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Original Research Article

Efficacy of 2-chloroprocaine for spinal anesthesia compared to 0.5% hyperbaric bupivacaine: A randomized controlled study

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ABSTRACT

Background: In 1980s, nine cases of neurotoxicity were reported following the use of 2-chloroprocaine (2-CP). But, Taniguchi et al found that it was due to low pH and antioxidant sodium bisulfite. Further studies confirmed that it was safe to use the drug. It provides spinal anesthesia adequately.
Objective: To study efficacy of 2-chloroprocaine for spinal anesthesia compared to 0.5% hyperbaric bupivacaine
Materials and Methods: This was a randomized controlled study. We used prospective double blind method. The study was done in 100 patients. Random allocation software was used to randomize patients in two groups. Group 1 patients (N=50) received 4 ml 1% 2-chloroprocaine while Group 2 patients (N=50) were given 2.5 ml 0.5% hyperbaric bupivacaine.
Results: Baseline parameters were similar in two groups ($p>0.05$). Parameters like Sensory onset, Height of Sensory blockade, Time for two segment regression, Duration of motor block, Time to void urine were significantly more patients belonging to Group-II (0.5% hyperbaric bupivacaine) compared to patients belonging to group-I (2-chloroprocaine) ($p<0.05$).
Conclusion: 4 ml 1% 2-chloroprocaine for intrathecal injection of lower limb and lower abdominal surgeries is more effective than 2.5 ml 0.5% hyperbaric bupivacaine.

1. Introduction

Regional anesthesia is preferred for lower limb surgeries as well as lower abdominal surgeries. Patient remains awake and it avoids the airway related problems. Compared to epidural anesthesia, spinal anesthesia is simple and rapid. It was first used with cocaine in 1851. Quincke's technique was used in 1899 by August Bier who also used cocaine as first real spinal anesthesia.[1]

In ambulatory surgeries, the drug of choice in spinal anesthesia was lignocaine. The onset of action is rapid with it. It produces good motor block. But, it is found to be associated with symptoms of the central nervous system although for short time. it can also lead to cauda equine syndrome.[2,3]

Studies have shown that small doses of hyperbaric bupivacaine may be **a** useful alternative in small doses. But, block density achieved is not sufficient with it. Duration of action of 2-chloroprocaine (2-CP) is short.[4] It has been reported as safe and reliable since 1952. It was commonly used during obstetric procedures.[5] In 1980s, nine cases of neurotoxicity were reported following the use of 2-chloroprocaine (2-CP). But, Taniguchi et al found that it was due to low pH and antioxidant sodium bisulfite. Further studies confirmed that it was safe to use the drug. It provides spinal anesthesia adequately.[6–8]

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Various studies[9–14] subsequently confirmed the safety profile of 2-chloroprocaine in the dose of 40-50 mg. spinal anesthesia achieved was adequate which lasted for 45-60 min. it is commonly used in lower limb and lower abdominal surgeries.

The aim of this study was to study efficacy of 2-chloroprocaine for spinal anesthesia compared to 0.5% hyperbaric bupivacaine.

2. Materials and Methods

This was a randomized controlled study. We used prospective double blind method. The study was done in 100 patients at Malla Reddy Narayana multispecialty hospital, Hyderabad. Random allocation software was used to randomize patients in two groups. This was a parallel trial. There were no changes to the trial after it was initiated.

Patients aged 20-50 years of either gender, undergoing elective surgical procedures using the spinal anesthesia, with duration of surgery less than 40 min were included in the present study. Patients having any chronic diseases as well as pregnant women were excluded.

Random allocation software was used to randomize patients in two groups. Group 1 patients (N=50) received 4 ml 1% 2-chloroprocaine while Group 2 patients (N=50) were given 2.5 ml 0.5% hyperbaric bupivacaine. Random allocation software was used to randomize the patients in two groups.

All patients underwent the pre-anesthetic check-up. Based on the fitness report, they were posted for surgery.

The person administering spinal anesthesia has not been involved in recording data. An independent observer not involved in drug preparation had measured subsequent parameters. The time counting was initiated when intrathecal injection was given. During the first 10 minutes, the various parameters (Hemodynamic parameters, SpO2 and respiratory rate) were recorded at an interval of every two minutes. After the first 10 minutes, till the surgery is over, these same parameters were recorded every 10 minutes. During the period after the surgery is over, same parameters were recorded every half an hour.

The time at which the sensory block was achieved was noted. The highest point of sensory block was also noted down. Bromage scale was used to assess the motor block.

Time of onset of sensory blockade, the height of sensory blockade, Onset of motor blockade as per Bromage scale, two segment regression time, Quality of sensory blockade (good, satisfactory, poor), Total duration of analgesia, Incidence of adverse effects, Time of ambulation, and Time of voiding of urine were also recorded.

Onset of sensory blockade was defined as the time duration between giving the drug and no pain felt by patient at T10 level.

Duration of sensory blockade was defined as time taken from the onset of sensory blockade till the two-segment regression time.

Quality of sensory blockade was appreciated as good, satisfactory, poor. Good quality of sensory blockade was considered when the it was adequate for surgical procedure without any analgesia. Poor quality of sensory blockade was considered when analgesia was required.

2.1. Statistical analysis

SPSS version 17.0 was used for data analysis. T test was used for comparison while using the continuous variables. P<0.05 was taken as statistical significance.

3. Results

Both the groups were comparable for age, pulse rate, Mean arterial pressure and SPO2 (Table 1).

Both the groups were comparable for sex and ASA grade (Table 2)

All studied parameters like Sensory onset (min), Height of Sensory blockade (min), Time for two segment regression (min), Duration of motor block (min), Time to void urine (min) were significantly lower in group I patients who received 2-chloroprocaine compared to group II patients who received 0.5% hyperbaric bupivacaine (p<0.05). (Table 3)

The scores of modified Bromage scale and the occurrence of adverse events were found to be comparable. There were not statistically significant differences in two groups with this regard (p>0.05). (Table 4)

4. Discussion

The present study findings are similar to the study done by Yoos et al.[14] They compared 2-CP 40 mg with bupivacaine 7.5 mg. they noted that the duration provided by the 2-CP was adequate. At the same time, the density of the block with the use of 2-CP was also adequate. The block was achieved very fast. The patients were able to return to ambulation in quick time.

Time for two segment regression was quicker with the use of the 2-chloropocaine when compared to 0.5% Hyperbaric Bupivacaine in the present study. Similar findings were also reported by Yoos et al[14] and Kopacz an Lacasse et al study.[15]

Yoos et al[14] used the 2-chloropocaine in the dose of 40 mg. Bupivacaine was used in the dose of 7.5 mg in second group of patients. They carried out a randomized controlled blinded trial. They studied the anesthesia test using the pin prick, strength of the muscles, electric stimulation. They also studied the simulated discharge criteria. Lacasse et al[15]used hyperbaric Bupivacaine in the dose of 7.5 mg. they also used 2-chloropocaine (2%) in the dose of 40 mg in another group of patients. From both studies, it is clear that 2-chloropocaine was more effective than hyperbaric bupivacaine. The discharge time was lesser with

Table 1: Clinical characteristics of two groups

	Group I		Group II		t	p
	Mean	SD	Mean	SD		
Age (years)	39.72	11.49	36.44	10.99	1.458	0.148
Pulse rate/min	77.6	7.97	77.7	7.39	0.091	0.928
Mean arterial pressure (mmHg)	77.5	6.3	75.8	8.8	1.09	0.278
SPO2	99.74	0.56	99.58	0.78	1.14	0.245

Table 2: Distribution of patients based on genderand ASA Grade

Parameters		Group I		Group II		Chi square	p
		Number	%	Number	%		
Sex	Male	40	80	40	80	0	1
	Female	10	20	10	20		
ASA grade	I	39	78	38	76	0	0.999
	II	11	22	12	24		

Table 3: Efficacy of 2-chloroprocaine for spinal anesthesia compared to 0.5% hyperbaric bupivacaine

Parameters	Group I (2-chloroprocaine)		Group II (0.5% hyperbaric bupivacaine)		t	p
	Mean	SD	Mean	SD		
Sensory onset (min)	3.9	1.18	5.6	1.36	6.72	<0.001
Height of Sensory blockade (min)	7.18	1.75	8.7	1.3	4.89	<0.001
Time for two segment regression (min)	53.46	8.52	73.2	4.1	14.77	<0.001
Duration of motor block (min)	79.44	9.5	95.4	8.2	9.03	<0.001
Time to void urine (min)	134.1	24.4	271.8	33.1	23.67	<0.001

Table 4: Comparison of Modified Bromage Score and adverse events in two groups

		Group I		Group II		Chi square	p
		No.	%	No.	%		
Modified Bromage scale	2 & 3	46	92	40	80	2.078	0.149
	4	4	8	10	20		
Adverse events	Yes	2	4	3	6	0	1
	No	48	96	47	94		

2-chloropocaine compared to hyperbaric bupivacaine. This difference was found to be statistically significant (p<0.05). The time for two segment regression was significantly longer with the hyperbaric bupivacaine compared to the 2-chloropocaine. The time for regression to L1 was significantly more with hyperbaric bupivacaine compared to 2-chloropocaine. The duration of motor blockade was also significantly lesser with 2-chloropocaine. Time to ambulation was also significantly more with hyperbaric bupivacaine. The time for complete regression to S2 was significantly more with hyperbaric bupivacaine.

In the present study patients who received the 2-Chloroprocaine were able to void the urine earlier than those patients who received the hyperbaric bupivacaine. Breebaart et al[16] also found from their study that patients who received the 2-Chloroprocaine were able to void the urine earlier than those patients who received the hyperbaric bupivacaine. This difference was found to be statistically significant (p<0.05).

In the present study it was noticed that patients who received the 2-Chloroprocaine were discharged from the hospital earlier compared to those patients who received the hyperbaric bupivacaine.

Sell and Pitkanen[17] used the 2-Chloroprocaine in doses ranging from 35-50 mg. the increment in the dose for each of the four groups of patients was of 5 mg. They observed that the time to discharge was slower in patients who received higher doses compared to patients who received lower doses. Similar observation was noticed with respect to the regression of sensory block. This difference was found to be statistically significant. They also observed that the higher level block was similar in four groups. They also noticed that time required for complete block regression was also similar in four groups of the patients.

Mulroy et al[18] stated that the time to void urine should not be taken as a mandatory parameter if they received the short acting drugs.

Hejtmanek and Pollock[19] carried out a retrospective study. They observed that neurotoxicity was not seen in patients who received the 2-CP drug. They stated that this drug was used as a drug of choice in their tertiary care center. Because it is safe and effective compared to lidocaine. So, this drug can be used in short ambulatory surgeries.

Casati et al[20] compared 2-CP with lidocaine. They found that the patients who received 2-CP had significantly faster recovery compared to patients who received the lidocaine ($p<0.05$). 2-CP was significantly more effective in faster time-to-ambulation. But, in terms of discharge of the patients from the hospital, both the groups were comparable.

5. Conclusion

Based on the present study findings in the given study patients we conclude that 1% 2-Chloroprocaine 40 mg for intrathecal injection of lower limb and lower abdominal surgeries is more effective than 0.5% Hyperbaric Bupivacaine. More multi-centric studies with larger sample size may be required to prove present study conclusion.

6. Source of Funding

None.

7. Conflict of Interest

None.

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