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Original research article

Comparison of efficacy of 1% 2-chloroprocaine with ilioinguinal and iliohypogastric nerve block versus 0.5% hyperbaric bupivacaine for spinal anaesthesia in patients undergoing caesarean section: A randomised clinical study

[1]Dr. Sneha Rajur, [2]Dr. Bhagyashri V Kumbar, [3]Dr. Faraz Ahmed, [4]Dr. Madhu KP

[1,2]Senior Resident, Department of Anaesthesiology, Gadag Institute of Medical Sciences, Gadag, Karnataka, India
[3]Senior Resident, Department of Anaesthesiology, Chamarajanagar Institute of Medical Sciences, Chamarajanagar, Karnataka, India
[4]Assistant Professor, BMCRI, Bangalore, Karnataka, India

Corresponding Author:
Dr. Madhu KP

Abstract

Caesarean sections are routinely done under spinal anaesthesia using 0.5% hyperbaric bupivacaine that has a long duration of action. As most of the caesarean sections are of short duration, we decided to compare 1% 2-chloroprocaine with routinely used bupivacaine as chloroprocaine has rapid onset of action, producing an excellent sensory and motor blockade. After ethical committee clearance and informed written consent, 70 uncomplicated singleton parturients of ASA I and II posted for elective caesarean section were randomised into chloroprocaine (CP) and bupivacaine (B) group of 35 each.
Onset of sensory block in group CP was 1.71±0.62min and in group B was 2.31±0.63min. Onset of motor block in group CP was 2.54±0.88min and in group B was 2.66±0.76min. Mean time for maximum sensory block in group CP was 12.77±3.52min and in group B was 22.34±6.46min and time for maximum motor block in group CP was 9.14±2.23min and in group B was 10.86±2.18min. Two segment regression time in group CP was 39.34±4.46min and in group B was 63.14±4.7min. Mean duration of sensory block in group CP was 2.08±0.25hr and in group B was 3.60±0.27hr and duration of motor block in group CP was 1.07±0.14hr and in group B was 3.42±0.41hr. VAS scores in first 6hrs were lesser in group CP than group B. Onset, maximum time, duration of sensory and motor block were lower in group CP than group B. hemodynamic parameters were comparable between the groups with no side effects.

Keywords: Chloroprocaine, bupivacaine, caesarean section

Introduction

Spinal anaesthesia is the most commonly administered anaesthetic technique for caesarean sections which is safe and reliable. It has got many advantages such as [1]

1. No airway manipulation.
2. Polypharmacy avoided.
3. Patient is awake.

4. Good sensory and motor blockade.
5. Prolonged postoperative analgesia.
6. Less incidence of post-operative nausea and vomiting.
7. Avoid risks of general anaesthesia like aspiration etc.

Bupivacaine, an amide long acting local anaesthetic has been routinely used for spinal anaesthesia in patients undergoing caesarean sections. It has prolonged duration of sensory and motor blockade causing unpredictable levels of anaesthesia with subsequent prolonged discharge time. This can delay early ambulation of the mother and maternal-neonatal bonding and can also increase the risk of deep vein thrombosis and its complications.
2-Chloroprocaine is an amino-ester local anaesthetic with faster onset and short duration of action. It is metabolised by pseudocholinesterase by rapid hydrolysis in the blood stream [1]. It is available in preservative free form as 10mg/ml solution and has been approved for intrathecal use [2].
Previous studies have shown that 2-chloroprocaine with 30-40 mg has rapid onset of action producing an excellent sensory and motor blockade with short duration of action of about 45 to 60 min when given intrathecally. It has been introduced recently in the Indian market and not many research articles have been published about 2-chloroprocaine being used for caesarean section under spinal anaesthesia. Hence we decided to compare it with routinely used Bupivacaine in ASA I and II uncomplicated singleton pregnant females coming for elective caesarean section under spinal anaesthesia [3].
Caesarean delivery through pfannenstiel incision is associated with significant degree of pain in the post-operative period. 79% of women experience pain at the incision site that can last upto 2 months. Inadequate postoperative analgesia will affect early ambulation, breastfeeding, maternal-neonatal bonding. It can also lead to chronic pain syndromes and poor quality of life [4].
Since 2-chloroprocaine is a short acting drug lasting for about 45-60 min, patients might develop pain at the operative site earlier when compared to bupivacaine. As per previous studies, Ilioinguinal and Iliohypogastric (IL-IH) nerve block it is beneficial to the mother in facilitating early mobilisation, infant care, and prevention of post- operative morbidity which in turn diminish the duration of hospital stay and increase the patient satisfaction. Hence we decided to supplement and evaluate bilateral IL-IH nerve block for post-operative analgesia using 0.25% bupivacaine in 2-chloroprocaine group [5, 6].
Hence we hypothized that spinal anaesthesia using 1% 2-chloroprocaine being short acting local anaesthetic will be sufficient for uncomplicated ASA I/II pregnant females coming for caesarean section under spinal anaesthesia and IL-IH nerve block will provide post- operative analgesia.

Methodology

The study population was randomly divided using computer generated randomization numbers into two groups by using www.random.org. with 35 patients in each group as group CP and group B.
Group CP: Received 3ml of 1% 2-chloroprocaine for spinal anaesthesia and Ilioinguinal-Iliohypogastric nerve block at the end of surgery.
Group B: Received 2ml of 0.5% hyperbaric bupivacaine for spinal anaesthesia.

After pre-anaesthetic check-up intradermal test dose of bupivacaine or 2- chloroprocaine was done on the previous night before surgery. Patients were kept nil by mouth for 6hrs. 18G IV cannula was secured on the dorsum of Right or Left upper limb and premedicated with 10mg metaclopramide and 50mg Ranitidine intravenously 30 min before surgery in the preoperative

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room. All patients were preloaded with 7-10 ml/kg of crystalloid solution.
After shifting the patient to operation theatre, standard monitors like Electrocardiography (ECG), plethysmography (SpO_2), Non-invasive blood pressure (NIBP) were connected and basal recordings were noted. With patient in right lateral position, spinal anaesthesia was performed under aseptic precautions using 25G Quincke-Babcock spinal needle at L3-L4 or L4-L5 intervertebral space by the anaesthetist managing the case. Oxygen at 5L/min was given via face mask throughout the surgery.
Onset of sensory blockade was assessed every minute after spinal anaesthesia and was taken as loss of sensation to cold swab at T10 dermatome checked in the mid axillary line and was considered as readiness for the surgery. Level of sensory blockade was assessed every 3 min and time required for peak block height and the maximum level of sensory blockade (the time from the completion of injection of the drug to the maximum sensory blockade attained) was noted.
Time for onset of motor blockade (the time taken from the completion of injection of the drug till the patient develops modified bromage scale 1 motor blockade) and the degree of motor blockade was noted using modified bromage scale. Time required for two segment regression, for regression to L1 and complete regression to S2 was also noted.
Intraoperative blood pressure (NIBP), hemoglobin saturation, heart rate, were recorded at baseline, 1 min, every 3 min for first 15 min, at 5 mins interval for next 15 min, at 10 mins interval until the end of surgery.
At the end of surgery, bilateral IL-IH nerve block was given to CP group using 0.25% bupivacaine 15 ml to each side by anatomical landmark technique by the same anaesthetist who had given spinal anaesthesia. The point 2cm superomedial to anterior superior iliac spine was marked. A Blunt needle of 22G was inserted perpendicular to this point and advanced to feel first pop and 5ml of drug was injected after negative
5ml of drug was injected. Then the needle was withdrawn to subcutaneous tissue to inject remaining 5ml of the drug in a fan shaped manner.
All the patients were followed up in the post -operative period by a blinded nurse to assess the duration of motor blockade (from the time of injection of spinal anaesthesia till the patient regained complete motor power), sensory blockade (from the time of injection of spinal anaesthesia till the patient regained sensation at S2 dermatome) and duration of analgesia (from the time of injection of spinal anaesthesia till the patient complained of pain at the site of surgery or operative site). Inj paracetamol (PCT) 1g IV was given whenever the patient complains of pain at the operative site with VAS score $\geq$4. The total consumption of paracetamol over 24 hrs was noted. Patients were pre-operatively instructed to use the visual analog scale from 0 to 10 (0: no pain, 10: maximum imaginable pain) which was used to assess the severity of pain post-operatively at regular intervals.
Whenever mean arterial pressure was less than 20% of the baseline (defined as Hypotension), Inj Ephedrine or Mephentramine 6mg was administered iv. When HR was<60/min (defined as Bradycardia), Inj Atropine 0.6mg iv was given and the same was noted.

Results

Table 1: Comparison of Time for onset of Sensory and Motor blockade between two Groups

Parameter	Group		P Value
	Group CP (N=35) Mean (SD)	Group B (N=35) Mean (SD)	
Sensory Onset (min)	1.71 (0.62)	2.31 (0.63)	<0.001*
Motor Onset (min)	2.54 (0.88)	2.66 (0.76)	0.565

Unpaired t Test, P Value *Significant

Table 1 shows the time for onset of sensory and motor blockade between two groups. The

mean onset time of sensory blockade in group CP was 1.71±0.62 min and in group B was 2.31±0.63 min with p value of <0.001. Hence there was statistically significant difference in the onset of sensory blockade between the groups.
The mean onset time of motor blockade in group CP was 2.54±0.88 min and in group B was 2.66±0.76 min with p value of 0.565. There was no significant difference in onset of motor blockade between two groups.

Table 2: Comparison of time required for maximum Sensory and Motor blockade between two Groups

Parameter	Group		P Value
	Group CP (N=35) Mean (SD)	Group B (N=35) (Mean (SD)	
Peak block height (min) (max sensory)	12.77 (3.52)	22.34 (6.46)	<0.001*
Max Motor (min)	9.14 (2.23)	10.86 (2.18)	0.002*

Unpaired t Test, P Value *Significant

Table 2 shows the mean time required for maximum sensory and motor blockade between two groups. The mean time required for peak block height (maximum sensory blockade) in group CP was 12.77±3.52 min and in group B was 22.34±6.46 min with p value of <0.001.The mean time of maximum motor blockade in group CP was 9.14±2.23 min and in group B was 10.86±2.18 min with p value of 0.002. Hence time required for maximum sensory and motor blockade was statistically significant in both groups.

Table 3: Comparison of Maximum level of Sensory blockade between two groups

Maximum level of Sensory blockade	Group	
	Group CP (N=35) N (%)	Group B (N=35) N (%)
Above T4	5 (14.3)	0
T4	29 (82.9)	35 (100.0)
T6	1 (2.9)	0

Chi-Square Test, P Value = 0.038, Significant

Table 3 shows maximum height of sensory block between two groups. 5 patients in group CP had above T4 level (14.3%), 29 patients had T4 (82.9%) and one patient had T6 (2.9%) level of sensory, where as in group B all 35 patients had T4 level (100%) of sensory block.

Table 4: Comparison of maximum Degree of Motor Blockade between two groups

Maximum Degree of Motor Block	Group	
	Group CP (N=35) N (%)	Group B (N=35) N (%)
1(complete)	28 (80.0)	23 (65.7)
2(near complete)	7 (20.0)	12 (34.3)

Chi-Square Test, P Value = 0.179, Not Significant

Table 4 shows comparison of maximum degree of motor blockade in both the groups. Percentage of patients with modified Bromage 1 in group CP was 80 (n=28) and in group B was 65.7 (n=23). Percentage of patients with modified Bromage 2 in group CP was 20 (n=7) and in group B was 34.3 (n=12) with p value of 0.179 which was statistically not significant.

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Table 5: Comparison of Various Block Parameters between two Groups

Parameter	Group		P Value
	Group CP (N=35) Mean (SD)	Group B (N=35) (Mean (SD)	
Two segment Regression time (min)	39.34 (4.46)	63.14 (4.7)	<0.001*
Duration of Motor blockade (hr)	1.07 (0.14)	3.42 (0.41)	<0.001*
Duration of Analgesia (hr)	4.02 (0.79)	3.77 (0.34)	0.097
PCT Consumption in 24 hr	2.37 (0.49)	2.51 (0.50)	0.235

Unpaired t Test, P Value *Significant

Table 5 shows comparison of various block parameters between two study groups. Mean duration of two segment regression time in group CP was 39.34±4.46 min and in group B was 63.14±4.7 with p value of <0.001 which was statistically significant.
Mean duration of motor blockade of group CP was 1.07±0.14 hr and in group B was 3.42±0.34 hr with p value of <0.001 which was statistically significant.
Mean duration of analgesia of group CP was 4.02±0.79 hr and in group B was 3.77±0.34 hr with p value of 0.097. Mean PCT consumption in 24hr in group CP was 2.37±0.49 and in group B was 2.51±0.50 with p value of 0.235. Hence there was no statistically significant difference in the duration of analgesia and PCT consumption between two groups.

Table 6: Comparison of Regression to L1 & S2 between two Groups

Parameter	Group		P Value
	Group CP (N=35) Mean (SD)	Group B (N=35) (Mean (SD)	
Regression to L1 (hr)	1.28 (1.53)	2.29 (0.12)	<0.001*
Regression to S2 (hr) (duration of sensory blockade)	2.08 (0.25)	3.60 (0.27)	<0.001*

Table 6 shows mean duration time of regression to L1 and S2 between both the groups. Time for regression to L1 in group CP was 1.28±1.53 hr and in group B was 2.29±0.12 hr with p value of <0.001. Time for regression to S2 (duration of sensory blockade) in group CP was 2.08±0.25 and in group B was 3.60±0.27 hr with p value of <0.001. Hence there was statistically significant difference in the time for regression to L1 and S2 in both the groups.

Table 7: Comparison of VAS Score between two groups

Time	Group		P Value
	Group CP (N=35) Mean VAS (SD)	Group B (N=35) Mean VAS (SD)	
2 hrs.	0.89 (0.67)	1.11 (0.67)	0.162
4 hrs.	1.91 (0.61)	2.43 (0.50)	<0.001*
6 hrs.	5.83 (0.74)	6.40 (0.84)	0.004*
12 hrs.	3.34 (0.63)	3.60 (0.69)	0.112
24 hrs.	4.91 (0.74)	5.17 (0.56)	0.108

Unpaired t Test, P Value *Significant

Table 7 shows comparison of VAS score between both the groups.
2hrs after surgery VAS score in group CP was 0.89±0.67 and in group B was 1.11±0.67 (p-value-0.162). At 4hrs and 6hrs VAS score in group CP was 1.91±0.61, 5.83±0.74 and in group B was 2.43±0.5, 6.4±0.84 with p value <0.005 which was statistically significant. At 12hrs and 24hrs VAS score in group CP was 3.34±0.63, 4.91±0.74 and in group B was 3.6±0.69, 5.17±0.56, with p value 0.1 which was statistically not significant.

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Discussion

In our study, the mean time for onset of sensory blockade in group CP was 1.71±0.62min and in group B was 2.31±0.63min (p <0.001) which was statistically significant. Sensory block onset was faster in CP group when compared to B group.

Study conducted by Ben Gys *et al.* [7] using intrathecal Prilocaine (60mg), 2-Chloroprocaine (40mg) and bupivacaine (10.5mg) in patients undergoing day care surgery, onset of sensory blockade in group CP was 2.8 (1.0-15.0)min and in group B was 3.4 (1.0-19.0)min (p<0.001) which was also statistically significant which is comparable to our study.

Study conducted by M.A. Lacasse *et al.* [8] in comparing 0.75% H bupivacaine (7.5mg) and 2% 2-chloroprocaine (40mg) for spinal anaesthesia for outpatient surgery, onset of sensory blockade in group CP was 6min and in group B was also 6min (p=0.5) which was not statistically significant. Their study showed delayed onset of sensory block for both the drugs when compared to our study.

Majority of the patients in group CP (82.9%) and all patients in group B (100%) had maximum level of sensory block of T4 which was sufficient for lower segment caesarean section with none requiring any supplementation of analgesics/anaesthetics in the intra operative period.

Study conducted by Ben Gys *et al.* [7] mean maximum sensory level in group CP was T4 and in group B was T3 whereas study by M. A. Lacasse *et al.* [8] mean maximum sensory level both in group CP and in group B was T7, may be because they have used higher concentration and lower volume of drug when compared to our study.

In our study, the mean time for maximum sensory blockade in group CP was 12.77±3.52min and in group B was 22.34±6.46min (p <0.001) which was statistically significant. Time for maximum sensory block in CP group was almost 10min lesser when compared to B group which is similar to the studies done by Ben Gys *et al.*7 (28.3min and 36.3min) M.A. Lacasse *et al.* [8] (15min and 18min) but in both studies it is delayed in both the groups when compared to our study.

In our study, mean time for two segment regression time in group CP was 39.34±4.46min and in group B was 63.14±4.7min with p value of <0.001 which was statistically significant. Similarly, in a study conducted by M.A. Lacasse *et al.* [8], mean time for two segment regression time in group CP was 50 ±18min and in group B was 75±37min with p value of <0.001 which is higher when compared to our study but CP group had faster regression time compared to B group which is similar to our study.

The mean time for regression to L1 and S2(duration of sensory blockade) in group CP was 1.28±1.53hr and 2.08±0.25 hr and in group B was 2.29±0.12hr and 3.60±0.27hr respectively with p value of <0.001 which was statistically significant. Regression to L1 and S2 in group CP was faster by almost one hour when compared to B group.

Study conducted by Ben Gys *et al.*7 mean time to complete sensory regression in group CP was 2.8 (1.0-8.1)hr and in group B was 5.3 (1.7-9.2)hr which was comparable to our study.

Study conducted by M. A. Lacasse *et al.* [8] mean time for regression to L1 and S2 in group CP was 1.36hr and 2.43hr and in group B was 2.66 hr and 5.48hr respectively with p value of <0.001 which was statistically significant and was comparable to our study. Both the above studies have shown that time required for regression to L1 and S2 in CP group is faster when compared to B group but they are longer in both the drugs group when compared to our study.

In our study, onset of motor blockade in group CP was 2.54±0.88min and in group B was 2.66±0.76min with p value of 0.565 which was statistically not significant. We couldn't find any literature for onset of motor blockade.

In our study, 80%(n=28) of patients in group CP and 65.7% (N=23) of patients in group B had grade 1 motor blockade, while the remaining patients had grade 2 motor blockade with p

value of 0.179 which was statistically not significant.
The mean time for maximum degree of motor blockade in group CP was 9.14±2.23min and in group B was 10.86±2.18min with p value of 0.002 which was statistically significant.
In our study, duration of motor blockade in group CP was 1.07±0.14hr and in group B was 3.42±0.41hr with p value of <0.001 which was statistically significant. CP group had less duration of motor blockade by more than two and half hrs when compared to B group which is beneficial to the mother for early mobilization and breast feeding.
Study conducted by Ben Gys *et al.* [7], M.A. Lacasse *et al.* [8] and S. Maes *et al.* [6] duration of motor blockade in group CP was 1.8hr, 1.26hr and 0.93hr and in group B was 3.1hr, 1.98hr and 1.6hr respectively. Duration of motor blockade was lesser in chloroprocaine group than bupivacaine group which is comparable to our study. In our study, duration of analgesia in group CP was 4.02±0.79hr and 3.77±0.34hr in group B with p value of 0.097. Duration of analgesia is similar in both the groups with no statistical significant difference may be because we supplemented CP group with IL-IH nerve block.
Study conducted by Ben Gys *et al.* [7], M. A. Lacasse *et al.* [8] and Ashwini S *et al.* [9], duration of analgesia in group CP was 2.8hr, 2.43hr and 1.03hr and in group B was 5.3hr, 5.48hr and 2.91hr respectively.
In all above 3 studies, CP group had shorter duration of analgesia when compared to B group as there were not given any block unlike our study.
In our study, PCT consumption in group CP in 24hrs was 2.37±0.49 and in group B was 2.51±0.50 with p value of 0.235 which was statistically not significant.
Study conducted by Y A Nigatu *et al.* [10] in determining the analgesic efficacy of bilateral ilioinguinal-iliohypogastric (IL-IH) nerve block for caesarean section under spinal anaesthesia, mean total tramadol consumption over 24hrs was reduced by more than 50% in IL-IH block group compared to control group (71.157±37.4 vs 219.51±39.73mg). Both the groups were supplemented with diclofenac sodium 75mg IM every 8hrly whereas in our study we did not give any other fixed dose analgesic other than PCT. Hence our study might not have shown difference in total PCT consumption over 24hrs.
In our study, VAS scores were less in CP group at 4 and 6 hr postoperatively with p value <0.005 with statistically significant difference. At 2, 12 and 24hrs also VAS score was lesser in CP group than B group but was not statistically significant.
Study conducted by Ben Gys *et al.* [7] and M. A. Lacasse *et al.* [8], VAS scores were more in group CP than group B, but in our study as we supplemented chloroprocaine group with IL-IH block, VAS scores were less in group CP than group B.

Conclusion

Hence it can be concluded that 1% 2-chloroprocaine can be used for low risk caesarean section as an alternative to 0.5% hyperbaric bupivacaine, since it has shorter time of onset, duration of sensory and motor blockade. Supplementation of Ilioinguinal- iliohypogastric nerve block decreases the severity of immediate post-operative pain and helps in early mobilization of the patient and allows better maternal-neonatal bonding and increases patient satisfaction.

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