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COMPARISON OF THE SAFETY AND EFFICACY OF INTRATHECAL BUPIVACAINE COMBINED WITH MIDAZOLAM VERSUS BUPIVACAINE FOR POSTOPERATIVE PAIN MANAGEMENT IN CAESAREAN SECTION

DR. NVNP Sai Pradeepika[1] Dr.Bhoopal Naik[2] Dr. N. Surendra Naik[3*]

[1]Assistant Professor, Department of Anaesthesia, Viswabharathi Medical College, Kurnool, Andhra Pradesh
2Associate Professor, Department of Anaesthesia, Viswabharathi Medical College, Kurnool, Andhra Pradesh.
3*Assistant Proffesor, Department of Anaesthesia, Viswabharathi Medical College, Kurnool, Andhra Pradesh

Corresponding Author

Dr. N. Surendra Naik

Assistant Professor, Department of Anesthesia, Viswabharathi Medical College, Kurnool, Andhra Pradesh

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Abstract

INTRODUCTION: Proper postoperative analgesia is crucial for patient recovery after a lower segment cesarean section (LSCS). Adding an intrathecal adjuvant to local anesthetics is an effective method for extending the duration of anesthesia. This study was conducted to compare the effectiveness and safety of combining intrathecal midazolam with bupivacaine with using bupivacaine alone in subarachnoid block for cesarean delivery.

MATERIALS AND METHODS: The research was done in the department of anesthesiology in pregnant women aged 20-40 years, ASA grade I/II, and included 60 patients scheduled for elective Caesarean section. The patients were randomly assigned to groups B (10 mg bupivacaine intrathecally) and BM (10 mg bupivacaine mixed with 2 mg of preservative-free midazolam intrathecally) using the chit technique. Onset times of sensory and motor blockade, duration of sensory and motor blockade, and duration of effective analgesia were recorded in both the groups. Adverse effects were also monitored to evaluate the safety profile of the analgesic regimens.

RESULTS: Group BM had an earlier onset of sensory and motor block, as well as a longer duration of sensory and motor block and effective analgesia, compared to group B. The difference was found to be statistically significant. Both groups had complications such as bradycardia, hypotension, nausea, and vomiting. In comparison to group BM, group B exhibited more bradycardia and hypotension, as well as an equivalent amount of nausea and vomiting.

CONCLUSION: This study concluded that adding intrathecal midazolam and bupivacaine in subarachnoid block for patients having caesarean deliveries shortened the time it took for sensory and motor block to occur, extended its duration, and sustained analgesia without raising the risk of complications. Thus, minimal side effects are possible while yet achieving acceptable post-operative analgesia.

KEYWORDS: Intrathecal midazolam, Bupivacaine, Subarachnoid block, Cesarean delivery, spinal anesthesia,

INTRODUCTION:

The safety of caesarean deliveries is exceptional in the present era of modern technology and facilities, primarily due to the availability of antibiotics, safe anesthesia, blood transfusion facilities, and recent advancements in surgical techniques. Spinal anesthesia is the optimal anesthetic technique for cesarean delivery due to its ease of use, rapid onset of anesthesia, complete muscle relaxation, reduced incidence of failed blocks, reduced drug dosages, minimal neonatal depression, and reduced incidence of aspiration pneumonitis [1]. The objective of effective postoperative analgesia is to provide a long-

lasting, continuous analgesia with minimal adverse effects. The addition of an intrathecal adjuvant to local anesthetics is a dependable technique for extending the duration of anesthesia. Opioids (fentanyl and buprenorphine), benzodiazepines (midazolam), ketamine, and neostigmine have been employed as adjuvants to local anesthetics for spinal anesthesia [2].

0.5% hyperbaric bupivacaine is the most frequently employed local anesthetic for spinal anesthesia. Limited duration is the most significant drawback of single substance spinal anesthesia. Adjuvants have been employed for a long time in conjunction with local anesthetics to extend the duration of anesthesia and analgesia. Opioids, such as morphine and fentanyl, are frequently employed to enhance the analgesic effects of local anesthetics in neuraxial blockade. However, the use of opioids is restricted by adverse effects such as pruritus, urinary retention, postoperative regurgitation, and respiratory depression [3].

Anxiolysis, amnesia, and sedation are the primary applications of benzodiazepines. The use of intrathecal midazolam for analgesia was initiated by the discovery of benzodiazepine receptors in the spinal cord. Numerous studies have demonstrated that the intrathecal or epidural administration of midazolam results in a dose-dependent modulation of spinal nociceptive processing in both humans and animals, and is not linked to anesthesia, respiratory depression, or neurotoxicity. The efficacy of intrathecal midazolam in postoperative analgesia in normal cesarean patients has been assessed by a variety of researchers [4,5].

This study was conducted to compare the effectiveness and safety of combining intrathecal midazolam with bupivacaine with using bupivacaine alone in subarachnoid block for cesarean delivery in a tertiary care hospital.

MATERIALS AND METHODS:

A hospital-based, comparative and interventional study was undertaken in the department of Anaesthesiology, Viswabharathi Medical College, Kurnool, Andhra Pradesh. The study included 60 patients who are scheduled for elective LSCS under spinal anaesthesia. Patients were selected based on predefined inclusion and exclusion criteria.

Inclusion Criteria: Age group of 20 to 40 years, Healthy parturients of ASA grade I or II Undergoing elective cesarean section, patients eligible for spinal anesthesia and without contraindications to the study drugs.

Exclusion Criteria: Patients with known allergies to bupivacaine or midazolam, Patients with pre-existing neurological disorders or chronic pain, Patients with a history of substance abuse, Patients with coagulation disorders or those on anticoagulant therapy, Any fetal compromise,

Approval from the institutional ethics committee was obtained. The astudy, which consisted of 60 healthy parturients who met the inclusion criteria, gave their written, informed permission. Using the chit technique, patients were split into groups B and BM at random. 10 mg of bupivacaine was administered intrathecally to the B group. 10 mg of bupivacaine and 2 mg of preservative-free midazolam were administered intrathecally to the BM group.

The standard monitoring methods were carried out throughout the surgical operation, and the patient's vital signs were initially measured and recorded. Each patient was given a preload of 10 mL/kg of Ringer lactate solution prior to spinal anesthesia. Strict aseptic procedures were followed while administering spinal anesthesia. The hemodynamic parameters of the patients, such as the breathing rate, oxygen saturation, maternal pulse rate, and non-invasive blood pressure, were continuously monitored and recorded during the procedure. Postoperative treatment was provided as usual. From the time the drug was injected into the patient until the first time more painkillers were used as a backup, the amount of time that the patient had effective pain relief was measured. Blood pressure, pulse rate, pain intensity, and SPO2 were measured at certain intervals after the procedure: 30 minutes, 1 hour, 2 hours, 4 hours, 6 hours, 8 hours, 12 hours, 16 hours, 20 hours, and 24 hours. side effects including low blood pressure, a sluggish heartbeat, and shallow breathing were tracked and recorded throughout the study. In both groups, the duration of effective analgesia, the onset timings of sensory and motor blockade, duration of sensory and motor blockade and duration of effective analgesia were recorded. Intravenous crystalloids and incremental doses of phenylephrine were used to treat hypotension, which was defined in our research as a drop in SBP of more than 25% from the baseline.

statistical analysis: SPSS version 23.0 was used for the analysis of the data. Students' t-test was used to analyze. the quantitative data between the groups, while the Chi-square test was used to analyze the qualitative data. Statistical significance was defined as a p-value of less than 0.05.

RESULTS:

A total of 60 pregnant women were included in the study, with 30 assigned to each group: Group B (10 mg bupivacaine) and Group BM (10 mg bupivacaine mixed with 2 mg of preservative-free midazolam). The demographic and clinical characteristics of the study participants are summarized in Table 1.

Table 1: demographic and clinical characteristics

	Group B (n=30)	**Group BM (n=30)**
Age (in years)	27.12±2.86	26.76±2.86
Height (in cms)	153.22±2.27	152.76±2.45
Weight (in kgs)	54.64±3.28	53.42±3.76
ASA status I II	 22 (73%) 08 (27%)	 21(70%) 09(30%)
Pulse Rate (per min.)	81.4±11.8	81.2±12.8
Systolic BP (mm Hg)	111.2±14.2	108.2±13.8
Diastolic BP (mm Hg)	74.6±6.4	73.8±7.2

Duration of surgery was comparable in both groups. Early onset of sensory and motor block, prolonged duration sensory and motor block as well as prolonged duration of effective analgesia was noted in group BM as compared to group B, and the difference was statistically significant as shown in Table 2

Table 2 : Comparison Of Parameters In Two Groups

	Group BM (n=30)	**Group B (n=30)**	**p value**
Onset of sensory block (min)	2.23±0.36	2.42 ±0.45	0.001*
Duration of sensory block (min)	140.27±15.26	118.42± 16.28	0.003*
Onset of motor block (min)	3.42±0.57	3.96±0.76	0.02*
Duration of motor block (min)	138.36±19.53	112.47±13.96	0.03*
Mean duration of effective Analgesia (min)	191.23±29.21	158.35±24.62	0.02*

*Significant

Complications such as bradycardia, hypotension, nausea and vomiting were noted in present study. Group B had increased number of bradycardia, hypotension and a equal number of nausea /vomiting as compared to group BM, difference was not statistically significant. In present study respiratory depression, incomplete block, pruritus were not seen as shown in Table 3

Table 3: Adverse effects

	Group BM (n=30)	**Group B (n=30)**	**p-value**
Bradycardia	2 (6.7%)	1 (3.3%)	0.07
Hypotension	2 (6.7%)	1 (3.3%)	0.12
Nausea/vomiting	1 (3.3%)	1 (3.3%)	0.08
Respiratory depression	0	0	0.13
Neurotoxicity	0	0	0.23

DISCUSSION:

Post-operative pain in cesarean delivery is mostly connected to the size and length of the block, visceral discomfort during uterine exteriorization, and management of other abdominal contents. A significant dosage of local anesthetic may result in an intense block with hypotension, bradycardia, and, in rare cases, cardiac arrest. Reducing the dosage of local anesthetic reduces the amplitude of hypotension without compromising anesthesia quality. Recently, intrathecal midazolam has been demonstrated to enhance the action of local anesthetics in SAB by acting on the BZDGABA receptor complex at the spinal cord level, resulting in segmental analgesia with no neurotoxic consequences [6].

The onset time for sensory block was faster in Group BM (2.23 ±0.36 minutes) than in Group B (2.42 ±0.45 minutes), similar to the findings of Bharti et al[7] and Sanwal et al[8]. However, Vaswani et al[9] reported a faster onset of sensory block with midazolam (2.26 ± 0.19 minutes vs 3.41 ± 0.41 minutes in control group).

Sanwal et al[8] found that the start timings for sensory blocks were similar with our results. Dodawad et al. [10] found that patients taking midazolam had a quicker start time for sensory block (1.10 ± 0.35 minutes) compared to the control group. In our investigation, the start time for motor block was 3.42+0.57 minutes in group BM and 3.96+0.76 minutes in group B, which was consistent with the results of Sanwal et al[8].

The duration of sensory block was significantly longer in the Bupivacaine-midazolam group compared to the Bupivacaine group (140.27±15.26 minutes in BM group vs 118.42±16.28 minutes in B group). This is consistent with the findings of Dodawad et al [10], who reported a significantly longer duration of sensory block in the midazolam group versus the control group. The Bupivacaine-midazolam group had a considerably longer motor block duration than the Bupivacaine group (138.36±19.53 minutes in group BM versus 112.47±13.96 minutes in group B). This conclusion is similar with the studies of Shadangi et al[11] and Dodawad et al[10], but Bharti et al[7] found a longer motor block in their midazolam group.

The duration of effective analgesia was substantially longer in the Bupivacaine-midazolam group. Compared to the Bupivacaine group (191.23±29.21 minutes versus 158.35±24.62 minutes in the B group). This result is similar with the investigations of Prakash et al [12] and Valentine et al [13].

The inclusion of intrathecal midazolam reduced the incidence of adverse effects such as nausea/vomiting, consistent with the results of Prakash et al[12] and Bharti et al[7]. It has been proposed that benzodiazepines' antiemetic effect may be due to an activity at the chemoreceptor trigger zone that reduces dopamine synthesis, release, and postsynaptic impact. Other side effects, such as bradycardia, hypotension, and shivering, were similar across the groups, and no patients had respiratory depression or neurotoxicity in any group.

CONCLUSION:

This study concluded that adding intrathecal midazolam and bupivacaine in subarachnoid block for patients having caesarean deliveries shortened the time it took for sensory and motor block to occur, extended its duration, and sustained analgesia without raising the risk of complications. Thus, minimal side effects are possible while yet achieving acceptable post-operative analgesia.

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