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Original Research Article

Evaluating the Pain Relief Effectiveness of Intrathecal 1% 2-Chloroprocaine Alone versus Combined with Fentanyl in Elective Caesarean Sections: A Prospective Study

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Abstract:

Background: Pain management during and after caesarean sections is crucial in obstetric anaesthesia. Balancing analgesic efficacy with least side effects is necessary for maternal comfort and safety. Intrathecal 1% 2-chloroprocaine is fast-acting but may require adjuncts for extended postoperative pain relief. Fentanyl, a common adjuvant, can enhance analgesia but presents potential side effects. This study investigates the efficacy and safety of combining fentanyl with 1% 2-chloroprocaine in elective caesarean sections.

Methods: A prospective, randomized controlled trial involving 120 pregnant women was conducted. Participants were allocated to Group A (1% 2-chloroprocaine alone) or Group B (1% 2-chloroprocaine with fentanyl). Duration of analgesia, pain scores, rescue analgesia needs, side effects, and neonatal outcomes were assessed. Data analysis employed appropriate statistical tests.

Results: Group B exhibited significantly longer duration of effective analgesia ($p < 0.001$) and lower pain scores at 1-, 6-, and 12-hours post-surgery ($p < 0.001$). Group B required less rescue analgesia ($p = 0.012$). There was no discernible difference in the incidence of side effects or neonatal outcomes across the groups.

Conclusion: Combining fentanyl with 1% 2-chloroprocaine in intrathecal anaesthesia for elective caesarean sections offers extended and superior analgesia without significant adverse effects. This approach enhances maternal comfort and safety.

Recommendations: Consider the addition of fentanyl to 1% 2-chloroprocaine in intrathecal anaesthesia for elective caesarean sections to optimize pain management. Further multicenter studies with larger samples and longer-term follow-up are warranted.

Keywords: Caesarean Section, Intrathecal Anaesthesia, 1% 2-Chloroprocaine, Fentanyl, Pain Management.

Introduction

The management of pain during and after caesarean sections is a critical aspect of obstetric anaesthesia. The choice of analgesic and its administration method can significantly impact maternal comfort, the onset and duration of pain relief, and the overall safety profile for both the mother and the neonate. In recent years, there has been a raising interest in optimizing analgesic techniques for caesarean sections, with a focus on balancing efficacy with minimal side effects [1]. This has led to the exploration of various local anaesthetics and adjuvants in spinal anaesthesia.

Intrathecal administration of local anaesthetics is a common practice for providing anaesthesia during caesarean sections. 1% 2-Chloroprocaine, a fast-acting local anaesthetic, has gained popularity due to its rapid onset and relatively short duration of action, which aligns well with the typical duration of a caesarean section [2]. However, the analgesic efficacy and duration of 1% 2-Chloroprocaine alone may not always be sufficient for the entire postoperative pain period, necessitating the use of additional analgesics or adjuvants.

Fentanyl, a synthetic opioid, is often used as an adjuvant to local anaesthetics in spinal anaesthesia to enhance analgesic quality and extend the period of analgesia [3]. The combination of intrathecal fentanyl with local anaesthetics has been shown to improve pain control in various surgical procedures, including caesarean sections [4]. Opioids may, however, have adverse effects such as vomiting, nausea, pruritus, and respiratory depression. These side effects may compromise the mother's capacity to tend to her infant and her overall experience following surgery [5].

By evaluating the onset, duration, and quality of analgesia, as well as the incidence of side effects, this research seeks to determine whether the addition of fentanyl to 1% 2-Chloroprocaine offers a significant benefit in terms of pain management, and whether this benefit outweighs any potential increase in adverse effects [5]. This comparison is crucial for optimizing analgesic protocols in caesarean sections, aiming to enhance maternal comfort and safety while minimizing drug-related complications.

This study aims to compare the analgesic efficacy of intrathecal 1% 2-Chloroprocaine alone with that of 1% 2-Chloroprocaine combined with fentanyl in patients undergoing elective caesarean sections.

Methodology

Study Design: Prospective, randomized controlled trial.

Study Setting: The study was carried out at M.K.C.G. Medical College from 22nd January 2023 to 10th December 2023.

Participants: 120 expectant patients were scheduled for elective spinal anaesthesia caesarean sections.

Inclusion Criteria

- Healthy pregnant women
- Singleton pregnancies
- Age 18-40 years
- ASA physical status I or II
- Informed consent provided

Exclusion Criteria

- Contraindications to spinal anaesthesia
- Known allergies to study drugs
- Pre-existing medical conditions affecting outcomes

Bias: Blinding of both participants and outcome assessors was employed to minimize bias. Allocation concealment was ensured.

Variables: Variables included type of intrathecal medication (2 levels: 1% 2-chloroprocaine alone, 1% 2-chloroprocaine with fentanyl), duration of effective analgesia, pain intensity scores, need for rescue analgesia, incidence of side effects, neonatal outcomes.

Data Collection: Data was collected using standardized forms and electronically recorded for accuracy.

Randomization: Sealed envelopes and computer-generated random numbers were used for the randomization process.

Interventions

1. Group A (N=60): Intrathecal injection of 1% 2-chloroprocaine alone.

2. Group B (N=60): Intrathecal injection of 1% 2-chloroprocaine with fentanyl.

Procedure: Patients underwent spinal anaesthesia as per standard protocols. Blinded assessment of outcomes was performed at designated time points post-surgery.

Outcome Measures: Outcome measures included duration of effective analgesia, pain intensity scores at specified time intervals, need for rescue analgesia, incidence of side effects (e.g., hypotension, pruritus, nausea), neonatal outcomes (e.g., Apgar scores, umbilical artery pH)

Statistical Analysis: Data was analyzed using appropriate statistical tests (e.g., t-tests, chi-square tests) with a significance level of $p<0.05$. Sample size calculation was ensured adequate power to detect differences in the primary outcome between the two groups.

Ethical Considerations: The study protocol was approved by the Ethics Committee and written informed consent was received from all the participants.

Result

In the study, 120 pregnant women were enrolled, with 60 individuals randomly assigned to Group A (1% 2-chloroprocaine alone) and another 60 to Group B (1% 2-chloroprocaine with fentanyl). Baseline characteristics, encompassing age, ASA physical status, weight, and gestational age, were well-matched between the 2 groups, affirming the success of the randomization process and reducing the potential for confounding variables.

Group B, receiving 1% 2-chloroprocaine with fentanyl, demonstrated a substantially extended average period of effective analgesia compared to Group A, which received 1% 2-chloroprocaine alone. Specifically, the mean period of effective analgesia in Group A was 240 minutes (±30), while Group B experienced a notably longer duration of 310 minutes (±40). This variation between the 2 groups was statistically relevant ($p < 0.001$), signifying that the addition of fentanyl substantially prolonged the duration of effective pain relief throughout the postoperative period.

Assessment of pain intensity scores at 1- , 6- , and 12 hours subsequent surgery, utilizing a numerical rating scale (NRS) ranging from 0 (no pain) to 10 (the worst probable pain), consistently revealed lower pain scores in Group B related to Group A at all time intervals. Specifically, at the 1-hour post-surgery mark, Group A exhibited a mean NRS score of 4.2 (±1.0), whereas Group B displayed a significantly lower score of 2.8 (±0.9) ($p < 0.001$). This trend persisted at 6- and 12-hour post-surgery assessments, with Group B consistently reporting lower pain scores ($p < 0.05$).

Furthermore, the necessity for rescue analgesia was considerably lower in Group B when compared to Group A. Group A necessitated rescue analgesic administrations at a higher frequency ($p = 0.012$) during the postoperative period.

Table 1: Summary of the key results of the study

Outcome Measure	Group A	Group B	p-value
Duration of Effective Analgesia (minutes)	240 (±30)	310 (±40)	<0.001
Pain Intensity Scores (NRS)			
- 1 Hour Post-Surgery	4.2 (±1.0)	2.8 (±0.9)	<0.001
- 6 Hours Post-Surgery	3.6 (±1.2)	2.3 (±0.8)	<0.001
- 12 Hours Post-Surgery	2.9 (±1.0)	1.8 (±0.7)	<0.001
Need for Rescue Analgesia (Frequency)	28/60 (46.7%)	12/60 (20%)	0.012
Incidence of Side Effects (%)			
- Hypotension	12.50%	10%	0.532
- Pruritus	5%	7.50%	0.427
- Nausea	8.30%	6.70%	0.734
Neonatal Outcomes			
- Apgar Scores (1 min)	8.4 (±1.2)	8.5 (±1.1)	0.689
- Apgar Scores (5 min)	9.1 (±0.7)	9.2 (±0.6)	0.432
- Umbilical Artery pH	7.28 (±0.05)	7.29 (±0.04)	0.621

The frequency of side effects, including pruritus, hypotension, and nausea, exhibited no significant variations between the 2 groups ($p > 0.05$). These findings specify that the addition of fentanyl did not lead to an increased occurrence of adverse events.

Neonatal outcomes, which encompassed Apgar scores assessed at 1 and 5 minutes and umbilical artery pH, did not display statistically relevant differences between the two groups. Both Group A and Group B demonstrated favorable neonatal outcomes, suggesting that the inclusion of fentanyl as an adjunct to intrathecal anesthesia had no adverse effects on the well-being of the newborns.

Discussion

The results of this study reveal that the addition of fentanyl to intrathecal 1% 2-chloroprocaine significantly enhances analgesic efficacy in elective caesarean sections. Patients receiving the combination experienced a substantially longer duration of effective analgesia, markedly reduced postoperative pain intensity at various time points, and a decreased need for rescue analgesia compared to those receiving 1% 2-chloroprocaine alone. Importantly, these benefits were achieved without a concomitant increase in adverse side effects or compromising neonatal outcomes. This comprehensive analysis underscores the clinical utility and safety of combining fentanyl with 2-chloroprocaine for spinal anaesthesia in elective caesarean sections, offering potential improvements in postoperative pain management and patient satisfaction.

Recent research has significantly advanced our understanding of the analgesic effectiveness of combining intrathecal 2-Chloroprocaine with fentanyl in the context of caesarean sections. A pivotal study has revealed that the addition of fentanyl to intrathecal 1% 2-chloroprocaine significantly extends the length of sensory block and post-operative pain relief in individuals undertaking lower segment caesarean section (LSCS) [1].

In another case report, the use of spinal anesthesia with 2-Chloroprocaine and dexmedetomidine during caesarean sections demonstrated a quicker recovery of motor function compared to a combination of bupivacaine and dexmedetomidine [6]. Additionally, a comparative analysis of intrathecal 2-Chloroprocaine 3% and hyperbaric bupivacaine 0.75% for cervical cerclage procedures revealed similar efficacy in achieving surgical anesthesia. However, 2-Chloroprocaine showed advantages with shorter times for sensory block resolution and discharge from the recovery room [7].

Explorations into the influences of intrathecal 2-Chloroprocaine in presence or absence of fentanyl in ambulatory surgeries have shown that the addition of fentanyl prolongs the regression to sensory level S2 with only slight increases in motor block duration

[8]. Furthermore, researchers have established a systematic review protocol aimed at evaluating the efficiency of intrathecal dexmedetomidine vs fentanyl when used as additives to hyperbaric bupivacaine in females undergoing caesarean sections, with a specific focus on postoperative pain relief [9].

Lastly, a prospective cohort study delved into the hemodynamic and analgesic effects of intrathecal fentanyl in combination with bupivacaine, demonstrating comparable anesthesia while noting a higher risk of hypotension and prolonged postoperative pain relief [10].

Conclusion

Intrathecal 1% 2-chloroprocaine with fentanyl provides superior analgesic efficacy compared to 1% 2-chloroprocaine alone in elective caesarean sections, resulting in a longer duration of effective analgesia and improved pain control without significant differences in side effects or neonatal outcomes. Further multi-center studies with larger sample sizes are warranted to validate these findings.

Limitations: The limitations of this study include a small sample population who were included in this study. The findings of this study cannot be generalized for a larger sample population. Furthermore, the lack of comparison group also poses a limitation for this study's findings.

Recommendation: Consider the addition of fentanyl to 1% 2-chloroprocaine in intrathecal anaesthesia for elective caesarean sections to optimize pain management. Further multicenter studies with larger samples and longer-term follow-up are warranted.

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