Comparative study on block characteristics between 2-Chloroprocaine and Bupivacaine for lower abdomen and lower limb surgeries under spinal anaesthesia

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Abstract
Spinal anaesthesia is the most convenient anaesthetic technique that offers many advantages over general anaesthesia for certain surgical procedures. The patient will be awake, polypharmacy can be avoided and airway manipulation is not needed in spinal anaesthesia. It reduces intraoperative blood loss especially for major lower limb orthopaedic surgeries, lesser incidence of thromboembolic events, provides reliable surgical analgesia with good muscle relaxation and adequate analgesia in the early postoperative period. After finding the suitability according to selection criteria patients were selected for the study and briefed about the nature of the study, the interventions used and written informed consent was obtained. Further, descriptive data of the patients like name, age, sex, detailed history, were obtained and recorded on predefined and pretested proforma. In this present study, thoracic dermatome level 8 was the most commonly achieved level in both the groups. More number of patients achieved thoracic dermatome level 6 block in group C. Hence the results were statistically significant with respect to highest level of sensory block achieved.

Keywords: 2-Chloroprocaine, Bupivacaine, spinal anaesthesia

Introduction
Spinal anaesthesia is a form of regional anaesthesia where conduction block of nerve roots is achieved by injecting local anaesthetic solution into the subarachnoid space through a lumbar puncture. Subarachnoid block (SAB) or spinal anaesthesia is most commonly used technique for surgeries on the lower part of the body and it is safe and reliable [1]. Spinal anaesthesia is the most convenient anaesthetic technique that offers many advantages over general anaesthesia for certain surgical procedures. The patient will be awake, polypharmacy can be avoided and airway manipulation is not needed in spinal anaesthesia. It reduces intraoperative blood loss especially for major lower limb orthopaedic surgeries, lesser incidence of thromboembolic events, provides reliable surgical analgesia with good muscle relaxation and adequate analgesia in the early postoperative period. The endocrine-metabolic response to surgery appears to be blunted when spinal anaesthesia is employed compared to the response during general anaesthesia. Spinal anaesthesia may be comparable with general anaesthesia in many aspects but literature suggests superiority with respect to the postoperative nausea and vomiting, post-operative analgesia and early recovery [2].

As there is a shift towards providing unassisted ambulation at the earliest, there seems to be a lot of interest in short acting local anaesthetics with predictable outcomes. The general requirement of the spinal anaesthetic is to have a well tolerated and reliable block. They should have a rapid onset, shorter duration of motor block, less or no postoperative urinary retention, possible bypass of post-anaesthesia Care Unit (PACU), predictable discharge times and less or no transient neurological symptoms [3].

Various local anaesthetics were used for spinal anaesthesia. But, Lidocaine gained more popularity during the early days with faster onset and faster recovery. The major disadvantage of spinal Lidocaine was very high incidence of transient neurological symptoms. Hence most anaesthesiologists and medical institutes do not prefer Lidocaine for spinal anaesthesia.

The next focus for providing the ideal local anaesthetic for spinal anaesthesia was turned on to low dose long acting local anaesthetics like Bupivacaine, but it produces a sensory and motor block of longer duration, urinary retention, dose dependent unpredictability in
duration of the block. Various other local anaesthetics were considered like Procaine, Mepivacaine, Artecaaine and 2-Chloroprocaine. Procaine with a high incidence of nausea, failed blocks and transient neurological symptoms and Mepivacaine with a high incidence of transient neurological symptoms were not ideal for spinal anaesthesia. Artecaaine compared to 2-Chloroprocaine was unsatisfactory due to a significantly longer duration of sensory block and motor block [4]. Chloroprocaine is an amino-ester local anaesthetic with a short half life due to rapid ester hydrolysis. It was introduced in the year 1952 for spinal anaesthesia by Foldes and McNall. But with the popularity of Lidocaine, 2-Chloroprocaine was not much preferred. Reports of accidental injection of large doses of intrathecal 2-Chloroprocaine causing neurological deficits were published in the early 1980s, which was attributed to low pH and sodium bisulphite. This finding has been disputed and a preservative free formulation have been used in volunteers and patients. Current evidence suggests that preservative free 2-Chloroprocaine is no more toxic than other local anaesthetics, and has a safe track - record in the published series and no transient neurological symptoms were observed [5].

Health care costs in part are being equated to the length of stay in the hospital. This is a result of post-operative nausea and vomiting, prolonged motor and sensory block, pain, urinary retention and also on the amount of drugs and materials used. General anaesthesia is costlier. The utilization of 2-Chloroprocaine for spinal anaesthesia would help us to have an early post operative recovery in an ambulatory setting. This in turn reduces health care costs and burden to the patient [6].

Methodology
After finding the suitability according to selection criteria patients were selected for the study and briefed about the nature of the study, the interventions used and written informed consent was obtained. Further, descriptive data of the patients like name, age, sex, detailed history, were obtained and recorded on predesigned and pretested proforma.

Pre-anaesthetic evaluation
A thorough pre-anaesthetic evaluation was performed by taking history and clinical examination. In all the patients, height, weight, basal heart rate, respiratory rate and blood pressure was measured and recorded. Investigations like complete blood count, urine for albumin, sugar and microscopy was done. Blood sugar, electrocardiogram and chest x-ray were performed when indicated.

Randomization and blinding
Patients were randomly allocated according to sealed envelope method to one of two groups, B or C. The groups were assigned to receive either 10 mg of 0.5% Bupivacaine heavy or of 1% 2-Chlororprocaine, which were loaded in a 5ml syringe by the anaesthesiologist performing the subarachnoid block. Thus only patients were blinded to the study drugs. Hence it was a single blinded study.

Anaesthesia procedure
In this study 100 patients of ASA Grade I and II, aged between 18-60 years undergoing lower abdomen and lower limb surgery were included.

Group B: 50 patients received intrathecal 10 mg of 0.5% Bupivacaine heavy.

Group C: 50 patients received intrathecal 50mg of 1% 2-Chlororprocaine.

The patients were kept fasting for 6 hours for solid food and 2 hours for clear liquids. Preoperatively a intravenous (IV) line was secured with either 18 G or 20 G cannula and IV ringer lactate solution at a rate of 7 ml/kg was started 30 minutes before spinal anaesthesia. The patients were then shifted to the operation theatre and monitors like electrocardiograph (ECG), pulse oximeter and non-invasive blood pressure monitor will be connected. Preoperatively systolic blood pressure (SBP), diastolic blood pressure (DBP), mean blood pressure (MBP) and heart rate (HR) were recorded. The patients were then placed in the sitting position to perform subarachnoid block. The Consultant performed the procedure while as a researcher I observed and documented the findings for my thesis. Under strict aseptic precautions spinal puncture was performed at L3 - L4 interspace with 25 G Quinke’s spinal needle and the drug was injected after free flow of CSF with the bevel of the needle facing upwards in sitting position. The drug was injected at a rate of one ml per 15 seconds. Patients were immediately placed in supine position after the SAB.

Parameters observed
Time of completion of spinal anaesthesia (Tsp) was noted along with time of start (Tsw) and end of surgery (Tew) as well. The evolution of both sensory and motor block was evaluated every minute until readiness to surgery, every 5 min after the maximum level of sensory block was reached(three consecutive observations with the same maximum level of sensory block), and then complete regression of sensory block to S1 was noted as well. Levels of motor and sensory block were measured every 30 min until the end of anaesthesia. Sensory block was verified by bilateral pinprick test using a 20-G hypodermic needle. Motor block was verified using a modified Bromage’s scale.

Modified Bromage Scale
1. Free movement of legs and feet
2. Just able to flex knees with free movement of feet
3. Unable to flex knees, but with free movement of feet
4. Unable to move legs or feet.

Time of readiness to surgery and time elapsed from the end of the spinal injection to surgery start (Tsp-Tss) were recorded. Readiness to surgery was defined according to the presence of an adequate motor block (Bromage’s score ≥ 2, Tmb) and loss of Pinprick sensation at T10 (Tsb).

Time to the maximum level of sensory block achieved (TsbMAX) was also recorded. During the block, HR, BP, ECG abnormalities and SpO2 were recorded every 10 min. The time interval to resolution of motor block was registered (Bromage’s score = 0, Tmb= 0), as well as time to the end of anaesthesia (Tea), defined as the time when Bromage’s score returned to 0 and sensory block recovered (regression to S1). Time to the first request for analgesia

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was noted (Tan) as well as time to unassisted ambulation (Tua).

Results

Table 1: Comparison of age and weight between two study groups (N = 100)

| Parameter          | Group         | B (n=50) Mean (SD) | C (n=50) Mean (SD) | P Value |
|--------------------|---------------|-------------------|-------------------|---------|
| Age (in Years)     |               | 38.06(11.76)      | 38.38(12.36)      | 0.894   |
| Weight (in Kg)     |               | 62.54(4.95)       | 62.36(5.03)       | 0.857   |

Unpaired t Test, P Value Not Significant

In this present study, both the groups had patients from 18 to 60 years of age. The average age of patients was 38.06 ± 11.76 years in group B and 38.38 ± 12.36 years in group C. The difference was not statistically significant. The weight distribution among the two groups was also not statistically significant.

Table 2: Association between highest level of sensory blockade and study groups (N=100)

| Sensory Level | Group         | B (n=50) n (%) | C (n=50) n (%) | P Value |
|---------------|---------------|---------------|---------------|---------|
| T6            |               | 5(10)         | 13(26)        |         |
| T8            |               | 31(62)        | 31(62)        |         |
| T10           |               | 14(28)        | 6(12)         | 0.034   |

Chi-Square Test, P Value Significant

In this present study, thoracic dermatome level 8 was the most commonly achieved level in both the groups. More number of patients achieved thoracic dermatome level 6 block in group C. Hence the results were statistically significant with respect to highest level of sensory block achieved.

Table 3: Comparison of block characteristics and durations between two study groups (N=100)

| Parameter                              | Group         | B (n=50) Mean (SD) | C (n=50) Mean (SD) | P Value |
|----------------------------------------|---------------|-------------------|-------------------|---------|
| Time to sensory block T10 Tsb in minutes |               | 8.54(1.77)        | 5.76(1.34)        | <0.001  |
| Time to motor block Bromage ≥2 Tnb in minutes |               | 6.72(1.05)        | 5.42(1.12)        | <0.001  |
| Time to maximum sensory block Tmax in minutes |               | 12.14(2.92)      | 9.12(1.88)        | <0.001  |
| Time to end of motor block Tmb0 in minutes |               | 188.6(16.25)     | 107(10.65)        | <0.001  |
| Time to end of anaesthesia Bromage 0 and sensory S1 Tea in minutes |               | 201.6(14.54)     | 129.8(7.13)       | <0.001  |
| Time of first analgesic requirement Tan in minutes |               | 200.4(17.43)     | 101.6(8.59)       | <0.001  |
| Time of unassisted ambulation Tua in minutes |               | 234.7(9.81)      | 140.2(6.84)       | <0.001  |

Unpaired t Test, P Value Significant

Discussion

Time required to achieve T10 blockade was around 8.54 ± 1.77 minutes for group B and 5.76 ± 1.34 minutes in group C. Camponovo C et al. [7] noted an onset of 8 minutes with 10 mg of Bupivacaine and 7 minutes with 50mg of 2-Chloroprocaine, which was not statistically significant (P=0.186). Lacasse M et al. [8] noted 6 minutes with both 7.5 mg Bupivacaine and 40mg 2-Chloroprocaine and with P=0.5, the difference was not statistically significant.

T 6 was the highest dermatome reached by patients in both group in our study. More number of patients in group C achieved T 6. Smith K et al. [9] demonstrated spinal level as high as T2 with plain 60 mg of 2-Chloroprocaine and T5 with plain 45 mg of 2-Chloroprocaine. Lacasse M et al. [8] demonstrated a highest level of T1 with Bupivacaine and 2-Chloroprocaine. Kouri ME et al. [10] demonstrated a highest level of T5 with 40 mg of plain 2-Chloroprocaine.

Group B patients took on an average 12.14 ± 2.92 minutes for sensory block to regress to S1 and group C took 9.12 ± 1.88 minutes to achieve peak block height. Camponovo C et al. [7] demonstrated 14 minutes and 8.5 minutes as the time required to achieve peak block height for Bupivacaine and 2-Chloroprocaine group respectively, which was statistically significant (P<0.001). Lacasse M et al. [8] demonstrated 18 and 15 minutes for time required to achieve peak block height for Bupivacaine and 2-Chloroprocaine group respectively, which was not statistically significant (P=0.15).

Time for sensory block to regress to S1 with Bupivacaine was 201.6 ± 14.54 and 129.8 ± 7.13 with 2-Chloroprocaine in our study. Camponovo C et al. [7] demonstrated 225 and 105 minutes as time required for sensory block to regress to S1 with Bupivacaine and 2-Chloroprocaine respectively, which was statistically significant (P<0.001). Lacasse M et al. [8] demonstrated found 329 ± 82 and 146 ± 38 minutes as time required for sensory block to regress to S2 with 7.5mg Bupivacaine and 40 mg 2-Chloroprocaine respectively, which was statistically significant (P<0.001).

The patients in group B required analgesic at 200.4 ± 17.43 and in group C at 101.6 ± 8.59 minutes in our study. Camponovo C et al. [7] demonstrated first analgesic required as 293 and 120 minutes for 10 mg of Bupivacaine and 50mg of 2-Chloroprocaine respectively, which was statistically significant (P=0.0212).

Sensory blockade in group B and group C patients was statistically significant (P<0.001) in all the parameters in our study, with group C i.e., 2-Chloroprocaine group patients showing faster onset, consistently higher levels, early regression of sensory block and early requirement of analgesic.

In this present study, group B required 6.72 ± 1.05 minutes and group C required 5.42 ± 1.12 minutes to achieve a modified Bromage scale of ≥ 2. Camponovo C et al. [7] demonstrated that Bupivacaine group required 6 minutes and 2-Chloroprocaine group required around 5 minutes for the same doses as our study to achieve a modified Bromage scale of ≥ 2, which was statistically significant (P=0.03). Yoos JR et al. [11] demonstrated that, 40 mg of 2-Chloroprocaine took 10 minutes to achieve 10 minutes post lumbar puncture to achieve modified Bromage scale of 3. In our study, time required to achieve modified Bromage scale of 0 was 188.6 ± 16.25 and 107 ± 10.65 minutes for group B and group C respectively. In the study by Camponovo C et al. [7], Bupivacaine group took 210 and 2-Chloroprocaine group took 100 minutes for the same, which was statistically significant (P<0.001).

Unassisted ambulation was achieved early in group C at 140.2 ± 6.84 compared to 234 ± 9.81 in group B in our study. Camponovo C et al. [7] demonstrated that Bupivacaine group took 290.5 minutes and 2-
Chloroprocaine group took 142.5 minutes to achieve unassisted ambulation, which was statistically significant (P<0.001).

Motor blockade in group B and group C patients was statistically significant (P<0.001) in our study, with group C i.e., 2-Chloroprocaine group patients showing faster onset of modified Bromage ≥ 2, early regression of motor block to modified Bromage scale of 0 and early unassisted ambulation.

The patients in both the groups in our study did not encounter any signs of TNS, which was enquired 1 and 7 days post lumbar puncture by using standard questionnaire of Pollock et al. [8]. In the study by Camponovo C et al. [7], no TNS was encountered in Bupivacaine and 2-Chloroprocaine group as well. Lacasse et al. [6] reported TNS once among 53 patients of 2-Chloroprocaine spinal anaesthesia and Hejtmaneck MR et al. reported four times among over 4000 patients in the Virginia Mason Medical Center data, very low numbers considering the recent increase in the use of 2-Chloroprocaine spinal anaesthesia. The randomized control trial by Lacasse et al. [8] reported a TNS incidence of 1.9% in both the 2-Chloroprocaine and Bupivacaine groups.

Conclusion

Based on the study, 2-Chloroprocaine can be used for spinal anaesthesia for infraumbilical surgeries. 2-Chloroprocaine as spinal anaesthetic produces well tolerated and reliable block with rapid onset, predictable duration of block and no complications. It can be used satisfactorily in procedures where patients need to be ambulated early and also for outpatient basis for day care surgeries on lower part of the body. PACU can be bypassed as well with 2-Chloroprocaine spinal anaesthesia.

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