



**WALLAGA UNIVERSITY
INSTITUTE OF HEALTH SCIENCES
SCHOOL OF MEDICINE
DEPARTMENT OF OBSTETRICS AND GYNECOLOGY**

**LABOR OUTCOMES OF TRANSCERVICAL FOLEY CATHETER
FOR CERVICAL RIPENING AND ASSOCIATED FACTORS AT
WALLAGA UNIVERSITY COMPREHENSIVE SPECIALIZED
HOSPITAL, ETHIOPIA**

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Resident)**

**APRIL, 2026
NEKEMTE, ETHIOPIA**



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**A THESIS SUBMITTED TO THE INSTITUTE OF HEALTH
SCIENCES, DEPARTMENT OF OBSTETRICS AND GYNECOLOGY,
IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE
SPECIALTY CERTIFICATE IN OBSTETRICS AND GYNECOLOGY**

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DECLARATION

I hereby declare that this research thesis titled “Labor outcomes of transcervical Foley catheter for cervical ripening and associated factors at Wallaga university comprehensive specialized hospital, Ethiopia” is my original work. To the best of my knowledge, this specific study has not been previously conducted in the target area. All sources referenced in this proposal have been properly cited and acknowledged in the reference section.

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ACKNOWLEDGEMENT

First and foremost, I am profoundly grateful to God for granting me the strength, wisdom, and perseverance needed to undertake and complete this research thesis. Without His guidance and grace, this journey would not have been possible. I would also extend my heartfelt gratitude in advance for my advisors for the assistance and invaluable guidance, constructive feedback, and continuous support.

ABBREVIATIONS

ANC	Antenatal Care
AOR	Adjusted Odds Ratio
BMI	Body Mass Index
CI	Confidence Interval
CSA	Central statistics agency
EB	Ethiopian Birr
FHR	Fetal Heart Rate
IOL	Induction of Labor
IUFD	Intra uterine fetal death
MCH	Maternal and Child Health
NICU	Neonatal Intensive Care Unit
OPD	Outpatient Department
OR	Odds Ratio
PG	Prostaglandin
PROM	Premature Rupture of Membranes
RCT	Randomized Controlled Trial
SPSS	Statistical Package for the Social Sciences
WUCSH	Wallaga University Comprehensive Specialized Hospital

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ABSTRACT

Background: Cervical ripening is essential for successful induction of labor when the cervix is unfavorable. The transcervical Foley catheter is a safe, low-cost mechanical method recommended in resource-limited settings. At Wallaga University Comprehensive Specialized Hospital (WUCSH), it is widely used; yet no recent study has evaluated its labor outcomes or identified factors predicting successful vaginal delivery. Without local evidence, clinical decisions and patient counseling rely on external data, which may not reflect this population.

Objective: To assess labor outcomes of transcervical Foley catheter use for cervical ripening and identify associated factors at Wallaga University Comprehensive Specialized Hospital, Ethiopia.

Methods: A retrospective cross-sectional study was conducted among 169 women who underwent cervical ripening with a transcervical Foley catheter from January to December 2025. Data were analyzed using SPSS version 27. Bivariate and multivariate logistic regression analyses were performed to identify factors associated with successful vaginal delivery within 24 hours. A $p\text{-value} < 0.05$ was considered statistically significant.

Results: The proportion of women who achieved successful vaginal delivery within 24 hours was 68.6% ((116/169; 95% CI: 61.1% – 75.5%)). The mean induction-to-delivery interval was 15.98 ± 3.25 hours, and the cesarean section rate was 31.4%. The mean Bishop score increased from 4.57 ± 0.50 to 9.17 ± 1.51 following Foley removal ($p < 0.001$). Multivariate analysis revealed that multiparity (AOR = 4.65, 95% CI: 1.37–15.85, $p = 0.014$) and shorter Foley duration (AOR = 0.63, 95% CI: 0.41–0.98, $p = 0.039$) were independent predictors of success. The model showed good fit (Hosmer-Lemeshow $p = 0.769$) and 79.0% predictive accuracy.

Conclusion: The transcervical Foley catheter is an effective first-line mechanical method for cervical ripening at WUCSH, achieving successful vaginal delivery within 24 hours in over two-thirds of women. However, success is strongly dependent on parity—nulliparous women have substantially lower odds and should be counseled accordingly and monitored more closely. The hospital should standardize protocols and audit outcomes regularly to improve patient selection and reduce unnecessary cesarean sections.

Keywords: Cervical ripening; Foley catheter; Induction of labor; Labor outcomes; Mode of delivery; Associated factors; Ethiopia

1. INTRODUCTION

1.1. Background

Induction of labor refers to the deliberate initiation of uterine contractions before the spontaneous onset of labor with the aim of achieving vaginal delivery when continuation of pregnancy poses a risk to the mother or fetus (1). The decision to induce labor requires careful consideration of both maternal and fetal indications as well as assessment of cervical readiness for labor. Common indications for induction include post-term pregnancy, hypertensive disorders of pregnancy, premature rupture of membranes, and maternal medical conditions such as diabetes mellitus (2,3). The success of induction of labor is strongly influenced by the condition of the cervix, which is most commonly assessed using the bishop score. This scoring system evaluates cervical dilation, effacement, consistency, position, and fetal station to predict the likelihood of successful vaginal delivery (4).

Methods of cervical ripening are broadly categorized into mechanical and pharmacological approaches. Mechanical ripening using a transcervical Foley catheter involves insertion of a balloon-tipped catheter through the internal cervical os, followed by inflation to apply direct pressure on the cervix. This mechanical stimulation promotes endogenous prostaglandin release, leading to cervical effacement and dilation (5). The Foley catheter is inexpensive, widely available, and associated with a lower risk of uterine tachysystole and hyperstimulation compared with pharmacological agents (6). However, its effectiveness may vary according to parity, and strict adherence to procedural protocols is required to minimize the risk of ascending infection (7). Pharmacological agents such as vaginal misoprostol are also effective and affordable, but their use is associated with a higher risk of uterine hyperstimulation, abnormal fetal heart rate patterns, and, in rare cases, uterine rupture (8,9).

Globally, both mechanical and pharmacological methods are widely used for cervical ripening, although preferences vary based on safety considerations, clinician experience, and resource availability. Mechanical methods are commonly preferred in women with a previous cesarean section or in clinical settings where avoidance of uterine hyperstimulation is a priority (7,10).

In Ethiopia, the choice of cervical ripening method is guided by national obstetric protocols; however, there is a growing need to evaluate the real-world outcomes of these methods within specific institutional contexts, such as Wallaga University Comprehensive Specialized Hospital (11–13).

1.2. Statement of the Problem

Induction of labor is among the most frequently performed obstetric interventions, accounting for approximately 20 to 25 percent of all deliveries worldwide (1). It is indicated when continuation of pregnancy poses a greater risk to maternal or fetal health than delivery, including conditions such as post-term pregnancy, hypertensive disorders, intrauterine growth restriction, and premature rupture of membranes (2,3,14). The success of induction largely depends on cervical favorability; most commonly assessed using the Bishop score. When the cervix is unfavorable, cervical ripening becomes essential to improve the likelihood of successful vaginal delivery and reduce the risk of failed induction (5,14).

The World Health Organization and Ethiopian national obstetric guidelines recommend the transcervical Foley catheter as an option for cervical ripening and induction of labor (1,13). The Foley catheter facilitates cervical dilation and effacement through direct mechanical pressure and stimulation of endogenous prostaglandin release (15). Despite its widespread use, reported labor outcomes vary across different clinical settings. While some studies suggest that pharmacological methods may shorten the induction-to-delivery interval, they also highlight differences in adverse effect profiles when compared with mechanical methods (8,16).

Mechanical methods such as the Foley catheter are associated with lower rates of uterine hyperstimulation and abnormal fetal heart rate patterns (8,15). However, they may cause maternal discomfort and, in rare instances, ascending infection due to the invasive nature of the procedure (7). These safety considerations are particularly relevant in low-resource settings where continuous fetal and uterine monitoring may not be consistently available (1,11).

Evidence from Ethiopia reflects this complexity. Studies conducted in Jimma and Dessie report spontaneous vaginal delivery rates ranging from 66 to 72 percent with different induction methods (12,17). A quasi-experimental study in Gedeo zone public hospitals found comparable outcomes between Foley catheter and vaginal misoprostol for cervical ripening (18). In Ethiopia, variations in induction practice persist, influenced by institutional protocols, provider preference, and resource availability (11,13). There is currently limited recent, context-specific evidence evaluating labor outcomes following transcervical Foley catheter use at Wallaga University Comprehensive Specialized Hospital. Therefore, this study aims to assess labor outcomes following transcervical Foley catheter use for cervical ripening and identify associated factors at Wallaga University Comprehensive Specialized Hospital, Ethiopia.

1.3. Significance of the Study

This study holds significant relevance for multiple stakeholders across different levels of the health system, ranging from national policy makers to individual patients.

At the policy and regulatory level, the finding was provide evidence to the Federal Ministry of Health, the Oromia Regional Health Bureau, and hospital administrators at Wallaga University Comprehensive Specialized Hospital. These stakeholders can utilize the evidence to evaluate current induction protocols, allocate resources more efficiently, and develop context-specific guidelines for cervical ripening.

At the institutional and facility level, the study was benefit hospital managers, quality improvement teams, and clinical department heads. The findings were help identify strengths and gaps in current induction practices, support the development of standardized protocols, and establish local benchmarks for labor outcomes. This may lead to more efficient use of limited resources, improved patient safety, and a reduction in unnecessary cesarean sections.

At the healthcare provider level, the study was assist obstetricians, residents, midwives, and general practitioners in understanding local success rates of transcervical Foley catheter use. Clinicians were gain evidence-based knowledge to guide patient selection, counsel women appropriately, and make informed decisions regarding the continuation or abandonment of

induction. The identification of factors associated with successful vaginal delivery was enable providers to stratify patients by risk and tailor management accordingly.

At the patient and community level, the study was ultimately benefit women who require induction of labor. Improved clinical decision-making was lead to better counseling, reduced maternal anxiety, shorter hospital stays, lower rates of unnecessary cesarean sections, and improved overall labor outcomes. Families and communities was benefit from reduced financial burdens associated with prolonged hospitalizations and surgical deliveries.

At the academic and research level, the study addresses an important evidence gap in Western Ethiopia, where data on mechanical cervical ripening methods remain limited. The finding was contributed to national and international literature, serve as a baseline for future research, and support academic capacity building at Wallaga University.

In summary, the significance of this study cascades from national policy makers who set induction guidelines, to hospital administrators who allocate resources, to clinicians who provide care, and finally to the individual pregnant woman who experiences the outcome of induction.

2. LITERATURE REVIEW

2.1. Cervical Ripening and Induction of Labor

Induction of labor is defined as the artificial initiation of uterine contractions before the spontaneous onset of labor in order to achieve vaginal delivery when continuation of pregnancy poses risks to the mother or fetus (1). It is one of the most common obstetric interventions globally, with reported rates varying across different settings (3).

The World Health Organization recommends that induction be undertaken only when clear maternal or fetal indications exist, including post-term pregnancy, premature rupture of membranes, hypertensive disorders, and intrauterine growth restriction (1). The success of induction is highly dependent on the pre-induction status of the cervix, which is commonly assessed using the Bishop score. A Bishop score below six generally indicates an unfavorable cervix and the need for cervical ripening prior to induction (4). Effective cervical ripening plays a critical role in determining the duration of labor, mode of delivery, and overall labor outcomes (14).

Cervical ripening methods are broadly classified into mechanical and pharmacological approaches. Mechanical methods such as the transcervical Foley catheter exert direct pressure on the internal cervical os and stimulate endogenous prostaglandin release (5,7). Pharmacological agents, particularly vaginal misoprostol, act by softening the cervix and enhancing uterine contractility through prostaglandin E₁ activity (8,9). Selection of the ripening method depends on patient characteristics, obstetric history, clinician preference, and availability of resources (2,11). In low-resource settings such as Ethiopia, balancing effectiveness, safety, and cost is essential, and national obstetric protocols provide guidance on the available options (13).

2.2. Labor Outcomes Following Foley Catheter Use

Evidence from randomized trials and observational studies indicates that mechanical methods such as the Foley catheter achieve successful vaginal delivery in approximately 58 to 70 percent of cases (5,6,16).

While some pharmacological agents may result in higher rates of delivery within 24 hours, the Foley catheter provides more consistent outcomes across diverse patient populations, with less variability once active labor is established (7,16).

The induction-to-delivery interval associated with Foley catheter use typically ranges between 18 and 22 hours (7,18). Although this duration may be longer than that of some pharmacological methods, the gradual progression of labor offers important safety advantages, particularly in reducing uterine tachysystole (8,15). Balloon volume also influences outcomes; Sandberg and colleagues demonstrated that use of a 60 mL balloon resulted in faster cervical dilation than a 30 mL balloon without increasing maternal or neonatal complications (5).

In the Ethiopian context, studies from Jimma University Hospital and Dessie Referral Hospital demonstrate the practical outcomes of mechanical methods in resource-limited settings. Girma and colleagues reported a mean induction-to-delivery interval of approximately 19.8 hours with mechanical methods at Jimma University Hospital (12). Dilnessa and colleagues found that the proportion of failed induction at Dessie Referral Hospital was influenced by cervical status at the time of induction, with unfavorable Bishop scores significantly associated with longer induction durations and higher cesarean section rates (17). Temesgen and colleagues, in a quasi-experimental study conducted in Gedeo zone public hospitals, reported comparable outcomes between Foley catheter and vaginal misoprostol for cervical ripening (18).

2.3. Factors Associated with Successful Vaginal Delivery Following Induction

The success of induction of labor is influenced by multiple maternal and obstetric factors. Understanding these factors is essential for patient counseling, clinical decision-making, and risk stratification.

2.3.1. Parity

Parity is consistently identified as one of the strongest predictors of successful vaginal delivery following induction. Nulliparous women have significantly longer induction-to-

delivery intervals and higher cesarean section rates compared to multiparous women (11,12). This is attributed to the fact that multiparous women have previously undergone cervical dilation and vaginal delivery, resulting in a more compliant cervix and more efficient uterine contractility (14).

2.3.2. Baseline Bishop Score

The pre-induction Bishop score is a well-established predictor of induction success. Women with higher baseline Bishop scores have shorter induction-to-delivery intervals and higher rates of vaginal delivery (4,18). A Bishop score of less than six is generally considered unfavorable and requires cervical ripening prior to induction. The relationship between Bishop score and induction success has been documented across multiple settings, including Ethiopian hospitals (11,12).

2.3.3. Maternal Age

Advanced maternal age has been associated with longer induction durations and higher cesarean section rates, although this effect is often confounded by parity and other medical comorbidities (2,3).

2.3.4. Indication for Induction

The indication for induction influences labor outcomes. Indications such as hypertensive disorders, oligohydramnios, and fetal growth restriction are associated with higher rates of cesarean section compared to post-term pregnancy or elective induction (2,3). The World Health Organization emphasizes that induction should be performed only when clear medical indications exist (1).

2.3.5. Balloon Volume and Traction

The volume of saline used to inflate the Foley catheter balloon may influence ripening outcomes. Sandberg and colleagues compared 30 mL and 60 mL balloons and found that the larger volume resulted in faster cervical dilation (5). The use of traction on the Foley catheter is another procedural variable that may affect outcomes, though evidence is limited and inconsistent (7,16).

2.3.6. Oxytocin Augmentation

Oxytocin is commonly used following Foley catheter removal to establish or augment labor when contractions are inadequate. The timing and dose of oxytocin administration may influence labor outcomes (14,19). Some protocols advocate for immediate oxytocin following Foley removal, while others allow a period of expectant management (6). The Ethiopian national obstetric management protocol provides guidance on the use of oxytocin following cervical ripening (13).

2.4. Comparison of Foley Catheter with Pharmacological Methods

Several studies have directly compared the transcervical Foley catheter with pharmacological agents for cervical ripening. Noor and colleagues conducted a randomized trial comparing Foley catheter with vaginal misoprostol and found comparable rates of vaginal delivery, although misoprostol was associated with a shorter induction-to-delivery interval (6). Ten Eikelder and colleagues, in a multi-centre non-inferiority trial, compared oral misoprostol with Foley catheter and reported that the Foley catheter was non-inferior in terms of cesarean section rates and had a better safety profile with respect to uterine hyperstimulation (16).

Jozwiak and colleagues specifically examined Foley catheter use in women with previous cesarean section and concluded that mechanical methods are preferred in this population due to the lower risk of uterine rupture compared to prostaglandins (7). Leduc and colleagues, in clinical practice guidelines for induction of labour, recommended mechanical methods as a safe option for cervical ripening, particularly when continuous fetal monitoring is not available (10).

In Ethiopia, Temesgen and colleagues, in a quasi-experimental study in Gedeo zone public hospitals, reported comparable outcomes between Foley catheter and vaginal misoprostol for cervical ripening (18). Shetty and colleagues compared multiple methods including vaginal misoprostol, dinoprostone gel, Foley catheter, and extra-amniotic saline infusion, providing evidence for the effectiveness of mechanical methods (20). Aquino and Cecatti, in a randomized controlled trial, compared misoprostol with oxytocin for labor induction and found misoprostol to be an effective alternative (19).

2.5. Physiological Basis of Mechanical Ripening

The mechanism by which the transcervical Foley catheter promotes cervical ripening involves both mechanical and biochemical pathways. The inflated balloon exerts direct pressure on the internal cervical os, leading to mechanical dilation and stretching of the cervical tissue (5). This mechanical stretch stimulates the release of endogenous prostaglandins from the decidua and fetal membranes, which in turn promote cervical softening, effacement, and dilation (14,15). Keirse, in a comprehensive review of natural prostaglandins for induction of labor, explained that the local release of prostaglandins following mechanical stimulation mimics the natural physiological process of cervical ripening that occurs prior to spontaneous labor (15).

The advantage of this mechanism is that the release of prostaglandins is localized and self-limited, reducing the risk of systemic side effects and uterine hyperstimulation that can occur with exogenous prostaglandin administration (8,9). This physiological basis explains why the Foley catheter is associated with lower rates of uterine tachysystole and abnormal fetal heart rate patterns compared to pharmacological agents (10,16).

2.6. Summary of Literature and Research Gaps

The existing literature consistently demonstrates that the transcervical Foley catheter is a viable method for cervical ripening, with reported success rates ranging from 58 to 70 percent and induction-to-delivery intervals of 18 to 22 hours (5–7,16). Parity, baseline Bishop score, and indication for induction are well-established predictors of successful vaginal delivery following induction (4,11,12,16,17). The Foley catheter compares favorably with pharmacological agents in terms of safety, particularly regarding uterine hyperstimulation, and is preferred in women with previous cesarean section (7,10).

However, several gaps remain in the literature. First, most studies have been conducted in high-income settings or large academic centers in Addis Ababa, with limited data from Western Ethiopia (11,12,18). Second, few studies have systematically examined factors associated with successful vaginal delivery following Foley catheter use in resource-limited settings (12,17). Third, institution-specific data from Wallaga University Comprehensive

Specialized Hospital are lacking, making it difficult to benchmark local outcomes against national or international standards.

This study aims to address these gaps by assessing labor outcomes following transcervical Foley catheter use for cervical ripening and identifying factors associated with successful vaginal delivery at Wallaga University Comprehensive Specialized Hospital, Ethiopia.

2.7. Conceptual framework

Adopted from the literature (2,3,18,19,4–7,11,12,14,16)

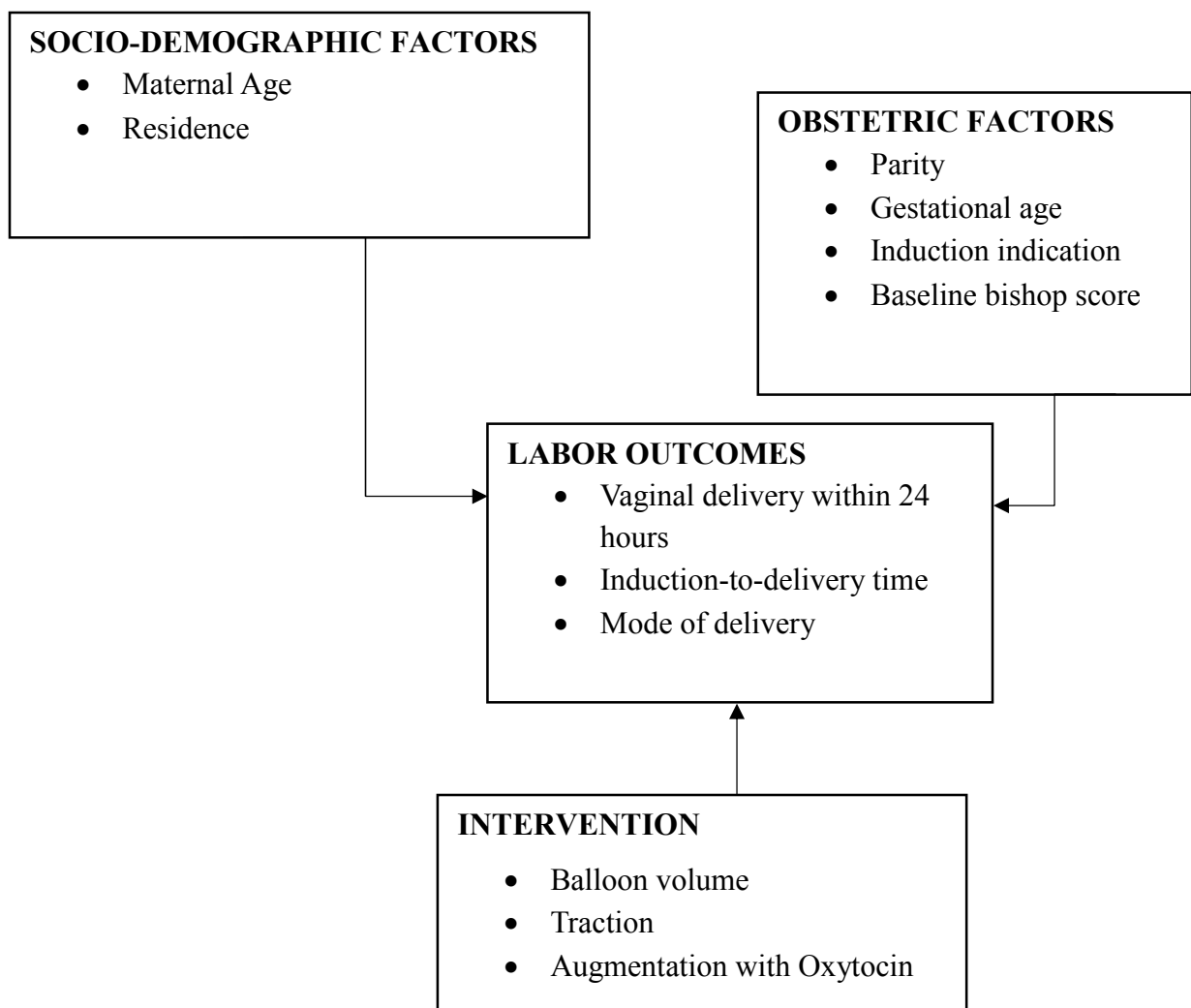


Figure 1: Conceptual framework

3. OBJECTIVES

3.1. General Objective

- To assess labor outcomes of transcervical Foley catheter use for cervical ripening and identify associated factors at Wallaga University Comprehensive Specialized Hospital, Ethiopia, from January to December 2025.

3.2. Specific Objectives

- To determine the proportion of successful vaginal delivery within 24 hours of Foley catheter insertion among women undergoing cervical ripening at Wallaga University Comprehensive Specialized Hospital.
- To determine the mean induction-to-delivery interval among women undergoing cervical ripening with a transcervical Foley catheter at Wallaga University Comprehensive Specialized Hospital.
- To determine the mode of delivery (spontaneous vaginal, assisted vaginal, or cesarean section) among women undergoing cervical ripening with a transcervical Foley catheter at Wallaga University Comprehensive Specialized Hospital.
- To identify factors associated with successful vaginal delivery within 24 hours following transcervical Foley catheter use for cervical ripening at Wallaga University Comprehensive Specialized Hospital.

4. METHODS AND MATERIALS

4.1. Study Setting and Period

The study was conducted at Wallaga University Comprehensive Specialized Hospital (WUCSH), located in Nekemte, the administrative capital of the East Wallaga Zone in the Oromia Regional State, western Ethiopia. Nekemte is situated at approximately 9°5'N latitude and 36°33'E longitude, at an elevation of 2,088 meters above sea level. The town is a major market center and serves as a transportation hub for the surrounding agricultural region. Based on available estimates, the population of Nekemte is approximately 110,688 permanent residents (CSA). The town's population includes a substantial proportion of women of reproductive age, contributing to the high demand for maternal health services in the area. The catchment area of Wallaga University Comprehensive Specialized Hospital extends beyond Nekemte town to serve a large, predominantly agricultural population across the East Wallaga Zone and neighboring districts.

WUCSH is a tertiary-level teaching and referral hospital that serves as the primary referral center for the East Wallaga Zone and surrounding areas. As a comprehensive specialized hospital, it provides a wide range of services including emergency medicine, surgery, internal medicine, pediatrics, and specialized obstetric and gynecologic care. The hospital plays a critical role in the regional health system by receiving referred patients from district hospitals, health centers, and primary care units throughout the zone.

The Department of Obstetrics and Gynecology is a busy clinical unit managing approximately 3,648 deliveries annually. The department is staffed by a multidisciplinary team including obstetricians, residents, midwives, and nurses, and is equipped with a dedicated labor ward and a neonatal intensive care unit. The department manages a high volume of high-risk pregnancies and obstetric emergencies, including induction of labor for various maternal and fetal indications.

The study reviewed medical records of women who underwent cervical ripening with a transcervical Foley catheter at the Department of Obstetrics and Gynecology, Wallaga University Comprehensive Specialized Hospital, from January 1, 2025, to December 31, 2025.

4.2. Study Design

A hospital-based retrospective cross-sectional study design was employed to assess labor outcomes following transcervical Foley catheter use for cervical ripening and to identify factors associated with successful vaginal delivery.

4.3. Study Population

4.3.1. Source Population

The source population consisted of all pregnant women who underwent induction of labor at the labor and delivery unit of WUCSH between January 1, 2025, and December 31, 2025.

4.3.2. Inclusion Criteria

Women were included in the study if they had a singleton pregnancy with a gestational age of 37 weeks or more, cephalic presentation, a Bishop score of 6 or less at the time of induction indicating an unfavorable cervix, and induction of labor initiated with a transcervical Foley catheter. Additionally, a complete medical record including the delivery note was required.

4.3.3. Exclusion Criteria

Medical records were excluded if they had major missing data critical to the study outcomes, such as undocumented time of Foley insertion, missing mode or time of delivery, or absent delivery outcome. Women who received any pharmacologic cervical ripening agent, such as vaginal misoprostol, prior to the Foley catheter were excluded. Documented contraindications to vaginal delivery present at the time of admission, including major placenta previa or classical uterine scar, also led to exclusion, as did a diagnosis of

intrauterine fetal death prior to the initiation of induction. However, none of the 169 sampled records met these exclusion criteria, and all were included in the final analysis.

4.3.4. Study Variables

Labor Outcome Variables: The primary labor outcome was successful vaginal delivery achieved within 24 hours of Foley catheter insertion, measured as a dichotomous variable (yes or no). Secondary labor outcomes included the induction-to-delivery interval measured in hours as a continuous variable, and mode of delivery categorized as spontaneous vaginal, assisted vaginal, or cesarean section.

Independent Variables (Associated Factors): The independent variables examined as potential associated factors included maternal age measured in complete years as a continuous variable ; residence categorized as urban or rural; parity categorized as nulliparous (zero) or multiparous (one or more); gestational age at induction measured in completed weeks as a continuous variable; indication for induction; baseline Bishop score measured as a continuous variable; balloon volume categorized as 60 mL or 80 mL; traction applied as yes or no; duration of Foley in place measured in hours as a continuous variable; and oxytocin augmentation used as yes or no.

4.4. Sample Size Determination

The sample size was calculated using the single population proportion formula with finite population correction, as the source population was finite and the initial sample size exceeded 5% of the population.

Initial sample size without finite population correction

The following formula was used:

$$n^0 = \frac{\left(\frac{Z^2 \alpha}{2} \times p \times (1 - p) \right)}{d^2}$$

- $Z\alpha/2 = 1.96$ (standard normal deviate for 95% confidence level)

- $p = 0.683$ (expected proportion of successful vaginal delivery within 24 hours, based on Temesgen et al., 2024)
- $d = 0.05$ (margin of error, 5%)

$$n^0 = \frac{((1.96)^2 \times 0.683 \times (1 - 0.683))}{(0.05)^2}$$

$$n^0 = \frac{(3.8416 \times 0.683 \times 0.317)}{0.0025}$$

$$n^0 = \frac{(3.8416 \times 0.2165)}{0.0025}$$

$$n^0 = \frac{0.8317}{0.0025}$$

$$n_0 = 332.68 \approx 333$$

Since the initial sample size (333) exceeded 5% of the estimated source population, the finite population correction formula was applied:

$$n = n_0 / (1 + ((n_0 - 1) / N))$$

- $n = 333$
- $N = 342$

The source population was estimated based on the following sequential eligibility criteria:

- Annual deliveries at WUCSH: 3,648
- Proportion undergoing induction of labor (20–25%): approximately 800 women
- Proportion with unfavorable cervix requiring cervical ripening (40–50%): approximately 360 women
- Women receiving transcervical Foley catheter without prior pharmacological ripening: approximately 342 women

$$n = 333 / (1 + ((333 - 1) / 342))$$

$$n = 333 / (1 + (332 / 342))$$

$$n = 333 / (1 + 0.9708)$$

$$n = 333 / 1.9708$$

$$n = 168.96 \approx 169$$

Thus, the required sample size was exactly 169 women. No additional contingency was needed as the finite population correction already accounted for the population size, and all eligible women during the study period were included.

4.5. Sampling Procedure

A systematic random sampling technique was used. A sampling frame was prepared from the HMIS maternity ward registry comprising all eligible women who underwent induction of labor with a transcervical Foley catheter during the study period. The registry was arranged in reverse chronological order from December 2025 to January 2025. The sampling interval (k) was calculated by dividing the total number of eligible records (N = 340) by the required sample size (n = 169), giving k approximately equal to 2.36. A random starting number between 1 and 2 was selected using a lottery method. Beginning from this randomly selected starting point, every second record was included while moving backward chronologically through the registry until the target sample size of 169 was obtained.

4.6. Data Collection Tool and Procedures

Data were extracted using a structured digital questionnaire developed on the KoboCollect platform. The form was designed based on the national obstetric management protocol and adapted from similar studies. It included skip logic and validation rules to ensure data quality at the point of entry. Four trained midwife data abstractors used tablets with the KoboCollect application to extract data directly from the physical medical records, including admission notes, partographs, and delivery notes, in the hospital records department. Data were entered into the digital form and submitted to a secure, cloud-based Kobo Toolbox server. The principal investigator supervised the process, verifying abstracted data against source documents for a random 20% of cases.

4.7. Data Quality Assurance

Prior to data collection, the KoboCollect form was pre-tested on approximately 7 records, representing 5% of the sample, from a pilot month. Data abstractors underwent a one-day training covering the study protocol, ethical handling of records, and use of the KoboCollect application. The digital form's built-in constraints prevented common entry errors. The principal investigator monitored incoming data on the Kobo Toolbox server in real time. A double-check of a random sample of records was performed, and following collection, data were exported to Microsoft Excel for consistency review before analysis.

4.8. Data Processing and Analysis

Data collected via the KoboCollect platform were downloaded from the secure server and exported to SPSS version 27 for comprehensive statistical analysis. Following the export process, the dataset underwent rigorous cleaning and coding to ensure consistency and accuracy.

Descriptive Analysis: Descriptive statistics, including frequencies, percentages, means, and standard deviations, were used to summarize the socio-demographic and obstetric characteristics of the study population. The primary labor outcome, the proportion of successful vaginal deliveries achieved within 24 hours of Foley catheter insertion, was presented as a percentage with a 95% confidence interval. The mean induction-to-delivery interval was calculated and reported in hours with its corresponding standard deviation. The mode of delivery was reported using frequencies and percentages.

Bivariate Analysis: To identify factors associated with successful vaginal delivery within 24 hours, bivariate logistic regression analysis was performed for each independent variable. Variables with a p-value of less than 0.25 in the bivariate analysis were considered candidates for the multivariate model. Additionally, chi-square tests were used to assess the association between categorical independent variables (such as parity group, traction applied, and balloon volume) and successful vaginal delivery. Independent t-tests were used to compare the mean baseline Bishop scores and mean duration of Foley in place between women who achieved successful vaginal delivery and those who did not.

Multivariate Analysis: Multivariate logistic regression analysis was performed to identify independent predictors of successful vaginal delivery within 24 hours while controlling for potential confounders. Adjusted odds ratios with 95% confidence intervals were calculated. A p-value of less than 0.05 was considered statistically significant.

Model Fit: The Hosmer-Lemeshow goodness-of-fit test was used to assess the adequacy of the logistic regression model. A p-value greater than 0.05 indicated a good fit.

4.9. Operational Definitions

Labor outcomes: For the purpose of this study, labor outcomes refer to three primary measurable events following transcervical Foley catheter use for cervical ripening: successful vaginal delivery within 24 hours of Foley insertion, induction-to-delivery interval, and mode of delivery. These outcomes collectively reflect the progress and results of induced labor(1–3).

Successful vaginal delivery within 24 hours: Delivery of the fetus via the vaginal route within 24 hours from the documented time of Foley catheter insertion (18).

Induction-to-delivery interval: The time in hours from Foley catheter insertion to delivery, regardless of mode of delivery (7,12,18).

Mode of delivery: The method by which the fetus is delivered, categorized as spontaneous vaginal delivery (delivery without the use of instruments or surgical intervention), assisted vaginal delivery (delivery with the use of vacuum extractor or forceps), or cesarean section (delivery through surgical incision of the abdominal and uterine walls) (2,3).

Assisted vaginal delivery: Delivery of the fetus using vacuum extractor or forceps when the second stage of labor is prolonged or when there is maternal or fetal indication for expedited delivery (2,3).

Nulliparity: Women who have never delivered a viable infant (parity = 0) (2,3).

Multiparity: Women who have delivered one or more viable infants (parity ≥ 1) (2,3).

Gestational age: Calculated from the first day of the last normal menstrual period (LNMP) and confirmed using early ultrasound when available. In cases where LNMP is uncertain or in late presentation without reliable dating, gestational age is estimated using the best

available ultrasound parameters, including biparietal diameter, head circumference, abdominal circumference, and femur length (2,3).

Unfavorable cervix: A Bishop score of less than 6 at the time of induction, indicating the need for cervical ripening (2,3).

Uterine tachysystole: More than five uterine contractions in 10 minutes, averaged over a 30-minute window (2,3).

Failed induction of labour: Failure to achieve regular (e.g. every 3 minutes) uterine contractions and cervical change after at least 6 - 8 hours of the maintenance dose of oxytocin administration, with artificial rupture of membranes if feasible.(13)

4.10. Ethical Considerations

Ethical approval was obtained from the Institutional Research Ethics Review Committee (IRERC) of Wallaga University. A formal Ethical clearance certificate was requested and granted for this retrospective review by a letter written on Feb. 2, 2026 with Ref. No IHSREC/19/128/2026. Confidentiality was strictly maintained; no patient identifiers were entered into the KoboCollect form. The digital database on the secure server was accessible only to the research team via password protection. The study adhered to the principles of the Declaration of Helsinki.

4.11. Dissemination of Findings

The finding was presented to the Department of Obstetrics and Gynecology at WUCSH and to Wallaga University. The results were compiled for publication in a peer-reviewed journal. A summary report with key findings was disseminated to the Oromia Regional Health Bureau and the Ethiopian Federal Ministry of Health.

5. RESULTS

5.1. Introduction

A total of 169 medical records of women who underwent cervical ripening with a transcervical Foley catheter at Wallaga University Comprehensive Specialized Hospital from January 1, 2025, to December 31, 2025, were reviewed. All 169 records met the inclusion criteria and were included in the final analysis.

5.2. Baseline Characteristics of Participants

The mean age of the study participants was 24.95 years with a standard deviation of 3.94 years. The majority of women, 163 (96.4 percent), were aged between 19 and 35 years, while 6 women (3.6 percent) were aged 18 years or younger. Regarding residence, 94 women (55.6 percent) lived in urban areas while 75 (44.4 percent) resided in rural areas.

Concerning obstetric characteristics, the mean parity was 1.46 with a standard deviation of 1.32. Nulliparous women constituted 56 (33.1 percent) of the study population, while multiparous women numbered 113 (66.9 percent). The mean gestational age at induction was 39.14 weeks with a standard deviation of 1.76 weeks. The most common indication for induction was oligohydramnios, accounting for 75 cases (44.4 percent), followed by hypertensive disorders in 36 cases (21.3 percent), post-term pregnancy in 27 cases (16.0 percent), bad obstetric history in 16 cases (9.5 percent), fetal growth restriction in 13 cases (7.7 percent), and other indications in 2 cases (1.2 percent). The mean baseline Bishop score before Foley catheter insertion was 4.57 with a standard deviation of 0.50 out of 13, indicating an unfavorable cervix in all participants as per the inclusion criteria.

Table 1: Baseline Characteristics of Women Undergoing Cervical Ripening with Foley catheter at WUCSH, Ethiopia, 2025 (N = 169)

Variable	Category	Frequency (n)	Percentage (%)
Maternal Age *			
	≤ 18	6	3.6
	19 – 35	163	96.4
	≥ 35	0	0.0
Mean age (years)	24.95 ± 3.94		
Residence			
	Urban	94	55.6
	Rural	75	44.4
Parity			
	Nulliparous	56	33.1
	Multiparous	113	66.9
Mean parity	1.46 ± 1.32		
Gestational age (weeks)*			
	Early term	67	39.6
	Full term	54	32.0
	Late term	21	12.4
	Post term	27	16.0
Mean Gestational age (weeks)	39.14 ± 1.76		
Indication for induction			
	Oligohydramnios	75	44.4
	Hypertension	36	21.3
	Post term pregnancy	27	16.0
	Bad obstetric history	16	9.6
	Fetal growth restriction	13	7.7
	Other	2	1.2
Baseline bishop score	4.56 ± 0.50		

*Age categories based on standard obstetric definitions: ≤18 years (adolescent pregnancy), 19-35 years (standard reproductive age), ≥35 years (advanced maternal age)

Gestational age categories based on standard obstetric definitions: early term (37-38 weeks), full term (39-40 weeks), late term (41 weeks), post-term (≥42 weeks) (2,3)

5.3. Foley catheter Procedural Characteristics

Regarding the Foley catheter procedure, the balloon inflation volume was 60 mL in 74 cases (43.8 percent) and 80 mL in 95 cases (56.2 percent). Traction was applied in the vast majority of cases, specifically 157 cases (92.9 percent). The mean duration the Foley catheter remained in place was 6.22 hours with a standard deviation of 1.30 hours.

Concerning the reason for removal, spontaneous expulsion occurred in 138 cases (81.7 percent), active labor was achieved in 28 cases (16.6 percent), the 12-hour limit was reached in 2 cases (1.2 percent), and other reasons accounted for 1 case (0.6 percent). Oxytocin augmentation was used in 140 cases (82.8 percent) after Foley removal to establish or augment labor.

Table 2: Foley catheter Procedural Characteristics (N = 169)

Variable	Category	Frequency (n)	Percentage (%)
Balloon volume (mL)			
	60	74	43.8
	80	95	56.2
Traction applied			
	Yes	157	92.9
	No	12	7.1
Duration of foley in place (hours)	6.22 ± 1.30		
Reason for removal			
	Spontaneous expulsion	138	81.7
	Active labor achieved	28	16.6
	12-hour limit reached	2	1.2
	Other reason	1	0.6
Oxytocin augmentation			
	Yes	140	82.8
	No	29	17.2

5.4. Change in Bishop Score Following Foley catheter Use

Following Foley catheter removal, the mean Bishop score increased significantly from 4.57 with a standard deviation of 0.50 at baseline to 9.17 with a standard deviation of 1.51, representing a mean change of 4.60 points with a standard deviation of 1.32. The paired t-test revealed that this difference was statistically significant ($p < 0.001$), indicating effective cervical ripening. The correlation between baseline and post-ripening Bishop scores was moderate and significant ($r = 0.551$, $p < 0.001$).

Table 3: Bishop Score Change Following Foley catheter Ripening (N = 169)

Variable	Mean $\pm$ SD	p-value*
Baseline bishop score	4.57 $\pm$ 0.50	
Post-ripening bishop score	9.17 $\pm$ 1.51	
Mean change in bishop score	4.60 $\pm$ 1.32	< 0.001

□ Paired t-test

5.5. Labor Outcomes

5.5.1. Primary Outcome: Successful Vaginal Delivery Within 24 Hours

The primary outcome of this study was the proportion of women who achieved successful vaginal delivery within 24 hours of Foley catheter insertion. Of the 169 women, 116 (68.6 percent) achieved successful vaginal delivery within 24 hours, while 53 (31.4 percent) did not.

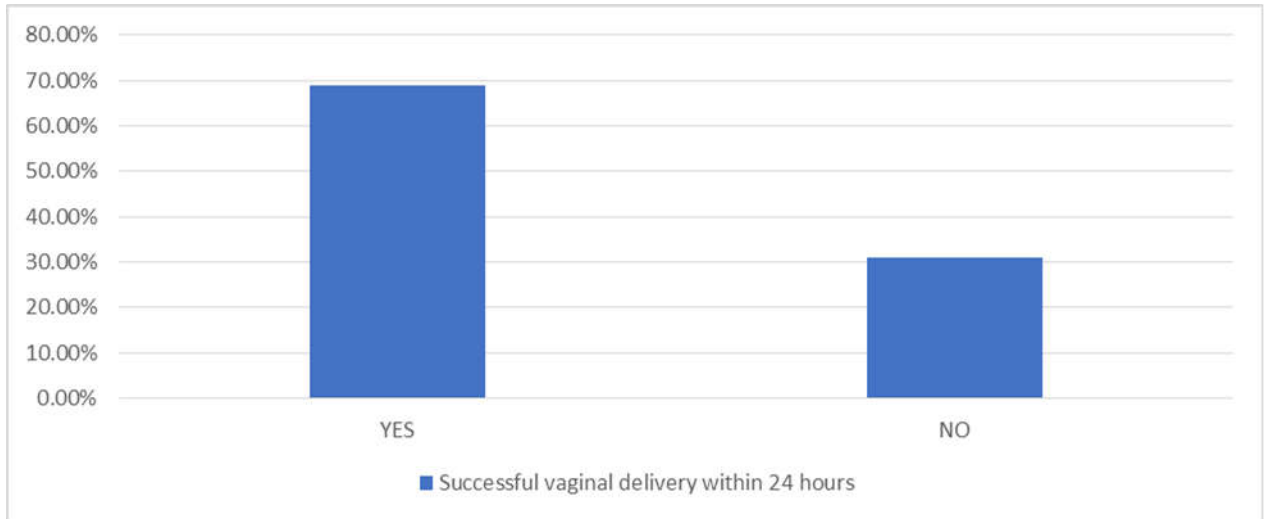


Figure 2: Successful Vaginal Delivery within 24 Hours

5.5.2. Induction-to-Delivery Interval

The mean induction-to-delivery interval for all deliveries was 15.98 hours with a standard deviation of 3.25 hours, ranging from 8 to 26 hours. When stratified by mode of delivery, women who had spontaneous vaginal delivery experienced a mean interval of 16.07 hours with a standard deviation of 2.93 hours (n = 102). Those who had assisted vaginal delivery had a mean interval of 16.86 hours with a standard deviation of 2.21 hours (n = 14). Women who underwent cesarean section had a mean interval of 15.58 hours with a standard deviation of 3.96 hours (n = 53).

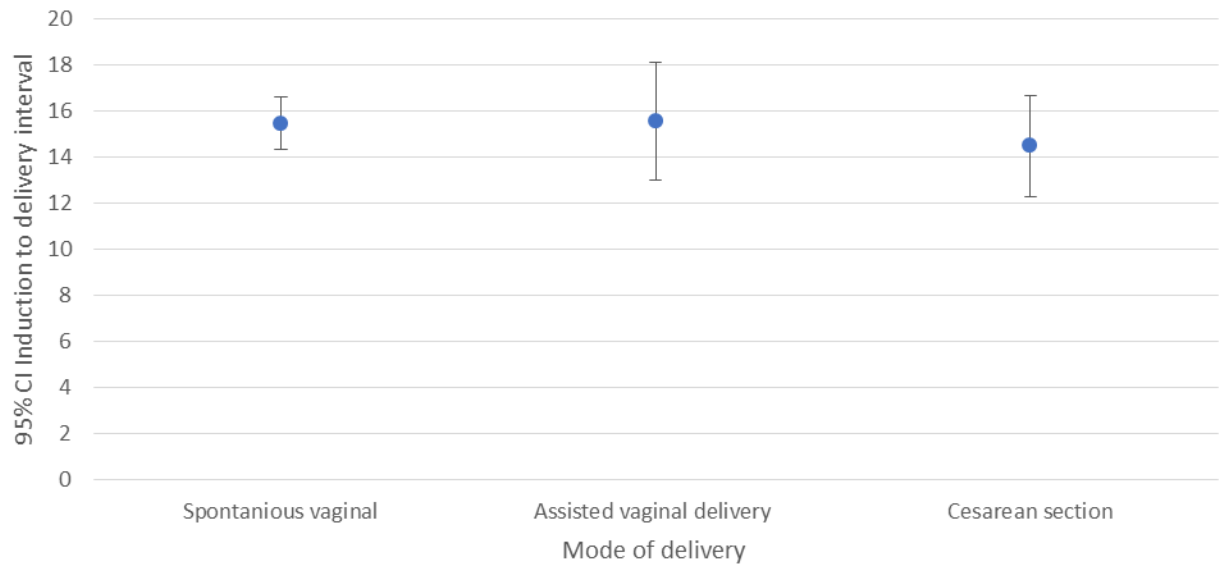


Figure 3: Induction-to-Delivery Interval by Mode of Delivery

5.5.3. Mode of Delivery

Of the 169 women, 102 (60.4 percent) had a spontaneous vaginal delivery, 14 (8.3 percent) had an assisted vaginal delivery using vacuum or forceps, and 53 (31.4 percent) underwent cesarean section.



Figure 4: Mode of Delivery

5.6. Factors Associated with Successful Vaginal Delivery

5.6.1. Bivariate Logistic Regression Analysis

Bivariate logistic regression was performed to identify factors associated with successful vaginal delivery within 24 hours. The following factors were significantly associated with success: maternal age, parity group, baseline Bishop score, and duration of Foley in place.

Multiparous women had 11.81 times higher odds of successful vaginal delivery compared to nulliparous women (95% CI: 5.49 to 25.38, $p < 0.001$). Each one-point increase in baseline Bishop score was associated with 7.01 times higher odds of success (95% CI: 3.37 to 14.57, $p < 0.001$). Each one-year increase in maternal age was associated with 1.32 times higher odds of success (95% CI: 1.18 to 1.47, $p < 0.001$). Each one-hour increase in duration of Foley in place was associated with 61 percent lower odds of success (OR = 0.39, 95% CI: 0.27 to 0.56, $p < 0.001$).

Balloon volume, traction applied, and gestational age were not significantly associated with successful vaginal delivery ($p > 0.05$ for all).

Table 4: Bivariate Logistic Regression Analysis of Factors Associated with Successful Vaginal Delivery within 24 Hours (N = 169)

Factor	Crude OR	95% CI	p-value
Maternal age (per 1-year increase)	1.32	1.18 – 1.47	< 0.001
Parity group (Multiparous vs. Nulliparous)	11.81	5.49 – 25.38	< 0.001
Baseline bishop score (per 1-point increase)	7.01	3.37 -14.57	< 0.001
Duration of Foley in place (per 1-hour increase)	0.39	0.27 – 0.56	< 0.001
Balloon volume (80 vs. 60)	1.53	0.79 – 2.93	0.205
Traction applied (Yes or No)	1.40	0.36 – 5.40	0.622
Gestational age (per 1-week increase)	1.05	0.87 -1.27	0.601

5.6.2. Multivariate Logistic Regression Analysis

Variables with $p < 0.25$ in the bivariate analysis (parity group, baseline Bishop score, and duration of Foley in place) were entered into a multivariate logistic regression model to identify independent predictors of successful vaginal delivery while controlling for potential confounders.

The Hosmer-Lemeshow goodness-of-fit test indicated that the model fit the data well ($\chi^2 = 1.818$, $df = 4$, $p = 0.769$). The Nagelkerke R Square value was 0.357, indicating that the model explained 35.7 percent of the variance in successful vaginal delivery. The overall classification accuracy of the model was 79.0 percent.

After adjusting for confounders, parity group and duration of Foley in place remained independently associated with successful vaginal delivery. Multiparous women had 4.65 times higher odds of successful vaginal delivery compared to nulliparous women (AOR = 4.65, 95% CI: 1.37 to 15.85, $p = 0.014$). Each one-hour increase in duration of Foley in place was associated with 37 percent lower odds of success (AOR = 0.63, 95% CI: 0.41 to 0.98, $p = 0.039$). Baseline Bishop score was not independently significant in the multivariate model (AOR = 1.24, 95% CI: 0.39 to 3.97, $p = 0.712$).

Table 5: Multivariate Logistic Regression Analysis of Factors Independently Associated with Successful Vaginal Delivery within 24 Hours (N = 169)

Factor	Adjusted OR	95% CI	p-value
Parity group (Multiparous vs. Nulliparous)	4.65	1.37 – 15.85	0.014
Baseline bishop score (per 1-point increase)	1.24	0.39 – 3.97	0.712
Duration of Foley in place (per 1-hour increase)	0.63	0.41 – 0.98	0.039

5.6.3. Independent T-Tests

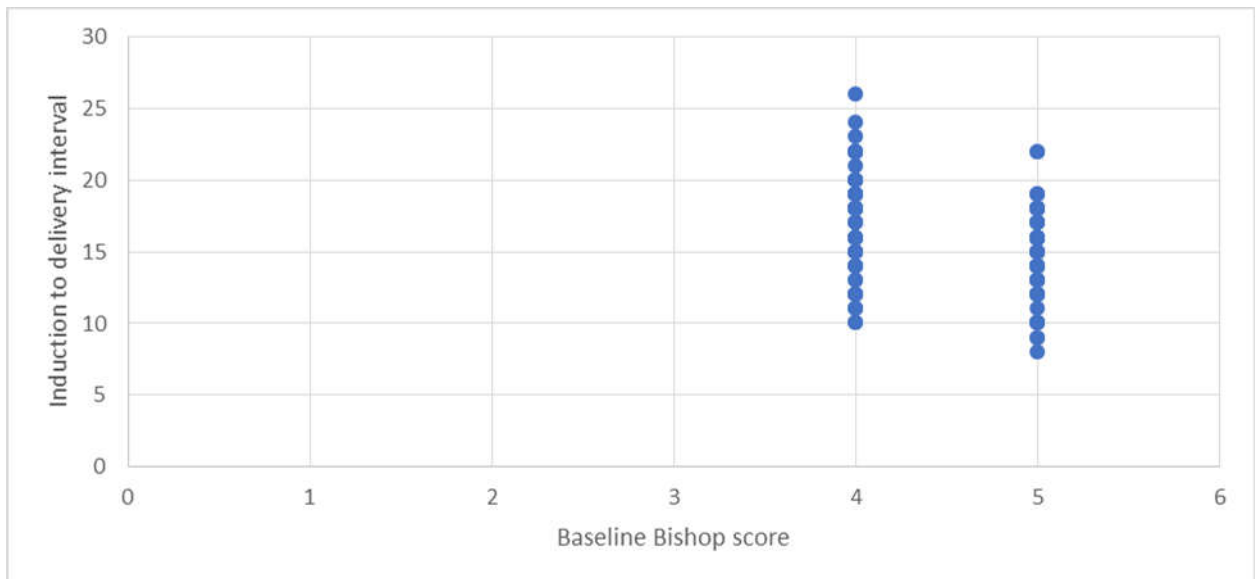
Independent t-tests revealed that women who achieved successful vaginal delivery had significantly higher baseline Bishop scores (mean difference = 0.46, $p < 0.001$) and significantly shorter duration of Foley in place (mean difference = -1.27 hours, $p < 0.001$) compared to those who did not achieve success.

Table 6: Comparison of Baseline Bishop Score and Foley Duration by Success (N = 169)

Variable	Success (n=116)	Failure (n=53)	Mean difference	p-value
Baseline bishop score	4.72	4.62	0.46	< 0.001
Duration of foley in place	5.83	7.10	-1.27	< 0.001

5.7. Correlation between Baseline Bishop Score and Induction-to-Delivery Interval

There was a significant negative correlation between baseline Bishop score and induction-to-delivery interval (Pearson correlation coefficient $r = -0.301$, $p < 0.001$). This indicates that women with higher (more favorable) baseline Bishop scores had shorter induction-to-delivery intervals.

**Figure 5:** Correlation between Baseline Bishop Score and Induction-to-Delivery Interval

5.8. Comparison of Induction-to-Delivery Interval by Balloon Volume

One-way ANOVA was performed to compare the mean induction-to-delivery interval between women who received a 60 mL balloon and those who received an 80 mL balloon. Women who received an 80 mL balloon had a slightly shorter mean induction-to-delivery interval (15.59 ± 3.07 hours) compared to those who received a 60 mL balloon (16.49 ± 3.42 hours). However, this difference was not statistically significant ($F = 3.221$, $p = 0.075$).

6. DISCUSSION

The finding that multiparous women had nearly five-fold higher odds of successful vaginal delivery within 24 hours following Foley catheter ripening is consistent with the well-established understanding that parity is one of the strongest predictors of induction success (1,2). This difference is biologically rooted in the prior cervical dilation and vaginal delivery that multiparous women have experienced, resulting in greater cervical compliance and more efficient myometrial contractility (3). From a clinical standpoint, this finding has immediate practical implications: nulliparous women should be counseled differently, monitored more closely, and possibly considered for alternative or adjunctive ripening strategies earlier than their multiparous counterparts. The strength of this association (AOR = 4.65) is comparable to that reported by Demissew and Mesfin in Addis Ababa teaching hospitals, where nulliparity was similarly identified as a major risk factor for failed induction(4).

The negative association between duration of Foley catheter placement and successful vaginal delivery—each additional hour reduced odds of success by 37%—initially appears counterintuitive. One might expect longer mechanical ripening to produce greater cervical change and therefore higher success rates. However, this finding likely reflects reverse causality: women with more favorable baseline cervical status achieve spontaneous Foley expulsion earlier and progress rapidly to active labor, while those with unfavorable cervixes require prolonged ripening yet remain less likely to achieve vaginal delivery(5). The independent t-test supports this interpretation: women who succeeded had mean Foley duration of 5.83 hours compared to 7.10 hours among those who failed ($p < 0.001$). Clinically, this suggests that if a Foley catheter remains in place beyond approximately six to seven hours without spontaneous expulsion or achievement of active labor, the clinician should reassess cervical status and consider alternative strategies rather than simply prolonging the ripening period.

Baseline Bishop score was strongly associated with success in bivariate analysis (OR = 7.01, $p < 0.001$) but lost statistical significance in the multivariate model (AOR = 1.24, $p = 0.712$). This attenuation indicates that the effect of baseline cervical status on final outcome is mediated largely through parity and the duration of Foley ripening. Nonetheless, the independent t-test still showed significantly higher baseline Bishop scores among women

who achieved successful vaginal delivery (4.72 vs. 4.26, $p < 0.001$). Therefore, while baseline Bishop score is not an independent predictor after adjusting for confounders, it remains a clinically useful initial assessment tool. The negative correlation between baseline Bishop score and induction-to-delivery interval ($r = -0.301$, $p < 0.001$) further supports this, though the modest strength of the correlation indicates that other factors beyond cervical status also influence labor duration.

The proportion of women achieving successful vaginal delivery within 24 hours was 68.6% (95% CI: 61.1% – 75.5%). This figure aligns closely with Ethiopian studies: Temesgen and colleagues reported approximately 70% within 24 hours using Foley catheter in Gedeo zone public hospitals(6), Girma and colleagues found 72% successful induction with mechanical methods at Jimma University Hospital(7), and Dilnessa and colleagues documented comparable outcomes in Dessie(8). International literature similarly reports vaginal delivery rates ranging from 58% to 70% with Foley catheter use(5,9). The consistency across diverse settings suggests that the Foley catheter produces reliable outcomes regardless of geographic or resource context, reinforcing its value as a first-line mechanical method, particularly where continuous fetal monitoring for pharmacological agents may be limited(10).

The mean induction-to-delivery interval of 15.98 hours observed in this study is shorter than the 18 to 22 hours typically reported in the literature(9,11). Three factors likely explain this difference. First, the high proportion of multiparous women (66.9%) in this cohort shortened labor duration considerably. Second, oxytocin augmentation was used liberally (82.8% of cases), which accelerates labor once cervical ripening is achieved. Third, the predominant use of higher balloon volumes (80 mL in 56.2% of cases) may have contributed to more efficient cervical dilation, although the difference between 60 mL and 80 mL did not reach statistical significance ($p = 0.075$). This latter finding is consistent with Sandberg and colleagues, who demonstrated that a 60 mL balloon produced faster dilation than 30 mL but found no significant advantage of 80 mL over 60 mL(5).

The cesarean section rate of 31.4% merits careful interpretation. This is higher than the 25% rate reported by Demissew and Mesfin from four teaching hospitals in Addis Ababa(4). However, the difference likely reflects case mix rather than inferior effectiveness of the

Foley catheter. In this study, 44.4% of inductions were performed for oligohydramnios—an indication known to be associated with higher cesarean section rates due to non-reassuring fetal heart rate patterns and reduced fetal tolerance of labor contractions(1,2). When oligohydramnios is the indication for induction, the goal is often expedited delivery for fetal indication rather than avoidance of cesarean section per se. Therefore, the observed cesarean rate should be interpreted in the context of a high-risk population rather than as a measure of Foley catheter failure.

The mean increase in Bishop score of 4.60 points (from 4.57 to 9.17, $p < 0.001$) demonstrates that the Foley catheter is highly effective at achieving cervical ripening. This magnitude of change is comparable to that reported by Yesuf in Ethiopian settings(12) and by Sandberg and colleagues internationally(5). The post-ripening Bishop score of 9.17 indicates that, following Foley removal, most women had a favorable cervix (Bishop score ≥ 6), which likely contributed to the subsequent successful induction. The moderate positive correlation between baseline and post-ripening Bishop scores ($r = 0.551$, $p < 0.001$) suggests that while women with higher baseline scores tend to achieve higher post-ripening scores, the mechanical action of the Foley catheter produces meaningful cervical change across all baseline scores.

The logistic regression model demonstrated good fit (Hosmer-Lemeshow $p = 0.769$) and correctly classified 79.0% of outcomes. The Nagelkerke R^2 of 0.357 indicates that the model explains approximately 36% of the variance in successful vaginal delivery—acceptable for medical research where outcomes are influenced by many unmeasured factors including maternal body mass index, fetal position, provider experience, and psychosocial variables(13).

Several findings were notably not associated with successful vaginal delivery. Balloon volume (80 mL vs. 60 mL), traction application, and gestational age all failed to reach statistical significance. The lack of association for balloon volume is consistent with existing evidence that volumes beyond 60 mL confer no additional benefit(5). Traction applied in 92.9% of cases was so uniformly used that its independent effect could not be reliably

assessed. Gestational age showed no association, likely because the study was restricted to term and post-term pregnancies (≥ 37 weeks), limiting variability.

The implications for clinical practice at Wallaga University Comprehensive Specialized Hospital are clear. The transcervical Foley catheter is an effective first-line mechanical method for cervical ripening. Nulliparous women require different counseling and closer monitoring than multiparous women. Prolonged Foley duration beyond six to seven hours should prompt clinical reassessment rather than continued expectant management. Either 60 mL or 80 mL balloon volume is acceptable, though the trend toward shorter intervals with 80 mL (15.59 vs. 16.49 hours) may justify the larger volume in selected cases. Finally, the high proportion of inductions for oligohydramnios (44.4%) suggests that this indication deserves focused clinical attention and possibly separate outcome monitoring.

7. STRENGTHS AND LIMITATIONS OF THE STUDY

7.1. Strengths

This study has several strengths. First, it provides recent, institution-specific data on labor outcomes following transcervical Foley catheter use for cervical ripening in Western Ethiopia, where such evidence was previously lacking. Second, the study achieved its calculated sample size of 169 participants, which provided adequate statistical power for the primary outcome and for multivariate logistic regression analysis. Third, the use of a structured digital data collection form with validation rules enhanced data quality and minimized entry errors. Fourth, the study employed rigorous statistical methods, including bivariate and multivariate logistic regression with assessment of model fit using the Hosmer-Lemeshow test and pseudo R-square calculation. Fifth, the identification of independent predictors of successful vaginal delivery (multiparity and duration of Foley in place) provides clinically useful information that can guide patient counseling and management decisions. Sixth, the study's focus on a homogenous population of women with unfavorable cervix (Bishop Score of 6 or less) enhances internal validity.

7.2. Limitations

Several limitations should be considered when interpreting the findings of this study. First, the retrospective design introduces potential for information bias and incomplete documentation, as the study relied entirely on the accuracy and completeness of medical records. Variables such as precise times of Foley insertion and removal, Bishop score assessments, and indications for interventions may have been inconsistently recorded.

Second, the single-center setting at Wallaga University Comprehensive Specialized Hospital means that the findings may not be generalizable to other hospitals with different patient populations, clinical protocols, or resource availability. The success rate and cesarean section rate observed in this study may reflect local practices and patient characteristics that differ from other institutions.

Third, the absence of a comparison group limits the conclusions that can be drawn. Without a control group, this study cannot determine whether the Foley catheter produces better, worse, or equivalent outcomes compared to other ripening methods such as misoprostol. The study describes outcomes associated with Foley catheter use but does not establish causality or comparative effectiveness.

Fourth, the oxytocin augmentation variable could not be included in multivariate logistic regression due to convergence issues, likely resulting from the high proportion of women receiving oxytocin (82.8 percent). This limits the ability to assess the independent effect of oxytocin on successful vaginal delivery.

Fifth, unmeasured confounders such as maternal body mass index, fetal position, provider experience, and the use of adjunctive methods such as amniotomy may have influenced outcomes but could not be assessed in this retrospective study.

Sixth, the duration of Foley in place variable had two missing values ($n = 167$ for that analysis), which slightly reduced the sample size for models including this variable. Seventh, the study did not assess patient-reported outcomes such as pain, satisfaction, or discomfort associated with Foley catheter placement.

8. CONCLUSION AND RECOMMENDATIONS

8.1. Conclusion

The transcervical Foley catheter is an effective first-line mechanical method for cervical ripening at Wallaga University Comprehensive Specialized Hospital, achieving successful vaginal delivery within 24 hours in over two-thirds of women (68.6%). This success rate is comparable to national and international standards, confirming that the Foley catheter performs reliably even in a resource-limited, high-risk obstetric population.

However, success is not uniform across all women. Multiparity is the single strongest predictor of success: multiparous women have 4.65 times higher odds of vaginal delivery within 24 hours compared to nulliparous women. This means that nulliparous women require different management. They should be counseled realistically about their lower chance of success, monitored more closely during the ripening process, and considered for earlier alternative or adjunctive strategies if progress is slow.

A critical and clinically actionable finding is that prolonged Foley duration reduces success. Each additional hour the Foley remains in place decreases the odds of success by 37%. Women who succeeded had the Foley in place for an average of 5.8 hours, compared to 7.1 hours among those who failed. Therefore, beyond six to seven hours without spontaneous expulsion or active labor, clinicians should reassess rather than simply wait longer. Extended ripening is not benign—it signals a less favorable cervix and a lower likelihood of eventual vaginal delivery.

The Foley catheter effectively ripens the cervix, with a mean Bishop score increase of 4.60 points ($p < 0.001$), moving most women from an unfavorable to a favorable cervix. This physiological effect is robust, but it does not guarantee success—particularly in nulliparous women or when ripening is prolonged.

8.2. Recommendations

Based on the findings of this study, the following recommendations are made for clinical practice, institutional policy, and future research.

8.2.1. Recommendations for Clinical Practice

First, the transcervical Foley catheter should continue to be used as a first-line mechanical method for cervical ripening at Wallaga University Comprehensive Specialized Hospital, given its 68.6 percent success rate for vaginal delivery within 24 hours.

Second, clinicians should recognize that multiparous women have significantly higher odds of successful vaginal delivery. Nulliparous women require closer monitoring, realistic counseling, and a lower threshold for considering alternative ripening methods or earlier cesarean section.

Third, prolonged Foley duration beyond approximately six to seven hours may indicate a less favorable cervix and lower likelihood of success. Clinicians should reassess cervical status and consider adjunctive methods such as oxytocin augmentation or alternative ripening strategies when Foley duration is prolonged.

Fourth, either 60 mL or 80 mL balloon volumes are acceptable for cervical ripening, as no statistically significant difference in success rates was observed between the two volumes.

8.2.2. Recommendations for Institutional Policy

First, Wallaga University Comprehensive Specialized Hospital should develop and implement a standardized protocol for Foley catheter cervical ripening based on the findings of this study, including clear guidelines for patient selection, balloon volume, duration of placement, and criteria for proceeding to oxytocin augmentation or cesarean section.

Second, regular audits of induction outcomes should be conducted to monitor success rates, cesarean section rates, and identify areas for quality improvement. Feedback should be provided to clinical staff to promote continuous learning.

Third, documentation practices should be strengthened to ensure consistent recording of key variables such as precise Foley insertion and removal times, Bishop scores, and indications for cesarean section. This was facilitate future research and quality improvement initiatives.

8.2.3. Recommendations for Future Research

First, prospective comparative studies comparing the transcervical Foley catheter with vaginal misoprostol for cervical ripening at Wallaga University Comprehensive Specialized Hospital are recommended to determine the optimal method in this specific setting and future prospective studies, including randomized controlled trials and quasi-experimental designs, should be conducted to establish stronger causal evidence on the effectiveness of transcervical Foley catheter compared to other cervical ripening methods. Such clinical research designs are more conclusive than retrospective studies and can provide higher-quality evidence to guide clinical practice. Researchers planning these studies must be ensured that ethical clearance can be obtained from the Institutional Research Ethics Review Committee.

Second, cost-effectiveness analyses comparing different ripening methods would help inform resource allocation decisions in a resource-limited setting.

Third, multicenter studies involving other hospitals in the Oromia region would enhance the generalizability of findings and allow for larger sample sizes for subgroup analyses.

Fourth, qualitative studies exploring patient experiences, satisfaction, and preferences regarding Foley catheter ripening would provide valuable complementary insights to the quantitative findings of this study.

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ANNEXE

Data Collection Form

Study Title: Labor Outcomes of Transcervical Foley catheter for Cervical Ripening and Associated Factors at Wallaga University Comprehensive Specialized Hospital, Ethiopia

Principal Investigator: Dr. Nahom Tadesse Bayisa

Hospital: Wallaga University Comprehensive Specialized Hospital (WUCSH)

Date of Data Abstraction: _ / _ / 2026

A. Patient Demographics and baseline data

No.	Variable	Response
1	Patient ID	
2	Maternal age (years)	
3	Residence	1. Urban 2. Rural
4	Parity	
5	Gestational age (in weeks)	
6	Indication for Induction	1. Post-term pregnancy 2. Hypertensive disorders 3. Fetal growth restriction 4. Oligohydramnios 5. Bad obstetric history Other (specify): ____
7	Baseline bishop score	

B. Foley catheter Procedure

No.	Variable	Response
8	Balloon inflation volume (ml)	
9	Traction applied	1. Yes 2. No
10	Duration foley in place (hr.)	

11	Reason for removal	1. Spontaneous expulsion 2. Active labor achieved 3. 12-hour limit reached Other (specify): _____
12	Oxytocin augmentation	1. Yes 2. No

C. Bishop score change

No.	Variable	Response
13	Bishop score after Foley removal	
14	Change in bishop score (calculated)	

D. Labor and Delivery Outcomes

No.	Variable	Response
15	Induction to delivery interval (hr.)	
16	Mode of delivery:	1. Spontaneous vaginal 2. Assisted vaginal delivery 3. Cesarean section
17	Vaginal delivery within 24hr	1. Yes 2. No
18	If cesarean, indication	1. Failed induction 2. Non-reassuring FHR tracing 3. CPD Other: ____

E. Data completeness

No.	Item	Status
19	Medical record complete for all required variables?	1. Yes 2. No