



## Original Research Article

## Comparison of 2-chloroprocaine 1% versus hyperbaric bupivacaine 0.5% for subarachnoid block in pregnant females posted for elective caesarean section

Ashwini S<sup>1</sup>, Kumara A B<sup>1,\*</sup><sup>1</sup>Dept. of Anaesthesiology, Shimoga Institute of Medical Sciences, Shivamogga, Karnataka, India

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## ABSTRACT

**Introduction and Objectives:** Caesarean sections generally done under subarachnoid block using 0.5% hyperbaric bupivacaine as the local anaesthetic of choice. As most caesarean sections are of short duration, we decided to study whether 1% 2-chloroprocaine would be suitable alternative to bupivacaine with primary outcome being duration of sensory blockade in elective lower segment caesarean sections.

**Materials and Methods:** In this prospective study, 60 pregnant females belonging to ASA status 1 and 2, posted for elective lower segment caesarean section were equally randomized into two groups. The first group received 1% chloroprocaine 25 mg (2.5 ml, Group CP) and second group received 0.5% hyperbaric bupivacaine 10 mg (2.0 ml, Group B), intrathecally. We measured the level of sensory and motor blockade, duration of sensory blockade and side effects.

**Results:** Mean duration of sensory blockade was  $61.83 \pm 23.54$  minutes for group CP, which is significantly shorter than group B which had  $174.67 \pm 41.17$  minutes (p Value <0.001). Group B had clinically significant incidences of hypotension (53.33% Vs 30%) compared to group CP.

**Conclusion:** Intrathecal low dose 1 % chloroprocaine is a safe and suitable alternative to low dose 0.5% hyperbaric bupivacaine for an uncomplicated elective lower segment caesarean section.

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## 1. Introduction

Today, nearly all of the uncomplicated elective lower segment caesarean section (LSCS) procedures are done mainly using subarachnoid block (SAB) and are of short duration. 0.5% hyperbaric bupivacaine is a standard and established long acting local anaesthetic used in almost all the spinal anaesthesia procedures now a days.<sup>1</sup> As surgeons, anaesthesiologists and patients prefer early recovery from anaesthesia; most of the surgeries done on ambulatory basis, so, short acting local anaesthetic would be preferred for short duration lower abdominal procedures like elective caesarean sections.<sup>2-4</sup>

LSCS require anaesthesia up to the level of T<sub>6</sub> for a comfortable and co-operative patient. Spinal blocks to T<sub>6</sub> usually require conventional doses of spinal anesthetics such as lignocaine 50 – 75 mg or bupivacaine 10 – 12.5 mg with

the attendant risk of hypotension, prolonged recovery and post-operative stay in the post-anesthesia care unit.<sup>5,6</sup>

Even though shorter acting agents such as lignocaine have been found to provide an acceptable profile for out-patient spinal anesthesia when used in conventional doses, but the use of lignocaine has declined due to concerns about the risk of transient neurological symptoms (TNS).<sup>7,8</sup> and most anaesthesiologists have therefore abandoned its use.<sup>7,8</sup> Similarly, mepivacaine has been associated with transient neurological symptoms.<sup>8</sup>

More recently, there has been a renewed interest in a reformulated preservative free preparation of 2-chloroprocaine (CP) for intrathecal use in short-duration ambulatory procedures.<sup>9-11</sup> CP solution with preservatives and antioxidants removed from currently available preparations, available as a 10 mg/ml solution was recently approved by the European Medicine Agency for intrathecal use.<sup>12</sup>

\* Corresponding author.

E-mail address: [kumarab\\_bmc@yahoo.co.in](mailto:kumarab_bmc@yahoo.co.in) (Kumara A B).

To date, there is little information on the clinical characteristics of bupivacaine compared with CP when employed in low intrathecal doses in patients undergoing elective LSCS.<sup>9</sup> Therefore; we compared the anesthetic characteristics of low intrathecal doses of 0.5% hyperbaric bupivacaine and 1% 2-chloroprocaine to determine if CP would be a suitable alternative for bupivacaine in patients undergoing elective LSCS.

## 2. Materials and Methods

After approval of Institutional Ethical Committee, this prospective, randomized, clinical study was conducted after informed and written consent in 60 pregnant females of 18 to 35 years of age, with ASA physical status 1 or 2, scheduled to undergo elective lower segment caesarean surgery under subarachnoid block.

Patients excluded were those with contraindications for subarachnoid block like; patient refusal, uncooperative patients, fluid restriction (cardiac or renal insufficiency), allergy or intolerance to local anaesthetics, coagulation disorders, neurologic disease or spine deformities and infection at the site of needle insertion.

In all patients selected for the study, a detailed history of present and past medical and surgical illnesses and medication use was taken and a detailed general physical examination, including airway assessment, spine and systemic examination with necessary laboratory investigations was done to confirm the previously mentioned inclusion and exclusion criteria.

All the patients were advised to remain nil per oral after midnight and in the morning, all the patients were explained once again about the SAB procedure, drugs used in the study and risk involved, conversion to general anaesthesia, in the pre-operative room patients were randomized in to one of the group using computer generated random list and shifted to OT, and on arrival into OT, an intravenous access (18 Gauge) secured and the patient preloaded with 500 ml Ringer lactate solution over a period of 20 to 30 minutes and inj. Ranitidine 50 mg and inj. Metoclopramide 10 mg 30 minutes prior to surgery. Basal vital parameters of the patients were noted.

Patient in sitting or lateral position with the help of an assistant, under aseptic precaution and draping subarachnoid block was performed using 25 G Quincke's spinal needle at L<sub>3</sub>-L<sub>4</sub> or L<sub>2</sub>-L<sub>3</sub> spinal inter space and after ensuring free flow of clear CSF, Group B was injected 2ml of 0.5% hyperbaric bupivacaine intrathecally and Group CP injected 2.5 ml of 1% preservative free 2-chloroprocaine intrathecally. Immediately patient was positioned supine. Pulse, NIBP, SpO<sub>2</sub>, and respiratory rate were recorded before the start of the procedure and every 3 minutes up to 24 minutes and every 6 minutes till the patient is shifted out from the recovery room. For bradycardia (heart rate <50 beats / min), 0.6 mg atropine i.v. injection was

given and hypotension (systolic BP < 90 mm Hg) was treated appropriately with i.v. fluids and vasopressors (Inj. mephentermine 3 mg i.v. incrementally).

Time of onset of sensory block was recorded as interval between the time of injection into the subarachnoid space and development of loss of sensation to pin prick at every 3 minute intervals till 18 minutes. Quality of analgesia was assessed using following grades: Grade 1 - complete analgesia and no sedatives administered, Grade 2 - Analgesia is complete and sedatives are administered only to relieve apprehension, Grade 3 - Analgesia is incomplete, inadequate or patchy and supplementation is needed with narcotics or ketamine or IV agents, and Grade 4 - Analgesia is very poor and the technique will be changed over to general anaesthesia. Motor blockade was assessed using modified Bromage scale<sup>5</sup> (0 = no motor movement, complete motor block; 1 = unable to flex knee, able to flex ankle; 2 = unable to straight leg raise, able to flex knee; 3 = no block, full straight leg raise possible). Surgeon's opinion is also taken during the procedure and degree of sensory and motor blockade is graded together as follows: Grade 1 - Complete block or good relaxation, Grade 2 - Partial block or intermediate, and Grade 3 - No block - Poor relaxation. Duration of analgesia (DOA) was measured as the interval between onset of sensory block and regression of sensory blockade by 2 segments; or complains of discomfort or pain at incision site.

Intra-operatively patients were carefully monitored for any untoward effects like, hypotension, bradycardia, respiratory distress, nausea, vomiting, shivering and treated accordingly. All the patients were observed for up to 24 hours postoperatively to note any complications such as headache, backache, nausea, vomiting, retention of urine, any symptom or signs of TNS (TNS was defined as pain/dysaesthesia of light to severe intensity originating in the gluteal region and radiating to the lower extremity, commencing within 24 hours of spinal administration).<sup>6</sup>

Statistical analysis was done by using SPSS version 16.0 for analyzing the collected data. Data were reported as arithmetic mean  $\pm$  standard deviation and continuous variables were presented as median (inter-quartile range) according to data distribution. Categorical variables were analyzed using Chi-square test or Fisher's test. Normal distribution of continuous variables was analyzed using Student's t-test. Continuous variables were compared using the Mann-Whitney U-test. A 'p' value of <0.05 was considered significant.

## 3. Results

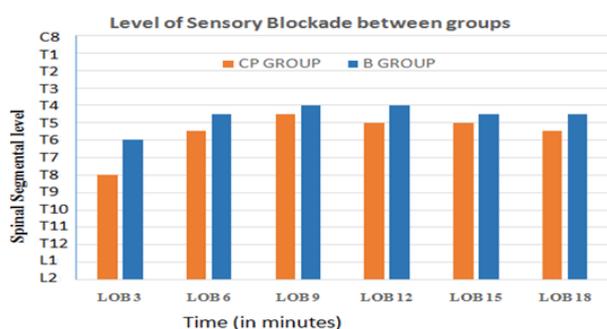
Both the groups were comparable with respect to age, weight, height and duration of procedure and were statistically not significant.

Onset of sensory blockade was comparable between the groups with median block height of T<sub>8</sub> and T<sub>6</sub> dermatome

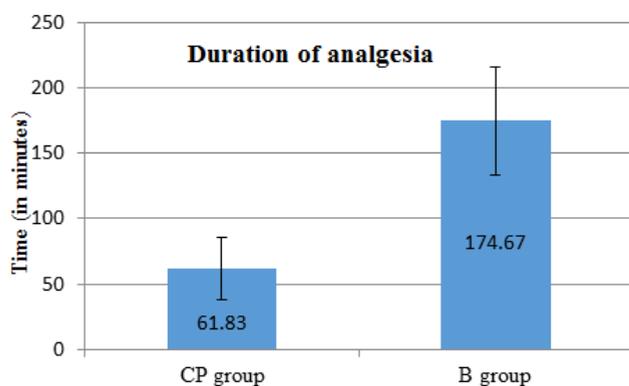
**Table 1:** Demographic profile of patients, # DOP- Duration of Procedure, ## DOA- Duration of Analgesia.

	CP group (n = 30)	B group (n = 30)	p Value
Age(in Years)	25.30 ± 2.67	24.47 ± 2.09	0.331
Weight (in KG)	62.87 ± 8.80	63.60 ± 6.85	0.614
Height (in CM)	154.90 ± 4.54	154.20 ± 3.97	0.602
DOP# (in minutes)	23.20 ± 7.29	26.00 ± 5.53	0.107
DOA## (in minutes)	61.83 ± 23.54	174.67 ± 41.17	<0.001*

levels achieved at 3 minutes in group CP and group B respectively (Table 2 and Figure 1). Sensory level of blockade between groups were statistically not significant till 15 minutes after SAB but was statistically significant at 18 minutes after intrathecal drug injection with p value 0.007.

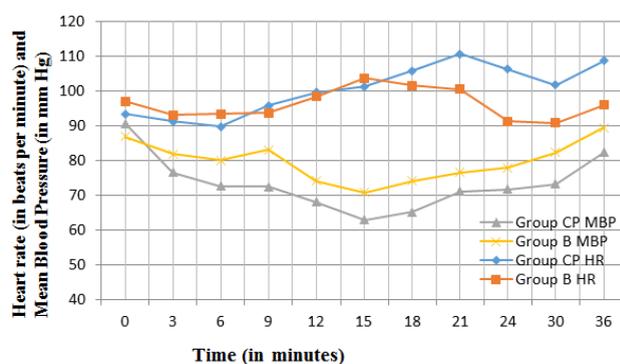
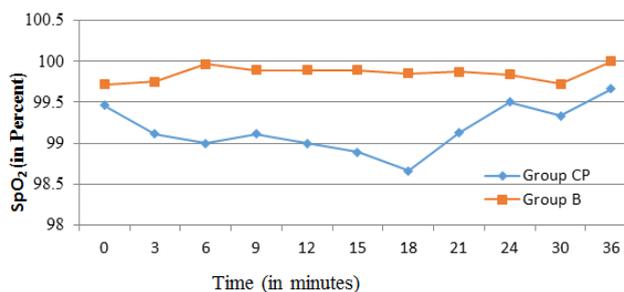
**Fig. 1:** Level of sensory blockade between the groups

Duration of sensory blockade for group CP had mean of 61.83 minutes and group B had 174.67 minutes (Figure 2) and median (IQR) duration of analgesia (DOA) for CP group is 50.00 minutes (50.00 to 80.00) and that of B group is 180.00 (130.00 to 200.00) which was statistically significant between the two groups (p-value <0.001).

**Fig. 2:** Duration of sensory blockade between the groups.

The mean values of heart rate, mean blood pressure and oxygen saturation of the patients between the groups were comparable and shown in Figures 3 and 4. Total of

16(53.33%) out of 30 patients in B group had hypotension to be treated with inj mephentermine i.v. in which 8 patients required twice, compared to 9(30%) patients in group CP out of which only two patients required inj mephentermine i.v. twice and one patient required thrice to maintain normotension, which was clinically significant but was statistically not significant (p value 0.067). Haemodynamic parameters / side effects and scores are shown in Table 3.

**Fig. 3:** Comparison of Heart Rate (HR) and Mean Blood Pressure (MBP) between the groups**Fig. 4:** Comparison of Oxygen Saturation (SpO<sub>2</sub>) between the groups.

Quality of analgesia was good with grade 0 in both the groups, none of the patients required supplementary analgesia intra-operatively. 4 patients in CP group had grade 1 motor blockade on modified Bromage scale which did not hinder the procedure, rest had Grade 0 and in group B all the patients had grade 0 motor blockade recorded at 15 minutes. Surgeons were satisfied with the adequacy of both sensory and motor blockade (surgeon's opinion - grade 1) in both

**Table 2:** Level of sensory blockade between the groups

Level of Block (in minutes from injection)	CP GROUP Median (min - max)	B GROUP Median (min - max)	p - Value
LOB 3	T8 (L1 - T4)	T6 (T2 - T10)	0.9
LOB 6	T6, T5 (T3 - T10)	T5, T4 (T4 - T8)	0.515
LOB 9	T5, T4 (T2 - T8)	T4 (T4 - T7)	1
LOB 12	T5 (T2 - T7)	T4 (T4 - T6)	0.273
LOB 15	T5 (T2 - T8)	T5, T4 (T4 - T6)	0.053
LOB 18	T5, T6 (T3 - T10)	T5, T4 (T4 - T6)	0.007*

**Table 3:** Haemodynamic parameter / Side effect and Scores. \*QA - Quality of Analgesia, \*\*QMB - Quality of Motor Blockade.

Parameter / Side Effect	CP Group	B Group	p-value
Hypotension	9 (30%), 2, 1	16 (53.33%), 8, 0	0.067
Bradycardia	1	0	-
Nausea	2	0	0.49
Vomiting	0	0	-
TNS	0	0	-
QA* at 15 minutes	30, 0, 0, 0	30, 0, 0, 0	-
QMB** at 15 minutes	26, 4, 0, 0	30, 0, 0, 0	0.112
Surgeon's Opinion	30, 0, 0	30, 0, 0	-

the groups.

#### 4. Discussion

Interest for short duration spinal anaesthetic agents for daycare/ambulatory and short duration lower abdominal surgeries, is re-emerging. 2-Chloroprocaine (2-CP) a local anaesthetic, initially used mostly for obstetric epidurals, is of short duration of action, its safety and reliability for spinal anesthesia has been reported since 1952.

Primary outcome of our study was duration of analgesia, which was  $61.83 \pm 23.54$  minutes in chloroprocaine group and  $174.67 \pm 41.17$  minutes in bupivacaine group, compared to M. A. Lacasse et al<sup>5</sup> found 50 and 75 minutes in chloroprocaine and bupivacaine for two segment regression; Yoos and Kopacz (2005)<sup>13</sup> study on 8 healthy volunteers of age  $38 \pm 7$  years, comparing chloroprocaine 40 mg vs bupivacaine 7.5 mg reported  $45 \pm 20$  minutes and  $74 \pm 20$  minutes for two segment regression.

We had a mean duration of surgery about 25 minutes, with maximum duration of surgery being 36 minutes, for which chloroprocaine is well suited with faster recovery, which is also asserted by a double blind study on 45 outpatients undergoing elective lower limb surgery under spinal anesthesia by Casati et al,<sup>10</sup> comparing three different doses (30 mg, 40 mg, and 50 mg) of 1% 2-chloroprocaine concluded that 40 mg and 50 mg provided adequate spinal anesthesia for lower limb outpatient procedures lasting 45 to 60 minutes without any significant side effects due to CP, and Lacasse et al.<sup>5</sup> in 2009 comparing preservative-free 2% 2-chloroprocaine 40 mg with 0.75% bupivacaine for spinal anesthesia in an elective ambulatory setting in 106 patients including gynaecological surgeries, found to

have adequate duration and depth of surgical anesthesia for short procedures with the advantages of faster block resolution and earlier hospital discharge compared with spinal bupivacaine 7.5 mg produces a satisfactory surgical block for procedures lasting <60 minutes; which was similar in our study, with block resolution faster with 1% 2-chloroprocaine 25 mg compared to 0.5% hyperbaric bupivacaine 10 mg in elective LSCS.

Lacasse et al<sup>5</sup> found to have equal incidences of complications like hypotension, headache between the groups which was similar in study by H. Vaghadia et al,<sup>6</sup> Teunkens et al<sup>11</sup> but we had higher incidences of hypotension in bupivacaine group 16 out of 30 patients (53.33% Vs 30%) compared 9 patients (n=30) in chloroprocaine group which was not significant with p value 0.067. Maes et al<sup>14</sup> even though had equal incidences of hypotension and requirement of vasopressors and duration of hypotension always less than 5 minutes found that prophylactic supplementation with colloids and phenylephrine could not always prevent hypotension in their study. In our study, we had a few patients in both the groups where repeated dose of inj. mephentermine was required along with fluid boluses to treat hypotension.

Incidences of TNS was feared the most with short acting spinal anaesthetics specially with lignocaine, mepivacaine and older preparations of chloroprocaine; none of the patients in our study had any incidence of TNS postoperatively, similar to selective spinal anesthesia for outpatient transurethral resection of the prostate (TURP), comparing 35 mg lignocaine mixed with 12.5 µg fentanyl or 40 mg CP mixed with 12.5 µg fentanyl by H. Vaghadia et al,<sup>6</sup> in 40 patients had 20% incidence of TNS with intrathecal lignocaine which is comparable to earlier study

reports to none in the chloroprocaine group. Casati et al,<sup>10</sup> comparing three different intrathecal doses (30 mg, 40 mg, and 50 mg) of 1% 2-chloroprocaine, reported no signs of transient neurologic symptoms in any of their patients and hence opined to conduct large sample study to ascertain earlier reports on TNS/neurological toxicity by 2-chloroprocaine.

Randomized controlled trial comparing 2-chloroprocaine 40 mg versus bupivacaine 7.5 mg intrathecally in elective caesarean section by Maes et al,<sup>14</sup> with motor blockade as primary variable had comparable motor block regression time between groups but bupivacaine group found to have wider variability and less predictability compared to chloroprocaine group; in our study, 4 patients in chloroprocaine (25 mg) group had grade 1 motor blockade on modified Bromage scale at 15 minutes, which did not hinder the procedure and in bupivacaine (10 mg) group all had grade 0 motor blockade which was statistically not significant (p value - 0.112) and surgeons were satisfied with muscle relaxation in both the groups. As faster recovery from motor blockade is preferred especially with pregnant females after a caesarean surgery for reducing the time for exclusive breast feeding, as opined by Maes et al.<sup>14</sup>

A review by Ghisi et al<sup>12</sup> on different doses of chloroprocaine and outcomes on their intrathecal use concluded that 1% or 2% chloroprocaine is an alternative for short and ultra-short procedures and when compared with spinal bupivacaine, it resulted in a significantly faster offset of sensory and motor blocks with similar onset time. Similarly, a prospective randomized double-blind study by Teunkens et al<sup>11</sup> on 99 patients undergoing knee arthroscopic surgery in ambulatory setting concluded that 40 mg chloroprocaine intrathecally in comparison to 40 mg lidocaine and 7.5 mg bupivacaine had shortest recovery time from sensory and motor blockade compared to lidocaine and bupivacaine, and had shorter voiding, ambulation and discharge times compared to bupivacaine (not for lidocaine).

Even though we couldn't study the time of voluntary bladder emptying by our study patients due to practice of bladder catheterization in our institute for 12 to 24 hours, systematic review by Choi et al<sup>15</sup> opined that short-acting neuraxial blockade is safe in both inpatient and ambulatory anesthesia, given the short duration of detrusor dysfunction with decreased incidence of postoperative urinary retention and subsequent catheterization/infection. A study by Breebaart et al,<sup>16</sup> on 100 patients undergoing day-case arthroscopy receiving either lidocaine 60 mg or chloroprocaine 40 mg intrathecally found no differences in voiding time in both the groups, although discharge and micturition was faster with chloroprocaine group than lidocaine. The lidocaine groups had more serious micturition problems (requiring single in and out bladder evacuation) compared with chloroprocaine groups, demonstrating a more favorable profile for chloroprocaine in the ambulatory setting.

## 5. Conclusion

We conclude that low dose 1% 2-chloroprocaine 25 mg can be a good alternative to 0.5% hyperbaric bupivacaine 10 mg for intrathecal use in an uncomplicated elective lower segment caesarean section.

## 6. Acknowledgement

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## 7. Source of Funding

None.

## 8. Conflict of Interest

None.

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**Kumara A B** Assistant Professor

### **Author biography**

**Ashwini S** Assistant Professor

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