Ghana College of Physicians and Surgeons

Obstetrics and Gynaecology

LABOUR INDUCTION: TRANSVAGINAL SONOGRAPHIC CERVICAL LENGTH VERSUS BISHOP SCORE IN PREDICTING VAGINAL DELIVERY AT KORLE-BU TEACHING HOSPITAL

Submitted to the Faculty of Obstetrics and Gynaecology, in partial fulfilment of the requirements for the conferment of a

Fellow of the Ghana College of Surgeons (FGCS)

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June, 2023

DEDICATION

I dedicate this dissertation to God, for His Strength, Grace and Wisdom to complete the research. To my loving parents, Mr. Michael Mensah and Mrs. Mary Mensah and my siblings, Mrs. Phyllis Ofosu and Miss Sandra Mensah for the inspiration and support and to the late Mrs. Felicia Sampson Lawson for the encouragement.

ACKNOWLEDGEMENT

I am thankful to Dr Isaac Koranteng, Head of Department for the approval to conduct the study in the department.

I am deeply indebted to my supervisors Prof. Kwame Adu-Bonsaffoh and Dr Kwaku Asah-Opoku, who meticulously guided my journey throughout the preparation of this dissertation.

I am extremely grateful to Dr Alim Swarray-Deen, Dr Jerry Coleman, Dr Titus Beyuo and Prof Seffah for their constructive criticism.

This endeavor would not have been possible without the help of Miss Sandra Mensah, Mrs. Felicia Sampson Lawson and Miss Sarah Avedzidah, who contributed in various ways during the data collection and analysis of the dissertation.

To the Residents and Midwives of the Obstetric Department of Korle-Bu Teaching Hospital, I express my deepest gratitude for their support.

DECLARATION BY CANDIDATE

I declare that the work presented in this dissertation is entirely mine and put together under supervision by my supervisors who are Consultants in the department of Obstetrics and Gynaecology at Korle Bu Teaching Hospital.
Except for references from related research works, which have been duly acknowledged, this dissertation is original. This research work has not been submitted for the award of any degree.

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We hereby declare that except for references from related research works which have been duly acknowledged, this dissertation was put together by the candidate under our supervision.

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ABBREVIATIONS

ACOG	American College of Obstetrics and Gynaecology
APH	Antepartum Haemorrhage
AUROC	Area under Receiver Operator Characteristic curve
BMI	Body mass index
BS	Bishop Score
CTG	Cardiotocography
CS	Composite score
EFW	Estimated fetal weight
FHR	Fetal Heart Rate
FSB	Fresh still birth
IUFD	Intrauterine fetal demise
KBTH	Korle- Bu Teaching Hospital
LMP	Last menstrual period
MFM	Maternal and Fetal Medicine
NICU	Neonatal intensive care unit
NPV	Negative predictive value
NST	Non-Stress Test
PCA	Posterior cervical angle
PPH	Postpartum Haemorrhage
PPV	Positive predictive value
PROM	Premature rupture of membranes
ROC	Receiver Operator Characteristic Curve
TVSCL	Transvaginal sonographic cervical length
TVS	Transvaginal sonography
UK	United Kingdom
USA	United States of America
USG	Ultrasonography
WHO	World Health Organization

ABSTRACT

BACKGROUND

Induction of labour is a common and important obstetric intervention for averting caesarean section whiles optimizing pregnancy outcomes. Traditionally, cervical assessment for favourability of induction has been done using the Bishop Score which involves invasive digital vaginal examination; with a score greater than 6 out of 13 considered favourable. Transvaginal sonographic cervical assessment of the cervix is considered a useful stand-alone tool for cervical assessment. It is less invasive and may be comparable to the Bishop Score in predicting successful induction, given the limitations of the Bishop Score.
The main objective of this study was to compare the transvaginal sonographic cervical length and the Bishop Score in the prediction of successful induction among pregnant women with low risk postdate pregnancies induced at Korle- Bu Teaching Hospital.

METHODOLOGY

This was an analytical cross-sectional study conducted between 1st July 2022 and 30th April 2023. The study population comprised women with low risk postdate pregnancies admitted to the maternity unit of Korle- Bu Teaching Hospital for a scheduled induction of labour. The Bishop Score and transvaginal sonographic cervical assessments were done for all participants before the start of induction. The primary outcome was the predictive abilities of the transvaginal sonographic cervical length and the Bishop Score in predicting vaginal delivery within 24 hours. Secondary outcomes included the pain scores post assessment, number of hours from induction to delivery and adverse maternal and perinatal outcomes.

Data analysis was done using STATA 17. Appropriate statistical tests for comparison of categorical and continuous values were used (independent t test, Wilcoxon Rank Sum test, Chi-square test and Fisher's exact test). Optimum cut off values were identified with Receiver Operator Characteristic Curves and the predictive values determined for both successful induction of labour and vaginal delivery.

RESULT

Of 184 women recruited, 168 participants were included in the final analysis. The rate of vaginal delivery was 82.1%. Successful induction occurred in 117 out of 168 participants (69.9%) with a confidence interval of 62.1-76.5.

Bishop Score ≥ 4 was predictive of both successful induction and vaginal delivery. Transvaginal sonographic cervical length ≤ 2.31cm was predictive of successful induction and transvaginal sonographic cervical length ≤ 2.5cm was predictive of vaginal delivery. The predictive values of transvaginal sonographic cervical length were (sensitivity: 48.7%, specificity: 66.7%, Area under Receiver Operator Characteristic curve: 0.5769). The predictive values of Bishop Score were (sensitivity: 80.3%, specificity: 41.2%, Area under Receiver Operator Characteristic curve: 0.6076). Ninety five percent of women preferred the transvaginal sonographic cervical length.

CONCLUSION

Bishop Score and transvaginal sonographic cervical length were shown to be comparable in predicting both successful induction and vaginal delivery when used for pre-induction cervical assessment. Transvaginal sonographic cervical length measurement was better tolerated by patients than Bishop Score assessment.

In a tertiary setting where expertise for and availability of transvaginal ultrasound exist, transvaginal sonographic cervical length may be the more desirable pre-induction cervical assessment tool or a viable alternative for patients who cannot tolerate the pain of Bishop Score assessment.

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CHAPTER 1

1.0 INTRODUCTION

1.1 BACKGROUND

Induction of labour is an important and common obstetric intervention. Globally, the incidence of induction of labour has risen greatly over the past decade and is recognized as one of the strategies employed to reduce primary caesarean section rates (1).Worldwide, about 1 in 4 pregnant women in developed countries, will have an induction of labour (2). Rates of induction of labour vary by location and institution; being higher in developed countries. In the United States of America (USA), about 22.5% of labour cases have induction of labour (3,4). On the other hand, Africa has an induction rate of about 4.4 % (5); 5–13% in sub-Saharan Africa (3) and 5–6% in South Africa (3). In Nigeria, incidence of 18–23% has been reported in Benin (3) and 3% in Sokoto (3). In Korle-Bu Teaching Hospital (KBTH), about 7-13% of labour cases require induction according to the monthly maternal morbidity and mortality statistics presented in the year 2021(6).

Induction of labour is done, when the benefits to mother or fetus outweighs the benefits of continuing the pregnancy. The goal of every induction is to have uncomplicated vaginal delivery. Predictors of success of induction are broadly classified into maternal, fetal and biochemical factors (7).Favourability of the cervix at the onset of induction is the most important marker of success. A favourable cervix is associated with a shorter duration of induction and a higher likelihood of vaginal delivery. Traditionally the Bishop Score (BS) is used to assess the favourability of the cervix (7).Other cervical scoring systems include the Fields system, Burnett, Caldor and Friedman modifications of the Bishop system, but these are rarely used for predicting labour outcome (8).Transvaginal sonographic cervical length (TVSCL) assessment is also an available tool for predicting success; a more common trend in developed countries (9). It is not widely used in developing countries currently because of unavailability of equipment and skills (10).

1.2 PROBLEM STATEMENT

Pre-induction cervical status is the most important factor in predicting success of induction of labour (7) with the BS currently being the most widely used assessment tool. The BS is cheap and can be used in low resource settings where transvaginal ultrasound

probes and provider skills may be unavailable (11), It is however fraught with several limitations. It is subjective with little reproducibility (11,12). Inter- and intra-observer variability exist, with a low perfect agreement (11,13). Digital examination is unable to assess the supravaginal cervix, which usually comprises about 50% of the cervical length (7). It is painful (14) and lastly, can only be audited by repeating a digital examination.

Although studies have compared BS and TVSCL (7,14–17), majority of these have been done in developed countries. Of the few done in low resource settings, none has been done in Ghana. Results from these studies have also been inconclusive, with inconsistent cut off values. Whilst some studies demonstrated that the TVSCL was superior to the BS (14,17), others showed the BS to be superior to the TVSCL (16) and others demonstrated the TVSCL to be a significant predictor but not superior to the BS (7,15). A drawback to the comparisons is the observation that these studies used different study populations. Whilst some studies used term pregnancies at 37-42 weeks' gestation (16,17), others used 40weeks and above(18). The studies also used different induction agents, doses and methods. This included dinoprostone used at a single dosage (16), dinoprostone at different doses (14), oxytocin or prostaglandin (19,20). All of these differences could have had impact on the success of labour induction. This requires further investigation into the subject matter with a homogenous group and a single induction agent.

The success rate of induction of labour at KBTH is about 77% according to our monthly maternal morbidity and mortality data presented in the year 2021(6). Success of induction of labour in only postdate pregnancies has been shown to be 74.13% in a study by Kabore et al at KBTH in 2015 (21). The BS is currently the assessment tool used to predict success of induction of labour for all patients. Although transvaginal probes are currently available in the Maternal and Fetal Medicine (MFM) Unit and the requisite skills also available; the TVSCL is not assessed for clients admitted for induction.
To the best of my knowledge, no facility in Ghana routinely assesses TVSCL before induction of labour and so induction success rates from TVSCL could not be compared with the BS currently being done at KBTH. Could the TVSCL be more accurate than the BS at KBTH for predicting success of labour inductions?

A more objective and reproducible assessment tool with proven superiority to use of BS in predicting successful induction of labour will be extremely useful in modern obstetric practice.

1.3 JUSTIFICATION OF STUDY

Inappropriate selection of candidates for labour induction results in unexpected prolonged labour induction and increased rates of failure of induction. This is associated with febrile morbidity, prolonged labour and increased caesarean section rates with its associated morbidities and mortalities (22). Appropriate selection of candidates for induction is necessary to improve success rates and mitigate these risks.

With pre-induction cervical status currently being the most important predictor of success (7), identifying a cervical assessment tool that proves superior at predicting success will be worth the search. Also, majority of studies were not done in low resource settings and so results cannot be directly transposed to our setting. Several factors influence the decision to intervene during labour management in low resource environments. Factors such as availability of cardiotocography (CTG), level of intrapartum monitoring, availability of theatre space and the cultural setting, can influence labour management (23).These points buttress the need to conduct this study, which will be the first in Ghana, to determine how the test results will be comparable in our setting.

Results from this study will add to the existing body of knowledge and aid obstetricians in choosing the superior tool of predicting success, aimed at increasing success rates of labour inductions in our setting. It will also be a guide for counselling patients for induction of labour since it will be able to predict probability of having a successful induction and guide in patient decision making.

1.4 AIM OF THE STUDY

The aim of this study was to compare the TVSCL and the BS in the prediction of successful labour induction among women with low risk postdate pregnancies (between 41 weeks and 43 weeks) induced at KBTH.

1.5 RESEARCH QUESTIONS

1. What proportion of postdate women deliver vaginally within 24 hours of induction?
2. Is there a difference in the predictive values of the TVSCL and BS for successful induction of labour?
3. Is there a correlation between TVSCL and the digital cervical length component of the BS?
4. Will a composite score of the TVSCL and some parameters of the BS and maternal parameters improve the prediction of successful induction of labour?
5. How acceptable will TVSCL and BS for pre-induction cervical assessment be to women undergoing postdate induction of labour?

1.6 SPECIFIC OBJECTIVES

1. To determine the proportion of postdate women that deliver vaginally within 24 hours of induction.
2. To determine the TVSCL and BS cut off values for predicting success of induction of labour at KBTH and compare their predictive values.
3. To examine the relationship between TVSCL and the digital cervical length component of the BS.
4. To determine if a composite score comprising the TVSCL and some parameters of the BS and maternal parameters will improve the prediction of successful induction of labour.
5. To compare the acceptability of TVSCL and BS for pre-induction cervical assessment in women undergoing postdate induction of labour.

1.7 HYPOTHESIS

NULL HYPOTHESIS

There is no difference in the predictive values of BS and TVSCL in predicting successful induction of labour at KBTH.

ALTERNATE HYPOTHESIS

There is a difference in the predictive values of BS and TVSCL in predicting successful induction of labour at KBTH.

CHAPTER 2

2.0 LITERATURE REVIEW

2.1 OVERVIEW OF INDUCTION OF LABOUR

Induction of labour is defined as the artificial initiation of labour before its spontaneous onset for the purpose of delivery of the feto- placental unit (4).

2.1.1 INCIDENCE OF INDUCTION OF LABOUR

Rates of induction vary by location and institution. In the USA, rates have increased from 9.5% in 1990 to 22.8% in 2012 (24,25). The United Kingdom (UK) reports about 20% of all deliveries are by induction of labour and Latin America has a rate of 11.4% (5,26). Rates are however lower in developing countries (5), with Africa reporting an induction rate of about 4.4% (5).

In sub-Saharan Africa, rates ranging from 5% to 13% have been quoted (3). In the study "unmet need for induction of labour in Africa", induction rates were 5.0% in Angola, 5.1% in Democratic Republic of Congo, 6.8% in Algeria, 3.9% in Kenya, 1.4% in Niger, 6.3% Nigeria and 2.5% in Uganda (5) and 5–6% in South Africa (3). In Nigeria, whilst incidence of as high as 18–23% has been reported in Benin (3) rates as low as 3% has also been reported in Sokoto (3). In Ghana there is limited data although induction is frequently practiced. In KBTH, about 7-13% of labour cases require induction according to the monthly maternal morbidity and mortality statistics (6).

2.1.2 HISTORY OF INDUCTION OF LABOUR

The practice of labour induction dates back to the ancient times, as far back as the time of Hippocrates. The methods used in the ancient times included physical manipulation and dilatation of the cervix, artificial rupture of membranes, use of herbal concoctions as enemas and placement of cervical irritants on the cervix to initiate the labour process. Medical advancements led to the introduction of newer techniques for induction of labour between the eighteenth and nineteenth centuries. Mechanical methods were used for induction, with the introduction of cervical dilators (27).

In the twentieth century, the discovery of oxytocin and subsequently its synthetic formula in 1955, revolutionized the field of obstetrics and Bell is reported as the first to have used oxytocin for induction of labour (27). Administration of oxytocin evolved from the intramuscular or subcutaneous route to intravenous administration as the former was associated with increased reports of uterine rupture and adverse outcomes. Prostaglandins as a method of induction of labour was first reported by Karim and colleagues in 1968 and also gained popularity in obstetrics (27).

Currently, medical knowledge has driven the advancement in the methods of induction of labour from the crude methods to safer evidence-based methods; making maternal and fetal safety a priority. These safer methods include medical, mechanical and surgical methods. Medical methods include prostaglandins (misoprostol, dinoprostone) of different varieties, doses and mode of administration. Mechanical methods include hygroscopic dilators (laminaria) and transcervical catheters (Foleys catheter and double balloon catheter). Surgical methods include artificial rupture of membranes and membrane stripping (27,28).

2.1.3 INDICATIONS FOR INDUCTION OF LABOUR

Indications can be broadly divided as obstetric, medical and elective (non-medical). Common obstetric indications include post term pregnancy; hypertensive disorders in pregnancy; premature rupture of membranes (PROM); intrauterine fetal demise (IUFD) and intrauterine growth restriction. Medical indications include maternal and fetal conditions which include diabetes, renal disease, hemoglobinopathies, significant pulmonary disease and chronic liver disease (3,29).

The commonest indication for induction varies by location. Whilst postdate pregnancy is reported as the commonest indication in studies done at Lagos and Ogoja, both in Nigeria (3,29)**,** PROM was the commonest indication in a study by Bukola et al titled "unmet need for induction of labour in Africa" (5); similar to a study in Latin America (26). In a study at KBTH, a tertiary hospital in Ghana in the year 2015, the commonest indication for induction was postdate, accounting for 65.9% of all the cases induced (21)**.**

2.1.4 CONTRAINDICATIONS OF INDUCTION OF LABOUR

Contraindications of vaginal delivery are also contraindications for induction of labour. Maternal contraindications include refusal to consent for procedure, previous hysterotomy, two or more previous caesarean sections, previous uterine rupture, previous extensive myomectomy or a prior classical uterine incision (27,28). Fetal contraindications include malpresentation, fetal distress, non-reassuring fetal status and severe intrauterine growth restriction. Other contraindications include placenta previa, vasa previa, cord prolapse or cord presentation (27,28).

2.2 DIGITAL CERVICAL ASSESSMENT METHODS

Cervical scoring systems have evolved over the years, with the first scoring systems using digital examination to assess the cervix (8). Currently newer scoring systems using ultrasound or fibronectin levels have been evaluated (12,30). The various cervical attributes are quantified into scoring systems to predict the likelihood of successful vaginal delivery (8).

2.2.1 CERVICAL SCORING SYSTEMS

Calkins in 1930, developed a scoring system based on intensity of uterine contractions and cervical parameters. The cervical parameters included consistency, cervical length and cervical wall thickness and these were assessed via a rectal examination. These parameters were rated on a scale of one to five, and patients with a favourable score were noticed to have shorter durations of labour (8).

Cocks in 1955, described five types of cervices. Types 1 and 2 cervices were classified as ripe and types 3 and 4 classified as unripe. Cocks concluded from his classification that unripe cervices had a greater probability of having an operative delivery and a sacral os a higher probability of having a caesarean section when induced (7,8).

Fields scoring system was developed in 1963. Ten parameters were used to assess the favourability for induction of labour. These included gestational age, estimated fetal weight (EFW), attitude of patient towards induction, presence of contractions, presence of vaginal

discharge and cervical parameters: softness, effacement, station, dilation and position. A multiparous woman with a score of 16 or greater or a nulliparous woman with a score of 18 or greater was considered favourable. A score of ten or below was associated with increase in operative delivery, increase in average labour duration and doubling of complication rates (8).

The arrival of intravenous oxytocin, led to increased inductions of labour. Bishop during his inductions noticed that cervical dilation, effacement and station had a correlation with the duration of labour in multiparous women but not in nulliparous women. Bishop developed a criterion that needed to be met before elective induction with oxytocin and amniotomy. These were multiparity, cervical dilation of three cm (3cm) or more, effacement of at least 60% and a station of -1 or greater. These cervical parameters were assessed with vaginal rather than rectal examination. In 1964, Bishop developed a pelvic score which later became known as the BS. This score was to be applied to only parous, uncomplicated, term, cephalic pregnancies. A score of 9 or above was associated with a safe and successful induction of labour (8).

2.2.2 BISHOP SCORE

The score was described in 1964 by Bishop, to determine which patients were candidates for elective induction of labour. The score is based on five parameters; namely cervical dilatation, effacement, consistency, position and station. The scoring system has a minimum score of zero (0) and a maximum score of thirteen (13). A score of 0 to 4 is considered unfavourable, 5 to 8 moderately favourable and a score of nine and above considered favourable for successful induction of labour (8). The BS was initially developed for parous women with term uncomplicated pregnancies with cephalic presentation, but currently it is used to assess any patient who is a candidate for induction.

Table 1: BS cervical scoring system

BS PARAMETER	0	1	2	3	SCORE
CERVICAL POSITION	POSTERIOR	CENTRAL	ANTERIOR	-	
CONSISTENCY	FIRM	MEDIUM	SOFT	-	
LENGTH (CM)	3	1-2	0.5-1	<0.5	
DILATATION (CM)	0	1-2	3-4	5-6	
STATION	-3	-2	-1	0+	

2.2.2.1 MODIFICATIONS OF THE BISHOP SCORE

Currently several modified versions of the BS exist. These include the Burnett, Friedman and Calder scores (8).

The Burnett score maintains all the five components of the BS, with each component having a maximum score of two, giving a total score of ten rather than thirteen. This scoring system changed the percentage effacement of the BS to length in centimetres. It is applicable to parous and cephalic presentations, with a score of 6 and above considered favourable. A score of nine or ten predicts a labour duration of less than four hours, whilst a score of six to eight predicts a labour duration of about six hours in about ninety percent of patients (8).

Friedman identified that various components of the BS affected the length of the latent phase in differing proportions after studying 406 multiparous women undergoing induction of labour. He proposed a weighted score; where dilation was twice the weight of consistency, station and effacement and four times the weight of cervical position (7,8).

2.2.2.2 ADVANTAGES AND DISADVANTAGES OF THE BISHOP SCORE

The BS assessment is cheap and comes at no added cost to the pregnant woman. In low resource areas where transvaginal probes may be unavailable, it may be the only option to assess cervical favourability (11).

The BS is however plagued with several limitations. The BS is subjective (11,12) and varies considerably among examiners with little reproducibility (12,14,31). Inter and intra observer variability exist. Agreement between observers evaluating BS is fair to substantial, with a low perfect agreement (11,13). The digital examination cannot assess the supravaginal cervix which usually comprises 50% of the cervical length (7). Digital examination to assess the BS is also more painful compared with transvaginal scanning (14,32) and the configuration of the internal cervical os cannot be determined by the digital exam (33). Finally, the score cannot be audited, unless repeating the vaginal examination.

2.3 SONOGRAPHIC METHODS OF CERVICAL ASSESSMENT

Obstetric ultrasound dates back to the 1950's when obstetrician Ian Donald and engineer Tom Brown developed the scan for clinical purposes. Evolution has occurred over the past years with several technological developments such as the use of transvaginal ultrasound, colour and power doppler, 3/4D imaging (34).

Sonographic cervical assessment is currently promoted in current obstetric practice mainly because of its objectivity. There are three methods to sonographically assess the cervix. These are the transabdominal, transperineal and transvaginal methods (35).
Each approach has its merit and demerits. The preferred method will depend on the clinical scenario and the availability of a healthcare provider with the expertise.(35)

2.3.1 TRANSABDOMINAL SONOGRAPHIC CERVICAL ASSESSMENT

Zemlyn in 1981 is reported in literature as one of the first to assess cervical length transabdominally (35). To evaluate the cervix, bladder filling is required. Whilst an empty bladder may hamper visualization of the cervix, a full bladder may also overestimate the cervical length and mask dilatation if present. Transabdominal sonography does not require any additional probe. The curvilinear probe, which usually is the most commonly available probe in various settings is what is required. It is easy to perform, especially at early gestations, but becomes more difficult as the pregnancy advances due to the fetal growth (35). Cervical assessment is also limited if there is maternal obesity. Attempts at improving cervical assessment transabdominally include the use of cervical hydrosonography as reported by Robinson et al in 2000 (35). This approach however cannot be done when membranes have ruptured.

2.3.2 TRANSPERINEAL SONOGRAPHIC CERVICAL ASSESSMENT

This approach involves placing the probe between the labia minora. No additional ultrasound probe is required, as it uses the same curvilinear probe used for transabdominal sonography. A protective cover for the probe however is required. The transperineal approach is considered less invasive and may be preferred if membranes have ruptured, but is less reliable when compared to the transvaginal approach because of shadowing by bowel content or pelvic bone (35).

2.3.3 TRANSVAGINAL SONOGRAPHIC CERVICAL ASSESSMENT

Transvaginal sonography (TVS) is used to diagnose conditions such as cervical insufficiency and predict patients at risk of preterm birth in modern obstetrics and currently TVSCL is being promoted as another cervical assessment tool apart from digital assessment (36). TVS has several advantages. The TVS can assess the entire cervical length without invading the endocervical canal and so confers an advantage over digital assessment (37). TVS is less painful and causes less discomfort compared to digital assessment (12,14,32). It is an objective test that can be easily reproduced. Images obtained can also be independently audited without having to repeat the scan. Images can also be easily documented and filed for future references (38). The probe is in close proximity to the cervix and so image degradation as occurs when scanning through abdominal fat is avoided. The need for bladder filling as required in transabdominal scans (38) and shadowing by content of the rectosigmoid colon in perineal scans are also avoided. An additional benefit of TVS is its ability to assess other cervical parameters such as changes at the internal os, presence or absence of funnelling, the funnel width and length if funnelling is present, the posterior cervical angle, and cervical configuration. The presence of amniotic fluid debris, sludge (39), membrane separation, vasa previa and placenta previa can also be identified during a transvaginal scan. Performing TVS however requires skill and availability of the transvaginal probe and comes at an added cost (10).

TVSCL is the most studied sonographic cervical parameter. It is assessed by measuring the cervix from the internal os to the external os after visualization of the entire endocervical canal (40). Assessment is done after bladder emptying. A sterile transvaginal probe is placed in the anterior fornix, withdrawn and reapplied until a good sagittal image is obtained with minimal pressure. The anterior and posterior cervical thickness width must be equal and there must be visualization of both the internal and external os and the entire endocervical canal. The field of view must be optimized to about 60% to 75%. Repeated images must be taken, usually over three minutes and the shortest best measurement recorded as the linear distance between the internal os and the external os (40). The cervical length can be measured as a single linear line, in two- line segments or by trace method (33,41). There are currently some clinically significant applications of the TVSCL accepted by the Fetal Medicine Foundation (9). The TVSCL is important in predicting patients at high risk of preterm delivery. It also predicts the time of delivery at term. For women who have been

planned to have a caesarean delivery, assessing TVSCL at term can be used to determine whether to carry out the caesarean section at 37 weeks or hold on delivery till 39 weeks (9).

For patients who undergo induction of labour, TVSCL is clinically important in predicting the likelihood of vaginal delivery or caesarean section and also predicts the induction to delivery interval (9). Different cut off values have been suggested to predict successful induction of labour. Values range from 1.8cm to 3.0cm (14,17,42).

TVSCL measurement is an objective test, with high interobserver agreement reported in literature (43,44). Andrea et al reported that the TVSCL was reproducible between different examiners with a concordance correlation coefficient of 0.76 (43). Stein and colleagues also reported a high interobserver agreement with an interclass coefficient of 0.986, with a mean interobserver difference of 2mm (44).
Irrespective of these findings, standardisation of the measurement, training of health care professionals and quality assurance programs can further improve the reliability of the measurement and minimize interobserver variability (45).

Funnelling is another cervical parameter, identified at the internal os. The endocervical mucosa acts as an important landmark to determine the presence and degree of funnelling (9). Sonographically, cervical funnelling is identified during transvaginal assessment when there is protrusion of membrane into the cervical canal (33). Whilst some studies describe it as the protrusion of amniotic membranes of three or more millimetres into the internal os (16), other studies use a distance of greater than five millimetres from the shoulder of the original internal os (46). Studies have shown that the presence of funnelling is associated with successful induction of labour (47,48). Studies have also identified that the presence of funnelling is associated with a shorter duration of labour and a shorter second stage of labour (47). In a study in Malaysia in 2019, Abdullah and colleagues reported funnelling as a significant predictor of vaginal delivery, with a three times higher probability of having a successful induction if funnelling was present (48).

Posterior cervical angle is the angle between the cervical canal and the posterior uterine wall. It provides a measure of the cervical position. It has been identified as a predictor of successful induction of labour (49). A study in Egypt in 2021, identified a posterior cervical angle cut off of 99 degrees in predicting successful induction (49). The posterior cervical angle also showed a significant negative correlation with induction to delivery (49).

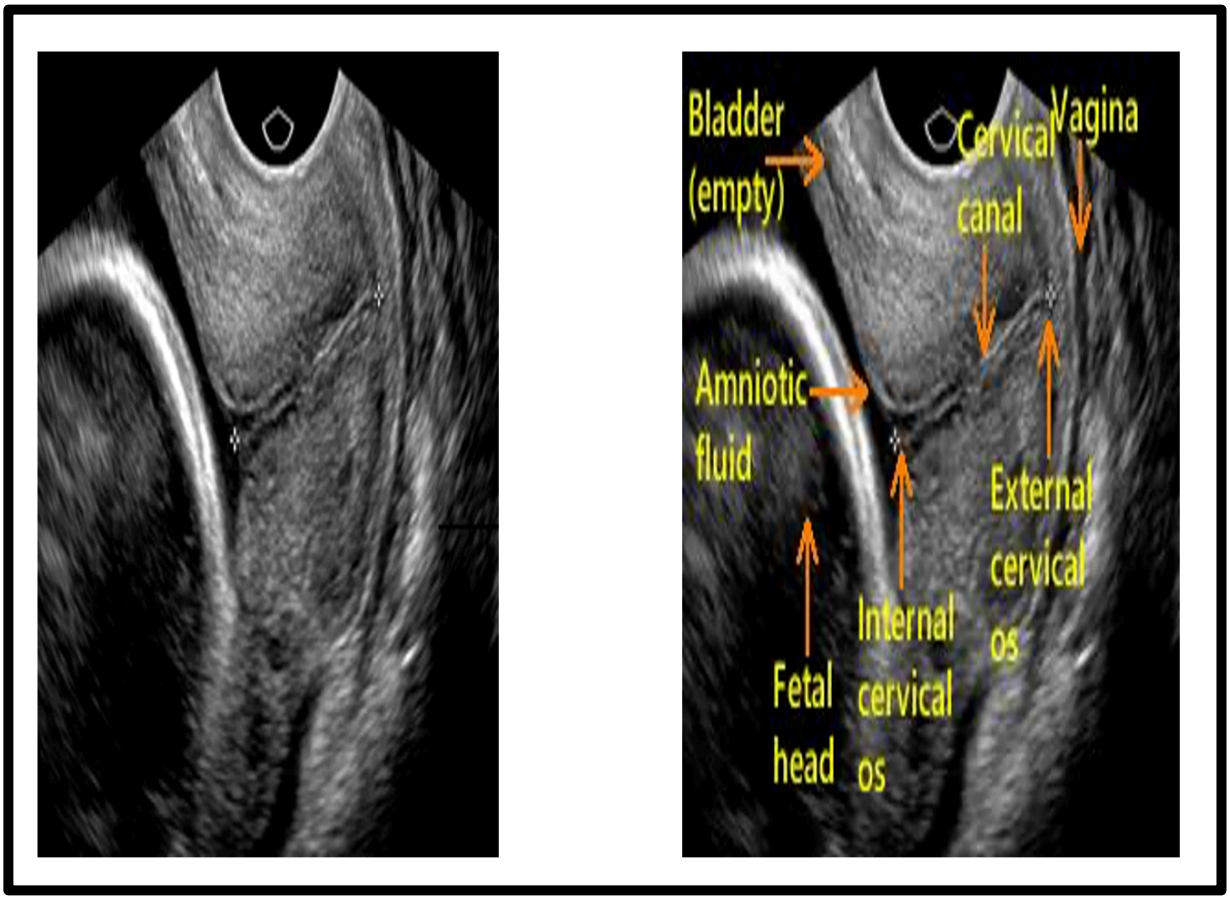

Figure 1 : Normal Transvaginal ultrasound image showing the cervix in the sagittal view (credit: obimages.net)

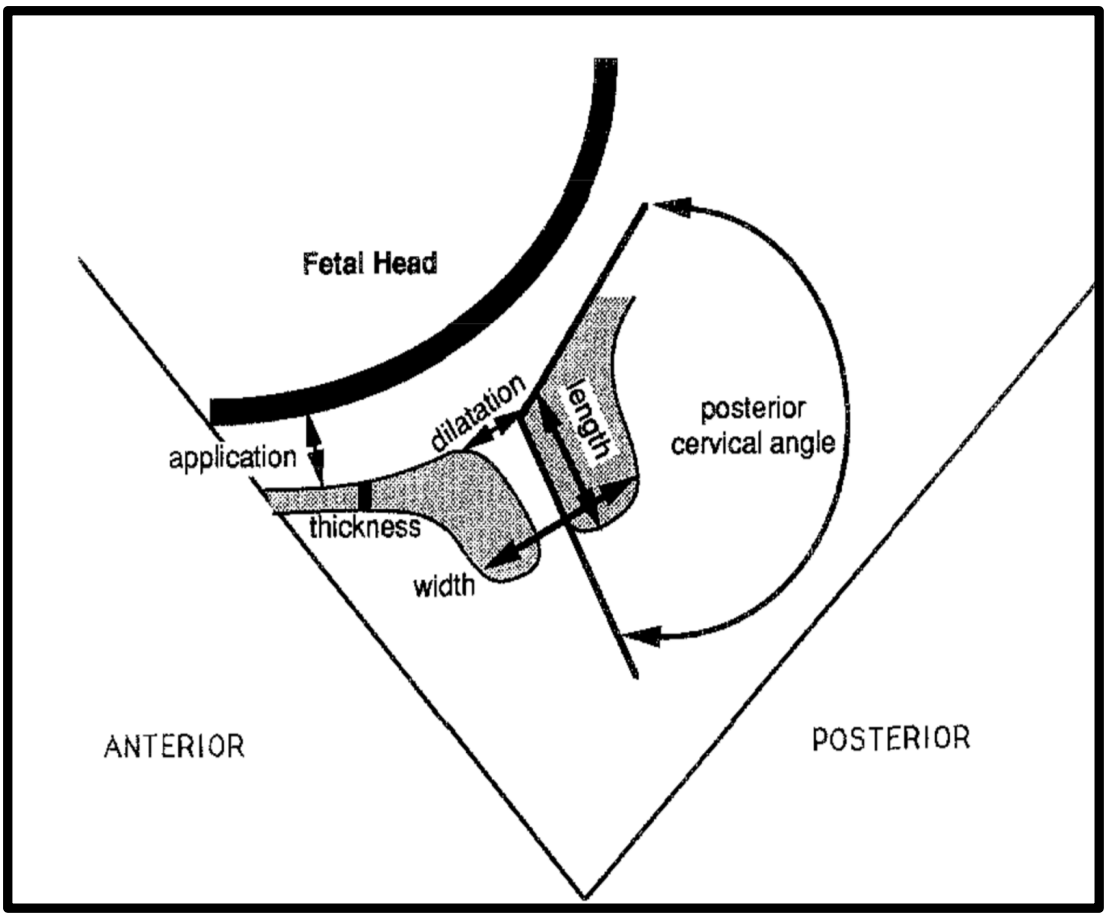

Figure 2 : A scheme of measurements obtained on Transvaginal ultrasound of the cervix in the sagittal plane.

2.4 COMPARING BISHOP SCORE WITH TRANSVAGINAL SONOGRAPHIC CERVICAL LENGTH ASSESSMENT

Several studies have compared TVSCL and BS in predicting successful induction of labour. Although a correlation exists between both BS and TVSCL with duration of labour (14,17,50), the question of which method is superior still remains unanswered. Whilst some studies have reported the TVSCL as superior (14,17,19,50,51), other studies have reported the BS as superior (16,52) and other studies have reported the inability of the TVSCL in predicting induction success (18).

A study in Iran, conducted between 2007 and 2009, reported that the TVSCL was a better predictor of caesarean section following induction compared to BS, with a potential to replace the BS if facilities are available (17). In the study, 200 women were assessed before induction of labour and it was identified that TVSCL at a cut off of 1.9cm and BS at a cut off

of 4 were predictive of caesarean delivery after induction (17). TVSCL was more sensitive (66.7% vrs 57.9%) and more specific (65% vrs 28.7%) when compared to the BS in predicting caesarean section. For the accuracy; TVSCL had a value of 69% whilst BS had a value of 39% (17). Pandis et al in a study conducted on 240 women in London in 2001, reported that the TVSCL was a better predictor of having a vaginal delivery within twenty-four hours using a cut off value of 2.8cm compared to a BS cut off of 3. The sensitivity at this cut off was 87% for TVSCL and 58% for BS (14). He identified that at a TVSCL of less than 1.9cm, vaginal delivery will occur within twenty-four hours in all the women; however, at a TVSCL of greater than 3.1cm, 85% would remain undelivered after twenty-four hours (14). Athulathmudali et al, in a study at Sri Lanka in 2021, reported that TVSCL of < 3.71cm was associated with a successful induction, with a sensitivity of 88% and a specificity of 74%. Also reported in the study was that BS was not a significant predictor of successful induction of labour, with an accuracy of 39% compared to 83% for TVSCL (50). Doaa Alaa et al in a study in Egypt, also identified that although both methods were significant in predicting success of induction, TVSCL was superior to the BS. The identified cut off values were 2.85cm for TVSCL and 6.5 for BS. Regarding the predictive values, TVSCL was both more specific (100% vrs 62%) and more sensitive (94% vrs 86%). The accuracy was also higher for TVSCL (97.3% vrs 80.3%) (42). Ana Gomez et al in a study in Spain, examined 177 women and identified cut off values of 2.52cm for TVSCL and 5 for BS to predict success of induction. TVSCL was identified to be a better predictor, with a specificity of 72% compared to 46% for the BS. Also identified was a higher false positive rate of 53% for BS compared to 28% for TVSCL (51). Other studies have also reported the TVSCL as being superior to the BS in predicting success (19,20,53).

Ransiri et al in 2018, identified the BS to be a predictor of successful induction whilst the TVSCL was not a significant predictor. A total of 428 nulliparous women were assessed in the study conducted at Sri Lanka and a BS cut off value of 3 significantly predicted success (18). A study conducted in Turkey, also reported no association between TVSCL and successful induction. This study was conducted between 2007 and 2008 and subsequently published in 2012. The BS was however statistically significant in predicting success (16).

Some studies have also reported the TVSCL as a significant predictor of success but not found to be superior to the BS (15,32,36,48,54–56). Abdullah reported that both methods were comparable in their prediction of success. Using a TVSCL cut off of 2.7cm and a BS cut off of 4, similar sensitivities of 69% and 67% were reported respectively. The

specificities were 60.9% for TVSCL and 55% for BS. The accuracy was 67.2% for TVSCL and 64.3% for BS (48). In Iran, a study conducted by Khazardoost and colleagues also reported similar findings at a cut off value of 5 for BS and 1.6cm for TVSCL (54). Brik et al, in a study in Spain, identified that for the 245 women assessed, both TVSCL and BS were predictive of failed induction of labour. The identified cut off values were 2.8cm for TVSCL and 3 for BS. The predictive abilities of both methods were similar, with reported accuracies of 74.5% for TVSCL and 77.7% for BS (57).

In all these studies, different induction agents, different definitions of success and heterogenous groups were evaluated. For the induction agents, whilst some studies used dinoprostone only (14,16,55), other studies used oxytocin alone (36) and other studies used more than one agent; dinoprostone or oxytocin (19,20,32). In terms of study population, some studies assessed only nulliparous women (18,19,54); whilst others assessed only primiparous women (55). Different indications for induction of labour were used. Different gestational ages were also assessed in the various studies. A gestational age of 37 weeks to 42 weeks in some studies (14,16,17,20,36,48) and 40 weeks and above in others (18). Differences in the definition of successful induction of labour were also used in the studies. Whilst some studies defined success as vaginal delivery in 24 hours (14,50), others defined success as vaginal delivery with no time limit (54), cervical dilatation of 8cm and above (18) or achieving active labour (56). All of the differences identified, may have affected the outcomes measured, the cut off values and the predictive abilities of the methods.

2.5 INDUCTION OUTCOMES

Vaginal delivery rates after induction of labour vary in literature (48,54,58). In Ghana, Adu-Bonsaffoh et al reported a vaginal delivery rate of 82.6% (58). Kabore et al, who assessed postdate pregnancies, reported a lower vaginal delivery rate of 74.3% (21). Khazardoost et al in their study in Iran, reported an even lower vaginal delivery rate of 57% (54). The heterogeneity in the study population of the various studies could have had a role in the varied vaginal delivery rates reported. Whilst Adu-Bonsaffoh et al studied multiple indications for the induction (58), Kabore et al studied only postdate pregnancies (21) and Khazardoost et al studied only nulliparous women (54).

2.5.1 DEFINITION OF FAILED AND SUCCESSFUL INDUCTION OF LABOUR

The criteria for defining failed induction of labour are not standardized and many studies have reported varied definitions of failed induction of labour (59,60).
Studies have defined failure as inability to achieve the active phase of labour (59,61). American College of Obstetrics and Gynaecology (ACOG) in the obstetric care consensus, recommend that a caesarean section be done for a failed induction of labour after there has been failure to reach active phase (6cm) after 12 to 18 hours of oxytocin with ruptured membranes (1). NICE in the induction of labour guidelines, defines unsuccessful induction as failure to initiate uterine contractions after a complete induction cycle (62). A workshop summary, which involved a collaboration between Society of Maternal-Fetal medicine and ACOG in 2012, defined failed induction as "failure to generate regular contractions and cervical change after at least 24 hours of oxytocin administration" (63).

Failure to achieve a vaginal delivery irrespective of the indication has also been defined in some studies (64). In this definition, maternal and fetal complications that necessitate termination of the induction and birth by caesarean section are considered as failed induction (64). Failure to ripen the cervix after induction or lack of progress of labour may also be considered as failed induction of labour (65).

It may be expected that if an induction is not successful, then it implies that it has failed. However, in literature, even the definition of success lacks uniformity. Whilst success may mean obtaining a vaginal birth, some guidelines may define success as vaginal birth which is time bound, usually between 24 to 48 hours (4) after induction (65). Although the definition of failed induction is crucial, the well-being of the mother and fetus must always be considered and the induction process not unduly prolonged just to avoid classifying the induction as failed.

2.5.2 PREDICTORS OF SUCCESSFUL INDUCTION OF LABOUR

Prolonged labour induction is associated with febrile morbidity, prolonged labour, fetal asphyxia and increased caesarean section rates (22). Careful selection of patients is therefore necessary to mitigate these risks. Several maternal and fetal factors have been suggested to predict the success of labour induction (7,66,67).

Maternal factors can be classified as cervical and non-cervical factors. Non cervical factors include parity, maternal age, maternal weight, maternal height, body mass index (BMI) and medical comorbidities (7,66–69). BMI of less than 30, age less than 35years and high parity have been associated with successful inductions (68–70). Medical comorbidities like hypertension and diabetes have also been associated with a lower success and increased risk of caesarean section (67). Cervical factors are assessed using the BS or TVSCL. The parameters assessed determine the favourability of the cervix and this is the most important factor to predict successful induction (7).

Fetal factors include the birth weight and the gestational age. Low birth weight and increasing gestational age are associated with a higher success of induction (7,70). Recent studies have also shown that biochemical markers can be used to predict success. Fetal fibronectin and insulin-like growth factor binding protein have been identified, but are still investigational (7,30).

Some studies have also mentioned the hospital site and the provider practice as predictors of success of induction (66).

2.5.3 COMPLICATIONS OF INDUCTION OF LABOUR

Adverse outcomes have been associated with the induction process (62). Maternal complications include an increased risk of caesarean delivery, uterine hyperstimulation, maternal infections, postpartum haemorrhage (PPH), uterine rupture and perineal trauma. Fetal complications include fetal distress, increased NICU admission and neonatal infections (27,62).

2.6 RELATIONSHIP BETWEEN TRANSVAGINAL SONOGRAPHIC CERVICAL LENGTH AND DIGITAL CERVICAL LENGTH

The digital cervical length is a component of the BS (8). Previous studies have reported that digital examination cannot assess the supravaginal cervix which usually comprises 50% of the cervical length (7,37). Whilst some studies have reported a weak relationship (71,72), other studies have reported a strong relationship (73) between these two measurements.

A study by Kanwar et al identified that digital examination of the cervix, underestimates the cervical length by an average of 1.36cm (19). Grotegot and colleagues in a study conducted at the Duke University Medical Centre in USA, assessed 726 women and identified that there was a significant relationship between the TVSCL and the digital cervical length (71). The strength of correlation however was weak, with a reported goodness of fit of 23% (71). The study also identified that whilst the digital cervical length was able to predict the time to spontaneous delivery, TVSCL could not significantly predict this outcome (71). In a study conducted in Egypt and published in 2021, 200 pregnant women were assessed and also identified that there was a relationship between the TVSCL and the digital cervical length. The reported correlation was however moderate, with a coefficient r of 0.629. The mean TVSCL was 1.810 ± 0.509 cm and the mean digital cervical length was 1.544 ± 0.36cm (72). Raji et al in a study in Nigeria also reported a relationship between TSVCL and the digital cervical length. The relationship was a positive linear relationship with a strong correlation. A coefficient r of 0.761 was reported (73).

A comparison of these studies identified that a single operator did both the TVSCL and the digital cervical assessment in the study with the stronger correlation (73), compared with the study by Hefila et al (72), where different examiners assessed the two methods. The use of a single operator could have possibly introduced some bias in the findings reported.

2.7 COMPOSITE SCORES TO IMPROVE PREDICTION OF SUCCESS OF INDUCTION OF LABOUR

With the increase in the induction of labour rates, identification of scores that can accurately predict success of this procedure is very important (74). Studies have attempted to develop composite scores to improve the predictive accuracy. Whilst some scores have proven superior (12,74), other scores have not proven superior in their predictive accuracy (18,75).

In a study conducted in southern India,131 pregnant women were recruited between 37 weeks to 42 weeks for induction of labour. A composite transvaginal ultrasound score was developed based on five parameters, with no inclusion of maternal clinical parameters. These parameters were the cervical length, funnel length, funnel width, cervical position and distance of fetal head from the external os (12). Each parameter was scored between zero (0) to two (2), with a maximum score of ten (10). Success of induction was defined as active

labour within twenty-four hours of induction in the study. The transvaginal ultrasound score was identified to be superior to the BS. The accuracy for the composite score was 90.7% compared to 81.5% for the BS. Similarly, at a cut off value of 4 for both scores, the specificity (92.86%) and sensitivity (77.42%) were higher for the transvaginal ultrasound score compared to the BS with specificity of 85.71% and sensitivity of 64.52% (12). Jochum et al, in a study in France, developed a new simplified 50-point score, to predict caesarean section after an induction of labour (74). Components of the score included the maternal height, parity, gestational age, cervical effacement, cervical dilatation, BMI and fetal station. This new score was compared with the modified BS and the Levine score in predicting caesarean section. The new score was identified to be superior to the modified BS with an accuracy of 81% compared to 74% for the modified BS (74). Seung Woo Yang et al in a study in Korea, assessed 205 pregnant women between 37 weeks and 41 weeks for induction of labour. A combination of the uterocervical angle and the BS was compared with BS alone in predicting success of induction, defined as active labour within 12 hours of induction. He reported that the combined score was more specific with a specificity of 96% compared to 76.9% for the BS (76). Laughon and colleagues assessed 5610 nulliparous women between 37 weeks and 42 weeks for induction of labour. A simplified BS was developed which comprised cervical effacement, cervical dilatation and station, with a score ranging from 0 to 9. When compared with the original BS to predict vaginal delivery after induction, the predictive values were identified to be comparable with sensitivities of 82.6% and 83.8% respectively (75). The identified cut off values were 5 for the simplified BS and 8 for the original BS (75). Ransiri et al developed a composite score where the digital cervical length of the BS was replaced with the sonographic cervical length and the score computed. A total of 428 nulliparous women, with gestation of 40 weeks and above, were assessed in the study conducted at Sri Lanka. Success was defined as cervical dilatation of 8cm. The accuracy for the new score was not superior to the BS or TVSCL in predicting success (18).

2.8 TOLERABILITY OF THE TRANSVAGINAL ULTRASOUND PROBE AND DIGITAL ASSESSMENT

With increasing use of the transvaginal ultrasound in obstetrics and gynaecological cases, a larger number of women will undergo this procedure. The transvaginal scan is an invasive procedure and for this reason, it may be hypothesized that women will find the procedure distressing and refuse to consent. Although the transvaginal scan and digital assessment are both invasive, studies have identified that the scan is better tolerated by patients than vaginal examination, mainly because it is less painful (14,32).

Studies conducted have shown that women are willing to have a TVS in their future pregnancy (73,77–79). Clement et al in 2003 reported that about 85.9% of women would definitely or probably have another TVS in future pregnancies (77). Majority of the women studied did not find the procedure a difficult experience and rated it as being less difficult than having a Pap smear or dental filling or venipuncture. It however was more difficult than having a transabdominal scan, although 91.6% of those who experienced pain described it as mild (77). Raji et al in a study conducted in Nigeria reported that 65.4% of women preferred the TVS to digital assessment for BS and 23.3% were indifferent of the two assessment methods (73). Akinmoladun et al also reported a low preference, with only 60.4% of women willing to have a transvaginal scan rather than digital assessment and 11.3% being indifferent (78). Okeji et al, also in a study in Nigeria, reported that 82% of participants were willing to have a TVS in future, with as high as 90.5% reporting no pain. Only 8.6% reported mild pain and 0.9% reported moderate pain from transvaginal sonographic assessment (79). Akintomide and colleagues also reported a high acceptance rate of 98.5% for transvaginal scan (80). Gunes et al, in a study at Turkey, identified a mean score of 3.92 for discomfort among 320 women who had digital vaginal assessment. The study identified that a history of emotional abuse, increased the level of discomfort by 4.5 times, whist a history of post-traumatic stress disorder increased the risk by 1.04 times. There was also an association between parity and discomfort, with increasing live births being associated with a reduction in the level of discomfort (81).

Several factors have been identified to predict the willingness of women to have a transvaginal scan done for them (77,82). These include the woman's parity, ethnicity, prior painful vaginal examination and educational level (77,79,82,83). Clement et al, identified that

primiparous women were more likely to accept the transvaginal scan (77). He also identified that Black Africans were more likely to accept the transvaginal scan (77).
Whilst Okeji et al identified that increasing educational level increases acceptability of transvaginal scans (79), Komolafe and colleagues identified that secondary education, rather than tertiary education was associated with a higher acceptability (83). Atalabi and colleagues on the contrary identified that there was no significant association between age, parity, religion, educational level or ethnicity and the willingness to have a transvaginal scan (82). He however identified that sexually active women were two times more likely to accept the transvaginal scan. Women with a history of vaginal douching were 1.3 times more likely to have a transvaginal scan. Women with a previous history of sexual abuse were also 1.7 times less likely to have a transvaginal scan done for them (82). Akinmoladun and colleagues, conducted a study on 424 women in Ibadan, Nigeria and also identified that religion, education or marital status had no effect on a woman's acceptability of having a transvaginal scan (78). The gender of the sonographer has also been reviewed in some studies. Whilst Okeji et al reported that 63.1% of women preferred a female practitioner (79), Atalabi et al reported that 54.2% were indifferent about the sex of the sonographer (82) and Akintomide et al reported that 46% were indifferent, 45% preferred a female sonographer and 9% preferred a male sonographer (80).

2.9 PREVALENCE OF POST DATE PREGNANCY

Pregnancy extending beyond the expected delivery date has traditionally been regarded as postdate pregnancy (84). This term is however avoided in current practice after the introduction of the new terminologies by ACOG for Term pregnancies (85). Postdate pregnancies will therefore include late term (41weeks – 41weeks+6 days) and post term (42weeks and above) pregnancies as defined in the current terminology (85).

A number of factors influence the prevalence of postdate pregnancy. These factors can be classified into maternal factors, fetal factors, genetic factors, environmental factors and healthcare factors (86).
Maternal parameters include advanced maternal age, nulliparity, obesity and previous history of postdate pregnancy. Nulliparous women compared to parous women, have a higher risk of having a postdate pregnancy (86). There is an increasing trend to deliver postdate if the pre-pregnancy BMI is high (87). Whilst obesity has been associated with postdate pregnancy,

underweight has been associated with high incidence of preterm delivery (86,87). Genetic factors include a positive family history of postdate pregnancy, paternal influence and women who are products of a prolonged pregnancy (86,88).

Fetal factors include a male fetus and fetal anomalies. Some anomalies associated are fetal anencephaly, fetal adrenal hypoplasia and fetal adrenal insufficiency (86).

Health care practice also influence the prevalence of postdate pregnancy. These include advances in prenatal care, use of routine ultrasound dating and guidelines for scheduled induction at an institution (86).

2.10 DIAGNOSIS OF POSTDATE PREGNANCY

Postdate pregnancy is diagnosed based on the estimated due date and the assessment of gestational age. This estimation can be done using the last menstrual period (LMP) or an early ultrasound dating scan (89). The LMP has some limitations in accurately identifying the gestational age and this occurs when there is irregularity of the menstrual cycle or uncertainty in recalling the exact date of the LMP or if there has been first trimester bleeding per vaginam (84). The use of LMP can therefore lead to overestimation of the gestational age resulting in overdiagnosis of postdate (84).

Suboptimally dated pregnancies are defined as pregnancies where the confirmation of gestational age is done after 22 weeks (90). A suboptimally dated pregnancy can increase the incidence of postdate diagnosis. WHO in the recent update on maternal and fetal assessment recommend ultrasound before 24 weeks to estimate gestational age (91).

The use of an early ultrasound improves the accuracy of estimating gestational age, decreasing the incidence of postdate pregnancies (86), hence reducing the need for unnecessary interventions for postdate pregnancies. First trimester ultrasound provides the most accurate method to determine the gestational age of pregnancies (89). The accuracy of ultrasounds in predicting the expected delivery date is not limited to only the first trimester. In resource limited areas where a first trimester dating scan may not be always achieved, a scan performed before 20 weeks can also be used for dating (92). However, the earlier a scan is done in the second trimester, improves its accuracy in predicting the gestational age (92).

2.11 COMPLICATIONS OF POSTDATE PREGNANCY

Maternal and fetal complications have been reported in postdate pregnancies. Fetal complications include stillbirth, early neonatal death, macrosomia, oligohydramnios, birth injuries, meconium aspiration, fetal asphyxia and post maturity syndrome (59,86). Maternal complications include increased risk of caesarean sections, increased operative vaginal delivery, anxiety, major degree perineal tears, labour dystocia, chorioamnionitis and PPH (86).

CHAPTER 3

3.0 METHODS AND MATERIALS

3.1 STUDY DESIGN

This was an analytical cross-sectional study, conducted between 1st July 2022 and 30th April 2023. Patients were enrolled at the time of presentation for induction of labour, had initial cervical assessment done (TVSCL and BS) and then were induced. There was no active intervention by the researcher, but the design focused on studying and drawing inferences from existing differences between patients.

3.2 STUDY SITE

The study was conducted at the Maternity unit of the Obstetrics and Gynaecology department of the KBTH, Accra. KBTH is the premier tertiary healthcare facility in Ghana and the third biggest referral centre in Africa. It provides services to the Greater Accra Region, surrounding regions and neighbouring countries. The Obstetrics and Gynaecology department has a 275-bed capacity for the obstetric unit; with a triage and emergency unit, antenatal clinics, two labour wards, six maternity lying-in wards, a fetal assessment and simulation centre, two operating theatres and a recovery ward. The average annual deliveries in the department is 10,000 (58). It has an average monthly induction rate of 13%, with a 77% success rate (6).

The range of cases seen at KBTH are mostly high-risk obstetric cases and referred cases. Some of them are referred purposely for induction of labour. In a month, the unit induces on average 75 patients. The highest number of patients induced in a month over the past six months is 100 and the lowest is 59. The common indications for induction of labour at KBTH over the past six months in decreasing order of frequency are postdate, hypertensive disorders, gestational diabetes, PROM and IUFD. Postdate accounts for about 45% of cases induced in a month and low risk postdate cases account for about 60% of the postdate cases induced in a month (6).

At KBTH, pregnancy extending beyond the expected delivery date is traditionally classified as postdate pregnancy. By this definition, pregnancies beyond 40 weeks' gestation are considered as postdate. The departmental protocol recommends that postdate pregnancies

at gestation of 41 weeks and above are scheduled for induction of labour. The usual standard of care for postdate induction of labour is the use of misoprostol. The diagnosis of postdate pregnancy is based on the estimated due date and the assessment of gestational age. This estimation is done using the LMP or an early ultrasound dating scan. Where a first trimester dating scan may not be always achieved, a scan performed before 20 weeks is also used for dating, although the department recognizes that, the earlier a scan is done, improves its accuracy in predicting the gestational age. Where there is no previous dating scan available, the LMP is used, although this occurs rarely.

In the preparation of patients for induction of labour at KBTH, patients are admitted a day prior to the scheduled induction. On admission, an initial evaluation is done to identify if the indication for the induction of labour still exists and is justifiable. An ultrasound scan and Non Stress Test (NST) are done to assess fetal well-being and any contraindication to induction of labour (e.g. EFW > 4Kg, anhydramnios, non-vertex presentation and abnormal NST) ruled out. The procedure is explained to the patient and an informed consent obtained.

Pre-induction cervical assessment is done using digital vaginal examination for all the women and the BS determined and recorded on the morning of the induction of labour. The BS is the assessment tool used to predict success for all patients scheduled for induction at the study site. Depending on the favourability of the cervix and the obstetric history, one of the recommended methods of induction is done. Methods of induction at KBTH include medical induction with misoprostol given 4-6 hourly per vaginam, transcervical catheter induction and amniotomy.

The study site, prior to 2021, used 50 ug of misoprostol for induction. This was obtained by dividing a 200ug tablet of misoprostol into four parts and a quarter inserted into the posterior fornix 4-6 hourly. Since 2021, 25ug misoprostol tablets have become readily available and is also in use at the study site. This is given 6 hourly per vaginam as recommended by the FIGO guidelines (93). After induction of labour is started, the patient is monitored on the induction chart and transferred to the labour ward when in active phase of labour defined as 4cm cervical dilatation and above. Successful induction of labour at the study site is defined as having a vaginal delivery after induction. Failure is defined as inability to achieve vaginal delivery. This includes failure to achieve effective uterine contractions; failure to achieve active labour; or any indication resulting in a caesarean section.

Ultrasound has become readily available at the study site since the establishment of the MFM subspecialty at KBTH in 2019. In addition, expertise has also improved markedly for TVSCL.

3.3 STUDY POPULATION

The study population were pregnant women with low risk postdate pregnancies admitted to the maternity unit of KBTH for a scheduled induction of labour. For the purposes of this study, postdate pregnancy was defined as late term (41weeks- 41weeks+6 days) and post term (42 weeks - 43 weeks) pregnancies. Low risk was defined as no maternal medical condition (hypertension, diabetes, sickle cell disease, renal disease or human immunodeficiency virus infection); no previous caesarean section and no fetal risk (intrauterine growth restriction or congenital anomalies)

3.4 ELIGIBILITY CRITERIA

The inclusion and exclusion criteria were as follows:

3.4.1 INCLUSION CRITERIA

1. Women with a singleton pregnancy between 41 weeks and 43 weeks
2. Women with a cephalic presentation.
3. Women scheduled for and willing to undergo medical induction with misoprostol.
4. Women with intact membranes at the time of cervical assessment.
5. Women who were willing to consent to partake in the study.

3.4.2 EXCLUSION CRITERIA

1. Women allergic to misoprostol.
2. Women with a prior failed induction of labour in the index pregnancy.
3. Women with an EFW > 4kg. (This was a departmental protocol for induction of labour).

4. Women who were less than 18 years. (They were excluded because of the need to seek parental consent for them).
5. Women with a pre-induction abnormal NST.
6. Women with an IUFD.
7. Women with a history of a collagen disease**.** (e.g. scleroderma because that could affect the cervical favourability).
8. Prior cervical surgery or cervical insufficiency

3.5 SAMPLE SIZE CALCULATION

From the study conducted by Pandis et al in the year 2002 at London (14), Induction was successful in 59.2% and unsuccessful in 40.8%. Sensitivity using BS was 58% and specificity was 77%. Based on this information and using the sample size formula for determining adequate sensitivity or specificity for diagnostic tests according to the method described by Jones et al (94), the sample size was calculated.

Sample size based on sensitivity

$$N(sN) = \{Z^2_{1-\alpha/2} \times Sn \times (1-Sn)\} / \{L^2 \times P\alpha\}$$

Sample size based on specificity

$$N(sP) = \{Z^2_{1-\alpha/2} \times Sp \times (1-Sp)\} / \{L^2 \times P\beta\}$$

where

N= number of patients (participants)

N(sN) = minimum sample size based on sensitivity

N(sP)= minimum sample size based on specificity

$Z_{1-\alpha/2}$ = 1.96 (standard normal deviate value that divides the central 95% of z distribution from 5% in the tails)

Sn= reported sensitivity (58% = 0.58)

Sp = reported specificity (77%. = 0.77)

L= precision desired on either side of sensitivity/specificity (10% = 0.1)

P^{α} = Prevalence of successful induction (59.2% = 0.592)

P^{β} = Prevalence of failure of induction (40.8% = 0.408)

Inputting the above into the sample size formula:

N(sN) = 158

N(sP) = 167

Therefore, a sample size of 167 was the minimum requirement with respect to both sensitivity and specificity.

Using a 10% mark up for loss to follow up and incomplete data

N= 184

3.6 SAMPLING TECHNIQUES

Low risk postdate pregnancies account for about 60% of all postdate cases induced in the department in a month (6). Based on the data from the department, it was estimated that the potential number of eligible participants per month would be 23. The total number of months required for data collection per this estimation was supposed to be eight months. However, before the start of the study, one of the major referring facilities to KBTH had a permanent doctor appointed at that facility, hence the number of postdate pregnancies referred to KBTH reduced. The period of the study was therefore extended in order to obtain the required sample size. Based on the issue of time constraint for the dissertation, the sampling technique used was sequential recruitment, where all eligible participants were approached and recruited in a sequential order.

Pregnant women who were admitted for a scheduled induction of labour were identified a day prior to the induction. Of these, patients with postdate as an indication for the induction with gestation between 41 weeks and 43 weeks were selected. The subset of patients who qualified as low risk postdate pregnancies as defined in the study population,

who met the inclusion criteria and consented to the study after counselling were recruited sequentially. Every next patient who met the inclusion criteria and came for induction of labour on account of postdate, was recruited on the obstetric ward.

3.7 DATA COLLECTION INSTRUMENT AND PROCEDURE

A questionnaire was administered by trained research assistants. Data items covered included demographic characteristics, obstetric history, indication for induction of labour, EFW and the NST results.

All participants had a transvaginal scan done for them on the morning of the induction. On average the measurement took about ten minutes per patient. Patient's perception of pain was assessed using a 10 POINT numerical pain rating scale and recorded after the scan was performed. The researcher was the sole performer of all the transvaginal scans for the study.

The BS was assessed by trained junior residents blinded to the TVSCL within thirty to sixty minutes from the sonographic assessment. This time interval was chosen because it was assumed that the pain perception from one form of assessment would have waned off. Patient's perception of pain was assessed after the digital assessment and recorded. Patients were then asked to choose their preferred method if they had the option to do so and indicate the reason for their choice. A total of 20 junior residents in the second and third year of residency in Obstetrics were trained for BS assessment. Each obstetric team had four of the trained residents to perform the digital assessment for participants admitted to their team.

Misoprostol was given intravaginally in all patients and the tablet was inserted into the posterior fornix. This was aimed at standardizing care and making the test easily reproducible. Induction of labour monitoring and labour management were undertaken as per the hospital's protocol, with no interference from the research team. All important labour events were recorded on the data abstraction form by the research assistant. This included: the time of first insertion of misoprostol; time of active labour (at least 4cm cervical dilatation); time of second stage; time of delivery; number of doses of misoprostol given; the need for augmentation and the maximum dose of oxytocin used; maximum number of contractions and duration; non reassuring fetal heart changes (bradycardia, persistent tachycardia, late deceleration); time of rupture of membranes during labour; newborn sex; birth weight; APGAR score; mode of delivery; NICU admission; maternal outcomes

(antepartum haemorrhage (APH), uterine rupture, PPH, chorioamnionitis) and reasons for failure of induction.

Pretraining was done for all research assistants. This was organized over a period of two days. Training involved the researcher going through the questionnaire and answering questions from the research assistants regarding the conduct of the study. A pilot study to test the instruments and assess feasibility was done involving 10 patients (5% of the calculated sample size) at the Fetal assessment centre of the Obstetric unit and the necessary modifications made, before conducting the actual research. The researcher performed the TVSCL whiles the trained junior residents assessed the BS. The residents were blinded to the results until completion of the pilot study.

To improve validity of results and minimize potential bias, the researcher had a certificate of competence to perform TVSCL from the Fetal Medicine Foundation; and had done a minimum of 60 transvaginal scans prior to conducting the study. Also, only trained junior residents assessed the BS of participants. Resident level Obstetricians are the cadre of medical doctors in postgraduate training, just below the rank of a Specialist. Since second and third year residents are more experienced, it was assumed that their technique of digital assessment would be more reliable, hence the decision to exclude the first year residents. Restricting the assessment to only the 20 selected trained residents would also reduce inter-observer variability, as the training was aimed at improving uniformity in the assessment.

The Primary outcome of the study was the predictive abilities of the TVSCL and the BS in predicting vaginal delivery within 24 hours. The secondary outcomes included: the number of hours from induction to delivery; pain scores post cervical assessment, vaginal delivery, the predictive abilities of the composite scores, number of doses of misoprostol used; need for oxytocin augmentation; maternal complications (abnormal uterine contractions: hypertonus or tachysystole, APH, uterine rupture, PPH, chorioamnionitis) and fetal complications (low APGARS: <7 at 5 minutes, NICU admission, abnormal fetal heart changes).

Definition of terms for the study:

- Successful induction of labour: vaginal delivery within 24hrs of onset of induction
- Failure of induction of labour: failure to have a vaginal delivery within 24 hours; that is failure to deliver a patient vaginally in whom a safe vaginal delivery was initially expected. It therefore included:
    - Failure to induce effective uterine contractions within 24 hours.
    - Inability to achieve active labour
    - Vaginal delivery after 24hrs of induction
    - The need to carry out Caesarean section for failure to progress, fetal distress, infection, cord prolapse or APH.

- Chorioamnionitis/ infection: temperature > 38 Celsius with either uterine tenderness or offensive liquor
- Bradycardia: fetal heart rate < 110bpm
- Tachycardia: fetal heart rate > 160bpm
- Tachysystole: > 5 contractions in a 10minute period
- Hypertonus: contraction lasting > 2minutes
- Active labour: cervical dilatation of 4cm and above
- Effective uterine contractions: 3-4 contractions lasting more than 40 seconds
- Sensitivity: test ability to designate a woman with the disease (successful induction of labour) as positive
- Specificity: test ability to designate a woman without the disease (failed induction of labour) as negative
- Positive predictive value (PPV): proportion of women with a positive result who actually have the disease (successful induction of labour)
- Negative predictive value (NPV): proportion of women with a negative result who do not have the disease (failed induction of labour) as negative

MEASUREMENT OF CERVICAL PARAMETERS WITH THE TRANSVAGINAL SCAN

The ultrasound scan was performed at the MFM - Fetal assessment centre of the obstetric department in the presence of a chaperone. The transvaginal probe of the GE-LOGIQ 5 Ultrasound machine was used for the study. The technique used was as per the Fetal Medicine Foundation online cervical assessment training module (9). The patient after emptying her bladder, was placed in a dorsal lithotomy position with a left tilt. A sheet was then placed over her thighs and legs to maintain privacy. A lubricated transvaginal probe, covered with a lubricated condom, was inserted into the vagina and directed in the anterior fornix, without exerting pressure on the cervix. A sagittal plane of the cervix was obtained. The endocervical mucosa was used as a guide to identify the internal and external os. The image was then magnified until the cervix occupied about 50% of the screen. The length of the cervix was measured as the linear distance between the “v shaped” internal os and the “triangular shaped” external os where both lips of the cervix come together. Three measurements were taken and the shortest measurement was recorded. Also noted were the presence or absence of funnelling and the position of the cervix.

At the end of each examination, the condom was discarded and the probe was wiped clean with tissue and an antiseptic wipe.

ASSESSMENT OF BISHOP SCORE

The BS was assessed after the transvaginal scan. With the patient in the dorsal position, the vulva was cleaned with an antiseptic solution (savlon) using the three-swab technique. Gloved examining fingers were inserted into the vagina and the cervix assessed. The parameters assessed included the cervical length, station, cervical dilatation, cervical consistency and cervical position. The BS was determined and the score documented as in the KBTH induction of labour chart. The data for each participant was captured on the day of the induction of labour.

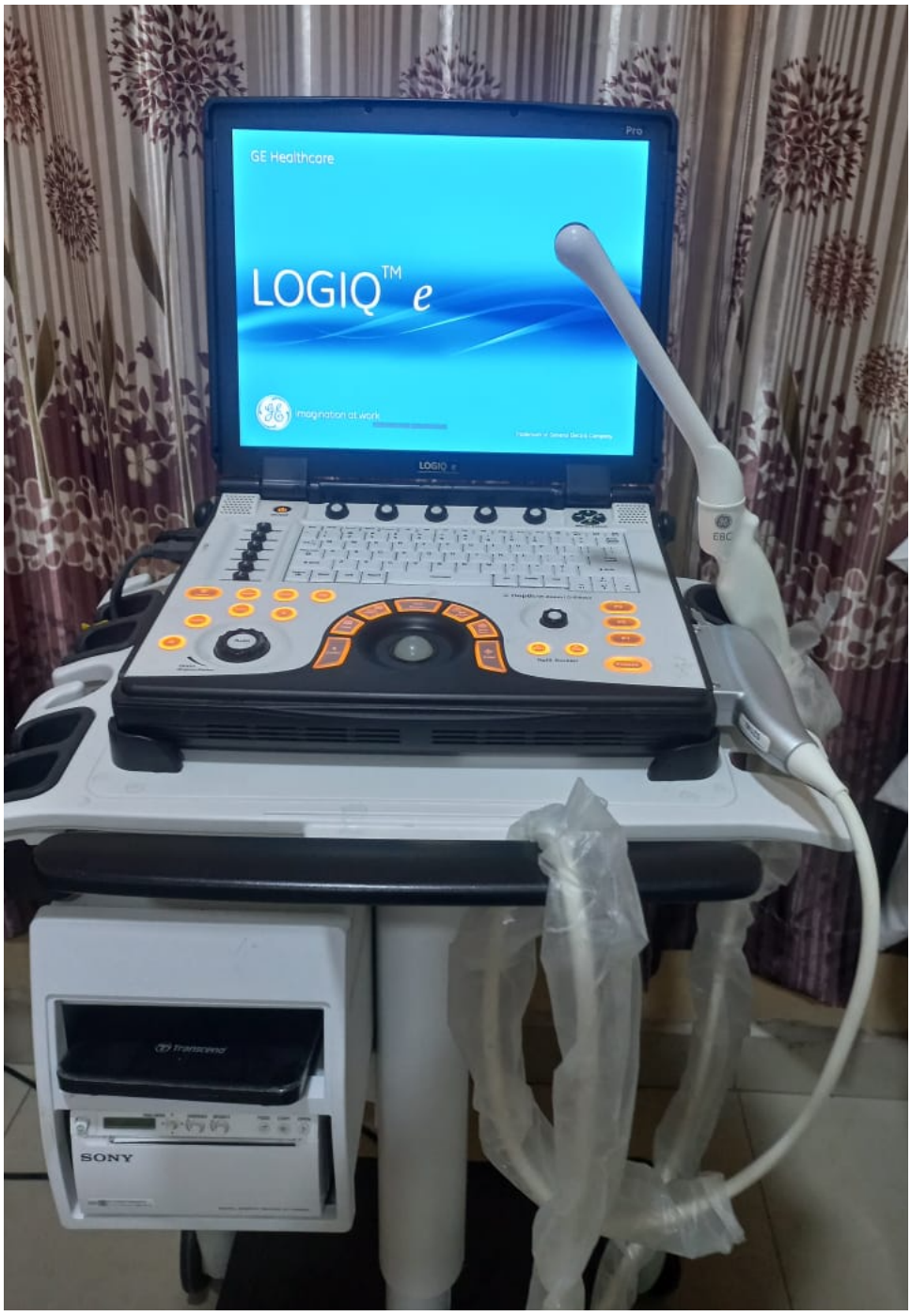

Figure 3: Image of the GE-LOGIC 5 ultrasound machine used for the study with the transvaginal probe

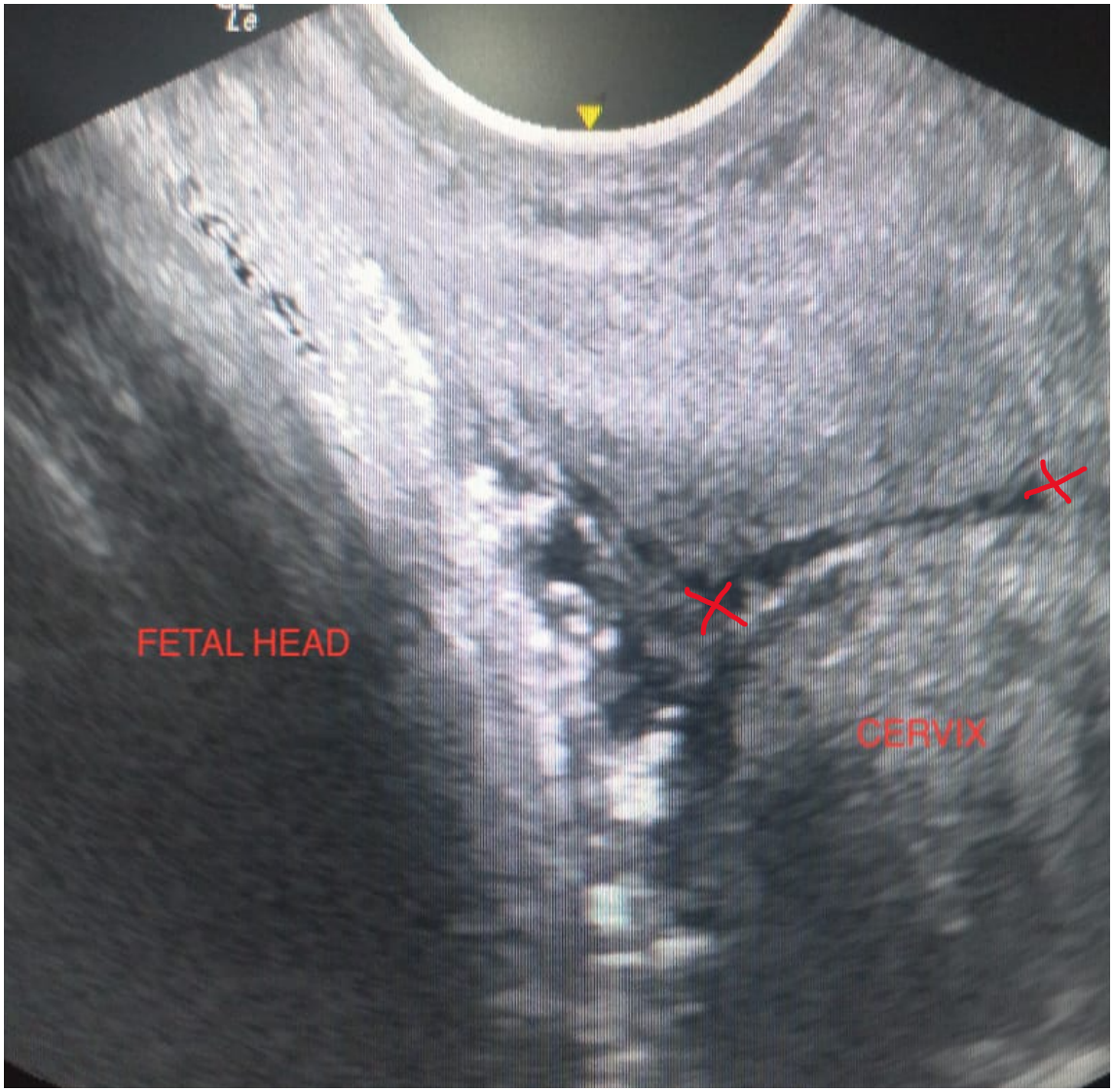

Figure 4:Transvaginal ultrasound image of the cervix showing correct placement of cursors for the measurement of the cervical length (credit: image of a participant of the study)

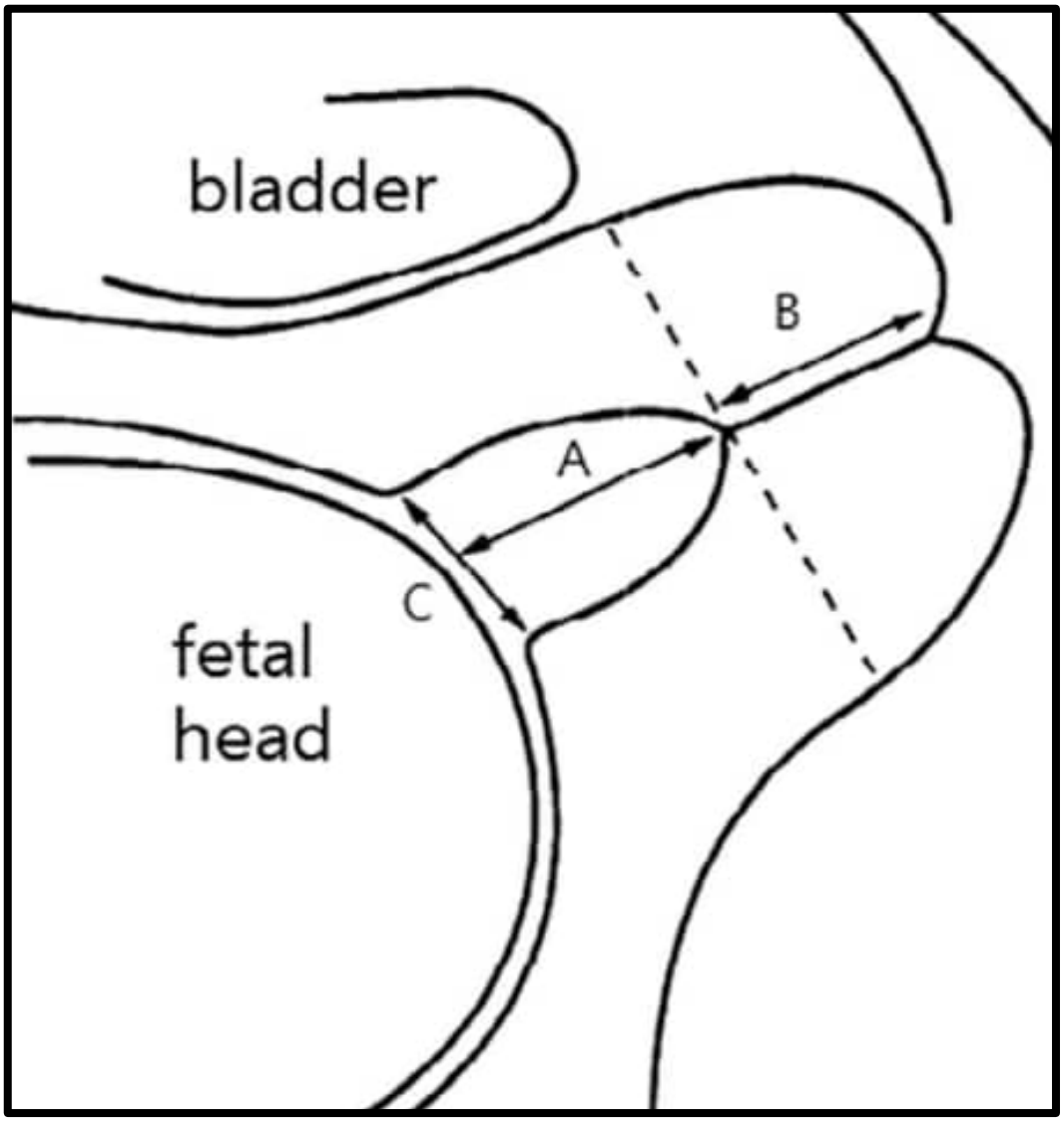

Figure 5: Transvaginal ultrasound image of the cervix with funnelling showing funnel length and funnel width

A: FUNNEL LENGTH
B: FUNCTIONAL CERVICAL LENGTH
C: FUNNEL WIDTH
(credit: https://www.researchgate.net/figure/Transvaginal-ultrasound-of-the-cervix)

INDUCTION OF LABOUR

Induction of labour was done using 25 micrograms of misoprostol given intravaginally every six hours for a maximum of four doses. Prior to the start of the induction, maternal vitals, abdominal examination and fetal heart rate were assessed and recorded. The misoprostol was inserted and the patient monitored on the KBTH induction of labour chart. Hourly monitoring of fetal heart rate was done using intermittent fetal doppler. Before the next dose of misoprostol, uterine contractions were ruled out. This was done by a midwife, every 6hours, approximately 30 minutes before the time for insertion of the next dose of misoprostol. If effective contractions were present (3-4 contractions lasting more than 40 seconds), the next dose of misoprostol was not given. At active phase of labour (at least 4cm cervical dilatation), patient was moved to the labour ward and monitored on the partograph as per the hospital's labour management protocol.

3.8. DATA MANAGEMENT AND ANALYSIS

Questionnaires and data collection sheets were used to collect data in this study. All the data captured were entered into Microsoft excel (version 16) on a personal computer, which was password protected. Computer files had security codes, accessible to only the research team. Data analyses were done using STATA 17. Descriptive statistics were presented in charts and tables. Parametric testing, specifically the Skewness and Kurtosis test was used to determine normality of the distribution of the continuous variables. Continuous variables that were normally distributed were expressed as mean with standard deviations. Non-parametric variables were expressed as median with interquartile ranges. Maternal age was categorised in years as either advanced maternal age (≥ 35) or not (<35) (95), maternal height categorised in centimetres as either short (≤ 150) or not (>150) (96), gestational age categorised into late term (41weeks- 41weeks+6 days) and post term (42 weeks - 43 weeks) (85), TVSCL and digital cervical length were categorised in centimetres at intervals of 0.5 and BS categorised into; unfavourable (0-4), moderately favourable (5-8) and favourable (≥ 9) (8).

Categorical variables were expressed as frequencies, proportions and percentages. Independent two sample t-test was used to determine the differences in means of normally distributed continuous variables (such as the mean transvaginal sonographic cervical length). Wilcoxon Rank Sum Test was used to compare the non-parametric variables between groups (such as the median digital cervical length). Chi-square test was used to determine the

association between categorical variables (such as having oxytocin augmentation or fetal heart rate abnormalities) and the categorical outcomes (such as successful or failed induction of labour). For categorical variables with a cell frequency of less than 5, the Fisher's exact test was used. Receiver- operating characteristics curves (ROC) were used to determine the best cut off values of TVSCL and BS for predicting successful induction outcome (vaginal delivery within 24 hours) and vaginal delivery. The Area under the ROC curve (AUROC) was then calculated to determine the discriminating ability of the tests at their optimum cut off. Using the identified cut off values, the data was then dichotomized into binary predictors. This meant that participants were grouped into two categories, based on the cut off values for an expected outcome. For example, for BS, the groups were either BS < 4 or BS ≥ 4; whilst for TVSCL, the groups were either TVSCL ≤ 2.31cm or TVSCL > 2.31cm for predicting successful induction of labour. ROC curves were redrawn using the point of interest from the dichotomized data (e.g., TVSCL ≤ 2.31cm; BS ≥ 4). Sensitivities, specificities, positive predictive values and negative predictive values of the TVSCL and BS for prediction of success of induction of labour (vaginal delivery within 24 hours of induction) and vaginal delivery were assessed from the dichotomized data. Multivariate logistic regression analysis was used to determine the effect of individual variables on the prediction of successful labour induction (vaginal delivery within 24 hours of induction) and vaginal delivery. Pearson's correlation was used to determine the relation between continuous variables such as TVSCL and the induction to delivery time interval. Success of induction of labour was expressed as a proportion of those that delivered vaginally within 24 hours with its confidence interval. In all statistical analysis, a p-value of ≤ 0.05 at a confidence interval of 95% was considered statistically significant.

3.9 ETHICAL AND LEGAL CONSIDERATIONS

Approval for the study was obtained from the Korle-Bu Teaching Hospital Scientific and Technical Committee / Institutional Review Board. Permission was also sought from the Head of Department of the Obstetric Unit. An informed consent was obtained from all the study participants. All participants were appropriately counselled on the objective and purpose of the study; all their concerns were addressed, after which the consent form was

signed voluntarily. Participants were assured that declining to participate in the study would not affect the quality of care received and their confidentiality was assured.

The researcher had undergone an online training on cervical assessment by the Fetal Medicine Foundation and had been certified. The researcher also had performed over 60 transvaginal scans prior to the start of the study and so was qualified to carry out the transvaginal ultrasound measurements. The cost of the transvaginal scans was waived off by the department and so no participant incurred additional costs for participating in the study.

CHAPTER 4

4.0 RESULTS

4.1 OVERVIEW

A total of 184 women were recruited for the study. There were 721 cases of inductions of labour in the department over the ten-month period. The total deliveries over the same period at the department was 5,807. Induction rate at KBTH over the study period therefore was 12.4% (721 inductions /5807 deliveries). Of the total inductions, 535/721 cases were scheduled for induction of labour, whiles 186/721 cases were unscheduled. The percentage of induction of labour cases that were scheduled at the department over the study period was 74.2%.

There were 276 cases of postdate pregnancies out of the 535 cases of scheduled inductions. The rate of postdate pregnancies scheduled for induction was 51.6%. Nineteen (19) cases of postdate pregnancies were not approached for the study and so a total of 257 women with postdate pregnancies were assessed for eligibility. The cases not approached occurred because of unavailability of the investigator who was involved in another academic assignment that took her away from the study site. A total of Seventy-three (73) cases were excluded from the study. Three (3) declined to participate. Interestingly, all three were healthcare workers; two nurses and one doctor. Thirty-nine (39) women were excluded because they did not meet the inclusion criteria. Of these, 10/39 women had catheter induction, 6/39 women had PROM, 13/39 women had a gestational age between 40 weeks and 40weeks 6 days,7/39 had abnormal NST, 2/39 women were less than 18 years and one (1/39) woman had a twin gestation. Sixteen women (16) went into labour before the recruitment phase and fifteen (15) cases could not be recruited because of unavailability of the transvaginal probe.

Of the 184 women recruited, only 168 women were included in the final analysis. Of the sixteen cases excluded in the final analysis; 4/16 were noticed to be in active labour after the BS assessment and so did not have the induction started for them. There were 5/16 cases of protocol deviation. These cases either received 50ug misoprostol instead of the recommended 25ug or there was a deviation in the dosing frequency. There were 2/16 cases that were lost to follow up and 5/16 cases requested to discontinue the induction process. Figure 6 shows the overview of induction of labour cases and figure 7 shows the flowchart of the study process from the initial assessment for eligibility to the final analysis.

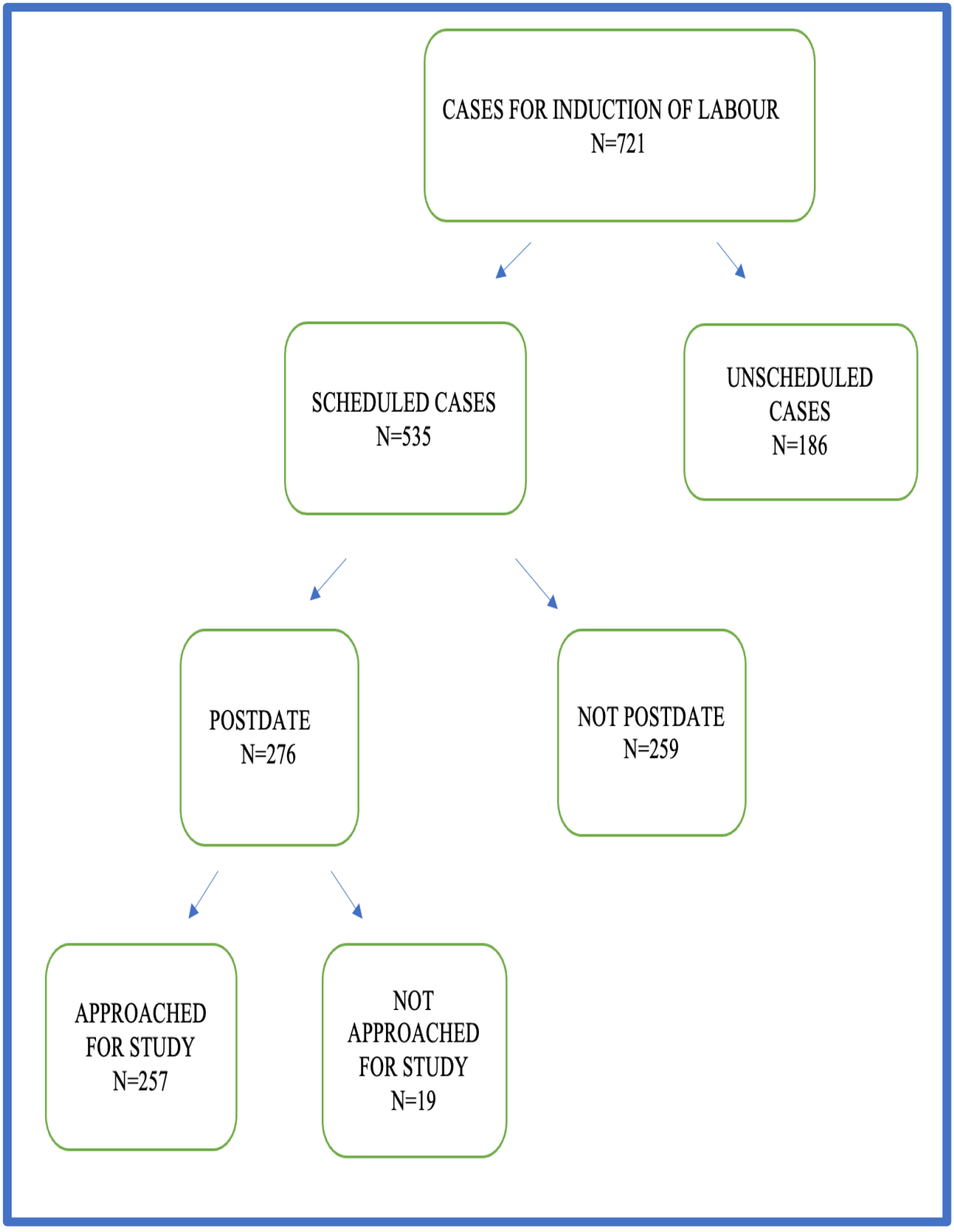

Figure 6: Overview of induction of labour cases over the study period

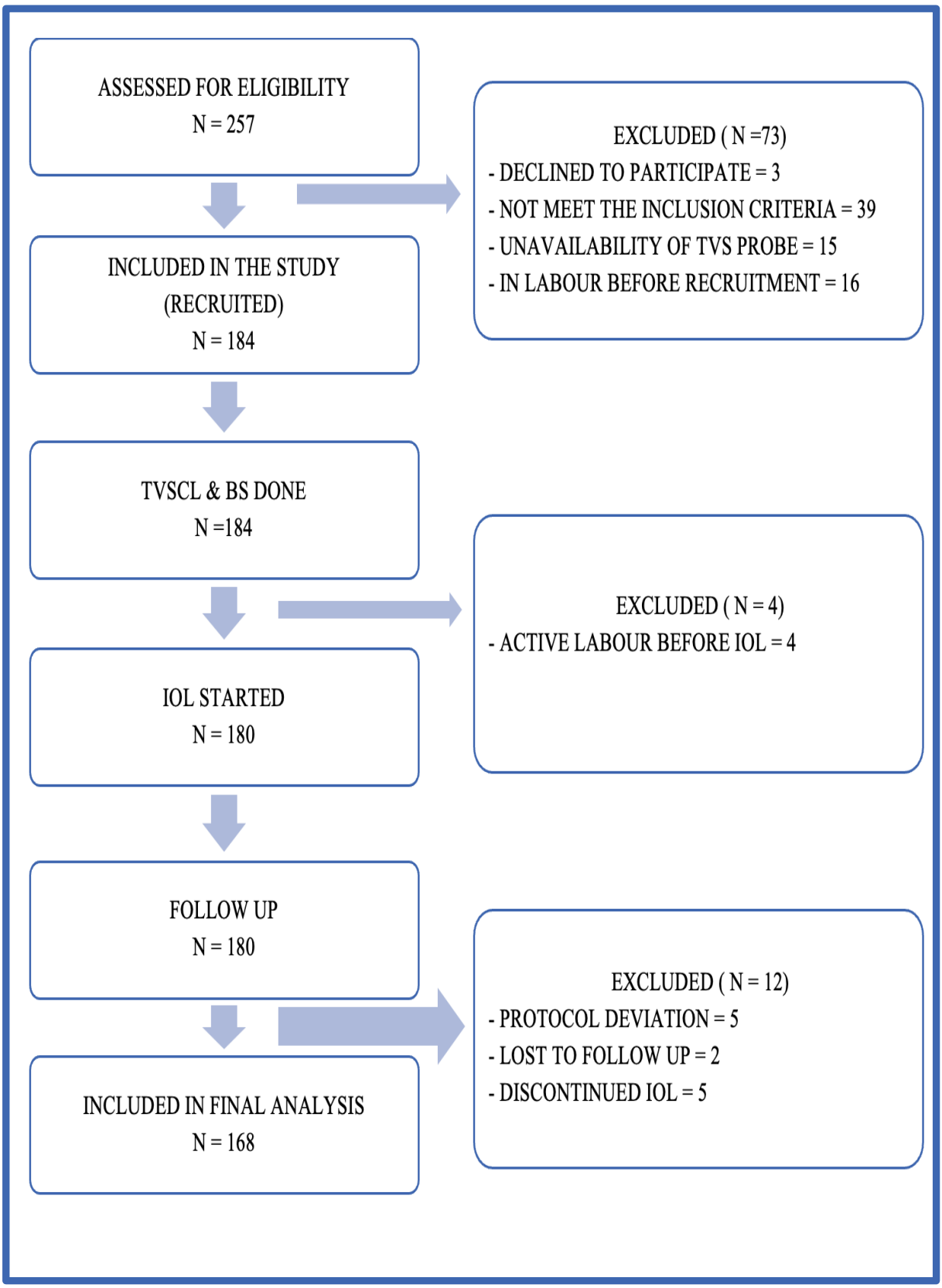

Figure 7: Flowchart of the study process

4.2 DEMOGRAPHIC DETAILS

The mean age of participants was 29.2 ± 5.2 years. Married women, 98/168 constituted 58.3% of the participants; 54/168 women (32.1%) were single and the remaining were cohabiting. Majority had some form of formal education 156/168 (93%), with tertiary level accounting for 28% of the total population. Regarding the BMI of participants, 62/168 women (36.9%) had a BMI in the obese range; 54/168 women (32.1%) were overweight and 51/168 women (30.4%) were of normal BMI. The predominant nationality of participants was Ghanaian, with one participant being a Nigerian. The sociodemographic details of participants are shown in Table 2.

4.3 MATERNAL OBSTETRIC CHARACTERISTICS

The gestational age at induction was less than 42 weeks in more than 90% of participants. The participants with a previous history of induction of labour were 17 (10.1%) and postdate was the indication for the previous indication in all the cases. Sixty-eight (68) women (40.5%) were nulliparous, 46 women (27.4%) were primiparous and the remaining multiparous. (See Table 3).

The earliest obstetric scan done was used to determine the gestational age of the women and confirm the diagnosis of postdate. Majority of women; 131/168 women (78%) had the first scan done before 20weeks gestation. Suboptimally dated pregnancy occurred in 13.7% (23/168) of study participants. Table 3 summarizes the gestational age at which the dating scan was done.

Table 2: Demographic Characteristics of participants

Characteristics	Frequency	Percent (%)
Age, in years		
< 35	142	84.5
≥ 35	26	15.5
Marital status		
Single	54	32.1
Married	98	58.3
Cohabiting	16	9.5
Level of education		
No formal education	12	7.1
Primary	56	33.3
Secondary	53	31.5
Tertiary	47	28.0
Occupation		
Professional	45	26.8
Trading	51	30.4
Artisan	51	30.4
Unemployed	21	12.5
Religion		
Christianity	134	79.8
Islam	34	20.2
Height (cm)		
≤ 150	11	6.5
> 150	157	93.5
BMI		
Underweight	1	0.6
Normal	51	30.4
Overweight	54	32.1
Obese I	48	28.6
Obese II	14	8.3

Table 3: Obstetric Characteristics of participants

Characteristics	**Frequency**	**Percent (%)**
Parity		
Nulliparous (Para 0)	68	40.5
Primiparous (Para 1)	46	27.4
Multiparous (Para 2+)	54	32.1
History of induction of labour		
No	151	89.9
Yes	17	10.1
Gestational age (In wks. + days)		
Late term (41+0 - 41+6)	162	96.4
Post term (42+0 – 43+0)	6	3.6
Had previous miscarriage		
No	81	48.2
Yes	87	51.8
Pregnancy Dating		
Optimally dated (≤ 22 weeks)	145	86.3
Suboptimally dated (> 22 weeks)	23	13.7
Dating Scan		
≤ 13 weeks	71	42.3
13 – 20 weeks	60	35.7
> 20 weeks	37	22.0

4.4 PREINDUCTION CERVICAL ASSESSMENT

The findings on preinduction cervical assessment are shown in Tables 4 - 6. The median BS of participants was 5 (3.0 -6.0) and the median TVSCL of participants was 2.5 (1.9 -3.0). Only 16/168 participants (9.5%) had presence of cervical funnelling on transvaginal scan.

Table 4: Pre-induction Cervical Assessment

Parameters	**Range**	**Median (IQR)**	**Mean (SD)**
BS	10.0	5 (3.0 -6.0)	4.85 (1.98)
TVSCL	4.78	2.5 (1.9 -3.0)	2.51 (0.91)
Digital Cervical Length	2.5	2.0 (1.0 -2.0)	1.88 (0.66)

The breakdown of the individual components of the BS is shown in Table 5. Majority of participants had either a centrally (49.4%) or posteriorly (43.5%) positioned cervix, while 50.6% had a soft cervix and 161 women (95.7%) had a station of -1 and lower. About 58.3% of women had either a moderately favourable or a favourable cervix (Bishop score > 4).

Table 5: Pre-induction Cervical Assessment- BS

Characteristics	**Frequency**	**Percent (%)**
Cervical Length (cm)		
0.5	1	0.6
1.0	45	26.8
1.5	2	1.2
2.0	92	54.8
3.0	28	16.7
Station		
-3	53	31.5
-2	76	45.2
-1	32	19.0
0	6	3.6
2	1	0.6
Dilatation (cm)		
0	49	29.2
1	76	45.2
2	34	20.2
3	9	5.4
Consistency		
Firm	14	8.3
Medium	69	41.1
Soft	85	50.6
Position		
Posterior	73	43.5
Central	83	49.4
Anterior	12	7.1
BS		
Unfavourable (0-4)	70	41.7
Moderately favourable (5-8)	94	55.9
Favourable (≥ 9)	4	2.4

Table 6: Pre-induction Cervical Assessment- TVS

Characteristics	**Frequency**	**Percent (%)**
TVSCL (cm)		
0.50-0.99	7	4.2
1.00-1.49	15	8.9
1.50-1.99	29	17.3
2.00-2.49	32	19.0
2.50-2.99	39	23.2
3.00-3.49	20	11.9
3.50-3.99	15	8.9
4.00-4.49	8	4.8
≥ 4.50	3	1.8
Presence of funnelling		
No	152	90.5
Yes	16	9.5
Transvaginal sonographic Cervical Position		
Straight	113	67.3
Curved	55	32.7

TVSCL had a positive correlation with the digital cervical length component of the BS (r = **0.241***, p = 0.002). This was a weak (low) positive correlation (r < 0.3), although it was significant. (See figure 8). The digital cervical length underestimated the TVSCL by an average of 0.63cm.

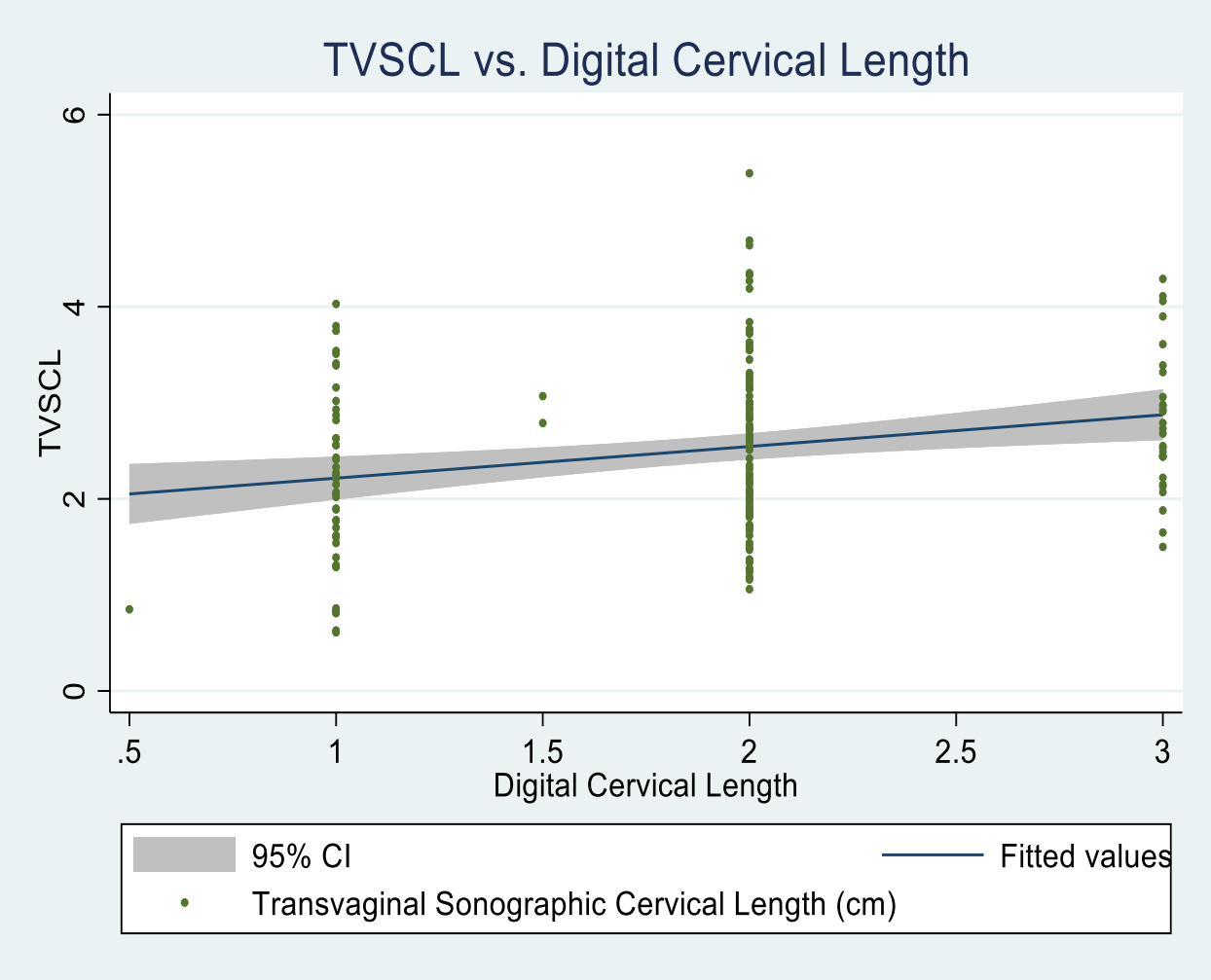

Figure 8: correlation between TVSCL and Digital cervical length

There was also a negative correlation between the TVSCL and the BS (r = **- 0.214***,p= 0.005). This was a weak (low) negative correlation (r < 0.3), although it was significant. (See figure 9).

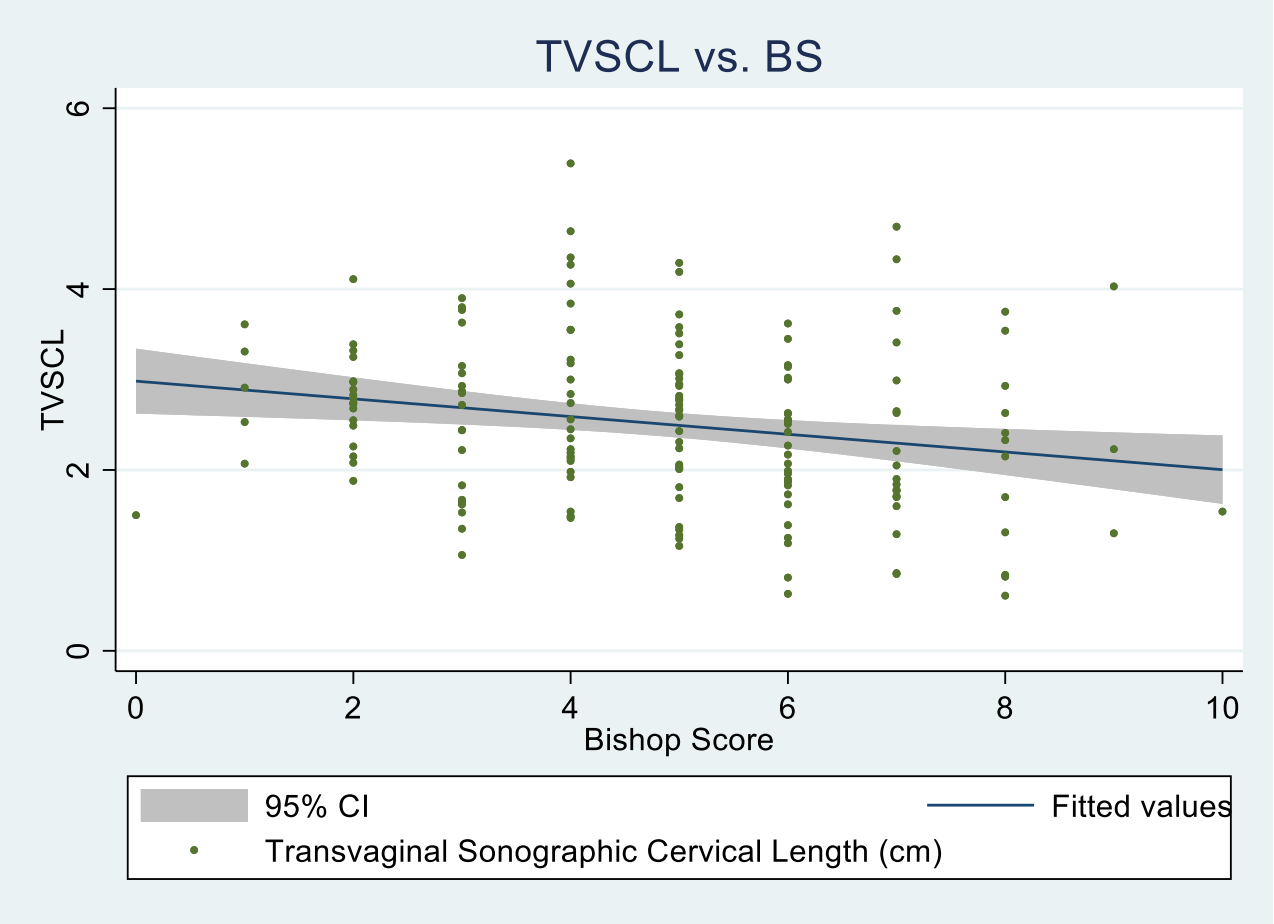

Figure 9: correlation between TVSCL and BS

4.5 MODE OF DELIVERY

Vaginal delivery occurred in 138/168 participants (82.1%). Of these, 117/138 women (84.8%) had vaginal delivery occurring within 24 hours of induction. The breakdown of the induction to vaginal delivery time interval and the mode of delivery is shown in Table 7. There were 30/168 deliveries (17.9%) by caesarean section. Figure 10 summarizes the indications for caesarean section.

Table 7: Mode of Delivery and Time of Induction to Vaginal Delivery

Characteristics	Frequency	Percent (%)
Mode of delivery		
Spontaneous Vaginal birth	135	80.3
Operative vaginal	3	1.8
Caesarean Section	30	17.9
Time of Induction to vaginal delivery		
≤ 24hrs	117	84.8
> 24hrs	21	15.2

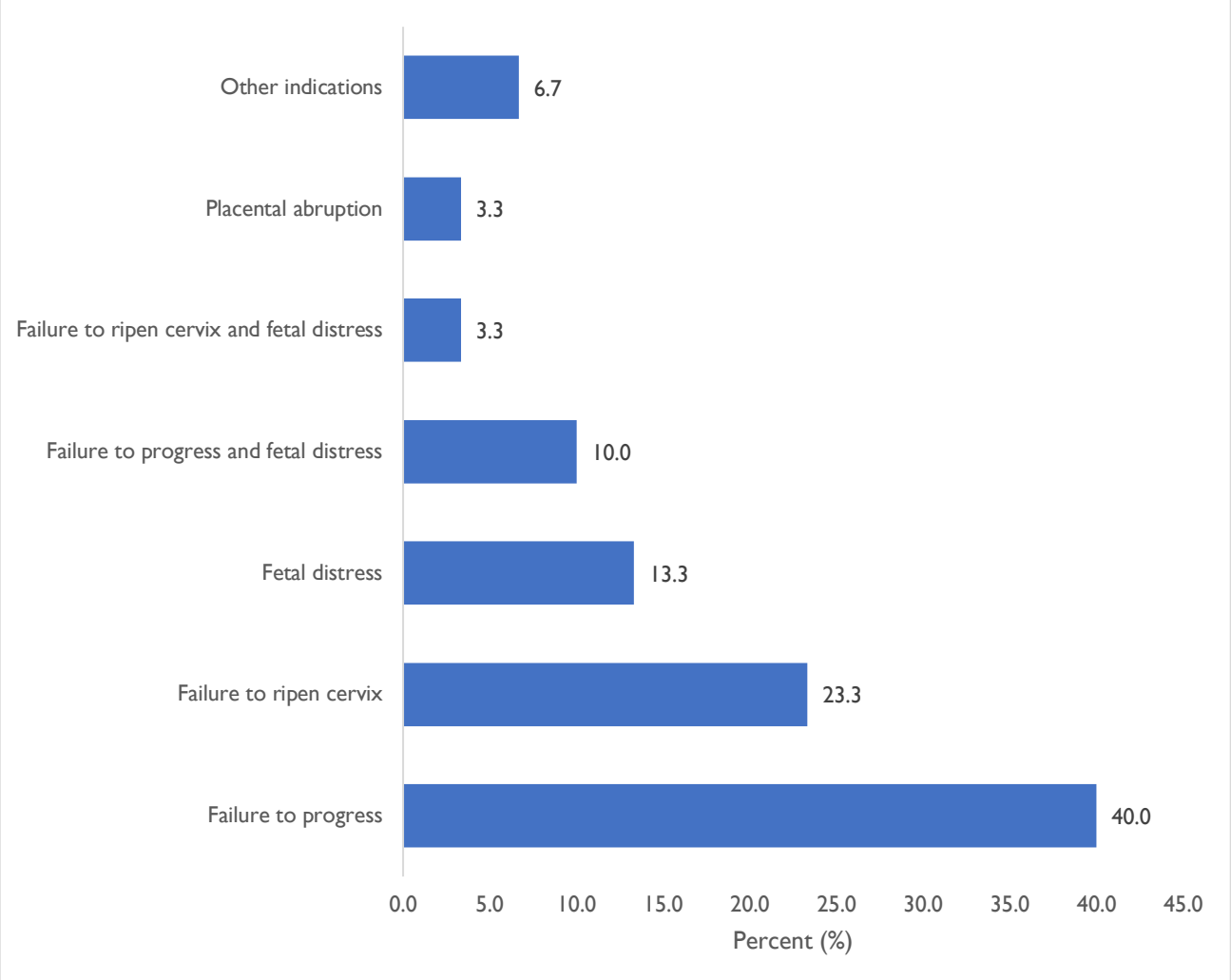

Figure 10: Indications for Caesarean section

4.6 INDUCTION OUTCOMES

The proportion of postdate women that delivered within 24 hours of induction was 125/168 (74.4%) with a CI of 67.1- 80.8. The proportion of postdate women that had a successful induction of labour (vaginal delivery within 24 hours) was 117/168 (69.6%) with a CI of 62.1-76.5. The induction to delivery interval was significantly different between outcome groups. Also, the induction to active phase interval was significantly longer in the failed induction of labour group. (Median:18 hours IQR 9.7-26.0 vrs 11.5 hours IQR 7.5-14.0; $p < 0.001$)

4.6.1 ASSOCIATION BETWEEN MATERNAL DEMOGRAPHIC CHARACTERISTICS AND LABOUR INDUCTION OUTCOME

Table 8 shows the maternal demographic characteristics between successful and failed induction of labour groups. Of all the demographic characteristics, only parity was statistically significant between groups ($p= 0.041$).

4.6.2 MATERNAL OUTCOME VARIABLES

The relationship between maternal outcome variables and outcome of induction of labour are demonstrated in table 9. The need for membrane rupture and oxytocin augmentation were statistically significant between groups. Also, the doses of misoprostol given and the blood loss were significantly higher in the failed induction of labour group. There were 4 cases of APH (2.4%), 2 cases of chorioamnionitis (1.2%) and 7 cases of PPH (4.2%). There were no cases of uterine rupture, tachysystole or maternal mortality. (See table 9).

Table 8: Association between Maternal demographic characteristics and Induction of Labour outcome

	Outcome of Induction of Labour				
Characteristics	**Failed IOL**	**Successful IOL**	**Total**	**X^2/t-test**	**P-value**
	N=51	**N=117**	**N=168**		
Age, in years				2.080	0.150
< 35	40 (78.4)	102 (87.2)	142 (84.5)		
≥ 35	11 (21.6)	15 (12.8)	26 (15.5)		
Parity				6.390	**0.041**
Nulliparous	28 (54.9)	40 (34.2)	68 (40.5)		
Primiparous	10 (19.6)	36 (30.8)	46 (27.4)		
Multiparous	13 (25.5)	41 (35.0)	54 (32.1)		
Height (cm)*				-	0.740
≤ 150	4 (7.8)	7 (6.0)	11 (6.5)		
> 150	47 (92.2)	110 (94.0)	157 (93.5)		
Mean Height (m)	1.6 (0.07)	1.6 (0.1)	1.6 (0.1)	-0.900	0.370
Median Weight (Kg)	72 (64.0, 83.0)	73 (62.0, 81.0)	73 (62.0, 81.3)	0.240	0.810
Median Body Mass Index	27.9 (24.5, 32.0)	27.6 (23.9, 31.0)	27.8(24.0, 31.2)	0.680	0.490

(*Fisher's exact test)

Table 9: Association between Maternal outcome measures and Induction of Labour outcome

Characteristics	Outcome of Induction of Labour			X^2/t-test	P-value
	Failed IOL	Successful IOL	Total		
	N=51	N=117	N=168		
Mean induction to delivery time (hrs.)	36.4 (22.5)	15.2 (4.8)		9.736	**<0.001**
Ruptured membrane during labour *				-	**<0.001**
No	10 (19.6)	0 (0.0)	10 (6.0)		
Yes	41 (80.3)	117 (100.0)	158 (94.0)		
Mode of membrane rupture				1.790	0.180
Artificial rupture of membrane	27 (65.9)	63 (53.8)	90 (57.0)		
Spontaneous rupture of membrane	14 (34.1)	54 (46.2)	68 (43.0)		
Oxytocin Augmentation				8.090	**0.004**
No	24 (47.1)	82 (70.1)	106 (63.1)		
Yes	27 (52.9)	35 (29.9)	62 (36.9)		
Median Induction to active phase (hrs.)	18 (9.7, 26.0)	11.5 (7.5, 14.0)	12 (7.7, 17.1)	3.640	**<0.001**
Median Dose of Misoprostol administered (mcg)	75 (50.0, 100.0)	50 (25.0, 50.0)	50 (50.0, 75.0)	6.960	**<0.001**
Median Blood loss (mls)	400 (300.0, 500.0)	250 (200.0, 300.0)	300 (250.0, 400.0)	6.610	**<0.001**

(*Fisher's exact test)

4.6.3 PERINATAL OUTCOME VARIABLES

There were no cases of still birth recorded among participants in the study. Majority of babies delivered were male (53%). The mean birth weight in the study was 3.4kg ± 0.5. Fetal heart rate (FHR) abnormalities occurred in 8.9% of participants during the period of labour. Breakdown of the FHR abnormalities were as follows; 9/15 had bradycardia, 3/15 had tachycardia and 3/15 had bradycardia with late decelerations. Seventeen babies (10.1%) required NICU admission. Indications for NICU admission are shown in figure11.
Table 10 summarizes the fetal outcome measures in relation to the outcome of IOL.

Table 10: Association between Fetal outcome measures and Induction of Labour outcome

	Outcome of Induction of Labour				
Characteristics	**Failed IOL**	**Successful IOL**	**Total**	X^2**/t-test**	**P-value**
	N=51	**N=117**	**N=168**		
Sex of Infant				2.810	0.094
Male	32 (62.7)	57 (48.7)	89 (53.0)		
Female	19 (37.3)	60 (51.3)	79 (47.0)		
1 Minute APGAR				0.150	0.700
< 7	15 (29.4)	31 (26.5)	46 (27.4)		
≥ 7	36 (70.6)	86 (73.5)	122 (72.6)		
5 Minutes APGAR*				-	1.000
< 7	3 (5.9)	8 (6.8)	11 (6.5)		
≥ 7	48 (94.1)	109 (93.2)	157 (93.5)		
Meconium-stained liquor				1.290	0.260
No	41 (80.4)	102 (87.2)	143 (85.1)		
Yes	10 (19.6)	15 (12.8)	25 (14.9)		
Baby admitted to NICU*				-	0.590
No	47 (92.2)	104 (88.9)	151 (89.9)		
Yes	4 (7.8)	13 (11.1)	17 (10.1)		
Birth weight (kg), Mean (SD)	3.5 (0.5)	3.3 (0.5)	3.4 (0.5)	2.110	**0.036**

(*Fisher's exact test)

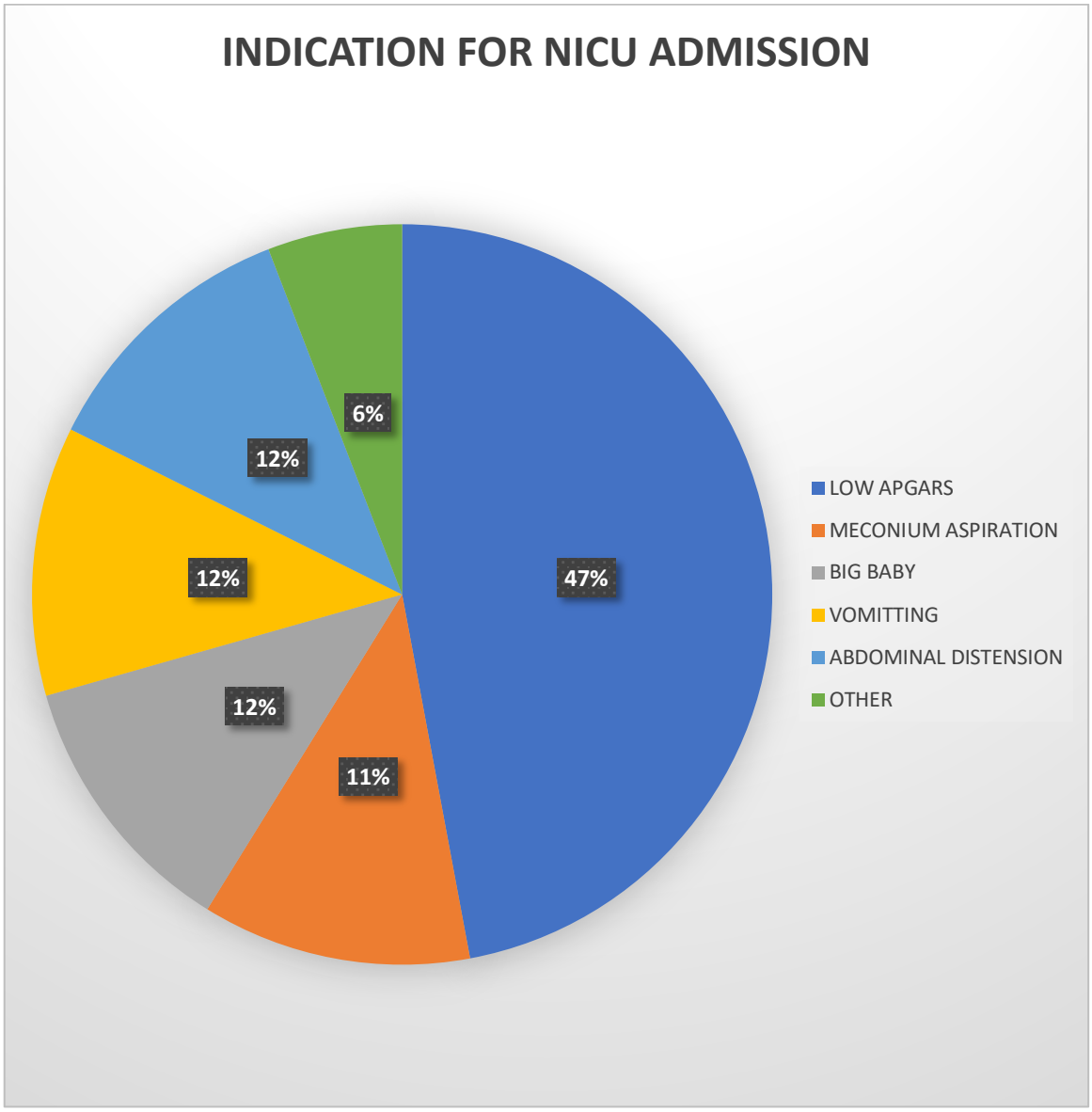

Figure 11:Indications for NICU admission

4.6.4 CERVICAL MEASURES

The mean BS was significantly higher in the successful induction group. (Mean 5.1± 1.9 and 4.3 ± 2.1, p=0.020). Although the TVSCL was higher in the failed induction group, this was not statistically significant. Analysing the individual components of the BS between outcome groups, only the position and station were statistically different between groups. (See Table 11).

4.6.5 PREDICTORS OF OUTCOME

Univariate and multivariate logistic regression analysis were performed on nine parameters to determine factors associated with successful induction of labour and successful vaginal delivery. The nine parameters were parity, BS, BS station, age, BMI, previous history of induction of labour, TVSCL, BS position and maternal weight.

4.6.5.1 Successful Induction of labour (vaginal delivery in 24 hours)

For the univariate analysis, high parity, high BS and high BS station were significant predictors of successful induction of labour. Parous women were 2.3 times more likely to have a successful induction of labour. Every unit increase in station was associated with a 1.8 times likelihood of having a successful induction of labour. Also, every unit increase in BS was associated with a 1.2 times likelihood of having a successful induction. Maternal age, weight, previous history of induction, BS position, TVSCL and maternal weight did not predict successful induction.

When the significant variables were included in the multivariable analysis, only parity was a significant predictor of successful induction of labour. Parous women were 2.1 times more likely to have a successful induction of labour (vaginal delivery in 24hours). (See Table 12).

4.6.5.2 Successful vaginal delivery

High parity was the only significant predictor of vaginal delivery. Parous women were 3.14 times more likely than nulliparous women to have a vaginal delivery. (Table 13).

Table 11: Association between Cervical parameters and Induction of Labour outcome

Characteristics	Outcome of Induction of Labour				
	Failed IOL	**Successful IOL**	**Total**	**X^2/t-test**	**P-value**
	N=51	**N=117**	**N=168**		
Presence of funnelling				0.430	0.510
No	45 (88.2)	107 (91.5)	152 (90.5)		
Yes	6 (11.8)	10 (8.5)	16 (9.5)		
Consistency*				-	0.320
Firm	2 (3.9)	12 (10.3)	14 (8.3)		
Medium	24 (47.1)	45 (38.5)	69 (41.1)		
Soft	25 (49.0)	60 (51.3)	85 (50.6)		
Position				12.100	**0.002**
Posterior	30 (58.8)	43 (36.8)	73 (43.5)		
Central	15 (29.4)	68 (58.1)	83 (49.4)		
Anterior	6 (11.8)	6 (5.1)	12 (7.1)		
Bishop score, Mean (SD)	4.3 (2.1)	5.1 (1.9)	4.9 (2.0)	-2.350	**0.020**
Transvaginal Sonographic Cervical Length (cm), Mean (SD)	2.7(0.9)	2.4(0.9)	2.5 (0.9)	1.730	0.085
Digital Cervical length (cm), Median (IQR)	2.0 (1.0, 3.0)	2.0 (1.0, 2.0)	2.0 (1.0, 2.0)	1.890	0.059
Dilatation, Median (IQR)	1.0 (0.0, 1.0)	1.0 (1.0, 2.0)	1.0 (0.0, 2.0)	-1.580	0.110
Station, Median (IQR)	-2.0 (-3.0, -2.0)	-2.0 (-2.0, -1.0)	-2.0 (-3.0, -2.0)	-2.610	**0.009**

(*Fisher's exact test)

Table 12: Determinants of Successful Induction of Labour among participants

Variables	**Unadjusted**			**Adjusted**	
	OR (95% CI)	**P-value**		**OR (95% CI)**	**P-value**
Parity					
Nulliparous	Ref			Ref	
Parous	2.34 (1.20, 4.58)	**0.013**		2.13 (1.07, 4.24)	**0.031**
BS	1.23 (1.03,1.46)	**0.022**		1.08 (0.86, 1.34)	0.519
BS (Station)	1.80 (1.15, 2.81)	**0.010**		1.54 (0.87, 2.66)	0.126
Age	0.98 (0.92, 1.05)	0.639			
BMI	0.96 (0.91, 1.02)	0.211			
Previous history of Induction	1.05 (0.35, 3.16)	0.929			
TVSCL	0.73 (0.50, 1.05)	0.087			
BS (Position)	1.53 (0.88, 2.68)	0.135			
Maternal weight	0.99 (0.97, 1.10)	0.505			

* Adjusted for parity, BS and BS station.

Table 13: Determinants of Successful Vaginal delivery among participants

Variables	**Unadjusted**	
	OR (95% CI)	**P- value**
Parity		
Nulliparous	Ref	
Parous	3.14 (1.38, 7.13)	**0.006**
Age, in years	0.99 (0.91, 1.06)	0.727
BMI	1.00 (0.93, 1.08)	0.951
Previous history of Induction	3.80 (0.48, 29.85)	0.204
BS	1.20 (0.98, 1.48)	0.077
BS (Station)	1.67 (0.98, 2.85)	0.060
TVSCL	0.69 (0.45, 1.07)	0.096
BS (Position)	1.26 (0.65, 2.45)	0.488
Maternal weight	1.01 (0.98, 1.04)	0.545

4.7 COMPARISON OF TRANSVAGINAL SONOGRAPHIC CERVICAL LENGTH ASSESSMENT AND BISHOP SCORE

4.7.1 OPTIMUM CUT OFF VALUE FOR TRANSVAGINAL SONOGRAPHIC CERVICAL LENGTH AND BISHOP SCORE AND THEIR PREDICTIVE VALUES

ROC curves constructed to determine the best cut off values for TVSCL and BS in predicting successful induction of labour (vaginal delivery within 24 hours) are shown in figure 12 and figure 13 respectively with the AUROC curve.

The TVSCL optimal cut off value was 2.31cm with a sensitivity of 49.0% and a specificity of 69.0% at the cut off value. The BS cut off value was 4 with a sensitivity of 65.0% and a specificity of 57.0% at the cut off value.

Using the identified cut off values from the ROC curves, the data was dichotomized into binary predictors (TVSCL: ≤ 2.31cm and > 2.31cm; BS ≥ 4 and < 4) and new ROC curves drawn for the category of interest (TVSCL ≤ 2.31cm; BS ≥ 4). Figure 14 shows the ROC curve for the dichotomized data for both TVSCL and BS.

Table 14 illustrates the predictive values of the TVSCL and BS (dichotomized) and their significance.

Table 14: Predictive values of TVSCL and BS (dichotomized) for Successful Induction of Labour (vaginal delivery within 24 hours)

	Cut off	Sensitivity (%)	Specificity (%)	AUC (95% CI)	PPV (%)	NPV (%)	Std. Err	P-value
TVSCL	≤ 2.31	48.7	66.7	58.0 (49.7, 65.7)	77.0	36.2	0.283	**<0.001**
BS	≥ 4.0	80.3	41.2	61.0 (52.4, 71.6)	75.8	47.7	0.483	**<0.001**

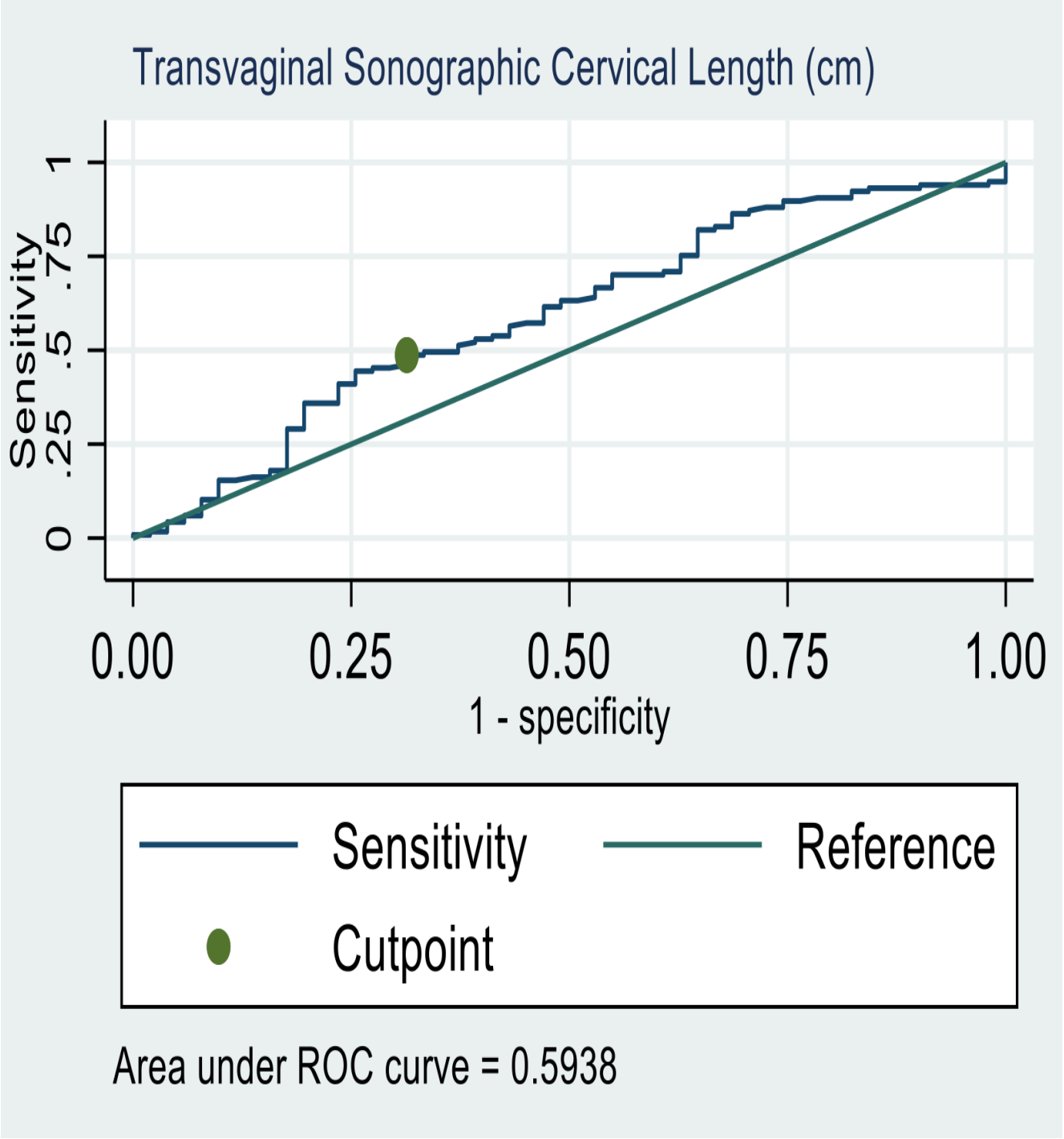

Figure 12:ROC curve for predicting successful induction of labour (TVSCL at 2.31cm)

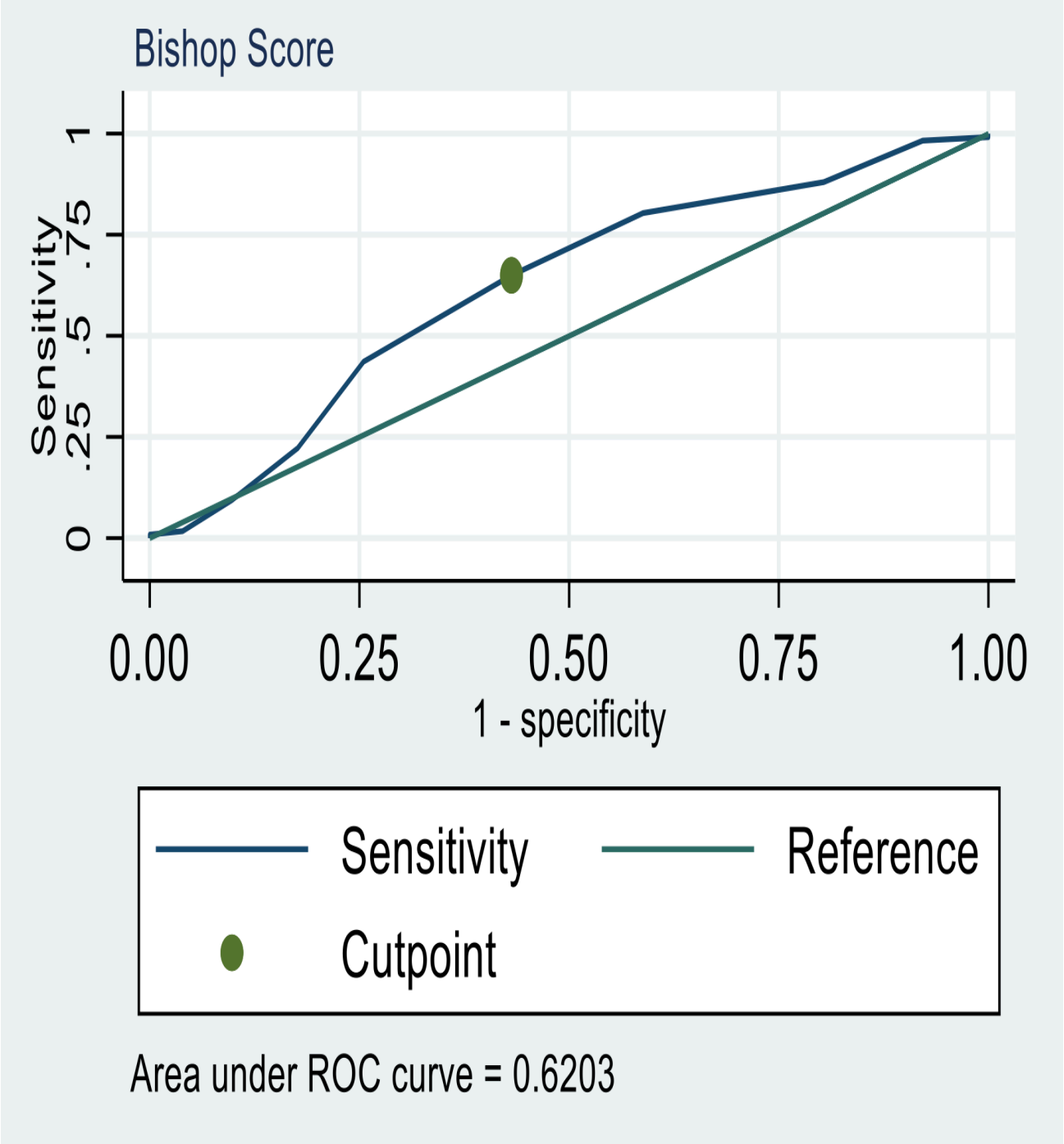

Figure 13: ROC curve for predicting successful induction of labour (BS at 4)

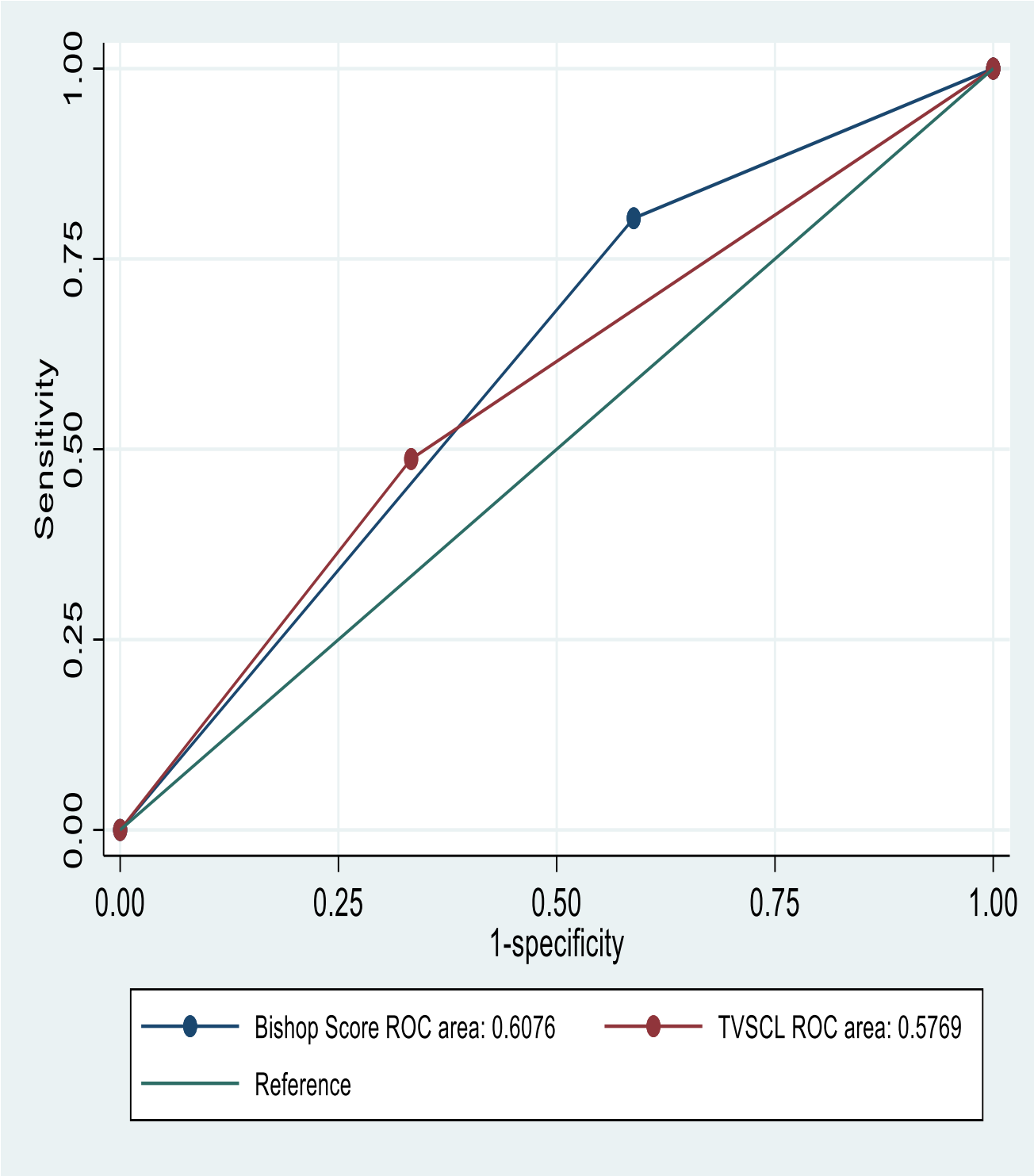

Figure 14: ROC curves for predicting successful induction of labour (DICHOTOMIZED: TVSCL and BS)

ROC curves were reconstructed to determine the best cut off values for TVSCL and BS in predicting vaginal delivery. Figures 15 and 16 show the AUROC curves for TVSCL and BS respectively.

The TVSCL optimal cut off value was 2.5cm with a sensitivity of 53.0% and a specificity of 70.0% at the cut off value. The BS cut off value remained 4 with a sensitivity of 62.0% and a specificity of 60% at the cut off value.

Using the identified cut off values from the ROC curves, the data was dichotomized into binary predictors (TVSCL: ≤ 2.5cm and > 2.5cm; BS ≥ 4 and < 4) and new ROC curves drawn for the category of interest (TVSCL ≤ 2.5cm; BS ≥ 4). Figure 17 shows the ROC curve for the dichotomized data for both TVSCL and BS.

Table 15 illustrates the predictive values of the TVSCL and BS (dichotomized) and their significance.

Table 15: Predictive values of TVSCL and BS (dichotomized) for Vaginal delivery

	Cut off	Sensitivity (%)	Specificity (%)	AUC (95% CI)	PPV (%)	NPV (%)	Std. Err	P-value
TVSCL	≤ 2.5	52.9	66.7	60.0 (52.0, 69.0)	88.0	23.5	0.300	**<0.001**
BS	≥ 4.0	77.5	43.3	60.0 (51.0, 70.0)	86.3	29.5	0.510	**<0.001**

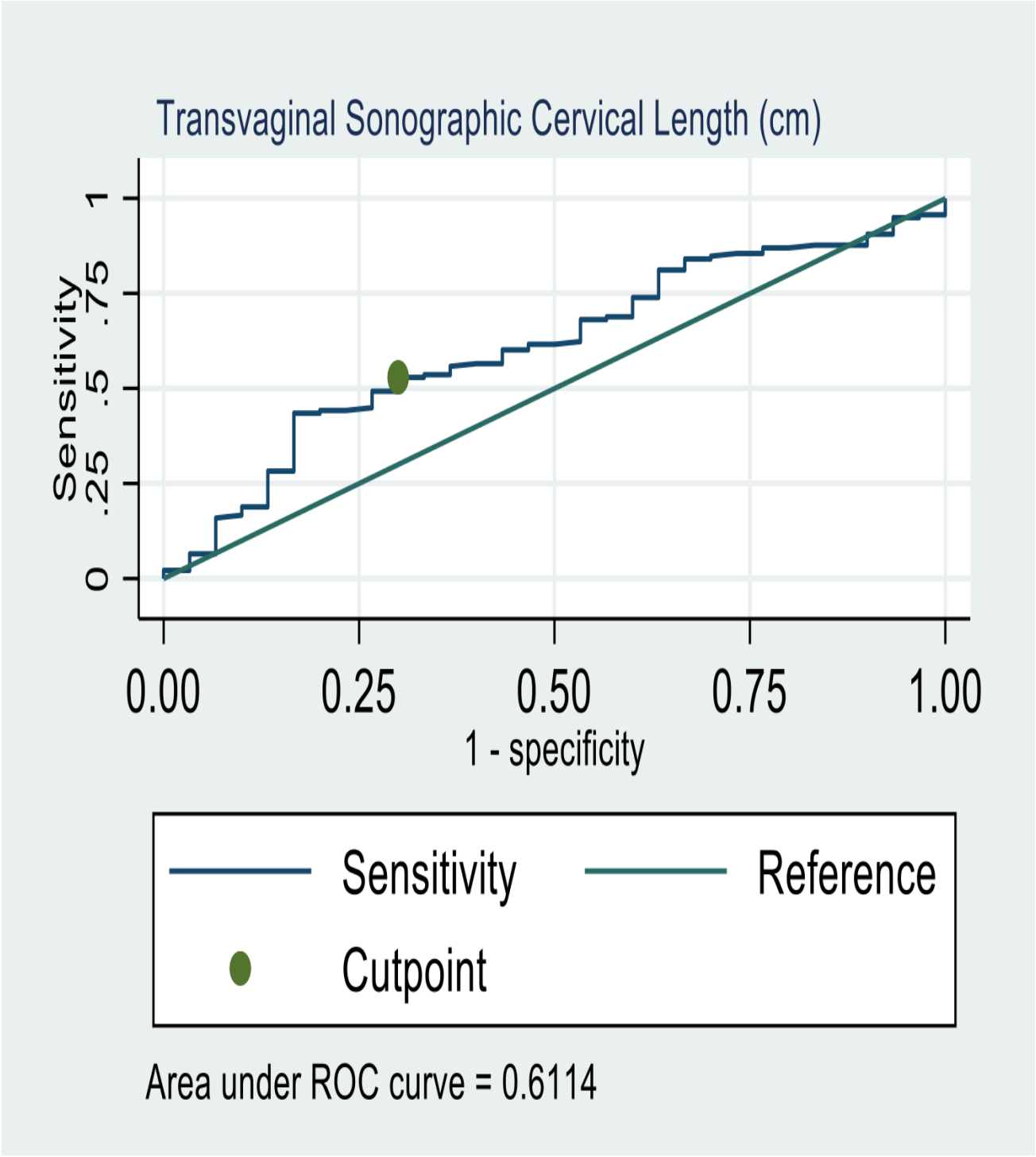

Figure 15: ROC curve for predicting vaginal delivery (TVSCL at 2.5cm)

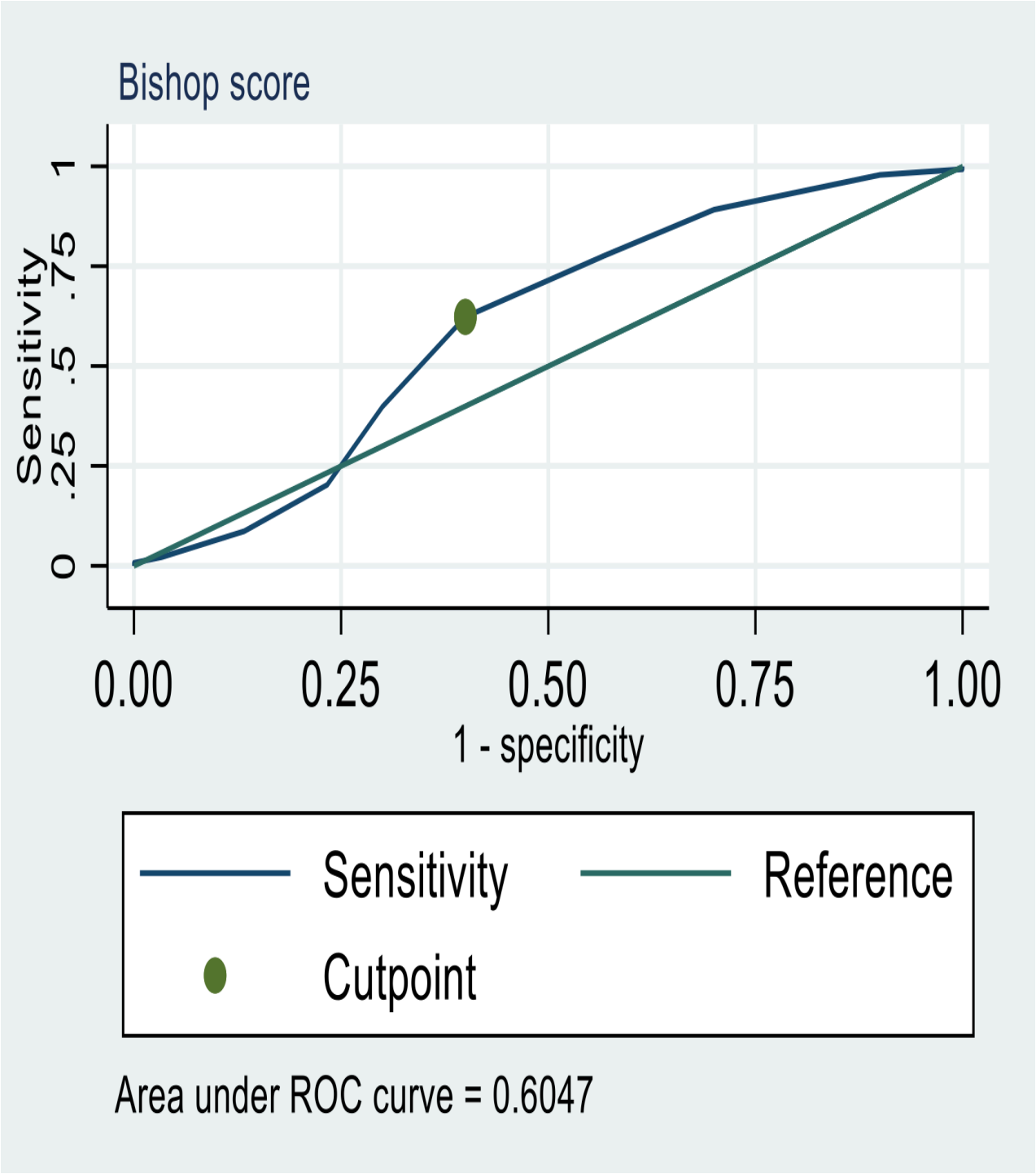

Figure 16: ROC curve for predicting vaginal delivery (BS at 4)

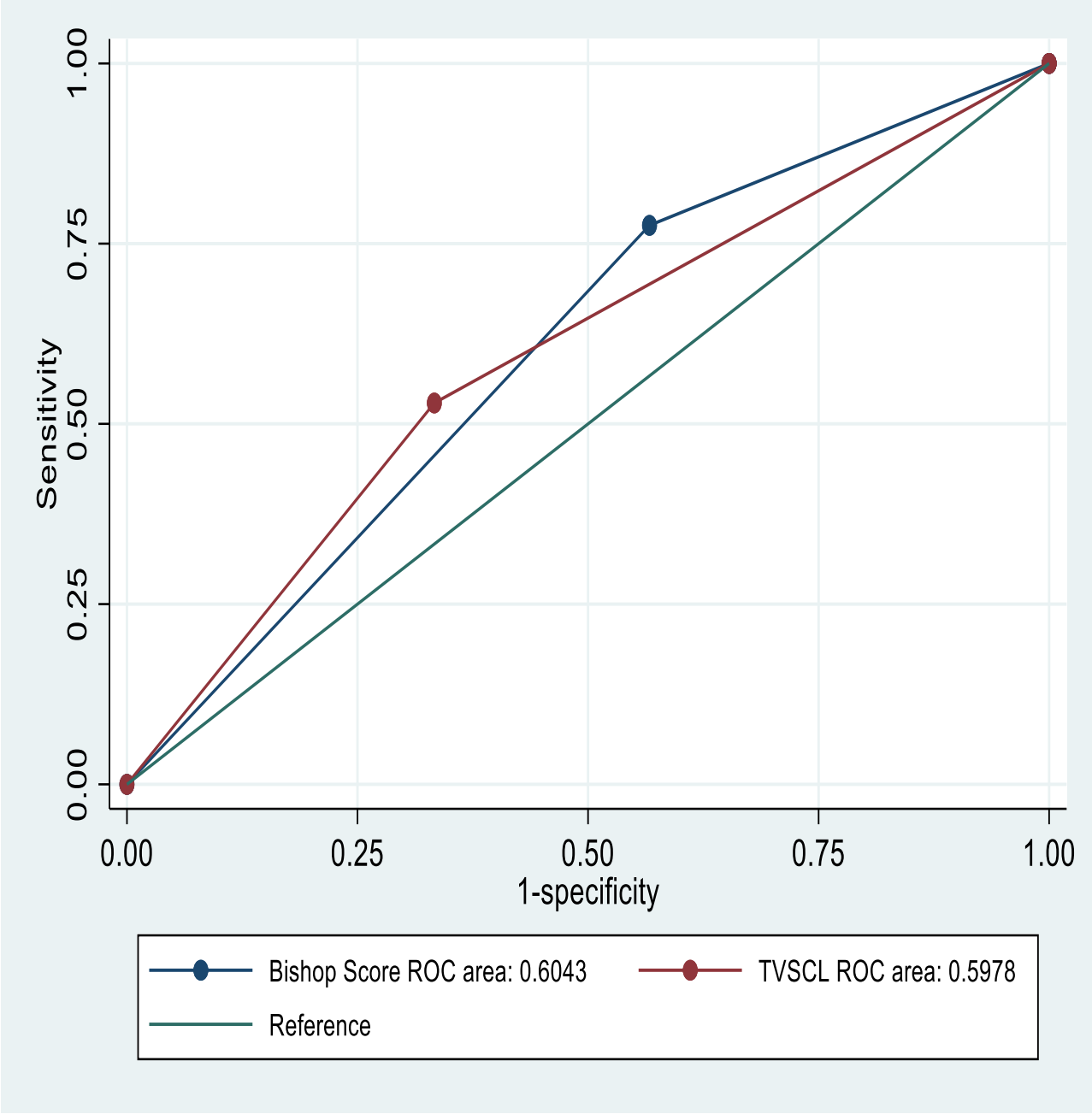

Figure 17: ROC curves for predicting vaginal delivery (DICHOTOMIZED: TVSCL and BS)

4.7.2 COMPARISON OF TRANSVAGINAL SONOGRAPHIC CERVICAL LENGTH AND BISHOP SCORE WITH OUTCOME MEASURES (PRIMARY AND SECONDARY)

At a TVSCL of ≤ 2.31cm, there was a significantly shorter induction to delivery time interval and induction to active phase interval. (See Table 16).

Table 16: Comparison of TVSCL with outcome measures

Characteristics	**Transvaginal Sonographic Cervical Length (cm)**				
	≤ Cut point (2.31 cm) N=74	**> Cut point (2.31 cm) N=94**	**Total N=168**	**X^2/t-test**	**P-value**
Induction of Labour				3.410	0.065
Failed	17 (23.0)	34 (36.2)	51 (30.4)		
Successful	57 (77.0)	60 (63.8)	117 (69.6)		
Median Induction to delivery time (in Hrs)	16.41 (12.1-23.3)	18.87 (13.6, 26.5)	17.95 (13.41, 24.38)	-2.060	**0.040**
Median Induction to active phase (in Hrs)	11.08 (6.4, 14.5)	12.5 (8.58, 18.25)	12 (7.7, 17.08)	-2.430	**0.015**
Median Dose of Misoprostol administered (mcg)	50 (25.0, 50.0)	50 (50.0, 75.0)	50 (50.0, 75.0)	-3.700	**<0.001**
Mean Birth weight (kg)	3.4 (0.5)	3.4 (0.5)	3.4 (0.5)	0.030	0.970
Oxytocin Augmentation				1.410	0.230
No	43 (58.1)	63 (67.0)	106 (63.1)		
Yes	31 (41.9)	31 (33.0)	62 (36.9)		
5 Minutes APGAR*				-	0.350
< 7	3 (4.1)	8 (8.5)	11 (6.5)		
≥ 7	71 (95.9)	86 (91.5)	157 (93.5)		
Median APGAR score at 5 mins	8 (8.0, 9.0)	8 (8.0, 9.0)	8 (8.0, 9.0)	0.160	0.870
Baby admitted to NICU				1.640	0.200
No	69 (93.2)	82 (87.2)	151 (89.9)		
Yes	5 (6.8)	12 (12.8)	17 (10.1)		

(*Fisher's exact test)

At a Bishop score of ≥ 4, there was a statistically significant difference in the outcome of induction; the induction to delivery time interval and the doses of misoprostol administered. (See Table 17).

Table 17: Comparison of BS with outcome measures

Characteristics	**Bishop Score**				
	< Cut point (4)	**≥ Cut point (4)**	**Total**	**X^2/t-test**	**p-value**
	N=44	**N=124**	**N=168**		
Induction of Labour				8.510	**0.004**
Failed	21 (47.7)	30 (24.2)	51 (30.4)		
Successful	23 (52.3)	94 (75.8)	117 (69.6)		
Median Induction to delivery time (Hrs)	20.1 (16.2 -28.8)	16.6 (12.2-22.8)	18.0 (13.4-24.4)	2.880	**0.004**
Median Induction to active phase (Hrs)	12.3 (8.9- 17.5)	12 (7.4-16.8)	12 (7.7-17.1)	0.970	0.330
Median Dose of Misoprostol administered (mcg)	75 (50.0-100.0)	50 (25.0 -75.0)	50 (50.0-75.0)	3.160	**0.002**
Mean Birth weight (kg)	3.4 (0.4)	3.4 (0.5)	3.4 (0.5)	0.140	0.890
Oxytocin Augmentation				1.010	0.320
No	25 (56.8)	81 (65.3)	106 (63.1)		
Yes	19 (43.2)	43 (34.7)	62 (36.9)		
5 minutes APGAR*				-	0.481
< 7	4 (9.1)	7 (5.6)	11 (6.5)		
≥ 7	40 (90.9)	117 (94.4)	157 (93.5)		
Median APGAR score at 5 mins	9 (8.0-9.0)	8 (8.0-9.0)	8 (8.0-9.0)	1.320	0.190
Baby admitted to NICU *				-	1.000
No	40 (90.9)	111 (89.5)	151 (89.9)		
Yes	4 (9.1)	13 (10.5)	17 (10.1)		

(*Fisher's exact test)

4.7.3 LINEAR CORRELATION BETWEEN CERVICAL PARAMETERS AND OUTCOMES

There was a positive correlation between TVSCL and the induction to delivery time interval (r = **0.180***, p= 0.020). This was a very low positive correlation (because r < 0.3). (See figure 18)

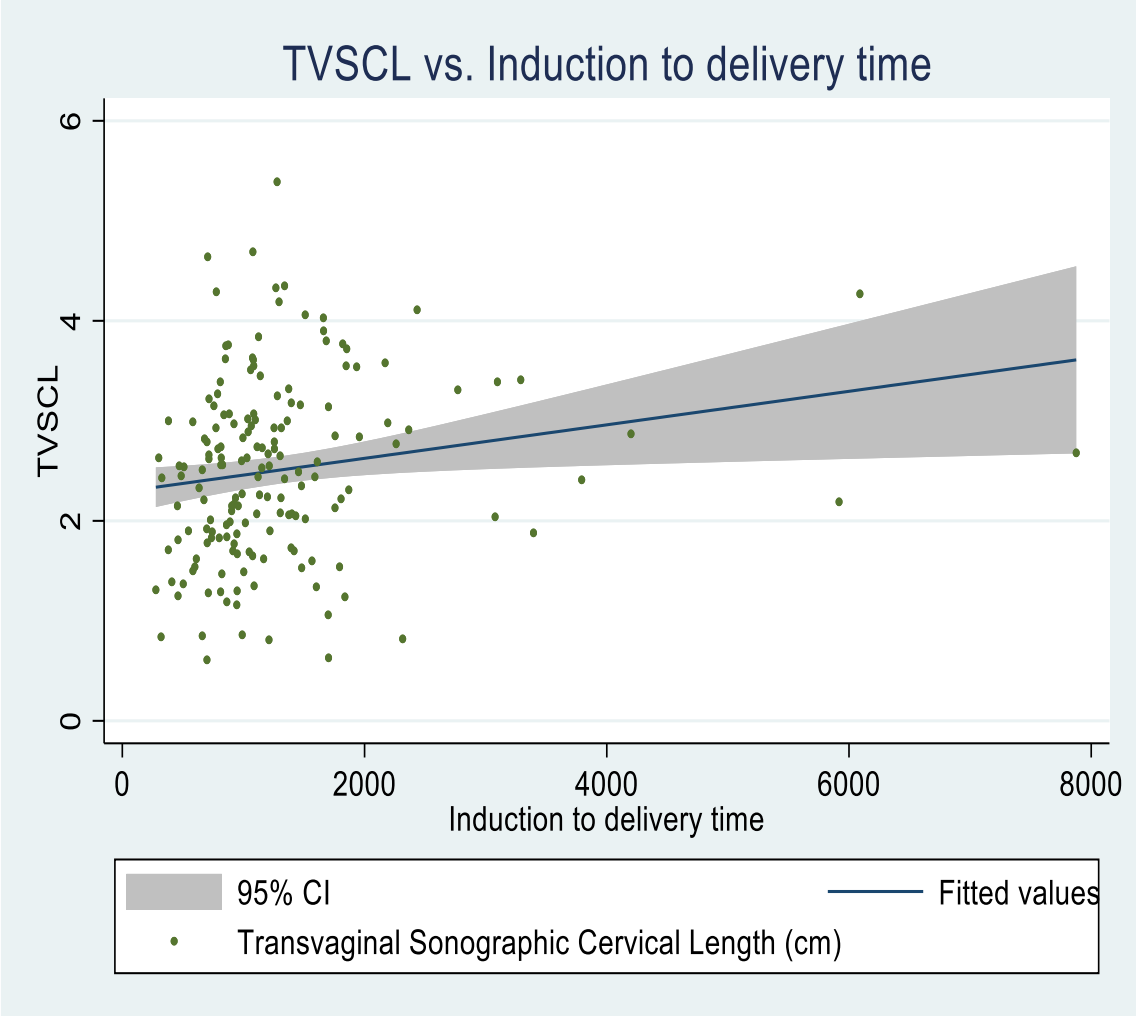

Figure 18: correlation between TVSCL and Induction to delivery time

There was a negative correlation between BS and the induction to delivery time interval (r = **-0.213***, p= 0.006). This was a low negative correlation (r < 0.3).
(See figure 19)

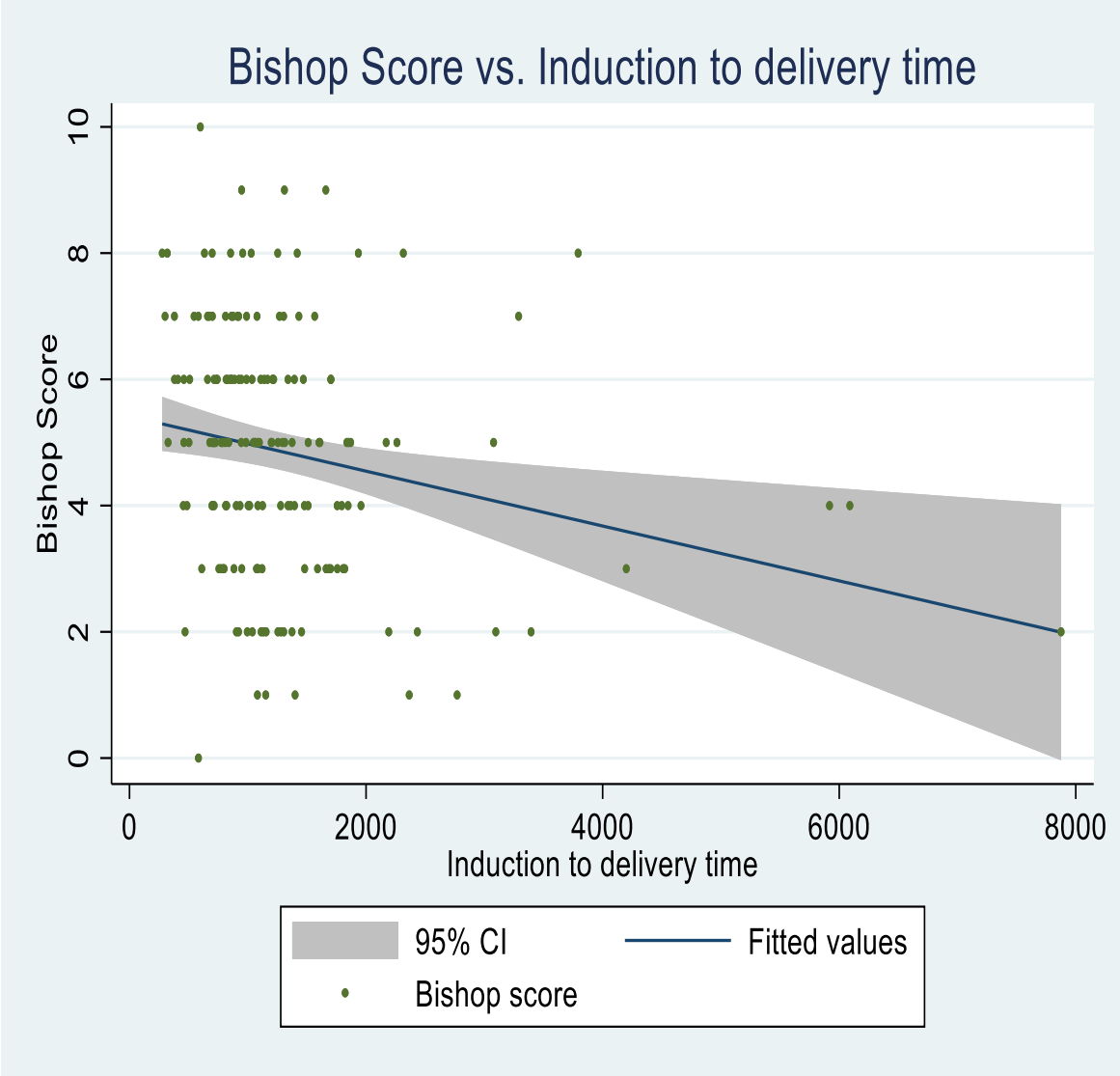

Figure 19: correlation between BS and Induction to delivery time

4.8 COMPOSITE SCORES OF TRANSVAGINAL SONOGRAPHIC CERVICAL LENGTH AND SOME PARAMETERS OF THE BISHOP SCORE AND MATERNAL OBSTETRIC CHARACTERISTICS

A total of 7 composite scores (CS) were generated and analysed to determine if there was an improvement in the predictive values. The components of the CS are shown in Table 18. The CS 1 was generated by replacing the digital cervical length of the BS with the TVSCL and recalculating the score. For CS 2 to CS 7, the score was generated by allocating a score of 2 if the TVSCL was ≤ 2.31cm and a score of 0 if the TVSCL was > 2.31cm; for components of the BS, the scoring system was maintained as in the original Bishop scoring system; for parity each parous act was scored. The overall score was the summation of the individual scores generated.

Table 18: Components of the CS

CS	COMPONENTS
CS1	TVSCL + (ALL BS PARAMETERS – DIGITAL CL)
CS2	TVSCL + BS STATION
CS3	TVSCL + BS POSITION
CS4	TVSCL + BS STATION + BS POSITION
CS5	TVSCL + BS POSITION + PARITY
CS6	TVSCL + BS STATION + PARITY
CS7	TVSCL + BS STATION + BS POSITION +PARITY

ROC curves constructed to determine the best cut off values for some selected CS in predicting successful induction of labour are shown in figures 20 - 22 with the AUROC curve.

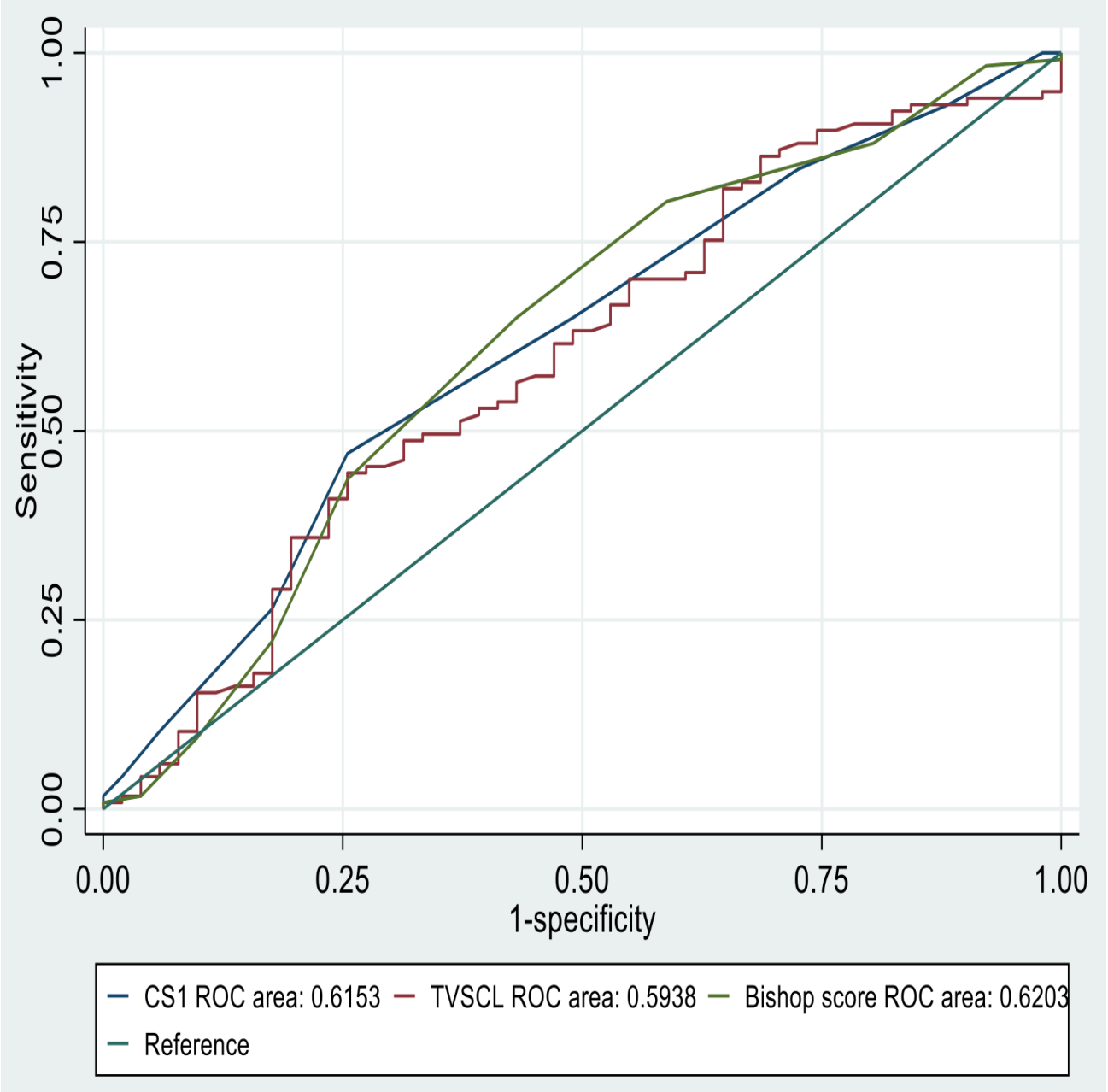

Figure 20: ROC curve for predicting successful induction of labour (CS 1, TVSCL, BS)

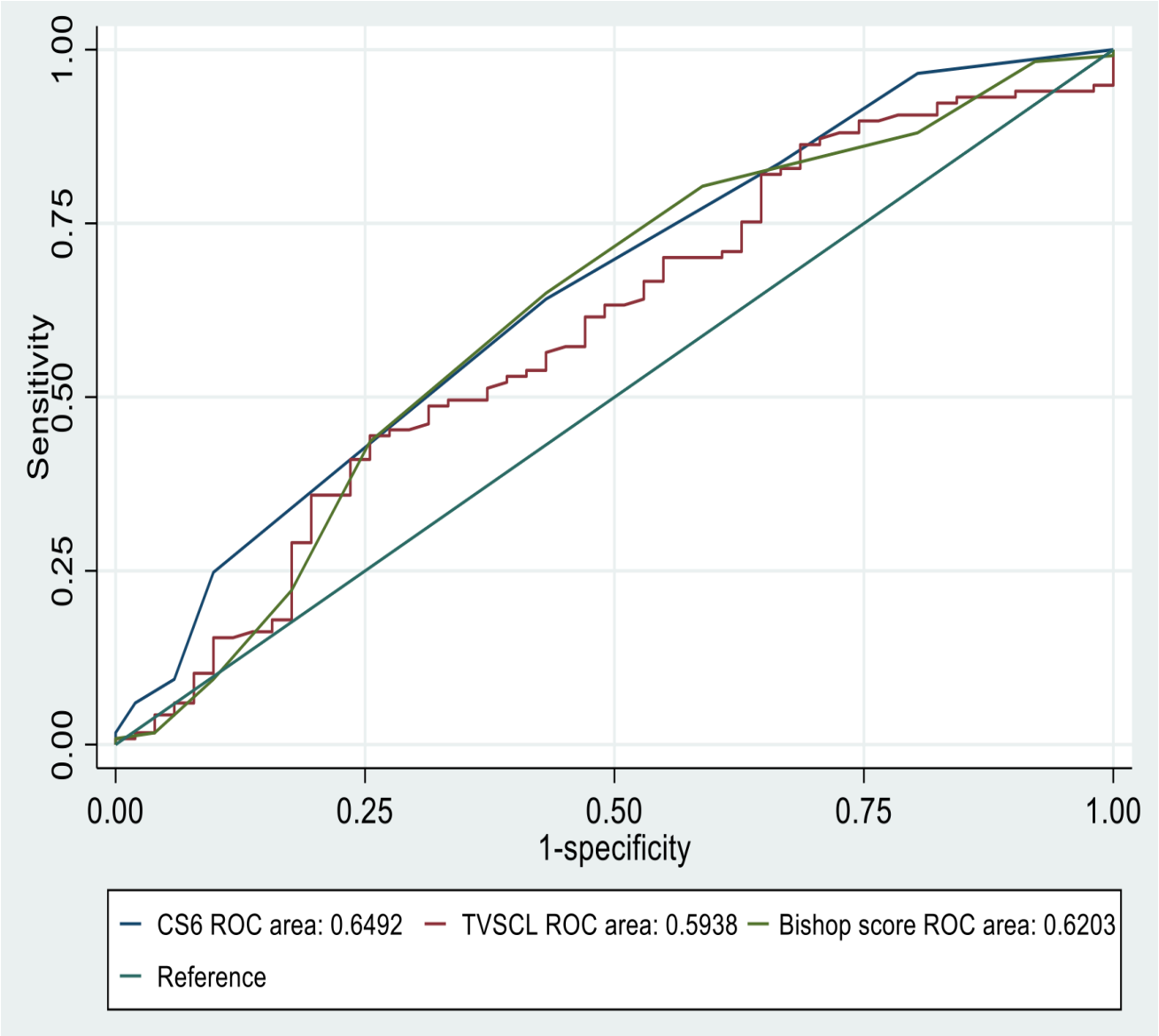

Figure 21: ROC curve for predicting successful induction of labour (CS 6, TVSCL, BS)

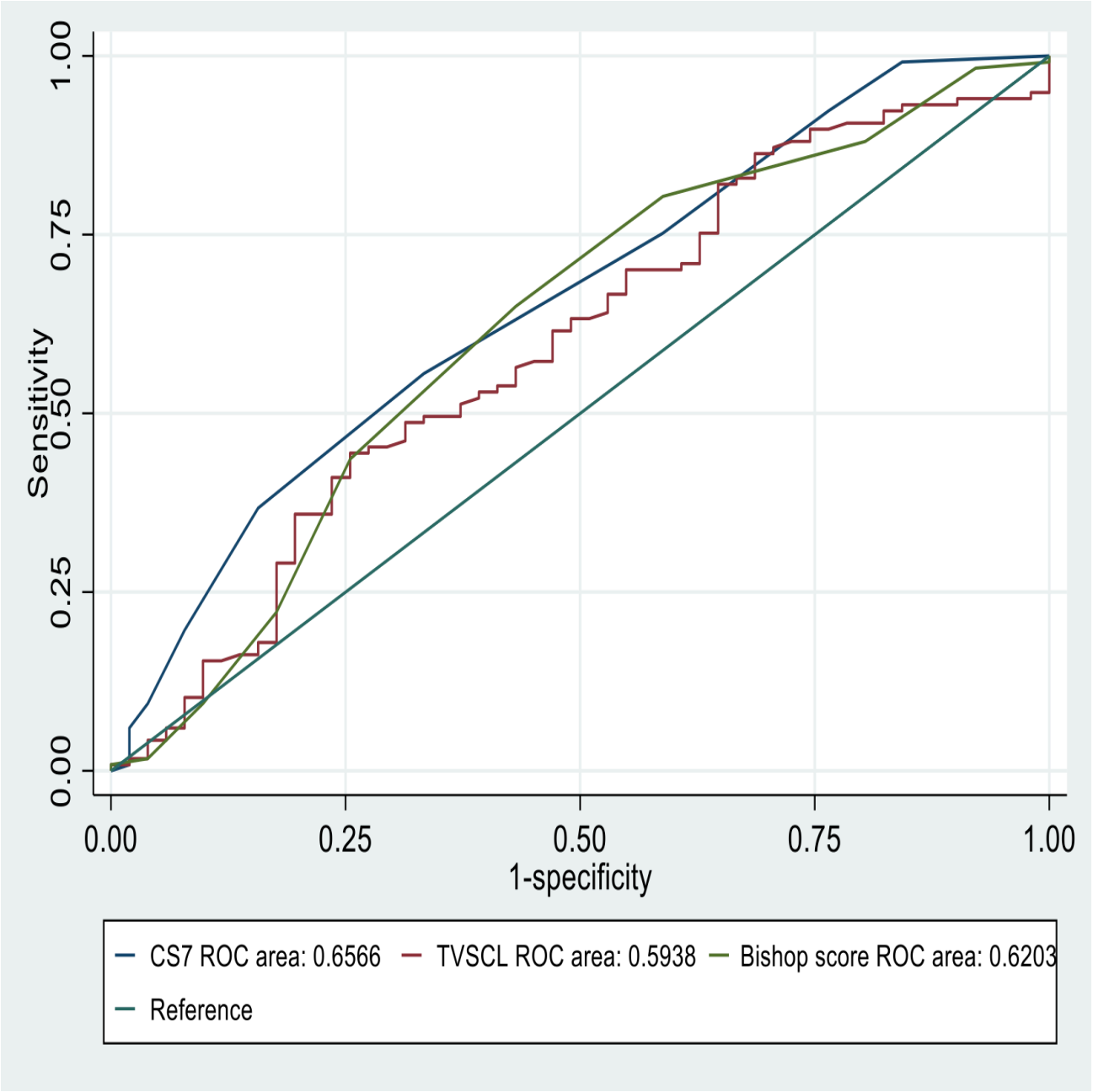

Figure 22: ROC curve for predicting successful induction of labour (CS 7, TVSCL, BS)

Using the identified cut off values from the ROC curves, the data was dichotomized into binary predictors and new ROC curves drawn.

Table 19 illustrates the predictive values of the CS that were significant and their significance levels. Although all the CS shown in table 20 significantly predicted successful induction of labour, none was superior to the BS.

Table 19: Predictive values of CS (dichotomized) for Successful induction of labour (vaginal delivery within 24 hours)

CS	Cut off	Sensitivity (%)	Specificity (%)	AUC (95% CI)	PPV (%)	NPV (%)	Std. Err	P-value
CS 1	≥4.0	65.0	51.0	58.0 (50.0, 66.0)	75.2	38.8	0.469	**<0.001**
CS 2	≥2.0	59.8	54.9	57.0 (49.0, 66.0)	75.3	37.3	0.611	**0.001**
CS 4	≥2.0	75.2	39.2	57.0 (49.0, 65.0)	73.9	40.8	0.535	**<0.001**
CS 5	≥2.0	81.2	33.3	57.0 (50.0, 65.0)	73.6	43.6	0.383	**<0.001**
CS 6	≥2.0	83.8	33.3	59.0 (51.0, 66.0)	74.2	47.2	0.389	**<0.001**
CS 7	≥3.0	75.2	41.2	58.0 (50.0, 66.0)	74.6	42.0	0.388	**<0.001**

The CS 1 optimal cut off value was 4. At CS 1 ≥ 4, sensitivity was 65.0% and specificity was 51.0%. The CS 6 optimal cut off value was 2. At CS 6 ≥ 2, sensitivity was 83.8% and specificity was 33.3%. The CS 7 optimal cut off value was 3. At CS 7 ≥ 3, sensitivity was 75.2% and specificity was 41.2%.

Figures 23 to 25 show the ROC curves for the dichotomized data for CS 1, CS 6 and CS 7, using the predictors of interest identified. (CS 1 ≥ 4.0, CS 6 ≥ 2 and CS 7 ≥ 3)

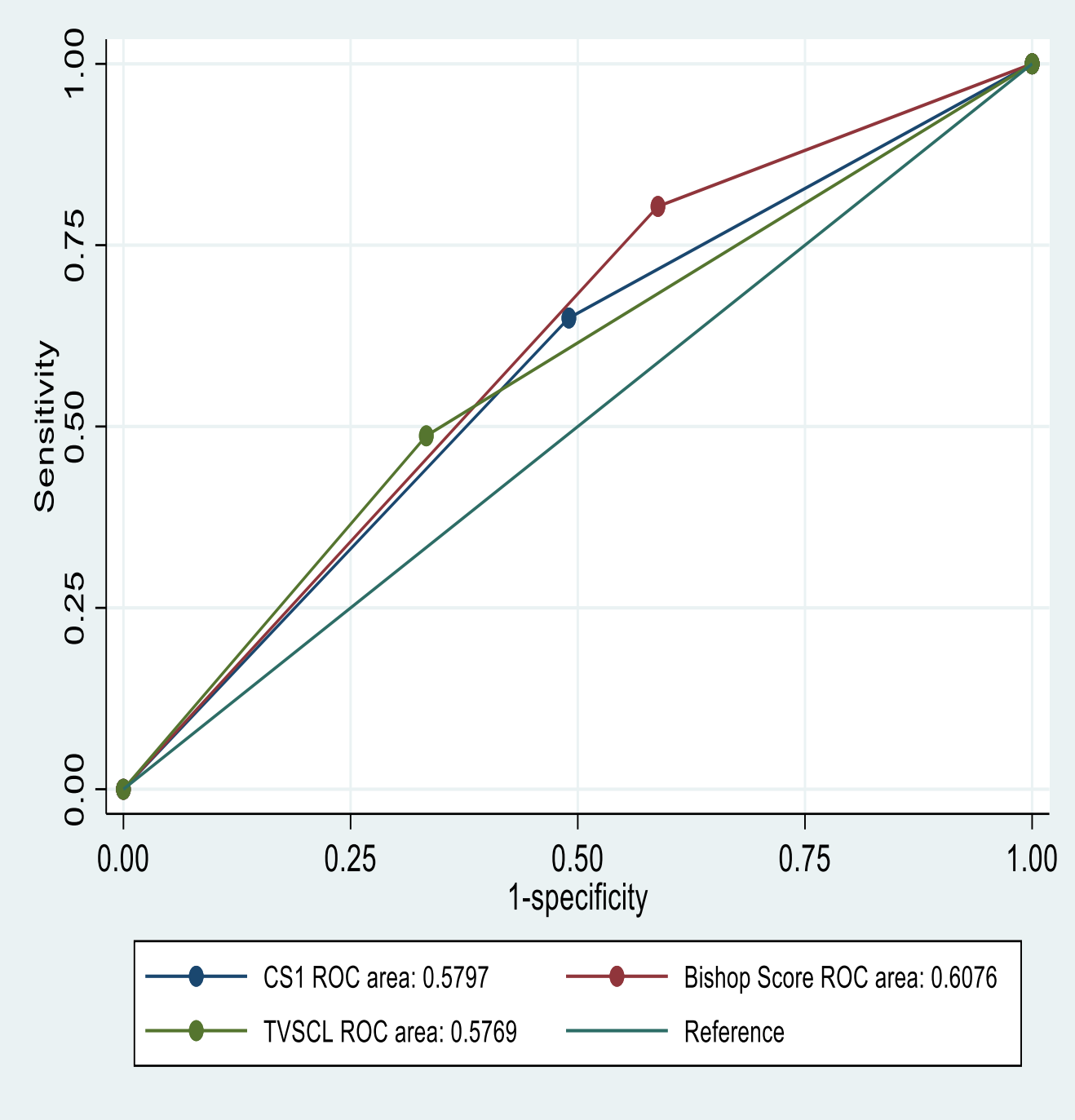

Figure 23: ROC curves for predicting successful induction of labour (DICHOTOMIZED: CS1, TVSCL and BS)

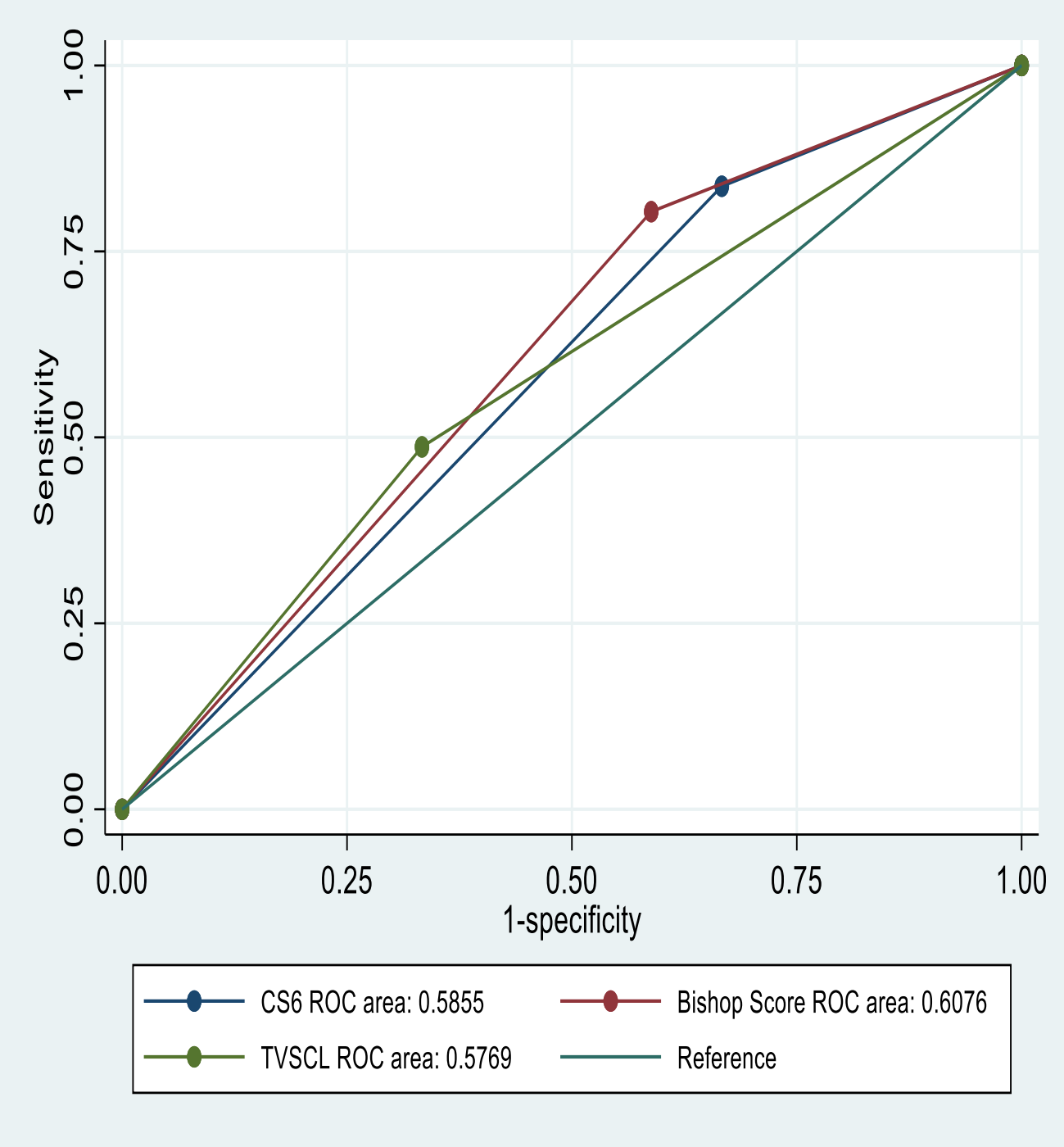

Figure 24: ROC curves for predicting successful induction of labour (DICHOTOMIZED: CS6, TVSCL and BS)

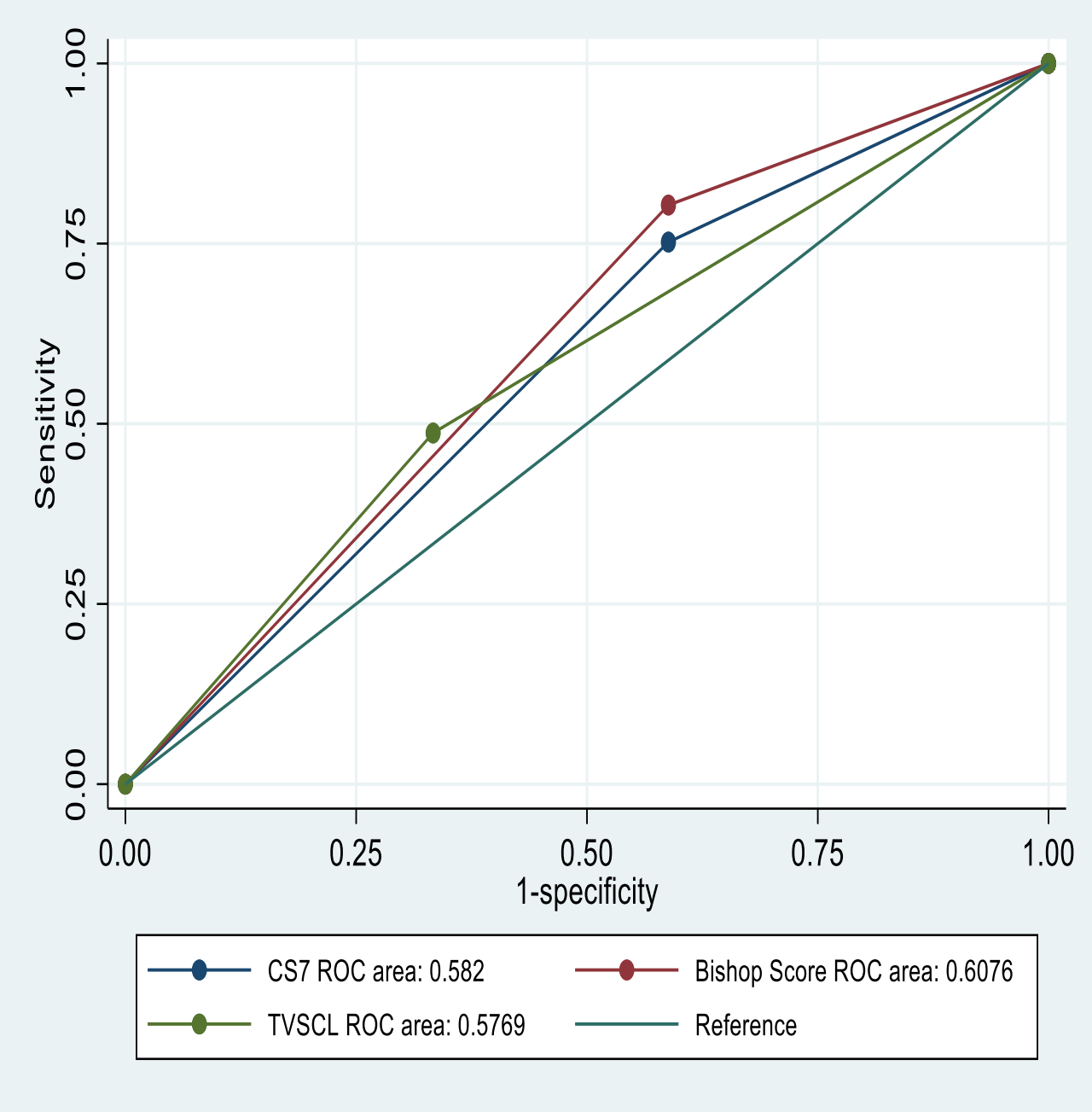

Figure 25: ROC curves for predicting successful induction of labour (DICHOTOMIZED: CS7, TVSCL and BS)

ROC curves were reconstructed to determine the best cut off values for the CS in predicting vaginal delivery. Figures 26 and 27 show the AUROC curves for selected CS. CS5 and CS 6 were superior to BS in predicting vaginal delivery. CS 5 had the highest accuracy with AUROC of 0.6225 (CI 0.53-0.72). At a CS 5 cut off value of ≥ 2, sensitivity was 81.2%; specificity 43.3%; PPV 86.8% and NPV 33.3%. Table 20 illustrates the predictive values of the CS and their significance.

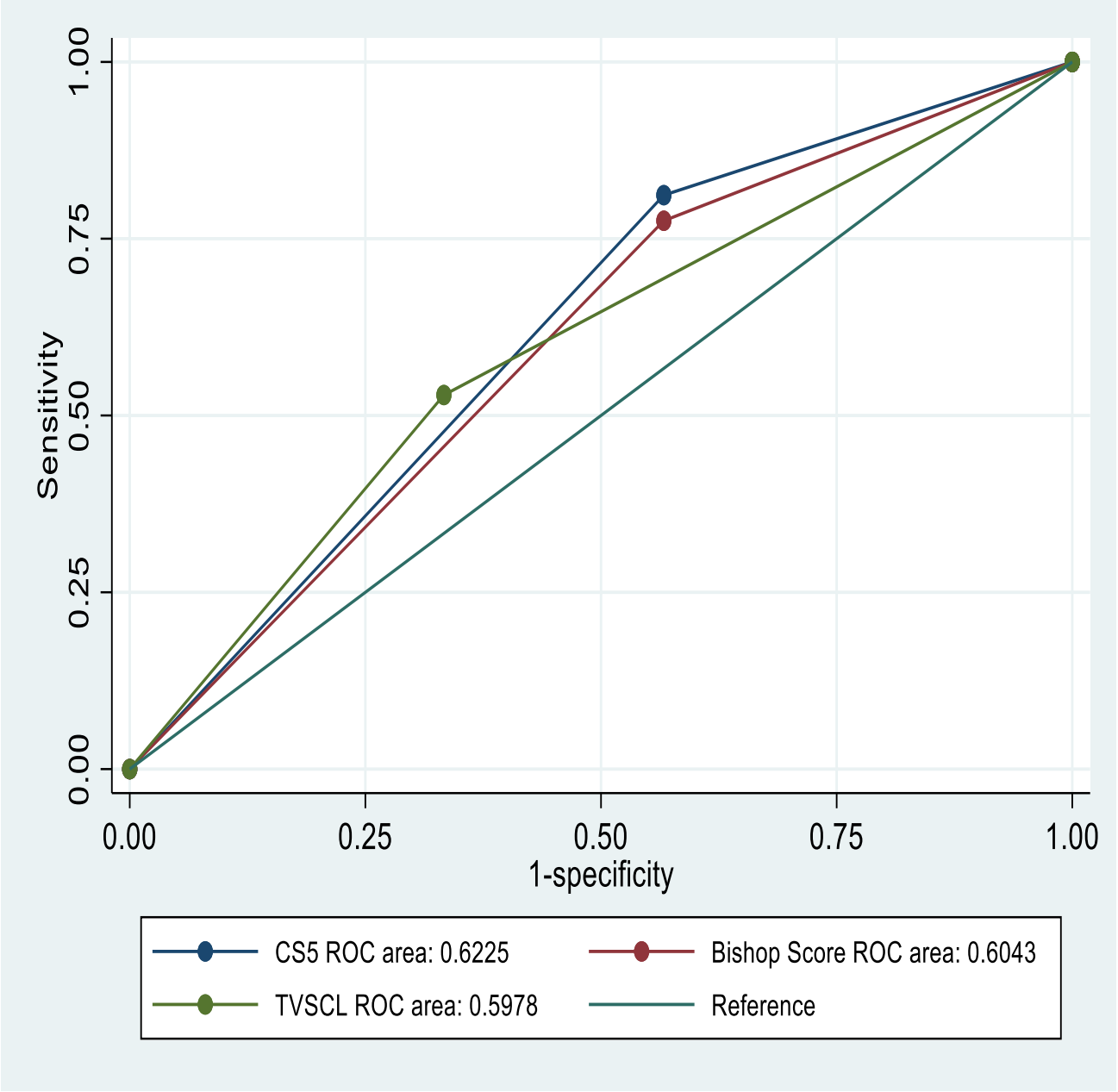

Figure 26: ROC curves for predicting vaginal delivery (DICHOTOMIZED: CS5, TVSCL and BS)

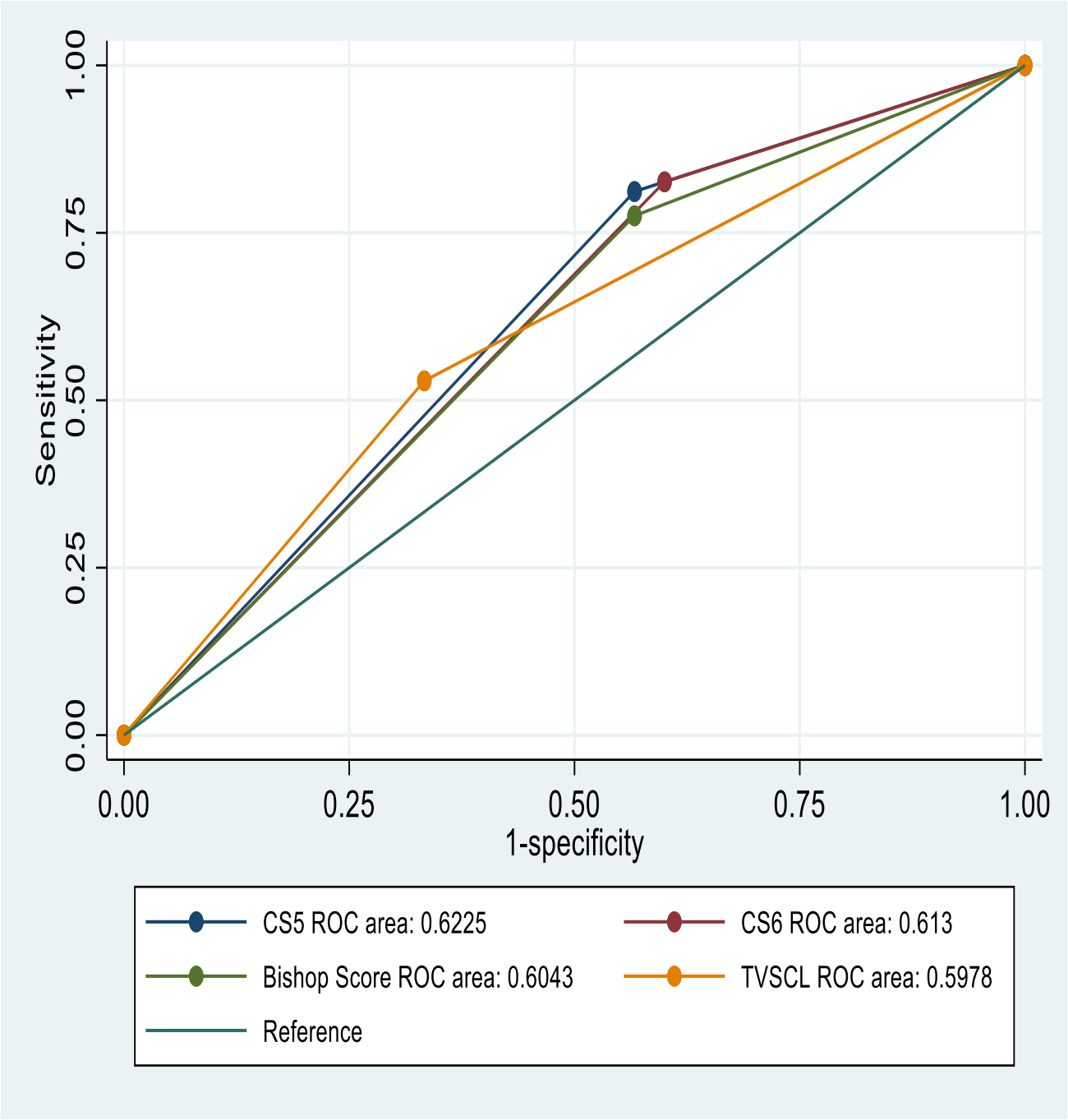

Figure 27: ROC curves for predicting vaginal delivery (DICHOTOMIZED: CS5, CS6, TVSCL and BS)

Table 20: Predictive values of CS (dichotomized) for Vaginal delivery

CS	Cut off	Sensitivity (%)	Specificity (%)	AUC (95% CI)	PPV (%)	NPV (%)	Std. Err	P-value
CS1	≥ 3	84.1	33.3	59.0 (50.0, 68.0)	85.3	31.3	0.671	**<0.001**
CS2	≥ 1	84.9	36.7	61.0 (51.0, 70.0)	86.0	34.4	0.506	**0.048**
CS3	≥ 1	77.5	40.0	59.0 (49.0, 69.0)	85.6	27.9	0.617	0.105
CS4	≥ 2	73.9	43.3	59.0 (49.0, 68.0)	85.7	26.5	0.737	**0.007**
CS5	≥ 2	81.2	43.3	62.0 (53.0, 72.0)	86.8	33.3	0.507	**<0.001**
CS6	≥ 2	82.6	40.0	61.0 (52.0, 71.0)	86.3	33.3	0.629	**0.001**
CS7	≥ 3	73.2	43.3	58.0 (49.0, 68.0)	85.6	26.0	0.661	**<0.001**

4.9 ACCEPTANCE OF CERVICAL ASSESSMENT METHODS

Majority of participants 161/168 (95.8%) preferred the transvaginal sonographic cervical assessment. Figure 28 shows the breakdown of participants preference for a method of cervical assessment.

The mean pain score post digital assessment was 5.98 ± 2.6 compared with a mean pain score post transvaginal sonographic assessment of 0.13 ± 0.47. The maximum pain score for TVSCL assessment was 3, whilst the maximum pain score for digital assessment was 10.

Of the 161 women who preferred the TVS; 160 /161 (99.4%) felt it was less painful with only one person reporting no difference in pain. Also, 120 women out of the 160 felt the TVS was also less invasive (75%).

Only 5/168 participants (3%) preferred the digital assessment. Although they felt it was more painful and invasive; 4 out of 5 thought it was more natural and 1 thought it prepared her for the process of labour.

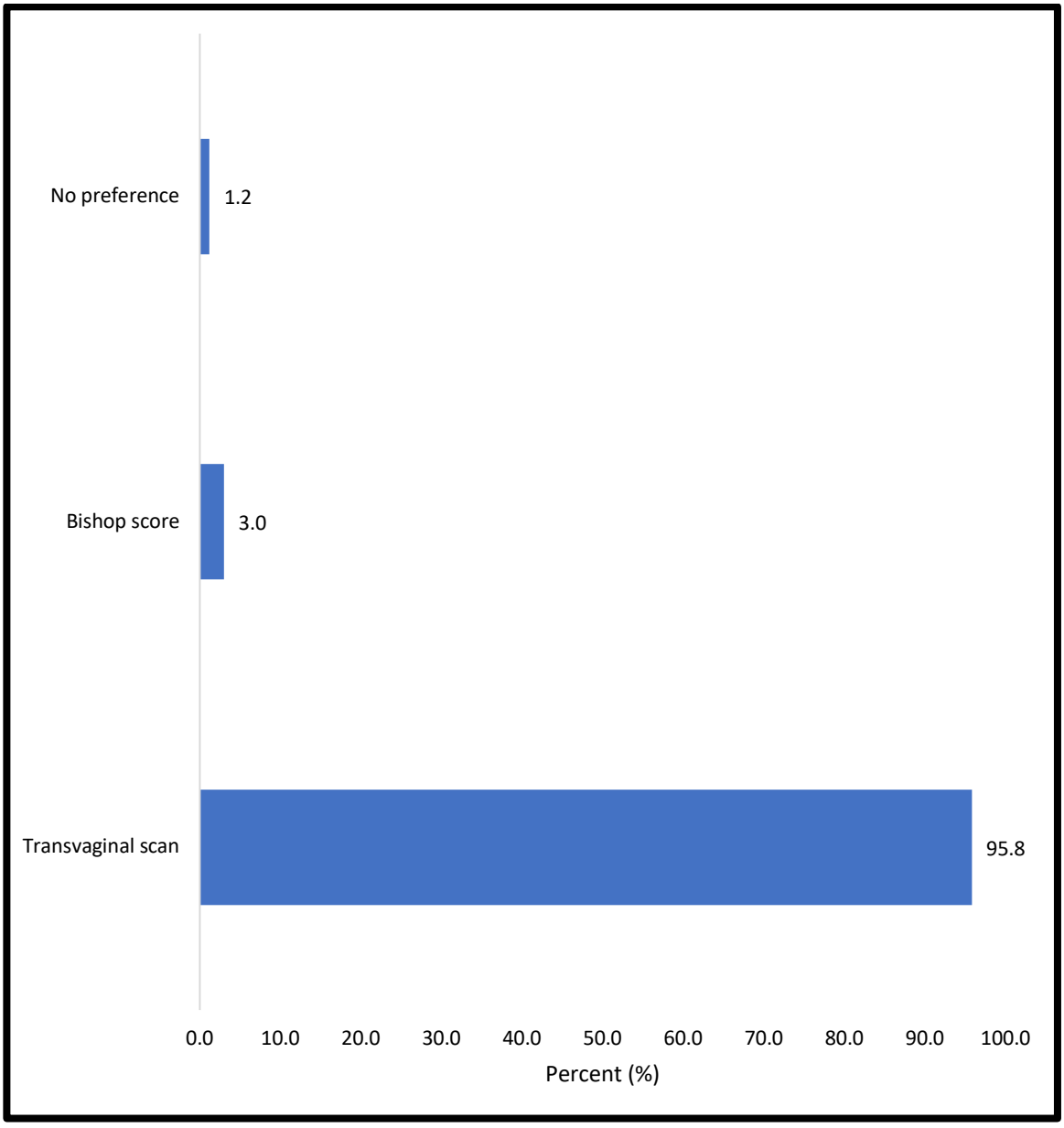

Figure 28: Participants Preference for a Pre-induction Cervical Assessment Method

An independent sample T test to determine the difference in mean pain scores post BS assessment between parous and nulliparous women demonstrated a significant difference between groups. (t (166) = 2.21), p = **0.029**. Nulliparous women (Mean = 6.51± 2.46) compared with Parous women (Mean = 5.62± 2.66). (See Table 21).

Table 21: Comparison of pains score post BS Assessment (Analysis by Parity)

	Mean	Std. Err	Std. Dev.	95% CI	t	P-value
Parity					**2.21**	**0.029**
Nulliparous	6.51	0.30	2.46	5.92 – 7.11		
Parous	5.62	0.27	2.66	5.09 – 6.15		
Combined	5.98	0.20	2.61	5.58 – 6.38		
Diff	0.89	0.41		0.09 – 1.70		

A linear regression conducted, revealed a strong negative correlation between parity and the post BS pain score. Parous women were less likely to experience a greater pain score. (β = -0.89, (95% CI; -1.70, -0.09), p=0.029). (See Table 22).

Table 22: Correlation between Parity and post BS Pain Score

	Coefficient	Std. Err	t	P-value	95% CI
Parity					
Nulliparous	Ref				
Parous	-0.89	0.41	-2.21	**0.029**	-1.70, -0.09
Constant	6.51	0.31	20.83	**< 0.001**	5.90, 7.13

Table 23: Correlation between Level of Education and post BS Pain Score

	Coefficient	Std. Err	t	P-value	95% CI
Educational level					
No formal education	Ref				
Primary	0.42	0.79	0.53	0.598	-1.14, 1.97
Secondary	2.13	0.79	2.69	**0.008**	0.57, 3.70
Tertiary	2.10	0.80	2.62	**0.010**	0.51, 3.58
Constant	4.58	0.72	6.40	**< 0.001**	3.17, 6.00

A linear regression conducted, revealed a strong positive correlation between level of education and the post BS pain score. Women with secondary or tertiary education were more likely to experience a greater pain score compared to women with no formal education.
Secondary education: (β = 2.13, (95% CI; 0.57, 3.70), p=0.008).
Tertiary education: (β = 2.10, (95% CI; 0.51, 3.58), p=0.010). (See Table 23).

Table 24: Correlation between Religion and post BS Pain Score

	Coefficient	Std. Err	t	P-value	95% CI
Religion					
Christian	Ref				
Islam	-0.72	0.50	-1.43	0.154	-1.70, 0.27
Constant	6.13	0.22	27.27	**< 0.001**	5.68, 6.57

Table 25: Correlation between Marital status and post BS Pain Score

	Coefficient	Std. Err	t	P-value	95% CI
Marital status					
Single	Ref				
Married	-0.10	0.44	- 0.23	0.817	- 0.97, 0.77
Cohabiting	-0.53	0.75	- 0.71	0.478	- 2.00, 0.94
Constant	6.09	0.36	17.08	**< 0.001**	5.39, 6.80

Religion and marital status did not significantly have an effect on the post BS pain score. Although Muslims were less likely to experience a greater pain score compared to Christians, this was not statistically significant. (See Table 24). Similarly, women who were married or cohabiting were less likely to experience a greater pain score compared to women who were single, but this was also not statistically significant. (See Table 25).

CHAPTER 5

5.0 DISCUSSION

The aim of the study was to compare the TVSCL and the BS in the prediction of successful labour induction among women with low risk postdate pregnancies induced at KBTH.

5.1 DEMOGRAPHIC AND MATERNAL OBSTETRIC CHARACTERISTICS OF THE STUDY POPULATION

The mean age of participants at induction in this study was 29.2 ± 5.2 years. This is similar to the findings by Kabore et al, who conducted a study on outcomes in elective induction of labour in postdate pregnancies at the same facility in 2015 (21). Majority of participants had some form of education, at the minimum, primary level of education. Only 7.1% had no formal education. This fairly literate set of participants could have accounted for their willingness to have the transvaginal scan performed and also their acceptance of TVSCL as reported in literature (79,83).

The induction rate in this study was 12.4%. This is higher than what has been reported in literature for Africa. In a study by Vogel et al, that analysed the pattern of induction of labour in Africa and Asia, induction rate determined for Africa was 4.4% (97). A Nigerian study conducted in Ogoja, however reported an induction rate of 11.5% similar to the findings of this study (29). The African countries included in the study by Vogel et al were Algeria, Angola, Nigeria, Congo Kenya, Uganda and Niger. The differences in socio-demographic characteristics or institutional practices (66) between these countries and Ghana, could be the difference in induction rates identified.

The rate of postdate pregnancies in the scheduled inductions over the study period was 51.6%. Two studies conducted in the same facility in the past decade, reported higher rates of postdate in the induced cases; 65.9% (21), 69.7% (58). The decrease in the rate of postdate cases in the current study could be due to the reduction in postdate referrals to the study site. A current practice over the past 5 years has been to send doctors at Residency level from KBTH to the peripheral facilities to manage some of the obstetric cases. Also, more Obstetrician specialists are being produced by the Ghana College of Surgeons and subsequently posted to the peripheral facilities to manage some of these cases. These practices have reduced the overall referrals to KBTH. Prevalence of postdate pregnancies

has been noticed to be dependent on the population characteristics. These include prior postdate pregnancy, nulliparity, male fetus, obesity and genetic predisposition (86,88).
In the current study almost 70% of the participants were either obese or overweight with less than 1% being underweight. These reinforce the findings of a study by Donna Halloran et al, that reported that increasing maternal BMI is associated with postdate pregnancies (87). Maternal obesity was however higher in the current study, compared to other studies that assessed the prevalence of maternal obesity in Ghanaian pregnant women (98,99). Diallo et al reported a prevalence of 37.3% (overweight or obese) among pregnant women in a metropolitan hospital in Cape coast in southern Ghana (98). Similarly, the percentage of pregnant women with overweight and obesity were 31.3% and 16.9% respectively in a study conducted in Accra (99). The higher percentage in the current study could be attributed to the cohort studied which was only postdate pregnancies.
Only 10% of the participants had a prior history of induction of labour, all of which were on account of postdate. This was however lower than that reported by Raji et al, who had 22% of their sample with a history of induction of labour and 18% with a history of postdate (73). The fact that Raji and colleagues (73), recruited pregnant women at 37 weeks and above for the study with varied indications and medical conditions, could have explained the difference in findings. About 60% of participants in the current study were parous, similar to findings by Kabore et al (21). Why nulliparous women failed to dominate as expected is not clearly understood.

Suboptimally dated pregnancy occurred in 13.7% of the participants. Over 80% had a booking scan before 22 weeks. This finding may be extrapolated to suggest that majority of women booked before 22 weeks of gestation. Also, 42.3% of women had a booking scan before 13 weeks and 78% before 20 weeks, implying a significant number of women had an early booking. A study conducted in the Accra Metropolis, reported that about 40% of women had their booking antenatal visit before 16weeks (100), which is similar to the current study. These findings are higher than what is reported by Lawani et al in Nigeria, who had only 2% of pregnant women booking before 13 weeks and 16.7% booking between 13 weeks and 27 weeks (29). The difference could be attributed to the differences in socio-demographic characteristics.

5.2 COMPARISON OF TRANSVAGINAL SONOGRAPHIC CERVICAL LENGTH AND BISHOP SCORE

5.2.1 OPTIMUM CUT OFF VALUES FOR TRANSVAGINAL SONOGRAPHIC CERVICAL LENGTH AND BISHOP SCORE

The study identified cut off values of 2.31cm for TVSCL and 4 for BS. At this cut off, both methods significantly predicted successful induction of labour (vaginal delivery within 24 hours). This is similar to studies by Ana Gomez et al, where the optimum cut off was 2.4cm for TVSCL and 4 for BS (53) and by Rane et al with a TVSCL cut off of 2.4cm (101). Although the cut off values are similar, these studies reported that the TVSCL was superior to the BS in predicting successful induction, contrary to our finding. Ana Gomez in their study defined successful induction of labour as vaginal delivery within 60hrs of prostaglandin use or within 12 hours of oxytocin use (53) and this may have accounted for the difference in results. In a prospective observational study conducted in Sri Lanka, Athulathmudali and colleagues identified a TVSCL cut off of 3.71cm for predicting successful induction (50), which was identified to be superior to the BS. Although the study had the same definition of successful induction as the current study, the study population included pregnancies with a gestational age of 37- 42 weeks and used a different induction method, which could have accounted for the higher cut off value compared to the current study.

For predicting vaginal delivery, the optimum cut off value for TVSCL was 2.5cm and its performance was comparable to the BS at 4. This finding is in agreement with the study by Abdullah et al (48), where at a cut off of 2.7cm and BS of 4, reported comparable performance with both methods. Khazardoost et al however quoted a shorter TVSCL cut off of 1.6cm and at this value had similar predictive values for vaginal delivery as a BS of 5 (54). The reason for the shorter cut off for TVSCL is however not clear, since it would have been expected to be higher since the participants in that study had a gestational age ranging from 37 weeks to 42 weeks.

5.2.2 PREDICTIVE VALUES

The AUROC curve for TVSCL and BS in predicting successful induction of labour was 58 and 61 respectively. Although the AUROC for BS was marginally higher than the

TVSCL, both were significant. Also, the ROC curves were noticed to cross each other, implying that these two methods actually complement each other and at certain regions of the curve, one method is preferred to the other.

Better performances have been reported in other studies for TVSCL. Rane et al found that the AUROC for TVSCL and BS were 82 and 72 respectively in predicting successful induction of labour (101). That study had a similar definition of successful induction as the current study, which was vaginal delivery in 24 hours. Athulathmudali, also reported a high AUROC for TVSCL 83, however they had a very low AUROC of 39 for BS (50). There is significant heterogeneity among these studies which could account for these varied degrees of accuracy. Athulathmudali sampled pregnant women at gestational age of 37 weeks and above (50), with varied indications for induction of labour. This differs from this current study that included only low risk postdate pregnancies. Also, the optimum cut off values were higher in that study compared to this current study. The cut off was 3.71cm compared to 2.31cm in the current study. Also, the method of induction of labour differed between the studies. Both Athulathmudali and Rane in their studies, used dinoprostone for induction (50,101). Rane et al further stratified the sample in terms of parity and favourability of the cervix. Nulliparous women with unfavourable cervix received a different regimen whilst multiparous women and those with a BS of 5 to 7 received a different regimen (101). The current study however, used the same protocol for all participants and the drug used was misoprostol.

Analysis of the predictive values of the binary predictors of TVSCL and BS in predicting successful induction of labour showed that TVSCL had a higher specificity (66.7% vrs 41.2%), whilst BS had a higher sensitivity (80.3% vrs 48.7%). Contrary to findings in this study, Raji and colleagues (73) found TVSCL to be more sensitive (52.4% vrs 47.6%) and BS to be more specific (82.1% vrs 78.6%). The study used similar cut off values and was done in Nigeria, a west African country, similar to this current study. Reasons for this difference is not clear. Other studies have also showed the TVSCL to be both more specific and more sensitive than the BS (50,101). In Rane et al, the sensitivity for TVSCL was 84% which was higher than that reported by this current study (101) and its specificity was 59%. In the current study, both methods had a high PPV, with TVSCL marginally outperforming the BS. (77% vs 75.8%).

When reanalysed to predict vaginal delivery, TVSCL was still more specific (66.7% vrs 43.3%) and BS more sensitive (77.5% vrs 52.9%), although the sensitivity of TVSCL improved from 48.7% as reported initially for predicting successful induction to 52.9%. Both methods however had similar accuracy, with an AUROC of 60 and were both significant. Although our findings concurred with that of Ana Gomez et al (53) who found TVSCL to be more specific (77% vrs 56%) and BS to be more sensitive (77% vrs 66%); other studies have demonstrated otherwise (48,54). Khazardoost reported that both methods had similar sensitivity (85% vrs 84%) and specificity (67% vrs 70%) (54). Similar findings of Khazardoost, have also been reported by Abdullah et al (48). Regarding the PPV, TVSCL once again marginally outperformed the BS (88% vrs 86.3%).

5.2.3 COMPARISON OF TRANSVAGINAL SONOGRAPHIC CERVICAL LENGTH AND BISHOP SCORE WITH OUTCOME MEASURES (PRIMARY AND SECONDARY)

Studies have noted the significant association between induction to delivery interval and both BS and TVSCL (14). In the current study, the induction to delivery interval was significantly shorter when the TVSCL was ≤ 2.31cm (17.41 hours versus 18.87 hours; p = 0.040). Similarly, the induction to delivery interval was significantly shorter when the BS was ≥ 4 (16.6 hours versus 20.1 hours; p = 0.004).

TVSCL at ≤ 2.31cm had a significantly shorter induction to active phase time (11.08 hours vrs 12.5 hours; p = 0.015), BS however did not demonstrate a significant difference in induction to active phase time.

Also worthy of note is the significant difference in the doses of misoprostol administered between groups at the cut off values. Participants with BS ≥ 4 had lower doses of misoprostol administered (75mcg vrs 50mcg; p= 0.002), contrary to the findings of Kabore and colleagues (21) who reported no significant association between misoprostol dose and the BS.

5.2.4 LINEAR CORRELATION BETWEEN CERVICAL PARAMETERS AND OUTCOMES

BS had a negative correlation with induction to delivery time, whilst TVSCL had a positive correlation with induction to delivery time, similar to the results of other studies (14,17,50). In a study conducted in Nigeria by Raji et al, there also was a negative correlation between BS and induction to delivery time; but there was no significant correlation between TVSCL and induction to delivery (73).

5.3 INDUCTION OUTCOMES

Successful induction rate for the study was 69.6% with a 95% CI of 62.1-76.5. Vaginal delivery occurred in 82.1% of participants, whilst the caesarean section rate was 17.9%. Our findings are in agreement with previous studies (14,58). Adu-Bonsaffoh et al (58) reported a vaginal delivery rate of approximately 80% (58) and Pandis et al reported a caesarean section rate of about 20% (14). However, Abdullah and Ana Gomez in their studies, found conflicting results, with higher caesarean rates of 29.6% (48) and 35.6% (53). The use of different induction agents in these studies; dinoprostone (53); combination of induction methods (48) and the gestational age of participants ranging from 36 to 42 weeks (48,53) could have explained the different rates. Ethnicity could also be a contributory factor, with the current study participants being Africans (GHANA), whilst Europeans in the study by Ana Gomez et al (SPAIN) (53), and Asians in the study by Abdullah et al (MALAYSIA) (48).

Kabore et al in their study on postdates in the same facility as this current study, reported a lower vaginal delivery rate of 74% (21). Although the study participants in both studies are similar (Ghanaians and postdate pregnancies), Kabore and colleagues used 50mcg misoprostol for induction and reported a higher rate of fetal distress necessitating caesarean sections. This could have accounted for the difference in vaginal delivery rates between studies. Whilst fetal distress accounted for about 43% of the caesarean sections in Kabore's

study (21), only about 26% of the indications for caesarean sections in the current study was due to fetal distress.

5.3.1 MATERNAL OUTCOMES

Significantly lower doses of misoprostol were required in the successful induction of labour group (Median 50 IQR 25-50 versus Median 75 IQR 50-100 doses, $p < 0.001$). This is similar to a study in Nigeria (73), where the mean number of doses of misoprostol were 1.8 in the successful group versus 4.5 in the failed group.

There was a significantly lower estimated blood loss in the successful induction of labour group in the current study. (Median 250mls IQR 200-300 versus Median 400mls IQR 300-500, $p < 0.001$). The mean birth weight was also significantly higher in the failed induction of labour group (3.5 ± 0.5kg versus 3.3 ± 0.5kg, $p = 0.036$). In the current study, the significantly higher birth weight in the failed group, could have accounted for the higher blood loss(102) . Also having a caesarean section is associated with more blood loss and so could have accounted for the higher blood loss in the failed induction group.

No cases of uterine rupture were reported in the study. A study conducted in the same facility in the year 2015, reported 5 cases of uterine rupture (2.6%) among cases induced over a six-month period (58). These cases occurred in only patients induced with misoprostol. The use of 50ug misoprostol in that study compared to 25ug misoprostol in the current study could have accounted for the difference in results. This finding reinforces the WHO recommendation that low dose misoprostol reduces maternal adverse outcomes like uterine rupture (2).

The findings of Raji et al, reported that oxytocin augmentation was not statistically significant between groups (73). In the current study however, the need for oxytocin augmentation was statistically significant between groups.

5.3.2 FETAL AND PERINATAL OUTCOMES

The mean birth weight for this study was 3.4 kg, which was slightly higher than the 3.1kg reported in the same facility in 2015 by Kabore and colleagues (21). Rates of other fetal and perinatal outcomes differed in the current study compared to previous studies (21,73). FHR abnormalities occurred in 8.9% of participants in the current study compared to 42.86% (21); meconium staining of liquor was reported in 14.9% compared to 26.3% (73)

and 38.1% (21). The high FHR abnormalities and meconium-stained liquor could be explained by the fact that higher doses of misoprostol (50mcg) were used for induction (21) compared to the 25mcg in the current study.

NICU admission rates was 10%, similar to that reported by Raji et al (73). Interestingly, Kabore reported a lower NICU admission rate of 4.3% (21). This difference could be due to the fewer participants (116) in that study (21). The highest indication for NICU admission was asphyxia occurring in 57% of babies admitted in the study by Raji et al (73), comparable to low APGARS in 47% of babies admitted in the current study. Babies with APGAR score of <7 at 5 minutes was 6.5%, slightly lower than the 9% reported by Raji and colleagues (73). Although the same dose of misoprostol was used in both studies, the difference in the frequency of dosing; four hourly (73) versus six hourly in the current study, could account for the difference.

No case of FSB was reported in the study. However, Adu-Bonsaffoh et al reported 7 cases of FSB in a retrospective study conducted at the same facility, with 94.1% of the still births occurring in patients induced with misoprostol (58). The study population in both studies however differed. The maternal medical conditions like sickle cell disease and preeclampsia which were included in that study, could have accounted for the higher still births.

The male babies delivered in this study was 53%. With the male fetus being a risk factor for postdate pregnancies (86,88), this slightly higher incidence could be the possible explanation.

5.3.3 CERVICAL MEASURES

The BS was significantly different between outcome groups, similar to findings by Ransiri et al (18). In the current study, mean BS in successful induction of labour group was 5.1 compared with 4.3 for the failed group; $p = 0.002$. Although the mean TVSCL was shorter in the successful induction group, it was not statistically significant in this current study.

Studies have noted the association between some components of the BS and induction of labour outcome. Pandis et al (14) reported a significant association between effacement and successful outcome. Rane et al identified dilatation, station and consistency as the

components of the BS associated with successful induction of labour (101). In the current study there was no significant difference in the dilatation, consistency or digital cervical length between outcome. However, station and position were the only two components of the BS that were significantly different between outcome groups. This finding is comparable with a study conducted in Spain where station was significantly associated with successful induction of labour (53).

5.3.4 PREDICTORS OF SUCCESSFUL INDUCTION OF LABOUR AND VAGINAL DELIVERY

High parity was a significant predictor of both successful induction of labour (vaginal delivery in 24 hours) and successful vaginal delivery. Low maternal BMI and increasing BS station were significant predictors of successful induction of labour in the univariate analysis but not in the multivariable analysis. These findings reinforce those of previous studies (14,68–70). Parity was a significant predictor of successful induction in studies by Batinelli et al, Pandis et al and Alavifard et al (14,68,70) and a predictor of vaginal delivery in the study by Abdullah et al (48). Similarly, BMI was predictive of success in previous studies (68,69) and BS station predictive of success in Ana Gomez's study (53).
Previous history of induction and maternal weight did not predict either successful induction or vaginal delivery.

5.4 RELATIONSHIP BETWEEN TRANSVAGINAL SONOGRAPHIC CERVICAL LENGTH AND DIGITAL CERVICAL LENGTH

This study identified a significant positive linear correlation between the TVSCL and the digital cervical length r= 0.241 p=0.002, similar to findings by Raji et al (73). The correlation was however stronger in that study compared to this current study; r = 0.761 vrs 0.241.

5.5 COMPOSITE SCORES

Six out of the seven CS generated, significantly predicted successful induction of labour. CS 1, CS 6 and CS 7 had the highest AUROC curves for the prediction of successful induction among all the CS generated. However, none was superior to the BS in predicting successful induction. On the contrary, Ransiri et al, who compared a modified BS (same as the CS 1 in the current study) to TVSCL and BS, reported that the modified BS did not significantly predict successful induction (18). The study defined successful induction of labour as cervical dilatation of > 8cm (18) and so may have accounted for the difference in results recorded.

When the best cut off values of the CS were generated to predict vaginal delivery, CS 5 and CS 6 significantly predicted vaginal delivery and were superior to the BS. CS 5 however had the highest accuracy with an AUROC of 0.6225 (CI 0.53-0.72).
At a CS 5 cut off value of ≥ 2, sensitivity was 81.2%; specificity 43.3%; PPV 86.8% and NPV 33.3%. Compared with the predictive values of the TVSCL and the BS, CS 5 had a higher sensitivity than the BS (81.2% vrs 77.5%) but a lower specificity than the TVSCL (43.3% vrs 66.7%). Of all three methods, TVSCL had the highest specificity and CS 5 had the highest sensitivity for predicting vaginal delivery.

5.6 ACCEPTABILITY

TVS was well tolerated by the participants in this current study. A total of 95.8% of participants preferred the TVS to the BS. Of these, 99.4% of them reported less pain on TVS assessment. About 75% of those who preferred the TVS also reported the procedure to be less invasive compared to the BS. These findings are compatible with those of previous studies (48,77,79). Okeji et al, in a study in Nigeria reported that 82% of women were willing to have a TVS with 90.5% reporting no pain (79), whilst Clement et al reported 85.9% were willing to have the TVS (77).
Contrary to our findings, Raji and colleagues reported a lower preference of 65.4% in a study at Ilorin in the Kwara state of Nigeria (73). In that study, 23.3% were indifferent and 11.3% preferred the BS (73). The lower preference could have been attributed to the conservative nature of participants in that locality as stated in that study, with a long acceptance of digital assessment as the natural method of assessment. Interestingly, about 65% of participants had

tertiary education (73), in contrast with the current study that had only 28% with tertiary education.

Gunes et al showed a negative correlation between the number of live births the woman had previously had and the level of discomfort from a digital vaginal assessment (81). In the current study there was also a similar association, with a strong negative correlation between parity and post BS pain. The mean post BS pain in nulliparous women was 6.51, which was significantly higher than that in the parous group 5.62, p=0.029.
The level of education had a significant effect on the post BS pain score. Women with secondary and tertiary education had a greater likelihood of experiencing more pain compared to women with no formal education. Religion and marital status had no significant effect on the post BS pain score.

5.7 CONSIDERATION FOR IMPLEMENTATION / PRACTICE IMPLICATIONS

An ideal screening test should be able to correctly identify all patients with a particular disease (successful induction) and also all those without the disease (failed induction). Majority of tests in reality will however fall short of being an ideal test. In the current study, TVSCL used as a binary predictor had a specificity of almost 67% in predicting successful induction. This implies that 67% of women who will have a failed induction will be correctly identified when screened. However, 33% of women who will have a failed induction will be incorrectly identified as having a successful induction (false positive). BS when used as a binary predictor had a sensitivity of 80% in predicting successful induction. This means that 80% of women who will have a successful induction will be correctly detected. However, 20% of women who will have a successful induction will be incorrectly identified as having a failed induction.

With the current findings of the study, it suggests that over 95% of women tolerated the TVSCL, and preferred it to the BS, mainly because it was less painful and also because it was less invasive.

Having a test which is extremely more comfortable, with similar accuracy to the current standard (BS) and a high PPV may be more desirable as a first line screening tool for predicting successful induction of labour. Using TVSCL as the first line screening tool for low risk postdate pregnant women (PPV of 77%), will at a cut off of ≤ 2.31cm predict 77% of those that will have a successful induction. These patients will then not be subjected to the painful BS assessment before having induction of labour. The patients with TVSCL >2.31cm

will then have the digital assessment for BS, which as suggested by this study is a more sensitive test. The use of the BS as the second screening test, will be able to identify the true positives from the high false negative rate of people with TVSCL >2.31cm, as such complement the TVSCL in its low sensitivity prediction ability.

This stepwise screening tool ("T-MENS" induction of labour screening tool) will in effect save a number of women from having the more painful and uncomfortable digital assessment for BS prior to the start of induction of labour. Both tests will complement each other if used as a stepwise screening tool. Fewer women with a high risk of having a failed induction will have induction started if this stepwise approach is done and so success rates of induction of labour will also be improved and the complications of failure reduced. An additional benefit will be a reduction in the number of women who will be subjected to the painful BS digital assessment.

If emphasis is on identifying women who will have a successful vaginal delivery after induction, the study identifies TVSCL as having the highest PPV of 88% and CS 5 as having the highest sensitivity of 81%. Therefore, using an initial TVSCL cut off of ≤ 2.5cm and subsequently subjecting patients with TVSCL > 2.5cm to CS 5 assessment (a combination of TVSCL and BS position and Parity) will complement each other in their predictive power and also reduce the number of patients who will have a full digital assessment to assess all five components of the BS.

Although CS 5 will still involve a digital assessment to identify the cervical position, it may possibly be less painful than assessing all five components of the BS, since there will be less manipulation of the cervix digitally.

Transvaginal scans may not be readily available in all hospitals in Ghana. However, in a tertiary setting like KBTH, where it is available and with the presence of MFM Specialists certified to perform TVSCL even at term, performance of TVSCL as the first screening tool may be useful to counsel patients on their probability of having a successful induction of labour whilst subjecting them to less pain. A subsequent stepwise screening with either BS or CS 5 may improve success rates of induction and success rates of vaginal delivery respectively in low risk postdate pregnancies, hence decrease the complications of failed induction of labour.

5.8 CONTRIBUTION TO KNOWLEDGE

This study, to the best of my knowledge is the first of its kind in the Ghanaian population and so contributes to the body of knowledge.

The study identified cut off values for both TVSCL and BS, that will be clinically useful in predicting successful induction of labour and vaginal delivery among Ghanaian women with low risk postdate pregnancies (between 41 weeks and 43 weeks) assessed for induction at KBTH.

The study identified a CS 5, which is a combination of the TVSCL, BS position and parity, to have a greater accuracy and also a better predictor than the BS in predicting vaginal delivery after induction of labour. Although this assessment involves digital examination, it may possibly be less painful than assessing all five components of the BS.

The study also introduces the "T-MENS" induction of labour screening tool, to enhance patient satisfaction and improve appropriate patient selection for induction of labour.

Lastly, the study identified that Ghanaian women also had a high acceptability for the TVSCL measurement than the BS assessment.

5.9 LIMITATIONS

- Participants were recruited from a single tertiary hospital and so findings may not be representative of the country. However, the attendants at KBTH come from a wide catchment area.
- The study failed to evaluate other transvaginal sonographic parameters, such as posterior cervical angle, the funnel length and funnel width and the distance of the presenting part from the cervical os, which could have had an impact on the predictive values.
- Cost implications were not factored in the acceptability of the transvaginal sonographic assessment
- The study did not compare equals during the discussion on predictive values. The predictive values of binary predictors were compared with the predictive values of a score identified as the optimum from serial scores in other studies. There may be some loss in detail as the point of interest (binary predictor) represents underlying

continuous values and a possible underestimation of the AUROC. It is advised that the interpretation given to the results is based on the inherent limitations of using binary predictors.

5.10 STRENGTHS

- A single operator performed all the transvaginal scans, so interobserver variability was eliminated.
- A single induction agent and protocol was used for all participants, standardising the induction process.
- Heterogeneity was minimized as only low risk postdate pregnant women were recruited for induction in the study.
- Previous studies have concentrated on the predictive values of a threshold score. This study however has tried to dichotomize the data, to make it more user friendly for the clinician and patient and very practical for clinical work.

CHAPTER 6

6.0 CONCLUSION

6.1 CONCLUSION

The successful induction rate was 69.6% and the vaginal delivery rate was 82.1% for low risk postdate pregnancies (between 41 weeks and 43 weeks) induced at KBTH.

The study has identified cut off values for both TVSCL and BS, that will be clinically useful in predicting successful induction of labour and vaginal delivery among Ghanaian women with low risk postdate pregnancies assessed for induction at KBTH. BS ≥ 4 and TVSCL ≤ 2.31cm predict successful induction of labour (vaginal delivery within 24 hours). For predicting vaginal delivery, TVSCL ≤ 2.5cm and BS ≥ 4. Both cervical assessment methods were comparable in their performance of predicting successful induction of labour or vaginal delivery. However, TVSCL was more specific, with a higher PPV and BS more sensitive.

CS 5, which is a combination of the TVSCL, BS position and parity, at a score of ≥ 2, has a greater accuracy and also a better predictor than the BS in predicting vaginal delivery and had the highest accuracy when all three methods were analysed.

Being parous was the only significant predictor of both successful induction of labour (vaginal delivery within 24 hours) and successful vaginal delivery.

Transvaginal scan was better than the digital assessment for BS, mainly because it was less painful and also because it was less invasive.

The stepwise screening tool ("T-MENS" induction of labour screening tool) when applied in induction assessment will reduce the number of women subjected to the more painful and uncomfortable digital assessment for BS prior to the start of induction of labour, thus improving their induction experience. Both tests will also complement each other in their predictive abilities. This will help in counselling women about induction of labour outcomes.

6.2 RECOMMENDATIONS

- TVSCL should be integrated in the pre-induction cervical assessment of postdate pregnancies at the KBTH MFM Fetal Assessment Centre of the unit and be used as a guide in patient counselling and decision making. It may be a viable alternative to the BS for women who cannot tolerate the pain of digital assessment because of either a previous bad experience or a personal preference, given its proven superior patient tolerability and its comparability to the current standard in predicting outcome.
- Women with low risk postdate pregnancies, who are seen at the KBTH Obstetric department with a TVSCL ≤ 2.31cm can be counselled that they have a 77% probability of having a vaginal delivery within 24 hours of misoprostol induction or 88% probability of having a vaginal delivery if their TVSCL is ≤ 2.5cm.
- The Department of Obstetrics and Gynaecology of the KBTH should consider a study to validate the role of the stepwise pre-induction cervical assessment tool ("T-MENS" induction of labour screening tool) in improving successful rates of induction of labour and improving overall patient experience.
- A multicenter study is recommended for the Ghana Heath Service or Ministry of Health to assess the predictive powers of the transvaginal ultrasound for successful induction of labour and successful vaginal delivery.
- A cost effectiveness study is recommended for further research, to identify the implications of cost on implementation strategies

LOGISTICS AND TIME SCHEDULE

YEAR	2022												2023					
Month	Jan	Feb	Mar	Ap	May	Jun	Jul	Au	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Ap	May	Jun
Writing of proposal and review																		
Submission for review and ethical clearance																		
Research assistant training and pretesting																		
Data collection																		
Data entry and cleaning																		
Data analysis and preparation of manuscript																		
Dissemina-tion																		

BUDGET AND RESOURCES

RESEARCH ACTIVITY	ITEM	UNIT COST (GHS)	TOTAL NO. OF MONTHS	QUANTITY	TOTAL COST (GHS)	TOTAL COST PER ACTIVITY (GHS)
SUBMISSION FOR REVIEW AND ETHICAL CLEARANCE	TYPING & PRINTING	35	-	7 COPIES	245	**765**
	BINDING	10	-	7	70	
	PENDRIVE	25	-	2	50	
	IRB FEE	200	-	-	200	
	STC FEE	200	-	-	200	
CONSUMABLES	CONDOM	55	-	2 BOXES	110	**1950**
	GEL	60	-	1	60	
	STERILE WIPES	90	-	2 PACKS	180	
	SCAN PAPER	90	-	2 ROLLS	180	
	GLOVES	50	-	2 PACKS	100	
	QUESTIONNAIRES	6.4	-	200	1280	
	STATIONERY	5	8	-	40	
TRAINING & STIPEND FOR RESEARCH ASSISSTANTS	RESEARCH ASSISTANTS	200	10	2	4000	**4000**
DATA ANALYSIS	STATISTICIAN	2500	-	1	2500	**2780**
	INTERNET	40	7	-	280	
DISSEMINATION	PRINTING	100	-	5	500	**800**
	BINDING	50	-	5	250	
	PENDRIVE	50	-	1	50	
MISCELLANEOUS					300	**300**
TOTAL						**10,595**

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APPENDICES

APPENDIX I: INFORMATION LEAFLET

INFORMATION LEAFLET FOR PARTICIPANTS

RESEARCH TOPIC:
LABOUR INDUCTION: TRANSVAGINAL SONOGRAPHIC CERVICAL LENGTH VERSUS BISHOP SCORE IN PREDICTING VAGINAL DELIVERY AT KORLE -BU TEACHING HOSPITAL (KBTH).

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i. BACKGROUND INFORMATION

I am Dr Teresa Mensah, a maternal and fetal medicine fellow in training in the department of Obstetrics and Gynaecology of the KBTH. My assistants and I are carrying out a study to compare two procedures (transvaginal sonographic cervical length and Bishop score in predicting successful delivery after induction of labour ("false labour") at KBTH.

We are happy to invite you to participate in the study. We would be very grateful if you could kindly read this leaflet or we will explain its content to you so that you can decide whether to take part in the study or not.

ii. PURPOSE OF THE STUDY

The study aims to determine if the two procedures mentioned above, differ in their ability to predict which patients will have a successful delivery after induction ("false labour") at KBTH.

iii. STUDY PROCEDURE AND PARTICIPANT INVOLVEMENT

Participants will be selected from patients who report to the department for a scheduled induction of labour on account of postdate.

Participation will involve you having a transvaginal ultrasound scan done in addition to the Bishop Score before the start of induction. The Bishop Score is the usual procedure done for all patients admitted for induction of labour. The Bishop Score is a method of assessment of the cervix ("neck of the womb") using the examining fingers of the doctor. It is done to assess the length, position, consistency and the extent of opening of the cervix before the start of the induction, to determine the likelihood of success of the induction ("false labour"). The transvaginal scan is a scan where the probe is inserted into the vagina to assess the cervix ("neck of the womb").

Participation in this research will also involve answering a questionnaire which will last about fifteen minutes. Information that will be required from you will include age, educational level and history of previous pregnancies. Other information will be obtained from your antenatal book. The information obtained will be useful in attempts to improve prediction of success and outcomes of induction of labour at KBTH.

iv. VOLUNTARY PARTICIPATION

Participation is voluntary. If you decide to participate in this study, you are at liberty to withdraw whenever you wish. The study will not affect whatsoever the kind of care you receive from the health staff.

v. COMPENSATION OR COST

There are no added costs involved in participating in this research. You will not be compensated financially if you decide to participate.

vi. POTENTIAL RISK AND DISCOMFORT

In accepting to take part in this study, the discomforts that you may have are mainly the slight discomfort with the passage of the transvaginal probe and the inconvenience in time taken to answer the questions. The study will not pose any risk to you or the fetus.

vii. CONFIDENTIALITY

The research team guarantee that all information obtained will be kept in the strictest confidence. Your name and identity are not needed for the study. The information you would provide however is going to be identified by a special code number and would be treated strictly as confidential. You are assured that your name shall not appear or be mentioned in any report that may come out as a result of this study.

APPENDIX II: PARTICIPANTS CONSENT FORM

I have explained fully to the subject the nature and purpose of the study and risk involved in its performance. I have addressed to the best of my knowledge all questions related to the study.

Signature …… Date …….
Researcher/ Research Assistant

I ……..have read the above information /the information has been read to me or translated to me and I have fully understood it.
My concerns have been fully addressed. My signature / thumb print below indicates that I agree to voluntarily take part in the study.

Signature/Thumbprint ……. Date ……

APPENDIX III: QUESTIONNAIRE

TITLE: LABOUR INDUCTION: TRANSVAGINAL SONOGRAPHIC CERVICAL LENGTH VERSUS BISHOP SCORE IN PREDICTING VAGINAL DELIVERY AT KBTH

IDENTIFICATION AND SOCIODEMOGRAPHIC CHARACTERISTICS

1. Participants ID : ……..
2. Age (years): …….
3. Marital status: [0] single [1] married [2] co-habiting
   [3] divorced [4] widowed
4. Highest Educational level completed: [0] none [1] basic(primary/JHS) [2]SHS
   [3] tertiary
5. Occupation: ……
6. Religion: [0] Christian [1]Islam [2]Traditional
   [3] other
7. Place of abode: ……
8. Height (booking): ……..
9. Weight (booking): ……..
10. BMI: …….

OBSTETRIC HISTORY

11. Gravidity: …….
12. Parity: ……
13. Gestational age: ……
14. EDD (first scan): ……
15. Previous history of Induction of labour: [0] YES [1] NO
16. If yes indication: ……..
17. State gestational age ……..
18. State outcome of Induction of labour……..

PREINDUCTION ASSESSMENT

19. Indication for Induction of labour: ……

20. NST done: [0] YES [1] NO

21. If yes: [0] REACTIVE

[1] NON REACTIVE (state components)

22. EFW: …….

23. BISHOP SCORE: [A]……..

[B]CL……

Consistency……..

Dilatation……..

Position……

Station……..

24. TVSCL: ……..……..

25. Date / time of Induction: ……..

OUTCOME DATA

26. Date / time of delivery: …….

27. Mode of delivery: [0] spontaneous vaginal [1]operative vaginal

[2] caesarean section

28. If CS, Indication for CS:[0] failure to progress [1] fetal distress

[2] placental abruption [3] uterine rupture

[4] failure to ripen cervix [5]other **(state)**

29. Time of active labour and dilatation: …….

30. Induction to active phase (hours): ……..

31. Time of second stage: ……

32. Time of delivery: ……

33. Induction to delivery time (hours): ……

34. Doses of misoprostol used: ……..

35. Time of membrane rupture: ……..

36. Membrane rupture: [0]Artificial rupture [1] spontaneous

37. Augmentation with oxytocin: [0] YES [1] NO

38. If yes: units/volume used ……..

39. Maximum number of contractions and duration: ……..

40. Non reassuring fetal heart changes: [0] YES [1] NO

41. If yes: [0]bradycardia [1]persistent tachycardia
[2] late deceleration

PERINATAL OUTCOME

42. Sex: [0] male [1] female

43. Birth Weight (gm): ……

44. Condition: [0] live [1] FSB

45. APGAR at 1MINUTE: ……

46. APGAR at 5 MINUTES: ……..

47. Meconium stained liqour: [0] YES. [1] NO

48. NICU admission: [0] YES [1] NO

49. If yes: indication for NICU admission: …….

50. Duration of admission: ……..

51. Perinatal mortality: [0]YES [1]NO

52. If yes, Cause of death: ……

MATERNAL OUTCOME

53. Tachysystole: [0] YES [1] NO

54. Hyperstimulation: [0] YES [1] NO

55. Chorioamnionitis: [0] YES [1] NO

56. APH: [0] YES [1] NO

57. PPH: [0] YES [1] NO

58. Estimated Blood loss: …….

59. Uterine rupture: [0] YES [1] NO

60. Patient pain score (POST TVS): …… ……

61. Patient pain score (POST BS): ……..

62. Preferred choice: …….

63. Why the preferred choice: [0] less painful [1] less invasive [2] other

APPENDIX IV: BISHOP SCORE

BISHOP SCORE	0	1	2	3	SCORE
CERVICAL POSITION	POSTERIOR	CENTRAL	ANTERIOR	-	
CONSISTENCY	FIRM	MEDIUM	SOFT	-	
LENGTH (CM)	3	1-2	0.5-1	<0.5	
DILATATION (CM)	0	1-2	3-4	5-6	
STATION	-3	-2	-1	0+	

APPENDIX V: PAIN NUMERICAL RATING SCALE

After Transvaginal Scan

On a scale of 0 to 10, with 0 being no pain at all and 10 being the worst pain imaginable, how would you rate your pain right now?

0 1 2 3 4 5 6 7 8 9 10

No pain worst pain imaginable

After Pelvic Assessment for Bishop Score

On a scale of 0 to 10, with 0 being no pain at all and 10 being the worst pain imaginable, how would you rate your pain right now?

0 1 2 3 4 5 6 7 8 9 10

No pain worst pain imaginable

APPENDIX VI: STC APPROVAL

In case of reply the number
And the date of this
Letter should be quoted
My Ref. No. KBTH/ms/03/22
Your Ref. No.....

KORLE BU TEACHING HOS.
P. O. BOX KB 77,
KORLE BU, ACCRA.

Tel: +233 302 667759/673034-
Fax: +233 302 667759
Email: Info@kbth.gov.gh
pr@kbth.gov.gh
Website: www.kbth.gov.gh

9th June, 2022

DR TERESA ABA MENSAH
DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY
KORLE-BU TEACHING HOSPITAL, ACCRA, GHANA

SCIENTIFIC AND TECHNICAL COMMITTEE APPROVAL
PROTOCOL IDENTIFICATION NUMBER: KBTH-STC 00063/2022

The Korle Bu Teaching Hospital Scientific and Technical Committee (KBTH-STC), on 9th June, 2022, approved your submitted study protocol.

TITLE OF PROTOCOL: "Labour Induction: Transvaginal Sonographic Cervical Length Versus Bishop Score in Predicting Successful Outcome at Korle Bu Teaching Hospital (KBTH)"

This approval requires that you **forward your approved document to Korle Bu Teaching Hospital –Institutional Review Board (KBTH-IRB) for the ethical aspect of the proposal to be assessed before the project can be initiated.**

PRINCIPAL INVESTIGATOR: Teresa Aba Mensah

This STC approval is valid till 30th March, 2023

You may, however, request extension of the approval period, or renewal as the case may be, should the study extend beyond the stated period.

Upon completion, you are required to submit a final report on the study to the STC. This is to enable the STC ensure among others that, the project has been implemented as per the approved protocol. You are also required to inform the KBTH-STC and Research Directorate of any publications that may emanate from the research findings.

Kindly note that, should the need arise, the KBTH-STC or IRB may institute appropriate measures to satisfy itself that study is being conducted according to the highest scientific and ethical standards.

Please note that any modification to the study protocol without Scientific Technical Committee (STC) approval renders this approval invalid.

Prof. G. Obeng Adjei
Chairman, KBTH-STC

Cc: The Chairman, KBTH-IRB

APPENDIX VII: ETHICAL CLEARANCE

In case of reply the number
And the date of this
Letter should be quoted
My Ref. No. KBTH/MB/623/22
Your Ref. No.....

KORLE BU TEACHING HOSPITAL
P. O. BOX KB 77,
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Tel: +233 302 667759/673034-6
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Email: Info@kbth.gov.gh
pro@kbth.gov.gh
Website: www.kbth.gov.gh

4th July, 2022

DR TERESA ABA MENSAH
DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY
KORLE BU TEACHING HOSPITAL
ACCRA

LABOUR INDUCTION: TRANSVAGINAL SONOGRAPHIC CERVICAL LENGTH VERSUS BISHOP SCORE IN PREDICTING SUCCESSFUL OUTCOME AT KORLE BU TEACHING HOSPITAL (KBTH)

KBTH-IRB /00036/2022

Investigator: **DR TERESA ABA MENSAH**

The Korle Bu Teaching Hospital Institutional Review Board (KBTH IRB) reviewed and granted approval to the study entitled: "Labour Induction: Transvaginal Sonographic Cervical Length Versus Bishop Score in Prediction Successful Outcome at Korle Bu Teaching Hospital (KBTH)"

Please note that the Board requires you to submit a final review report on completion of this study to the KBTH-IRB.

Kindly, note that, any modification/amendment to the approved study protocol without approval from KBTH-IRB renders this certificate invalid.

Please report all serious adverse events related to this study to KBTH-IRB within seven days verbally and fourteen days in writing.

This IRB approval is valid till 30th June, 2023. You are to submit annual report for continuing review.

Sincere regards,

DR. DANIEL ANKRAH
VICE CHAIR (KBTH-IRB)
FOR: CHAIR (KBTH-IRB)

Cc: The Chief Executive Officer, KBTH
The Director of Medical Affairs, KBTH

APPENDIX VIII: INSTITUTIONAL APPROVAL

In case of reply the number
And the date of this
Letter should be quoted.
My Ref. No. KBTH/RD/23/22
Your Ref. No.....

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6th July, 2022

DR TERESA ABA MENSAH
DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY
KORLE BU

INSTITUTIONAL APPROVAL: KORLE BU TEACHING HOSPITAL-SCIENTIFIC AND TECHNICAL COMMITTEE/INSTITUTIONAL REVIEW BOARD (KBTH-STC/IRB/00036/2022

Following approval of your study entitled "Labour Induction: Transvaginal Sonographic Cervical Length versus Bishop Score in Prediction Successful Outcome at Korle Bu Teaching Hospital (KBTH)" by the Korle Bu Teaching Hospital-Scientific and Technical Committee/Institutional Review Board.

I am pleased to inform you that institutional approval has been granted for the conduct of your study in Korle Bu Teaching Hospital.

Please contact the Head of Department to discuss the commencement date of the study.

Please note that, this institutional approval is rendered invalid if the terms of the Institutional Reviewed Board/Scientific and Technical Committee approval are violated.

Sincere regards,

Dr. Ali Samba
Director of Medical Affairs
For: Chief Executive

RESEARCH PERSONNEL AND THEIR ROLES

- DR TERESA ABA MENSAH: PRINCIPAL INVESTIGATOR
- PROF KWAME ADU-BONSAFFOH: SUPERVISOR
- DR KWAKU ASAH-OPOKU: SUPERVISOR
- MADAM FELICIA SAMPSON LAWSON: RESEARCH ASSISSTANT
- MADAM SARAH AVEDZIDAH: RESEARCH ASSISSTANT