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Risk Prediction Model for Success of Vaginal Birth After Cesarean Section, at Felege Hiwot Comprehensive Specialized Hospital, Northwest Ethiopia: Prognostic Study.

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BAHIR DAR UNIVERSITY
DEPARTMENT OF EPIDEMIOLOGY AND BIostatISTICS
SCHOOL OF PUBLIC HEALTH
COLLEGE OF MEDICINE AND HEALTH SCIENCES

**RISK PREDICTION MODEL FOR SUCCESS OF VAGINAL BIRTH AFTER CESEAREAN
SECTION, AT FELEGE HIWOT COMPREHENSIVE SPECIALIZED HOSPITAL,
NORTHWEST ETHIOPIA: PROGNOSTIC STUDY.**

BY: FILIPOS MESAY

**A RESEARCH THESIS TO BE SUBMITTED TO DEPARTMENT OF EPIDEMIOLOGY
AND BIostatISTICS, SCHOOL OF PUBLIC HEALTH, COLLEGE OF MEDICINE AND
HEALTH SCIENCES, BAHIR DAR UNIVERSITY IN PARTIAL FULFILLMENT OF THE
REQUIREMENTS FOR THE DEGREE OF MASTERS OF PUBLIC HEALTH IN
EPIDEMIOLOGY.**

APRIL, 2022

BAHIR DAR, ETHIOPIA

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NORTHWEST ETHIOPIA, PROGNOSTIC STUDY.

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COMPREHENSIVE SPECIALIZED HOSPITAL, NORTHWEST ETHIOPIA:
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ABSTRACT

Background: Trial of labor after cesarean delivery is defined as an attempt at vaginal delivery in women with a previous caesarean section. Recently there are studies that determine the risk factors for success of VBAC; but in current situation they do not jointly allow prediction of success of VBAC in individual patients in daily practice. Thus, developing risk prediction model and risk score for VBAC, guide health professionals to select pregnant women who are candidate for VBAC.

Objective: To develop prediction model and clinical risk score for the success of vaginal birth after caesarean section among women after a previous caesarean section.

Method: Prognostic study design was conducted from 30th February 2017 to 30th March 2021 at Felege Hiwot Comprehensive and Referral Hospital. The sample size (700 subjects) was calculated based on rule of thumb assumptions by assuming 10 events per predictor. Simple random sampling technique was used for selecting study units. Data was coded and entered into Epidata, version 3.02 and was analyzed by using R statistical programming language version 4.0. For model development binary logistic regression was done to investigate the relationship between each predictor and success of vaginal birth after cesarean section. Variables with ($p < 0.25$) from the bi-variable logistic regression analysis were entered into a backward multivariable logistic regression model, and significant variables ($p < 0.05$) were retained in the multivariable model. The model performance was evaluated by calculating, ROC curve, Calibration plot, Hosmer-Lemeshow test and p value. To make internal validation bootstrapping were done,

Result: The success rate of vaginal birth after cesarean section was 67%. Previous success full vaginal birth after cesarean section, rupture of membranes, initiation time of ANC, onset of labor, parity and time from previous delivery had a statistically significant association with VBAC success ($P < 0.05$, AUC of 0.748 (95%CI: 0.714–0.781) sensitivity of 68.23 % and specificity of 71.86%. At the threshold scores of 3.

The model goodness of test had a p-value of 0.255.

Conclusion and Recommendation: In general, this study showed the probability of predicting vaginal birth using, the optimal combination of parity, rupture of membrane, onset of labor, previous history of VBAC, inter delivery interval and initiation time of ANC. The incidence of success of VBAC was (67%). Thus, using this model could help to identify pregnant women who have a higher probability of having success of VBAC to be candidate for VBAC.

Keywords: Prediction Model, vaginal birth after cesarean section, Ethiopia.

ABBREVIATIONS / ACRONYMS

ACOG American College of Obstetrics and Gynecology

ACOG the American College of Obstetricians and Gynecologists

ANC Ante Natal Clinic

CS Cesarean Section

EmOC Emergency Obstetrics Care

EmRCS Emergency Repeat Cesarean Section

ERCS Elective Repeat Cesarean Section

RCOG the Royal College of Obstetricians and Gynecologists

SSA Sub-Saharan Africa

TOA Trial of Scar

TOLAC Trial of Labor after Cesarean

VBAC Vaginal Birth after Cesarean Section

WHO World Health Organization

BMI Body mass index

TOL Trial of labor

ROC A receiver operating characteristic curve

AUC Area under curve

G Gram

KM Kilometer

Table of Contents

ACKNOWLEDGMENT	V
ABBREVIATIONS / ACRONYMS	VII
LIST OF FIGURES	XI
LIST OF ANNEXES.....	I
1. INTRODUCTION.....	1
Background	1
Statement of the problem	3
Significance of the study.....	5
2. Literature review.....	6
Vaginal Birth after Cesarean Section.....	6
The Predictors of Successful VBAC and Patient Selection Criteria.....	6
2.5. Complications of Vaginal Birth after Cesarean and prediction models of VBAC.....	8
Conceptual framework	10
3.1 General Objective	11
3.2. Specific objectives	11
Methods.....	12
Study Area and period.....	12
Study design.....	12
Source population	12
Study population	12
Study unit.....	13
The inclusion and exclusion criteria	13
Inclusion Criteria.....	13

Exclusion Criteria	13
Study variables	13
Independent Variables	13
Dependent Variable	13
Operational definitions of the variables	14
Sample size determination and Sampling procedures.....	14
Sampling method and procedures	15
Data quality control.....	16
Data processing and Analysis	16
Model Development and Validation.....	16
Risk Score Development.....	17
Ethical considerations	17
5. RESULT.....	18
Socio-demographic characteristics	18
Maternal Obstetric Related Factors	18
Development of prediction model for success of vaginal birth after cesarean section.....	20
6. Discussion	28
7. LIMITATION AND STRENGTH.....	31
8. CONCLUSION	32
9. RECOMMENDATION	33
10. REFERENCES	34
ANNEX	38
Annex 2: Data extraction checklist.....	40

LIST OF TABLES

Table 1: Socio-demographic characteristics of mothers who gave birth at FHCSH from February 30/2017 to March 30/2021.....	17
Table 2:current and past Obstetric related factors of mothers who gave birth by VBAC at FHCSH from February 30/2019 to March 30/2021	18.
Table 3: Bivariable logistic regression analysis for development of VBAC prediction model.....	19
Table 4: Coefficients and risk-scores of each predictor included in the model to predict success of VBAC (n = 700).....	23
Table 5. Risk classification of successful VBAC using simplified prediction score (n =700).....	26

LIST OF FIGURES

Figure 1=Conceptual framework for developing and validating a risk score for prediction of successful VBAC using maternal characteristics in Felege Hiwot Comprehensive Specialized Referral Hospital, Northeast Ethiopia,...	9
Figure 3: Shows discriminative performance of the newly developed model including the prenatal and intrapartum variables	21.
Figure 4 ; shows ROC (AUC) of risk prediction model after boost trapping for success of VBAC among mothers who deliver at FHCRH from February 30/2017 to March 30/2021...	22
Figure 5; the calibration of my model has a p-value of 0.255, which indicates the goodness of calibration. This analysis includes mothers who gave birth at FHCSH from February 30/2009 to March 30/2013 (n = 700)...	24
Figure 6: A decision curve plotting net benefit of the model against threshold probability and corresponding Cost-benefit ratio.	25
Figure 7: Area under the ROC curve for the simplified risk score to predict risk of successful VBAC among mothers who gave birth at FHCSH from February 30/2019 to march 30/2021	27

LIST OF ANNEXES

Annex I: Participant information sheet 38

Annex 2: Data extraction checklist **Error! Bookmark not defined.**



1. INTRODUCTION

Background

Globally, about 21.1% of women gave birth by caesarean section, which is distributed irregularly and ranges from 5% in sub-Saharan Africa to 42.8% in Latin America and the Caribbean.(1) The 2016 Ethiopian demographic and health survey found that 1.9% of women delivered by CS. The overall prevalence of caesarean section in Ethiopia among those who gave birth at the health institutions was 29.55%, ranging from 11.03% to 63.75%.(2) But, the World Health Organization identifies that a CS rate above the ideal rate of 10–15% in any region has no justification and is unnecessary, which in turn leads to morbidity and mortality that is the result of CS.(3)

Trial of labor after CS is defined as an attempt of vaginal delivery in women with a previous caesarean section.(4) In 1981, vaginal birth after cesarean section , was recognized as a safe and acceptable option after a previous low transverse Caesarean delivery (5).Trial of labor after cesarean delivery represents one of the major changes in obstetric practice in recent times and has been considered a key method for the reduction of the cesarean delivery rate (6).

Trial of labor after cesarean section should be considered among women with a uterine scar if there are no contraindications, and successful VBAC can be safely achieved for both mother and infant in most cases(7).The National Institutes of Health Consensus Development Conference Panel released a statement on VBAC in March 2010.It emphasized that pregnant women with a prior cesarean should receive appropriate counseling concerning VBAC versus elective repeat cesarean in order to make an informed decision. This counseling would presumably include individualized risk-benefit assessment of trial of labor with likelihood of successful VBAC (8).

There are many factors which stated from different literatures which determine the success of vaginal birth after cesarean section. The American College of Obstetricians and Gynecologists (ACOG) (9) and Royal College of Obstetricians and Gynecologists (RCOG) (10). Agree that women with a history of one previous low transverse cesarean delivery, a clinically adequate pelvis, and no prior classical uterine scar or rupture are good candidates to attempt a vaginal birth after cesarean delivery (VBAC), provided that they deliver at an institution staffed by physicians and anesthesiologists with adequate resources.

According to the results of recent studies, maternal age <40 years, normal Body Mass Index (BMI), gestational age ≤ 40 weeks, neonate weight <4000 g, and inter-delivery interval ≥ 2 years are associated with successful VBAC.(11) Nevertheless, lack of previous vaginal delivery, induction of labor, and preterm delivery are some risk factors for VBAC failure (12).

Recent studies shows that, VBAC is associated with less blood loss during delivery, shorter duration of hospitalization and decreased rate of blood transfusion, intra partum and postpartum infection and thromboembolic events and increase rate of VBAC would decrease economic burden of nations and individuals.(8,9)

As if VBAC has many advantages for women with previous cesarean section, it has also its own complication if women's who are candidate for VBAC were not selected appropriately. Different scholars stated those complications that were related with VBAC. Women who are unsuccessful following VBAC have the highest morbidity. For this reason, Trial of labor after CS should be considered in women who have no contraindications (13) .Major complications associated with failed VBAC include scar dehiscence, hysterectomy and uterine rupture, death, neonatal respiratory morbidity and mortality but successful VBAC is associated with less blood loss, significantly lower risk of neonatal respiratory morbidities and placenta previa, and a shorter hospital stay with a more rapid recovery.(14)

Statement of the problem

The increasing cesarean delivery rate in both the developed and developing countries, including Ethiopia, raises concerns regarding the management of subsequent deliveries after cesarean delivery (15).

The global rate of CS is 18.6%, with South America having the highest rate by region of 42.4% (16). 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, The rate of CS increase in Africa, 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.(17) the rate of successful VBAC ranges between 60-80% Successful VBAC depends on careful selection of the pregnant women for VBAC(18).In Sub- Sahara Africa, the rate of successful VBAC ranges between 65%-75%. (19), however this varies across countries. A cohort study done in Mali and Senegal had a success rate of 44%.(20) A study done at a teaching hospitals in Ethiopia Addis Ababa had a success rate of vaginal birth after cesarean section was 65% .(21)

On the other hand VBAC has its own complication for pregnant women, who does not selected for VBAC accurately, for this different researcher finds short term or long term maternal complications. The severe complications include uterine rupture, hysterectomy, urinary bladder injuries, thromboembolic events, fistula ,neonatal and maternal death .(22) The less severe complications are blood transfusion, postpartum hemorrhage, endometritis, puerperal fever, infection, wound infection and prolonged hospital stay.(23) The long term maternal complications include; infertility, placenta previa and percreta due to a repeat cesarean section, adhesions and chronic pelvic pain.(24) At me lamed study about complication of vaginal birth after cesarean section find that, postpartum hemorrhage occurred in 2.2% of me lamed study population. (25)In Ramirez report, He is also study on complication of VBAC, uterine rupture frequency was 2.4%, and most cases occurred after induction, (26).according to Blanchet findings (4.2%) of study populations neonates in VBAC group needed resuscitation or NICU admission(27)Celeste reported that low Apgar score and NICU admission are more frequent in patients with VBAC failure.(28) Phelan reported VBAC neonatal mortality rate 4.5 in 1000 live births .(29), it seems that neonatal complications could be reduced effectively by focusing on the selection criteria for VBAC. Lower incidence of breastfeeding is expected on unsuccessful VBAC (CS) because of anesthesia and recovery time delayed the skin contact between mother and child, particularly in first hours after birth .(30)

The crucial questions are how to reliably predict successful vaginal birth after cesarean section and how to determine and quantify the probability of success of VBAC that is acceptable for women's. Hence, a personalized prediction of VBAC may lead to a more refined counseling. Furthermore, with regard to clinical outcomes, personalized prediction could contribute to risk estimation because actual incidences of major maternal morbidity and mortality are lowest in women who have a VBAC (0.2%), followed by women having an Emergency cesarean section (0.8%), and are highest in women having unsuccessful VBAC (3.8%)(31). To ensure the success rate of VBAC, predictive models have been developed to predict successful VBAC(32)

However, a more accurate prediction of the outcome of maternal VBAC may not only help clinicians' assist patients in selecting delivery mode, but also avoid complications. At the time of admission, an accurate prediction of successful VBAC may persuade more women to try VBAC, thus reducing the risk of complications due to multiple cesarean deliveries (33). Previously VBAC prediction models have been developed to support the counseling process and informed decision making. Some of the models use antepartum variables collected during antenatal visits, (32). Whereas others use both the antepartum and intrapartum variables to predict the probability of successful VBAC at admission for labor and delivery service. The most utilized and validated model in the United States and Europe is the one first reported by Gorman et al. in 2007 (34). The model is based on six maternal characteristics—age, body mass index (BMI) (kg/m²), race, prior vaginal delivery, prior VBAC, and a recurring indication for cesarean delivery—that can be obtained at the first prenatal visit (35). The probability of VBAC can be determined by entering these characteristics into a simple calculator.(36) The model was internally validated in an independent cohort of clients(37). And later validated externally in Canada, Japan, Australia, and the Netherlands. The model was found to be similarly valid and useful in predicting VBAC success in these countries as it was in the United States(38). But the majority of the prediction models were developed in a non-African population. These models cannot be directly translated to African settings as differences in obstetrical policy and the entirely different mix of ethnicities may impair the performance and validity of the models.(39)

Without population-validated and evidence-based calculators for successful TOLAC, women are counseled based on physicians' experiences and evidence from other countries, which could lead to biased decisions. Therefore my research conducts development of prediction model and clinical risk score for vaginal birth after cesarean section for practical use in day today physician patient jointly decision making regarding vaginal birth after cesarean section.

Significance of the study

The finding of the study on clinical risk score will be used for physicians in joint physician-patient decision while offering VBAC. It is also used as additional source of information for investigator, who is interested to study in this area.

In addition, it guides physicians by simplifying the way in promptly selecting women who is candidate for VBAC, by identifying the women with high probability of successful VBAC.

The study would also be important for policy makers and program designers that work on neonatal and maternal health. The findings of this study might help different stakeholders of federal and regional health officers and hospitals to see important ways to improve maternal and neonatal complications during delivery.

2. Literature review

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.(40)

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 .(41).

However the rates of trial of scar are decreasing in developed countries .(42) the studies indicates that a change in health policies and fear for litigations are the major causes .(43)

In spite of this the rate of successful VBAC remains the same.(44), 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. (45)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 (46)

In Africa the main concern regarding VBAC is the safety in terms of measures to manage the associated complications.(47) 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. (48) 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(49)

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.(40) 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 VBAC 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. (4). In India an observational study showed that prior vaginal delivery was a strong predictor of successful VBAC. (50)

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 .(51) 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.(21) 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

Studies done on the induction of labor in patients who are trying the scar have shown that induction is not associated with increasing risk. (52) 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. (53)

The stage of labor at admission for the trial of scar has an effect on the success rate of VBAC. (4) 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 predictors of successful VBAC .(4)

Women who present with fetal head station greater than -2 had poor prognosis for VBAC .(54) 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.(55)

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. (56) The effect of cervical dilation at previous cesarean was evaluated by .(57) 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 .(58)

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/m² is associated with failure of VBAC .(59)

The age factor is contradictory, some studies find that it is not a significant predictor .(21) whereas other studies state that maternal age equal to or more than 35 years is associated with reduced likelihood of VBAC .(50)

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 .(54) 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.(60)

2.5. Complications of Vaginal Birth after Cesarean and prediction models of VBAC.

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 .(14).

The less severe complications are blood transfusion, postpartum hemorrhage, endometritis, puerperal fever, infection, wound infection and prolonged hospital stay .(61) The long term maternal complications include; infertility, placenta previa and percreta due to a repeat cesarean section, adhesions and chronic pelvic pain .(62)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 VBAC, and elective repeat CS in labor .(63) Women who have successful VBAC have lower risk of morbidity compared to those with elective repeat CS, on the other hand failure of VBAC is associated with a higher risk of morbidity compared to elective repeat CS .(63)

Uterine rupture is the most significant severe complication of VBAC. 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% .(64) 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 .(65) The risk of rupture increases with the number of scars and the type of scar .(66)

The inter-delivery interval of the of less than 18 months is associated with an increased risk of uterine rupture.(67) Women with an inter delivery interval of more than 24 months have the best outcome.

For prediction of success of VBAC without considering current obstetric characteristics, six predictors were identified: ethnicity, previous VBAC, previous vaginal birth, inter delivery time, previous CS indications and pre pregnancy BMI. The prognostic performance of the model was assessed in the validation cohort using the receiver operating characteristic curve (AUC) of 70%.(37)

Any prior vaginal delivery, previous history of successful VBAC, arrest of descent and presentation were significant predictors for success of VBAC with AUC of 81% .(68)

A study conducted in China showed that, significant predictors which predicts success of VBAC with model AUC 0.77 (95% CI 0.73 to 0.81), and the Hosmer-Lemeshow test result was not significant (p=0.82). Were rupture of membrane, vaginal delivery, and estimated fetal weight, onset of labor, gestational age and bishop score.(69)

Women who had a previous vaginal delivery and a previous VBAC were more likely to attempt a VBAC. Women who had an intended VBAC also had a significantly lower BMI, although the actual difference between groups was small. On the other hand, women with a previous CS due to no progressive labor more often opted for ERCS.(39)

A study conducted in Ethiopia showed that, significant predictors which predicts success of VBAC with model AUC = 0.87 (0.81 – 0.93). And the Hosmer-Lemeshow test result was not significant (p=0.455). Rupture of membrane, fetal station, success of VBAC, Were rupture of membrane, vaginal delivery, and estimated fetal weight, onset of labor, gestational age and bishop score. (70)

Conceptual framework

Below are the abstract frameworks of the study which shows the relationships of different variables with outcome variables are socio demographic, current maternal obstetric hx, and previous maternal obstetric hx, which is adapted in different researches and slightly modified. (1, 7, 14, 21, 23).

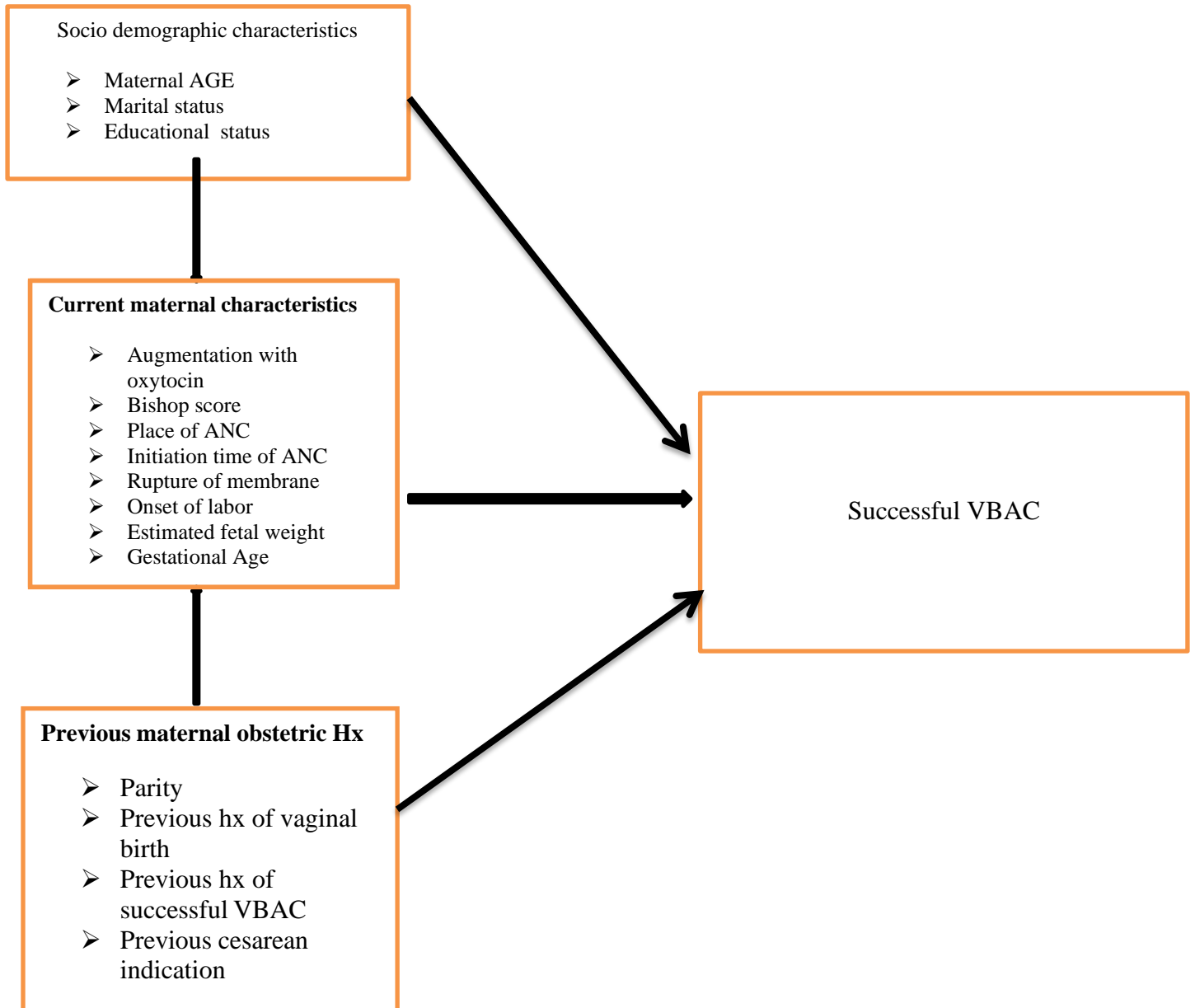


Figure 1=Conceptual framework for developing and validating a risk score for prediction of successful VBAC using maternal characteristics in Felege Hiwot Comprehensive Specialized Referral Hospital, Northeast Ethiopia, 2021.

3. Objectives

3.1 General Objective:

To develop prediction model and clinical risk score for success of vaginal birth after caesarean section (VBAC) among women after a previous caesarean section (CS).

3.2. Specific objectives:

- ✓ To determine the incidence of success of vaginal birth after caesarean section at Felege Hiwot comprehensive referral hospital, 2021.
- ✓ To develop predictive model for success of vaginal birth after caesarean section at FelegeHiwot comprehensive referral hospital, 2021.
- ✓ To develop clinical risk score for success of vaginal birth after caesarean section at FelegeHiwot comprehensive referral hospital, 2021.

Methods

Study Area and period

The study was conducted from March (1- 30) in 2021 among women delivered at Felege Hiwot comprehensive specialized hospital (FHCSH) which is found in Bahir Dar city. Bahir Dar is the capital city of Amhara national regional state and is found 575kms northwest of Addis Ababa.

Felege Hiwot comprehensive specialized hospital was established with the German State government during the regime of Emperor H/ Selassie I in April, 1963 G.C and is one of the oldest public hospitals in the Northwestern part of the country and located at northern end of the city near Lake Tana and aspires to see a healthy, productive and prosperous society and become a center of medical service Excellency by 2029. During its establishment, it was planned to serve for 25,000 people. Currently it serves more than 10 million people coming from Bahir Dar city; west Go jam zone, east Go jam zone, Awi zone, North and South Wollo zones, South& North Gondar zones and some parts of Benishangul Gumuz and Oromia regions.

The hospital has currently a total of 1431 man power (5 obstetrician and gynecologist and 63 midwives among others) in different disciplines. It has a total 500 formal beds, 11 wards (emergency ward and Inpatient wards such as Gynecological &Obstetric, Surgical, orthopedics, Medical, Pediatric, L&D, Eye unit, NICU, psychiatrics, oncology and 22 OPDS), 39 clinical and nonclinical departments /service units / providing laboratory, Diagnostic, curative & Rehabilitation service at outpatient & inpatient bases as well as disease prevention & health promotion services(85).

Study design

Prognostic study design was conducted. The theoretical design of the present study was; incidence of success of vaginal birth after cesarean section as a function of multiple predictors of current and previous obstetric history.

Source population

The domain of the study was all pregnant mothers with previous cesarean section who are candidate for VBAC.

Study population

All pregnant women with previous cesarean delivery scar, candidate for VBAC and who try of VBAC at FHCSH from February 30/2017 to march 30/2021.

Study unit

Selected cards of those Mothers who gave birth at FHCSH from February 30/2017 to March 30/2020.

The inclusion and exclusion criteria

Inclusion Criteria

Mothers who have recorded data and tries VBAC at FHCRH from February 30/2019 to March 30/2021.

Exclusion Criteria

Mothers who have no recorded data in Felegehiwet comprehensive and referral hospital.

Mothers who does not try vaginal birth after cesarean section not in Felegehiwet comprehensive and referral hospital (Referral, after start of labor).

Mothers who has more than one previous cesarean section

Study variables

Independent Variables

In this study the following were the independent variables;

Socio-demographic information age of the patient, marital status, and educational status

Previous obstetric history of the patients, parity, previous vaginal deliveries, previous history of successful VBAC, previous cesarean indication, parity, and chronic diseases

Current obstetrical information: gestation age by date, mode of labor induction, bishop score on admission, augmentation, onset of labor, rupture of membrane, place of ANC, initiation time of ANC, estimated fetal weight and interdelivery time from previous delivery.

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

Dependent Variable

The dependent variable of this study is success of vaginal birth after cesarean section (it categorized as successful VBAC and failed VBAC).

Operational definitions of the variables

Successful VBAC: was defined in this study as vaginal delivery of the fetus (spontaneous or instrument-assisted), regardless of neonatal and maternal complications.

Cesarean section: is an operation done to deliver a baby through incision of the uterus.

An unsuccessful 1 VBAC: is defined as failure to achieve a vaginal birth after caesarean section in women undergoing a TOLAC and the delivery ending by emergency CS.

Potential predictors

Contemporary methodological guidelines for prognostic modeling state that potential predictors should be preselected based on clinical reasoning and evidence from previous reports, instead of observed significant relations with outcome variables in the same data set. This method results in higher external validity and less over-fitting of the developed model.(71)

Therefore, we preselected potential predictors based on previously published prediction models, expert opinions, and articles reporting on risk factors for a successful intended VBAC.(34)

We preselected predictor variables from obstetrical history, medical history, and demography of the patient. The final set of potential predictors that were considered for the model included:

From **socio demographic variables**, Educational level, marital status, and Age

From previous obstetrical history, previous VBAC, indication of previous CS, inter delivery interval,

From present obstetrical history place of ANC follow up ,initiation time of ANC follow up, rupture of membranes , Bishop score, gestational age, onset of labor (spontaneous or induced),chronic diseases, estimated fetal weight, oxytocin augmentation.

Sample size determination and Sampling procedures

The sample size was calculated based on rule of thumb assumption. First, at least 10 events were collected for each potential predictor of VBAC that was evaluated in the multi-variable regression analysis(72). According to the formula $N = (n \times 10)/I$ where N is the sample size, n is the number of candidate predictor variables and I is the estimated event rate in the population [68].but for the purpose of statistical power I used 15 events per predictors. An event is defined as the least frequent outcome status failed vaginal birth after cesarean section in the context of this study. Considering, a study done in Teaching Hospitals of Addis Ababa University, VBAC failure rate of 32 % was reported. (70)In order to develop a model with 15 potential predictors at least 225 events are required .hence the sample size became, $15 \times 15 / .32\% = 700$

Sampling method and procedures

Simple random sampling technique was employed to select participants using medical registration number of delivered mother from delivery registration book. First all mother with previous cesarean section delivered at FHCSH from February 30/2017 to March 30/20201 was identified from the delivery registration book. After that records of of mothers who meet the inclusion criteria was included in the study. Subsequently, a sampling frame was prepared. Finally, study unit was selected by using computer generated random number.

The primary source of data was the admission log books at outpatient department where the card number of patients admitted with previous cesarean scar will be trace. Then those offered VBAC was identified from delivery log books and ward discharge summary. Participants were selected from the available charts with in the study periods until sample size was full filled by using systematic random sampling.

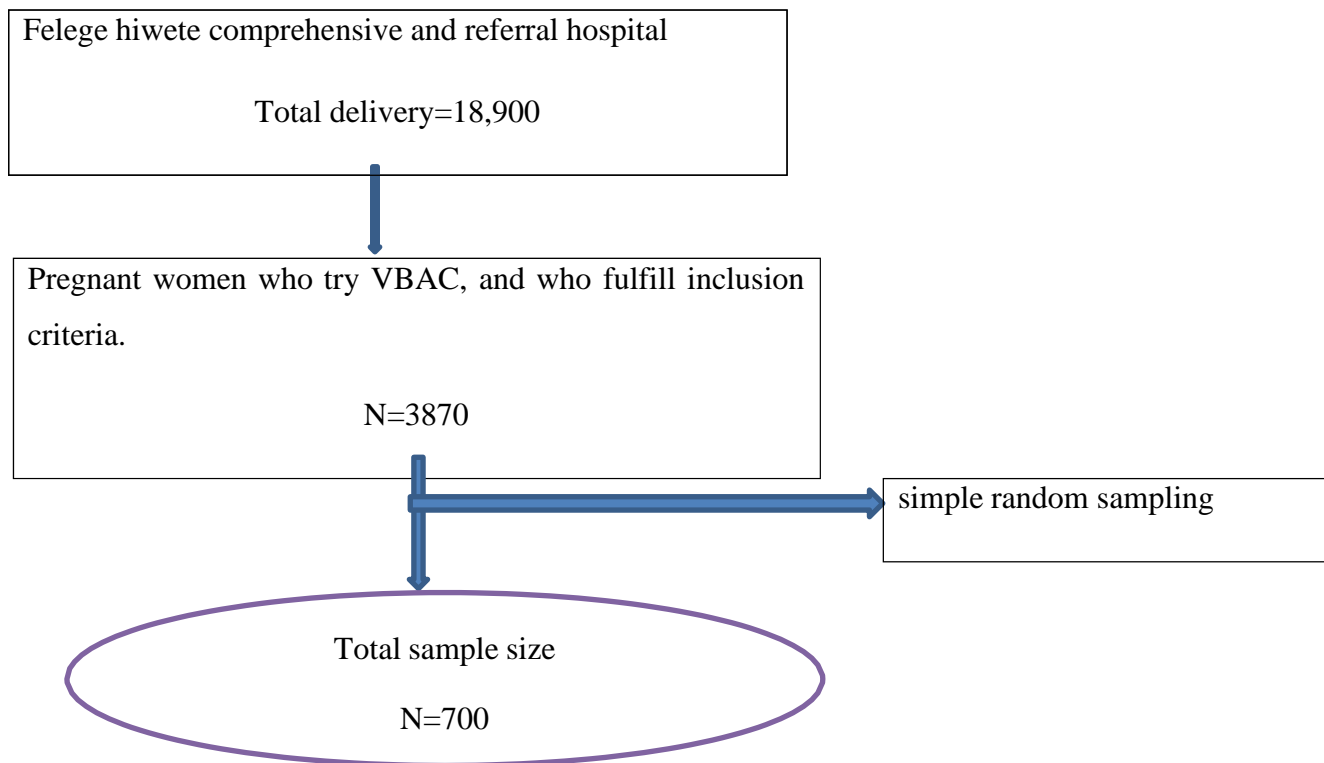


Figure 2: Diagram of sampling techniques at Felege Hiwot Comprehensive Specialized Hospital, Northeast Ethiopia, in 2021

Data quality control

Training was given for data collectors and supervisors about the objective of the research, how they will collect the data, keep the collected data, and supervise the data collection process. Afterward, pretest will be done on 5% of the sample size in order to assure that data collectors and supervisors are competent enough to collect and supervise the data collection process. Checklist was developed in English.

Data processing and Analysis

Data was entered into epidata version 3.02 and statistically analyzed by R software version 4.0. For model development binary logistic regression was done to investigate the relationship between each predictor and success of VBAC. Variables with ($p < 0.25$) from the binary logistic regression analysis will be entered into a backward stepwise multiple logistic regression model, and significant variables ($p < 0.05$) was retained in the multiple logistic regression model. The results of significant predictors were reported as coefficients, odds ratios (ORs), and 95% confidence intervals (CI). The discrimination was assessed by calculating the The area under the ROC curve (AUC), sensitivity, and specificity. Calibration plots of observed and predicted probabilities of success of VBAC and the Hosmer Lemeshow goodness of fit statistic was generated. Internal validation of the model was calculated by bootstrapping 1000 samples with replacement.

Model Development and Validation

For model development bivariable logistic regression was done to obtain insight into the association of each potential predictor and success of VBAC. Variables with ($p < 0.25$) from the bivariable analysis were entered into a backward stepwise multivariable logistic regression model, and significant variables ($p < 0.05$) were retained in the multivariable model. The results of significant predictors were reported as coefficients with 95% confidence intervals (CI).

To check for the model accuracy, we computed the area under the ROC curve (discrimination) and calibration plot (calibration) using `-classifier plots` and `-givitiR` packages of R respectively. The AUC ranged from 0.5 (no predictive ability) to 1.

The regression coefficients and its 95% confidence levels, and the AUC will be adjusted for over fitting or over-optimism using bootstrapping technique. To make internal validation, we computed 1000 random bootstrap samples with replacement on all predictors in the data.

The model's predictive performance after bootstrapping is considered as the performance that can be expected when the model is applied to future similar populations.

To evaluate the clinical and public health impact of the model, we performed a decision curve analysis (DCA), of standardized net benefit across a range of threshold probabilities (0 to 1). In the DCA, the model was compared against two extreme scenarios; –intervention for all and –no intervention.

In our case, the intervention considered selection of mothers who are candidate for success full VBAC to facilitate appropriate selection of mothers in order to decrease complication, morbidity, and death which is related to multiple cesarean sections.

Risk Score Development

To construct an easily applicable TOLAC prediction score, we transformed each coefficient from the model to a rounded number by dividing to the lowest coefficient. The number of points was subsequently rounded to the nearest integer. We determined the total score for each individual by assigning the points for each variable present and adding them up. The predicted probability of success of VBAC was presented according to two categories of the risk score for reasons of statistical stability and practical applicability. , allowing each pregnant woman to be classified as at high or low risk of VBAC.

Ethical considerations

The ethical clearance was obtained from ethical review board of Bahir Dar University, college of medicine and health sciences Institutional review board. The chief executive officers at each hospital will give permission to conduct the study Information was treated as confidential and was used only for research purpose.

5. RESULT

Socio-demographic characteristics

From a total of 700 study cards 469 (89%) were in the age group of <35 years. 579(82.7%) mother's educational status was grade >9 and 679 (97%) were married.

Table 1: Socio-demographic characteristics of mothers, who was candidate for VBAC, gave birth at FHCSH from January 30/2017 to January 30/2021

Variable	Category	Frequency	Percent (N=700)
Age	>35 yrs.	107	15.3
	<=35 yrs.	593	84.7
Marital status	Married	679	97
	Un married	21	3
Educational status	>=9	579	82.7
	<9	121	17.3

Maternal Obstetric Related Factors

From the total of mothers who delivered at FHCSH 700 more than two-third 667 (95.3%) were multipara. Concerning past obstetric history, 169 (24.1%) of them had not history of previous vaginal delivery, 27(3.9%) of them had a history of chronic diseases, and 96(18.9%) of them had the previous cesarean indication were recurrent, 258(36.9%) had previous history of successful VBAC.

Regarding current obstetric characteristics, 187(26.7%) participants gave birth by spontaneous vaginal birth, the majority of the participants are bishop score of <=5,478 (68.3%) and 136 (19.4%) of the participants had a history of rupture of membrane. 29 (4.1%) had oxytocin augmentation, 81 (11.6) % had ANC follow up at hospitals during the current pregnancy.

Table 2: Current and past Obstetric related factors of mothers who gave birth by VBAC at FHCSH from January 30/2019 to January 30/2021

Variables	Category	Frequency	Percent
Parity	Primipara	33	4.7
	Multipara	667	95.3
history of vaginal birth	Yes	258	79.9
	No	442	19.1
History of successful VBAC	Yes	44	36.9
	No	656	63.1
Previous cesarean indication	Recurrent	128	18.3
	Non recurrent	572	81.7
Oxytocin augmentation	Yes	29	4.1
	No	671	95.9
Bishop score	>5	222	32.7
	<5	478	68.3
Place of ANC	Health centers	619	88.4
	Hospitals	81	11.6
Initiation time of ANC	First trimester	170	24.3
	Second trimester	530	75.7
Rupture of membrane	ruptured	136	19.4
	intact	564	89.6
Onset of labor	Spontaneous	186	26.7
	Induced	514	83.3
Estimated fetal weight	>4kg	337	48.1
	<=4kg	365	51.9
Gestational age	37-39wks	542	77.4
	>=40wks	158	22.6

Development of prediction model for success of vaginal birth after cesarean section

Out of 700 trial of VBAC, 469 (67%) had successful VBAC. Variables with $P < 0.25$ in the bivariable logistic regression analysis were, estimated fetal weight, educational status, previous history of vaginal delivery, previous history VBAC, place on ANC, initiation time of ANC, chronic disease, onset of labor, rupture of membrane, bishop score, and parity.

Table 3: Bivariable logistic regression analysis for development of VBAC prediction model

Variables	Category	VBAC		COR	95 % CI	P-value
		Yes	No			
History of vaginal birth	Yes	328	141	3.117	(2.10,4.84)	0.005*
	No	28	203	1		
History of VBAC	Yes	188	70	1.539	(1.10,2.15)	<0.001*
	No	281	161	1		
Chronic disease	No	8	19	5.165	(2.22,11.98)	0.001*
	Yes	461	212	1		
Estimated fetal weight	≤4kg	296	117	1.311	(0.95,1.79)	<0.01*
	>4kg	200	114	1		
Rupture of membrane	Intact	122	14	5.45	(3.05,9.71)	<0.001*
	Ruptured	347	217	1		
Bishop score	> 5	183	39	3.15	(2.13,4.65)	< 0.001
	≤5	192	286	1		
Initiation of ANC	First trimester	38	6	0.71	(-31, 1.73)	0.16
	Second trimester	431	225	1		
Oxytocin	Yes	14	15	2.275	(1.07,4.76)	0.16
	No	455	226			

Parity	multi para	14	19	2.913	(1.43, 5.92)	<0.003*
	Primi para	455	212	1		
Onset of labor	spontaneous	160	26	4.083	(2.60,6.40)	0.01
	Induced	309	205	1		
Time from previous delivery	>2yrs	99	10	5.017	(2.75,9.13)	<0.04*
	<=2yrs	370	10	1		
Gestational Age	37-39wks	116	42	1.479	(0.97,2.19)	0.019*
	>=40 wks.	353	138	1		

Results of the multivariable analysis are shown in table. Previous success of VBAC, rupture of membranes, initiation time of ANC, onset of labor, parity and time from previous delivery were retained in the final model. . The discriminatory power of the model has AUC of 0.754(95% confidence interval: 0.720– 0.787).

Classifiers that give curves closer to the top-left corner indicate a better performance. As a baseline, a random classifier is expected to give points lying along the diagonal (FPR = TPR). A perfect result would be the point (0, 1) indicating 0% false positives and 100% true positives. Using the coefficients (β) the predicted risk cutoff point was a probability of (you den= 0.4998), the model has sensitivity of 69.7%, specificity of 71.8%, positive predictive value of 83.4%, and negative predictive value of 53.9%.

The calibration test had a p-value of 0.255, indicating that the model does not misrepresent the data or calibration of the model was visually accurate since observed and predicted probabilities were similar.

Validation of the model with the bootstrap technique showed hardly any indication of undue influence by particular observations, resulting AUC of 0.744 (corrected 95% CI: 0.710 –0.778)

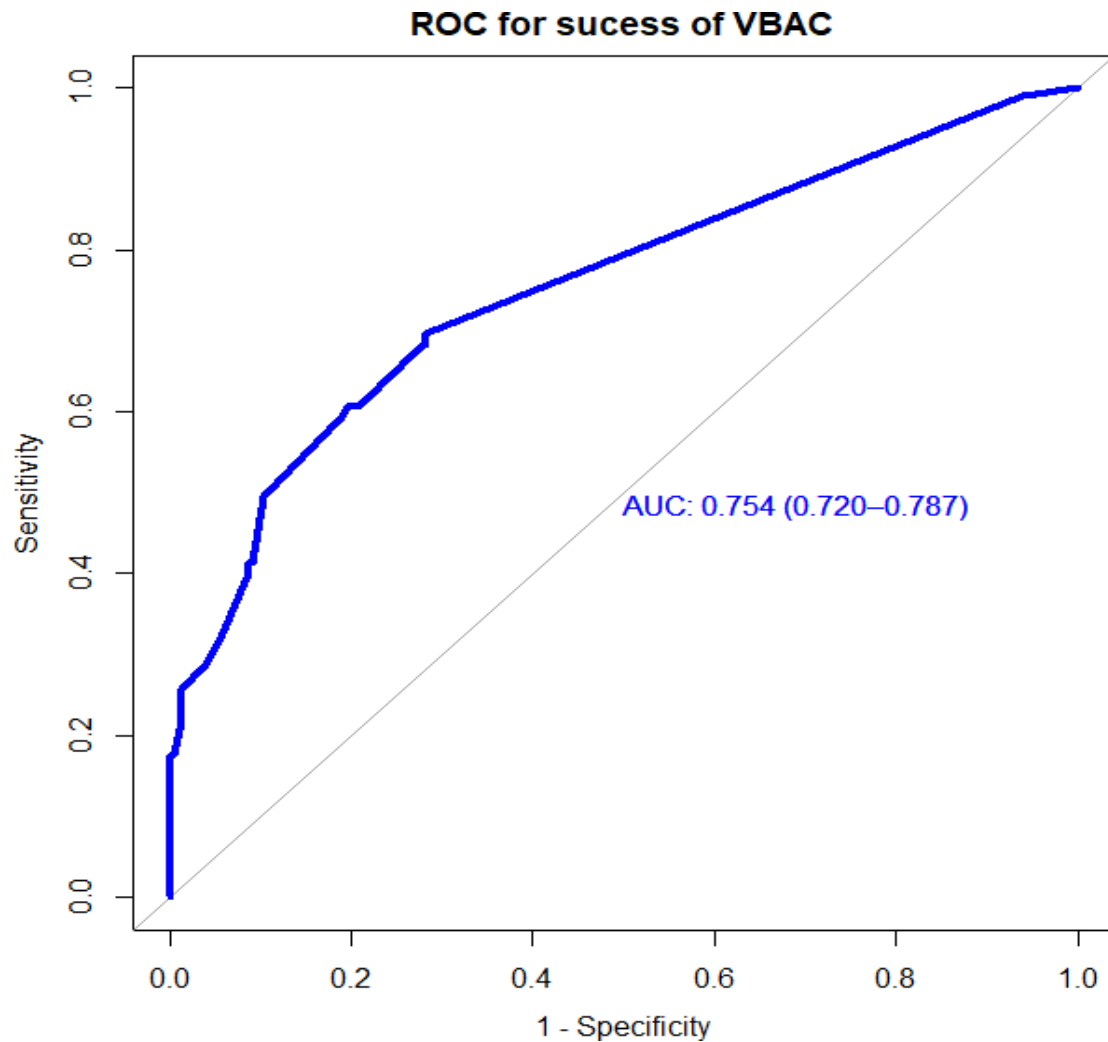


Figure 3: Shows discriminative performance of the newly developed model including the prenatal and intrapartum variables. The ROC of my model after boost trapping has an AUC of 0.754 (95% CI 0.718-0.79), which indicates a good discriminative ability.

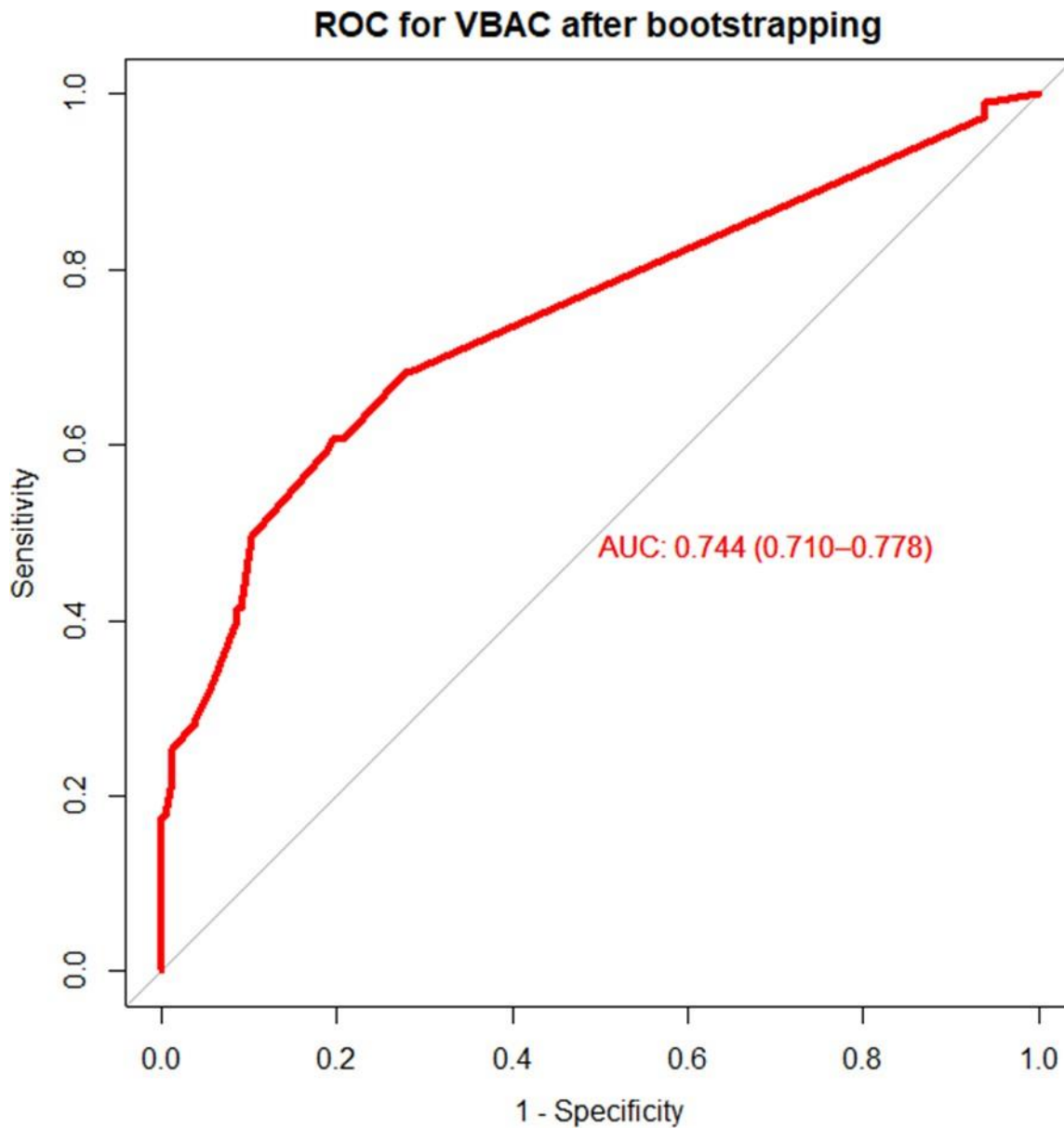


Figure 5: ROC (AUC) of risk prediction model after bootstrapping for vaginal birth after cesarean section among mothers who gave birth at FHCSH from February30/2017 to March 30/2021. AUC (area under the curve), ROC (Receiver operating characteristic curve).

Simplified risk score: we divided the coefficient of predictors included in the reduced model by the smallest.

Table 4: Coefficients and risk-scores of each predictor included in the model to predict VBAC (n = 700)

Predictors Variables	Multivariable analysis			
	Original β (95 % CI)	Bootstrap β	P Value	Risk score
Time from previous delivery (>2yrs)	1.761(1.134 , 2.512)	1.708	<0.001	3
Hx of successful VBAC (yes)	1.137(0.211, 2.222)	1.084	0.020	2
Rupture of membrane (ruptured)	1.495(0.9186 , 2.140)	1.471	<0.013	3
parity (multi Para)	1.199(0.405, 2.028)	1.176	<0.001	2
Onset of labor(spontaneous)	1.265(0.799 , 1.763)	1.152	<0.020	2
ANC initiation time(first TMR)	0.605(0.135 , 1.094)	0.593	<0.001	1

Linear predictors for estimated probability of success of VBAC= $1/(1 + \exp - (1.266 + 1.762 * \text{time from previous delivery}(>2\text{yrs}) + 1.137 * \text{previous hx of successful VBAC (yes)} + 1.495 * \text{rupture of membrane}(\text{ruptured}) + 1.199 * \text{parity}(\text{multipara}) + 1.265 * \text{onset of labor}(\text{spontaneous}) + 0.604 * \text{time of initiation of ANC follow up}(\text{second TMR}))$

The calibration test had a p-value of 0.255, indicating that the model does not misrepresent the data or calibration of the model was visually accurate since observed and predicted probabilities were similar.

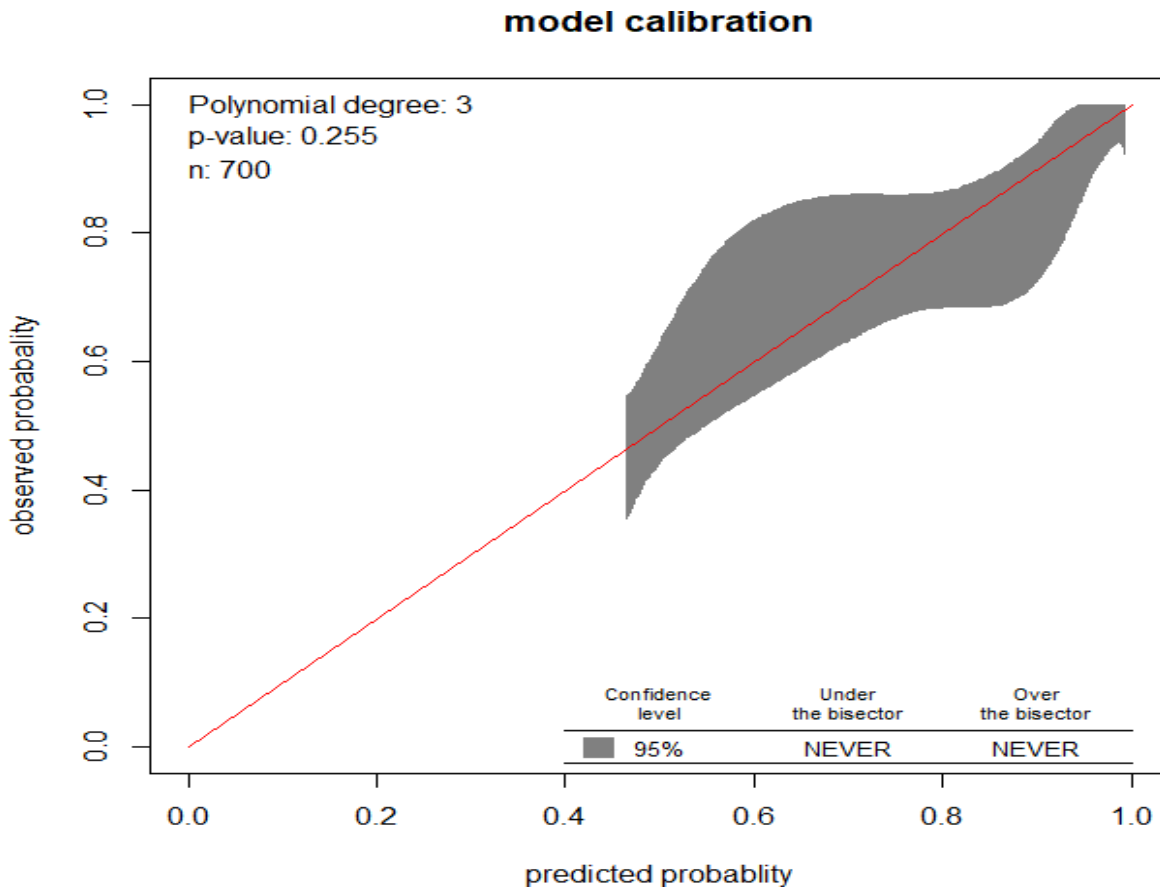


Figure 4; the calibration of my model has a p-value of 0.255, which indicates the goodness of calibration. This analysis includes mothers who gave birth at FHCSH from February 30/2017 to March 30/2013 (n = 700).

The model has the highest net benefit across the entire range of threshold probabilities, which clearly indicates that the model has the highest clinical and public health value. Hence, referral decision made using the model has a higher net benefit than not referring at all or referring all regardless of their risk thresholds.

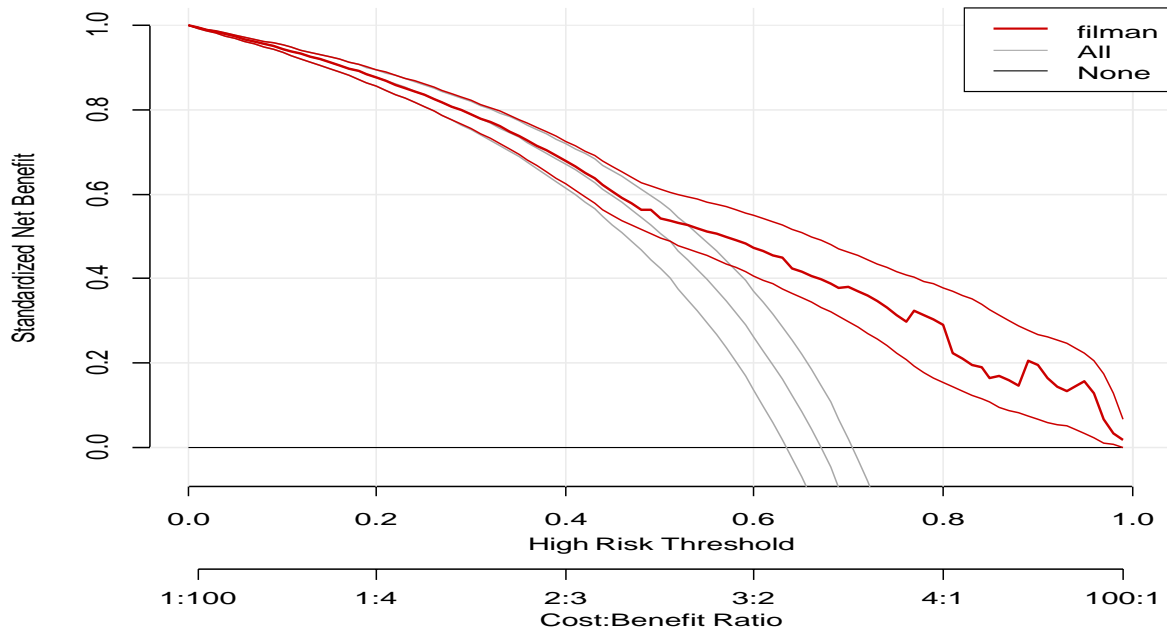


Figure 5: A decision curve plotting net benefit of the model against threshold probability and corresponding cost-benefit ratio.

Risk Classification Using a Simplified Risk Score We created a simplified risk score

From the model for practical use, the reduced model's prediction score was simplified by rounding all regression coefficients. The simplified score had a considerably comparable prediction accuracy with the original β coefficients, with an [AUC of 0.748 \(95%CI: 0.714–0.781\)](#) .The possible minimum and maximum scores a mother can have are 0 and 13, respectively.

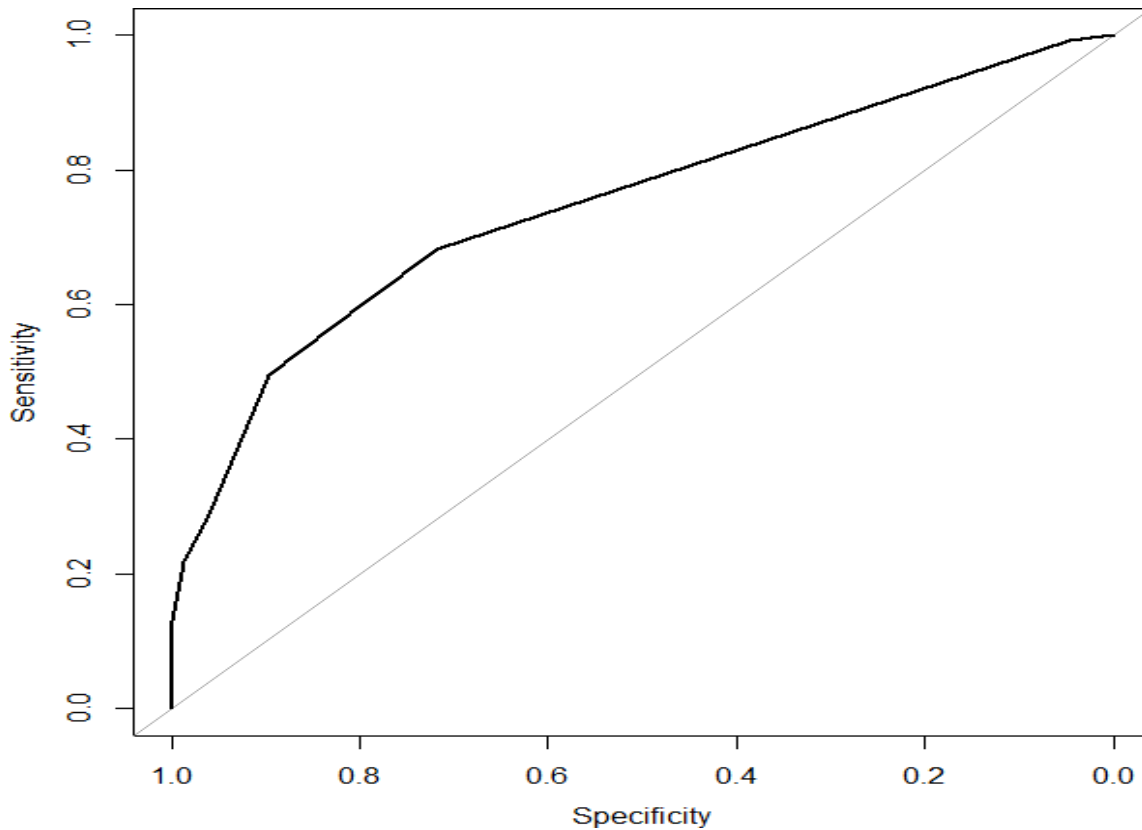


Figure 4: Area under the ROC curve for the simplified risk score to predict risk of failed VBAC among mothers who gave birth at FHCSH from February 30/2019 to March 30/2021.

Table 5: Risk classification of successful VBAC using simplified prediction score (n =700)

Score*(risk category)	Prediction Model Based on Maternal Characteristics		
	Number of mothers	Incidence of	Success Of VBAC
<3 (Low)	368 (52.57%)	185 (49.7%)	
≥3 (High)	332 (47.4%)	284 (85.5%)	
Total	700(100%)	469 (67%)	

When dichotomized to low risk (<3) and high risk (≥3) based on the risk score, 332 (47.4%) were categorized as high risk and 368 (52.57%) as low risk for successful VBAC. Using –You denll, the suggested threshold score to predict success of VBAC using risk scores is ≥3 with a sensitivity of 68.23% and specificity of 71.86%.

6. Discussion

The present study was designed to develop and validate risk score to predict success of VBAC using maternal characteristics among mother who gave birth in FHCSH.

Thus, predicting success of VBAC the probability of in pregnant women is essential to take appropriate measures accordingly. Identifying women with high probability of successful VBAC is an important task for clinical care providers. However, in low and middle income countries, there are only a few methods available for reliably predicting actual success of VBAC in women. Previously, the focus of research was to explain the maternal determinants of success of VBAC. In recent years, the focus shifted to predicting success of VBAC optimally using a combined set of characteristics.

Maternal characteristics were identified in this retrospective study to build a successful VBAC prediction risk score. The optimal combination of maternal factors to predict preterm birth include residency, parity, previous history of successful vbac, rupture of membranes, inter delivery interval, onset of labor ,and initiation time of ANC. according to the prediction model. The model has AUC of 0.748 (95%CI: 0.714–0.781) Furthermore, we discovered that utilizing (you den) as an optimal cut point, the sensitivity and specificity of this prediction model achieved 68.23 percent and 71.86 percent, respectively, at the score threshold of 3.

VBAC has long been proposed as a viable measure to reduce overall cesarean delivery rates in both the low- and middle income and high-income countries [(73)]. A study conducted in sub-Saharan Africa reported that VBAC is safe and its success rates range between 60% and 80% if complemented with careful client selection and good management of labor (19).

However, important challenges related to VBAC trialing exist in low-income settings like Ethiopia, where there a.re bottlenecks in the ability to provide high-quality intrapartum care, including inconsistent availability of comprehensive emergency obstetric care functions.(74)

Moreover, a recent study in Ethiopia also showed the TOLAC rate of 38.5% (75). In our study, more than two-thirds (67%) of the participants had successful VBAC. This finding is similar to the results of a meta-analysis that reported a VBAC success rate of 69% in sub-Saharan African countries [19].

Similarly, other studies also reported comparable levels of VBAC success rates in the United States (71%),](76), India (73%)(74), Ghana (61%) (77), Nigeria (73%) ,(78)

One studies also report lower VBAC success rates in Ethiopia (44.5%) (75), Nigeria (45.1%)(79), and Brazil (45%) (80).

The VBAC success rate in the present study was lower than that in the studies in Japan (91.5%), (81)Australia (83%)(82), and China (80%) (83)which might be due to variation in the maternity care system between Ethiopia and these countries.

The variation in VBAC success rates among different studies could be due to different criteria for TOLAC and differences in predictors of VBAC such as past obstetric performance like prior VBAC, ethnic differences, prior vaginal delivery, and indication for prior cesarean delivery.

The relatively high rate of the successful VBAC revealed in the present study might also reflect the meticulous selection of cases for the provision of TOLAC, as the study took place are comprehensive and referral hospitals for the undergraduate and postgraduate students.

This high degree of cumulative probability of VBAC success should be used to counsel pregnant women for the subsequent mode of delivery in similar settings.

Studies conducted by Krait et al, women with spontaneous onset of labor were more likely to have successful VBAC (19), which is similar with my study.

Gestational age was not found a significant predictor of success in this study. There are reports which found that gestational age above 40 weeks is associated with poor success (84) .

Inter delivery interval that is greater than two years has nearly six times more likely to have success of delivery. On other reports it was found that interval of less than two years was associated with poor success (85). This could be partly due to recall bias.

A mother with prior successful VBAC was found to be associated with success which is similar to other reports (81)Many authors reported history of prior spontaneous vaginal delivery as important determinant for success in VBAC. But our study failed to show this.

A study conducted in China showed that a model developed using gestational age, history of successful VBAC, rupture of membrane, bishop score, and onset of labor and estimated birth weight for the

prediction of overall success of vbaac with AUC of (0.70).which has slight difference with my study, this may be because of difference in predictor variables that was used in final model. (69)

My research coincide with a study conducted in America that a prediction model using predictor variables maternal age, BMI, prior vaginal delivery, prior vaginal delivery and indication for prior cesarean section with prediction of success of vbaac with AUC of (73.4) (37) and a study conducted at western Europe a model with predictors of ethnicity,pre pregnancy BMI, previous cesarean for non-progressive labor, estimated fetal weight and previous vaginal delivery with AUC (72.3).(86)

7. LIMITATION AND STRENGTH

This study was subject to several limitations. Missing data are unavoidable due to the retrospective nature of the study.

Our obstetric population is from comprehensive and referral hospital which may not represent the population in Ethiopia and limit the generalizability to more heterogeneous populations.

My study also had strength; it tries to include very important predictor variables that may have significant role for prediction model.

8. CONCLUSION

A relatively high success rate of TOLAC (69%) was established in women with a previous history of CS, which implies that TOLAC is a potential important strategy for decreasing CS rates in Ethiopia.

Thus, the optimal combination of maternal characteristics such as parity, rupture of membrane ,onset of labor, previous history of VBAC, inter delivery interval and initiation time of ANC shows the possibility of predicting success of VBAC using a simple prediction model constructed from maternal characteristics.

In addition, a risk score calculation based on a combination of predictors was effective and had comparable accuracy with the model-based approach of original β coefficients.

The prediction score was used to risk stratifies pregnant women with previous only one cesarean section and identifies those who were more likely to have successful VBAC. Following that, a woman with high chance of successful VBAC might be considered as good candidate for VBAC.

The model predicting success of TOLAC generated in the study could be a potential tool for more directed TOLAC counseling for women with a primary caesarean delivery.

9. RECOMMENDATION

FOR RESEARCHERS

The predicting success of TOLAC generated in the study could be a potential tool for more directed TOLAC counseling for women with a primary caesarean delivery. Further prospective validation studies with larger sample sizes and in the general population should be undertaken to confirm efficacy before pervasive application among Ethiopian women.

FOR MOTHERS

Women with one previous should be made aware that the outcomes of TOS and inform 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.

FOR PHYSICIANS

Physicians should consider different predictors studied by different scholars, those may have significant role in determination of success of vaginal birth after cesarean section. I recommend health workers to consider and use clinical risk score developed by this research.

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ANNEX

Annex I: Participant information sheet

Title of the Research Project: Developing and validating a risk score for prediction of Successful VBAC at Felege Hiwot comprehensive specialized hospital, Northwest Ethiopia: retrospective follow up study, 2021.

Name of Investigator: Filipos Mesay (BSc in Public Health)

Name of the Organization: Bahir Dar University, College of Health Science and Medicine, School of Public Health, Department of Epidemiology and Biostatistics.

Name of the Sponsor: Bahir Dar University.

Introduction: This information sheet is prepared for FHCSH. The form aims to make the above concerned office clear about the purpose of the research, data collection procedures and get permission to conduct the research.

Purpose: Development and validation of risk prediction for vaginal birth after cesarean section at Felege Hiwot comprehensive specialized hospital, Northwest Ethiopia, 2021.

Procedure: To achieve the above objective, information that is necessary for the study was taken from selected medical records of delivery register.

Risk and /or Discomfort: Since the study was conducted by taking appropriate information from the medical chart, it did not inflict any harm on the patients. The name or any other identifying information will not be recorded on the data extraction tool and all information taken from the chart will be kept strictly confidential and in a safe place. The information retrieved will only be used for the study purpose.

Benefit: The research has no direct benefit for one whose document/ record was included in this research. But the indirect benefit of the research for the participant and other clients in the program is clear. This is because if program planners are preparing predicted plans there is a benefit for clients in the program of getting appropriate care and treatment services. The research work had a paramount direct benefit for clinicians to stratify patients as high risk or low risk, thus to provide appropriate management.

Confidentiality: To assure confidentiality the data on the chart was collected without the name of the clients and the information was collected from this research project was kept confidential. Besides, it was not revealed to anyone except the investigator.

Person to contact: This research project was reviewed and approved by the institutional review board of College of Health Science, school of public health, Bahir Dar University. If you have any questions you can contact any of the following individuals (Investigator and Advisors) and you may ask at any time you want.

Filipos Mesay, Bahir Dar University, College of Health Science and Medicine, School of Public Health, Department of Biostatistics and Epidemiology, principal investigator.

Cell phone: +251-984929331, E-mail: mesayfilipos16@gmail.com Ergoye Melese (MPH& Assistant professor in Biostatistics), Bahir Dar University, College of Health Science and Medicine, School of Public Health, Department of Biostatistics and Epidemiology, principal advisor.

Gebeyaw Wudie(MPH &assistant professor in Epidemiology), Bahir Dar University, College of Health Science and Medicine, School of Public Health, Department of Biostatistics and Epidemiology, co-advisor

Annex 2: Data extraction checklist

Code:

Name of data collectorsignature.....

Name of supervisor.....signature.....

Date

Data extraction checklist (for developing and validation of risk prediction model for VBAC)

Part I: Socio demographic characteristics			
S.no	Variables	Category	Skip
100	Age	1.>35 years 2.<=35 years	
101	Education	>Grade 9 <=Grade 9	
102	Marital status	1.unmarried 2.married	

Part II: Current and past obstetrics characteristics

202	Parity	
203	History of the previous Vaginal birth after cesarean section	Yes No	
204	History of previous vaginal birth	Yes No	
205	Chronic Diseases	Yes No	
206	Previous Cesarean section indication	Recurrent non recurrent	
207	Time from previous delivery	<2 years >2 years	
210	Estimated fetal weight	<4 kg >= 4kg	
211	Rupture of membrane	Spontaneous Artificial	
213	Initiation time of ANC	First trimester Second trimester	

214	Time from previous delivery	> 2yrs <=2 yrs	
211	Bishop score	>5 <=5	
212	Oxytocin	Yes No	
213	Gestational age	37-39 wks. >=40 wks.	

Declaration form

Declaration

I, the under signed, declared that this is my original work, has never been presented in this or any other University, and that all the resources and materials used for the research, have been fully acknowledged.

Principal investigator

Name: _____ Signature: _____ Date: _____

Advisors

Name: _____ Signature: _____ Date: _____

Name: _____ Signature: _____ Date: _____

Department head

Name: _____ Signature: _____ Date: _____

Declaration form

Declaration

I, the under signed, declared that this is my original work, has never been presented in this or any other University, and that all the resources and materials used for the research, have been fully acknowledged.

Principal investigator

Name: Filipos Mesek Signature: [Signature] Date: 18/08/14

Advisors

Name: _____ Signature: _____ Date: _____

Name: Gob Jawim Signature: [Signature] Date: _____

Department head

Name: Gob Jawim Signature: [Signature] Date: _____

INTERNAL EVALUATOR

Name: Zebelem A Signature: [Signature] Date: _____