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

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Abstract

Background

Induction of labor is defined as iatrogenic stimulation of uterine contractions to cause the delivery of fetus before the onset of spontaneous labour. An unfavorable cervix is a critical factor the obstetrician must overcome to improve the efficacy of induction of labor. At present, both medical and mechanical methods have been applied for cervical ripening in women with an unfavorable cervix. In developing countries like Ethiopia, conventionally cheap and feasible method used for preinduction cervical ripening is transcervical Foley's catheter and misoprostol become practically important. So this study is designed to investigate the effectiveness of the most commonly ripening techniques (Foley catheter and vaginal misoprostol) in Gedeo zone.

Method

This is a quasi-experimental study to compare the effectiveness of Foley catheter and vaginal misoprostol for cervical ripening for labor induction. It was conducted in 120 pregnant mothers coming for induction who fulfil the inclusion criteria. Sixty mothers were assigned to the Foley catheter (group 1) and the remaining 60 mothers were grouped to misoprostol (group 2). Data was collected consecutively with a structured tool for both groups by trained data collector. Data analysis was done using the SPSS version 25. Chi-square analysis was used for comparing proportions of categorical variables while the student's independent 't' test was used for comparing means of continuous variables where applicable. To calculate the time intervals, log rank test life table was used. P- Value was calculated to declare level of statistical significance at $P < 0.05$.

Result

the 41(68.3%) participants of folley catheter group and the 49(81.7%) of misoprostol group had favourable cervix within the 24 hrs. The mean time interval from the starting of ripening to favourable cervix was found shorter in the misoprostol group (10.27 ± 2.506) than the Foley catheter group (11.78 ± 2.151). In the induction of labor incidence of meconium was more in the misoprostol group than the Foley catheter group. The successful outcome of the induction was 33(80.5%) in Foley catheter group and (35(71.4%) misoprostol group. The mean time interval between starting of induction to delivery was almost the same between the two groups (7.56 + 2.97) and (6.96 + 2.226) respectively.

Introduction

Induction of labor is artificial stimulation of uterine contractions to initiate labour before the natural onset of labour. Labor is usually initiated by cervical ripening agents, artificial rupture of membranes, and uterine stimulation with oxytocin(1). Induction of labor with the goal of achieving vaginal delivery prior to

spontaneous onset of labor is recommended when the benefits of delivery out-weight the risk of continuing the pregnancy(2). The ripeness of the cervix is of critical for successful labour induction. Induction of labour is a common obstetric intervention and world-wide, 20–30% of deliveries are induced. In Abakaliki, Ebonyi State rate of induction of labour was 2.76% and the success rate was 75.4%(3). The most common indication for caesarean section was ‘failure to progress’ with or without a non-reassuring foetal heart rate pattern(4).

An unfavorable cervix is critical to improve the efficacy of induction of labor. At present, both medical and mechanical methods have been applied for cervical ripening in women with an unfavorable cervix(5).The Foley catheter balloon is one of the oldest mechanical devices commonly used for cervical ripening and induction of labor. Foley catheters achieves vaginal delivery, with fewer maternal, and neonatal side effects(6). Prostaglandins are now widely used cervical ripening agent in induction of labor(7) .Vaginal prostaglandins are more cost-effective compared to the Foley catheter balloon(8).

Mostly labor sets spontaneously but for various obstetrical and medical indications it needs to be induced when the benefits to either the mother or the fetus outweigh those of continuing the pregnancy. Labor induction in the presence of an unfavorable cervix leads to increased prolonged labor, increased incidence of chorioamnionitis and cesarean section. Hence, the use of cervical ripening agents prior to conventional methods of induction is now a standard practice. Many cervical ripening procedures and techniques are available, yet none is ideal(9). There was lower rate of vaginal delivery within 24h among women induced via Foley catheterisation, and conclude that misoprostol is more effective than Foley catheterisation(13)(8).Misoprostol use changed unfavourable Bishop Score in to favourable in 28.4% of the cases. Twenty percent of patients achieved favourable Bishop Score by the use of Foley catheter. Misoprostol and Foley catheter have failure rates of 35.2% and 30%, respectively. In this study, Foley catheter use was found to be less likely to prolong labor (10).

In developing countries cheap and feasible method used for preinduction cervical ripening is trans cervical Foley’s catheter(11). Nowadays, misoprostol, is being considered best medication for labor induction(12). Advantages of misoprostol include effectiveness, low cost, stability at room temperature, and ease of administration but the main worry with its use is excessive uterine response(13).

The rate of failed induction is high in many studies conducted in Ethiopia. In Addis Ababa vaginal delivery accounted in 62.2% of the induced cases and the cesarean section delivery rate was 37.8%. The rate of failed induction was 25.4%(10). In Jimma referral hospital, rate of successful induction was 65.7% of the study subjects, but 21.4% of the mothers experienced failed induction (14). In Dessie referral hospital 53.3% of women delivered vaginally within 8 hours after induction was started, while 42.6% delivered by caesarean section (CS). From women who delivered by caesarean section 63(19.7%) undergone CS due to failed induction of labour(15).

Most of our countries hospitals use different ripening procedures and the selection depends on the preference of gynaecologist on duty. Not only this but many studies show that there is no fast and hard rule to choose the method of cervical ripening. So this study is designed to investigate the effectiveness

of the most commonly ripening techniques (Foley catheter and vaginal misoprostol) in Gedeo zone public hospitals.

Method

Study area, Study period and Study design:

This study was conducted in Gedeo zone public hospitals. There are four general hospitals in the entire zone. The study was done from Sep. 30, 2021 to September 30, 2022. A quasi experimental design was enrolled to compare the effectiveness of Foley catheter and misoprostol for cervical ripening.

Source population:

All pregnant mothers 35 and above weeks of gestational age coming to public hospitals of Gedeo zone for labour induction were source populations. All pregnant mothers coming to public hospitals of Gedeo zone for labour induction during the study period. Women who fulfil eligible criteria for cervical ripening and indications of induction were included.

Sample size determination:

The sample size calculated using the proportion of for two independent population with Stata 14 sample size calculation table. It was tried to estimate the sample size using mean and standard deviation of continuous variables and proportions of categorical variables from a research done in Addis Ababa and Bahrdar(16). Final the appropriate sample size was found to be 109 total participants. After adding 10% lost to follow (109+11=120) the last sample size becomes 120 pregnant mothers. From these 120 pregnant mothers 60 mothers were Foley catheter (group 1) and the remaining 60 mothers were misoprostol (group 2). Finally these mothers were proportionally allocated to the four public hospitals of Gedeo zone based on their previous data.

Sampling procedure

Firstly, the aim and method of the study will be clearly explained to the participants. If they agreed to be enrolled in the study, the will be supported to put they signature on the informed consent sheet. Those who allowed for Foley catheter will be assigned as group 1 and those who categorized to misoprostol were labelled as group 2 participants.

Interventions

In Group one, Foley catheter was introduced into the cervical canal just beyond the internal OS with fingers or by direct visualization with the help of a sterile speculum. The catheter then taped with traction to the inner aspect of thigh of the patient until spontaneous expulsion. If not expelled spontaneously the catheter removed after 24 hours. In Group two, misoprostol inserted per vaginally every 4 hours for 24 hrs. Once, the cervix becomes favourable, misoprostol administration will be discontinued.

Data collection procedure:

The tool was developed by principal investigator and co-investigators after in depth review of different literatures. Data was collected before induction from the mother and from her chart. Two data collectors took training on research methodology, aim of study and the way how to handle if a problem happened for each site.

Data quality control:

To keep quality of data, data collectors were trained in methodology, aim of the research and data collection procedures. The questionnaire was designed carefully and prepared in English language. Pre-test was piloted on 10% of total sample size which is 12 women in Hawass specialized Hospital. The data was cleaned and supervised by investigators.

Data analysis:

Data analysis was done using the SPSS version 25 software. Chi-square analysis was used for comparing proportions of categorical variables while the student's" t" test was used for comparing means of continuous variables where applicable. To calculate the total time of induction, log rank test life table was used. P- value was calculated to declare level of statistical significance at $P < 0.05$.

Operational definitions:

- **Successful cervical ripening:** is defined as if the cervix becomes favourable for induction within 24 hours after ripening have been started.
- **Foley catheter**: Is an 18 F type Foley catheter that inserted for 12hours to the trans cervical os and then its balloon was inflated with 30 ml of sterile 0.9% saline or sterile water to dilate the cervix mechanically(17).
- **misoprostol**: Misoprostol is a tablet which could be administered orally and vaginally for induction of labour or cervical ripening(18).
- **Cervical ripening**: is stimulating the cervix to be softened and dilated preceding birth mechanically by Foley catheter, and medically with misoprostol for initiating labour induction

Results

1. Socio demographic, reproductive and obstetrics characteristics of participants

A total of 120 participants (60 for Foley catheter and 60 for misoprostol) were enrolled in the study. From the participants of both group the majority45 (39.4%) and 93(76%) were found to be age above 31 years old and married respectively. About 81% of participants are multigravida and multi para. Oligohydramnious and preeclampsia were major indications for cervical ripening and labour induction.

Around 90 (75%) of the participants had a favourable cervix after taking the respective method of ripening (Table 1)

2. Comparison of the two groups

The gestational age and gravidity of participants across the two groups was insignificantly vary as in the table below. All the participants had Bishop Score of less than six (table 2).

3. Outcome of the ripening process

The major outcomes of the ripening process shows there is an association among misoprostol and cervical status (favourable cervix). The time interval from the starting of ripening to favourable cervix was found shorter in the misoprostol group than the Foley catheter group (table 3).

4. Outcome of induction in the two groups

In the induction of labor incidence of meconium was more in the misoprostol group than the Foley catheter group. The outcome of the induction (successful/failed) was varied insignificantly between the two groups. The time interval between induction and delivery was almost the same between the two groups (table 4).

5. Time intervals in the log rank test

The Kaplan Meier graph of the time interval between cervical ripening and favourability of Cervix (figure 1), and interval between induction and delivery time have be done using the log rank test of survival analysis (figure 2).

Discussion

Creating favourable cervix is the main activity of obstetricians to induce and manage labor efficiently. There are several methods of cervical ripening techniques but Foley catheter and misoprostol are commonly used methods. Misoprostol is an absorbed and undergoes rapid de-esterification to its Misoprostol acid which is crucial for the clinical activation. Foleys balloon catheter uses to bring cervical ripening by mechanical dilatation of cervix and by releasing Prostaglandin from amniotic membranes. In this study 90(75%) of the participants (41(68.3%) in Foley catheter and 49(81.7%) of Misoprostol) had favourable cervix. This is consistent with a study done in Jos University Teaching Hospital, Nigeria, In the misoprostol group, 58 (77.3%) women achieved cervical ripening compared to 43 (57.3%) in the Foley catheter balloon group(19).

Achievement of favourable cervix at the required time is key parameter of effectiveness of cervical ripening techniques. In the current study the mean time to favourable cervix was significantly vary between the two groups (11.78hrs+2.151) for Foley catheter and (10.27hrs+2.506) for misoprostol (p value= 0.003). But In a study done in Jos University Teaching Hospital, Nigeria, In the misoprostol group,

58 (77.3%) women achieved cervical ripening within 12 h, compared to 43 (57.3%) in the Foley catheter balloon group. Spontaneous vaginal delivery within 12 h was 88.0% and 66.3% in the misoprostol and Foley catheter group, respectively(19).

The mode of delivery of the participants of Foley catheter and misoprostol shows a variation. The Foley catheter group had better vaginal delivery than those misoprostol group (33(80.5%) versus 35(71.4%)). But In a study done in Jos University Teaching Hospital, Nigeria, spontaneous vaginal delivery within 12 h was 88.0% and 66.3% in the misoprostol and Foley catheter group, respectively(19). In another study done in India, the incidence of failed induction was 1.33% in both the groups and all these subjects underwent Cesarean section(18). In study done in Ethiopia in the Misoprostol group, there were 78 (72.2%) cases and 30 (27.8%) cases of vaginal and caesarean deliveries. In the Foley catheter group, there were 94 (84.7%) cases and 17 (15.3%) cases of vaginal and caesarean deliveries respectively(16).

The induction–delivery time interval was found shorter in the misoprostol group than in the Foley catheter group ((6.96hrs+2.226) versus (7.56hrs+2.97)). In India the induction to delivery interval (mean ± SD) in women induced with intravaginal misoprostol was 14.03 ± 7.61 hours while that of women induced with Trans cervical Foley catheter was 18.40 ± 8.02 hours. The induction to delivery interval in misoprostol group was significantly shorter than that in Foley catheter group(17)(20). In a study conducted in Brazil the time interval from the start of induction to the occurrence of vaginal delivery, there was also a significant difference. The mean time for this interval was shorter for the misoprostol group (21,22). Similar study in India shows Induction-delivery interval was significantly shorter in misoprostol group than that in catheter (11.58 hours vs 19.45 hours(19).

Conclusion

the misoprostol was found to be better method of cervical ripening than Foley catheter in case of bringing higher rate of favourable cervix in shorter time interval. The rate of successful induction was better in the misoprostol group than in the Foley catheter groups. The mean induction to delivery interval, participants with misoprostol goes to labor in shorter time than the Foley catheter group but the mean fetal heart beat is higher among misoprostol participants.

Declarations

Ethical approval and consent for participation:

An official letter on ethical clearance for the research were taken from the ethical clearance and research board of Dilla University college of health science and medicine with a code of **006/21-11**. The participant of the study were informed the purpose of the study and all information obtained to be kept confidential and it mean only for the purpose of the study. The participants' personal information were not known and exposed to any one and to prevent this coding were used. After the participant becomes willing to participate on the study, they put their signature on the provided place on the cover page of the

questionnaire. Finally the written informed consent was taken from every participant. This study has been performed in accordance with the Declaration of Helsinki and is approved by ethic committee of Dilla University.

PUBLICATION CONSENT

Not applicable

Authors' contribution

Tesfaye Temesgen, Zerihun Figa, Melkam Andargie, Dr Fitsum Solomon,Mesfin Abebe and Asrat Alemu were involved in the designing, literature writing, conceptualization of the objectives and methodology, and statistical analysis of the result. Ahmedin Sefa, Abbas Ahmed, Rediat Gido, and Dawit Gtachew and Fikru Bedecha were participated in, data cleaning, supervising, and manuscript writing. Finally, all authors read and approved the final draft of the manuscript.

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Availability of data and materials

All related data has been presented within the manuscript. The dataset supporting this article is available from the main author, **Tesfaye Temesgen** by an email address of **tesfayeteme11@gmail.com.**

Competing interests

All authors declare that they have no competing interests

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Tables

Table 1: socio demographic, reproductive and obstetrics characteristics of participants (n=120)

Variable	Category	Frequency	Percent
Age	18-20	11	9.0
	20-30	61	50.0
	31 and above	45	39.4
Marital status	Married	93	76.2
	Divorced	18	14.8
	Widowed	9	7.4
Educational status	No formal education	38	31.1
	Primary school	24	19.7
	Secondary	32	26.2
	College and above	26	21.3
Husband educational status	No formal education	44	36.1
	Primary school	30	24.6
	Secondary school	26	21.3
	College and above	20	16.4
Residency	Urban	52	42.6
	Rural	68	55.7
Gravidity	Primigravida	21	17.2
	Multigravida	99	81.1
Parity	Primi para	21	17.2
	Multipara	99	81.1
Indication for induction	IUFD	6	4.9
	Oligohydrominous	32	26.2
	Post term	19	15.6
	Preeclampsia	25	20.5
Cervical status	Favorable	90	73.8
	Unfavorable	30	24.6
Mode of delivery	Vaginal	68	55.7
	S/c	22	18.0

Table 2: BASILINE CHARACTERISTICS OF the Foley and misoprostol GROUPS (n=120)

Parameter		Foley catheter (group 1)	Misoprostol (group 2)	P value
Gravidity	Primigravida	5(8.3%)	15(25.0%)	0.031
	Multi	55(91.7%0	45(75.0%)	
Parity	Primigravida	5(8.3.0%)	15(25.0%)	0.031
	Multi	55(91.70%)	45(75.0%)	
Bishop score<6		60	60	
Gestational age		60(35.95±2.93	60(35.38±3.309))	0.323

table 3: result of the ripening process between the two groups (n=120)

Parameter		Foley catheter (group 1)	Misoprostol (group 2)	P value
Cervical status	Favourable	41(68.3%)	49(81.7%)	0.046
	Unfavourable	19(31.7%)	11(18.3%)	
Time to favorable cervix		41(11.78±2.151)	49(10.27±2.506)	0.003

Table 4: maternal and neonatal outcomes of induction of labor in the two groups (n=120)

Parameter		Foley catheter (group 1)	Misoprostol (group 2)	P value
Presence of meconium	No	27(69.2%)	36(75.0%)	0.092
	Yes	14(30.8%)	13(25.0%)	
Outcome of induction	Succeeded	33(80.5%)	35(71.4%)	0.08
	Failed	8(19.5%)	14(28.6%)	
Time interval(induction to delivery)		41(7.56±2.97	49(6.96±2.226)	0.276
FHB		38(131±25)	48(136±20)	0.397

Figures

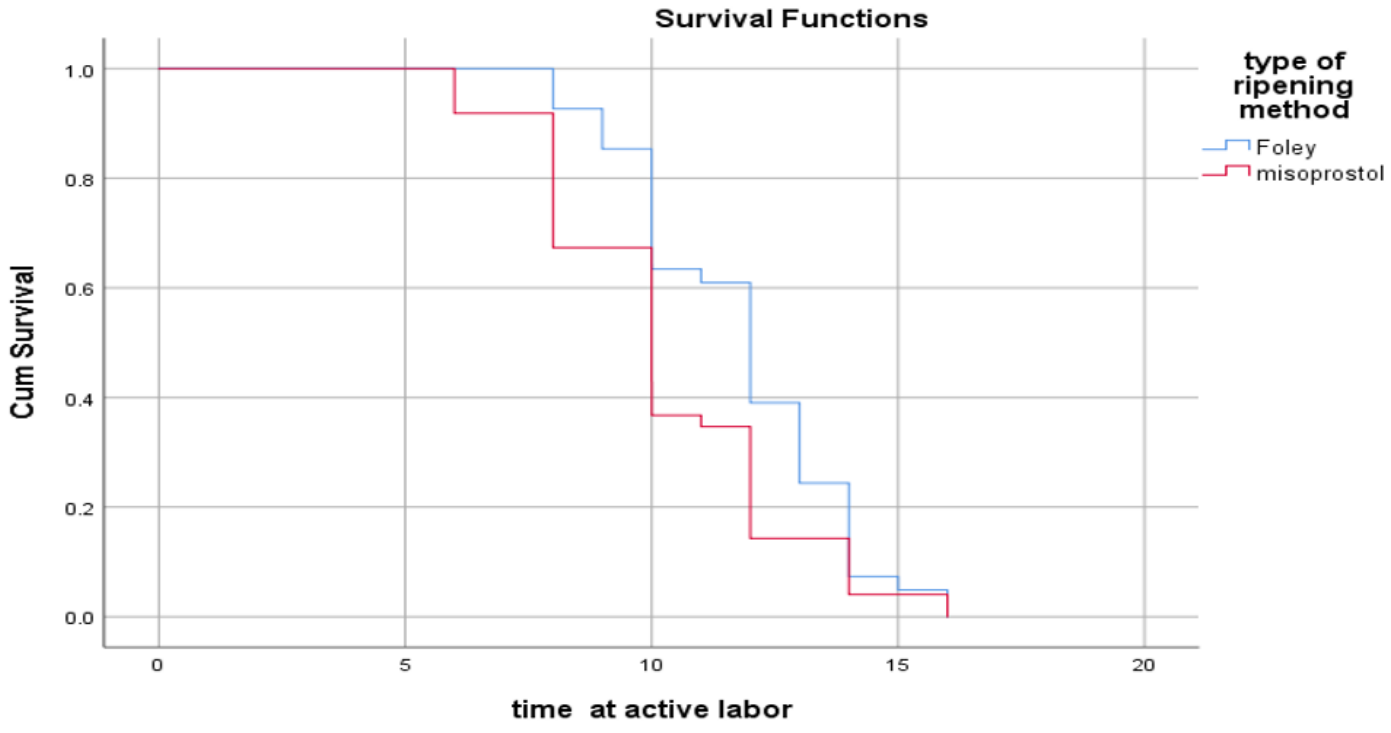

Figure 1

time to favourable cervix after insertion of foley catheter and misoprostol (n=120)

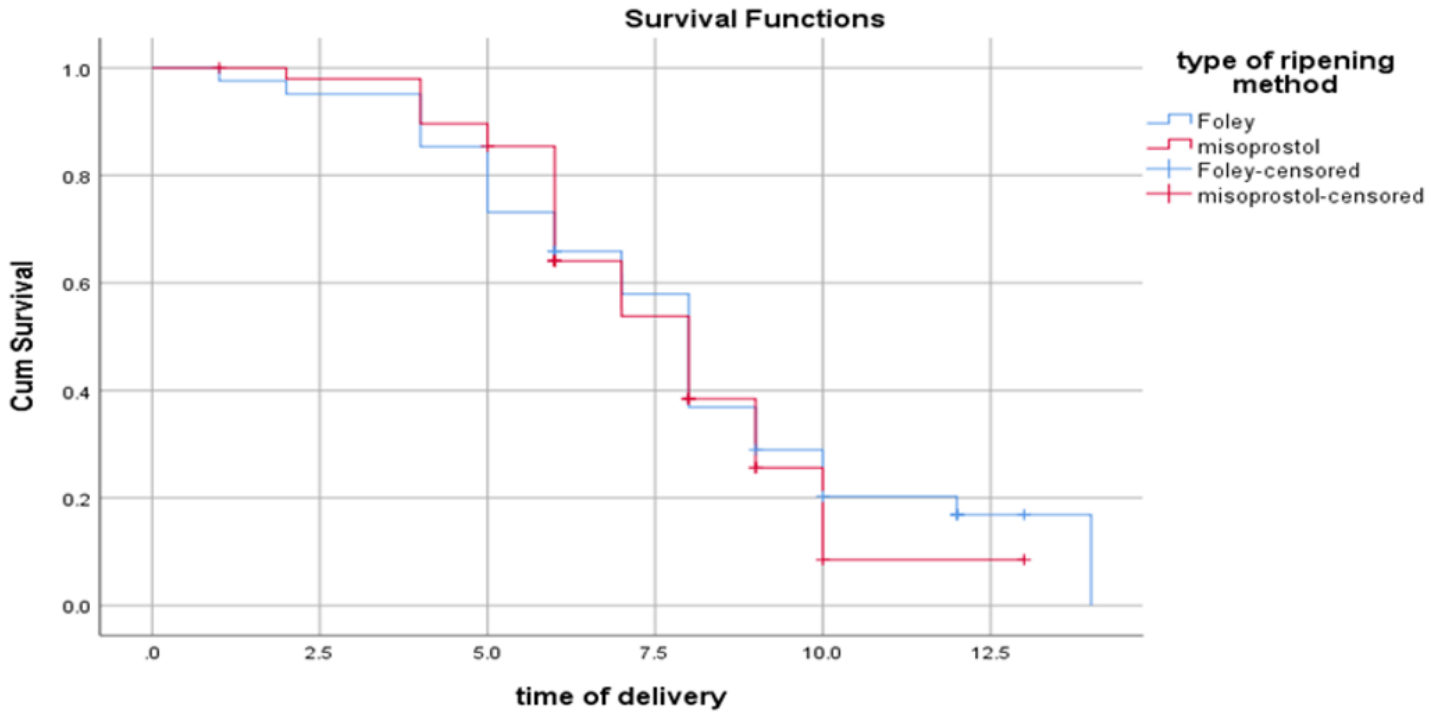

Figure 2

the induction-delivery interval across the two groups (n=120)