COMPARISON OF PREDICTION OF SUCCESSFUL INDUCTION BY USING TRANSVAGINAL ULTRASONOGRAPHIC CERVICAL LENGTH VERSUS MODIFIED BISHOP SCORE FOR TERM PREGNANT WOMEN

DISSERTATION SUBMITTED FOR

In partial fulfilment of the regulations for the award of the degree of

MASTER OF SURGERY

BRANCH - II

M.S. (OBSTETRICS AND GYNAECOLOGY)

THE TAMILNADU DR.MGR MEDICAL UNIVERSITY,

CHENNAI,

TAMIL NADU.

APRIL 2016

CERTIFICATE

This is to certify that the dissertation titled "**COMPARISON OF PREDICTION OF SUCCESSFUL INDUCTION BY USING TRANSVAGINAL ULTRASONOGRAPHIC CERVICAL LENGTH VERSUS MODIFIED BISHOP SCORE FOR TERM PREGNANT WOMEN"** is the bonafide work of **Dr. S. MUKILVIZHI,** in partfulfillment of the requirements for M.S (Obstetrics and Gynaecology) (Branch–II) examination of **The Tamilnadu Dr. M. G. R Medical University**, to be held in **APRIL 2016**. The Period of study was from May 2015 to September 2015.

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DECLARATION

I, **Dr. S. MUKILVIZHI,** solemnly declare that dissertation titled **"Comparison of Prediction of Successful Induction by Using Transvaginal Ultrasonographic Cervical Length Versus Modified Bishop Score for Term Pregnant Women"** is a bonafide work done by me at Kilpauk medical college, Chennai, during the period from May 2015 to September 2015,under the guidance and supervision of **Dr. T.K. SHAANTHY GUNASINGH. MD., DGO., HOD,** Professor of **Obstetrics and Gynaecology**, Kilpauk Medical College. This dissertation is submitted to **The Tamilnadu Dr. M.G.R. Medical University**, towards part fulfillment for M. S. Branch – (II), Part- II examination**.**

Place: Chennai

Date: **Dr. S. MUKILVIZHI**

ACKNOWLEDGEMENT

I sincerely thank **Prof. Dr. R. NARAYANA BABU**, **MD. DCH, DEAN**, Kilpauk Medical College for permitting me to do this study.

I sincerely thank of **Dr. T.K. SHAANTHY GUNASINGH. MD., DGO.** Head of the Department, Kilpauk Medical College for her concern, care, guidance and help.

I would like to express my sincere thanks to **Assistant Professors** who have guided me in completing this dissertation. I thank my colleagues and others for their immense help in completing this study. I also extend my gratitude for their support and encouragement during this study.

I thank all those patients who participated in the study, without whom this study would have been only a dream.

LIST OF ABBREVIATION

TVS	-	Trans Vaginal Sonography
GDM	-	Gestational Diabetes Mellitus
RCOG	-	Royal College of Obstetrician and Gynecologist
GA	-	Gestational Age
CX Length	-	Cervix Length
ROC	-	Receiver Operating Characteristics curve
PGE2	-	Prostoglandin E2
AUC	-	Area under curve
FH rate	-	Fetal Heart rate

INSTITUTIONAL ETHICAL COMMITTEE
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CERTIFICATE OF APPROVAL

The Institutional Ethical Committee of Govt. Kilpauk Medical College, Chennai reviewed and discussed the application for approval "Comparison of prediction of successful induction by using transvaginal ultrasonographic cervical length versus modified bishop score for term pregnant women – For Dissertation Purpose" submitted by Dr.S.Mukilvizhi, Post Graduate in MS (O&G), Govt. Kilpauk Medical College, Kilpauk, Chennai-10.

The Proposal is APPROVED.

The Institutional Ethical Committee expects to be informed about the progress of the study any Adverse Drug Reaction Occurring in the Course of the study any change in the protocol and patient information /informed consent and asks to be provided a copy of the final report.

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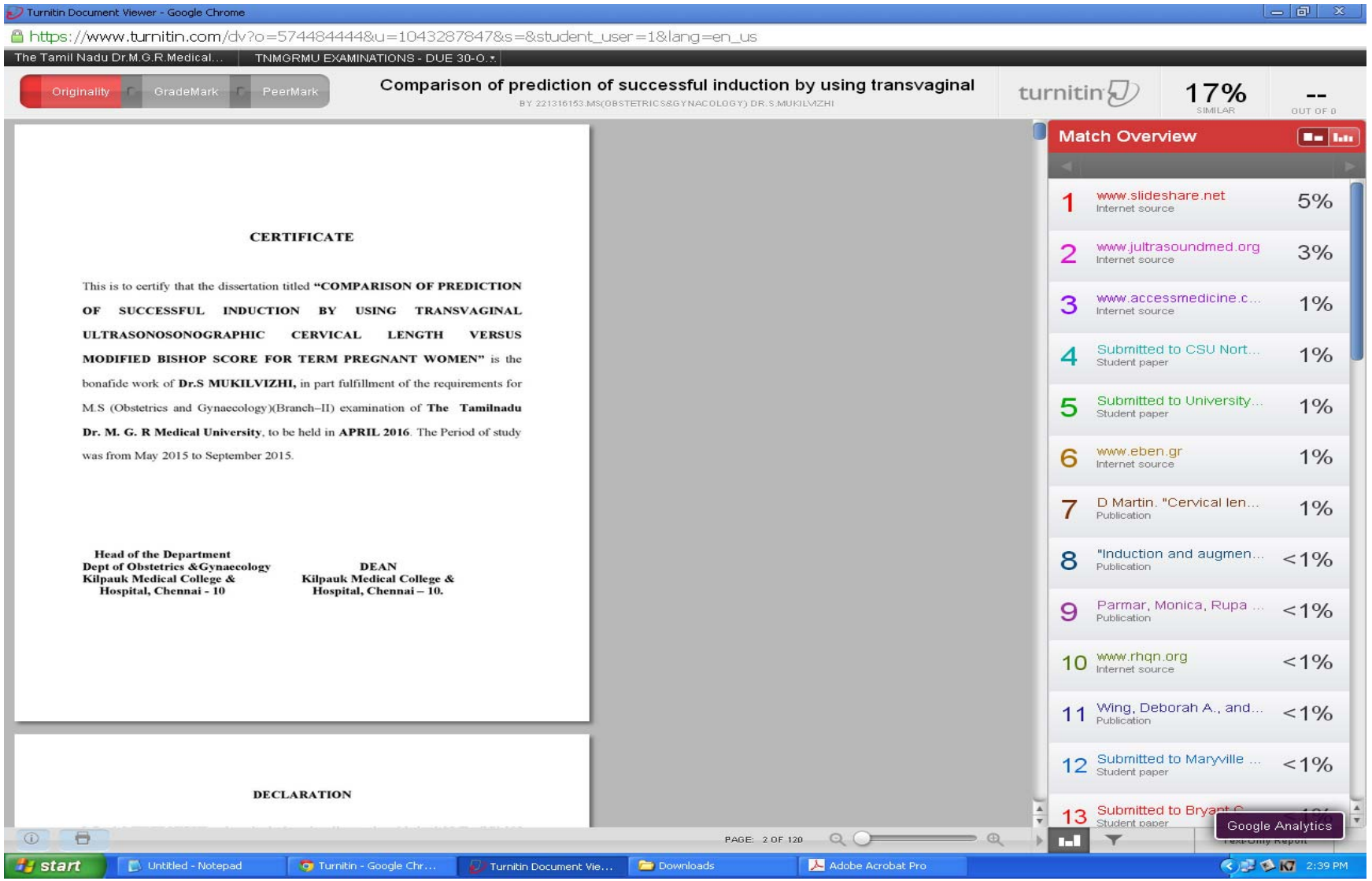
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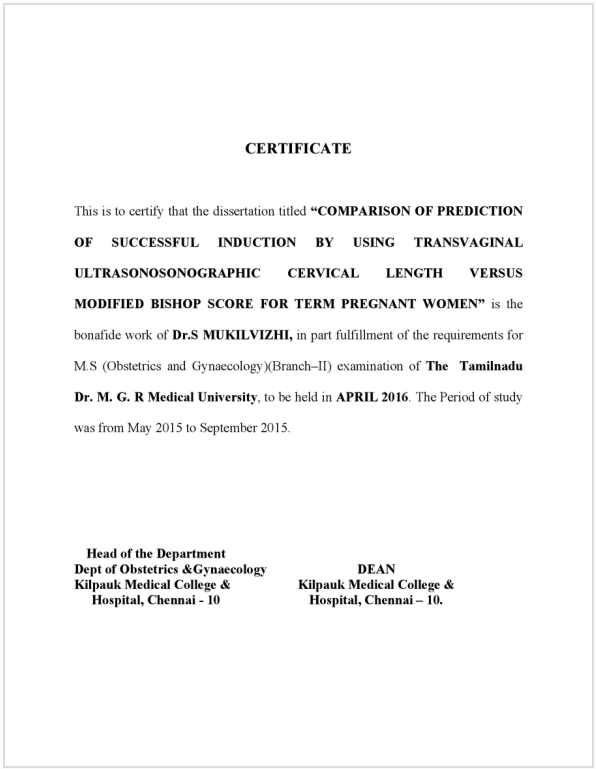

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CONTENTS

INTRODUCTION

Induction of labour is defined as intention to initiate the uterine contraction artificially, resulting in progressive effacement and dilation of cervix. 20% of pregnant women underwent induction of labour in all pregnancies. (Pandis et al., 2001;) (laencina et al., 2007). Cervical ripeness is assessed by Bishop score, but this shows high inter and intra observer variability. The alternative method is measurement of cervix by transvaginl sonography(TVS) which is a more objective method for assessing cervical length.

Cesarean delivery is more hazardous and also has a high risk in subsequent pregnancies. So successful induction of labour helps to reduce cesarean delivery and its complication.

TVS is used to assess the cervix and to find out the changes in internal os. Cervical length and funneling measurement by TVS is used for prediction of preterm labour and still controversy exists about whether ultrasonographic measurement of cervix is reliable for the prediction of induction in term pregnancy. Parity and indication for induction are influencing the mode of delivery and total duration of the labour. Initiation of labour is defined as successful labour induction that is represented by 3-4 centimeters of cervical dilations and regular uterine contractions.

Cervical length by TVS could independently predict the successful induction of labour in term pregnancy and to compare the usefulness of cervical length by TVS with Modified Bishop score in predicting the labour outcome.

REVIEW OF LITERATURE

Induction of labour is defined as stimulating the uterine contraction before the onset of spontaneous labour.

Augmentation is defined as stimulation of spontaneous contractions if the uterine contraction is insufficient. Induction of labour will be successful if the cervix is favorable. The ripeness of the cervix is to help the process of cervical softening, effacement and dilatation, reducing the induction - delivery time..

BISHOP SCORE

One of the quantifiable method to predict the outcome of labour induction is the Bishop score described by Bishop in 1964. A Bishop score of 9 conveys a high likelihood for a successful induction. Most practitioners considered that a woman whose cervix is 2 cm dilated, soft, and midposition, 80 percent effaced and fetal occiput at –1 station would have successful labour induction.

Bishop Scoring System

Factor					
Score	**Dilatation of cervix**	**Effacement (%)**	**cervix position**	**Cervix Consistency**	**Station**
0	Closed	0–30	posterior	Firm	-3
1	1–2	40–50	imposition	Medium	-2
2	3–4	60–70	anterior	Soft	-1
3	5	80	–	—	+1,+2

If Bishop score is 4 or less, it indicates unfavorable cervix but according to Arulkumaran et al, the Bishop score of 6 indicates unfavorable cervix.When the score is high,the induction will be quick and the risk of failed induction is lower. According to Chandra et al, there were no ultrasonographic characteristics for predicting successful labour induction.

OTHER METHOD OF CERVICAL ASSESMENT

Calkins method

Calkins in 1930 was the first cervical scoring system. He used the intensity of contraction, consistency, thickness of cervix and cervical length. Scales ranged from 1-5, in which 2 was considered as soft and 3 was considered as firm.

Cocks method

Cocks in 1955, described 5 types of cervix.1 and 2 were considered as ripe,3 and 4 considered as unripe,5 was considered as cervical anomaly.

Field's scoring

Field's scoring included the cervical factors, gestational age, estimated fetal weight, attitude of the patient, presence of uterine contraction and increased vaginal discharge.

ULTRASOUND ASSESSMENT OF CERVIX

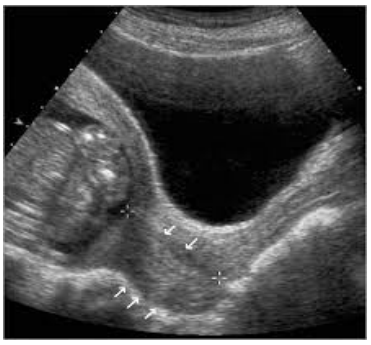
Available methods are

1. Trans abdominal
2. Trans labial
3. Trans perineal
4. Transvaginal approach

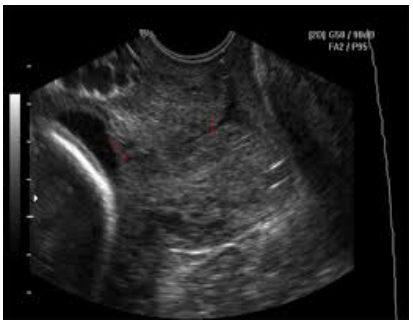
Trans abdominal approach:

Distention of the bladder is required for visualization of the cervix. In this method cervical length is more than actual length because of the distention of the bladder.

Trans abdominal scan showing measurement of cervical length



The translabial and transperineal methods are not successful methods because of reduced visualization of cervix due to bowel gas.



Transvaginal sonographic examination

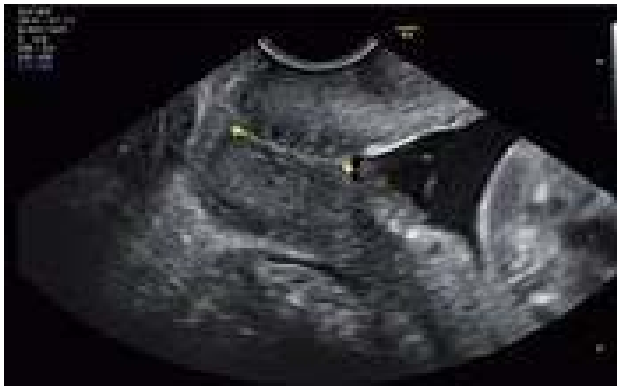
The following points are noted

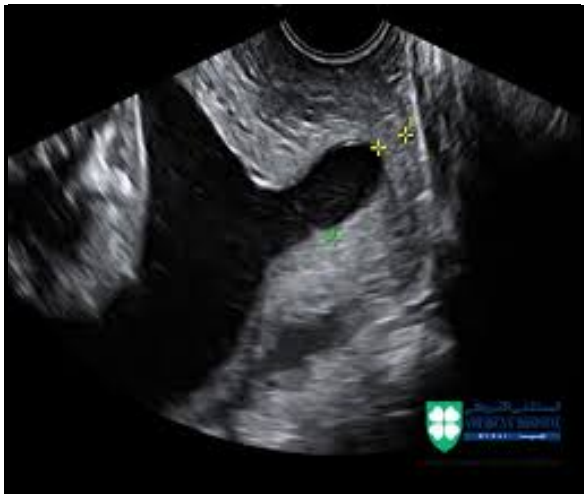
1) Cervical length,

2) Funneling

3) Width of the funnel

4) Length of the funnel





FUNNELING OF THE CERVIX

Ultrasonographic cervical measurement is a better predictor for the risk of cesarean delivery in labor induction than the Bishop score (Gabriel et al). Ware V, and Raynor BD showed that there was no difference in the mode of delivery in relation to various cervical lengths. Hatfield and associates (2007) in their meta-analysis assessed cervical length by transvaginal sonography. This was used to predict successful induction of labour, But according to Crane et al., (2006), cervical length determination by sonography was not superior to the use of Bishop score.

The presence of wedging detected by transvaginal ultrasonography was significantly associated with the latent-phase and total duration of induced labor but not in digital cervical examination. (Boozarjomehri et al). The length of the cervix and the Bishop score could predict the labor duration and the successful outcome of labour. (Ware and Raynor)

PHYSIOPHARMACOLOGY OF LABOUR:

Labour is characterized by onset of effective contraction, effacement and dilatation of cervix resulting in delivery of fetus, placenta and membranes. Estrogen, progesterone, prostaglandin, relaxin, corticosteroid and calcium play a role in human labour.

MYOMETRIUM AND ITS GAP JUNCTION

The myometrium contains smooth muscle cells arranged in longitudinal, transverse and oblique directions with intervening blood vessels. The electron microscopy shows gap junctions between two neighbouring cells. Electrical signal to all neighbouring myometrial cells are transmitted through gap junctions and leading to effective contraction. Oestrogen and prostaglandin induce gap junction while progesterone inhibits gap junction formation. Coding protein for this gap junction is connexin 43, which is elevated near term and during labour.

REGULARITY OF UTERINE CONTRACTION

Action and myosin interaction cause uterine contraction. Myosin is a principle protein dependent on calcium. Calcium interacts with calmodulin and phosphorylates the myosin light chain kinase. The phosporylated myosin interacts with action and produces contraction.

ROLE OF PEPTIDE HORMONES IN LABOUR

Oxytocin

Oxytocin is traditionally used as an agent for induction and augmentation of the labour. It induces contraction in a previously sensitized uterus. Oxytocin increases intracellular ionic calcium. It causes

amplification of both frequency and duration of electrical discharge from myometrial cells and also promotes synthesis and release of prostaglandins. Prostaglandin E2 and F2 Alfa from uterine decidua cause myometrial contractility. The effect of the oxytocin is increased in late pregnancy and during labour. Oxytocin receptors appear after 20 weeks of gestation, so the myometrium is insensitive to oxytocin in early pregnancy. Progesterone inhibits the development of oxytocin receptors and estrogen stimulates the development of oxytocin receptors.The antagonist of oxytocin is Atosiban.

Relaxin produces cervical ripening, its main action is activation of collagenase.

Adrenergic stimulation

Stimulation of alfa and beta receptors cause contraction and relaxation of myometrium respectively. Estrogen causes reduction of myometrial sensitivity to beta agonist induced relaxation. This effect is antagonized by progesterone.

Cholinergic system

Acetyl choline[Ach] induces uterine contraction, but the level is unchanged during pregnancy and labour. Intravenous Ach induces labour at term very effectively but its side effects are unacceptable.

Role of prostaglandin

The prostanoids belong to G-protein-coupled receptors, most of them are produced in myometrium (Myatt and Lye, 2004). Most of the prostaglandins are uterotonics and some act as smooth muscle relaxants.

Prostaglandins are produced by arachidonic acid and is released by the action of the phospholipases A_2 or C on membrane phospholipids. The Arachidonic acids are converted to unstable endoperoxides(EP) prostaglandin G_2 and then to prostaglandin H_2 by COX (cyclooxygenase). These enzymes are the target of many nonsteroidal anti-inflammatory drugs (NSAID). Active prostaglandins, including PGE2, PGF_2 and PGI2 are derived from Prostaglandin H_2.

The prostaglandins act through number of G-protein-coupled prostaglandin receptors (Coleman and associates, 1994). PGE_2 and PGI_2 are maintaining the uterine relaxation by increasing the cAMP signaling, yet PGE_2 can cause uterine contractility by acting through EP_1 and EP_3 receptors. COX 2 is spatially regulated in myometrium and cervix. (Myatt and Lye, 2004)

Phases of Parturition

Parturition needs a lot of changes in function of both uterus and cervix. Parturition is divided into four phases that are related to the changes of the myometrium and cervix during pregnancy.

PHASE 1 - PARTURITION

Quiescence of uterus and Cervical Softening

Uterine smooth muscle quiescence with maintenance of cervical structural integrity is seen in 95% of pregnancy. In parturition PHASE 1 uterus undergoes extensive changes in its size and vascularity to accommodate the pregnancy. The unresponsiveness of the myometrium continues until near the end of pregnancy.

False pain is characterized by irregular, low intensity and short duration of uterine contraction. Usually discomfort is confined to the lower abdomen and groin. False labour is more common near the end of the pregnancy especially in multiparous women.

Cervix

1) Acts as a barrier to protect the reproductive tract from infection
2) Maintenance of cervical competence in spite of the increasing gravitational forces by the expanding uterus
3) Progressive increase in tissue compliance of the cervix due to extracellular matrix changes for preparation of birth.

In nonpregnant women, the cervix is closed and firm similar to nasal cartilage. The cervix is easily distensible by the end of pregnancy and its consistency is similar to the lips of the oral cavity. This softening

is due to increase in tissue compliance. Unfavorable pregnancy outcome that ends most often in preterm delivery is due to alteration in cervical anatomical and structural integrity. According to Hibbard and associates (2000) cervical shortening between 16 and 24 weeks has been associated with an increased risk of preterm delivery

Structural Changes with Softening

Increased vascularity, stromal hypertrophy, glandular hypertrophy and hyperplasia, and changes in extracellular matrix cause cervical softening. Progressive increase in turnover of matrix components during phase 1 of parturition and an increase in collagen solubility cause softening of cervix. In Ehlers-Danlos and Marfan syndromes with inherited defects in collagen and elastin synthesis or assembly cause cervical incompetence

PHASE 2 - PARTURITION: PREPARATION FOR LABOUR

Progression of uterine changes start in the last 6 to 8 weeks of pregnancy. Thus, understanding myometrial and cervical modifications during phase 2 provides a better understanding of events leading to normal and abnormal labour.

Myometrial Changes

Oxytocin receptor, prostaglandin F receptor and connexin 43 are the contraction- associated proteins (Smith, 2007). Myometrial oxytocin receptors, surface areas of gap junction proteins such as connexin 43 lead to increased uterine irritability and responsiveness to uterotonics agents that stimulate contractions. Formation of the lower uterine segment from the isthmus is another critical change in phase 2.With this development, the fetal head often descends to the pelvic inlet called lightening.

Cervical Ripening during Phase 2

The cervix must undergo more extensive remodeling prior to the initiation of contractions. Cervical modifications during the second phase principally involve connective tissue changes to produce cervical softening. The total amount and composition of proteoglycans and glycosaminoglycans within the matrix are altered during this transformation. The smooth muscle is predominantly in uterine corpus whereas the cervix is primarily connective tissue. Smooth muscle, fibroblasts and epithelia are the cellular components of the cervix.

Endocervical Epithelia

Endocervical epithelial cells proliferate during pregnancy and endocervical glands occupy a significant percentage of cervical mass by

the end of pregnancy. Mucus-secreting columnar and stratified squamous epithelia lining the endocervical canal which protect against microbial invasion Hydration may be regulated by expression of aquaporins – water channel proteins, Claudins 1 and 2 tight junction that regulate the maintenance of barrier function and paracellular transport of ion and solutes.

Cervical Connective Tissue

The cervix is comprised primarily of extracellular connective tissue. Only 10 to 15 percentage is smooth muscle. Extracellular connective tissue is composed of type I, III, and IV collagen, glycosaminoglycans, proteoglycans, and elastin.

Collagen

The major portion of the cervix is made up of collagen. Collagen is the most abundant mammalian protein. Each collagen molecule is composed of three alpha chains, which wind around each other to form procollagen. Multiple collagen triple-helical molecules cross linked to one another by the actions of lysyl oxidase to form long fibrils. In cervical ripening collagen fibrils are disorganized, and there is increased spacing between fibrils.

Inflammatory Changes

In Phase 2, the inflammatory cells invade stroma. Cervical ripening is considered as an inflammatory process and cervical chemoattractants attract inflammatory cells, which release proteases and cause degradation of collagen and other matrix components. There is increased cervical expression of chemokines and collagenase/protease activity.

Induction and Prevention of Cervical Ripening

Direct application of prostaglandins E_2 (PGE2) and F_2 to promote cervical ripening.

Prostaglandin alters collagen and other related glycosaminoglycan concentrations.

PARTURITION -PHASE 3

Phase 3 is active labour, that is contraction of uterus causes progressive cervical dilatation followed by delivery.

Phase 3 is divided into the three stages of labour.

1. The first stage begins with uterine contractions to bring about cervical thinning, termed Effacement. This stage ends when the

cervix is fully dilated about 10 cm to allow the passage of the fetal head.

2. The second stage begins with fully dilated cervix to delivery of fetus

3. The third stage begins after delivery of the fetus and ends with the delivery of the placenta

First Stage of Labour

Cervical Changes during First-Stage of Labour

Effacement and dilatation of the cervix take place in the already ripened cervix resulting in uterine contractions. During effacement of cervix there may be no fetal descent. In nulliparas the presenting part typically descends slowly and steadily. In multiparas, descent may be rapid in particularly those of high parity.

"Taking up" of the cervix is cervical effacement. It manifests as shortening of the cervical canal to a mere circular orifice with almost paper-thin edges. The muscular fibers at level of the internal cervical os are taken up into the lower uterine segment.

Second Stage of Labour

Engagement of the head is accomplished before the labour begins in many nulliparas. Active descent usually takes place after dilatation has progressed. In nulliparas, increased rates of descent are observed during cervical dilatation. At this time, the speed of descent is also maximal and is maintained until the presenting part reaches the perineal floor.

PARTURITION -PHASE 4 : THE PUERPERIUM

The myometrium remains in a state of rigid and persistent contraction and retraction after an hour of delivery. This directly compresses large uterine vessels and allows thrombosis of their lumen and prevents postpartum hemorrhage.

Cervical Dilatation during Labour

Cervical dilatation is characterized by a large influx of leukocytes into the cervical stroma (Sakamoto and co-workers, 2004, 2005). IL-8 and its receptors are increased soon after delivery in cervical tissue. The composition of glycosaminoglycans, proteoglycans and poorly formed collagen fibrils that were necessary during ripening and dilatation and must be rapidly removed to allow reorganization and recovery of cervical structure. After parturition, rapid recovery of cervical structure involves

processes that resolve inflammation, promote tissue repair, and recreate dense cervical connective tissue and structural integrity.

INDICATIONS FOR INDUCTION OF LABOUR

Induction is indicated when the benefits outweigh those of continuing the pregnancy to either mother or fetus.

1. Ruptured membranes with chorioamnionitis
2. Severe preeclampsia
3. Membrane rupture without labour
4. Gestational hypertension
5. Postterm pregnancy
6. Chronic hypertension and diabetes

Contraindications

Fetal factors

1. Macrosomia
2. Multiple pregnancy
3. Severe hydrocephalus
4. Malpresentation
5. Nonreassuring fetal status

Maternal contraindications

1. Previous classical cesarean section
2. Contracted or distorted pelvic anatomy
3. Abnormal placentation
4. Active genital herpes infection
5. Cervical cancer

Maternal complications:

1. Cesarean delivery
2. Chorioamnionitis
3. Uterine atony

Cesarean Delivery Rate

Cesarean delivery rate is increased in nulliparas undergoing induction (Luthy and colleagues, 2004; Yeast and associates, 1999). A number of investigators have reported two to threefold risks of cesarean delivery rate with induction. (Hoffman and Sciscione, 2003; Maslow and Sweeny, 2000; Smith and colleagues, 2003).

Cesarean rate is inversely related to favorability of the cervix at induction, that is pre-induction cervical ripening may not lower the cesarean delivery rate in a nullipara with an unfavorable cervix.The risk

is increased in nulliparas more than 41 weeks with an unengaged head increases 12-fold compared with that of those with an engaged vertex (Shin and associates, 2004). There is no increased risk if the engaged fetal head is occiput posterior at the time of induction (Peregrine and coll).

Chorioamnionitis

Women whose labor was induced have an increased incidence of chorioamnionitis than women with spontaneous labour.

Uterine Atony

Postpartum atony and Hemorrhage are more common. Intractable atony is the indication for a third of all cesarean hysterectomies. It is more prevalent in women with induced or augmented labor or in those with chorioamnionitis.

Elective Labour Induction

Elective induction has been done for the convenience of the practitioner or the woman and her family. Despite this, the American College of Obstetricians and Gynecologists do not support this practice, except for logistical reasons such as a risk of rapid labor, a woman who lives at long distance from the hospital or psychosocial indications.If

elective induction is considered at term, these risks must be discussed and informed consent to be obtained.

Expectations of Labour Induction

Several factors increase the success of labor induction and include

1. Multiparity,
2. Body mass index (BMI) <30
3. Favorable cervix, and
4. Birthweight <3500 g.

METHODS OF INDUCTION

Methods used for cervical ripening include pharmacological preparations and various forms of mechanical cervical distension.

Pharmacological Techniques

Prostaglandin E_2

Local application of prostaglandin E_2 dinoprostone is commonly used for cervical ripening according to American College of Obstetricians and Gynecologists recommendations. Its gel form Cerviprime is available in a 2.5ml syringe for an intracervical application of 0.5 mg of dinoprostone. The woman to be placed in supine position, the tip of a pre-

filled syringe is placed intracervically, and the gel is deposited just below the internal cervical os. After this application she has to be placed in left lateral position for minimum 30 minutes. Doses can be repeated every 6 hours, with a maximum of three doses recommended in 24 hours. Prostaglandin E2 improves the Bishop scores when coupled with oxytocin, lowered induction to delivery times compared with those of women treated with oxytocin alone but they could not find benefit in lowering the cesarean delivery rate (Owen and colleagues (1991).

Administration

Prostaglandin preparations should only be administered in or near the delivery suite, and at the same time uterine activity, fetal heart rate monitoring should be performed according to American College of Obstetricians and Gynecologists, (1995). When contractions begin, they are usually apparent in the first hour and show peak activity in the first 4 hours. A study from Perry and Leaphart (2004) compared intracervical gel with the intravaginal insert (Prepidil) and found that intravaginal placement resulted in quicker delivery. But when more than two sequential doses of a prostaglandin E2 insert were used, 59 percent of women required emergency cesarean delivery in their study, according to Chan and associates (2004). According to manufacturer guidelines

following prostaglandin E_2 administration, oxytocin induction should be delayed for 6 to 12 hours.

SIDE EFFECTS

1. Uterine tachysystole is defined as 6 contractions in a 10-minute period.
2. Uterine hypertonus is described as a single contraction lasting longer than 2 minutes.
3. Uterine hyper stimulation leads to nonreassuring fetal heart rate pattern.

Contraindications to prostaglandin agents

It includes asthma, glaucoma, or increased intraocular pressure and manufacturer recommendations caution against its use in women with ruptured membranes.

PROSTAGLANDIN E 1

Misoprostol is a synthetic prostaglandin E1, approved as a 100 or 200 microgram tablet for treatment of peptic ulcers, and used "off label" for preinduction cervical ripening and administered via orally or vaginally. The off-label use of misoprostol is controversial according toWagner (2005), Weeks and associates,(2005). In 2000, G. D. Searle &

Company notified that misoprostol is not approved for labour induction or abortion. Despite this, the American College of Obstetricians and Gynecologists (2000) quickly reaffirmed its recommendation for the use of this drug because of proven safety and efficacy at a dose of 25 microgram.

VAGINAL ADMINISTRATION

Several investigators have reported that misoprostol tablets placed into the vagina were either of equivalent or superior efficacy compared with intracervical prostaglandin E2 gel. This was found in studies by von Gemund and associates, 2004 and Wing and co-workers, 1995. The American College of Obstetricians and Gynecologists (1999) reviewed 19 randomized trials in which more than 1900 women were given intravaginal misoprostol in doses ranging from 25 to 200 microgram. They recommended 25-microgram dose a fourth of a 100 microgramtablet. The drug is evenly distributed among these quartered tablets.

Misoprostol use may decrease the need for oxytocin induction and reduce induction to delivery intervals based on study by Sanchez-Ramos and colleagues, (1991). The study by Wing and co-workers, (1995) showed that 50 microgram misoprostol intravaginal dose has been

associated with significantly increased uterine tachysystole, meconium passage, and meconium aspiration compared with prostaglandin E2 gel. Prostaglandin E1 use in women with a prior cesarean delivery causes uterine rupture as reported by Wing and colleagues (1998) but Plaut and associates (1999) reported uterine rupture in 5 out of 89 women and these women had a prior classical cesarean incision and induced with misoprostol. Currently, the consensus is that prior uterine surgery, including cesarean delivery, precludes the use of misoprostol (American College of Obstetricians and Gynecologists, 2004).

ORAL ADMINISTRATION

When given orally Prostaglandin E1 tablets are effective. Windrim and associates (1997) reported oral misoprostol administration to be of similar efficacy as intravaginal administration.

Labour Induction with Prostaglandin E_1

For cervical ripening or labour induction both vaginal and oral misoprostol can be used. Hofmeyer and Gulmezoglu (2007) reported that for labour induction, vaginal misoprostol followed by oxytocin if needed, to be superior to oxytocin alone. Rates of delivery section were variable. Some studies showed decreased rates of cesarean with misoprostol whereas others found no difference in rates of cesarean delivery. Lin and

co-workers, 2005; Lo and associates, 2003 study said that 100 microgram of oral or 25 microgram of vaginal misoprostol is similar in efficacy with intravenous oxytocin for labour induction in women at or near term with either prematurely ruptured membranes or a favorable cervix. Misoprostol may be associated with an increased rate of hyper stimulation. In some occasions, PGE1 may prove ineffective and require subsequent augmentation with oxytocin. For labour augmentation, Villano and colleagues, 2010 study showed that the oral misoprostol 75 microgram given at 4-hour intervals for a maximum of two doses, to be safe and effective.

Labour Induction and Augmentation with Oxytocin

Mostly, pre-induction cervical ripening and labour induction are simply a continuum. Often "ripening" will also stimulate labour. Synthetic oxytocin is one of the most commonly used medications in the United States. It was the first synthesized polypeptide hormone. It may be used for induction or for augmentation of labour.

With oxytocin use, fetal heart rate and uterine contraction monitoring is similar to that for any high-risk pregnancy. Contractions can be monitored either by palpation or by electronic means of recording uterine activity.

Intravenous Oxytocin Administration:

The goal of induction or augmentation is to produce cervical change and fetal descent, while avoiding development of a nonreassuring fetal status. Usually, oxytocin should be discontinued if the number of contractions persists with a frequency greater than five in a 10-minute period or seven in a 15-minute period or with a persistent nonreassuring fetal heart rate pattern. The mean half-life is approximately 5 minutes so when it is stopped, its concentration in plasma rapidly falls. According to Seitchik and co-workers (1984) found that the uterus contracts within 3 to 5 minutes of beginning of an oxytocin infusion and that a plasma steady-state is reached in 40 minutes. Response depends upon the preexisting uterine activity, cervical status, pregnancy duration, and individual biological differences. Caldeyro-Barcia and Poseiro (1960) reported that the uterine response to oxytocin increases from 20 to 30 weeks and increases rapidly at term.

OXYTOCIN DOSES:

One ampoule is 1 ml which contains 5 units usually is diluted into 500 ml of a crystalloid solution (RL or NS) and administered by infusion pump. To avoid bolus administration, the infusion should be inserted into the main intravenous line close to the venipuncture site. A number of

oxytocin regimens for labour stimulation are recommended by the American College of Obstetricians and Gynecologists as given below.

Regimen	Starting dose (mU/min)	Incremental Increase (mU/min)	Interval (min)
Lowdose	0.5–1.5	1	15–40
	2	4, 8, 12, 16, 20 25, 30	15
Highdose	4	4	15
	4.5	4.5	15–30
	6	6[a]	20–40[b]

Satin and colleagues (1992), from Parkland Hospital, evaluated an oxytocin regimen using an initial and incremental dosage of 6 mU/min compared with one using 1 mU/min. Increases at 20-minute intervals were provided as needed. Among 1,112 women undergoing induction, the 6-mU/min regimen resulted in a shorter mean admission to delivery time, fewer failed inductions, and no cases of neonatal sepsis. With this protocol, uterine hyperstimulation is managed by oxytocin discontinuation followed by resumption. Thereafter, the dosage is increased at 3 mU/min when appropriate instead of the usual 6-mU/min increase for women without hyperstimulation.

Xenakis and colleagues (1995) reported benefits using an incremental oxytocin regimen starting at 4 mU/min. Nulliparas randomized to the 4.5 mU/min dosage had a significantly lower cesarean delivery rate for dystocia compared with those given 1.5 mU/min dosage.

So benefits favor for higher-dose regimens of 4.5 to 6 mU/min compared with lower dosages of 0.5 to 1.5 mU/min.

MECHANICAL TECHNIQUE

Transcervical Catheter

A Foley catheter may be placed through the internal cervical os. Downward tension is created by taping the catheter to the thigh. A modification of this procedure, termed extra-amnionic saline infusion (EASI), consists of a constant saline infusion through the catheter into the space between the internal cervical os and placental membranes. Catheter placement, with or without continuous saline infusion, results in improved cervical favorability and frequently stimulates contractions according to Guinn and associates, (2004).

Extra-Amnionic Saline Infusion (EASI)

This technique has been reported as to significantly improve the Bishop score and decrease induction to delivery times. In another study, Guinn and colleagues (2000) randomized women to intracervical prostaglandin E_2, laminaria tent plus intravenous oxytocin, or EASI plus oxytocin. The cesarean delivery rate was similar with all three interventions. The mean induction to delivery time of 18 hours with

catheter infusion was significantly less than the 21 hours with laminaria plus oxytocin or the 25 hours with prostaglandin E_2 gel.

In one another follow-up study by Sciscione and co-workers (2004) it was shown that cervical ripening with a Foley catheter did not increase the risk of preterm birth in a subsequent pregnancy.

Hygroscopic Cervical Dilators

Cervical dilatation can be done by using hygroscopic osmotic cervical dilators. These mechanical dilators was successfully used when inserted prior to pregnancy termination according to Hale and Pion, (1972). More recently, it is used for cervical ripening before labour induction. Their use appears to be safe but anaphylaxis was reported in laminaria insertion (Cole and Bruck, 2000; Nguyen and Hoffman, 1995). Their cost is low and placement and removal are easy.

Gilson and associates (1996) reported that there was a rapid improvement of cervical favorability in women randomized to hygroscopic dilators prior to oxytocin induction, and found that there was no beneficial effect on the vaginal delivery rate or induction to delivery interval compared with those of participants given oxytocin only.

Membrane Sweeping for Labour Induction

Induction of labour by membrane "stripping" is a common practice. McColgin and colleagues (1990) reported that stripping was safe and decreased the incidence of postterm pregnancy and there was significant increased serum levels of endogenous prostaglandins with stripping (McColgin and associates, 1993). Allott and Palmer (1993) in their study found that two thirds of those who underwent stripping entered spontaneous labor within 72 hours compared with one third of the other group. The incidence of ruptured membranes, infection, and bleeding was very less and another important thing is subsequent induction for postterm pregnancy at 42 weeks was significantly decreased with stripping.

Amniotomy

Artificial rupture of membranes release endogenous prostaglandin and result in labour. But it takes longer time for onset of uterine contraction, so risk of maternal and fetal infection is more and when it is combined with early oxytocin infusion, the induction delivery interval was shorter (Moldin and Sundell 1996). RCOG does not recommend amniotomy alone for induction of labour except if there is any contraindication to pharmacological intervention.

NONPHARMACOLOGICAL METHODS OF INDUCTION

The human semen contains high natural prostaglandin concentration. It might induce contraction (Benvold EC,1987) when deposited in the vagina in sexual intercouse. In Cochrane review,it was found that there were no observed benefit.

Breast stimulation causes uterine contraction but the mechanism was not known and nipple stimulation also causes contraction but time taken for induction is not known and relatively reduces the postpartum hemorrhage.

AIM OF THE STUDY

To predict the mode of delivery in women administered dinoprostone gel for induction of labour

OBJECTIVES

1. To predict successful induction by transvaginal ultrasonographic cervical length and modified bishop score in women administered Dinoprostone gel for induction of labour.

2. To compare the performance of both by sensitivity, specificity and area under curve(AUC) for its efficacy in prediction of good labour outcome.

INCLUSION CRITERIA

1) 37 completed or greater weeks

2) Vertex presentation

3) Membranes should be intact

4) Less than 2 cm of cervical dilatation

EXCLUSION CRITERIA

1. Any contra-indication to induction of labour
2. Nonreassuring CTG
3. Previous uterine surgery
4. Contra-indications to prostaglandins or vaginal delivery

INDICATIONS FOR INDUCTION OF LABOUR

1. Postdated pregnancy- 41 completed weeks or greater
2. Oligohydramnios
3. Preeclampsia
4. Gestational diabetes
5. IUGR

SAMPLE SIZE

$$\frac{Z^2 X\ P[1-P]}{D^2}$$

$$= \frac{1.96X1.96[0.89(1-0.89)]}{0.05\ X0.05}$$

$$=150$$

MATERIALS AND METHODS

The pregnant women at term, in vertex presentation and with cervical dilatation 2 cm and below were selected for this study. This study was conducted in Department of Obstetrics and Gynaecology, Kilpauk Medical college & Hospital. Informed written consent was obtained from all participants. Under strict aseptic precaution, their cervical length was measured by TVS followed by Bishop score. In Ultrasonographic Assessment of the Cervix, Transvaginal sonographic cervical assessment was done and the parameters like cervical length, the presence of funneling, funnel width and funnel length were obtained.

The length of the cervix is measured by using transvaginal real-time ultrasonography with an empty bladder. The transducer is placed in the anterior fornix of the vagina. Three anatomic landmarks were noted in sagittal view :the internal os, the external os and the endocervical canal. The image was enlarged while visualizing the three landmarks simultaneously. Gentle pressure was exerted on the cervix by the transducer to allow the visualization of three land marks. This procedure was repeated three times and the shortest measurement was recorded.

Modified Bishop Score (APPENDIX 1)

SCORE	0	1	2	3
Dilatation in cm	Closed	1-2	3-4	5
Length in cm	>4	3-4	1-2	0
Consistency	Firm	Medium	soft	-
position	Posterior	Midline	Anterior	-
Station	-3	-2	-1,0	+1,+2

The Modified Bishop scoring system had all components of Bishop score but effacement was considered in terms of cervical length in centimeters. If the Bishop score is 4 or less and the Nonstress test is normal, a prostaglandin E2 (PGE2) gel was introduced into the endocervical canal within 1 hour of cervical assessment. Dinoprostone gel contains 0.5 mg of dinoprostone available in a 2.5 ml preloaded syringe for intracervical application.

The woman was placed in a dorsal position. Cervix is held with sponge holding forceps.The tip of the cannula was inserted just below the internal os. Then the gel is instilled into the cervix. The woman is kept in a left lateral position for the next 30 minutes. FH is monitored. Bishop score was assessed after 6 hours. If there is no improvement in Bishop score,the second dose of gel will be readministered and a total of 3 doses

will be administered. Patient reviewed for improvement in Bishop score 6 hours later. If the cervix is 50% effaced, 2 cm dilated then labour will be accelerated by artificial rupture of membrane and oxytocin infusion. Successful induction was identified by active labour within 24 hours of gel induction.

STATISTICAL ANALYSIS

1. Chi square test:

This test shows the relationship between two categorical variables. Its value reflects the strength of this relationship.

2. For continuous variable, t test (2 groups), one way of Analysis of variance (ANOVA) (more than 2 groups) were used. If the values are not following normal, Non parametric ANOVA were used.
3. Receiver-operating characteristic (ROC) curves are an excellent way to compare diagnostic tests.

The ROC curves representing excellent, good, and worthless tests plotted on the same graph. The accuracy of the test depends on how well the test separates the group being tested into those with and without the disease in question. Accuracy is measured by the area under the ROC curve. An area of 1 represents a perfect test; an area of .5 represents a

worthless test. A rough guide for classifying the accuracy of a diagnostic test is the traditional academic point system:

- .90-1 = excellent (A)
- .80-.90 = good (B)
- .70-.80 = fair (C)
- .60-.70 = poor (D)
- .50-.60 = fail (F)

p value

The probability that a finding has occurred randomly rather than as a result of a treatment or other intervention. A *p* value = < 0.05 is often considered significant, but the lower this figure, the stronger the evidence.

RESULTS

The study population included 150 at term women. In this study, the cervical length by TVS and Modified Bishop score were used to predict the successful induction of labour. The following results were obtained.

Table 1.RELATION BETWEEN AGE GROUP AND INDUCTION

AGE GROUPS		INDUCTION		
		SUCCESSFUL INDUCTION	FAILED INDUCTION	Total
Till 20 yrs	Count	21	7	28
	% within AGE GROUP	75.0%	25.0%	100.0%
	% group in toto	21.4%	13.5%	18.7%
21 to 30 yrs	Count	73	41	114
	% within AGE GROUP	64.0%	36.0%	100.0%
	% group in toto	74.5%	78.8%	76.0%
31 yrs and above	Count	4	4	8
	% within AGE GROUP	50.0%	50.0%	100.0%
	% group in toto	4.1%	7.7%	5.3%
Total	Count	98	52	150
	% within AGE GROUP	65.3%	34.7%	100.0%
	% group in toto	100.0%	100.0%	100.0%

Chi square=2.071 P= 0.355 Not significant

Table 1 shows that majority of successful induction belonged to the 21-30 years age class interval (n=73, 74.5%) with a mean age of 23.82 years. The association between the study groups with age distribution is considered to be statistically not significant since $p < 0.355$ as per Chi square test.

Figure 1

RELATION BETWEEN AGE GROUP AND INDUCTION

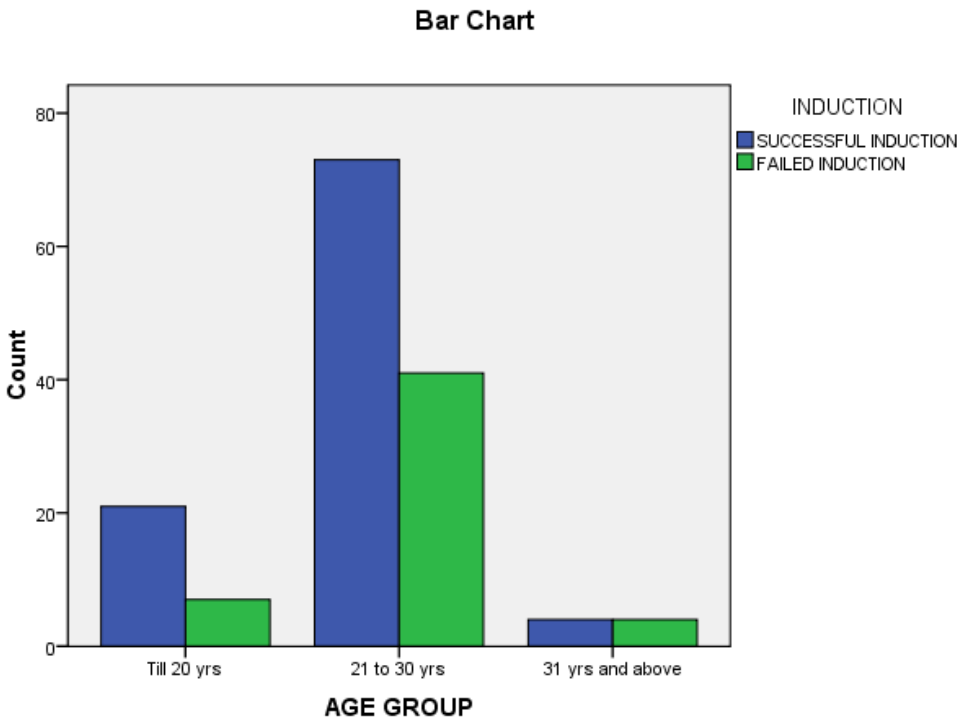


FIGURE 1 Shows that majority of successful induction is seen between 21-30 years .

TABLE 2 : RELATION BETWEEN PARITY AND INDUCTION OF LABOUR

PARITY			INDUCTION		
			SUCCESSFUL INDUCTION	FAILED INDUCTION	Total
	NULLI PAROUS	Count	60	41	101
		% within PARITY	59.4%	40.6%	100.0%
		% within INDUCTION	61.2%	78.8%	67.3%
		Group in toto			
	MULTI PAROUS	Count	38	11	49
		% within PARITY	77.6%	22.4%	100.0%
		% within INDUCTION			
		% group in toto	38.8%	21.2%	32.7%
	Total	Count	98	52	150
		% within PARITY	65.3%	34.7%	100.0%

Chi square = 4.796 p=0.029 significant

Figure 2 : RELATION BETWEEN PARITY AND INDUCTION OF LABOUR

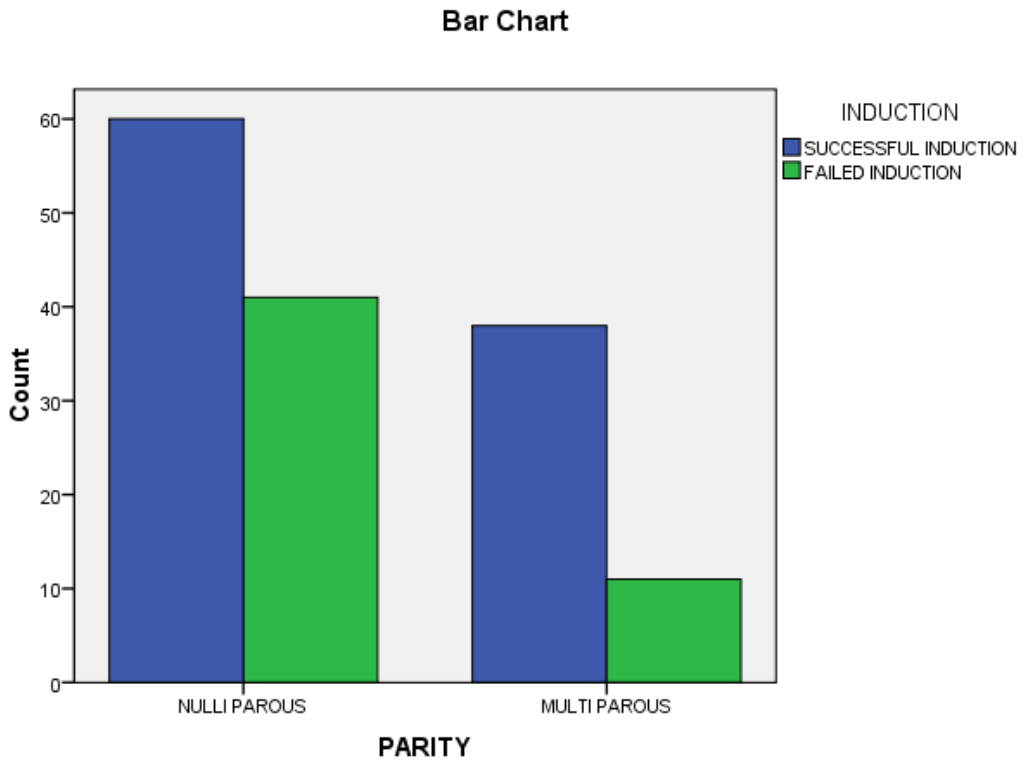


Table 2 and Figure 2 shows that,the percentage of failed induction (78.8%) was more in nulliparous women than multiparous women (21.2%). Percentage of successful induction is more in multiparous (77.6%) than nulliparous women (59.4%). This is statistically significant since the p value is 0.029.

Table 3 : RELATION BETWEEN GESTATIONAL AGE AND INDUCTION OF LABOUR

GESTATIONL AGE		INDUCTION		
		SUCCESSFUL INDUCTION	FAILED INDUCTION	Total
37 WEEKS	Count	4	3	7
	% within GESTATIONAL AGE	57.1%	42.9%	100.0%
	% within INDUCTION	4.1%	5.8%	4.7%
	% of Total	2.7%	2.0%	4.7%
38 WEEKS	Count	5	1	6
	% within GESTATIONAL AGE	83.3%	16.7%	100.0%
	% within INDUCTION	5.1%	1.9%	4.0%
	% of Total	3.3%	.7%	4.0%
39 WEEKS	Count	17	8	25
	% within GESTATIONAL AGE	68.0%	32.0%	100.0%
	% within INDUCTION	17.3%	15.4%	16.7%
	% of Total	11.3%	5.3%	16.7%

40 WEEKS	Count	52	32	84
	% within GESTATIONAL AGE	61.9%	38.1%	100.0%
	% within INDUCTION	53.1%	61.5%	56.0%
	% of Total	34.7%	21.3%	56.0%
41 WEEKS	Count	20	8	28
	% within GESTATIONAL AGE	71.4%	28.6%	100.0%
	% within INDUCTION	20.4%	15.4%	18.7%
	% of Total	13.3%	5.3%	18.7%
Total	Count	98	52	150
	% within GESTATIONAL AGE	65.3%	34.7%	100.0%
	% within INDUCTION	100.0%	100.0%	100.0%
	% of Total	65.3%	34.7%	100.0%

Chi-Square Tests-2.039, P value-0.729

Table 3 shown that percentage of successful induction is more in 40weeks group 53.1%.The association between gestational age and induction of labour statistically not significant since p value is 0.729

Table 4 : RELATION BETWEEN BISHOP SCORE AND INDUCTION OF LABOUR

BISHOP SCORE			INDUCTION	
			SUCCESSFUL INDUCTION	FAILED INDUCTION
	>4	Count	61	25
		% within BISHOP SCORE	70.9%	29.1%
		% within INDUCTION	62.2%	48.1%
		% of Total	40.7%	16.7%
	LESS THAN OR EQUAL TO 4	Count	37	27
		% within BISHOP SCORE	57.8%	42.2%
		% within INDUCTION	37.8%	51.9%
		% of Total	24.7%	18.0%
	Total	Count	98	52
		% within BISHOP SCORE	65.3%	34.7%
		% within INDUCTION	100.0%	100.0%
		% of Total	65.3%	34.7%

Chi-Square 2.788 , P value 0.095

Figure 3 : RELATION BETWEEN BISHOP SCORE AND INDUCTION OF LABOUR

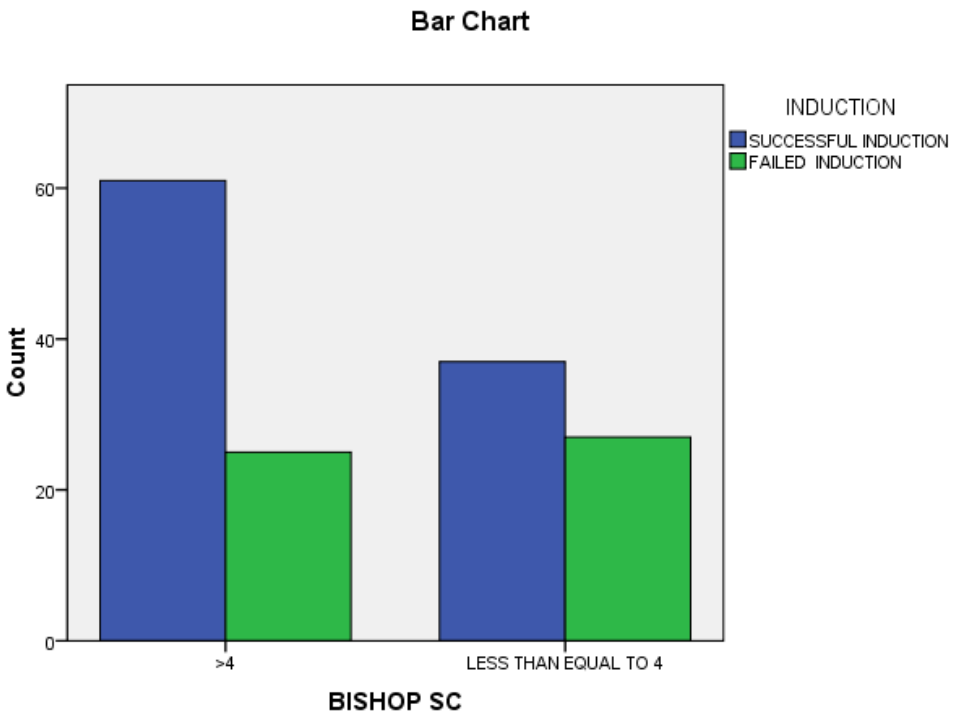


Table 4 &Figure 3 shows that majority of successful induction belongs to Bishop score >4 group (n=61,70.9%) . Failed induction is more in less than equal to 4. The association between Bishop score and induction of labour is not statistically significant.

Table 5 : RELATION BETWEEN CERVICAL LENGTH AND INDUCTION OF LABOUR

CERVICAL LENGTH			INDUCTION	
			SUCCESSFUL INDUCTION	FAILED INDUCTION
	Less than or equal to 3 cm		98	15
		% within CERVICAL LENGTH	86.7%	13.3%
		% within INDUCTION	100.0%	28.8%
		% of Total	65.3%	10.0%
	>3CM	Count	0	37
		% within CERVICAL LENGTH	.0%	100.0%
		% within INDUCTION	.0%	71.2%
		% of Total	.0%	24.7%
	Total	Count	98	52
		% within CERVICAL LENGTH	65.3%	34.7%
		% within INDUCTION	100.0%	100.0%
		% of Total	65.3%	34.7%

Chi-Square 92.563 P value 0.000

Figure 4

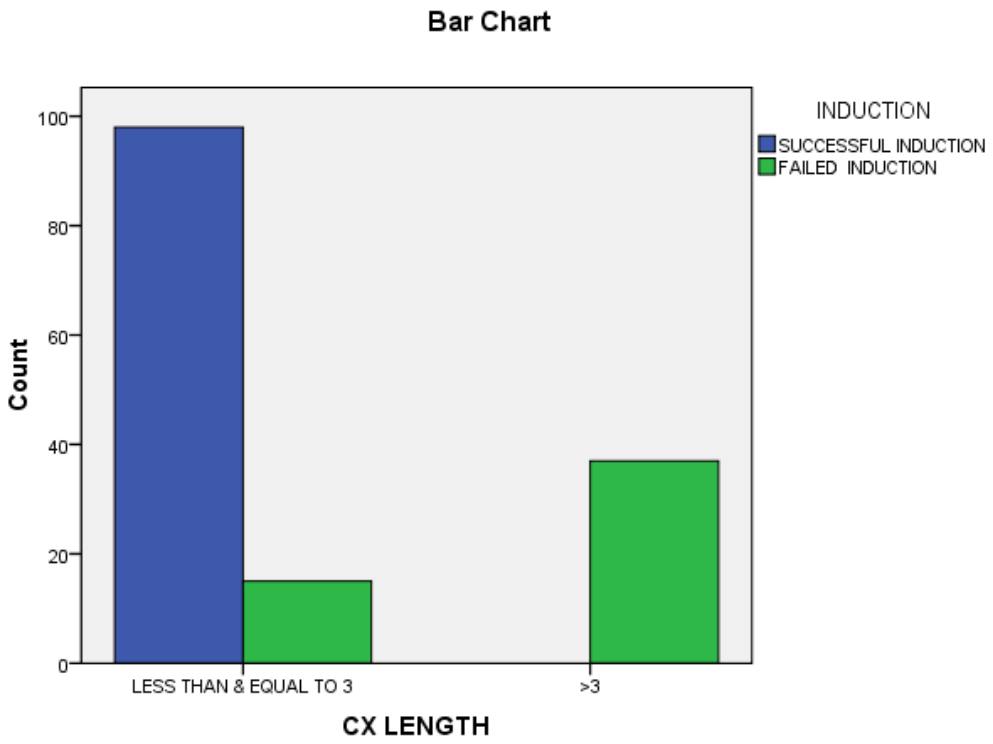


Table 5 and Figure 4 shows that failed induction is more if the cervical length is > 3 cm (n=37,100%). The association between cervical length and induction of labour is statistically significant since the p value is 0.000.

Table 6 : RELATION BETWEEN PRESENCE OF FUNNELING AND INDUCTION OF LABOUR

PRESENCE OF FUNNELING		INDUCTION		
		SUCCESSFUL INDUCTION	FAILED INDUCTION	Total
YES	Count	20	1	21
	% within PRESENCE OF FUNNELING	95.2%	4.8%	100.0%
	% within INDUCTION	20.4%	1.9%	14.0%
	% of Total	13.3%	.7%	14.0%
NO	Count	78	51	129
	% within PRESENCE OF FUNNELING	60.5%	39.5%	100.0%
	% within INDUCTION	79.6%	98.1%	86.0%
	% of Total	52.0%	34.0%	86.0%
Total	Count	98	52	150
	% within PRESENCE OF FUNNELING	65.3%	34.7%	100.0%
	% within INDUCTION	100.0%	100.0%	100.0%
	% of Total	65.3%	34.7%	100.0%

Chi-Square 9.642 , p value 0.002

Figure 5 : RELATION BETWEEN PRESENCE OF FUNNELING AND INDUCTION OF LABOUR

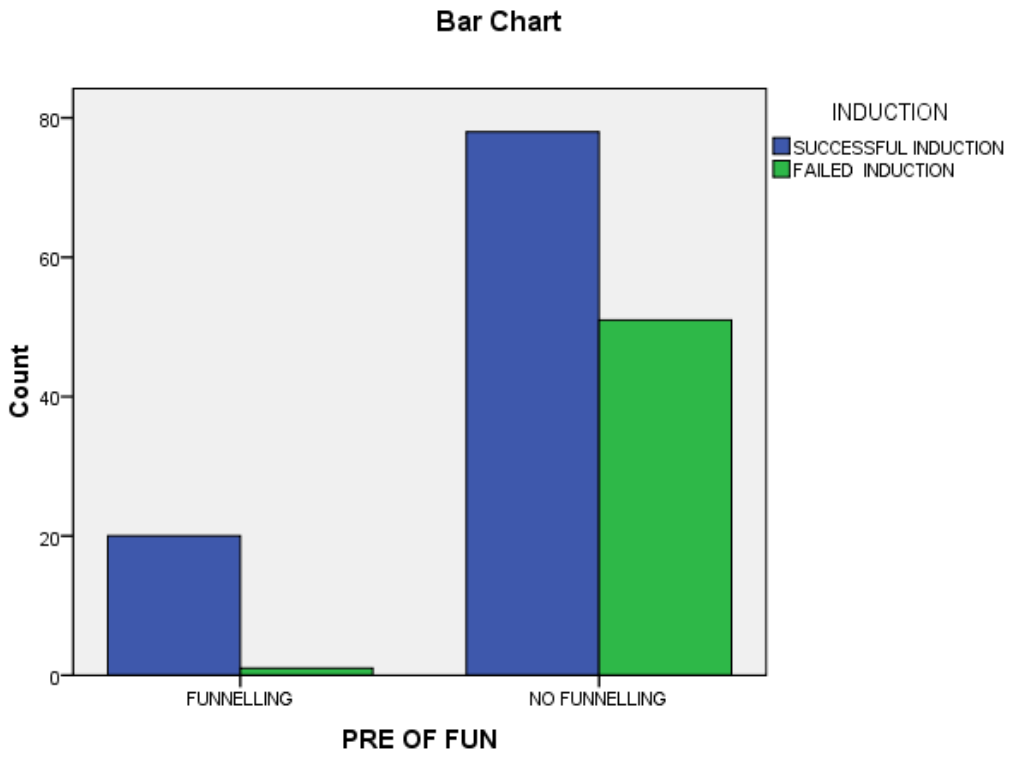


Table 6 & Figure 5 shows that successful induction is more if there is funneling of cervix (n=20,95.2%). This is statistically significant since p value is 0.002.

Table 7 : RELATION BETWEEN INDICATION FOR INDUCTION AND OUTCOME OF INDUCTION

INDICATION FOR INDUCTION		INDUCTION		Total
		SUCCESSFUL INDUCTION	FAILED INDUCTION	
40 to 41 Weeks of Pregnancy	Count	58	26	84
	% within INDICATION FOR INDUCTION	69.0%	31.0%	100.0%
	% within INDUCTION GROUP IN TOTO	59.2%	50.0%	56.0%
PREECLAMPSIA	Count	24	10	34
	% within INDICATION FOR INDUCTION	70.6%	29.4%	100.0%
	% within INDUCTION GROUP IN TOTO	24.5%	19.2%	22.7%
OLIGO-HYDROMNIAS	Count	11	12	23
	% within INDICATION OF INDUCTION	47.8%	52.2%	100.0%
	% within INDUCTION GROUP IN TOTO	11.2%	23.1%	15.3%
GDM	Count	5	4	9
	% within INDICATION FOR INDUCTION	55.6%	44.4%	100.0%
	% within INDUCTION GROUP IN TOTO	5.1%	7.7%	6.0%
Total	Count	98	52	150
	% within INDICATION OF INDUCTION	65.3%	34.7%	100.0%

Chi-Square =4.419 p=0.220 not significant

\

Table 7 shows that the majority of the successful induction group patients had 40 to 41 Weeks of pregnancy as the indication for induction (n=84, 69).The association between the study groups and indication for induction is considered to be not statistically significant since p =0.220 as per chi square test.

ANALYSIS OF BISHOP SCORE WITH VARIABLES

Table 8 : RELATION BETWEEN PARITY AND BISHOP SCORE

PARITY		BISHOP SCORE >4	BISHOP SCORE ≤ 4	Total
NULLI PAROUS	Count	58	43	101
	% within PARITY	57.4%	42.6%	100.0%
	% within BISHOP SCORE	67.4%	67.2%	67.3%
	% of Total	38.7%	28.7%	67.3%
MULTI-PAROUS	Count	28	21	49
	% within PARITY	57.1%	42.9%	100.0%
	% within BISHOP SCORE	32.6%	32.8%	32.7%
	% of Total	18.7%	14.0%	32.7%
Total	Count	86	64	150
	% within PARITY	57.3%	42.7%	100.0%
	% within BISHOP SCORE	100.0%	100.0%	100.0%
	% of Total	57.3%	42.7%	100.0%

Chi-Square-0.001, P Value-0.974

Figure 6 : RELATION BETWEEN PARITY AND BISHOP SCORE

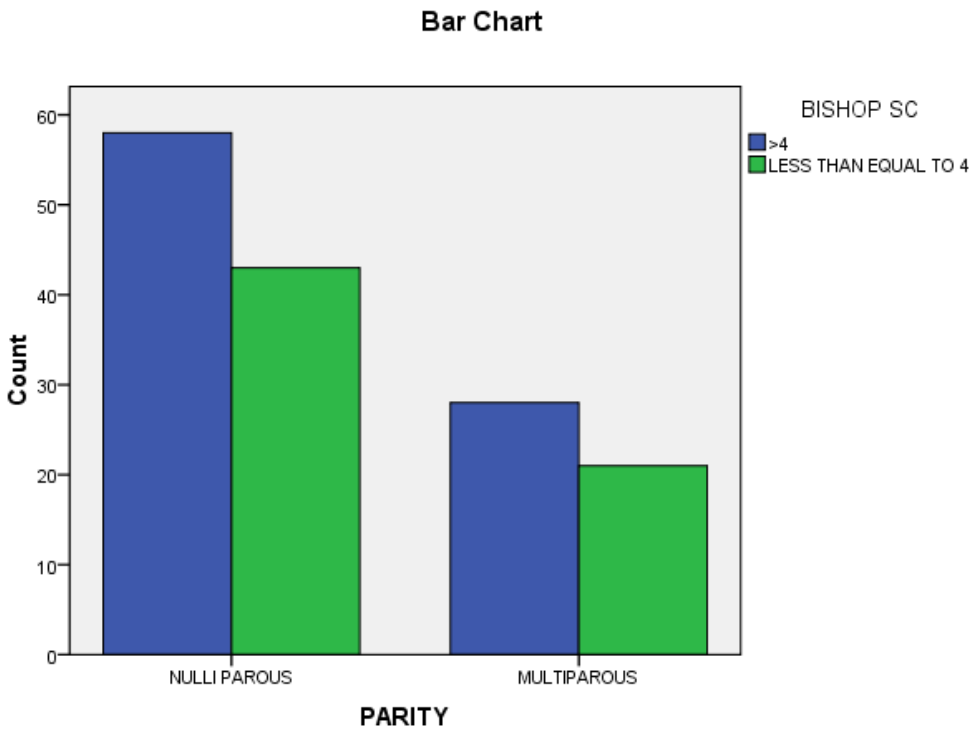


Figure 6 and Table 8 shows that majority of the Bishop Score > 4 group patients belonged to the nulliparous (n=58, 67.4%). In the Bishop Score < 4 group patients, majority belonged to nulliparous (n=43, 42.6%). The association between the study groups and parity distribution is considered to be not statistically significant since p > 0.974 as per Chi square test.

Table 9 : RELATION BETWEEN GESTATIONAL AGE AND BISHOP SCORE

GESTATIONAL AGE		BISHOP SCORE		
		>4	≤	Total
37 WEEKS	Count	6	1	7
	% within GESTATIONAL AGE	85.7%	14.3%	100.0%
	% within BISHOP SCORE	7.0%	1.6%	4.7%
	% of Total	4.0%	.7%	4.7%
38 WEEKS	Count	4	2	6
	% within GESTATIONAL AGE	66.7%	33.3%	100.0%
	% within BISHOP SCORE	4.7%	3.1%	4.0%
	% of Total	2.7%	1.3%	4.0%
39 WEEKS	Count	13	12	25
	% within GESTATIONAL AGE	52.0%	48.0%	100.0%
	% within BISHOP SCORE	15.1%	18.8%	16.7%
	% of Total	8.7%	8.0%	16.7%
40 WEEKS	Count	44	40	84
	% within GESTATIONAL AGE	52.4%	47.6%	100.0%
	% within BISHOP SCORE	51.2%	62.5%	56.0%
	% of Total	29.3%	26.7%	56.0%

41 WEEKS	Count	19	9	28
	% within GESTATIONAL AGE	67.9%	32.1%	100.0%
	% within BISHOP SCORE	22.1%	14.1%	18.7%
	% of Total	12.7%	6.0%	18.7%
Total	Count	86	64	150
	% within GESTATIONAL AGE	57.3%	42.7%	100.0%
	% within BISHOP SCORE	100.0%	100.0%	100.0%
	% of Total	57.3%	42.7%	100.0%

Chi-square test-4.919, p value0.296

Table 9, shows that majority of the Bishop Score > 4 group patients belonged to the40 weeks gestational age (n=44, 52.4%). In the Bishop Score < 4 group patients, majority belonged 40 weeks gestational age (n=40, 47.6%). The association between the study groups and gestational age distribution is considered to be not statistically significant since p value > 0.296 as per Chi-Square test.

Table 10 : RELATION BETWEEN CERVICAL LENGTH AND BISHOP SCORE

CERVICAL LENGTH			BISHOP SCORE		
			>4	LESS THAN OR EQUAL TO 4	Total
	LESS THAN & EQUAL TO 3	Count	71	42	113
		% within CERVICAL LENGTH	62.8%	37.2%	100.0%
		% within BISHOP SCORE	82.6%	65.6%	75.3%
		% of Total	47.3%	28.0%	75.3%
	>3	Count	15	22	37
		% within CERVICAL LENGTH	40.5%	59.5%	100.0%
		% within BISHOP SCORE	17.4%	34.4%	24.7%
		% of Total	10.0%	14.7%	24.7%
	Total	Count	86	64	150
		% within CERVICAL LENGTH	57.3%	42.7%	100.0%
		% within BISHOP SC0RE	100.0%	100.0%	100.0%
		% of Total	57.3%	42.7%	100.0%

Chi-square test-5.662, p value-0.017

Figure 7 : RELATION BETWEEN CERVICAL LENGTH AND BISHOP SCORE

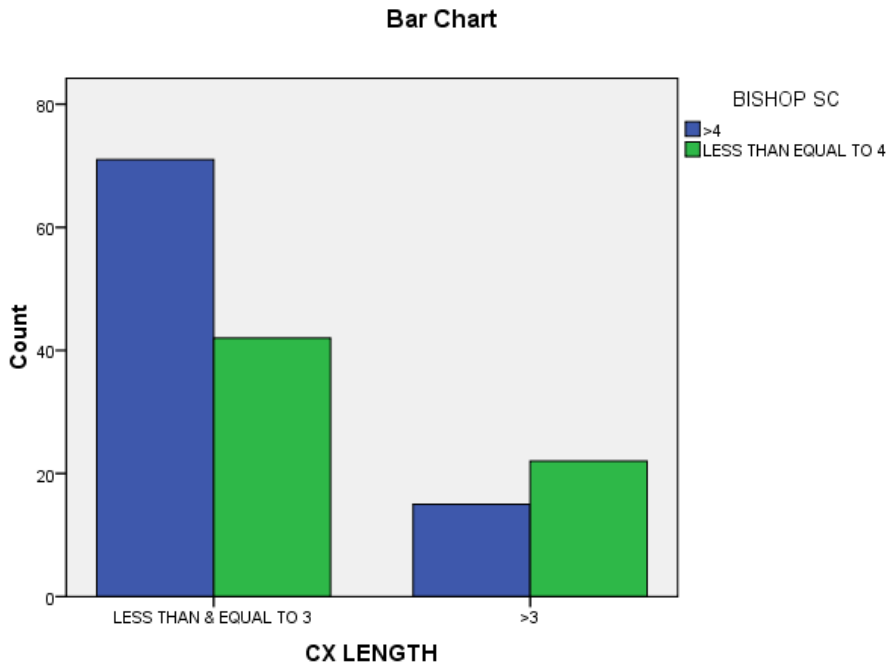


Table 10 and Figure 7 shows that majority of patients belonging to Bishop Score > 4 Group had cervical length measurements ≤ 3 cm (n=71,62.8%%). In Bishop Score < 4 Group, the majority belonged to cervical length measurements ≤ 3 cm (n=42,37.2%). The increased incidence of cervical length measurements ≤ 3 cm in Bishop Score > 4 Group compared to the Bishop Score < 4 Group is statistically significant as the p value is 0.017 as per Chi-square test.

Table 11 : RELATION BETWEEN DURATION OF INDUCTION AND BISHOP SCORE

DURATION OF INDUCTION		BISHOP SCORE		
		>4	LESS THAN OR EQUAL TO 4	Total
< 10 hrs	Count	65	35	100
	% within DURATION OF INDUCTION	65.0%	35.0%	100.0%
	% within BISHOP SCORE	75.6%	54.7%	66.7%
	% of Total	43.3%	23.3%	66.7%
> 10 hrs	Count	17	20	37
	% within DURATION OF INDUCTION	45.9%	54.1%	100.0%
	% within BISHOP SCORE	19.8%	31.3%	24.7%
	% of Total	11.3%	13.3%	24.7%
Immediately taken for LSCS due to fetal distress	Count	4	9	13
	% within DURATION OF INDUCTION	30.8%	69.2%	100.0%
	% within BISHOP SCORE	4.7%	14.1%	8.7%
	% of Total	2.7%	6.0%	8.7%
Total	Count	86	64	150
	% within DURATION OF INDUCTION	57.3%	42.7%	100.0%
	% within BISHOP SCORE	100.0%	100.0%	100.0%
	% of Total	57.3%	42.7%	100.0%

Chi-Square Tests-8.114, P Value -0.017

Figure 8 : RELATION BETWEEN DURATION OF INDUCTION AND BISHOP SCORE

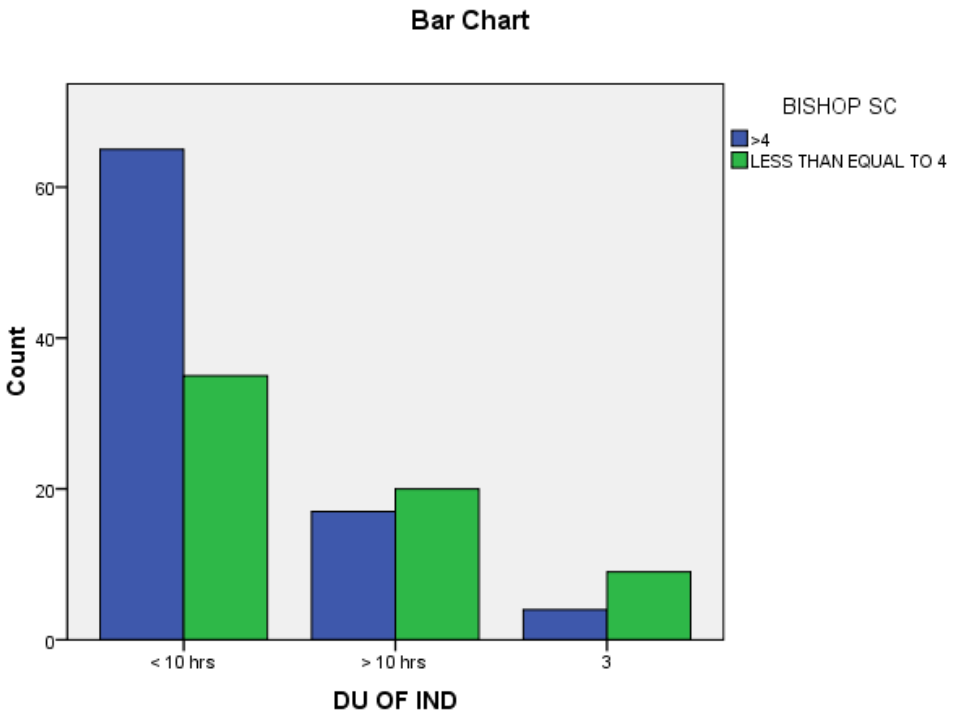


Table 11 and Figure 8 shows that,in patients belonging to Bishop Score > 4 Group, the majority had duration of induction < 10 hours (n=65, 65%). The increased incidence of duration of induction < 10 hours in Bishop Score > 4 Group compared to the Bishop Score < 4 Group is statistically significant as the p value is 0.017 as per Chi-square test .

Table 12 : RELATION BETWEEN MODE OF DELIVERY AND BISHOP SCORE

MODE OF DELIVERY		BISHOP SCORE		
		>4	LESS THAN EQUAL TO 4	Total
LABOUR NATURAL	Count	60	37	97
	% within MODE OF DELIVERY	61.9%	38.1%	100.0%
	% within BISHOP SCORE	69.8%	57.8%	64.7%
	% of Total	40.0%	24.7%	64.7%
CESAREAN SECTION	Count	26	27	53
	% within MODE OF DELIVERY	49.1%	50.9%	100.0%
	% within BISHOP SCORE	30.2%	42.2%	35.3%
	% of Total	17.3%	18.0%	35.3%
Total	Count	86	64	150
	% within MODE OF DELIVERY	57.3%	42.7%	100.0%
	% within BISHOP SC0RE	100.0%	100.0%	100.0%
	% of Total	57.3%	42.7%	100.0%

Chi-Square Test-2.295, P value-0.130

Table 12 shows that, majority of the Bishop Score > 4 group patients had labour natural as mode of delivery (n=60, 61.9%). In the Bishop Score < 4 group patients, majority belonged to labour natural (n=37, 38.1%). The association between the study groups and mode of delivery is considered to be not statistically significant since p > 0.130 as per Chi square test.

ANALYSIS OF CERVICAL LENGTH VARIABLES

Table 13 : RELATION BETWEEN PARITY AND CERVICAL LENGTH

PARITY		CERVICAL LENGTH		
		LESS THAN & EQUAL TO 3cm	>3cm	Total
NULLI PAROUS	Count	73	28	101
	% within PARITY	72.3%	27.7%	100.0%
	% within CERVICAL LENGTH	64.6%	75.7%	67.3%
	% of Total	48.7%	18.7%	67.3%
MULTI PAROUS	Count	40	9	49
	% within PARITY	81.6%	18.4%	100.0%
	% within CERVICAL LENGTH	35.4%	24.3%	32.7%
	% of Total	26.7%	6.0%	32.7%
Total	Count	113	37	150
	% within PARITY	75.3%	24.7%	100.0%
	% within CERVICAL LENGTH	100.0%	100.0%	100.0%
	% of Total	75.3%	24.7%	100.0%

Chi-square test-1.554,P value-0.213

Figure 9 : RELATION BETWEEN PARITY AND CERVICAL LENGTH

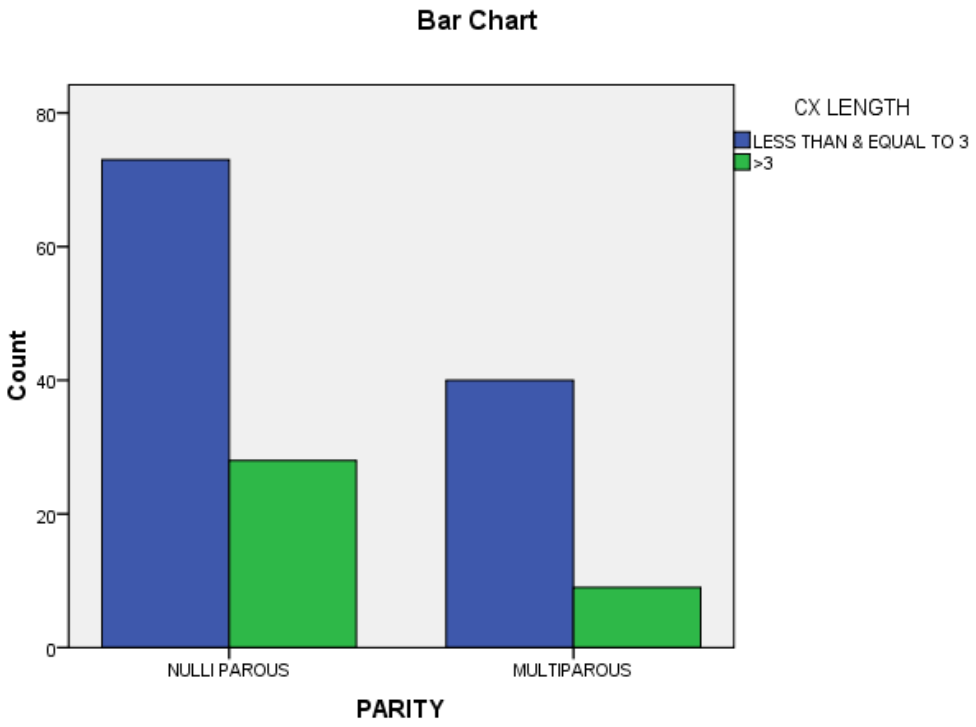


Table 14 and Figure 9 shows that majority of cervical length less than or equal to 3cm group patients belonged to the nulliparous groups (n=73, 72.3%) In the cervical length >3cm group patients, majority belonged to nulliparus (n=28, 27.7%). The association between the study groups and parity distribution is considered to be not statistically significant since p value is > 0.213 as per Chi square test.

Table 14 : RELATION BETWEEN GESTATIONAL AGE AND CERVICAL LENGTH

GESTATIONAL AGE		CERVICAL LENGTH		
		LESS THAN OR EQUAL TO 3cm	>3cm	Total
37 WEEKS	Count	5	2	7
	% within GESTATIONAL AGE	71.4%	28.6%	100.0%
	% within CERVICAL LENGTH	4.4%	5.4%	4.7%
	% of Total	3.3%	1.3%	4.7%
38 WEEKS	Count	6	0	6
	% within GESTATIONAL AGE	100.0%	.0%	100.0%
	% within CERVICAL LENGTH	5.3%	.0%	4.0%
	% of Total	4.0%	.0%	4.0%
39 WEEKS	Count	19	6	25
	% within GESTATIONAL AGE	76.0%	24.0%	100.0%
	% within CERVICAL LENGTH	16.8%	16.2%	16.7%
	% of Total	12.7%	4.0%	16.7%

40 WEEKS	Count	61	23	84
	% within GESTATIONAL AGE	72.6%	27.4%	100.0%
	% within CERVICAL LENGTH	54.0%	62.2%	56.0%
	% of Total	40.7%	15.3%	56.0%
41 WEEKS	Count	22	6	28
	% within GESTATIONAL AGE	78.6%	21.4%	100.0%
	% within CERVICAL LENGTH	19.5%	16.2%	18.7%
	% of Total	14.7%	4.0%	18.7%
Total	Count	113	37	150
	% within GESTATIONAL AGE	75.3%	24.7%	100.0%
	% within CERVICAL LENGTH	100.0%	100.0%	100.0%
	% of Total	75.3%	24.7%	100.0%

Chi-Square test-2.519 p value is-0.641

Table 14shows that majority of the cervical length less than or equal to 3 cm group patients belonged to the 40 weeks gestational age groups (n=61, 72.6%). In the cervical length > 3cm group patients, majority belonged 40 weeks gestational age (n=23, 27.4%). The association between the study groups and gestational age distribution is considered to be not statistically significant since p value > 0.641 as per Chi-Square test.

Table 15 : RELATION BETWEEN INDICATION OF INDUCTION AND CERVICAL LENGTH

INDICATIO OF INDUCTION			CERVICAL LENGTH		
			LESS THAN & EQUAL TO 3cm	>3cm	Total
	40 to 41 Weeks of Pregnancy	Count	65	19	84
		% within INDICATION OF INDUCTION	77.4%	22.6%	100.0%
		% within CERVICAL LENGTH	57.5%	51.4%	56.0%
		% of Total	43.3%	12.7%	56.0%
	PRE-ECLAMPSIA	Count	26	8	34
		% within INDICATION OF INDUCTION	76.5%	23.5%	100.0%
		% within CERVICAL LENGTH	23.0%	21.6%	22.7%
		% of Total	17.3%	5.3%	22.7%
	OLIGOHYDROMNIOS	Count	14	9	23
		% within INDICATION OF INDUCTION	60.9%	39.1%	100.0%
		% within CERVICAL LENGTH	12.4%	24.3%	15.3%
		% of Total	9.3%	6.0%	15.3%

GDM	Count	8	1	9
	% within INDICATION OF INDUCTION	88.9%	11.1%	100.0%
	% within CERVICAL LENGTH	7.1%	2.7%	6.0%
	% of Total	5.3%	.7%	6.0%
Total	Count	113	37	150
	% within INDICATION OF INDUCTION	75.3%	24.7%	100.0%
	% within CERVICAL LENGTH	100.0%	100.0%	100.0%
	% of Total	75.3%	24.7%	100.0%

Chi-Square test-3.693, p value -0.297

Table 15 shows that majority of cervical length ≤ 3cm group belongs to 40 to 41 Weeks of pregnancy (n=65, 77.4%). In the cervical length >3cm group patients, majority belonged 40 to 41 Weeks of pregnancy (n=19,22.6%). The association between the study groups and indication of induction is considered to be not statistically significant since p value is > 0.297 as per Chi-Square test.

Table 16 : RELATION BETWEEN DURATION OF INDUCTION AND CERVICAL LENGTH

DURATION OF INDUCTION		CEVICAL LENGTH		
		LESS THAN & EQUAL TO 3cm	>3cm	Total
< 10 hrs	Count	86	14	100
	% within DURATION OF INDUCTION	86.0%	14.0%	100.0%
	% within CERVICAL LENGTH	76.1%	37.8%	66.7%
	% of Total	57.3%	9.3%	66.7%
> 10 hrs	Count	24	13	37
	% within DURATION OF INDUCTION	64.9%	35.1%	100.0%
	% within CERVICAL LENGTH	21.2%	35.1%	24.7%
	% of Total	16.0%	8.7%	24.7%
Immediately taken for LSCS due to fetal distress	Count	3	10	13
	% within DURATION OF INDUCTION	23.1%	76.9%	100.0%
	% within CERVICAL LENGTH	2.7%	27.0%	8.7%
	% of Total	2.0%	6.7%	8.7%
Total	Count	113	37	150
	% within DURATION OF INDUCTION	75.3%	24.7%	100.0%
	% within CERVICAL LENGTH	100.0%	100.0%	100.0%
	% of Total	75.3%	24.7%	100.0%

Chi square test-27.409, p value-0.000

Figure 10 : RELATION BETWEEN DURATION OF INDUCTION AND CERVICAL LENGTH

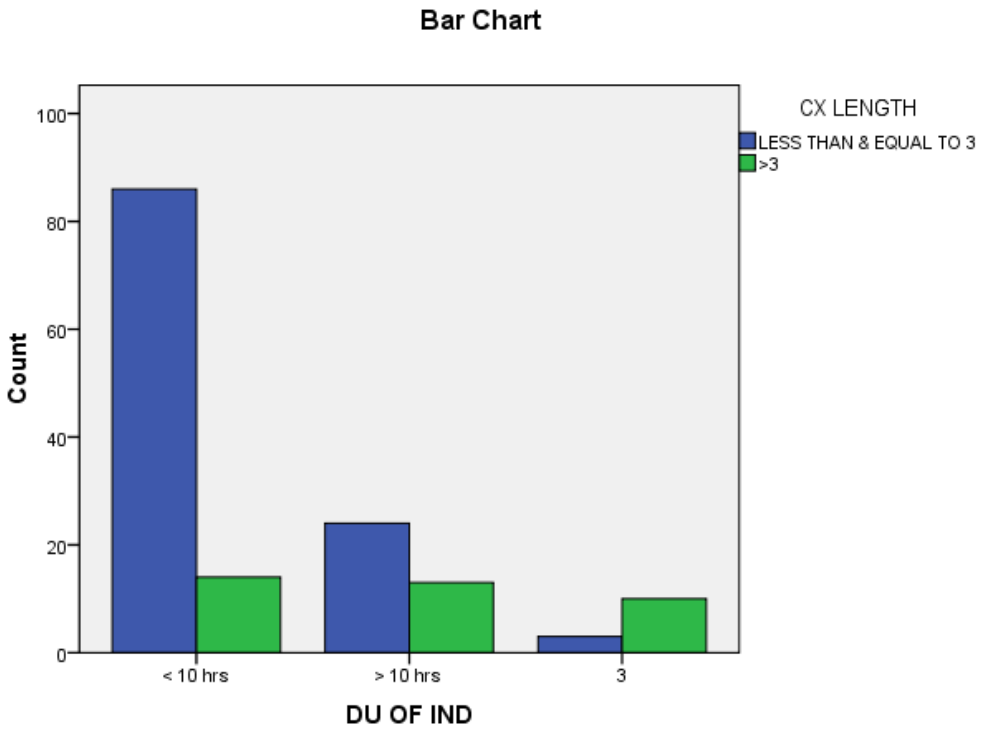


Table 16 and Figure 10 shows that, in patients belonging to cervical length less than or equal to3 Group, the majority had duration of induction < 10 hours (n=86, 86%). In cervical length >3 Group, the majority belonged to the same class interval (n=14,14%). The increased incidence of duration of induction < 10 hours in cervical length less than or equal to3 compared to the cervical length >3 Group. This is statistically significant as the p value is 0.000 as per Chi-square test .

Table 17 : RELATION BETWEEN MODE OF DELIVERY AND CERVICAL LENGTH

MODE OF DELIVERY		CERVICAL LENGTH		
		LESS THAN & EQUAL TO 3cm	>3cm	Total
LABOUR NATURAL	Count	97	0	97
	% within MODE OF DELIVERY	100.0%	.0%	100.0%
	% within CERVICAL LENGTH	85.8%	.0%	64.7%
	% of Total	64.7%	.0%	64.7%
CESAREAN SECTION	Count	16	37	53
	% within MODE OF DELIVERY	30.2%	69.8%	100.0%
	% within CERVICAL LENGTH	14.2%	100.0%	35.3%
	% of Total	10.7%	24.7%	35.3%
Total	Count	113	37	150
	% within MODE OF DELIVERY	75.3%	24.7%	100.0%
	% within CERVICAL LENGTH	100.0%	100.0%	100.0%
	% of Total	75.3%	24.7%	100.0%

Chi –square test-89.890, p value -0.000

Table 17 shows that, majority of the cervical length less than or equal to3cm group patients had natural labour as mode of delivery (n=97, 100%). In the cervical length >3cm group patients, majority belonged to cesarean delivery (n=37,69.8%). The association between the study groups and mode of delivery is considered to be statistically significant since p value is 0.000 as per Chi square test.

Table 18 : RELATION BETWEEN INDICATION FOR LSCS AND CERVICAL LENGTH

INDICATION FOR LSCS		CERVICAL LENGTH		
		LESS THAN & EQUAL TO 3cm	>3cm	Total
FETAL DISTRESS	Count	10	19	29
	% within INDICATION FOR LSCS	33.3%	66.7%	100.0%
	% within CERVICAL LENGTH	58.8%	54.1%	55.6%
	% of Total	18.5%	37.0%	55.6%
FAILED INDUCTION	Count	4	14	18
	% within INDICATION FOR LSCS	22.2%	77.8%	100.0%
	% within CERVICAL LENGTH	23.5%	37.8%	33.3%
	% of Total	7.4%	25.9%	33.3%
FAILED ACCELERATION	Count	3	3	6
	% within INDICATION FOR LSCS	50.0%	50.0%	100.0%
	% within CERVICAL LENGTH	17.6%	8.1%	11.1%
	% of Total	5.6%	5.6%	11.1%
Total	Count	17	37	53
	% within INDICATION FOR LSCS	31.5%	68.5%	100.0%
	% within CERVICAL LENGTH	100.0%	100.0%	100.0%
	% of Total	31.5%	68.5%	100.0%

Chi square test-1.717, p value -0.424

Table 18 shows that majority of cervical length >3 cm, had taken for cesarean delivery due to fetal distress(n=20,66.7%). In cervical length ≤3cm had taken for cesarean delivery for fetal distress (n=10,33.3%). This is not statistically significant.

FIGURE 11

ROC CURVE

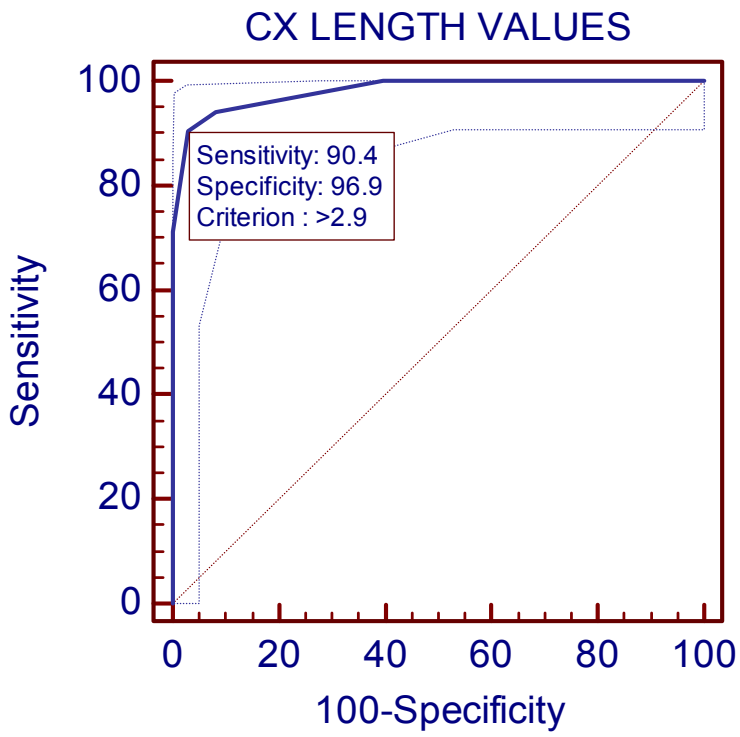


Table 19 : Area under the ROC curve (AUC)

Area under the ROC curve (AUC)	0.981064
Standard Error[a]	0.00866
95% Confidence interval[b]	0.944225 to 0.996310
z statistic	55.520
Significance level P (Area=0.5)	<0.0001

[a] DeLong et al., 1988
[b] Binomial exact

Youden index

Youden index J	0.8732
Associated criterion	>2.9

Table 19 and Figure 11 shows that in the prediction of failed induction of labour the cut off value for cervical length is >2.9cm ,area under the ROC curve (AUC) is 0.981064, sensitivity is 90.4%,specificity is 96.9%. It indicates that cervical length is good in predicting successful induction of labour.

FIGURE 12

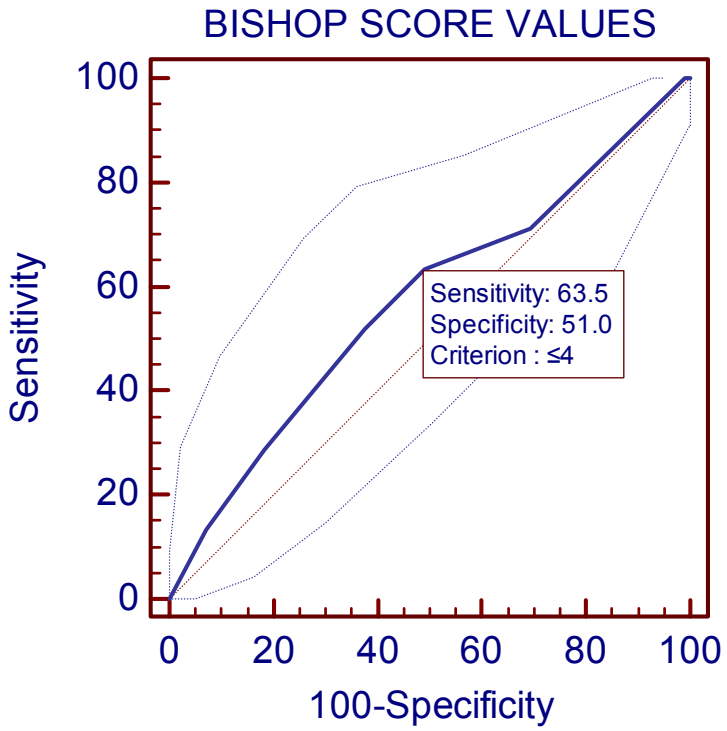


Table 20

Area under the ROC curve (AUC)

Area under the ROC curve (AUC)	0.572410
Standard Error[a]	0.0497
95% Confidence interval[b]	0.489138 to 0.652764
z statistic	1.458
Significance level P (Area=0.5)	0.1449

Youden index

Youden index J	0.1448
Associated criterion	≤4

Table 20 and Figure 12 shows that in the prediction of failed induction of labour, the cut off value for Bishop score is ≤4 ,area under the ROC curve (AUC) is 0. 572410.sensitivity is 63.5%, specificity is 51.0%. It indicates that no significant relationship was found between bishop score and successful induction.

Accuracy Statistics – Cervical length

Table 21RELATION BETWEEN INDUCTION AND CERVICAL LENGTH AND BISHOP SCORE VALUE

	INDUCTION	N	Mean	Std. Deviation	Std. Error Mean	p
BISHOP SCORE VALUES	>4	52	3.71	1.808	.251	0.103
	≤4	98	4.19	1.660	.168	
CX LENGTH VALUES	≤2.9 cm	52	3.246	.2880	.0399	0.000
	>2.9 cm	98	2.652	.1818	.0184	

From the above table the mean values of Bishop score ≤4 is 4.19 .This is statistically not significant since the p value is 0.103.Mean value of cervical length ≤2.9 cm is 3.245 and p value is 0.000 The association between cervical length and induction of labour was statistically significant.

Table 22 : Cervical length classification >2.9cm and Induction Crosstabulation

			INDUCTION		Total
			Success	Failed	
Cervical length classification >2.9cm	No	Count	95	5	100
		% within INDUCTION	96.9%	9.6%	66.7%
	Yes	Count	3	47	50
		% within INDUCTION	3.1%	90.4%	33.3%
Total		Count	98	52	150
		% within INDUCTION	100.0%	100.0%	100.0%

Table 22 shows that, if the cervical length is <2.9 cm the successful induction of labour was 96.9% and if the cervical length is >2.9 the successful rate was 3.1%.This shows the test result was statistically significant (p=0.000).

Parameter	Estimate	Lower - Upper 95% CIs	Method
Sensitivity	90.38%	(79.39, 95.82[1])	Wilson Score
Specificity	96.94%	(91.38, 98.95[1])	Wilson Score
Positive Predictive Value	94%	(83.78, 97.94[1])	Wilson Score
Negative Predictive Value	95%	(88.82, 97.85[1])	Wilson Score
Diagnostic Accuracy	94.67%	(89.83, 97.27[1])	Wilson Score
Cohen's kappa (Unweighted)	0.8812	(0.7212 - 1.041)	

- The sensitivity of cervical length is more high (90.38).This means that high positive level of cervical length test (≤2.9cm) often occur in those who have successful induction.
- The specificity is also high (96.94%).This means that negative level of cervical length test (>2.9cm) often occur in those who do not have successful induction.
- A positive predictive value of 94% means that only 94% of the patients with a positive cervical length test actually have successful induction.
- A negative predictive value of 95% means that 95 of patients with a negative cervical length test have a 95% chance of being failed induction.
- Cohen's kappa - 0.8812 shows very good agreement in prediction of successful induction of labour by cervical length measured by TVS.

DISCUSSION

In this study cervical Length by transvaginal ultrasonography showed a significant predictability for successful labor induction. Moreover when we compared the performance of cervical length in predicting the likelihood of successful induction with that of the Bishop score by ROC curve analysis, cervical length was a superior test (z = 55.520; P <0 .000).

This study suggest that cervical length measured by transvaginal ultrasonography is more reliable before labor induction than the Bishop score. The . Soon Ha Yang et al 2004, they found that cervical length by TVS did not improve the prediction cervical inducibility than Bishop score. So our study had contradiction with the previous study.

In this study parity,cervical length by TVS and presence of funneling predicting the successful induction of labour. According to Chandra et al(2001) found that no ultrasonographic characteristic predicted successful labor induction as well as digital cervical examination. They reported that clinical parameters such as maternal age, maternal weight, cervical dilatation, and effacement independently predicted successful labor induction. So our study had contradiction with previous study results.

This study results show patients belonging to cervical length less than or equal to 3 cm Group, the majority had duration of induction is < 10 hours (n=86, 86%). The increased incidence of duration of induction < 10 hours in cervical length less than or equal to 3 cm compared to the cervical length >3 cm group is statistically significant as the p value is 0.000. According to Pandis et al (2001) found that the transvaginal ultrasonographic measurement of cervical length was superior to the Bishop score in predicting the duration of the induction delivery interval and the likelihood of vaginal delivery within 24 hours of induction. So my study results had similar finding as with previous study results.

This study results shows that majority of the cervical length less than or equal to 3cm group patients had natural labour as mode of delivery (n=97, 100%). In the cervical length >3cm group patients, majority belonged to cesarean delivery (n=37,69.8%). (P value = 0.000) .Gabriel et al (2002) in their study found that cervical length measured by ultrasonography was a better predictor for cesarean delivery in labor induction than the Bishop score. So my study had similar finding as with previous study.

In this study majority of successful induction belongs to cervical length ≤ 3 cm group (n=98,86.7 %) .The association between cervical length and induction of labour was statistically significant. The majority

of successful induction belongs to Bishop score >4 group (n=61, 70.9%). The association between Bishop score and induction of labour was not statistically significant. Ninetyseven percent of women with cervical length of 3.0 cm or less had successful induction of labor even though they had Bishop scores of less than 4, according to Soon Ha Yang et al(2004). Therefore, more liberal application of ultrasonography to preinduction cervical assessment in term pregnancy would enable obstetricians to predict the outcome of labor induction and to select a safer and more efficient policy of induction.

SUMMARY

In this study the total sample size was 150.The pregnant women at term, who have reason for induction such as postdatism, preeclampsia, oligohydramnios, Gestational diabetes mellitus(GDM) in cephalic presentation , singleton and with < 2 cm cervical dilatation were selected for this study. This study was conducted in Labour ward, Department of Obstetrics and Gynaecology, Kilpauk Medical college & Hospital. Informed consent was obtained from all participants. Under strict aseptic precaution, their cervical length was measured by TVS followed by Bishop score. In Ultrasonographic Assessment of the Cervix, Transvaginal sonographic cervical assessment was done and the parameters like cervical length, the presence of funneling, funnel width and funnel length were obtained. If the Bishop score is 4 or less and the non stress test is normal, a prostaglandin E2 (PGE2) gel was inserted into the endocervical canal within 1 hour of cervical assessment. Dinoprostone gel contains 0.5 mg of dinoprostone available in a 2.5 ml preloaded syringe for intracervical application.

The woman was placed in a dorsal position and the cervix held with sponge holding forceps. The tip of the cannula was inserted just below the internal os. Then the gel was instilled into the cervix. For the next 30 minutes the woman was kept in a left lateral position. Then

careful FH monitoring is done, their cervical measurements were assessed 6 hours later. If there is no improvement in Bishop score second dose of gel will be administered. A total of 3 doses can be administered. If there is improvement in Bishop score labour will be accelerated by artificial rupture of membrane and oxytocin infusion.

The insertion of the first PGE2 gel is considered as beginning of induction. Successful induction was identified by active labour within 24 hours of gel induction. Among the Pregnant women, 64% of them delivered vaginally (n=97).Cesarean delivery was performed in 36% (n=53) due to fetal distress ,failed induction and failed acceleration . Induction was successful in 88% (n=132) and 18 of them failed to have active labour within 24 hours of induction and they underwent cesarean delivery. The majority of them had duration of induction < 10 hours (n=86, 86.1%) if the cervical length is ≤ 3cm (p=0.000). If the bishop score is >4 the successful rate of induction is 61.9% (p = 0.130). The successful rate of induction of labour is more if the cervical length is ≤ 2.9 cm (96.9%), in which the p value is 0.000.So this result is statistically significant. The ROC curve shows increased specificity and sensitivity for Cervical length. Parity has a significant relationship with the duration of induction. The presence of funneling was shown significant relation with induction in our study (n=20,95.2%) (p=0.002.)

CONCLUSION

This study suggests that the measurement of cervical length by transvaginal ultrasonography is an independent predictor of successful labor induction and also the duration of induction. The TVS cervical length is a better method than the Bishop score. This study result had similar findings as with previous study results. Cervical length by TVS is more reliable and accurate than digital examination . Ultrasonographic cervical assessment is known as a reproducible, objective, and quantitative method and also easy to perform. Therefore, more liberal application of ultrasonography to preinduction cervical assessment in term pregnancy would enable obstetricians to predict the outcome of labor induction.

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PROFORMA

NAME -

AGE -

IP NO -

ADDRESS -

OBSTETRIC HISTORY -

1. OBSTETRIC SCORE -
2. LMP -
4. EDD -
5. CONSANGUINITY -
6. ABORTIONS -
7. STILL BIRTH -

MEDICAL HISTORY:

1. HYPERTENSION -

2.DIABETES -

3.TUBERCULOSIS -

4.BRONCHIAL ASTHMA -

5.HEART DISEASE -

6.EPILEPSY -

7.DRUG INTAKE -

8.OTHERS -

INDICATION FOR LABOUR INDUCTION-

MODIFIED BISHOPS SCORE:

CERVICAL DILATATION -

CERVICAL LENGTH -

CONSISTENCY -

POSITION -

STATION OF HEAD -

SONOGRAPHIC CERVICAL ASSESSMENT:

CERVICAL LENGTH -

PRESENCE OF FUNNELING -

FUNNEL LENGTH -

FUNNEL WIDTH -

AGENT USED FOR INDUCTION -

TIME OF GEL INSERTION -

AUGMENTATION WITH OXYTOCIN -

USE OF ANALGESIA -

TIME OF DELIVERY -

MODE OF DELIVERY:

LABOUR NATURAL -

CESAREAN SECTION -

INDICATION FOR LSCS -

PERIOD BETWEEN INDUCTION AND DELIVERY-

APGAR SCORE AT 1 AND 5MIN -

FETAL WEIGHT AT BIRTH -

SIGNATURE OF THE INVESTIGATOR:

SIGNATURE OF THE GUIDE

APPENDIX 1

MODIFIED BISHOP SCORE

SCORE	**0**	**1**	**2**	**3**
DILATATION [IN CMS]	Closed	1-2	3-4	5
LENGTH[IN CMS]	>4	3-4	1-2	0
CONSISTENCY	Firm	Medium	soft	-
POSITION	Posterior	Midline	Anterior	-
STATION	-3	-2	-1,0	+1,+2

PATIENT CONSENT FORM

Study detail : **"COMPARISON OF PREDICTION OF SUCCESSFUL INDUCTION BY USING TRANSVAGINAL ULTRASONOGRAPHIC CERVICAL LENGTH VERSUS MODIFIED BISHOP SCORE FOR TERM PREGNANT WOMEN"**

Study centre :

Patients Name :

Patients Age :

Identification Number :

Patient may check (_/) these boxes

I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction. ☐

I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving reason, without my legal rights being affected. ☐

I understand that sponsor of the clinical study, others working on the sponsor's behalf, the ethical committee and the regulatory authorities will not need my permission to look at my health records, both in respect of current study and any further research that may be conducted in relation to it, even if I withdraw from the study I agree to this access. ☐

However, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study. ☐

I agree to take part in the above study and to comply with the instructions given during the study and faithfully cooperate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or well-being or any unexpected or unusual symptoms. ☐

I hereby consent to participate in this study. ☐

I hereby give permission to undergo complete clinical examination ☐

Signature/thumb impression: Signature of investigator:

Patients Name and Address: Study investigator's Name:

நோயாளி ஒப்புதல் படிவம்

ஆராய்ச்சியின் விவரம் : **"COMPARISON OF PREDICTION OF SUCCESSFUL INDUCTION BY USING TRANSVAGINAL ULTRASONOGRAPHIC CERVICAL LENGTH VERSUS MODIFIED BISHOP SCORE FOR TERM PREGNANT WOMEN"**

ஆராய்ச்சி மையம் : அரசு கீழ்பாக்கம் மருத்துவக் கல்லூரி மருத்துவமனை

நோயாளியின் பெயர் : நோயாளியின் வயது:

பதிவு எண் :

நோயாளி கீழ்கண்டவற்றுள் கட்டங்களை (✓) செய்யவும்

1 மேற்குறிப்பிட்டுள்ள ஆராய்ச்சியின் நோக்கத்தையும் பயனையும் முழுவதுமாக புரிந்து கொண்டேன். மேலும் எனது அனைத்து சந்தேங்களையும் கேட்டு அதற்கான விளக்கங்களையும் தெளிவுபடுத்திக் கொண்டேன். ☐

2 மேலும் இந்த ஆராய்ச்சிக்கு எனது சொந்த விருப்பத்தின் பேரில் பங்கேற்கிநேன் என்றும், மேலும் எந்த நேரத்திலும் எவ்வித முன்றிவிப்பு மின்றி இந்த ஆராய்ச்சியிலிருந்து விலக முழுமையான உரிமை உள்ளதையும் இதற்கு எவ்வித சட்ட பிணைப்பும் இல்லை என்பதையும் அறிவேன். ☐

3 ஆராய்சியாளரோ, ஆராய்ச்சி உதவியாளரோ, ஆராய்ச்சி உபயத்தாரரோ, ஆராய்ச்சி பேராசிரியரோ, ஒழுங்குநெறி செயற்குழு உறுப்பினர்களோ எப்போது வேண்டுமானாலும் எனது அனுமதியின்றி எனது உள்நோயாளி மற்றும் புற நோயாளி பதிவுகளை இந்த ஆராய்ச்சிக்காகவோ அல்லது எதிர்கால பிறஆராய்ச்சிகளுக்காகவோ பயன்படுத்திக் கொள்ளலாம் என்றும் மேலும் இந்த நிபந்தனை நான் இவ்வராய்ச்சிலிருந்து தகும் என்றும் ஒப்புக்கொள்கிறேன். ஆயினும் எனது அடையாளம் சம்பந்தப்பட்ட எந்த பதிவகளும் (சட்டபூர்வமான தேவைகள் தவிர) வெளியிடப்படமாட்டது என்ற உறுதிமொழியின் பெயரில் இந்த ஆராய்ச்சிலிருந்து கிடைக்கப்பெறும் முடிவுகளை வெளியிட மறுப்பு தெறிவிக்கமாட்டேன் என்று உறுதியளிக்கிறேன். ☐

4. இந்த ஆராய்ச்சி, அதன் பயன்பாடுகளையும், பின் விளைவுகளையும் அறியும் முயற்சி என்பதை மருத்துவர் மூலம் அறிந்து கொண்டேன். ☐
5. இந்த ஆராய்ச்சிக்கு நான் முழுமனதுடன் சம்மதிக்கின்றேன் என்றும் மேலும் ஆராய்ச்சி குழுவினர் எனக்கு அளிக்கும் அறிவுரைகளை தவறாது பின்பற்றுவேன் என்றும் உறுதியளிக்கிறேன். ☐
6. இந்த ஆராய்ச்சிக்குத் தேவைப்படும் அனைத்து மருத்துவப்பரிசோதனைகளுக்கும் ஒத்துழைப்பு தருவேன் என்று உறுதியளிக்கிறேன். ☐
7. இந்த ஆராய்ச்சிக்கு யாருடைய வற்புறுத்தலுமின்றி எனது சொந்த விருப்பத்தின் பேரிலும் சுயஅறிவுடனும் முழுமனதுடனும் சம்மதிக்கின்றேன் என்று இதன் மூலம் ஒப்புக்கொள்கிறேன். ☐

நோயாளியின் கையொப்பம் / பெருவிரல் கைரேகை

இடம்: தேதி:

ஆராய்ச்சியாளரின் கையொப்பம்:

இடம்: தேதி:

S.NO	NAME	AGE	PARITY	GA	IND OF IND	BISHOP SCORE VALUES	CX LENGTH VALUES	BISHOP SC	CX LENGTH	PRE OF FUN	F.LENGTH	F.WIDTH	NO OF GEL	OXY ACC	INDUCTION	DU OF IND	MOD	IND LSCS	B.WT	DU OF LAB
1	KAMALA	27	1	3	2	1	2.1	2	1	2			1	2	0	1	1		2	1
2	MEERA	22	1	4	1	1	2.4	2	1	2			1	2	0	1	1		1	1
3	VENILA	21	1	4	1	1	2.6	2	1	2			1	2	0	1	1		1	1
4	NAGAJOTI	22	1	3	2	1	2.6	2	1	2			2	1	0	2	1		2	1
5	ARUNA	20	1	4	1	1	2.8	2	1	2			2	1	0	1	1		1	1
6	PACIAMAL	22	1	3	2	1	2.8	2	1	2			1	1	0	1	1		2	1
7	KAVITHA	24	2	3	3	1	2.8	2	1	1			1	1	0	1	1		2	1
8	JOTHI	22	1	4	1	1	2.8	2	1	2			3	2	1	2	2	2	1	3
9	KALA	22	1	5	1	1	3	2	1	2			1	1	1	2	2	1	1	3
10	BHUVANA	26	2	4	3	1	3.1	2	2	2			3	2	1	2	2	2	1	3
11	SASIKALA	24	1	4	1	1	3.2	2	2	2			3	3	1	2	2	2	2	3
12	PREMA	25	2	4	1	1	3.4	2	2	2			3	2	1	3	2	2	2	3
13	RAJESWRAI	20	1	4	3	1	3.6	2	2	2			3	2	1	3	2	2	1	3
14	MALATI	22	1	4	1	1	3.8	2	2	2			1	1	1	1	2	1	2	3
15	DHANAM	20	1	4	2	2	2.2	2	1	2			1	2	0	1	1		2	1
16	VIJAYA	24	1	4	1	2	2.5	2	1	2			1	1	0	1	1		1	1
17	DIVYA	22	2	4	1	2	2.6	2	1	2			1	1	0	1	1		1	1
18	MEENATCHI	23	1	4	1	2	2.6	2	1	2			1	1	0	1	1		2	1
19	ANJALA	28	2	4	1	2	2.6	2	1	2			2	1	0	2	1		2	2
20	PRIYA	25	2	5	1	2	2.6	2	1	1	1	1	1	1	0	1	1		2	1
21	SUGUNA	20	1	4	3	2	2.6	2	1	2			1	1	0	1	1		1	1
22	SEETHA	24	2	5	1	2	2.7	2	1	2			2	2	0	1	1		1	1
23	PREMA	30	2	4	1	2	2.8	2	1	2			1	1	0	1	1		2	1
24	MEGALA	27	2	4	3	2	2.8	2	1	2			2	1	0	2	1		1	2
25	SUBHA	30	2	4	1	2	2.9	2	1	2			1	2	1	3	2	1	1	3
26	DHIVYA	23	1	4	1	2	2.9	2	1	2			3	2	1	2	2	2	1	3
27	JAYASRI	21	1	3	2	2	3	2	1	2			1	1	0	1	1		2	1
28	DEEPA	23	1	4	1	2	3	2	1	2			2	1	1	2	2	3	2	3
29	PALANI	22	2	4	3	2	3.1	2	2	2			2	2	1	3	2	1	2	3
30	PRIYA	20	1	4	2	2	3.1	2	2	2			1	2	1	3	2	1	3	3
31	LAKSHMI	26	1	3	2	2	3.2	2	2	2			2	1	1	3	2	1	1	3
32	AMUDHA	30	2	4	1	2	3.5	2	2	2			2	1	1	2	2	3	2	3
33	GEETHA	22	1	5	1	2	4	2	2	2			1	1	1	2	2	3	2	3
34	MEERA	20	1	3	3	3	2.4	2	1	1	2	2	1	1	0	1	1		2	1
35	SABITHA	35	2	4	1	3	2.5	2	1	2			1	1	0	1	1		2	1
36	PRIYA	26	2	4	1	3	2.5	2	1	2			1	1	0	1	1		2	1

37	RANI	25	2	5	1	3	2.5	2	1	2			2	1	0	2	1		1	1
38	SAMSATH	23	1	5	1	3	2.5	2	1	2			1	1	0	1	1		2	1
39	KARPAGAM	25	1	5	1	3	2.6	2	1	2			1	1	0	1	1		2	1
40	DEVI	27	1	2	2	3	2.6	2	1	2			1	2	0	1	1		2	1
41	NAELVENI	30	2	4	1	3	2.6	2	1	2			1	1	0	1	1		2	1
42	NAGAMMAL	25	1	4	4	3	2.6	2	1	2			1	1	0	1	1		2	1
43	RAMYA	22	1	4	1	3	2.7	2	1				2	1	0	2	1		2	2
44	BHUVANA	19	1	3	2	3	2.8	2	1	2			2	1	0	2	1		2	2
45	POORNIMA	22	1	5	1	3	2.8	2	1	2			1	2	0	1	1		2	1
46	KALAISELVI	22	2	4	2	3	2.8	2	1	1	1	1	1	2	0	2	1		2	1
47	BABY	20	1	2	4	3	2.8	2	1	2			2	1	0	2	1		1	2
48	KOWSALYA	21	1	4	3	3	2.8	2	1	2			1	1	0	1	1		1	1
49	SARALA	33	2	4	2	3	2.8	2	1	2			1	1	0	1	1		2	1
50	KAVITHA	20	1	3	4	3	2.8	2	1	2			1	1	0	1	1		2	1
51	PANJAVARNAM19		1	4	2	3	2.8	2	1	1			1	1	0	1	1		1	1
52	KALPANA	21	1	4	1	3	3	2	1	2			1	1	0	1	1		2	1
53	LAVAYA	24	1	4	1	3	3.1	2	2	2			1	1	1	1	2	3	1	3
54	DEVI	22	2	3	2	3	3.2	2	2	2			1	1	1	1	2	1	1	3
55	MUTHAMIL	22	1	4	1	3	3.2	2	2	2			1	1	1	1	2	1	2	3
56	KASTHURI	21	1	1	3	3	3.2	2	2	2			1	2	1	1	2	1	2	3
57	NANDINI	23	1	3	2	3	3.4	2	2	2			3	2	1	2	2	2	2	3
58	MAHALAKSMI	27	1	5	1	3	3.5	2	2	2			1	2	1	3	2	1	1	3
59	MANJUMATHA	26	2	4	1	3	3.5	2	2	2			3	2	1	2	2	2	1	3
60	KALAVANI	21	1	3	2	3	3.5	2	2	2			1	1	1	1	2	1	2	3
61	SARANYA	25	1	4	3	3	3.6	2	2	2			1	2	1	3	2	1	2	3
62	LAVANYA	26	1	4	1	3	3.6	2	2	2			3	2	1	2	2	2	1	3
63	KAVITHA	24	1	4	1	3	3.6	2	2	2			3	1	1	3	2	2	2	3
64	VIOLET	35	2	4	3	3	3.6	2	2	2			3	2	1	2	2	2	1	3
65	SASIKALA	24	2	4	1	4	2.2	1	1	2			2	2	0	2	1		1	2
66	BARANI	26	2	4	1	4	2.4	1	1	2			2	1	0	2	1		1	2
67	UMA	19	1	4	1	4	2.5	1	1	2			1	1	0	1	1		1	1
68	REVATI	25	1	4	3	4	2.6	1	1	2			1	1	0	1	1		2	1
69	CHENJAMMA	19	1	4	2	4	2.6	1	1	2			1	1	0	1	1		2	1
70	VAIDEGI	21	2	5	1	4	2.6	1	1	2			1	1	0	1	1		2	1
71	PUSHBA	25	1	5	1	4	2.6	1	1	2			3	2	0	2	1		2	2
72	MEGALA	27	2	4	1	4	2.8	1	1	1	1	1	2	1	0	2	1		2	2
73	KOKILA	26	2	5	1	4	2.8	1	1	2			1	1	0	1	1		2	1
74	JAYALAKSMI	26	2	5	1	4	2.8	1	1	2			1	1	0	1	1		1	1
75	BANUPRIYA29	29	2	4	1	4	2.9	1	1	2			2	1	0	2	1		2	2
76	AJIMA	27	1	4	1	4	3	1	1	2			3	2	1	2	2	2	2	3
77	UDAYA	20	1	3	2	4	3.2	1	2	2			3	2	1	2	2	2	2	3
78	HEMALATHA	20	1	4	2	4	3.5	1	2	2			3	2	1	2	2	2	1	3
79	SOBANA	24	1	1	3	4	3.6	1	2	2			1	2	1	2	2	2	1	3
80	ALICE	33	1	3	2	4	3.7	1	2	2			2	1	1	2	2	1	1	3

81	DIVYA	24	1	5	1	4	3.8	1	2	2			3	2	1	2	2	2	2	3
82	KOKILA	26	2	4	1	5	2.4	1	1	2			1	2	0	1	1		2	1
83	SUMATHI	29	2	3	2	5	2.4	1	1	2			1	2	0	3	2	1	2	1
84	RUBINI	19	1	2	2	5	2.5	1	1	1	1	1	1	1	0	1	1		2	1
85	REKINSUKLA	25	5	1	1	5	2.5	1	1	1	1	1	1	2	0	1	1		2	1
86	GOMATHI	20	1	4	1	5	2.5	1	1	2			2	1	0	2	1		2	1
87	VIJALAKMI	22	1	1	3	5	2.6	1	1	1	1	1	1	2	0	1	1		1	1
88	BHARANI	20	1	4	1	5	2.6	1	1	2			1	1	0	1	1		2	1
89	JAYASHREE	21	1	3	2	5	2.6	1	1	2			1	1	0	1	1		2	1
90	SAMSATH	23	1	5	1	5	2.6	1	1	2			2	1	0	2	1		1	1
91	UMA	22	1	4	1	5	2.6	1	1	2			2	2	0	2	1		1	2
92	MEERA	20	1	4	4	5	2.6	1	1	2			2	1	0	2	1		2	1
93	BHAVANESWARI	26	1	4	1	5	2.6	1	1	2			1	1	0	1	1		1	1
94	AMUTHA	24	1	5	1	5	2.8	1	1	2			1	2	0	1	1		1	1
95	KAVITHA	27	2	5	1	5	2.8	1	1	1	1	1	1	2	0	1	1		1	1
96	UMA	25	1	4	2	5	2.8	1	1	2			2	1	0	1	1		2	1
97	SENBAGAM	20	1	4	2	5	2.8	1	1	1	1	1	1	1	0	1	1		2	1
98	RAJESWARI	25	1	3	2	5	2.8	1	1	1	2	2	1	1	0	1	1		2	1
99	PUSHPA	25	1	3	2	5	2.8	1	1	2			1	1	0	1	1		1	1
100	ANBARASI	21	1	2	4	5	2.8	1	1	2			1	1	1	1	2	1	1	3
101	SUGUNA	18	1	4	1	5	2.9	1	1	1	1	1	1	2	0	1	1		2	1
102	KAVITHA	23	2	5	1	5	2.9	1	1	2			1	1	0	1	1		2	1
103	PANJACARNAM	31	2	4	2	5	3	1	1	2			1	1	1	1	2	1	2	3
104	VEMBU	20	1	5	1	5	3	1	1	2			1	1	1	1	2	3	2	1
105	SABITHA	25	1	5	1	5	3.5	1	2	2			1	2	1	3	2	1	1	3
106	SILAMBARASI	29	1	3	2	6	2.1	1	1	2			1	2	0	1	1		2	1
107	DEVI	24	1	4	1	6	2.4	1	1	1	1	1	1	2	0	1	1		2	1
108	SUGANYA	23	1	3	3	6	2.4	1	1	2			1	1	0	1	1		2	1
109	MAHALAKSMI	24	1	4	4	6	2.4	1	1	2			1	1	0	1	1		2	1
110	PRIYA NAGARAJ	26	2	4	1	6	2.5	1	1	1	1	1	1	1	0	1	1		2	1
111	ANJALI	24	1	1	3	6	2.6	1	1	1	2	2	1	1	0	1	1		1	1
112	SHANKARI	24	2	3	2	6	2.6	1	1	2			1	1	0	1	1		1	1
113	PRIYA	25	2	2	2	6	2.6	1	1	1	1	1	1	2	0	1	1		1	1
114	KAVITHA	23	2	5	1	6	2.6	1	1	1	1	1	1	2	0	1	1		2	1
115	VIJAYAKUMARI	21	1	4	1	6	2.6	1	1	2			1	1	0	1	1		2	1
116	UMARANI	28	2	4	1	6	2.6	1	1	2			1	1	0	1	1	1	2	1
117	GOVITHAMMAL	32	2	5	1	6	2.6	1	1	2			2	2	0	1	1		1	1
118	DIVYA	21	1	4	2	6	2.6	1	1	1	1	1	1	2	0	1	1		2	1
119	MARI	28	1	4	1	6	2.6	1	1	2			1	1	0	1	1		2	1
120	MENAGA	21	2	5	1	6	2.7	1	1	2			1	1	0	1	1		2	1
121	ANANTHI	22	1	5	1	6	2.7	1	1	2			1	1	0	1	1		1	1
122	BAKYLAKMI	20	1	4	1	6	2.7	1	1	1	1	1	1	2	0	1	1		1	1
123	RANI	28	2	4	1	6	2.7	1	1	2			2	2	0	1	1		1	1
124	PRIYA	21	1	4	1	6	2.8	1	1	2			1	1	0	1	1		1	1
125	GOWRI	24	1	5	1	6	2.8	1	1	2			1	2	0	1	1		2	1
126	H.LATHA	35	2	1	3	6	2.8	1	1	2			1	2	0	1	1		1	1

127	PARMESWARI	19	1	3	2	6	2.8	1	1	2			1	2	0	1	1		1	1
128	SHENBAGAM	20	2	4	1	6	2.8	1	1	2			1	1	0	1	1		1	1
129	PRIYA	20	1	3	2	6	2.8	1	1	2			1	1	0	1	1		1	1
130	VIJAYALAKSMI	29	2	4	1	6	2.8	1	1	2			1	1	0	1	1		2	1
131	AMALA	23	2	4	1	6	2.8	1	1	2			1	1	0	1	1		1	1
132	GEETHA	22	2	4	1	6	2.8	1	1	2			1	1	0	1	1		1	1
133	LAVANYA	30	1	4	2	6	2.8	1	1	2			3	2	1	2	2	2	2	1
134	KALPANA	24	1	4	1	6	2.9	1	1	2			1	1	0	1	1		2	1
135	SUGANYA	22	1	5	1	6	2.9	1	1	2			2	1	0	1	1		2	1
136	PARKATH NISA	29	1	4	4	6	3	1	1	2			1	2	1	2	2	1	1	3
137	NANDINI	21	1	4	3	6	3	1	1	2			1	1	1	1	2	1	2	3
138	ROSALIN	22	1	3	3	6	3	1	1	2			1	2	1	1	2	1	1	3
139	DEVI	28	1	3	4	6	3	1	1	2			1	2	1	3	2	1	1	3
140	SENBGAVALLI	21	1	1	3	6	3	1	1	2			1	1	1	1	2	3	1	3
141	SHANTA	24	2	4	1	6	3.1	1	2	2			1	2	1	3	2	1	3	3
142	PRABA	27	2	4	3	6	3.1	1	2	1			1	1	1	1	2	1	2	3
143	MYTILI	18	1	4	1	6	3.1	1	2	2			1	1	1	1	2	1	1	3
144	GAYATRI	26	1	4	4	6	3.1	1	2	2			1	1	1	1	2	1	1	3
145	IRUTAYAMARY	31	1	5	1	6	3.1	1	2	2			1	1	1	1	2	1	1	3
146	KALPANA	21	1	5	1	6	3.2	1	2	2			1	2	1	1	2	1	1	3
147	JANANI	20	1	4	1	6	3.2	1	2	2			2	1	1	1	2	2	2	3
148	CHARAMMA	22	1	4	3	6	3.2	1	2	2			2	1	1	1	2	1	1	3
149	JANAKI	27	1	4	1	6	3.2	1	2	2			1	2	1	1	2	1	1	1
150	SUGANYA	20	1	2	3	7	3	1	1	2			1	1	0	1	1		1	1

INDUCTION 0-SUCCESSFUL,1-FAILED

PARITY 1-NULLIPAROUS, 2-PAROUS

GESTATIONAL 1-37WKS,2-38WKS,3-39WKS,4-40WKS,5-41WKS

INDICATION FOR INDUC 40 to 41 weeks, 2-PREECLAMPSIA, 3-OLIGOHYDROAMNIOS, 4-GDM

MODIFIED BISHOP SCORE 1-MO 4 , 2- 4 OR LESS THAN 4

CERVICAL LEN 1-3 OR LI S THAN 3 M, 2->3CM

PRESENCE OF FUNNELING 1-YES, 2-NO

FUNNEL LENGTH 1-<1CM, 2->1CM

FUNNEL WIDTH 1-<1CM 2->1CM

NO OF GEL 1-1, 2-2 ,3-3

OXYTOCIN ACCELERATION 1-YES, 2-NO

DURATION OF INDUCTION 1-<10 HOURS, 2> 10 HOURS, 3. Immediately taken for LSCS due to fetal distress

MODE OF DELIVERY 1-LABOUR NATURAL, 2-CAESERIAN SECTION,

INDICATION FOR CAESERIAN 1-FETAL DISTRESS, 2-FAILED INDUCTION 3-FAILED ACCLERATION

BIRTH WEIGHT 1-<3KG , 2- 3 TO 3.5 KG 3 - 3.5 TO 4 KG

DURATION OF LABOUR 1-<3 HOURS, 2-> 3 HOURS