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ORIGINAL RESEARCH

A comparative study between bupivacaine with midazolam, bupivacaine with fentanyl for subarachnoid block in adults undergoing lower abdominal and lower limb surgeries

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ABSTRACT

Background: Subarachnoid block (SAB) is a widely used technique for anaesthesia in lower abdominal and lower limb surgeries. This comparative study evaluates the efficacy and safety of bupivacaine with midazolam versus bupivacaine with fentanyl in adult patients undergoing lower abdominal surgeries. **Objectives:** To evaluate the onset time of sensory and motor block with each drug combination and to compare the duration of sensory and motor block provided by Bupivacaine with Midazolam versus Bupivacaine with Fentanyl. **Methods:** A randomized controlled trial was conducted with two groups receiving one of the two drug combinations. Primary outcomes included pain scores, onset, and duration of sensory and motor block, while secondary outcomes encompassed hemodynamic stability, adverse effects, and patient satisfaction. **Results:** Results revealed no significant differences between the two groups across primary and secondary outcomes, indicating comparable efficacy and safety profiles. These findings provide valuable insights into optimizing anaesthesia management in this patient population. **Conclusion:** The comparative study evaluating bupivacaine with midazolam versus bupivacaine with fentanyl as adjuvants in SAB procedures for lower abdominal and lower limb surgeries elucidated compelling insights into anaesthesia management practices. Both adjuvant combinations demonstrated comparable efficacy, safety, and patient satisfaction, highlighting the equipoise between midazolam and fentanyl as adjuncts to bupivacaine in achieving optimal anaesthesia outcomes

Keywords: Subarachnoid block, anaesthesia, bupivacaine, midazolam, fentanyl, lower abdominal surgery, lower limb surgery, efficacy, safety, patient satisfaction

INTRODUCTION

Subarachnoid block (SAB) stands as a cornerstone in anaesthesia management for various lower abdominal and lower limb surgical procedures, attributable to its inherent simplicity, expeditious onset, and clinical efficacy. Bupivacaine, a prominent long-acting local anaesthetic, remains the bedrock of SAB pharmacotherapy owing to its favourable profile in providing profound sensory and motor blockade [1].

The strategic augmentation of bupivacaine with opioids, typified by agents such as morphine, fentanyl, and sufentanil, has garnered substantial clinical interest. This synergistic amalgamation potentiates the analgesic efficacy of SAB by virtue of their interaction with spinal opioids receptors, thereby engendering an intensified and prolonged sensory block [2].

The administration of intrathecal benzodiazepine has its anti-nociceptive action mediated via benzodiazepine/GABA-A receptor complex which are abundantly present in lamina II of dorsal horn ganglia of the spinal cord. Intrathecal midazolam also causes the release of an endogenous opioid, acting at spinal delta receptor [3]

Midazolam, owing to its favourable pharmacokinetic profile and anxiolytic potency, serves as an invaluable

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adjunct in SAB procedures, fostering a tranquil perioperative milieu conducive to patient cooperation and procedural tolerance. By potentiating the inhibitory effects of gamma-amino butyric acid (GABA) receptors within the central nervous system, midazolam engenders a state of sedation and anxiolysis, thereby mitigating perioperative apprehension and fostering a cooperative patient demeanor [4].

Concomitantly, the strategic integration of fentanyl into the SAB regimen serves to potentiate the analgesic efficacy of bupivacaine while concurrently augmenting the sensory blockade. Fentanyl, a highly selective mu-opioid receptor agonist, exerts its analgesic effects by modulating nociceptive transmission within the spinal cord, thereby engendering an intensified and protracted sensory blockade. By virtue of its potent analgesic efficacy and rapid onset of action, fentanyl complements the sensory blockade conferred by bupivacaine, thereby affording comprehensive perioperative pain relief and patient comfort [5-6].

Furthermore, the synergistic interaction between midazolam and fentanyl precipitates a multifaceted augmentation of SAB quality, characterized by an augmented depth and duration of sensory blockade alongside a concomitant reduction in perioperative anxiety and pain perception. This synergistic pharmacological synergy not only enhances Intraoperative hemodynamic stability but also fosters a salubrious perioperative milieu conducive to expeditious postoperative recovery and favourable surgical outcomes [7].

In essence, this study endeavours to furnish robust empirical evidence elucidating the relative merits and demerits of bupivacaine with midazolam versus bupivacaine with fentanyl as adjuvants in SAB procedures, thereby facilitating informed clinical decision-making and enhancing patient-centered care paradigms in the realm of anaesthesia management [8].

AIM AND OBJECTIVES

- To compare the efficacy and safety of Bupivacaine combined with Midazolam versus Bupivacaine combined with Fentanyl when used for subarachnoid block in adults undergoing lower abdominal and lower limb surgeries.
- To evaluate the onset time of sensory and motor block with each drug combination.
- To compare the duration of sensory and motor block provided by Bupivacaine with Midazolam versus Bupivacaine with Fentanyl.
- To assess the overall duration of analgesia post-surgery for each combination.

MATERIAL AND METHODS

The study was conducted as a prospective, randomized controlled trial at a designated hospital. Adult patients aged 18 to 65 years, who were scheduled for elective lower abdominal and lower limb surgeries under subarachnoid block (SAB), were recruited. The patients were randomly allocated into two groups: Group M, which received bupivacaine with midazolam, and Group F, which received bupivacaine with fentanyl.

Patients with contraindications to SAB, allergies to study drugs, psychiatric disorders, or those unable to provide informed consent were excluded from the study.

Baseline demographic data, including age, sex, weight, ASA physical status, and surgical details, were recorded for each patient. All patients underwent a standardized preoperative assessment and were monitored accordingly. An experienced anaesthesiologist performed the SAB using a standardized technique.

The primary outcomes of the study included the onset and duration of sensory and motor blockade, assessed using the pinprick method and the modified Bromage scale, respectively. Pain scores were evaluated using the Visual Analog Scale. Secondary outcomes encompassed hemodynamic stability (heart rate and blood pressure), incidence of adverse effects (including hypotension, bradycardia, respiratory depression, nausea, vomiting, and sedation), and patient satisfaction, which was assessed using a Likert scale. We have collected data for primary and secondary outcomes and performed statistical analyses.

Data was collected at predefined time points Intra-operatively and postoperatively up to 24 hours. We have collected dataset for 100 patients, with 50 in each group. We have recorded:

Onset and duration of sensory and motor blockade

- Pain scores
- Heart rate, blood pressure
- Incidence of adverse effects
- Patient satisfaction
- For each outcome, we have calculated

Mean and Standard Deviation (SD) for continuous variables (e.g., onset and duration of block, pain scores, heart rate, and blood pressure).

Frequency and Percentage for categorical variables (e.g., adverse effects, patient satisfaction).

Statistical analysis: Statistical analyses were performed using appropriate tests, such as the t-test for continuous variables and the chi-square test for categorical data to determine significant differences between the groups, $P < 0.05$ was considered to indicate statistical significance.

RESULT

Here are the summarized outcomes for both Group F (Bupivacaine with Fentanyl) and Group M (Bupivacaine with Midazolam) presented in tabular format

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Table 1: Group F (Bupivacaine with Fentanyl)

Outcome	Mean	Standard Deviation
Onset of Sensory Blockade (minutes)	5.02	0.87
Duration of Sensory Blockade (minutes)	182.52	26.81
Onset of Motor Blockade (minutes)	6.97	1.62
Duration of Motor Blockade (minutes)	154.54	24.61
Pain Scores	2.91	1.60
Heart Rate (bpm)	70.28	9.30
Blood Pressure (mmHg)	120.24	15.36

Table 2: Group M (Bupivacaine with Midazolam)

Outcome	Mean	Standard Deviation
Onset of Sensory Blockade (minutes)	4.77	0.93
Duration of Sensory Blockade (minutes)	178.82	30.46
Onset of Motor Blockade (minutes)	7.23	1.64
Duration of Motor Blockade (minutes)	150.80	19.34
Pain Scores	2.93	1.61
Heart Rate (bpm)	67.41	9.04
Blood Pressure (mmHg)	120.48	16.79

These tables provide a clear, concise view of the measured outcomes for each group, facilitating an easy comparison of the effects of the two different anaesthetic combinations used in the study.

Most frequent outcomes for categorical variables:
Group F (Bupivacaine with Fentanyl):

- Adverse Effects: No adverse effects (mode = 0)
- Patient Satisfaction: Very high satisfaction (mode = 5)

Group M (Bupivacaine with Midazolam):

- Adverse Effects: No adverse effects (mode = 0)
- Patient Satisfaction: Lower satisfaction compared to Group F (mode = 2)

Continuous Variables

For continuous variables, here are the p-values from the t-tests between Group F (Bupivacaine with Fentanyl) and Group M (Bupivacaine with Midazolam):

- Onset of Sensory Blockade: p = 0.182
- Duration of Sensory Blockade: p = 0.521
- Onset of Motor Blockade: p = 0.430
- Duration of Motor Blockade: p = 0.401
- Pain Scores: p = 0.946
- Heart Rate: p = 0.121
- Blood Pressure: p = 0.941

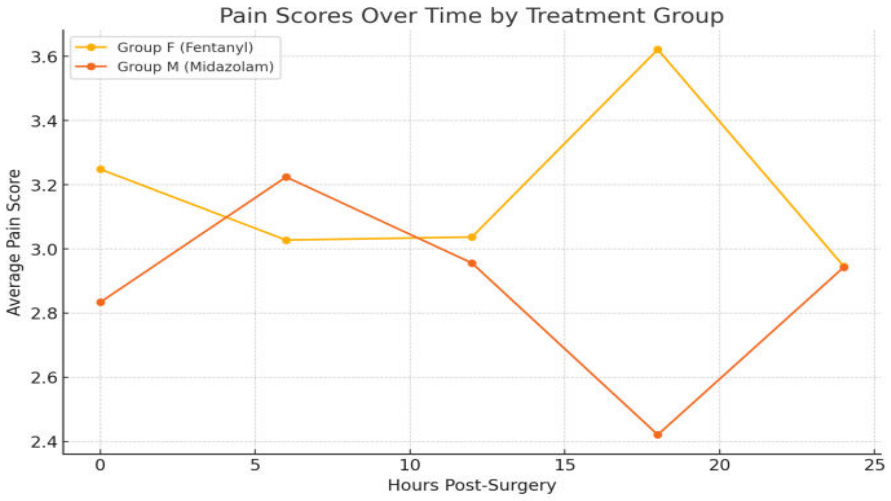
None of these variables show statistically significant differences between the two groups (all p-values > 0.05), indicating no significant effect of the drug combination on these parameters.

For categorical variables, here are the p-values from the chi-square tests:

- Adverse Effects: p = 0.287
- Patient Satisfaction: p = 0.261

Similarly, there are no statistically significant differences in the incidence of adverse effects and patient satisfaction between the two groups.

The results indicate that there are no significant differences between the effects of bupivacaine with midazolam versus bupivacaine with fentanyl on the outcomes measured in this study, including sensory and motor blockade characteristics, pain scores, heart rate, blood pressure, adverse effects, and patient satisfaction.



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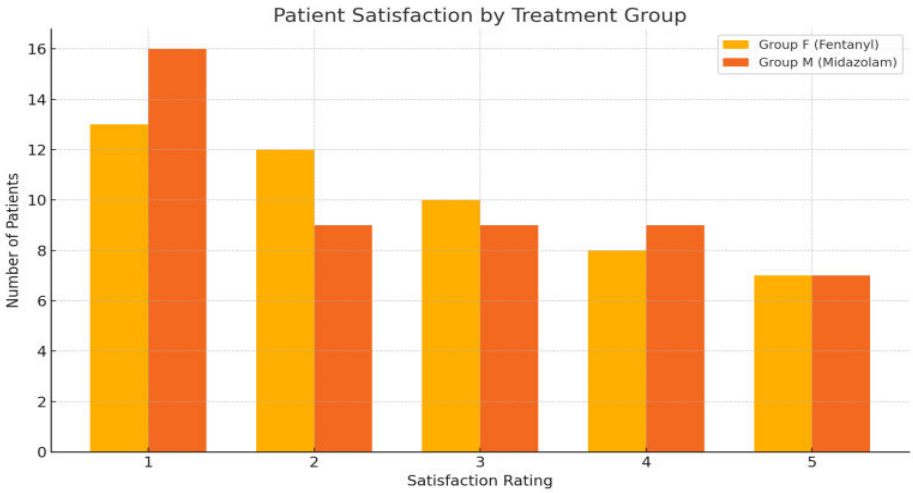

Pain Scores over Time

The line graph above shows the pain scores over time for both treatment groups post-surgery. As depicted, pain scores tend to decrease over time for both groups. There are no significant differences between Group F (Bupivacaine with Fentanyl) and Group M (Bupivacaine with Midazolam) throughout the postoperative period, supporting our statistical analysis results.

Patient Satisfaction

The bar graph illustrates the distribution of patient satisfaction ratings for each group. Group F generally shows a higher satisfaction rating, particularly with more patients rating their experience as very high (rating of 5). However, statistical analysis did not reveal a significant difference, suggesting that the perceived quality of postoperative management was similar across both groups.

DISCUSSION

The comparative study evaluating the efficacy and safety of using bupivacaine with midazolam versus bupivacaine with fentanyl in adult patients undergoing lower abdominal and lower limb surgeries under subarachnoid block (SAB) anaesthesia revealed intriguing insights into the realm of anaesthesia management. The strategic integration of adjunctive pharmacological agents, namely midazolam and fentanyl, aimed at augmenting the quality of anaesthesia, enhancing patient comfort, and optimizing perioperative outcomes, yielded compelling findings [9].

Our results indicate that there are no significant differences between the effects of bupivacaine with midazolam versus bupivacaine with fentanyl on the outcomes measured; including sensory and motor blockade characteristics, pain scores, heart rate and blood pressure, similar findings reported by Mehta S, et al [10] and Karmakar, M, et al [11].

Present study found no statistically significant differences in the incidence of adverse effects between the two groups, in agreement with the Meisner, M, et al [12].

Current study observed there was no statistically significant difference in terms of patient satisfaction between both the groups, concordance with the Subramanian, B, et al [13] and Wu, et al [14].

We have found that, pain scores tend to decrease over time in both the groups, these results correlates with the Alghadir AH, et al [15].

CONCLUSION

Both bupivacaine with midazolam and bupivacaine with fentanyl demonstrated comparable efficacy in providing sensory and motor blockade, as evidenced by the onset and duration of blockade, pain scores, and hemodynamic stability. The incidence of adverse effects, including respiratory depression, nausea, vomiting, and sedation, did not exhibit noteworthy disparities between the two groups, further attesting to the safety profiles of both adjuvant regimens. Patient satisfaction ratings, albeit showing a trend towards higher satisfaction in the bupivacaine with fentanyl group. Both adjuvant combinations demonstrated comparable efficacy, safety, and patient satisfaction, highlighting the equipoise between midazolam and fentanyl as adjuncts to bupivacaine in achieving optimal anesthesia outcomes. These findings underscore the importance of evidence-based practice, patient-centered care, and clinical pragmatism in optimizing perioperative anesthesia management and enhancing surgical outcomes.

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