EVALUATION OF EFFECTIVENESS AND SAFETY OF PHARMACOLOGICAL AND MECHANICAL LABOR INDUCTION METHODS AMONG PREGNANT WOMEN ATTENDING PUBLIC REFERRAL HOSPITALS IN DAR ES SALAAM, TANZANIA

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By

Emanuel Erasto

A Dissertation Submitted in (Partial) Fulfillment of the Requirements for the Degree of Master of Pharmacy in Hospital and Clinical Pharmacy

Muhimbili University of Health and Allied Sciences
October, 2021

CERTIFICATION

The undersigned certifies that they have read and hereby recommends for examination of dissertation entitled, "***Evaluation of Effectiveness and Safety of pharmacological and mechanical labor induction methods among Pregnant Women attending Public Referral Hospitals in Dar es salaam, Tanzania"*** in (partial) fulfillment of the requirements for the degree of Master of Pharmacy in Hospital and Clinical Pharmacy of Muhimbili University of Health and Allied Sciences.

_____

Dr. Ritah Mutagonda

(Supervisor)

Date: _____

_____

Prof. Omary Minzi

(Co-Supervisor)

Date: _____

DECLARATION AND COPYRIGHT

I, **Emanuel Erasto**, declare that this **dissertation** entitled, "Evaluation of effectiveness and safety of pharmacological and mechanical labor induction methods among pregnant women attending public referral hospitals in Dar es salaam, Tanzania" is my own original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

Signature: _____ **Date: _____**

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DEDICATION

I dedicate this dissertation first to my wife, Costansia Ernest and second to my parents Mr & Mrs Erasto Ngomuo and lastly to my children.

This work also is dedicated to God Almighty who has been my source of strength throughout this program.

ABSTRACT

Background: Induction of labor aims to initiate or accelerate uterine contraction and cervical ripening for spontaneous vaginal delivery (SVD). Currently, balloon catheter, oxytocin and prostaglandin derivatives are the standard modes of labor induction used in Tanzania. However, to our understanding, there is scarcity of information in Tanzania on the effectiveness and safety of the different methods used to induce labor.

Objectives: The study aimed to determine the effectiveness and safety of the different modes of labor induction among term and post-term pregnant women at referral hospitals in Dar es salaam.

Methods: This was a hospital-based prospective cohort study carried out at referral hospitals in Dar es salaam. The study was conducted from March to June 2021. A total of 322 pregnant women were involved. A case report form (CRF) was used to collect participants' socio-demographic, obstetrics, and clinical characteristics. The primary outcome was the proportion of pregnant women who had SVD within 24 h after labor induction. The secondary outcome respiratory distress, neonatal care, apgar score and blood loss were also collected during 24 hours follow up time. Data were analyzed using a statistical package for social sciences (SPSS) version 23, whereby descriptive statistics were used to summarize study variables. Cox logistic regression analysis was used to show the association between the dependent and independent variables, and p-value of <0.05 was considered as significant.

Results: Of the 322 pregnant women enrolled in the study, SVD was 95% in oxytocin, 80% in misoprostol, 80% in balloon catheter and 69% in dinoprostone groups. The median time from induction to SVD was significant with oxytocin compared to other modes of labor induction (5.42 h with $p<0.001$). Gravidity and comorbidities were significantly associated with SVD ($p<0.05$). Thirty-six (36%) pregnant women who were exposed to dinoprostone had poor neonatal outcomes (Apgar score <7 at 5 min, RDS) and maternal blood loss (>500 mL) was also highly presented in this group compared to other modes of induction.

Conclusion: Induction of labor after exposure to four different modes of induction showed that oxytocin was most effective and safe in inducing labor with the shortest median time compared to misoprostol, dinoprostone and balloon catheter. The desirable maternal and neonatal outcomes were also significant in women who used the oxytocin compared to other modes of induction.

Key words: Spontaneous vaginal delivery, Modes of induction, Term and post-term pregnant, Referral hospital, respiratory distress syndrome (RDS)

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LIST OF ACRONYMS

CS	Cesarean section
MNH	Muhimbili National Hospital
MoHCDGEC	Ministry of Health Community Development Gender Elderly and Children
MUHAS	Muhimbili University of Health and Allied Sciences
PROM	Premature rapture of membrane
SPSS	Statistical Package for Social Sciences
SVD	Spontaneous vaginal delivery
WHO	World Health Organization
RDS	Respiratory distress syndrome

DEFINITIONS OF KEY TERMS

Spontaneous vaginal delivery: Normal vaginal delivery (Obstetric and gynecological disorders, 2010).

Post term pregnancy: Pregnancy with more than 41 weeks (MNH obstetrics and gynecology guidelines, 2019)

Bishop score: Scoring system that can assist in predicting whether induction of labor will be required (MNH Obstetrics and gynecology guidelines, 2019)

Labor induction: is the stimulation of uterine contraction during pregnancy before labor begins on its own to achieve vaginal birth (WHO, Induction of labor at or beyond term, 2018).

Pharmacological induction: Is an attempt of labor induction with the use of agents such as prostaglandin (E1 and E2) and oxytocin which can be administered intravaginally or intravenously, respectively (Mechanical and pharmacological methods of labor induction, 2016).

Mechanical induction: Is a procedure of putting pressure on the cervix to help it soften, thin and begin to open for vaginal birth e.g., the use of balloon catheter (Mechanical and pharmacological methods of labor induction, 2016).

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Induction of labor is defined as the use of artificial methods resulting in labor after the age of fetal viability and before the spontaneous onset of labour(1)**.** Labor induction has gradually increased in the world, whereby in every four pregnant women one has to be induced after out weighing the risk of maternal and/or fetal waiting for spontaneous vaginal delivery (SVD) (2). The World Health Organization (WHO) recommends induction of labor after outweighing the benefits and risks of mothers' and unborn child (3). WHO Global Survey on Maternal and Perinatal Health, which surveyed 24 countries, showed that 9.6% of deliveries involved labor induction (3). In 2006, in the United States of America, the induction rate was 22.5%, which is more than two-fold of that of reported by WHO (3). Induction of labor is one way of assisting pregnant women in undergoing SVD. In obstetrics, labor induction aims to save the mother and unborn child's lives by reducing the risk of adverse neonatal and pregnancy outcomes. The modes of labor induction may vary from one place or region to another, depending on availability and affordability.

There are two common modes of labor induction in Tanzania, which are mechanical and pharmacological. During mechanical induction, the balloon catheter is used, which has an exceptionally low risk of adverse outcomes to pregnant women (4). The pharmacological mode of labor induction is the common method employed in many health facilities around the country (5).

The choice of the best drug to use for pharmacological induction is still challenging to gynecologists due to variations in efficacy and safety. Different studies on the use of oxytocin, misoprostol, dinoprostone and foley catheter report differences in effectiveness and safety of these interventions to pregnant women and the fetus (6). Oxytocin is commonly used in many facilities to augment labor or supplement other modes of induction to achieve SVD. Despite

the increase in technology, availability of specialists, and various drugs used for labor induction, there is a high increase in cesarean section (CS) to pregnant women, especially in developing countries like Tanzania. Recently, a study done by *Tarimo et al* (2020) reported that about 20% of CS in Tanzania is due to failure of labor induction (7).

To identify which mode of labor induction performs well in Tanzania, a study to determine the effectiveness and safety of both mechanical and pharmacological approaches is warranted. Therefore, this study aimed to evaluate the effectiveness and safety of different modes of labor induction among term and post-term pregnant women at referral hospitals in Dar es salaam.

There are some common indications of pregnant women to be induced after outweighing the benefit and risk to mother and fetus such as postdates, intra uterine growth restrictions (IUGR), fetal macrosomia,oligohydramnios, isoimmunization, gestational diabetes, chorioamnionitis, pre-labor rapture of membranes(PROM), hypertensive disorders of pregnancy and other maternal conditions and also the risk (blood loss, Rds and low score) and benefit (avoiding cesarean section) of different modes of labor induction explained by Clifford et al, in the retrospective cohort study done at tertiary hospital in Northern Tanzania(7).

The choice of modes of labor induction has no any significance with the gestational age of pregnant women with regards to effectiveness and safety of different modes of labor induction, also the maternal adverse outcome and neonatal adverse outcome may not be affected by gestational age(8)**.**

1.2 Problem Statement

The past 30 years have witnessed deployment of different methods of induction of labor. For instance, in Tanzania medication like oxytocin, dinoprostone, misoprostol and balloon catheter have been used for labor induction for some years. Owing to the sensitive nature of labor, the effectiveness and safety of labor induction methods has always been of much concern during delivery. To our best level of understanding data on effectiveness and safety of pharmacological and mechanical labor induction methods among pregnant women in Tanzania are scarce. Therefore, this study aimed at assessing the effectiveness and safety of pharmacological (oxytocin, misoprostol and dinoprostone) and mechanical (balloon catheter) labor induction methods among pregnant women attending public referral hospitals in Dar es salaam, Tanzania.

1.3 Conceptual Framework

Exposure of pregnant women at term to different modes of labor induction in the labor ward is expected to result in SVD. Several factors can affect effectiveness of the various methods of labor induction. These are age of the pregnant women, clinical characteristics, gestational age, parity, fetal weight & age, vaginal pH, and bishop score. Therefore, the dependent variable of this study is the proportion of pregnant women who have SVD and the secondary outcomes are the neonatal and maternal outcomes.

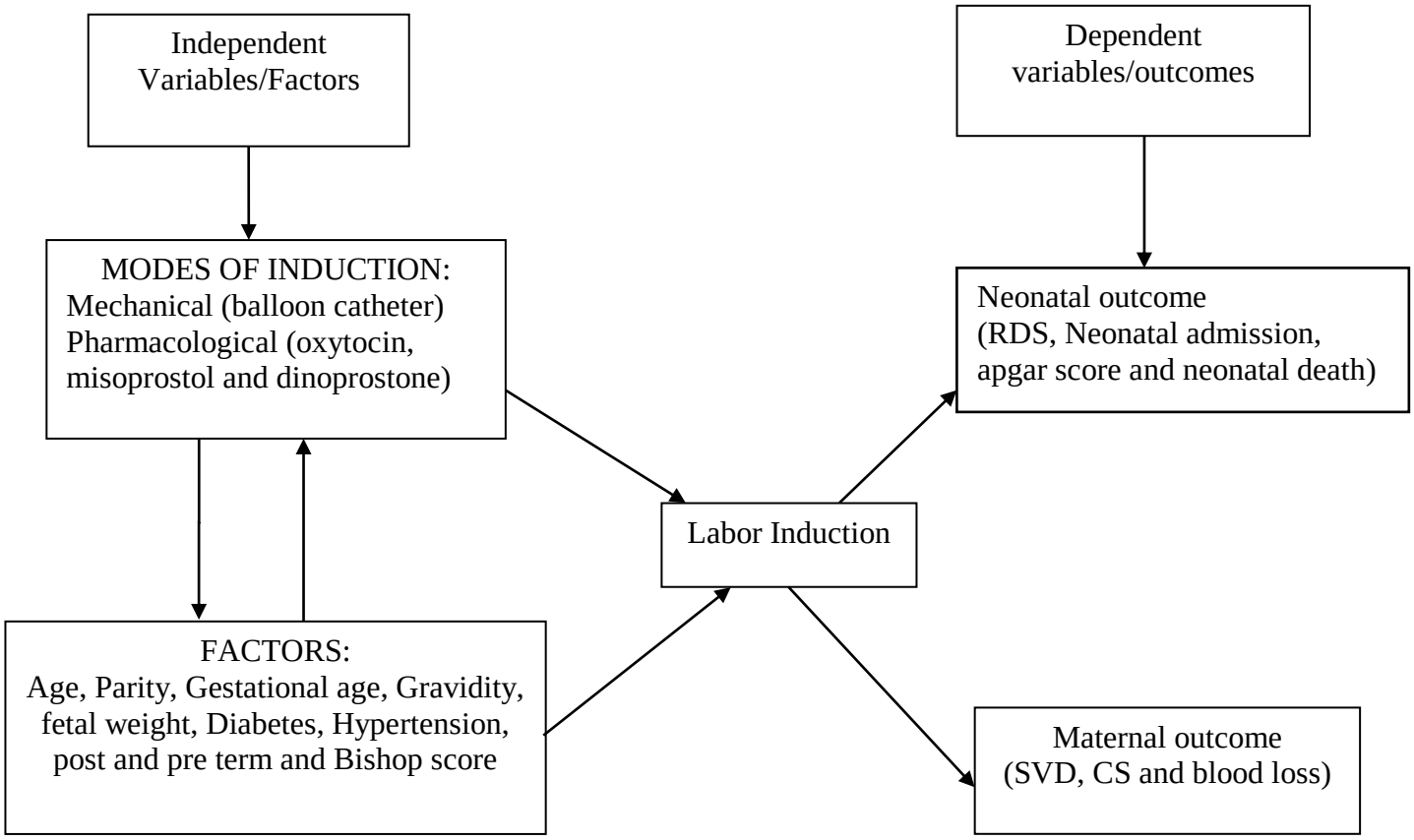

Figure 1: Conceptual framework

1.4 Rationale

Current practice the choice of the best drug to use for pharmacological and mechanical labor induction methods is still challenging to gynecologists due to variations in efficacy and safety data of different modes used in labour induction. Different studies on the use of oxytocin, misoprostol, dinoprostone and foley catheter report differences in effectiveness and safety of these interventions to pregnant women and the fetus(6). The reason for conducting this study was lack of adequate data informing practitioners about the safety and efficacy of the available agents. The findings of this study provide baseline information to healthcare providers, especially gynecologists, on the effectiveness and safety mode of labor induction, which will help reduce CS and the number of deaths among pregnant women associated with induction failure.

At the national level, these findings may help update the guidelines on the management of pregnant women, which will help reduce maternal mortality and ensure better outcome of the neonate.

1.5 Broad Research Question

Which is the effectiveness and safety of pharmacological and mechanical labor induction methods among pregnant women attending public referral hospitals in Dar es salaam?

1.5.1 Specific Research Question

i. What is the proportion of pregnant women who undergo SVD within 24 h after exposure to pharmacological (oxytocin, misoprostol and dinoprostone) induction methods?
ii. What is the proportion of pregnant women who undergo SVD within 24 h after exposure to mechanical (balloon catheter) induction methods?
iii. What is the time interval from induction to SVD with pharmacological (oxytocin, dinoprostone and misoprostol) labor induction methods of pregnant women at public referral hospitals in Dar es salaam?
iv. What is the time interval from induction to SVD with mechanical (balloon catheter) labor induction methods of pregnant women at public referral hospitals in Dar es salaam?
v. What is the proportion of adverse outcome of pharmacological (oxytocin, misoprostol and dinoprostone) and mechanical (balloon catheter) on neonatal and maternal outcomes?
vi. What are the factors associated with SVD among pregnant women after exposure to pharmacological or mechanical modes of labor induction?

1.6 Objectives

1.6.1 General Objective

To determine the effectiveness and safety of pharmacological and mechanical labor induction methods among pregnant women at public referral hospitals in Dar es salaam.

1.6.2 Specific Objectives

i. To determine the proportion of pregnant women who had SVD within 24 h after pharmacological (oxytocin, misoprostol and dinoprostone) labor induction methods at public referral hospitals in Dar es salaam.
ii. To determine the proportion of pregnant women who had SVD within 24 h after mechanical (balloon catheter) labor induction methods at public referral hospitals in Dar es salaam.
iii. To determine the time interval between induction of labor and SVD within 24 h following induction of labor at public referral hospitals in Dar es salaam.
iv. To determine factors (socio-demographics and obstetric characteristics) associated with SVD among pregnant women following labor induction at public referral hospitals in Dar es salaam.
v. To determine the proportion of **adverse outcome** of pharmacological and mechanical labor induction methods on composite maternal and neonatal.

1.7 Literature Review

1.7.1 Spontaneous Vaginal Delivery after Labor Induction

A previous study reported that pregnant women show better outcomes after combining mechanical and pharmacological in nulliparous and multiparous groups as it shortens mean time to vaginal delivery compared to using one agent alone (9). Another study reviewing dinoprostone vaginal insert reported that the devices are effective and safe. Also, the devices release the drug in efficient dose control, so recommend the device as a right choice in promoting cervical ripening for unfavorable cervix at term (10).

A metanalysis on intracervical foley catheter plus intravaginal misoprostol and intravaginal misoprostol alone for cervical ripening showed that pregnant women with viable gestation and no PROM who used once intracervical foley catheter and intravaginal misoprostol had shorter induction time and decreased uterine contraction compare to intravaginal misoprostol alone (11). A study done in primigravid term pregnancy beyond 40 weeks of gestation without pregnancy complications induced with misoprostol and dinoprostone, reported that the use of vaginal misoprostol 50 μg and dinoprostone 3 mg to this group, has shown use of vaginal misoprostol at six hours interval is more effective compare to dinoprostone (12)

Comparative studies on misoprostol and dinoprostone showed both are safe and effective on cervical ripening and labor induction. However, although misoprostol is cost-effective compared to dinoprostone, it is associated with more complications such as uterine hyperstimulation, tachysystole and fetal distress syndrome(13). Therefore, studies for a safe dose of misoprostol are recommended. The study also reported a high failure of SVD in the group exposed to dinoprostone compared to misoprostol. Moreover, the group exposed to misoprostol took shorter time to vaginal delivery (13).

1.7.2 Factors Affecting Spontaneous Vaginal delivery

A study examining the effect of vaginal pH on efficacy of dinoprostone for induction of labor showed that parity influences vaginal pH and vaginal pH in turn affects cervical ripening and bishop score before labor induction. High vaginal pH was associated with fast response after induction with dinoprostone, resulting in SVD. Knowing the vaginal pH will help predict how fast is the delivery after induction with dinoprostone (14).

A study on the prevalence and risk factors for CS delivery following labor induction at a tertiary hospital in north Tanzania reported that a detailed assessment is needed before labor induction. There was an association with parity, fetal weight, and postdates, and urban residence. Practical evaluation of the factors mentioned will ensure a good outcome after labor induction to pregnant women and decrease the number of CS due to labor induction failure (7).

Also, a study on obstetric outcome after multiple doses of vaginal dinoprostone for cervical ripening found that there is a high increase of emergency CS to pregnant woman exposed to more than two doses of dinoprostone in comparison to pregnant woman exposed to one or two doses of oxytocin infusion for labor induction (15).

Labor induction can be affected by many obstetrics and clinical characteristics presented by pregnant women at the labor ward. Collection of this information in detail before using any modes of labor induction is essential for successful labor induction. The study on the prevalence of failed induction in Ethiopia reported how different characteristics affect labor induction. Therefore, screening is needed to reduce this burden of labor induction to pregnant women (16).

1.7.3 Safety of Induction Modes in neonates

The safety of neonates during the selection of which mode to use is essential. A study done on pregnant women using foley catheter plus vaginal misoprostol and vaginal misoprostol alone showed that there is a high risk of neonatal intensive care unit admission with the use of vaginal misoprostol alone compared to foley catheter plus vaginal misoprostol (3)

A study where nulliparous women with PROM were induced labor with oxytocin and dinoprostone showed that neonatal admission for special care was low in the group exposed to dinoprostone than to oxytocin (17).

According to Porras et al, study of effectiveness and safety of dinoprostone and cook's balloon for labor induction pregnant with small for gestational age fetuses and bishop score of <7 shows that pregnant women use dinoprostone 10mg has the reduces time to delivery compared to cook's balloon with a low need for oxytocin(18)**.**

CHAPTER TWO

2.0 METHODOLOGY

2.1 Study Design

The design was an observational prospective cohort study whereby pregnant women were enrolled before delivered and followed up 24 h after labor induction.

2.2 Study Site and Duration

The study was carried out at referral hospitals found in Dar es Salaam with different maternity admission capacities and adequately trained health care professionals. The study sites included were Temeke hospital in Temeke District, Amana hospital in Ilala District, Mwananyamala hospital in Kinondoni District and Muhimbili National Hospital located at Ilala District in Dar es Salaam. Obstetrics and gynecology are among the advanced specialty in these facilities, with a high number of pregnant women admitted at the labor wards. At the study site the common professionals present were obstetrics and gynecologists, registrars and midwives. The induction of labor per all public referral hospital around Dar es Salaam is 1500 pregnant women per annum. The induction of labor in all sites were conducted under the supervision of specialist based on the experience in practice at the specific site. The study was conducted for four months from March to June 2021.

2.3 Study Population

All pregnant women admitted to the labor ward of the referral hospitals in Dar es Salaam.

2.3.1 Inclusion criteria

Pregnant women who were prescribed with pharmacological and mechanical labor induction methods to facilitate SVD.

Pregnant women with gestational age of 37 weeks or above and other complication such as pregnancy induced hypertension (severe eclampsia) were enrolled in the study after filling the consent form.

2.3.2 Exclusion criteria

Pregnant women with no live birth were not enrolled in the study.

Pregnant women who did not consent to participate in the study.

Pregnant women use more than one labor induction modes were not enrolled in the study.

2.4 Sample Size and Sampling Technique

The sample size was calculated by using the formula below:

$n=[Z_a\sqrt{(1+1/m)}\ p(1-p)+Z_b\sqrt{P_0(1-P_0)/m+P_1(1-P_1)}]^2/(P_0-P_1)^2$; $P=P_1+mP_0/m+1$,

n= Total number of desired study subjects (case) to identify true relative risk with two-sided type I error,

m= Number of subjects (control) per experimental subjects is 2,

Z_b= It is the desired power = 80%,

Z_a= Critical value and a standard value for the corresponding level of confidence (At 95%CI it is 1.96),

P_0= Proportion of pregnant mother who underwent spontaneous vaginal delivery after induction with foley catheter 71.5%

P_1= Proportion of pregnant mother who underwent spontaneous vaginal delivery after induction with pharmacological modes = 75.8%

P = integral proportion for both modes of induction 74%.

After calculation, the sample size was 322 pregnant women.

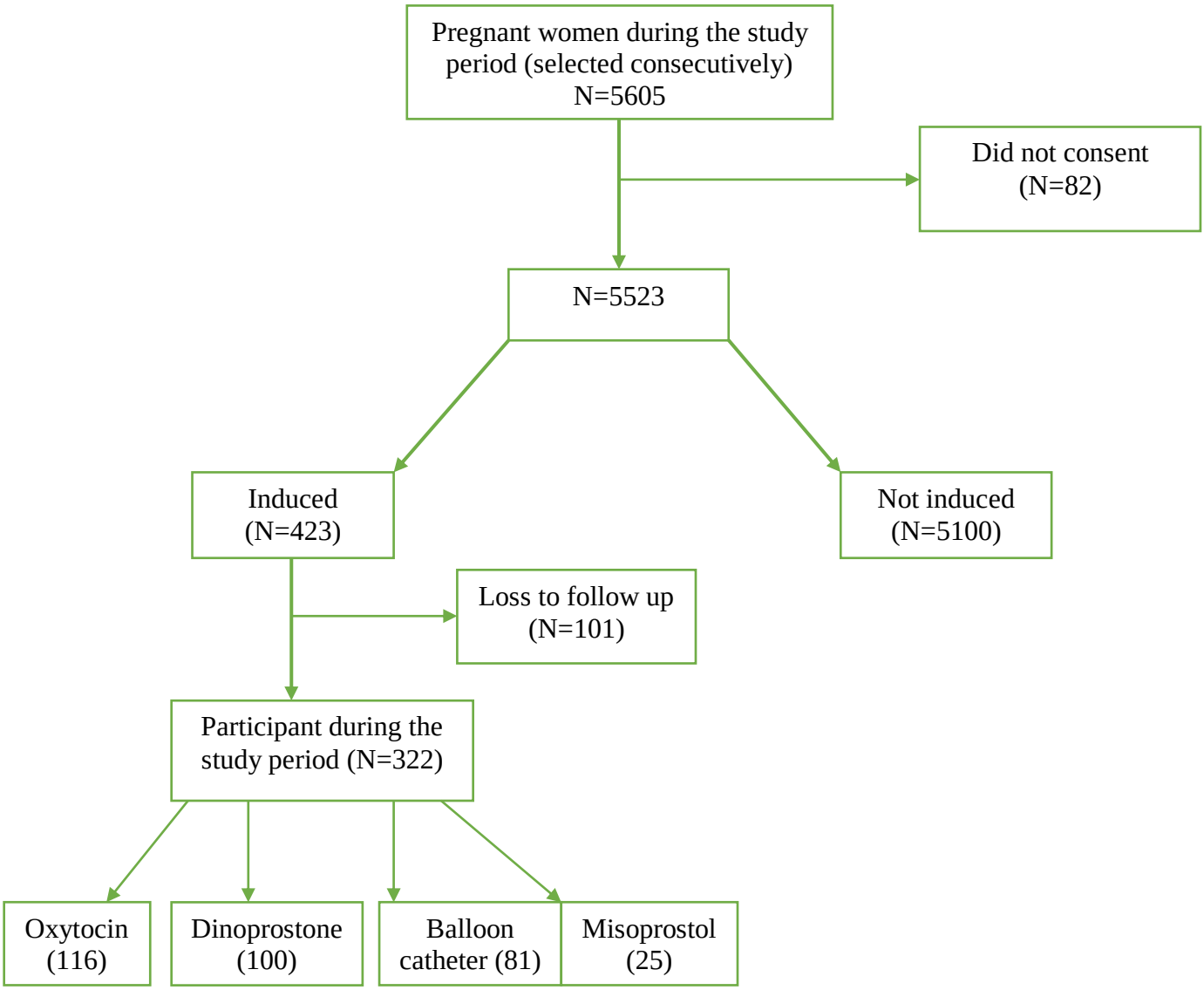

Figure 2: Flow chart for recruitment of study participants

The sampling technique was non-probability-consecutive sampling whereby every pregnant woman who came to the labor ward for delivery was requested a consent and those consented and induced for labor were enrolled. During the study period pregnant women admitted at Amana referral hospital (1661), Mwananyamala referral hospital (1593), Temeke referral hospital (1243) and Muhimbili national hospital (1108). The process of assigning the number to participant (Temeke-73, MNH-113, Amana-96 and Mwananyamala-40) was done consecutively to those consented and prescribed with any modes of labor induction at the study site. Enrollment continued until the required sample size was attained.

2.5 Data Collection and management

2.5.1 Data collection tool

The data was collected using a case report form. The different characteristics at enrollment and the outcome after induction of all pregnant women admitted in the labor ward were documented. The case report form comprised of socio-demographic data (age, sex, weight), obstetrics characteristics (gestational age, parity, gravidity), clinical characteristics (fetal weight, hypertension, diabetes, pre- or post-term), mode of induction (pharmacological or mechanical) and maternal and fetal outcomes (SVD, blood loss and Caesarian section for the mother and intensive care admission, RDS, apgar score and death for the neonate).

2.5.2 Data collection procedure

The starting point for data collection was labor ward, whereby the pregnant women were enrolled before delivery and the induction methods. The mainly starting point for labor induction was maternal complications such as hypertension and postdates. The brands of the drugs used during indication of labor were all registered with TMDA with different strength misoprostol 25mcg, dinoprostone 3mg and oxytocin 5IU. The formulations and routes of medicines used during the study period were tablets misoprostol inserted vaginally, tablets dinoprostone inserted vaginally and intravenous oxytocin. The study participants during the study period there is no one using more than one modesmode of induction at once was observed**.** The standard time for collecting data at the labor ward was 24 h, whereby failure of

SVD within 24 h was considered as a failure of induction. The time from induction to delivery was accurately recorded per individual pregnant women for all modes of induction. The tool was pre-tested at MNH by collecting data from twenty pregnant women and analyzed to see if it would answer the study objectives. After pre-testing of the tool, all necessary amendments were done prior to data collection. The midwives working at the labor ward in selected health facilities were trained on filling the case report form, and all the information was collected at the labor ward after the pregnant women consented to participate in the study in writing.

2.5.3 Data Management

All filled case report forms were re-checked on the collection day to ensure quality of the data. Data were entered in an excel sheet, and it was kept in a password-secured computer to ensure confidentiality of participants' information. The principal investigator kept all filled tools to ensure confidentiality until the appropriate time (at least five years) of destruction.

2.6 Variables

2.6.1 Dependent variables

i. Proportion of participants who had SVD
ii. Time interval between induction of labor and delivery,
iii. Adverse neonatal outcomes
iv. Adverse maternal outcomes

2.6.2 Independent Variables

i. Mechanical (balloon catheter)
ii. Pharmacological (oxytocin, misoprostol and dinoprostone)
iii. Factors such as Age, Parity, Gestational age, Gravidity, Bishop score, hypertension and diabetes

2.7 Data Analysis

The overall proportion of pregnant women who had SVD within 24 h after induction of labor at public referral hospitals in Dar es salaam was determined by analyzing pregnant women who delivered spontaneously out of all study participants and that are treated as effective labor induction. The data were presented in bar chart with error bar to show proportional of pregnant women delivered vaginal and those undergo cesarean section during the study period. Then the proportion of pregnant women who had SVD was clustered based on the mode of induction followed by comparing the proportion of SVD between different modes of induction whereby the chi-square test was used to test for the significant difference between these groups. Log-rank test was used to compare the median time between induction of labor and SVD using different modes of induction. Factors associated with SVD among pregnant women following labor induction at referral hospitals in Dar es salaam were determined by using the cox regression analysis.

Proportion of neonatal outcomes such as admission after birth, respiratory distress syndrome, Apgar score and death after exposure to any modes of labor induction were also determined. After exposure to any mode of labor induction, the proportion of maternal outcome (blood loss) was determined by calculating the average blood loss, followed by a comparison using the Kruskal Wallis test. Statistical Package for Social Sciences (SPSS program version 23) was used for analysis, whereby, the p-value of less than 0.05 was considered significant.

2.8 Ethical Consideration

Ethical clearance was obtained from MUHAS ethical committee before starting to conduct the study (DA.282/298/01.C/). Permission letters to access the selected hospitals were obtained from the appropriate authority. The study imposed no harm to the study participants, and all participants' information was highly confidential.

CHAPTER THREE

3.0 RESULTS

This study recruited a total of 322 pregnant women out of 5605 who gave birth in the visited hospitals during the three months of data collection i.e. from March to June 2021. Among 241 (74.8%) used the pharmacological methods and 81 (25.2%) participant used mechanical methods of induction. Participants had a median age of 27 years. Among the 322 participants, 61.5% were at term, while 38.5% were post-term pregnant women. Additionally, 42.5% of pregnant women were primigravida, while 57.5% were multigravida. Also, majority (65.2%) of the participants presented with different comorbidities. The baseline characteristics of the pregnant women are shown in Table 1.

Table 1: Socio-demographic, clinical and obstetrics characteristics of study participants (N=322)

Variable	**Category**	**Frequency (n)**	**Percentage (%)**	**Median (Range)**
Facility	MNH	113	35.1	
	Amana	96	29.8	
	Temeke	73	22.7	
	Mwananyamala	40	12.4	
Modes of	Oxytocin	116	36	
Induction	Dinoprostone	100	31.1	
	Balloon catheter	81	25.2	
	Misoprostol	25	7.8	
Age (years)	<18	6	1.9	27 (17, 43)
	18-35	292	90.7	
	>35	24	7.5	
Marital status	Married	312	96.9	

	Not married	10	3.1	
Maternal weight	<70	155	48.1	70.0 (47.0,
(kg)	>70	167	51.9	121.0)
Gestation Age	Term	198	61.5	
	Post term	124	38.5	
Gravidity	Primigravida	135	42.5	
	Multigravida	187	57.5	
Comorbidities	Yes	210	65.2	
	No	112	34.8	
Maternal Risk	Yes	28	8.7	
	No	294	91.3	
Fetal weight (g)	<2500	51	15.8	3000 (500.0,
	2500-3999	259	80.4	4900.0)
	>4000	12	3.7	

3.1 Proportion of pregnant women with SVD

Pregnant women exposed to oxytocin showed a high proportion of SVD (95%) compared to other modes of labor induction and a lower proportion was observed in the group exposed to dinoprostone (69%). Also, the proportion of pregnant women delivered by CS was high in the group exposed to dinoprostone (31%) and the lowest in the group exposed to oxytocin (5.2%). The difference in the proportion of pregnant women who had SVD after exposure to different modes of labor induction was statistically significant ($p<0.001$), as shown in Figure 3 below.

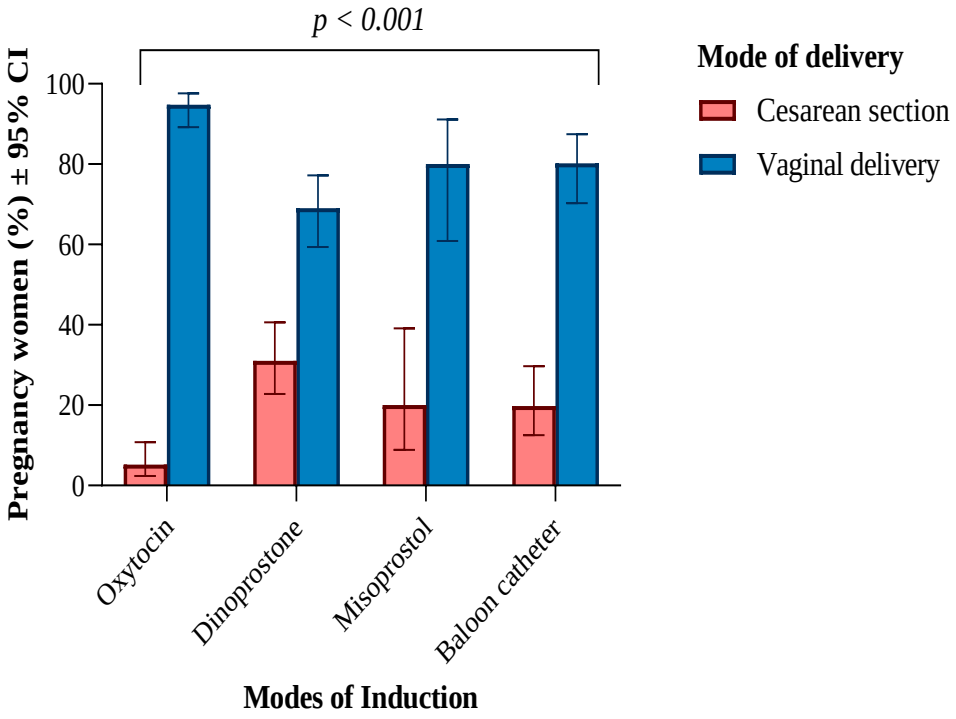

Figure 3: Proportion of the pregnant women who had SVD after exposure to different modes of labor induction.

3.2 Time to SVD after exposure to different modes of labor induction.

After exposure with different modes of labor induction within 24 h, oxytocin showed a short time (5.42 h) to from induction to SVD while dinoprostone took a long time (13 h). The median time after pregnant women were exposed to all modes of labor induction within 24 h is shown in Table 2.

Table 2: Median Estimates of time for SVD (hours)

	Median	**Lower**	**Upper**
OXYTOCIN	5.42	4.50	6.00
DINOPROSTONE	13.00	12.00	14.00
MISOPROSTOL	10.58	8.00	17.00
BALOON CATHETER	8.00	7.00	10.00

Comparison of median time with log-rank test shown in Table 3 showed a significant difference in median time with each mode of labor induction except dinoprostone with misoprostol and balloon catheter with misoprostol.

Table 3: Pairwise Comparisons

		Test	v	SE	z	p
OXYTOCIN	DINOPROSTONE	Log-rank	-60.88	5.41	-11.253	< .001
OXYTOCIN	MISOPROSTOL	Log-rank	-24.15	4.77	-5.067	< .001
OXYTOCIN	BALOON CATHETER	Log-rank	-36.73	6.09	-6.028	< .001
DINOPROSTONE	MISOPROSTOL	Log-rank	4.10	3.34	1.228	0.220
DINOPROSTONE	BALOON CATHETER	Log-rank	20.11	5.17	3.886	< .001
MISOPROSTOL	BALOON CATHETER	Log-rank	3.98	4.01	0.992	0.321

Note. P-values are Bonferroni-corrected.

3.3 Factors associated with SVD

The rate of SVD with pregnant women exposed to different modes of labor induction was good in age group above 35 years, multigravida group, those exposed to oxytocin, those with comorbidities and those with fetal weight at range of 2500mg-4000mg. The comparison of rate difference within those different factors were statistically significant ($p<0.05$) except for gestation age which was not statistically significant as shown in Figure 4 below.

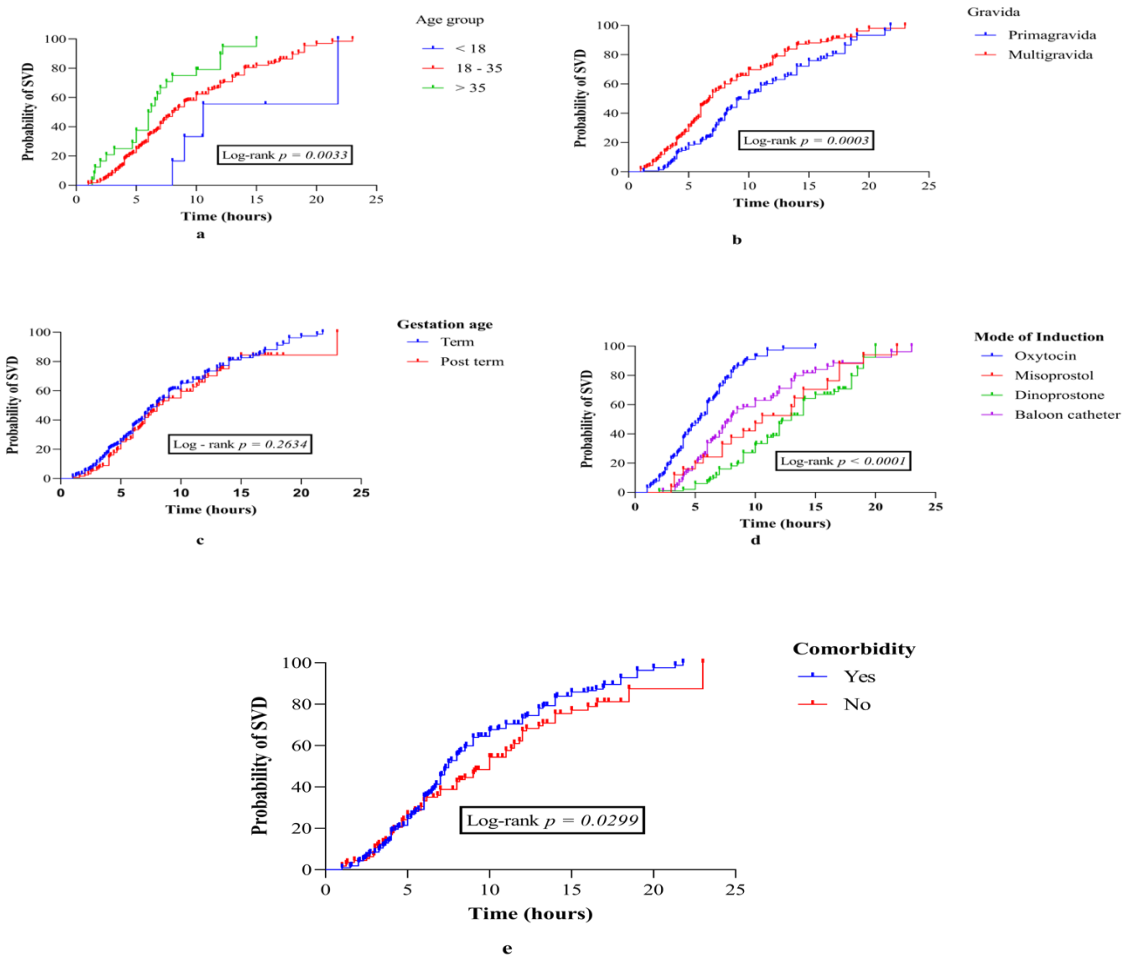

Figure 4: Shows the rate of SVD with factors as shown in figure a, b, c, d and e

3.4 Factors associated with SVD among pregnant women

Multivariate analysis showed an independent association of different factors that influenced SVD. These were gravida, comorbidities, and different induction modes, as shown in Table 4. Multigravida women were two times likely to have SVD compared to primigravida. Pregnant women with comorbidities were 1.47 times likely to have SVD compared to those with no comorbidities. Also, pregnant women induced with oxytocin were three times more likely to have SVD than those exposed to balloon catheters. Moreover, pregnant women exposed to dinoprostone were less likely by 42% to have SVD than those exposed to balloon catheters.

Table 4: Univariate and Multivariate analysis of the factors associated with SVD among pregnant women

	Univariate analysis			Multivariate analysis		
	c HR	95% CI	P - value	a HR	95% CI	P - value
Age in years	1.02	0.99 – 1.04	0.104	0.99	0.97 – 1.02	0.718
Gestational age						
Post term	0.87	0.67 – 1.12	0.273			
Term	Ref					
Gravida						
Multigravida	1.57	1.22 – 2.01	< 0.001	1.57	1.15 – 2.13	0.004
Primigravida	Ref					
Comorbidities						
Yes	1.33	1.02 – 1.73	0.034	1.47	1.11 – 1.95	0.007
No	Ref					
Mode of induction						
Oxytocin	3.04	2.19 – 4.21	< 0.001	3.13	2.25 – 4.36	< 0.001
Dinoprostone	0.53	0.37 – 0.74	< 0.001	0.58	0.41 – 0.84	0.003
Misoprostol	0.75	0.45 – 1.24	0.256	0.88	0.52 – 1.50	0.650
Balloon catheter	Ref					

Key: cHR: crude hazard ratio, aHR: adjusted hazard ratio, SVD: Spontaneous vaginal delivery

3.5 Neonatal intensive care admission

Among all pregnant women exposed to different modes of labor induction, 54 (17%) neonates were admitted for neonatal care in the neonatal ward. Out of all neonates admitted in the neonatal ward, most (36%) were from pregnant women exposed to dinoprostone. The least (3%) were from pregnant women exposed to oxytocin. The proportion of neonatal admission against different modes of induction at 95% CI was significant ($p<0.001$) as shown in Figure 6.

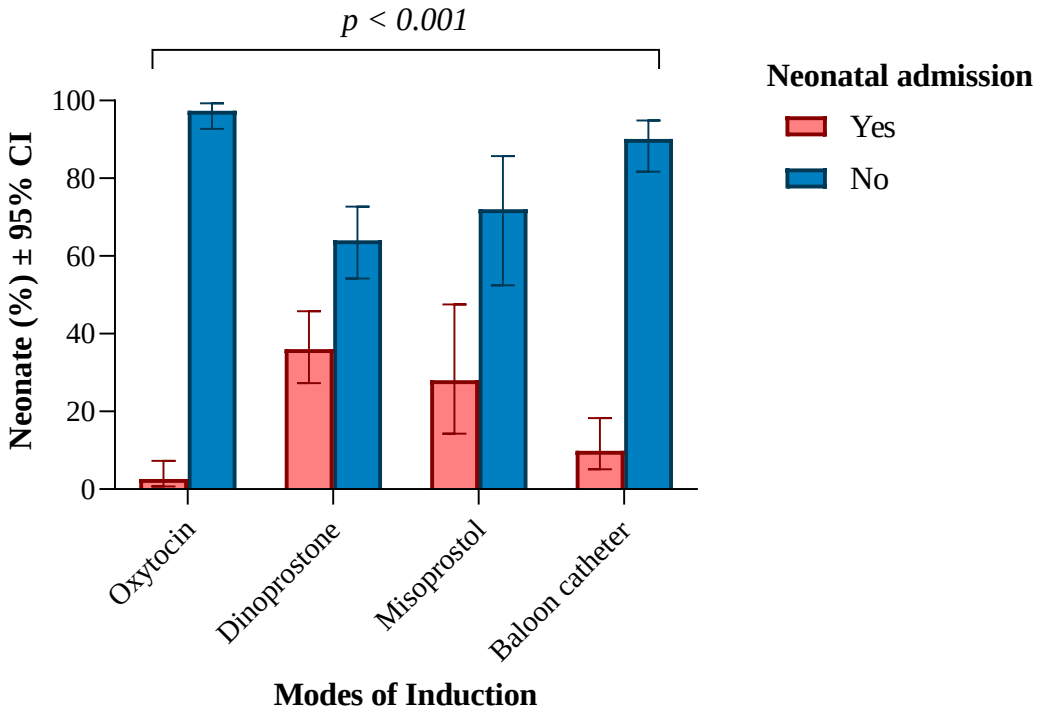

Figure 5: Proportion of neonatal admission after exposure to different modes of labor induction at referral hospital in Dar es salaam.

3.6 Neonatal outcome among pregnant women exposed to different modes of labor induction at referral hospital in Dar es salaam

Among all pregnant women exposed to different modes of labor induction, 70 (21.7%) neonates showed poor outcome. Poor neonatal outcome was observed with high proportion of low apgar score (<7 in 5min, 24), respiratory distress (28), and neonatal death (20) to group of pregnant women exposed to misoprostol. Neonatal outcome was good to those pregnant women exposed to oxytocin. Neonatal outcome among pregnant women exposed to different modes of labor induction was tested with chi-square test and show significance. Most of the babies who had the weight of 2500-3900mg with their mother mostly exposed to dinoprostone are the one who presenting with high proportional of poor neonatal outcome.

Table 5: Neonatal outcomes after exposure of the mother to different modes of labor induction

Variables	Mode of Induction				
	Oxytocin (%)	**Dinoprostone (%)**	**Misoprostol (%)**	**Balloon Catheter (%)**	**P-value**
APGARScore (5min)					
< 7	3 (2.6)	11 (11.0)	6 (24.0)	4 (4.9)	0.002
≥ 7	113 (97.4)	89 (89.0)	19 (76.0)	77 (95.1)	
Neonatal admission					
Yes	3 (2.6)	36 (36.0)	7 (28.0)	8 (9.9)	< 0.001
No	113 (97.4)	64 (64.0)	18 (72.0)	73 (90.1)	
Respiratory distress					
Yes	3 (2.6)	13 (13)	7 (28)	2 (2.5)	
No	113 (97.4)	87 (87)	18 (72)	79 (97.5)	<0.001
Neonatal death					
Yes	1 (0.9)	2 (2)	5 (20)	2 (2.5)	
No	115 (99.1)	98 (98)	20 (80)	79 (97.5)	0.001

3.7 Blood loss after exposure to different modes of labor induction at referral hospital in Dar es salaam

Pregnant women exposed to dinoprostone lost more blood (> 500mls) during delivery period compared to other pregnant women exposed to other modes of labor induction. Blood loss during the delivery was significantly different when women were exposed to different modes of labor induction ($p<0.001$) as shown in the figure below.

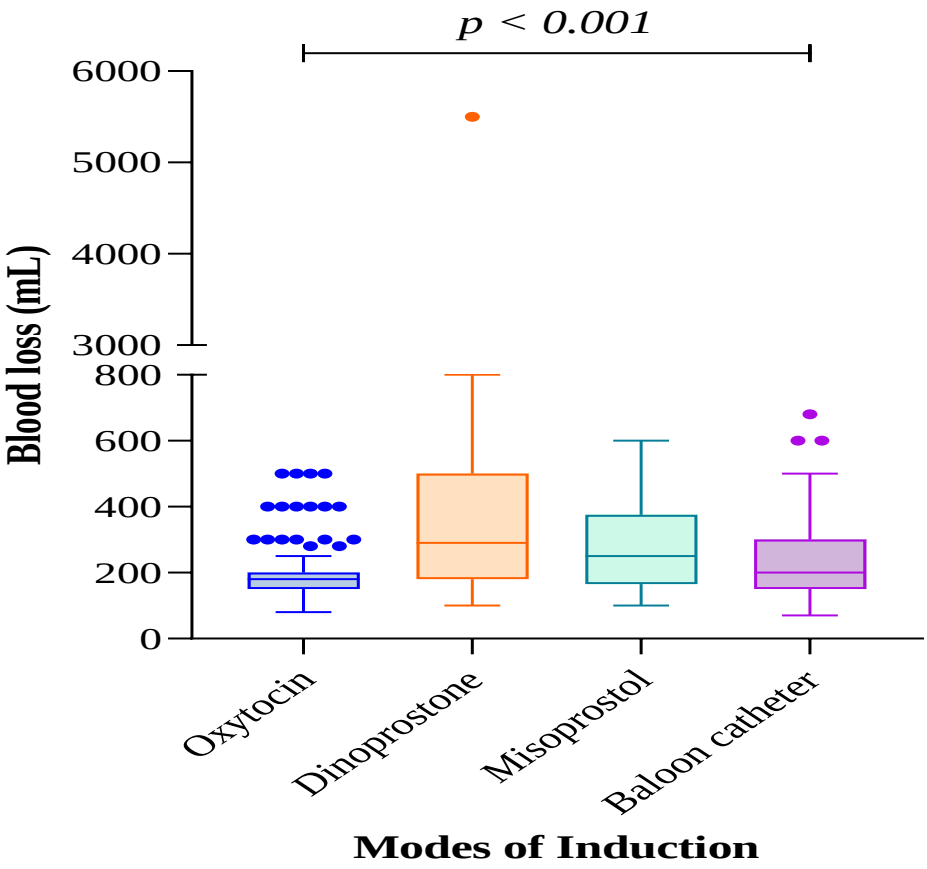

Figure 6: Blood loss after exposure to different modes of labor induction at referral hospital in Dar es salaam.

CHAPTER FOUR

4.0 DISCUSSION

In this study the aim was to find out the effective and safety modes of labor induction which can guide the medical practitioner to use the available modes with regards to their effectiveness and safety. Findings showed that participants exposed to oxytocin had shorter median time to SVD and had minimal maternal and neonatal adverse outcomes. This findings shows some similarities with other study for the fact that many participant exposed to oxytocin delivered the fetus with weight <2500mg(19).

The overall proportion of pregnant women who had SVD after exposure to different modes of labor induction was 82%. The study done by Onder et al. at Turkey also reported a high proportional of pregnant women with poor bishop score delivered vaginally with short median time from induction to delivery (20). Pregnant women exposed to oxytocin were three times more likely to deliver vaginally compared to those exposed to balloon catheters. The overall proportion of pregnant women failed after exposure to different modes of labor induction was low (18%) while in group exposed to oxytocin it was 5.2%.

The median time taken from induction to delivery was shorter in group of pregnant women exposed to oxytocin (5.42hours). The study done in Turkey and Italy showed similarities in shortest time from induction to SVD in comparison to dinoprostone, this results may also be due to bishop score of >=6, exclusion of comorbidities and fetal weight >=4500mg(20) (19).

Success of induction of labor can also be influenced by a number of factors. In our findings multigravida, comorbidities and modes of induction showed independent association with our primary outcome (SVD). Similar results were observed in a study conducted in South Sudan by Garang et al, which reported parity and modes of induction are independently associated with SVD (4).

Other study done on primigravida group with high rate of CS, comparing the effectiveness of the vaginal misoprostol 50mcg and oral dinoprostone 3mg reported that misoprostol at interval time of six hours are more effectively and safe compare to dinoprostone(12). Different clinical and obstetric characteristics reported in this study to affect SVD were also observed in another study in northern part of Tanzania (7)(16).

The outcome after exposure to these different four modes of induction labor found that, apgar score within five minutes, neonatal admission, respiratory distress, blood loss and neonatal death all are significantly different among all modes of labor induction. Pregnant women exposed to oxytocin had low risk of neonatal admitted in neonatal ward for care (3%). Also, the maternal outcome of those pregnant women exposed to oxytocin had low blood loss (<500mls) during delivery compared to other modes of labor induction used.

A study done by Ramya et al in India also showed similar results regarding poor outcome of induction after using dinoprostone in different population. This signifies that, there is a true relationship regarding the findings of our study on labor induction with different modes and safety among pregnant women and neonates (13). The study in China reported misoprostol is more efficient for induction with poor outcome compared to dinoprostone (21). Other study on different modes of labor induction showed some similarities on safety of neonatal after exposure to different modes of labor induction on proportional of neonatal admission after exposure to different modes of induction(3)(17).

Therefore, oxytocin showed significance in effectiveness and safety compare to other modes of labor induction and these results give a chance for further study on doses with large population around the country.

CHAPTER FIVE

5.0 LIMITATION, CONCLUSION AND RECOMMENDATIONS

5.1 Study Limitation

The study faced one major limitation, some pregnant women were induced at the site (Amana, Temeke and Mwananyamala) after complication were referred to MNH, so they were excluded from the study after reaching the labor ward this contribute to loss to follow-up. Also, bishop score was not measured as standard requirement before induction, which was a challenge to know if the pregnant women meet the criteria for induction as standard which also help to choose which modes of induction to use.

5.2 Conclusion

Oxytocin was more effectiveness and safe in inducing SVD with short median time and low poor maternal and neonatal outcome compared to other modes of induction. This findings were observed with pregnant women having different comorbidities (hypertension), different gestational age (term and post term), different gravidity (primigravida or multigravida) and different maternal weight.

5.3 Recommendations

Large cohort group should be studied to build evidence to policy maker and MoHCDGEC to consider oxytocin as first choice in guidelines for obstetrics and gynecology and advocate on its monitoring during usage. Further study can be done in dosage of oxytocin which show the effectiveness and safety to the population. The guidelines should state before any labor induction bishop score must be done and documented.

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APPENDIX

Appendix I Informed Consent (English Version)

TITLE: EVALUATION OF EFFECTIVENESS AND SAFETY OF PHARMACOLOGICAL AND MECHANICAL LABOR INDUCTION METHODS AMONG PREGNANT WOMEN ATTENDING PUBLIC REFERRAL HOSPITALS IN DAR ES SALAAM, TANZANIA

PRINCIPLE INVESTIGATOR: EMANUEL ERASTO

INSTTUTION: MUHIMBILI UNIVERSITY OF HEALTH AND ALIED SCIENCE

P.O. BOX 65001, DAR ES SALAAM

CONTACT: EMAIL e.erasto8@gmail.com

MOBILE NO; 0717062435

PURPOSE OF STUDY: You are being asked to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please read the following information carefully and ask the researcher if there is anything that is not clear or if you need more clarification.

The purpose of this study is to evaluate the effectiveness and safety of different modes of labor induction in referral hospitals in Dar es salaam.

The study seeks to answer the following questions:

i. What proportional of pregnant women, undergo spontaneous vaginal delivery after induction of labor with different modes within 24hours at labor ward?
ii. What proportional of time interval between induction of labor and delivery of pregnant woman after using different induction modes within twenty-four hours(24hrs)?

iii. What proportional of neonatal intensive care unit admission after labor induction within 24hours from labor ward?

iv. What factors, associate with failure of SVD/ caesarian section among pregnant women who were induced labor

STUDY PROCEDURES: You shall meet with the researcher/ research assistant for, assessment after reaching the labor ward for induction and data will be filled in case report form. All the information will be documented and kept in your file and used during management of complications in your respective clinic. Other information will be collected from your medical file

RISKS: We do not expect that any harm will happen to you because of joining this study. Sometimes a minimal pain may occur during insertion of dinoprostone or misoprostol vaginally.

BENEFITS: If you agree to take part in this study, will benefit by knowing the result after being exposed to any modes of labor induction. Data obtained on evaluation of the effectiveness and safety of different modes of labor induction to pregnant mother at term will be used to improve services to pregnant mother to those facilities and Tanzania at large. CONFIDENTIALITY; For the purposes of this research study, your comments will not be anonymous. Every effort will be made by the researcher to preserve your confidentiality including the following:

- Assigning code numbers for participants that will be used on all research notes and documents

- Keeping notes, case report form, and any other identifying participant information in a locked file cabinet in the personal possession of the researcher.

Participant data will be kept confidential except in cases where the researcher is legally obligated to report specific incidents.

CONTACT INFORMATION: If you have questions at any time about this study, or you experience adverse effects as the result of participating in this study, you may contact the researcher whose contact information is provided on the first page. If you have questions regarding your rights as a research participant, or if problems arise which you do not feel you can discuss with the Primary Investigator, please contact the Institutional Review Board through +255 022 2152 489, drp@muhas.ac.tz, also you can contact the supervisor Dr. Ritha Mtagonda at +255713816481 or e-mail rittdavisrida@yahoo.com

VOLUNTARY PARTICIPATION: Your participation in this study is voluntary. It is up to you to decide whether or not to take part in this study. If you decide to take part in this study, you will be asked to sign a consent form. After you sign the consent form, you are still free to withdraw at any time and without giving a reason. Withdrawing from the study will not affect the treatment and care at the facility. If you withdraw from the study before data collection is completed, your data will be returned to you or destroyed.

CONSENT: I have read and I understand the provided information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this study.

Participant's signature _____ Date _____

Investigator's signature _____ Date _____

Appendix II Consent Form (Swahili Version)

Fomu ya utoajiidhini

TAFITI: KUFUATILIA UTENDAJI KAZI NA USALAMA WA NJIA ZILIZOPO ZA KUMUANZISHIA UCHUNGU MAMA MJAMZITO KATIKA HOSPITALI ZA SERIKALI ZA RUFAA DAR ES SALAAAM, TANZANIA

MTAFITI MKUU: EMANUEL ERASTO

TAASIS: CHUO KIKUU CHA AFYA NA TIBA SHIRIKISHI MUHIMBILI

Baruapepe: e.erasto8@gmail.com

Namba ya simu: +255717062435

Ndugu mshiriki,

Unaombwa kushiriki kwenye utafiti.

Kabla hujaamua kushiriki ni muhimu ukajua sababu za kushiriki na mambo yatakayohusiana na utafiti. Tafadhari soma taarifa zifuatazo kwa makini na kisha umuulize mtafiti kama kuna jambo ambalo utakuwa hujalielewa ili upate ufafanuzi. Dhumuni la utafiti huu ni kufuatilia utendaji kazi na usalama wa njia zilizopo za kumuanzishia uchungu mama mjamzito anapofikia wakati wa kujifungua katika hospitali za rufaa Dar es salaam.

Utafiti huu utasaidia kujibu maswali yafuatayo:

i. Nisehemu gani ya kina mama wajawazito waliofikia kipindi cha kujifungua walipotumia njia tofauti zilizopo walijifungua kwa njia ya kawaida ndani ya saa 24?
ii. Nisehemu gani ya muda ilipita tangu kina mama wajawazito walipotumia njia tofauti zilizopo kuanzisha uchungu mpaka kujifungua kawaida ndani ya saa24?
iii. Nisehemu gani ya Watoto waliozaliwa na wamama wajawazito waliotumia njia tofauti zilizopo kuanzishia uchungu walihitaji uanaglizi maalumu baada ya kujifungua ndani ya saa24?

iv. Ni vitu gani humpelekea mama mjamzito aliyetumia njia za kumsaidia kupata uchungu aweze kujifungua kawaida kushindwa?

TARATIBU ZA UTAFITI: Utakutana na mtafiti mkuu/msaidizi kwa ajili ya mahojiano na uchunguzi wa awali wakati wa uwekewaji wa dawa ya uchungu ufikapo wodi ya kujifungulia.

Taarifa zako zingine zitachukuliwa kwenye jalada lako la matibabu. Matokeo yako baada ya kutumia njia yoyote ya kuanzisha uchungu yatawekwa kwenye jalada lako la matibabu ili kusaidia kukupatia huduma baada ya kujifungua wewe na mtoto.

ATHARI ZA KUSHIRIKI KWENYE UTAFITI: Hakuna athari zozote utakazopata kwa kushiriki kwenye utafiti huu, isipokuwa maumivu kidogo sehemu za ukeni wakati wa kuwekewa dawa ya uchungu.

FAIDA ZA KUSHIRIKI KWENYE UTAFITI: Taarifa zitakazopatikana kutokana na utafiti huu, zitasaidia kuboresha huduma kwa kina mama wajawazito waliofikia wakati wa kujifungua kwenye hospitali za rufaa zilizopo Dar es salaam na taifa kwa ujumla.

SIRI

Kwa manufaa ya utafiti huu, taarifa zako hazitakuwa na jina. Pamoja na hayo, juhudi zitafanywa na mtafiti kutunza siri zakoikiwemo kufanya yafuatayo:

- Kuweka namba maalumu ya mshiriki ambayo itatumika kwenye nyaraka na kumbukumbu zote za utafiti.

- Kuweka maandishi, tafsiri za usaili, na taarifa zinginezo za mshiriki kwenye jalada lilofungwa kwenye kabati inayoweza kufikiwa na mtafiti pekee.

- Taarifa za mshiriki zitatunzwa kwa siri, isipokuwa pale itakapohitajika kisheria kutolea taarifa jambo mojawapo.

  KWA MAWASILIANO: kama una swali lolote na muda wowote kuhusu utafiti huu, unaweza kuwasiliana na mtafiti mkuu kwa namba za mawasiliano zilizowekwa

kwenye ukurasa wa kwanza. Ikiwa una maswali juu ya haki zako kama mshiriki, au kama kuna shida imejitokeza na unaisi huwezi kujadili na mtafiti, tafadhari wasiliana na bodi ya taasisi inayoratibu na kusimamia tafiti (IRB) kwa namba zifuatazo: +255 022 2152 489, drp@muhas.ac.tz, pia waweza kuwasiliana na msimamizi wa utafiti Dr. Ritha Mtagonda katika namba +255713816481 au barua pepe rittdavisrida@yahoo.com.

KUSHIRIKI KWA HIARI: Kushiriki kwenye utafiti huu ni hiari. Una uhuru wa kuamua kushiriki ama kutokushiriki kwenye utafiti huu. Kama ukiamua kushiriki kwenye utafiti huu, utaweka sahihi yako kwenye fomu ya utoaji wa idhini (informed consent form**).** Hata kama utakuwa umeshajaza fomu ya utoaji wa idhini ya kushiriki, unayo nafasi ya kujitoa wakati wowote hata bila kutoa sababu ya kufanya hivyo. Kujitoa kwenye utafiti, hakutaathiri **tiba wala huduma uliyostahili kupatiwa katika kituo.** Ukijitoa kwenye utafiti kabla zoezi la kukusanya taarifa halijakamilika, utapewa taarifa zako ama zitaharibiwa.

IDHINI: Nimesoma na kuelewa taarifa nilizopewa na kupata nafasi ya kuuliza maswali. Nafahamu kuwa ushiriki wangu ni wa hiari, na kwamba nipo huru kujitoa wakati wowote bila kutao sababu na bila gharama zozote. Nafahamu kuwa nitapewa nakala ya fomu hii ya idhini ya kushiriki. Nakubali kwa hiari kushiriki kwenye utafiti huu.

Sahihi ya mshiriki_____ Tarehe _____

Sahihi ya mtafiti _____ Tarehe _____

Appendix III Case Report Form

DEMOGRAPHIC AND OBSTETRICS DATA

ID number…….

Age……

BMI……...

Weight……

Marital status…….

Contact……...

Cash/credit……

Parity…….

Gestation age……

Gravida……..

LMP…….

EDD……..

MODE OF INDUCTION

Pharmacologically……

Mechanical……...

hyperstimulation…….....

MATERNAL OUTCOME

Blood loss……

Uterine

Other…….

ANTENATAL RISK FACTOR

None……

Gestational diabetes……

Hypertension……..

Anemia……

Malaria……

Other……

NEONATAL OUTCOME

Gender……

Fetal weight…….

Apgar score……

Respiratory distress(yes/no) …….

Neonatal admission for special care…….

CESAREAN SECTION (yes/no)

Reasons; Fetal distress……

Failed induction……

Previous CS (yes/no) ……..

PARAMETER

Pre-induction bishop score……..

Bishop score change 12hrs……..

Induction to active labor onset…….

Induction to delivery…….....

Vaginal delivery……...