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Original Research Paper

Anaesthesiology

A COMPARATIVE STUDY OF INTRATHECAL 1% 2-CHLOROPROCAINE WITH FENTANYL AND DEXAMETHASONE AS AN ADJUVANT IN ELECTIVE CAESAREAN SECTIONS

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INTRODUCTION

The era of obstetric anaesthesia has its roots traced back to the noteworthy Scottish obstetrician, James Young Simpson. It is documented that during childbirth, Simpson administered Ether to a woman[1], marking the beginning of an era of immense medical advancement in obstetric anaesthesia.

Spinal anaesthesia, being one of the most preferred techniques for caesarean section, has stood the test of time owing to its remarkable attributes of being safe, reliable, being easily administered, and cost-effective. This technique offers rapid onset of anaesthesia, adequate muscle relaxation, causes less neonatal depression, fewer complications, and boasts of a low failure rate. Additionally, most complications associated with general anaesthesia, such as aspiration of gastric contents, difficult airway management, and respiratory distress in infants, can be averted using spinal anaesthesia technique.

Bupivacaine has traditionally been a commonly chosen agent for spinal anesthesia due to its long duration of action. However, its usage is not without concern, as it has been found to obstruct a patient's postoperative progress, increase the length of stay[2,3,4], and potentially impact perioperative outcomes, particularly in parturients.

Lidocaine, an amino amide with a short duration of action, was a popular agent for a considerable period. However, due to its repeated association with TNS[5,6,7] and other side effects, its usage has waned over time. Significantly an intriguing alternative to the aforementioned agents is chloroprocaine. Chloroprocaine has been found to be comparable to Bupivacaine, and its usage results in a faster recovery of patient's autonomy. In its early years, numerous reports of neurological deficits were reported in patients receiving accidentally high doses of intrathecal Chloroprocaine during epidural labour analgesia, which were attributed to the addition of sodium bisulphate, a preservative. In 2005, with the emergence of a preservative-free formulation, Chloroprocaine was reintroduced into clinical practice. Its average duration of action was found to be around 40 minutes, making it an attractive option for surgeries with shorter duration of time, though it led to early post- operative pain, which was deemed undesirable.

Fentanyl, a short-acting lipophilic opioid, is capable of stimulating μ1 & μ2 receptors, potentiating the afferent sensory blockade, and facilitating the reduction in the dose of local anaesthetics. Studies comparing Fentanyl to other agents have found that it is superior in terms of efficacy and safety.

Steroids, on the other hand, have been shown to be a viable alternative to Fentanyl, particularly when used with low doses of short-acting local anesthetics in short surgeries requiring prolonged analgesia. Dexamethasone, a synthetic glucocorticoid, exerts its action by reducing inflammation, blocking the transmission of nociceptive, serbfi-C and suppressing ectopic neural discharge. Many studies have reported no complications associated with intrathecal dexamethasone. Although dexamethasone has been used intrathecally for many years alongside bupivacaine and levobupivacaine, it has not been evaluated in conjunction with intrathecal chloroprocaine.Thus, we propose a comparison of the efficacy and safety of 1% 2-chloroprocaine with Fentanyl and Dexamethasone as an adjuvant in elective caesarean section. This study seeks to contribute significantly to the existing body of knowledge on obstetric anaesthesia, ultimately enhancing clinical practice and patient outcomes.

METHODS:

The present study utilized a rigorous and well-validated prospective, randomized, double-blind, parallel-group, comparative design that received full approval from the institutional ethical committee (IEC,SPMC/2021/3623) (CTRI/2023/05/053035). Prior to enrollment, written informed consent was obtained from both the mother and her relatives, and rigorous exclusion criteria were applied to ensure that only eligible patients were included.

Specifically, only ASA class II parturients between the ages of 18-35 years undergoing lower segment cesarean section (LSCS) were included in the study. Patients who refused to participate, had allergies to study drugs, coagulation defects, local site infection, raised intracranial pressure, body mass index (BMI) <20 or >30, or severe hypovolemia were excluded.

The primary objective of the study was to assess and compare the onset, duration, and quality of sensory and motor block, as well as the duration of postoperative analgesia and analgesic consumption during the first 8 hours. The secondary objective was to observe perioperative hemodynamic changes, side effects, and complications. To ensure unbiased allocation, patients were randomly assigned to two groups of 30 each, using a computer-generated series, with allocation

concealment through sealed opaque envelopes. The study drug was prepared by an anesthesiologist who was not involved in the study.The study drugs were administered as follows according to the group assigned.

Table1: Allocation of groups based on study drugs

Groups	Drugs	Volume	No. of Patients	Total Volume
A	Inj.1% 2-Chloroprocaine +Inj Fentanyl + Inj. Normal Saline	2.5ml+0.5ml +0.5 ml NS	30	3.5ml
B	Inj.1% 2-Chloroprocaine + Inj. Dexamethasone	2.5ml +1.0ml	30	3.5ml

To ensure proper patient safety and minimize the risk of adverse events, a thorough pre-anesthesia check-up was conducted a day before surgery. This included a detailed history, general physical examination, systemic examination, airway assessment, and lumbar spine examination. Patients were also kept nil by mouth for 6 hours for light meals and 2 hours for clear sdiufl before surgery. Prior to the procedure, the anesthesia plan was explained to all parturients, and the anesthesia workstation, subarachnoid block (SAB) equipment, and resuscitation equipment were prepared.

The patient was then shifted to the operation room (OR), and a multipara monitor was attached to record baseline heart rate (HR), blood pressure (BP), and oxygen saturation (SpO2) throughout the procedure .An intravenous line was secured with a 22G/24G intravenous (IV) cannula, and injection ringer lactate was administered at the rate of 10ml/kg. The patient was placed in the lateral decubitus position, and lumbar puncture was performed in the midline at L3-L4 intervertebral space with 25G Quincke cutting spinal needle, after confirming free aspiration of cerebrospinal fluid.

The predetermined volume of the study drug was injected intrathecally, and the patient was immediately turned supine, with not more than 30 degrees tilt for easy spreading of the drug. Extra caution was taken during tilting to avoid complications, and lumbar puncture was performed by the same anesthesiologist in all patients.

Sensory and motor blocks were assessed every 2 minutes by pinprick in skin dermatomes T6-L5 until the onset of sensory blockade.

Sensory block was assessed with bilateral non traumatic pin prick with a 23-gauge blunt needle, and the facial expression was observed. The onset of sensory block was defined as the time when the patient felt a dull sensation to prick/pinch at T6 level, and the time for complete sensory block was defined as the complete loss of sensation to prick/pinch (temperature, touch, and pain).

Sample Size, Data Collection And Analysis:

Medcalc Statistical software was used for sample size calculation.
Alpha-5%
Beta-20%
Power of study-80%
Dataloss-30%
n= (Z /2+Z)2*2* 2/d2

Data was recorded in Microsoft Excel software. Group comparisons were made using t-test/Mann–Whitney U test for normally/non-normally distributed continuous data, respectively.

Chi-square test was used for categorical variables. Statistical Package for Social Sciences (SPSS) version 23 was used for analysis. P<0.05 was taken as the cut-off for statistical significance.

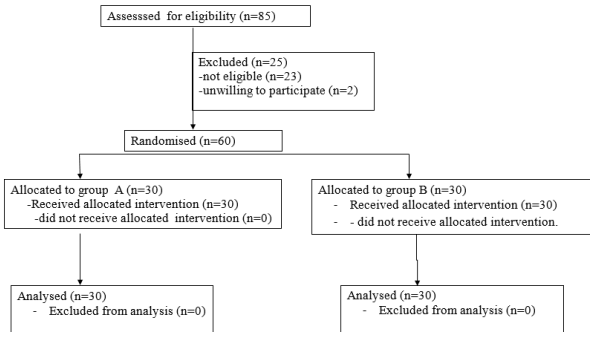

Fig1: CONSORT chart of patients recruited and analyzed

Table 2: Association between Demographic Parameters

Parameters	Group		p value
	A (n= 30)	B (n= 30)	
Age (Years)	25.80 ± 3.90	26.13 ± 3.97	0.70_5^1
Weight (Kg)	62.80 ± 5.12	60.63 ± 4.80	0.09_6^3
Height (cm)	160.73 ± 5.51	160.67 ± 5.90	0.96_4^3

Table 3: Comparison of block characteristics between the two groups

Parameters	Group		p value
	A (n= 30)	B (n= 30)	
Sensory Block: Onset (minutes)	3.46 ± 0.53	3.83± 0.82	0.17_4^1
Time of Peak Sensory Block (minutes)	4.44±0.67	4.77±0.88	0.47_3^1
Sensory Block: Duration of Block (minutes)***	91.38± 17.81	75.12± 8.97	$<0.001^1$
Timeto2-segment regression(minutes)	58.76± 6.20	53.17±6.02	0.00_1^3
Time to first rescue analgesia (minutes)	107.48±21.65	83.22±9.48	$<0.001^4$
Motor Block: Onset (minutes)	3.87 ± 0.61	4.11± 0.88	0.510^1
Motor Block: Duration of Block*** (minutes)	70.53± 8.90	64.27± 7.22	0.00_4^3

****Significantatp<0.05,1:Wilcoxon-Mann-WhitneyUTest,2:Chi-SquaredTest,3:t-test,4:Fisher's Exact Test*

RESULTS:

In our study, we compared demographic characteristics, sensory and motor block characteristics, and hemodynamic parameters in two groups of patients undergoing regional anesthesia. We found that age, sex, BMI, ASA status and weight were similar in both groups [Table 2].

There were no significant differences between the groups in terms of onset of sensory block, time of peak sensory block, level of sensory block, or onset of motor block. However, the time for 2 segment regression of sensory block was longer in both group A and group B, with a statistically significant p-value of 0.001.

Additionally, we observed that the duration of sensory blockade was longer in group A compared to group B, with a statistically significant difference ($p < 0.001$) [Table 3].

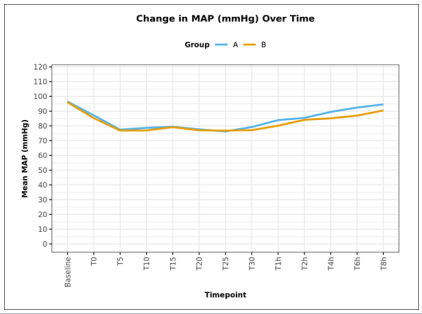

Figure 2: Line diagram depicting the change in MAP (mmHg) over time in both the groups.

Baseline hemodynamic parameters, including mean arterial pressure (MAP) and heart rate (HR), were comparable in both groups, and none of the patients developed severe hypotension or bradycardia. We have illustrated the MAP and HR in both groups at different time-points in [Figure 2, 3]. Furthermore, none of the patients included in the study, required additional sedation, general anesthesia, or airway management.

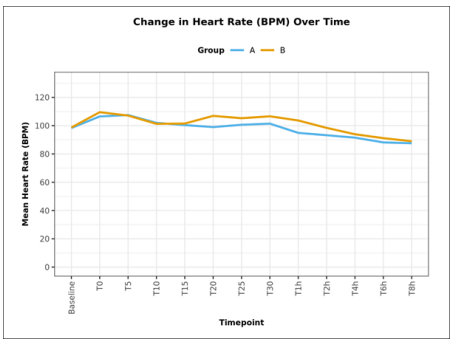

Figure 3: line diagram depicting the change in Heart Rate (BPM) over time in the two groups.

The time (mins) to first rescue analgesia (VAS > 3) in the post-operative period was compared between both the groups and there was statistically significant difference between both the groups with group B (83.2±9.48) requiring earlier rescue analgesia compared to group A (107.48±21.65) [Figure 4].

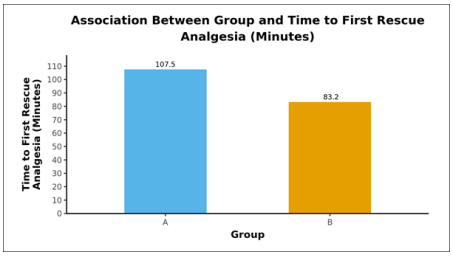

Figure 4: Bar graph depicting association between group and time to first rescue analgesia (minutes).

Larger proportion of study population had excellent patient and surgeon satisfaction scores in group A when compared to group B [Table 4].

Table 4: Comparison of complications and satisfaction scores between the groups

Parameters	Group A (n= 30)	Group B (n= 30)	p value
Complication : Hypotension(Yes)	0 (0.0%)	0 (0.0%)	1.00_0^2
Complication: Bradycardia (Yes)	0 (0.0%)	0 (0.0%)	1.00_0^2
Complication : Emergency Drug Requirement (Yes)	6 (20.0%)	9 (30.0%)	0.37_1^2
Patient Satisfaction Score* **			$<0.001^4$
Excellent	25 (83.3%)	4 (13.3%)	
Good	5 (16.7%)	19 (63.3%)	
Fair	0 (0.0%)	6 (20.0%)	
Poor	0 (0.0%)	1 (3.3%)	
Surgeons Satisfaction Score* **			$<0.001^2$
Excellent	26 (86.7%)	6 (20.0%)	
Good	4 (13.3%)	24 (80.0%)	

DISCUSSION:

Spinal anesthesia has been the preferred technique for cesarean sections due to its better profile compared to general anesthesia. However, the search for an ideal local anesthetic for spinal anesthesia has spanned decades. Traditional lidocaine showed TNS in many studies, and although bupivacaine became the most commonly used and preferred spinal agent for centuries, it also has various side effects, including hypotension, bradycardia, arrhythmia, delayed ambulation, urinary retention, and the most dreadful side effect of inadvertent intravascular injection.

In 1952, 2-Chloroprocaine, an aminoester with a short duration of action, was introduced. However, its intrathecal use led to TNS in many cases. Recently, its preservative-free formulation has been reintroduced and has shown promising results in its early regression of motor block. Early regression, especially after C-section, can lead to early breastfeeding, less postoperative complications, and possibly early discharge. Since then, it has been used in many studies with opioids, clonidine, buprenorphine to prolong the duration of sensory block.

To compare the efficacy and safety of 1% Chloroprocaine with fentanyl and dexamethasone as an adjuvant in spinal anesthesia, we conducted a prospective, randomized double-blinded hospital-based study in 60 parturients undergoing a cesarean section in Sardar Patel Medical College, Bikaner (Raj.).Approval from the Institutional Ethical Committee and valid written informed consent from patients' relatives was taken before starting the study.

The demographic characteristics like age, weight, height, BMI, and ASA status of the study population were similar in both groups, with no statistically significant differences, similar to the study done by Mahmoud Ali Ahmed El-Shourbagy [8]. There was no significant difference in the trend of MAP and HR over time in both groups.

The onset of sensory block in Group A and Group B was 3.46 (0.53) and 3.83 (0.82) mins, and the time of peak sensory block (minutes) was 4.44 (0.67) and 4.77 (0.88), respectively. Both were statistically insignificant and similar to the studies done by Arvind Khare et al. [9]and Geeta Singariya et al. [10] respectively. The time for 2 segment regression of sensory block (minutes) in Group A and Group B was 58.76 (6.20) and 53.17 (6.02), respectively, which was longer in Group A than in Group B, with a significant difference between the two groups ($t=3.544, p=0.001$).The duration of sensory blockade (minutes) was 91.38 (17.81) and 75.12 (8.97) in Group A and Group B, respectively, which was longer in Group A than in Group B and statistically significant ($W= 735.500$, $p = <0.001$). Our findings were comparable to the study done by B. Bhaskara et al.[11]

This , might be due to the use of fentanyl as an adjuvant in Group A.

The time to first rescue analgesia was 107.48 (21.65) and 83.22 (9.48) in Group A and Group B, respectively, showing that rescue analgesia was required in the dexamethasone group earlier. There was no significant difference between the groups in terms of onset of motor block. The duration of motor block (minutes) in Group A and Group B was 70.53 (8.90) and 64.27(7.22) (minutes), respectively, which was higher in Group A than in Group B, and the difference was statistically significant ($t = 2.992$, $p = <0.004$).

There was a significant difference between the groups in terms of distribution of Patient Satisfaction Score ($p = <0.001$). Participants in the group Group A had the larger proportion of Patient Satisfaction Score: Excellent.

Participants in the group Group B had the larger proportion of Patient Satisfaction Score: Good. Participants in the group Group B had the larger proportion of Patient Satisfaction Score: Fair. Participants in the group Group B had the larger proportion of Patient Satisfaction Score: Poor.

Thus, our study showed fentanyl as a better adjuvant when compared with dexamethasone, for spinal anaesthesia in C-section patients.

CONCLUSION:

Our study suggests that adding fentanyl as adjuvant to 1% 2-Chloroprocaine in spinal anaesthesia may provide a longer duration of sensory blockade and motor block compared to Chloroprocaine with dexamethasone. The use of fentanyl also resulted in delayed time to first rescue analgesia, which may be laicfienebin reducing postoperative complications and enabling early discharge from the hospital. The absence of tnacfiingis differences in MAP and HR trends between the two groups suggests that Chloroprocaine does not have significant hemodynamic effects. Overall, our findings support the potential of Chloroprocaine as a promising alternative to traditional local anesthetics for spinal anesthesia in obstetric patients undergoing cesarean section.

Limitations:

Further studies with larger sample sizes and longer follow-up periods are warranted to validate our results and establish the safety and ycacfifeof Chloroprocaine as an adjunct to spinal anesthesia in obstetric patients.

Declaration of patient consent :

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient has given her consent for clinical information to be reported in the journal. The patients understand that their names and initials will not be published, and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest: There are no conflicts of interest.

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