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Original Article

EVALUATING THE EFFECTS OF INTRATHECAL HYPERBARIC BUPIVACAINE COMBINED WITH TWO BUPRENORPHINE DOSES IN ADULT INFRAUMBILICAL SURGERIES: A RANDOMIZED DOUBLE-BLIND CONTROLLED TRIAL

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ABSTRACT

Objective: Spinal anesthesia is a cornerstone in managing perioperative pain, particularly for infraumbilical surgeries. However, its inherent limitation in duration necessitates enhancements for prolonged efficacy. Buprenorphine, known for its potent analgesic properties when administered intrathecally, may enhance and extend the analgesic effects of spinal anesthesia when combined with Bupivacaine.

Methods: In this prospective, randomized, double-blind study conducted at Jhalawar Medical College and SRG Hospital, 90 patients scheduled for elective infraumbilical surgeries were divided into three groups: Group A (n=30) received 0.5% Bupivacaine 2.5 ml with 0.5 ml saline, Group B (n=30) received Bupivacaine 2.5 ml with 90µg Buprenorphine, and Group C (n=30) received Bupivacaine 2.5 ml with 60µg Buprenorphine. Parameters assessed included heart rate, sedation scores, duration of motor and sensory blocks, and total duration of analgesia.

Results: Significant differences were noted in the duration of motor and sensory blocks, with Group B showing prolonged effects compared to Groups A and C ($P<0.001$). Group B also exhibited higher sedation scores and heart rates post-administration, indicating deeper and prolonged anesthesia. The total duration of analgesia was significantly longer in Group B (389.93±19.93 min) compared to Group A (164.17±8.35 min) and Group C (163.23±18.00 min).

Conclusion: Adding Buprenorphine to Bupivacaine for spinal anesthesia significantly extends the analgesic duration and improves the quality of anesthesia in infraumbilical surgeries. These findings suggest that Buprenorphine is a valuable adjuvant in spinal anesthesia, enhancing patient comfort and reducing the need for additional postoperative pain management.

Keywords: Spinal anesthesia, Buprenorphine, Bupivacaine, Infraumbilical surgery, Postoperative analgesia, Perioperative pain management

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INTRODUCTION

Pain management and anesthesia are pivotal in modern surgical procedures, providing essential comfort and pain relief to patients during and post-surgery. Central to these methods is spinal anesthesia, a technique rooted in the history of medicine since its inception by August Bier in 1898. As a form of central neuraxial blockade, spinal anesthesia involves injecting local anesthetic agents directly into the cerebrospinal fluid within the subarachnoid space [1]. This method offers a robust pain control mechanism, particularly advantageous in surgeries of the lower limbs, surpassing the pain relief efficacy of both intravenous and epidural approaches in certain surgical contexts [2].

The utility of spinal anesthesia is vast, proving to be the anesthesia method of choice due to its capacity to lower postoperative morbidity and mortality. These benefits are evident when used either independently or alongside general anesthesia, contributing to improved patient outcomes and yielding cost-effective solutions for healthcare institutions. This technique is also particularly beneficial for patients with respiratory conditions, minimizing the risks associated with intubation such as laryngospasm [3].

Furthermore, spinal anesthesia enhances airway patency, reduces surgical blood loss, and accelerates the return of gastrointestinal function, factors which collectively improve the safety and efficiency of surgical procedures. Additionally, the induced sympathectomy from spinal anesthesia increases tissue blood flow and oxygenation, stimulates peristalsis, and reduces the surgical stress response by suppressing the neuroendocrine system. These effects contribute to a decreased hypercoagulable state noted in surgical patients [4].

However, spinal anesthesia is not devoid of challenges. The duration of anesthesia provided by this technique is relatively short, necessitating interventions to extend its effects to cover a broader range of surgeries. The risks, such as infection and complications related to difficulty in accessing the subarachnoid space in patients with anatomical variations, are significant. Moreover, the sympatholytic effect of local anesthetics can lead to complications like bradycardia and hypotension, which, while managed by dosage adjustments, cannot be completely eliminated [5].

To address these issues, the use of adjuvants such as opioids, which have gained popularity due to their ability to provide more profound sensory blocks without significant impact on motor function and sympathetic activity, is explored. Intrathecal opioids, first introduced for acute pain management in 1979, have been increasingly recognized for their role in enhancing postoperative analgesia. The combination of local anesthetics and opioids, such as the use of bupivacaine with buprenorphine, provides a synergistic effect that extends the duration of analgesia while minimizing adverse effects [6].

This study aims to delve deeper into the pharmacological synergy between bupivacaine and Buprenorphine in spinal anesthesia, focusing on their efficacy and safety for infraumbilical surgeries in adults. Through a rigorous comparative analysis, this research will contribute valuable insights towards optimizing spinal anesthesia practices and enhancing patient outcomes in surgical pain management.

MATERIALS AND METHODS

Study setting and ethical approval

This randomized, controlled study was conducted at Jhalawar Medical College and SRG Hospital, Rajasthan, after obtaining approval from the institutional ethics committee. Written informed consent was procured from all participants. A total of 90 patients undergoing elective infraumbilical surgeries were included in the study, randomly assigned into three groups:

- **Group A (n=30)**: 0.5% Bupivacaine 2.5 ml with 0.5 ml saline.
- **Group B (n=30)**: 0.5% Bupivacaine 2.5 ml with Buprenorphine 90µg in 0.5 ml saline.
- **Group C (n=30)**: 0.5% Bupivacaine 2.5 ml with Buprenorphine 60µg in 0.5 ml saline.

Participants

Eligible participants were aged 18-60 y, of either sex, with an ASA physical status of I or II, weighing 50-80 kg, and taller than 150 cm. Exclusion criteria included allergies to local anesthetics or opioids, local infection, pregnancy, lactation, raised intracranial tension, progressive neurodegenerative disorders, spine deformities, hypovolemic shock, bleeding diathesis, or coagulopathy.

Double blinding and randomization

The study employed a double-blind methodology where neither the anesthesiologist administering the drug nor the patients were aware of the group assignments. Randomization was achieved using a computer-generated list to divide the patients into three groups.

Materials required

The required materials included disposable syringes (20cc and 5cc), sterile gloves, Betadine, spirit, sponge holding forceps, sterile gauze pieces, sterile sheets, IV infusion sets, crystalloids and colloids, a 25G Quincke spinal needle, and all necessary emergency drugs for resuscitation.

Procedure

Pre-operative preparation involved overnight fasting, premedication with 0.5 mg Alprazolam, and routine investigations (CBC, BT, CT, ECG, Chest X-ray). In the operating room, patients were preloaded with Ringer's lactate solution (10 ml/kg), and baseline vitals were recorded. Under aseptic conditions and either in a lateral or sitting position, the 25G Quincke spinal needle was inserted into the L3-L4 space. Upon confirming a clear flow of CSF, 3.0 ml of the test drugs was injected intrathecally. Patients were then positioned supine, and monitoring was continued throughout the procedure.

Monitoring and observations

Vital parameters such as heart rate, noninvasive blood pressure, SpO2, and respiratory rate were monitored at specific intervals during and post-surgery. Adverse events and hemodynamic changes were recorded and managed accordingly.

Assessment of blockade and analgesia

Sensory blockade was assessed using the pinprick test and Hollmen scale at predetermined intervals. Motor blockade was evaluated using the Modified Bromage Scale. Duration of analgesia was monitored using the Visual Analogue Scale (VAS) for pain, with rescue analgesia provided if VAS exceeded 4.

Statistical analysis

Data were analyzed using Microsoft Excel 2010 and GraphPad Prism 6.05. Categorical variables were expressed in frequencies and percentages, while quantitative variables were presented as means and standard deviations. The chi-square test and ANOVA were utilized to evaluate the statistical significance of the observed differences. A P-value<0.05 was considered statistically significant.

RESULTS

The study demonstrated statistically significant differences in several key parameters among the three groups treated with varying concentrations of Buprenorphine combined with Bupivacaine.

Heart rate variations

Initial heart rates at the beginning of the study did not differ significantly across the groups (P = 0.743). However, from 3 h post-administration, Group B consistently exhibited higher heart rates compared to Groups A and C, with statistically significant differences noted from the 3-hour mark onwards (P = 0.014 at 3 h, P<0.00014 at 12 h).

Sedation scores

Sedation scores showed significant variations over time. By the 3 h interval, Group B had higher scores (mean = 2.00), indicating deeper sedation compared to Groups A and C, with the differences reaching statistical significance (P ≤ 0.0004). This trend of higher sedation in Group B persisted through various time points up to 24 h (P ≤ 0.0023 at 24 h).

Motor block duration

There were significant differences in the duration of motor block among the groups. Group B experienced the longest duration of motor block (159.37±7.12 min), significantly longer than both Group A (138.60±6.99 min) and Group C (140.93±6.35 min) with a P-value<0.001.

Analgesia duration

The total duration of analgesia varied significantly, with Group B showing a markedly longer period of analgesia (389.93±19.93 min) compared to Group A (164.17±8.35 min) and Group C (163.23±18.00 min), P<0.001. This extended effect in Group B suggests a potentiated analgesic effect due to higher dosages of Buprenorphine.

Comprehensive analysis of anesthetic parameters

When examining the overall effects of the treatments, data from the comprehensive parameters table further supported the superior efficacy of the regimen in Group B. The duration of motor block was significantly longer in Group B (159.30±6.08 min) as well as the regression of sensory to S1 (175.10±6.51 min for Group B compared to 149.77±6.13 min for Group A), and the total duration of analgesia was 296.73±11.93 min in Group B, significantly exceeding that of the other groups (P<0.001).

Table 1: Comparison of heart rate (BPM) among three groups

Time interval	Group A (Mean±SD)	Group B (Mean±SD)	Group C (Mean±SD)	P value
0 min	80.23±5.94	79.03±6.24	79.60±5.90	0.743
3 h	77.00±5.87	80.60±5.44	76.67±5.66	0.014
5 h	78.20±5.29	79.87±5.58	76.13±6.16	0.0434
7 h	78.13±5.59	79.87±5.58	76.30±6.46	0.0354
9 h	78.27±5.40	81.20±5.27	76.20±5.90	0.0034
12 h	78.20±5.59	81.17±5.27	75.27±5.96	0.00014
18 h	78.13±5.06	79.87±5.58	75.07±5.96	0.0044
24 h	78.53±5.61	79.93±5.62	75.20±4.63	0.0024

Table 2: Comparison of sedation score among three groups

Time	Group A (Mean±SD)	Group B (Mean±SD)	Group C (Mean±SD)	P value
3 h	1.60±0.50	2.00±0.00	1.70±0.47	0.0004
4 h	3.53±1.17	2.00±0.00	3.60±1.13	<0.001
9 h	1.57±0.50	2.00±0.00	1.67±0.48	0.0001
11 h	1.63±0.49	2.00±0.00	1.50±0.51	<0.001
15 h	1.53±0.51	2.00±0.00	1.60±0.50	<0.001
18 h	1.70±0.47	2.00±0.00	1.63±0.49	0.0009
24 h	1.73±0.45	2.00±0.00	1.67±0.48	0.0023

Table 3: Comparison of motor block duration (min) among three groups

Group	Mean±SD	P value
Group A	138.60±6.99	<0.001
Group B	159.37±7.12	
Group C	140.93±6.35	

Table 4: Comparison of total duration of analgesia among three groups

Group	Mean±SD	P value
Group A	164.17±8.35	<0.001
Group B	389.93±19.93	
Group C	163.23±18.00	

Table 5: Comparison of parameters according to groups

Parameter	Group A (Mean±SD)	Group B (Mean±SD)	Group C (Mean±SD)	P value
Duration of Motor Block	140.17±6.66	159.30±6.08	163.63±7.20	<0.001
Regression of Sensory to S1	149.77±6.13	175.10±6.51	180.07±10.27	<0.001
Total Duration of Analgesia	164.60±7.09	296.73±11.93	395.40±27.51	<0.001

DISCUSSION

The integration of opioids in spinal anesthesia, particularly Buprenorphine, presents a significant enhancement in the duration and quality of analgesia, as evidenced by the results from our study [7]. The findings demonstrated that higher dosages of Buprenorphine combined with Bupivacaine significantly increased the duration of both motor and sensory blocks. This is in line with the pharmacological synergy expected from the combination, which enhances the analgesic efficacy while potentially reducing the requirement for postoperative systemic analgesics [8].

Group B, which received a higher dosage of Buprenorphine, exhibited not only prolonged analgesia but also a higher rate of sedation and increased heart rates compared to Groups A and C. These physiological changes, although statistically significant, remained within clinically acceptable ranges and suggest a heightened block efficacy that could be beneficial in extensive surgical procedures requiring robust pain management [9]. The sustained heart rate increase noted in Group B raises important considerations about cardiovascular effects when higher doses of opioids are used intrathecally, warranting careful patient selection and monitoring [10].

The increased duration of motor block observed in Group B might pose a drawback in ambulatory surgery settings where rapid recovery of motor function is desired. However, in the context of surgeries requiring extended postoperative pain control, this characteristic could be seen as beneficial. This aligns with previous studies indicating that opioids can significantly prolong spinal blockade duration without compromising safety when appropriately dosed and monitored [11].

Furthermore, the results underscore the importance of balancing opioid potency with potential side effects such as sedation and hemodynamic changes. The variations in sedation scores among the groups may reflect not only the analgesic depth but also the impact on patient comfort and satisfaction, which are crucial outcomes in the context of anesthesia management [12].

The study's findings are consistent with the literature suggesting enhanced postoperative outcomes when local anesthetics are combined with opioids, particularly in terms of extending analgesia duration and improving overall patient experiences during recovery. However, the implications for clinical practice will necessitate considerations regarding the optimal dosing, monitoring for potential side effects, and ensuring that patient selection criteria are rigorously defined to maximize benefits while minimizing risks.

CONCLUSION

The study confirmed that the addition of Buprenorphine to Bupivacaine in spinal anesthesia significantly extends the duration of both sensory and motor blocks without compromising safety, thereby enhancing postoperative analgesia. These results support the use of Buprenorphine as a potent adjuvant in spinal anesthesia for infraumbilical surgeries, offering a valuable option for achieving extended analgesia. Future research should focus on refining dosing strategies to optimize the balance between analgesia duration and side effects, ensuring tailored and effective pain management strategies in diverse surgical populations.

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Nil

AUTHORS CONTRIBUTIONS

All authors have contributed equally

CONFLICT OF INTERESTS

Declared none

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