

Cervical Ripening for Induction of Labor: A Randomized Comparison between Vaginal Misoprostol versus Foley's Catheter Placement in a Nigeria Tertiary Hospital

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Abstract

Background: Cervical ripening is prerequisite of successful induction of labor. Vaginal misoprostol and Foley's catheter placement have been widely used for this purpose but the data are not always sufficient. We attempted to determine which (misoprostol versus Foley's catheter) is more effective/safer in Nigerian setting. **Methods:** A randomized controlled trial was performed at Federal Teaching Hospital Abakaliki, Nigeria, involving 135 term pregnant women requiring cervical ripening and labor induction. Participants were randomly allocated to misoprostol versus catheter group. The following were recorded/measured/analyzed: Bishop's score, age, parity, body mass index, gestational age, labor duration, indication, oxytocin use, mode of delivery, and Apgar score. Chi square test and t test were used where appropriate. **Results:** At 24 hours, all of misoprostol group were either in labor, had ripe cervix, or had delivered, whereas 35.4% of catheter group had still unripe cervix ($\chi^2 = 29.856$, $P = 0.0001$). Misoprostol group was less likely to require oxytocin infusion ($\chi^2 = 52.600$, $P = 0.0001$) and less likely to require cesarean delivery (cesarean: misoprostol versus catheter: 11% versus 34% ($\chi^2 = 9.800$, $P = 0.001$)). Total medical cost for misoprostol was less than that of catheter ($\chi^2 = 14.703$, $P = 0.0001$). **Conclusion:** 50 μ g vaginal misoprostol, compared with catheter placement, was more effective, cheaper, and safe as a procedure of cervical ripening before induction of labor.

Keywords

Cervical Ripening, Labor Induction, Misoprostol, Balloon Catheter

1. Introduction

Induction of labor requires cervical ripening and many strategies have been reported for cervical ripening, among which misoprostol and Foley's catheter are widely known. Which is better of the two is not always determined, especially in Nigeria, thus we attempted to determine it as well as the benefits and harms of the methods [1]. In about 10% of all pregnancies, the cervix is unfavorable and there are conflicting reports on the relationship between the Bishop's score (cervical changes) and the success of labor induction. Some showed inverse while others showed no relationship [2] [3] [4].

There are conflicting reports on the efficacies, cost and safeties of the use of Foley's catheter and misoprostol for cervical ripening and induction of labor. Some reported in favor of catheter, others reported in favor of misoprostol while some reported similar effects [2] [5]-[10]. Some studies however demonstrated increased risk of maternal and fetal infection with the use of catheter [11] [12].

Studies have also demonstrated increased risk of hyper stimulation, non-reassuring fetal heart rate pattern, admission into the newborn unit and uterine rupture associated with misoprostol [13] [14] [15] [16] [17]. The case of uterine rupture was recorded in the study that used 100 µg of misoprostol [17]. The rate of induction is on the increase, 35.5% in Sri Lanka, 24.5% in USA, 33% in Europe, 12.7% in Ibadan Nigeria and 11.5% in Abakaliki [3] [18]. Studies on maternal mortality in Ebonyi State have reported high maternal mortality ratios both in the rural and urban areas where uterine rupture was reported as a major cause due to injudicious use of uterotronics [19] [20] [21] [22].

Objectives:

- 1) To determine and compare the efficacies and safeties of misoprostol and balloon catheter for cervical ripening and induction of labor.
- 2) To determine the effective and safe dosage of misoprostol for cervical ripening and induction of labor for our clients.
- 3) To determine and compare the cost of each method.

Research Questions: Is there a difference in the efficacy, cost and safety of intracervical Foley's catheter balloon and intravaginal misoprostol for cervical ripening and induction of labor?

2. Materials and Methods

2.1. Background

Ebonyi state is a low resource state, it has one urban and one semi-urban setting while the rest are rural settings. Ignorance and poverty is prevalent and with tendency to high parity and low acceptance rate for contraception and family planning. The Federal Teaching Hospital is the tertiary hospital located at Abakaliki the capital city of the state. It serves as the referral center for the state and some parts of the surrounding states. Most of the labor induction and cervical ripening in the state take place in the center.

2.2. Study Population

This is a randomized controlled trial that included all parturients requiring cervical ripening at term in the Obstetrics and Gynecology unit of the Federal Teaching Hospital, Abakaliki during the study period. The parturients were recruited by simple random sampling method (lucky dip) till the required sample size was obtained. The exclusion criteria were those who refused consent, pre-term delivery, vaginal infection, non-cephalic presentation, multiple gestation, low lying placenta/previa, vaginal bleeding, previous cesarean section and ruptured membranes. Parturients who gave consent, had low bishop score (≤ 5), term singleton cephalic presenting fetus with intact membranes and no contraindication to vaginal delivery were recruited into the study. The purpose and methods of the study as well as the possible adverse events that can occur were explained to the parturients in details and informed consent obtained prior to enlisting them into the study.

2.3. Sample Size Calculation

Considering a formula for sample size calculation in a randomized clinical trial by Marlies Noordzii *et al.* [23]

$$n = 2 \left[(a + b)^2 \delta^2 \right] / (\mu_1 - \mu_2)^2$$

$$n = 62.8$$

= 63 parturients in each group giving a total of 126 parturients.

A response rate of about 90% was anticipated thus the final sample size was;

$$N = 126 / 0.9 = 140, \text{ i.e. } 70 \text{ parturients per arm.}$$

2.4. Study Design

This was a randomized controlled trial made up of two arms or groups. The first arm or group—1 had cervical ripening with intra-cervical extra-amniotic Foley's balloon catheter while group—2 had cervical ripening with intra-vaginal misoprostol. The parturients were selected by simple random sampling method and recruited into the arms of the study. Each parturient picked by simple lucky dip from a pool of folded papers with inscription group 1 or group 2 in a bag in a double blinded manner and were recruited into the group picked among the two arms of the study.

2.5. Procedure

The Bishop's score of the cervix was accurately determined and documented before cervical ripening. Bishop's score of ≥ 6 was considered ripe or favorable for induction.

Catheter arm

Size 18 Foley's catheter was introduced through the cervix to the extra-amniotic space with the aid of a speculum and sponge-holding forceps by strict aseptic technique. The vulva was swabbed thoroughly with chlorhexidine swab before

the procedure. Sterile speculum was inserted into the vagina to expose the cervix. With good light source, the catheter was carried with sterile sponge holding forceps making sure it does not touch the vaginal wall and introduced through the cervical os into the uterine cavity but in the extra-amniotic space. The catheter balloon was then inflated with 30 ml of sterile water for injection. The catheter was then placed with minimal traction by strapping the end to the inside of the parturient's thigh. The parturient was observed for 12 hours after which it was removed if it has not fallen off. The procedure was repeated for another 12 hours if the cervix is not ripe with the first procedure. The process was considered to have failed if the cervix is not ripe after the second procedure and another method of cervical ripening was employed. At the expulsion or removal of the catheter, the Bishop's score was reassessed to determine cervical ripening and those whose cervixes were ripe were observed for two hours for evidence of spontaneous labor.

Misoprostol arm

In this arm, 50 µg (1/4th of 200 µg) misoprostol tablet was placed in the posterior fornix of the vagina every 6 hours for a maximum of 4 doses. At each insertion the vulva was thoroughly swabbed with chlorhexidine swab and aseptic procedure was maintained. The parturient was monitored closely to rule out hyper stimulation. Before the insertion of subsequent doses, the parturient was re-evaluated for the presence of contractions and Bishop's score noted. Those with ripe or favorable cervix and or contractions had no further insertions. Those with unripe cervix had further insertions to a maximum of 4 doses, while those with ripped cervix were observed for 2 hours to see if they will go into active labor.

Both arms received prophylactic antibiotics of ampiclox. Those who transformed into active labor within 2 hours of observation were transferred into the labor room and their labor monitors with partograph with the aim of at least 1 cm cervical dilatation per hour, failure of which the labor was augmented with intravenous oxytocin. Those who did not transform into active labor within this period had synchronous induction of labor with oxytocin and artificial rupture of membranes and partograph monitoring. Oxytocin titration for induction of labor was done with 10 IU (international unit) of oxytocin in 1 liter of normal saline starting with 10 drops per minute and escalating by 10 drops every 45 minutes till end point of 3 strong uterine contractions in 10 minutes or 60 drops per minute. The procedures was considered to have failed if after 24 hours the cervix was not ripe for induction or after 16 hours of induction, adequate uterine contractions leading to vaginal delivery was not achieved or the procedure ended in caesarean section.

2.6. Data Collection

Information on age, height, weight, parity, gestational age, Bishop's score, indications for induction, mode of delivery, complications, apgar scores and cost

were obtained. The information obtained was recorded in the data collation sheet designed for the study.

2.7. Data Analysis

The coded data was fed into the computer using IBM SPSS program (2007), Illinois USA version 20 and analysis done. Descriptive and inferential statistics were used for quantitative variables, chi square was used to compare categorical variables while t-test was used to compare mean. $P < 0.05$ was considered significant.

2.8. Ethical Issues

Full ethical approval was obtained from the Research and Ethics Committee (REC) of Federal Teaching Hospital, Abakaliki where the study was conducted in conformity with the Helsinki Declaration (REC No. 24/02/2015-22/071015). The study was also registered with the PRS of clinicaltrials.gov (Protocol ID: NCT02574338, Unique ID: MSFC-2015-CT). Informed consent was obtained from the parturients before recruitment into the study and confidentiality was ensured.

3. Results

A total of 135 parturients requiring cervical ripening and induction of labor for various indications were recruited by simple lucky dip into the study in a randomized pattern into two groups 1 & 2. There was no difference in the maternal age, parity, body mass index and gestational age at cervical ripening between the groups $p > 0.05$ (Table 1).

The commonest indication in the study for cervical ripening and induction of labor was postdate pregnancy (70.4%), followed by preeclampsia (20%) (Table 2). At 12 hours, 60/70 (85.7%) of the parturients that received misoprostol were either in labor or had their cervix ripe already after one or two insertion/s. Among the parturients that had catheter only 21/65 (32.3%) had their cervix ripe and none went into spontaneous labor. This difference was significant ($\chi^2 = 40.055$, $p < 0.0001$) (Table 3). At 24 hours, all parturients in the misoprostol group had delivered or in labor had ripe cervix while the catheter group had 23/65 (35.4%) parturients whose cervix were not ripe. This was also significant ($\chi^2 = 29.856$, $p < 0.0001$) (Table 3).

The age and parity of the parturients had significant effect on the outcome of cervical ripening and labor induction while body mass index and gestational age did not (Table 4). The time taken for the cervix to ripe as shown by the number of insertions received by parturients had very significant effect on the duration of labor ($\chi^2 = 38.024$, $p < 0.0001$) (Table 5).

Majority of the parturients in the misoprostol group (60.0%) did not require the use of oxytocin in their labor and this was very significant. ($\chi^2 = 52.600$, $p < 0.0001$) (Table 6).

Table 1. Sociodemographic characteristics of the parturients.

Variable	Catheter group	Misoprostol group	Total	X ²	P
Age					
20 - 24	7	10	17		
25 - 29	23	24	47		
30 - 34	23	24	47	0.0725	0.7877
35 - 39	10	10	20		
40 - 44	2	2	4		
Parity					
1	18	24	82		
1 - 4	45	44	89	0.4622	0.4965
≥5	2	2	4		
Body Mass Index					
18.5 - 24.9	17	13	30		
25.0 - 29.9	32	30	62	0.0921	0.8645
≥30	15	28	43		
Gestational age					
<38 weeks	3	9	12		
38 - 40 weeks	11	20	31	0.3514	0.5533
>40 weeks	51	41	92		

Table 2. Indication for cervical ripening/induction of labor.

Indication	Group		Total	%
	Catheter	Misoprostol		
Postdate	52	43	95	70.4
Preeclampsia	10	17	27	20.0
Fetal death	1	2	3	2.2
Others	2	8	10	7.4

Table 3. Cervical ripening at 12 and 24 hours.

Catheter	Misoprostol		x ²	p	
	Riped	Unripped			Riped
@ 12 hours					
	21 32.3%	44 67.7%	60 85.7%	10 14.3%	40.055 <0.0001
@ 24 hours					
	42 64.6%	23 35.4%	70 100%	0	29.856 <0.0001

The parturients in the misoprostol group had less failed procedure (11.4%) compared to those of the catheter group (33.8%). The difference was significant. Most of the failed procedure misoprostol group was due to non-reassuring fetal heart rate (87.5%) (**Table 7**).

There was no difference in apgar scores of the two groups (**Table 8**). The mean cost for group 1 that had catheter was USD5 ± 1 while that of group 2 that received misoprostol was USD2 ± 1. This was very significant (t-test = 14.703, $p \leq 0.0001$) (**Table 9**).

Table 4. Sociodemographic variables and cervical ripening at 12 hours.

Variable	Catheter		Misoprostol		χ^2	<i>p</i>
	Ripid	Unripid	Ripid	Unripid		
Age						
20 - 24	2	5	7	3		
25 - 29	5	18	19	5		
30 - 34	8	15	22	2		
35 - 39	6	4	10	0		
40 - 44	0	2	2	0	5.551	0.009
Parity						
0	2	16	16	8		
1 - 4	18	27	42	2		
≥5	1	1	2	0	10.854	0.002
Body Mass Index						
18.5 - 24.9	6	11	8	4		
25.0 - 29.9	12	20	27	3		
≥30.0	3	12	25	3	4.297	0.058
Gestational age						
<38 weeks	1	2	8	1		
38 - 40 weeks	4	7	18	2		
>40 weeks	16	35	34	7	0.634	0.160

Table 5. Time taken for the cervix to ripe and duration of labor.

Group	Time of ripening	Labor duration		χ^2	<i>p</i>
	Hours (hrs)	≤8 hrs	>8 hrs		
Catheter					
1 insertion	12	15	7		
2 insertions	24	16	27		
Misoprostol					
1 or 2 insertion	6 - 12	53	7		
≥3 insertions	12 - 24	6	4	38.024	<0.0001

Table 6. Oxytocin use for induction/augmentation of labor.

Procedure	Group		χ^2	<i>p</i>
	Catheter	Misoprostol		
Induction	56	18		
%	86.2	25.7		
Augmentation	5	10		
%	7.7	14.3		
None	4	42		
%	6.2	60.0	52.600	0.0001

Table 7. Mode of delivery/indication for abdominal delivery.

Route	Group				χ^2	<i>p</i>
	Catheter	%	Misoprostol	%		
Vaginal	43	66.2	62	88.6		
Abdominal	22	33.8	8	11.4	9.800	0.001
Indication						
NRFR	8	36.4	7	87.5		
Failure to progress	14	63.6	1	12.5		

*NRHR—non-reassuring fetal heart rate.

Table 8. Apgar scores at 1st and 5th minutes in the groups.

Apgar score	Group				x ²	P
	Catheter	%	Misoprostol	%		
1 st minute						
≥7	60	92.3	64	91.4	0.035	0.242
<7	5	7.7	6	8.6		
5 th minute						
≥7	64	98.5	68	97.1	0.270	0.391
<7	1	1.5	2	2.9		

Table 9. Mean cost per patient in each group.

Group	Number	Mean	std	t	P
Catheter	65	USD 5	1	14.703	<0.0001
Misoprostol	70	USD 2	1		

+USD—United States Dollar.

4. Discussion

A total of 135 parturients at term were recruited into this study, 65 parturients in the catheter arm and 70 in the misoprostol arm. At 24 hours, 64.6% of the catheter arm had ripe cervix while 35.4% had unripe cervix. In the misoprostol arm, all 70 (100%) had ripe cervix at 24 hours. Thirty four percent of parturients in the catheter arm ended with abdominal delivery while only 11.4% of those in the misoprostol arm had abdominal delivery. These differences were statistically significant. This demonstrates the superiority of misoprostol to catheter for cervical ripening and subsequent induction of labor. There are varied reports from studies in the past, some reported similar efficacies while others reported superiority of prostaglandins [2] [5]-[10] [15]. A study in Lagos, Nigeria demonstrated the superiority of misoprostol to catheter for cervical ripening and induction of labor [15]. Other studies demonstrated shorter induction–delivery interval for misoprostol, low cesarean section rate and more likelihood of delivery within 24 hours [13] [14]. However, Tobawei and Oboro concluded from their study that the efficacy and safety of low dose misoprostol compared with balloon catheter in developing countries are undetermined [17].

The indication for abdominal delivery in the misoprostol arm was mainly due to non-reassuring fetal heart rate. There were similar reports from previous studies [14]. This study however demonstrated no difference in the apgar scores in the catheter and misoprostol groups. This shows that there may not be any net adverse effect of misoprostol on the neonatal outcome. This is however different from the study Martinez Kreft *et al.* which reported increased referral to neonatal intensive care for parturients that received 50 µg of misoprostol for labor induction [13].

The age and parity of parturients had significant effect on the outcome. Young nulliparous parturients and those of lower parity had poorer outcome compared

to those of higher parity. This may be due to poorer response to uterotonics that may be prevalent in this group [24] [25] [26]. The body mass index and gestational age however did not have significant effect on outcome. This may be due to local administration of the agents which are more likely to act locally. The parturients recruited in the study all had term pregnancies when adequate receptor elaboration assumed to have occurred.

The time taken for the cervix to ripe had direct effect on the labor duration. The parturients whose cervixes were ripe within 12 hours were more likely to deliver within 8 hours. This was statistically significant. Majority of the parturients in the catheter arm required oxytocin use for induction or augmentation of labor but those in misoprostol group went into active labor spontaneously, did not require oxytocin and were also more likely to deliver vaginally within 24 hours. This difference was very significant. There had been similar reports from previous studies [2] [15] [16].

There was no case of infection recorded during the study period. This may be due to the use of prophylactic antibiotics as well as strict asepsis ensured during the procedure. A systemic review with meta-analysis of 30 randomized controlled trials comparing mechanical methods with pharmacologic agents or placebo, however demonstrated increased maternal and neonatal infection among the parturients that underwent mechanical methods of cervical ripening [11]. A study in Italy however demonstrated the safety of cervical ripening with the Foley catheter with negligible risk of infection [12]. This study has also shown that the dose of misoprostol used was effective and safe as there was no case of uterine hyper stimulation or rupture recorded. The study in Lagos Nigeria reported uterine hyper stimulation and rupture but 100 µg of misoprostol was used in the study [15].

Finally, the parturients in the catheter arm spent more than double the amount spent by those in misoprostol for cervical ripening, hence demonstrating the cost effectiveness of misoprostol compared to catheter.

5. Conclusion

We conclude that 50 µg vaginal misoprostol, compared with catheter placement, was more effective, cheaper, and safe as a procedure of cervical ripening before induction of labor.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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