution of motor block was 100 minutes vs. 210 minutes respectively. In another study done by Marie-Andrée Lacasse et al,[20] where 0.75% hyperbaric bupivacaine 7.5 mg (n = 53) was compared with 2% preservative-free 2-CP 40 mg (n = 53), the average time to discharge readiness was 277 min in the 2-CP group and 353 min in the bupivacaine group, a difference of 76 min (95% confidence interval [CI]: 40 to 112 min; P < 0.001), which could be synonymous to duration of motor blockade.

In a study done by Jain N et al,[17] wherein Group A (n = 50) received 5 ml (50 mg) intrathecal isobaric 1% 2-CP, and Group B (n = 50) received 2 ml (10 mg) intrathecal hyperbaric 0.5% bupivacaine in Spinal Anaesthesia, the mean time for onset of motor block was 3.27 ± 0.62 min in Group A and 4.34 ± 0.71 min in Group B. Thus, the mean time for onset of motor block was found to be significantly shorter in Group A than in Group B (P < 0.001). The mean duration of motor block in Groups A and B was 95.78 ± 9.85 min and 186.26 ± 13.56 min, respectively. The mean duration of motor block was significantly shorter in Group A than Group B (P < 0.001).

In another study done by David H Kim et al,[21] who conducted a retrospective chart review of all patients from June to December 2016 at our institution who had ambulatory surgeries, when the median chlorprocaine dosage was 44 mg (interquartile range [IQR], 40 to 50) was used, the median duration of motor block was 148 min (IQR, 123 to 181) whereas it was 90 minutes in the present study. In an observational study done by Chaudhari B et al,[22] which was conducted in 30 individuals in group A for drug 2- chlorprocaine 40 mg, 30 patients in group B for Bupivacaine 10 mg, motor regression was 85.38±27.91 minutes and 138.85±24.6 minutes with p value <0.00001 respectively.

In another study done by SC MIms et al,[23] where 360 patients were included in the final analysis (bupivacaine n=236, chlorprocaine n=124), the median (IQR) intrathecal dose was 7.5 (7.5, 9) mg and 45 (45, 50) mg in the bupivacaine and chlorprocaine groups respectively, the time (median [IQR]) from spinal anesthesia to hospital discharge was significantly shorter in the chlorprocaine group compared with the bupivacaine group (218 [180, 253] vs. 370 [309, 424] min, P<0.001). Through the spectrum of various studies done by various authors in different ambulatory settings, it has been consistently found that the loss of motor blockade and ambulation was faster in chlorprocaine group in comparison to bupivacaine group.

The limitations of the study were the titration of the baricity and dosage of the test drugs. Where bupivacaine was hyperbaric and 10mg, chlorprocaine was isobaric and 40mg. Equipotency of the two test drugs was not well established. Thus, there were a lot of discrepancies between the present study and the earlier ones regarding the exact durations of sensory and motor blockades. Also, the present study did not calculate the exact duration of the sensory blockade by documenting the end point of sensory anaesthesia. Instead only two segment regression time was documented hence only a trend regarding the sensory blockade could be commented upon but not the exact duration of the sensory blockade. Also, the time to full ambulation, time to micturition and discharge times were not included in the study. The VAS score also was not taken into consideration to assess the remnant of any post operative analgesia in both the groups in the present study. The comparison of hemodynamic parameters also was overlooked. Inspite of all these fallacies, this study has an exceptional advantage of proving that 1% Isobaric Chlorprocaine is more advantageous than 0.5% Hyperbaric Bupivacaine in ambulatory surgeries.

CONCLUSION

This study was done on 40 female patients divided into 20 in each group BP (0.5% Hyperbaric Bupivacaine 2ml - 10mg) and CP (1% Isobaric 2-Chlorprocaine 4ml - 40mg) posted for ambulatory

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gynecological surgeries including cerclages, dilatation and curettages and benign cervical polypectomies under spinal anaesthesia over a period of 6 months divided into ASA grade I/II. Chlorprocaine has a faster onset of paresthesias, faster assent of sensory block to T10 dermatomal level, higher dermatomal level (higher extent of sensory block), faster two segment regression time (lesser duration of sensory blockade), faster motor recovery from bromage III/IV to Bromage I (lesser duration of motor blockade) in comparison to Bupivacaine. Though, according to the present study, the strength of motor blockade was similar in both the groups. Hence, it can be summarized that Chlorprocaine was more advantageous than Bupivacaine in spinal Anaesthesia for Ambulatory gynaecological surgeries.

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