

Factors associated with delayed onset of active labor following administration of vaginal Misoprostol among women at Mbarara Regional referral hospital, Uganda: A prospective cohort study

Rogers Kajabwangu (rogerskajabwangu@gmail.com)

Mbarara University of Science and Technology https://orcid.org/0000-0003-0371-7261

Francis Bajunirwe

Mbarara University of Science and Technology

Henry Lukabwe

Mbarara University of Science and Technology

Esther Atukunda

Mbarara University of Science and Technology

Baraka Munyanderu

Mbarara University of Science and Technology

Emilio Sanchez

Mbarara University of Science and Technology

Joanita Nakalinzi

Kampala International University

Godfrey Rwambuka Mugyenyi

Mbarara University of Science and Technology

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Abstract

Background Vaginal misoprostol has been recommended by the World Health Organization as one of the effective methods for induction of labor. Globally 9.6% of all deliveries follow induction of labor. Although the goal of labor induction is to initiate active labor with subsequent vaginal delivery, some mothers undergoing labor induction delay to get into active labor and some fail completely. The factors associated with delayed onset of active labor following labor induction with vaginal misoprostol have not been sufficiently explored in resource limited settings.

Methods We conducted a prospective cohort study over a period of 6 months on the antenatal ward and labor suit of Mbarara Regional Referral Hospital, southwestern Uganda. We enrolled mothers of gestational age at least 28 weeks, with indication for labor induction. They received 50 micrograms of vaginal misoprostol every 6 hours with a maximum of 4 doses and were followed up until onset of active labor. Onset of active labor was considered delayed if it occurred at more than 12 hours after administration of the first dose of vaginal misoprostol. Bivariate and multivariate analysis was done to determine the factors associated with delayed onset of active labor.

Results Eighty-eight mothers underwent induction of labor, 22.7% had delayed onset of active labor. After adjusting for potential confounders, low/no parity (Relative Risk or RR 2.67, p-value=0.01), low gestational age (RR 3.1, p-value=0.006) and higher BMI (RR 0.36, p-value=0.005), were associated with delayed onset of active labor following vaginal misoprostol administration.

Conclusion Nulliparity, gestational age less than 37weeks are associated with delayed onset of active labor following labor induction with vaginal misoprostol while BMI of 26 and above is protective from delayed onset of labor.

Background

Induction of labor (IOL) refers to techniques for stimulating uterine contractions to accomplish delivery of the feto-placental unit prior to the onset of spontaneous labor (1). These techniques may be mechanical or pharmacological but the goal of labor induction is to stimulate the uterus into active labor and ultimately achieve vaginal delivery. Because induction of labor is not risk-free, it should generally be performed when there is a clear medical indication, when the expected benefits outweigh its potential harms. Indications for induction of labor among others include gestational age of 41 completed weeks or more, pre-labor rupture of amniotic membranes, hypertensive disorders, maternal medical complications, fetal death, fetal growth restriction, chorioamnionitis, and vaginal bleeding. (2, 3).

Although methods for induction of labor include mechanical and pharmacologic approaches, the latter are more desirable. Among the pharmacologic methods, prostaglandins remain the single most effective means of achieving cervical ripening and inducing labor, providing good clinical effectiveness and patient satisfaction. Compared to other prostaglandins, misoprostol, a synthetic prostaglandin E_1 is preferred because it is stable at room temperature, relatively inexpensive and can be given via several routes

namely oral, vaginal, sublingual, and buccal, making it an ideal agent for induction of labor, particularly in settings where resources are limited (4-6). Vaginal misoprostol has been recommended by the World Health Organization as one of the effective methods for induction of labor. (2)

Although induction of labor has potential for preventing maternal complications and improving pregnancy outcomes (7), some women who undergo induction of labor fail to achieve active labor and vaginal delivery. Currently, there is limited research in resource limited settings to understand how frequently this occurs and even more importantly, the predictors of this failure. Understanding these factors helps to identify mothers who should not be subjected to IOL for fear of creating complications especially in rural settings where access to advanced obstetric care is limited. Therefore, the aim of this study was to determine the frequency of delayed onset of labor following labor induction and determine the associated factors in a resource limited setting.

Methods

Study design and setting

We enrolled pregnant women at the maternity ward of Mbarara Regional Referral Hospital, a public hospital that serves as the major referral site for the south western region of Uganda with a catchment population of over 5 million. Annually 12,000 deliveries are conducted at the hospital, and 4.2% of them follow induction of labor. We enrolled women presenting at the labor ward and followed them through to labor onset to ascertain study outcomes..

Eligibility criteria

Women were eligible if they were admitted on the maternity and met the indication for induction of labor. The mothers should have had 28 weeks of gestation or above, admitted for cervical ripening and/or induction of labor with vaginal misoprostol. We excluded those with known allergy to misoprostol.

Sample size and power calculation.

We used a cohort study design to calculate the sample size and assumed that mothers nulliparous mothers would have a 1.5 fold increase in the risk of having a failed IOL. Assuming a 95% confidence interval, a sample size of 88 mothers was sufficient to detect this relative risk with a power of 80%.

Data collection

Between October 2017- February 2018, data were collected using an interviewer administered questionnaire and from patient examination findings. The primary or dependent variable was delayed onset of active labor. Although there is a lack of complete consensus on the standard criteria for diagnosing successful or failed induction of labor, we considered onset of active labor as a measure of success rather than mode and time to delivery, which depend on an interaction of many factors, some of which are unrelated to the induction process(8, 9). Active onset of labor was defined as having adequate

uterine contractions and a cervical dilatation of 4cm or more. Delayed onset of active labor was defined as failure to achieve active labor after 12hours following initiation of labor induction.

Failed induction of labor was defined as failure to achieve active labor after 24 hours following initiation of labor induction

The independent variables included the following: age, address, income, alcohol intake, smoking, body mass index, use of herbs,HIV status, being on anti-diabetic medication, hypertension, concurrent medications, parity, gestational age, membrane status and Bishop score.

After the clinical team on maternity ward made the decision to perform induction of labor on a mother, the study team would approach her for consent. Women were followed up with 2-hourly reviews until onset of active labor. The research team did not have a role in decision making regarding the mothers who would get IOL.

Data analysis

The data were entered into MS Excel and exported to STATA version 13 for analysis. The sociodemographic and baseline obstetric, medical and behavioral factors were described using means and medians for continuous variables and proportions for categorical variables. The mean time to onset of active labor was calculated as the time interval between administration of vaginal misoprostol and onset of active labor for each mother.

The proportion of delayed onset of active labor was calculated as number of mothers who experienced delayed onset of active labor as numerator with those who received misoprostol as a denominator and a 95% confidence interval was calculated.

The proportion of mothers with failed induction (failure to achieve active labor after 24hours of misoprostol administration) was presented as a percentage of all mothers who underwent induction of labor with vaginal misoprostol during the study. A 95% confidence interval was calculated. The factors associated with delayed onset of active labor were established using risk ratios in both bivariate and multivariate analysis. All factors found to be significantly associated with delayed onset of active labor in bivariate analysis were further assessed in a multivariate analysis using logistic regression. A manual backward stepwise selection method was used in the multivariate model building. A significance level of 5% was used at all times. Both unadjusted and adjusted risk ratios with their corresponding 95% confidence intervals were reported.

Ethical clearance

Permission to conduct the study was obtained from the ward manager and the Department of Obstetrics and Gynecology. We received approval from the Faculty of Medicine research committee, and the Mbarara University of Science and Technology Research Ethics Committee provided final ethics approval for the study.

Results

Figure 1: Flow diagram to show patient recruitment in the study

Overall, 96 women underwent induction of labor during the study period. Of these, 4 were excluded because other routes of Misoprostol administration such as oral, were used. We also excluded 4 women who declined to consent. Figure 1 shows the summary of the patient flow and enrollment. Eighty-eight women were enrolled in the study.

Baseline characteristics of study participants (n = 88)

Tables 1 and 2 show the baseline demographic, obstetric and medical characteristics of the participants.

The mean age was 27 years and majority of the participants were aged between 25–34 years. Most of the participants were Protestants from Mbarara district, peasant farmers that had attended at most primary level of education.

Most of the participants were HIV negative, did not take alcohol and never used herbs, and were not taking antihypertensive medication. The average BMI at the time of delivery was 27.7 kg/m². Most of the mothers were multiparous, had attended four or more antenatal visits, with gestational age ranging between 37 and 41 weeks. The commonest reason for induction of labor was post-dated pregnancy

Proportion of mothers with delayed onset of active labor following vaginal administration of misoprostol

Twenty of the eighty eight mothers (22. 7%) experienced delayed onset of active labor that is, it took more than 12 hours before onset of active labor. The average time to onset of active labor was 7.7 ± 5.8 hours. The median time to onset of active labor was 6 hours

Proportion of patients who had delayed onset of active labor by parity

Of the 28 nulliparous women enrolled, 10 (35.7%) of them had delayed onset of labor following induction with vaginal misoprostol while only 16.7% (10 out of 60 women) of multiparous women (parity of two or more) had delayed onset of active labor.

Number of misoprostol doses required to achieve active labor

Figure 2: Number of misoprostol doses needed by mothers to achieve active labor

49 (57.7%) of the mothers got into active labor after administration of only one dose of vaginal misoprostol. 22%, 11% and 3% got into active labor following administration of 2, 3 and 4 doses of vaginal misoprostol respectively. On average, 1.6 ± 0.84 doses of misoprostol were required for a mother to get into active labor and the summary of the doses is shown in Figure 2.

Proportion of mothers who had failed induction of labor

2.3% of the mothers who underwent induction of labor with vaginal misoprostol had failed induction, namely they took more than 24 hours before achieving active labor.

Factors associated with delayed onset of active labor following vaginal misoprostol administration

Bivariate analysis of factors associated with delayed onset of active labor following vaginal misoprostol administration

Table 3 shows the results of the bivariate assessment between several factors and delayed onset of labor. Being on antihypertensive treatment, BMI, parity, gestational age and intrauterine fetal status (whether the fetus was dead or alive at the beginning of labor induction), were the factors associated with delayed onset of active labor on bivariate analysis. The rest of the socio-demographic, medical and obstetric characteristics including tribe, religion, level of education, occupation and use of herbs are not shown in the table and were not associated with delayed onset of labor following misoprostol administration.

Multivariate analysis of factors associated with delayed onset of active labor following vaginal misoprostol administration

Table 4 showing results from multivariate analysis regarding the association of participant characteristics with delayed onset of active labor following vaginal misoprostol administration

After adjusting for confounders, being nulliparous, and having gestational age less than 37weeks were significantly associated with delayed onset of active labor following vaginal misoprostol administration. BMI of 26 or higher reduced the odds of having delayed onset of active labor by more than 2 times.

Discussion

In our cohort of 88 women at a large maternity ward in Mbarara, southwestern Uganda, 22.7% of the mothers had delayed onset of active labor following misoprostol administration. The proportion is higher than that found in studies done in similar settings in resource limited countries. In a study done by Veena, etal, at a multispecialty teaching hospital in Bangalore, the proportion of mothers who failed to attain active labor within 12 hours of initiating labor induction, was 11.5%.(10). Their study however used sublingual misoprostol at an interval of 4 hours, which might explain the difference.

The average time to onset of active labor was 7.7 hours. These findings were similar to the findings of Ayaz, et al, (11, 12) (Ayaz et al., 2009),where 25ug of vaginal misoprostol administered every 3hours. When 25ug of was administered every four hours, the mean induction to active labor onset time was 8.5 \pm 5.1 hours. (13).

The proportion of mothers with failed induction of labor in this study was 2.3% This is in concordance with the findings from a study done in Nigeria in which 2% of the mothers who received vaginal

misoprostol 50ug six hourly did not get into active labor despite receiving the 3doses of misoprostol according to their protocol.(14)

In contrast, in a study done in India, 9.62% of the mothers who received a similar dose 50ug of vaginal Misoprostol like in our study failed to get into active labor after 24 hours of administration of the drug. However, in their study, active labor was diagnosed only when the mother had 3 or more contractions in 10mins, each lasting at least 60seconds thus possibly explaining the higher proportion.(15). In an even more contrasting study done in China, 52% of the mothers receiving vaginal misoprostol failed to achieve onset of active labor with in 24hours. The participants in this study were nulliparous Chinese women who received 25ug of vaginal misoprostol four hourly with a maximum of 3doses and this explains the difference in the findings.(16)

Our study found parity to significantly associated with delayed onset of active labor. Nulliparous women were 3 times more likely to have delayed onset of active labor compared to their multiparous counterparts. Whether labor is induced or spontaneous, its progression is slower in nulliparous women compared to multiparous women. (17–19)

Women with preterm pregnancies (gestational age less than 37 weeks) were more likely to have delayed onset of active labor, In a relatively similar study done in Uganda, induction-delivery time, a fair indicator of labor progression, reduced with increasing gestational age. (20). Crane and colleagues noted that most of the women with high gestational age attained active labor after only 4 to 6 hours while their counterparts with lower gestational age took longer.(21). Other researchers have however not found gestational age to affect labor progression. (22)

In this study, body mass index of 26 and above (measured at the time of delivery), was protective from delayed onset of active labor. Previously, some studies have found increasing BMI to be associated with delayed labor progression (23–25). These studies however predominantly considered BMI measured before 20weeks of gestation. Also, the participants in these studies had generally higher BMI compared to our study which had generally lean women with an average BMI of 27. Other studies have however found no effect of BMI on labor duration. (26, 27).

Bishop Score was not significantly associated with delayed onset of active labor in our study, a finding in agreement with other studies elsewhere in India (10), and the United States(17). However, some studies have found that higher Bishop score significantly decreases the induction to delivery interval. (28, 29)

Membrane status was not significantly associated with delayed onset of active labor. This is partially in agreement with the findings elsewhere (30) who considered induction success to be delivery within 24 hours. Kehl, etal, however found higher induction success rate as evidenced by high vaginal delivery rate within 24 hours in mothers with ruptured membranes compared to those with intact ones. (28). Their study however used oral and not vaginal misoprostol

Our study has some strengths. First, it was conducted in southwestern Uganda, making it one of the few studies to investigate this subject in resource-limited settings. Secondly, we assessed women in real time and followed them through to ascertain study endpoints. However, our study has some limitations. Misoprostol was only available in the strength of 200 micrograms. It was therefore challenging to break the tablet into exactly equal proportions. We used a surgical blade to ensure that the tablet was divided into 4 equal parts. We also did not use cardiotocography to record uterine contractions and fetal wellbeing, as we did not have access to this equipment. Instead, we used abdominal palpation in short intervals to assess uterine contractions.

Conclusion

In conclusion, nulliparity and gestational age less than 37weeks are associated with delayed onset of active labor following labor induction with vaginal misoprostol. This finding suggests that women with these characteristics may need monitoring for a longer duration following initiation of labor induction. For obstetricians and midwives operating in settings where both human and infrastructural resources are limited, this is important guidance in managing these mothers. BMI of 26 and above is protective from delayed onset of active labor. More follow up studies with measurements of pre-pregnancy BMI need to be carried out to further evaluate its effect on the labor-induction process in our setting.

List Of Abbreviations

MoHMinistry Of Health

IOLInduction of Labor

MRRHMbarara Regional Referral Hospital

MUSTMbarara University Of Science And Technology

REC Research Ethics Committee

MCHMaternal and Child Health

WOAWeeks of Amenorrhoea

BMI Body mass index

Declarations

Ethical approval and consent to participate

The protocol was presented to the department of obstetrics and gynaecology and approval obtained from the Mbarara University of Science and Technology Research Ethics Committee (reference number 06/08–

17). Written informed consent was obtained from all participants before enrollment into the study.

Consent for publication

Not applicable

Availability of data and materials

The data set from which conclusions were drawn are presented in the main paper. Data are available from the corresponding author on reasonable request, after obtaining relevant approvals from Research Ethics Committee at Mbarara University of Science and Technology.

Competing interests

The authors declare that they have no competing interests.

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Author's contribution

RK and GRM conceived the idea. RK and GRM supervised data collection. RK, FB, HL, BM, EA, ES and JN participated in data analysis and/or interpretation. RK, GRM and FB wrote the first draft. All authors read, revised and approved the final draft of the manuscript.

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Tables

Table 1: Baseline demographic characteristics of study participants (n=88) (page 11)

Characteristic	Frequency n(%)	
Age in years(mean, SD) 27.0 (5.9)		
Age categories		
18-24	33 (37.7)	
25-34	42 (47.7)	
35-42	13 (14.8)	
District		
Mbarara	58 (65.9)	
Isingiro	19 (21.6)	
Others	11 (12.5)	
Religion		
Catholic	25 (28.4)	
Protestant	32 (36.3)	
Moslems	15 (17.1)	
Pentecostals	16 (18.2)	
Marital status		
Married	86 (97.7)	
Single/separated/divorced	2 (2.3)	
Level of education		
No formal	6 (6.8)	
Primary	36 (40.9)	
Secondary	28 (31.8)	
Tertiary	18 (20.5)	
Occupation		
Unemployed	20 (22.7)	
Peasant farmer	28 (31.8)	
Business	26 (29.6)	
Professional	14 (15.9)	

Table 2: Baseline medical, behavioral and obstetric characteristics (page 11)	

Characteristic	Frequency	
	n (%)	
HIV treatment		
Not on treatment	79 (89.8)	
On treatment	9 (10.2)	
Antihypertensive medication		
Not on treatment	82 (93.2)	
On treatment	6 (6.8)	
Recent intake of herbs		
Had not taken	57 (64.8)	
Had taken	31 (35.2)	
Prior alcohol intake		
No Prior intake	85 (96.6)	
Prior intake	3(3.4)	
ВМІ		
Normal (18.5- 25.9)	30 (34.1)	
Overweight (26-29.9)	32 (36.4)	
Obese (30 or more)	26 (29.6)	
Antenatal visits		
Less than 4	20 (22.7)	
4	48 (54.6)	
More than 4	20 (22.7)	
Parity		
0	27 (30.7)	
1 to 4	48 (54.6)	
5 or more	13 (14.8)	
Gestational age		
29 to 36 weeks	16 (18.2)	
37 to 41 weeks	55 (62.5)	
42 or more weeks	17 (19.3)	

Reason for Induction	
Elective	13 (14.8)
Pre-Labor Membrane Rupture	18 (20.5)
Pre-Eclampsia	5 (5.7)
Intra-Uterine Fetal Death	14 (15.9)
Post-Term Pregnancy	17 (19.3)
Postdated Pregnancy	19 (21.6)
Oligihydramnios	2 (2.3)

Table 3:Bivariate logistic analysis (page 13)

VARIABLE	Crude RR(95% CI	P-value
Age categories		
18-24	Reference	
25-34	5.12 (0.74, 35.28)	0.097
35-42	1.86 (0.25 , 14.05)	0.549
District		
Mbarara	Reference	
Others	1.93(0.91,4.12)	0.088
HIV treatment		
Not on treatment		
On treatment	0.98 (0.27 , 13.4)	0.970
Antihypertensive treatment		
Not on treatment		
On treatment	2.41 (0.98 , 5.97)	0.057
Prior alcohol intake		
No prior intake		
Prior intake	1.49 (0.29 ,7.75)	0.635
BMI		
Normal (18.5 - 25.9)		
Overweight and Obese (>=26)	0.38 (0.18 , 0.79)	0.01
Antenatal visits		
<4	1.09(0.43, 2.74)	0.853
4	Reference	
>4	0.87(0.31,2.42)	0.793
Parity		
Nulliparous	2.14 (1.01, 4.55)	0.047
Multiparous	Reference	

Gestational age			
29-36	3.44 (1.53 ,7.70)	0.010	
37-41	Reference		
>=42	1.62 (0.55, 4.72)	0.378	
Membrane status	1.46(0.48 ,4.43)		
Intact	Reference	0.507	
Ruptured	Reference		
Intrauterine fetal status			
Alive			
Dead	2.27 (1.05 , 4.88)	0.037	
Bishop score			
<7	Reference		
>/= 7	1.89 (0.61 , 5.84)	0.269	

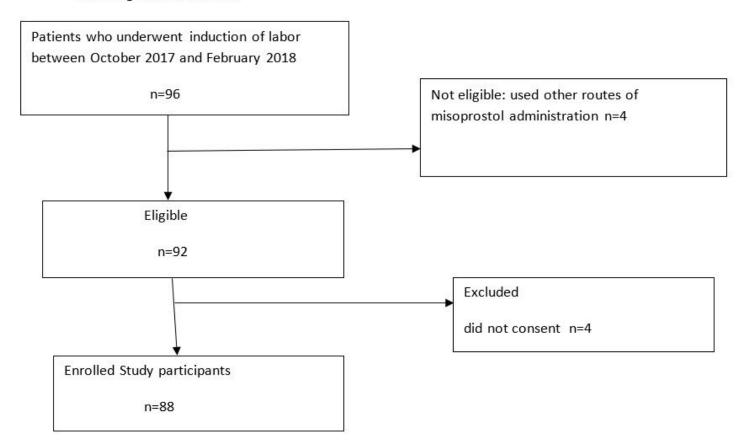
^{*}significant at 0.05 level

Table 4: multivariate analysis (page 13)

Variable	Unadjusted	p-	Adjusted RR (95%	p-value
	RR(95% CI	value	CI)	
Parity				
Nulliparous	2.14 (1.01, 4.55)	0.047	2.67 (1.26, 5.66)	0.010
Multiparous	Reference			
Gestational age				
29-36	3.44 (1.53 ,7.70)	0.010	3.13 (1.38, 7.07)	0.006
37-41	Reference			
>=42	1.62 (0.55, 4.72)	0.378	1.90 (0.69, 5.23)	0.214
Antihypertensive				
treatment	2.41 (0.98 ,5.97)	0.057	3.10 (0.90, 11.1)	0.080
Yes				
No				
Intrauterine Fetal status				
Alive				
Dead	2.27 (1.05 ,	0.037	1.08 (0.40, 2.97)	0.877
	4.88)			
BMI				
18.5 - 25.9				
>=26	0.38 (0.18 ,0.79)	0.010	0.360 (0.18, 0.73)	0.005

Figures

Participant enrolment



Flow diagram to show patient recruitment in the study

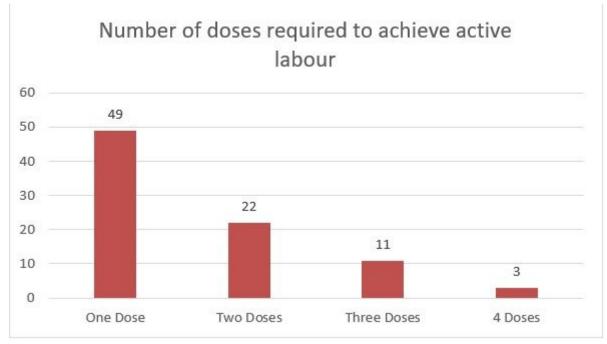


Figure 2

Number of misoprostol doses needed by mothers to achieve active labor