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Comparision of 1% Chloroprocaine With 0.5% Bupivacaine in Spinal Anaesthesia for Short Duration Surgical Procedures

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KEYWORDS

spinal, anesthetic, duration, sensory, motor

ABSTRACT:

Background: Search of a newer and safer anesthetic has always been a need in anaesthesiology. Reliable surgical anesthesia should be fast, with rapid recovery and minimal side effects. Lignocaine and bupivacaine are commonly used anesthetic agents but they have their side effects, a preservative-free 2-chloroprocaine (2-CP) seems to be a promising, being a short-acting agent of increasing popularity in recent years.

Aims & Objectives: The aim of our study was to compare subarachnoid block with 1% 2-Chloroprocaine and 0.5% Bupivacaine with respect to total duration of the sensory and motor blockade and time for complete regression of sensory and motor block.

Materials and Methods: A double blinded randomised controlled trial was carried out on 100 patients undergoing short duration ambulatory surgical procedures in only emergency operation theatre under subarachnoid block. They were randomly assigned into two groups of 50 each. Group B was administered 3cc of 0.5% Bupivacaine while patients in Group C were administered 3cc of 1% 2-Chloroprocaine intathecally. The extent and the duration of sensory and motor blockade, time required for complete regression of sensory and motor block, hemodynamic stability and time for complete ambulation were assessed in two groups.

Results: The time for onset of sensory and motor blockade as well as the time taken to attain the highest level of blocked sensory dermatome and degree of motor blockade was similar in both the groups. All the patients developed complete motor blockade.

Conclusion: intrathecal 2-Chloroprocaine 30 mg produces a satisfactory block for short surgical procedures lasting <60 min duration and is a better alternative than bupivacaine for such procedures.

INTRODUCTION: The quest for searching newer and safer anaesthetic agents has always been one of the primary needs in anaesthesiology practice. The two widely used local anaesthetics are lignocaine also known as lidocaine and bupivacaine.[1] There is a high incidence of transient neurological symptoms associated with the use of lignocaine when used in spinal anaesthesia whereas bupivacaine produces sensory and motor blocks of prolonged duration. Furthermore, urinary retention (or a prolonged interval to first voiding) which delays the time for discharge is frequently associated with Bupivacaine.[2] As a result, the search for the ideal local anaesthetic for outpatient spinal anaesthesia is still continuing. An alternative

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choice a preservative-free 2-chloroprocaine (2-CP) seems to be a promising, being a short-acting agent of increasing popularity in recent years.[3]

This study was designed to compare 2-CP with bupivacaine for spinal anaesthesia in short duration infraumbilical surgeries. The following data were recorded: peak block height and time to reach peak block height, time for regression of two segments, time for regression to L1, and time for complete regression of motor and sensory block. In addition, time to reach readiness for surgery, length of surgery, time for first voiding of urine, time to ambulate were noted and any complications related to the drug were also noted. The aim of our study was to compare subarachnoid block with 1% 2-Chloroprocaine and 0.5% Bupivacaine with respect to total duration of the sensory and motor blockade and time for complete regression of sensory and motor block.

MATERIALS AND METHODS: A double-blinded randomised controlled trial was conducted involving 100 patients undergoing short duration (</= 60 minutes) infraumbilical surgical procedures under subarachnoid block at Goa Medical College. The study protocol was approved by the ethical committee and ethical clearance was obtained.

Inclusion criteria:

- ASA physical status 1 & 2
- Age group - >18 yrs & <70 yrs
- Weight - BMI 19 – 30 kg/m2
- Either Sex
- Duration of surgical procedure- less than or equal to 60 minutes
- Surgical procedures – infraumbilical (below level of T10 dermatome)

Exclusion criteria:

- Pregnant and lactating females
- Patients with contraindications to spinal anaesthesia
- Intra-abdominal surgeries
- Patients requiring post-op urinary catheterisation
- Allergy to Local Anaesthetic agents

Pre anaesthetic check-up was done for all patients, which included a detailed history, physical examination and examination of spine for deformity and infection. Investigations were done as per requirement. The procedure of spinal anaesthesia and information regarding Bupivacaine and Chloroprocaine, along with the likely adverse effects following their administration in subarachnoid space were explained to the patients and written informed consent was taken from each patient.

Patients were kept nil by mouth at least 6 hours prior to surgery. Hundred patients belonging to ASA grade 1 and 2 were randomised by using a computer generated code, into two groups of 50 each, who received the following medications intrathecally:

Group B received 3cc (15mg) of Bupivacaine Hydrochloride (0.5%) intrathecally

Group C received 3cc (30mg) of 2-Chloroprocaine Hydrochloride (1%) intrathecally

The subarachnoid block was administered in the sitting position, under strict asepsis. After the subarachnoid block was administered, the following parameters were monitored intraoperatively; Heart rate, Blood pressure, oxygen saturation, respiratory rate immediately and at 2,5,10,15,20,30,40,50,60 minutes respectively. The sensory level was tested by pin prick method and the highest dermatological level of sensory blockade was noted. The time taken to achieve the highest sensory level was also noted, which was defined as the time from injection of the intrathecal drug to the loss of pin prick sensation at the highest dermatome. Motor blockade was assessed by Bromage scale.

Bromage scale

0 = no block, full straight leg raise possible;

1 = unable to straight leg raise, able to flex knee;

2 = unable to flex knee, able to flex ankle;

3 = no motor movement, complete motor block

A Bromage scale of 3 was considered as complete paralysis. Total duration of sensory and motor blockade was noted.The time for the first voluntary voiding of urine and complete ambulation were also noted. Patients were followed up for 24 hours postoperatively after administration of block. Respiratory rate, SpO2, sensory block, motor block was assessed. Patients were monitored for adverse effects namely bradycardia, hypotension, high spinal block, respiratory depression, PONV and urinary retention.

STATISTICAL ANALYSIS: Wilcoxon test and Fisher's exact test has been used to find the significance of study parameters on continuous scale between the two groups (inter group analysis). The Pearson chi-square test was used to assess the

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statistical significance in the gender distribution, ASA status, type of surgery, highest level attained and adverse effects. The Wilcoxon Rank sum test (Mann Whitney test) was used to assess statistical significance between groups with regard to heart rate and blood pressure. P value <0.005 was considered statistically significant.

RESULTS: The participants were distributed equally in Group B [50(50%)] who received Intrathecal 0.5% Bupivacaine and Group C [50(50%)] who received Intrathecal 1% 2- Chloroprocaine. There were 62% participants who belonged to ASA Grade I and 38% participants belonged to ASA Grade II. In both the groups the gender distribution was similar with 39 (78%) of the participants being males and 11 (22%)of the participants being female. The mean (SD) of sensory block onset (min) in the Group B was 2.51 (0.71). The mean (SD) of sensory block onset (min) in the Group C group 2.56 (0.82). The median (IQR) of Sensory Block Onset (Min) in the Group: B was 2 (1) whereas in the Group C was also 2 (1). The sensory block onset (min) in the Group B ranged from 1 - 5. The sensory block onset (min) in the Group C ranged from 1 - 5. Onset time for sensory block (min) between two groups was not found to be statistically significant (W = 1240.000, p = 0.943).[Table 1] Association between group and sensory block highest level is shown in Table 2. The mean (SD) of time (min) for motor block onset in the Group B was 2.29 (0.71). The mean (SD) of time (min) for motor block onset in the Group C was 2.64 (0.99). The median (IQR) of time (min) for motor block onset in the Group B was 2 (1) whereas in the Group C was 3 (1). The time (min) for motor block onset in the Group: B ranged from 1 – 4 whereas in the Group: C ranged from 1 – 5 min.Time (min) for motor block onset between two groups was not found to be statistically significant (W = 995.500, p = 0.064).[Table 3]

Association between group and highest level of motor block is shown in figure 1. The mean (SD) of time (min) for regression of sensory block to L1 in the Group B was 164.08 (16.35). The mean (SD) of time (min) for regression of sensory block to L1 in the Group C was 68.82 (8.27). The median (IQR) of time (min) for regression of sensory block to L1 in the Group B was 162.5 (10) whereas in the Group C was 70 (10). The time (min) for regression of sensory block to L1 in the Group B ranged from 120 – 200 whereas the time (min) for regression of sensory block to L1 in the Group C ranged from 55 - 100. There was a significant difference between the 2 groups in terms of time (min) for regression of sensory block to L1 (W = 2500.000, p = <0.001), with the median time (min) for regression of sensory block to L1 being longer in the Group B.[figure 2]

The mean (SD) of time (min) for regression of motor block to Bromage 0 in the Group B was 185.90 (16.31). The mean (SD) of time (min) for regression of motor block to Bromage 0 in the Group C was 78.12 (8.43). The median (IQR) of time (min) for regression of motor block to Bromage 0 in the Group B was 182.5 (10). The median (IQR) of time (min) for regression of motor block to Bromage 0 in the Group C was 80 (15). The time (min) for regression of motor block to Bromage 0 in the Group B ranged from 140 – 240 while the time (min) for regression of motor block to Bromage 0 in the Group C ranged from 65 - 100. There was a significant difference between the 2 groups in terms of time (min) for regression of motor block to Bromage 0 (W = 2500.000, p = <0.001), with the median time (min) for regression of motor block to Bromage 0 being longer in the Group B.[figure 3]

No side effects were obsereved in 43 (86%) of the participants in the Group B and 48 (96%) participants in Group C. Only 1 (2%) participant in Group C had side effects as Nausea/Vomiting. Seven (14%) of the participants in the Group B and 1 (2%) participant of Group C had side effects as hypotension. Distribution of side effects between two groups was not found to be statistically significant($X^2 = 5.775$, p = 0.059).[figure 4] The mean (SD) of total duration (min) of motor block in the Group B was 214.70 (17.74). The mean (SD) of total duration (min) of motor block in the Group C was 93.80 (6.59). The median (IQR) of total duration (min) of motor block in the Group B was 220 (20). The median (IQR) total duration (min) of motor block in the Group C was 95 (10). The total duration (min) of motor block in the Group B ranged from 150 – 250 whereas in the Group: C it ranged from 80 – 110 min. Total duration (min) of motor block between two groups was statistically significant (W = 2500.000, p = <0.001), with the median total duration (min) of motor block being longer in the Group B.[figure 5]

The mean (SD) of total duration (min) of sensory block in the Group B was 212.30 (20.13). The mean (SD) of total duration (min) of sensory block in the Group C was 89.20 (8.23). The median (IQR) of total duration

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(min) of sensory block in the Group B was 210 (30). The median (IQR) of total duration (min) of sensory block in the Group C was 90 (10). The total duration (min) of sensory block in the Group B ranged from 180 - 250. The total duration (min) of sensory block in the Group C ranged from 70 - 110. Total duration (min) of sensory block between two groups was found to be statistically significant (W = 2500.000, p = <0.001), with the median total duration (min) of sensory block being highest in the Group B.[figure 6]

DISCUSSION: Spinal anaesthesia has been the choice of anaesthetic method for infraumbilical and various lower limb surgeries.[4] But, some of its features like delayed ambulation, risk of urinary retention, and pain after block regression may prohibit its use for short duration surgeries.[5] Many clinicians are selecting general anaesthesia because of its relative predictability and to avoid undesirable side effects associated with spinal anaesthesia.[6] For example, lidocaine is frequently associated with transient neurologic symptoms (TNS), procaine is often unpredictable in duration and is associated with a frequent incidence of nausea. Small-dose bupivacaine has been used for spinal anaesthesia for procedures of short duration in attempts to avoid local anaesthetics such as lidocaine and procaine, known to cause adverse side effects mentioned above. But it causes frequent urinary retention, prolonged discharge time, and unpredictable levels of anaesthesia dependent on dose[7-10]. Hence the selection of proper local anaesthetic agent for short duration is very important. The ideal anaesthetic agent has to allow fast onset of action and also rapid regression of its actions with minimal side effects. New formulation of preservative free 2-chloroprocaine(2-CP) has been evaluated for use in the subarachnoid space and seems to be a predictable drug, ideal for short duration ambulatory surgical procedures.[11] We observed that intrathecal administration of 3cc (30mg) of 1% 2-Chloroprocaine when compared to 3cc (15mg) of 0.5% Bupivacaine had significantly shorter duration of sensory and motor block and also faster ambulation time.

The mean (SD) Onset of Sensory Block in the Group B was 2.51 (0.71) min whereas in the Group C it was found to be 2.56 (0.82) min. hence, there was no significant difference between the groups in terms of onset of sensory block (min) (W = 1240.000, p = 0.943). This was consistent with the results obtained by Marie-Andre´e Lacasse et al[12] and Yoos et al[13] in their study which did not show significant difference between two groups with respect to onset time for sensory block.

The highest level of sensory block attained was T4 and all the patients at least attained minimum level of T10. Majority patients in both group had sensory block height of T5. There was no significant difference between the two groups in terms of distribution of Highest Level of sensory block attained in both the groups (X^2 = 4.137, p = 0.381). These results were consistent with those in study conducted by Marie-Andre´e Lacasse et al[12] in which maximum level was T7 and minimum of T10 dermatome. However, the data of Marie-Andre´e Lacasse et al cannot be compared directly to ours as they used a different dose of drug. i.e. 2-CP-40mg and Bupivacaine-7.5mg was used in their study.

The mean (SD) time to reach highest sensory level in the group B was 7.46 (1.82) min whereas in the group C was 7.20 (2.18) minutes. The median (IQR) of time to reach highest sensory dermatome level (min) in the group B and group C was 7 (2) min. Hence, there was no significant difference between the groups in terms of time to Reach Highest sensory Level (Min) (W = 1273.000, p = 0.874). This was again consistent with the results found by by Marie-Andre´e Lacasse et al[12] and Yoos et al[13] although their time duration was slightly higher than our study due to different doses used in their study. They had used CP-40mg and Bupivacaine-7.5mg in their study.

The mean (SD) time (min) for onset of Motor Block in the Group B was 2.29 (0.71) while in the Group C was 2.64 (0.99). So, there was no significant difference between the groups in terms of Motor Block Onset time (min) (W = 995.500, p = 0.064) in either group. This was again consistent with the results found by by Marie-Andre´e Lacasse et al[12] and Yoos et al[13] in their study**.**

The mean (SD) time (min) to reach the highest motor block Bromage 3 in Group B was 5.49 (0.85) while in the Group C it was 5.06 (1.29). There was no significant difference between the groups in terms of Time (min) to reach highest level Bromage 3 (W = 1466.500, p = 0.115). This was similar to the results of studies by Yoos et al[13] in which they found 2-CP required mean time 10 +/-0(min) while Bupivacaine took 12 +/-5(min) and doses used were CP-40mg and Bupivacaine-7.5mg. In another study by C.

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Camponovo et al[14] it was found to be 5 min in CP group and 6 min in Bupivaine group using 50 mg of plain 1% 2- chloroprocaine & 10 mg of plain 0.5% bupivacaine.

The mean (SD) of time for regression of sensory block To L1 in our study in Group B was 164.08 (16.35) min whereas in the Group C was 68.82 (8.27) min. Thus we found that, in 2-CP group the regression was 2.4 times faster compared to Bupivacaine group. There was a significant difference between the 2 groups in terms of time (min) for regression of sensory block to L1 (W = 2500.000, p = <0.001), with the median time for regression of sensory block to L1 being longer in the Group B.This was consistent with the results of Yoos et al[13], Lacasse et al[12], Kouri ME et al[15] in their study used 40mg of 1% 2-CP and 2% lidocaine 40mg in their study and compared the parameters. In another study, by Gonter AF et al[16] it was seen that time for regression for block to L1 in 2-CP group was 42±30 and for Procaine group was 75±15(p <0.05). They used 30mg 2-CP and 80 mg Procaine in their study.

The mean (SD) of time (min) for regression of motor block to Bromage 0 (min) in the Group B was 185.90 (16.31) while in the Group C was 78.12 (8.43). Time for regression of motor block) in the Group B ranged from 140 – 240 min while for the Group C ranged from 65 – 100 min. There was a significant difference between the 2 groups in terms of time (min) for regression of motor block to bromage 0 (W = 2500.000, p = <0.001), with the median time for regression of sensory block to L1 (min) being longer in the Group B.

Our results were similar with the results of Lacasse et al[12] who found the time to be 76 min vs. 119 min for CP and Bupivacaine respectively when CP-40mg and Bupivacaine-7.5mg was used. Casati et al[17] in their study found it to be 60min for 2-CP group and 100 min in Lidocaine group in which they used 50mg of 1% 2-CP and 50 mg of 1% Lidocaine intrathecally.

The mean (SD) of total duration (min) of motor block in the Group B was 214.70 (17.74) and in the Group C was 93.80 (6.59). The median (IQR) of total duration (min) of motor block in the Group B was 220 (20) while in the Group C was 95 (10) min. There was a significant difference between the 2 groups in terms of total duration of motor block (W = 2500.000, p = <0.001), with the median total duration of motor block being higher in the Group B. This result was also consistent with that by Camponovo et al[14] who found duration of 100 min with 2-CP vs. 210 min with Bupivacaine, Lacasse et al[12] who found 76 min with 2- CP vs. 119 min with Bupivacaine in their similar studies. Casati et al[17] in his study found total duration of motor block to be 100 min for 1% Lidocaine(50mg) and 60min for 1% 2-Chloroprocaine(50mg)

The mean (SD) of total duration (min) of sensory block in the Group B was 212.30 (20.13) and in the Group C was 89.20 (8.23). The median (IQR) of total duration (min) of sensory block in the Group B was 210 (30) while in the Group C was 90 (10). There was a significant difference between the 2 groups in terms of total duration of sensory block (W = 2500.000, p = <0.001), with the median total duration of sensory block being significantly longer in the Group B. Camponovo et al[14] in their study used 50 mg of plain 1% 2- Chloroprocaine and 10 mg of plain 0.5% Bupivacaine. Yoos et al[13] and Lacasse et al[12] both used CP-40mg and Bupivacaine-7.5mg in their study. Casati et al[17] in their study used 50mg of 1% 2-CP and 50 mg of 1% Lidocaine intrathecally.

It was observed that 14.0% of the participants in the Group B had Hypotension (MAP<20% of baseline). While 2.0% of the participants in the Group C had Nausea/Vomiting and only 2.0% of the participants had hypotension following spinal anaesthesia.This shows that incidents of hypotension were relatively higher in patients receiving Bupivacaine.None of the patients were found to develop any Transient Neurologic symptoms in our study and this finding was consistent with results of study in 2004 by Yoos et al[18].

CONCLUSION: Intrathecal 2-CP 30 mg produces a satisfactory block for short surgical procedures lasting <60 min duration and is a better alternative than bupivacaine for such procedures. When compared with hyperbaric spinal 0.5%bupivacaine 15 mg, resulted in a significantly faster regression of the motor and sensory block, shorter time to ambulation and micturition, and faster recovery followed by earlier discharge from hospital in these patients. Future work may confirm our predication that choosing 2-CP for spinal anaesthesia in an ambulatory surgery setting may free up the PACU and ambulatory surgical unit resources with a corresponding decrease in total perioperative health costs.

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Table 1: Comparison of the 2 Groups in Terms of onset of sensory block (n = 100)

Sensory Block: Onset (Min)	Group		Wilcoxon Test	
	B	C	W	p value
Mean (SD)	2.51 (0.71)	2.56 (0.82)	1240.000	0.943
Median (IQR)	2 (1)	2 (1)		
Range	1 - 5	1 - 5		

Table 2: Association between group and sensory block highest level (n = 99)

Sensory Block: Highest Level	Group						Fisher's Exact Test	
	B		C		Total			
	N	%	N	%	N	%	X^2	p value
T4	14	28.0%	11	22.4%	25	25.3%	4.137	0.381
T5	20	40.0%	15	30.6%	35	35.4%		
T6	15	30.0%	18	36.7%	33	33.3%		
T8	1	2.0%	4	8.2%	5	5.1%		
T10	0	0.0%	1	2.0%	1	1.0%		
Total	50	100.0%	49	100.0%	99	100.0%		

Table 3: Comparison of the 2 Groups in terms of time (min) for motor block onset (n =100)

Motor Block: Onset (Min)	Group		Wilcoxon Test	
	B	C	W	p value
Mean (SD)	2.29 (0.71)	2.64 (0.99)	995.500	0.064
Median (IQR)	2 (1)	3 (1)		
Range	1 - 4	1 - 5		

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Figure 1: Association between group and highest level of motor block (n = 100)

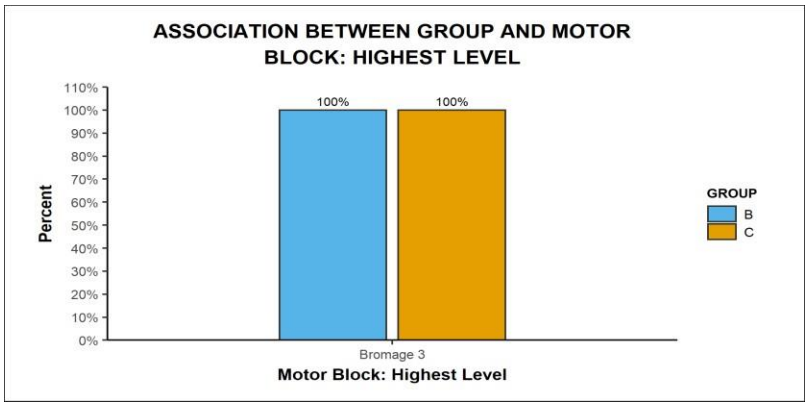

Figure 2: Comparison of the 2 Groups in terms of time (min) for regression of sensory block to L1 (n = 100)

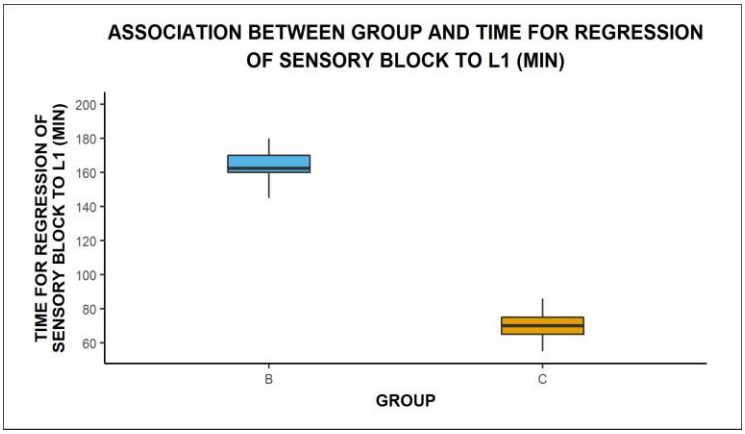

Figure 3: Comparison of the 2 Groups in Terms of Time for Regression of Motor Block To Bromage 0 (n = 100)

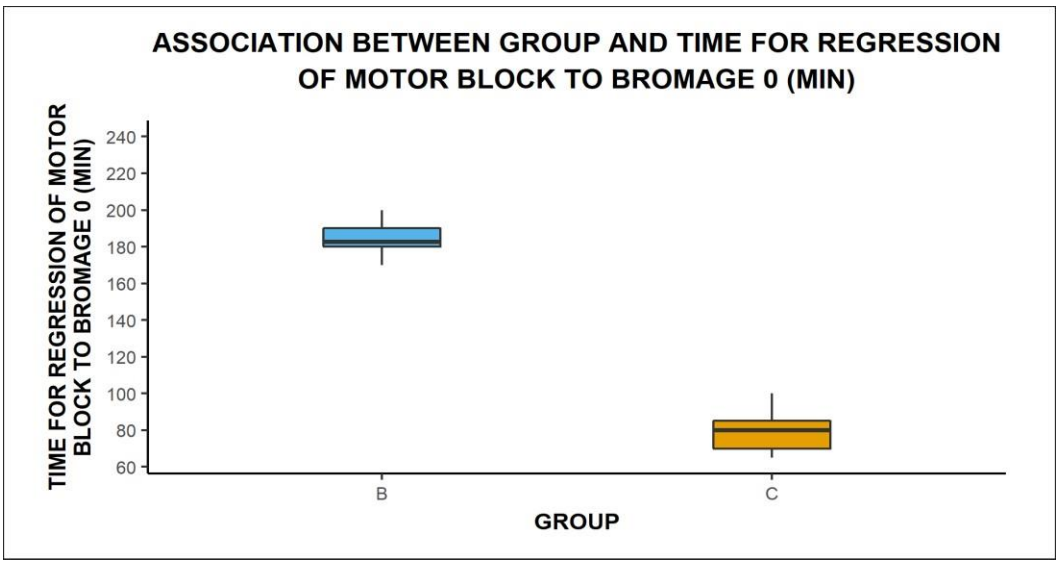

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Figure 4: Association Between Group and Side Effects (n = 100)

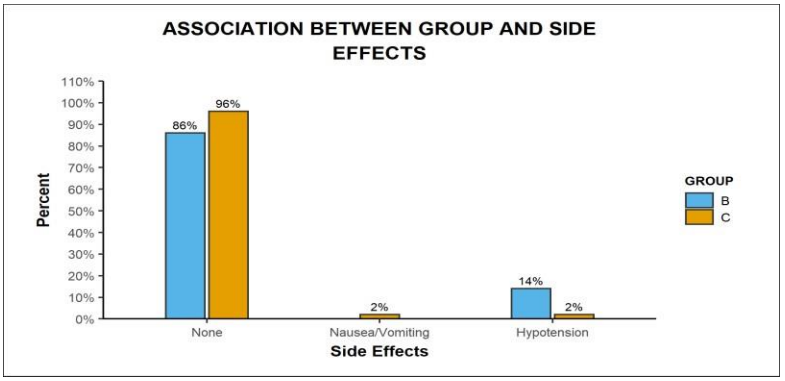

Figure 5: Comparison of the 2 Groups in terms of total duration (min) of motor block (n = 100)

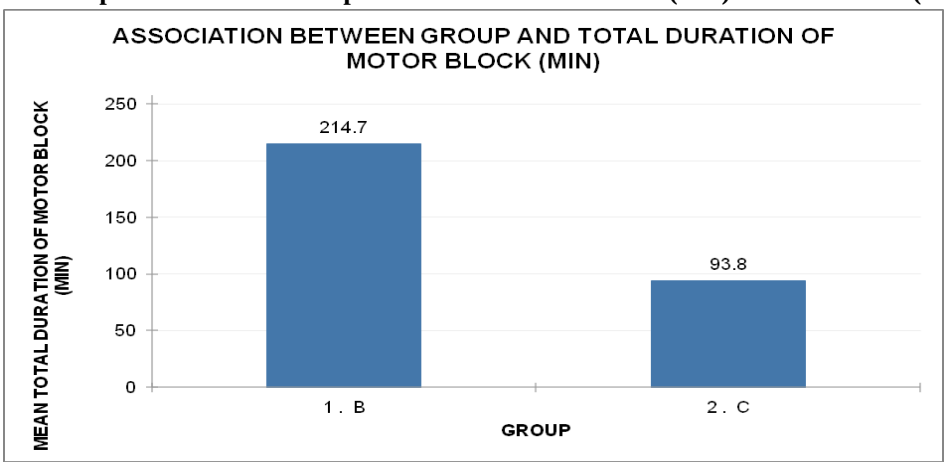

Figure 6: Comparison of the 2 Groups in terms of total duration (min) of sensory block (n = 100)