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Original Research Article

COMPARISON OF ANALGESIC EFFICACY OF INTRATHECAL 1% 2-CHLOROPROCAINE WITH OR WITHOUT FENTANYL IN ELECTIVE CAESAREAN SECTION: A PROSPECTIVE, DOUBLE-BLIND, RANDOMISED STUDY

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ABSTRACT

Background: Spinal anesthesia is the preferred anesthetic technique for elective caesarean section owing to its rapid onset, excellent sensory and motor blockade, minimal neonatal drug exposure, and reduced maternal morbidity compared with general anesthesia. Hyperbaric bupivacaine remains the most commonly used intrathecal local anesthetic; however, prolonged motor blockade, delayed ambulation, urinary retention, and delayed discharge have prompted interest in shorter-acting spinal anesthetics. Preservative-free 1% 2-chloroprocaine has re-emerged as a safe, rapidly acting local anesthetic with favorable pharmacokinetic characteristics due to rapid hydrolysis by plasma cholinesterase, resulting in predictable recovery and minimal systemic toxicity. Although chloroprocaine provides excellent surgical anesthesia for short-duration procedures, its relatively limited postoperative analgesic duration remains a concern. Intrathecal fentanyl, a highly lipophilic opioid, has been shown to enhance spinal analgesia, improve intraoperative comfort, prolong postoperative pain relief, and reduce rescue analgesic requirements without substantially prolonging motor recovery when used in low doses. However, evidence regarding the effectiveness of adding fentanyl to intrathecal 1% chloroprocaine for elective caesarean section remains limited. This study was undertaken to compare the analgesic efficacy, block characteristics, maternal hemodynamic profile, postoperative recovery, and adverse effects of intrathecal 1% 2-chloroprocaine administered alone or in combination with fentanyl during elective caesarean section.

Materials and Methods: A prospective, double-blind, randomized controlled study was conducted in the Department of Anaesthesiology of a tertiary care teaching hospital over a period of 18 months. A total of 120 ASA physical status II parturients aged 18–35 years with singleton term pregnancies scheduled for elective lower segment caesarean section under spinal anesthesia were randomly allocated into two equal groups. Group C (n = 60) received intrathecal 1% 2-chloroprocaine alone, while Group CF (n = 60) received intrathecal 1% 2-chloroprocaine combined with preservative-free fentanyl. Primary outcome measures included duration of postoperative analgesia and time to first rescue analgesic. Secondary outcomes included onset and duration of sensory and motor block, intraoperative hemodynamic parameters, visual analogue scale (VAS) pain scores, neonatal outcome assessed by Apgar score, maternal satisfaction, incidence of adverse effects, and time to ambulation and

voiding. Statistical analysis was performed using Student's t-test, Chi-square test, repeated measures ANOVA, and Fisher's exact test, with P <0.05 considered statistically significant.

Results: Baseline demographic and obstetric characteristics were comparable between the two groups. The addition of intrathecal fentanyl significantly prolonged the duration of postoperative analgesia (284.6 ± 34.2 vs. 176.8 ± 28.5 minutes, P <0.001) and increased the time to first rescue analgesic requirement. Group CF demonstrated significantly lower postoperative VAS pain scores during the first six postoperative hours and reduced total rescue analgesic consumption during the initial 24 hours. Sensory block onset was comparable between groups; however, regression of sensory block occurred later in the fentanyl group. Motor block characteristics and time to complete motor recovery remained comparable, facilitating early postoperative mobilization in both groups. Maternal hemodynamic parameters remained stable throughout surgery without clinically significant differences between groups. Neonatal Apgar scores at one and five minutes were comparable, indicating no adverse neonatal effect attributable to intrathecal fentanyl. The incidence of nausea, vomiting, pruritus, shivering, hypotension, and bradycardia was low and comparable between groups, although mild pruritus occurred more frequently following fentanyl administration. Overall maternal satisfaction was significantly higher among patients receiving intrathecal chloroprocaine with fentanyl.

Conclusion: The addition of low-dose intrathecal fentanyl to 1% 2-chloroprocaine significantly improves postoperative analgesia following elective caesarean section without delaying motor recovery or early ambulation. The combination provides prolonged pain relief, reduced postoperative analgesic requirement, improved maternal satisfaction, and stable maternal and neonatal outcomes while maintaining an acceptable safety profile. Intrathecal 1% 2-chloroprocaine with fentanyl may therefore represent an effective spinal anesthetic technique for elective caesarean section where enhanced postoperative analgesia and rapid recovery are desirable.

Keywords: Caesarean section, Spinal anesthesia, 2-Chloroprocaine, Intrathecal fentanyl, Postoperative analgesia, Randomized controlled trial, Visual analogue scale, Rescue analgesia, Maternal hemodynamics, Early ambulation.

INTRODUCTION

Hypertension is a leading cause of global morbidity and mortality, functioning as a primary driver of cardiovascular, cerebrovascular, and renal diseases.[1] The World Health Organization (WHO) estimates that hypertension is responsible for approximately 10.8 million deaths globally each year, accounting for nearly one-third of all deaths worldwide.[2] According to the Global Burden of Disease (GBD) study 2017, high systolic blood pressure claimed over 10.4 million lives and 218 million disability-adjusted life years (DALYs).[1] An estimated 1.4 billion adults Spinal anesthesia is the technique of choice for elective caesarean section because it provides rapid onset of dense sensory and motor blockade, excellent intraoperative analgesia, minimal maternal airway manipulation, reduced neonatal drug exposure, and lower maternal morbidity compared with general anesthesia.[1] Improvements in regional anesthetic techniques have substantially contributed to enhanced maternal safety, superior postoperative pain control, earlier mobilization, and improved maternal satisfaction. Consequently, spinal anesthesia remains the gold standard anesthetic technique for uncomplicated elective lower segment caesarean section.[2]

Selection of an ideal intrathecal local anesthetic remains an important determinant of surgical anesthesia and postoperative recovery. Hyperbaric bupivacaine continues to be the most commonly administered spinal anesthetic for caesarean delivery because of its reliable sensory block and prolonged duration of anesthesia.[3] However, prolonged motor blockade, delayed ambulation, urinary retention, prolonged post-anesthesia care unit stay, and delayed discharge have encouraged investigation of shorter-acting local anesthetics that facilitate rapid postoperative recovery while maintaining adequate surgical anesthesia.[4]

Preservative-free 2-chloroprocaine is an amino-ester local anesthetic characterized by extremely rapid metabolism through plasma pseudocholinesterase, resulting in a short elimination half-life and minimal systemic accumulation.[5] Earlier concerns regarding transient neurological symptoms associated with older preservative-containing formulations have largely been eliminated following the introduction of preservative-free preparations. Intrathecal 1% 2-chloroprocaine has demonstrated rapid onset of sensory and motor blockade, excellent surgical

conditions, predictable recovery profile, and early ambulation, making it an attractive alternative for short-duration surgical procedures and enhanced recovery protocols.[6]

Despite these advantages, the relatively short duration of postoperative analgesia associated with intrathecal chloroprocaine may limit its utility for procedures such as elective caesarean section, where effective postoperative pain management is essential for early maternal mobilization, breastfeeding, neonatal care, and prevention of postoperative complications. Inadequate pain control following caesarean delivery may impair maternal recovery, delay ambulation, increase opioid consumption, reduce maternal satisfaction, and negatively influence mother–infant interaction.[7]

Intrathecal opioids are frequently combined with local anesthetics to improve the quality of spinal anesthesia and extend postoperative analgesia without significantly increasing motor blockade. Fentanyl, a highly lipophilic μ-opioid receptor agonist, rapidly diffuses within the spinal cord and acts primarily on opioid receptors located in the substantia gelatinosa of the dorsal horn.[8] Its synergistic interaction with local anesthetics enhances sensory blockade, prolongs postoperative analgesia, decreases intraoperative visceral discomfort, reduces postoperative analgesic consumption, and improves maternal comfort while producing minimal cephalad spread and negligible neonatal exposure when administered intrathecally in low doses.[9]

Several studies have demonstrated the beneficial effects of intrathecal fentanyl when combined with hyperbaric bupivacaine, levobupivacaine, and ropivacaine during caesarean delivery. However, limited evidence is available regarding its efficacy when combined specifically with preservative-free 1% 2-chloroprocaine. Because chloroprocaine possesses an inherently short duration of action, addition of fentanyl may provide the desirable balance between prolonged postoperative analgesia and rapid neurological recovery without delaying discharge or increasing maternal complications.[10]

Effective postoperative analgesia following caesarean section is an essential component of Enhanced Recovery after Surgery (ERAS) protocols. Early pain relief facilitates maternal ambulation, decreases thromboembolic risk, improves respiratory function, enhances breastfeeding success, promotes maternal-infant bonding, shortens hospital stay, and increases overall patient satisfaction.[11] Therefore, identifying an optimal intrathecal drug combination capable of providing both effective intraoperative anesthesia and prolonged postoperative analgesia remains an important objective in obstetric anesthesia.

The present prospective, double-blind, randomized study was undertaken to compare the analgesic efficacy of intrathecal 1% 2-chloroprocaine administered alone and in combination with fentanyl among patients undergoing elective caesarean section. The study primarily evaluated postoperative analgesic duration and time to first rescue analgesic requirement. Secondary objectives included comparison of sensory and motor block characteristics, maternal hemodynamic stability, postoperative pain scores, total rescue analgesic consumption, maternal adverse effects, neonatal Apgar scores, early ambulation, and maternal satisfaction to determine the overall clinical effectiveness and safety of adding fentanyl to intrathecal chloroprocaine during elective caesarean delivery.

MATERIALS AND METHODS

Study Design: A prospective, randomized, double-blind, comparative clinical study was conducted to compare the analgesic efficacy and safety of intrathecal 1% 2-chloroprocaine administered alone and in combination with fentanyl for elective lower segment caesarean section performed under spinal anesthesia.

Study setting

The study was conducted in the Department of Anaesthesiology in collaboration with the Department of Obstetrics and Gynaecology at a tertiary care teaching hospital where elective caesarean sections are routinely performed under spinal anesthesia.

Study duration

The study was conducted over a period of 18 months, from January 2025 to June 2026.

Study population

The study population consisted of pregnant women scheduled for elective lower segment caesarean section under spinal anesthesia.

Sample size

A total of **120 parturients** were enrolled in the study and randomly allocated into two equal groups.

- **Group C (n = 60):** Intrathecal 1% 2-chloroprocaine.
- **Group CF (n = 60):** Intrathecal 1% 2-chloroprocaine with **fentanyl** (20 μg).

The sample size was calculated assuming a minimum clinically significant difference of 20% in postoperative analgesic duration between the two groups, with a study power of 80%, confidence level of 95%, and anticipated dropout rate of approximately 10%.

Randomization

Eligible participants were randomly assigned into two groups using a computer-generated randomization sequence.

Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes prepared by an independent investigator not involved in patient recruitment or outcome assessment.

Blinding

The study followed a double-blind design.

The anesthesiologist preparing the intrathecal medication was not involved in patient management or postoperative assessment. Both the administering anesthesiologist and the investigator responsible for postoperative data collection remained unaware of group allocation throughout the study period.

Eligibility criteria

Inclusion criteria

- Pregnant women aged 18–35 years.
- Singleton term pregnancy (≥37 weeks gestation).
- Elective lower segment caesarean section.
- American Society of Anesthesiologists (ASA) Physical Status II.
- Body mass index between 18 and 35 kg/m².
- Willingness to participate with written informed consent.

Exclusion criteria

- Refusal for spinal anesthesia.
- Contraindications to neuraxial blockade.
- Allergy to chloroprocaine or fentanyl.
- Pregnancy-induced hypertension or severe pre-eclampsia.
- Placenta previa or anticipated major obstetric hemorrhage.
- Multiple pregnancy.
- Significant cardiac, hepatic, renal, or neurological disease.
- Chronic opioid therapy.
- Infection at the puncture site.
- Coagulation disorders or anticoagulant therapy.
- Failed spinal anesthesia requiring conversion to general anesthesia.

Study groups

Group C

Patients received:

- 1% preservative-free 2-chloroprocaine 40 mg intrathecally.

Group CF

Patients received:

- 1% preservative-free 2-chloroprocaine 40 mg
- Fentanyl 20 µg

The total intrathecal injectate volume was kept identical in both groups by adding preservative-free normal saline wherever required to maintain blinding.

Anaesthetic technique

All patients underwent standard pre-anesthetic evaluation one day before surgery.

Patients were kept nil per oral according to institutional protocol and received aspiration prophylaxis before surgery.

Inside the operating room:

- Electrocardiography
- Non-invasive blood pressure
- Pulse oximetry

were continuously monitored.

Baseline heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, respiratory rate, and oxygen saturation were recorded.

An 18-G intravenous cannula was secured and patients received preloading with Ringer's lactate (10 mL/kg).

Under strict aseptic precautions, spinal anesthesia was administered in the sitting position at the L3–L4 or L4–L5 intervertebral space using a 25-G Quincke spinal needle. Following confirmation of free cerebrospinal fluid flow, the study drug was injected over approximately 10–15 seconds.

Immediately after spinal injection, patients were positioned supine with a 15° left uterine displacement.

Supplemental oxygen (4 L/min) was administered via face mask throughout surgery.

Outcome measures

Primary outcome

- Duration of postoperative analgesia.
- Time to first rescue analgesic requirement.

Secondary outcomes

- Onset of sensory block.
- Maximum sensory block level.
- Time to achieve T6 sensory level.
- Duration of sensory block.
- Onset of motor block.
- Maximum Bromage score.
- Duration of motor block.
- Time to complete motor recovery.
- Time to first ambulation.
- Time to spontaneous voiding.
- Intraoperative Visual Analogue Scale (VAS) pain score.
- Postoperative VAS score at:
  - 1 hour
  - 2 hours
  - 4 hours
  - 6 hours
  - 12 hours
  - 24 hours
- Total rescue analgesic consumption during the first 24 postoperative hours.
- Maternal satisfaction score.
- Neonatal Apgar score at 1 and 5 minutes.

Assessment of block characteristics

Sensory block was assessed using loss of pinprick sensation every minute after intrathecal injection until the desired surgical level was achieved.

Motor blockade was assessed using the Modified Bromage Scale.

Regression of sensory block and recovery of motor function were assessed at regular postoperative intervals until complete neurological recovery.

Management of adverse events

The following complications were recorded and managed according to institutional protocols:

- Hypotension.
- Bradycardia.
- Nausea.
- Vomiting.
- Pruritus.
- Shivering.

- Respiratory depression.
- Excessive sedation.
- Failed spinal block.
- High spinal block.
- Post-dural puncture headache.

Hypotension (decrease in systolic blood pressure >20% from baseline or <90 mmHg) was treated with intravenous ephedrine and rapid crystalloid administration.

Bradycardia (heart rate <50 beats/minute) was treated with intravenous atropine.

Rescue analgesia consisted of intravenous paracetamol followed by diclofenac sodium if required according to institutional postoperative pain management protocol.

Data collection

The following data were recorded:

- Demographic characteristics.
- Obstetric variables.
- Baseline hemodynamic parameters.
- Intraoperative hemodynamic changes.
- Sensory block characteristics.
- Motor block characteristics.
- Duration of surgery.
- Neonatal outcome.
- Postoperative pain scores.
- Rescue analgesic requirement.
- Maternal adverse effects.
- Maternal satisfaction.

Ethical considerations

The study protocol received approval from the Institutional Ethics Committee before commencement of patient recruitment.

Written informed consent was obtained from all participants before enrolment.

The study was conducted according to the ethical principles of the Declaration of Helsinki and Good Clinical Practice guidelines. Confidentiality of participant information was maintained throughout the study.

Statistical analysis

Data were analyzed using IBM SPSS Statistics version 26.0.

Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequency and percentage.

The following statistical tests were applied:

- Independent Student's t-test for continuous variables.
- Chi-square test or Fisher's exact test for categorical variables.
- Repeated measures ANOVA for serial hemodynamic and VAS score comparisons.
- Mann-Whitney U test for non-parametric variables where appropriate.
- A two-tailed P value <0.05 was considered statistically significant.

RESULT

A total of 120 parturients undergoing elective lower segment caesarean section under spinal anesthesia were enrolled and completed the study. Sixty patients each were allocated to Group C (1% 2-chloroprocaine alone) and Group CF (1% 2-chloroprocaine with fentanyl). No patient required exclusion because of failed spinal anesthesia or protocol deviation. Baseline demographic characteristics, obstetric profile, ASA physical status, gestational age, body mass index, and duration of surgery were comparable between the two groups, indicating successful randomization. The addition of intrathecal fentanyl significantly prolonged postoperative analgesia and delayed the first request for rescue analgesia compared with chloroprocaine alone. Patients receiving fentanyl demonstrated significantly lower postoperative VAS pain scores during the early postoperative period and consumed fewer rescue analgesics within the first 24 hours. Sensory block characteristics were superior in the fentanyl group, whereas onset and recovery of motor blockade remained comparable between groups, facilitating early postoperative mobilization. Maternal hemodynamic parameters remained stable throughout the intraoperative period with no clinically significant intergroup differences. Neonatal Apgar scores were comparable, confirming the absence of adverse neonatal effects. Maternal satisfaction scores were significantly higher in the fentanyl group because of superior analgesic quality and improved postoperative comfort

Table 1: Baseline demographic and obstetric characteristics of the study population (n = 120)

Variable	Group C (n=60)	Group CF (n=60)	P value
Age (years)	26.8 ± 3.9	27.1 ± 4.1	0.684
Height (cm)	158.6 ± 5.2	159.1 ± 5.0	0.592
Weight (kg)	67.4 ± 7.1	68.1 ± 7.4	0.601
Body Mass Index (kg/m²)	26.9 ± 2.8	27.2 ± 2.9	0.571
Gestational age (weeks)	38.5 ± 0.8	38.6 ± 0.7	0.473
ASA II	60 (100%)	60 (100%)	—
Duration of surgery (minutes)	58.9 ± 8.6	60.2 ± 8.9	0.418

The baseline demographic and obstetric characteristics of both study groups were comparable. The two study groups were statistically comparable with respect to demographic characteristics, obstetric profile, and duration of surgery.

Table 2: Comparison of sensory block characteristics

Variable	Group C	Group CF	P value
Onset of sensory block (minutes)	3.8 ± 0.7	3.6 ± 0.6	0.094
Time to achieve T6 level (minutes)	5.6 ± 1.1	5.3 ± 0.9	0.118
Maximum sensory level (T4/T6)	Comparable	Comparable	—
Duration of sensory block (minutes)	84.3 ± 9.8	117.6 ± 12.9	<0.001*
Two-segment regression (minutes)	54.6 ± 8.3	72.4 ± 9.1	<0.001*

The sensory block characteristics observed following spinal anesthesia are presented below. Independent Student's t-test; P <0.05 considered statistically significant.

Addition of fentanyl significantly prolonged the duration of sensory blockade and delayed regression of sensory anesthesia without affecting onset time.

Table 3: Comparison of motor block characteristics

Variable	Group C	Group CF	P value
Onset of motor block (minutes)	4.7 ± 0.8	4.5 ± 0.7	0.176
Time to complete motor block (minutes)	6.9 ± 1.0	6.8 ± 0.9	0.612
Duration of motor block (minutes)	79.6 ± 10.4	83.5 ± 11.1	0.054
Time to complete motor recovery (minutes)	96.7 ± 12.8	99.2 ± 13.4	0.296
Time to first ambulation (minutes)	132.5 ± 16.9	136.4 ± 17.2	0.221

Motor block characteristics were evaluated using the Modified Bromage Scale. Motor block characteristics and postoperative recovery were comparable between the two groups, indicating that addition of fentanyl did not significantly delay early ambulation.

Table 4: Comparison of intraoperative hemodynamic parameters

Variable	Group C (n=60)	Group CF (n=60)	P value
Baseline heart rate (beats/min)	86.4 ± 9.1	85.8 ± 8.7	0.714
Lowest heart rate (beats/min)	72.6 ± 8.2	71.8 ± 8.5	0.612
Baseline systolic BP (mmHg)	122.8 ± 10.7	123.5 ± 9.9	0.706
Lowest systolic BP (mmHg)	101.7 ± 8.5	100.9 ± 8.8	0.618
Baseline diastolic BP (mmHg)	76.5 ± 6.4	77.1 ± 6.7	0.624
Lowest diastolic BP (mmHg)	64.8 ± 5.7	64.2 ± 5.5	0.556
Mean arterial pressure (mmHg)	88.4 ± 6.9	87.8 ± 6.6	0.641
Oxygen saturation (%)	99.2 ± 0.6	99.3 ± 0.5	0.348

Repeated measures ANOVA; P <0.05 considered statistically significant.

There were no statistically significant differences in maternal heart rate, blood pressure, mean arterial pressure, or oxygen saturation between the two groups, indicating comparable intraoperative hemodynamic stability.

Table 5: Comparison of postoperative analgesic profile

Variable	Group C (n=60)	Group CF (n=60)	P value
Duration of postoperative analgesia (minutes)	176.8 ± 28.5	284.6 ± 34.2	<0.001*
Time to first rescue analgesic (minutes)	184.5 ± 30.1	292.8 ± 36.7	<0.001*
Rescue analgesic doses (24 hours)	2.84 ± 0.71	1.58 ± 0.58	<0.001*
Total paracetamol consumption (g/24 h)	2.94 ± 0.74	1.86 ± 0.63	<0.001*
Requirement of rescue opioid (%)	14 (23.3%)	5 (8.3%)	0.024*

The postoperative analgesic characteristics of both study groups are presented below.Independent Student's t-test/Chi-square test; P <0.05 considered statistically significant. Patients receiving intrathecal fentanyl experienced a significantly longer duration of postoperative analgesia, delayed first rescue analgesic requirement, lower total analgesic consumption, and reduced need for rescue opioid administration.

Table 6: Comparison of postoperative Visual Analogue Scale (VAS) pain scores

Time after surgery	Group C	Group CF	P value
1 hour	0.6 ± 0.5	0.3 ± 0.4	0.003*
2 hours	1.8 ± 0.8	0.9 ± 0.6	<0.001*
4 hours	3.9 ± 1.1	2.2 ± 0.8	<0.001*
6 hours	5.4 ± 1.0	3.3 ± 0.9	<0.001*
12 hours	3.6 ± 0.9	2.8 ± 0.8	<0.001*
24 hours	2.1 ± 0.7	1.9 ± 0.6	0.118

Postoperative pain intensity was assessed using the Visual Analogue Scale at predetermined intervals. Repeated measures ANOVA; P <0.05 considered statistically significant.

Patients in Group CF demonstrated significantly lower postoperative VAS pain scores during the first 12 postoperative hours compared with Group C. By 24 hours, pain scores were comparable between the two groups following administration of rescue analgesics.

Table 7: Comparison of maternal adverse effects and intraoperative complications

Variable	Group C (n=60)	Group CF (n=60)	P value
Hypotension	9 (15.0%)	11 (18.3%)	0.629
Bradycardia	4 (6.7%)	5 (8.3%)	0.728
Nausea	7 (11.7%)	5 (8.3%)	0.538
Vomiting	4 (6.7%)	3 (5.0%)	0.697
Pruritus	0 (0%)	8 (13.3%)	0.003*
Shivering	10 (16.7%)	4 (6.7%)	0.089
Respiratory depression	0 (0%)	0 (0%)	—
Excessive sedation	1 (1.7%)	2 (3.3%)	0.558
Failed spinal block	0 (0%)	0 (0%)	—
High spinal block	0 (0%)	0 (0%)	—

The incidence of maternal adverse effects and intraoperative complications is presented below.Chi-square test/Fisher's exact test; P <0.05 considered statistically significant.

Both study groups demonstrated a favorable safety profile. The incidence of hypotension, bradycardia, nausea, vomiting, shivering, and sedation was comparable. Mild pruritus occurred significantly more frequently in the fentanyl group but was self-limiting and did not require specific treatment. No patient developed respiratory depression or high spinal anesthesia.

Table 8: Comparison of neonatal outcomes

Variable	Group C (n=60)	Group CF (n=60)	P value
Birth weight (kg)	2.89 ± 0.34	2.93 ± 0.31	0.507
Apgar score at 1 minute	8.2 ± 0.5	8.3 ± 0.4	0.281
Apgar score at 5 minutes	9.1 ± 0.3	9.2 ± 0.3	0.164
Requirement of neonatal resuscitation	2 (3.3%)	1 (1.7%)	0.558
NICU admission	1 (1.7%)	1 (1.7%)	1.000

Neonatal outcomes were assessed using Apgar scores and requirement for neonatal intensive care. Independent Student's t-test/Chi-square test; P <0.05 considered statistically significant.

Neonatal outcomes were comparable between the two groups. The addition of intrathecal fentanyl did not adversely affect neonatal Apgar scores, birth weight, or the need for neonatal intensive care.

Table 9. Comparison of maternal recovery profile and satisfaction

Variable	Group C (n=60)	Group CF (n=60)	P value
Time to first ambulation (minutes)	132.5 ± 16.9	136.4 ± 17.2	0.221
Time to spontaneous voiding (minutes)	208.4 ± 26.3	214.8 ± 27.9	0.198
Length of postoperative hospital stay (days)	3.8 ± 0.6	3.7 ± 0.5	0.364
Maternal satisfaction score (0–10)	8.2 ± 0.8	9.4 ± 0.6	<0.001*
Patients recommending same technique	48 (80.0%)	58 (96.7%)	0.006*

Maternal recovery characteristics and patient satisfaction are summarized below. Independent Student's t-test/Chi-square test; P <0.05 considered statistically significant. Early postoperative recovery, ambulation, spontaneous voiding, and hospital stay were comparable in both groups. However, maternal satisfaction was significantly higher among patients receiving intrathecal fentanyl owing to superior postoperative analgesia and improved perioperative comfort.

Table 10: Overall perioperative outcomes

Outcome	Group C (n=60)	Group CF (n=60)	P value
Successful completion of surgery under spinal anesthesia	60 (100%)	60 (100%)	—
Adequate intraoperative analgesia	54 (90.0%)	59 (98.3%)	0.052
Excellent surgical conditions	55 (91.7%)	59 (98.3%)	0.115
Rescue intraoperative analgesia required	6 (10.0%)	2 (3.3%)	0.143
Overall successful anesthetic outcome	56 (93.3%)	60 (100%)	0.079
Major maternal complications	0 (0%)	0 (0%)	—
Maternal mortality	0 (0%)	0 (0%)	—
Neonatal mortality	0 (0%)	0 (0%)	—

The overall perioperative outcomes of both study groups are presented below.

The addition of intrathecal fentanyl provided superior analgesic efficacy while maintaining excellent maternal and neonatal safety. Both techniques achieved successful spinal anesthesia in all patients, with no major perioperative complications or mortality.

Tables Summary

Table 1: Baseline demographic, anthropometric, and obstetric characteristics were comparable between the two groups, confirming successful randomization and homogeneity of the study population.

Table 2: Addition of intrathecal fentanyl significantly prolonged the duration of sensory blockade and delayed sensory regression without affecting the onset of sensory anesthesia or maximum sensory level achieved.

Table 3: Motor block characteristics, recovery time, and early ambulation were comparable between the groups, indicating that low-dose fentanyl did not prolong motor recovery or delay postoperative mobilization.

Table 4: Maternal heart rate, blood pressure, mean arterial pressure, and oxygen saturation remained stable throughout surgery in both groups, demonstrating comparable intraoperative hemodynamic stability.

Table 5: Patients receiving intrathecal fentanyl experienced significantly prolonged postoperative analgesia, delayed first rescue analgesic requirement, lower 24-hour analgesic consumption, and reduced opioid rescue requirements.

Table 6: Postoperative VAS pain scores were significantly lower in the fentanyl group during the first 12 postoperative hours, reflecting superior postoperative pain control. Pain scores became comparable by 24 hours following rescue analgesia.

Table 7: Both anesthetic techniques exhibited excellent safety profiles. Mild pruritus was more frequent following fentanyl administration, whereas hypotension, bradycardia, nausea, vomiting, shivering, respiratory depression, and excessive sedation were comparable between groups.

Table 8: Neonatal outcomes, including birth weight, Apgar scores, neonatal resuscitation, and NICU admission, were comparable, confirming that intrathecal fentanyl did not adversely affect neonatal well-being.

Table 9: Maternal recovery parameters, including ambulation, spontaneous voiding, and hospital stay, were similar in both groups. However, maternal satisfaction and willingness to recommend the anesthetic technique were significantly greater in the fentanyl group.

Table 10: Both intrathecal techniques provided effective surgical anesthesia with excellent maternal and neonatal safety. Nevertheless, the addition of fentanyl resulted in superior analgesic quality, improved patient satisfaction, and reduced postoperative analgesic requirements without increasing perioperative complications.

DISCUSSION

The present prospective, double-blind, randomized study compared the analgesic efficacy of intrathecal 1% 2-chloroprocaine administered alone and in combination with fentanyl in parturients undergoing elective caesarean section under spinal anesthesia.[1] The study demonstrated that the addition of intrathecal fentanyl significantly prolonged postoperative analgesia, delayed the requirement for rescue analgesia, reduced postoperative pain scores and total analgesic consumption, and improved maternal satisfaction without adversely affecting maternal hemodynamic stability, neonatal outcome, or early postoperative recovery.[2] These findings suggest that fentanyl is an effective intrathecal adjuvant to chloroprocaine for enhancing postoperative analgesia while preserving the advantages of a short-acting spinal anesthetic.[3]

Rapid postoperative recovery has become an important objective in modern obstetric anesthesia, particularly with the increasing adoption of Enhanced Recovery After Surgery (ERAS) protocols.[4] Although hyperbaric bupivacaine remains the standard intrathecal local anesthetic for caesarean delivery, prolonged motor blockade and delayed mobilization may adversely influence maternal recovery and breastfeeding.[5] Preservative-free 2-chloroprocaine has emerged as a valuable alternative because of its rapid onset, predictable recovery profile, minimal systemic toxicity, and early ambulation.[6] However, its relatively short duration of postoperative analgesia limits its utility when used alone for caesarean section.

One of the principal findings of the present study was the significant prolongation of postoperative analgesia following the addition of fentanyl to intrathecal chloroprocaine. Patients receiving fentanyl experienced nearly one hundred minutes longer postoperative pain relief compared with those receiving chloroprocaine alone and demonstrated a significantly delayed requirement for rescue analgesia.[7] This prolonged analgesic duration can be attributed to the synergistic interaction between fentanyl and chloroprocaine within the spinal cord. Fentanyl binds to μ-opioid receptors in the substantia gelatinosa of the dorsal horn, suppressing nociceptive transmission without significantly influencing sympathetic or motor pathways. Consequently, prolonged sensory analgesia is achieved while preserving rapid motor recovery.[8]

Postoperative pain scores assessed using the Visual Analogue Scale were significantly lower in the fentanyl group throughout the first twelve postoperative hours. Better pain control during this period is particularly important following caesarean section because adequate analgesia facilitates early breastfeeding, maternal–infant bonding, coughing, deep breathing, early ambulation, and prevention of thromboembolic complications. Reduced postoperative pain also minimizes physiological stress responses, decreases maternal anxiety, and contributes to greater overall patient comfort.[9,10]

The study further demonstrated a significant reduction in postoperative rescue analgesic consumption among patients receiving intrathecal fentanyl. Lower postoperative analgesic

requirements reduce exposure to systemic non-steroidal anti-inflammatory drugs and opioids, thereby minimizing adverse drug effects such as gastrointestinal irritation, excessive sedation, nausea, vomiting, and opioid-related respiratory depression. Reduced systemic opioid administration is particularly advantageous in postpartum women because it facilitates earlier interaction with the newborn and promotes successful initiation of breastfeeding.[11]

An important observation of the present investigation was that addition of fentanyl significantly prolonged sensory blockade without producing clinically significant prolongation of motor blockade. Preservation of rapid motor recovery remains one of the principal advantages of chloroprocaine-based spinal anesthesia.[12] Early recovery of lower limb motor function facilitates early ambulation, decreases the risk of venous thromboembolism, improves maternal confidence, and supports implementation of ERAS protocols following caesarean section. The comparable times to ambulation and spontaneous voiding observed in both groups indicate that low-dose intrathecal fentanyl enhances analgesia without delaying functional recovery.[13]

Maternal hemodynamic stability remained satisfactory throughout the intraoperative period in both study groups. No statistically significant differences were observed in heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, or oxygen saturation between the two anesthetic techniques.[14] These findings indicate that the addition of 20 µg intrathecal fentanyl does not produce clinically significant cardiovascular instability when combined with chloroprocaine for elective caesarean section. Maintenance of stable maternal hemodynamics is particularly important during obstetric anesthesia because maternal hypotension may compromise uteroplacental perfusion and fetal oxygen delivery.[15]

The incidence of maternal adverse effects was low in both groups. Hypotension, bradycardia, nausea, vomiting, and shivering occurred with similar frequency irrespective of intrathecal fentanyl administration. Mild pruritus was significantly more frequent in the fentanyl group, representing the only opioid-related adverse effect demonstrating statistical significance.[16] However, pruritus was self-limiting, did not require pharmacological treatment, and did not affect patient satisfaction. Importantly, no patient developed respiratory depression, excessive sedation, high spinal anesthesia, or neurological complications, confirming the favorable safety profile of low-dose intrathecal fentanyl.[17]

Neonatal safety remains a major concern whenever intrathecal opioids are administered during caesarean section. In the present study, Apgar scores at one and five minutes, neonatal birth weight, requirement for neonatal resuscitation, and neonatal intensive care admission were comparable between the study groups. These findings indicate that intrathecal fentanyl, because of its highly lipophilic nature and minimal placental transfer when administered intrathecally in low doses, does not adversely influence immediate neonatal adaptation.[18,19]

Maternal satisfaction represents an important quality indicator in obstetric anesthesia. Women receiving intrathecal chloroprocaine with fentanyl reported significantly greater satisfaction because of superior postoperative pain relief, reduced requirement for supplemental analgesia, improved perioperative comfort, and earlier ability to care for their newborn. Enhanced patient satisfaction contributes positively to the overall childbirth experience and has become an increasingly recognized outcome measure in contemporary obstetric anesthesia research.[20]

The findings of the present study have important clinical implications. Intrathecal chloroprocaine combined with fentanyl provides an optimal balance between rapid postoperative recovery and prolonged postoperative analgesia. This combination appears particularly suitable for elective caesarean section in institutions implementing Enhanced Recovery after Surgery pathways, where early ambulation, effective pain control, reduced opioid consumption, and improved maternal satisfaction are primary goals. Furthermore, preservation of neonatal safety and maternal hemodynamic stability supports routine clinical use of this anesthetic technique in appropriately selected patients.

The present study possesses several strengths. The prospective randomized double-blind design minimized selection and observer bias, while comparable baseline demographic and obstetric characteristics ensured adequate group homogeneity. Standardized anesthetic protocols and uniform postoperative assessment improved internal validity. Simultaneous evaluation of block characteristics, analgesic efficacy, maternal hemodynamics, adverse effects, neonatal outcomes, and patient satisfaction provides a comprehensive assessment of the clinical effectiveness of intrathecal chloroprocaine with fentanyl.

Certain limitations should also be acknowledged. The study was conducted at a single tertiary care center with a relatively modest sample size, which may limit generalizability. Long-term maternal neurological outcomes and breastfeeding success beyond hospital discharge were not evaluated. Only a single dose of intrathecal fentanyl was investigated; therefore, dose-response relationships could not be established. Future multicenter randomized controlled trials comparing different fentanyl doses and other intrathecal adjuvants such as dexmedetomidine, clonidine, or buprenorphine would further clarify the optimal spinal anesthetic regimen for elective caesarean section. Additionally, incorporation of ERAS-specific recovery parameters, cost-effectiveness analyses, and long-

term maternal satisfaction outcomes would provide valuable evidence for routine clinical practice.

Strengths of the Study

- The prospective, randomized, double-blind study design minimized selection, observer, and performance bias, thereby improving the internal validity of the findings.
- Random allocation of participants into two comparable study groups ensured homogeneity of baseline demographic and obstetric characteristics.
- Standardized spinal anesthesia technique, perioperative monitoring, and postoperative analgesic protocol reduced confounding variables and enhanced reliability of outcome assessment.
- The study comprehensively evaluated both anesthetic efficacy and safety by assessing sensory and motor block characteristics, duration of postoperative analgesia, rescue analgesic consumption, maternal hemodynamic profile, adverse effects, neonatal outcomes, and maternal satisfaction.
- The inclusion of postoperative VAS pain assessment at multiple predefined intervals enabled objective evaluation of analgesic efficacy over the first 24 postoperative hours.
- Maternal and neonatal safety outcomes were simultaneously evaluated, making the findings directly applicable to routine obstetric anesthesia practice.
- The study assessed early recovery parameters including motor recovery, ambulation, spontaneous voiding, and maternal satisfaction, which are important components of Enhanced Recovery After Surgery (ERAS) protocols.
- The findings provide clinically relevant evidence supporting the use of intrathecal fentanyl as an effective adjuvant to 1% 2-chloroprocaine for elective caesarean section.

Limitations of the Study

- The study was conducted at a single tertiary care teaching hospital, which may limit the generalizability of the findings to other healthcare settings.
- Although adequately powered, the sample size was relatively modest, and larger multicentre randomized controlled trials are required to validate these findings.
- Only healthy ASA II parturients undergoing elective caesarean section were included; therefore, the results cannot be extrapolated to emergency caesarean sections or high-risk obstetric patients.
- Only one dose of intrathecal fentanyl (20 µg) was evaluated, precluding assessment of dose-response relationships and determination of the optimal fentanyl dose.
- Long-term maternal outcomes, including persistent postoperative pain, chronic neurological symptoms, breastfeeding success, and quality of life, were not evaluated.
- Patient-reported recovery outcomes beyond hospital discharge were not assessed.
- Biochemical markers of surgical stress and inflammatory response were not measured.
- Cost-effectiveness analysis and overall healthcare resource utilization were beyond the scope of the study.

CONCLUSION

The present prospective, double-blind, randomized study demonstrated that the addition of 20 µg intrathecal fentanyl to 1% preservative-free 2-chloroprocaine significantly enhanced the quality and duration of postoperative analgesia in patients undergoing elective caesarean section under spinal anesthesia. Compared with chloroprocaine alone, the combination produced prolonged postoperative analgesia, delayed first rescue analgesic requirement, significantly lower postoperative VAS pain scores, and reduced total analgesic consumption during the first 24 postoperative hours.

Importantly, these analgesic benefits were achieved without clinically significant prolongation of motor blockade or delay in postoperative ambulation and recovery. Maternal hemodynamic parameters remained stable throughout the intraoperative period, while neonatal outcomes, including Apgar scores and NICU admission rates, were comparable between the two groups, confirming the maternal and neonatal safety of the technique.

Although mild pruritus occurred more frequently following intrathecal fentanyl administration, its incidence was low, self-limiting, and did not affect overall patient satisfaction. No cases of respiratory depression, excessive sedation, high spinal anesthesia, or major neurological complications were observed. Maternal satisfaction was significantly greater in the fentanyl group owing to superior analgesic quality and improved postoperative comfort.

Overall, intrathecal 1% 2-chloroprocaine combined with fentanyl offers an excellent balance between rapid neurological recovery and prolonged postoperative analgesia, making it a valuable spinal anesthetic technique for elective caesarean section. The combination is particularly suitable for contemporary obstetric anesthesia practice and Enhanced Recovery After Surgery (ERAS) pathways, where effective pain control, early ambulation, reduced opioid consumption, and improved maternal satisfaction are key objectives.

Future multicentre randomized controlled trials involving larger patient populations, evaluation of different fentanyl dosages, comparison with other intrathecal adjuvants, and assessment of long-term maternal and neonatal outcomes are recommended to further establish the optimal spinal anesthetic regimen for elective caesarean delivery.

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