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A prospective comparative study to assess block characteristics of 2-chloroprocaine and bupivacaine for lower limb surgeries under spinal anaesthesia

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Abstract

For decades, lignocaine was the local anaesthetic of choice for spinal anaesthesia in ambulatory surgeries. Its advantages are rapid onset of action and good motor block manifested as good muscle relaxation. Its use has become limited because of transient neurologic symptoms and cauda equina syndrome following intrathecal injection. After obtaining the approval of scientific, ethics committee and written informed consent, a total of 100 patients undergoing elective lower limb surgeries under spinal anaesthesia were selected. Patients were explained before operative procedure. Pre-anaesthetic check- up was carried out preoperatively with a detailed history, general physical examination and systemic examination. Airway assessment and spinal column examination was done. In the present study it was observed that there was a statistically difference in the bromage score between groups, score 2 was significantly higher in group II, score 3 was significantly higher in group I $p < 0.05$. In the present study it was observed that Mean time (in minutes) to pass urine was significantly lower in group I than compared to group II $p <0.05$.

Keywords: 2-Chloroprocaine, bupivacaine, lower limb surgeries

Introduction

Regional anaesthesia is the preferred technique for most of the lower abdominal and lower limb surgeries. It allows the patient to remain awake and minimizes or completely avoids the problems associated with airway management. Spinal anaesthesia technique is simple to perform and the onset of anaesthesia is more rapid than epidural anaesthesia, allowing the surgical incision to be sooner. Spinal anaesthesia is one of the most common approaches for most of the lower abdominal and lower limb surgeries [1, 2].

Spinal anaesthesia with cocaine was initially produced inadvertently by Leonard J Corning in 1885 [1]. Quincke in 1891 demonstrated a safe, predictable means of performing lumbar puncture. In 1899, August Bier used Quincke's technique to inject cocaine in order to produce operative anaesthesia, which was the first real spinal anaesthesia [3].

For decades, lignocaine was the local anaesthetic of choice for spinal anaesthesia in ambulatory surgeries. Its advantages are rapid onset of action and good motor block manifested as good muscle relaxation. Its use has become limited because of transient

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neurologic symptoms and cauda equina syndrome following intrathecal injection [2, 3]. After many studies, use of hyperbaric bupivacaine, a long acting local anaesthetic was made by small doses. But, the density of block was insufficient [4].
An amino-ester local anaesthetic, 2-chloroprocaine (2-CP), is of shorter duration of action[4]. Initially used mostly for obstetrical epidurals, its safety and reliability for spinal anaesthesia has been reported since 1952 [5], concerns about its use were raised in the 1980s following the description of nine cases of neurotoxicity.
Taniguchi *et al*. [6] study debated the concept that chloroprocaine-related neurologic toxicity reported in the 1980s after unintentional spinal injection during attempted epidural anaesthesia was caused by the combination of low pH and the antioxidant sodium bisulfite [7, 8].
Studies in volunteers and reports on use of spinal 2-chloroprocaine in clinical practice support the safety profile of the preservative free formulation of 40 to 50 mg of plain 1% chloroprocaine provided adequate spinal anaesthesia for lower limb and lower abdominal surgeries lasting 45 to 60 minutes.
The present study hypothesized the same characteristic of onset of spinal blockade, but faster recovery profile with 2-Chloroprocaine compared to Bupivacaine.

Methodology

Study design: A Prospective randomized study.
Place of the study: Department of Anaesthesiology.
Study population: Total 100 patients of 18-60 years of age belonging to ASA grade I and ASA grade II scheduled to undergo lower limb surgeries will be studied.

The inclusion criteria

- Patients of both sex aged between 18 to 60 years.
- Patients undergoing lower limb surgery under spinal anesthesia.
- ASA grade I and II.

The exclusion criteria

- Patient's refusal to participate.
- Patients suffering from cardiac (Arrhythmias, heart blocks) and pulmonary diseases.
- Patients with known allergy to test drug.
- Patients with gross spinal abnormality, localized skin sepsis, hemorrhagic diathesis, neurological involvement/diseases.
- Patients with head injury, raised intra cranial pressure, raised intra ocular pressure.
- Patients with psychiatric disorders.
- Patients with asthma.
- Patients with epilepsy.
- Pregnant patients undergoing non-obstetric surgeries.

Sampling procedure

With the approval of ethical committee and taking informed consent, 100 patients were randomly divided into two groups of 50 each. A prospective randomized study was planned.
Group 1: 50 patients will receive intrathecal 50 mg of 1% 2-Chloroprocaine.
Group 2: 50 patients will receive intrathecal 10mg of 0.5% hyperbaric bupivacaine.

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Pre-operative assessment

Pre anaesthetic check-up was carried out pre-operatively with a detailed history, general physical examination and systematic examination. Airway assessment and spinal column examination was done. The procedure of spinal anaesthesia and administration of needed drugs was explained to the patient and written informed consent was obtained.

Investigations

- Complete blood picture.
- Bleeding time.
- Clotting time.
- Prothrombin time and INR.
- Platelet count.
- Serum creatinine.
- Blood urea.
- Liver function test.
- Blood sugar.
- Blood grouping and Rh typing.
- ECG.
- Chest X ray.
- Urine analysis.

After obtaining the approval of scientific, ethics committee and written informed consent, a total of 100 patients undergoing elective lower limb surgeries under spinal anaesthesia were selected. Patients were explained before operative procedure. Pre- anaesthetic check- up was carried out preoperatively with a detailed history, general physical examination and systemic examination. Airway assessment and spinal column examination was done.
Inclusion criteria were American Society of Anaesthesiologists (ASA) physical status I or II, either sex, age 18–60 years, presenting for lower limb surgeries. Exclusion criteria were patient allergic to drug, heart block/dysrhythmia. Hundred slips were made in such a manner that fifty slips had Group 1 written on it and the other fifty had Group 2. The slips were numbered from 1 –100, mixed and kept in a box. One slip was taken and the drug was drawn accordingly and labelled with the number in accordance with the randomization. The slips were coded and the solution was prepared by an anaesthesiologist who was not involved in the study. At the end of the study, decoding was done.

Results

Table 1: Onset of Sensory Block in both groups

	Group I		Group II		t value	p value
	Mean	SD	Mean	SD		
Sensory onset	3.9	1.18	5.6	1.36	6.72	<0.001

In the present study it was observed that Mean sensory onset (in minutes) was significantly lower in group I than compared to group II $p < 0.05$.

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Table 2: Height of sensory blockade in both groups

	Group I		Group II		t value	p value
	Mean	SD	Mean	SD		
Height of Sensory blockade	7.18	1.75	8.7	1.3	4.89	<0.001

In the present study it was observed that Mean height of sensory block was significantly lower in group I than compared to group II p <0.05.

Table 3: Onset of Motor Blockade -Modified Bromage Score in both groups

	Group I		Group II	
	No.	%	No.	%
2	0	0	7	14
3	46	92	33	66
4	4	8	10	20
Total	50	100	50	100
chi square	11.71		p value	0.03

In the present study it was observed that there was a statistically difference in the bromage score between groups, score 2 was significantly higher in group II, score 3 was significantly higher in group I p < 0.05.

Table 4: Duration of motor block in both groups

	Group I		Group II		t value	p value
	Mean	SD	Mean	SD		
Duration of motor block	79.44	9.5	95.4	8.2	9.03	<0.001

In the present study it was observed that Mean duration (in minutes) of motor block was significantly lower in group I than compared to group II p <0.05

Table 5: Time for Two Segment Regression in both groups

	Group I		Group II		t value	p value
	Mean	SD	Mean	SD		
Time for two segment regression	53.46	8.52	73.2	4.1	14.77	<0.001

In the present study it was observed that Mean Time in minutes for two segment regression was significantly lower in group I than compared to group II p <0.05

Table 6: Time taken for ambulation

	Group I		Group II		
	Mean	SD	Mean	SD	p-value
Time taken for ambulation	181.12	5.64	264.58	5.41	<0.001 (highly significant)

In the present study, it was observed that Mean time taken for ambulation (in minutes) was significantly lower in group I compared to group II p < 0.05

Table 7: Time to void urine

	Group I		Group II		t value	p value
	Mean	SD	Mean	SD		
Time to void urine	134.1	24.4	271.8	33.1	23.67	<0.001

In the present study it was observed that Mean time (in minutes) to pass urine was significantly lower in group I than compared to group II $p < 0.05$

Discussion

We conducted a randomized, Prospective Comparative study to evaluate the effect of spinal anaesthesia with 1% 2-chloroprocaine 50mg for lower limb surgeries, we measured time of onset and duration of sensory block, haemodynamic changes, Modified Bromage score, duration of motor block, time taken for ambulation and voiding of urine and any adverse effects. All these were measured from the time of subarachnoid block.

This was supported by Yoos *et al*. (2005) [9] who compared 2-CP 40 mg with bupivacaine 7.5 mg. They concluded that spinal 2-CP provides adequate duration and density of block for ambulatory surgical procedures, and it has a significantly faster resolution of block and return to ambulation.

They designed this double-blind, randomized, crossover, volunteer study to compare 40 mg of 2-CP with small-dose (7.5 mg) Bupivacaine with measures of pinprick anaesthesia, motor strength, tolerance to tourniquet and electrical stimulation, and simulated discharge criteria.

Peak block height (2-CP average T7 [range T3–10]; Bupivacaine average T9 [range T4–L1]), regression to L1 (2-CP 64 ± 10 versus Bupivacaine 87 ± 41 min), an tourniquet tolerance (2-CP 52 ± 11 versus Bupivacaine 60 ± 27 min) did not differ between drugs ($P = 0.15$, 0.12, and 0.40, respectively). However, time to simulated discharge (including time to complete block regression, ambulation, and spontaneous voiding) was significantly longer with Bupivacaine (2-CP 113 ± 14, Bupivacaine 191 ± 30 min, $P = 0.0009$). No subjects reported transient neurologic symptoms or other side effects. They concluded that spinal 2-CP provides adequate duration and density of block for ambulatory surgical procedures, and has significantly faster resolution of block and return to ambulation compared with 7.5 mg of Bupivacaine.

In our study, we used 10 mg of 0.5% Hyperbaric Bupivacaine for intrathecal injection for lower limb surgeries. We measured time of onset and duration of sensory block, haemodynamic changes, modified Bromage score, duration of motor block, time taken for ambulation and voiding of urine and any adverse effects.

Hundred patients undergoing elective lower limb surgeries received either 10mg of 0.5% Hyperbaric Bupivacaine or 50 mg of 1% 2-Chloroprocaine.Sensory blockade was verified with the pinprick test; motor blockade was documented by using a modified Bromage scale. Inter group differences between 2-Chloroprocaine and Bupivacaine were significantly less with 2-Chloroprocaine with regard to onset of sensory blockade and motor blockade, both groups showed slight reductions in heart rate and mean arterial pressure, but there was no difference in intergroup haemodynamics. We conclude that intrathecal 2-Chloroprocaine has got faster onset of both sensory and motor blockade.

In our study, we conclude that two segment regression and regression of motor blockade is earlier with 2-Chloropocaine than 0.5% Hyperbaric Bupivacaine which is supported by Yoos and Kopacz [9] and Lacasse *et al*. [10].

In our study we found that the two segment regression is earlier with 2-chloroprocaine than 0.5% Hyperbaric bupivacaine.

In the first study, 40 mg of 2-CP was compared with 7.5 mg of bupivacaine in a double-blind, randomized, crossover, volunteer study in terms of pinprick anaesthesia, motor strength, tolerance to tourniquet and electrical stimulation and simulated discharge criteria.

In the second study, Lacasse *et al*. [10] compared 7.5 mg of hyperbaric Bupivacaine 0.75% to 40 mg of 2-CP 2% in 106 patients. A total of 106 patients were enrolled in this randomized double-blind study. Spinal anaesthesia was achieved with 0.75% hyperbaric Bupivacaine 7.5 mg ($n = 53$) or 2% preservative-free 2-CP 40 mg ($N = 53$). The primary endpoint for the

study was the time until reaching eligibility for discharge.
Secondary outcomes included the duration of the sensory and motor blocks, the length of stay in the post anaesthesia care unit, the time until ambulation, and the time until micturition.
Their data showed peak sensory block height T7 (T1-T10), two-segment regression (min) 50 (18), time for complete regression to S2 (min) 146 (38), duration of motor block 76 (25) for 40mg 2-CP group.
In our study, we observed sensory block height Mean (SD) as T7.18 (1.75), two segment regression (min) 53.46 (8.52), duration of motor block (min) 79.44 (9.5).
Our observation matches with the above study. Two segment regression and duration of motor block was marginally more in our study. This may be because we have used 2-CP 50 mg. But this was not clinically significant.
The observations they made in Bupivacaine group were, peak sensory block height T7 (T1-T11), two segment regression (min) 75 (37), time for complete regression (min) 160 (62), duration of motor block (min) 119 (93), time to ambulation (min) 265 (65), time to micturition 338 (99).
In our study, in Bupivacaine group, peak sensory block height was T8.7 (SD 1.3), two segment regression (min) 73.2 (SD4.1), duration of motor block 95.4 (SD), time to ambulation (min) 264.5 (5.41), time to micturition (min) 271.8 (33.1). Duration of motor block, ambulation and micturition were shortened in our study, but not clinically significant.
The authors in both studies found significantly longer discharge times with low-dose Bupivacaine than with 2-CP. All offset variables showed a faster resolution of the spinal block after 2-CP, including time for two-segment regression, time for regression to L1, time for complete regression to S2, duration of motor blockade, time-to-ambulation as well as time to first analgesic requirement.
In our study we found that time of voiding of urine is much earlier with 2- Chloroprocaine when compared to hyperbaric Bupivacaine which was supported by Breebaart *et al*. who also demonstrated a longer interval to first voiding in patients having spinal anaesthesia with long acting local anaesthetics (Levobupivacaine and Ropivacaine) compared with those with shorter-acting agents. This delay may be explained by the need for a regression of the sensory block to at least the S3 dermatome in order to obtain normal detrusor function. Onset and quality of the block were comparable between groups. Time to regain Bromage 1 and L2 regression were shorter for the CP group compared with the L group. Voiding (168 ± 44 min) and discharge (178 ± 52 min) were approximately 40 min faster for the CP group compared with the L group. Pre-load provided faster bladder filling but there were no differences in voiding time within the CP or L group. The CP+ group (166 ± 36 min) was discharged faster than both L groups (226 ± 57 min, 227 ± 59 min). More serious micturition problems occurred in the L+ group compared with both CP groups.
In our study, we observed time to void was 134.1 (24.4) min in 2-CP group which was less compared to their time. But this may not be very significant as recently discharge does not consider voiding mandatory except in some circumstances.

Conclusion

In this study, we conclude that,1% 2-Chloroprocaine 50 mg for intrathecal injection of lower limb surgeries produces adequate duration and depth of surgical anaesthesia for short procedures with the advantages of faster block resolution and earlier hospital discharge compared with intrathecal 0.5% Hyperbaric Bupivacaine.

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