TRANSCERVICAL FOLEY'S CATHETER VERSUS TRANSCERVICAL FOLEY'S CATHETER AIDED BY INSTARIPE FOR INDUCTION OF LABOUR- A COMPARATIVE STUDY

Dissertation submitted to

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OBSTETRICS AND GYNAECOLOGY

M.S. BRANCH – II

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CERTIFICATE

This is to certify that the dissertation entitled "**TRANSCERVICAL FOLEY'S CATHETER VERSUS TRANSCERVICAL FOLEY'S CATHETER AIDED BY INSTARIPE FOR INDUCTION OF LABOUR- A COMPARATIVE STUDY''** is a bonafide work done by **Dr. VIDHYA PRIYANKA. B.D** in the institute of Madurai Medical College, Madurai in partial fulfillment of the university rules and regulations for award of MS Degree in Obstetrics and Gynaecology under my guidance and supervision during the academic year 2018-2019.

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This is to certify that the dissertation entitled "**TRANSCERVICAL FOLEY'S CATHETER VERSUS TRANSCERVICAL FOLEY'S CATHETER AIDED BY INSTARIPE FOR INDUCTION OF LABOUR- A COMPARATIVE STUDY"** bonafide work done by Dr. VIDHYA PRIYANKA.B.D in the institute of Madurai Medical College, Madurai in partial fulfillment of the university rules and regulations for award of MS degree in Obstetrics and Gynaecology under my guidance and supervision during the academic year 2018-2019.

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I solemnly declare that this dissertation entitled "**TRANSCERVICAL FOLEY'S CATHETER VERSUS TRANSCERVICAL FOLEY'S CATHETER AIDED BY INSTARIPE FOR INDUCTION OF LABOUR- A COMPARATIVE STUDY"** was done by me at the Department of Obstetrics and Gynaecology, Govt. Rajaji Hospital, Madurai Medical College, Madurai during 2018-2019 under the guidance and supervision of **Prof. Dr. N. SUMATHI, M.D, DGO.,** This dissertation is submitted to the Tamil Nadu Dr. M.G.R Medical University towards the partial fulfillment of requirements for the award of M.S Degree in Obstetrics and Gynaecology (Branch II)

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Dr. Vidhya Priyanka. B.D

CONTENTS

INTRODUCTION

INTRODUCTION

Labor is a process through which the fetus moves from the intrauterine to the extra uterine environment. The progress of Medicine in general and of Obstetrics in particular has allowed for more high risk pregnancies to evolve to term or close to term, with maternal or fetal pregnancy interruption before the onset of spontaneous labor. This associated to the fact that vaginal delivery has become the best choice for women and health professionals has created the growing need to induce labor in women with unripe cervices.[1] Induction refers to the process whereby uterine contractions are initiated by medical or surgical means before the onset of spontaneous labor. if the cervix is unfavorable, a successful vaginal birth is less likely. Therefore, in the face of a situation indicating pregnancy interruption it is fundamental to assess the cervix conditions to predict induction success. Out of all the scoring systems available, Bishop's scoring is the commonly used one, which helps to delineate those patients who are more likely to have successful induction. The duration of labor is inversely correlated with the Modified Bishop score; a score that exceeds 6 describes the patient most likely to achieve a successful vaginal birth. Modified Bishop scores of less than 6 usually require that a cervical ripening method be used before other methods.

Cervical feature	Score			
	0	1	2	3
Dilation (cm)	< 1	1-2	3-4	> 4
Length of cervix (cm)	> 3	2	1	< 1
Station (relative to ischial spines)	-3	-2	-1 / 0	+1 / +2
Consistency	Firm	Medium	Soft	–
Position	Posterior	Mid	Anterior	–

Non pharmacologic approaches to cervical ripening and labor induction have included herbal compounds, castor oil, hot baths, enemas, sexual intercourse, breast stimulation, acupuncture, acupressure, transcutaneous nerve stimulation, and mechanical and surgical modalities. Pharmacologic agents available for cervical ripening and labor induction include prostaglandins, misoprostol, mifepristone, and relaxin. When the Modified Bishop score is favorable, the preferred pharmacologic agent is oxytocin. The difference between cervical ripening and labor induction is many times difficult, almost artificial, depending, onthe method used, if only one dose or more than one drug or increased ministration time of a specific agent.[2] The ideal method for cervical ripening would be a non-invasive method causing the same physiological changes in the cervix. It is known that ideal conditions are difficult to obtain with the use of a stand-alone product. Under the mechanical methods, the use of a catheter in the extra amniotic space occurred the first time in 1853 by Krause quoted by Hamilton, a method named after him.[2] At that time a rigid

catheter was used. After that the Foley catheter, a flexible catheter was used to induce labor in women with unripe cervices with 94% of success. Instaripe, a rapid cervical ripening device was devised by Dr. Panicker. The device is used along with foley's catheter to accelerate cervical ripening and induction of labor. It was hypothesized to evaluate the efficacy of this device in accelerating cervical ripening and induction.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Methods for Cervical Ripening and Induction of Labor

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Induction of labor is common in obstetric practice. According to the most current studies, the rate varies from 9.5 to 33.7 percent of all pregnancies annually. In the absence of a ripe or favorable cervix, a successful vaginal birth is less likely. Therefore, cervical ripening or preparedness for induction should be assessed before a regimen is selected. Assessment is accomplished by calculating a Bishop score. When the Bishop score is less than 6, it is recommended that a cervical ripening agent be used before labor induction. Nonpharmacologic approaches to cervical ripening and labor induction have included herbal compounds, castor oil, hot baths, enemas, sexual intercourse, breast stimulation, acupuncture, acupressure, transcutaneous nerve stimulation, and mechanical and surgical modalities. Of these nonpharmacologic methods, only the mechanical and surgical methods have proven efficacy for cervical ripening or induction of labor. Pharmacologic agents available for cervical ripening and labor induction include prostaglandins, misoprostol, mifepristone, and relaxin. When the Bishop score is favorable, the preferred pharmacologic agent is oxytocin.

Mechanical methods for induction of labour

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Abstract

Background

Mechanical methods were the first methods developed to ripen the cervix and induce labour. During recent decades they have been substituted by pharmacological methods. Potential advantages of mechanical methods, compared with pharmacological methods, may include simplicity of preservation, lower cost and reduction of the side effects.

Objectives

To determine the effects of mechanical methods for third trimester cervical ripening or induction of labour in comparison with placebo/no treatment, prostaglandins (vaginal andintracervical prostaglandin E2 (PGE2), misoprostol) andoxytocin.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (30 April 2011) and bibliographies of relevant papers.

Selection criteria

Clinical trials comparing mechanical methods used for third trimester cervical ripening or labour induction with methods listed above it on a predefined list of methods of labour. A comparison with amniotomy will be added, should this comparison be made in future trials.

Different types of intervention have been considered as mechanical methods: (1) introduction of laminaria tents, or their synthetic equivalent (Dilapan), into the cervical canal; (2) the introduction of a catheter through the cervix into the extraamniotic space, withor without traction; (3) use of a catheter to inject fluids in the extra-amniotic space. In addition, we made other comparisons: (1) specific mechanical methods (balloon catheter and laminaria tents) compared with any prostaglandins or with oxytocin; (2) addition of prostaglandins or oxytocin to mechanical methods compared with prostaglandins alone.

Data collection and analysis

Two review authors independently assessed trials for inclusion and assessed risk of bias. Two review authors independently extracted data.

Main results

For this update we have included a further 27 studies. There view includes 71 randomised controlled trials (total of 9722 women), ranging from 39 to 588 women per study. Most studies reported on caesarean

section, all other outcomes are based on substantially fewer women. Four additional studies are on going. Mechanical methods versus no treatment: one study (48 woman) reported on women who did not achieve vaginal delivery within 24hours (risk ratio (RR) 0.90; 95% confidence interval (CI)0.64 to 1.26). The risk of caesarean section was similar between groups (six studies; 416 women, RR 1.00; 95% CI 0.76 to 1.30). There were no cases of severe neonatal and maternal morbidity.

Mechanical methods versus vaginal PGE2 (17 studies; 1894 woman): The proportion of women who did not achieve vaginal delivery within 24 hours was not significantly different (three studies; 586 women RR 1.72; 95% CI 0.90 to 3.27); however, for the subgroup of multiparous women the risk of not achieving delivery within 24 hours was higher (one study; 147 women RR4.38, 95% CI 1.74to 10.98), with no increase in caesarean sections (RR 1.19, 95% CI 0.62-2.29). Compared with intracervical PGE2 (14 studies; 1784 women and misoprostol there was no significant difference in the proportion of women not achieving vaginal delivery within 24 hours. Mechanical methods reduced the risk of hyperstimulation with fetal heart rate changes when compared with vaginal prostaglandins: vaginal PGE2 (eight studies; 1203 women, RR 0.16; 95% CI0.06 to 0.39) and misoprostol (3% versus 9%) (nine studies; 1615 women, RR 0.37; 95% CI 0.25 to 0.54). Risk of caesarean section

between mechanical methods and prostaglandins was comparable. Serious neonatal and maternal morbidity were infrequently reported and did not differ between the groups.

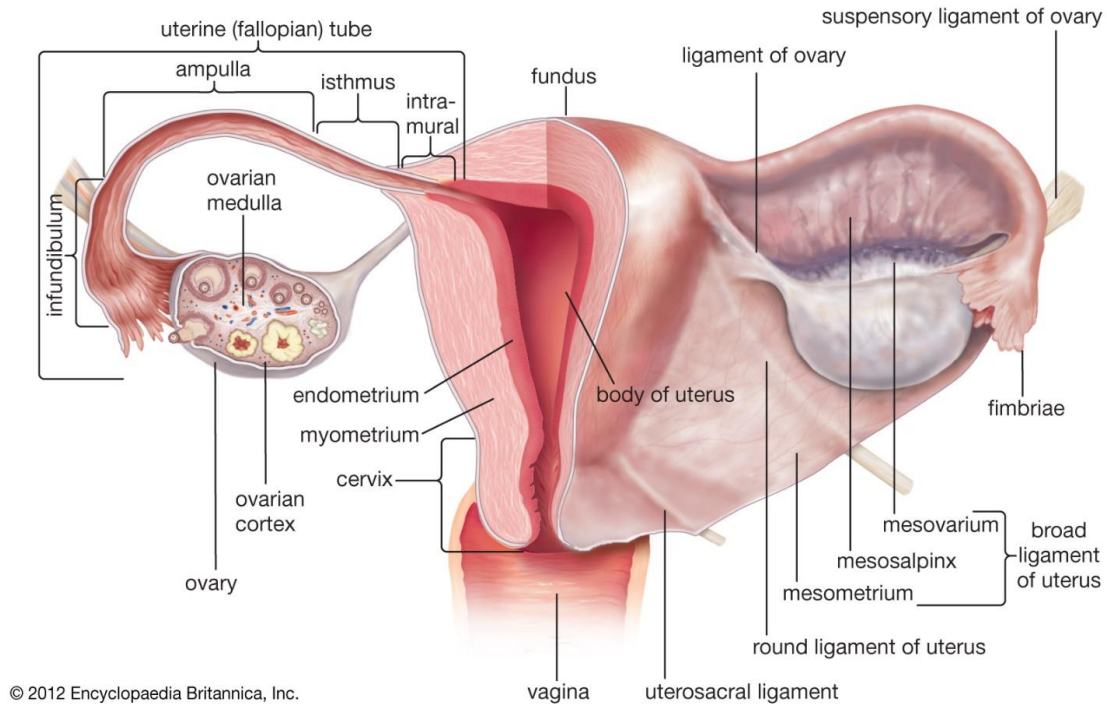
Mechanical methods compared with induction with oxytocin (reduced the risk of caesarean section -five studies; 398 women, RR 0.62;95% CI 0.42 to 0.90). The likelihood of vaginal delivery within 24 hours was not reported. Hyperstimulation with fetal heart rate changes was reported in one study (200participants), and did not differ. There were no reported cases of severe maternal or neonatal morbidity.

Authors' conclusions

Induction of labour using mechanical methods results in similar caesarean section rates as prostaglandins, for a lower risk of hyperstimulation. Mechanical methods do not increase the overall number of women not delivered within 24 hours, however the proportion of multiparous women who did not achieve vaginal delivery within 24 hours was higher when compared with vaginal PGE2. Compared with oxytocin, mechanical methods reduce the risk of caesarean section.

Uterus

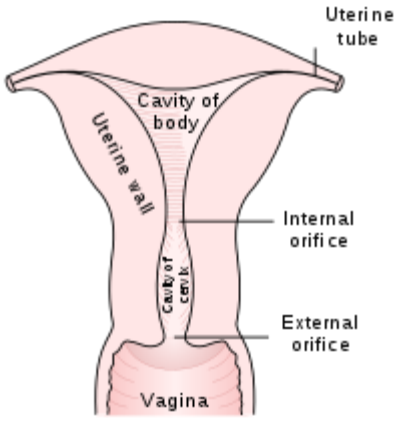
Gross anatomy



The uterus is a dynamic female reproductive organ that is responsible for several reproductive functions, including menses, implantation, gestation, labor, and delivery. It is responsive to the hormonal milieu within the body, which allows adaptation to the different stages of a woman's reproductive life. The uterus adjusts to reflect changes in ovarian steroid production during the menstrual cycle and displays rapid growth and specialized contractile activity during pregnancy and childbirth. It can also remain in a relatively quiescent state during the prepubertal and postmenopausal years. [1, 2]

The uterus has an inverted pear shape. In the adult, it measures about 7.5 cm in length, 5 cm wide at its upper part, and nearly 2.5 cm in thickness. It weighs approximately 30-40 grams.

Parts



The uterus is divisible into two portions: body and cervix. About midway between the apex and base, is a slight constriction known as the isthmus. The portion above the isthmus is termed the body, and that below, the cervix. The part of the body which lies above a plane passing through the points of entrance of the uterine tubes is known as the fundus. The body gradually narrows from the fundus to the isthmus. The cavity of the body is a mere slit, flattened anteroposteriorly. It is triangular in shape:

- the base being formed by the internal surface of the fundus between the orifices of the uterine tubes
- the apex by the internal orifice of the uterus through which the cavity of the body communicates with the canal of the cervix

The uterine cervix, although anatomically a part of the uterus, has a different function and is associated with separate pathological entities. This lowest section extends downward from the isthmus until it opens into the vagina. The uterine cavity opens into the vaginal cavity, and the two make up what is commonly known as the birth canal.

Embryology

The early development of the uterus is quite complex. At about eight weeks of gestation, primordia for both female and male internal genitalia [paramesonephric (Mullerian) and mesonephric (Wolffian)] ducts appear. The sexual differentiation process involves a series of steps which occur due to growth factors, hormonal signals, and inherited genetic influences.

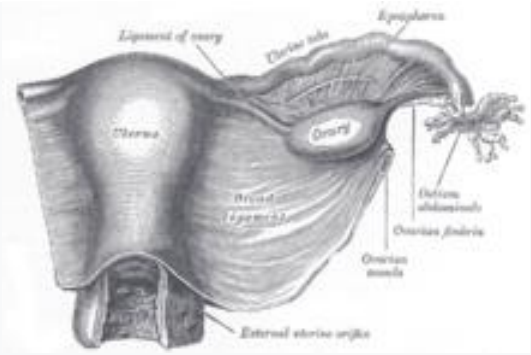
In the female embryo, because of the absence of a Y chromosome and lack of testosterone from any testicular tissue, the normal sequence of developmental events result in canalization and fusion of the paramesonephric (Mullerian) ducts in the middle of the pelvis which gives rise to the female pelvic organs. At this time, the mesonephric (Wolffian) ducts regress. Any abnormality that occurs during this phase of development may result in a variety of paramesonephric anomalies.

Layers of uterus

The uterus is comprised of three tissue layers which include the following:

- Endometrium: the inner lining and consists of the functional (superficial) and basal endometrium. The functional layer responds to reproductive hormones. When this layer is shed, this results in menstrual bleeding. If there is damage to the basal endometrium, this can result in the formation of adhesions and fibrosis (Asherman syndrome). During pregnancy, the uterine glands and blood vessels in the endometrium further increase in size and number and form the decidua. Vascular spaces fuse and become interconnected, forming the placenta, which supplies oxygen and nutrition to the embryo and fetus.[3,4]
- Myometrium: the muscle layer and is composed of smooth muscle cells.
- Serosa/Perimetrium: the thin outer layer composed of epithelial cells.

Support



Uterus covered by the broad ligament

The uterus is primarily supported by the pelvic diaphragm, perineal body, and urogenital diaphragm. Secondarily, it is supported by ligaments, including the peritoneal ligament and the broad ligament of uterus.[5]

Major ligaments

It is held in place by several peritoneal ligaments, of which the following are the most important (there are two of each):

Name	From	To
Uterosacral ligaments	Posterior cervix	Anterior surface of sacrum
Cardinal ligaments	Side of the cervix	Ischial spines
Pubocervical ligaments5	Side of the cervix	Pubic symphysis

Axis

Normally the uterus lies in anteversion & anteflexion. In most women, the long axis of the uterus is bent forward on the long axis of the vagina, against the urinary bladder. This position is referred to as anteversion of the uterus. Furthermore, the long axis of the body of the uterus is bent forward at the level of the internal os with the long axis of the cervix. This position is termed anteflexion of the uterus[6]. The uterus assumes an anteverted position in 50% women, a retroverted position in 25% women, and a midposed position in the remaining 25% of women.[7]

Position

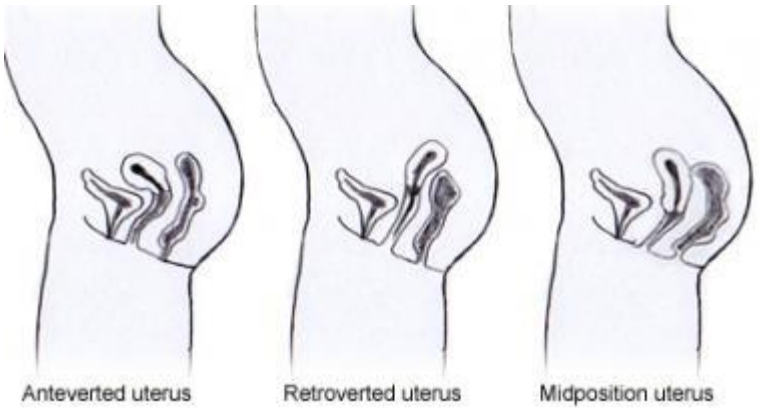
The uterus is in the middle of the pelvic cavity in frontal plane (due to ligamentum latum uteri). The fundus does not surpass the linea terminalis, while the vaginal part of the cervix does not extend below interspinal line. The uterus is mobile and moves posteriorly under the pressure of a full bladder, or anteriorly under the pressure of a full rectum. If both are full, it moves upwards. Increased intra-abdominal pressure pushes it downwards.

The mobility is conferred to it by musculo-fibrous apparatus that consists of suspensory and sustentacular part. Under normal circumstances the suspensory part keeps the uterus in anteflexion and

anteversion (in 90% of women) and keeps it "floating" in the pelvis. The meaning of these terms are described below:

Distinction	More common	Less common
Position tipped	"Anteverted": Tipped forward	"Retroverted": Tipped backwards
Position of fundus	"Anteflexed": Fundus is pointing forward relative to the cervix	"Retroflexed": Fundus is pointing backward

The sustentacular part supports the pelvic organs and comprises the larger pelvic diaphragm in the back and the smaller urogenital diaphragm in the front.



The pathological changes of the position of the uterus are:

- retroversion/retroflexion, if it is fixed
- Hyper anteflexion – tipped too forward; most commonly congenital, but may be caused by tumors

- anteposition, retroposition, lateroposition – the whole uterus is moved; caused by parametritis or tumors
- elevation, descensus, prolapse
- rotation (the whole uterus rotates around its longitudinal axis), torsion (only the body of the uterus rotates around)
- inversion

In cases where the uterus is "tipped", also known as retroverted uterus, the person may have symptoms of pain during sexual intercourse, pelvic pain during menstruation, minor incontinence, urinary tract infections, fertility difficulties 8 and difficulty using tampons. A pelvic examination by a doctor can determine if a uterus is tipped.

Position during different stages

In the fetus the uterus is contained in the abdominal cavity, projecting beyond the superior aperture of the pelvis. The cervix is considerably larger than the body.

At puberty the uterus is pyriform in shape, and weighs from 14 to 17 g. It has descended into the pelvis, the fundus being just below the level of the superior aperture of this cavity. The palmate folds are distinct and extend to the upper part of the cavity of the organ.

During menstruation the organ is enlarged, more vascular, and its surfaces rounder; the external orifice is rounded, its labia swollen, and the lining membrane of the body thickened, softer, and of a darker color.

During pregnancy the uterus becomes enormously enlarged, and by the eighth month reaches the epigastric region. The increase in size is partly due to growth of pre-existing muscle, and partly to development of new fibers.

After parturition the uterus nearly regains its usual size, weighing about 42 g; but its cavity is larger than in the virgin state, its vessels are tortuous, and its muscular layers are more defined. The external orifice is more marked, and its edges present one or more fissures.

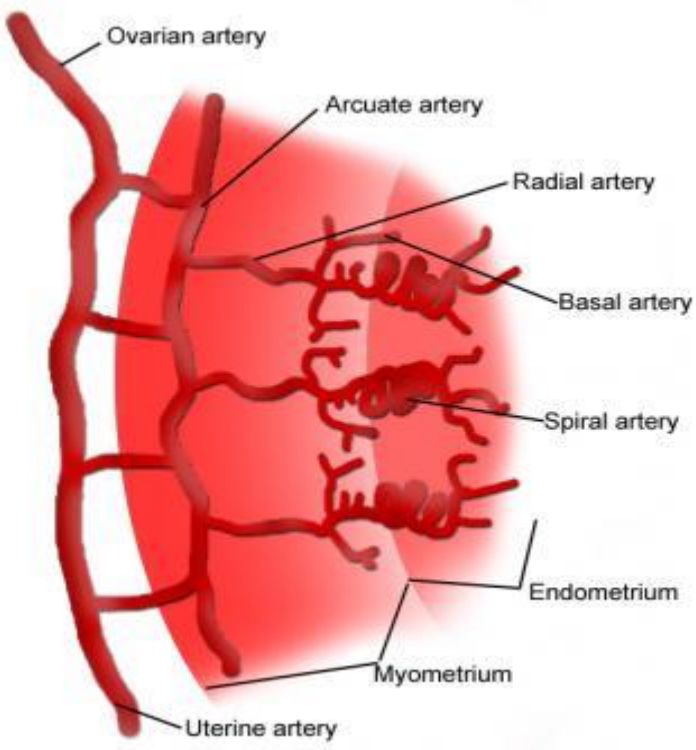
In old age the uterus becomes atrophied, and paler and denser in texture; a more distinct constriction separates the body and cervix. The internal orifice is frequently, and the external orifice occasionally, obliterated, while the lips almost entirely disappear.

Blood supply

- Arterial supply:

Blood is provided to the uterus by the ovarian and uterine arteries, the latter of which arise from the anterior divisions of the internal iliac artery. The uterine artery occasionally gives off the vaginal artery (although this is usually a separate branch of the internal iliac around),

which supplies the upper vagina, and the arcuate arteries, which surround the uterus. It then further branches into the radial arteries, which penetrate the myometrium to provide blood to all layers, including the endometrium (see the following image).



Once these vessels reach the endometrial level, they branch into the basal arteries and spiral arteries, which support the specialized functions of each layer. The basal arteries are not responsive to hormones; they support the basal endometrial layer, which provides the proliferative cells for endometrial growth. The spiral arteries supply the functionalis layer and are uniquely sensitive to steroid hormones. In ovulatory cycles in which pregnancy does not occur, menses results following constriction of

these terminal arteries, causing endometrial breakdown with desquamation of the glands and stroma.

- Venous drainage: uterine vein draining into internal iliac vein
- In the impregnated uterus the arteries carry the blood to, and the veins convey it away from, the intervillous space of the placenta

Lymphatic drainage

- Fundus: para-aortic nodes
- Body/cervix: internal and external iliac nodes; superficial inguinal nodes (via round ligament)

Nerve supply

Nerves from T11 and T12 innervate the uterus. The sympathetic supply is from the hypogastric plexus, and the parasympathetic supply is from S2 to S4.

Function

The reproductive function of the uterus is to accept a fertilized ovum which passes through the utero-tubal junction from the fallopian tube. The fertilized ovum divides to become a blastocyst, which implants into the endometrium, and derives nourishment from blood vessels which develop exclusively for this purpose. The fertilized ovum becomes an embryo, attaches to a wall of the uterus, creates a placenta, and develops into a fetus (gestates) until childbirth. Due to

anatomical barriers such as the pelvis, the uterus is pushed partially into the abdomen due to its expansion during pregnancy. Even during pregnancy the mass of a human uterus amounts to only about a kilogram (2.2 pounds).

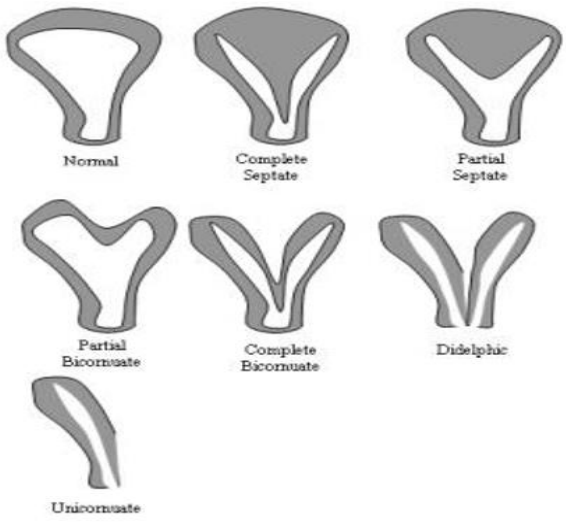
The uterus also plays a role in sexual response, by directing blood flow to the pelvis and ovaries, and to the external genitals, including the vagina, labia, and clitoris.

There is also some evidence that the uterus plays a role in cognition in a similar way to the ovaries. A study on rat models found that when the uterus was removed, the rats performed more poorly on spatial memory tasks. Prof. Bimonte-Nelson, the co-author of the study, explained: "....the body's autonomic nervous system, which regulates "automated" metabolic processes, such as heart rate, breathing, digestion, and sexual arousal, also has links to the uterus and brain."[10] No similar studies have yet been conducted on humans.

Pathophysiologic Variants

Paramesonephric (Mullerian) anomalies

Paramesonephric (Mullerian) anomalies have been classified by Buttram and Gibbons based on the degree and type of fusion or canalization defect



Labour

Definition

Labour is a physiologic process during which the products of conception (ie, the fetus, membranes, umbilical cord, and placenta) are expelled outside of the uterus. Labor is achieved with changes in the biochemical connective tissue and with gradual effacement and dilatation of the uterine cervix as a result of rhythmic uterine contractions of sufficient frequency, intensity and duration.[11]

Labor is a clinical diagnosis. The onset of labor is defined as regular, painful uterine contractions resulting in progressive cervical effacement and dilatation. Cervical dilatation in the absence of uterine contraction suggests cervical insufficiency, whereas uterine contraction without cervical change does not meet the definition of labor.

Epidemiology

Data from number a studies have suggested that normal labor can progress at a rate much slower than that Friedman and Sachtleben had described.[12] Zhang et al examined the labor progression of 1,162 nulliparas who presented in spontaneous labor and constructed a labor curve that was markedly different from Friedman's: The average interval to progress from 4-10 cm of cervical dilatation was 5.5 hours compared with 2.5 hours of Friedman's labor curve.[13] Kilpatrick et al and Albers et al also reported that the median lengths of first and second stages of labor were longer than those Friedman suggested.[14,15]

A number of investigators have identified several maternal characteristics obstetric factors that are associated with the length of labor. One group reported that increasing maternal age was associated with a prolonged second stage but not first stage of labor.[16]

While nulliparity is associated with a longer labor compared to multiparas, increasing parity does not further shorten the duration of labor.[17] Some authors have observed that the length of labor differs among racial/ethnic groups. One group reported that Asian women have the longest first and second stages of labor compared with Caucasian or African American women, and American Indian women had second

stages shorter than those of non-Hispanic Caucasian women.[18] However, others report conflicting findings.[19]

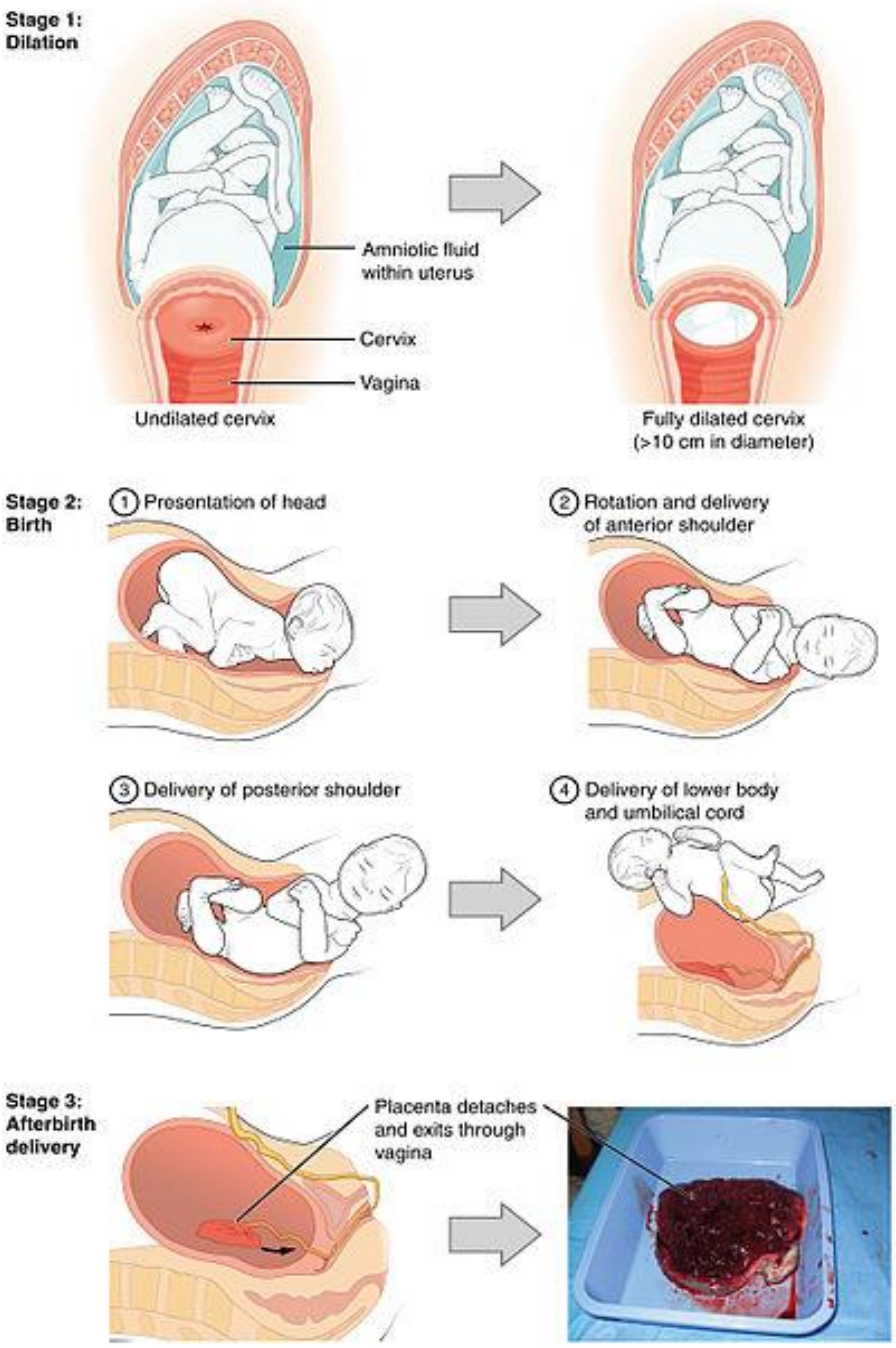
In one large retrospective study of the length of labor, specifically with respect to race and/or ethnicity, the authors observed no significant differences in the length of the first stage of labor among different racial/ethnic groups. However, the second stage was shorter in African American women than in Caucasian women for both nulliparas (-22 min) and multiparas (-7.5 min). Hispanic nulliparas, compared with their Caucasian counterparts, also had a shortened second stage, whereas no differences were seen for multiparas. In contrast, Asian nulliparas had a significantly prolonged second stage compared with their Caucasian counterparts and no differences were seen for multiparas.[20]

According to a systematic review of 13 trials involving 16,242 women, most women whose prenatal and childbirth care were led by a midwife had better outcomes compared with those whose care was led by a physician or shared among disciplines. Patients who received midwife-led pregnancy care were less likely to have regional analgesia, episiotomy, and instrumental birth and more likely to have no intrapartum analgesia or anaesthesia, spontaneous vaginal birth, attendance at birth by a known midwife, and a longer mean length of labor. They were also less likely to have preterm birth and fetal loss before 24 weeks gestation.

However, the average risk ratio for caesarean births did not differ between groups, and there were no differences in fetal loss / neonatal death at 24 or more weeks gestation or in overall fetal / neonatal death.[21]

Vaginal birth

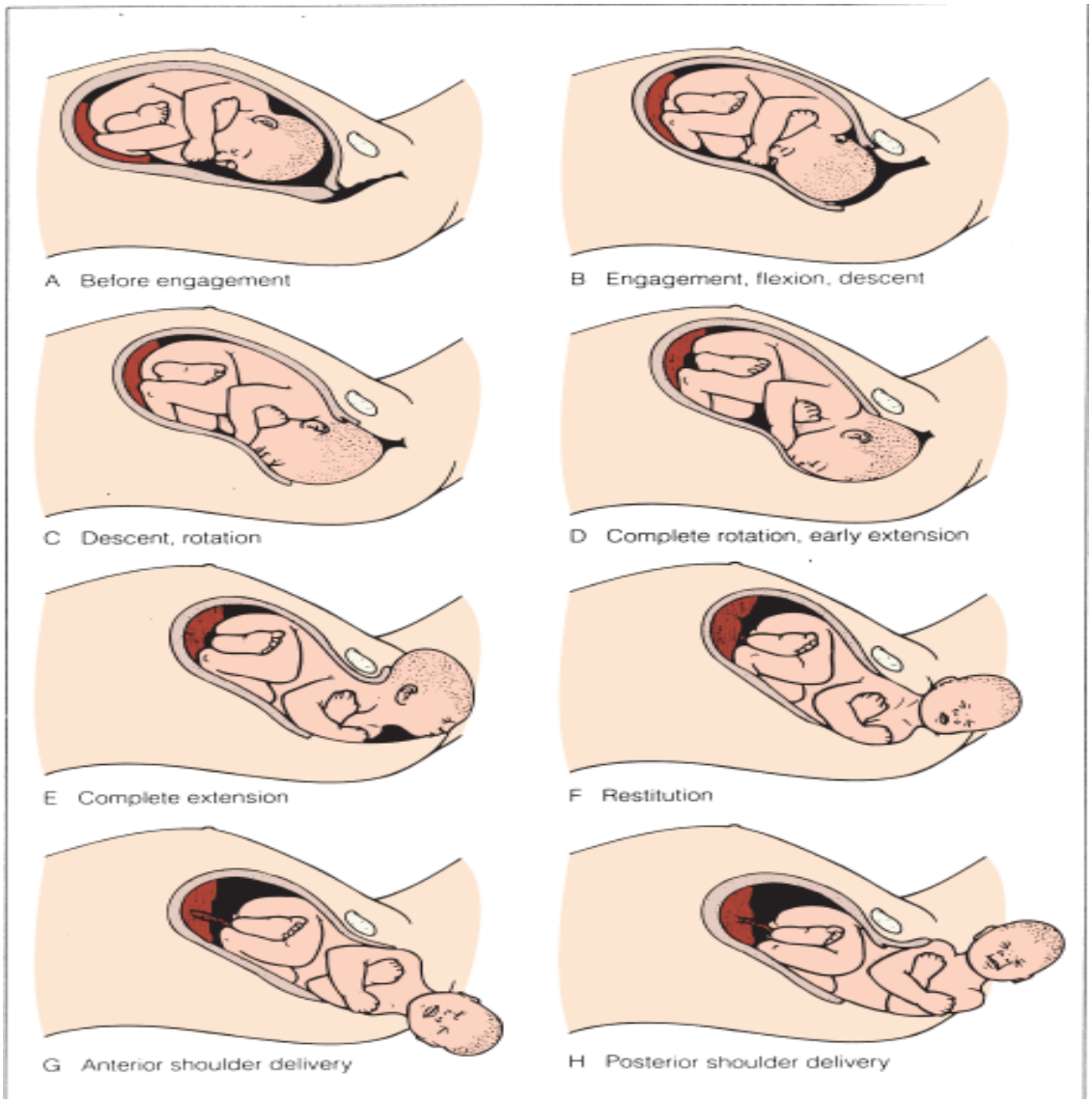
Humans are bipedal with an erect stance. The erect posture causes the weight of the abdominal contents to thrust on the pelvic floor, a complex structure which must not only support this weight but allow, in women, three channels to pass through it: the urethra, the vagina and the rectum. The infant's head and shoulders must go through a specific sequence of maneuvers in order to pass through the ring of the mother's pelvis.



Mechanism of Labor

The ability of the fetus to successfully negotiate the pelvis during labor involves changes in position of its head during its passage in labor.

The mechanisms of labor, also known as the cardinal movements, are described in relation to a vertex presentation, as is the case in 95% of all pregnancies. Although labor and delivery occurs in a continuous fashion, the cardinal movements are described as 7 discrete sequences, as discussed below. [22]



Engagement

The widest diameter of the presenting part (with a well-flexed head, where the largest transverse diameter of the fetal occiput is the

biparietal diameter) enters the maternal pelvis to a level below the plane of the pelvic inlet. On the pelvic examination, the presenting part is at 0 station, or at the level of the maternal ischial spines.

Descent

The downward passage of the presenting part through the pelvis. This occurs intermittently with contractions. The rate is greatest during the second stage of labor.

Flexion

As the fetal vertex descents, it encounters resistance from the bony pelvis or the soft tissues of the pelvic floor, resulting in passive flexion of the fetal occiput. The chin is brought into contact with the fetal thorax, and the presenting diameter changes from occipitofrontal (11.0 cm) to suboccipito-bregmatic (9.5 cm) for optimal passage through the pelvis.

Internal rotation

As the head descends, the presenting part, usually in the transverse position, is rotated about 45° to anteroposterior (AP) position under the symphysis. Internal rotation brings the AP diameter of the head in line with the AP diameter of the pelvic outlet.

Extension

With further descent and full flexion of the head, the base of the occiput comes in contact with the inferior margin of the pubic symphysis.

Upward resistance from the pelvic floor and the downward forces from the uterine contractions cause the occiput to extend and rotate around the symphysis. This is followed by the delivery of the fetal head.

Restitution and external rotation

When the fetal head is free of resistance, it untwists about 45° left or right, returning to its original anatomic position in relation to the body.

Expulsion

After the fetal head is delivered, further descent brings the anterior shoulder to the level of the pubic symphysis. The anterior shoulder is then rotated under the symphysis, followed by the posterior shoulder and the rest of the fetus.

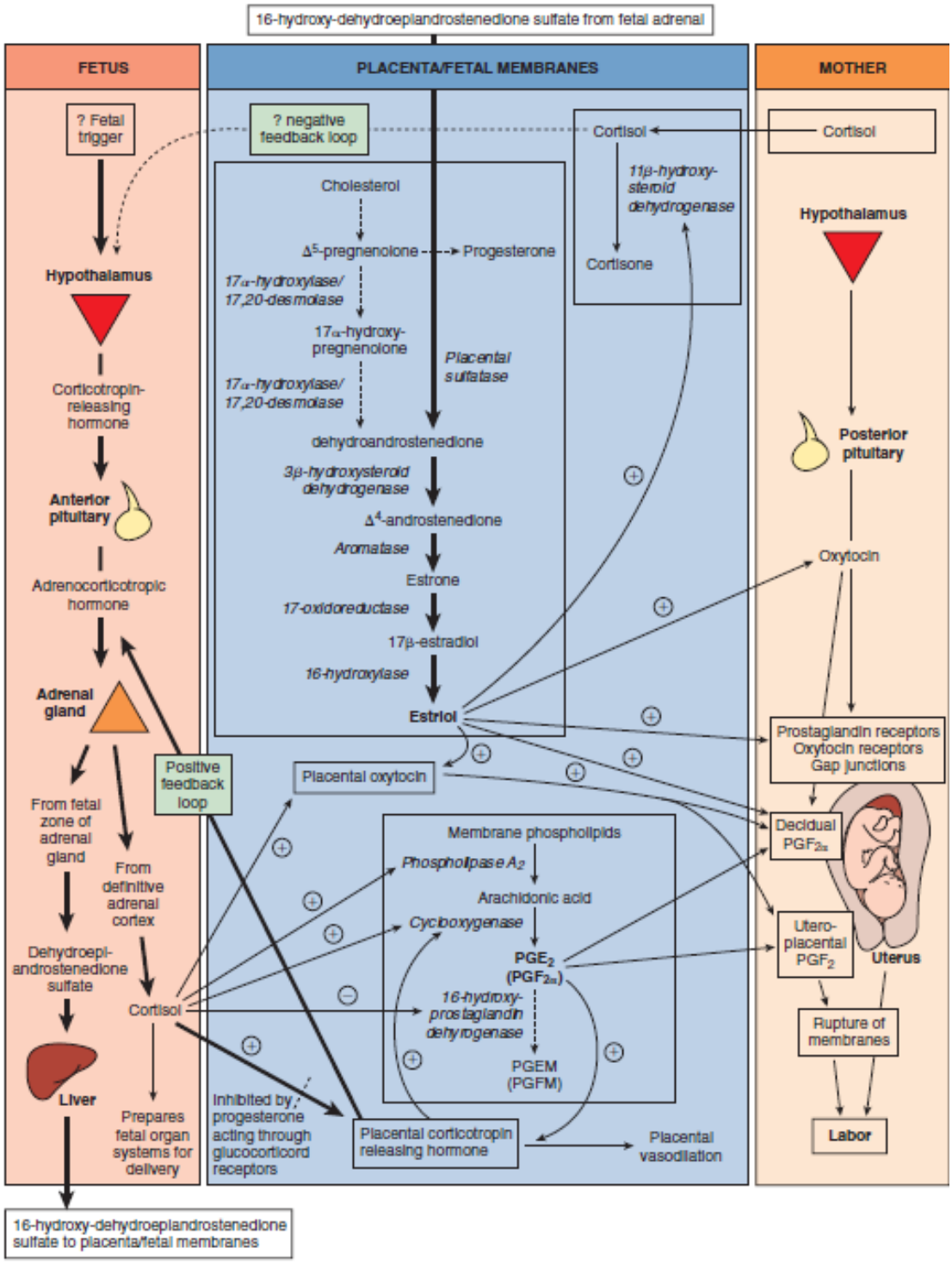
Station refers to the relationship of the fetal presenting part to the level of the ischial spines. When the presenting part is at the ischial spines the station is 0 (synonymous with engagement). If the presenting fetal part is above the spines, the distance is measured and described as minus stations, which range from −1 to −4 cm. If the presenting part is below the ischial spines, the distance is stated as plus stations (+1 to +4 cm). At +3 and +4 the presenting part is at the perineum and can be seen.[23]

The fetal head may temporarily change shape substantially (becoming more elongated) as it moves through the birth canal. This

change in the shape of the fetal head is called *moulding* and is much more prominent in women having their first vaginal delivery.[24]

Cervical ripening is the physical and chemical changes in the cervix to prepare it for the stretching that will take place as the fetus moves out of the uterus and into the birth canal. A scoring system called a Bishop score can be used to judge the degree of cervical ripening in order to predict the timing of labor and delivery of the infant or for women at risk for preterm labor. It is also used to judge when a woman will respond to induction of labor for a postdate pregnancy or other medical reasons. There are several methods of inducing cervical ripening which will allow the uterine contractions to effectively dilate the cervix.[25]

Onset of labour

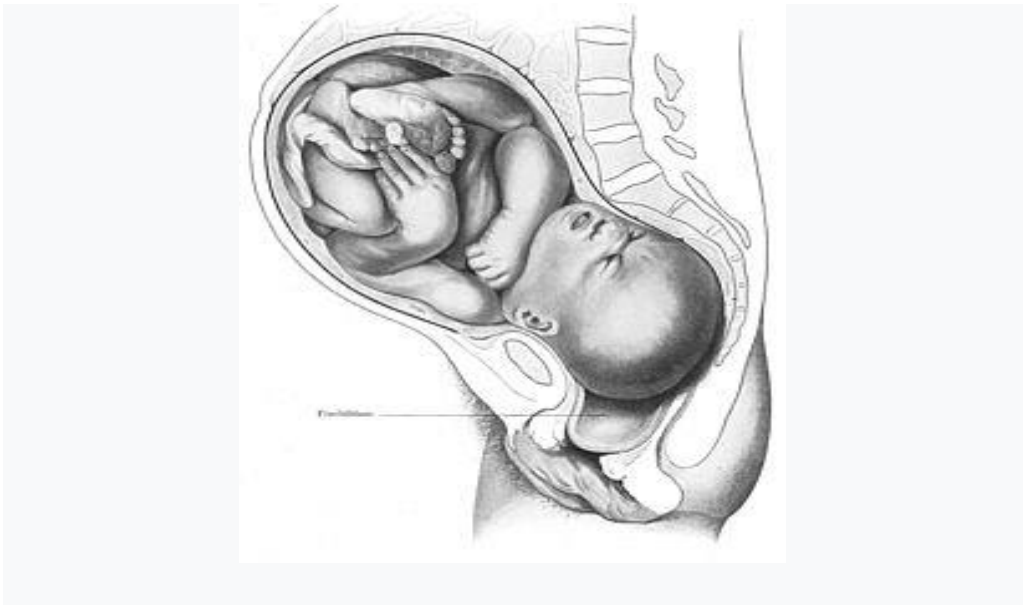


There are various definitions of the onset of labor, including:

- Regular uterine contractions at least every six minutes with evidence of change in cervical dilation or cervical effacement between consecutive digital examinations.[26]
- Regular contractions occurring less than 10 minutes apart and progressive cervical dilation or cervical effacement.[27]
- At least three painful regular uterine contractions during a 10-minute period, each lasting more than 45 seconds.[28]
    - **First stage: latent phase**
    - The latent phase is generally defined as beginning at the point at which the woman perceives regular uterine contractions.[29] In contrast, Braxton Hicks contractions, which are contractions that may start around 26 weeks gestation and are sometimes called "false labor", are infrequent, irregular, and involve only mild cramping.[30]
    - Cervical effacement, which is the thinning and stretching of the cervix, and cervical dilation occur during the last few weeks of pregnancy. Effacement is usually complete or near complete and dilation is about 5 cm by the end of the latent phase.[31] The degree of cervical effacement and dilation may be felt during a vaginal

examination. The latent phase ends with the onset of the active first stage.

- **First stage: active phase**



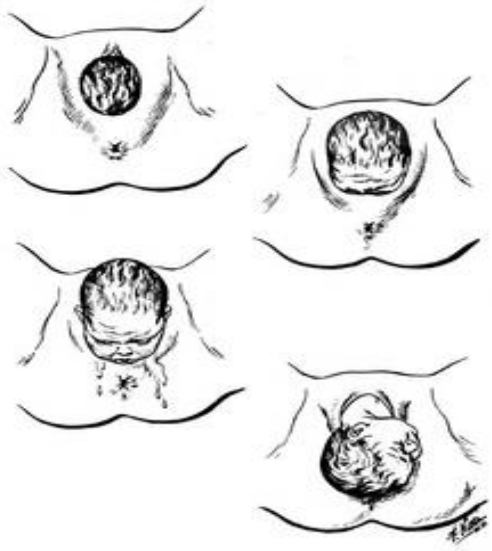
- Engagement of the fetal head
- The active stage of labor (or "active phase of first stage" if the previous phase is termed "latent phase of first stage") has geographically differing definitions. The World Health Organization describes the active first stage as "a period of time characterized by regular painful uterine contractions, a substantial degree of cervical effacement and more rapid cervical dilatation from 5 cm until full dilatation for first and subsequent labour.[32] In the US, the definition of active labor was changed from 3 to 4 cm, to 5 cm of cervical dilation for multiparous women, mothers who had given birth previously, and at 6 cm for nulliparous women,

those who had not given birth before.[33] This was done in an effort to increase the rates of vaginal delivery.[34]

- Health care providers may assess a laboring mother's progress in labor by performing a cervical exam to evaluate the cervical dilation, effacement, and station. These factors form the Bishop score. The Bishop score can also be used as a means to predict the success of an induction of labor.
- During effacement, the cervix becomes incorporated into the lower segment of the uterus. During a contraction, uterine muscles contract causing shortening of the upper segment and drawing upwards of the lower segment, in a gradual expulsive motion. The presenting fetal part then is permitted to descend. Full dilation is reached when the cervix has widened enough to allow passage of the baby's head, around 10 cm dilation for a term baby.
- A standard duration of the latent first stage has not been established and can vary widely from one woman to another. However, the duration of active first stage (from 5 cm until full cervical dilatation) usually does not extend beyond 12 hours in first labors ("primiparae"), and usually does not extend beyond 10 hours in subsequent labors ("multiparae"). The median duration of active

first stage is four hours in first labors and three hours in second and subsequent labours.[35]

- **Dystocia of labor**, also called "dysfunctional labor" or "failure to progress", is difficult labor or abnormally slow progress of labor, involving progressive cervical dilatation or lack of descent of the fetus. Friedman's Curve, developed in 1955, was for many years used to determine labor dystocia. However, more recent medical research suggests that the Friedman curve may not be currently applicable.[36]
- **Second stage: fetal expulsion**



- The expulsion stage begins when the cervix is fully dilated and ends when the baby is born. As pressure on the cervix increases, women may have the sensation of pelvic pressure and an urge to begin pushing. At the beginning of the normal second stage, the

head is fully engaged in the pelvis; the widest diameter of the head has passed below the level of the pelvic inlet. The fetal head then continues descent into the pelvis, below the pubic arch and out through the vaginal introitus (opening). This is assisted by the additional maternal efforts of "bearing down" or pushing. The appearance of the fetal head at the vaginal orifice is termed the "crowning". At this point, the woman will feel an intense burning or stinging sensation.

- When the amniotic sac has not ruptured during labor or pushing, the infant can be born with the membranes intact. This is referred to as "delivery en caul".
- Complete expulsion of the baby signals the successful completion of the second stage of labor.
- The second stage varies from one woman to another. In first labors, birth is usually completed within three hours whereas in subsequent deliveries, birth is usually completed within two hours.[37] Labors longer than three hours are associated with declining rates of spontaneous vaginal delivery and increasing rates of infection, perineal tears, and obstetric hemorrhage, as well as the need for intensive care of the neonate.[38]

- **Third stage: placenta delivery**
- The period from just after the fetus is expelled until just after the placenta is expelled is called the third stage of labor or the involution stage. Placental expulsion begins as a physiological separation from the wall of the uterus. The average time from delivery of the baby until complete expulsion of the placenta is estimated to be 10–12 minutes dependent on whether active or expectant management is employed.[39] In as many as 3% of all vaginal deliveries, the duration of the third stage is longer than 30 minutes and raises concern for retained placenta.[40]
- Placental expulsion can be managed actively or it can be managed expectantly, allowing the placenta to be expelled without medical assistance. Active management is the administration of a uterotonic drug within one minute of fetal delivery, controlled traction of the umbilical cord and fundal massage after delivery of the placenta, followed by performance of uterine massage every 15 minutes for two hours.[41] In a joint statement, World Health Organization, the International Federation of Gynaecology and Obstetrics and the International Confederation of Midwives recommend active management of the third stage of labor in all vaginal deliveries to help to prevent postpartum hemorrhage.[42,43,44]

- Delaying the clamping of the umbilical cord for at least one minute or until it ceases to pulsate, which may take several minutes, improves outcomes as long as there is the ability to treat jaundice if it occurs. For many years it was believed that late cord cutting led to a mother's risk of experiencing significant bleeding after giving birth, called postpartum bleeding. However a recent review found that delayed cord cutting in healthy full-term infants resulted in early haemoglobin concentration and higher birth weight and increased iron reserves up to six months after birth with no change in the rate of postpartum bleeding.[45,46]

Fourth stage

The "fourth stage of labor" is the period two hours immediately after delivery. The terms postpartum and postnatal are often used for this period.[47] The woman's body, including hormone levels and uterus size, return to a non-pregnant state and the newborn adjusts to life outside the mother's body. The World Health Organization (WHO) describes the postnatal period as the most critical and yet the most neglected phase in the lives of mothers and babies; most deaths occur during the postnatal period.[48]

Labor induction

In many cases and with increasing frequency, childbirth is achieved through induction of labor or caesarean section. Caesarean section is the removal of the neonate through a surgical incision in the abdomen, rather than through vaginal birth.[49] Childbirth by C-Sections increased by 50% even in developed countries from 1996 to 2006.[47] Induced births and elective cesarean before 39 weeks can be harmful to the neonate as well as harmful or without benefit to the mother. Therefore, many guidelines recommend against non-medically required induced births and elective cesarean before 39 weeks.[50] The 2012 rate of labor induction has more than doubled from 1990 to 2010 in some developed countries like USA.[51] The American Congress of Obstetricians and Gynecologists (ACOG) guidelines recommend a full evaluation of the maternal-fetal status, the status of the cervix, and at least a 39 completed weeks (full term) of gestation for optimal health of the newborn when considering elective induction of labor. As Per these guidelines, the following conditions may be an indication for induction, including:

- Abruptio placentae
- Chorioamnionitis
- Fetal compromise such as isoimmunization leading to hemolytic disease of the newborn or oligohydramnios

- Fetal demise
- Gestational hypertension
- Maternal conditions such as gestational diabetes or chronic kidney disease
- Preeclampsia or eclampsia
- Premature rupture of membranes
- Postterm pregnancy

Induction is also considered for logistical reasons, such as the distance from hospital or psychosocial conditions, but in these instances gestational age confirmation must be done, and the maturity of the fetal lung must be confirmed by testing. The ACOG also note that contraindications for induced labor are the same as for spontaneous vaginal delivery, including vasa previa, complete placenta praevia, umbilical cord prolapse or active genital herpes simplex infection.[52]

In general cervical induction methods could be divided into pharmacological or non pharmacological.

Non-Pharmacological methods:

Herbal supplements

Castor oil, hot baths, and enemas

Sexual intercourse

Breast stimulation

Acupuncture/transcutaneous nerve stimulation

Mechanical modalities

Surgical methods

Pharmacologic

Prostaglandins

Antiprogesterone agent.

Non pharmacological methods

HERBAL SUPPLEMENTS

Given rapid growth in the herbal-supplement industry, it is not surprising that patients request information about alternative agents for labour induction. Commonly prescribed agents include evening primrose oil, black haw, black and blue cohosh, and red raspberry leaves. Although evening primrose oil is the remedy most commonly used by midwives, it is unclear whether this substance can ripen the cervix or induce labour. Black haw, which has been described as having a uterine tonic effect, has been used to prepare women for labour. Black cohosh has a similar mechanism of action, while blue cohosh may stimulate uterine contractions. Red raspberry leaves are used to enhance uterine contractions once labour is initiated. The risks and benefits of these agents are still unknown because the quality of evidence is based on

along tradition of use by a certain population and anecdotal case reports. The only conclusion that can be made atthis time is that the role of herbal remedies in cervical ripening or labour induction is still uncertain.[53]

CASTOR OIL, HOT BATHS, AND ENEMAS

Castor oil, hot baths, and enemas also have been recommended for cervical ripening or labour induction. The mechanisms of action for these methods are unknown. Review of the literature indicates that one poorly designed study involving 100 participants studied castor oil versusno treatment. While there did not appear to be any difference in obstetric or neonatal outcomes, all women ingesting the castor oil reported being nauseated. At this time, no evidence supports the use of these three modalities as viable methods for cervical ripening or labour induction.[53,54]

SEXUAL INTERCOURSE

Sexual intercourse is commonly recommended for promoting labour initiation. Sexual relations usually involve stimulation of the breasts and nipples, which can promote the release of oxytocin. With penetration, the lower uterine segment is stimulated. This stimulation results in a local release of prostaglandins. Female orgasms have been shown to include uterine contractions, and human semen contains prostaglandins, which are responsible for cervical ripening. Only one study of 28 women resulted in minimally useful data, so the role of sexual

intercourse as a method of promoting labour initiation remains uncertain.[53,55]

Breast massage and nipple stimulation

Breast massage and nipple stimulation have been shown to facilitate the release of oxytocin from the posterior pituitarygland. The most commonly prescribed technique involves gently massaging the breasts or applying warm compresses to the breasts for one hour, three times a day. Six randomized studies, involving 719 women using and not using this type of intervention have demonstrated that after 72 hours there were fewer pregnant women not in labour in the group using nipple stimulation and a lower risk for post-partum hemorrhage.[56] Oxytocin is released, and studies have demonstrated an abnormal fetal heart rate (FHR) tracing similar to that occurring in oxytocin challenge testing in higher-risk pregnancies.This abnormal rate may be caused by a reduction in placental perfusion and fetal hypoxia.1 Two poorly designed studies conducted in the 1970s and 1980s demonstrated a difference in the intervention groups, but the poor study design suggests that evidence is lacking to support breast stimulation as a viable method of inducing labor.[53]

ACUPUNCTURE/TRANSCUTANEOUSNERVE STIMULATION

Acupuncture involves the insertion of very fine needles into designated locations with the purpose of preventing or curing disease. In the Chinese system of medicine, it is thought that acupuncture stimulates channels of qi (pronounced “chee”), or energy. This energy flows along 12 meridians, with designated points along these meridians. Each point is given a name and a number and is associated with a specific organ system or function. In Western medicine, it is thought that acupuncture and transcutaneous nerve stimulation (TENS) may stimulate the release of prostaglandins and oxytocin. Most of the studies involving acupuncture were poorly designed and do not meet the rigorous criteria for analysis set forth by the Cochrane reviewers. A well-designed randomized controlled trial (RCT) is needed to evaluate the role of acupuncture and TENS in labor induction.[57]

MECHANICAL MODALITIES

All mechanical modalities share a similar mechanism of action namely, some form of local pressure that stimulates the release of prostaglandins.[58] Among them there are different types of catheters (including the Foley catheter) and hygroscopic dilators introduced in the cervicalcanal or extra-amniotic space. The risks associated with these methods include infection (endometritis and neonatal sepsis have been

associated with natural osmotic dilators), bleeding, membrane rupture, and placental disruption.

Mechanical methods were never totally abandoned but extensively replaced by pharmacological methods in the last decades. There is a recent trend of reintroducing it for clinical use because of some advantages and availability of sterile devices, controlling one of the principal contraindications, infection. Potential advantages of mechanical methods in comparison with pharmacological ones include easy conservation, low cost and less side effects. Nevertheless, there is contraindication of its use in pregnant women with low inserted placentas, with premature rupture of membranes and as it was already stated there could be higher incidence of puerperal infection and discomfort among users of these methods.[59]

Hygroscopic dilators

Hygroscopic dilators predominantly act by absorbing water from the cervix, thereby dehydrating the cervix and making it ‘soft’ and ‘ripe’. As the dilator expands, it has a mechanical expanding dilation effect, which stimulates endogenous prostaglandin release, there by actively aiding the ripening process. The products available include natural osmotic dilators (e.g. Laminaria japonicum) and synthetic osmotic dilators (e.g. Lamicel). The main advantages of using hygroscopic

dilators include outpatient placement and no FHR-monitoring requirements.

Technique for Insertion of Hygroscopic Dilators

The perineum and vagina are prepped with antiseptic. Using a sterile speculum examination to visualize the cervix, the dilator is introduced into the endocervix, allowing the “tails”to fall into the vagina. Dilators are progressively placed until the endocervix is “full.” The number of dilators used is noted in the medical record. A sterile gauze pad is placed in the vagina to maintain the position of the dilators.

Laminaria (*Laminaria digitata or Laminaria japonica*), use has been described since the Eighteenth Century but its use was abandoned due to the risk of infection. In the70's with the new sterilization techniques its use was resumed with satisfactory results.[60,61]

Balloon devices

The use of a catheter in the extra-amniotic space occurred the first time in 1853 by Krause quoted by Hamilton, a method named after him. At that time a rigid catheter was used.[62] After that the Foley catheter, a flexible catheter was used to induce labour in women with unripe cervices with 94% of success.[63] At times this method is still described like the modified Krause method and because it is more acceptable and less

risky it has been more utilized that the classically described method. Balloon devices provide mechanical pressure directly on the cervix as the balloon is filled. The mechanism of the Foley catheter is based on the presence of a mechanical factor acting continuously on the cervix and in addition because it separates the chorion from the decidua releasing local prostaglandins.[64]A Foley catheter (26 Fr) or specifically designed balloon devices can be used.

Technique for Placement of Balloon Dilators

The catheter is introduced into the endocervix by direct visualization or blindly by locating the cervix with the examining fingers and guiding the catheter over the hand and fingers through the endocervix and into the potential space between the amniotic membrane and the lower uterine segment. The balloon reservoir is inflated with 30 to 50 mL of normal saline.The balloon is retracted so that it rests on the internal os. Additional steps that may be taken:

• Apply pressure by adding weights to the catheter end. Constant pressure: attach 1 L of intravenous fluids to the catheter end and suspend itfrom the end of the bed. Intermittent pressure: gently tug on the catheter end two to four times per hour.

• Saline infusion:

Inflate catheter with 40 mL of sterile water or saline. Infuse sterile saline at a rate of 40 mL per hour using an infusion pump. Remove six hours later or at the time of spontaneous expulsion or rupture of membranes (whichever occurs first).[65]

• Prostaglandin E2 infusion.[66]

Double balloon catheter

Atad et al.15 first described the double balloon catheter in1991. In 2005, the US Food and Drug Administration (FDA) approved the 'Atad Ripener Device', an 18 French natural latex, 3-lumen catheter with double balloons, each with a capacity of 80 ml, placed 2 cm apart at the distal end. The double balloon is thought to be superior to a Foley catheter because the forces of dilation occur from both sides of the cervical os, whereas the Foley catheter only exerts force on the internal os, particularly when placed on traction.[67]The FDA approved the Cook cervical ripening balloon in2013.[68] This is an 18 French silicone double balloon catheter (balloon capacity 80ml each), which comes with an optional stylet to aid insertion.

Single balloon Foley catheter versus double balloon catheter

Recent evidence shows no significant difference in delivery intervals or modes of birth between use of the single balloon Foley

catheter over the double balloon catheter.[69,70,71] The Foley catheter is not currently licensed for preinduction cervical ripening unlike the double balloon catheters.

Balloon volumes

A 2014 systematic review and meta-analysis compared the use of low volume (30 ml) and high volume (60 ml, 80ml) Foley bulbs. Attainment of a favourable cervix was more likely with the use of high volume catheters. High volume Foley catheters resulted in a significantly reduced likelihood of failure to deliver within 24 hours (relative risk [RR] 0.70 ; 95% confidence interval [CI] 0.54 – 0.90), and the reduction was greater with use of 80 ml Foley catheters than with 30 ml Foley catheters (RR 0.57; 95% CI 0.40–0.81). The rate of caesarean section with use of 80ml Foley catheters was not significantly different to that observed with the 30 ml Foley catheters (RR 0.82; 95% CI0.48–1.41), but the overall risk ratio slightly favoured the high volume Foley catheters.[72,73] Alarge RCT is required, using caesarean section as a primary outcome for low versus high volume catheters.

Balloon traction

A 2013 RCT compared the use of inner thigh taping with using traction with a 500 ml weighted bag of fluid in women with an intracervical 30 ml Foley catheter for pre-induction cervical ripening. No

differences were identified in the time to delivery, delivery within a 24-hour period, rate of caesarean sections, pain scores or the use of epidural analgesia. These results were similar for nulliparous and multiparous women. A statistically significant shorter catheter expulsion interval was identified in the traction group, with no improvement in outcomes.[74]

Infection risk with balloon catheters

There is a reported theoretical risk of infection with the use of mechanical methods, but the evidence to support or refute this claim is sparse. According to a 2012 Cochrane review, there is no evidence of an increased risk of infection with mechanical methods; however, the authors advised caution in interpreting this finding in view of the limited available evidence.[74]

SURGICAL METHODS

Stripping of the Membranes. Stripping of the membranes causes an increase in the activity of phospholipase A2 and prostaglandin as well as causing mechanical dilation of the cervix, which releases prostaglandins. The membranes are stripped by inserting the examining finger through the internal cervical os and moving it in a circular direction to detach the inferior pole of the membranes from the lower uterine segment.[75,76] Risks of this technique include infection, bleeding, accidental rupture of the membranes, and patient discomfort. The Cochrane reviewers concluded

that stripping of the membranes alone does not seem to produce clinically important benefits, but when used as an adjunct does seem to be associated with a lower mean dose of oxytocin needed and an increased rate of normal vaginal deliveries.[77]

Amniotomy. Membrane stripping was initially suggested in1810 by James Hamilton for labour induction. It is a very often used simple technique with few comparative studies until recently. It is hypothesized that amniotomy increases the production of, or causes a release of, prostaglandins locally. Risks associated with this procedure include umbilical cord prolapse or compression, maternal or neonatal infection, FHR deceleration, bleeding from placenta previa or low-lying placenta, and possible fetal injury.[75]

Evaluation of results from 19 controlled studies determined that this intervention was associated to a reduced rate of post-term pregnancies, i.e. beyond 41 weeks, less need for the application of other induction methods, no increased risk for premature rupture of membranes or neonatal infection.[78]

Technique for Performing Amniotomy

A pelvic examination is performed to evaluate the cervix and station of the presenting part. The fetal heart rate is recorded before and after the procedure. The presenting part should be well applied to the cervix.The membranes over the fetal head are removed by the examining finger. A cervical hook is inserted through the cervical os by sliding it along the hand and fingers (hook side toward the hand).The membranes are scratched or hooked to effect rupture. The nature of the amniotic fluid is recorded (clear, bloody, thick or thin, meconium).

However NICE does not recommend the use of an amniotomy, with or without oxytocin, as a primary method of labour induction, unless there are specific contraindications to the use of PGs.[79] Data on the effectiveness and safety of amniotomy and intravenous oxytocin alone are lacking.[80] The immediate versus delayed use of an oxytocin infusion after amniotomy for the purpose of IOL was compared in asmall randomised controlled trial (RCT) in 2009. The likelihood of being in established labour 4 hours after amniotomy, and having a shorter amniotomy to delivery interval, was higher in the immediate infusion group.[81] A more recent RCT compared immediate and delayed (4 hours) oxytocin use in parous women and found that both options were

reasonable, thus the decision should be based on local resources and maternal choice.[82]

Pharmacologic methods

Among these methods there are the drugs involved in collagen degradation and or myometrical contractility onset, i.e. relaxin, estrogens, corticosteroids, oxytocin, prostaglandins, mifepristone and hyaluronidase.

Prostaglandins

When many studies attempted to determine the role of Prostaglandin (Pg) in the uterus cervix and which of them would cause effects similar to physiological processes, it was determined that PgF2α would be the one causing cervical changes more similar to physiological ones.[83] Afterwards with the development of PgE2 in form of a gel forcervical use, it became the choice Pg for cervical ripening and labor induction in developed countries. Prostaglandins act on the cervix to enable ripening by anumber of different mechanisms. They alter the extracellular ground substance of the cervix, and PGE2 increases the activity of collagenase in the cervix. They cause an increase in elastase, glycosaminoglycan, dermatan sulfate, and hyaluronic acid levels in the cervix. A relaxation of cervical smooth muscle facilitates dilation. Finally, prostaglandins allow for an increase in intracellular calcium levels, causing contraction of myometrial muscle.[84,85] Risks associated

with the use of prostaglandins include uterine hyperstimulation and maternal side effects such as nausea, vomiting, diarrhea, and fever. Currently, two prostaglandin analogues of PgE2 are available for the purpose of cervical ripening, dinoprostone gel and dinoprostone inserts. The gel form contains 0.5 mg of dinoprostone, while pessary contains 10 mg of dinoprostone.[86]

Technique for Placement of Dinoprostone Gel

Patient selection:

Patient is afebrile.

No active vaginal bleeding is present.

Fetal heart rate tracing is reassuring.

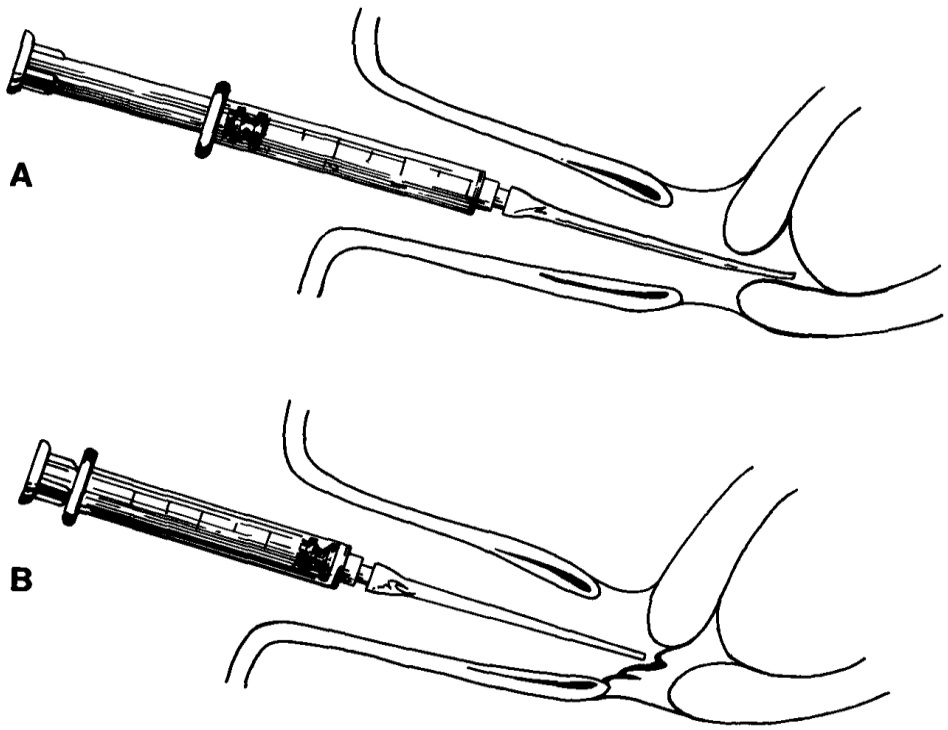
Patient gives informed consent.

Bishop score is < 4.

Bring gel to room temperature before application, per manufacturer's instructions. Monitor fetal heart rate and uterine activity continuously starting15 to 30 minutes before gel introduction and continuing for 30 to 120 minutes after gel insertion. Introduce the gel into the cervix as follows: If the cervix is uneffaced, use the 20-mm endocervical catheter to introduce the gel into the endocervix just below the level of the internal os. If the cervix is 50 percent effaced, use the 10-

mm endocervical catheter. After application of the gel, the patient should remain recumbent for 30 minutes before being allowed to ambulate. May repeat every six hours, up to three doses in 24 hours. End points for ripening include strong uterine contractions, a Bishop score of ≥8, or a change in maternal or fetal status. Maximum recommended dosage is 1.5 mg of dinoprostone (3 doses) in 24 hours.

Do not start oxytocin for six to 12 hours after placement of the last dose, to allow for spontaneous onset of labor and protect the uterus from over stimulation.



The Cochrane reviewers examined 52 well-designed studies using prostaglandins for cervical ripening or labor induction. Compared with

placebo (or no treatment), useof vaginal prostaglandins increased the likelihood that a vaginal delivery would occur within 24 hours. In addition, the cesarean section rate was comparable in all studies. The only drawback appears to be an increased rate of uterine hyperstimulation and accompanying FHR changes.[87,88]

Misoprostol is a synthetic PGE1 analogue that has been found to be a safe and inexpensive agent for cervical ripening, although it is not labeled by the U.S. Foodand Drug Administration for that purpose.[89] Clinical trials indicate that the optimal dose and dosinginterval is 25 mcg intravaginally every four to six hours.[84] Higher doses or shorter dosing intervals are associatedwith a higher incidence of side effects, especially hyperstimulation syndrome, defined as contractions lasting longer than 90 seconds or more than five contractions in10 minutes. Risks also include tachysystole, defined as six or more uterine contractions in 10 minutes for two consecutive 10 minute periods, and hypersystole, a single contraction of at least two minutes' duration. Finally, uterine rupture in women with previous cesarean section is also a possible complication, limiting its use to women who do not have a uterine scar.[58] The Cochrane reviewers concluded that use of misoprostol resulted in an overall lower incidence of cesarean section. Additional review of the literature indicates that misoprostol is an effective agent for cervical ripening.[90]

Mifepristone

Mifepristone or RU 486 is a progesterone antagonist used since 1988 especially in Western Europe. It was initially developed as an abortifacient. Progesterone inhibits contractions of the uterus, while mifepristone counteracts this action. It causes dilation of the cervical canal and increases uterine contractility, thus reducing the required doses of prostaglandin to expel the embryo. It has been recently used in cases of post-term pregnancies in comparison with a group receiving placebo. This study involved 180 of which 97 used mifepristone, with a statically significant difference related to labor time, the mean oxytocin dosage used and the occurrence of vaginal delivery in the group using the medication. Bishop score did not vary following theuse of RU486 or placebo. The conclusion is that its action in cervix ripening is modest but it does reducethe need of other drugs to induce labor.[91] It probably is a new field for future research on cervical ripening and labor induction in viable pregnancies. A systematic review concluded that data are insufficient to assess the efficacy of mifepristone for cervical ripening and there are no comparative studies of this method with others such as, for example prostaglandins. Nevertheless, when compared to placebo there is evidence that the risk for C-section is lower for women treated with this substance.[92]

Miscellaneous methods:

Experimental studies in lambs indicated an increase of estrogen concentration in serum and progesterone reduction before parturition onset. The hypothesisis that these changes would stimulate the production of prostaglandins, then favoring the onset of labor.[93] A systematic review determined the lack of data leading to definitive conclusions, nevertheless the studies analyzed do not indicate differences between women using estrogens for cervical ripening when compared to women using placebo.[94] The role of corticosteroids in the labor process is not well known yet. Classical experimental studies indicated the value of cortisol secretion by the fetal adrenal gland to the onset of parturition in lambs. In addition, glycocorticoids infusion in lamb's fetus has induced preterm delivery. Some studies tried to showthat the use of glycocorticoids in post-term pregnant women in the intra-amniotic space could induce labor, nevertheless there are no clinical trials to comparethese results with other methods for cervical ripening or labor induction.[95] As for oxytocin it is known that when used intravenously, it encourages and coordinates uterine activity, affecting myometrial muscles and increasingthe frequency and intensity of contractions which inturn will cause cervical changes. This mechanism is more easily obtained in term or post-term pregnancies due to the physiological increase of endogenous estrogen at

this time, which promotes the stimulation of oxytocin receptors thus facilitating the action of exogenous oxytocin.[96] Oxytocin has been safely used for decades and theresults are satisfactory for labor induction. The proposal to use in women with unfavorable cervical conditions is through serial induction sessions of 10 to 12 hours a day, followed by rest, with duration ofthree tofour consecutive days. Nevertheless, different studies have demonstrated that its efficacy for cervical ripening is lower than other more specific methods. Comparing oxytocin results with other methods of cervix ripening / induction, results were less favourable for women using oxytocin only, with lower vaginal delivery rates and longer induction time.[97]

INSTARIPE-PANICKER'S RAPID CERVICAL RIPENING DEVICE

Instaripe is a new device designed by Dr. Panicker, to be used along with the conventional foleys catheter to enhance its efficiency. It is a specially designed conical tubular device made of soft autoclaveable and reusable silicon. It is 8cm in length and 3cm in diameter on one end, the other end is 1cm in diameter and is connected to a stainless steel tube of 8mm diameter and 3 cm length. The stainless steel tube has a slit at the tip on one side.

As opposed to the conventional method, where the foley's catheter is just fixed to patient's thigh, the catheter is hooked through the instaripe device in this technique (as shown in the picture).

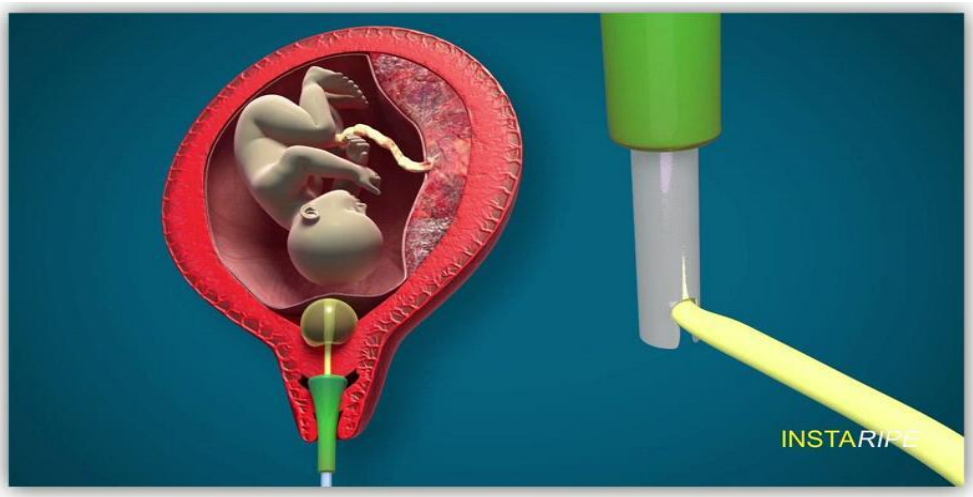


Fig No: (3) Foley's catheter pulled down with force and fixed to the side hole of the device under tension.

This enables the better fitting of foley's bulb into cervix and thus resulting in a sustained traction over it. With increasing utilization of balloon catheter for induction, this device is expected to further augment the process.

AIM AND OBJECTIVES

AIM AND OBJECTIVES

To compare the efficacy of foley's catheter induction aided by Panicker's cervical ripening device with normal foley's catheter induction.

MATERIALS AND METHODS

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Source of data:

- Antenatal cases in Department of Obstetrics and Gynaecology, Madurai medical college, Madurai.

Methods of collection of data:

- **Study design:** Comparative, Prospective Study.
- **Study period:** 6 months
- **Sample design**: Simple Random Sampling
- **Sample size:** 100
- **Inclusion Criteria:**

  Antenatal women

  1. Term pregnancy
  2. Singleton pregnancy
  3. Cephalic presentation
  4. Reassuring foetal status

- **Exclusion Criteria:**

  1. Previous LSCS
  2. CPD
  3. Ruptured membranes
  4. Twins
  5. Polyhydraminos
  6. Abnormal placental position - placenta previa
  7. Abruptio placenta
  8. Associated maternal complications- heart disease, prior

uterine surgery / myomectomy

9. Any contraindication to vaginal delivery
10. Any contraindication to labour induction
11. Patient not willing inspite of counselling

Methodology:

This study will be conducted at Government Rajaji Hospital, Madurai for a period of 6 months. Hundred antenatal cases who have a gestational age of 38 weeks, singleton pregnancy with a cephalic presentation, reassuring foetal status and those with a Bishop's score of ≤ 6 are included. The exclusion criteria includes ruptured membranes, twin pregnancy, polyhydramnios, placenta previa and any contraindication for the labor induction. A written informed consent will be taken from all the cases who are under study.

Group F:

Under aseptic conditions, with the patients lying in the lithotomy position, the cervix assessed on a Bishop's scoring scale. A 16 French Foley catheter is inserted into the endocervical canal, beyond the internal os and the balloon is inflated with 60ml of sterile water.

The catheter is strapped to the thigh with gentle traction. The catheter is either removed at 24 hours or it is expelled spontaneously and it is checked whether the modified Bishop's score improved.

Group FI:

Under aseptic conditions, with the patients lying in the lithotomy position, the cervix assessed on a Bishop's scoring scale. After inserting the 16 French Foley catheter through instaripe device, foley's catheter is inserted into the endocervical canal, beyond the internal os and the balloon is inflated with 60ml of sterile water and the ripening device is slowly introduced into the vagina after lubricating with xylocaine jelly, to press on to the cervix. Then the foley is pulled down with force and fixed on to the side hole of the device under tension.

The catheter is either removed at 6 hours or it is expelled spontaneously and it is checked whether the modified Bishop's score improved.

Tests that were carried out in the study

1. Hemoglobin
2. RFT
3. LFT
4. Blood grouping & typing
5. Urine – albumin, sugar, deposits
6. GCT
7. USG abdomen and pelvis

- Primary outcomes like cervical score improvement, induction delivery interval, and secondary outcomes like neonatal APGAR score were evaluated.

RESULT AND ANALYSIS

RESULTS AND ANALYSIS

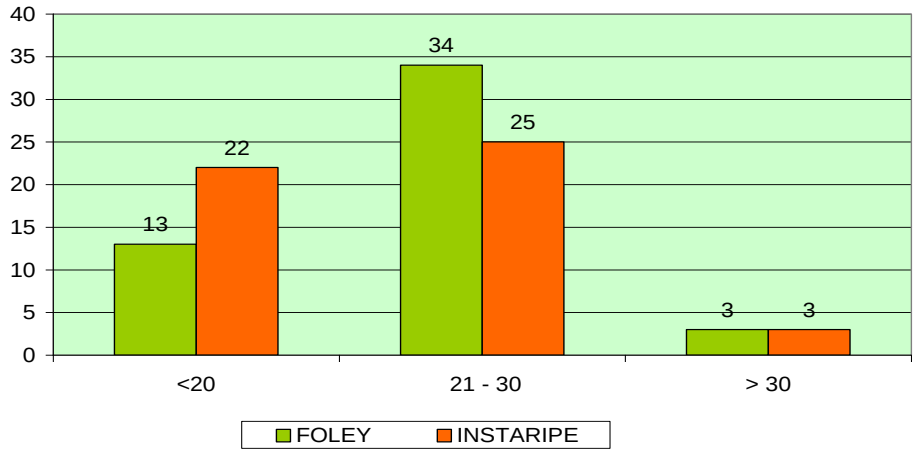
This study was done in hundred patients, who are admitted in labor ward for safe confinement. The data collected from the both groups in the preformed proforma were analysed and statistically verified by non parametric Chi square (X^2) test. A p value of < 0.05 was considered to be statistically significant.

Demographic profile

Even though the age distribution in both the study groups varied slightly, it was not statistically significant.

AGE	FOLEY	INSTARIPE
<20	13	22
21 - 30	34	25
> 30	3	3
TOTAL	50	50
Mean	24	22.58
SD	4.486	4.352
P'value	0.111 Not sig	

AGE - COMPARISON

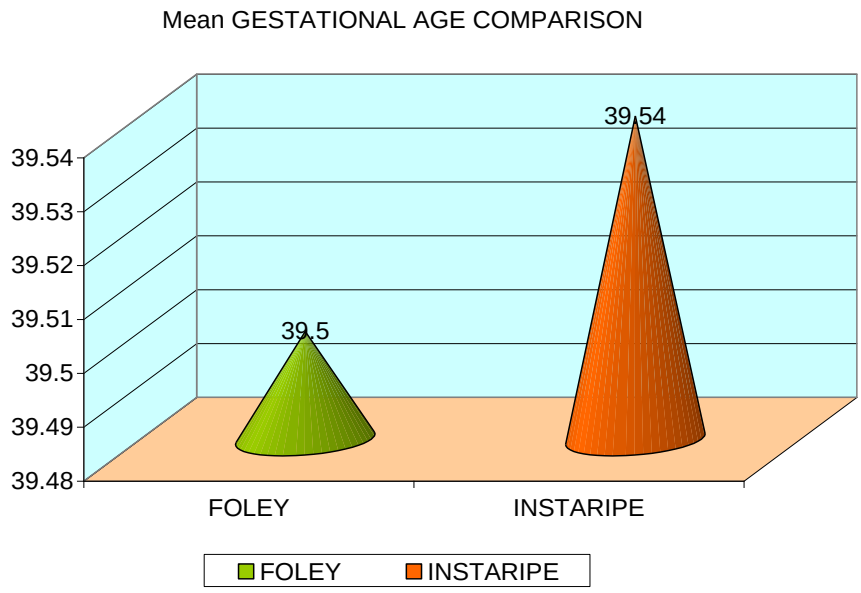


Obstetric profile

Gestational age

The gestational age of patients belonging to both the groups were comparable.

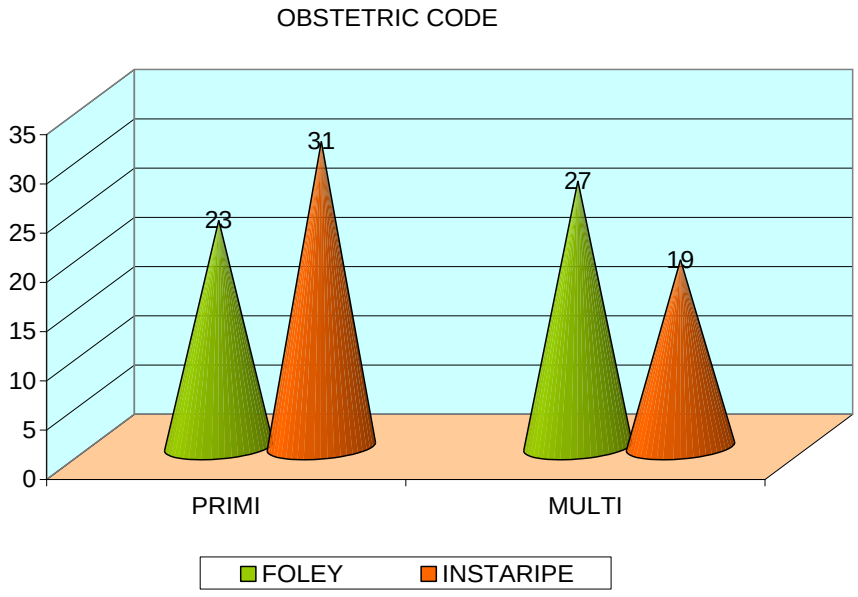
GA	FOLEY	INSTARIPE
< 39	21	22
> 39	29	28
TOTAL	50	50
Mean	39.5	39.54
SD	0.863	0.994
P'value	0.83 Not sig	



Obstetric code

As seen from the table and the graph, the number of primigravida and multigravida in these groups were slightly different, but it was not statistically significant.

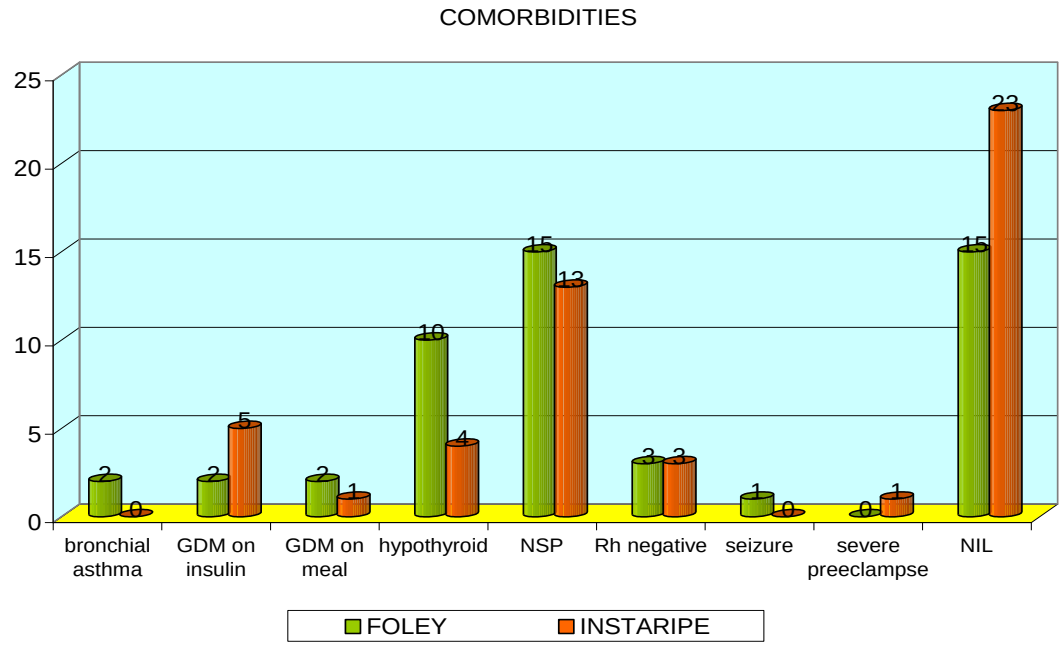
OBS CODE	FOLEY	INSTARIPE
PRIMI	23	31
MULTI	27	19
TOTAL	50	50
P'value	0.16 Not sig	



Comorbid conditions

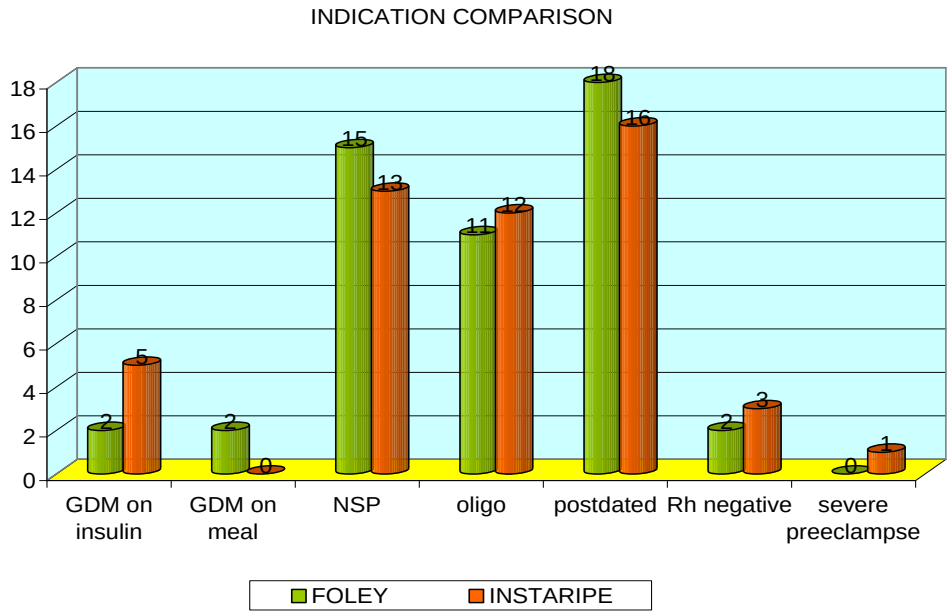
It is evident from the table and graph there were 35 patients in the foley group with some comorbidity (bronchial asthma, GDM, hypothyroid, NSP, Rh neg, seizure, severe pre eclampsia)

COMORBIDITIES	FOLEY	INSTARIPE
Bronchial asthma	2	0
GDM on insulin	2	5
GDM on meal	2	1
Hypothyroid	10	4
NSP	15	13
Rh negative	3	3
Seizure	1	0
Severe preeclampsia	0	1
NIL	15	23
TOTAL	50	50
P' value	0.264 Not sig	



Indication

Although there were multiple indications for induction in both the groups, the common reasons for induction were oligohydramnios, post-dated pregnancy and unfavourable cervix with poor Bishop score.

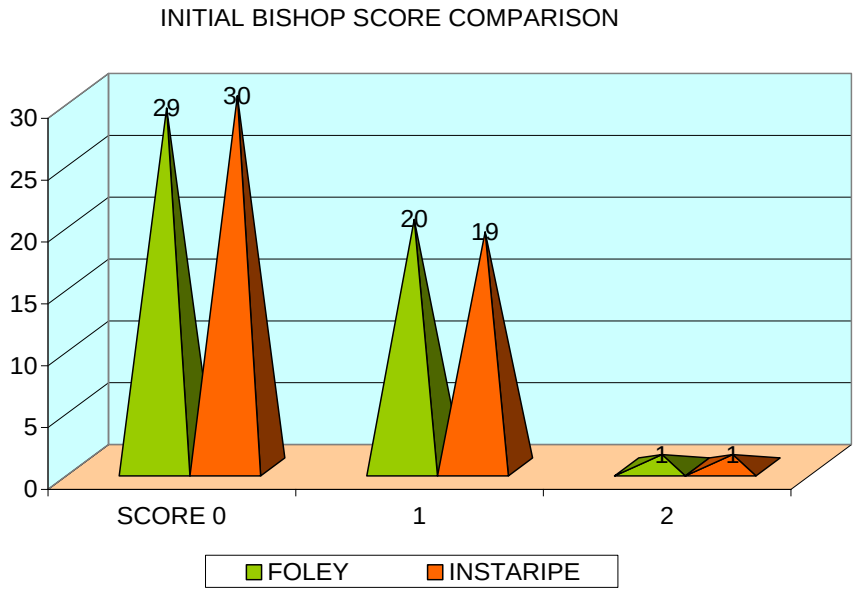


Bishop score

Initial score before induction

Before induction using either of the methods, the bishop scores were similar between the groups.

INITIAL BISHOP	FOLEY	INSTARIPE
SCORE 0	29	30
1	20	19
2	1	1
TOTAL	50	50
P' value	0.979 Not sig	

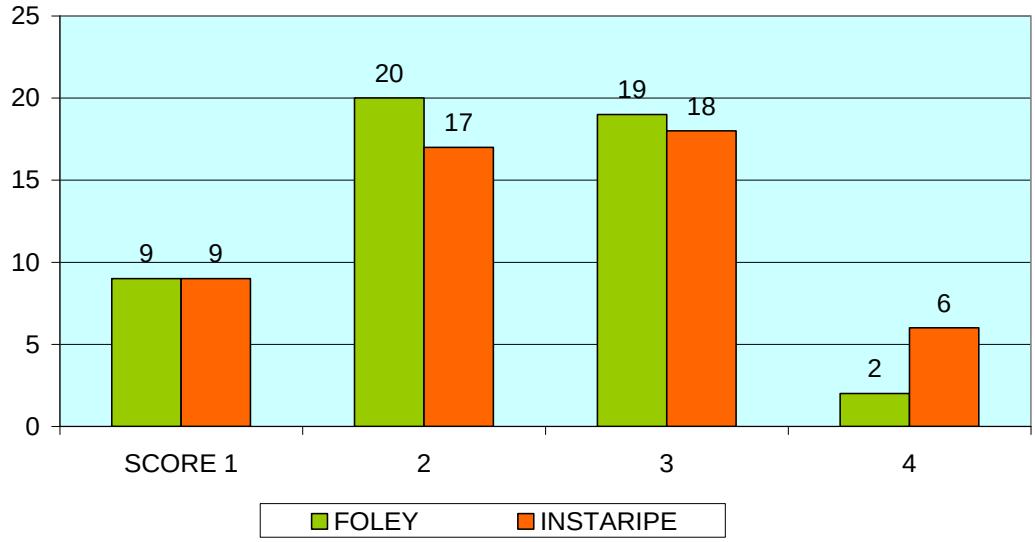


Review Bishop score

From the table and graph it is clear that more number of patients had a better score after induction with instaripe method (while 6 patients in instaripe group had a score of 4 just 2 patients had a similar score in foleys group).

REVIEW BISHOP	FOLEY	INSTARIPE
SCORE 1	9	9
2	20	17
3	19	18
4	2	6
TOTAL	50	50
P' value	0.518 Not sig	

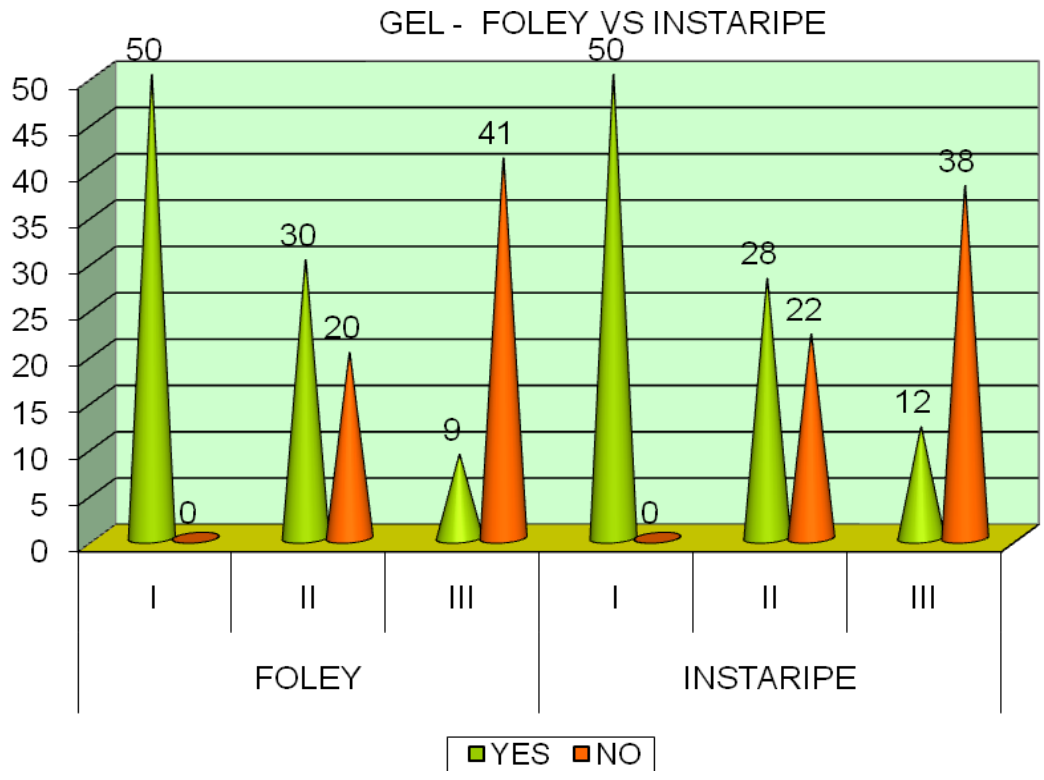
REVIEW BISHOP COMPARISON



Requirement of PgE2 Gel instillation

The number of patients requiring PgE2 gel instillation decreased as the stage of labour progressed forward in both the groups and there was no significant difference between the groups in this regard.

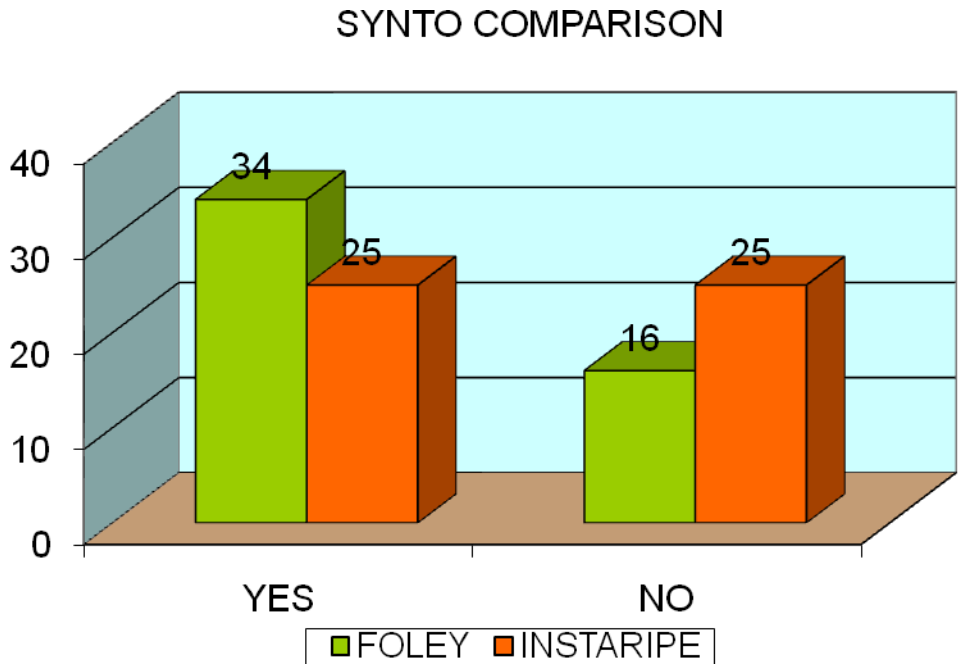
GEL	FOLEY			INSTARIPE		
	I	II	III	I	II	III
YES	50	30	9	50	28	12
NO	0	20	41	0	22	38
TOTAL	50	50	50	50	50	50
P'value						



Oxytocin augmentation

The number of patients requiring oxytocin augmentation were more in the Foleys group as compared to the Instaripe group (34 in Foleys group vs 25 in Instaripe group). But this difference was statistically insignificant.

OXYTOCIN	FOLEY	INSTARIPE
YES	34	25
NO	16	25
TOTAL	50	50
P'value	0.104 Not sig	

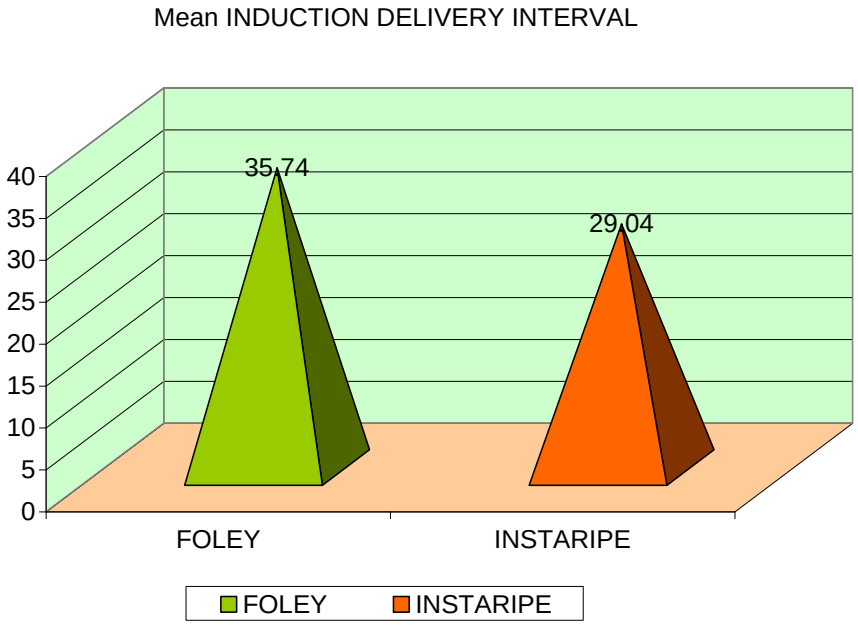


Induction delivery interval

On comparing the interval between the induction and delivery,

12 patients delivered within 25 hours in the instaripe group whereas just 7 patients in the foleys group delivered within time period. On the other hand, more number patients delivered in the Foleys group than the Instaripe group during the 46-55 and >55 hours time interval (8 vs 1 and 4 vs 0 respectively). These delivery interval period were clinically and statistically significant with the p value of 0.001

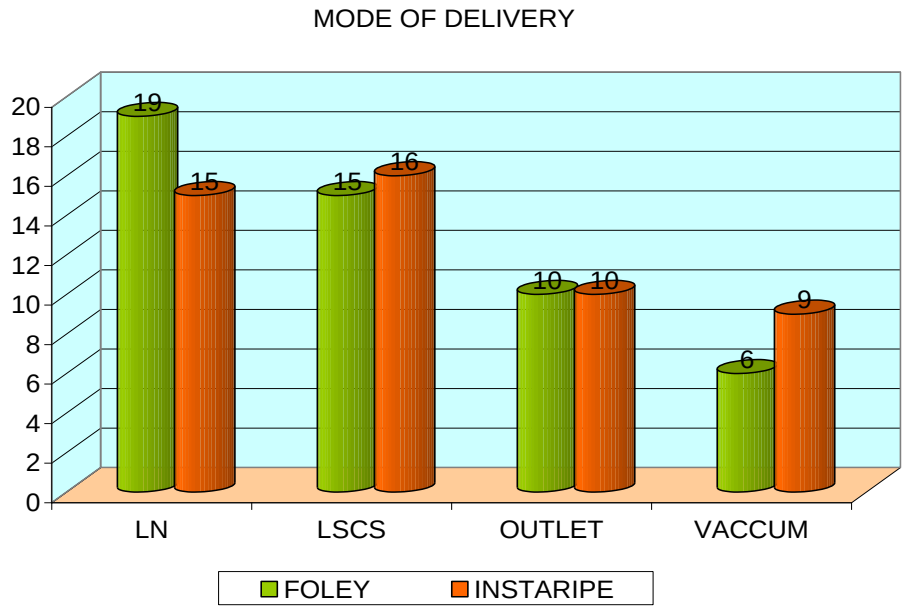
INDUCTION DELIVERY INTERVAL (hours)	FOLEY	INSTARIPE
< 25	7	12
26 - 35	23	24
36 - 45	8	10
46 - 55	8	1
> 55	4	0
TOTAL	50	47
Mean	35.74	29.04
SD	11.485	8.281
P' value	0.001 Significant	


Mean INDUCTION DELIVERY INTERVAL
40
35
30
25
20
15
10
5
0
35.74
29.04
FOLEY
INSTARIPE
FOLEY
INSTARIPE

Mode of delivery

More number of patients in the Foleys group had natural labour (19) as compared to the Instaripe group (15). While just 6 patients in the Foleys group warranted vacuum assisted delivery, 9 patients required this technique in the other group. But these differences were statistically insignificant.

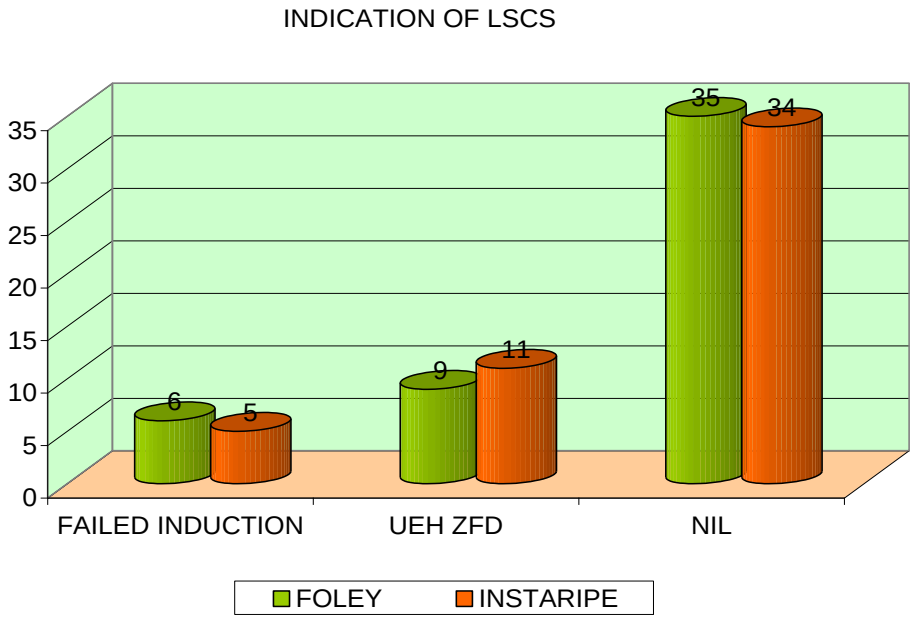
MODE OF DELIVERY	FOLEY	INSTARIPE
LN	19	15
LSCS	15	16
OUTLET	10	10
VACCUM	6	9
TOTAL	50	50
P' value	0.776 Not sig	



Indication for LSCS

Similar number of patients underwent caeserean section in both the groups and indications for the same were also similar between the groups.

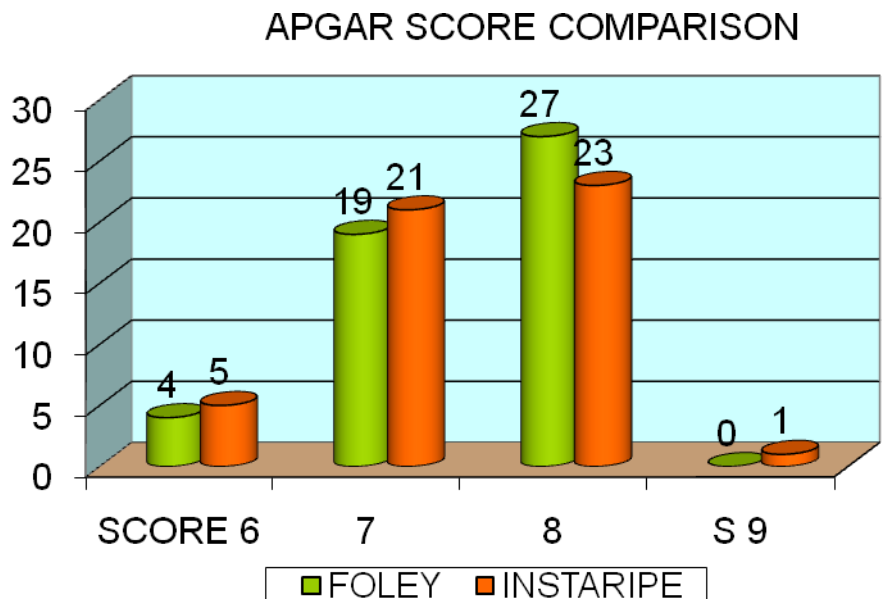
INDICATION OF LSCS	FOLEY	INSTARIPE
FAILED INDUCTION	6	5
UEH FD	9	11
NIL	35	34
TOTAL	50	50
P' value	0.843 Not sig	



APGAR SCORES

There was no significant difference between the groups with regards to the APGAR score of the babies born in these groups, as almost similar number of babies had score 6,7,8 and 9 in both the groups.

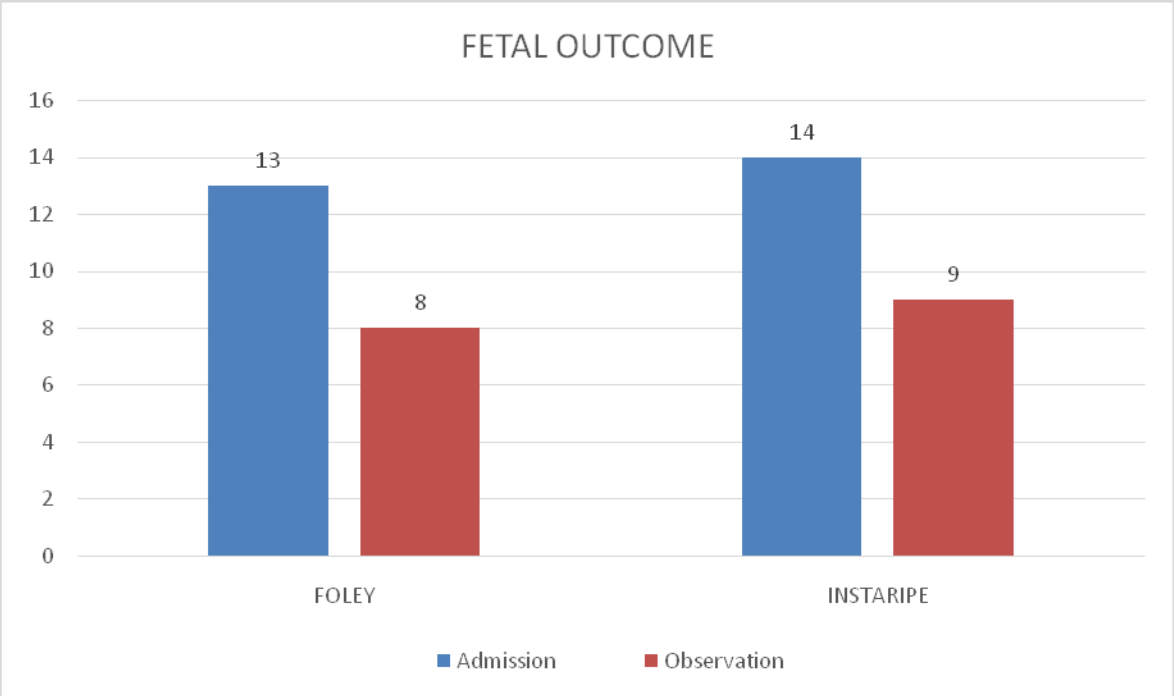
APGAR	FOLEY	INSTARIPE
SCORE 6	4	5
7	19	21
8	27	23
S 9	0	1
TOTAL	50	50
P' value	0.675 Not sig	



Fetal outcome

On analysis, it is observed that similar number of babies (21 in Foleys group and 23 in Instaripe group) required admission and observation in these groups.

COMPLICATION FETAL	FOLEY	INSTARIPE
ad	13	14
ob	8	9
NIL	29	27
TOTAL	50	50
P' value	0.92 Not sig	



DISCUSSION

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Among the various methods being used for induction due to various reasons, mechanical methods are commonly being used. These mechanical techniques are considered more advantageous than the other methods as these more conservative, inexpensive and associated with lesser side effects with adequate expertise.

Osmotic dilators are not the common ones that are used nowadays. Balloon devices which are being used have both mechanical and biochemical mechanism in inducing labour. So we compared 2 different techniques of balloon devices: one with Foleys catheter and the other method, where Foleys catheter is aided by the Instaripe device.

After excluding any difference in the confounding factors like age, gestational age, obstetric code, comorbidities; we found that Instaripe device augmented the induction process as compared to the Foleys method. Even though the review Bishop score was not statistically significant between the groups, more patients had a higher score of 4 in the Instaripe group (6), which seemed to be clinically significant.

More importantly the induction – delivery interval was significantly decreased in the instaripe group, as it was just 29.04 hours in instaripe group while it was 35.74 hours in the other group. Not many studies are available using this instaripe device. One of the RCT done in 2013 done

by Gibson et al, where they compared the simple Foleys technique with balloon traction method, revealed that there was no significant difference between the groups with respect to time to delivery, delivery within a 24-hour period, rate of caesarean sections, pain scores or the use of epidural analgesia. These results were similar for nulliparous and multiparous women.[74] These results are in contrast with our result. The difference in the way the traction was applied might have been responsible for this different result.

CONCLUSION

CONCLUSION

Instaripe, Panicker's rapid cervical ripening device, specially designed conical tubular device to aid the foley catheter in induction. From our study, it can be said that the induction delivery interval can be shortened if Instaripe device is used to aid Foleys catheter to provide sustained traction.

However review bishop score, requirement of gel instillation, oxytocin augmentation, incidence of LSCS or instrumental delivery, neonatal APGAR scores, were not significantly different between the groups.

As not many studies are available regarding the use of Instaripe, we need more randomized controlled trial to make conclusive recommendations for its use.

Nevertheless, Instaripe can still be considered for use along with Foley's catheter as it evidently decreases the induction delivery interval as per study.

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PROFORMA

PROFORMA

NAME: Group :

AGE:

IP NO.: UNIT:

DATE OF ADMISSION:

DATE OF DELIVERY: DATE OF DISCHARGE:

OBSTETRIC CODE:

ADDRESS:

PHONE NO:

BOOKED/ UNBOOKED:

LMP: EDD:

GESTATIONAL AGE:

COMORBIDITIES:

PAST H/O:

MENSTRUAL H/O:

MARITAL H/O:

OBSTETRIC H/O:

GENERAL EXAMINATION:

SYSTEMIC EXAMINATION:

VITALS: PR- BP-

PER ABDOMINAL EXAMINATION:

DIAGNOSIS:

INDICATION FOR INDUCTION:

DATE & TIME OF INDUCTION:

PV & BISHOP SCORE:

REVIEW PV & BISHOP SCORE:

CERVIPRIME GEL: YES/ NO

OXYTOCIN ACCELERATION: YES/ NO

DATE & TIME OF DELIVERY:

INDUCTION- DELIVERY INTERVAL:

WOMEN DELIVERED: <24HOURS / 24 - 48HOURS / >48HOURS

MODE OF DELIVERY: LABOUR NATURALIS / FORCEPS/ VACUUM / CAESAREAN

INDICATION FOR CAESAREAN: FAILED INDUCTION/ FETAL DISTRESS / NON PROGRESS OF LABOUR

BABY DETAILS:

MALE/ FEMALE

BIRTH WEIGHT-

APGAR: 1' - 5' -

NICU ADMISSION- YES / NO, IF YES REASON FOR ADMISSION

PN STAY AND FOLLOW UP:

SIGNS OF CERVICAL ISCHEMIA:

CONSENT FORM

I hereby give my consent to participate in the study being conducted by Dr. VIDHYA PRIYANKA, B.D., Post Graduate in the Department of Obstetrics and Gynaecology, Madurai Medical College, Madurai and allow Foley / Instaripe induction for study purposes.

Place: Signature of the parents / guardian

Date:

ETHICAL CLEARANCE CERTIFICATE

CERTIFICATE - II

This is to certify that this dissertation work "**TRANSCERVICAL FOLEY'S CATHETER VERSUS TRANSCERVICAL FOLEY'S CATHETER AIDED BY INSTARIPE FOR INDUCTION OF LABOUR- A COMPARATIVE STUDY"** of the candidate **Dr.*VIDHYA PRIYANKA, B.D*** with *R*egistration Number 221716105, *for the award of M.S.*, in the branch of **OBSTETRICS AND GYNAECOLOGY** personally verified *by* urkund.com website for the purpose of plagiarism Check. I found that the uploaded thesis file contains from introduction to conclusion pages and result shows *19* percentage of plagiarism in the dissertation.

Prof. Dr. N. SUMATHI M.D., DGO
HEAD OF THE DEPARTMENT
Dept. of Obstetrics & Gyanecology,
Madurai Medical College,
Madurai.

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Chennai, Tamil Nadu)

ETHICS COMMITTEE CERTIFICATE

Name of the Candidate	:	Dr.B.D.Vidhya priyanka
Designation	:	PG in MS., Obstetrics & Gynecology
Course of Study	:	2017- 2020
College	:	MADURAI MEDICAL COLLEGE
Research Topic	:	Transcervical foley's catheter versus transcervical foley's catheter aided by instaripe for induction of labour - A comparative study
Ethical Committee as on	:	17.05.2019

The Ethics Committee, Madurai Medical College has decided to inform that your Research proposal is accepted.

Member Secretary | Chairman | Dean / Convenor

Prof Dr V Nagaraajan
M.D., MNAMS, D.M., Dsc.,(Neuro), Dsc
CHAIRMAN
IEC - Madurai Medical College
Madurai

DEAN
Madurai Medical College
Madurai-20

மதுரை மருத்துவக் கல்லூரி
27 MAY 2019
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PLAGIARISM CERTIFICATE

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Significance: 19 %

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https://emedicine.medscape.com/article/260036-overview
https://www.cochrane.org/CD003392/PREG_breast-stimulation-for-cervical-ripening-and-induction-of-labour
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Instances where selected sources appear:

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MASTER CHART

MASTER CHAT

S. NO.	NAME	AGE	GA	OBS CODE	COMORBIDITIES	INDICATION	FOLEY		GEL			SYNTO	INDUCTION DELIVERY INTERVAL	MODE OF DELIVERY	INDICATION OF LSCS	APGAR	COMPLICATION
							INITIAL BISHOP	REVIEW BISHOP	I	II	III						FETAL
1		22	40	PRIMI	hypothyroid	postdated	0	1	y			y	39	LN		7	
2		18	39	MULTI	NSP	NSP	0	2	y	y		y	32	OUTLET		8	ob
3		20	38	PRIMI	hypothyroid	oligo	1	3	y	y		y	30	LN		7	
4		30	38	MULTI		oligo	2	3	y	y			27	LN		8	
5		24	38	MULTI	GDM on insulin	GDM on insulin	1	3	y				32	LN		8	ad
6		19	39	MULTI		oligo	0	1	y	y	y		42	LSCS	FAILED INDUCTION	7	ad
7		21	41	PRIMI	hypothyroid	postdated	1	2	y	y			26	LSCS	UEHZFD	6	ad
8		18	39	MULTI	NSP	NSP	1	2	y	y		y	23	VACCUM		7	
9		21	38	PRIMI	hypothyroid	NSP	0	3	y				26	OUTLET		7	
10		18	40	MULTI	GDM on meal	GDM on meal	1	3	y				25	LN		7	
11		28	40	MULTI		postdated	1	3	y				22	OUTLET		7	ob
12		17	41	PRIMI		postdated	0	1	y	y			39	LSCS	UEHZFD	7	ad
13		29	40	MULTI	NSP	NSP	1	3	y			y	29	LN		7	
14		19	40	MULTI	Rh negative	postdated	0	1	y	y	y	y	26	OUTLET		7	ad
15		24	39	MULTI	NSP	NSP	1	3	y			y	38	LN		8	ad
16		23	40	PRIMI		postdated	0	2	y	y		y	30	VACCUM		8	
17		20	39	PRIMI		oligo	0	1	y	y	y		42	LSCS	FAILED INDUCTION	8	ob
18		18	40	MULTI	NSP	NSP	0	2	y	y			28	VACCUM		8	
19		24	41	PRIMI		postdated	0	3	y	y		y	32	LN		8	
20		27	38	MULTI		oligo	1	3	y			y	23	LN		7	ob
21		25	40	PRIMI	Rh negative	Rh negative	0	2	y	y		y	18	OUTLET		8	
22		22	40	MULTI		postdated	1	3	y				50	LN		8	
23		25	39	PRIMI	NSP	NSP	0	1	y	y	y		20	LSCS	FAILED INDUCTION	7	

24		21	41	MULTI	hypothyroid	postdated	0	2	y	y	y		26	LSCS	UEHZFD	6	ad
25		21	39	PRIMI	NSP	NSP	0	3	y			y	33	OUTLET		6	ad
26		26	40	PRIMI	Rh negative	Rh negative	0	2	y			y	51	LSCS	UEHZFD	8	ad
27		22	39	MULTI	NSP	NSP	0	2	y				26	LSCS	UEHZFD	6	ad
28		25	40	PRIMI		postdated	0	3	y			y	50	LN		8	
29		29	40	MULTI	NSP	NSP	1	3	y			y	34	LN		7	
30		25	39	PRIMI	hypothyroid	oligo	0	2	y	y		y	26	LSCS	UEHZFD	8	
31		27	40	MULTI	bronchial asthma	postdated	1	3	y			y	31	LN		8	
32		29	39	MULTI	NSP	NSP	1	1	y	y		y	26	LN		8	ob
33		33	40	MULTI	hypothyroid	postdated	1	3	y			y	23	OUTLET		8	
34		30	38	PRIMI	seizure	oligo	0	2	y	y	y	y	42	OUTLET		8	ob
35		20	40	MULTI		postdated	0	3	y			y	59	LN		8	
36		26	40	PRIMI		oligo	0	2	y	y		y	37	LSCS	UEHZFD	7	ad
37		22	40	MULTI	hypothyroid	postdated	1	3	y	y			48	LN		8	
38		28	40	MULTI	NSP	NSP	1	2	y	y	Y	Y	60	LSCS	FAILED INDUCTION	7	ob
39		24	40	PRIMI		postdated	0	2	y	y		Y	26	VACCUM		8	
40		34	38	MULTI	GDM on insulin	GDM on insulin	1	2	y	y		Y	32	OUTLET		8	ad
41		22	40	PRIMI		postdated	0	2	y	y			34	LSCS	UEHZFD	7	
42		30	39	MULTI	hypothyroid	oligo	1	2	y	y	Y	Y	32	LSCS	FAILED INDUCTION	8	ob
43		19	40	PRIMI	NSP	NSP	0	2	y	Y		Y	58	OUTLET		8	
44		31	40	MULTI	GDM on meal	GDM on meal	1	4	y			Y	34	LN		8	
45		18	38	PRIMI	hypothyroid	oligo	0	2	y	Y		Y	52	VACCUM		7	
46		18	39	MULTI	NSP	NSP	1	4	y			Y	50	LN		7	
47		23	39	PRIMI	bronchial asthma	oligo	0	2	y	Y		Y	59	VACCUM		7	ad
48		26	40	PRIMI	NSP	NSP	0	1	y	Y		Y	48	LSCS	UEHZFD	8	
49		30	40	PRIMI	NSP	postdated	0	1	y	Y	Y	Y	52	LSCS	FAILED INDUCTION	8	
50		29	40	MULTI		postdated	0	3	y			Y	39	LN		8	

S. NO.	NAME	AGE	GA	OBS CODE	COMORBIDITIES	INDICATION	INSTA RIPT		GEL			SYNTO	INDUCTION DELIVERY INTERVAL	MODE OF DELIVERY	INDICATION OF LSCS	APGAR	COMPLICATION
							INITIAL BISHOP	REVIEW BISHOP	I	II	III						FETAL
1		22	39	PRIMI	GDM on insulin	GDM on insulin	0	2	Y	Y		Y	36	outlet		8	ad
2		19	41	MULTI		postdated	0	3	Y			Y	27	LN		8	
3		21	38	MULTI		oligo	0	2	Y	Y		Y	26	LSCS	UEHZFD	6	ad
4		20	40	PRIMI	NSP	NSP	1	4	Y			Y	16	outlet		8	
5		30	39	MULTI		oligo	1	3	Y	Y			24	LN		8	
6		27	38	PRIMI	NSP	NSP	0	1	Y	Y	Y		30	LSCS	failed induction	7	ad
7		22	40	PRIMI	hypothyroid	postdated	1	3	Y			Y	19	VACCUM		8	
8		21	41	MULTI		postdated	1	3	Y			Y	16	LN		9	
9		32	37	PRIMI	severe preeclampse	severe preeclampse	0	2	Y	Y		Y	26	outlet		7	ad
10		24	40	PRIMI	NSP	NSP	0	2	Y	Y			25	LSCS	UEHZFD	8	
11		18	39	MULTI	GDM on insulin	GDM on insulin	1	4	Y			Y	17	VACCUM		8	ad
12		19	40	PRIMI		oligo	0	2	Y	Y	Y		28	LN		7	ob
13		18	41	PRIMI		postdated	0	3	Y	Y		Y	29	LN		8	
14		20	40	MULTI	NSP	NSP	2	4	Y			Y	14	LN		8	
15		19	40	PRIMI	GDM on meal	postdated	0	2	Y	Y	Y	Y	32	outlet		7	ob
16		22	40	PRIMI		postdated	0	3	Y	Y		Y	30	VACCUM		8	
17		29	38	MULTI		oligo	0	2	Y	Y		Y	26	LSCS	UEHZFD	8	ad
18		17	40	PRIMI		oligo	0	3	Y			Y	28	outlet		7	
19		22	38	MULTI	hypothyroid	oligo	1	4	Y				21	LN		7	ad
20		25	39	PRIMI	NSP	NSP	0	3	Y			Y	20	VACCUM		8	
21		21	40	MULTI		postdated	1	4	Y				18	LN		7	
22		22	40	PRIMI	hypothyroid	postdated	1	1	Y	Y		Y	42	LSCS	UEHZFD	7	ob
23		20	39	PRIMI		oligo	1	3	Y				18	LN		8	
24		19	39	MULTI	GDM on insulin	GDM on insulin	1	3	Y			Y	26	outlet		7	ad
25		26	41	PRIMI		postdated	1	3	Y	Y			33	LN		8	
26		18	39	PRIMI	NSP	NSP	0	2	Y	Y	Y	Y	38	VACCUM		7	ob

27		32	39	MULTI	NSP	NSP	1	3	Y				26	LSCS	UEHZFD	7	
28		19	40	PRIMI		postdated	0	2	Y	Y	Y		50	LN		8	
29		28	40	PRIMI	NSP	NSP	1	3	Y	Y		Y	34	VACCUM		8	
30		21	40	MULTI	Rh negative	rh negative	1	3	Y			Y	24	LN		8	
31		20	40	PRIMI		postdated	0	2	Y	Y			31	LSCS	UEHZFD	6	ad
32		29	38	MULTI	NSP	NSP	1	4	Y				20	LN		8	
33		32	39	PRIMI	GDM on insulin	GDM on insulin	1	2	Y				23	LSCS	UEHZFD	7	
34		20	40	MULTI	Rh negative	rh negative	1	3	Y	Y			32	outlet		7	ob
35		28	38	MULTI	hypothyroid	oligo	0	1	Y	Y	Y		36	LSCS	failed induction	7	ob
36		30	41	PRIMI	NSP	NSP	0	1	Y				37	LSCS	UEHZFD	6	ad
37		20	39	PRIMI		oligo	0	2	Y			Y	32	LN		8	
38		19	41	PRIMI		postdated	0	1	Y	Y	Y		42	LSCS	failed induction	7	ob
39		21	40	PRIMI		oligo	0	2	Y				26	LSCS	UEHZFD	6	ad
40		18	39	MULTI	NSP	NSP	0	2	Y			Y	32	LSCS	UEHZFD	7	
41		27	40	PRIMI		postdated	0	3	Y	Y			34	outlet		7	
42		23	39	MULTI	NSP	NSP	1	3	Y			Y	32	outlet		8	ad
43		26	39	PRIMI	NSP	NSP	0	1	Y	Y	Y		36	LSCS	failed induction	8	
44		18	41	MULTI		postdated	0	2	Y				31	LSCS	UEHZFD	7	ad
45		19	39	PRIMI		oligo	0	1	Y	Y		Y	41	VACCUM		7	
46		24	38	MULTI	GDM on insulin	GDM on insulin	1	3	Y	Y		Y	38	VACCUM		8	
47		26	41	PRIMI		postdated	0	1	Y	Y	Y		41	LSCS	failed induction	7	ob
48		19	40	PRIMI	Rh negative	rh negative	0	1	Y	Y	Y		40	outlet		6	ad
49		18	40	PRIMI		postdated	0	2	Y	Y	Y		28	VACCUM		8	
50		19	40	PRIMI		oligo	0	2	Y	Y	Y		29	LN		7	ob