

**BIRTH OUTCOMES AFTER A PREVIOUS CESAREAN SECTION: AN
OBSERVATIONAL CROSS-SECTIONAL STUDY IN BOMET COUNTY**

KENYA

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**A Thesis Submitted to the Institute of Postgraduate Studies of Kabarak University
in Partial Fulfillment of the Requirements for the Award of the Master of Medicine
in Family Medicine**

KABARAK UNIVERSITY

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DEDICATION

In loving memory of my mother, the late Jane Lamweya Lahalwa.

ABSTRACT

To curb the increasing cesarean section (CS) rates, a trial of labor after cesarean section (TOLAC) is recommended for women who have had one prior CS. However, TOLAC success rates from different regions are highly variable—with most available data originating from developed countries. Success rates in most low-resource countries, particularly those in Africa, remain largely unassessed. Data on TOLAC successes and risks is important to inform the selection of candidates likely to achieve a successful TOLAC, especially in low-resource settings. Thus, this study evaluated TOLAC success rates, associated outcomes, and factors associated with success/failure of TOLAC in Bomet County, a low-resource setting in Kenya. The study adopted a prospective observational cross-sectional approach to characterize the outcomes of TOLAC. The primary maternal and neonatal outcomes were compared in women who had a vaginal birth after a cesarean section (VBAC) with those who had an emergency repeat cesarean section (ERCS) following a failed TOLAC in pregnant women who presented at Tenwek Hospital and Longisa County Referral Hospital in Bomet, Kenya from 21st October 2022 to 8th June 2023. In total, 170 women with one previous scar who presented to the two study centers were included in the study. The TOLAC success rate was 48.2% with the most common indications for emergency repeat cesarean section being failure to progress (34.1%) and non-reassuring fetal status (31.8%). Factors associated with successful TOLAC included inter-delivery interval >60 months (p=0.044), parity 2-4 (p<0.001) and previous vaginal delivery with focus on previous successful VBAC (p<0.001). Mal-presentation, in particular breech presentation, and non-reassuring fetal status (NRFS), as indications for previous cesarean section, were associated with a successful VBAC (p<0.001, 0.033). A birth weight of >3500g was associated with increased risk of ERCS. Moreover, a failed TOLAC was associated with a prolonged hospital stay of more than 4 days (p=0.012). Secondary outcomes considered in the study included both maternal and neonatal factors. For maternal outcome measures that were assessed; blood transfusion rate, delivery trauma, and maternal infection rates were at 6.5%, 11.8% and 9.4% respectively with no maternal mortality reported. For neonatal outcomes, neonatal death and NICU admission were at 2.9% and 15.3% respectively, with the most common indication for NICU admission being neonatal asphyxia and risk of sepsis. Altogether, these findings suggest that TOLAC remains a viable option with better outcomes if successful. However, TOLAC candidates should be evaluated based on the contextual factors of a given setting, hence careful patient selection is recommended to improve outcomes associated with TOLAC.

Keywords: *Emergency Repeat Cesarean Section (ERCS), Trial of Labour after Cesarean Section (TOLAC), VBAC.*

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ABBREVIATION AND ACRONYMS

ACOG	American College of Obstetrics and Gynecology
APGAR	Appearance, Pulse, Grimace, Activity & Respiration
ANC	Antenatal clinic
CPD	Cephalo-pelvic disproportion
CS	Cesarean section
CSR	Cesarean section rate
CTG	Cardiotocograph
ERCS	Emergency repeat cesarean section
EFW	Estimated fetal weight
IQR	Interquartile range
KAFP	Kenya Association of Family Physicians
KDHS	Kenya Demographic and Health Survey
KNBS	Kenya National Bureau of Statistics
LMIC	Low Middle Income Countries
LTUS	Low Transverse Uterine Scar
MOH	Ministry of Health
MMR	Maternal Mortality Ratio
NMR	Neonatal Mortality Rate
NRFS	Non-reassuring fetal status
NICU	Neonatal Intensive Care Unit
OR	Odds ratio
PRCS	Planned Repeat Cesarean Section
SDG	Sustainable Development Goal
TOLAC	Trial of labor After Cesarean section
UN	United Nations
UON	Unmet obstetric need
VBAC	Vaginal Birth after Cesarean section
WHO	World Health Organization

CONCEPTUAL AND OPERATIONAL DEFINITION OF TERMS

Asphyxia- Birth asphyxia, defined as the failure to establish breathing at birth demonstrated by APGAR score <7 at the 5th minute.

Birth Outcomes – Specific measurable indicators that assess the health and well-being of both the newborn and mother in the immediate perinatal period.

Cesarean Section Rate - The percentage of births achieved by cesarean section of total births regardless of the outcome.

Inter-Pregnancy Interval - Time in months between cesarean section in first pregnancy and the start of amenorrhea in next ongoing pregnancy.

Maternal and Fetal Complications – A record of any maternal and foetal health issues during pregnancy, labor, and delivery.

Neonatal Mortality- Neonatal death occurring within 28 days of life.

Perinatal Mortality- fetal deaths that occurs more than 20 weeks' gestation, which are also referred to as “stillbirth”.

Postpartum Infection - Infection that develops after the delivery of the neonate as described by temperature >38⁰ c, wound infection-purulent discharge, uterine tenderness, purulent lochia, extended antibiotic with elevated white blood cells and chorioamnionitis.

Previous Scar - Previous cesarean section

TOLAC - Planned attempt to deliver vaginally by a woman with a previous scar regardless of the outcome. (Trial of Labor After Cesarean section).

Unsuccessful TOLAC (ERCS) -Failure to achieve a vaginal birth after cesarean section in women undergoing a TOLAC and the delivery ending by “emergency” (unscheduled) cesarean section.

Unmet Obstetric Need - Refers to the difference between what the health care system should provide to deal with obstetric problems in a given population and the care it actually provides.

Vaginal Birth After Cesarean Section - Successful TOLAC, defined as spontaneous or instrumental (assisted by vacuum or forceps) vaginal delivery in a woman undergoing TOLAC. (Vaginal Birth After Cesarean).

Uterine Rupture - Separation of the entire thickness of the uterine wall with or without partial fetal extrusion in the abdominal cavity.

CHAPTER ONE

INTRODUCTION

This chapter introduces the study and highlights the research problem as synthesized from the cited literature. In addition, the objectives that guided the study and the research questions that were addressed are herein described.

1.1 Background to the Study

Cesarean section (CS) is a lifesaving surgical procedure when medically indicated. This procedure is the most common surgical operation performed in many Low Middle-Income Countries (LMIC) facilities. Therefore, optimizing CS is of clinical importance since both underuse and overuse often lead to higher maternal and perinatal mortality. Lower CS rates levels could indicate an unmet need for CS as an essential health care service which contributes to an increase in morbidity and mortality (Betran et al., 2021). A higher rate of more than the 10% as recommended by WHO is not associated with improved maternal and neonatal outcomes and may be associated with negative outcomes such as infections, and hemorrhage that burden both human and financial resources (WHO, 2015).

In the recent past, there has been a steady increase in the rates of CS both in developed and developing countries (Betrán et al., 2016; Barber et al., 2011). This increase continues to raise concerns of whether primary or repeat cesarean sections are necessary, with repeat cesarean section being the primary indication for most cesarean sections. The rise has been occasioned by several changes in the practice environment such as continuous electronic fetal monitoring, decrease in operative vaginal deliveries and a decrease in attempts to conduct breech vaginal deliveries (Goetzinger & Macones, 2008; Lee et al., 2008). The once-popular dogmatic mantra: “Once a cesarean section, always a

cesarean section” (Cragin, 1916) also had far-reaching consequences contributing to the increase in CS deliveries with associated morbidity and mortality.

WHO recommends that women with a previous cesarean scar who meet some set criteria can attempt a trial of labor as a way of reducing the rate of cesarean section (WHO, 1985, ACOG 2019). Trial of Labor after Cesarean section delivery (TOLAC) is the attempt to deliver vaginally after a cesarean section regardless of the outcome (ACOG, 2019). This offers women who desire to deliver vaginally that possibility. The set criteria to be considered for TOLAC include, one previous cesarean section, lower transverse uterine incision in the previous CS, cephalic presentation and no other uterine scar such as myomectomy (Lalonde, 2005). Additionally, the facility in which a woman with previous scar can attempt TOLAC should have resources to perform emergency repeat cesarean section (ERCS) within an appropriate period of time preferably within ten minutes of the decision. Such resources should include; a qualified clinician who is able to monitor labor and perform an ERCS, a clinician capable of administering obstetric anesthesia, nursing personnel to assist in the ERCS and a clinician capable of performing neonatal resuscitation should there be a need (ACOG 2019).

TOLAC may be considered successful following a successful vaginal birth after cesarean delivery (VBAC) and an intact uterine scar (Nkwambong et al., 2016). Among the benefits of TOLAC as highlighted by ACOG, 2019 include, avoidance of major abdominal surgery, lowered rates of thromboembolic events, and shorter recovery periods. Moreover, TOLAC offers a decreased risk of maternal consequences associated with multiple surgeries for women considering future pregnancies. Such maternal consequences may include hysterectomy, visceral injury, transfusion, infection and abnormal placentation. The decision to go through labor for women with a previous scar, however, depends on several factors ranging from medical and obstetric indications to

maternal preferences and the delivery settings (ACOG, 2019). Therefore, good candidates for TOLAC should be able to balance the risk associated with TOLAC with high chances of success and low risk as possible in order to optimize the positive outcomes.

The support of TOLAC by various organization shifted the paradigm and this led to an increase in VBAC rates from 5% to 28.3% by 1996. This increase was associated with an overall decrease in the world wide rate of CS from 22.8% in 1989 to 20% in 1996 (Flamm et al., 1990; Harer, 2002; Menacker et al., 2006). With the increase in TOLAC, however, there was a notable increase in the incidence of uterine rupture and other complications associated with TOLAC. This led to a decline in TOLAC rates for fear of litigations and some facilities actually stopped offering TOLAC (Lydon-Rochelle et al., 2001; Yang et al., 2009; Yap et al., 2001). Nevertheless, International health communities and several health organizations, including the National Institute of Health and ACOG, have stated that TOLAC is a reasonable option for women with one previous scar and called on organization to facilitate TOLAC access (ACOG, 2019; Bernstein, 1984).

The rate of CS in sub-Saharan Africa (SSA) has been steadily increasing with the current rate being 5.0% with a projection of a rise to 8% by 2030, which is still below the recommended WHO threshold (Betran et al., 2021). While the cesarean section rate (CSR) in SSA is low, its gradually increasing with a marked difference in the socioeconomic status (van der Spek et al., 2020). In Kenya, for instance, a national representative survey conducted in 2014 indicated that the CSR is at 2.4% among the poorest quartile and 19% in the richest quartile (KDHS 2014). Further, a remarkable difference between the public and private facilities is apparent. Notably in Kenya, the rate in public facilities is 11.6% while that of private facilities is at 19.7% (Yaya et al., 2018). This raises a concern of an unmet need for cesarean section among the low

socioeconomic while a notable overuse among those of high socioeconomic status is apparent. Underuse has been associated with increase in maternal and neonatal morbidity while overuse has not been associated with any increased benefit but may in the long run be associated with increased maternal morbidity especially in subsequent pregnancies (Betrán et al., 2018).

Sociodemographic factors play a major role in increasing rates of CS in many LMIC. Women with higher levels of financial resources and higher levels of education are more likely to have a cesarean delivery than those from low-resourced backgrounds with low levels of education (Harrison & Goldenberg, 2016). In low resource setting, frequent use of CS in tertiary facilities has been ascribed to unskilled primary care health workers who do not detect danger signs promptly hence delay in referral (Litorp et al., 2015). In addition, SSA countries face complex scenarios relating to women's mode of delivery with increased morbidity and mortality due to limited access to CS, unsafe provision of CS, and instances of overuse of CS which drain resources and adds to avoidable morbidity and mortality (Betran et al., 2021). In Kenya, for instance, the Maternal Mortality Rate (MMR) is 355 deaths per 100,000 live births; close to 250,000 mothers suffer from disabilities caused by complications related to childbirth per year. This MMR represents an average which may mask a greater problem as some marginalized counties in Kenya recorded as high as 1000 deaths per 100,000 live births (Prestinaci et al., 2015, MOH, 2017).

Both planned repeat cesarean section (PRCS) and VBAC are associated with risks including; hemorrhage with an increased need for blood transfusion, hysterectomy, and infection. (Hibbard et al., 2001). However, a successful uncomplicated VBAC is associated with decreased maternal morbidity in the current pregnancy and subsequent pregnancies compared to repeat CS. The morbidity and mortality risks are even higher

for both the mother and fetus if the repeat CS is performed as an emergency. Notwithstanding the less risks compared to ERCS, VBAC is still associated with an increase in neonatal morbidity and mortality compared to PRCS (Lehmann et al., 2019). As such, some authors argue that the success of TOLAC should be assessed not only by the ability of women to deliver vaginally but also by the neonatal and maternal outcomes (Wanyonyi & Ngichabe, 2014).

In order to enhance the safety of TOLAC, various professional bodies have developed best practice guidelines (ACOG, 2019; Lalonde, 2005). Some of the measures included: a single previous scar, previous low transverse uterine scar (LTUS), continuous fetal heart monitoring during TOLAC, and a facility capable of performing an emergency CS should the need arise. Most of these set criteria are barely met in resource-poor settings. A 2006 survey by the WHO indicated a critical shortage of healthcare workers with a deficit of approximately 2.4 million doctors, nurses and midwives with the greatest shortage noted in sub-Saharan Africa (SSA). This shortage has further been exaggerated by geographical mal distribution (Wakaba et al., 2014; WHO, 2006). The deficiency of skilled personnel compounded by a lack of important equipment (e. g. for continuous fetal monitoring) presents challenges on the access of TOLAC in SSA countries (Scott, 2014).

There are also challenges of record-keeping with access to operative records with information regarding the previous CS being often unavailable in most SSA facilities. Such information is critical is important in the selection of suitable TOLAC candidates. For example, due to the risks of uterine rupture, TOLAC may not be recommended when the incision type of the previous CS is unknown. Further, ACOG guides that TOLAC may not be a reasonable safe option for patients with a prior transfundal uterine incision and a prior uterine rupture (ACOG, 2019). Such operative history can only be available

where proper medical records keeping and maintenance systems are well established. Apart from patient management, medical records have been useful in TOLAC studies several of which have been retrospective.

Various observational studies have assessed the success rate of TOLAC, with the rate reported at 60-80% worldwide (Dodd et al., 2013). Wanyonyi (2010) has estimated the rate of vaginal birth to be between 54 and 97% in SSA. This success rate, however, varies with large margins in different setups. For instance, a retrospective study in Kiambu, Kenya, documented a TOLAC success rate of 50.7%, which is below that of developed countries (Musila et al., 2015). A separate study done at Pumwani hospital, Nairobi, Kenya, documented a success rate of 45.5% (Kimotho, 2009). Further research is needed to help understand the TOLAC success rate disparity in Africa while considering both maternal and neonatal outcomes.

This study, therefore, sought to assess the success rate of TOLAC and establish the maternal and fetal factors associated with successful TOLAC in women with one previous scar within the low-resource setting of Bomet, Kenya. Secondary maternal outcomes included hemorrhage requiring blood transfusion, postpartum infection, and death, while secondary neonatal outcomes included APGAR score, admission to NICU and neonatal death.

1.2 Statement of the Problem

Kenya's maternal and neonatal mortality rates are still very high, especially in rural areas lacking emergency services. With up to 90% of the countries in the world reporting a disruption of one or two essential services due to the COVID-19 pandemic (Sachs et al., 2021), the available emergency services in rural Kenya are undoubtedly further constrained. For every woman who dies, it is estimated that 20-30 others suffer severe

injury or complication related to childbirth and pregnancy— mostly due to preventable issues such as hemorrhage and sepsis (Reichenheim et al., 2009).

A pregnant woman with one previous scar can either deliver via PRCS or TOLAC depending on the patient's preference, indication and outcomes of the previous CS, and other factors associated with the current pregnancy. Both modes of delivery are associated with risks to both the mother and the neonate. However, ERCS is associated with worse outcomes than both PRCS and TOLAC(Hibbard et al., 2001). Careful selection of patients to undergo TOLAC should therefore be considered.

TOLAC is a common practice in the two study locations of Tenwek Hospital and Longisa County Referral Hospital. Approximately 300 women with previous scars attempted TOLAC in 2020. The available documentation for 2020 did not specify failed TOLAC attempts versus PRCS. Therefore, there is a need to generate local data to guide the practice of offering TOLAC based on maternal and perinatal outcomes.

1.3 Justification of the Study

Kenya suffers from notably high maternal and neonatal mortalities. Maternal and neonatal mortalities are estimated at 355 deaths per 100,000 live births and 22 deaths per 1000 live births, respectively (MOH, 2017). This represents a concerning disparity, when compared to the United Nations' Sustainable Development Goal number three, which was set to reduce maternal mortality and improve maternal care by 2030. SDG goal 3 recommends a target of no higher than 70 maternal deaths per 100,000 live births (UN General Assembly, 2015; WHO, 2016; Solberg, 2015). Most of this morbidity and mortality is due to preventable causes such as hemorrhage and infection. Pregnant women with previous cesarean scar have an increased risk of developing complications

compared to women with no previous scar. As such, selection of the mode of delivery should be considered based on a careful risk/benefit analysis.

While TOLAC is a common practice in the two referral hospitals selected for this study, there have been no studies in the region that have assessed the outcomes of TOLAC. To address this lack of data, this study was designed to assess the success rate of TOLAC. The factors associated with successful TOLAC and identification of maternal and neonatal outcomes in the two referral hospitals of Longisa County Referral Hospital and Tenwek Hospital in Bomet County, a rural county in South-Western of Kenya were also described. Overall, the study provides a glimpse into the safety and risks associated with TOLAC.

1.4 Objectives of the Study

1.4.1 Primary Objective of the Study

To determine the success rate of TOLAC at Tenwek Hospital and Longisa County Referral Hospital from 21st October 2022 to 8th June 2023.

1.4.2 Specific Objectives of the Study

- i. To describe the factors associated with successful TOLAC at Tenwek and Longisa County Referral hospitals from 21st October 2022 to 8th June 2023.
- ii. To describe the maternal complications associated with TOLAC at Tenwek and Longisa County Referral hospitals from 21st October 2022 to 8th June 2023.
- iii. To describe the perinatal complications associated with TOLAC Tenwek and Longisa County Referral hospitals from 21st October 2022 to 8th June 2023.

1.5 Research Questions

- i. What is the success rate of TOLAC at Tenwek and Longisa hospitals?
- ii. What factors are associated with successful TOLAC at Tenwek and Longisa hospitals?
- iii. What are the maternal complications of TOLAC at Tenwek and Longisa County Referral hospitals?
- iv. What are the neonatal complications of TOLAC at Tenwek and Longisa County Referral hospitals?

1.6 Significance of the Study

Although there are several studies addressing TOLAC and VBAC outcomes, their scope has mainly represented urban areas and tertiary institutions with presumably well-equipped units that have the capacity to perform immediate cesarean section and monitor intrapartum reliably. Therefore, the data from this study which focuses on a resource-limited environment, are an important contribution to the TOLAC and VBAC literature which is lacking research in this setting. Additionally, most studies regarding TOLAC and VBAC outcomes are retrospective; so they may not accurately estimate TOLAC risks. Moreover, poor record-keeping limits the reliability of retrospective reviews in each study's local settings.

To overcome the poor recording limitations, this study undertook prospective data collection. Observations included maternal and perinatal outcomes that may be affected by the mode of delivery, as well as factors related to the success of a trial of labor resulting in vaginal birth. These data will help guide patient selection for TOLAC and aid in appropriate counseling of patients on their preferred mode of delivery.

1.7 Scope of the Study

According to the KDHS report in 2019, Bomet County had an estimated population of 875,689 people. About 22% of this population is comprised of the women of reproductive age group 15-49 years. It is a rural community whose major source of income is farming. This study focused on women aged 15-49 years presenting to the two major referral facilities in Bomet County with one previous scar and no obvious contraindication to TOLAC. These two hospitals are the main referral facilities in the county, and both have the resources and capacity to offer emergency cesarean section.

1.8 Study Limitations

A number of limitations were noted during the study. Firstly, the study did not collect information on postnatal hemoglobin (Hb) level to be able to get the change difference (delta) in the pre- and post-delivery Hb levels as a marker of blood loss. Changes in Hb may be a more objective measure of the severity of post-partum hemorrhage than estimated blood loss, which was used in this study. The delta Hb level measure is routinely performed at Tenwek hospital but not in Longisa hospital. Hence, using the delta Hb level measure would have led to incomplete data from Longisa hospital dataset. However, the women who actually required blood transfusion were assessed using the vital signs and patient's signs and symptoms from both hospitals. Secondly, the patient's perception of the care received during the birthing experience was not taken into consideration in this study.

The patient's perception is useful in understanding her experience and concerns. This would have helped in assessing patients' satisfaction as part of improving holistic care. However, since this was entirely an observational study, the patients were only interviewed at admission for biodata, obstetric history and consent. Future studies can

consider post-delivery interviews to assess patients' satisfaction. Thirdly, this study was not adequately powered to assess maternal mortality. This is because mortality is a rare occurrence and would have required a large sample size to detect association.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

The practice of TOLAC has received significant coverage in literature from several studies throughout the world. However, most of these studies were conducted in urban centers and tertiary facilities—with most TOLAC studies in Kenya being retrospective in design. This chapter is a synthesis of literature on TOLAC practices and associated outcomes with a highlight of the available knowledge gaps.

2.2 General Overview on Literature Review

Cesarean section (CS) is the most common surgical procedure in low-middle-income countries (LMIC). The procedure is a lifesaver when medically indicated and helps avert both maternal and neonatal mortality. In 1916, Cragin delivered an address entitled “Conservatism in Obstetrics”, in which he coined the phrase “once a cesarean, always a cesarean”. In most of the 20th century, clinicians followed this dogma leading to a steady rise in the Cesarean section rate (CSR). Factors responsible for the rise in cesarean section in part are due to safe anesthesia, advances in operative technology, and safe blood transfusion services (Gupta et al., 2014). Nevertheless, classic CS with vertical incision extending to the fundus was associated with increased uterine rupture with increased maternal morbidity and mortality hence persistence of Cragin’s dogma (Parveen et al., 2022).

The introduction of transverse lower uterine segment incision reduced the risk of uterine rupture and maternal morbidity significantly. Overall, the increase in relative safety of CS has consequently led to an increase in ‘CS on demand’ with additional factors including: advanced maternal age, increased rates of obesity, medical disorders and

utilization of assisted conception technologies (Pearson & Shoo, 2005). The CSR at a population level signifies the level of access to this life saving intervention and may serve as a composite indicator for quality of care especially in areas where the perinatal/maternal mortality are still high (Gichangi et al., 2001; Echoka et al., 2014). However, observations over the years by the international health community noted that a CS rate above the 10-15% range is not associated with improved maternal and neonatal outcomes (WHO, 1985; Bernstein, 1984).

Worldwide, an estimated 3.2 million lifesaving CS do not happen especially in the LMIC whereas 6.2 million unnecessary CS happen in the most of the middle and high income countries (Kranti et al., 2019). The disparity raises a concern of overuse and underuse of CS both of which are driven by various factors including health care policy, health care financing, perception of care professionals, socioeconomic status, trust in health care systems and patients' preference (Boatin et al., 2018; Kranti et al., 2019; McCall et al., 2021). Both underuse and overuse of CS have adverse effects on both the mother and the neonate. As with any surgery, CS is associated with both short and long term complications which may extend to years beyond the current pregnancy with detrimental effect to both the mother and the neonate as well as future pregnancies (Betran et al., 2016; Makinde et al., 2020). Specifically, CS increases the risk of abnormal placentation in future pregnancies, and women with at least one previous scar have 2.6 times risk of placenta previa in subsequent pregnancies—with the risk intensifying with the increase in number of cesarean sections (Maroyi et al., 2021). In addition to the increased morbidity associated with cesarean section, cesarean section is also associated with increases in financial burden in developing countries (Parveen et al., 2022).

In a bid to reduce the rate of CS, the United States' National Institute of Health, during a consensus development conference in 1980, made a recommendation in favor of

TOLAC—citing that this is a reasonable option of delivery in women with one previous scar. This recommendation challenged the dogmatic mantra by Cragin (Bernstein, 1984). A new phrase was coined; “once a cesarean section, always a hospital delivery and twice a cesarean section preferably a cesarean section” (Pradhan et al., 2018). For close to thirty years, TOLAC has been offered as a delivery option in women with a previous cesarean section (Guise et al., 2010). TOLAC recommendations have been driven in part by the increasing rate of cesarean section worldwide (Vogel et al., 2015).

However, concern for maternal and perinatal safety with the rising incidence of uterine rupture has challenged the choice of TOLAC, leading to a reduction of TOLAC for fear of litigation (Habak & Kole, 2020; Rossi et al., 2008). Although the incidence of uterine rupture in women with previous scars varies across the countries, it is higher in the LMIC, as noted in WHO Multi-Country Survey on Maternal and Newborn Health (WHOMCS) (Motomura et al., 2017). The incidence rate ranges from 0.1% in developed countries to 2.5% in developing countries, with Kenya being reported at 0.8% (Motomura et al., 2017). It is estimated that 14-33% of women with uterine rupture will have hysterectomy done with close to 2.8% perinatal mortality (Guise et al., 2010).

Whereas both PRCS and TOLAC are associated with potential risks and benefits to both the neonate and the mother, ERCS, however, poses a greater risk of mortality and morbidity to both the neonate and the mother (Hibbard et al., 2001). Thus, decision making regarding the choice of TOLAC or PRCS should take into consideration various factors such as patient’s personal preference, the obstetric history, data on the risks and benefits of TOLAC and availability of TOLAC the delivery setting. Indeed, TOLAC is considered a reasonable option for many pregnant women with one prior lower transverse uterine scar (LTUS), with success rates commonly quoted at 70% (Rossi et al., 2008). Therefore, the goal should be to empower the woman with a previous scar to

make an informed decision regarding the mode of delivery (Biraboneye et al., 2017). This should incorporate an evidence-based approach into the decision-making process, taking into consideration individualized risk assessment (NIH, 2010). Nevertheless, in view of using TOLAC to curb the rising rate of CS, the WHO still emphasizes that efforts should be made to ensure that CS is available for all women who are in need rather than focusing on a specific rate (Betran et al., 2016). Hence, careful consideration in selecting patients to whom TOLAC is offered is recommended (ACOG, 2019).

2.3 Successful VBAC

Since the risks of VBAC are tied to the failure of TOLAC, the prediction of a successful VBAC is inherent in the decision-making process (Zhang et al., 2020). Various factors have been associated with successful VBAC including: history of previous vaginal delivery, non-recurring indications for previous CS such as mal-presentation or non-reassuring fetal status (NRFS), rupture of membranes at admission, maternal age of less than 40 years, birth weight of less than 4000g, spontaneous labor and a favorable Bishop score at admission. On the other hand, some of the factors associated with TOLAC failures include the history of stillbirth, history of shoulder dystocia, the inter-delivery interval of less than twenty-four months, obesity, gestation of more than 40 weeks, presence of meconium, malposition and recurring indication for previous CS such as prolonged second stage of labor, poor labor progress which may indicate cephalopelvic disproportion (CPD) (Birara & Gebrehiwot, 2013; Kimotho, 2009).

There have been attempts to develop VBAC calculators that take into consideration factors in labor that can guide successful predictions of a TOLAC. However, the VBAC calculators may not be accurate and may overestimate the likelihood of successful VBAC in some instances (Kawakita & Yasukawa 2020). Furthermore, some models

require information on previous CS, such as indication and location of prior uterine incision, which may not be available. Other modalities that have also been suggested to predict patients with a higher likelihood of having successful VBAC include clinical pelvimetry and estimated fetal weight (EFW), which may also be inaccurate (Trojano et al., 2019). Estimated fetal weight (EFW), for instance, of more than that of the previous pregnancy of which a CS was done is associated with increased incidence of ERCS with EFW of greater than 4000g associated with increased risk of uterine rupture, ERCS, dystocia and 3rd and 4th degree perineal tears. Notably, however, third trimester ultrasound are poor predictors of macrosomia and may not, in isolation, be reliably used in decision making regarding TOLAC (Trojano et al., 2019).

Failed operative vaginal delivery in previous pregnancy is associated with lower rates of VBAC, however, certain studies have indicated that this is not an absolute contraindication to TOLAC as success rates have been noted to be close to 80% (Birara & Gebrehiwot, 2013). Clinically adequate pelvis has been associated with increase chance of successful VBAC with a recommendation of X-ray / MR pelvimetry as an assessment tool (Anikwe et al., 2021; Franz et al., 2017; Harper et al., 2013; Xing et al., 2019). While clinical pelvimetry is frequently used to assess women with a higher probability of VBAC, this assessment has not been found to be highly predictive of VBAC (Ceni et al., 2021; Guise et al., 2010). Institutional factors may also influence the success rate of TOLAC. Hence, combining all these factors may help increase the estimation accuracy (Liao et al., 2020).

2.4 TOLAC Safety Enhancement

To optimize the safety of TOLAC, several professional bodies have insisted on adherence to stringent criteria in patient selection and intrapartum care of patients who

opt for TOLAC. The criteria include a previous low transverse uterine incision, non-recurring indication for previous CS such as non-reassuring fetal status (NRFS), and no contraindication to vaginal delivery such as placenta previa and mal-presentation. The guidelines also recommend that delivery takes place in an institution capable of offering emergency CS (within 10 minutes of the decision), with continuous electronic fetal monitoring and adequate staffing for constant monitoring of progress, emergent obstetric anesthesia, and neonatal resuscitation (ACOG, 2019; Clinical & Guidelines, 2005). Despite having clear guidelines for TOLAC, the evidence on the effect of VBAC rates is still unclear since the safety of TOLAC has been informed by observational studies (Catling-Paull et al., 2011). Bearing in mind the heterogeneity of health care delivery, one cannot use the findings of one institution to inform the practice of the other (Wanyonyi & Muriithi, 2015). As such, the lack of randomized controlled trials poses an uncertainty towards the benefits and harm of TOLAC as compared to PRCS (Dodd et al., 2013).

A preference cohort study by Crowther et al. (2012) that included a small nested randomized design to compare the risks and benefits of TOLAC against PRCS indicated that PRCS was associated with a lower risk of fetal and neonatal mortality and other serious morbidities. The study also showed a lower risk of major hemorrhage in the PRCS group. These findings echoed the Canadian Perinatal Surveillance System, which reported an increased relative risk but a low absolute rate of severe maternal morbidity and mortality in the TOLAC group compared to PRCS (Young et al., 2018). This study notably contradicts several other studies that indicate VBAC is associated with a decrease in maternal and neonatal morbidity and mortality (Lehmann et al., 2019). In their expert opinion, Wanyonyi & Ngichabe, (2014) recommend that the success of

TOLAC be measured by the ability of the mother to not only deliver vaginally but to deliver a healthy baby without complications in the puerperium.

2.5 TOLAC Socioeconomic Determinants

Studies in LMIC have shown a much lower success rate ranging from 27.4% to 53.6% (Agarwal et al., 2007). Some of the reasons postulated for this low rate include; delays in access to healthcare services, lack of personnel, lack of constant availability of operating rooms in cases of emergency, poor record-keeping, unavailability of painless labor, and unknown details of indication and type of previous cesarean section (Thapsamuthdechakorn et al., 2018). In Kenya, currently, there is no consensus on management and preferred route of delivery among women with one previous scar. The practice has been influenced mainly by women's preferences, outcomes of previous CS, and institutional incidence of scar dehiscence or uterine rupture (Koigi-Kamau et al., 2005).

Women preferences on their chosen mode of birth delivery have been associated with their socioeconomic status. However, some women may simply be restricted by barriers due to geographical, financial or cultural factors. A previous study identified higher social class, higher family income, and visit to a private practitioner as key three determinants that increased the risk of women declining VBAC in Hong Kong (Pang et al., 2009). Another study in Ethiopia reported a threefold likelihood of successful VBAC in women who live in rural areas than those who living in urban areas (Dereje et al., 2022). However, the preference differences between rural and urban areas may not necessarily be a simple matter of income and social class. In their systematic review and meta-analysis, Mekonnen & Asfaw(2023) have ascribed the rural and urban differences to be due to women in rural areas fearing surgery and their lifestyle. Arguably, the rural and

urban differences may also be due to issues of equity and access to TOLAC services which are a challenge in most resource-limited remote settings. Attanasio & Paterno (2021) have also examined the question of ethnicity/race that may compound decision-making processes that lead to differences in TOLAC and VBAC correlates. In general, socioeconomic determinants need to be understood in their context in the different TOLAC settings with an aim of ensuring equitable access and fostering informed decision making to both the patient and service provider after a prior cesarean section (Attanasio & Paterno, 2021).

2.6 The Economic Cost of TOLAC

The decision to undergo TOLAC or PRCS has important economic implications. This understanding is crucial in order to maximize health outcomes and the proper stewardship of limited resources (Rogers et al., 2017). In general, most studies have found virginal birth to be cheaper to the health system than cesarean sections owing to the surgical intervention in the former that may also profoundly impact women's health related quality of life (Fawsitt et al., 2013). The costing of TOLAC and PRCS delivery is not straightforward as it goes beyond the hospital charges that are passed on to the patient as the cost of care. Nevertheless, economic evaluations based on cost-effective analysis (CEA) have shown TOLAC to be substantially less expensive than PRCS (Fawsitt et al., 2013). Wymer et al. (2014) have further demonstrated the cost-effectiveness of TOLAC accrues with subsequent deliveries based on sensitivity analyses.

2.7 Critical Gaps in TOLAC Literature

To address all the aforementioned TOLAC safety concerns, there is a need to generate knowledge that is context specific to the low-resource settings focusing on both maternal

and neonatal outcomes. An understanding of TOLAC in diverse settings and populations is anticipated to resolve issues of contention and non-consensus, including the appropriate selection of patients for TOLAC, management and the preferred route of delivery among women with one previous scar.

To date, the decisions relating to labor management during TOLAC remain largely subjective thus necessitating high-quality evidence to guide TOLAC practice in various settings. For example, although augmentation of labor can increase the chances of successful TOLAC, labor augmentation has been associated with increased risks of uterine rupture and dehiscence (Zhang et al. 2021). Therefore, augmentation requires precise evidence data that would be useful for optimizing the processes. This includes, dosage, timing, and duration of augmentation in different clinical scenarios. Such precise data is not well established in literature.

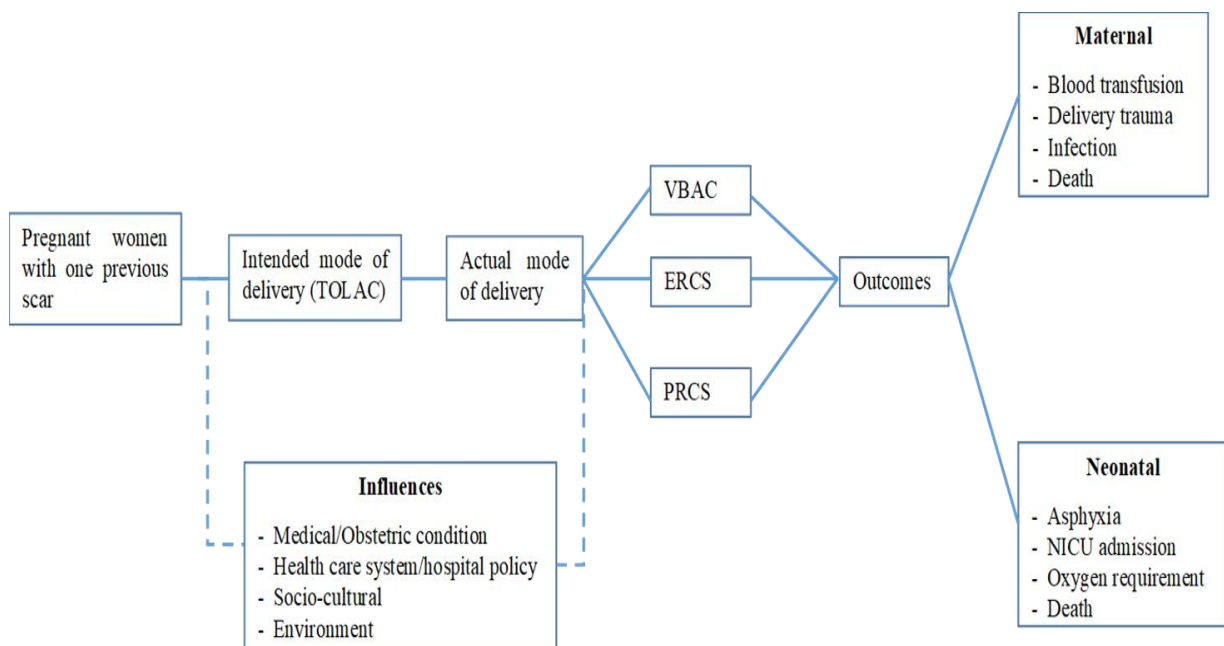
Another critical literature gap is the understanding of women's preferences regarding the different birth delivery options available to them. In a TOLAC gap analysis and quality improvement initiative, Delpero et al., 2021 highlight patient consent to be among the important areas for quality improvement. While international standards and TOLAC guidelines recognize patients' consent as among the important steps in optimizing patient-centered evidence-based care, the preferences and values of patients have not always been considered as evidenced by scarcity of literature on the subject (Kaimal et al., 2010). Hence, there is a need to understand how to communicate TOLAC risks while accommodating the patient preferences for shared obstetrical decision-making. Such understanding should be within the context of the different, social, economic and cultural settings. Ultimately, this understanding will be helpful in developing guidelines from the national level through the ranks to the individual patient/provider level.

2.8 Conceptual Framework

A conceptual overview of the study is as visualized in Figure 1. Briefly, a woman with one previous scar can choose to deliver vaginally or via repeat CS. Various factors influence the choice, including medical and obstetric conditions, hospital policy and socio-cultural factors. The actual mode of delivery could be a VBAC, PRCS, unplanned vaginal delivery or ERCS. The ERCS could be because of failed TOLAC or the establishment of labor prior to the planned CS date. Either mode of delivery could be associated with adverse outcomes to the mother, such as hemorrhage, infection, uterine rupture. The neonatal outcomes include birth asphyxia, NICU admission, and death. These are associated with prolonged hospital stay with increased risk of morbidity and mortality for both the mother and the baby.

Figure 1

A conceptual framework of the study



CHAPTER THREE

RESEARCH DESIGN AND METHODOLOGY

3.1 Research Design

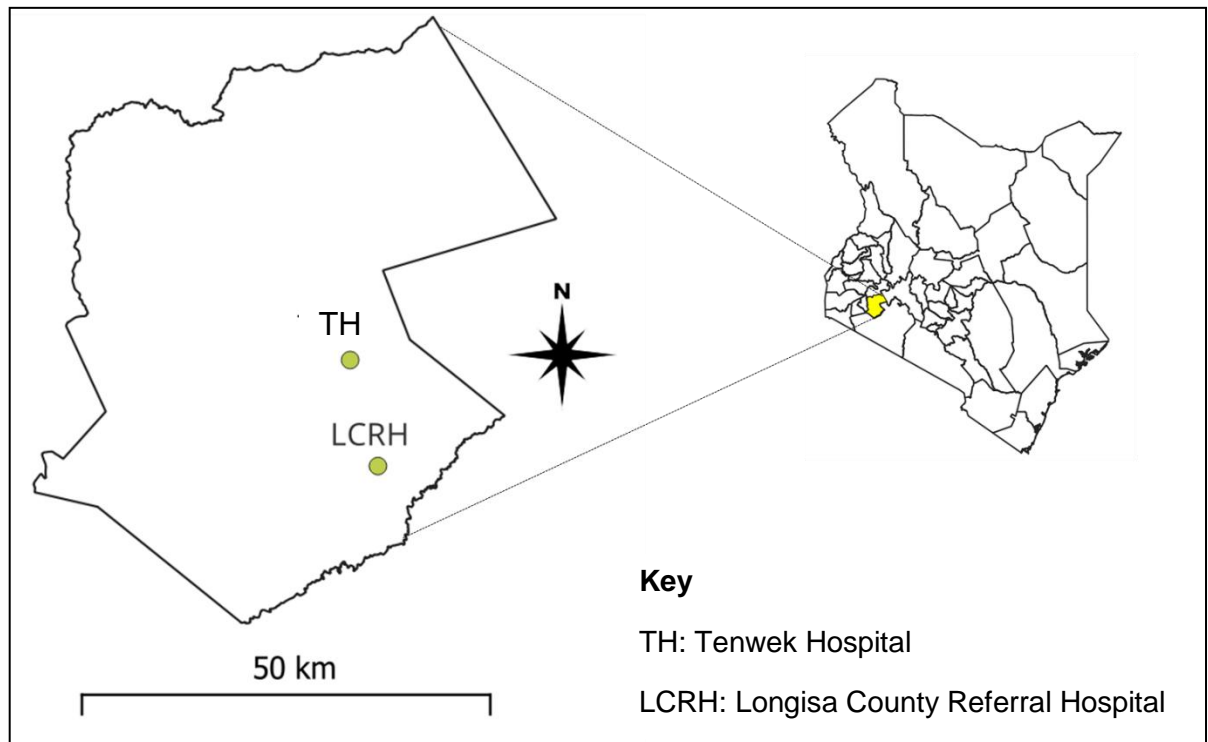
The study adopted a prospective observational cross-sectional approach that aimed to assess success rates of VBAC during a trial of labor. Secondary objectives included neonatal and maternal outcomes and factors associated with a successful trial of labor in women with one previous scar in the two level 5 referral hospitals in Bomet County.

3.2 Location of the Study

The study location was Bomet county which has a largely agricultural rural population of 875,689 according to the Kenya 2019 census data (KNBS 2019). The KDHS reports that 88% of all births in the county are delivered by a skilled provider, which is slightly lower than the national average of 89% in Kenya. The study was conducted in the two level 5 referral hospitals in the county; Tenwek Hospital, a level 5b faith-based referral institution, and Longisa County Referral Hospital, a level-5 government facility (Figure 2). Tenwek requires informed consent for TOLAC and includes screening criteria for candidates (Appendix V); on the other hand, Longisa practices TOLAC for every patient with one previous cesarean section. Since these two are the only level 5 facilities in the county, they care for most of the pregnant women with previous cesarean delivery. These hospitals are capable of offering quality comprehensive emergency obstetric care as they do have basic equipment and qualified personnel with 24-hour care. Further, both hospitals get referrals from other facilities within the county, as well as medical and self-referrals from outside the county.

Figure 2

Map showing locations of the study hospitals in Bomet County, Kenya. (Image credit: own).



3.3 Study Population

Of the 441,379 total female population in Bomet county, 22% are of the reproductive age having a total fertility rate (number of children per woman) of 3.4, which matches the national average in Kenya (KNBS, 2019; KDHS 2022). The study targeted a population that included all pregnant women with one previous scar who desired TOLAC in the two facilities with no obvious contraindication to TOLAC.

3.4 Sampling Procedures and Sample Size

The sampling methodology and sample size determination was as outlined below.

3.4.1 Sampling Approach

The study adopted the purposive sampling techniques where all gravid women who presented to the two facilities at > 36 weeks' gestation with one previous scar and had agreed to attempt trial of labor were recruited. The recruitment continued consecutively for those fulfilling the inclusion criteria until the calculated sample size was achieved.

Half of the targeted sample size was to be from the government facility, while the other half was to be from the faith-based facility. The study was projected to run for six months based on the average number of patients seen in the two facilities in a month.

3.4.2 Sample Size Calculation

Hospital records from the two hospitals in Bomet County indicated a total of 300 attempted TOLAC in the year 2020 with no clear record of how many of these were successful. Longisa County referral hospital had a record of approximately 180 while Tenwek hospital had approximately 120 cases of trial of labor obstetrics ward. This was retrieved by counting manually from the nurses' report of the two facilities.

As an overarching study objective was to determine TOLAC success rates in low resource setting of Tenwek and Longisa hospital, the sample size (n) calculation was based on the formula for calculating sample size for cross-sectional studies as described by Daniel (1999) with an adjustment made for small population described by Thrusfield (2005) to estimate a proportion or apparent prevalence with specified precision. Thus,

$$n = \frac{Z^2 P(1 - P)}{d^2}$$

Where:

Z = value from standard normal distribution corresponding to desired confidence level
($Z=1.96$ for 95% CI)

P was the expected proportion set at 0.5 in this study based on a retrospective study in Kiambu, Kenya that revealed a success rate of 50.7%, (Musila et al., 2015).
 d was the desired precision set at 0.05.

The adjustment for finite population size was given by $n = \frac{N \times n}{N+n}$

Hence, from a study population of ($N=300$), the calculated sample size (n) was 169.

3.4.3 Recruitment Procedure

The study recruited two clinical officers—one for each of the facilities. The recruitment was based on willingness and availability of the research assistants for the entire study duration. Recruitment of patients for study was done at admission to the respective facility for delivery. A validated questionnaire was used as described by (Kimotho, 2009). The administered questionnaire included a survey of demographics, details of the previous cesarean delivery, and details of current pregnancy such as number of antenatal care visits, comorbidities noted in this pregnancy, cervical dilatation at admission and gestational age (Appendix ii).

Patients were counseled on the mode of delivery as per the facility's protocol. In both facilities, counseling is done during the antenatal clinic visit, and if patients prefer PRCS, they are booked for elective CS. If they opt for TOLAC, they await spontaneous labor upon which they then come to the facility. If labor is not spontaneous at 40 weeks' gestation, they come to the facility and are then counseled for possible induction or scheduled for PRCS as per the facility's protocol. For those who do not attend the clinic,

counseling was done on the two modes of delivery at admission to the hospital by the nurses, medical officer, and/or the obstetrician on duty. The decision to take a patient for emergency repeat cesarean section was done by either the medical officer or the obstetrician on duty, while the monitoring of labor was done by the nursing staff. The role of the research assistant was observational by interviewing the patient at admission and following them up until discharge. The patients who opted for TOLAC were followed up until discharge.

3.4.4 Study Subjects

The selection of the study subjects followed a stringent inclusion and exclusion criteria as outlined below.

3.4.4 (a) Inclusion Criteria

- i. One previous cesarean section
- ii. Single intrauterine pregnancy
- iii. Gestational age greater than 36 weeks
- iv. Cephalic presentation
- v. Duration of at least 18 months after the primary cesarean section.

3.4.4 (b) Exclusion Criteria

- i. Documented prior classical uterine incision in the previous CS
- ii. History of uterine myomectomy
- iii. Documented previous history of uterine rupture
- iv. Fetal anomalies

3.5 Data Collection Procedure

The research assistants were trained on filling the interview guides in a standard way and collected the data under the direct supervision of the principal investigator. The respondents were approached at admission and asked to participate in the study after a verbal explanation by the research assistant. Thereafter, a written consent was sought from all eligible and consenting women, legal guardians or next of kin for the study.

3.6 The Study Questionnaire

The study tool was adopted from a retrospective study done at Pumwani hospital, Nairobi County that assessed the outcome of TOLAC in women with one previous scar (Kimotho, 2009). The questionnaire had been pre-tested and validated (Appendix ii).

The questionnaire was divided into two parts; the first part was filled at admission and included; data on demographics, previous pregnancies and antenatal clinic visits. The second part focused on both neonatal and maternal outcomes. This included information regarding the outcomes of delivery and actual mode of delivery that were retrieved directly from the patient and neonate charts in the hospital database at the time of discharge by the research assistant.

3.7 Data Analysis

The data analysis involved exploratory, descriptive and inferential approaches. Data analysis was preceded by data cleaning which involved checking for missing data entries, uniformity and factorization of categorical data in Microsoft Excel. Observation with missing data values were expunged from analysis. Data was then exported to Statistical Package for Social Sciences (SPSS) v24 for analysis with the assistance of a statistician.

Variable data was categorized into ordinal and continuous variables. Descriptive statistics included measures of central tendency and dispersion i.e., mean (standard deviation) or median (interquartile range) for parametric and non - parametric continuous variables respectively. Categorical data was described using frequencies and percentages. Moreover, categorical variables were analyzed by odds ratios and Pearson’s chi-squared test. A *p* value of 0.05 was applied for statistical significance. The data analysis approaches to address the objectives in this study were as summarized in Table 1 below.

Table 1

Data Analysis Approaches Applied for the Study Objectives

Objectives	Data analysis methodology
To assess the maternal and neonatal outcomes of TOLAC in Tenwek and Longisa hospitals.	Descriptive statistics
To evaluate TOLAC success rates in Tenwek and Longisa hospitals.	Descriptive statistics
To identify the success and risk factors associated with TOLAC in Tenwek and Longisa hospitals.	Odds ratio and Pearson’s chi-squared test.

3.8 Data Handling

Since the consent forms contained patient information, they were dropped in a sealed box and will not be retrieved to be traced back to the patient after the study. The filled interview guide had only unique patient numbers with no identifiable information of the participants. The filled interview guides will be available only to the researcher, supervisors and statistician if need be. The interview guides will be maintained for a

minimum of 10 years in a safe sealed box or until the university archivist provides approval to discard the data.

3.9 Ethical Consideration

The study was approved by Tenwek Hospital and Kabarak IREC Committees as well as NACOSTI (Appendices iii - iv).

To avoid influencing the women's decision on their desired mode of delivery, the research team did not participate in the counseling process. Moreover, the study monitored outcomes based on decisions that are already made. The study's rationale was explained to the patients and consent was obtained for their participation. Completed consent forms (showing a signature or a thumb print) were stored securely and separately from the transcripts.

Interviews were conducted in an identified isolated room to ensure the privacy of the participants is maintained. All the information (data) collected from research participants was handled and stored very carefully to ensure that confidentiality is maintained. Further, this thesis contains no potentially identifying details of individual participants.

CHAPTER FOUR

DATA ANALYSIS, PRESENTATION AND DISCUSSION

4.1 Introduction

This chapter highlights the findings from the study. The chapter is organized first starting with a general description of the demographic characteristics of the study participants summarized in table 2, followed by an outline of the result analysis per the objectives set for the study. Data analysis and results are explained in detail, and their significance to the study is discussed.

4.2 Demographic Characteristics of the Study Participants

Records of 170 women who underwent trial of labor after a cesarean section (TOLAC) and their neonates in Tenwek hospital and Longisa county referral hospital from 21st October 2022-8th June 2023 were analyzed. The study participants' mean age was 28.1 (SD 4.8) with the women ages ranging between 18 and 42 years old. Moreover, the median age was 27.0 (IQR 24-32 years) with most of the participants being married (92.4%).

As for their occupation, 43.5% were casual laborers with 28.2%, 16.5% and 11.8% being unemployed, in formal employment and self-employed respectively. Seventy-one point eight percent (71.8%) of the patients had at least secondary school level of education (See Table 2).

Table 2*Demographic Characteristics of the Study Participants*

	Number of participants(<i>n</i> =170)	Percent
Age in years		
18 – 25	59	34.7
26 – 35	101	59.4
36 – 45	10	5.9
Marital status		
Married	157	92.4
Single	10	5.9
Separated	3	1.8
Occupation		
Formal	28	16.5
Self	20	11.8
Casual	74	43.5
Unemployed	48	28.2
Education		
Primary	21	12.4
Secondary	122	71.8
Tertiary	27	15.9

4.3 Success Rate of TOLAC

The success rate was determined by the actual mode of delivery. VBAC was considered a success while an ERCS was considered a failed TOLAC. Of the 170 deliveries, 82 delivered by VBAC, which represents 48.2% of all the deliveries (see Figure 3). There were various indications for failed TOLAC with the most common indication being poor progress of labor (34.1%) followed by non-reassuring fetal status (NRFS) (31.8%). The least common indications for failed trial of labor were neonatal macrosomia, failed induction and abruption placentae (1.1% each.) Repeat cesarean section for maternal choice after the onset of labor accounted for 13.6% of the repeat cesarean section as

summarized in table 3. Most of the repeat cesarean sections occurred during the active phase of labor at 60.2% (see Table 4).

Figure 3

The success rate (%) of VBAC

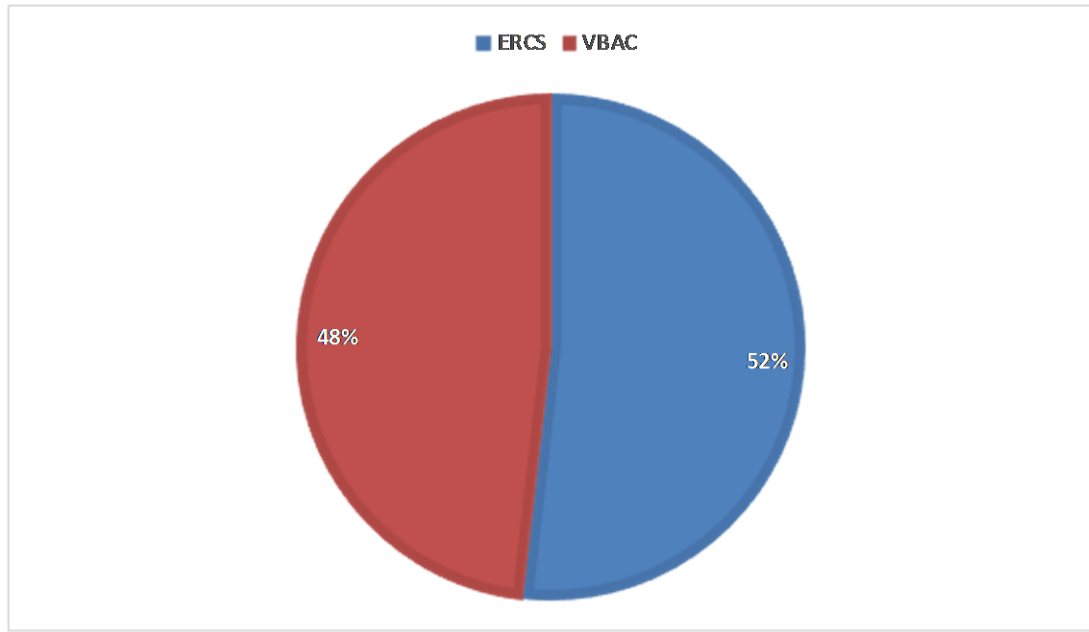


Table 3

Indications for Cesarean Section Observed in this Study

	Frequency (n=88)	Percent
Poor progress	30	34.1
NRFS	28	31.8
Maternal choice	12	13.6
Malposition	4	4.5
Arrest of 2 nd stage	5	5.7
“Impending uterine rupture”	3	3.4
Cord presentation	2	2.3
Abruption	1	1.1
Failed induction	1	1.1
Macrosomia	1	1.1

Table 4*Recorded Cervical Dilation at time of Cesarean Section*

Dilation at CS	Frequency (88)	Percent
<6 cm	35	39.7
>6 cm	53	60.3

4.4 Maternal and Perinatal Complications Associated with TOLAC

The maternal complications that were assessed included: hemorrhage with need for blood transfusion, infection postpartum as described by temperature $>38^{\circ}$ c, wound infection, uterine tenderness, purulent lochia, or extended antibiotic coverage. Delivery associated trauma included uterine rupture, operative visceral injury, perineal and cervical lacerations. Maternal death was assessed. Neonatal complications included APGAR score of <7 at 5 minutes, NICU admission for whatever indication and neonatal death.

Results on maternal complications indicate that 6.5% of the women received a blood transfusion, 72.7% of whom had ERCS compared to 27.3% who had a VBAC. 9.4% of women were treated for infection with one case of surgical site infection, and 11.8% of women incurred delivery associated trauma. The most common delivery associated trauma reported in this study were cervical and vaginal lacerations with 1 case (0.59%) of bladder injury at cesarean section and no uterine rupture reported. No maternal mortality was reported in the two facilities for the duration of the study (See Table 5).

Perinatal complications assessed in this study included APGAR score of <7 at the fifth minute, admission to NICU, oxygen requirement and perinatal and neonatal death. Newborns with an APGAR score at 5 minutes of <7 were at 6.5%. Admissions to NICU involved 15.3% of newborns. The most common indication for NICU admission was low APGAR score at 5 minutes (30.7%) and risk of sepsis (19.2%). "Risk of sepsis" included

findings of prolonged rupture of membranes or foul smelling amniotic fluid. Additional indications included oxygen requirement (15.4%), “risk of hypoglycemia” due to neonatal macrosomia (11.5%), jaundice (7.7%), meconium aspiration (7.7%), seizures (3%) and for monitoring (3%) (See Table 6).

There were 5 perinatal deaths (2.9%). Of the 5 perinatal deaths, 4 were delivered via ERCS for NRFS with 2 of them being fresh stillbirths. 1 additional perinatal death was delivered via VBAC and had meconium aspiration.

Table 5

Observed Maternal and perinatal Complications Associated with TOLAC

Maternal complications	Frequency (<i>n</i> =170)	Percent
Blood transfusion		
Yes	11	6.5
No	159	93.5
Infection		
Yes	16	9.4
No	154	90.6
Delivery associated trauma		
Yes	20	11.8
No	150	88.2
Perinatal complications		
APGAR score		
<7	11	6.5
≥7	159	93.5
NICU admission		
Yes	26	15.3
No	144	84.7
Neonatal death		
Yes	5	2.9
No	165	97.1

Table 6*Indications for Admission to NICU*

	Frequency (<i>n</i> =26)	Percent
Birth asphyxia	8	30.7
Risk of sepsis	5	19.2
Oxygen requirement/assisted ventilation	4	15.4
Risk of hypoglycemia	3	11.5
Jaundice	2	7.7
Meconium aspiration	2	7.7
Monitoring	1	3.8
Seizures	1	3.8

4.5 Factors Associated with Successful TOLAC

Women aged between 26 to 35, and 36 to 45 years had increased likelihood of having a successful TOLAC (OR 1.3) compared to the 18 to 25 years old age group. Those who were self-employed were less likely to have successful TOLAC when compared to those in formal employment (OR 0.5), while those who were casually employed and unemployed had an equal probability of having a successful TOLAC when compared to the formal (OR 1.0). Women with an inter-delivery interval period of 25-48 months had 1.3 times odds of having a successful VBAC while those between 49-60 had an equal chance as compared to those with inter-delivery interval of less than 24 months. Further, those with inter-delivery interval of >60 months were 2.7 times more likely to have a successful trial of labor after a cesarean section as compared to those with an inter-delivery interval of less than 24 months (p=0.044). Analysis regarding parity at enrolment indicated that those who had a parity of between 2-4 had a 3.8 likelihood of having vaginal delivery as compared to those who were para one (p<0.001), while those with parity of more than 5 having an odd of 4.6 (p=0.077). Notably, however, the probability of having a successful TOLAC increased with history of prior successful trial of labor

with an odds ratio of 7.2 ($p < 0.001$). Women with 1-2 previous vaginal deliveries had a 3.2 likelihood of having a vaginal delivery ($p = 0.002$) and those with more than three prior deliveries having a 4.5 likelihood of having successful TOLAC ($p = 0.008$) compared to those with no prior vaginal delivery.

Birth weight of 2000-2500g, 3001-3499 and >3500 g were associated with 1.0, 0.8 and 0.4 times the likelihood respectively of having successful trial of labor as compared to those with infants weighing between 2500 and 3000g. With a statistically significant difference being noted in those weighing >3500 g ($p = 0.020$).

The women who had mal-presentation as the indication for the first cesarean section were 7.0 times more likely to have a successful VBAC as compared to those who had CPD ($p = 0.001$), while those with NRFS as an indication for previous CS having a probability of 3.4 ($p = 0.033$). Prolonged labor and CPD in the previous cesarean section delivery were associated with increased probability of failed TOLAC. There was no statistical significant difference in the other indications of the previous cesarean section in relation to the mode of delivery. (See Table 7).

Nine women out of the one hundred and seventy women (5.29%) analyzed were on follow-up for some medical condition. Of the nine, four (44%) had hypertension, while the rest were treatment for the following conditions HIV (1), epilepsy (1), syphilis (1), hemorrhoids (1), and open reduction with internal fixation for shaft of femur fracture (1). Although not statistically significant ($p = 0.365$), those with medical/surgical conditions were less likely to have a successful trial of labor as summarized in Table 7.

Table 7*Factors Associated with Successful TOLAC*

Age in years, <i>n</i> (%)	VBAC(<i>n</i> =82)	ERCS(<i>n</i> =88)	OR (95% CI)	p-value
18 – 25	26 (31.7)	33 (37.5)	Reference	
26 – 35	51 (62.2)	50 (56.8)	1.3 (0.7 – 2.5)	0.433
36 – 45	5 (6.1)	5 (5.7)	1.3 (0.3 – 4.9)	0.728
ANC visit, <i>n</i> (%)				
<4	35 (42.7)	30 (34.1)	1.4 (0.8 – 2.7)	0.250
≥4	47 (57.3)	58 (65.9)	Reference	
Inter-delivery interval, <i>n</i> (%)				
≤24	12 (14.6)	18 (20.5)	Reference	
25 – 36	17 (20.7)	20 (21.7)	1.3 (0.5 – 3.4)	0.625
37 – 48	15 (18.3)	18 (20.5)	1.3 (0.5 – 3.4)	0.662
49 – 60	11 (13.4)	17 (19.3)	1.0 (0.3 – 2.8)	0.956
>60	27 (32.9)	15 (17.0)	2.7 (1.0 – 7.1)	0.044
Previous VD after first CS, <i>n</i> (%)				
Yes	25 (30.5)	5 (5.7)	7.2 (2.6 – 20.1)	<0.001
No	57 (69.5)	83 (94.3)	Reference	
Parity, <i>n</i> (%)				
1	36 (43.9)	66 (75.0)	Reference	
2 – 4	41 (50.0)	20 (22.7)	3.8 (1.9 – 7.4)	<0.001
≥5	5 (6.1)	2 (2.3)	4.6 (0.8 – 24.8)	0.077
Occupation, <i>n</i> (%)				
Formal	14 (17.1)	14 (15.9)	Reference	
Self	7 (8.5)	13 (14.8)	0.5 (0.2 – 1.8)	0.304
Casual	37 (45.1)	37 (42.0)	1.0 (0.4 – 2.4)	1.000
Unemployed	24 (29.3)	24 (27.3)	1.0 (0.4 – 2.5)	1.000
Total vaginal deliveries, <i>n</i> (%)				
0	38 (46.3)	66 (75.0)	Reference	
1 – 2	31 (37.8)	17 (19.3)	3.2 (1.6 – 6.5)	0.002
≥3	13 (15.9)	5 (5.7)	4.5 (1.5 – 13.6)	0.008
Medical history, <i>n</i> (%)				
Yes	3 (3.7)	6 (6.8)	0.5 (0.1 – 2.1)	0.365
No	79 (96.3)	82 (93.2)	Reference	
First CS indication, <i>n</i> (%)				
Cervical dystocia	1 (1.2)	0 (0.0)	-	-
CPD	5 (6.1)	17 (19.3)	Reference	
Failed induction	1 (1.2)	0 (0.0)	-	-
Malpresentation/Malposition/ Breech/Cord presentation	29 (35.4)	14 (15.9)	7.0 (2.2 – 23.0)	0.001
Multiple gestation	2 (2.4)	3 (3.4)	2.3 (0.3 – 17.6)	0.434
NRFS	28 (34.1)	28 (31.8)	3.4 (1.1 – 10.5)	0.033
Pre-eclampsia/Eclampsia/HTN	3 (3.7)	4 (4.5)	2.6 (0.4 – 15.4)	0.308
Prolonged labor	11 (13.4)	19 (21.6)	2.0 (0.6 – 6.8)	0.286
Shoulder dystocia	0 (0.0)	1 (1.1)	-	-
Unknown	2 (2.4)	2 (2.3)	3.4 (0.4 – 30.7)	0.275

4.6 Complications Associated with TOLAC

Both maternal and neonatal complications associated with trial of labor after a cesarean section were noted in this study as summarized in Table 8. The maternal factors assessed included hemorrhage with need for blood transfusion, delivery trauma, infection and length of hospital stay.

Delivery trauma reported included perineal and cervical tears with one case of bladder injury at cesarean section while no uterine rupture was recorded in both Longisa and Tenwek hospitals. VBAC was associated with a significantly increased risk of delivery trauma (OR 25 and p-0.002) discounting the “trauma” of cesarean section itself.

Though not statistically significant (p-0.164), successful trial of labor was associated with a decrease in need for blood transfusion (OR 0.4) and a decreased risk of postpartum infection (p-0.706) (OR-0.8). Length of stay typically in the two study facilities, for an uncomplicated vaginal delivery is 24 hours while that of a cesarean section is 2 days. Prolonged hospital stay was defined as a hospital stay of more than 4 days which could indicate a complication. A statistically significant decreased probability of a prolonged hospital stay of more than 4 days was found with VBAC (OR 0.2; p-0.012).

The neonatal risk factors assessed included the APGAR score at 5 minutes, admission to NICU and death. VBAC was associated with decreased incidence of APGAR score of <7 (OR 0.7) and decrease in NICU admission (OR 0.7) but neither reached statistical significance. VBAC was associated with reduced incidence of neonatal death (OR- 0.3) but didn't reach statistical significance (p-0.232).

Table 8*Complications Associated with TOLAC (VBAC Compared to ERCS)*

Blood transfusion, <i>n</i> (%)	VBAC	ERCS	Odds Ratio	<i>p</i> value
Yes	3 (3.7)	8 (9.1)	0.4 (0.1 – 1.5)	0.164
No	79 (96.3)	80 (90.9)	Reference	
Infection, <i>n</i> (%)				
Yes	7 (8.5)	9 (10.2)	0.8 (0.3 – 2.3)	0.706
No	75 (91.5)	79 (89.8)	Reference	
Delivery associated trauma, <i>n</i> (%)				
Yes	19 (23.2)	1 (1.1)	25.2 (3.4 – 201.2)	0.002
No	63 (76.8)	87 (98.9)	Reference	
APGAR score, <i>n</i> (%)				
<7	4 (4.9)	7 (8.0)	0.6 (0.2 – 2.1)	0.420
≥7	78 (95.1)	81 (92.0)	Reference	
Birth weight, <i>n</i> (%)				
2000 – 2500	9 (11.0)	7 (8.0)	1.0 (0.3 – 3.1)	0.951
2501 – 3000	24 (29.3)	18 (20.5)	Reference	
3001 – 3500	33 (40.2)	30 (34.1)	0.8 (0.4 – 1.8)	0.631
>3500	16 (19.5)	33 (37.5)	0.4 (0.2 – 0.9)	0.020
NICU admission, <i>n</i> (%)				
Yes	10 (12.2)	16 (18.2)	0.6 (0.3 – 1.5)	0.281
No	72 (87.8)	72 (81.8)	Reference	
Neonatal death, <i>n</i> (%)				
Yes	1 (1.2)	4 (4.5)	0.3 (0.03 – 2.4)	0.232
No	81 (98.8)	84 (95.5)	Reference	
Hospital stay, <i>n</i> (%)				
Not prolonged	78 (95.1)	72 (81.8)	Reference	
Prolonged	4 (4.9)	16 (18.2)	0.2 (0.1 – 0.7)	0.012

4.7 Discussion

In this study, 170 women with subsequent pregnancy greater than or equal to 18 months from their primary CS were evaluated/assessed. Of the 170 women, the TOLAC success rate was calculated at 48.23%. This study rate falls within the range calculated in two

previous retrospective studies done in Pumwani and Kiambu hospitals in Kenya which reported a success rate of 45.5% and 50.1% respectively (Kimotho, 2009; Musila et al., 2015). However, the study rate is generally lower than the rate demonstrated in various studies done in developed countries, most of which report a success rate of 60-80% (Birara & Gebrehiwot, 2013; Parveen et al., 2022).

The large disparities of TOLAC success rates and outcomes between developed and developing countries have been ascribed to various factors including delays in access to healthcare services, lack of personnel, lack of constant availability of operating rooms in cases of emergency, poor record-keeping, unavailability of painless labor, and unknown details of indication and type of previous cesarean section (Thapsamuthdechakorn et al., 2018). Even so, there is also a notable difference in the rate of TOLAC across studies ranging from 20 to 80% worldwide. These differences across studies have been largely attributed to patient selection. With careful patient selection, the rate of patients undergoing TOLAC may decrease with a resultant increase with successful VBAC rate (Parveen et al., 2022; Thapsamuthdechakorn et al., 2018).

According to ACOG, factors including inter-delivery interval, no contraindication to vaginal delivery, and non-recurring indication of the primary CS are important guides in proper patient selection for successful TOLAC. In this present study, inter-delivery interval of more than 60 months and malpresentation, in particular breech presentation, as the indications for primary cesarean section were associated with increased probability of successful TOLAC. The most common indication for emergency repeat cesarean section was poor progress of labor followed by non-reassuring fetal status. Previous studies have reported the most common indication for failed TOLAC to be fetal distress followed by failed induction (Mounika et al., 2022; Gupta et al., 2014). These studies have

recommended continuous intrapartum fetal and maternal monitoring to help minimize the risk associated with ERCS.

Although intrapartum management of TOLAC patients is similar to that in patients with an unscarred uterus, patients with a previous scar are more at risk given the increased chances of uterine rupture. Therefore, continuous intrapartum fetal and maternal monitoring assists in understanding the response of fetal heart rate to the maternal uterine contractions as the labor progresses. Such monitoring may help reduce incidences of neonatal seizures due to hypoxia during labor and injuries to the mother as it informs the decision when to undertake ERCS (ACOG 2019). However, the capacity to undertake continuous intrapartum fetal and maternal monitoring is limiting in most rural hospitals in Kenya. In this study for example, the capacity for continuous fetal and maternal monitoring was only available at Tenwek hospital and not Longisa hospital despite the former being the government referral center in the county.

The current study demonstrated that maternal choice after onset of labor played a significant role in ERCS, accounting for 13.6% of failed TOLAC. This phenomenon was also noted in a study done in Iraq, which suggested that a lack of anesthesia, such as epidural anesthesia, during the labor period could be the underlying cause (Srwa & Nihayat 2021). A systematic review by Jenabi et al. (2020) noted that in the last twelve years there has been an increase in the number of cesarean sections being conducted for maternal request without medical or obstetric indication. Further, the study noted that maternal request was associated with higher levels of education and formal employment. The current study did not elucidate the reasons for maternal choice for repeat cesarean section, but anecdotally noted most ERCS were conducted at active phase of labor (53%). Jenabi et al. (2020) argued that maternal choice for cesarean section to be due to fear of childbirth, fear of labor pains, and avoidance of labor pains.

Maternal choice and requests underscores the need for patients to be provided with evidence-based information to guide their decision-making when considering TOLAC. Where TOLAC is anticipated, women should be consented for TOLAC and ERCS. Informed consent for TOLAC should include an evidence-based discussion of the risks associated with TOLAC as well as the success rate of TOLAC (ACOG 2019). Even though this was not a comparative study between Longisa and Tenwek hospitals; it was, however, observed that only Tenwek hospital routinely administers a TOLAC consent form. In Tenwek Hospital, patients are required to sign a TOLAC consent form after being counseled on the mode of delivery. While in Longisa county referral hospital, it is presumed that the patients are counseled on the mode of delivery during the ANC visits and at admission. However, there was no evidence of consent taken in the course of this study.

The maternal complications assessed in the current study included delivery trauma, receipt of blood transfusion, and postpartum infection. The birth trauma assessed in this study included uterine rupture, perineal and cervical lacerations and visceral injuries. There were no reported cases of uterine rupture in the current study, though, one case of bladder injury was reported in the ERCS group. Other delivery traumas that were reported included perineal and cervical tears in the VBAC group. Uterine rupture has been cited in several studies as the reason for decline in TOLAC rates worldwide with the incidence reported to increase with failed TOLAC (Habak & Kole, 2020; Bangal et al., 2013; Dodd et al., 2013). A study in India reported an incidence of uterine rupture of 0.5% while that of scar dehiscence was at 2.1% (Parveen et al., 2022). As in the present study, no patient was reported to have had hysterectomy in the India study. Nevertheless, other studies have reported varied incidences of uterine rupture ranging from 0.5-4.2% (Balachandran et al., 2014; Bangal et al., 2013; Parveen et al., 2022).

Delivery trauma such as uterine rupture during TOLAC may cause bleeding that may require blood transfusion. Notably, however, blood transfusion in this study was higher in the ERCS than in the TOLAC group. Other studies have also reported an increased rate blood transfusion in patients with a ERCS in Nigeria within SSA (Oboro et al., 2010). A cohort study done in England assessing the risk factors associated with birth at term in both nulliparous and multiparous noted that the risk of post-partum hemorrhage (PPH) with need for transfusion in nulliparous women with low risk pregnancy was 2.6% while that of multiparous women with low risk pregnancy was at 1.2%. Previous cesarean section was categorized as high risk pregnancy with risk of PPH with need for blood transfusion at 6.7% (Jardine et al., 2020). In this current study, hemorrhage with need for blood transfusion was at 6.5% which is similar to the cohort study in England.

The possibility for blood transfusion is among important consideration for facilities in which TOLAC is to be practiced given the increased risk of uterine rupture and ERCS complications including PPH that may require blood transfusion in such settings. Like most LMICs, Kenya has a high demand blood transfusion services but suffers dire shortages. An estimated seven people require a blood transfusion every 10 minutes while only 16% of the blood needed in Kenya is being collected (WHO 2022; World Bank 2022). Timely access to blood transfusion is a critical healthcare intervention for emergency situations such as the obstetric hemorrhage from both TOLAC and ERCS. The observation that ERCS was associated with a higher transfusion rate in this study underpins the need for facilities practicing TOLAC to be ready for such emergencies.

Postpartum infection is any bacterial infection of the reproductive tract after delivery. In this study, it was described by described by temperature $>38^{\circ}$ c, wound infection-purulent discharge, uterine tenderness, purulent lochia, extended antibiotic use with elevated white blood cells and chorioamnionitis (Belfort et al., 2010). The incidence of

postpartum infection in this study was noted to be 9.4% with a higher rate in the ERCS compared to the TOLAC group. Generally, both TOLAC and ERCS are not without risks of infection, however, the infection rate is likely to increase when ERCS becomes necessary (Armstrong, 2011). A number of studies report the incidence of postpartum infection to be more in women who undergo cesarean section as opposed to vaginal delivery with the risk increasing in women who had undergone labor before the cesarean section (Axelsson et al., 2018; Allen et al., 2003; Leth et al., 2009). In their study, Allen et al., (2003) noted that incidence of endometritis was five to ten times more following a cesarean section delivery as compared to vaginal delivery.

Surgical site infection is reported to complicate about 2-7% of cesarean section deliveries with history of prior cesarean section increasing the risk. This has been thought to be due to poor vascularization of scar tissue from prior surgery (Axelsson et al., 2018; Olsen et al., 2008). Postpartum infection accounts for significant and often preventable maternal morbidity and mortality. It is among the top five causes of maternal mortality globally as it accounts for 10-15% of maternal mortality in the postpartum period (Prestinaci et al., 2015). Postpartum infection increases social burden as well as increases in maternal anxiety, risk of postpartum depression and interferes with bonding and negatively impacts breast feeding (Belfort et al., 2010).

Neonatal complications assessed in this study included a five-minute APGAR score of less than 7, admission to NICU, and neonatal death. These complications were noted to be higher in the failed TOLAC group as compared to VBAC. These results are similar to various studies done which indicate that neonatal morbidity was highest in cases of failed trial of labor compared to VBAC and PRCS (Oboro et al., 2010; Thapsamuthdechakorn et al., 2018). In a cohort study done in England APGAR score of less than 7 at 5 minutes in nulliparous low risk women was at 1.2% while that of multiparous women and

previous scar which was considered as high risk pregnancy was at 2.9%. The APGAR score was reported in the current study at 6.8%, which is worse compared to the above mentioned study (Jardine et al., 2020). Although not statistically significant, the low APGAR scores in the VBAC group had a rate of 4.9% which differed from the failed TOLAC rate of 8% (OR 0.6).

As regards the perinatal death of 2.9% in this study, it comparably higher than a 2.4% rate reported by Ayah *et al.*, (2018) from a cross sectional study done in six primary referral hospitals in Kiambu and Nairobi. In the same study by Ayah et al., (2018), perinatal mortality in Kiambu and Nairobi was reported to be 2.6 times higher in public hospitals than in private and faith based hospitals—and this was attributed to differences in the quality of care. Of note, the perinatal deaths were among the unconsented and unmonitored group of patients.

The study assessed various factors associated with the success/failure of TOLAC. Among the factors assessed included patients' demographics such as age and occupation, co-morbidities and past obstetric history such as parity, indication for first cesarean section, inter-delivery interval, and previous vaginal deliveries. Among important factors on the obstetric history, a parity of between 2-4 was associated with successful TOLAC. Parity has been a considered a prognostic variable for evaluating patients undergoing TOLAC (Lopian et al. 2023). As such, this study confirms observations of other studies that patients with no previous vaginal deliveries undergoing TOLAC are at a higher risk of adverse TOLAC outcomes than multiparous (parity 2-4) and grand multiparous (>5 parity) women (Lopian et al. 2023; Kalok et al. 2018).

Thus, a previous vaginal delivery (particularly a previous successful VBAC) was also noted to be a positive predictor of VBAC in this study. This observation confirms recent

evidence from systematic reviews by Wu et al. (2019) and Mekonnen & Asfaw (2013). Kalok et al. (2018) argue the reason why a previous vaginal delivery has a higher chance of successful VBAC is that multiparous women have a higher likelihood of developing effective uterine contractions in labor and have less challenges in subsequent pregnancies. However, this claim requires further study.

Inter-delivery period or inter-pregnancy interval—as also referred by other authors, was an important determinant on VBAC success or failure in this study. In particular, a short inter-delivery interval of less than 24 months was associated with failure while a period of >60 months was associated higher chances of VBAC success in this study. In general, most studies and guidelines support an association of short delivery-intervals with VBAC failure. For example, ACOG guidelines suggest that an inter-delivery period of < 19 months reduced the success rate of VBAC (ACOG, 2019), while the Society of Obstetricians and Gynecologists of Canada associate an inter-delivery period of < 18 months with an increased risk of uterine rupture when attempting TOLAC. Further, a multicenter cohort study in China on the optimal inter-delivery period concluded that an inter-delivery period of <24 and >120 months increased the risk of major maternal and neonatal TOLAC outcomes.

Neonatal birth weight of more than 3500g were associated with an increased risk of ERCS. This finding confirms previous studies that have shown fetal weight to be of high prognosis value on TOLAC success (Maroyi et al., 2021; Thapsamuthdechakorn et al., 2018; Parveen et al., 2022). A consistent finding is that the greater the fetal weight, the lower the likelihood of a successful VBAC. A previous VBAC study in the West African setting calculated that the CS rate for women with a fetal weight of more than 3450g increased by 3 times, and the probability of VBAC success was reduced by 50% for those with a neonatal weight of more than 3700g (Adany and McCarthy, 2007). Mi et al.

2021 posit the possible reason why a larger fetal weight lowers VBAC success rates is that a heavy fetus may cause excessive traction of the lower uterine fibers, resulting in incomplete or complete rupture of the muscle layer of the lower uterus—eventually leading to VBAC failure.

Various studies have indicated that CPD/failure to progress as the indication for initial CS may be associated with 50-67% successful VBAC as compared to breech presentation whose success rate is 89% (Birara&Gebrehiwot, 2013; Maroyi et al., 2021; Wu et al., 2019). As such, the indication for previous cesarean section is an important predictor of a successful VBAC (Trojano et al., 2019). This study noted malpresentation including breech ($p < 0.001$) and NRFS ($p = 0.033$) as the indications for previous CS were associated with a higher probability of successful VBAC, as compared to CPD.

Higher socioeconomic status has previously been associated with increased probability of failed trial of labor (Lehmann, et al., 2018). Further, results from studies in rural Ethiopia and Turkey have shown higher VBAC success rates in women from rural residences compared to urban setups (Mekonnen & Asfaw 2023; Senturk et al., 2015). Arguably, the reasons given for the observations range from preference of the women due fear of surgery to affordability that maybe due to socioeconomic status. This study, however, did not note a statistically significant difference in patient's occupation or education in relation to success/failure of TOLAC. With the two hospitals in the study serving a mostly rural population, it may also be argued that there could be limitations on the choice of education and employment as surrogate measures of socioeconomic status in this study's local context. For example, employment in this rural context may not necessarily mean an individual has a higher socioeconomic status.

Various international organizations have recommended at least eight visits including Kenya's National Guidelines for Quality Obstetrics and Perinatal Care, which are based on the WHO Recommendations on Focused Antenatal Care. (ACOG, 2019; Tunçalp et al., 2017; MOH 2022). This is a change from the previous Kenyan guidelines which recommended four visits. In this study all the participants had attended at least two ANC visit with only one participant having attended eight visit as currently recommended. The majority of the participants had more than four visits. There was no statistically significant difference in the mode of delivery in those who had four or more visits as compared to those with less than four visits. The study did not seek to elucidate the effect and practicality of the current guidelines on the mode of delivery.

CHAPTER FIVE

SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

This chapter summarizes the major findings and draws the key conclusions of this study with important implications for policy and future research.

5.2 Summary of Major Findings

TOLAC is a safe and reasonable delivery option in women with a previous cesarean section because VBAC reduces maternal morbidity that are associated with multiple CS deliveries (ACOG 2019; Guise et al., 2010). However, the practice of TOLAC requires stringent criteria in patient selection and intrapartum care of patients in order to optimize on safety and enhance VBAC positive outcomes. There have been several studies addressing TOLAC and VBAC outcomes across the world. These studies, however, have been conducted mainly in urban areas and tertiary institutions with at most well-equipped units that have the capacity to perform immediate cesarean section and monitor intrapartum reliably. But due to the heterogeneity of health care delivery in different settings, there is need for continued research to contextualize the practice of TOLAC in local settings to identify the risks and required resources for better guidance on practice. Thus, this study provides a glimpse into the safety and risks associated with TOLAC in poor-resource settings of Kenya's Bomet County. The study assessed TOLAC success rates and identified factors associated with success, as well as the complications associated with TOLAC in women with one previous scar.

5.2.1 TOLAC Success Rate

The success rate in this study was calculated a 48.23% TOLAC success rate in 170 women with subsequent pregnancy greater than or equal to 18 months from their primary CS. This success rate is similar to the studies done in Kiambu and Pumwani hospitals in Kenya. However, the rate is lower than the rate demonstrated in various studies in developed countries, most of which report a success rate of 60-80%.

5.2.2 Factors Associated with Successful TOLAC

A number of factors which would potentially influence the outcomes of trial of labor and ultimately the actual mode of delivery were considered. Of the factors that were assessed, only previous vaginal delivery, longer inter-delivery intervals, neonatal birth weight, and parity had statistically significant associations with success of TOLAC. Moreover, neonatal weight of >3500g was associated with an increased risk of TOLAC while a previous VBAC had a positive association with TOLAC.

5.2.3 Maternal Complications Associated with TOLAC

This study demonstrates risk factors associated with failed TOLAC in a low-resource setting including increased risk of blood transfusion, infections and increased hospital stay. There were no reported cases of uterine rupture in the current study, though, one case of bladder injury was reported in the ERCS group. Other delivery traumas that were reported included perineal and cervical tears in the VBAC group. Notably, however, blood transfusion in this study was higher in the ERCS than in the TOLAC group—albeit not statistically significant. The incidence of postpartum infection in this study was noted to be 9.4% with a higher rate in the ERCS compared to the TOLAC group.

5.2.4 Perinatal Complications Associated with TOLAC

The neonatal risk factors include increased risk of admission to NICU, five-minute APGAR <7, and increased risk of perinatal and neonatal mortality. There was no statistical significant difference between ERCS and VBAC groups.

5.3 Conclusion

This study's findings suggest that even though the success rate was lower compared to that of the developed countries, TOLAC still remains a viable option with better outcomes than cesarean section if successful. Therefore, the practice of TOLAC in any facility should anticipate possible failures and ensure the facility is equipped to handle the complications that may arise before attempting the procedure. Like previous studies in Kenya, close to half of the patients who attempted TOLAC in this study had a successful VBAC. With the two study facilities being in a resource limiting setting, a careful TOLAC patient selection with due consideration to the available resources and personnel could improve VBAC success rates. TOLAC candidates should therefore be evaluated based on the contextual factors of a given setting.

Compared to those who had a VBAC, ERCS was associated with worse outcomes in this study. ERCS becomes a necessity once TOLAC fails, and as previous highlighted in the reviewed literature above, both TOLAC and ERCS are not without risks but TOLAC complications are worse if it fails. Thus, selecting TOLAC candidates with low risks for failure is likely to reduce the need for ERCS. Furthermore, based on this study's analysis, evaluation of the CS rate should not center entirely on whether it is too high or too low. Rather, it should focus on the appropriateness of the CS performed, taking into account all the relevant information, including TOLAC risks and outcomes. While there is an unmet burden of CS as essential health care service in Sub-Saharan Africa, this study

suggests that clinicians should consider TOLAC as a mode of delivery by stratifying risk using the identified characteristics, which might allow the already limited obstetrical resources in SSA to be distributed to the neediest.

However, since there is still a significant risk of negative outcomes with TOLAC, attempting to prevent the need for by reducing the primary cesarean section rate and consider a repeat CS only when most prudent by stratifying risk

5.4 Recommendation

The findings of this study have important implications for TOLAC practice in low-resource settings with a bearing on policy and areas for further research. The decision on the planned mode of delivery must be shared between the expectant woman and the health care worker taking into account the individual risk factors and likelihood of success.

5.4.1 Policy Recommendation

This study recommends that there should be a focus to encourage women to undergo VBAC when there are no contraindications. This recommendation will require a comprehensive policy framework and national guidelines on the rate of primary cesarean section and on practice of TOLAC in Kenya. Among the key considerations to be addressed should include; a set criterion of who should attempt TOLAC ,facility resources e.g. for continuous fetal heart monitoring during TOLAC, and capabilities of performing an emergency CS should the need arise, as well as non-obstetric reasons such as maternal choice.

5.4.2 Recommendation for Further Research

For further research, this study recommends studies to compare between planned repeat cesarean section and trial of labor after cesarean section in women with one previous scar in resource poor setups. The factors found to be associated with success and failed TOLAC may be utilized to develop machine learning predictive models that help in accurate patient selection of patients. However, more studies and data will be required to test such predictive models.

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APPENDICES

Appendix I: Consent/Assent Form for Participation in the Study

STUDY TITLE: BIRTH OUTCOMES AFTER A PREVIOUS CEASEREAN SECTION: AN OBSERVATIONAL COMPARATIVE STUDY IN TWO REFERRAL HOSPITALS IN BOMET COUNTY

PI: EUNICE ONDEGO Affiliated Institution TENWEK HOSPITAL

Co-investigator(s) Dr. CHERYL COWLES Affiliated Institution TENWEK HOSPITAL

Dr. AMOS OTARA Affiliated Institution EGERTON UNIVERSITY

Introduction

You are invited to participate in this research study being undertaken by the above listed investigators. This form will help you gather information about the study so that you can voluntarily decide whether you want to participate or not. You are encouraged to ask any question regarding the research process as well as any benefit or risk that you may accrue by participating. After you have adequately been informed about the study, you will be requested to either agree or decline to participate. Upon agreeing to participate in the study, you will be further requested to affirm that by appending your signature/thumbprint on this form. Accepting or declining to participate in this study does not in any way waive the following rights which you're entitled to:

- a) Voluntary participation in the study;
- b) Withdrawing from the study at any time without the obligation of having to give an explanation and;
- c) Access to services which you're entitled to

A copy of this form will be provided to you for your own records

Should I continue YES/NO _____

This study has been reviewed and approved by Kabarak University Research Ethics Committee (KUREC)

What is the Purpose of the Study?

The main purpose of this study is to assess the success rate of the trial of labour and determine factors associated with the success and failure of trial of labour.

Who can Take Part in the Study?

The study targets at least 169 women who meet the following criteria

- i. One previous scar
- ii. Single intrauterine pregnancy
- iii. Gestational age >36 weeks
- iv. Cephalic presentation

In Case You Agree to Participate in the Study, What Will Happen?

This is what is going to happen once you have agreed to participate in the study:

- You will fill a questionnaire which will not take more than 10 minutes. Your name or contact information will not be recorded in the questionnaire.
- Second, a qualified and well-trained interviewer will ask you questions in a private place where you will feel comfortable.
- Some of the information regarding the outcome of the delivery will be completed from your patient file records.
- The information we collect will be kept confidential. The research reports and publications will not reveal your identity.

What potential risks are Associated with Participation in this Study?

We do not anticipate any risks with your participation in this study. Nevertheless, you are free to decide if you want to participate in the study or not. Whether or not you participate in the study will not affect the care you will receive at the facility.

Privacy & Confidentiality

Privacy is the right of an individual to have some control over how his or her personal information/data is collected, used, and/or disclosed. Confidentiality is the duty to ensure information(data)is kept secret only to the extent possible/reasonable.

Your name or contact details will not be recorded and the information we collect will be kept confidential. The filled interview guides will be dropped in a sealed box not to be retrieved and traced back to you after the study. The filled interview guides will only be available to the researcher, supervisors, and statistician if need be. After analysis, the interview guides will be stored in a safe sealed box for a minimum of 10 years or until the University archivist provides approval to discard the data. The research reports and publications will not reveal your identity.

In case you aren't comfortable answering any of the questions during the interview because of feeling embarrassed or uncomfortable, it will be within your rights to decline. Otherwise, every measure has been taken to ensure that the interview is conducted in a private area with minimal to no interference so that you feel comfortable.

What Benefits are you Going to Accrue by Participating in the Study?

The findings of this study are anticipated to be relevant in assessing the safety and risks of Trial of labor after caesarean section (TOLAC) in low-resource settings. Additionally, evaluating factors associated with the success of TOLAC will help guide clinicians on patient selection, thus improving outcomes for both the mother and neonate.

What will it Cost You to Participate in the Study?

Apart from your time, we do not anticipate you will incur any cost should you participate in the study

**Will Any Expenditure that You Incur by Participating in the Study be Refunded?
Or will you be Paid for Participating in the Study?**

We will not be able to provide you with any payment or gift for being in the research, but we will appreciate your participation.

In Case I Have any Further Questions/ Concerns in Future Whom Should I Contact?

In the event that you need further clarification or questions regarding your continued participation in the study feel free to contact the PI Eunice Ondego (+254 711 477893).

In case of concerns regarding your rights and/or obligations as a research participant do

not hesitate to contact the secretary, KUREC on +254 710 360700.

What Alternative Options are Available to Me?

The decision on whether to participate or not is absolutely voluntary. You will be free to withdraw from the study at any point during the study without providing any explanation.

How Will the Findings of this Study be Communicated or Shared?

The findings will be described in a master’s thesis and at least one scientific research article. Further, we anticipate presenting the findings in one seminar or scientific conference.

Statement of Consent

I have comprehensively read the consent form or/the information has been comprehensively read to me by the researcher. I have understood what the study is about and all the questions and concerns that I had have been responded to in a clear and concise. The study benefits and foreseeable risks have been explained to me. I totally understand that my decision to participate in this study is voluntary and I have the right to withdraw at any point during the study.

I freely consent to participate in this study

Signing this form does not in any way imply that I have given up the rights am entitled to as a participant.

I agree to participate in this research YES_____ NO_____

Participant’s Name _____

Participant’s Signature/Thumb _____ Date _____

Appendix II: Questionnaire

Date (dd/mm/yy) unique Number

Birth plan 1. TOLAC 2. ERCS

- 1. Date and time of admission (dd/mm/yy) 00.00hrs
.....
- 2. Date and time of delivery (dd/mm/yy) 00.00hrs
.....
- 3. Date and time of discharge (dd/mm/yy) 00.00hrs
.....
- 4. Post-delivery hospital stay

Section A: Biodata

- 5. Age
.....
- 6. Marital status
 - a. Single b. Married c. Separated d. Divorced e. Widowed
- 7. Education level
 - a. None b. Primary c. Secondary d. Tertiary
- 8. Occupation
 - a. Unemployed b. Casual worker c. Formal employment d. Self employed

Section B: Antenatal Clinic

- 9. Center for ANC attendance in index pregnancy
- 10. Number of visits
- 11. Parity

Section C: Information on First Cesarean Section

12. Type of cesarean section

a. Elective

b. Emergency

13. Reason for CS

i) Recurrent reasons

CPD

Others.....

ii) Non current reason

NRFS

Malposition

Poor progress

Others.....

14. Duration of labor prior to CS

.....hours

15. Gestational age at CS.....

months/weeks/days

16. Complications after previous CS

a. Sepsis

b. hemorrhage

c. Others

.....

17. Length of time since previous CS

delivery.....months

18. Number of previous vaginal births (tick all that apply)

a. Prior to CS

.....

b. After CS

.....

Data collection

Information on Current Pregnancy

19. Complication on index pregnancy (tick all that apply)

a. Hypertension

b. Diabetes

c. Other (specify)

.....

20. Has any assessment before TOL been done

a. Yes- go to Q21

b. No -go to Q22

21. Assessment done prior to decision making (tick all that apply)

a. Erect lateral pelvimetry done

b. Clinical pelvimetry done

c. scan to estimate fetal weight

d. clinical estimation of fetal weight

e. other (specify)

Section D: Delivery

20. Cervical dilatation on admission to labor

ward.....cm

21. Cervical effacement at

admission.....%

a. >75%

b. 75-25%

c. <25%

22. Mode of delivery

i. VBAC

ii. EMCS

23. Indication of CS

1. NRFS

2. Poor progress

3. Impending uterine rupture

4. Malposition

5. Maternal choice

6. Others

24. Cervical dilatation at the time of CScm

25. Gestation at delivery.....months

Section E: Outcomes to Measure

26. Estimated blood loss mls

27. Blood transfusion requirementunits

28. Delivery trauma (tick all that apply)

- a. None
- b. Vaginal or cervical tear repaired in theatre
- c. Hysterectomy
- d. visceral trauma
- e. uterine rupture

29. Infection post-delivery (*tick all that apply*) hours after delivery

- a. Temperature >38^o c
- b. Wound infection-purulent discharge
- c. Uterine tenderness
- d. Purulent lochia
- e. Uterine sub involution
- f. No signs of infection
- g. extended antibiotic

30. Birth weight of babygrams

31. APGAR score at 5 min

32. Fetal status post-delivery (tick all that apply)

- a. Well go to Q35
- b. Admitted to NICU Go to Q33
- c, perinatal and neonatal death Go to Q34

33. Reason for admission to NICU

- a. Asphyxia
- b. Birth trauma
- c. Others (specify)

34. Perinatal/Neonatal death information

- i. Post-delivery.....hours/days
- ii. Cause of death.....

35. Maternal status on discharge

- a. Well
- b. Discharge on treatment
-

- c. Maternal death
 - i. Timing in relation to delivery hours/days
 - ii. Cause of death
- 36. Maternal postnatal hospital stay.....day of discharge

Appendix III: KUREC Approval



KABARAK UNIVERSITY RESEARCH ETHICS COMMITTEE

Private Bag - 20157
KABARAK, KENYA
Email: kurec@kabarak.ac.ke

Tel: 254-51-343234/5
Fax: 254-051-343529
www.kabarak.ac.ke

OUR REF: KABU01/KUREC/001/25/10/22

Date: 17-10-2022

EUNICE C. ONDEGO
GMMF/M/2694/09/18
Kabarak University

RE: BIRTH OUTCOMES AFTER A PREVIOUS CESAREAN SECTION: AN OBSERVATIONAL CROSS-SECTIONAL STUDY IN BOMET COUNTY

This is to inform you that **KUREC** has reviewed and approved your above research proposal. Your application approval number is **KUREC-251022**. The approval period is **17/10/2022 -17/10/2023**.

This approval is subject to compliance with the following requirements:

- i. All researchers shall obtain an introduction letter to NACOSTI from the relevant head of institutions (Institute of postgraduate, School dean or Directorate of research)
- ii. The researcher shall further obtain a RESEARCH PERMIT from NACOSTI before commencement of data collection & submit a copy of the permit to **KUREC**.
- iii. Only approved documents including (informed consents, study instruments, MTA Material Transfer Agreement) will be used
- iv. All changes including (amendments, deviations, and violations) are submitted for review and approval by **KUREC**:
- v. Death and life-threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to **KUREC** within 72 hours of notification;
- vi. Any changes, anticipated or otherwise that may increase the risk(s) or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to **KUREC** within 72 hours;
- vii. Clearance for export of biological specimens must be obtained from relevant institutions and submit a copy of the permit to **KUREC**;
- viii. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal and;
- ix. Submission of an executive summary report within 90 days upon completion of the study to **KUREC**

Sincerely,

Prof. Jackson Kletu PhD.
KUREC-Chairman

Cc Vice Chancellor
DVC-Academic & Research
Registrar-Academic & Research
Director-Research Innovation & Outreach
Institute of Post Graduate Studies



*As members of Kabarak University family, we purpose at all times and in all places, to set apart in one's heart, Jesus as Lord.
(1 Peter 3:15)*



Kabarak University is ISO 9001:2015 Certified

Appendix IV: Ethical Clearance



TENWEK HOSPITAL

- A Ministry of Africa Gospel Church

Postal Address:
P.O. Box 39-20400
Bomet-Kenya

Telephone: (254) 728-091900, 20-2045542
E-mail: info@tenwekhsop.org
Website: www.tenwekHospital.org

Date: August 8th, 2022

Dear Dr. Ondego and Dr. Cowles,

RE: 2022-0016; "Birth Outcomes After a Previous Cesarean Section: An Observation Cross-sectional Section in Bomet County"

This is to inform you that the Tenwek Hospital ISERC has reviewed the documents submitted and corrections and approved your research proposal. The approval period is **8th August 2022 to 7th August 2023**.

This approval is subject to compliance with the following requirements.

- i. Only approved documents including informed consents, proposal, and study instruments to be used.
- ii. All changes including amendments, deviations, and violations are submitted for review and approval by the Tenwek Hospital ISERC.
- iii. Death and life-threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to the Tenwek Hospital ISERC within 72 hours of notification.
- iv. Any changes anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to the Tenwek Hospital ISERC within 72 hours.
- v. Clearance for export of biological specimens must be obtained from relevant institutions if applicable.
- vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Fill out an annual renewal form from the website and attach a comprehensive progress report to support the renewal.
- vii. Submission of an executive summary report within 90 days upon completion of the study to the Tenwek Hospital ISERC.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology, and Innovation (NACOSTI) <https://research-portal.nacosti.go.ke> and any other relevant clearances needed.






Blessings in your study.
Sincerely,


Dr. Miriam Wanjala
ISERC Chairperson on behalf of the ISERC Committee



Tenwek Hospital is a Christian community committed to excellence in compassionate healthcare, spiritual ministry and training for service.

Appendix V: NACOSTI Research Permit

 <p>REPUBLIC OF KENYA</p>	 <p>NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY & INNOVATION</p>
RefNo: 946961	Date of Issue: 19/October/2022
RESEARCH LICENSE	
	
<p>This is to Certify that Dr. EUNICE EUNICE ONDEGO of Kabarak University, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Bomet on the topic: BIRTH OUTCOMES AFTER A PREVIOUS CESAREAN SECTION: AN OBSERVATIONAL CROSS-SECTIONAL STUDY IN BOMET COUNTY KENYA for the period ending : 19/October/2023.</p>	
License No: NACOSTI/P/22/21093	
946961	
Applicant Identification Number	Director General NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY & INNOVATION
	Verification QR Code
	
<p>NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.</p>	
See overleaf for conditions	

Appendix VI: Tenwek Tolac Form

Tenwek Consent for Trial of Labor after a Cesarean Section

Patient Name

UHID number

Date

You are considering a vaginal birth after your previous cesarean section. Most women have a 70% success rate for a vaginal delivery.

The risk of **labor after a cesarean section** is that the uterus has a 1 in 100 risk of rupture at the area of the previous scar which can be serious for both mother and baby. For the baby if the uterus ruptures there is a 10-25% chance of brain damage or death. For the mother, it could result in emergency surgery that could include removal of the uterus (hysterectomy), blood loss, infection or death. The risk is higher if your labor has to be induced.

The risks of **cesarean section** include bleeding, infection, injury to bowel or bladder or other organs, damage to the uterus requiring hysterectomy, complications of anesthesia with rare risk of death, or blood clots.

These **risks are with every cesarean section** but higher if it is done after a trial of labor or as an emergency.

I have read or had explained to me the risks of a trial of labor after a cesarean section.

The alternative to a trial of labor is a repeat cesarean section.

I choose to attempt a trial of labor.

Patient/ authorized representative

Relationship to patient

Date and time

Provider Declaration:

I have explained the risks of a trial of labor compared to a cesarean section to the patient. I believe that the patient understands and has had her questions addressed.

Medical representative signature

Printed name

Date

Witness name

Witness signature

Date

Appendix VII: Paper Acceptance Letter



KABARAK JOURNAL OF RESEARCH & INNOVATION

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OUR REF: KABU01/KJRI/07/07/31

10th November, 2023

Dear E. Ondego,

SUBJECT: PAPER ACCEPTANCE

We are pleased to let you know that your submission to Kabarak Journal of Research & Innovation (KJRI) has been accepted for publication. Details of the submission are as follows:

TITLE

AN OBSERVATIONAL CROSS-SECTIONAL STUDY OF TRIAL OF LABOR AFTER A CESAREAN SECTION OUTCOMES IN BOMET COUNTY, KENYA

AUTHORS

Eunice CAROLYNE ONDEGO*, Amos OTARA, Peter HALESTRAP, and Cheryl COWLES

ISSUE

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VOLUME

Vol. 4

Congratulations on this achievement and thank you so much for choosing KJRI.

Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read 'Dr. Michael N. Walekhwa'.

Dr. Michael N. Walekhwa
Editor in Chief

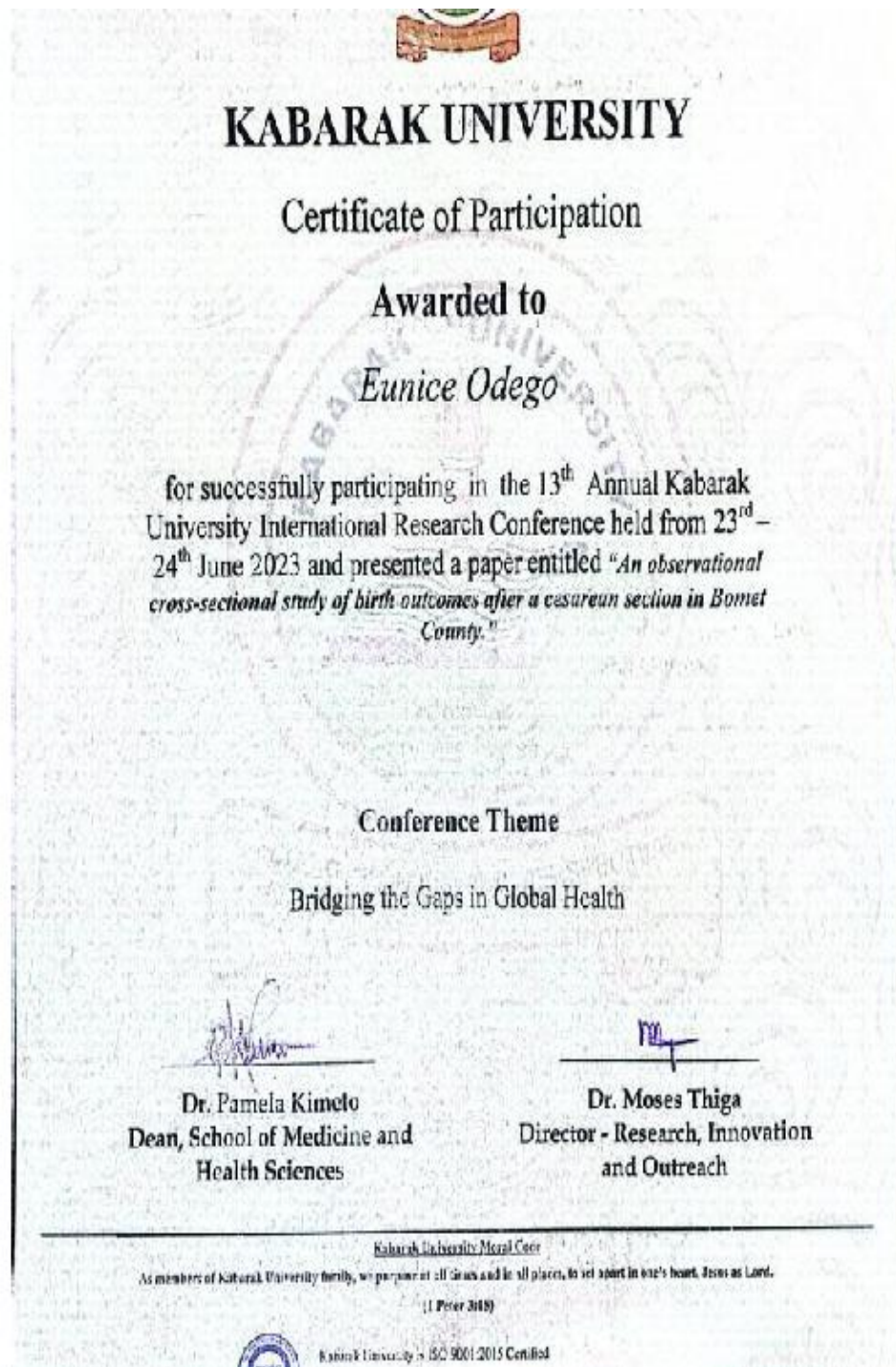
As members of Kabarak University family, we purpose at all times and in all places, to set apart in one's heart, Jesus as Lord. (1 Peter 3:15)

Kabarak University is



ISO 9001:2015 Certified

Appendix VIII: Certificate of Conference Participation (Kabarak)



Appendix IX: Certificate of Conference Participation (KAFP)

