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MASTER OF MEDICINE IN OBSTETRICS AND GYNECOLOGY

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BY

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DECLARATION

AND

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I, **Maria Angelica Rweyemamu**, declare that this thesis is my own original work and that it has not been presented to any other University for a similar or any other degree award.

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CERTIFICATION

The undersigned certify that they have read and hereby recommended for acceptance by the University of Dodoma dissertation entitled "Predictors and outcomes of women attempting vaginal birth after cesarean delivery at Iringa regional referral hospital" in partial fulfillment of the requirements for the degree of Master of Medicine in Obstetrics and Gynecology of the University of Dodoma.

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DEDICATION

To my parents

Who have always believed in my potential.

ABSTRACT

Background: The rate of Cesarean section has been increasing worldwide. In Tanzania the rate has doubled from 3% in 2004/2005 to 6% in 2015/2016. Previous Cesarean section as an indication for repeat Cesarean Section has increased from 7.2% in 2000 to 17% in 2011, repeat cesarean section is associated with long term complications like placenta accrete, hemorrhage, uterine rupture and a high fetal and maternal morbidity and mortality. Vaginal birth after Caesarean Section (VBAC) is an acceptable mode of delivery. However, in current practice VBAC is now replaced by repeat caesarean section.

Objective: This study aimed to determine the predictors and outcomes of women attempting Vaginal Birth After Cesarean delivery at Iringa Regional Referral Hospital.

Methods: Hospital prospective cohort study on women with one previous scar with gestation age >28 weeks. The sampling method was purposive and involved all women with one previous scar presenting at the hospital during the study duration. Data was analyzed by using SPSS version 20.

Results: 132 patients with one previous scar were involved in the study, 40(30%) patients were low risk and therefore eligible for Trial Of Labor After Cesarean (TOLAC) delivery, 41(31%) had Elective Repeat Cesarean Section (ERCS), and 51 had Emergency Repeat Cesarean Section (EmRCS). The success rate of VBAC was 55%, the main predictors of VBAC were maternal age of < 25 years and birth weight of < 3 Kg. Advanced cervical dilation, station of presenting part, spontaneous membrane rupture, gestation age <38 had clinical effect on TOLAC though was not significant. The rate of scar dehiscence was 5%, hysterectomy was 5% and post partum hemorrhage with blood transfusion was 7.5%. Maternal and neonatal outcomes of women undergoing TOLAC and ERCS were similar.

Conclusion: The rate of Successful VBAC is 55%, the significant predictors are maternal age and fetal birth weight. Women who undergo TOLAC may develop complication such as scar dehiscence, postpartum hemorrhage and may have peri-partum hysterectomy. Neonates of women who undergo TOLAC may have low score. The maternal and neonatal outcomes are similar to those of women undergoing ERCS.

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ABREVIATIONS

ACOG	American College of Obstetrics and Gynecology
ANC	Ante Natal Clinic
CS	Cesarean Section
EmOC	Emergency Obstetrics Care
EmRCS	Emergency Repeat Cesarean Section
ERCS	Elective Repeat Cesarean Section
IRRH	Iringa Regional Referral Hospital
MNH	Muhimbili National Hospital
SSA	Sub-Saharan Africa
TOA	Trial Of Scar
TOLAC	Trial Of Labor After Cesarean
VBAC	Vaginal Birth After Cesarean Section
WHO	World Health Organization

CHAPTER ONE

INTRODUCTION

1.1 General Introduction

Cesarean Section (CS) is an important obstetrical intervention that can save and improve the maternal and neonatal outcome in many obstetrical complications. The rate of primary cesarean deliveries has been increasing world-wide. World Health Organization (WHO) has come to a conclusion that cesarean section rates less than 15% are associated with a decrease in maternal and neonatal mortality ("WHO Statement on Caesarean Section Rates," 2014). The global rate of CS is 18.6%, with South America having the highest rate by region of 42.4% (Betrán et al., 2016). The same review identifies Africa as having the lowest CS rates, with West Africa having the lowest rates of 3%. Despite many indications that lead to an increase of CS, most studies have identified that more than 50% are due to a primary CS (Barber et al., 2011). Consequently more women present to the hospitals with previous scars leading to an increased rate of repeat CS. Areas that have an increasing rate of repeat CS have a decreasing rate of Vaginal Birth After Cesarean Section (Barber et al., 2011).

The rate of CS increase in Africa differs, northern Africa is experience high increase while the Sub Saharan Africa (SSA) has an almost stable, steady rate with other regions having decreasing CS rates (Betrán et al., 2016). The major challenges in SSA are the inequality in accessibility of CS, with high rates in urban areas and low rates in rural areas. In a Benin the rate of CS differs greatly across economic status and urban and rural areas, almost doubles across economic status and across locations (Harrison & Goldenberg, 2016). The main indications of CS in SSA are

obstructed labor, fetal mal presentation and a previous CS. In Ghana the relationship between CS rates and VBAC are inversely proportional (Seffah & Adu-Bonsaffoh, 2014). An increase in the rate of TOLAC will reduce the rate of increase and number of CS and reduce economic burden that a repeat CS has on health system (Gilbert et al., 2013). When compared, complications of ERCS and TOLAC do not differ significantly though one group may present a higher risk than the other. ERCS has a higher risk of hysterectomy, blood transfusions and postpartum febrile morbidity (Cheng et al., 2011).

VBAC is an acceptable and safe mode of delivery; this is when a woman with a previous CS is planned beforehand to deliver vaginally in subsequent pregnancy. World-wide the rate of successful VBAC ranges between 60-80% (Grobman, 2010). Successful VBAC depends on careful selection of the pregnant women for Trial of Labor After CS (TOLAC). American College of Obstetrics and Gynecology (ACOG) has identified previous history of vaginal birth and spontaneous labor as strong predictors of successful TOLAC (American College of Obstetricians and Gynecologists, 2010). Women with one previous scar and low risks have high success rates of TOLAC and their outcomes are comparable to those with ERCS (Kabore et al., 2016). Low risk women are those that have one cesarean delivery and a low transverse uterine incision with no contraindication to vaginal delivery (American College of Obstetricians and Gynecologists, 2010). There are other factors that may modify the risks and chances of a successful trial of labor, these include; fetal size, number of previous CS, gestation age, indication for previous CS , referral patients, maternal age, bishop score and spontaneous labor (Gupta,

Jeeyaselan, Guleria, & Gupta, 2014; Obeidat et al., 2013) these are known as the predictors of successful VBAC.

In Sub- Sahara Africa, the rate of successful VBAC ranges between 65%-75% (Boulvain, Fraser, Brisson-Carroll, Faron, & Wallast, 1997) however this varies across countries. A cohort study done in Mali and Senegal had a success rate of 44% (Kabore et al., 2016), a study done at a teaching hospitals in Ethiopia Addis Ababa had a success rate of 65% (Birara & Gebrehiwot, 2013). Some authors have argued that being in a resource limited environment VBAC is considerably unsafe to be practiced in SSA (S. Z. Wanyonyi & Ngichabe, 2014). SSA faces the challenge of infrastructure, skilled health personnel, and limitation in referral systems, resulting in low success rates of TOLAC and poor maternal fetal outcomes (Kabore et al., 2016).

Over the decade the rate of CS has doubled in Tanzania from 3% to 6%, urban areas have the highest rates of CS, with Dar-Es-Salaam having the highest rate of CS of 17% (MoHCDGEC, 2015). Despite an increase in the rate of primary CS, there is a tremendous improvement in maternal and fetal outcomes (Muganyizi, Kidanto, Kazaura, & Massawe, 2008). However another study in Tanzania revealed that a considerable percent of the emergency CS were done on doubtful indications (Maaløe, Bygbjerg, Onesmo, Secher, & Sorensen, 2012). The trend of a previous CS as an indication for CS has been increasing from 7.2 % in 2000-2002 to 17% from 2009-2011 (Litorp, Kidanto, Nystrom, Darj, & Essén, 2013). Tanzania like other SSA countries has limited studies that have explored VBAC. A study done at Muhimbili National Hospital showed a success rate of 55% with high maternal and perinatal morbidity, more than 50% of the women undergoing trial of scar were

referred to MNH, the time to delivery from the decision time was prolonged, with poor labor monitoring (Pembe & Othman, 2010).

1.2 Problem Statement

More women with a previous scar are delivered by cesarean section leading to an increasing rate of repeat cesarean section (Litorp et al., 2013; Litorp, Roost, Roost, Kidanto, & Nystrom, 2016). Repeat CS is associated with poor maternal outcomes with long term complications like risks to developing placenta accreta, rupture of uterus, surgical injuries, hysterectomy and death (Cheng et al., 2011; Clark & Silver, 2011). The risk to complications increases with number of CS, parity and socio economic status (Nuamah et al., 2017). Infants born by CS also have an increased risk of developing asthma, inflammatory bowel disease and type 1 diabetes (Black, Bhattacharya, Philip, Norman, & McLernon, 2016). In addition repeat CS when compared to VBAC is associated with a high economic burden to the health system and costly to the woman (Rogers, Rogers, Kilgore, Subramaniam, & Harper, 2017). Most women do not have an expected mode of delivery indicated on their ANC card, and do not have a birth plan and do not know what to expect during birth next to CS (Pembe & Othman, 2010).

1.3 Study Objectives

1.3.1 Main Objective

To evaluate the predictors and obstetric outcomes of trial of labor after one previous cesarean delivery in comparison to those of women who are elected for a repeat CS at Iringa Regional Referral hospital

1.3.2 Specific Objectives

1. To determine the success rate of low risk women undergoing trial of scar at Iringa Regional Referral Hospital
2. To determine the predictors of successful Vaginal Birth After Cesarean delivery at Iringa Regional Referral hospital.
3. To determine the maternal outcomes of women undergoing Trial Of Labor at Iringa Regional Referral Hospital
4. To determine the neonatal outcomes of women undergoing Trial Of Labor at Iringa Regional Referral Hospital.
5. To compare the outcomes of women undergoing Elective Repeat Cesarean Section and women undergoing Trial Of Labor at Iringa Regional Referral hospital.

1.3.3 Research Questions

This study aimed at answering the following questions:

1) What is the success rate of Trial Of Labor in women with low risk profile at Iringa Regional Referral Hospital?
2) What predicting factors are associated with a successful Trial of Labor at Iringa Regional Referral Hospital?
3) What are the maternal complications and morbidities associated with Trial of Labor at Iringa Regional Referral hospital?
4) What are the fetal complications and morbidities associated with Trial of labor at Iringa Regional Referral Hospital?

5) What is the difference in outcome between Elective Repeat Cesarean Section and Trial of Labor after at Iringa Regional Referral Hospital?

1.4 Significance of the Study

The outcomes of this study will help to guide health workers in counseling and developing individualized birth plan for women with one previous scar. The study outcomes will also guide practitioners at Iringa Regional Referral hospital in decision making concerning the mode of delivery of women with one previous scar and eventually reduce the unnecessary repeat CS. This study will help to put a check on the rising rates of cesarean section and in the long run reduce maternal morbidity, mortality and the economic burden of CS on the health system.

CHAPTER TWO

LITERATURE REVIEW

2.1 Cesarean Section Rates

With increasing rates of CS in the world, pregnant women with previous scars are increasing (Gibbons et al., 2012). WHO recommends that a C/S rate that is less than 15 % is associated with a decrease in maternal and neonatal mortality. However there is no proof that a higher rate of CS is associated with increasing rates of maternal deaths ("WHO Statement on Caesarean Section Rates," 2014). The rate of increase is higher in developed countries compared to developing countries. In America the increasing rate of CS was accounted for by a rising rate of primary and secondary CS. The main reason to an increase in primary CS was that ACOG allowed elective CS as per maternal request. The increase in repeat C/S was due to fear of complications and financial litigations for malpractice increased (Barber et al., 2011).

Africa has the lowest rates of CS in the world (Betrán et al., 2016). Though the rate of increase is low in Sub-Saharan Africa the increment is real. Previous CS accounts for 14% of CS, though this vary by region (Chu et al., 2012). Access to CS in Africa is dictated by socio-demographic factors with level of education and financial status being the greatest factors (Nilsen, Østbye, Daltveit, Mmbaga, & Sandøy, 2014).

The burden of increasing CS in Tanzania lies in the urban areas (MoHCDGEC, 2015). According to the same DHS Iringa region has CS rate that is 11.9% almost double the national level with 4% of them being elective CS. Studies done in Tanzania show the rate of CS at tertiary hospitals to be high, Muhimbili National

Hospital has a rate of more than 30% (Muganyizi et al., 2008). The rate of CS is higher in patients who are referred to the hospitals (Sørbye, Vangen, Oneko, Sundby, & Bergsjø, 2011; Worjoloh et al., 2012). Studies done to evaluate the indications for CS in rural areas came to a conclusion that some areas have a high CS and many of CS are not indicated this was mainly due to lack of clinical knowledge and intervention skills (Litorp et al., 2013; Maaløe et al., 2012).

2.2 Repeat Cesarean Section

Primary CS accounts for 50% of all CS in developed countries resulting in more women presenting with a previous scar, 90% of these women will end up with a repeat CS (Barber et al., 2011). The rising rate of repeat CS is strongly associated with the falling trend of VBAC (Rosenstein et al., 2013). Despite having a low CS rate developing countries are facing the same increment in repeat CS as in developed countries mainly because they have more women presenting with previous scar and they lack the human resource and strict guidelines to enable TOLAC (Litorp et al., 2013; Mittal, Pardeshi, Mayadeo, & Mane, 2014). In India main indication of repeat CS was fetal distress, scar tenderness and labor arrest (Mittal et al., 2014), in Africa cephalopelvic disproportion, failure to progress, pre-eclampsia/eclampsia and post-date (Seffah & Adu-Bonsaffoh, 2014).

Repeat CS are associated with complication like placenta accreta, adhesions, bowel injuries bladder injuries, prolonged operation time, excessive blood loss and blood transfusions this are more in women with more than 4 CS (Clark & Silver, 2011). The prevalence of complications tends to increase with an increasing number of CS deliveries, parity, and socio economic status (Nuamah et al., 2017; Silver, 2010).

Infants born during a repeat CS may have a risk of developing childhood diseases like asthma, inflammatory bowel disease and type 1 diabetes (Black et al., 2016).

2.3 Vaginal Birth after Cesarean Section

Vaginal Birth After Cesarean Section is safe option for women with a cesarean scar. ACOG has given recommendation on the practice of VBAC, trial of labor gives the women an opportunity to deliver vaginally and avoid the complications associated with a repeat CS (American College of Obstetricians and Gynecologists, 2010). The rates of successful VBAC worldwide ranges from 60%-80% , A study done in London showed that more than 2/3 of women undergoing trial of scar had successful VBAC (Knight et al., 2014). However the rates of trial of trial of scar are decreasing in developed countries (Grobman et al., 2011) the studies indicates that a change in health policies and fear for litigations are the major causes (Cox, 2011; Grobman, 2010). In spite of this the rate of successful VBAC remains the same (Eden et al., 2012; Grobman et al., 2011), in order to overcome these challenges studies done in countries with the highest rates of VBAC have concluded that working in a team, according to the guidelines and having a good rapport with the woman is fundamental (Lundgren, van Limbeek, Vehvilainen-Julkunen, & Nilsson, 2015).

Given the low rates of CS in Africa, and the low coverage of access to CS it would be contradictory to say that there is a need to reduce rates of CS, however not providing a check to the rising rates of CS would lead to high morbidity of women and thus a greater financial burden on the health systems (Harrison & Goldenberg, 2016). In Africa the main concern regarding VBAC is the safety in terms of measures to manage the associated complications (S. Wanyonyi & Muriithi, 2015; S. Z. Wanyonyi & Ngichabe, 2014). In situations where trial of scar has been done

in tertiary hospitals and private hospitals success rates have been comparable to those in middle income countries, studies done in Nigeria show a success rate of 50% in tertiary hospitals, and 69% in a private hospital setting (Ezechi et al., 2005; Ugwu, Iyoke, Onah, Egwuatu, & Ezugwu, 2014). A study done in a rural area of Zimbabwe had a VBAC success rate of 44% and in rural Tanzania a rate of more than 50% was achieved (Spaans, Van Der Velde, & Van Roosmalen, 1997; van Roosmalen, 1991).

2.4 The Predictors of Successful VBAC and Patient Selection Criteria

It is recommended that the risks (low as possible) and benefits (high as possible) should be balanced in order to achieve a successful VBAC (American College of Obstetricians and Gynecologists, 2010). Trial of scar has two main strong predictors which are previous vaginal delivery and spontaneous labor; however there are other minor factors can affect it. Selection of patients for TOS depends on the predictive characteristics of the patient for successful VBAC.

Previous vaginal delivery has a high predictive value for successful VBAC. Studies have shown that an increasing parity is associated with a successful VBAC (Birara & Gebrehiwot, 2013; Senturk, Cakmak, Atac, & Budak, 2015). In India an observational study showed that prior vaginal delivery was a strong predictor of successful VBAC (P= 0.001) (Doshi, Jain, & Vazirani, 2010a). Previous successful VBAC is another positive indicator for VBAC, a study done to evaluate the effect of successive vaginal births after VBAC in America concluded that with increasing parity after VBAC the success rate increased and the risk for maternal and fetal complications decreased (Mercer et al., 2008).

The mode of onset of labor, whether by induction or spontaneous has a significant effect trial of scar. Studies have shown that women who start labor spontaneously have a significant success rate (Birara & Gebrehiwot, 2013; Gupta et al., 2014) . A study done in women with spontaneous labor showed that even in this group of women other factors play an important role in the success of VBAC (Obeidat et al., 2013). Studies done on the induction of labor in patients who are trying the scar have shown that induction is not associated with increasing risk to complication (Harper et al., 2012; Schmitz et al., 2013). A study done by induction of women using a double balloon catheter for cervical ripening followed by oxytocin showed that this method was safe to use in women with a previous scar (De Bonrostro Torralba et al., 2017).

The stage of labor at admission for the trial of scar has an effect on the success rate of VBAC (Birara and Gebrehiwot 2013; Senturk et al. 2015) . Women with a higher bishop score at admission have a higher success rate. In turkey cervical dilation above 4 and effacement of more than 50% were significant (P= 0.001) predictors of successful VBAC (Senturk et al., 2015). Women who present with fetal head station greater than -2 had poor prognosis for VBAC (Abdelazim et al., 2014a).

The events that led to the previous CS have an effect on success of trial of scar. Factors like the stage of labor and indication of the previous cesarean; women with a non-recurring indication in the previous cesarean like fetal mal presentation or fetal distress have better outcomes compared to those with indications like poor progress of labor or failure of induction (Gupta et al., 2014). Women who were sectioned when in the second stage of labor were more likely to have successful VBAC

compared to those in the first stage (Lewkowitz, Nakagawa, Thiet, & Rosenstein, 2015). The effect of cervical dilation at previous cesarean was evaluated by (Obeidat et al., 2013) whereby women who had cervical dilation of more than 7 cm had a higher probability to deliver vaginally. The gestation age at which the prior CS was done does not affect the success of VBAC (Harper et al., 2009).

Maternal and fetal factors have an influence on the outcome of trial of labor though they are not major contributing factors. The major maternal factors that will influence VBAC are Body mass index (BMI) and age; studies have shown that a high BMI greater than 25kg/m^2 is associated with failure of VBAC (Abdelazim et al., 2014b; Gunatilake et al., 2013). The age factor is contradictory, some studies find that it is not a significant predictor (Birara & Gebrehiwot, 2013) whereas other studies state that maternal age equal to or more than 35 years is associated with reduced likelihood of VBAC (Doshi et al., 2010a). Fetal factors that can affect VBAC are gestation age and fetal weight; gestation age of more than 40 week at the time of trial of scar has reduces the chance of success (Abdelazim et al., 2014b), the success of VBAC is inversely proportional to the fetal weight, women with a fetal weight less than 3 kg have higher chances of VBAC (Doshi et al., 2010a; Gomal Medical College., Ahmad, Abbasi, & Anwar, 2003a).

2.5 Complications of Vaginal Birth after Cesarean

Obstetrical literature has divided the complications of VBAC as either short term or long term maternal complications. The short term maternal outcomes are further divided into either adverse/severe immediate complications and less severe complication. The severe complications include uterine rupture, hysterectomy,

urinary bladder injuries, thromboembolic events and death (Patel & Jain, 2010). The less severe complications are blood transfusion, postpartum hemorrhage, endometritis, puerperal fever, infection, wound infection and prolonged hospital stay (Lydon-Rochelle, Cahill, & Spong, 2010; Patel & Jain, 2010). The long term maternal complications include; infertility, placenta previa and percreta due to a repeat cesarean section, adhesions and chronic pelvic pain (Silver, 2010). Most studies have evaluated the complications depending on the perinatal circumstances; the risks of successful VBAC are compared to those of elective repeat CS, failure of TOLAC, and elective repeat CS in labor (Tahseen & Griffiths, 2010). Women who have successful VBAC have lower risk of morbidity compared to those with elective repeat CS, on the other hand failure of TOLAC is associated with a higher risk of morbidity compared to elective repeat CS (Kabore et al., 2016; Patel & Jain, 2010; Silver, 2010; Tahseen & Griffiths, 2010).

Uterine rupture is the most significant severe complication of TOLAC. Uterine rupture with involvement of the placental site is fatal to the fetus. The risk of uterine rupture in a woman with a previous low segment CS is less than 1% (de Lau, Gremmels, Schuitemaker, & Kwee, 2011; GROBMAN et al., 2008). Many studies have been done in order to develop a predictive model for uterine rupture but they haven't been successful. Uterine rupture is less in women with prior vaginal delivery (GROBMAN et al., 2008). The risk of rupture increases with the number of scars and the type of scar (Macones et al., 2005). The inter-delivery interval of the of less than 18 months is associated with an increased risk of uterine rupture (Bujold & Gauthier, 2010) . Women with an inter delivery interval of more than 24 months have the best outcome.

Conceptual Model: This is illustrated in Figure 1.

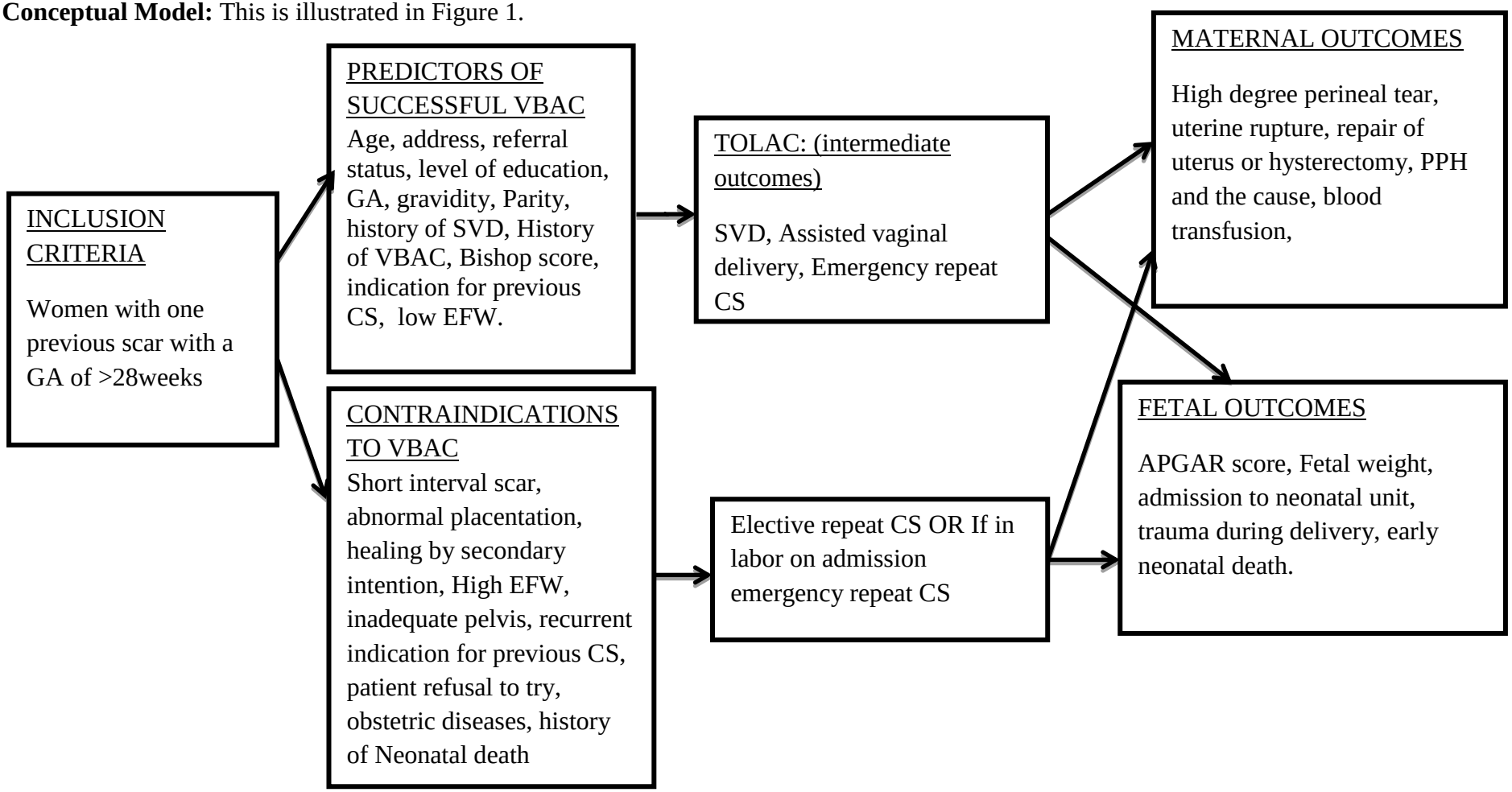

Figure 1: Conceptual model

CHAPTER THREE

METHODS AND MATERIALS

3.1 Study Design

This was prospective quantitative study. The study design was used because the study involved follow up of women from the antenatal period to the post natal period. The cohort study design also allows for comparison of outcomes between two proportions of a single population.

3.2 Study Location and Duration

The study was conducted from February 2018 to May 2018. This study was conducted at the Iringa Regional Referral Hospital (IRRH). IRRH is a teaching and a referral hospital for high risk patients in the Iringa region. Iringa Regional Referral hospital serves Iringa region, Njombe region, part of Dodoma region, and part of Morogoro region, Agriculture is the main economic activity of Iringa region with other activities like animal herding and urban areas mainly has business and the working class. The rate of CS in Iringa region is 11.9% almost twice the national rate (MoHCDGEC, 2015) urban areas have the highest rates compared to rural areas.

The department of Obstetrics and Gynecology at IRRH has got a bed capacity of 72 patients distributed within 4 wards, labor ward has a capacity of 12 beds, with the remaining antenatal, postnatal and gynecological ward having an average of 24 beds each. The labor ward has its own theater and available staff for 24 hours in case of any emergency CS. The department hosts resident doctors for Obstetrics and Gynecology from the University of Dodoma who are available throughout the day.

The department had a total of 5139 deliveries for the year 2017, out of which spontaneous vaginal deliveries were 2623 and CS were 2516. CS made 49% of all deliveries in the hospital last year, though not published more than 50% of patients with previous scars underwent a repeat CS. On average the labor ward has 428 deliveries a month of which 218 are vaginal deliveries and 210 are CS. The labor ward admits an average of 14 patients in a day of which half of them delivered by CS.

The labor ward has well equipped neonatal resuscitation unit which has a resuscitation table, manual resuscitation bags, suction machine, oxygen concentrator, penguin manual suckers, and a radiant warmer. The labor ward has an obstetrician, one medical doctor, two assistant medical officers, 14 midwives and resident doctors from UDOM. The staff members are skilled at handling obstetric emergencies and neonatal resuscitation. The labor ward is adjacent to a neonatal unit that is well equipped with neonatal support equipment's and skilled staff members.

3.3 Study Population

The target population for this study involved all women with one previous scar and above 28 weeks gestation age who delivered at IRRH.

3.3.1 Inclusion Criteria

- Singleton pregnant women,
- Above 28 weeks but less than 42 weeks of gestation;
- One previous cesarean delivery,
- Fulfill the ACOG criteria for Trial Of Scar After Cesarean, as shown in appendix 4.

3.3.2 Exclusion Criteria

- Patients with a permanent indication for the primary cesarean section,
- Patients with an inter-delivery interval of less than 24 months,
- Patients who had poor healing with wound infection during the primary cesarean section,
- History of perinatal fetal death during primary cesarean delivery,
- Women who developed fistula post-delivery.

3.4 Sample Size

The sample size was calculated by using prevalence from a study done on outcomes in SSA; where the prevalence of developing at least one complication in women undergoing TOLAC was compared to those who underwent ERCS (Kabore et al., 2016), the formula for the calculation of sample size for an independent cohort by Schlesselman was used (Kasiulevičius, Šapoka, & Filipavičiūtė, 2006). This is shown in equation (i):

$$n = \frac{[Z_{\alpha}\sqrt{(1+1/m)\bar{p}(1-\bar{p})} + Z_{\beta}\sqrt{p_0(1-p_0)/m + p_1(1-p_1)}]^2}{(p_0 - p_1)^2} \quad \text{..... (i)}$$

Where: $\boldsymbol{n}$ = sample size for the cohort study

$\boldsymbol{m}$ = the ratio of p_0/p_1

$\boldsymbol{p_0}$ = the prevalence of events in the unexposed group = 0.29

$\boldsymbol{p_1}$ = the prevalence of events in the unexposed group =0.44

$\boldsymbol{\alpha}$ = is the probability of making a type 1 error

$\boldsymbol{\beta}$ = 1- power (80%)

$\bar{p}$ = the mean of the probability of events in the population which is calculated by using the formula given in equation (ii)

$$\bar{p} = \frac{p_1 + mp_0}{m+1} \quad \text{..... (ii)}$$

The above values were entered into the STATA software automatic calculation of sample size for cohort study for one proportion and gave the result for sample size to be;

n = 82

The minimum sample size required for the study was 82 patients.

3.5 Sampling Method

This study is a hospital based study and thus included all patients who fit the inclusion criteria. Purposive sampling method was used to sample the participants. The women were allocated for either TOLAC or ERCS depending on the predictive criteria for TOLAC. The ratio of the women who underwent TOLAC to ERCS were determined at the end of the study and did not have to be specified at the beginning, by assuming that the two groups are similar since they are derived from the same population proportion.

3.6 Data Collection and Tools

The women were recruited from the antenatal clinic and antenatal ward, the women who fit the American College of Obstetrics and Gynecology (ACOG) recommendation for the trial of scar were then counseled to give informed consent to participate in the study, and they were requested to sign a consent form. Each was assigned a serial number for follow up. An obstetric ultra sound was done for a more

accurate estimation of fetal weight, placenta location and other fetal and obstetric complications. Socio demographic information and obstetric history information was then filled into a structured questionnaire by the researcher as illustrated in Appendices. Patients who were not in labor were given the researchers mobile phone number for contact on symptoms of labor initiation and were discharged with instructions on danger signs and to stay at a residence near the hospital or easily accessible. On admission the patients were examined by the researcher or research assistant for estimation of fetal size, fetal lie, fetal heart rate, pelvic adequacy and cervical bishop score. The patients were admitted in antenatal ward if in latent phase of labor, and in labor ward if in active phase of labor. On admission to the labor ward, the patient had secured intra venous access, catheterization, Hb-grouping and cross match and information was given to the theater, anesthetic and neonatal unit about the patient. Labor was managed by using a standard WHO partograph. Labor was abandoned when there was poor progress of the labor in terms of dilation and descent of the presenting part, signs and symptoms of obstructed labor, excessive vagina bleeding, presence of signs impending rupture like signs of fetal distress, lower abdominal tenderness and pain, increased maternal purse rate and decrease in maternal blood pressure. Women who were elected for CS and those who underwent emergency CS were observed intraoperative for scar dehiscence and uterine rupture, excessive blood loss and the cause of blood loss, traumatic injuries to the bladder uterine tear and the need for cesarean hysterectomy. Patients were observed for post-partum complication like hemorrhage, admission of infant to neonatal unit, neonatal death. The mothers who have neonatal admission were followed for the period of

admission. The mothers were observed for three days post-partum for immediate complications.

3.7 Data Entry and Analysis

Socio demographic data; obstetric information; and labor outcomes were coded and entered into SPSS version 20. The data were cleaned and explored for simple frequency and prevalence, means, and deviations; this helped in identifying any missing data, out of range data and repetition.

The prevalence of one previous scar among the patients was analyzed by frequency statistics. The prevalence of the women with one previous scar who underwent TOLAC and were successful was calculated by simple frequency statistics, in order to determine the success rate.

The positive predictors of successful vaginal delivery after one previous scar were determined by running cross-tabulation and calculation of the chi-square and fisher's exact test and p-value. Those predictors that had p-value of less than 0.05 were taken to be significant.

The neonatal outcomes of all the study participants were studied depending on the mode of delivery of the mother and the frequencies of each outcome were determined by simple distribution statistic. The chi square test and Fishers exact test were then be used to determine if the mode of delivery of the mothers have a significant effect on the neonatal outcome.

Intra-partum and post-partum maternal outcomes frequency were also calculated by simple distribution and the significant association with the mode of delivery was determined by the chi square test and the fisher's exact test.

The significant predictors of successful TOLAC were run in binary logistics regression to develop a model of prediction for TOLAC and calculation of the odds ratio with a 95% confidence interval.

3.8 Validity and Reliability

In this study the researcher and the research assistants performed antenatal assessment on the same women and the results were compared to crosscheck for similarity and consistency. The researcher and research assistants performed important procedure like estimation of fetal weight by physical examination, assessment of pelvic adequacy, and bishop scoring of a woman in labor.

The results of the above mentioned procedures by the researcher and research assistants were compared to the results of a consultant obstetrician. The researcher and research assistant had a working experience of at least two years in the field of obstetrics and hence were conversant with above mentioned procedure and management of labor. The researcher and research assistants used the ACOG guidelines (American College of Obstetricians and Gynecologists, 2010) in patient selection for TOLAC. This acted as a tool and reduced bias in patient selection.

3.9 Description of Variables

Independent Variables

In this study the following were the independent variables;

- Socio-demographic information e.g. age of the patient, marital status, occupation and referral from another health facility, and address
- Previous obstetric history of the patients e.g. gravidity, parity, number of previous vaginal deliveries, and history of early neonatal death
- History of index pregnancy, gestation age by date, presentation, placentation and admissions during pregnancy.
- Index pregnancy labor: mode of labor induction, bishop score on admission, indication for emergency repeat CS/ elective repeat CS, duration of labor.

The independent variables were used as the predictors for the outcomes of TOLAC, they were analyzed by cross tabulations to determine which amongst these are significant.

Dependent Variables

The dependent variables of this study was the short term maternal and neonatal outcomes associated with the mode of delivery

Modes of delivery of the women with one previous scar

- Successful vaginal delivery after a previous cesarean delivery: this included both assisted and spontaneous vaginal delivery.
- Emergency cesarean section which was done in the presence of failed trial of labor and women presenting in labor but do not fulfill the criteria for TOLAC.
- Elective repeat cesarean section

Short term maternal outcomes

- Uterine rupture
- Hysterectomy
- Post-partum hemorrhage
- Post-partum blood transfusion
- High degree pereneal tear
- Repair of the uterus
- Maternal death

Short term fetal outcomes

- APGAR score at 1^{st} and 5^{th} minute after delivery
- fetal weight
- perinatal mortality and
- Admission to neonatal unit
- Early neonatal death

3.10 Ethical Clearance

UDOM ethical committee was sought for ethical clearance of this study and permission to conduct the study was sought from the Administration IRRH and department of obstetrics and gynecology. Informed consent was obtained from the study participants on admission; however those who were not willing to participate in the study were not deprived of the intended services offered. Confidentiality was maintained by conducting the interview in privacy, the trained research assistants were required to remain non-judgmental to whatever they listened to or to any reaction/s of the respondents.

3.11 Study Funding and Budget

This study was funded by the Higher Education Students Loans Board, and the budget was prepared according to the University of Dodoma post-graduate fee structure

CHAPTER FOUR

RESULTS

4.1 Demographic Information.

Out of the 1143 women who delivered at IRRH 132 (11.5%) women had one previous scar. Out of the 132 women who were involved in the study, 40(30.3%) women were fit for trial of scar, 41(31%) women underwent ERCS, and 51(38.6%) women underwent EmRCS without TOS. The women were assigned trial of scar depending on the predictive criteria of ACOG. Fifty three participants (40.2%) of the study sample had a primary level of education, 68% (n=90) were in the age group of 25-34 years and 89.4% (n=118) were married, these groups had a higher proportions compared to other proportions of education, age group and marital status respectively, as illustrated in Table 1. There was small difference in the proportions of women depending on their areas of residence and their occupational status

Table 1: Demographic characteristic of the study sample (N=132)

Characteristic	Frequencies	Percentages
Age Groups		
15-24	28	21.2
25-34	90	68.2
35-44	14	10.6
Address		
Urban	67	50.8
Rural	65	49.2
Education Level		
College	31	23.5
Primary	53	40.2
Secondary	48	36.4
Marital Status		
Married	118	89.4
Single	14	10.6
Occupation		
Business	44	33.3
Employed	36	27.3
Peasant	52	39.4

4.2 The Rate of Successful Trial of Labor after Cesarean Delivery.

The women who underwent trial of labor were 40, out of these 22(55%) women delivered vaginally and the remaining 18 (45%) women were delivered by emergency CS. The main indications for the emergency CS were cervical dystocia and scar tenderness. The success rate of trial of labor after CS is 55%. There was no significant difference in proportions of the women who delivered vaginally and those who delivered by CS (p=0.527) as shown in Table 2.

Table 2: The success rate of Trial of Scar (TOS)

Mode of delivery	Frequency (n=40)	Percent (%)	*p* value
EMRC	18	45.0	0.527
SVD	22	55.0	

4.3 The Predictors of Successful Vaginal Birth after Cesarean Section.

The demographic and obstetric characteristics that were thought to have an effect on successful TOLAC were all analyzed by cross-tabulation and chi square values with *p-value* of < 0.05 were taken to be of significance. The characteristics that had values <5 in more than 25% of the cells Fishers exact test was used. Those that showed interesting relationships with successful TOLAC and significant p-value are the ones that are presented in Table 3.

Table 3: The predictors of successful Vaginal Birth After Cesarean delivery

Variables	TOLAC Fail (n=18)	TOLAC Success (n=22)	Chi-square	p-value
Age				
<=25	3 (21.4%)	11(78.6%)	4.835	0.028
>25	15(57.7%)	11(42.3%)		
Referral status				
No	18(52.9%)	16(47.1%)		
Yes	0(0.0%)	6(100%)	5.775*	0.024
Gestation Age				
<=38	6(37.5%)	10(62.5%)	0.606	0.436
>38	12(50.0%)	12(50.0%)		
History of VBAC				
No	16(45.7%)	19(54.3%)		
Yes	2(40.0%)	3(60.0%)	0.58*	1
History of SVD				
No	12(44.4%)	15(55.6%)		
Yes	6(46.2%)	7(53.8%)	0.010	0.919
cervical dilation on admission				
0-4(cm)	10(58.8%)	7(41.2%)	2.283	0.131
5-10(cm)	8(34.8%)	15(65.2%)		
Membrane status				
Intact	10(62.5%)	6(37.5%)	3.240	0.072
Rupture	3(27.3%)	8(72.7%)		
Station of presenting part				
-3—1	15(53.6%)	13(46.4%)	2.771	0.096
0-3	3(25.4%)	9(75%)		
Birth Weight				
≤ 3	4(21.1%)	15(78.9%)	8.386	0.004
> 3	14(66.7%)	7(33.3%)		

** > 25% of the cells had values < 5 therefore Fisher's Exact test was used.*

The women who were less than 25 years (78.6%) were more likely to deliver vaginally than women above 25 years (42.3%) with a *p-value* of 0.028. All the referral women (100%) who were low risk and underwent TOLAC had successful vaginal delivery; the proportional difference of success between them and those who were not referred (47.1%) was significant with a *p-value* of 0.024. Fetal birth weight of < 3.0 Kg was found to be significantly associated with successful VBAC with *p-value* of 0.004. Progress in cervical dilation, membrane status and station of the presenting part on admission to the labor ward had higher percentages of successful VBAC although the *p-values* > 0.05 therefore not statistically significant.

Table 4: Binary logistic regression for variables with significant prediction of successful Trial Of Labor After Cesarean delivery

Covariates	significant error	degree of freedom	p-value	Odds Ratio	95% C.I FOR OR	
					Lower	Upper
Age group	0.763	1	0.035	5	1.121	22.297
Birth weight	.729	1	.006	7.500	1.798	31.283

The variables that had a *p-value* < 0.05 were then run in binary logistic regression in order to create a model of prediction for successful vaginal delivery and find odds ratio of each variable in relation to mode of delivery. Table 4 shows binary regression logistics of the predictors and mode of delivery. The variables that had significant difference in proportions were age, birth weight and referral status. The age and birth weight had significant *p-value* < 0.05 in the binary logistic regression equation.

4.4 Maternal Outcomes of Women Who Underwent Trial Of Labor After Cesarean Delivery.

The maternal outcomes which were of interest to this study were presence of hemorrhage, uterine dehiscence or rupture, assisted vaginal delivery, repair of the uterus and intra-partum hysterectomy. Out of the 22 women who delivered vaginally 4 (18.1%) had assisted delivery by vacuum extraction, and one of the women was admitted with breech presentation but due to the delay in cesarean delivery due to unavailable theater and arrival of theater staff, she delivered by assisted breech delivery and developed scar dehiscence, Post-partum hemorrhage and underwent hysterectomy. Three women developed hemorrhage; two of these women were due to scar dehiscence. The prevalence of hysterectomy among the women who were tried was 5% (n=2), and uterine rupture was 5% (n=2). The prevalence of hemorrhage was 7.5% (n=3) in women who underwent trial of scar.

4.5 Neonatal Outcomes of Women Who Underwent Trial of Labor After Cesarean Section.

Out of the 40 women who were tried, there was one still birth pre-partum IUFD, there was no fresh still birth and no early neonatal death. The neonates who were admitted to Neonatal unit had two indications; three were due to low Apgar score and one due to early neonatal sepsis. The women who got low score infants had delivered vaginally and the infant who developed neonatal sepsis was delivered by emergency CS.

4.6 Comparison of maternal and neonatal outcomes between women who underwent Trial Of Labor After Cesarean Delivery and those who delivered by Elective Repeat Cesarean Section.

The ERCS (n=41) were due to obstetric indications e.g. bad obstetric history17(41.5%) such as placenta previa, placental calcification and hydramnios, week scar 13(31.7%), macrosomia 8(19.5%) and refusal to trial of scar 3(7.3%). The maternal outcomes of women who underwent TOS verses those who had elective CS were similar; there was no significant difference in the outcomes *p-value* > 0.05. Table 5 shows the maternal outcomes of women who were tried verses those who had elective CS. The women who underwent TOLAC had a higher proportional (7.5%, 5%, 5%) of developing hemorrhage, uterine rupture and hysterectomy compared to those who had ERCS (2.4%, 2.4%, 0%) respectively. The neonatal outcomes of women who underwent TOLAC were not different from those of who had ERCS. The two groups had an equal number of neonatal admissions, though the indications differed. Those who underwent TOLAC had a higher proportion of low score (7.5%) compared to those who had ERCS (2.4%) this difference in proportions was not significant p-value > 0.05.

Table 5: Comparison of maternal outcome in Trial Of Labor versus Elective Repeat Cesarean Section

Outcome	ERCS (n=41)	TOLAC (n=40)	p- value
Hemorrhage			
Yes	1(2.4%)	3(7.5%)	0.359
No	40(97.6%)	37(92.5%)	
Uterine tear/rupture			
Yes	0(0%)	2(5%)	
No	41(100%)	37(95%)	0.241
Hysterectomy			
Yes	0(0%)	2(5%)	
No	41(100%)	38(95%)	0.241

CHAPTER FIVE

DISCUSSION OF RESULTS

5.1 Overview

The socio demographic characteristics of the women were similar to other women studied elsewhere in SSA. These findings are similar to those found in Nigeria where the mean age was 32.1 ±4.7 years and the range was 23-44 years, 98.6% were married (Ugwu et al., 2014). In Egypt the mean age of women who were fit for TOL was 26.7 ± 4.09 and the gestation age mean was 38.2 ± 1.22 this gestation age is similar to that observed in the current study which was 38.89 ± 1.768 (Abdelazim et al., 2014a). The proportion of women presenting to the hospital with one previous scar (11%), is similar to that found at Muhimbili national hospital (Pembe & Othman, 2010). This similarity can be explained by the fact that IRRH is also a referral hospital for Iringa region and serves bordering parts of Dodoma, Morogoro and Njombe region. The percentage of women presenting with one previous scar is similar to that found in Nigeria 15.1% (Ugwu et al., 2014). Iringa regional hospital has the same prevalence of one previous scar as other referral hospitals in the country and SSA.

5.2 The success rate of low risk women undergoing trial of scar.

In the current study the success rate of TOLAC was 55%, the rate is lower than the average rate for SSA, which ranges between 65%-75% (Boulvain et al., 1997). The low rate could be due to early termination of trial of scar and early initiation of labor monitoring at a low cervical dilation which could have been false labor. However this is identical to that got at MNH which was also 55% (Pembe & Othman, 2010), it is similar to that got in Mali 51.1% and in Nigeria 50% in women with low risk

previous scars (Kabore et al., 2016; Ugwu et al., 2014). The success rate is clinically significant and comparable to other studies done in SSA and Tanzania. The similarities in success rate are due to similar settings and resources of the hospitals where the studies were carried out.

5.3 The predictors of successful Vaginal Birth After Cesarean delivery

The main predictors of successful TOLAC that were significant in our study were age of the woman and the weight of the neonate, these had a significant p-value <0.05. Age of less than 25 was more likely to deliver vaginally with an odds ratio 5 CI 1.2-22.3. Other studies have found that Age higher than 35 is associated with a lower success rate (Doshi, Jain, & Vazirani, 2010b). Advanced age is associated with increased parity and thus high success rate (Obeidat et al., 2013) .A lower age level (25 years) of successful TOLAC in our situation may be due to the fact that being in a developing country, we have early marriage and conception occur at a younger age than developed countries (MoHCDGEC, 2015). Other studies have found maternal age to be insignificant (Abdelazim et al., 2014a). Other studies however have found an increase in successful VBAC with decreasing maternal age (Doshi et al., 2010a).

Women who delivered infants with a birth weight of less than 3 Kg were more likely to deliver vaginally than those with a higher birth weight with an odds ratio of 7.5 CI 1.8-31. Vaginal delivery is more likely to occur with medium weight fetus between 2.5 Kg and 3.5 Kg. In this study Birth weight was estimated by use of ultra sound and those with a birth weight > 3.5 Kg did not undergo trial of scar. Other

studies have also reported a decrease in successful VBAC with increasing fetal weight (Gomal Medical College., Ahmad, Abbasi, & Anwar, 2003).

There was no significant association between a previous history of vaginal delivery, or a history of VBAC with successful TOLAC, this is contradictory to other studies and the fact that it is a major indicator of success. This may be due to the lower number of women who underwent trial of scar compared to other studies. A study done in New Delhi India had the same results and concluded that it was due to a small sample size (Gupta et al., 2014).

Other predictors which were not statistically significant but showed a higher proportion of successful TOLAC included gestation age, spontaneous rupture of membranes, station of the presenting part and cervical dilation. These are indications of labor progress on admission. Women who had progressed into the active phase of labor were more likely to deliver vaginally. These predictors have a clinical significant and effect on the success rate of TOL. Studies regarding these predictors are controversial some studies have found these factors predictive (Kabore et al., 2016; Senturk et al., 2015) while others have found no significance in these factors (Gupta et al., 2014; Obeidat et al., 2013). These studies have a common conclusion that these factors had an important effect on the success of VBAC; this makes these factors to be clinically significant.

A study done in Ethiopia had cervical dilation of >7 at admission to be significantly associated with VBAC these women were already in the active phase of 1st stage of labor, the study found that women who had cervical dilation <4 cm were more likely to have EmRCS this was explained by the fact that low cervical dilation was more

likely to be false labor and thus poor progress in cervical dilation and ending with CS (Gebrehiwot, 2013). The proportion of women admitted to labor ward with a cervical dilation of ≤4 cm was 17(42.5 %) in the current study and one of the main indications for EmRCS was cervical dystocia; this may be the reason why a higher cervical dilation had a high proportion of successive vaginal delivery.

5.4 Maternal Outcomes of Women who underwent Trial of Labor After Cesarean delivery.

VBAC is associated with a slight increase in maternal morbidity; in this study women who had TOL had a slightly higher proportion of maternal complications. SSA countries have reported similar rates of blood transfusion 7.6% hysterectomy 3.3%, uterine rupture 3.9% and general morbidity of 18.5% (Oboro et al., 2010). Studies done in Tanzania have shown varying morbidity and mortality, a study done at Muhimbili had uterine rupture of 2% (Pembe & Othman, 2010) and one maternal death, another study done in Tanzania had uterine rupture rate 6.7% (van Roosmalen, 1991).

5.5 Neonatal Outcomes of women who underwent Trial of Labor After Cesarean section.

Neonates born to women who underwent TOL had a main indication of low score for neonatal admission, however all the infants recovered after resuscitation and were able to be discharged within three days of admission. Neonatal sepsis was found in one infant born after failure of TOL. Studies have reported a significant higher rate of low score in women with successful TOL (Ugwu et al., 2014). A review of literature reported that neonates of women with failed TOL are more

likely to have neonatal sepsis as a result of increased risks such as prolonged rupture of membranes, failure of TOL, and operative delivery (Patel & Jain, 2010). Studies comparing neonatal outcomes of the two groups of women have reported a higher rate of need for resuscitation and respiratory morbidity in infants born by ERCS (Patel & Jain, 2010).

5.6 Comparison of outcomes of women who underwent Trial of Labor verses those who had Elective Repeat Cesarean section.

The maternal and neonatal outcomes of women who had ERCS and those who had TOLAC were similar, this was due to the fact that our study involved low risk women and like other studies that involved low risk there was no difference in morbidity and mortality. Other studies have reported similar findings and have concluded that TOLAC is safe option for women with a previous lower transverse scar (Birara & Gebrehiwot, 2013; Doshi et al., 2010a; Kabore et al., 2016; Senturk et al., 2015).

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

The rate of successful VBAC at IRRH is 55%. This rate is comparable to previous studies; women with one previous scar have a chance at vaginal delivery if they are selected with minimum risks and high prediction. The main predictors that were found significant were age less than 25 years and birth weight of less than 3Kg. The probability of successful VBAC increases with a decrease in age although this is a controversial predictor but in this study it was found to be significant. The lower the birth weight the higher the probability of successful VBAC.

VBAC is associated with relative maternal and neonatal complications; the major complications are PPH secondary to scar dehiscence, peri-partum hysterectomy and blood transfusion. The neonates born to women delivered vaginally were mainly admitted to neonatal unit due to low score. In this study there was no maternal and neonatal death. Women who are undergoing TOLAC need close monitoring during labor and should deliver at well-equipped tertiary hospitals

The women who underwent TOS had similar outcomes to those who had ERCS. There was no significant difference in the prevalence of maternal and neonatal complications between the two groups. There are minor differences in the indications for neonatal admission and the cause of maternal complications.

6.2Recommendations

- One previous scar should not be an absolute indication of a repeat cesarean delivery. Women should be given an opportunity to deliver vaginally. Screening of suitable candidates should begin during the antenatal clinic; women should be given education and information regarding delivery after a cesarean section.

- IRRH can reduce the rate of CS by decreasing the number of women who are having repeat CS, this can be done by active counseling of women during antenatal visits and screening for women who fit the criteria for TOS and have women with one previous scar to be birth prepared with a known mode of delivery before the onset of labor.

- More studies for longer durations and including a bigger sample size need to be done in order to have clearer predictors and determine other factors that can improve maternal and neonatal outcomes.

- The risks that are associated with TOS can be reduced by close monitoring of women in labor and having a team capable of handling peri partum complications. The team should include the neonatal department, theater team and obstetric team.

- Women with one previous scar should be made aware that the outcomes of TOS and ERCS are similar, but TOS has the advantage of reducing long term complications of having multiple cesarean scars. This will increase community awareness and thus early initiative to seek medical counseling among women with previous scar.

6.3 Strength of the study

- The current study was a prospective study therefore true real time cause and effect relationships were observed.
- This study involved single population and therefore the participants were identical with the only difference being Trial of labor.
- The current study was mainly focused on short term outcomes with close monitoring therefore we did not have any loss to follow-up.

6.4 Limitations and Suggestions For Further Studies

1. This study was done in partial fulfillment of the Master in Medicine in Obstetrics and Gynecology. To avoid any bias due researcher's personal academic interests that may have occurred, it would be best that;
    a. further studies be conducted with multiple data collectors,
    b. using other researchers in data analysis, and
    c. allowing other department personnel to review the results and give suggestions.
2. This study was also limited by short duration and a small sample size this can be solved by;
    a. longer duration studies involving large sample size can be done in order find out more on VBAC.

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APPENDICES

Appendix 1: Questionnaire

Part I: Demographic Variables

1. Is the mother a referral patient?
   a) Yes ☐
   b) No ☐
2. If yes what is the reason for referral?

   ……
   ……
3. 1.1 Age …….

   1.2 Address ……..

   3.3 Marital Status
      a) Single ☐
      b) Married ☐

   3.4 education level
      a) Primary ☐
      b) Secondary ☐
      c) College ☐

   3.5 Occupation …….

Part II: Obstetrical Variables

4. 2.1 LNMP ……

   2.2 EDD ……

   2.3 GA ……

   2.4 Gravidity ……

   2.5 Parity ……

   2.6 Living children ……

Part III: Past Obstetrical Variables

5. What is the indication for past cesarean section
   ……

6. Inter delivery interval (months)
   ……

7. Do you have a history of successful vaginal delivery after Cesarean section?
   a) Yes ☐
   b) No ☐

8. Do you have a history of spontaneous vaginal delivery?
   a) Yes ☐
   b) No ☐

9. Do you have a history of still birth or perinatal death?
   a) Yes ☐
   b) No ☐

Part IV: Current Obstetrical Variable

10. Estimated fetal weight by USS
    ……

11. Pelvic adequacy
    ……

12. Cervical dilation on admission to labor ward
    ……

13. Membranes status on admission to labor ward
    a) Intact ☐
    b) Spontaneous rupture of membranes ☐
    c) Artificial rupture during examination ☐

14. Presence of meconium
    a) Yes ☐
    b) No ☐

15. Station of the presenting part on a scale of -3 to 3
    ……

16. Mode of delivery
    ☐

a) Vaginal delivery

b) Cesarean delivery ☐

17. Indication for emergency cesarean section

……

18. Duration of labor (hours)

……

Part V: Outcomes

19. Did the patient have post-partum hemorrhage?

a) Yes ☐

b) No ☐

20. What was the cause of post-partum hemorrhage?

……

21. Was there uterine rupture or scar dehiscence?

a) Yes ☐

b) No ☐

22. If yes was it repaired?

a) Yes ☐

b) No ☐

23. Did the patient undergo hysterectomy within 1 week of delivery?

a) Yes ☐

b) No ☐

24. Did the patient require assisted delivery during the second stage of labor?

a) Yes ☐

b) No ☐

25. If yes did the baby incur any birth trauma?

a) Yes ☐

b) No ☐

26. Did the patient have a high degree perineal tear?

a) Yes ☐

☐

b) No

27. What is the birth weight of the baby?

……

28. What is the APGAR score of the baby?

a) 1st minute ……...

b) 5th minute ……...

29. Was the baby admitted to neonatal unit?

a) Yes ☐

b) No ☐

30. If yes what was the reason for admission?

……

31. Is the bay alive on discharge from the hospital?

a) Yes ☐

b) No ☐

32. If the answer for 39 is no then what is the cause of neonatal death?

……
……

33. Did the mother receive blood transfusion?

a) Yes ☐

b) No ☐

34. What was the reason for blood transfusion?

……
……

35. Was the mother alive on discharge?

a) Yes ☐

b) No ☐

36. If not what is the cause of maternal death?

……
……

Appendix 2: Study information and Consent Form

I am **Dr. Maria Angelica Rweyemamu,** a Master of Medicine student at the University of Dodoma (UDOM), College of Health Sciences (CHS). I am a resident doctor at Iringa Regional Referral Hospital (IRRH). I am conducting a study on the "Predictors and outcomes of women attempting vaginal delivery after cesarean section at Iringa Regional Referral Hospital (IRRH)". This study is in partial fulfillment of my Master in Medicine in Obstetrics and Gynecology. The study is going to be conducted from February 2018 to May 2018. The study will involve women who will be recruited from the antenatal ward and labor ward. This study will include all women with one previous scar who are willing to participate.

Vaginal Birth After Cesarean section (VBAC) is when a woman is planned before hand to deliver vaginally while having a previous Cesarean delivery.

I request you to read the instructions and fill in the details. Please note that your personal details will be kept strictly confidential and may be used solely for research purposes.

Purpose of Doing The Study

This study will help the department of obstetrics and gynecology to know the success rate of VBAC this will help change the management of women with one previous scars presenting to the hospital.

This study will determine the predictors of successful VBAC which will help in the patient selection and therefore reduce the risks that may be associated with VBAC. This will lead to development of a guideline that can be used in patient management at IRRH.

The results of the study is aimed at creating awareness that not all women with a previous scar are supposed to deliver by operation in coming pregnancies and that VBAC is a safe mode of deliver when practiced on low risk women in well-equipped environment. This will decrease the number of women with multiple scars and the complications associated with the scars during pregnancy in the community.

Role of the Participants

- Your participation is voluntary and you may choose to withdraw from the study at any time during your hospital stay
- Participants will not be required to incur any extra costs as a result of participating in the study
- The study will provide investigations like ultrasound and blood grouping and cross match free of charge
- Basic medical expenses associated with management of the patient will be covered by the patient
- Participants have a right to ask questions in case of any doubts and you will be answered
- All the information acquired during the study is confidential and will only be used for the purposes mentioned above and for academic purposes with no disclosure of the patient's identity.
- Participants are entitled to the results of the study which will be available at the department of obstetrics and gynecology IRRH and will be published in scientific journals without disclosure of participants identity.
- The principal researcher will be available in case of any inquiries or complications and can be contacted from the contacts given below
- If the participant chooses to participate in the study you are kindly requested to sign a consent form which is attached to this study information.
- Participants who choose not to participate will be given medical attention as required and will not be made to feel any segregation at any level, their choice will remain confidential.

Role of the Researcher

- To make sure that all women who participate in the study are well investigated, counseled and have a clear understanding of the study
- To monitor all women involved in the study and follow them up post-delivery until discharge from the hospital

- Make sure that the participants receive appropriate management during the study period, and intervene whenever medically indicated
- To work with the neonatal unit and follow up on all neonates of women involved in the study.

Thank you for taking the time to read the study information, this study is aimed at improving patient care at the hospital. In case of any inquiries about the study please contact

DR. MARIA ANGELICA RWEYEMAMU MOB: 0786507500/ 0620491770

Consent Forms

- I have been advised that I have two options of modes of delivery and I have been educated on the complications and benefits of each mode of delivery. That the first option is Elective cesarean delivery and the second mode is vaginal birth after cesarean Section
- I understand that I have the option of an elective repeat cesarean section or a trial of labor to attempt a vaginal birth after cesarean
- I have had all of my questions answered and have all of the information I need to make an informed decision
- understand and accept the risks of a trial of labor after a previous cesarean section/vaginal birth after cesarean delivery
- I choose to proceed with a trial of labor in an attempt to have a vaginal birth.

  Patient or Legal Representative Signature: _____

  Print Patient or Legal Representative Name: _____

  Witness Signature: _____

  Date: _____Time: _____

  Certification: I have explained to my patient the risks, benefits, and alternatives to a trial of labor after a previous cesarean section in an attempt to have a vaginal birth and have answered all questions. The patient has demonstrated a full understanding of the explanations.

  Provider Signature: _____

  Date: _____ Time: _____

Appendix 3: Maalezo ya Utafiti na Fomu ya Idhini

Mimi naitwa Dokta **Maria Angelica Rweyemamu** ni mwanafunzi wa uzamili katika Chuo Kikuu cha Dodoma (UDOM) kwenye Chuo cha Science za Afya (CHS). Ninasoma Uzamili kwenye Afya ya akina Mama na Ujauzito. Mimi ni daktari mkazi kwenye hospitali ya Rufaa ya Iringa. Ninafanya utafiti unaohusiana na " kujifungua kwa njia ya kawaida baada ya kua umejifungua kwa operesheni katika uzao wa nyuma". Washiriki wa utafiti huu watatoka kwenye wodi ya akina mama wajawazito. Utafiti huu utafanyika kuanzia mwezi Feburuali 2018 mpka mwezi Mei 2018. Utafiti huu utahusisha wanawake wote ambao wamewahi kujifungua kwa oparesheni kwa uzao wa nyuma.

Kujifungua kwa njia ya kawai wakati mwanamke ana kovu ni pale ambapo mwanamke mwenye kovu moja anapangiwa kujifungua kwa njia ya kawaida katika mimba ya sasa.

Naomba usome maelezo haya ili uweze kuelewa utafiti huu. Naomba ufahamu kua utambulisho wako utakua siri na taarifa zote zitakazopatika zitatumika tu kwa ajiri ya utafiti tu na sio vinginevyo.

Dhumuni la Kufanya Utafiti Huu

Utafiti huu utasaidia kitengo cha akina mama na uzazi kufahamu kiwango cha mafanikio cha kujifungua kwa njia ya kawaida kwa wanawake ambao wana historia ya kujifungua kwa operesheni.

Majibu ya utafiti huu yatawezesha kujulikana kwa sababu na mambo ambayo yanasaidia mwanamke mwenye kovu la kujifungua kufanikiwa kujifungua kwa njia ya kawaida, hasa kwa wanawake wanaojifungua katika Hospitali ya Rufaa ya Iringa.

Hili litasaidia madaktari kua na mwongozo wa kutumia kuwahudumia wanawake kama hawa.

Matokeo ya utafiti huu yatasaidia kutengeneza ufahamu katika jamii ya kwamba sio kila mwanamke mjamzito mwenye kovu la uzazi inabidi ajifungue kwa operesheni. Hivyo kupunguza idadi ya wanakwake wenye kovu la operesheni ya kujifunua zaidi ya moja, pia madhara ya kujifungua ukiwa na makovu mengi.

Majukumu ya Mshiriki Katika Utafiti

- Ushiriki wa mshiriki katika utafiti ni wa kujitolea na ana uhuru wa kujitoa kwenye ushiriki wakati wowote wa utafiti huu.
- Mshiriki hatahitajika kuingia gharama yoyote ya ziada ambayo itatokana na ushiriki wake katika utafiti huu
- Utafiti huu utatoa vipimo vya picha ya sauti (atrasaundi), wingi wadamu na kundi la damu bure, mshiriki hatalipia vipimo hivi.
- Gharama nyinginezo za matibabu ya kujifungua zitakazojitokeza kipindi cha utafiti zitalipwa na mshiriki.
- Mshiriki ana haki ya kuuliza swali lolote kuhusiana na utafiti huu na atapewa majibu yanayostahiri.
- Taarifa zote zitakazopatikana katika utafiti huu ni za siri. Taarifa hizi zitatumika kwa malengo yaliyotajwa hapo juu na kwa malengo ya kitaaluma tu bila kutoa utambulisho wa mshiriki.

- Mshiriki ana haki ya kufahamu matokeo ya utafiti huu, na matokeo haya yatapatikana mwisho wa utafiti katika kitengo cha akina mama na ujauzito Hospitali ya Rufaa ya Iringa.

- Mtafiti mkuu wa utafiti huu atapatikana kwa ajili ya kujibu mwaswali ya mshiriki na kama kutakua kuna jambo lolote ambalo mshiriki angependa kumfahamisha mtafiti. Namba ya mtafiti inapatikana mwisho wa maelezo haya.

- Kama mwanamke ataamua kushiriki katika utafiti huu, anaombwa kujaza na kuweka sahihi kwenye fomu ya idhini ili aweze kushiriki katika utafiti huu.

- Mshiriki ambaye ataamua kujiondoa katika ushiri huu, ataendelea kupokea huduma stahiki katika hospitali bila ubaguzi wowote na maamuzi yake yatakua ni siri ya utafiti huu.

Majukumu ya Mtafiti

- Kuhakikisha kwamba washiriki wote wanafanyiwa vipimo vinavyohitaji, na kupewa na kuelewa maelezo yanayohusu utafiti.

- Kufatilia washiriki wote wa utafiti hii kipindi chote cha matibabu na baada ya matibabu ya hospitalini kukitokea shida yoyote.

- Kuhakikisha kwamba washiriki wanapewa matibabu yaliyo sahihi na kufanya mabadiliko ya matibabu pale ambapo itahitajika.

- Kushirikiana na kitengo cha watoto wachanga na kufatilia aafya ya watoto wachanga wa akina mama watakao shiriki

Asante kwa kusoma maelezo ya utafiti. Utafiti huu unakusudi la kubosresha huduma katika Hospitali ya Rufaa ya Iringa. Kama kuna wasiwasi au swali lolote unaweza kuwasiliana na mtafiti mkuu kupitia namba ya simu ya mknoni.

Dokta. MARIA ANGELICA RWEYEMAMU 0786507500/0620491770

Fomu ya Idhini

- Nimepewa ushauri kwamba nina uwezo wa kuchagua njia ya kujifungua kati ya njia mbili zilizopo. Njia ya kwanza ya kujifungua ni kwa upasuaji na pia naweza kujifungua kwa njia ya kawaida.

- Nimeelezwa ya kwamba niko huru kuchagua njia ambayo inaendana na matakwa yangu

- Pia nimeelimishwa juu ya matatizo yanayoweza kunipata kwa kila njia ya kujifungua, na nimejibiwa maswali yote niliokua nayo kabla ya kufanya maamuzi

- Nimelewa na pia nakubali kuzipokea hatari zinazohusiana na kujifungua kwa njia ya kawaida baada ya kufanyiwa operation kwa uzazi uliopita

- Nimeamua kuendelea na jaribu la kujifungua kwa njia ya kawaida

  Sahihi ya mgonnjwa _____

  Sahihi ya mwakilishi _____

  Kidole gumba cha mwakilishi au mgonjwa _____

  Tarehe _____ muda _____

Hati ya kubaliono:

Nimemuelimisha mgonjwa wangu juu ya hatari,faida na chaguo alilonalo juu ya kujifungua kwa njia ya kawaida baada ya kua amejifungua kwa upasuaji kwa uzazi uliopita na pia nimejibu maswali yake kabla ya kufanya maamuzi na ameonyesha uelewa juu ya maelekezo na mjibu niliompa

Sahihi ya mtoa huduma _____

Tarehe _____ mda _____

Appendix 4: ACOG summary on the practice bulletin 184 on Vaginal Birth After CS

Benefits of VBAC

- Option for women who want to experience vaginal birth
- Avoiding major surgery and its complications like ;
    - Hemorrhage
    - Thromboembolism
    - Infection
    - Prolonged hospital stay
- Decrease in the complications associated with repeat CS
    - Hysterectomy
    - Bowel and bladder injury
    - Transfusion
    - Infection
    - Abnormal implantation like placenta previa and accreta

Risks to TOLAC

- Emergency repeat CS
- Uterine rupture

Prediction model and calculation of prediction probability: A model was developed for women with one lower segment transverse cesarean scar, singleton pregnancy with cephalic presentation. This model yielded a multivariable logistic regression calculation of the prediction probability. The calculators are available on line. This can be used for specific chance estimation; however it does not improve the maternal outcomes.

Contraindications to TOLAC

- Previous classical or T incision
- Previous history of uterine rupture
- History of extensive trans fundal surgery
- Contraindication for vaginal delivery like placenta previa

Women with more than 1 previous CS

- Women with two previous CS can be considered for TOLAC they have the same risk as 1 previous CS
- There is limited data on TOLAC for women with >2 previous scars

Macrosomia

- Macrosomic fetus of birth weight more than 4000g - 4500g have a lower likelihood of VBAC
- Previous birth weights and current estimated birth weight should be taken into consideration when deciding for TOLAC

Gestation age >40 weeks

- Gestation age > 40 weeks is associated with lowered likelihood of VBAC
- Women with Gestation age > 40 weeks should not be

excluded in the study because there isn't enough evidence.

Previous low vertical uterine scar

- There is limited information on the risk of uterine rupture in this group.
- The obstetrician may choose to continue with TOLAC but should take this into consideration.

Unknown type of prior uterine incision

- It is safe to assume that if it is not indicated then it was a lower segment transverse incision.
- High index of suspicion if previous CS was done at a preterm gestation which would be classical incision.

Twin gestation

- Women with a twin gestation who are candidates for vaginal delivery can be candidates for TOLAC
- They should have one previous CS

Obesity

- This is not an absolute contraindication for TOLAC.
- An increasing BMI is associated with decrease in VBAC.
- BMI can't be considered alone hence women with BMI >30 can be candidates to TOLAC depending on other characteristics.

Induction of Labor

- There is a potential risk of uterine rupture and a decrease in achieving VBAC with any induction method
- Oxytocin may be used in the augmentation of labor, though it is associated with an increased risk in uterine rupture
- Cervical ripening can be achieved by use of mechanical methods such as trans cervical catheter
- Misoprostol should not be used in cervical ripening of women with one previous scar and term pregnancy

Labor care

- Women undergoing TOLAC have a normal labor patterns
- similar standards should be used to evaluate labor progress

Diagnosis of uterine rupture

- fetal bradycardia
- increased uterine contractions
- vaginal bleeding
- loss of fetal station
- onset of new intense uterine pain

Delivery

- delivery is conducted as any other delivery
- excessive PV bleeding and signs of hypovolemia may indicate uterine rupture and should prompt further evaluation

Appendix 5: Ethical Clearance Letter

THE UNIVERSITY OF DODOMA

OFFICE OF THE DEPUTY VICE CHANCELLOR - ARC

DIRECTORATE OF RESEARCH AND PUBLICATIONS, CONSULTANCY AND INSTITUTIONAL COLLABORATION

P.O. BOX 251,
DODOMA, TANZANIA
TEL: +255 026 2310301 FAX: +255 0262310005 WEBSITE: www.udom.ac.tz

UDOM/DRP/134 VOL VI/66-11 **11th August, 2018**

Ms. Maria Angelica, R.
The University of Dodoma

RE: REQUEST FOR ETHICAL CLEARANCE

This is to inform you that the research proposal titled: **The Predictors and Outcome of Women Attempting Vaginal Birth after Cesaren Delivery at Iringa Regional Referral Hospital** has been granted ethical clearance pending the observation below.

The Institutional Research Review Committee (IRRC) noted with concern that ethical issues have not been clearly stated.

You are required to address the following two points and resubmit to the office of DRP,CIC.

1. Please indicate clearly how you will take care of unexpected complications that may arise from attempting vaginal delivery.
2. Also give in detail how the study is going to reduce the risk of complications associated with repeated cesarian delivery.

Kindly be so informed.

Prof. F. Fabian
Chairperson Institutional Research Review Committee

cc. DVC-ARC

Appendix 6: Dissertation Corrections

s/No.	Section	Comments	corrections
1	Research title	The Title is adequate, relevant and covers the objectives of the study.	Title remains the same
2	Background	Abstract is well written and gives the clear summary of the study -Background is long but it explains the problem that is intended to be studied	-The abstract remains the same -The background was shortened from 4.5 pages to 3 pages.
3	Statement of research problem	-The section starts with a strong statement that there are doubtful indications for cesarean section in Tanzania this is not true and it should not be taken as a justification of this study. Other problems that are seen are considerable - Objectives are smart and clear, but objective 2 should be to determine the predictors and not to establish the predictors - transfer the research questions from pg 13 to pg 6	- the statement has been removed as seen on pg 4 - Objective 2 has been changed pg 4. -The research questions have been transferred and are now on pg 5.

4	Significance of research	- The significance is briefly and adequately given. However the study cannot directly help other hospitals to develop a guideline on delivery of women with 1 previous scar.	- The statement has been omitted from the section as on pg 5
5	Literature review	- covered the study quest for information well	- No changes were made to the literature review
6	Methodology	- Study design is a prospective cohort. Time of the study goes to duration and area subsection, and how was it done from till sept 2018 and dissertation submitted in sept 2018? -It is important to show the department of Obstetrics capacity, number of staff and any special neonatal abilities etc. - Inclusion criteria is correct but describes that participants should fit the criteria for trial of c/s scar - Variables are not clear to understand, there are independent, intermediate and final outcomes ; this is	- Study design has been corrected pg 14. - The time of the study has been corrected and put under the section of duration and area of the study pg 14 - the capacity of the hospital and neonatal resuscitation capacity has been shown pg 14/15 - The inclusion criteria have been corrected with reference to appendix 4 which is the summary of

		a straight forward study but there is a complication in assigning variables -The independent variables are in a paragraph, how will you use them for analysis? Just decide on short term or long term outcomes.	ACOG recommendation for trial of scar. Pg 15 - Variables have been corrected; independent variables have been put in bullet format with omission of irrelevant variable. Pg 20 -Dependent variables been changed to two categories 1) mode of delivery 2) short term maternal and neonatal outcomes pg 21
7	Data analysis	Analysis plan was clearly presented	No changes were made to the analysis plan
8	Results presentations	- It will be more appropriate to start with a short general statement of the study, explaining the total number of participants and age range. Then put the 1st table of results with socio demographic results.	-Changes made as seen on page 23 - Corrections on pg 23 - Omission of figures, table and explanation, as seen

		Starting straight with a table looks blunt. - Table 4.1 shows a comparison of socio demographic values that are not correct. Present table 2 as the first table. - Doing Bivariate analysis in pg 26 was not right, it cannot be done in that way you need to mention the % and say which was VBAC and which was not. - Pg 27, you are presenting predictors of successful VBAC why not say that on the title of the table 3? The title that is seen is out of context. - Pg 28 talks of the entire table 4, it is repeating the whole findings, it is not necessary. Just say significant results and the reader will find the rest. - pg 29 and 30 are repeating the same information in table 4 that is redundant. The candidate mentions women with ruptured	on pg 25/ 26 - It was not feasible to combine table 3 and 4 due to clouding of results in one table. - Tables presenting comparison of outcomes and p values with mode of delivery have been omitted as seen on pg 27. Outcomes are mentioned and explained. -Table 8 and explanations have been omitted from the results.

		women on pg 30, what did you intend to say there? - Table 5 can be combined with table 4, only ad the OR and 95 % CI with the p value it will cover the predictors objective. However you cannot have significant association with a sample size of 40 or so participants. The power is so small. - Talking of outcomes you were just supposed to say what happened no analysis for mode of delivery and outcomes. Refer to the objectives. - Table 8 in pg 34 is not answering or replying any objective of interest to the study. It is rather confusing I recommend the candidate to remove it.	
9	Results relevance	The results are relevant but candidate needs to refer to his objective to present the results. The title mentions nothing about comparison so remove the fifth	-Results have been presented according to objectives

		objective. Otherwise table 8 is not an objective of the study and population is very small to establish association	
10	Discussion	The discussion loses track of the main objectives because they are not presented well, there is lack of logical flow, and paragraphs are not connected. Discuss only information related to objectives.	The discussion was reviewed and rearranges with omission of some information, and is related to the objectives pg 29- 32
11	Conclusion and recommendations	- Conclusions should mention the success rate of VBAC, predictors, maternal and fetal outcomes of VBAC and comparison of TOLAC and ERCS. Outside this is irrelevant in this section it makes it unnecessarily long. - Recommendations come from the conclusions (results) and not otherwise, review and rewrite it. - Issues of decision of TOLAC being decided by patient and physician is not	- Conclusion was corrected and arranged depending on objectives pg 33 - Recommendations were also reviewed and come from the results. - omission of speculations was done pg 34

		a result of the study. It looks more of a speculation.	
12	References	Adequate	
13	Appendices	Questionnaire is long and contains some repeated questions. Many responses were not connected to the study objectives	- Omission of irrelevant question and review of responses pg
14	Consent form	It lacks study information and patient has to sign. It also has to contact the PI in case of troubles the participant can access help	-Study information was given verbally during study period and written information has been included before the consent form which was signed by the participants prior to enrollment. Pg 52-54