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Onset And Duration Of Analgesia With Magnesium Sulphate Versus Fentanyl As Adjuvants To Epidural Bupivacaine For Labour Analgesia: Prospective Comparative Study

Md. Abdur Rahim[*1], Mohammad Mahabubuzzaman[2], Shamima Akter[3], Md. Saiful Islam [4], Md. Humayun Kabir[5], Md. Akkasur Rahman[6], Subrata Kumar Das [7], Humaiun Kabir[8], Md. Shahidullah Humayun Kabir[9]

[1]*Specialist, Neuro- Intensive Care, Square Hospitals Ltd, Dhaka, Bangladesh*

[2]*Anesthesiologist, National Institute of Traumatology and Orthopaedic Rehabilitation (NITOR), Dhaka, Bangladesh*

[3]*Assistant Professor, Department of Anesthesiology, Dhaka Medical College, Dhaka, Bangladesh*

[4]*, Assistant Professor, Department of Anesthesia, Green life Medical College*

[5]*junior Consultant, Department of Anesthesiology,* Mugda Medical *College & Hospital, Dhaka, Bangladesh*

[6]*Anesthesiologist, Rajshahi Medical College Hospital, Rajshahi, Bangladesh*

[7]*Junior Consultant, Dhaka Medical College Hospital, Dhaka, Bangladesh*

[8]*Consultant, Anesthesia &ICU, Star K.S Hospital, Lakshmipur, Bangladesh*

[9]*Senior Consultant, Anesthesia & ICU, National Institute of Traumatology and Orthopaedic Rehabilitation (NITOR), Dhaka, Bangladesh*

Corresponding Author: *Dr. Md. Abdur Rahim, Specialist, Neuro- Intensive Care, Square Hospitals Ltd, Dhaka, Bangladesh. E-mail: raselofrmc48@gmail.com*

Abstract

Background: *Labour pain is a significant concern for expectant mothers, and epidural analgesia remains the gold standard for its management. However, the efficacy of epidural analgesia can be enhanced by adjuvants. This study aimed to compare the onset and duration of analgesia provided by magnesium sulphate versus fentanyl as adjuvants to epidural bupivacaine for labour analgesia.*

Methods: *This prospective comparative study was conducted on 60 pregnant women requesting epidural labour analgesia at Dhaka Medical College, Dhaka. Participants were randomized into two groups: Group A received 0.125% plain bupivacaine with 25 µg fentanyl, and Group B received 0.125% plain bupivacaine with 50 mg magnesium sulphate. Various parameters like onset and duration of analgesia, number of top-ups, and adverse effects were recorded.*

Result: *The onset of analgesia was significantly quicker in Group B (10.23±2.75 min) compared to Group A (16.93±4.87 min) (p=0.025). The duration until the first top-up requirement was also significantly longer in Group B (178.46±43.54 min) compared to Group A (103.67±30.54 min) (p=0.001). Group B required fewer total top-ups (1.8±0.75) compared to Group A (3.4±0.80) (p=0.036). No significant differences were observed in maternal and fetal heart rates between the two groups.*

Conclusion: *Magnesium sulphate may offer advantages over fentanyl as an adjuvant to epidural bupivacaine for labour analgesia, particularly in terms of onset and duration of analgesia and the number of top-ups required. These findings could have significant implications for clinical practice. Further studies are needed to validate these results.*

Keywords: *Labor, Epidural, Analgesia, Fentanyl, Magnesium Sulphate, Bupivacaine*

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I. INTRODUCTION

Labour pain is a complex and subjective experience, often cited as one of the most intense forms of pain a person can endure (1–3). Epidural analgesia is widely considered the gold standard for managing this pain due to its high efficacy and safety profile (4,5). The technique involves administering local anesthetic agents like bupivacaine through an epidural catheter placed in the epidural space in the lower back (5,6). However, it has been observed that epidural analgesia alone may not provide sufficient pain relief throughout labour for some women (7,8). To enhance the analgesic profile of bupivacaine and mitigate its side effects such as motor block and hypotension, adjuvants are often added (9). Two such commonly used adjuvants are magnesium sulphate and fentanyl. Magnesium sulphate, a non-competitive NMDA receptor antagonist, has been observed to potentiate the analgesic effects of local anesthetics without causing significant motor block (10). A study in 2020 noted that even a low dose of epidural magnesium sulphate was effective in labour analgesia without adverse effects (11). Another study comparing the onset of sensory block in lower abdominal surgeries found that both magnesium sulphate and fentanyl as adjuvants to bupivacaine had similar onset times (12). Fentanyl, a highly potent μ-opioid receptor agonist, is frequently used for its ability to prolong analgesia (13,14). However, its use has been associated with undesirable side effects like pruritus, nausea, vomiting, and respiratory depression in both the mother and neonate (15). A study comparing epidural bolus administration of 0.125% bupivacaine with 0.0002% fentanyl versus 0.25% plain bupivacaine for labour analgesia found that the analgesia provided by both techniques was similar (16). While both magnesium sulphate and fentanyl are widely used as adjuvants, there is a lack of high-quality evidence directly comparing their onset and duration of analgesia when combined with epidural bupivacaine. Previous studies have yielded inconsistent results, with some suggesting that magnesium sulphate provides longer analgesia, while others found no significant differences between the two drugs (17,18). No previous studies have been conducted in our setting to address this knowledge gap, making this prospective comparative study particularly relevant. The aim of this Prospective Comparative study is to compare the onset and duration of analgesia provided by magnesium sulphate versus fentanyl as adjuvants to epidural bupivacaine for labour analgesia among women at a tertiary care hospital in Dhaka, Bangladesh. The study hypothesizes that magnesium sulphate will provide non-inferior analgesia to fentanyl with fewer side effects due to its novel mechanism of action and favorable safety profile.

II. METHODS

This prospective comparative study was conducted at the Department of Anesthesia, Analgesia, Palliative and Intensive care medicine in collaboration with the obstetric department, Dhaka Medical College, Dhaka. The study was carried out on 60 pregnant women requesting epidural labour analgesia over a period of 6 months, from October 2020 to March 2021. The participants were divided into two groups of 30 each by computer-generated randomization. Group A received 0.125% plain bupivacaine with 25 μg fentanyl as adjuvant (0.5% plain bupivacaine 2.5ml +25 microgram fentanyl+ 7ml normal salaine =10 ml) while Group B received 0.125% plain bupivacaine with 50 mg magnesium sulphate as adjuvant(0.5% plain bupivacaine 2.5 ml+50 mg MgSO4 10% 0.5 ml+7 ml normal saline= 10 ml)administered epidurally via epidural catheter followed by 1st top-up dose of 8 ml 0.125% plain bupivacaine in both groups. Labour analgesia was maintained by 8 ml 0.125%plain bupivacaine hourly after 1st top -up dose administration. Pain was assessed using a 10 cm VAS scale before and after drug administration. 1st top-up dose given when VAS >3. Additional top up dose of 6 ml 0.125% plain bupivacaine when VAS Score> 3.Sensory and motor blockade levels were evaluated using standard scales. Maternal monitoring included non-invasive blood pressure, heart rate and fetal heart rate monitoring. Duration of analgesia, number of top-up doses, highest sensory and motor blockade levels achieved were recorded. Adverse effects were also noted. Data was analyzed using appropriate tests and a p value of <0.05 was considered statistically significant.

III. RESULTS

Table 1: Distributions of participants according to Demographics and Labour Characteristics (n=60)

Characteristics		**Group A (n=30)**	**Group B (n=30)**	**p-value**
Mean age(year)		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	Primi	25(83.34%)	24(80.00%)	0.132^{NS}
	Multi	5(16.67%)	6(20.00%)	0.146^{NS}
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}

The table shows the distributions of participants according to their demographics and labour characteristics in both Group A and Group B. In terms of mean age, there was no significant difference between the groups with values of 25.45±6.35 years in Group A and 26.63±5.21 years in Group B. Similarly, BMI, parity, gestational age and cervical dilatation upon recruitment did not significantly differ between the two groups. Regarding duration of labour, the mean duration of the first stage of labour was 237.96±57.87 minutes in Group A and 244.63±62.42 minutes in Group B, which was not statistically significant. Likewise, the mean duration of the second stage of labour was 98.23±27.74 minutes and 89.78±29.76 minutes in groups A and B respectively without any significant difference.

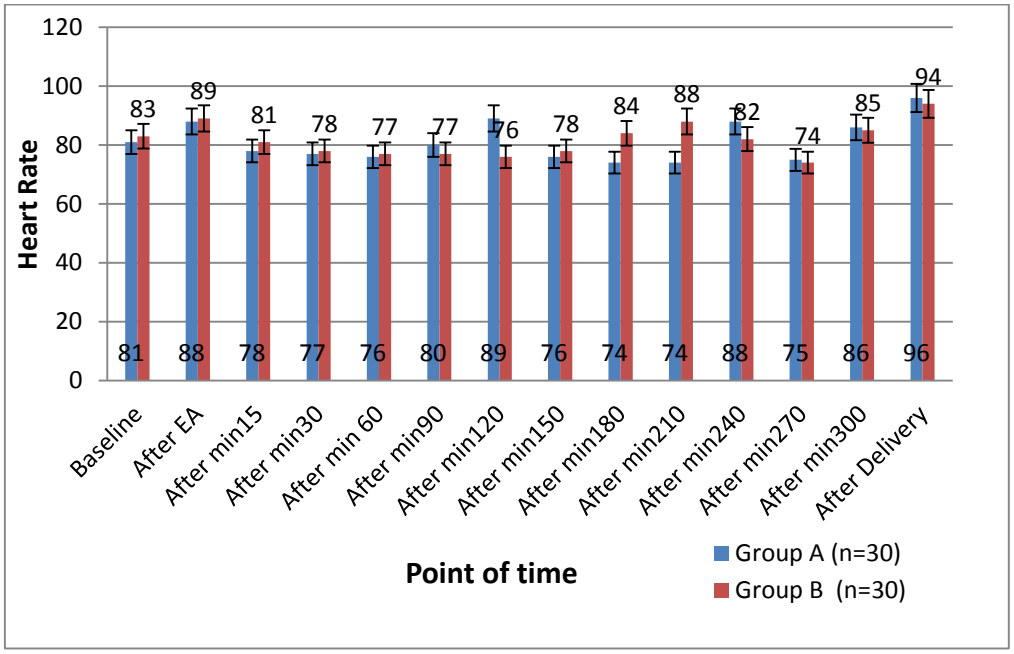

Figure 1: Distribution of participants by maternal heart rate at different intervals.

In Figure 1, the maternal heart rate of participants in both Group A and Group B was monitored at various intervals. The groups, each with 30 participants, showed no significant differences in heart rate at most time points, including baseline, after epidural analgesia (EA), and up to 150 minutes post-EA ($p>0.05$). However, notable exceptions were observed at 120, 180, 210, and 240 minutes, where the heart rates differed significantly between the groups ($p<0.05$) Specifically, at 120 minutes. Group A had a higher heart rate (89 beats/min) compared to Group B (76 beats/min). Conversely, at 180, 210, and 240 minutes, Group B exhibited higher heart rates than Group A. Heart rates were comparable again after 270 minutes and post-delivery ($p>0.05$).

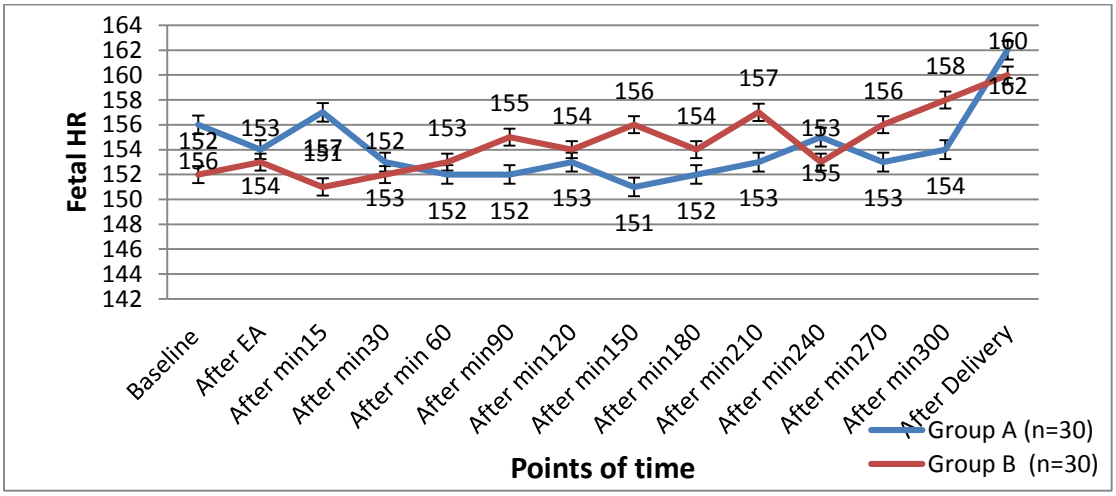

Figure 2: Distribution of participants by fetal heart rate at different intervals.

In Figure 2, the fetal heart rate was monitored for both Group A and Group B, each consisting of 30 participants. Across all time intervals, including baseline, after epidural analgesia (EA), and up to 300 minutes post-EA, no statistically significant differences were observed between the two groups ($p>0.05$). The heart rates remained within a narrow range for both groups throughout the monitoring period and post-delivery.

Table 2: Distributions of participants according to Level of sensory block, Motor block and Unintentional Dural puncture (n=60)

Characteristics		**Group A (n=30)**	**Group B (n=30)**
Level of sensory block	T8	20 (66.7%)	19 (63.27%)
	T10	10 (33.3%)	11(36.63%)
Motor Block (Lower half of the Body)	M. Bromage score 0	26 (86.68%)	27 (90%)
	M. Bromage score 1	4 (13.32%)	3 (10%)
Unintentional Dural puncture		2 (6.67%)	3 (10%)

In Table 2, the distribution of participants according to the level of sensory block, motor block, and unintentional dural puncture is presented for both Group A and Group B, each with 30 participants. For the level of sensory block, Group A had 20 participants (66.7%) at T8 and 10 participants (33.3%) at T10. Group B had a similar distribution with 19 participants (63.27%) at T8 and 11 participants (36.63%) at T10. Regarding motor block in the lower half of the body, assessed using the Modified Bromage score, 26 participants (86.68%) in Group A and 27 participants (90%) in Group B had a score of 0. A score of 1 was observed in 4 participants (13.32%) in Group A and 3 participants (10%) in Group B. Unintentional dural puncture occurred in 2 participants (6.67%) in Group A and 3 participants (10%) in Group B. Overall, the groups were comparable in these clinical characteristics.

Table 3: Distributions of participants according to Onset of Analgesia, Duration of Analgesia, Total number of top-ups, Total volume and Amount of top-up doses (n=60)

Characteristics	**Group A (n=30)**	**Group B (n=30)**	**p-value**
Onset of analgesia (min)	16.93±4.87	10.23±2.75	<0.025^S
Duration of analgesia (1st top-up requirement; min)	103.67±30.54	178.46±43.54	<0.001^S
Total number of top-up	3.4±0.80	1.8±0.75	<0.036^S
Total top-up epidural volume (ml)	25±4.65	17±5.65	<0.001^S
Total top-up epidural amount (Bupivacaine) (mg)	31.25±5.81	21.25±7.06	<0.001^S

In Table 3, various characteristics related to analgesia are compared between Group A and Group B, each consisting of 30 participants. Statistically significant differences were observed in all measured parameters. The

onset of analgesia was quicker in Group B, with a mean time of 10.23 minutes (±2.75), compared to 16.93 minutes (±4.87) in Group A (p=0.025S). The duration until the first top-up requirement for analgesia was significantly longer in Group B, averaging 178.46 minutes (±43.54), as opposed to 103.67 minutes (±30.54) in Group A (p=0.001S). Additionally, Group A required a higher total number of top-ups, averaging 3.4 (±0.80), compared to 1.8 (±0.75) in Group B (p=0.036S). The total volume of epidural top-up was also higher in Group A, with a mean of 25 ml (±4.65), compared to 17 ml (±5.65) in Group B (p=0.001S). Similarly, the total amount of Bupivacaine used for top-ups was higher in Group A, averaging 31.25 mg (±5.81), as opposed to 21.25 mg (±7.06) in Group B (p=0.001S).

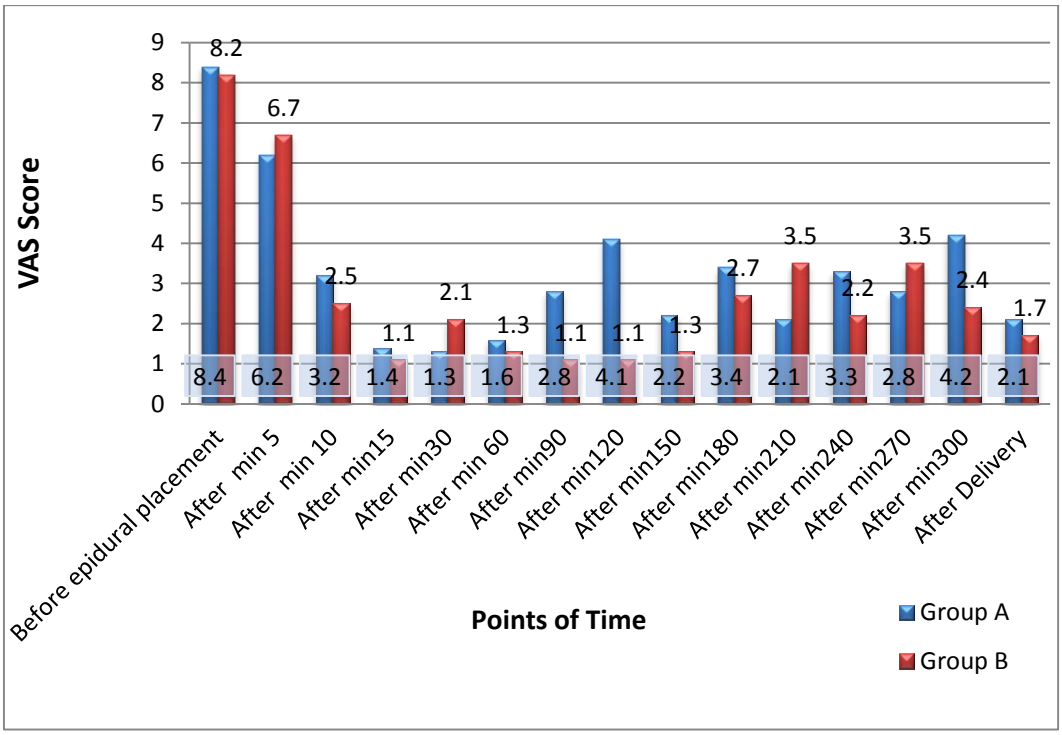

Figure 3: Trends in VAS score of the participants (n=60)

In Figure 3, the Visual Analog Scale (VAS) scores for pain were monitored for both Group A and Group B, each consisting of 30 participants. The VAS scores were generally comparable between the two groups at most time points, including before epidural placement and up to 90 minutes post-epidural (p>0.05). However, significant differences were observed at specific intervals. At 10 minutes post-epidural, Group B had a lower VAS score (2.5) compared to Group A (3.2) with a p-value of <0.05. At 120 minutes, Group A had a higher VAS score (4.1) compared to Group B (1.1), also with a p-value of <0.05. Interestingly, at 210 and 240 minutes, the VAS scores diverged significantly again but in opposite directions; Group B had a higher score at 210 minutes (3.5 vs. 2.1, p<0.05), while Group A had a higher score at 240 minutes (3.3 vs. 2.2, p<0.05). At 300 minutes, Group A had a significantly higher VAS score (4.2) compared to Group B (2.4) with a p-value of <0.05. After delivery, the VAS scores were again comparable between the groups (p>0.05).

IV. DISCUSSION

In the present study, the onset of analgesia was significantly quicker in the magnesium sulphate group, with a mean time of 10.23 minutes (±2.75), compared to 16.93 minutes (±4.87) in the fentanyl group (p=0.025). This finding is corroborated by a study that reported a faster onset of sensory block at T8 when magnesium sulphate was used as an adjuvant (19). The duration until the first top-up requirement for analgesia was also significantly longer in the magnesium sulphate group, averaging 178.46 minutes (±43.54), as opposed to 103.67 minutes (±30.54) in the fentanyl group (p=0.001). This aligns with a study that showed an increased duration of analgesia when magnesium sulphate was used as an adjuvant (20). Regarding the total number of top-ups required, the magnesium sulphate group needed fewer, averaging 1.8 (±0.75), compared to 3.4 (±0.80) in the fentanyl group (p=0.036). This is consistent with previous studies that reported the opioid-sparing effects of magnesium sulphate (21). The total volume of epidural top-up was also lower in the magnesium sulphate group, with a mean of 17 ml (±5.65), compared to 25 ml (±4.65) in the fentanyl group (p=0.001). Similarly, the total amount of bupivacaine

used for top-ups was lower in the magnesium sulphate group, averaging 21.25 mg (±7.06), as opposed to 31.25 mg (±5.81) in the fentanyl group (p=0.001) (20). In terms of maternal and fetal heart rates, no significant differences were observed between the two groups at most time points. However, a study found that fentanyl as an adjuvant could lead to undesirable side effects like pruritus, nausea, vomiting, and respiratory depression in both mother and neonate (22). Our study did not report these side effects, possibly due to the lower doses used. The level of sensory block and motor block were comparable between the two groups, which is consistent with another study that found comparable demographic, hemodynamic, and respiratory parameters between groups receiving epidural bupivacaine with different adjuvants (23). Unintentional dural puncture rates were also similar between the two groups, which is a crucial safety parameter. VAS scores for pain were generally comparable between the two groups at most time points. However, significant differences were observed at specific intervals, which could be due to the different pharmacokinetics and pharmacodynamics of the two adjuvants used. This is supported by a study that found fentanyl provided superior analgesia when compared to magnesium sulphate in terms of duration of motor and sensory blockade (23). In summary, our findings suggest that magnesium sulphate may offer advantages over fentanyl as an adjuvant to epidural bupivacaine for labour analgesia, particularly in terms of onset and duration of analgesia, and the number of top-ups required. These results could have significant implications for clinical practice, particularly in settings where prolonged analgesia and reduced opioid consumption are desirable.

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.

V. CONCLUSION

In conclusion, this prospective Comparative study provides compelling evidence that magnesium sulphate may serve as a more effective adjuvant to epidural bupivacaine for labour analgesia compared to fentanyl. Specifically, the magnesium sulphate group demonstrated a quicker onset of analgesia, longer duration until the first top-up requirement, and fewer total top-ups, all of which were statistically significant. Both maternal and fetal heart rates remained stable across both groups, and no significant adverse effects were observed. These findings have important clinical implications, suggesting that magnesium sulphate could be a preferable choice for enhancing epidural analgesia in labour, particularly in settings where prolonged analgesia and reduced opioid consumption are desirable. Further large-scale studies are warranted to validate these results and to explore the long-term safety profile of magnesium sulphate as an adjuvant.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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