KAIRUKI UNIVERSITY

SCHOOL OF MEDICINE

DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY

RESEARCH REPORT

EFFECTIVENESS OF DINOPROSTONE IN INDUCTION OF LABOUR COMPARED TO BALLOON CATHETER WITH OXYTOCIN AMONG PREGNANT WOMEN ATTENDING REGIONAL REFERRAL HOSPITALS IN DAR ES SALAAM TANZANIA

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A DISSERTATION SUBMISSITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR MASTER OF MEDICINE IN OBSTETRICS AND GYNAECOLOGY OF KAIRUKI UNIVERSITY.

2025

CERTIFICATION

It is hereby certified that the undersigned has read and hereby recommends acceptance by Kairuki University, a dissertation titled: "**EFFECTIVENESS OF DINOPROSTONE IN INDUCTION OF LABOUR COMPARED TO BALLOON CATHETER WITH OXYTOCIN AMONG PREGNANT WOMEN ATTENDING REGIONAL REFERRAL HOSPITALS IN DAR ES SALAAM TANZANIA"** in partial fulfillment of the requirements for the degree of Master of Medicine in Obstetrics and Gynaecology'.

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ACKNOWLEDGMENT AND DEDICATION

First and foremost, I wish to express my deepest gratitude to Dr. Monica Chiduo and Dr. Boniphace Silivester for their expertise, guidance, and unwavering support throughout the course of this research. Their mentorship, constructive feedback, and encouragement have been invaluable and have greatly enriched the quality of this work.

I am also sincerely grateful to Kairuki University for providing the academic environment and institutional support that made this study possible. My special appreciation goes to the dedicated staff at the Regional Referral Hospitals in Dar es Salaam for their cooperation and assistance during the data collection process.

I extend my heartfelt thanks to the study participants whose willingness to share their time and information made this research feasible and meaningful.

To my fellow third-year residents, thank you for your friendship, collaboration, and moral support. Your willingness to assist and encourage me along this journey has been a source of strength and motivation.

Finally, I extend my heartfelt appreciation to my family for their constant support, patience, and belief in me. Your encouragement has been my greatest driving force.

This acknowledgment also extends to all individuals and institutions who contributed in any way through advice, supervision, administrative or secretarial support to the successful completion of this study.

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LIST OF ABBREVIATIONS

APGAR	Appearance, Pulse, Grimace, Activity, Respiration
ANC	Antenatal Care
CS	Cesarean Section
DM	Diabetes Mellitus
IU	International Units
IUGR	Intrauterine Growth Restriction
KCMC	Kilimanjaro Christian Medical Centre
KU	Kairuki University
MPDSR	Maternal and Perinatal Death Surveillance and Response
NICU	Neonatal Intensive Care Unit
PI	Principal Investigator
PROM	Pre-Labour Rupture of Membranes
PPH	Postpartum Hemorrhage
RRH	Regional Referral Hospital
SDG	Sustainable Development Goals
STATA	Statistical Analysis Software
WHO	World Health Organization

OPERATIONAL DEFINITIONS

Balloon catheter: A balloon catheter is a medical device that is inserted into the cervix and then inflated to mechanically dilate through a gentle pressure, facilitating Labour induction in pregnant women.(1).

Dinoprostone: It refers to a synthetic prostaglandin E2 (PGE2) utilized to soften and prepare the cervix for Labour induction in pregnant women (2).

Induction of Labour: It refers to the medical or mechanical initiation of uterine contractions prior to the natural onset of Labour to facilitate vaginal delivery(3).

Outcome of induction of Labour: It refers to the quantifiable outcomes or impacts of Labour induction techniques, encompassing aspects such as the time to delivery, the mode of delivery, the health status of both the mother and newborn, and any complications that occur during Labour and delivery (4).

Oxytocin: It is described as a synthetic hormone given through an intravenous route to trigger uterine contractions and facilitate Labour induction in pregnant women. (5).

ABSTRACT

Background

Labour induction is an essential obstetric intervention when continuation of pregnancy poses risks to the mother or fetus. In Dar es Salaam, Tanzania, regional referral hospitals (RRHs) commonly use Dinoprostone and balloon catheter with oxytocin for induction. However, comparative evidence on their effectiveness and outcomes remains limited in this context.

Objective

To compare maternal and neonatal outcomes between Dinoprostone and balloon catheter with oxytocin among women undergoing labour induction at RRHs in Dar es Salaam, Tanzania.

Methodology

A hospital-based observational follow-up study was conducted from 1st April to 30th June 2025 among 288 pregnant women requiring induction at Amana, Mwananyamala, and Temeke RRHs. Participants were selected through simple random sampling stratified by hospital. Data on socio-demographic characteristics, obstetric history, induction method, and maternal and neonatal outcomes were collected using a structured questionnaire via the KOBO Toolbox platform. Data were analyzed with STATA 15 using descriptive, bivariate, and multivariate analyses; statistical significance was set at $p < 0.05$.

Results

Women induced with Dinoprostone had significantly higher odds of caesarean delivery compared to those who delivered vaginally (aOR = 2.41; 95% CI:

1.289–4.503). Induction with Dinoprostone was also strongly associated with shorter Labour duration; women with Labour lasting 11–14 hours (aOR = 0.248; 95% CI: 0.132–0.466) and 15–18 hours (aOR = 0.325; 95% CI: 0.136–0.782) had lower odds of having been induced with Dinoprostone compared to those with Labour lasting 6–10 hours. Maternal health status, APGAR scores at 1 and 5 minutes, and birth weight showed no significant association with the induction method.

Conclusion

Both induction methods were effective and resulted in comparable neonatal outcomes. However, Dinoprostone induced labour more rapidly but carried a greater risk of caesarean delivery than balloon catheter with oxytocin. These findings highlight the need to balance efficacy and surgical risk when selecting an induction method, particularly in resource-limited settings where access to emergency obstetric care may be constrained.

CHAPTER ONE

1.0 INTRODUCTION

1.1. Background

Labour induction is a critical intervention in obstetric practice, employed when continuing the pregnancy poses risks to the mother or fetus . labour induction can be elective, planned for risks like pre-labour rupture of membranes (PROM), diabetes mellitus (DM), or postdate pregnancy, abnormal fetal size above 4000gm, or emergency induction, done immediately for urgent conditions prolonged PROM, severe Intrauterine Growth Restriction (IUGR), intrauterine infection such as chorioamnionitis, post-term pregnancy (beyond 42 weeks), preeclampsia, or eclampsia (6). Induction methods include pharmacological approaches, using medications like Dinoprostone, mifepristone, misoprostol and oxytocin and mechanical methods like ballon catheter, amniotomy and membrane sweaping (7). In addition to pharmacological and mechanical methods, non-pharmacological approaches such as nipple stimulation and breast massage have also been used in some clinical settings. These methods stimulate endogenous oxytocin release to promote contractions, but they are not widely adopted due to inconsistent effectiveness and lack of strong clinical guidelines supporting their routine use (8)

Among the pharmacological methods used for induction, Dinoprostone, a synthetic analog of prostaglandin E2 (PGE2), is widely used for labour induction. It binds to receptors on uterine smooth muscle cells, initiating

cervical ripening and uterine contractions. This softens and thins the cervix, preparing it for dilation during childbirth, while promoting labour progression. Often, oxytocin is used alongside Dinoprostone to enhance uterine contractions, increasing their intensity and frequency (9)

In addition to the pharmacological options, the balloon catheter method is a mechanical approach to labour induction involving the insertion and inflation of a balloon within the cervix to promote dilation and softening. This pressure stimulates the release of prostaglandins, aiding cervical ripening and labour onset (10) The catheter remains until adequate dilation is achieved. Oxytocin may be administered intravenously to enhance contractions, working synergistically with the balloon catheter to ensure efficient Labour progress. This combined method aims to achieve vaginal delivery, protecting maternal and fetal health while reducing the risk of complications from cesarean sections.

However, the success of induction is influenced bny several maternal and clinical factors, including maternal age, parity, gestational age at induction, Body Mass Index, and cervical status (11) According to WHO, in developed countries, up to 20% of total deliveries at term now involve induction of labour. In Africa, labour induction rates remain lower, but methods like balloon catheters are more widely used in low-resource settings due to their cost-effectiveness and safety, with 4.4% of deliveries involve labour induction (12)

In Tanzania and more specifically In Dar es Salam, Oxytocin (48.5%) and the combination of Foley's catheter with Oxytocin (28.4%) are the main methods used for labour induction (13). Despite the usefulness of the three methods, there is limited comparative local data on outcomes of labour induction of these three methods. The results will guide clinical decisions, improve maternal and neonatal health, and help optimize obstetric care in Dar es Salaam.

To better contextualize the local trends, globally, the prevalence of labour induction varies, ranging from 6.8% to 33% across Europe, 24.5% in the United States, and up to 35.5% in Sri Lanka, reflecting a rising trend in industrialized countries where approximately one in four pregnant women undergoes induction of labour (14). In Tanzania, IOL is increasingly employed to manage high-risk pregnancies, with regional variations in both prevalence and clinical practice. At Kilimanjaro Christian Medical Centre (KCMC), a retrospective cohort study found a 21.6% prevalence of IOL among 53,338 deliveries from 2000–2015, with oxytocin and mechanical methods commonly used. IOL was associated with reduced rates of caesarean section and neonatal intensive care unit admissions, but also showed increased risks of uterine rupture and low Apgar scores . In Dar es Salaam, a prospective study across RRH revealed that oxytocin (48.5%) and the combination of Foley's catheter with oxytocin (28.4%) were the predominant methods. The study found that IOL significantly improved fetal outcomes, with 87% of newborns achieving Apgar scores ≥7, although failure of induction was the leading cause of caesarean sections (26.3%) . Despite the promising outcomes, both studies

emphasized the need for more localized, comparative evidence to guide optimal method selection and improve safety and effectiveness in different clinical settings (15,16).

1.2. Problem statement

Health complications arising from delayed or inappropriate labour induction continue to threaten maternal and neonatal health (17). In Tanzania, clinicians frequently use Dinoprostone and balloon catheter with oxytocin for labour induction (18). However, there is no local evidence comparing the effectiveness and safety of these methods in routine clinical practice, leading healthcare workers to rely on findings from developed countries, which may not reflect local contexts.

The problem is that a high rate of failed or prolonged labour induction has been reported, ranging between 19% and 25% (19,20)and contribute to maternal exhaustion, infections, rupture of membranes, postpartum hemorrhage, and increased likelihood of cesarean delivery, as well as adverse neonatal outcomes like birth asyphxia and fetal death (21). Factors contributing to these problems may include maternal characteristics (e.g., age, parity), cervical status, hospital practices, and induction protocols, yet these are not well documented in Tanzanian settings.

The knowledge gap lies in the lack of local comparative data on the maternal and neonatal outcomes of Dinoprostone versus balloon catheter with oxytocin.

Addressing this gap is essential to inform evidence-based decisions for induction method selection and optimize maternal and neonatal health. This study therefore aims to compare the outcomes of Dinoprostone and balloon catheter with oxytocin among women undergoing labour induction in regional referral hospitals in Dar es Salaam, Tanzania.

1.3. Rationale of the study

Generating evidence on maternal and neonatal outcomes of labour induction methods in Tanzania will enable healthcare providers to make informed, evidence-based decisions. This study has the potential to improve delivery care by identifying safer and more effective induction methods, thereby reducing complications and enhancing maternal and neonatal health. Key beneficiaries include pregnant women, maternity care providers, and policymakers involved in clinical guideline development. The findings can inform clinical protocols, training programs, and policy decisions, ultimately strengthening the quality and safety of childbirth care in Tanzanian healthcare settings.

1.4. Research questions

I. What are the maternal and neonatal outcomes following labour induction with Dinoprostone?

II. What are the maternal and neonatal outcomes following labour induction with balloon catheter with oxytocin?

III. How do these outcomes compare across the two induction methods?

1.5. Study objectives

Broad objective

To compare clinical outcomes of Dinoprostone versus balloon catheter with oxytocin for labour induction among pregnant women at RRH in Dar es Salaam, Tanzania.

Specific objectives

i. To determine maternal and neonatal outcomes following labour induction with Dinoprostone.
ii. To assess the maternal and neonatal outcomes following labour induction with balloon catheter with oxytocin.
iii. To compare the differences in outcomes between Dinoprostone and balloon catheter with oxytocin in labour induction.

Hypotheses

i. Null Hyppthesis (H_0): There is no significant difference in clinical outcomes between pregnant women induced with Dinoprostone and those induced with a balloon catheter followed by oxytocin at regional referral hospitals in Dar es Salaam.
ii. Alternative Hypothesis (H_1): There is a significant difference in clinical outcomes between pregnant women induced with Dinoprostone and those induced with a balloon catheter followed by oxytocin at regional referral hospitals in Dar es Salaam.

1.6. Conceptual frame work

The conceptual framework of this study illustrates the relationship between maternal characteristics, contextual factors, and the choice of induction method Dinoprostone or balloon catheter with oxytocin and how these influence the induction process and related health outcomes. Independent variables such as maternal age, parity, gestational age, and Bishop score, as well as confounding factors like obstetric complications and facility resources, may affect the intervention and subsequent outcomes. The framework outlines how these elements interact with the induction process, particularly in terms of time to delivery and labour monitoring, ultimately influencing both maternal outcomes (e.g., mode of delivery, uterine hyperstimulation, infection, PPH) and neonatal outcomes (e.g., Apgar score, Neonatal Intensive Care Unit (NICU) admission, birth weight).

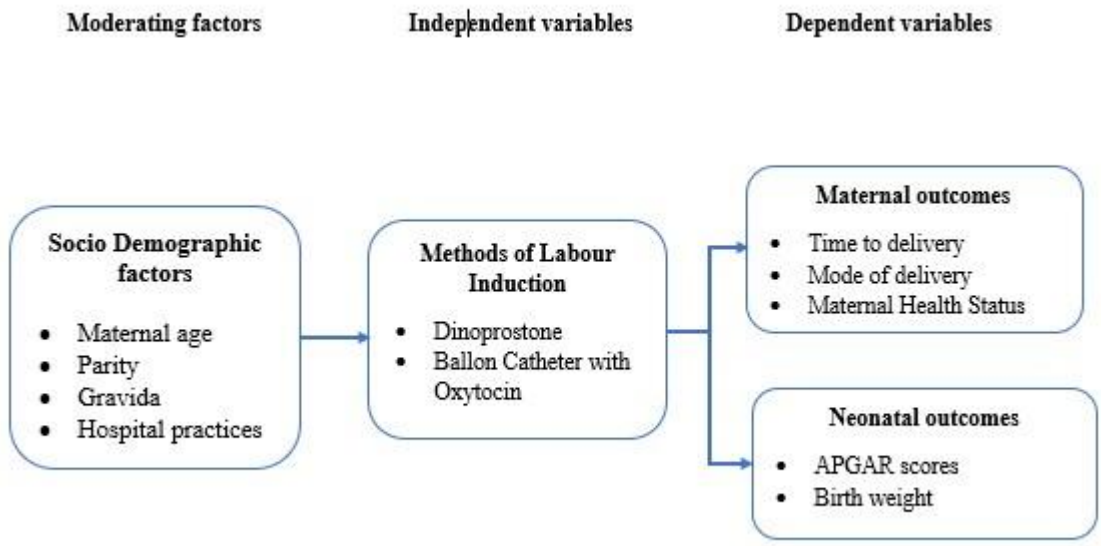

Figure 1:1: Conceptual framework illustrating the relationship between methods of induction and their outcomes.

Note: The conceptual framework used in this study is adapted from analytical approaches used in previous induction studies (e.g., L. Levine et al., 2016 (22) and Huiyan Ren et al., 2023 (23)), which model the relationship between induction method and delivery outcomes while accounting for maternal and obstetric factors as potential modifiers.

CHAPTER TWO

2.0 LITERATURE REVIEW

Labour induction involves medically stimulating uterine contractions to achieve vaginal birth, reducing risks from prolonged pregnancies, preeclampsia, fetal demise,pre labour rupture of membranes and intrauterine growth restrictions (24). Common methods include pharmacological approaches like prostaglandins (Dinoprostone) and oxytocin, and mechanical methods like balloon catheters (25). The choice of method depends on clinical indications and the health needs of the mother and fetus.

2.1. Outcomes of Labour induction using Dinoprostone among pregnant women

Labour induction using Dinoprostone has been extensively studied in both developed and developing countries, reflecting its widespread application in obstetric practice. In developed countries, the incidence of labour induction has risen significantly, with the UK reporting rates of approximately 34%, largely driven by medical indications such as post-term pregnancy and preeclampsia (26). Studies in these settings highlight Dinoprostone's efficacy in achieving successful labour induction, with the majority of women delivering vaginally. However, complications such as uterine hyperstimulation and fetal distress have been documented, leading to higher rates of cesarean sections in some cases, even in resource-rich healthcare systems.

In Ethiopia, labour induction reported to be 65% of the overall success rate, with preeclampsia/eclampsia accounting for 46.7% of inductions, followed by pre-labour rupture of fetal membranes at 33.5% (4). In Nigeria, the success rate of labour induction with Dinoprostone was reported to be 82.2% (27). From a study done in Kenya, it was reported that Mothers induced with Dinoprostone had a lower risk of death compared to those induced with other methods or experiencing uterine rupture, and the risk of dying during childbirth reported to increase when Maternal and Perinatal Death Surveillance and Response (MPDSR) activities were strengthened (28).

In Tanzania, specifically in Dar es Salaam, Labour induction using Dinoprostone has shown mixed outcomes. A local study reported that 61.7% of women undergoing induction with Dinoprostone achieved spontaneous vaginal delivery, while 38.3% required emergency cesarean sections. Failed Labour induction was the most frequently observed maternal complication, occurring in 14.2% of cases. Neonatal outcomes were generally favorable, with 99.2% of neonates achieving Apgar scores of 7 or higher at 5 minutes. However, 6.7% of neonates presented with meconium-stained amniotic fluid, and 8.3% required admission to the neonatal ward for further care (29).

While Dinoprostone remains a widely used Labour induction method, the literature reveals its limitations. Common complications include uterine hyperstimulation, fetal distress, and increased likelihood of cesarean delivery, alongside maternal side effects such as nausea, vomiting, and headache (27).

These findings suggest that although Dinoprostone is effective, its performance and safety profile can vary significantly across different contexts.

Although labour induction has been widely studied,particularly from developed countries, provide a strong evidence base for Dinoprostone's efficacy and safety. There is limited evidence from developing countries like Tanzania on maternal and neonatal outcomes across different induction methods. Context-specific factors such as healthcare infrastructure, patient characteristics, and clinical practices that may influence these outcomes are not well explored, highlighting the need for localized research.

2.2. Outcomes of Labour induction using balloon catheter with oxytocin among pregnant women

In Lusaka, Zambia, the balloon catheter was the second most common Labour induction method (83%). It was previously reported to be no statistically significant association between induction using an intracervical balloon catheter and uterine hyper-stimulation, precipitous Labour, antepartum or postpartum hemorrhage, and uterine rupture (30). In Makelele, Uganda, 13.3% of participants were ripened by a balloon catheter, while oxytocin infusion was used in 61.8%. Of the induced mothers, 70.5% delivered spontaneously, 5.5% required instrumental delivery, and 24% underwent Cesarean section due to Labour induction failure. The induction success rate was 76%, with a failure rate of 7.2% (26). In Dar es Salaam, Tanzania, previously reported common methods for Labour induction were Oxytocin

(48.5%) and a combination of Foley catheter with Oxytocin (28.4%). Induction with the balloon catheter and oxytocin has been associated with improved fetal outcomes, including enhanced Apgar scores. However, failure of Labour induction remains a primary factor contributing to higher cesarean section rates (13).

Low-dose oxytocin regimens are as effective and safe as high-dose regimens for Labour induction following cervical ripening with a balloon catheter. This suggests that low-dose oxytocin could be a viable option for Labour induction, potentially reducing the risk of hyperstimulation and other complications associated with higher doses.

Although Labour induction with a balloon catheter and oxytocin can be advantageous, it comes with risks. Uterine hyper-stimulation and excessive contractions may cause fetal distress, leading to cesarean sections. Mothers might experience side effects like nausea, vomiting, headaches, or fluid overload. There is a possibility of failed induction, requiring other methods or cesarean delivery, and an increased risk of infection from cervical manipulation. Prolonged induction can result in maternal exhaustion, a higher likelihood of surgical interventions, and psychological impacts such as anxiety and disappointment (31)

In conclusion, In Dar es Salaam, Tanzania, current practices regarding Labour induction utilizing Dinoprostone and balloon catheter with oxytocin present a multifaceted landscape with both notable successes and significant challenges

(32). While these pharmacological and mechanical methods are commonly employed to initiate Labour and facilitate childbirth, their effectiveness can be influenced by various factors including resource availability, healthcare infrastructure, and clinical protocols (33).

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Although Labour induction with a balloon catheter and oxytocin can be advantageous, it comes with risks. Uterine hyper-stimulation and excessive contractions may cause fetal distress, leading to cesarean sections. Mothers might experience side effects like nausea, vomiting, headaches, or fluid overload. There is a possibility of failed induction, requiring other methods or cesarean delivery, and an increased risk of infection from cervical manipulation. Prolonged induction can result in maternal exhaustion, a higher likelihood of surgical interventions, and psychological impacts such as anxiety and disappointment. In Dar es Salaam, Tanzania, current practices regarding Labour induction utilizing Dinoprostone and balloon catheter with oxytocin present a multifaceted landscape with both notable successes and significant challenges. While these pharmacological and mechanical methods are commonly employed to initiate Labour and facilitate childbirth, their effectiveness can be influenced by various factors including resource availability, healthcare infrastructure, and clinical protocols (9,34)

Evidence suggests that low-dose oxytocin regimens are as effective and safe as high-dose regimens when used after cervical ripening with a balloon

catheter. However, such findings require local validation, given the contextual differences in monitoring capacity and clinical oversight in Tanzanian referral hospitals.

There is insufficient research comparing outcomes across different induction methods in local settings, and the safety and effectiveness of low-dose versus high-dose oxytocin regimens remain underexplored. Context-specific factors such as healthcare infrastructure, clinical protocols, and patient characteristics that may influence maternal and neonatal outcomes have not been fully investigated, highlighting the need for localized, evidence-based studies.

2.3. The comparative outcomes of Labour induction of Dinoprostone and balloon catheter with oxytocin pregnant women

Several studies have compared the efficacy and safety of dinoprostone and balloon catheter with oxytocin. A a meta-analysis of randomized controlled trials done in China found no significant difference in the rates of vaginal delivery and cesarean section between the two methods (35).

Another study from France found that the double balloon catheter combined with oxytocin did not significantly reduce the need for oxytocin in Labour induction compared to dinoprostone. Both methods were similarly effective in terms of maternal and neonatal outcomes (36). Contrary, a study done in China revieled that Dinoprostone was associated with a lower need for

oxytocin compared to the double balloon catheter (DBC), with rates of oxytocin being significantly higher in the DBC group (77.9% vs 19.6%, $p < 0.001$) (37).

Additionally, the dinoprostone was associated with a higher need for oxytocin augmentation and a higher incidence of uterine hyperstimulation. Dinoprostone has shown a higher rate of vaginal deliveries (89.9%) compared to the balloon catheter (62.7%). This mean delivery time for Dinoprostone was shorter to 11.08 hours while the balloon catheter recorded to 13.6 hours. In some extent Dinoprostone reduced the need for additional oxytocin during Labour induction (37,38)

Only one study done in Dar es salaam shows that induction with Dinoprostone was associated with improved Apgar scores, suggesting better neonatal outcomes (13) . There is a lack of localized, comparative research assessing both methods' effectiveness and safety in Tanzanian settings, taking into account context-specific factors such as healthcare infrastructure, clinical protocols, and patient characteristics.

CHAPTER THREE

3.0 METHODOLOGY

3.1. Study design

This was an observational prospective study conducted from 1st April to 30th June 2025.. A follow-up study design was employed to directly observe and compare the outcomes of Labour induction methods using Dinoprostone and balloon catheter with oxytocin in real time. This design allowed for the collection of current, relevant data on maternal and fetal health outcomes, enabling a clear comparison of efficacy and safety between the two methods.

3.2. Study setting

This study was conducted at three Regional Referral Hospitals (RRH) in Dar es Salaam, Tanzania — Amana, Mwananyamala, and Temeke. Temeke Regional Referral Hospital had 78 beds dedicated to maternity and antenatal care (ANC) and averaged about 10,400 births per year, of which 3,815 were by cesarean section and 5,360 by vaginal delivery. Amana Regional Referral Hospital had a total bed capacity of 600, with 72 beds allocated to maternity and ANC services, and recorded an average of 7,622 births per year, of which 3,192 were by cesarean section and 4,430 by vaginal delivery. Mwananyamala Regional Referral Hospital also had 72 maternity and ANC beds and handled approximately 10,425 births per year, including 4,015 cesarean sections and 6,240 vaginal deliveries.

Between January and March 2024, Temeke, Amana, and Mwananyamala RRHs recorded averages of 2,600, 1,906, and 2,606 births per quarter, respectively, with induction of Labour accounting for 2.9%, 2.4%, and 3% of these births. The data on hospital capacities and delivery volumes were obtained from official Ministry of Health reports and verified through the Medical Records Departments of each hospital. These hospitals, with their large capacities and high birth rates, provided an ideal setting for comparing the outcomes of Labour induction methods among pregnant women.

3.3. Study population

This study included pregnant women attending Temeke, Amana, and Mwananyamala Regional Referral Hospitals in Dar es Salaam who underwent Labour induction.

3.4 Sample Size

The study sample size has been estimated using the Kish Leslie Formula;

$$n = \frac{Z^2 p[1-p]}{\varepsilon^2}$$

Where:

- n: Minimum estimated sample size.
- Z: Standard normal deviation (Z = 1.96 for a 95% confidence interval).
- p: Expected proportion or prevalence (e.g., prevalence of factors and outcomes related to Labour induction at a tertiary hospital in Northern

Tanzania). Based on the study by Tarimo et al., 2020, this was set to 21.63% (p = 0.2163).

- ε: Margin of error (precision), set at 5% (\varepsilon = 0.05).

Substituting the values into the formula:

$n = \frac{1.96^2 * 0.2163[1-0.2163]}{0.05^2}$ = 260 Participants

The minimum sample size for a 95% confidence level was 260 participants. Therefore, the estimated sample size was divided by the number of study population to ensure adequate representation from each hospital. Adding 10% to account for non-responses, the expected minimum sample size was 286 participants. The total sample size of 288 was divided among the three hospitals , resulting in 106 participants each from Temeke and Mwananyamala hospitals, and 76 participants from Amana hospital. This approach ensured that the sample from each hospital reflected its relative contribution to the total number of births.

3.5 Sampling procedure

The total sample size was allocated proportionally to each hospital based on their average quarterly number of deliveries, using recent delivery records obtained from the Medical Records Departments.

The three study sites—Temeke, Amana, and Mwananyamala Regional Referral Hospitals in Dar es Salaam were purposively selected because they are high-

volume facilities that frequently perform labour inductions, making them suitable for studying the methods of interest (Dinoprostone and balloon catheter with oxytocin).

Within each hospital, eligible participants were identified from the daily admission logs of women scheduled for labour induction. A complete list of eligible women was prepared, and participants were then randomly selected from this list to ensure that each had an equal chance of inclusion, minimizing selection bias. Recruitment continued until the required sample size for each hospital was achieved, according to the predefined inclusion and exclusion criteria.

3.5.1 Inclusion criteria

All women who were planned for induction at Temeke, Amana, and Mwananyamala Regional Referral Hospitals were included in the study after providing written informed consent. Participants with conditions such as non-urgent unfavorable cervical status, preeclampsia with severe features, eclampsia, uncontrolled diabetes, intrauterine fetal death (IUFD), intrauterine growth restriction (IUGR), post-term pregnancy (41–42 weeks), or oligohydramnios were included in the study.

3.5.2 Exclusion criteria

Participants were excluded from the study if they had ruptured membranes prior to induction, declined to provide informed consent, developed

complications such as non-reassuring fetal status before the induction process, placenta calcification, or fetal macrosomia.

3.6 Data collection tools

A pre-designed questionnaire was used to collect data. The questionnaire was meticulously designed to gather comprehensive information on each participant, including sections for demographic details, medical and obstetric history, induction method used, and labour progression. Additionally, it captured maternal and fetal outcomes, any complications, and interventions required. This standardized format ensured consistent and thorough data collection across all study sites, facilitating accurate comparison of outcomes between Dinoprostone and Balloon Catheter with Oxytocin.

The questionnaire was developed based on structured clinical data collection tools used in recent obstetric studies assessing induction methods and delivery outcomes (e.g., Xiaohua Liu et al., (23)). Variables were aligned with standard labour monitoring practices, including Bishop score, maternal vital signs, mode of delivery, and neonatal Apgar scores.

3.7 Data collection procedures

Data collection methods included clinical examinations conducted by qualified healthcare professionals to assess maternal and fetal health. Structured interviews were employed to gather socio-demographic information and patient history, providing a formalized method of data collection used in

quantitative research. This involved the researcher asking a standardized set of pre-written questions to every participant in exactly the same way, ensuring uniformity, reliability, and objective comparison of responses.

Data collection was conducted by six trained research assistants with relevant qualifications in health sciences. The team comprised three registered general practitioners (one assigned to each hospital) responsible for inducing labor, and three nurse-midwives (one assigned to each hospital) who monitored the progress of labor. Their roles included conducting interviews, recording data, and ensuring accuracy throughout the data collection process. These research assistants were supervised by the Principal Investigator (PI) to maintain high-quality data collection. The PI ensured that the research assistants received comprehensive training covering questionnaire administration, data collection procedures, the administration of Dinoprostone and balloon catheter with oxytocin, and.

After obtaining informed consent, data on each participant's socio-demographics, indications for induction, and maternal and fetal outcomes were recorded using the pre-designed questionnaire.

3.7.1 Procedure and criteria

This section outlined the procedures, steps, and criteria for the use of Dinoprostone, Balloon Catheter and Oxytocin in clinical practice.

Procedure 1: Dinoprostone administration

Criteria for use:

- Recommended for patients with a low Bishop score indicating an unripe cervix.
- Not suitable for patients with contraindications to prostaglandins, such as asthma or hypersensitivity.

Steps and details for Dinoprostone administration

Steps	Details
1. Preparation	Retrieve the Dinoprostone 3mg tab from the freezer immediately before use. Thawing is not required.
2. Patient positioning	Position the patient in the dorsal lithotomy position or the standing position with one foot elevated on a stool.
3. Insertion and administration	Perform hand hygiene, wear sterile gloves and aseptically Insert dinoprostone tab intravaginally, directing it toward the posterior fornix while ensuring to avoid the cervical canal.
4. Post-administration	Advise the patient to remain in the supine position for at least 30 minutes post-insertion to ensure proper absorption.
5. Monitoring	Check fetal heart rate every 30 minutes and reassess after 6–8 hours.
6. Follow-up	Patient will be monitored for fetal heart rate every 30min and abdominal pelvic assement after 6-8hrs post insertion, if no progress 2nd dose of dinoprostone 3mg is

	introduced and monitoring continues for the next 24hrs, if no progress at all a patient will be subjected to emergency caesarian delivery as failure of induction.

Procedure 2: How to put balloon catheter

Criteria for use:

- Can be used for patients with variable Bishop scores but is particularly effective for moderately favorable cervices.
- Recommended for patients with contraindications to prostaglandins, such as asthma or grand multiparity.

Steps and details for Balloon Catheter use

Steps	Details
1. Preparation	• Wash your hands thoroughly and wear sterile gloves. • Prepare the balloon catheter kit, ensuring all necessary supplies are available. • Explain the procedure to the patient and obtain informed consent.
2. Positioning	• Have the patient lie on their back with knees bent and feet supported by stirrups (dorsal lithotomy position).
3. Insertion	• Use a speculum to visualize the cervix. • Gently insert the balloon catheter through the cervical canal into the uterine cavity. • Ensure the balloon is positioned correctly within the uterine cavity.
4. Inflation	• Inflate the balloon with sterile water using a syringe. The amount of water to be used will depend on the specific catheter's instructions (usually around 30-60 mL).
5. Securing	• Once the balloon is inflated, gently pull back on the catheter to ensure the balloon is snug against the internal os of the cervix. • Secure the catheter to the patient's thigh or abdomen to prevent displacement.
6. Monitoring	• Monitor the patient for signs of labour progression and any potential complications. • Regularly check the balloon catheter to ensure it remains in place and the balloon is properly inflated.

7. Removal/Fall out	• When labour is established or if there are any signs of complications, deflate the balloon and carefully remove the catheter. • If Fall out; then do per vaginal examination obtain cervical dilation and possibility of augmentation with oxytocin drug intravenously.

Procedure 3: Adjusting the Oxytocin dosage

Criteria for use:

• Suitable for patients who consent to pharmacological augmentation of labour.

• Requires prior cervical assessment and monitoring to ensure safe administration.

Steps and details for Oxytocin administration

Steps	Details
1. Starting dose	Primigravida A: oxytocin (IV) 5IU in 500mls of 0.9% sodium chloride the initial dose should be 8-10drops/Minute, the titration may be gradually increased at intervals not shorter than 20 minutes. Multiparous B: oxytocin (IV) start with low dose e.g., 2.5IU in 500mls of fluid titrate as above. Regulate the dose according to response.
2. Incremental	If there are no significant contractions after 20-30 minutes, the infusion rate can be increased not more than 5drops/minute, until a contraction pattern similar to that of normal Labour is established.
3. Monitoring	Continuously monitor the maternal and fetal heart rates, contractions, and overall progress of Labour.
4. Ceiling dose	The recommended maximum rate is 40mU/min used in infusion rates to avoid overstimulation and potential complications.
5. Adjustments	If contractions become too frequent or intense, the infusion rate should be decreased or temporarily stopped.
6. Ongoing assessment	Regularly assess the progress of Labour and adjust the dosage accordingly. Close communication with the healthcare team is essential.

3.8 Data management and analysis

Data were cleaned and prepared prior to analysis to ensure accuracy and consistency. This process involved identifying and removing duplicate entries, addressing out-of-range values, and managing missing data. Non-critical missing data were excluded, while critical missing data were handled through imputation where feasible to minimize bias. Microsoft Excel was used for data cleaning, and all cleaned data were exported to STATA version 15 for analysis.

Descriptive statistics were used to summarize the study variables. Continuous variables, such as maternal age and time to delivery, were presented as means with standard deviations if the data were normally distributed. If normality was not satisfied, medians with interquartile ranges were reported instead. Categorical variables, including induction methods and mode of delivery, were summarized as frequencies and percentages to facilitate clear comparisons between the groups.

Comparative analyses were conducted to assess differences in outcomes between the two Labour induction methods, Dinoprostone and the balloon catheter with oxytocin. For categorical outcomes, such as the success of Labour induction or mode of delivery, chi-square tests were used to determine associations. For continuous outcomes, such as time to delivery, independent t-tests were applied if the data were normally distributed. In cases where continuous variables were not normally distributed, the Mann-Whitney U test was employed to assess differences between the groups.

To further explore variations in outcomes, subgroup analyses were performed based on gestational age, such as term versus post-term pregnancies, and parity, including primiparous and multiparous women. These analyses provided additional insights into how patient characteristics might influence the effectiveness and safety of each induction method.

The results were presented using a combination of tables and visual aids to enhance interpretability. Bar charts illustrated the distribution of categorical outcomes, while box plots were used to display differences in continuous outcomes, such as time to delivery, between the two groups. Statistical significance was set at a p-value of <0.05 for all analyses to ensure that the findings were robust and meaningful.

3.9 Study variables

3.9.1 Independent variables

- Maternal age
- Parity
- Gestational age
- Bishop's score
- Method of induction
- Gravidity

3.9.2 Dependent variables

- Induction-to-delivery time
- Mode of delivery
- Maternal complications (e.g., uterine hyperstimulation, fever, PPH)
- Neonatal outcomes (Apgar score, birth weight, NICU admission)

3.10 Ethical consideration

This study was conducted in adherence to ethical principles to ensure the safety and well-being of participants. All procedures involved in the study were part of routine clinical practice, including Labour induction methods, clinical examinations, and medical record reviews. No experimental procedures were introduced, and no interventions deviated from established clinical guidelines, thereby minimizing risks to participants.

Potential adverse effects that could arise during Labour induction included uterine hyperstimulation, fetal distress, maternal discomfort, and infections. To prevent and manage these risks:

- Uterine Hyperstimulation: Participants were closely monitored during Labour induction, and any signs of hyperstimulation were promptly addressed by adjusting or discontinuing the induction agent in accordance with clinical guidelines.
- Fetal Distress: Continuous fetal monitoring was employed to detect early signs of distress, with appropriate interventions, including cesarean delivery, undertaken when necessary.
- Maternal Discomfort: Participants received proper counseling and pain management to ensure their comfort throughout the induction process.
- Infections: Strict adherence to sterile techniques and infection control protocols was maintained during all procedures to minimize the risk of infections.

- Maternal Privacy: Privacy in the Labour ward and delivery room was safeguarded using curtains and screens to create private spaces for each birthing woman, ensuring respectful and dignified care.

Ethical review and approval were obtained from the Kairuki University Ethics and Review Committee IREC-KU. In addition, permission to conduct the study was granted by Hospital Medical Officers in charge and Head of department at the study sites. Only participants who provided informed consent were included.

Confidentiality was rigorously upheld, with no names or identifiable clinical information disclosed outside the research team. Research codes were used instead of participant names. All procedures complied with relevant ethical guidelines and regulations, ensuring respect for participants' rights and dignity. Any clinical observations made during the study were shared with the attending healthcare providers to support patient management.

CHAPTER FOUR

4.0 Results

4.1 Socio-demographic characteristics of study participants

Table 1:Socio demographics characteristics of study participants (n=288)

VARIABLE	CATEGORY	Frequency (n), (%)
Hospital	Amana RRH	76 (26.4)
	Mwananyamala RRH	106 (36.8)
	Temeke RRH	106 (36.8)
Age group	15-19 years	36 (12.5)
	20-24 years	50 (17.4)
	25-35 years	155 (53.8)
	35-45 years	47 (16.3)
Gravida	Primigravida	96 (33.3)
	Multigravida	155 (53.8)
	Grand multigravida	37 (12.9)
Para	Nulliparous	100 (34.7)
	Multiparous	166 (57.6)
	Grand multiparous	22 (7.7)

A total of 288 pregnant women were included in this study. The participants ages ranged from 16 to 45 years, with a mean age of 27.8 years (SD = 6.4).

Mwananyamala and Temeke referral hospitals each contributed over one-third of participants (36.8%), while Amana RRH accounted for 26.4%. The majority of participants were aged 25–35 years (53.8%). Most women were multigravida (53.8%) and multiparous (57.6%). Table 1 details the socio-demographic characteristics of the study participants included in the study.

4.2 Maternal and neonatal outcomes following Labour induction with Dinoprostone.

Table 2: Maternal Outcomes Following LaborLabour Induction with Dinoprostone (n = 144)

Variable	Category	Frequency (n), (%)
Mode of Delivery	Vaginal	99 (68.8)
	C/S	45 (31.2)
Time to delivery	6-10 Hours	56 (38.9)
	11-14 Hours	67 (46.5)
	15-18 Hours	21 (14.6)
Maternal Health status	Stable	141 (97.9)
	At Risk	3 (2.1)

The majority of women (68.8%) delivered vaginally, while 31.2% required Caesarean section following Labour induction. The duration from induction to

delivery varied, with 38.9% of women delivering within 6–10 hours, 46.5% within 11–14 hours.

Assessment of maternal health status at the time of delivery indicated that 97.9% of the women remained clinically stable. Table 2 describe the maternal outcomes following Labour induction with Dinoprostone.

Table 3: Neonatal outcomes following LaborLabour Induction with Dinoprostone (n = 144)

Variable	Category	Frequency (n), (%)
APGAR 1 min Score	0-3 min	6 (4.2)
	4-6 min	16 (11.1)
	7-10 min	122 (84.7)
APGAR 5 min Score	0-3 min	6 (4.2)
	4-6 min	2 (1.4)
	7-10 min	136 (94.4)
Birth weight	<2.5 Kg	17 (11.8)
	2.5-4.0 kg	127 (88.2)
	>4.0kg	0 (0.0)

Neonatal outcomes indicated that 84.7% of newborns had an APGAR score of 7–10 at 1 minute. At 5 minutes, 94.4% of newborns recorded an APGAR score of 7–10

In terms of birth weight, the majority (88.2%) weighed between 2.5–4.0 kg, Table 3 describe the neonatal outcomes following Labour induction with Dinoprostone.

4.3 Maternal and neonatal outcomes following Labour induction with balloon catheter with oxytocin.

Table 4: Maternal Outcomes following LaborLabour Induction with balloon catheter with oxytocin (n = 144)

Variable	Category	Frequency (n), (%)
Mode of Delivery	Vaginal	121 (84.0)
	C/S	23 (16.0)
Time to delivery	6-10 Hours	28 (19.4)
	11-14 Hours	97 (67.4)
	15-18 Hours	19 (13.2)
Maternal Health status	Stable	143 (99.3)
	At Risk	1 (0.7)

The majority of mothers, about 84%, delivered vaginally,. In terms of Labour duration, approximately 67.4% of deliveries occurred within 11 to 14 hours. Regarding maternal health status at delivery, nearly all mothers (99.3%) Table 4 describes maternal outcomes following Labour induction with balloon catheter combined with oxytocin.

Table 5: Neonatal outcomes following LaborLabour Induction with balloon catheter with oxytocin (n = 144)

Variable	Category	Frequency (n), (%)
APGAR 1 min Score	0-3 min	4 (2.8)
	4-6 min	7 (4.9)
	7-10 min	133 (92.3)
APGAR 5 min Score	0-3 min	4 (2.8)
	4-6 min	0 (0)
	7-10 min	140 (97.2)
Birth weight	<2.5 Kg	20 (13.9)
	2.5-4.0 kg	123 (85.4)
	>4.0kg	1 (0.7)

At 1 minute after birth, the majority of newborns had APGAR scores between 7-10 minutes, accounting for 92.3%. At 5 minutes after birth, 97.2% of newborns scored between 7-10 minutes,.

Regarding birth weight, 85.4% of newborns weighed between 2.5 and 4.0 kilograms. Table 5 describes maternal outcomes following Labour induction with balloon catheter combined with oxytocin.

4.4 Differences in Outcomes Between Dinoprostone and Balloon Catheter with Oxytocin in Labour Induction

Table 6: Differences in Outcomes Between Dinoprostone and Balloon Catheter with Oxytocin in Labour Induction

Variable	Category	Method of induction		P -Value
		Balloon catheter with oxytocin	Dinoprostone	
Mode of delivery	Vaginal	121 (55.0)	99 (45.0)	**0.002**
	C/S	23 (33.82)	45 (66.2)	
Time to delivery	6-10 hours	28 (33.3)	56 (66.7)	**0.001**
	11-14 hours	97 (59.1)	67 (40.9)	
	15-18 hours	19 (47.5)	21 (52.5)	
Maternal Health status	Stable	143 (50.4)	141 (49.6)	0.314*
	At Risk	1 (25.0)	3 (75)	
APGAR 1 min Score	0-3 min	4 (40.0)	6(60.0)	
	4-6 min	7 (30.4)	16 (69.6)	
	7-10 min	133 (52.2)	122 (47.8)	
	0-3 min	4 (40.0)	6 (60.0)	0.321*

APGAR 5 min Score	4-6 min	0 (0.0)	2 (100.0)	
	7-10 min	140 (50.7)	136 (49.3)	
Birth weight	<2.5 Kg	20 (54.1)	17 (45.9)	0.602*
	2.5-4.0 kg	123 (49.2)	127 (50.8)	
	>4.0kg	1 (100.0)	0 (0.0)	

*Note: * Chi-square test; ** Fisher's Exact Test.*

Vaginal delivery was more frequent in the group induced with balloon catheter plus oxytocin, accounting for 55%, compared to 45% in the dinoprostone group, and this difference was statistically significant (p = 0.002). Conversely, cesarean sections were more common in the dinoprostone group (66.2%) than in the balloon catheter group (33.82%).

Regarding time to delivery, a higher proportion of deliveries occurred within 6 to 10 hours in the dinoprostone group (66.7%) compared to the balloon catheter group (33.3%), with this difference also reaching statistical significance (p = 0.001).

Most mothers in both groups were stable, with approximately half in each group experiencing stable maternal health status, and no statistically significant difference was found (p = 0.314).

The distribution of APGAR scores at one minute, categorized as low (0–3), moderate (4–6), and good (7–10), was similar between the two groups, with no significant difference reported. Similarly, APGAR scores at five minutes showed no significant difference between the groups (p = 0.321).

Lastly, the distribution of birth weights less than 2.5 kg, between 2.5 and 4.0 kg, and greater than 4.0 kg was comparable across both groups, with no statistically significant difference observed (p = 0.602). Table 6 describes the differences in outcomes between dinoprostone and balloon catheter with oxytocin in Labour induction.

4.5 Bivariate and Multivariable Analysis of Labour Induction Methods

Table 7: Factors Associated with Method of LaborLabour Induction (Dinoprostone vs. Balloon Catheter with Oxytocin)

Variable	Category	Bi-variable analysis			Multivariable analysis		
		cOR	95% CI	P-value	AOR	95% CI	P-Value
Mode of delivery	Vaginal	Ref			Ref		
	C/S	2.391	1.354 - 4.221	0.003	2.409	1.289 - 4.503	0.006*
Time to delivery	6-10 hours	Ref			Ref		
	11-14 hours	0.345	0.199 - 0.599	0.000	0.248	0.132 - 0.466	0.000*
	15-18 hours	0.553	0.256 - 1.192	0.130	0.325	0.136 - 0.782	0.012*

Maternal Health status	Stable	Ref			Ref		
	At Risk	3.042	0.313 - 29.601	0.338	1.231	0.099 - 15.175	0.871
APGAR 1 min Score	0-3 min	Ref			Ref		
	4-6 min	1.524	0.325 - 7.149	0.593	0.855	0.131 – 5.564	0.870
	7-10 min	.612	0.169 - 2.218	0.455	0.290	0.054 – 1.555	0.149
APGAR 5 min Score	0-3 min	Ref			Ref		
	4-6 min	1			1		
	7-10 min	0.647	0.178 - 2.346	0.508	1		
Birth weight	<2.5 Kg	Ref			Ref		
	2.5-4.0 kg	1.215	0.608 - 2.428	0.582	1.693	0.697 – 4.113	0.245
	>4.0kg	1			1		

*Note: cOR= crude Odd ratio, AOR =adjusted Odds ratio, * significant p - value <0.05*

The associations between several maternal and neonatal factors and the method of Labour induction were examined using both bivariate and multivariable logistic regression analyses as described in Table 7.

In bivariate analysis, women who were induced with Dinoprostone had higher odds of deliver by cesarean section and was significantly compared to vaginal delivery (cOR = 2.391; 95% CI: 1.354–4.221). This association remained statistically significant in multivariate analysis (aOR = 2.41; 95% CI: 1.289–4.503), indicating that women who had caesarean delivery 2.409 times higher odds to have been induced with Dinoprostone than those who delivered vaginally.

Compared to Labour lasting 6–10 hours, those with Labour lasting 11–14 hours had significantly lower odds of induction by Dinoprostone in both bivariate (cOR = 0.345; 95% CI: 0.199–0.599) and multivariable analysis (aOR = 0.248; 95% CI: 0.132–0.466). Similarly, Labour lasting 15–18 hours was associated with reduced odds of Dinoprostone induction, although this was not statistically significant at the bivariate level (cOR = 0.553, 95% CI: 0.256–1.192, p = 0.130), it became significant after adjustment (aOR = 0.325, 95% CI: 0.136–0.782). These findings suggest that induction with Dinoprostone is more common among women with shorter Labour duration.

Mothers categorized as "At Risk" had higher crude odds of Dinoprostone induction compared to stable mothers (cOR = 3.042, 95% CI: 0.313–29.601), but this association was not statistically significant (p = 0.338). After adjusting

for other variables, the association was further attenuated and remained non-significant (aOR = 1.231, 95% CI: 0.099–15.175). This indicates no clear evidence that maternal health status influenced the choice of induction method in this study.

Neither moderate (4–6min) nor good (7–10min) APGAR scores at 1 minute were significantly associated with induction method in both bivariate and multivariable analyses. The adjusted odds ratios showed no significant difference between categories when compared to low APGAR scores (0–3 minutes). This suggests that early neonatal condition as measured by APGAR at 1 minute was not influenced by the induction method.

APGAR scores at 5 minutes similarly showed no significant association with the induction method. Both crude and adjusted analyses failed to demonstrate meaningful differences between score categories.

There was no significant association between birth weight categories and induction method. Although the odds ratio for normal birth weight (2.5–4.0 kg) compared to low birth weight (<2.5 kg) was slightly higher in the adjusted model (aOR = 1.693), this did not reach statistical significance (p = 0.245). Thus, birth weight did not appear to affect the likelihood of induction with Dinoprostone versus balloon catheter.

CHAPTER FIVE

5.0 Introduction

This study assessed maternal and neonatal outcomes following Labour induction with Dinoprostone and balloon catheter with oxytocin, as well as factors associated with the choice of induction method. The findings revealed that mode of delivery and time to delivery were significantly associated with the method of induction, while maternal health status, APGAR scores, and birth weight showed no significant associations.

5.1 Discussion

The study found that women who underwent caesarean section had significantly higher odds of having been induced with Dinoprostone compared to those who delivered vaginally. This is consistent with previous research from sub-Saharan Africa conducted by Pandya et al., 2024, Babich et al., 2024, , Debele et al., 2021, where Dinoprostone use has been linked with higher caesarean rates, often attributed to hyperstimulation and failed induction (39–41).

Studies conducted by Beshir et al., 2021 in Ethiopia reported that Dinoprostone was associated with an increased likelihood of caesarean delivery, mainly due to non-reassuring fetal heart rates and failed progress of Labour (17). Similarly, Tanzanian studies conducted by Erasto et al., 2025, Kagwisage et al., 2020, on Labour induction outcomes have raised concerns about the higher

caesarean rates among women induced with prostaglandins compared to mechanical methods (34,42) .

This study implies the critical need for healthcare providers to adopt an individualized, evidence-based approach when selecting labour induction methods. Careful selection of induction agents can reduce the likelihood of cesarean delivery and enhance maternal safety, particularly in low-resource settings where surgical capacity is limited and the risks associated with cesarean sections are higher. The findings emphasize the importance of clinical judgment, adherence to updated guidelines, and consideration of patient-specific factors in ensuring safe and effective labour management.

Regarding time to delivery, this study observed that shorter Labour duration (6–10 hours) was significantly associated with the use of Dinoprostone, whereas longer Labour durations were more common with balloon catheter use.

This aligns with other African studies conducted suggesting that Dinoprostone leads to faster cervical ripening and shorter induction-to-delivery intervals . However, the higher rate of caesarean delivery linked with Dinoprostone in studies conducted by López Jiménez et al., 2023, Daykan et al., 2018 raises questions about whether the benefit of shorter Labour duration outweighs the risk of adverse delivery outcomes (43,44).

This study implies the need for individualized labour induction protocols that balance the goal of timely delivery with maternal and neonatal safety. Such protocols would support clinicians in making informed decisions by carefully weighing the benefits of shorter labour against the risks of complications, including cesarean delivery. This is especially critical in low-resource settings like Tanzania, where limited surgical capacity and challenges in post-operative care can amplify the consequences of adverse outcomes.

No significant association was found between the method of induction and maternal health status, APGAR scores at 1 and 5 minutes, or birth weight. These findings are consistent with study conducted by Blomgren et al, 2025 and Tantu et al., 2025 in similar low-resource settings such as Uganda and Ethiopia , which suggest that although the choice of induction method may influence Labour outcomes such as mode of delivery and time to delivery it does not appear to have a direct effect on immediate neonatal outcomes. This implies that both Dinoprostone and balloon catheter with oxytocin may be considered comparable in terms of neonatal safety in the short term when induction is clinically indicated (45,46).

However, these findings contrast with a study conducted in the northern part of Tanzania by Tarimo et al., 2022, which applied a machine learning approach and reported mixed results regarding neonatal outcomes following Labour induction . In that study, factors such as birth weight, maternal age, and gestational age emerged as significant predictors of low APGAR scores after

induced vaginal deliveries. The difference in findings may be attributed to the disparity in sample size 7716 induced vaginal deliveries in the northern Tanzania study versus 288 deliveries in the this study. The larger sample size likely provided greater statistical power to detect associations that this study may have been underpowered to identify. This highlights the need for cautious interpretation of these results and suggests that further large-scale studies may be necessary to fully understand the relationship between induction methods and neonatal outcomes in different settings. (47).

The finding that neither the method of induction nor the choice between Dinoprostone and balloon catheter with oxytocin showed a significant association with APGAR scores at 1 and 5 minutes or with birth weight suggests that both induction methods have a comparable immediate neonatal safety profile. For healthcare workers particularly doctors, nurses, and midwives this reinforces the clinical understanding that the choice of induction method should not be primarily guided by concerns over short-term neonatal outcomes like APGAR scores or birth weight. Instead, attention should remain on appropriate patient selection, correct use of induction protocols, and vigilant intrapartum monitoring. These practices are essential to ensuring safe deliveries, as neonatal outcomes appear more influenced by overall Labour management rather than the induction method alone.

5.2 Study limitations and mitigations strategies

This study was subject to certain limitations. The use of purposive sampling may have introduced selection bias; however, recruiting participants from

multiple regional hospitals was intended to enhance representativeness. Missing or incomplete data were minimized through careful monitoring and validation during data collection. Where necessary, imputation techniques were applied, and sensitivity analyses were performed to assess their impact.

The relatively short study duration may have limited the ability to capture seasonal variations in Labour induction outcomes. Additionally, as the study was conducted within a specific regional context, the generalizability of the findings to other settings may be constrained. These limitations were acknowledged, and the results interpreted within the context of the study environment.

5.3 Conclusion

This study compared maternal and neonatal outcomes following labour induction with Dinoprostone and balloon catheter with oxytocin. The findings revealed that the choice of induction method influences delivery outcomes, particularly the mode of delivery and duration of labour. Dinoprostone was associated with a shorter induction-to-delivery interval but a higher likelihood of cesarean section, whereas balloon catheter with oxytocin showed a lower cesarean rate with comparable neonatal outcomes.

These results suggest that while both methods are effective for labour induction, the selection should be guided by patient condition, facility capacity, and clinical judgment to ensure optimal maternal and neonatal outcomes.

Strengthening adherence to evidence-based induction protocols and promoting individualized care could enhance safe and effective labour management in Tanzania and similar low-resource settings.

5.4 Recommendations

1. Clinicians should adopt an individualized, evidence-based approach when selecting labour induction agents, considering maternal condition, cervical status, and facility capacity to minimize the risk of cesarean delivery and optimize maternal outcomes.
2. Strengthening adherence to updated national and WHO and Tanzania new labour induction guideline is essential to promote safe and effective induction practices and ensure consistency in clinical decision-making.
3. Further analytical and longitudinal studies are warranted to assess the long-term maternal and neonatal outcomes associated with different induction methods, providing a stronger evidence base for clinical protocols and policy formulation in Tanzania.

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APPENDICES

Appendix I: Consent form (English version)

KAIRUKI UNIVERSITY

Title of the study: effectiveness of dinoprostone in the induction of labour compared to the balloon catheter with oxytocin among pregnant women attending regional referral hospitals in Dar es Salaam, Tanzania

Purpose of the study

As part of the requirement for the award Master of Medicine in Obstetrics and Gynaecology of Kairuki University (KU). I, Nasra Al-amin Ally have to carry out the research. This study is concerned effectiveness of dinoprostone in the induction of labour compared to the balloon catheter with oxytocin among pregnant women attending regional referral hospitals in Dar es Salaam, Tanzania.

Why have you been asked to participate?

You have been asked to participate because you are eligible candidate to provide data for this study.

What will the study involve and how long will you be in the study?

The study will involve collection of data of effectiveness of dinoprostone in the induction of labour compared to the balloon catheter with oxytocin among pregnant women attending regional referral hospitals in Dar es Salaam, Tanzania. This study will be conducted for three months.

Do you have to take part?

Participation in this study is voluntary. If you agree to participate, you will sign a consent form. Participants have option of withdrawing or discontinuing from this study at any time before and anytime during data collection.

Confidentiality

Participation in this study will be kept confidential. All responses provided will be kept confidential and the information will be used for this study only. No identification information shall be published. Any extracts from what you say that are quoted in the final report will be entirely anonymous.

What will happen to the data collected?

Data collected will be kept confidential from third parties including workers, superiors etc. Data collected will be helpful in establishing the comparative local data on the two induction methods in Dar es salaam, Tanzania.

What will happen to the results?

The results of this study will be used in my final report for the award Master of Medicine in Obstetrics and Gynaecology of Kairuki University (KU). The results may also be presented and published in scientific journal.

Possible benefits/ disadvantages of taking part

There is a benefit of participating in this study, the findings will help clinicians and decision makers on prioritizing and management of these patients as per

our local settings. There will be no direct disadvantages/harm as the effect of taking part in this study.

Whom to contact

In case of any problem, or query concerning this study, please contact the Principal Investigator……, at phone number……

Who has reviewed this study?

This study has been reviewed by KU joint Ethics committee.

Consent form for participant below age of 18years old.

I…… (Name of the parent/guardian) agree to participate in Dr. …… study.

I have read the information sheet and understood the purpose and nature of the study. I am participating voluntarily. I understand that I can withdraw from the study, without repercussions, at any time, whether before it starts or while I am participating. I understand that anonymity will be ensured in write up by distinguishing my identity. I understand that the data collected can be used for scientific publication

Signature of the parent/ward…….

Date……

If illiterate; Thumb print…….

If child has assented Yes ☐ No ☐

Witness name……signature…….

Statement by the researcher/person taking consent.

I have accurately read out the information sheet the potential participant, and to the best of my ability made sure that the participant understands what will be done. I confirm that the participant was given an opportunity to ask questions about the outcomes between Dinoprostone and Ballon Catheter with Oxytocin in Induction of Labour among Pregnant Women, and all questions asked by the participant have been answered correctly and to the best of my knowledge and ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name of the researcher/person taking consent……Signature …… Date……

Appendix II: Assent form (Swahili version)

Kichwa cha Utafiti: Ufanisi wa dinoprostone katika uanzishaji wa uchungu ikilinganishwa na katheta ya puto pamoja na oksitosini miongoni mwa wanawake wajawazito wanaohudhuria hospitali za rufaa za mkoa mjini Dar es Salaam, Tanzania

Lengo la Utafiti: Kama sehemu ya mahitaji ya shahada ya Uzamili ya Udaktari katika Obstetric na Gynecology ya Chuo Kikuu cha Kairuki (KU), mimi, Nasra Al-amin Ally, ninahitaji kufanya utafiti huu. Utafiti huu unahusu Ufanisi wa dinoprostone katika uanzishaji wa uchungu ikilinganishwa na katheta ya puto pamoja na oksitosini miongoni mwa wanawake wajawazito wanaohudhuria hospitali za rufaa za mkoa mjini Dar es Salaam, Tanzania.

Kwanini Umeombwa Kushiriki?: Umeombwa kushiriki kwa sababu wewe ni mgombea anayefaa kutoa data kwa ajili ya utafiti huu.

Utafiti Utahusisha Nini na Utachukua Muda Gani?: Utafiti utahusisha ukusanyaji wa data kwa kulinganisha Ufanisi wa dinoprostone katika uanzishaji wa uchungu ikilinganishwa na katheta ya puto pamoja na oksitosini miongoni mwa wanawake wajawazito wanaohudhuria hospitali za rufaa za mkoa mjini Dar es Salaam, Tanzania. Utafiti huu utafanyika kwa muda wa miezi mitatu.

Je, Ni Lazima Ushiriki?: Kushiriki katika utafiti huu ni hiari. Ikiwa utakubali kushiriki, utasaini fomu ya idhini. Washiriki wana chaguo la kujitoa au kusitisha

kushiriki katika utafiti huu wakati wowote kabla na wakati wowote wa ukusanyaji wa data.

Usiri: Kushiriki katika utafiti huu kutahifadhiwa siri. Majibu yote yatakayowasilishwa yatabaki siri na habari hiyo itatumika kwa ajili ya utafiti huu tu. Hakuna taarifa za utambulisho zitakazochapishwa. Dondoo zozote kutoka kwa yale utakayosema ambazo zitanukuliwa katika ripoti ya mwisho zitakuwa bila kutambulishwa kabisa.

Nini Kitafanyika kwa Data Itakayokusanywa?: Data itakayokusanywa itahifadhiwa siri kutoka kwa watu wengine wakiwemo wafanyakazi, wakubwa, nk. Data itakayokusanywa itasaidia kuanzisha data za eneo la ndani za ulinganishaji juu ya mbinu mbili za kusababisha uchungu Jijini Dar es Salaam, Tanzania.

Nini Kitafanyika kwa Matokeo?: Matokeo ya utafiti huu yatatumika katika ripoti yangu ya mwisho kwa ajili ya shahada ya Uzamili ya Udaktari katika Obstetric na Gynecology ya Chuo Kikuu cha Kairuki (KU). Matokeo hayo pia yanaweza kuwasilishwa na kuchapishwa katika jarida la kisayansi.

Manufaa/Madhalio Yanayoweza Kutokea ya Kushiriki: Kuna manufaa ya kushiriki katika utafiti huu, matokeo yatasaidia madaktari na watoa maamuzi katika kipaumbele na usimamizi wa wagonjwa hawa kulingana na mazingira yetu ya ndani. Hakutakuwa na hasara/athari za moja kwa moja kutokana na kushiriki katika utafiti huu.

Mawasiliano: Endapo kuna tatizo lolote, au swali kuhusu utafiti huu, tafadhali wasiliana na mtafiti mkuu ……, kwa nambari ya simu ……

Nani Aliyehakiki Utafiti Huu?: Utafiti huu umehakikiwa na Kamati ya Maadili ya Pamoja ya KU.

Fomu ya Idhini kwa Mshiriki Mwenye Umri Chini ya Miaka 18: Mimi …… (Jina la mzazi/mlezi) nakubali kushiriki katika utafiti wa Dkt. …… Utafiti huu. Nimesoma karatasi ya maelezo na kuelewa lengo na asili ya utafiti. Ninashiriki kwa hiari. Ninaelewa kuwa naweza kujitoa katika utafiti huu, bila athari zozote, wakati wowote, kabla ya kuanza au wakati ninashiriki. Ninaelewa kuwa kutambulishwa kutahakikishwa katika maandishi kwa kutofautisha utambulisho wangu. Ninaelewa kuwa data itakayokusanywa inaweza kutumika kwa ajili ya uchapishaji wa kisayansi. Sahihi ya mzazi/mlezi……. Tarehe…… Ikiwa hajui kusoma; Alama ya kidole……. Ikiwa mtoto ameridhia Ndiyo Hapana Shahidi jina……sahihi……..

Taarifa na Mtafiti/Mtu Anayechukua Idhini: Nimesoma kwa usahihi karatasi ya maelezo kwa mshiriki anayewezekana, na kwa uwezo wangu wote kuhakikisha kwamba mshiriki anaelewa kitakachofanyika. Ninathibitisha kuwa mshiriki alipewa fursa ya kuuliza maswali kuhusu matokeo kati ya Dinoprostone na Katheta ya Puto na Oxytocin katika Kusababisha Uchungu kwa Wanawake Wajawazito, na maswali yote yaliyoulizwa na mshiriki

yamejibiwa kwa usahihi na kwa uwezo wangu wote. Ninathibitisha kuwa mtu huyo hakupewa shinikizo la kutoa idhini, na idhini imetolewa kwa hiari na hiari.

Jina la mtafiti/mtu anayechukua idhini…….Sahihi …… Tarehe……

Appendix III: Questionnaire (English version)

Patient Information

- Patient ID: _____
- Age: _____
- Date of Admission: _____
- Hospital: _____

Indication for Induction: _____

Medical History

- Obstetric History:
    - Gravida: _____
    - Para: _____
    - Previous Inductions: Yes / No
    - Complications in Previous Pregnancies:

      _____

Examination Findings

- Vital Signs:
    - Temperature: _____ °C
    - Blood Pressure: _____/_____ mmHg
    - Pulse: _____ bpm
    - Respiratory Rate: _____ breaths/min

- General Examination:
    - Overall wellbeing: _____
    - heart: heartbeat awareness;YES or NO _____
    - Chest: difficult in breathing; YES or NO _____
    - Abdomen: tender;YES or NO _____
    - Nerve/Numbness: present/ or not _____
- Cervical Assessment:
    - Bishop Score: _____

Induction Method

- Method Used: Dinoprostone / Balloon Catheter with Oxytocin
- Dosage and Administration:
    - Dinoprostone: _____
    - Balloon Catheter and Oxytocin:_____

Labour and Delivery Outcomes

- Time to Delivery: _____
- Mode of Delivery: Vaginal / Cesarean Section
- Maternal Health Status:
- Neonatal Health Status:
    - Apgar Score at 1 min: _____
    - Apgar Score at 5 min: _____
    - Birth Weight: _____ kg

- Any Complications: _____

_____

_____

Appendix IV: Questionnaire (Swahili version)

Fomu ya Kliniki

Taarifa za Mgonjwa

- Kitambulisho cha Mgonjwa: _____
- Umri: _____
- Tarehe ya kulazwa:_____
- Hospitali: _____
- Sababu ya Kuanzisha Uchungu: _____

Historia ya Matibabu

- Historia ya Ujauzito:
    - Gravida: _____
    - Para: _____
    - Kusababisha Uchungu Kwa Mara ya Awali: Ndiyo / Hapana
    - Madhara Katika Ujauzito wa Awali: _____

Matokeo ya Uchunguzi

- Dalili Muhimu:
    - Joto la Mwili: _____ °C
    - Shinikizo la Damu: _____/_____ mmHg
    - Mapigo ya Moyo: _____ bpm
    - Kasi ya Kupumua: _____ pumzi/min

- **Uchunguzi wa Kimwili:**
    - Mwonekano wa Jumla: _____
    - Moyo: moyo kwenda mbio; Ndiyo/ hapana _____
    - Mfumo wa Kupumua: shida kwenye upumuaji Ndiyo/hapana_____
    - Mfumo wa Mmeng'enyo: Tumbo kuuma; ndiyo au hapana_____
    - Mfumo wa Neva: mwili kufa ganzi; Ndiyo/hapana _____

- **Tathmini ya Shingo ya Uzazi:**
    - Alama za Bishop: _____

Njia ya Kusababisha Uchungu

- Njia Iliyotumika: Dinoprostone / Katheta ya Puto na Oxytocin
- Kipimo na Utaratibu:
    - Dinoprostone: -_____
    - Katheta ya Puto na Oxytocin:_____

Matokeo ya Uchungu na Kuzaa

- Muda uliotumika kujifungua: _____
- Njia ya Kujifungua: Kwa Njia ya Kawaida / Upasuaji wa Cesarean
- Hali ya Afya ya Mama:
- Hali ya Afya ya Mtoto:

- Alama za Apgar Dakika 1: _____
- Alama za Apgar Dakika 5: _____
- Uzito wa Mtoto: _____ kg
- Madhara Yeyote: _____