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Original Research Article

Comparison of 1% Chloroprocaine Alone to 1% Chloroprocaine with Clonidine During Daycare Surgeries under Spinal Anesthesia

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Abstract

Background: Bupivacaine was associated with delayed movements and urinary retention owing to the prolonged residual blockade, whereas, lignocaine shows transient neurological symptoms limiting their use during daycare surgeries under spinal anesthesia. 1% Chloroprocaine being free of preservatives can be used as an alternative to lignocaine in daycare surgeries.

Aim: The present study was conducted to compare the efficacy of 1% Chloroprocaine alone to 1% Chloroprocaine with Clonidine during daycare surgeries under Spinal anesthesia.

Methods: The present study included 58 subjects divided into two groups of 29 subjects each where Group I subject underwent day care surgery under spinal anesthesia using 1% Chloroprocaine and Group II subjects using Chloroprocaine with Clonidine. The parameters assessed were first mobilization, analgesia duration, peak level dermatome, motor, and sensory block duration, and onset time.

Results: First mobilization time was significantly higher in Group 1 (210+-17.77) where chloroprocaine was used as compared to Group2 (120.5±14.72) where the combination of clonidine with chloroprocaine was used ($p<0.0001$). Higher analgesia duration was seen in Group II (193.65±12.03) compared to Group I (100.3±15.21). This was statistically significant with $p<0.0001$. The duration of the motor block was higher in Group II with 76.39±9.46 minutes compared to Group I, where the duration was 69.95±7.64 minutes. Onset time for the motor block was significantly lesser for group II where chloroprocaine was used with clonidine was 9.75±1.74 mins compared to Group I where only chloroprocaine was used as 11.33±2.92 mins. This was statistically significant with $p=0.01$. Also, sensory block onset time was significantly lesser for Group II (7.76±2.06) mins compared to Group I where it was 9.5±2.84 mins with $p=0.01$

Conclusion: The present study concludes that using clonidine with Chloroprocaine in low dose provides prolonged analgesia, better anesthesia quality, and increases the duration of motor and sensory block compared to Chloroprocaine alone.

Keywords: Anesthesia, Chloroprocaine, Clonidine, Daycare surgery, Lidocaine, Spinal anesthesia.

Introduction

One of the most commonly used anesthetic modalities is spinal anesthesia, especially the surgeries conducted on the lower limbs and abdomen. However, it is associated with a few disadvantages including delayed voluntary movements, urine retention risk secondary to prolonged motor blockade as seen with Bupivacaine and lignocaine shows transient neurological symptoms and pain after its anesthetic effects wear off limiting their use in daycare surgeries under spinal anesthesia. Hence, selecting an appropriate anesthetic agent of choice to be used during daycare surgeries under spinal anesthesia is vital in ambulatory surgeries. [1]

Various advancements made in the anesthetic field, surgery, and postoperative care allow wide use of daycare surgeries where subjects are discharged on the same day of surgery with reduced hospitalization duration, minimal psychologic effects, reduced cost, and better satisfaction of subject underwent surgery. Chloroprocaine is one anesthetic agent which fits all criteria needed to be suitable for day care surgeries under spinal anaesthesia. It was first used for daycare surgeries in 1952. [2] However, several cases reported neurologic deficit following surgery in subjects where a high dose of Chloroprocaine was used during epidural labor, which were attributed to the addition of antioxidant (sodium bisulfite) to the Chloroprocaine. The combined use of low pH with sodium bisulfite resulted in the persistence of the symptoms related to the neurologic deficit. For use in short-duration surgeries, recently, Chloroprocaine composition without antioxidant and sodium bisulfite has been introduced. [3]

To attain better results in terms of anxiolysis, antiemetic action, prolonged analgesia, and better sensory and motor block quality, various anesthetic agents are used in combination with intrathecal Clonidine. Also, clonidine does not lead to respiratory depression or pruritis as seen with the opioid agents. The data concerning the use of Chloroprocaine with clonidine in daycare surgeries under spinal anesthesia are scarce in the literature. [4] Hence, the present study was conducted to assess the safety profile, duration, and efficacy of 1% Chloroprocaine alone to 1% Chloroprocaine with Clonidine during daycare surgeries under Spinal anesthesia in Indian subjects.

Materials and methods

The present prospective, randomized, observational clinical study was conducted to assess the safety profile, duration, and efficacy of 1% Chloroprocaine alone to 1% Chloroprocaine with Clonidine during daycare surgeries under Spinal anesthesia in Indian subjects. The study was conducted at Department of Anaesthesia, Shri Shankaracharya Institute of Medical Sciences, Bhilai, Chhattisgarh from July 2021 to December 2021 after obtaining clearance of the concerned Ethical committee. The study population was comprised of the subjects undergoing day care surgeries under spinal anesthesia at the institute. After explaining the detailed study design, informed consent was taken from all the subjects.

Inclusion criteria for the study were subjects undergoing daycare surgeries under spinal anesthesia of infraumbilical region, ASA grade I/II, the age range of 18-50 years, from any gender, the surgical procedure of under 60 minutes, and subjects who were willing to participate in the study. The exclusion criteria were subjects with a history of anesthesia allergy, coagulopathy, bleeding disorder, pregnant females, renal/hepatic disease, neurologic disorder, cardiovascular disease, and the subjects who were not willing to participate in the study.

After final inclusion, detailed history was recorded and the subjects underwent thorough systemic, physical, and general examination. This was followed by routine blood investigations conducted before surgery including serum creatinine, blood urea, blood sugar, complete blood count, chest X-ray, and E.C.G

The study included a total of 58 subjects from both the genders within the age range of 18-50 years and the mean age of 35.68±4.24 years. The subjects were randomly divided into two groups of 29 subjects each. Group I subjects underwent day care surgery under spinal anesthesia using 1% Chloroprocaine 40 mg with 0.2 ml Normal saline and Group II subjects were given spinal anesthesia using Chloroprocaine 40 mg with 0.2ml (30mcg) Clonidine. All subjects were kept nil orally for a minimum of 6 hours before surgery. On entry to operation theatre parameters assessed at baseline were mean arterial blood pressure, diastolic and systolic blood pressure, and pulse rate. SpO2 was also taken into consideration. Intravenous access was established in all the subjects using a cannula under aseptic conditions. In sitting position subarachnoid block was given at L3-L4 intervertebral space with 25 G Quincke's needle and the parameters were assessed after supine positioning of the patient.

The parameters assessed were mobilization, analgesia duration (minutes), peak level dermatome, motor block duration, sensory block duration and onset time of motor and sensory block.The onset time was assured using pinprick. Motor block onset time was assessed using a modified Bromage scale. Hemodynamic parameters were also assessed in all the study subjects.

Mean arterial blood pressure, diastolic and systolic blood pressure, and pulse rate was assessed at 5, 10, 30-, 60-, 90-, and 120-minutes following anesthesia. 6mg Mephenteramine inj was given when the mean arterial pressure fall was below 20% compared to baseline values. The pulse rate of fewer than 60 beats was administered with 0.2 mg IV Glycopyrrolate.

The collected data were subjected to the statistical evaluation using SPSS software version 21 (Chicago, IL, USA) and one-way ANOVA and t-test for results formulation. The data were expressed in percentage and number, and mean and standard deviation. The level of significance was kept at $p<0.05$.

Results

The present prospective, randomized, observational clinical study was conducted to assess the safety profile, duration, and efficacy of 1% Chloroprocaine alone to 1% Chloroprocaine with Clonidine during daycare surgeries under Spinal anesthesia in Indian subjects. The study included a total of 58 subjects from both genders within the age range of 18-50 years and the mean age of 35.68±4.24 years who were randomly divided into two groups. The demographic characteristics of the study subjects are listed in Table 1.

Table 1: Demographic characteristics of the study subjects

Characteristics		Group I	Group II	p-value
Age range (years)		18-50	19-48	0.741
Mean age (years)		37.61±9.34	37.3±7.94	0.814
Gender	Males	21	23	0.383
	Females	8	6	
Weight (kg)		56.31±10.98	57.41±4.95	0.618
Duration of surgery (min)		33.31±9.47	34.48±8.91	0.664

It was seen that the age range of subjects from Group I and II respectively were 18-50 and 19-48 years which was statistically non-significant with p=0.741. Mean age was statistically non-significant which was 37.61±9.34 years for Group I and 37.3±7.94 years for group II (p=0.814). There were 21 males and 8 females in group I, whereas, there were 23 males and 6 females in group II. This difference was statistically non-significant with p=0.383. The weight difference between the two groups was statistically non-significant where the group I subjects had a weight of 56.31±10.98kgs and Group II had a weight of 57.41±4.95 kgs (p=0.618). The duration of surgery in Group I was 33.31±9.47 minutes, whereas, for Group II, this duration was 34.48±8.91 minutes. This intergroup difference was also statistically non-significant with p=0.664.

On assessing the various clinical parameters in the two groups of the study subjects, it was seen that first mobilization time was significantly higher in group II (210.3±17.77) where chloroprocaine was used compared to group I (120.5±14.72) where the combination of clonidine with chloroprocaine was used (p<0.0001). Higher analgesia duration was seen in Group II (193.65±12.03) compared to Group I (100.3±15.21). This was statistically significant with p<0.0001. The duration of the motor block was higher in Group II with 76.39±9.46 minutes compared to Group I, where the duration was 69.95±7.64 minutes. The level of peak dermatome was above T6 in 1 (3.44%) subjects of Group II and no subject from Group I, T6-T9 was seen in 27.58% (n=8) study subjects from Group I and 62.06% (n=18) subjects from Group II, and in 68.96% (n=20) subjects from Group I and 31.03% (n=9) subjects from Group II. Onset time for the motor block was significantly lesser for group II where chloroprocaine was used with clonidine was 9.75±1.74 mins compared to Group I where only chloroprocaine was used as 11.33±2.92 mins. This was statistically significant with p=0.01. Also, sensory block onset time was significantly lesser for Group II (7.76±2.06) mins compared to Group I where it was 9.5±2.84 mins with p=0.01 as shown in Table 2.

Table 2: Clinical parameters in two groups of the study subjects

Parameter		Group I (n=29)	Group II (n=29)	p-value
First mobilization time (mins)		120.5±14.72	210.3±17.77	<0.0001
Analgesia duration (mins)		100.3±15.21	193.65±12.03	<0.0001
Motor block duration (mins)		69.95±7.64	76.39±9.46	0.006
Peak level dermatome % (n)	Above T6	-	3.44 (1)	0.013
	T6-T9	27.58 (8)	62.06 (18)	
	T10-T12	68.96 (20)	31.03 (9)	
Motor block onset time (mins)		11.33±2.92	9.75±1.74	0.01
Sensory block onset time (mins)		9.5±2.84	7.76±2.06	0.01

Discussion

The present prospective, randomized, observational clinical study was conducted to assess the safety profile, duration, and efficacy of 1% Chloroprocaine alone to 1% Chloroprocaine with Clonidine during daycare surgeries under Spinal anesthesia in Indian subjects. The study included a total of 58 subjects from both genders within the age range of 18-50 years and the mean age of 35.68±4.24 years were randomly divided into two groups.

The study results showed that the age range of subjects from Group I and II respectively

were 18-50 and 19-48 years which was statistically non-significant with p=0.741. Mean age was statistically non-significant which was 37.61±9.34 years for Group I and 37.3±7.94 years for group II (p=0.814). There were 21 males and 8 females in group I, whereas, there were 23 males and 6 females in group II. This difference was statistically non-significant with p=0.383. The weight difference between the two groups was statistically non-significant where the group I subjects had a weight of 56.31±10.98kgs and Group II had a weight of 57.41±4.95 kgs (p=0.618). The duration of surgery in Group I was 33.31±9.47 minutes, whereas, for Group II, this duration was 34.48±8.91 minutes. This intergroup difference was also statistically non-significant with p=0.664. These results were consistent with the results of Davis BR et al [5] in 2005 and Palas T [6] in 2003 where subjects with comparable demographics were assessed by the authors in their studies.

On assessing the various clinical parameters in the two groups of the study subjects, it was seen that first mobilization time was significantly higher in group I (210.3±17.77) where chloroprocaine was used compared to group II (120.5±14.72) where the combination of clonidine with chloroprocaine was used compared to group I (120.5±14.72) where the combination of clonidine with chloroprocaine was used (p<0.0001). Higher analgesia duration was seen in Group II (193.65±12.03) compared to Group I (100.3±15.21). This was statistically significant with p<0.0001. The duration of the motor block was higher in Group II with 76.39±9.46 minutes compared to Group I, where the duration was 69.95±7.64 minutes. These results were in agreement with the studies of Lacasse MA et al [7] in 2011 and Etezadi F et al [8] in 2013 where authors have reported results similar to the present study concerning clinical parameters.

The level of peak dermatome was above T6 in 1 (3.44%) subjects of Group II and no subject from Group I, T6-T9 was seen in 27.58% (n=8) study subjects from Group I and 62.06% (n=18) subjects from Group II, and in 68.96% (n=20) subjects from Group I and 31.03% (n=9) subjects from Group II. Onset time for the motor block was significantly lesser for group II where chloroprocaine was used with clonidine was 9.75±1.74 mins compared to Group I where only chloroprocaine was used as 11.33±2.92 mins. This was statistically significant with p=0.01. Also, sensory block onset time was significantly lesser for Group II (7.76±2.06) mins compared to Group I where it was 9.5±2.84 mins with p=0.01. These results were comparable to the studies of Vaghadia H et al [9] in 2012 and Choi S et al [10] in 2012 where authors have reported similar clinical parameters following the use of Chloroprocaine anesthesia in their studies.[11]

Conclusion

Within its limitations, the present study concludes that using clonidine with Chloroprocaine in low dose provides prolonged analgesia, better anesthesia quality, and increases the duration of motor and sensory block compared to Chloroprocaine alone. However, the present study had a few limitations including a small sample size, short monitoring time, and geographical area biases. Hence, more longitudinal studies with a larger sample size and longer monitoring period will help reach a definitive conclusion.

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