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Efficacy of Vaginal Misoprostol and Intracervical Catheterization in Labour Induction for Vaginal Delivery in Eclampsia Patients

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Abstract

Background: Eclampsia, a severe complication of pregnancy characterized by seizures, remains a significant cause of maternal and neonatal morbidity and mortality. Effective and safe labor induction methods are crucial for managing eclampsia, particularly in resource-limited settings. This study compares the efficacy and safety of vaginal misoprostol and intracervical Foley's catheterization for labor induction in eclamptic patients. The aim of the present study was to compare the vaginal misoprostol and intracervical catheterization to induce labor in eclamptic patients. **Material & Methods:** This prospective randomized clinical trial was conducted at the Eclampsia unit of Dhaka Medical College & Hospital, Bangladesh. Sixty antepartum eclamptic patients were enrolled with 30 receiving vaginal Misoprostol (25µg every 6 hours for 24 hours) and 30 undergoing intracervical Foley's catheterization. The study assessed induction-delivery interval, mode of delivery and maternal and neonatal complications. Baseline characteristics including age, socioeconomic status, gravidity, gestational age and Bishop's Score were recorded. **Results:** The induction to active labor interval averaged 9.13 ± 3.45 hours for the Misoprostol group and 10.27 ± 3.26 hours for the Catheterization group (p=0.197). Active labor to delivery times were 6.48 ± 4.20 hours and 5.67 ± 5.79 hours respectively (p=0.566). Total induction to delivery times were comparable at 15.48 ± 5.02 hours for Misoprostol and 15.92 ± 6.12 hours for Catheterization (p=0.771). Vaginal delivery was achieved in 76.67% of the Misoprostol group and 83.33% of the Catheterization group. Complication rates including tachysystole (10% vs. 6.67%), uterine hyperstimulation (3.33% vs. 0%) and maternal fever (6.67% vs. 3.33%), were similar in both groups. Neonatal outcomes such as mortality (36.67% vs. 30%) and NICU admissions (36.67% vs. 30%) showed no significant differences. **Conclusion:** Both vaginal misoprostol and intracervical Foley's catheterization are equally effective and safe for labor induction in eclampsia with comparable induction times, delivery outcomes and complication rates. These findings are significant for resource-limited settings, guiding clinical decisions in labor induction for eclamptic patients.

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Keywords:- Misoprostol, Foley's Catheterization, Labor Induction, Eclampsia, Delivery

INTRODUCTION

Labor induction, a pivotal intervention in obstetrics, becomes particularly crucial in managing eclampsia, a severe pregnancy complication marked by seizures. This condition, a part of the spectrum of hypertensive disorders in pregnancy, poses significant risks to both mother and fetus.[1] In such scenarios, the timely and effective induction of labor is not just a therapeutic approach but a critical preventive strategy to avert further complications. Eclampsia, along with pre-eclampsia, its antecedent, continues to be a leading cause of maternal and neonatal morbidity and mortality globally despite advancements in maternal healthcare.[2] The management of eclampsia primarily revolves around controlling seizures and ensuring the prompt delivery of the fetus, often necessitating labor induction. Selecting an induction method is a delicate balance between efficacy, safety and the urgency of the clinical situation, making the improvement of labor induction techniques especially in resource-limited settings, a matter of great importance. Globally, hypertensive disorders during pregnancy including pre-eclampsia and eclampsia remain significant contributors to maternal mortality, accounting for up to 14% of such deaths annually.[3] In Bangladesh, despite a shift towards hospital-based deliveries, these conditions still account for approximately 20% of maternal deaths.[4] The rapid progression of neurological disturbances in eclampsia underscores the urgent need for safe and effective labor induction methods in these patients.[5] International guidelines typically advocate for delivery initiation within 12 hours of eclampsia onset.[6,7] However, there is a notable scarcity of evidence guiding the best practices for labor induction particularly in settings where certain resources may be limited.[8] This study aims to bridge this gap by comparing the effectiveness and safety of two prevalent labor induction methods—vaginal misoprostol and intracervical Foley's catheterization—in Bangladeshi women with eclampsia requiring urgent labor induction. In Bangladesh, the maternal mortality ratio, although improved due to increased hospital births, remains a concern at 173 deaths per 100,000 live births.[9] Pre-eclampsia and eclampsia contribute to nearly a fifth of these deaths and are associated with increased risks of preterm birth, fetal health complications and both acute and long-term maternal health issues.[4,5] Clinical management focuses on seizure control, stabilizing the mother's condition and the safe delivery of the baby.[6] Despite international guidelines recommending rapid delivery post-seizure onset, the evidence underpinning this recommendation is limited. The majority of deliveries in Bangladesh now occur in hospitals and maternal care centers which has improved access to emergency obstetric care but also highlights the need for effective and rapid labor induction methods that are suitable for these settings.[8,10] Various methods are employed for inducing labor in the third trimester but direct comparisons of these methods in eclampsia patients are rare. Prostaglandins such as misoprostol are known for their efficacy but their availability can vary in different settings.[11] Intracervical Foley's catheterization offers a low-cost mechanical method for cervical

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ripening but the induction-to-delivery interval can range widely.[12] The safety of these methods, especially concerning the risk of uterine rupture, remains a topic of ongoing debate.[13,14,15] Additionally, most research on labor induction methods originates from well-resourced ccenter limiting their general applicability to settings like Bangladesh.[8,16] Given the shift towards hospital-based deliveries in Bangladesh, it is essential to explore the feasibility and rapidity of labor induction methods in urgent delivery situations in these environments. This study addresses this need through a randomized trial comparing vaginal misoprostol (25mcg every 6 hours) and intracervical Foley's catheterization for third-trimester labor induction in women with eclampsia. We hypothesize that misoprostol will lead to shorter time for vaginal delivery compared to the Foley's catheter. Secondary outcomes to be analyzed include the mode of delivery, maternal and neonatal adverse effects, postpartum hemorrhage rates, and overall maternal and neonatal outcomes. The findings are anticipated to significantly contribute to the limited evidence based clinical practices in settings like Bangladesh. With eclampsia continuing to be a significant cause of preventable morbidity in vulnerable populations, identifying accessible, safe and effective methods for urgent labor induction is of utmost importance.

MATERIAL AND METHODS

This prospective randomized clinical trial study was conducted at the Eclampsia Unit of the Department of Obstetrics and Gynaecology, Dhaka Medical College & Hospital (DMCH), Dhaka, Bangladesh over a six-month period. The study population comprised antepartum eclamptic patients admitted to the eclampsia unit of DMCH who met the inclusion criteria and had none of the exclusion criteria. The inclusion criteria were eclampsia with a gestational age of 28 weeks or more, singleton pregnancy and cephalic presentation. Patients were excluded if they had renal failure, acute pulmonary edema, hepatic failure, HELLP syndrome, more than two previous cesarean sections, or other causes of fits. The study involved two groups: The Misoprostol group, where 30 patients received vaginal misoprostol (25µg) in the posterior vaginal fornix every 6 hours for 24 hours, and the Catheterization group, where 30 patients underwent intracervical Foley's catheter insertion, inflated with 30 ml of sterile water at the level of the internal os and left in situ until spontaneously expelled. The sample size, initially calculated to be 384 based on a 95% confidence interval and a 50% prevalence rate of the disease was limited to 60 due to time and resource constraints. Simple random sampling was employed for participant selection. Informed written consent was obtained from each patient's attendant after explaining the study objectives, procedures and potential risks. Data were collected through face-to-face interviews and physical examination using a semi-structured questionnaire and checklist, focusing on key variables such as induction-delivery interval, mode of delivery, failure to achieve induction, need for augmentation, maternal and fetal complications and any systemic side effects. The operational definitions used in the study included induction of labor as the non-spontaneous initiation of uterine contractions leading to progressive cervical dilatation and effacement, and pre-induction scoring based on the modified Bishop's score. Quality control

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measures were implemented to ensure data accuracy and relevance. Data analysis was conducted using SPSS version 21.0. Qualitative data were expressed in frequency, percentage and quantitative data as mean (SD). Associations between categorical variables were analyzed using the chi-squared test and continuous variables with the t-test or Mann-Whitney U test, as appropriate. A p-value of less than 0.05 was considered statistically significant. Ethical considerations were rigorously followed with approval from the local ethical committee of Dhaka Medical College Hospital. The study's aims, procedures, risks and benefits were clearly communicated to participants in an understandable language and confidentiality was maintained throughout.

RESULTS

Age distribution showed a similar pattern in both groups. In the Misoprostol Group, 26.67% (n=8) were aged ≤20, 66.67% (n=20) were aged between 21-30 and 6.67% (n=2) were over 30. The Catheterization Group had 20.00% (n=6) aged ≤20, 73.33% (n=22) between 21-30 and 6.67% (n=2) over 30. The mean age was 24 ± 4.44 years in the Misoprostol Group and 25.97 ± 4.33 years in the Catheterization Group with age ranges of 18-32 and 19-35 years, respectively. The difference in age distribution between the two groups was not statistically significant (p=0.826). Regarding socioeconomic status, in the Misoprostol Group, 50.00% (n=15) were classified as lower class, 6.67% (n=2) as lower middle class, 40.00% (n=12) as middle class and 3.33% (n=1) as higher class. In the Catheterization Group, these figures were 40.00% (n=12) for lower class, 3.33% (n=1) for lower middle class, 50.00% (n=15) for middle class and 6.67% (n=2) for higher class. The difference in socioeconomic status distribution was not statistically significant (p=0.718). In terms of gravidity, the Misoprostol Group had 66.67% (n=20) primi gravidas and 33.33% (n=10) multi gravidas, while the Catheterization Group had 53.33% (n=16) primi gravidas and 46.67% (n=14) multi gravidas. This difference was also not statistically significant (p=0.429). For gestational age, the distribution was 40.00% (n=12) for 28-32 weeks, 26.67% (n=8) for 33-36 weeks and 33.33% (n=10) for 37-40 weeks in the Misoprostol Group. In the Catheterization Group, the distribution was 46.67% (n=14) for 28-32 weeks, 20.00% (n=6) for 33-36 weeks and 33.33% (n=10) for 37-40 weeks. The gestational age distribution between the groups showed no significant difference (p=0.803). [Table 1]

In the Misoprostol Group, the distribution of Bishop Scores was as follows: 3.33% (n=1) had a score of 0-2, 33.33% (n=10) had a score of 3-4, 40.00% (n=12) had a score of 5-6 and 23.33% (n=7) had a score greater than 6. In the Catheterization Group, the distribution was 3.33% (n=1) for a score of 0-2, 46.67% (n=14) for a score of 3-4, 33.33% (n=10) for a score of 5-6 and 16.67% (n=5) for a score greater than 6. The mean Bishop Score in the Misoprostol Group was 5.23 ± 1.01, while in the Catheterization Group, it was slightly lower at 4.47 ± 1.16. However, the difference in the mean Bishop Score between the two groups was not statistically significant (p=0.226). [Table 2]

In the Misoprostol Group, the average time from induction to active labor was 9.13 ± 3.45 hours. In contrast, the Catheterization Group had a slightly longer average time of 10.27 ± 3.26 hours for the same phase. However, this difference was not statistically significant (p=0.197). Regarding the time from active labor

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to delivery, the Misoprostol Group had an average duration of 6.48 ± 4.20 hours, while the Catheterization Group had an average of 5.67 ± 5.79 hours. Again, the difference between the two groups was not statistically significant (p=0.566). The total time from induction to delivery was also compared. In the Misoprostol Group, this duration averaged 15.48 ± 5.02 hours and in the Catheterization Group, it was slightly longer at 15.92 ± 6.12 hours. However, this difference was not statistically significant (p=0.771). [Table 3]

In the Misoprostol Group, 76.67% (n=23) of the patients had a vaginal delivery, while 23.33% (n=7) underwent a cesarean section. In comparison, the Catheterization Group had a slightly higher rate of vaginal deliveries with 83.33% (n=25) delivering vaginally and 16.67% (n=5) requiring a cesarean section. The difference in the mode of delivery between the two groups was not statistically significant (p=0.519). [Table 4]

In the Misoprostol Group, tachysystole was observed in 10.00% (n=3) of patients, uterine hyperstimulation in 3.33% (n=1), meconium-stained liquor in 3.33% (n=1) and maternal fever in 6.67% (n=2). Conversely, in the Catheterization Group, tachysystole occurred in 6.67% (n=2) of patients but there were no cases of uterine hyperstimulation or meconium-stained liquor and maternal fever was noted in only 3.33% (n=1) of patients. Statistical analysis revealed no significant differences in the occurrence of these complications between the two groups. [Table 5]

Neonatal mortality was observed in 36.67% (n=11) of the neonates in the Misoprostol Group and 30% (n=9) in the Catheterization Group. The rate of NICU (Neonatal Intensive Care Unit) admission was identical to the mortality rates in both groups with 36.67% (n=11) in the Misoprostol Group and 30% (n=9) in the Catheterization Group. However, these differences in mortality and NICU admission rates between the two groups were not statistically significant with a p-value of 0.793 for both outcomes. The mean fetal weight was similar between the groups with the Misoprostol Group having a mean weight of 2.49 ± 0.43 kg and the Catheterization Group having a mean weight of 2.52 ± 0.59 kg, yielding a non-significant p-value of 0.94. Regarding the APGAR scores which assess the newborn's physical condition, the mean APGAR score at 1 minute was 5.26 ± 2.19 in the Misoprostol Group and 6.26 ± 1.95 in the Catheterization Group. At 5 minutes, the scores were 6.55 ± 2.16 for the Misoprostol Group and 7.25 ± 2.05 for the Catheterization Group. However, these differences in APGAR scores at 1 and 5 minutes were not statistically significant with p-values of 0.803 and 0.784, respectively. [Table 6]

Table 1: Distribution of participants by baseline characteristics (N=60)

Variables	Misoprostol Group (n=30)		Catheterization group (n=30)		p-value
	n	%	n	%	
Age					
≤20	8	26.67%	6	20.00%	0.826
21-30	20	66.67%	22	73.33%	

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>30	2	6.67%	2	6.67%	
Mean ± SD	24 ± 4.44		25.97 ± 4.33		
Range	18-32		19-35		
Socioeconomic Status					
Lower class	15	50.00%	12	40.00%	0.718
Lower middle class	2	6.67%	1	3.33%	
Middle class	12	40.00%	15	50.00%	
Higher class	1	3.33%	2	6.67%	
Gravidity					
Primi Gravida	20	66.67%	16	53.33%	0.429
Multi Gravida	10	33.33%	14	46.67%	
Gestational Age					
28 - 32	12	40.00%	14	46.67%	0.803
33 - 36	8	26.67%	6	20.00%	
37 - 40	10	33.33%	10	33.33%	

Table 2: Distribution of the patients according to Bishop Score (n=60)

Bishop Score	**Misoprostol Group (n=30)**		**Catheterization group(n=30)**		**p-value**
	n	**%**	**n**	**%**	
0-2	1	3.33%	1	3.33%	0.565
3-4	10	33.33%	14	46.67%	
5-6	12	40.00%	10	33.33%	
>6	7	23.33%	5	16.67%	
Mean ± SD	5.23 ± 1.01		4.47 ± 1.16		0.226

Table 3: Distribution of the patients according to Induction times for patients with successful vaginal birth (n=60)

Time interval (Hours)	**Misoprostol group (n=30)**	**Catheterization group (n=30)**	**p-value**
Induction → active labor (h)	9.13 ± 3.45	10.27 ± 3.26	0.197
Active labor → delivery (h)	6.48 ± 4.20	5.67 ± 5.79	0.566
Induction → delivery (h)	15.48 ± 5.02	15.92 ± 6.12	0.771

Table 4: Distribution of the patients according to Mode of delivery (n=60)

Mode of Delivery	**Misoprostol Group (n=30)**		**Catheterization group (n=30)**		**p-value**
	n	**%**	**n**	**%**	
Vaginal Delivery	23	76.67%	25	83.33%	0.519
Cesarean Section	7	23.33%	5	16.67%	

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Table 5: Distribution of the patients according to Complication during the induction period to delivery.

Complications	Misoprostol Group (n=30)		Catheterization group (n=30)		p-value
	n	%	n	%	
Tachysystole	3	10.00%	2	6.67%	0.641
Uterine hyperstimulation	1	3.33%	0	0.00%	1
Meconium stained liquor	1	3.33%	0	0.00%	1
Maternal fever	2	6.67%	1	3.33%	0.544

Table 6: Distribution of the patients according to neonatal complications

Neonatal Outcome	Misoprostol group (n=30)	Catheterization group (n=30)	p-value
Mortality	11 (36.67%)	9 (30%)	0.793
NICU Admission	11 (36.67%)	9 (30%)	0.793
Mean Fetal Weight	2.49 ± 0.43	2.52 ± 0.59	0.94
Mean APGAR Score at 1 Minute	5.26 ± 2.19	6.26 ± 1.95	0.803
Mean APGAR Score at 5 Minute	6.55 ± 2.16	7.25 ± 2.05	0.784

DISCUSSION

In our study, the evaluation of baseline characteristics such as age, socioeconomic status, gravidity and gestational age revealed a remarkable similarity between the Misoprostol and Catheterization groups. Specifically, in the age distribution, 26.67% of the Misoprostol group and 20% of the Catheterization group were aged ≤20 years, while the majority, 66.67% and 73.33% respectively, fell within the 21-30 age range. The socioeconomic status was also evenly distributed with 50% of the Misoprostol group and 40% of the Catheterization group belonging to the lower class, and 40% and 50% respectively from the middle class. In terms of gravidity, 66.67% of the Misoprostol group and 53.33% of the Catheterization group were primigravida. These findings are critical as they establish a level playing field for comparing the two induction methods ensuring that any observed differences in outcomes can be attributed to the induction methods themselves rather than demographic or obstetric variations. This uniformity in baseline characteristics echoes the findings of Mundle et al. (2016) who also reported no significant differences in key demographic and obstetric parameters when comparing Foley Catheter with Oral Misoprostol in pre-eclamptic women. Thus, it reinforces the robustness of our study design.[17] Regarding the Bishop Score, a pre-induction evaluation of the cervix, our study observed a marginally higher mean score in the Misoprostol group (5.23 ± 1.01) compared to the Catheterization group (4.47 ± 1.16). However, this difference did not reach statistical significance (p-value = 0.226), suggesting that the initial cervical readiness for labor induction was comparable between the two groups. This finding is particularly relevant as it implies that the initial cervical condition, assessed by the Bishop Score, may not be a decisive factor in choosing between these two induction methods. This observation is in line with the study by Sharma et al. (2021) who found no significant difference in Bishop Scores when comparing intracervical Foley catheter and vaginal misoprostol with vaginal misoprostol

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alone.[18] The analysis of induction times in our study, encompassing the duration from induction to active labor, active labor to delivery and the overall induction to delivery interval, revealed no significant differences between the Misoprostol and Catheterization groups. Specifically, the mean time from induction to active labor was 9.13 ± 3.45 hours for the Misoprostol group and 10.27 ± 3.26 hours for the Catheterization group. The active labor to delivery interval averaged 6.48 ± 4.20 hours and 5.67 ± 5.79 hours respectively. The total time from induction to delivery was 15.48 ± 5.02 hours for the Misoprostol group and 15.92 ± 6.12 hours for the Catheterization group. These findings suggest that both methods are similarly efficient in progressing from induction to delivery, a conclusion that aligns with the observations made by Davalagi et al. (2019). They reported comparable induction-delivery intervals between groups induced with vaginal Misoprostol versus intracervical Foley's catheter and vaginal Misoprostol.[19] This parity in induction times is significant as it indicates that the choice between these two methods can be based on factors other than time efficiency. Regarding the mode of delivery, our study found that the rates of vaginal delivery and cesarean section were closely matched between the two groups. In the Misoprostol group, 76.67% achieved vaginal delivery compared to 83.33% in the Catheterization group. Conversely, cesarean sections were necessary for 23.33% of the Misoprostol group and 16.67% of the Catheterization group. These proportions underscore the effectiveness of both induction methods in facilitating vaginal delivery. This observation is corroborated by the findings of Sharma et al. who also reported no significant difference in the mode of delivery when comparing a combination of intracervical Foley catheter and sublingual misoprostol with sublingual misoprostol alone.[20] The similarity in delivery modes between the two groups in our study and in Sharma et al.'s research suggests a comparable efficacy of these methods in achieving the desired outcome of vaginal delivery, reinforcing the notion that either method can be effectively employed depending on the clinical context and patient preferences. In our study, the incidence of complications including tachysystole, uterine hyperstimulation, meconium-stained liquor and maternal fever was observed to be low and showed no significant differences between the Misoprostol and Catheterization groups. Specifically, tachysystole occurred in 10.00% of the Misoprostol group and 6.67% of the Catheterization group. Uterine hyperstimulation was noted in 3.33% of the Misoprostol group with no cases in the Catheterization group. Meconium-stained liquor was reported in 3.33% of the Misoprostol group, again with no cases in the Catheterization group. Maternal fever was observed in 6.67% of the Misoprostol group and 3.33% of the Catheterization group. These low and comparable rates of complications suggest the relative safety of both induction methods. This finding is in line with the study by Mundle et al. (2016) which also reported low rates of uterine hyperstimulation, reinforcing the notion that both vaginal Misoprostol and intracervical Foley catheterization are safe options for labor induction in eclampsia patients.[17] Regarding neonatal outcomes, our study found that mortality rates, NICU admissions, mean fetal weights and APGAR scores at 1 and 5 minutes were similar between the two groups. Specifically, neonatal mortality was 36.67% in

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the Misoprostol group and 30% in the Catheterization group. NICU admissions were reported for 36.67% of neonates in the Misoprostol group and 30% in the Catheterization group. The mean fetal weight was 2.49 ± 0.43 kg for the Misoprostol group and 2.52 ± 0.59 kg for the Catheterization group. The mean APGAR scores at 1 minute were 5.26 ± 2.19 for the Misoprostol group and 6.26 ± 1.95 for the Catheterization group and at 5 minutes, they were 6.55 ± 2.16 and 7.25 ± 2.05, respectively. These findings are significant as they suggest that both induction methods are equally safe for neonates, a crucial consideration in the management of labor in eclampsia patients. The parity in neonatal outcomes between the two groups underscore the importance of focusing on other factors such as patient preference and resource availability when choosing between these induction methods.

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.

CONCLUSIONS

In conclusion, our study provides valuable insights into the efficacy and safety of both vaginal Misoprostol and intracervical Foley catheterization for labor induction in eclampsia patients. The findings demonstrate that both methods are equally effective in terms of induction times and achieving vaginal delivery with no significant differences in the rates of cesarean sections. More importantly, the incidence of complications such as tachysystole, uterine hyperstimulation, meconium-stained liquor and maternal fever was low and comparable between the two groups, indicating the safety of both methods. Furthermore, neonatal outcomes including mortality, NICU admissions, mean fetal weight and APGAR scores, were similar for both groups, suggesting that neither method poses additional risks to neonates. These results are particularly relevant for settings like Bangladesh where the choice of induction method must balance efficacy, safety and resource availability. Our study contributes to the limited evidence base and supports informed decision-making in the clinical management of labor induction in eclampsia patients, emphasizing the need for individualized patient care.

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