A comparison of transcervical foley catheter and intravaginal misoprostol for cervical ripening and labour induction in a tertiary hospital in North-Central Nigeria

Olasinde, A.[1], Aboyeji, A.P.[2], Omokanye, L.O.[2], Ogunlaja, O.A.[3], Lawal, B.O.[2], Olasinde, Y.T.[4], Adeyemi, A.[2].

[1]Department of Obstetrics and Gynaecology, General Hospital, Ilorin, Nigeria
[2]Department of Obstetrics and Gynaecology, University of Ilorin Teaching Hospital, Ilorin, Nigeria
[3]Department of Obstetrics and Gynaecology, Bowen University Teaching Hospital, Ogbomoso, Nigeria
[4]Department of Paediatrics, Bowen University Teaching Hospital, Ogbomoso, Nigeria

Article Info

Article type:
Original Article

Article history:
Received: September 6, 2023
Accepted: April 11, 2024
Published: September 15, 2024

Keywords:
Vaginal misoprostol, Foley catheter, Induction of labour, Cervical Ripening

Corresponding author:
Olasinde, A.
ORCID-NO: https://orcid.org/0000-0002-4364-9016
stevad2002@yahoo.com

The article can be accessed at:
www.rjhs.org

http://dx.doi.org/10.4314/rejhs.v12i3.3

Abstract

Background: Induction of labour is an important procedure in obstetric practice therefore, a safe and suitable method should be considered for cervical ripening and labour induction. This study compared the efficacy and safety of intravaginal misoprostol and intra-cervical Foley catheter for cervical ripening and labour induction.
Methods: This study was carried out among parturients in a tertiary hospital between December 2017 and October 2018.Seventy-eight parturients with unfavourable cervix were randomized into two groups, to receive either 4hourly intravaginal misoprostol for a maximum of six doses or have passage of intra-cervical Foley balloon catheter over a maximum of 12 hours. Data was analyzed using SPSS software version 23, $p<0.05$was considered statistically significant.
Results: The study showed no difference in vaginal delivery rates (misoprostol, 61.6%; Foley, 53.9%; p= 0.49) between the two methods of cervical ripening. The induction to delivery interval for the vaginal misopostol group (14.25±5.21hours) was similar to the Foley catheter group (10.39±0.42hours; p=0.10). However, there was higher Bishop's score after cervical ripening in the vaginal misoprostol group (p=0.001).
Conclusion: The maternal and perinatal outcomes in this study have shown that no method is superior to another when efficacy and safety of vaginal misoprostol and Foley catheter are concerned for cervical ripening and IOL. Hence any of these two methods should be considered suitable for IOL with unripe cervix.

Comparaison du Cathéter de Foley Transcervical et du misoprostol intravaginal pour la maturation cervicale et le déclenchement du travail dans un hôpital tertiaire du centre-nord du Nigéria

Résumé
Contexte de l'étude: Le déclenchement du travail est une procédure importante dans la pratique obstétricale. Par conséquent, une méthode sûre et appropriée doit être envisagée pour la maturation cervicale et le déclenchement du travail. Cette étude a comparé l'efficacité et l'innocuité du misoprostol intravaginal et du cathéter de Foley intra-cervical pour la maturation cervicale et le déclenchement du travail.
Méthode de l'étude : Cette étude a été réalisée auprès de parturientes dans un hôpital tertiaire entre décembre 2017 et octobre 2018. Soixante-dix-huit parturientes présentant un col défavorable ont été randomisées en deux groupes, pour recevoir soit du misoprostol intravaginal toutes les 4 heures pour un maximum de six doses, soit un passage intra-vaginal. - cathéter cervical à ballonnet de Foley sur une durée maximale de 12 heures. Les données ont été analysées à l'aide du logiciel SPSS version 23, p <0,05 a été considéré comme statistiquement significatif.
Résultat de l'étude : L'étude n'a montré aucune différence dans les taux d'accouchement vaginal (misoprostol, 61,6 % ; Foley, 53,9 % ; p = 0,49) entre les deux méthodes de maturation cervicale. L'intervalle d'induction jusqu'à l'accouchement pour le groupe misopostol vaginal (14,25 ± 5,21 heures) était similaire à celui du groupe cathéter de Foley (10,39 ± 0,42 heures ; p = 0,10). Cependant, le score de Bishop était plus élevé après la maturation cervicale dans le groupe misoprostol vaginal (p = 0,001).
Conclusion : Les résultats maternels et périnatals de cette étude ont montré qu'aucune méthode n'est supérieure à une autre lorsque l'efficacité et la sécurité du misoprostol vaginal et du cathéter de Foley concernent la maturation cervicale et la LIO. Par conséquent, chacune de ces deux méthodes doit être considérée comme appropriée pour les LIO avec col non mûr.
Mots-clés : Misoprostol vaginal, cathéter de Foley, déclenchement du travail, maturation cervicale

INTRODUCTION

Pre-induction cervical ripening is an integral part of labour induction and one of the key determinants of successful induction of labour.(1,2) It is an extensive remodelling of the cervical tissue during pregnancy or labour with resultant softening and dilatation of the cervical canal.(3,4) In the practice of obstetrics, artificial initiation of labour becomes inevitable when the risks of continued pregnancy outweigh the benefits to the foetus and/or the mother.(5,6) The goal of labour induction is to achieve a timely and uncomplicated vaginal delivery with minimal adverse effects to the mother or newborn.(2,4)

A number of cervical ripening agents are available and are categorized into the older mechanical agents (such as osmotic dilators and Foley's catheter) and the more recent pharmacological agents (such as prostaglandin E1 (PGE1) e.g., misoprostol and prostaglandin E2 (PGE2) e.g. dinoprostone).(7) The optimal method for pre-induction cervical ripening and labour induction is however not established.(8)

In low-middle income countries (LMICs), Foley's catheter and misoprostol are the commonest methods used for cervical ripening due to affordability, stability at room temperature and ease of administration. Different studies have however reported varying results on efficacy and safety of these methods, but most of the studies are foreign and may not reflect what obtains in our locality. This study therefore aimed to compare the efficacy and safety of vaginal misoprostol and Foley's catheter for cervical ripening and IOL among parturients in a tertiary hospital in North-central Nigeria.

MATERIAL AND METHODS

This was a prospective randomized study carried out between December 2017 and October 2018 in the Department of Obstetrics and Gynaecology (O&G) of the University of Ilorin Teaching Hospital (UITH), Ilorin, Nigeria. Participants were consenting pregnant women with indications for induction of labour and with an unfavourable cervix at term and beyond. The UITH is a referral centre for Kwara state and neighbouring states such as Osun, Oyo and Kogi. The Department of O&G consists of the antenatal and family planning clinics, antenatal & postnatal wards, delivery suite and obstetric theatre, with an adjoining neonatal intensive care unit. Eligible patients were recruited from the antenatal clinic and antenatal wards using a randomized control sampling technique.

The inclusion criteria included gestational age > 37 weeks based on last menstrual period (LMP) or first trimester sonography, need for pregnancy termination due to foetal or maternal indication, unfavourable cervix (Bishop score $\leq$5), singleton gestation, live foetus, cephalic presentation, intact foetal membranes, and mild pre-eclampsia. Women were excluded from the study if any of the following criteria were encountered: multiple pregnancy, dead foetus, previous Caesarean delivery or other uterine surgery, placenta previa, chorioamnionitis, bronchial asthma, heart disease or known hypersensitivity to prostaglandins, vaginal bleeding, foetal distress, need for immediate delivery, foetal macrosomia, and oligohydramnios.

We determined the minimum sample size for the study using the formula for comparison two proportion:RCT(9).

$$n_{1=}\frac{(Z_{1-\alpha/2}+Z_{1-\beta})^2 P_1(1-P_1)+P_2(1-P_2)}{(P_1-P_2)^2}$$

$n_{1=}$ calculated sample size in each group

$Z_{1-\alpha/2}$= 1.96 and $Z_{1-\beta}$= 0.84

P_1= 0.87 (Proportion of women who had successful vaginal delivery following cervical ripening with misoprostol)

P_2= 0.57 (Proportion of women who had successful vaginal delivery following the use of Foley's catheter). P_1 and P_2 were obtained from a previous study (6).

The calculated sample size in each group was thirty one (31). The inclusion of 20% attrition made each group thirty nine (39) participants.

A total of seventy-eight (78) women requiring induction of labour at term with an unfavourable cervix (Bishop score $\leq$ 5) were recruited in the study. They were randomized into two groups: 39 women in each arm of the study, Group I (had intravaginal misoprostol for cervical ripening) and Group II (had cervical ripening with intracervical foley catheter). The randomization of participants was accomplished by using a set of computer-generated (Stat-Trek Generator) 78 random numbers tagged 1 and 2 in a disordered fashion. Each consecutive generated number was written on an index card and placed in serially numbered opaque, sealed envelopes. The envelopes were labelled 1 to 78 and arranged according to their serial numbers then placed in a big box by an independent statistician. Eligible women were asked to pick an envelope serially from the big box without replacement, Eligible women were assigned utilizing these computer-generated random numbers, into two sample groups: group I (vaginal misoprostol) for random numbers tagged 1, group II (Foley's catheter) for

random numbers tagged 2. A clear explanation of the study was given and written consent was obtained, before enrolment into the study. Women in group I received commercially prepared misoprostol (Misoclear - produced by Acme formulation Pvt Limited, India, marketed by Marie Stopes International Nigeria) at 25microgram (μg) vaginally and women in group II had extra-amniotic transcervical Foley catheter for cervical ripening.

We obtained approval for the study from the Ethics Committee of the University of Ilorin Teaching Hospital, Kwara State, Nigeria (UITH/CAT/189/19A/189).

Detailed history was taken and recorded with special reference to age, parity, menstrual and obstetric history. Gestational age was calculated from the first day of last menstrual period or first-trimester obstetric ultrasound for those unsure of their last menstrual period. Physical examination was done with complete obstetric examination performed; Per abdomen-fundal height of uterus, foetal heart sound(FHS), presentation, engagement of the foetal head determined; Per vaginal-pelvis assessment of the cervical status using Bishop's score recorded. Preliminary laboratory investigations included: haemoglobin (Hb) concentration, blood group and crossmatch, urine analysis and ultrasound.

Group I had placement of 25 μg misoprostol tablet in the posterior vaginal fornix if needed; it was repeated up to 6 doses every 4 hours (h). Vaginal examination was performed every 4 hours; if the Bishop's score was unfavourable or uterine contractions did not begin, the patient received another dose. In the presence of adequate uterine contractions (lasting about 40 - 50 secs every 3 min), the next dose was not administered. If the effective uterine contractions did not begin 4 hours after the last dose, and one hour after amniotomy then oxytocin infusion was used for augmentation of labour in the presence of a favourable cervix.

Group II had a size 18 Foley Catheter (produced by Well Lead Medical Company Ltd, China, marketed by Lifesign Health care) inserted through the cervix into the extra-amniotic space under aseptic conditions and the bulb was inflated with 50milliliters(ml) of sterile water. Traction was applied to the catheter until the balloon was taut against the internal cervical os. The external end of the catheter was taped with traction to the inner thigh of the patient until spontaneous expulsion. When this did not occur after 12 hours, the catheter was deflated and removed.

When spontaneous catheter expulsion occurred or when the Bishop's score of 6 or more was achieved after removal of catheter then amniotomy was performed in labour ward and IOL commenced with continuous oxytocin infusion if uterine contractions were inadequate (<3 contractions per 10 min) with initial oxytocin base mixture concentration of 10mIU/ml, starting at a dose of 5mIU/min and increased at 30minute intervals to achieve effective uterine contractions. The maximum oxytocin flow rate was 30mIU/min.

In both groups, vaginal examination was done 4hourly to assess Bishop's score and progress of labour. Participants were monitored clinically for progress of labour and foetal well-being.

For this study, failed induction was defined as failure to deliver vaginally within 24 hours of onset of randomized method or recourse to caesarean delivery.

Relevant data pre-induction of labour and during induction process were recorded in the study proforma and were subsequently analysed using Statistical Package for Social Sciences (SPSS) version 23. Continuous data were reported as mean and standard deviation (SD). The Student's T-test was used to analyse continuous data whilst the chi- square test and Fisher's exact test were used for the non-parametric data. $P<0.05$ was considered statistically significant.

RESULTS

The demographic characteristics of the women in the two groups are comparable. The mean ± SD age of women in the misoprostol arm was similar to that of women in the Foley's catheter group (28.69±5.61years vs 30.03±4.02 years; $p=0.232$). The commonest indication for induction of labour in the two arms was post-datism. Other details are as shown in Table 1.

The mean initial Bishop's score in the two groups were similar. However, the median (IQR)Bishop's score at favourable cervical status (ripened cervix) for the vaginal misoprostol group was statistically significantly higher than in the intracervical Foley catheter group [8.00(7.00 – 10.00) vs 6.00(4.00 – 7.00); $p<0.001$]. The mean± SD induction to delivery interval recorded for the vaginal misoprostol group, 14.50 ± 5.24hours, was comparable to that of women who had cervical ripening with transcervical Foley catheter 13.34 ± 3.59hours. ($p=0.384$) Other details are as shown in Table 2.

Regarding the outcome of IOL in Table 3, a higher number of women in the vaginal

misoprostol group had spontaneous rupture of membrane 15/39 (38.5%), when compared to Foley's catheter group, 3/39 (7.7%). However, the number of women who had abnormal uterine contractions such as hyperstimulation, need for oxytocin augmentation and mode of delivery in the two arms of the study were comparable.

Successful vaginal delivery was achieved in 60.9% of patients who had vaginal misoprostol without need for oxytocin augmentation of labour as against 27.3% in the Foley's catheter group; this was statistically significant (Table 4).

From the neonatal outcome in Table 5, irrespective of the mode of delivery, there was no case of stillbirth in the two groups. There was no significant difference in the Apgar scores at first and fifth minutes of life in both groups. Conversely, the 20.9% of the neonates delivered to women who had Foley's catheter had need for neonatal intensive care admission compared to none in the misoprostol group and this was significant.

Figure 1 (Kaplan-Meier curve) revealed the proportion of vaginal delivery (event) that occurred within 24 hours. These showed no remarkable difference in the proportion of women who achieved vaginal delivery within 24 hours in both groups.

DISCUSSION

IOL is an important obstetric procedure which has helped to reduce the burden of Caesarean section and increased the chance of vaginal delivery with fitting indications. This study revealed the comparative advantages of transcervical extra-amniotic Foley catheter insertion with the use of vaginal misoprostol for cervical ripening in IOL.

The result of this study shows no significant difference in the induction delivery interval between the two study groups, those who had transcervical foley catheter and those who had vaginal misoprostol for IOL. This was comparable to the finding in a similar study by Adeniji *et al (*10,11). However, this was in contrast to findings in other related studies(8,12,13) that demonstrated significantly shorter induction to delivery interval in the vaginal misoprostol group. These results made some clinicians to believe that vaginal misoprostol was a more effective option for IOL and the use of Foley catheter to be limited; and this is without consideration of the reported comparative advantages and safety of Foley catheter with vaginal misoprostol from other similar studies (10,14).

A meta-analysis by Fox *et al* (15) suggested that there was similar effectiveness between vaginal misoprostol and transcervical foley catheter in achieving vaginal delivery, and within a comparable time frame. Correspondingly, this current study also demonstrated that the administration of vaginal misoprostol and the insertion of a transcervical Foley catheter for IOL had comparable effectiveness in achieving vaginal delivery (61.6% Vs 53.9%) with no significant difference in the need for oxytocin use in these groups. Yue Li *et al*[16]in a systemic review and meta-analysis on the same research topic corroborated the relative similarity in the rate of successful vaginal delivery in the two method groups in the reviewed studies but reported an additional need for oxytocin use in the transcervical Foley catheter balloon insertion groups for IOL when compared with the vaginal misoprostol group.

There is a clear disparity from some other studies, (8,13) however, this has favoured the use of vaginal misoprostol due to a significantly higher rate of vaginal delivery from it when compared with the Foley catheter group. This consequently has contributed to the tilt in preference of obstetricians for the use of vaginal misoprostol for initiating induction process, especially in the developing countries.

Despite the reported superiority efficacy of vaginal misoprostol above the Foley catheter in IOL from some studies, (17–19) there were likewise relatively higher maternal and perinatal adverse effects in vaginal misoprostol recorded in those studies. On the contrary, this present study revealed rare abnormalities in uterine contractility and perinatal outcomes which were similar in both groups; this is not different from documented outcomes by Chung *et al (*20) and Prager *et al (*21).

Most of these studies with varying documented superior efficacy of vaginal misoprostol above transcervical Foley catheter had a higher doses of misoprostol used for IOL which were cut pills into smaller pieces with the tendency of irregular dosage. However, our study utilized the lowest commercially prepared 25 micrograms (µg) pills of misoprostol (Misoclear). Also, the maximum tolerable volume of sterile water was used to inflate the catheter balloon. This may be responsible for the difference in results between our study and the earlier ones.

CONCLUSION

In conclusion, it is shown that between the two methods evaluated for cervical ripening and IOL in this study, there is no single technique proven to be superior; hence there is no need for selection bias of one method over the other by the physicians. This will prevent the trend of some obstetrics procedure from going obsolete in practice.

REFERENCES

1. Ahmed Y, Nwobodo EI, Ekele BA, Nnadi DC, Gana MA, Shehu CE. Misoprostol use for cervical ripening and induction of labour in a Nigerian teaching hospital. *Niger J Clin Pract* 2007; 10: 234–237. PMID: 18072452
2. Laxmi M, Vibhuti T, Kavisha L. A cross sectional study to compare effects of mechanical dilatation and sublingual misoprostol on induction of labor in a tertiary level government hospital. *Int J Reprod Contracept Obstet Gynecol* 2016; 5: 624–628. DOI: http://dx.doi.org/10.18203/2320-1770.ijrcog20160495
3. Thakur A, Uprety D, Yadav P, Dahav P, Thakur D. Randomized clinical trial comparing the efficacy of vaginal misoprostol and Foley catheter for cervical ripening and induction of labour. *Heal Renaiss* 2011; 9: 88–90. DOI: https://doi.org/10.3126/hren.v9i2.4979
4. Kwawukume EY, Ekele BA. Physiology and management of labour. In: Kwawukume EY, Ekele BA, Danso KA, Emuveyan EE (eds). *Comprehensive Obstetrics in The Topics*. Assemblies of God Literature Centre Ltd: Accra, 2015, pp 90–96.
5. Charaya E, Dahiya K. Comparative study of combined Foley bulb and vaginal misoprostol with vaginal misoprostol alone for cervical ripening and induction of labour. *Br J Med Heal Res* 2016; 3: 73–79. ISSN: 2394-967.
6. Noor N, Ansari M, Ali SM, Parveen S. Foley Catheter versus Vaginal Misoprostol for Labour Induction. Int J Reprod Med. 2015;2015:845735. doi: 10.1155/2015/845735. Epub 2015 Oct 18. PMID: 26557725; PMCID: PMC4628666.
7. Kehl S, Ziegler J, Schleussner E, Tuschy B, Berlit S, Kirscht J *et al.* Sequential use of double-balloon catheter and oral misoprostol versus oral misoprostol alone for induction of labour at term (CRBplus trial): a multicentre, open-label randomised controlled trial. *BJOG* 2015; 122: 129–136. DOI: 10.1111/1471-0528.13116
8. Osoti A, Kibii DK, Tong TMK, Maranga I. Effect of extra-amniotic Foley's catheter and vaginal misoprostol versus vaginal misoprostol alone on cervical ripening and induction of labor in Kenya, a randomized controlled trial. BMC Pregnancy Childbirth. 2018 Jul 12;18(1):300. doi: 10.1186/s12884-018-1793-2.
9. Charan J, Biswas T. How to calculate sample size for different study designs in medical research. *Indian J Psychol Med* 2013; 35: 121–126. DOI: 10.4103/0253-7176.116232
10. Adeniji OA, Oladokun A, Olayemi O, Adeniji OI, Odukogbe AA, Ogunbode O *et al.* Pre-induction cervical ripening: Transcervical foley catheter versus intravaginal misoprostol. *J Obstet Gynaecol (Lahore)* 2005; 25: 134–139. doi: 10.1080/01443610500040737.
11. Temesgen T, Figa Z, Gido R, Ahmed A, Getachew D, Andargie M, et al. Comparison of effectiveness of Foley catheter versus vaginal misoprostol for cervical ripening in induction of labour in Gedeo zone public hospitals, Ethiopia, 2022. Quasi-experimental design. DOI: 10.21203/rs.3.rs-2364842/v1.
12. Arya SB, Sinha M, Goel JK. A comparative study of intracervical foley's catheter with oxytocin and vaginal misoprostol for induction of labour. International Journal of Reproduction, Contraception, Obstetrics and Gynecology. 2020 Sep 1;9(9):3660-5. DOI: http://dx.doi.org/10.18203/2320-1770.ijrcog20203836
13. Abdi N, Alavi A, Pakbaz F, Darabi H. Vaginal misoprostol versus intracervical Foley catheter for cervical ripening in postdate primigravid women: a randomized clinical trial. BMC pregnancy and childbirth. 2021 Dec;21:1-6. DOI: https://doi.org/10.1186/s12884-021-04011-0
14. de Oliveira MV, von Oberst P, Corrêa Leite GK, Aguemi A, Kenj G, de Toledo Leme VD *et al.* Cervical Foley catheter versus vaginal misoprostol for cervical ripening and induction of labor: A randomized clinical trial. *Rev Bras Ginecol e Obstet* 2010; 32: 346–351. doi: 10.1590/s0100-72032010000700007.
15. Fox N, Saltzman D, Roman A, Klauser C, Moshier E, Rebarber A. Intravaginal misoprostol versus Foley catheter for labour induction: a meta-analysis. *BJOG* 2011; 118: 647–654. DOI: 10.1111/j.1471-0528.2011.02905.x
16. Yue L, Zhigang H, Liwen S, Jiawen Z, Jinbo W, Jiajing C. Foley catheter balloon versus prostaglandins for cervical ripening and labor induction: a systematic review and meta-analysis. *Int J Clin Exp Med* 2016; 9: 7573–7584.
17. Owolabi AT, Kuti O, Ogunlola IO. Randomised trial of intravaginal misoprostol and intracervical Foley catheter for cervical ripening and induction of labour. *J Obstet Gynaecol (Lahore)* 2005; 25: 565–568. doi: 10.1080/01443610500231450.
18. Roudsaria F V, Ayatia S, Ghasemia M, Mofrada MH, Shakerib MT, Farshidia F *et al.* Comparison of vaginal misoprostol with Foley catheter for cervical ripening and induction of labor. *Iran J Pharm Res* 2011; 10: 149–154. PMID: 24363694; PMCID: PMC3869583
19. Afolabi BB, Oyeneyin OL, Ogedengbe OK. Intravaginal misoprostol versus Foley catheter for cervical ripening and induction of labor. *Int J Gynaecol Obstet* 2005; 89: 263–7. doi:10.1016/j.ijgo.2005.02.010

20. Chung JH, Huang WH, Rumney PJ, Garite TJ, Nageotte MP. A prospective randomized controlled trial that compared misoprostol, Foley catheter, and combination misoprostol-Foley catheter for labor induction. *Am J Obstet Gynecol* 2003; 189: 1031–1035. doi: 10.1067/s0002-9378(03)00842-1.

21. Prager M, Eneroth-Grimfors E, Edlund M, Marions L. A randomised controlled trial of intravaginal dinoprostone, intravaginal misoprostol and transcervical balloon catheter for labour induction. *BJOG* 2008; 115: 1443–50. doi: 10.1111/j.1471-0528.2008.01843.x

Table I: Demographic profile and indication for IOL of participants

Variable	Group A n (%)	Group B n (%)	Total N (%)	χ^2	*p* value
Age group (years)					
Mean ± SD	28.69±5.61	30.03±4.02		-1.206[t]	0.232
Parity					
Nulliparous	14 (35.9)	8 (20.5)	22 (28.2)	2.279	0.131
Multiparous	25 (64.1)	31 (79.5)	56 (71.8)		
Median (IQR)	1 (1 – 3)	1 (1 – 2)		78.000[U]	0.606
Gestational age (weeks)					
Mean ± SD	40.10 ± 1.64	39.74 ± 1.85		0.909[t]	0.366
Indication for induction					
Postdatism	14 (35.9)	18 (46.2)	32 (41.0)	0.848	0.357
Prolonged pregnancy	8 (20.5)	6 (15.4)	14 (17.9)	0.348	0.555
Hypertensive disorders in pregnancy	17 (43.6)	12 (30.8)	29 (37.2)	1.372	0.241
Sensitized RH negative mother	0 (0.0)	1 (2.6)	1 (1.3)	1.013 [F]	1.000
GDM	0 (0.0)	2 (5.1)	2 (2.6)	2.053 [F]	0.494

χ^2: Chi square test; F: Fisher's exact test; t: Independent Samples T test; U: Mann-Whitney U test
Group A = Vaginal misoprostol alone group, Group B= Foley's catheter alone group.
GDM= gestational diabetes mellitus

Table II: Mean Bishop's Score and Induction time of participants with successful vaginal delivery

Variable	Group A	Group B	U/t	*p* value
Bishop's score before cervical ripening				
Mean ± SD	2.59 ± 1.57	2.28 ± 1.56		
Median (IQR)	3.00 (1.00 – 4.00)	2.00 (1.00 – 4.00)	673.500[U]	0.375
Bishop's score at favourable cervix				
Mean ± SD	8.39 ± 2.28	6.00 ± 2.07		
Median(IQR)	8.00(7.00 – 10.00)	6.00(4.00 – 7.00)	233.500[U]	**<0.001***
Induction to delivery interval	**(hour: min)**			
Mean ± SD	14:50 ± 5:24	13:34 ± 3:59	0.879[t]	0.384
Nulliparous	19:25 ± 1:52	-		
Multiparous	12:32 ± 5:07	13:34 ± 3:59	-0.691[t]	0.494

U: Mann Whitney U test; t: Independent Samples T test *: p value <0.05
Group A = Vaginal misoprostol alone group, Group B= Foley's catheter alone group.

Table IV: Induction delivery- interval and vaginal delivery among participants with need for oxytocin

Variable	Group A n (%)	Group B n (%)	Total N (%)	χ^2	p value
Participants with need for oxytocin					
Vaginal delivery					
Yes	10 (62.5)	15 (88.2)	25 (75.8)	2.972[F]	0.118
No	6 (37.5)	2 (11.8)	8 (24.2)		
Induction delivery interval					
Mean ± SD	15:24 ± 5:42	14:44 ± 4:10		0.337[t]	0.739
Participants without need for oxytocin					
Vaginal delivery					
Yes	14 (60.9)	6 (27.3)	20 (44.4)	5.140	**0.023***
No	9 (39.1)	16 (72.7)	25 (55.6)		
Induction delivery interval					
Mean ± SD	14:25 ± 5:21	10:39 ± 0:42		1.693[t]	0.108

χ^2: Chi square test; F: Fisher's exact test; t: Independent Samples T test; *: p value <0.05.
Group A = Vaginal misoprostol alone group, Group B= Foley's catheter alone group

Table V: Neonatal outcome

Variable	Group A n(%)	Group B n(%)	Total N (%)	χ^2	*p* value
Apgar 1 min					
< 7	14 (35.9)	13 (33.3)	27 (34..6)	0.057	0.812
= 7	25 (64.1)	26 (66.7)	51 (65.4)		
Apgar 5 min					
= 7	39 (100.0)	39 (100.0)	78 (100.0)		
Birth weight					
< 2.5	2 (5.1)	1 (2.6)	3 (3.8)	1.085[F]	0.753
2.5 – 3.9	35 (89.7)	34 (87.2)	69 (88.5)		
= 4.0	2 (5.1)	4 (10.3)	6 (7.7)		
NICU admission					
Yes	0 (0.0)	8 (20.5)	8 (10.3)	8.914[F]	**0.005***
No	39 (100.0)	31 (79.5)	70 (89.7)		
Outcome of NICU admission (n = 8)					
Discharged	0 (0.0)	8 (100.0)	8 (100.0)		
Perinatal mortality					
No	39 (100.0)	39 (100.0)	78 (100.0)		

χ^2: Chi square test; Y: Yates corrected Chi square; *: p value <0.05 (i.e. statistically significant)
Group A = Vaginal misoprostol alone group, Group B= Foley's catheter alone group

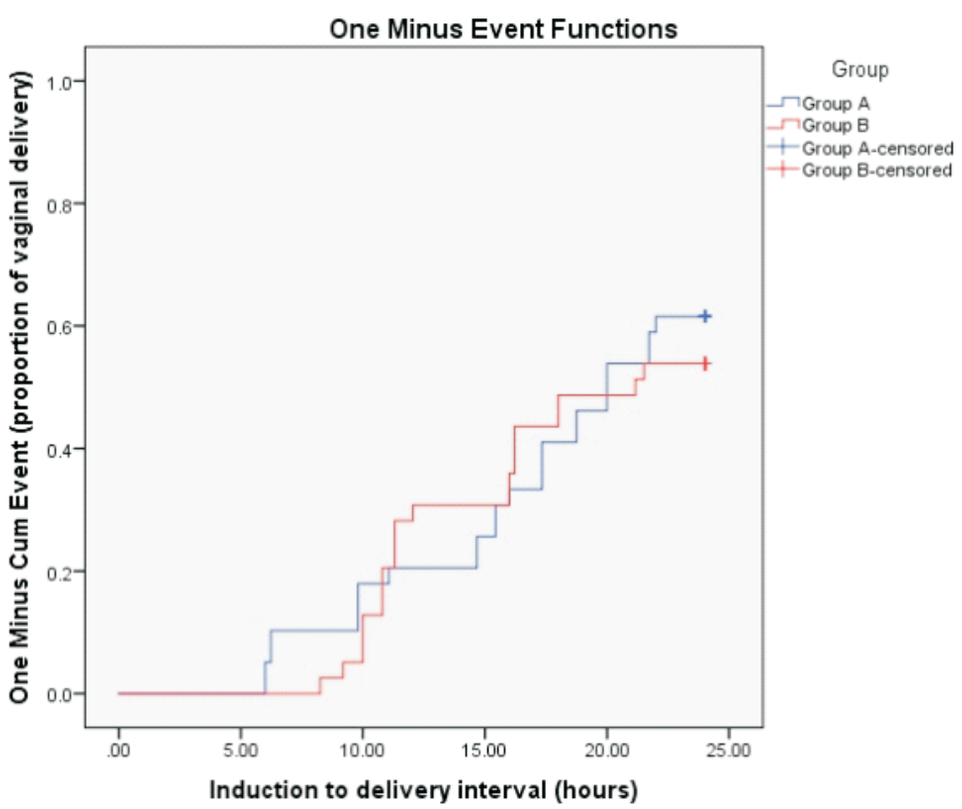

Figure 1: Kaplan-Meier curves showing the proportion of vaginal delivery (event) that had occurred within 24 hours.

Table VI: Proportion of patients who had vaginal delivery at 8, 12 and 24 hours from the point of induction

Duration (hours)	Group A n (%)	Group B n (%)	Total N (%)	χ^2	*p* value
= 8					
Yes	4 (10.3)	0 (0.0)	4 (5.1)	4.216[F]	0.115
No	35 (89.7)	39 (100.0)	74 (94.9)		
= 12					
Yes	8 (20.5)	11 (28.2)	19 (24.4)	0.626	0.429
No	31 (79.5)	28 (71.8)	59 (75.6)		
= 24					
Yes	24 (61.5)	21 (53.8)	45 (57.7)	0.473	0.492
No	15 (38.5)	18 (46.2)	33 (42.3)		

χ^2: Chi square test; *: p value <0.05 (i.e. statistically significant).
Group A = Vaginal misoprostol alone group, Group B= Foley's catheter alone group