**ADDIS ABABA UNIVERSITY**
**COLLEGE OF HEALTH SCIENCES**
**SCHOOL OF NURSING AND MIDWIFERY**
**POSTGRADUATE PROGRAM**

# EFFICACY OF TRANSCERVICAL FOLEY CATHETER VERSUS INTRAVAGINAL MISOPROSTOL AS A CERVICAL RIPENING METHOD AND ASSOCIATED FACTORS IN SELECTED PUBLIC HOSPITALS OF ADDIS ABABA, ETHIOPIA, 2020.

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## APPROVAL BY THE BOARD OF EXAMINATION

This thesis by Shimels Marye is accepted in its present form by the board of examiners as satisfying the thesis requirement for the degree of Masters in Maternity and Reproductive Health Nursing.

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# LIST OF ABBREVIATIONS AND ACRONYMS

**ACOG**: American College of Obstetricians and Gynecologists

**ANC**: Antenatal Care

**AOR**: Adjusted Odd Ratio

**APGAR:** Appearance, Pulse, Grace, Activity, Reflex

**BMI:** Body Mass Index

**CI**: Confidence Interval

**CS**: Cesarean Section

**EDHS**: Ethiopian Demographic and Health Survey

**FHB:** Fetal Heart Beat

**IDI:** Induction Delivery Interval

**IOL:** Induction of Labor

**IUFD**: Intra Uterine Fetal Death

**IUGR**: Intra Uterine Growth Restriction

**MMR**: Maternal Mortality Rate

**NICU**: Neonatal Intensive Care Unit

**PG:** Prostaglandin

**PIH:** Pregnancy Induced Hypertension

**PPH:** Postpartum Hemorrhage

**PROM**: Premature Rupture of the Membranes

**SDG:** Sustainable Development Goal

**SPSS**: Statistical Package for Social Scientists

**SSA:** Sub Saharan Africa

**UNICEF:** United Nations International Children's Emergency Fund

**WHO:** World Health Organization

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# ABSTRACT

***Background****:* Many women who undergo labor induction have an unfavorable cervix. Therefore, cervical preparation by using a safe and effective method is necessary to increase the chance of successful induction. ***Objective*****:** To compare the efficacy of transcervical Foley catheter and intra-vaginal misoprostol as a pre-induction cervical ripening method and associated factors at selected public hospitals of Addis Ababa, Ethiopia, 2020. ***Methods:*** A retrospective institution based cross-sectional study was conducted from October to November 2020 in selected Hospitals of Addis Ababa, Ethiopia. The consecutive sampling method was used to enroll a sample size of 204 study participants for each group of cervical ripening methods, by using delivery and induction registration books. The first group was women primed by transcervical Foley catheter and the second was those by intra-vaginal misoprostol. Data were collected by questionnaire and entered into a computer using Epi-data version 4.6.2 statistical program then it was exported to SPSS version 25 for analysis. Selected baseline characteristics and outcome measures were compared using the independent sample T-test and Fisher's exact or Chi-Square test for continuous and categorical variables respectively. Lastly, the significance of the statistical association was assured using OR at a 95% confidence interval and p-value <0.05. **Result:** The rate of success of induction ($\chi 2 = 5.892$; P=0.015) and mean change in Bishop's (P<0.001) score were found to be significantly higher in the Foley catheter group. But the rate of uterine hyperstimulation (P =0.02), fetal heart rate abnormality (P=0.01), maternal and neonatal adverse effects (P=0.04), and NICU admission (P=0.01) were significantly higher in the misoprostol group. Parity (AOR=4.45(95% CI: 2.01- 9.82) and gestational age (AOR=0.45(95%CI: 0.22-0.90), were significant predictors of success in misoprostol group compared to residential address (AOR=0.46(95%CI: 0.26-0.95) in the Foley group. **Conclusion and recommendation:** This study showed that a transcervical Foley catheter increases the success rate of induction and decreases maternal and neonatal complications associated with induction of labor. The result suggested that safety issues need to be taken into consideration when misoprostol is planned to use especially in multiparous women.



**Keywords:** Misoprostol, Foley Catheter, Cervical Ripening, Addis Ababa

# 1. INTRODUCTION

## 1.1. Background

The goal of obstetric is achieving a pregnancy that results in a pleasurable outcome, a healthy mother and a healthy infant. For most pregnant women, labor starts naturally and results in vaginal delivery at term. But sometimes because of medical or obstetrics complications of pregnancy, artificial initiation or cervical priming and labor induction is often required (1, 2).

Induction is the procedure of starting uterine contractions before the beginning of normal labor to obtain vaginal delivery by medical or surgical means and is one of the most widely practiced obstetric procedures (3, 4). It is primarily done when the baby's birth is considered more advantageous to the mother or the fetus than awaiting the natural start of labor. There should be a delicate balance between uterine contractions, cervical progress, and maternal and fetal condition to achieve the goal. The general aim of induction is to obtain immediate vaginal birth by inducing uterine contractions before the natural onset to minimize maternal and neonatal mortality and morbidity. Induction of labor involves a complete interaction between oxytocin and prostaglandins and its success largely depends on cervical, fetal, maternal, and birth canal conditions (5, 6).

The process of softening, partial dilation, and shortening of the cervix or cervical preparation typically done before uterine contractions begin and are essential for the labor progress. It is the result of complex biochemical processes, whereby various enzymes stimulate chemical reactions that result in rearrangement and realignment of the collagen fibers thus the cervix thins, softens, relaxes, and opens in response to uterine contractions that force the cervix over the present fetal portion (7).

Many women who undergo labor induction have an unfavorable cervix, which leads to prolonged and exhausting labor, chorioamnionitis, and cesarean section so that some cervical ripening agent pharmaceutical or mechanical is often used. Cervical preparation is most

commonly performed to increase the chance of successful induction of labor (8). More than 24% of pregnant women who underwent induction required cervical priming (9, 10).

Misoprostol is among the pharmacological agents and has been proved by several studies to be an effective, easily stored, and relatively cheap agent for cervical ripening (10).

Mechanical techniques such as transcervical Foley catheter is safe for cervical priming and has been shown to reduce induction to delivery interval, decrease cesarean delivery rate, and increase the rate of vaginal delivery (11). It is preferable for cervical ripening as it is cheap, safe, effective, widely available, and stable at room temperature and inserted into the woman's uterine cavity through the cervix and vagina then filled with a predetermined volume of fluid (12, 13).

## 1.2. Statement of the problem

According to a 2017 WHO survey, around 295,650 women died from preventable causes linked to pregnancy and childbearing. 94% of these deaths occurred in developing and low-income countries. The maternal death rate in the poorest countries is high, estimated at 415 maternal deaths per hundred thousand live births, which are 40 times larger than in Europe. In the same year around 542 maternal deaths per hundred thousand live births were occurred in sub-Saharan countries, and the lifelong risk was one in 37 compared to just one in 7,800 in Australia and New Zealand. Similarly, high numbers of neonates are also dying in the world as a 2016 UNICEF report around 19 neonates dies for every 1000 live births. Ethiopia is among the sub-Saharan countries which have high maternal and neonatal mortality. According to the 2016 EDHS survey, in Ethiopia, the maternal and neonatal deaths were 412 per hundred thousand live births and 48 per thousand live births respectively (14, 15, 16).

To alleviate this gross rooted problem, immediate, innovative, and strategic interventions should be designed and implemented to accelerate progress and bring performance on maternal and neonatal health back on track, and possibly progress toward achieving the sustainable SDG targets. One of the options is advancing the promotion, quantity, quality, and use of services for the treatment of complications that arise during pregnancy and childbirth (8, 17, 18).

Induction of labor by using the most effective, and the safest method of the cervical ripening agent is one component of these quality services and directly relevant to reducing neo-maternal morbidity and mortality as it has the potentials for preventing Fetomaternal problems and improving outcomes of pregnancy (11). Although this is often an appropriate intervention, the achievement of normal birth for a woman who needs labor induction is among the main challenges facing obstetricians today (8). To alleviate these challenges, obstetricians, midwives and other qualified health care providers at the maternity unit have been used several methods to prepare the ripeness of the cervix before labor induction (19). Among these methods of ripening transcervical Foley catheter and intra-vaginal misoprostol are the commonest (20).

Even though these two methods are used frequently, the effectiveness and safety of one over the other are contradictory. A study conducted in Iran reported that misoprostol was safe and effective to minimize the duration of induction and decrease the number of cesarean deliveries (21). The same findings were stated in some other studies carried out in India (22, 23). Whereas study in Addis Ababa shows that a Foley catheter was better for ripening the cervix and increase the number of vaginal delivery (12).

However, even if cervical ripening methods are increasingly practicing before induction of labor to achieve the desired birth outcome, the prevalence of failed induction in Ethiopia is high. A study in Woldia general hospital Northeast Ethiopia reported that the prevalence of failed induction was 37.4% with more occurrences in primipara mothers and women with a Bishop's Score of less than six (24). Another study in Welaita Sodo hospital showed that the prevalence of failed induction was 26.5%. Failed induction has the potential to lead to cesarean birth and its complications (25). These complications and risks put a huge challenge for practicing induction of labor for managing complications of pregnancy and risks associated with continuing the pregnancy.

Although Foley catheter and intra-vaginal misoprostol play a vital role in the success rate of induction, the effective and the safest method among the two is not well studied in the study area, as well as in the country. Therefore, this study seeks to fill this gap by identifying the safest and more effective method of cervical ripening.

## 1.3. Significance of the study

In poor resource nations like Ethiopia, a method, which is effective, safe, easily storable, and cheaper, is always welcome. However, like many other sub-Saharan countries, the effective and safest method of the cervical ripening agent in Ethiopia is not adequately studied. Therefore, this study was aimed to compare the effectiveness and safety of intravaginal misoprostol and transcervical Foley catheter as a pre-induction cervical ripening method and associated factors. New data on an effective and safe method of compared cervical ripening agents may therefore be available.

Hence, it will have significance for different stakeholders, first for the health institutions and health services providers in local settings and other parts of the country to have evidence-based practices on pre-induction cervical ripening methods. Second, it will provide information for the federal health minister and other stakeholder's works in obstetrics to develop a uniform clinical guideline for pre-induction cervical ripening agents across the country. Third, it will enable women who need priming and induction of labor to get improved quality of care in health institutions. Finally, since there are no sufficient studies exist on this title, the data will also help researchers and academic institutions to do further studies on the effective and the safest pre-induction cervical ripening agent in Ethiopia and abroad.

# 2. LITERATURE REVIEW

## 2.1. Indications for cervical ripening and induction of labor

Labor induction can only be carried out whenever there is a valid clinical indication for it. The decision to conduct labor induction is made when the baby's birth is considered more advantageous to the mother or the fetus than awaiting the natural onset of labor. Fetomaternal, socio-cultural or a combination of these causes are the key indicators of labor induction These indications may also either be evident or anticipated (1, 5, 19).

Maternal indications include medical conditions that are caused or aggravated by pregnancy (like hypertensive disorders of pregnancy, diabetes mellitus, placental abruption, and certain respiratory, hepatic, and cardiac disorders) and discomforts such as from multiple pregnancies and polyhydramnios. Also, induction can be done for allowing essential treatment to be commenced such as for cervical cancer, relieving emotional distress after intrauterine death; or alleviating anxiety about the baby's well-being. Fetal indications include prolonged pregnancy, suboptimal intrauterine growth, rhesus immunization, fetal compromise, and cholestasis of pregnancy (1, 4).

A study in Saudi revealed that the leading causes of induction of labor were post-term pregnancy (31%), GDM (23.2%), and PROM accounting for 15 (26)

A controlled trial study in India (2014) shows that the most common indication for cervical priming and IOL were Diabetes mellitus (25.4%) and postdate (23.8%) for mother primed with Foley catheter and postdate (36.5%) and PIH (14.3%) for those primed with intra-vaginal misoprostol (27).

According to a study done in Nigeria Pre-labor rupture of membranes (26.0%), Post-term pregnancy (25.0%), intrauterine fetal death (18.3%), Hypertensive disorders (13.5%), and IUGR (3.8%) were the leading causes of induction of labor (28).

A study in Welayita Sodo showed that PROM 48.1%, Post-term 35.2%, and Medical disorders with pregnancy 12.1% were the common causes of labor induction. Similarly, a study done in

Weliso shows, the leading causes of induction of labor were PROM 35.5%, post-term (27.6%), pregnancy-induced hypertension (21.0%), and IUFD (15.8%) (29).

## 2.2. Methods of pre-induction cervical ripening

Ripening is the result of complex biochemical processes that cause physical softening and dispensability of the cervix. The process leads to partial effacement and opening of the cervix with its purpose is to facilitate favorability and to reduce the time to delivery and the incidence of failed induction (11, 30).

Various cervical ripening agents are available, containing both pharmacological and mechanical. The medical agents are administered vaginally in the fornix and may be repeated after six hours if required but, the non-pharmacological method is used by insertion of a Foley catheter into the cervix. According to ACOG, Misoprostol and trans-cervical catheter are approved and recommended because of their high safety profile and comparative effectiveness. Besides, they are often preferred over PGE2 tablets gel and insert given their low cost, availability, and ease of use (3, 12).

### 2.2.1. Misoprostol (Cytotec)

Misoprostol (Cytotec) a prostaglandin E1 (PGE1) marketed as a gastric cytoprotective agent, that can be given sublingually, orally, or vaginally, and has been approved by several studies to be an effective, easily stored, and relatively inexpensive agent for priming and induction (10). Evidence showed that, for women with low Bishop's score cervix, Intra-vaginal misoprostol was more effective than placebo and Foley catheter as a pre-induction ripening agent. According to studies done in Nigeria, vaginal misoprostol (50-100 micrograms) was more likely than vaginal PGE2 to achieve vaginal delivery and favorable cervix within 24 hours (21, 31).

A study in India showed that the need for oxytocin and ARM for labor augmentation was significantly higher in women primed with Foley catheter than women with intra-vaginal misoprostol 77.2% versus 48.3% and 95.5% versus 66.7%, respectively. Induction to the delivery interval in women primed with intra-vaginal misoprostol was 14.03 ± 7.61hrs while that of women primed with trans-cervical Foley catheter was 18.40 ± 8.02 hrs. Contraction

complication was observed in11.7% of women in the intra-misoprostol group compared to no cases in the trans-cervical Foley catheter group (32).

**2.2.2. Transcervical Foley catheter**

A transcervical Foley catheter uses when labor induction is mandatory to ripening the unripe cervix. It works by both a direct stretching of the cervix and a local inflammatory response that releases matrix metalloproteinase and prostaglandins (33).

When the cervix is undilated, firm, and long, membrane stripping is frequently impractical. In this situation, trans-cervical Foley catheter insertion above the internal os into the endocervix may be a more reasonable approach to initiate cervical ripening. The most effective and safest way of inserting a transcervical Foley catheter is under direct visualization by retracting with a speculum. The balloon is inflated with 30-80 ml of saline and pulled snugly against the internal os by taped to the thigh under traction. The catheter will be put in place until it will fall out spontaneously or 12hrs have elapsed (30, 32).

A study in Maharashtra, India revealed that trans-cervical Foley catheter was an efficient, safe, cost-effective, reversible cervical ripening method with similar cesarean delivery rates to prostaglandins and a lower risk of maternal and neonatal complications (34).

A study done in Portugal showed that 71% of the women were successfully delivered vaginally after a transcervical Foley catheter used as a cervical ripening agent and concluded Foley catheter was safe and effective for women with an immature cervix (35).

A study comparing misoprostol, transcervical catheter, and the association of the transcervical Foley catheter with prostaglandin E2 indicated no difference between these methods of cervical ripening. There was only a high percentage of tachysystole with less oxytocin need in the intra-misoprostol group but with no difference related to the type of delivery. Some advantages of the Foley catheter compared to prostaglandin cervix ripening agents are, low cost, and principally the possibility of using it in women with a previous cesarean section (36).

## 2.3. Efficacy and Safety of cervical ripening agents

Priming and induction is not riskless practice, it has the chance to lead to failure rate and adverse neo-maternal effects. Since the general aim of using cervical ripening agents is to achieve vaginal delivery and minimize the number of cesarean deliveries and related complications, this study considers efficacy is the capacity of cervical ripening methods (trans-cervical Foley catheter and intra-vaginal misoprostol) to achieve the desired goal of priming and induction and measured by the success rate of induction primarily and progress of ripening and induction secondary (37, 38), whereas Safety means being protected from undesirable outcomes of cervical ripening methods (trans-cervical Foley catheter and intra-vaginal misoprostol) and measured by the incidence of excessive uterine activity (tachysystole is six or more uterine contractions per 10 minutes or hyperstimulation, if combined with the abnormal fetal heartbeat, or hypertonus is a single contraction of $\geq$ 2 minutes duration) primarily and the incidence of immediate adverse neonatal and maternal outcomes secondary (37, 39). The major maternal risk of priming and induction is the risk of morbidity and mortality associated with cesarean delivery. Prolonged priming to delivery interval may result in pyrexia, poor maternal and neonatal outcomes (8).

The outcome of induction can be either failure or success. The definition of successful and failed induction differs from study to study. According to ACOG, SMFM & NICHD, ”failed induction should be diagnosed if there is a failure to generate regular contractions and cervical change for at least 24 hours of oxytocin administration with ARM whereas successful induction is defined as “vaginal birth of a baby with minimum neo-maternal discomfort and side effects, within a specified period of time” (1, 3, 8).

### 2.3.1. Efficacy and Safety of Misoprostol versus Foley catheter for cervical ripening.

Studies have looked to investigate and compare the effectiveness and the safest cervical ripening agent. A study in New York found that intra-vaginal misoprostol and the Foley catheter were similarly effective and timely. However, significantly higher rates of uterine tachysystole and meconium passage were found in the intra-vaginal misoprostol group. Two mothers have developed contraction complications in the intra-vaginal misoprostol group, both of which delivered immediately by cesarean section (40). But another study in the same area showed that the mean priming to delivery interval was significantly longer in the intra-vaginal misoprostol group (22.57hrs miso vs Foley 12.27hrs) ($P < 0.01$). The development of chorioamnionitis was

27.3% in the intra-vaginal misoprostol group compared with 11.5% in the Foley catheter group. But no statistically significant variations between the groups regarding contraction complications, vaginal and cesarean delivery rate, and fifth minutes Apgar score. However, the need for oxytocin was significantly higher in the transcervical Foley catheter group (P <. 0.01) (41).

In contrast, a controlled trial in India reported that intra-vaginal misoprostol was effective to achieve a favorable Bishop Score (8.01 ± 1.45 miso vs 5.01 ± 1.48 Foley), more vaginal delivery (72% miso vs 18% Foley), and less cesarean section rate (28% miso vs 80% Foley) than the transcervical Foley catheter. But, fetal distress (30 (60%) Foley vs 10 (20%) miso) and prolonged latent phase of labor (12% Foley versus 0% miso) were significantly higher in the Foley catheter group as compared to intra-vaginal misoprostol (22).

Similarly study in Iran showed that the rate of success of induction was significantly higher in the intra-vaginal misoprostol group (89.8% vs 62.7%: p < 0.01) compared to the Foley catheter group. The mean of induction to delivery was 11.08 ± 5.6hrs in the intra-vaginal misoprostol group, in comparison to 13.5 ± 16.9hrs in the transcervical Foley catheter group. Uterine hyperstimulation was observed in 2% of the intra-vaginal misoprostol group and no one of the Foley catheter group and 5% of intra-vaginal misoprostol and 6% of the transcervical Foley catheter group was developed PPH secondary to uterine Atony (21).

A study in Bangladesh, to compare the two methods showed that both intra-vaginal misoprostol and Foley catheter had similar effectiveness to improve the unripe cervix. Transcervical Foley Catheter is associated with a lower incidence of contraction complications and a higher rate of successful induction (89.2%) in comparison to misoprostol (64%). But misoprostol was better in terms of mean duration of onset of labor pain (3.0 + 2.2 hours miso vs 7.3 + 3.0 hours Foley), priming to full dilatation [8.9 + 3.8hrs miso vs 12.0 + 4.5hrs Foley] and priming to delivery interval (9.2 + 4.1hrs vs 14.8 + 5.2hrs Foley) (42).

A study on comparison of pre and post-induction bishop's score improvement in transcervical Foley's catheter versus intra-cervical dinoprostone showed that pre-induction Bishop's score was four in 57% of mothers in the Foley catheter group compared to five in 68% of mothers in intra-cervical dinoprostone group (p = 0.01). Mean admission Bishop's score was 4.35 ± 0.55 in the transcervical Foley catheter group as compared to 4.69 ± 0.49 in the intra-cervical dinoprostone

group ($p < 0.01$). Similarly, the change in Bishop Score was greater than eight among 64% of women in the intra-cervical dinoprostone group compared to 44% of women in the transcervical Foley catheter group ($p = 0.04$). The mean change in Bishop's score in the intra-cervical dinoprostone group was significantly high ($7.39 \pm 11.32$) in compression with to Foley group ($6.92 \pm 1.30$) ($p = 0.01$). But the mean duration of cervical priming was significantly high in the transcervical Foley catheter group ($10.27 \pm 1.96$hrs) compared to the intra-cervical dinoprostone group ($7.6 \pm 2.9$) ($p< 0.01$). The mean induction to the delivery interval was comparable between groups ($18.9 \pm 4$ hours Foley vs dinoprostone $12.2 \pm 3.7$: $p < 0.01$). Significantly higher numbers of vaginal deliveries were noted in the intra-cervical dinoprostone group (73%) as compared to the transcervical Foley catheter group (66%) ($p = 0.02$) (43).

A controlled trial of PGE2 gel, transcervical Foley catheter, and intra-vaginal misoprostol reveals that there were no statically significance variation between the groups in terms of improvement of Bishop's score ($5.5 \pm 1.8$ and $5.6 \pm 1.9$ Foley's catheter) and induction to the delivery interval ($15.2 \pm 4.2$ PGE2 gel vs $16.3 \pm 4.3$ Foley vs $17.3 \pm 4.1$ miso). But there was a statically significance difference between the groups concerning oxytocin need (37% in PGE2 gel, 23% in Foley's catheter, and 40% in misoprostol) and rate of cesarean delivery (37% vs 23% vs 40% respectively) (44).

According to a study in Nigeria, Intra-vaginal misoprostol was more effective in achieving favorable bishop score within 12hrs (38% vs 61%) and 24hrs (3% vs 18%) than transcervical Foley catheter (45). Similarly, another study in the same area revealed that significantly higher numbers of mothers were achieved favorable cervical status within 6-12hrs of priming in the misoprostol group (98%) compared to the transcervical Foley catheter group (69%). 26.6% of mothers in the intra-vaginal misoprostol group and 6.5% of mothers in the transcervical Foley catheter groups were developed spontaneous labor before induction. But, no significant variation within the groups in terms of induction to the delivery interval and the vaginal delivery rate (7).

A study in Ethiopia revealed that change in Bishop Score, oxytocin need (75.7% Foley vs 43.2% miso), and vaginal delivery rate (84.7% vs 72.2%) were found to be significantly larger in the transcervical Foley catheter group. But no difference was seen regarding priming to the delivery interval within the groups. In the case of safety measures, there were 14 (12.6%) cases of

hyperstimulation in the misoprostol group compared to no tachysystole associated with FHR abnormality in the transcervical Foley catheter group (P-value < 0.01). FHR abnormality was significantly (p-value < 0.01) higher in the misoprostol group (26.1%) compared to (6.3%) in the transcervical Foley catheter group. Uterine rupture was occurred in three mothers in the intra-vaginal misoprostol group compared to no cases in the transcervical Foley group. Neonatal resuscitation was made for 9.9% of neonates in the Foley catheter group and 15.3% of neonates in the intra-vaginal misoprostol group. Furthermore, there were three END in the intra-vaginal misoprostol group and one in the transcervical Foley catheter group (12).

The above literature suggests that even if comparing the effectiveness and safety of cervical ripening method was studied in the field of obstetrics, consistently superior to the other concerning safety and effectiveness was varied from study to study and setting to setting.

## 2.4. Factors associated with Efficacy

Many risk factors are affecting the effectiveness and safety of cervical ripening agents. The factors can be grouped as Socio-demographic factors, obstetrics characteristics, and indications and methods of cervical ripening and induction of labor (24, 44).

### 2.4.1. Socio-demographic factors

Various studies showed that the safety and effectiveness of cervical ripening agents can be influenced by the woman's Socio-demographic characteristics such as age and residence. According to a prospective study in Nepal, the Failure rate was 53.8% among mothers with age greater than 30yrs old and 28.2% in those less than 30yrs (47). Based on a study in Latin America, it was found that mothers from poor socio-economic areas were at a greater risk for poor pregnancy outcomes (48). In another study in Hawassa, Ethiopia showed that mothers with age greater than 30 years were found to be more at risk (28.8%) [AOR=9.210 (2.70-31.35)] than others (6.4%) to have failed induction of labor (25). Similarly, a study in Welayita found that age was a significant predictor for the success of labor induction; the odds of women with age of fewer than 24 years were two times [AOR=2.437 (1.126-5.275)] higher than those who were the age 25 and above to experience successful induction (29).

### 2.4.2. Obstetrics Factors

Obstetrics factors such as parity, bishop score, gestational age, fetal heart rate pattern, and birth weight have an association for achieving safe and effective vaginal delivery after cervical ripening and induction labor. Different studies found that there were significant rises in the duration of labor, maternal pyrexia, cesarean section, and birth asphyxia in primigravida. A study done in Pakistan reported that the failed induction rate was 4.6 times higher in nulliparous patients compared to their multiparous counterparts (49). Similarly, in Saudi Arabia, a statistically significant rise in odds of CS was found in nulliparous women compared with multiparous women (26). Priming and labor induction in nulliparous also increase the risk of instrumental vaginal delivery, blood transfusion, longer hospital stay, need for immediate care for the newborn, and its admission to an intensive-care unit (48).

A study in Welayita showed that the failed induction rate was 4.6 times higher in nulliparous patients (25.3%) compared to their multiparous counterparts (6.8%) (29). Moreover, a study in Hawassa health facilities revealed that Primipara women had 3.11 more risk of going to cesarean delivery than multipara (AOR = 3.11,95% CI. 1.1-9.6) (25).

Pre-induction assessment of cervical status or favorability is fundamental for the clinician to estimate the likelihood of effectiveness and safety of cervical ripening and induction of labor. One quantifiable method predictive of effectiveness and safety of cervical ripening agents is the Bishop (1964) score, which consists of cervical dilatation, consistency, effacement and position, and descent. If the cervix is mature (has a score of six or more), labor is usually successfully induced. If it is unfavorable (has a score of five or less), cervical preparation should be done before induction (1, 48). More than a quarter of women frequently have an indication for induction but with an immature cervix (8, 49). There is an increasingly ineffective induction rate as the bishop's score declines. A study in Australia reported that an unfavorable cervix increases the chance of failure rate, duration of induction, and cesarean sections (51).

A study in Nepal showed that the rate of induction failure was 40.8% in women with a Bishop's Score of 5 or less versus 24.1 % in women with the favorable cervix (47).

In Ethiopia Girma, W, et al. (2016) have shown that women who had unfavorable Bishop Score at admission have 5.3 times more likely to have failed induction as compared to those women

with favorable Bishop score (AOR = 5.28, 95 % CI.2.005-13.878) (46). Similarly, another study in Hawassa showed that the rate of failed induction was 4.54 times more likely in mothers with admission bishop score of less than five [AOR =4.54(95% CI:1.56-13.19] than those with a bishop score of greater than five (25). Moreover, a study in Welayita significant association between women bishop score and success of labor induction was observed, in which women with bishop score greater than 5 were about 7 times more probable to have successful induction when compared to those with five or less [AOR =7.5(2.44-23.07)] (29).

A facility-based comparative cross-sectional study, at three teaching hospitals of Addis Ababa University, showed that cervical ripening reduces the high rate of cesarean sections for failed labor induction. Cesarean section secondary to induction failed and non-reassuring fetal heartbeat pattern together was 40.8 % in the oxytocin protocol group and 16.3 % in the prostaglandin and oxytocin protocol (52).

Studies showed that variables such as birth weight, non-reassuring fetal heartbeat rate pattern, and gestational age are considered as fetal factors that affect the efficacy and safety of cervical ripening agents (46).

A study done in Pakistan showed that the rate of failed induction was higher among women who had gestational age greater than 40wks (47.8%). It was also investigated that the women who had macrosomic babies were 2.5 times higher to have a failure of induction compared to patients with normal birth weight (49). A study in Austria showed that gestational age greater than 39wks was associated with increased $3^{rd}/4^{th}$-degree tear in primipara women.

A finding was done in Spain also reported that the rate of cesarean-sections was higher among women who had PIH (29.8%) and in women with post-term pregnancies (27.3%) compared to among women with PROM ( 21.1%) (53).

Similarly study in Hawassa showed that the rate of failed induction was 6.57 times more likely in mothers with greater gestation [AOR=6.571 (2.18, 19.72)] than others (25). An institution-based study in Welayita found that the induction success was 0.36 times lower among mothers with non-reassuring fetal heart rate (AOR=0.36(0.13-0.98) (29).

## 2.5 Conceptual framework

Under this framework, the efficacy of cervical ripening agents was likely to be contributed by the following categories of factors, namely; socio-demographic factors, obstetric factors, indications, and methods of priming and labor induction factors.

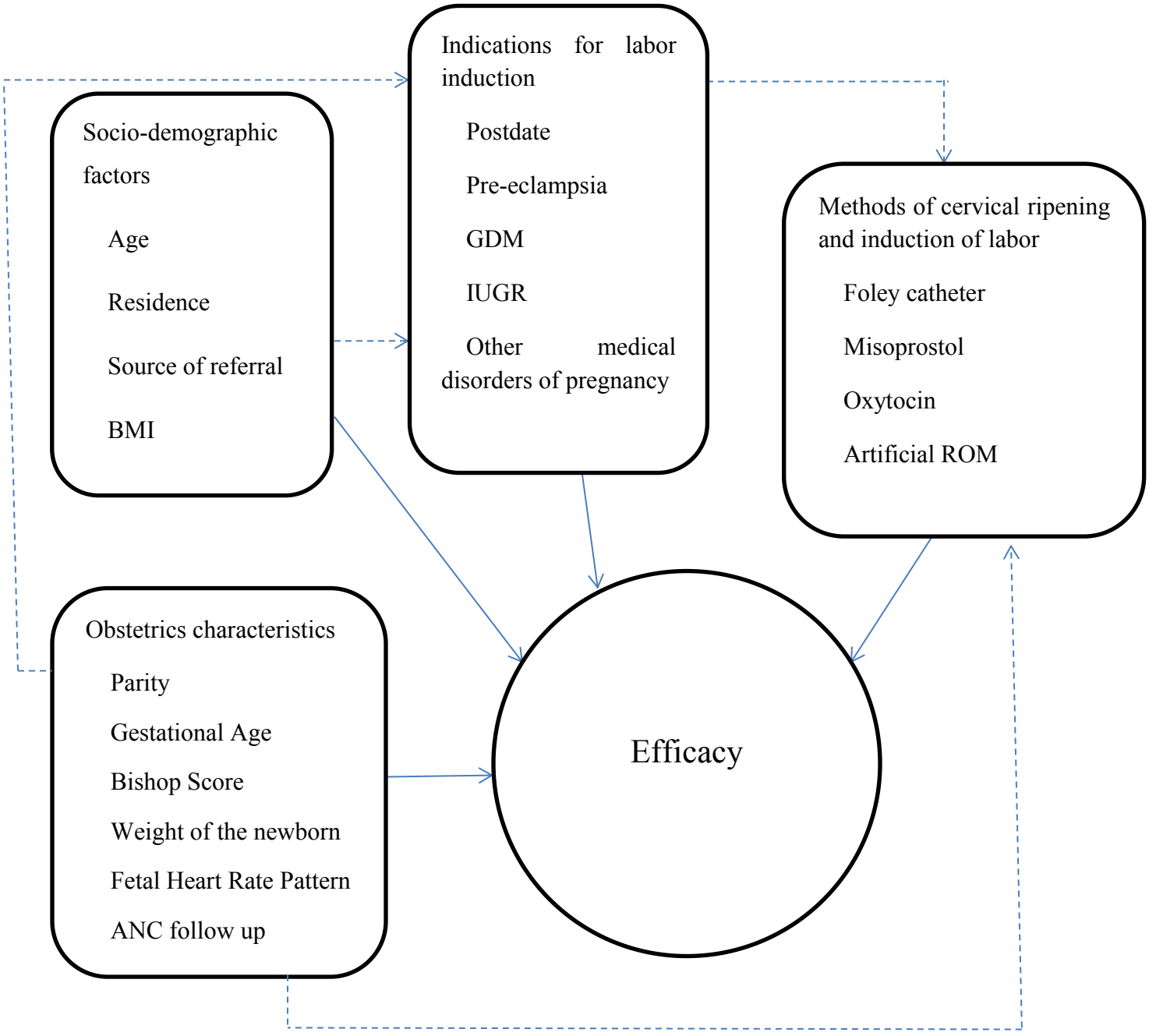


**Figure 1: Conceptual framework adapted from other studies (24, 25)**

# 3. OBJECTIVES

## 3.1 General Objective

To compare the efficacy of transcervical Foley catheter and intra-vaginal misoprostol as a pre-induction cervical ripening method and associated factors at selected public hospitals of Addis Ababa, Ethiopia.

## 3.2 Specific Objectives

- To compare the efficacy of transcervical Foley catheter and intra-vaginal misoprostol as a pre-induction cervical ripening methods.
- To investigate factors associated with the efficacy of transcervical Foley catheter as a pre-induction cervical ripening method, and
- To investigate factors associated with the efficacy of intra-vaginal misoprostol as a pre-induction cervical ripening method.

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# 4. METHOD AND MATERIAL

## 4.1. Study area and period

The study was conducted in four purposely selected public hospitals of Addis Ababa, the capital city of Ethiopia from October 1 to November 30, 2020. Based on the 2017 population projection conducted by the Central Statistical Agency of Ethiopia (CSA), Addis Ababa has a total population of 3,194,999 with male 1,515,001 and female 1,679,998 respectively with an annual growth rate of 2.7 %. The city has 41 hospitals (13 public and 28 NGO and private), 29 health centers, and 382 modern private clinics (54). This study was conducted at Tikur Anbesa Specialized Hospital, St Paul Hospital Millennium Medical College, St Peter Specialized Hospital, and Gandhi Memorial Hospital. Tikur Anbesa Specialized Hospital is the largest tertiary referral hospital in the country. It is located in Lideta Sub City, Keble 07. About 5000 deliveries are attended each year and 60% of those are operative deliveries. St. Paul's Hospital Millennium Medical College is the second-largest public hospital in the nation and located in Gullele Sub City. It provides Antenatal care and delivery services for more than 2500 and 6000 women per year respectively. Gandhi Memorial Hospital has stayed on service for more than 50yrs providing service for the highest number of women, located in Kirkose sub-city. The average number of deliveries per year is about 7000 of which 30% comprise operative deliveries. St. Peter Specialized Hospital is currently located in Gullele Sub-city, Shiromeda, and administered under the Federal Democratic Republic of Ethiopia Ministry of Health (FMOH). Out of the thirteen governmental hospitals in Addis Ababa, eleven of them provide delivery service by cesarean section. Among those 13 hospitals, Ammanuel mental health hospital and federal police hospital were excluded due to not providing delivery services (52, 54).

## 4.2. Study design

Institutional based retrospective cross-sectional study was conducted.

## 4.3. Population

### 4.3.1 Source population

All medical records of women who had given birth after primed and induced at public hospitals of Addis Ababa from January 2019 to September 2020.

#### 4.3.2. Study population

All selected medical records of women who had given birth after primed by trans-cervical Foley catheter and intra-vaginal misoprostol and meet the inclusion criteria at selected public hospitals of Addis Ababa from January 2019 to September 2020.

## 4.4. Eligibility criteria

#### 4.4.1. Inclusion criteria

- Women of all parity's
- Women who had bishop score of less than 6
- Women who had regular fetal heart rate pattern
- Women who had intact membrane

#### 4.4.2. Exclusion criteria

- Women who were primed and induced before 28weeks of gestation
- Women who had congenital malformations of the fetus, Intrauterine fetal death, and chorioamnionitis
- Lost card

## 4.5. Sample size determination

#### 4.5.1 Sample size determination and Sampling procedure

The sample size was calculated using a double population proportion. Below were the lists of assumptions and formula that were considered in calculating the sample

$$n = \frac{\left[ Z\frac{\alpha}{2}\sqrt{(1+1/r)p(1-p)} + Z\beta\sqrt{p1(1-p1)+\frac{p2(1-p2)}{r}} \right]^2}{(p1-p2)^2}$$

Where, n= Sample size to be determined

$Z\frac{\alpha}{2}$ = Level of statistical significance at 95% confidence level =1.96

N= total sample size=n*2

r= $\frac{n\ 1}{n\ 2}$ =1:1, n1=n2

P (population proportion) = $\frac{P1+rP2}{1+r}$

Zβ= Desired power of 80% =0.84

P1= (population proportion for effectiveness of trans-cervical Foley catheter)

P2= (population proportion for effectiveness of intra-vaginal misoprostol)

P1-P2 =Difference between proportions

Assumptions: - 95% confidence interval (Z $\frac{\alpha}{2}$ = 1.96), 80% power (Z$\beta$ =0.84)

Since for this study effectiveness of cervical ripening method was the primarily outcome measures of efficacy, the sample size was calculated based on the proportion found in other study.

A study at Addis Ababa and Bahirdar found that the effectiveness of trans-cervical Foley catheter and intra-vaginal misoprostol as a pre-induction cervical ripening agent was 84.7% and 72.2% respectively (12).

By using the double population proportion formula the sample size becomes 185 for each group and by considering 10% incomplete data the sample size became 185 + 19=204 for each group. Total sample size was N= 2*n=204*2=408. Two hundred four mothers' charts were selected for trans-cervical Foley catheter and 204 for the intra-vaginal misoprostol group.

### 4.6. Sampling technique

Out of the thirteen governmental hospitals in Addis Ababa, eleven of them provide delivery service by cesarean section. In this study, St Paul Hospital Millennium Medical College, St Peter Specialized Hospital, Gandhi Memorial Hospital, and Tikur Anbesa Specialized Hospital were purposively selected based on their high number of admissions and method used for cervical ripening and induction of labor. St Paul Hospital Millennium Medical College and Tikur Anbesa

Specialized Hospital uses Foley catheters for cervical ripening and induction of labor whereas Gandhi Memorial Hospital and St Peter Specialized Hospital use misoprostol. The number of samples for each Hospital was allocated proportionally after identifying the average monthly admissions for priming and induction of each hospital. According to the hospital's induction registration book, the average monthly number of admissions for priming and inductions were 84 at Gandhi Memorial Hospital, 78 at St Paul Hospital Millennium Medical College, 72 at Tikur Anbesa Specialized Hospital, and 68 at St Peter Specialized Hospital for five consecutive months. The samples for the transcervical Foley catheter group were selected from St Paul Hospital Millennium Medical College and Tikur Anbesa Specialized Hospitals whereas for intra-vaginal misoprostol group from Gandhi Memorial Hospital and St Peter Specialized Hospital due to the cervical priming method they used.

Finally, an individual study participant of both groups was selected using a consecutive sampling method including every chart which met the inclusion criteria until the total sample size for this study was obtained using the delivery registration book.

Then the allocation for each hospital was done as follows:

For trans-cervical Foley catheter group

NX = (n/N) Y where

NX= the sample size allocated for "X'' hospital

Y =Population size that "X'' hospital averagely admit for priming and induction per month by trans-cervical Foley catheter.

n = Total sample size for trans-cervical Foley catheter =204

N= Total population size (average number of admissions at St Paul Hospital Millennium Medical College and Tikur Anbesa Specialized Hospital) = X1+X2 = 150

For St Paul Hospital Millennium Medical College = (204/ 150)78 =106

For Tikur Anbesa Specialized Hospital= (204/ 150)72=98

Sample size for trans-cervical Foley catheter =204

For intra-vaginal Misoprostol group

NX= (n/N) Y where

NX= the sample size allocated for "X'' hospital

Y= Population size that "X'' hospital averagely admit for priming and induction per month by Intra-vaginal misoprostol.

n = Total sample size for intra-vaginal misoprostol =204

N= Total population size (average number of admissions at St Peter Specialized Hospital and Gandhi Memorial Hospital) = X1+X2 = 152

For Gandhi Memorial Hospital = (204/ 152)84 =113

For St Peter Specialized Hospital = (204/ 152)68=91

Sample for intra-vaginal Misoprostol =204

Total sample size = Sample size for trans-cervical Foley catheter + Sample size for intra-vaginal Misoprostol =204+ 204=408.

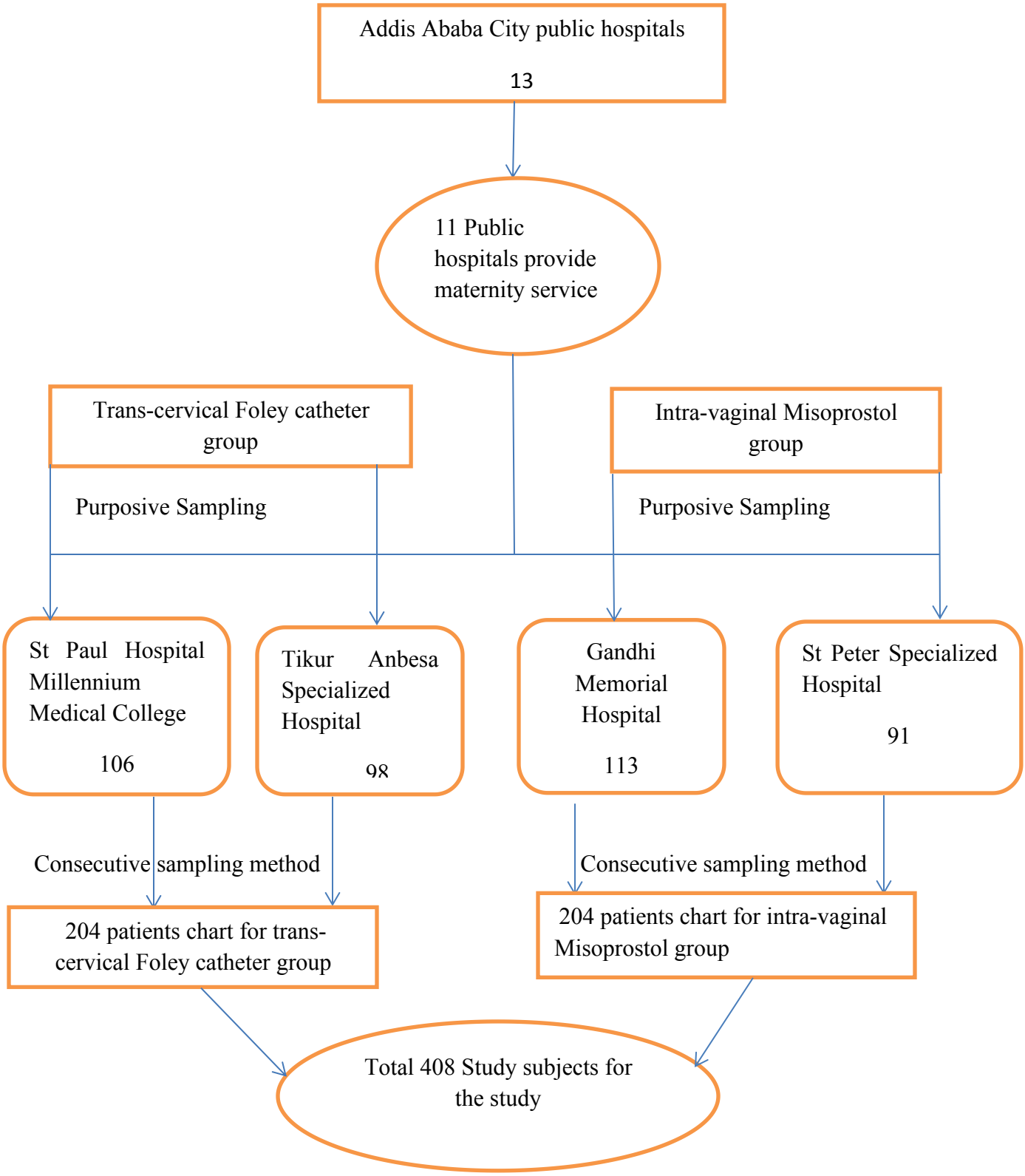



**Figure 2: Schematic presentation of sampling procedures**

## 4.7 Study Variables

### 4.7.1 Dependent variable:

- Efficacy of cervical ripening methods

### 4.7.2 Independent variables:

- Women socio-demographic factors (age, residence, BMI and the source of referral)
- Obstetric characteristics (ANC follow up, parity, gestational age, Bishop score, weight and sex of the newborn, and Fetal Heart Rate Pattern)
- Indications of induction (post-term pregnancy, pregnancy-induced hypertension, DM, and IUGR)
- Methods of induction of labor (intra-vaginal misoprostol, Foley catheter, oxytocin, or Artificial ROM)

## 4.8 Operational definitions

**Induction of labor:** an artificial initiation of uterine contraction prior to the natural onset after 28 weeks of gestation.

**Cervical ripening:** a pre-labor preparedness of the consistency, position, effacement, and dilatation of the cervix for induction after 28 weeks of gestation.

**Efficacy:** the effectiveness of cervical ripening method (trans-cervical Foley catheter and intra-vaginal misoprostol) to achieve the desired goal of priming and induction of labor and primarily assessed by successful induction.

**Pattern of labor outcome of induction**: Failed or successful induction of labor.

**Failed induction of labor: -** diagnosed if a woman delivered by cesarean section because of failure to achieve either sufficient uterine contraction (≥3 contractions in ten minutes' period lasting ≥40 seconds) or failed to obtain favorable cervical changes (reach at least 4cm in dilatation and fully effaced) despite being on oxytocin drip for at least six hours or diagnosed as failed induction by the treating residence.

**Successful induction: -** when a woman had achieved vaginal birth (either spontaneous or assisted by instrumental delivery) after labor was induced.

**Change in Bishop Score:** for the transcervical Foley catheter group, it is the change between the initial score (at the insertion of the Foley catheter) and the score at the period of removal of the transcervical Foley catheter. In the intravaginal misoprostol, it is the difference between the initial score (at the placement of the first dose) and the score assigned after six hours of the final dose of intra-vaginal misoprostol.

**Priming to delivery duration:** The duration from the placement of ripening agent until delivery.

**Safe:** when adverse maternal and neonatal effects not occurred after administration of cervical ripening agents (intravaginal misoprostol and transcervical Foley catheter).

**Tachysystole:** when the women develop at least 6 uterine contractions per ten minutes period.

H**ypertonus:** when the women develop a single contraction lasting two or more minutes.

**Hyperstimulation:** when the women had either hypertonus or tachysystole with fetal heart rate abnormalities.

**Adverse Maternal outcome:** when the following complications occurred after priming commenced; hyperstimulation, postpartum hemorrhage, third or fourth-degree perineal tear, uterine rupture, maternal pyrexia, and maternal death.

**Adverse neonatal outcome:** when the following complications occurred after cervical ripening commenced; stillbirth, low APGAR score, NICU admission, birth injury, or neonatal death.

**Non-reassuring fetal heart rate:** Fetal heartbeat of either below 120 beats per minute or above 160 beats per minute following priming.

**Low appearance, pulse, grimace, activity, and respiration (APGAR) score:** Apgar score of less than seven for the first five minutes of birth.

**Stillbirth:** The death of the fetus during the intrapartum period (after cervical ripening started and before delivery).

## 4.9 Data Collection

The data were collected using a pre-tested structured questionnaire which has socio-demographic features, obstetrics history and characteristics, detail of efficacy measure questions on ripening and induction (progress of cervical ripening and induction of labor, and pattern of labor outcome

of induction), and safety measure questions. The questionnaire was adapted from 2018 WHO recommendation for induction of labor, WHO global survey for maternal and perinatal health, mode of delivery and pregnancy outcomes forms, and reviewing the literature (22, 36, 37, 38, 39).

Four BSC trained midwives were obtained the information by review of medical records (patient charts, delivery registration books, and neonatal registration books) using the predesigned checklist during the working hours (from eight in the morning till five in the afternoon). The questionnaires were designed in English. Two MSc midwives had supervised the data collection process closely and they were followed by the principal investigator. The process was continued until the required number of samples was obtained.

### 4.10 Data quality control

To keep data quality, a range of mechanisms were employed. Two days of training was given for data collectors and supervisors on the objective and relevance of the study, how to gather the appropriate information, procedures of data collection techniques, inclusion/exclusion criteria, and the whole contents of the questionnaire. The checklists were collected from data collectors each day by the principal investigator and checked for any errors. Then appropriate measures were taken accordingly. Through the course of data collection, the data collectors were supervised and there were regular phone contacts between principal investigator, data collectors, and supervisors to discuss and correct problem which were raised during the data collection period. A pre-test was done by taking 5 percent of the sample size for each group at Alert Hospital and necessary modifications in the questionnaires were made based on the nature of gaps identified.

### 4.11 Data processing and analysis

The collected data were coded and entered into Epi data version 4.6.2. After the entry was completed the data was transferred to SPSS version 25 and cleaned before analysis. Selected baseline characteristics and outcome measures were compared using the independent sample T-test for continuous variables and the Fisher's exact or Chi-square test for categorical variables as appropriate. Variables at (P-value <0.2) detected at bivariate level were a candidate for a multivariate logistics regression model to control for possible confounding variables, to examine

association, and to produce crude and adjusted odds ratio along with their corresponding confidence limits (95% CI). A P-value below 0.05 was considered to be statistically significant.

### 4.12 Ethical consideration

Ethical clearance was received prior to data collection from the Institutional Review Board of School of Nursing and Midwifery, College of Health Sciences, Addis Ababa University. Permission was obtained from selected hospitals, and the confidentiality of information was ensured by not recording the name of the samples or other identifiers.

### 4.13 Dissemination of the result

The findings of this study will be presented to the Addis Ababa University Scientific Community and submitted to the College of Health Science School of Nursing and Midwifery. The results will also be communicated to local health planners and other relevant stakeholders to enable them to consider recommendations during their planning process. It will also be proved to the selected hospitals. Finally, the soft copy will be accessible thought the University library portal and attempt will be made to publish in national or international journals.

# 5. RESULT

A total of 408 patient documents (204 for each group) were reviewed depending on the eligibility criteria and availability of the documents, yielding a response rate of 100%.

## 5.1. SOCIO-DEMOGRAPHIC CHARACTERISTICS

Most of the participants, 29.4% of mothers in the transcervical Foley catheter group and 37.7% of mothers in the intra-vaginal misoprostol group belonged to the age group of 25-29 years. There were no statistically significant differences (P>0.05) between the groups regarding the source of referral, Age, marital status, and residence. With regards to BMI, there were statically significant differences ($\chi_2$ =34.397, P<0.01) between the groups.

**Table 1: Socio-demographic characteristics of study groups who undergone priming and induction of labor in selected Hospital of Addis Ababa, 2019-2020 (n=408).**

| Variable | Foley catheter group | | Misoprostol group | | $\chi_2$ | P-value |
|---|---|---|---|---|---|---|
| | No | Percent | No | Percent | | |
| **Age** | | | | | 6.313 | 0.177 |
| <20 | 21 | 10.3% | 14 | 9.6% | | |
| 20-24 | 52 | 25.5% | 59 | 28.9% | | |
| 25-29 | 60 | 29.4% | 77 | 37.7% | | |
| 30-34 | 38 | 18.6% | 30 | 14.7% | | |
| >34 | 33 | 16.2% | 24 | 11.8% | | |
| **Residence** | | | | | 0.309 | 0.578 |
| Urban | 146 | 71.6% | 151 | 74.0% | | |
| Rural | 58 | 28.4% | 53 | 26.0% | | |
| **Marital status** | | | | | 1.217 | 0.270 |
| With partner | 177 | 86.8% | 169 | 82.8% | | |
| Without partner | 27 | 13.2% | 35 | 17.2% | | |
| **Source of referral** | | | | | 3.572 | 0.168 |
| Self | 10 | 4.9% | 10 | 4.9% | | |
| Health center | 145 | 71.1% | 128 | 67.7% | | |
| Hospital | 49 | 24.0% | 66 | 32.4% | | |
| **BMI** | | | | | 34.397 | <0.001 |
| <18.5 | 8 | 3.9% | 8 | 3.9% | | |
| 18.5-24 | 107 | 52.5% | 161 | 78.9% | | |
| >24 | 89 | 43.6% | 35 | 17.2% | | |

NOTE: BMI: body mass index, $\chi_2$: chi-square test

## 5.2. OBSTETRIC CHARACTERISTICS

Both groups were similar in terms of baseline obstetric characteristics such as parity, gestational age, and sex of the baby. This study revealed that ANC follow-up (P=0.027), and mean admission bishop score (P<0.001) were significantly different between the groups (P=0.027). The mean admission bishop score was 2.71±0.702 in the trans-cervical Foley catheter group, compared to 3.15±0.942 in the Intra-vaginal misoprostol group which was statistically significant (P<0.001).

**Table 2: Obstetrics characteristics of study groups who undergone priming and induction of labor in selected Hospital of Addis Ababa, 2019-2020 (n=408).**

| Variables | Foley catheter group | | Misoprostol group | | $\chi^2$ | P-value |
|---|---|---|---|---|---|---|
| | No | Percent | No | Percent | | |
| **Parity** | | | | | 1.272 | 0.259 |
| Primi | 134 | 65.7% | 123 | 60.3% | | |
| Multi | 70 | 34.3% | 81 | 39.7% | | |
| **Gestational Age** | | | | | 4.870 | 0.088 |
| <37 | 24 | 11.8% | 16 | 7.8% | | |
| 37-42 | 113 | 55.4% | 101 | 49.5% | | |
| ≥42 | 67 | 32.8% | 87 | 42.7% | | |
| **ANC follow up** | | | | | 4.869 | 0.027 |
| Yes | 181 | 88.7% | 165 | 80.9% | | |
| No | 23 | 11.3% | 39 | 19.1% | | |
| **Sex of the newborn** | | | | | 0.246 | 0.620 |
| Male | 109 | 53.4% | 104 | 52.2% | | |
| Female | 95 | 46.6% | 100 | 47.8% | | |
| **Weight of the new Born** | | | | | 8.940 | 0.011 |
| <2.5 | 46 | 22.5% | 30 | 14.7% | | |
| 2.5-4 | 138 | 67.6% | 164 | 80.4% | | |
| >4 | 20 | 9.8% | 10 | 4.9% | | |
| **Admission bishop score** | 2.71±0.702 | | 3.15±0.942 | | | <0.001 |

NOTE: ANC: antenatal care, $\chi^2$: chi-square test

## 5.3. Indications and methods of induction of labor

The most common indications of induction were PIH and post-term, accounting for 44.6% and 32.9% in the Foley group whereas post-term (43.2%) and PIH (35.8%) in the intra-vaginal Misoprostol group. There was a significant variation between the groups in terms of methods of induction ($\chi_2$ =13.414, P=0.001). This study also revealed that more than fold number of mothers in the intra-vaginal misoprostol group were induced by misoprostol compared to the Foley catheter group, 39(22.9%) and 18(9.6%) respectively.

**Table 3: Indications and Methods of induction of study groups who undergone priming and induction of labor in selected Hospital of Addis Ababa, 2019-2020 (n=408).**

| Variables | Foley catheter group | | Misoprostol group | | $\chi_2$ | P-value |
|---|---|---|---|---|---|---|
| | No | Percent | No | Percent | | |
| **Indication of induction** | | | | | 8.182 | *0.042* |
| Post-term | 67 | 32.9% | 88 | 43.2% | | |
| GM/GDM | 19 | 9.3% | 26 | 12.7% | | |
| PIH | 91 | 44.6% | 73 | 35.8% | | |
| IUGR | 27 | 13.2% | 17 | 8.3% | | |
| **Method of induction** | | | | | 13.414 | 0.001 |
| Oxytocin | 161 | 86.1% | 120 | 70.6% | | |
| Misoprostol | 18 | 9.6% | 39 | 22.9% | | |
| ARM | 8 | 4.3% | 11 | 6.5% | | |

NOTE: GM/GDM: Gestational Diabetic Mellitus, IUGR: Intrauterine Growth Retardation, PIH: Pregnancy-induced hypertension, ARM: Artificial Rupture of Membrane: $\chi_2$: chi-square test

## 5.4. Labor and delivery profile

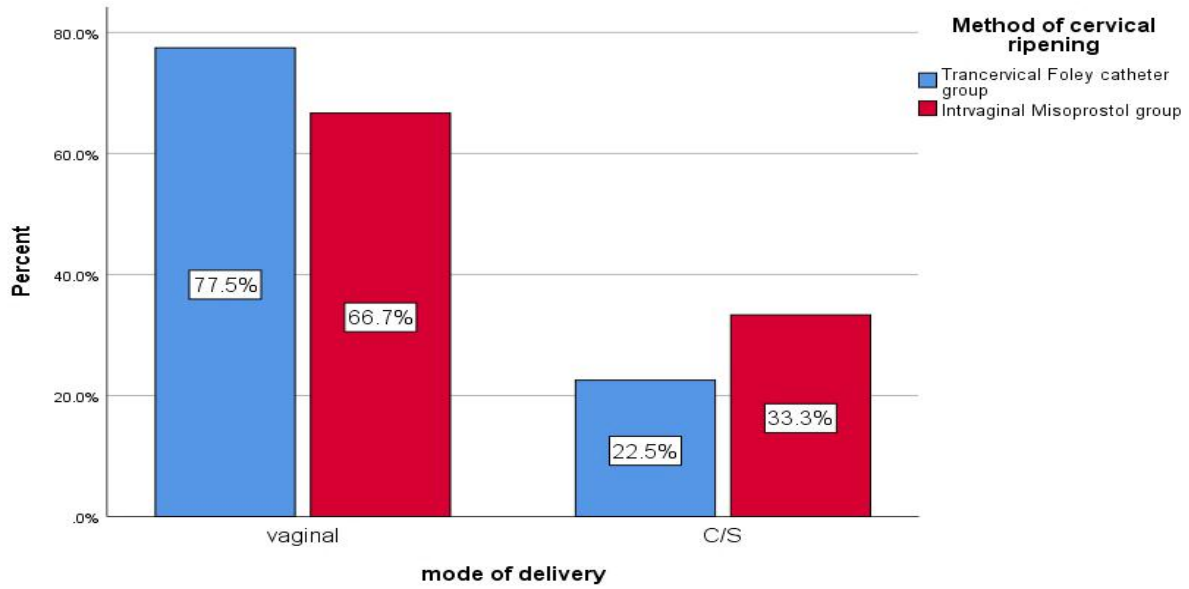
There was a statistically variation in the establishment of true labor before induction among the groups, 17(8.3%) in the Foley catheter group and 34(16.7%) in the intra-vaginal misoprostol group ($\chi_2$ =6.476; P=0.01). The mean change in Bishop's score in the Foley catheter group (6.06±0.902) was significantly high compared to the intra-vaginal misoprostol group (5.71±1.074) (P<0.001). In the present study, the meantime for cervical ripening and priming to delivery interval were significantly short in the Foley catheter group. Most of the mothers in the trans-cervical Foley catheter group 134/161(83.2%) achieved adequate contraction at the third dose of oxytocin IV infusion, compared to 64/120 (53.3%) in the intra-vaginal misoprostol group. Subjects in the intra-vaginal misoprostol group significantly required less oxytocin in labor than subjects in the Foley group ($\chi_2$ = 30.788; P < 0.001). The vaginal birth rate was found to be significantly higher in the Foley catheter group (158(77.5%)) ($\chi 2$ = 5.892; P=0.015 compared to 136 (66.7%) in the intra-vaginal misoprostol group. In this study, the commonest indications for cesarean section were failed induction (43.5%), fetal distress (37%), and LFSOL plus GIII MSAF (13%) in the Foley catheter group compared to fetal distress (60.3%), failed induction (22.1%) and CPD (8.8) in the intra-vaginal misoprostol group**.**

**Table 4: Labor and delivery profile of study groups who undergone priming and induction of labor in selected Hospital of Addis Ababa, 2019-2020 (n=408).**

| Variables | Foley catheter group | | Misoprostol group | | $\chi^2$ | P-value |
|---|---|---|---|---|---|---|
| | Number | Percent | Number | Percent | | |
| **Labor started before induction** | | | | | 6.476 | 0.001 |
| Yes | 17 | 8.3% | 34 | 16.7% | | |
| No | 187 | 91.7% | 170 | 83.3% | | |
| **Adequate contraction achieved after induction** | | | | | 0.898 | 0.343 |
| Yes | 180 | 96.3% | 160 | 94.1% | | |
| No | 7 | 3.7% | 10 | 5.9% | | |
| **phase of oxytocin contraction was achieved** | | | | | 30.788 | <0.001 |
| 1st | 2 | 1.3% | 6 | 5.1% | | |
| 2nd | 19 | 11.8% | 43 | 35.8% | | |
| 3rd | 134 | 83.2% | 64 | 53.3% | | |
| Not achieved | 6 | 3.7% | 7 | 5.8% | | |
| **Mode of delivery** | 158 | | | | 5.892 | 0.015 |
| vaginal | | 77.5% | 136 | 66.7% | | |
| C/S | 46 | 22.2% | 68 | 33.3% | | |
| **Indication for C/S** | | | | | 10.179 | 0.038 |
| Failed induction | 20 | 43.5% | 15 | 22.1% | | |
| Fetal distress | 17 | 37% | 41 | 60.3% | | |
| CPD | 3 | 6.5% | 6 | 8.8% | | |
| LFSOL plus GIII meconium | 6 | 13% | 4 | 5.9% | | |
| Others | 0 | 0% | 2 | 2.9% | | |
| **Mean change in bishop score** | 6.06±0.902 | | 5.71±1.074 | | <0.001 | |
| **Mean duration of cervical ripening** | 9.29±2.039 | | 10.78±2.306 | | <0.001 | |
| **Mean duration of labor** | 8.03±2.768 | | 8.52±3.044 | | 0.090 | |
| **Mean priming to delivery interval** | 17.38±4.121 | | 19.48±4.228 | | <0.001 | |

NOTE: CPD: cephalo pelvic disproportion, LFSOL: latent first stage of labor, C/S: cesarean section, $\chi^2$: chi-square test

In this study, efficacy was measured by the success of induction and labor induction was considered successful when labor ends up with spontaneous vaginal delivery. Accordingly, as shown in figure 3 from 204 reviewed records in the Foley catheter group 158 (77.5%) of them delivered vaginally compared to 136 (66.7%) in the intra-vaginal misoprostol group.




NOTE: C/S: cesarean section

**Figure 3: Comparison of labor outcome of induction of labor between the groups who undergone priming and induction in selected Hospital of Addis Ababa, 2019-2020 (n=408).**

## 5.5. Maternal and Neonatal complications

17.6% of women in the misoprostol group develop uterine contraction abnormalities compared to 7.4% in the Foley catheter group ($\chi 2 = 9.882$: P =0.02). Although significantly more newborns in the intra-vaginal misoprostol group developed adverse neonatal outcomes ($\chi 2=8.254$; P=0.04). The immediate maternal complications observed were PPH, Maternal pyrexia, and Post-partum sepsis but not statically significant between the groups. The developments of meconium-stained amniotic fluid and lower APGAR scores in the fifth minute were higher in the misoprostol group but not statistically significant. In the intra-vaginal misoprostol group there was one early neonatal death but not in the Foley catheter group. In this study, it was observed that 15.2% of neonates in the intra-vaginal misoprostol group and 5.4% of neonates in the Foley catheter group required immediate admission to NICU ($\chi 2=11.464$; P=0.001). Similarly abnormal FHB ($\chi 2=5.996$; P=0.014) were significantly higher in intra-vaginal misoprostol.

**Table 5: Maternal and Neonatal complications of study groups who undergone priming and induction of labor in selected Hospital of Addis Ababa, 2019-2020 (n=408).**

| Variables | Foley catheter group | | Misoprostol group | | $\chi^2$ | P-value |
|---|---|---|---|---|---|---|
| | Number | Percent | Number | Percent | | |
| **Contraction/s complication** | | | | | 9.882 | 0.002 |
| Yes | 15 | 7.4% | 36 | 17.6% | | |
| No | 189 | 92.6% | 168 | 82.4% | | |
| **If yes what Contraction/s complication present (N=15 in Foley=36 in miso)** | | | | | 0.418 | 0.811 |
| tachysystole | | | | | | |
| hyper tonus | 4 | 26.7% | 8 | 22.9% | | |
| hyperstimulation | 2 | 13.3% | 3 | 8.6% | | |
| | 9 | 60% | 24 | 68.6% | | |
| **Adverse maternal outcome** | | | | | 1.380 | 0.240 |
| Yes | 11 | 5.4% | 17 | 8.3% | | |
| No | 193 | 94.6% | 187 | 91.7% | | |
| **Maternal complications** | | | | | 3.777 | 0.287 |
| PPH | 7 | 63.6% | 11 | 64.7% | | |
| Maternal pyrexia | 1 | 9.1% | 0 | 0% | | |
| Post-partum sepsis | 2 | 18.2% | 6 | 35.3% | | |
| Admission to ICU | 1 | 9.1% | 0 | 0% | | |
| **Membrane ruptured following priming and induction** | | | | | 5.681 | 0.017 |
| Yes | 31 | 15.2% | 50 | 24.6% | | |
| No | 173 | 84.8% | 153 | 75.4% | | |
| **Meconium stained amniotic fluid** | | | | | 0.166 | 0.684 |
| Yes | 8 | 25.8% | 15 | 30% | | |
| No | 23 | 74.2% | 35 | 70% | | |
| **Abnormal FHR (NRFHRP)** | | | | | 5.996 | 0.014 |
| Yes | 32 | 15.7% | 52 | 25.5% | | |
| No | 172 | 84.3% | 152 | 74.5% | | |
| **New born status at birth** | | | | | 1.002 | 0.317 |
| Alive | 204 | 100% | 203 | 99.5% | | |
| Early neonatal death | 0 | 0% | 1 | 0.5% | | |
| Still birth | 0 | 0% | 0 | 0% | | |
| **Adverse neonatal outcome** | | | | | 8.254 | 0.004 |
| Yes | 13 | 6.4% | 31 | 15.2% | | |
| No | 191 | 93.6% | 173 | 84.8% | | |
| **5th minutes APGAR score** | | | | | 2.106 | 0.147 |
| Less than 7 | 17 | 8.3% | 26 | 12.7% | | |
| 7 and above | 187 | 91.7% | 178 | 87.3% | | |
| **Newborn admit to NICU** | | | | | 11.464 | 0.001 |
| Yes | 11 | 5.4% | 32 | 15.7% | | |
| No | 193 | 94.6% | 172 | 84.3% | | |

NOTE: PPH: postpartum hemorrhage, NICU: neonatal intensive care unit, NRFHRP: non reassuring fetal heart rate pattern, $\chi^2$: chi-square test

## 5.6. Comparison of bivariate and multivariate results

Since for this study the major outcome measure of efficacy is the success of induction, Socio-demographic related characteristics, obstetrics related characteristics, methods, and reason of induction related characteristics were included in the analysis to see the significant association with success of induction. In both groups, all variables were first tested in binary logistics regression. Hence, variables p-value <0.2 were entered into multivariate logistics regression. On bivariate analysis; Age, residential address, parity, ANC follow-up, bishop score, Apgar score, and Admission to NICU were found to be statistically significant in the transcervical Foley catheter group whereas Age, parity, ANC follow-up, NICU admission rate, bishop score, Gestational Age, and Apgar score were statistically significant in the intra-vaginal misoprostol group.

During multivariate logistics regression; only residential address was statistically significant in the trans-cervical Foley catheter group compared with Parity, and gestational Age were found to be statistically significant predictors of successful induction in the intra-vaginal misoprostol group. The result demonstrated that multigravida women were four times more likely to have successful induction compared to primigravida women (AOR=4.45(95% CI: 2.01- 9.82) in the misoprostol group. On the other side success of induction was 0.46 times less likely (AOR=0.46(95%CI: 0.23-0.95) among those women from urban areas compared to the rural areas in the Foley catheter group. Also, gestational age was statistically significant predictors of successful induction in misoprostol group. The success of induction was 0.45 times less likely among women with 42 and more weeks of gestation compared with those with gestational age of less than 37 weeks (AOR=0.45(95%CI: 0.22, 0.90).

**Table 6: Bivariate and Multivariate Logistic regression analyses of factors associated with successful induction of labor among women who underwent induction of labor after primed by Trans-cervical Foley catheter at selected Hospital of Addis Ababa, 2019 -2020 (n=408).**

| Variables | Successful induction | | COR 95% | AOR 95% |
|---|---|---|---|---|
| | Yes | No | | |
| **Age** | | | | |
| <20 | 15(71.4%) | 6(28.6%) | 0.70(0.21, 2.29) | 0.45(0.12, 1.63) |
| 20-24 | 42(78.8%) | 11(21.2%) | 0.41(0.18, 1.24) | 0.56(0.20, 1.59) |
| 25-29 | 47(80%) | 12(20%) | 0.44(0.17, 1.13) | 0.44(0.16, 1.20) |
| 30-34 | 33(86.8%) | 5(13.2%) | 0.27(0.08, 0.86) | 0.31(0.90, 1.04) |
| >34 | 21(63.6%) | 12(36.4%) | 1.00 | 1.00 |
| **Residential address** | | | | |
| Urban | 120(82.2%) | 26(17.8%) | 0.41(0.21, 0.82) | **0.46(0.23, 0.95)** |
| Rural | 38(65.5%) | 20(34.5%) | 1.00 | 1.00 |
| **Parity** | | | | |
| Primi | 101(75.4%) | 33(24.6%) | 1.00 | 1.00 |
| Multi | 57(81.4%) | 13(18.6%) | 1.43(0.70, 2.94) | 1.11(0.47, 6.40) |
| **ANC follow-up** | | | | |
| Yes | 145(80.1%) | 36(19.9%) | 3.10(1.26, 7.63) | 2.35(0.91, 6.04) |
| No | 13(56.5%) | 10(43.5%) | 1.00 | 1.00 |
| **Bishop score at time of induction** | | | | |
| less than 6 | 38(70.4%) | 16(29.6%) | 1.00 | 1.00 |
| 6 and above | 120(80%) | 30(20%) | 1.68(0.83,3.41) | 1.78(0.84, 3.79) |
| **APGAR score** | | | | |
| Greater than 7 | 149(79.7%) | 38(20.3%) | 3.49(1.26, 9.64) | 1.32(0.27, 6.46) |
| 7 and less | 9(52.9%) | 8(47.1%) | 1.00 | 1.00 |
| **Admission to NICU** | | | | |
| Yes | 5(45.5%) | 6(54.5%) | 0.22(0.63, 0.75) | 0.25(0.07, 0.89) |
| No | 153(79.3%) | 40(20.7%) | 1.00 | 1.00 |

**Table 7: Bivariate and Multivariate Logistic regression analyses of factors associated with successful induction of labor among women who undergone induction of labor after primed by Intra-vaginal misoprostol at selected Hospital of Addis Ababa, 2019-2020 (n=408).**

| Variables | Successful induction | | COR 95% | AOR 95% |
|---|---|---|---|---|
| | Yes | No | | |
| **Age** | | | | |
| <20 | 4(28.6%) | 10(71.4%) | 5.00(1.19,21.02) | 1.67(0.28, 9.92) |
| 20-24 | 40(67.8%) | 19(32.2%) | 0.95(0.35,2.61) | 0.38(0.10, 1.53) |
| 25-29 | 50(64.9%) | 27(35.1%) | 1.08(0.41,2.85) | 0.86(0.24, 3.03) |
| 30-34 | 26(86.7%) | 4(13.3%) | 0.31(0.08,1.19) | 0.43(0.09, 2.10) |
| >34 | 16(66.7%) | 8(33.3%) | 1.00 | 1.00 |
| **Parity** | | | | |
| Primi | 69(56.1%) | 54(43.9%) | 1.00 | 1.00 |
| Multi | 67(82.7%) | 14(17.3%) | 3.75(1.90, 7.37) | **4.45(2.01, 9.82)** |
| **ANC follow-up** | | | | |
| Yes | 114(69.1%) | 51(30.9%) | 1.73(0.85, 3.53) | 1.33(0.54, 3.29) |
| No | 22(56.4%) | 17(43.6%) | 1.00 | 1.00 |
| **Gestational age** | | | | |
| Less than 37 | 10(79.2%) | 6(20.8%) | 1.00 | 1.00 |
| 37-42 | 78(77.9%) | 23(22.1%) | 0.74(0.25, 2.21) | 0.44(0.12, 1.60) |
| 42 and above | 48(76.1%) | 39(23.9%) | 0.36(0.19, 0.68) | **0.45(0.22, 0.90)** |
| **Bishop score at time of induction** | | | | |
| less than 6 | 53(61.6%) | 33(38.4%) | 1.00 | 1.00 |
| 6 and above | 83(70.3%) | 35(29.7%) | 1.48(0.82,2.66) | 1.70(0.84, 3.45) |
| **APGAR score** | | | | |
| Greater than 7 | 129(72.5%) | 49(27.5%) | 1.00 | 1.00 |
| 7 and less | 7(26.9%) | 19(73.1%) | 7.15(2.83, 18.06) | 2.62(0.50, 13.87) |
| **NICU Admission** | | | | |
| Yes | 9(28.1%) | 23(71.9%) | 0.14(0.06,0.32) | 0.10(0.04, 0.26) |
| No | 127(73.8%) | 45(26.2%) | 1.00 | 1.00 |

# 6. DISCUSSION

This stud was carried out to compare transcervical Foley catheter and Intra-vaginal Misoprostol as a pre-induction cervical ripening method to determine their effectiveness and associated factors at selected hospitals of Addis Ababa. In the present study, there was no statistical difference between demographic variables like maternal age, residential address, and source of referral, parity, and gestational age between the two groups. Most of the women were primigravida.

Mean change in Bishop Score was significantly higher in the trans-cervical Foley catheter group (6.06±0.902) vs Misoprostol (5.57±1.074). Similarly, a significantly short duration of cervical ripening was observed in the transcervical Foley catheter group (9.29±2.039hrs catheter vs Misoprostol 10.78±2.306hrs). This is against study done in India and Nigeria (22,43,45), but studies were done in the USA and Bangladesh shown that there was no statistically significant difference between studied groups in terms of change in bishop score and duration of cervical ripening (40, 42). According to a study in India mean change in Bishop Score was significantly higher in the misoprostol group (5.01±1.48 catheter vs 8.01±1.45 Misoprostol). This discrepancy may be due to the difference in study design and sample size. Moreover, it may be due to the inflation volume of the Foley catheter used in this study was 60ml, but other studies used 30ml to inflate transcervical Foley catheter during priming.

In this study success of induction, the main indicator of efficacy is statistically higher in the transcervical Foley catheter group. In the Foley catheter group, 77.50% of them delivered vaginally compared to 66.70% in the misoprostol group. Also, priming to the delivery duration was significantly lower in the Foley catheter group (17.38±4.12hrs) compared to 19.48±4.23hrs in the intra-vaginal misoprostol group. This finding is different from studies done in India, Nigeria, Kenya, and Iran (21,22,43). A study in Iran reported that the vaginal birth rate was significantly larger in the intra-vaginal misoprostol group 89.8% compared to 62.7% in the Foley catheter category ($p < 0.01$). Induction to delivery duration was significantly shorter in the intra-vaginal misoprostol group (11.1 ± 5.6hrs) compared to (13.6 ± 16.9hrs) in the Foley catheter category. Similarly study in India revealed that significantly higher numbers of women delivered vaginally in the intra-vaginal misoprostol group than the Foley Group (76.7% miso vs Foley 56.8%). In addition, the duration of induction was significantly shorter among the intra-vaginal

misoprostol group (14.0±7.6hrs compared to 18.4±8.0hrs : $p < 0.01$) (32). The most important cause for the inconsistency in these results may be the higher repeated doses of intra-vaginal misoprostol 25 μg every 4hrs, up to 6 doses were given but in this study 25 μg, every 6hrs intra-vaginal misoprostol up to 3 doses were used for cervical ripening. Also, it may be due to the difference in sample size, and study design. But this finding is consistent with the study done in the USA, Portugal, Bangladesh, and Bahirdar (12, 35, 40, 41).

A study done at Gandhi and Felegehiwot hospitals showed that change in Bishop Score (5.67 Foley vs 5.33 miso) and vaginal delivery rate (84.7%Foley vs 72.2%miso) were higher in the transcervical Foley catheter group as compared to the Misoprostol group. These results were consistent with the present study. The consistency might be due to similarity in the inflation volume of the Foley catheter (50-60ml) and the dose of intra-vaginal misoprostol used for cervical ripening (25 μg every 6hrs intra-vaginal misoprostol up to 3 doses) or it may be due to similarity in geographical location.

Oxytocin need was significantly higher in the Foley catheter group and this goes with the finding of many studies (7, 22, 41, 42). It may be due to the pharmacological effect of prostaglandin and the potential of the Foley catheter in stimulating the uterine contraction by itself is somehow limited.

In this study, adverse neonatal outcome (6.4% Foley vs miso 15.2%), uterine contraction abnormalities (7.4% Foley vs miso 17.6%), abnormal FHR, and neonatal NICU admission rate (5.4% Foley vs miso 15.7%) were found to be statistically higher in the intra-vaginal misoprostol group as compared to the transcervical Foley catheter group. This finding is supported by studies done in Bahirdar, Nigeria, India, and Iran (12, 22, 28, 32). A study in India showed that hyperstimulation was observed in 11.7% of mothers in the intra-vaginal misoprostol group compared to no case of uterine hyperstimulation in the catheter group (32). Also, a study in Ethiopia showed that uterine contraction abnormalities (0% catheter vs 12.6% misoprostol), abnormal FHR (6.3% catheter vs 26.1% misoprostol), meconium stained liquor (8.1% catheter vs 13.5% misoprostol), NICU admissions, and low APGAR scores were found to be significantly higher in the misoprostol group (12). This similarity might be due to the misoprostol effect of increasing uterine contractions, which increases the potential of FHR abnormality, NICU

admission rate, and low Apgar score. So, safety issues need to be taken into consideration when misoprostol is planned to use for cervical ripening.

Related to the factors associated with the main outcome measure, which was the success of labor induction the study shows that parity was a significant predictor for induction success, its success rate was 4 times more likely in multipara women, but it was 0.45 times less likely among women with the gestational age of 42 and above weeks than those with the gestational age of fewer than 37 weeks [AOR=0.45(95%CI: 0.22-0.90)] in the misoprostol group. On the other hand only residential address was the predictor of success in the Foley catheter group. This finding is parallel to the study done in Pakistan, Saudi, and Hawasa (25, 26, 49). This higher rate of success in multipara may be due to primipara woman has more risk of developing complications that need Cesarean Section or because they are less likely to achieve adequate contraction than multi. For gestational age, it might be due to that advanced gestational age (post-term pregnancy) increase the risk of Cesarean section.

# 7. STRENGTH AND LIMITATION OF THE STUDY

## 7.1. Strength of the study

- The study adds significant contribution into one of the frequently practiced obstetrics intervention in the country, especially in the study area.
- It can be a base for further similar study or large scale study.
- Add significant contribution for Addis Ababa city health bureau and Addis Ababa city health facilities.

## 7.2. Limitation of the study

Like all other research, this research had also certain limitations.

- The study design used was a retrospective cross-sectional. It will be more powerful had a randomized controlled trial been conducted. Also, since it was a retrospective study it only depends on available data.
- Lack of similar study to discuss more.
- The study was done only in Addis Ababa so the result, not representative of all over the county.

# 8. CONCLUSION

In conclusion, the present study showed that transcervical Foley catheter was effective than Intra-vaginal misoprostol as a cervical ripening method because it increases the success of induction rate (77.5% vs 66.7%), decrease the priming to the delivery duration, and was better to ripening the unfavorable cervix. The rates of adverse neo-maternal outcomes, uterine hyperstimulation, abnormal FHR, and neonatal NICU admission were significantly higher in the Intra-vagina misoprostol group. So, the safety concerns need to be taken into consideration when intra-vagina misoprostol is planned to use. Parity and Gestational age in the misoprostol group and residential address in the transcervical group were predictors of induction success.

# 9. RECOMMENDATION

Based on study results the following recommendations are forwarded.

**For the health facilities and health care providers**

- To consider that transcervical Foley catheter is better in terms of the success rate of induction and maternal and neonatal safety issues than Intra-vaginal misoprostol when uses as a pre-induction cervical ripening method.

**For researchers**

- Further study needs to be carried out in the future, to provide national data set for evaluating and monitoring this important intervention, and provide information for health services provision.

**For Midwifery and Nursing practice**

- The result showed transcervical Foley catheter is better in terms of mean change in Bishop's score, reducing priming to delivery interval and number of cesarean deliveries, and maternal and neonatal safety profiles than Intra-vaginal misoprostol. This result suggested that efficacy and safety issues need to be taken into consideration when intra-vagina misoprostol is planned to use.

**For policymakers/ FMOH**

- It was found that a significantly high rate of cesarean section, maternal and neonatal complications, and uterine hyperstimulation were observed in the Intra-vaginal Misoprostol group than the transcervical Foley catheter group. Therefore, the federal health minister and other stakeholders recommended to revising the guidelines regarding effective and safe pre-induction cervical ripening methods.

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# 11. ANNEXES

## Annexes I: Information sheet and consent

Hello! How are you? My Name is _____. I am a member of the research team from Addis Ababa University, College of Health Science, School of Nursing, and Midwifery Department of Midwifery. Now I am collecting data from patient medical records to compare the efficacy of transcervical Foley catheter versus intra-vaginal misoprostol as a pre-induction cervical ripening agent and associated factors at public hospitals of Addis Ababa, Ethiopia, 2020. I have obtained permission from the hospital ethical review committee to conduct the study. I am kindly requesting you for the chart to take some information. In the end, it is hoped that the information taken from the chart could help to provide appropriate induction and delivery services for laboring women. I would like to assure you that the name of the women will not be used and the information obtained will not be given to anyone else and no reports of the study will ever identify the women. If a report of results is published, only information about the total group will appear. Are you willing to give the chart?

1. Yes 2. No Signature_____

THANK YOU

## Annex II Questionnaire

Checklist Participant Medical Record Number _____Please encircle or enter in the appropriate space. Part 1 (Socio-Demographic information)

| No | Question | Answer and code |
|---|---|---|
| 101 | Age of the women | _____ In Years |
| 102 | Marital status | 1. Married<br>2. Single<br>3. Divorced<br>4. Widowed |
| 103 | Residential address | 1. Urban<br>2. Rural |
| 104 | What is woman educational level? | 1. Can't read and write<br>2. Grade 1-8<br>3. Grade9-12<br>4. Diploma and above |
| 105 | From where did the mother referred? | 1. Self<br>2. Health Centre<br>3. Hospital |
| 106 | Height of the women | _____ |
| 107 | Weight of the women in Kg | _____ |

Part II obstetrics characteristics and history

| No | Question | Answer |
|---|---|---|
| 201 | Number of previous births | 1. Prime Para<br>2. Multi Para |
| 202 | Gestational age (wk.) based on LNMP | 1. < 37 wk.<br>2. 37-40wk<br>3. >42 wk.<br>4. Unknown LNMP |
| 203 | Have ANC follow up? | 1. Yes<br>2. No |
| 204 | Diastolic Blood pressure at admission | _____mmHg |
| 205 | Indication(s) for cervical ripening and Induction of | 1. Post term pregnancy |

| | | |
|---|---|---|
| | labor | 2. DM/GDM<br>3. PIH / hypertensive disorders<br>4. Others specify_____ |

Part III Efficacy measure questions on cervical ripening and induction of labor

| No | Question | Answer |
|---|---|---|
| 301 | Bishop score at admission | _____ |
| 302 | Method of cervical ripening | 1. Trans-cervical Foley catheter<br>2. Intra-vaginal misoprostol |
| 303 | If intra-vaginal misoprostol, the amount of dose used for cervical ripening | 1.1st dose<br>2nd dose<br>3.3rd dose |
| 304 | If intra-vaginal misoprostol, bishop score assigned 6hours after the last dose of intra-vaginal misoprostol. | _____ |
| 305 | Bishop score at time of priming, at 12hrs of priming, at time of induction start fill 1, 2, 3 respectively | 1. _____<br>1. _____.<br>2. _____ |
| 306 | If trans-cervical Foley catheter, bishop score at the time of expulsion. | _____ |
| 307 | Duration of cervical ripening (in hours)? | _____ |
| 308 | Contraction starts before induction? | 1. Yes<br>2. No |
| 309 | Method of induction | 1. Oxytocin<br>2. Misoprostol<br>3. ARM |
| 310 | If oxytocin infusion was the method of induction at which phase were contraction achieved? | 1. At first phase<br>2. Second phase<br>3. Third phase<br>4. Not achieved |
| 311 | Does adequate contraction achieve after induction? | 1. Yes<br>2. No |

| | | |
|---|---|---|
| 312 | Duration of latent, active, second and third stage of labor fill 1(for latent), 2(for active), 3(for second), and 4(for third) respectively (in hours)/ | 1. _____<br>2. _____<br>3. _____<br>4. _____ |
| 313 | Duration of priming to delivery (in hours)? | _____ |
| 314 | Mode of delivery, | 1. Vaginal delivery<br>2. Cesarean section |
| 315 | If delivery was by Caesarean Section, what was the indication? | 1. Failed induction of labor<br>2. Prolonged labor<br>3. Fetal distress<br>4. Cephalopelvic Disproportion<br>5. Others indicators (specify)_____ |

Part IV safety measure questions to assess maternal and neonatal condition following cervical priming and induction of labor

| No | Question | Answer |
|---|---|---|
| 401 | Contraction/s complication following cervical ripening and induction of labor present? | 1.Tachysystole<br>2.Hypertonus<br>3.Hyperstimulation |
| 402 | Maternal complication/s following cervical ripening and induction of labor? | 1. No complication<br>2. uterine rupture,<br>3. third- or fourth degree perineal tear,<br>4. postpartum hemorrhage,<br>5. maternal pyrexia<br>6. wound infection or post-partum sepsis<br>7. Admission to ICU<br>8. Maternal death. |

| | | |
|---|---|---|
| 403 | Membrane already ruptured following priming and induction? | 1. No<br>2. Yes |
| 404 | If membrane rupture meconium-stained amniotic fluid present following induction of labor? | 1. Yes<br>2. No |
| 405 | If membranes already rupture did Liquor foul smell? | 1. Yes<br>2. No |
| 406 | Does Non-reassuring fetal heart rate following cervical ripening and induction of labor present? | 1. No<br>2. Yes |
| 407 | Newborn Status at birth? | 1. Alive<br>2. Meconium aspiration syndrome<br>3. Stillbirth,<br>4. Low APGAR score,<br>5. Birth injury or<br>6. Neonatal intensive care unit admission<br>7. Early neonatal death. |
| 408 | If the newborn had a low APGAR score at birth did Neonatal resuscitation was made? | 1.yes<br>2. no |
| 409 | APGAR score at 1st and 5th min | 1. at 1st min_____<br>2. at 5th min_____ |
| 410 | Birth weight | _____ |
| 411 | Sex of the newborn | 1. Male<br>2. Female |

- Data collector

Name _____signature_____

Date and time _____Hospital code _____

Questionnaire code_____

Checked by:

Name _____ signature _____Date

THANK YOU