e-ISSN:2319-9865
p-ISSN:2322-0104

Research & Reviews: Journal of Medical and Health Sciences

Effectiveness and Safety of Low Dose Vaginal Misoprostol Compared to Trans Cervical Foley Catheter for Cervical Ripening and Induction of Labor in Post Term Pregnant Women Admitted to Gandi Memorial Hospital, Addis Ababa and Felege Hiwot Referral Hospital, Bahir Dar, Ethiopia

Hailemariam Segni[1*], William Haleke[1], Elias Ali[2]

[1]Department of Obstetrics and Gynecology, College of Health Sciences, Jimma University, Jimma, Ethiopia

[2]Department of Health Economics, Management and Policy, College of Health Sciences, Jimma University, Jimma, Ethiopia

Research Article

Received date: 08/05/2015
Accepted date: 17/10/2015
Published date: 24/10/2015

***For Correspondence**

Hailemariam Segni (MD), Associate Professor and Consultant, Department of Obstetrics and Gynecology, College of Health sciences, Jimma University, Jimma, Tel: +251911408061, Ethiopia.

E-mail: hmullu@yahoo.com

Keywords: Misoprostol, Foley Catheter, Cervical Ripening, Labor Induction, Jimma.

ABSTRACT

Background: Post term pregnancy is one of the common indications of induction of labor in contemporary obstetric practice. However, the majority of women with post term pregnancy have unfavorable cervices. Therefore, it is mandatory to achieve cervical ripening in this group of women before proceeding to labor induction. These cervical ripening methods often result in onset of labor which makes them also labor inducing agents. There is paucity of studies comparing the effectiveness and safety of the aforementioned methods. Thus, this study compared the effectiveness and safety of low dose vaginal misoprostol with trans cervical Foley catheter for cervical ripening and induction of labor in post term pregnant women.

Method: The study was conducted from January to December 2014 at Gandi Memorial Hospital and Felege Hiwot Referral Hospital. Quasi-experimental study design was employed and 111 post term pregnant women were enrolled to each group of cervical ripening methods. Foley catheter, number 18 gauge, was inserted trans cervically and inflated with 50 ml of normal saline in women of group I at FHRH. Women in group II received 25 µg of misoprostol vaginally every 6 hrs for a maximum of 2 doses at GMH. Oxytocin infusion began when an indication comes to picture. Results were tabulated and statistically analyzed.

Results: Baseline obstetric variables such as gestational age and parity were not statistically different in both groups. Maternal age was found to be statistically significant (28.40 vs. 26.02 yrs; P=0.000). Change in Bishop score is marginally significant in favour of the Foley catheter group even after controlling for maternal age (5.67 vs. 5.33; P=0.040). Vaginal delivery within 24 hours and ripening to delivery intervals were not statistically different in both groups. Rate of vaginal delivery was found to be marginally significant being higher in the Foley catheter group (84.7% vs. 72.2%; P=0.013). When stratified for parity, the significance was in multiparous women (93.4% vs. 78.3%; P=0.012). Need for oxytocin was significantly higher in the Foley catheter group (75.7% vs. 43.2%; P<0.0001).

Indications for caesarean section were NRFHRP and failed induction, no statistical difference was seen in both groups. Uterine tachysystole with FHR

e-ISSN:2319-9865
p-ISSN:2322-0104

abnormality (0 vs. 12.6%; P<0.001) and abnormal FHR is significantly higher in the Misoprostol group (6.3% vs. 26.1%; P<0.0001). More importantly 3 cases of uterine rupture with 2 intrapartal fetal loss were encountered in the misoprostol group and all were multiparous women. Both groups were not statistically different for rates of meconium stained amniotic fluid, neonatal birthweight, low APGAR scores and NICU admissions. Furthermore 3 cases and 1 case of ENND occurred in the Misoprostol and Foley catheter group respectively. There were no cases of chorioamnionitis, endomyometritis, uterine atony and maternal death in both groups.

Recommendation: Foley catheter is relatively better in ripening the cervix with more need for oxytocin compared to misoprostol in post term pregnancy. Safety issues need to be taken into account while deciding to use misoprostol as a cervical ripening agent especially for multiparous post term pregnant women. Foley catheter with 50 ml volume inflation is used for multiparous post term pregnant women. Either method can be used in nulliparous ones based on individual clinical judgement. Randomized controlled trial with larger sample size needs to be conducted in the future.

INTRODUCTION

Post term pregnancy is defined as a pregnancy that continues to or beyond 42 completed weeks from the first day of the last normal menstrual period (LNMP). Although some cases of post term pregnancy likely result from an inability to recall the exact date of LNMP, many cases result from a true prolongation of gestation. The reported frequency of post term pregnancy is approximately 6% [1]. Post term pregnancy has considerable risks for both the fetus and the pregnant woman. Therefore induction of labor, i.e. initiation of labour by artificial means, has been reported to prevent adverse pregnancy outcomes in this group of women [2]. In the majority of women with post term pregnancy their cervix is unfavourable [3]. To make the cervix favourable, various methods like mechanical or drugs can be used. These agents have an additional advantage in that they may also result in onset of labor [4]. Among the mechanical methods, the commonly used one is a rubber made tube which has inflatable balloon at its tip and it is known as Foley catheter. This method is preferable as it is relatively cheap, widely available, effective and stable at room temperature. It is inserted to the woman's uterine cavity through her vagina and cervix then filled with a predetermined volume of sterile fluid. This will inflate its balloon while the other end of the tube is taped under traction to the woman's inner thigh eventually resulting in dilatation of the cervix making her ready for labour [4]. The other option is using drugs to make the cervix favourable. Of these, the one used most often is misoprostol. It initiates contraction of the uterus as well as ripening of the cervix. It can be given to the woman by oral, vaginal or rectal routes. It is inexpensive, stable at room temperature, and available in more than 80 countries, making it particularly useful in resource-poor settings. World Health Organization (WHO) recognizes the crucial role of misoprostol in reproductive health and has incorporated recommendations for its use on induction of labor where appropriate facilities are available [5].

The main goal of labor induction is to achieve vaginal delivery in a situation where the benefits of delivery outweigh the risks of continuing the pregnancy [6]. Induction of labor is directly relevant to the health related Millennium Development Goals (MDGs). It has potentials for preventing maternal complications and improving pregnancy outcome [7]. A policy of labour induction compared with expectant management is associated with fewer perinatal deaths and fewer Caesarean Sections (C/S) [2].This is a priority consideration in low income countries where available resources need to be judiciously utilized [7]. Post-term pregnancy is one of the common indications for induction of labour as it has been shown to reduce adverse maternal and perinatal outcomes. Unfortunately, about 92% of these women have unfavourable cervix at 42 weeks of gestation [3]. Cervical status is determined using the Bishop pelvic scoring system. Induction of labour with an unfavourable cervix is associated with prolonged labour compared to spontaneous onset of labour or induction of labour with a favourable cervix. Also an increase in instrumental deliveries and a higher rate of caesarean sections are seen in unfavourable cervix [8]. To increase the success of labour induction it is essential to achieve cervical ripening in women with an unfavourable cervix. Cervical ripening implies the process of preparing the cervix by promoting dilatation and effacement. Although several methods of labor induction exist, no single agent is superior to others or universally indicated for all women undergoing labor induction [4]. Misoprostol, a synthetic prostaglandin E 1 (PGE1) analogue and transcervical Foley catheter are among the commonly used cervical ripening methods. Misoprostol leads to biochemical remodelling of the cervix as well as initiates uterine contraction. The recently recommended dose of vaginal misoprostol for induction of labor at term and beyond is low dose (25 microgram (µg), 6-hourly), given the increasing sensitivity of uterine receptors to misoprostol with increasing gestational age [5,9]. The Foley catheter acts by mechanically dilating the cervix and releasing endogenous prostaglandins. These two methods are preferred as they are relatively inexpensive making them accessible in

resource poor settings, stable at room temperature and easy to administer. The Foley catheter has an added advantage in that it is reversible and lacks systemic side effects [4]. Most studies that compared the safety and effectiveness of low dose vaginal misoprostol with transcervical foley catheter were limited to term pregnancies with various indications for labor induction. Majority of them report significantly shorter mean induction to vaginal delivery interval in the misoprostol group. No statistically significant differences were observed in the rates of C/S, chorioamnionitis, uterine atony, low first and fifth minute American Pediatrics Gross Assessment Record (APGAR) scores, Neonatal Intensive Care Unit (NICU) admissions and meconium stained amniotic fluids between the two groups. One of these studies reported significant improvement of the Bishop score in the misoprostol group [10-14]. With regard to rate of vaginal delivery, one study reported it to be significantly higher in the misoprostol group [14]. However, two studies showed no statistically significant differences between the two groups [12,15]. One study showed significantly higher vaginal delivery rate at 12 and 20 hours after cervical ripening started in the misoprostol group [10].

Timely labor and delivery is of paramount importance in obstetric practice. This appears to be reasonable particularly in women with post term pregnancy given the associated risks for both the fetus and the pregnant woman. So induction of labor remains the only option for this group of women. The high rate of unfavourable cervix in these women poses a challenge for successful labor induction. These can be tackled through administration of cervical ripening agents. Although several methods of cervical ripening agents exist, no one method failed to be consistently superior to the other with regard to safety and effectiveness. Thus this research with the aim of providing one solution to the inconsistencies so far created focusing on two induction methods which are applicable in low income countries as they are widely available, relatively inexpensive and effective. As there is no similar research undertaken to date, the results of these study will be a valuable reference for the clinical practice of labor induction in women with post term pregnancy not only for our country but also for other low income countries worldwide. It also opens door for further research to be done on such kinds of women in the future.

METHOD AND MATERIALS

The study was conducted at Gandi Memorial Hospital (GMH) and Felege Hiwot Referral Hospital (FHRH) from January 1, 2014 to December 31, 2014. GMH is located at Addis Ababa, Ethiopia whereas FHRH is located at Bahir Dar, about 500 kilometers to the North of the capital city, Addis Ababa. Both are teaching hospitals whereby Medical Interns and Resident physicians do the daily clinical practice under the supervision of the senior physicians. A Quasi- experimental study design was employed and the source population was all women found to be post term (GA of ≥ 42 weeks) from the first date of reliable LNMP or from obstetric ultrasound done till 20 weeks of GA of which women with post term pregnancy that met the inclusion criteria and found to be admitted during the study period were the study population. GMH uses misoprostol for cervical ripening and induction of labor whereas FHRH uses Foley catheter. At GMH 25 µg of misoprostol, which is prepared by breaking the 200 µg tablet, is inserted every 6 hours for a maximum of 2 doses to the posterior vaginal fornix using a digital vaginal exam on the date of admission. Intravenous oxytocin infusion is started 6 hours after the last dose of misoprostol in those with no labor onset. A woman in whom labor begins after misoprostol insertion, Oxytocin is used if latent phase of labor is prolonged (>8 hrs) or active phase of labor abnormality encountered in the presence of inadequate uterine contractions. On the other hand at FHRH after a sterile speculum is inserted and the anterior lip of the cervix is grasped with a tenaculum, ring forceps is used to push the distal end of number 18 gauge Foley catheter through the cervix into the extra-amniotic space. It is then inflated with 50 ml of sterile saline and pulled back snugly against the internal cervical os and taped to the inner aspect of thigh with minimum traction. Catheter is left in place till expelled spontaneously, otherwise it is removed 12 hours after insertion. Once the catheter is extruded and no labor by then, intravenous oxytocin infusion is initiated. Both hospitals use the protocol prepared by the Federal Ministry of Health (FMOH) of Ethiopia for induction or augmentation of labor using oxytocin. According to the protocol 2 International Unit (IU) of oxytocin is added to 1000 ml of Normal saline or Ringers lactate. The number of drops is increased every 30 minutes starting from 20 drops/ min (2 milli International Unit per minute (mIU/min)) till adequate uterine contraction is achieved which is 3-5 contractions every 10 minutes each lasting more than 40 seconds or maximum dose (40 mIU/min) is reached. Labor is followed using 'induction chart' that includes date, time (every 30 minute observation), oxytocin (miu in a liter, miu/ minute, drops/ minute), contractions (frequency, duration), fetal and maternal conditions, and cervical status. Once active labor is diagnosed, it is monitored using a modified WHO partograph with individualized Alert Line based on cervical dilation at a gradient of 1 cm/h and Action Line 2 h to the right of the Alert Line. Intermittent FHR monitoring using pinnard fetoscope and uterine activity monitoring is done during labor follow up. If abnormal uterine activity is detected, the patient is turned to her left side; oxygen inhalation started and oxytocin infusion is discontinued. If it is corrected with these management and both the mother and fetus are in a good condition, the oxytocin infusion is re-started at half dose of the last dose. Amniotomy is performed when feasible. Failed induction is diagnosed if there is no cervical change or fetal descent while in latent phase of labor or adequate uterine contractions are not achieved after 6 to 8 hours of oxytocin administration and use of the maximum dose for 4 to 6 hours. Inclusion Criteria used were: Bishop score ≤ 4, singleton pregnancies, vertex presentation, normal FHRP, capacious pelvis based on clinical pelvimetry while cases with intrauterine fetal death (IUFD), ruptured membranes, previous any uterine surgery, clinically detected vaginal infection, estimated fetal weight ≥ 4000 gms, any other obstetrical or medical complications, contra-indication to prostaglandin use were excluded from the study.

Beginning from the first date of data collection, a non-probability consecutive sampling technique was used to select the participants.

The demographic characteristics and clinical outcomes of interest were recorded in customized data extraction proforma designed for the study.

The data were recorded by attending midwife nurse under the supervision of resident physician whose responsibility is to examine and admit post term pregnant women to the wards, follow them in labor till delivery and afterwards for the development of any complications. The obstetrician on duty will be consulted for any queries that may occur in these processes. Given the experience of these physicians practising the ripening and induction techniques for many years at both hospitals, we didn't find the necessity of performing a pre-test feasibility study.

The midwife nurses who collect the data were given a brief orientation on data extraction from patient chart as well as on inclusion/exclusion criteria. Logistic support relevant for the study was provided for the data collectors. The resident physician checks 10% of the data for accuracy and completeness. Regular supervision by the resident physician and assistance if the midwife has any queries was undertaken.

All data were summarized on master sheet after they were coded and fed to computer to make ready for analysis. After double entry into a computer database using EPi Info, data were analyzed using statistical package for social scientists (SPSS) version 16 software. To calculate the mean difference in continuous outcome variables between the two groups, student's independent t-test was used. In the test of association between the predictor and continuous outcome variables, the effect of potential confounders was controlled using generalized linear models. For the categorical outcome variables, risk difference was calculated for each predictor variables. Statistical association between the predictor variable and categorical outcome variables was calculated using z-test. For these variables, potential confounders were controlled by running a binary logistic regression model. Mean differences and tests of association have 95% Confidence Intervals as an indicator of statistical significance and precision. A P value ≤ 0.05 is a cut-point to determine the statistical significance of the tests. Values less than or equal to 0.05 were considered statistically significant.

The study was approved by IRB of Jimma University, College of health Sciences and permission letter was submitted to the responsible authorities of both hospitals to have permission for data collection. Although safety of each induction methods is a matter of concern that was addressed with this study, these methods are already being practiced in these hospitals and no new intervention was done to the subjects under study. All participants were told about the study and a written informed consent was obtained once they agreed to be involved in the study.

RESULT

A total of 235 post term pregnant women were admitted to both hospitals during the study period. Of these 13 were excluded from the study as 8 of them had big babies, 4 had previous c/d and 1 with IUFD. Among the 222 women enrolled, cervical ripening using Foley catheter was made for 111 and there is difficulty during attempt of insertion for 1 patient as the closed cervix failed to admit the device. She was then given misoprostol making the total number for this group 111. Among the misoprostol group, 50 of them required only one dose of misoprostol while the rest required two doses of misoprostol. Among the Foley group, rupture of membranes during insertion encountered in 2 cases. The Foley is removed after 12 hours of insertion in 51 cases while in the rest expelled by it.

Both groups were similar in terms of baseline obstetric characteristics such as parity and gestational age. There were a total of 112 nullipara and of these 50 of them were in the Foley catheter group. Out of the 110 multipara, 61 were in the Foley catheter group. Maternal age was found to be statistically significant **(Table 1)**.

Table 1. "Demographic and baseline obstetric characteristics of post term pregnant women admitted to Gandi Memorial Hospital, Addis Ababa and Felege Hiwot Referral Hospital, Bahirdar, Ethiopia from January to December, 2014 by cervical ripening method."

Characteristic	Mean (Percent)		Mean (Risk) Difference	95% CI	P-value
	Group I (111)+	Group II (111)*			
Maternal Age (yrs), mean	28.40	26.02	2.38	1.08, 3.68	0.000
Gestational Age (wks) ,mean	42.49	42.42	0.07	-0.04, 0.18	0.096
Nulliparous, n (%)	44.6%	55.4%	10.8%	-23.9%, 4.1%	0.071

+Foley catheter group *Misoprostol group

Profile of labor and delivery in both groups is shown in **Table 2**. Change in Bishop Score is of marginal statistical significance in favour of the Foley catheter group. No difference is seen regarding ripening to active phase of labor and ripening to delivery intervals in both groups. Oxytocin need and vaginal delivery rate were found to be significantly higher in the Foley catheter group. In the Misoprostol group, there were 78 (72.2%) cases and 30 (27.8%) cases of vaginal and caesarean deliveries. The remaining 3 cases were complicated by uterine rupture. All of them were multiparous women and had tachysystole with FHR abnormality. Two doses of misoprostol were inserted for two cases and one of the two required oxytocin. Both had intrapartal fetal death. For the third case, one dose of misoprostol inserted and she required oxytocin. Her newborn is salvaged. In the Foley catheter group, there were 94 (84.7%) cases and 17 (15.3%) cases of vaginal and caesarean deliveries respectively. Even though parity is not a confounding variable, we stratified rate of vaginal deliveries by parity in both groups. It showed vaginal delivery rate is higher in

both nullipara and multipara in the Foley catheter group but it was significant only in multipara. Indication for caesarean section was NRFHRP for 6 (35.3%) cases and failed induction for 11 (64.7%) cases in the Foley catheter group. In the Misoprostol group, NRFHRP and failed induction accounted for 20 (66.7%) cases and 10 (33.3%) cases respectively and it was not statistically significant, P value=0.138. There were 18 cases of tachysystole in both groups. Those associated with FHR abnormality were 14. All occurred in the misoprostol group which is statistically significant. In those not associated with FHR abnormality, 3 of them occurred in the Foley catheter group. Rate of meconium stained liquor was not statistically significant between both groups. Whereas, abnormal FHR was significantly higher in the misoprostol group **(Table 3)**.

Table 2. "Profile of labor and delivery of post term pregnant women admitted to GMH, Addis Ababa and FHRH, Bahirdar, Ethiopia from January to December, 2014 by cervical ripening method."

Variables	Mean (Percent)		Mean (Risk) Difference	95% CI	P-value
	Group I (111)	Group II (111)			
Change in Bishop Score (mean)	5.67	5.33	0.34	-0.41, 0.71	0.040
Vaginal delivery within 24hrs, n (%)	76 (80.0%)	62 (79.5%)	0.5	0.49, 2.16	0.269
Ripening to delivery (hrs) , mean	20.50	20.36	0.14	-1.43, 1.72	0.429
Oxytocin need, n (%)	84 (75.7%)	48 (43.2%)	32.5	0.19, 0.46	<0.0001
Vaginal delivery, n (%)	94 (84.7%)	78 (72.2%)	12.5	0.8, 24.2	0.013
Nullipara, n (%)	37 (74.0%)	42 (67.7%)	6.3	-12.4, 24.9	0.24
Multipara, n (%)	57 (93.4%)	36 (78.3%)	15.1	4.1, 11.5	0.012

Table 3. "Intrapartum complications of post term pregnant women admitted to Gandi Memorial Hospital, Addis Ababa and Felege Hiwot Referral Hospital, Bahirdar, Ethiopia from January to December, 2014 by cervical ripening method."

Variables	Percent		Risk Difference	95% CI	P-value
	Group I (111)	Group II (111)			
Tachysystole with FHR abnormality, n (%)	0	14 (12.6%)	-12.6	-18.6, -3.7	<0.001
Meconium stained liquor, n (%)	9 (8.1%)	15 (13.5%)	-5.4	-14.4, 3.0	0.101
Abnormal FHR, n (%)	7 (6.3%)	29 (26.1%)	19.8	-30.1, -9.6	<0.0001

Birthweight is not significantly different between both groups. The rate of NICU admissions, lower APGAR scores at the first and fifth minutes were higher in the misoprostol group but not statistically significant **(Table 4)**. Neonatal resuscitation made for 11 (9.9%) neonates in the Foley catheter group and 17 (15.3%) neonates in the misoprostol group. Furthermore there were 3 ENND in the misoprostol group and 1 in the Foley catheter group. Other than the uterine rupture, there were no other maternal complications like uterine atony, chorioamnionitis, endometritis or maternal death.

Table 4. Neonatal outcomes of post term pregnant women admitted to Gandi Memorial Hospital, Addis Ababa and Felege Hiwot Referral Hospital, Bahirdar, Ethiopia from January to December, 2014 by cervical ripening method

Variables	Percent		Risk Difference	95% CI	P-value
	Group I (111)	Group II (111)			
Tachysystole with FHR abnormality, n (%)	0	14 (12.6%)	-12.6	-18.6, -3.7	<0.001
Meconium stained liquor, n (%)	9 (8.1%)	15 (13.5%)	-5.4	-14.4, 3.0	0.101
Abnormal FHR, n (%)	7 (6.3%)	29 (26.1%)	19.8	-30.1, -9.6	<0.0001

* 2 cases of Intrapartal fetal deaths are excluded.

After controlling for maternal age, it was found out that change in Bishop Score and vaginal delivery rate were marginally significant in favour of the Foley catheter group. Rate of vaginal delivery within 24 hours is not statistically different in both methods. The need for oxytocin is significantly higher in the Foley catheter group. Abnormal FHR is significantly higher in the Misoprostol group. Rate of meconium stained liquor and 1-min APGAR score <7 were not different in both groups **(Table 5)**.

Table 5. "Main outcome variables of post term pregnant women admitted to Gandi Memorial Hospital, Addis Ababa and Felege Hiwot Referral Hospital, Bahirdar, Ethiopia from January to December, 2014 by cervical ripening method after controlling for maternal age."

Variables	Group I (111)			Group II (111)
	B or Exp (B)	95% CI for B or Exp (B)	P-value	Reference
Change in Bishop score (B)	0.275	0.002, 0.547	0.048	
Vaginal delivery within 24hrs, Exp (B)	0.910	0.426, 1.947	0.809	
Need for oxytocin, Exp (B)	7.799	3.827, 15.892	0.000	
Vaginal delivery, Exp (B)	0.500	0.253, 0.987	0.046	
Abnormal FHR, Exp (B)	0.210	0.85, 0.518	0.001	
Meconium stained liquor, Exp (B)	0.655	0.271, 1.586	0.348	
1-min APGAR score <7, Exp (B)	0.724	0.316, 1.660	0.446	

DISCUSSION

In this study we compared Foley catheter and low dose of vaginal Misoprostol for cervical ripening and labor induction to

determine their effectiveness and safety solely limited to post term pregnant woman which was not done before. Both groups were similar in terms of baseline obstetric parameters. Maternal age is significantly different. Therefore we controlled outcome variables of interest for maternal age.

Change in Bishop Score after introduction of cervical ripening methods was marginally significant in favour of the Foley catheter group. This is against the finding in study done by Lemyre M et al, which reported significant improvement of Bishop Score in the Misoprostol group [10]. The inflation volume of Foley catheter used in this study was 30 ml and also 3 doses of misoprostol were inserted for all patients in this group. In another one study that used large dose of Misoprostol, pre-induction Bishop Score was not statistically different in both groups. Further study with larger sample size need to be conducted in the future.

Achievement of vaginal delivery within 24 hours, which is a main indicator of effectiveness, is not statistically different in both groups even after controlling for maternal age. The same applies for ripening to vaginal delivery interval. Two previously published studies came out with a similar finding to our study regarding achievement of vaginal delivery within 24 hours. Only few studies reported no significant difference between the two cervical ripening methods concerning ripening to vaginal delivery interval. The majority favour misoprostol in shortening this interval. This might be due to higher dose of misoprostol is used in these studies.

Oxytocin need is significantly higher in the Foley catheter group even after controlling for maternal age and this goes with the finding in almost all other studies done so far. This shows the ability of Foley catheter in inducing labor by itself is somehow limited.

Vaginal delivery rate is significantly higher in the Foley catheter group in our study and after controlling for maternal age, it is marginally significant. Multipara have significantly higher vaginal delivery rates when Foley catheter is used whereas nullipara still have higher rate but not statistically significant. C/d rate mirrors that of vaginal delivery rate. All of the studies done so far reported comparable vaginal delivery rates between both cervical ripening methods. All of them used Foley catheter with 30 ml volume inflation. Among these, one study stratified vaginal delivery rates for parity and reported no difference in nullipara as well as multipara. In this study, indications for caesarean section were failed induction and NRFHRP which are not different statistically in both groups as also reported in few other studies.

Safety parameters like tachysytole with FHR abnormality and abnormal FHR were found to be significantly higher in the misoprostol group as compared to the Foley catheter group in our study. Only two studies came out with a similar finding to ours. In the rest of the studies still rate of tachystole is higher in the misoprostol group but statistical significance was not reached. Furthermore, in our study we encountered 3 cases of uterine rupture of which two had intrapartal fetal loss in the misoprostol group. Only one study done by B.B. Afolabi et al. reported two cases of uterine rupture with misoprostol use but they used single dose of 100 µg misoprostol [16]. With regard to other parameters like meconium stained liquor, NICU admissions, low first and fifth minute APGAR scores, it is still higher in the misoprostol group but not statistically significant. This finding is similar to all studies conducted previously. Therefore, safety is a big concern with misoprostol use particularly in multiparous women.

We found three ENND in the misoprostol group and one in the Foley catheter group. No other similar study done previously reported such outcome. No case of chorioamnionitis, uterine atony or maternal death was seen in our study.

However, this study is not without limitations. The encountered limitations are:

- The study design we used is Quasi-expermental. It will be more powerful had randomized controlled trial been conducted.
- Lack of previously conducted similar study not only in our country but also in other low income countries.
- Non-blinding of clinicians to the method of labor induction may introduce some form of bias on decision of oxytocin augmentation for the Foley group and on caesarean section rate for abnormal FHR in the misoprostol group.

In conclusion,

- Foley catheter is relatively better in ripening the cervix but with more need for oxytocin compared to misoprostol when used in post term pregnancy.
- Both methods have comparable effectiveness in achieving vaginal delivery within acceptable time period but higher vaginal delivery rate is seen in the Foley catheter group particularly for multiparous post term pregnant women.
- Higher rates of tachysystole with FHR abnormality, abnormal FHR and uterine rupture encountered in the Misoprostol group. Thus, these safety issues need to be taken into account while deciding to use misoprostol as a cervical ripening agent especially for multiparous post term pregnant women.
- No case of chorioamnionitis or endometritis was seen in both groups. Therefore, fear of infection previously thought to occur with the use of Foley catheter should not limit clinicians in using this cervical ripening method.

Hence, it is recommended that

- Foley catheter with 50 ml volume inflation should be used for multiparous post term pregnant women. As to the nulliparous post term pregnant women, either method can be used based on individual clinical judgement.

- Randomized controlled trial with larger sample size focusing on change in Bishop score, cost analysis and maternal satisfaction with the use of each cervical ripening method in post term pregnant women need to be conducted in the future.

ACKNOWLEDGEMENT

We would like to acknowledge Jimma University for funding and data collectors and mothers who took part in the study.

REFERENCES

1. American College of Obstetricians and Gynecologists. Practice Bulletin No. 146: Management of late-term and post-term pregnancies. Obstet Gynecol. 2014; 124: 390-396.
2. Gülmezoglu AM, et al. (2012) Induction of labour for improving birth outcomes for women at or beyond term (Cochrane review). In: The Cochrane Library. John Wiley & Sons, Ltd., Chichester, UK.
3. Harris BA et al. The unfavourable cervix in prolonged pregnancy. Obstet Gynecol. 1983; 62: 171-174.
4. Cromi A, et al. Cervical ripening with the Foley catheter. International Journal of Gynaecology and Obstetrics. 2007; 97: 105–109.
5. Tang J, et al. WHO recommendations for misoprostol use for obstetric and gynaecologic indications. International Journal of Gynaecology and Obstetrics. 2013; 121: 186–189.
6. American College of Obstetricians and Gynecologists: Induction of labor. Practice Bulletin No. 107, August 2009, Reaffirmed 2013b.
7. Fawole B, et al. Unmet need for induction of labor in Africa: secondary analysis from the 2004 - 2005 WHO Global Maternal and Perinatal Health Survey (A cross-sectional survey). BMC Public Health. 2012; 12: 722.
8. Bailit JL, et al. Maternal and neonatal outcomes by labor onset type and gestational age. Am J Obstet Gynecol. 2010; 202: 245.e1-245.e12.
9. WHO: WHO recommendations for induction of labor. Geneva: World Health Organization; 2011.
10. Lemyre M, et al. Foley catheter or vaginal misoprostol for cervical ripening: A Randomized controlled trial. AJOG. 2006; 10: 350.
11. Kashanian M, et al. Cervical ripening and induction of labor with intravaginal misoprostol and Foley catheter cervical traction. International Journal of Gynecology and Obstetrics. 2006; 92: 79-80.
12. Tabowei TO and Oboro VO. Low dose intravaginal misoprostol versus intracervical balloon catheter for pre – induction cervical ripening. East African Medical Journal. 2003; 80: 91-94.
13. Moraes FOB, et al. A randomized controlled trial comparing vaginal misoprostol versus Foley catheter plus oxytocin for labor induction. Acta Obstetricia et Gynecologica. 2010; 89: 1045–1052.
14. Roudsari FV, et al. Comparison of Vaginal Misoprostol with Foley Catheter for Cervical Ripening and Induction of Labor. IJPR. 2011; 10: 149-154.
15. Chung JH, et al. 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.
16. Afolabi BB, et al. Intravaginal misoprostol versus Foley catheter for cervical ripening and induction of labor. International Journal of Gynecology and Obstetrics. 2005; 89: 263-267.