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Comparison of Complications with Magnesium Sulphate & Fentanyl as Adjuvants for Epidural Labor Analgesia

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Abstract **Original Research Article**

Introduction: Effective and safe analgesia during labor has remained an ongoing challenge. Many pharmacological and non-pharmacological methods of labor analgesia have been adopted over the years. Of these, neuraxial or regional analgesia has become the most popular method. Possible regional anesthesia techniques include epidural analgesia, spinal analgesia, or a combination of epidural and spinal analgesia. This study aimed to compare the complications with magnesium sulfate and fentanyl as adjuvants for epidural labor analgesia. ***Methods:*** This prospective comparative study was conducted at the Department of Anaesthesia, Analgesia, Palliative and Intensive Care Medicine in collaboration with the obstetric department, Dhaka Medical College, Dhaka.Bangladesh. The study was carried out from October 2020 to March 2021. A total of 60 patients were assigned by computer- generated random table to one group (Group A) and another group (Group B). Group-A (n=30): Group-A received Fentanyl 25 micrograms as adjuvant to bupivacaine (0.5% plain bupivacaine 2.5 ml+25 microgram of fentanyl 0.005% 0.5 ml + 7 ml normal saline=10 ml) via epidural catheter. Group B received MgSO4 50 mg as an adjuvant to bupivacaine (0.5% plain bupivacaine 2.5 ml + 50 mg of MgSO4 10% 0.5 ml +7 ml normal saline=10 ml) via epidural catheter. Data were statistically described in terms of mean ± standard deviation (±SD), or frequencies (number of cases) and percentages when appropriate. Comparison of numerical variables between the study groups was done using the student t-test for independent samples. For comparing categorical data, a Chi-square (x^2) test was performed. P values of less than 0.05 were considered statistically significant. F-value was determined by the Repeated measured ANOVA test where data were repeated more than one time. All statistical calculations were done using the computer program SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) version 22 for Microsoft Windows. Informed written consent was taken from the participants and the local committee approved the research protocol. ***Result:*** The mean age of the parturient was (25.45±6.35) years in Group A and (26.63±5.21) years in Group B. Based on the parity most of the parturients were primipara. Group A (83.34%) were primipara and Group B (80%) were primipara. There was no statistically significant difference in the aspect of gestational age, cervical dilatation, and duration of the stage of labor between the two groups (p-value was > 0.05). There had been no significant difference in VAS score before epidural placement and after delivery of the fetus between the two groups (p-value was > 0.05). The heart rate of the parturient was statistically significant at 120 min, 180 min, 210 min, and 240 min in between the two groups (p-value was <0.05). Parturients of Group A had developed adverse effects like hypotension (6.67%), bradycardia (6.67%), nausea (10%), vomiting (10%), and pruritus (3.34%) & Group B developed hypotension (10%), bradycardia (6.67%), nausea (3.34%), and vomiting (3.34%). No patient had pruritus. P-value was not significant between the two groups. (p-value >0.05). ***Conclusion:*** This study concluded that there had been no statistically significant difference regarding complications (hypotension, bradycardia, nausea, vomiting, and pruritus) between magnesium sulfate and fentanyl as adjuvants for epidural labor analgesia. However, the heart rate of the parturient was statistically significant at 120 min, 180 min, 210 min, and 240 min in between the two groups.

Keywords: Labor, Epidural Analgesia, Anesthesia, Complications.

INTRODUCTION

Regional analgesia is effective in providing pain relief in labor. Regional analgesia can be an epidural, a spinal, or a combination of the two. An epidural is when pain-relieving drugs are injected into the part of the body that surrounds the spinal column (epidural space). It is most common for these drugs to be infused through a very fine tube (catheter) positioned in the epidural space [1]. An epidural analgesia is an effective form of pain relief during labor. Many women have concerns regarding its safety. Furthermore, epidural services and anesthetic support may not be available consistently across all centers [2]. The first reported case of regional anesthesia used in labor occurred in 1900 when a physician from Switzerland administered spinal cocaine to six of his patients. Two years later, spinal anesthesia was used for the first time for cesarean delivery in the U.S [3]. In the late 1960s, epidural analgesia became more accepted, especially among academic health centers and private hospitals. Epidural labor analgesia using local anesthetic solutions combined with an opioid is commonly used for the relief of labor pain. Low-concentration local anesthetic solutions with opioids have been shown to reduce motor block without compromising labor analgesia [4, 5]. However, the onset of analgesia can be delayed. There is some evidence that the addition of fentanyl or magnesium sulfate bolus at the initiation of labor epidural analgesia can improve the onset and quality of analgesia and decrease motor block [6- 8]. Sensory nerve roots within the epidural space can be blocked by using a low concentration of a local anesthetic solution. Extension of epidural local anesthetic agent is influenced by the volume of local anesthetic agent administered [9]. Magnesium has postsynaptic N-methyl D- aspartate (NMDA) calcium channel-blocking properties and has been used successfully to potentiate opioid analgesics and to treat neuropathic pain in animals [10]. The administration of magnesium sulfate in the perioperative period was associated with fewer analgesic requirements in the postoperative period [11]. Other studies examined different routes of magnesium administration such as the intravenous or the intrathecal route and were found to improve anaesthetic and analgesic quality [12]. Epidural magnesium was found to reduce the use of postoperative analgesia without increases in side effects [13, 14]. The addition of magnesium to spinal bupivacaine– fentanyl anesthesia improves the duration of spinal analgesia for labor without any side effects [15]. The addition of magnesium to epidurally administered bupivacaine and fentanyl in patients undergoing elective cesarean section with combined spinal-epidural anesthesia helped to improve the quality of postoperative analgesia [16]. This study aimed to compare the complications with magnesium sulfate and fentanyl as adjuvants for epidural labor analgesia.

OBJECTIVE

General Objective

- To compare the complications with magnesium sulfate and fentanyl as adjuvants for epidural labor analgesia.

Specific Objectives

- To know the demographics of the respondents.
- To see some labor characteristics of study subjects.
- To assess maternal heart rate.

METHODS

This prospective comparative study was conducted at the Department of Anaesthesia, Analgesia, Palliative, and Intensive Care Medicine in collaboration with the obstetric department, Dhaka Medical College, Dhaka.Bangladesh. The study was carried out from October 2020 to March 2021. A total of 60 pregnant women with a full-term pregnancy, who requested epidural analgesia for labor was selected as the study population as per inclusion and exclusion criteria. A purposive sampling technique was used in this study. 60 patients were assigned by computer- generated random table to one group (Group A) and another group (Group B). Group-A (n=30): Group-A received Fentanyl 25 micrograms as adjuvant to bupivacaine (0.5% plain bupivacaine 2.5 ml+25 microgram of fentanyl 0.005% 0.5 ml + 7 ml normal saline=10 ml) via epidural catheter. Group B received MgSO4 50 mg as an adjuvant to bupivacaine (0.5% plain bupivacaine 2.5 ml + 50 mg of MgSO4 10% 0.5 ml +7 ml normal saline=10 ml) via epidural catheter. Intravenous fluid loading with 10- 15 ml /kg of Ringer's lactate solution was given. Patients were then placed in the sitting position, and local anesthesia infiltration of the skin and subcutaneous tissues was done at the level of L2–3 or L3–4 with 2–3 mL of lidocaine 0.5%. The mid-lumbar extradural space L2–L3/L3–L4 was identified by using a loss of resistance to air with an 18 G Tuohy needle and an epidural catheter (Perifix 18 G catheter; B. Braun, Melsungen, Germany) was inserted 4–5 cm into the epidural space in a cephalic direction and aspirated for detection of cerebrospinal fluid or blood in the space. Then the catheter was fixed and patients were repositioned with left uterine displacement. 3 mL of 2% lidocaine with 15 µg of epinephrine as a test dose was injected. In the absence of intravascular or intrathecal placement of the catheter, the study drug (In Group-A, 0.5% plain bupivacaine 2.5 ml+25 microgram of fentanyl 0.005% 0.5 ml + 7 ml normal saline=10 ml and in Group-B, 0.5% plain bupivacaine 2.5 ml + 50 mg of MgSO4 10% 0.5 ml +7 ml normal saline=10 ml) was injected 5 min after the test dose. The time of the injection of the study drug was considered as T =0 and assessments were done accordingly. The analysis compared tracings obtained at least 30 min before epidural and recorded during epidural

analgesia. Data were statistically described in terms of mean ± standard deviation (±SD), or frequencies (number of cases) and percentages when appropriate. Comparison of numerical variables between the study groups was done using the Student t-test for independent samples. For comparing categorical data, a Chi-square (x^2) test was performed. P values of less than 0.05 were considered statistically significant. F-value was determined by the Repeated measured ANOVA test where data were repeated more than one time. All statistical calculations were done using the computer program SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) version 22 for Microsoft Windows. Informed written consent was taken from the participants and the local committee approved the research protocol

Inclusion Criteria

- Patient with full-term pregnancy with vertex presentation and in active labor with a cervical dilatation of 3-5 cm.
- Patients having normal fetal heart rate pattern (CTG) before the time of induction.
- Patients who had given consent to participate in the study.

Exclusion Criteria

- Patients who had cervical dilatation >5 cm before epidural catheter insertion.
- Patient with anticoagulant therapy, preterm labor, breech presentation, obstructed labor, infection at the local site of catheter placement, and anatomical deformity of the spine.
- Patients with BMI > 35 kg/m^2.
- Patients who did not want to participate in the study.

RESULTS

Table 1: Distribution of respondents according to demography and parity (N=60)

characteristics	Group A	Group B	p-value
Mean age (years)	25.45±6.35	26.63±5.21	0.234^{NS}
BMI (kg/m^2)	22.23±4.88	23.52±4.21	0.186^{NS}
Parity			
Primipara	25(83.34%)	24(80.00%)	0.132^{NS}
Multipara	5(16.67%)	6(20.00%)	0.146^{NS}

Values are expressed as Mean±SD and within parenthesis percentage (%) over the column in total. Pearson chi-squared Test (χ^2) was performed. NS: Statistically not significant.

The mean age of the parturient was (25.45±6.35) years in Group A and (26.63±5.21) years in Group B. Based on the parity most of the parturients were primipara. Group a (83.34%) were primipara and Group B (80%) were primipara. [Table 1]

Table 2: Distributions of parturient according to labour characteristics (N=60)

Characteristics		Group A (n=30)	Group B (n=30)	p-value
Gestational age (weeks)		39.5±2.5	40±1.5	0.153^{NS}
Cervical dilatation (cm)		3.5±0.5	3.8±0.8	0.142^{NS}
Duration of the stage (min)	1st	237.96±57.87	244.63±62.42	0.240^{NS}
	2nd	98.23±27.74	89.78±29.76	0.189^{NS}

Values are expressed as Mean±SD and within parenthesis percentage (%) over the column in total. Pearson chi-squared Test (χ^2) was performed. NS: Statistically not significant.

There was no statistically significant difference in the aspect of gestational age, cervical dilatation, and duration of the stage of labor between the two groups (p-value was > 0.05). [Table 2]

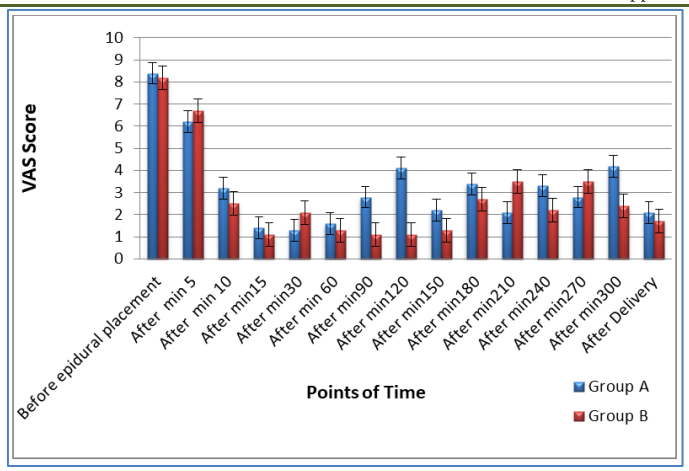

Figure 1: Distributions of parturient according to VAS score. (N=60)

The mean VAS score was significantly lower in Group B at 10 min in comparison to Group A which was statistically significant (p-value was < 0.05). The VAS score was statistically significant at 120 min, at 210 min, at 240 min, and at 300 min in between the two groups (p-value was < 0.05). There had been no significant difference in VAS score before epidural placement and after delivery of the fetus between the two groups (p-value was > 0.05). [Figure 1]

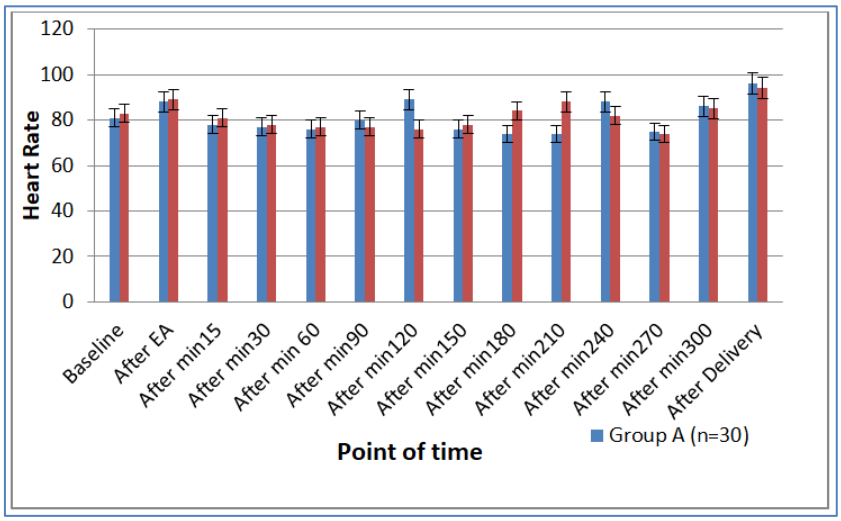

Figure 2: Distributions of parturient according to Heart Rate (N=60)

Values of the heart rate of the parturient at baseline, after epidural drug administration, at different time intervals, and after delivery.

The heart rate of the parturient was statistically significant at 120 min, 180 min, 210 min, and 240 min in between the two groups (p-value was <0.05). [Figure 2]

Table 3: Distributions of parturient according to maternal adverse effects (N=60)

Complication		Group A (n=30)	Group B (n=30)
Maternal	Hypotension	2 (6.67%)	3(10%)
	Bradycardia	2(6.67%)	2(6.67%)
	Nausea	3 (10%)	1(3.34%)
	Vomiting	3 (10%)	1(3.34%)
	Pruritus	1(3.34%)	0 (0.0%)

Values are expressed within parenthesis percentage (%) over the column in total.

Parturients of Group A had developed adverse effects like hypotension (6.67%), bradycardia (6.67%), nausea (10%), vomiting (10%), and pruritus (3.34%) & Group B developed hypotension (10%), bradycardia (6.67%), nausea (3.34%), and vomiting (3.34%). In Group-B no patient had pruritus. P-value was not significant between the two groups. (P-value >0.05) [Table 3].

DISCUSSION

Epidural labor analgesia is the gold standard technique to relieve labor pain during the childbirth of a parturient. Currently, many adjuvants are used with local anesthetic agents. Of them, fentanyl and magnesium sulfate are used with local anesthetic agents to provide faster onset and longer duration of analgesia of local anesthetic agents such as bupivacaine without any significant adverse effects. The demographics and labor characteristics of the patients were well-matched between the two groups. The mean age of the parturient was (25.45 ± 6.35) years in Group- A and (26.63 ± 5.21) years in Group B. Based on the parity most of the parturients were primipara. Group a (83.34%) were primipara and Group B (80%) were primipara. There was no statistically significant difference in the aspect of gestational age, cervical dilatation, and duration of the stage of labor between the two groups (p-value was > 0.05).

We observed that the heart rate of the parturient was statistically significant between the two groups (p-value was < 0.05) at 120 min, at 180 min, at 210 min, and 240 min because at that time VAS score was high. The Mean Arterial Pressure of the parturient was not statistically significant between the two groups (p-value was > 0.05). The mean VAS score was significantly lower in Group B at 10 min in comparison to Group A which was statistically significant (p-value was < 0.05). The VAS score was statistically significant at 120 min, at 210 min, at 240 min, and at 300 min in between the two groups (p-value was < 0.05). There had been no significant difference in VAS score before epidural placement and after delivery of the fetus between the two groups (p-value was > 0.05). Hasanein, R., El-Sayed, W. and Khalil, M., (2013) stated when single-dose epidural magnesium sulfate was added to bupivacaine fentanyl in labor resulted in a statistically significant VAS score at 10 min (p-value was < 0.01) that co-relates with our study [17]. Parturients of Group A had developed adverse effects like hypotension (6.67%) bradycardia (6.67%), nausea (10%), vomiting (10%), and pruritus (3.34%), and in Group B developed hypotension (10%), bradycardia (6.67%), nausea (3.34%), and vomiting (3.34%). In Group-B no patient had pruritus. Yousef A. A and Amr Y.M. (2010), a study on the effect of adding magnesium sulfate to epidural bupivacaine and fentanyl in elective cesarean section using combined spinal-epidural anesthesia and found statistically no significant difference in the incidence of hypotension, nausea, and vomiting in between two groups (p- value was >0.05), which was quite similar to the present study [18].

Limitations of the Study

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

CONCLUSION

This study concluded that there had been no statistically significant difference regarding complications (hypotension, bradycardia, nausea, vomiting, and pruritus) between magnesium sulfate and fentanyl as adjuvants for epidural labor analgesia. However, the heart rate of the parturient was statistically significant at 120 min, 180 min, 210 min, and 240 min in between the two groups.

FUNDING: No funding sources

CONFLICT OF INTEREST: None declared

ETHICAL APPROVAL: The study was approved by the Institutional Ethics Committee

RECOMMENDATION

Dose titration of Magnesium sulfate & Fentanyl in epidural labor analgesia in multiple centers can be carried out. Moreover, further studies should be conducted in multiple centers involving a larger sample size.

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