COMPARISON OF DOUBLE BALLOON CATHETER VERSUS FOLEY CATHETER FOR CERVICAL RIPENING IN POSTDATED PREGNANCY

A Dissertation submitted to

THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY

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REG NO: 221916651

DEPARTMENT OF OBSTETRICS & GYNAECOLOGY

GOVT. THENI MEDICAL COLLEGE HOSPITAL

THENI – 625 531

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This is to certify that this dissertation entitled, "**COMPARISON OF DOUBLE BALLOON CATHETER VERSUS FOLEY CATHETER FOR CERVICAL RIPENING IN POSTDATED PREGNANCY**" is a bonafide record of the work done by **DR. T.S.ABIRAMI** under my guidance and supervision in the **Department of Obstetrics & Gynaecology** during the period of her post Graduate study at Govt. Theni Medical College & Hospital, Theni for the degree of M.S., Obstetrics & Gynaecology from OCTOBER 2020 – OCTOBER 2021.

Dr. B.SHANTHIRANI M.D., DGO.,
Professor & Head of the Department,
Department of O&G
Govt. Theni Medical College & Hospital,
Theni.

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This is to certify that that dissertation entitled "**COMPARISON OF DOUBLE BALLOON CATHETER VERSUS FOLEY CATHETER FOR CERVICAL RIPENING IN POSTDATED PREGNANCY"** is a bonafide & genuine research work carried out by **Dr. T.S.ABIRAMI, REG NO: 221916651** postgraduate in Department of **Obstetrics & Gynecology** Govt. Theni Medical College, Theni, in partial fulfillment of regulations of the Tamil Nadu Dr.M.G.R., Medical University for the award of degree of M.S Obstetrics & Gynecology.

Dr. R.BALAJINATHAN,M.D.,FICP.,
DEAN,
Govt. Theni Medical College & Hospital,
Theni.

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DECLARATION

I **Dr. T.S.ABIRAMI REG NO: 221916651,** solemnly declare that the dissertation titled, "**COMPARISON OF DOUBLE BALLOON CATHETER VERSUS FOLEY CATHETER FOR CERVICAL RIPENING IN POSTDATED PREGNANCY"** has been prepared by me at the department of Obstetrics & Gynaecology. Govt. Theni Medical College & Hospital, Theni.

This is submitted to **The Tamil Nādu Dr. M.G.R. Medical University,** Chennai in partial fulfillment of the requirements for the award of M.S. Degree Examination (Obstetrics & Gynaecology) to be held in May 2022. This record of work has not been submitted previously by me for the award of any degree or diploma from any other university.

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Date: **Dr. T.S.ABIRAMI**

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Dr. T.S.ABIRAMI

CONTENTS

CHAPTER 1

INTRODUCTION

The induction of labour is an increasingly common procedure in the obstetrics field. The ideal methods for cervical ripening are those that are safe to both the mother and fetus, of low cost, cause minimal maternal discomfort and does not require extensive monitoring. A wide variety of methods are available; these may be divided into pharmacological and mechanical methods [1]. Various methods have been used to induce labour, among which balloon catheters play an important role.

Compared with pharmacological agents, mechanical methods, which were the first methods developed to ripen the cervix or induce labour [2], have similar levels of effectiveness but incur fewer episodes of adverse events (such as uterine tachysystole), have lower costs and are easier to preserve.

Mechanical methods, such as hygroscopic dilators, balloon catheters, and devices designed for cervical ripening have all been shown to be safe and effective for cervical ripening [3].

The balloon catheter, including both double- and single-balloon catheters, appears to be a widely accepted mechanical method and is recommended by the WHO for the induction process. The original version of the Foley (single-balloon) catheter was initially described by Barnes in 1863

but was not described again until 1967, by Embrey and Mollison [4]. In 1991, Atad described the first double-balloon variation. The Cook Cervical Ripening Balloon (CCRB), which uses an identical mechanism to that of the Atad catheter, was approved by the United States Food and Drug Administration (USFDA) in 2013 [5]. Only the double-balloon catheter (either Atad or Cook) is specifically designed and licensed for labour induction.

Compared with the Foley catheter, which has a single balloon, a double-balloon catheter has proven to have additional utility in the unripe cervix by applying pressure on both the external and internal orifice of the uterus (os) [6,7]. However, a single balloon catheter may be more than 35 times cheaper compared to a double balloon catheter, which can be a burden on resources in a low resource labor ward setting.

CHAPTER 2

AIM OF STUDY

To compare the efficacy of two mechanical devices –cooks double balloon catheter versus foley catheter for cervical ripening in postdated pregnancies.

CHAPTER 3

REVIEW OF LITERATURE

Ahmed et al. [8] compared the efficacy of two mechanical devices for pre-induction of labor cervical ripening: the Foley catheter and the Cook cervical ripening balloon. Spontaneous expulsion of the Foley catheter was encountered more frequently than the Cook (89.2% vs 78.4%; P = 0.03). However, the median Bishop score was significantly higher when using the Cook compared with the Foley catheter after balloon removal (6 vs 5; P = 0.03). The duration from balloon insertion to expulsion and from insertion to delivery was significantly shorter in the Foley group compared with the Cook balloon group (6:19 ± 2:1 vs 7:26 ± 2:25 h; P = 0.03 and 13:50 ± 4:00 vs 15:16 ± 4:30 h; P = 0.03, respectively). There were no significant differences in other outcomes, such as the amount of oxytocin units used, mode of delivery, pain encountered during or after insertion and overall patient satisfaction. They concluded that the use of the Cook cervical ripening catheter results in greater cervical ripening compared with the Foley catheter. However, the duration from balloon insertion to expulsion and then delivery were significantly shorter when using the Foley catheter; therefore, we recommend its use, particularly in low resource settings.

Mohammed et al. [9] did a randomized control trail on Transcervical Foley's catheter versus Cook balloon for cervical ripening in stillbirth with a scarred uterus. 200 pregnant women with stillbirth, unfavorable cervix and scarred uterus were recruited into this study. In group I (n = 100), cervical ripening was done using Foley's catheter. In group II (n = 100), cervical ripening was done using Cook cervical ripening balloon. Time from balloon insertion to expulsion and from balloon insertion to delivery was significantly shorter in Foley's catheter group. However, the difference between the two groups regarding time from balloon insertion to active labor, time from balloon expulsion to delivery, cervical ripening, cesarean section, instrumental delivery, pain score, need for analgesia, hospital stay and maternal satisfaction was not statistically significant. Foley's catheter and Cook cervical ripening balloon are comparable regarding efficacy and safety profile when used to ripen the cervix in pregnant women with stillbirth, unfavorable cervix and scarred uterus.

Liu et al. [10] evaluated double- versus single-balloon catheters for labour induction and cervical ripening. From a total of 1326 articles, 7 RCTs involving 1159 women were included. There were no significant differences in primary outcomes (RR, 0.88 [0.65, 1.2]; p-value, 0.43) or secondary outcomes identified between single- and double-balloon catheters. However, heterogeneity existed for some aspects. In Conclusion both kinds of balloon

catheter have similar levels of efficacy, efficiency, safety and patient satisfaction; however, the single-balloon method is considered to be more cost-effective.

Peng et al. [11] evaluate the efficacy and safety of the induction of labour in mid-trimester pregnancy using a double-balloon catheter (DBC) within 12 h versus within 12-24 h. In this retrospective study, a total of 58 pregnant women at 14 + 0 weeks to 27 + 6 weeks of gestation were enrolled as research subjects. All 58 cases were successful vaginal deliveries, and no one chose to undergo caesarean section. The success rate of induction (successful abortion of the foetus and placenta without the implementation of dilation and evacuation) was higher in the DBC group within 12-24 h (96.3%, 29/31) than in the DBC group within 12 h (71.0%, 18/27) ($p < 0.05$). Additionally, the time from DBC removal to delivery in the DBC group within 12-24 h was significantly shorter than that in the DBC group within 12 h (3.0 h versus 17.8 h) ($p < 0.05$), and the degree of cervical dilation after DBC removal in the DBC group within 12-24 h was larger than that in the DBC group within 12 h ($p < 0.05$).In the clinic, the placement time of DBC generally lasts for approximately 12 h. However, considering that the cervical condition is immature in the mid-trimester, properly extending the placement time of DBC to 24 h will benefit cervical ripening and reduce the chance of dilation and evacuation.

Salim et al. [12] Compared single- and double-balloon catheters for labor induction. 520 records identified, five randomized trials (996 women; 491 with single-balloon and 505 with doubleballoon catheters) were considered eligible and included in the meta-analysis. Time from catheter insertion to delivery did not differ between the two types of catheter ($p = 0.527$; WMD -0.87; 95% CI: -3.55, 1.82). The incidence of cesarean delivery also did not differ ($p = 0.844$; RR 0.97; 95% CI: 0.69, 1.35). Delivery within 24 h, delivery mode, incidences of intrapartum fever or chorioamnionitis, and neonatal Apgar score <7 at 5 min did not differ between the two types of catheter as well. Women who were induced with the single-balloon catheter were more satisfied ($p = 0.029$; WMD 0.56; 95% CI: 0.06, 1.06). They conclused that time from catheter insertion to delivery and delivery mode were comparable between the two types of catheter.

Samuel et al. [13] conducted a study on single versus double-balloon catheters for the induction of labor of singleton pregnancies. They compared the efficacy of single- versus double-balloon catheter (SBC vs. DBC) for cervical ripening and labor induction with an unfavorable cervix. Nine research databases were searched for original articles published in all languages up to November 2017 comparing both devices for labor induction. Five RCTs and one qRCT were included. Primary outcome measures were time from intervention (device placement) to birth time, vaginal delivery and

cesarean section rates, and maternal satisfaction with the procedure. Risk of bias was evaluated with the Cochrane tool. Random effects models were used to combine data for meta-analyses. Summary measures were reported as mean differences and risk ratios (RR) with 95% confidence intervals. Regardless of parity, pooled analyses of the six trials (n =1060 women) found that mean intervention to birth time, vaginal delivery and cesarean section rates, and maternal satisfaction to the procedure were similar for both studied groups (SBC vs. DBC). Measured primary outcome measures were similar regardless of the type of device used for labor induction of singleton pregnancies.

Yang et al. [14] reviewed Double-balloon versus single-balloon catheter for cervical ripening and labor induction. They searched Embase, PubMed and the Cochrane Library for randomized or quasi-randomized controlled trials to compare the use of single-balloon to double-balloon catheters. The risk ratio (RR) or mean difference (MD) with a 95% confidence interval (CI) was calculated using fixed-effects or random-effects models. Four studies involving a total of 793 pregnant women were included. There were no significant differences in the rate of cesarean (RR 1.09, 95% CI 0.86, 1.38; P = 0.48), or vaginal deliveries within 24 h (RR 0.94, 95% CI 0.82, 1.09; P = 0.42), the mean time to delivery (MD 0.39, 95% CI -0.90, 1.68 h; P = 0.55) or Bishop score improvement (MD 0.62, 95%CI -0.18, 1.42; P = 0.13) between the groups. Women who received the double balloon catheter had a

similar risk of maternal intrapartum fever and post-partum hemorrhage. Pain during ripening was only reported in one trial and was significantly higher with the double balloon, whereas pain during device insertion was measured in two trials: one reported no difference while the other reported significantly increased pain with the double balloon. The double-balloon and single-balloon (Foley) catheters had similar effectiveness and safety. The Foley catheter is significantly cheaper, widely available and accessible, has a longer history of use and remains the logical choice over the double-balloon catheter for cervical ripening.

Atad et al. [15] conducted a study to determine the efficacy of the double balloon device (the Atad Ripener Device) in ripening and dilatation of the unfavourable cervix for induction of labour. The Atad Ripener Device caused an increase in the Bishop score in all subgroups with a mean change of 4.6 (from 2.0 prior to induction to 6.6 upon removal of the Atad Ripener Device; $P < 0.05$). The mean time interval from insertion of the Atad Ripener Device to delivery was 18.9 h, and from removal to delivery was 6-9 h. Caesarean section was performed in 39/250 patients (1 6%), and the others had a normal vaginal delivery. They concluded that 1. The double balloon device induces significant ripening and dilatation of the unfavourable cervix. 2. Induction of labour was successfully achieved following removal of the Atad Ripener Device. 3. Our caesarean section rate was low compared with

rates reported for women with an unfavourable cervix induced by other methods.

Hallack et al. [16] did a comparative study of Prostaglandin E,, Oxytocin, and the Double-Balloon Device in Inducing Labor. Thirty subjects were included in the PGE2 group, 30 in the oxytocin group, and 35 in the Atad Ripener Device group. The postpartum course was comparable in all. The change in Bishop score in the PGE2 and Atad Ripener Device groups was significantly better than in the oxytocin group (median and range of 5[0-9] and 5[0-7], respectively, versus 2.5 [0-9]; $P < .01$). Cervical dilation more than 3 cm was more frequent in the Atad Ripener Device group compared with both the PGE2 and oxytocin groups (85.7 versus 50 and 23.3%, respectively; $P < .01$). The trial of induction failed in only two patients (5.7%) in the Atad Ripener Device group, compared with six (20%) in the PGE2 and 16 (53.3%) in the oxytocin groups ($P < .001$). Mean (+/- standard deviation) induction-to-delivery interval was 21.3 +/- 7.0 hours in the Atad Ripener Device group, 23.2 +/- 12.5 hours in the PGE2 group, and 28.2 +/- 14.7 hours in the oxytocin group. The success rate for vaginal delivery was significantly better in the Atad Ripener Device and PGE2 groups compared with the oxytocin group (77.1 and 70%, respectively, versus 26.7%; $P < .01$).The Atad Ripener Device had a significantly better success rate for cervical dilation and a lower failure rate than those for PGE2 and oxytocin. The PGE2 and Atad Ripener Device

groups had better results than the oxytocin group in regard to Bishop score change and induction-to-delivery interval. The Atad Ripener Device may be a superior method for cervical ripening and labor induction in patients with unfavorable cervices.

Khotaba et al. [17] conducted study on Induction of labor in women with previous cesarean section using the double balloon device. Cervical ripening (Bishop Scores above 5) was achieved in 82.3% of the induced women with subsequent vaginal delivery in 78.6% and repeat cesarean section in 22.3%. An important observation of the results was the chances to achieve a vaginal delivery according to the second Bishop score that was recorded 12 hours following the insertion of the device. When the second was above 5 the chances for vaginal delivery were 79.4%. The mean time from removal of the device to delivery was 10.8 hours. No complications were noted using the device. They concluded the double balloon device appears to be a safe and effective method of inducing labor in women with a previous lower segment cesarean section. Wide scale studies and further use of the device for induction of labor in women who have had previous cesarean sections are warranted.

CHAPTER 4

ANATOMY, PHYSIOLOGY OF LABOR AND LABOR INDUCTION

4.1 Anatomy of Uterus

The uterus is a dynamic female reproductive organ that is responsible for several reproductive functions, including menses, implantation, gestation, labor, and delivery.

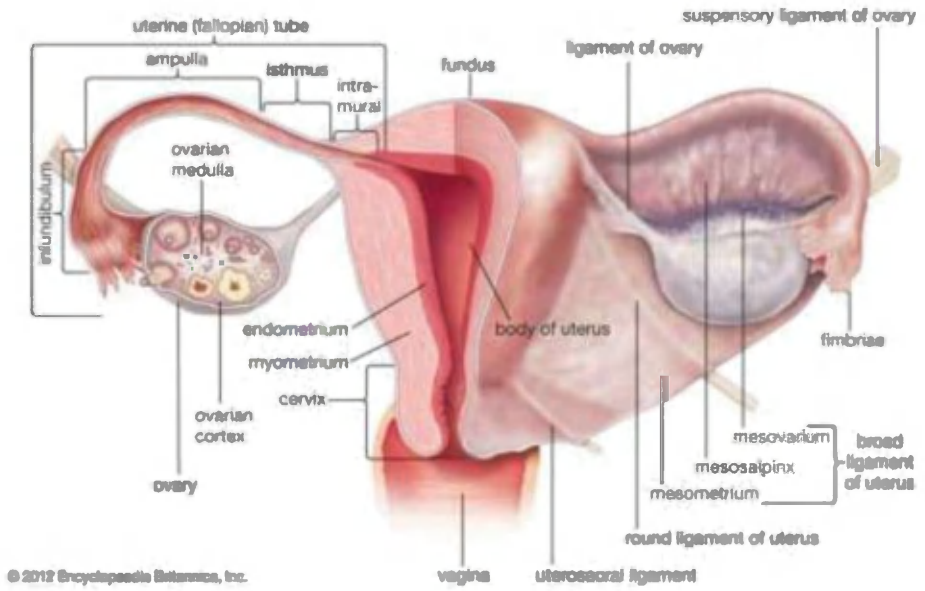

Figure 4.1 Anatomy of Uterus

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 [18, 19]. 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.

4.1.1 Parts of uterus

The uterus is divisible into two portions:

1. Body
2. 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:

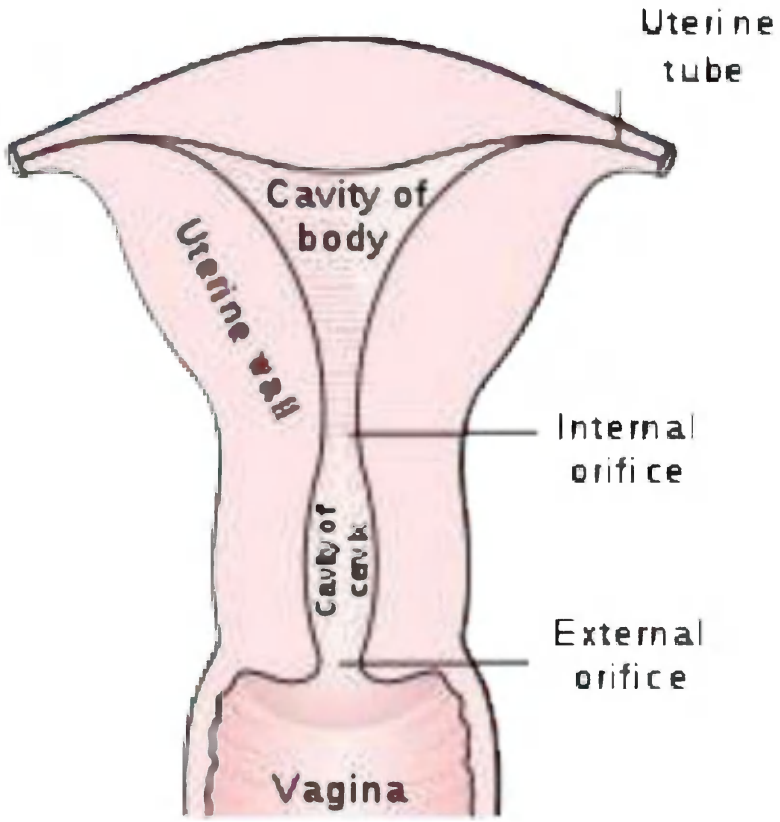

Figure 4.2 Parts of uterus

- 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.

PHYSIOLOGY OF CERVICAL RIPENING

Cervix is composed of an extra cellular matrix consisting predominantly of collagen with elastin and proteoglycans, cellular portion consisting of smooth muscle and fibroblasts, epithelium and blood vessels. Abnormal remodelling of collagen can cause dysfunctional labour. The relative rate of connective tissues with smooth muscle is not uniformly distributed throughout the length of cervix.

The distal portion of cervix has a greater ratio of connective tissue than the upper one.

There will be extensive remodeling of cervix from early gestation and throughout the postpartum period. The remodelling process is extremely complex involves timed biochemical cascades, interaction between the cellular matrix and cervicalstromal inflammatory cells such as neutrophils and macrophages. Remodelling of cervix allows the uterus the complex task to maintain the pregnancy at term and later.

CHANGES RESPONSIBLE FOR CERVICAL RIPENING

In the cervix the main glycosaminoglycans

Dermatin sulphate and chondrotin sulphate, both are hydrophobic.

Extracellular matrix (ECM)

Collagen is the predominant content of the ECM.

Type 2 and Type 3 collagen ,present in cervix is highly rigid

COLLAGEN-

Actively synthesized and continuously remodelled by collagenase

- Secreted from both cervical cells and neutrophils in an apparently slow and precise fashion throughout the pregnancy.
- The collagen is degraded by collagenase whose production is influenced by PG's both intra-cellularly and extra-cellularly ,weakening the collagen matrix which causes 'softening' or 'ripening' to allow delivery.

Near term, the collagen concentration decreases with increase in collagenases and elastases activity as it is remodelled into fine fibres

The decrease in collagen is clinically evident as a "softer cervix". As labour begins, these are significant changes in the level of hyaluronic acid, cytokines (IL-1, IL-8) and collagenase that further degrade collagen.

ELASTIN

Elastin is another important component of Extra Cellular Matrix of cervix. Elastin fibres are organized in parallel to and between collagen fibres. They assemble in a band 20-30 micro meter thick. These thin sheets are capable of being stretched in any direction. Elastin, in its closed state allow the uterus to retain the fetus during gestation with mechanical stress, the elastic

component can be distended twice its length to allow the cervix to dilate for parturition.

CELLULAR COMPONENT

Smooth muscle cells (20%) and fibroblasts (60%) make up the cellular component of uterine cervix. Early in gestation cervix undergoes hyperplasia as these cells proliferate. As the pregnancy advances the cells go from a proliferative phase to quiescent phase in which physiologic cell death occurs, decorin becomes upregulated, that helps to disperse collagen fibres. This disorganization of collagen then aids in an influx of water and aids in increasing ability of cervix to distend.

ELEMENTS AFFECTING CERVICAL RIPENING

The various elements implicated include decorin, hyaluronic acid, hormones, cytokines and proteases all thought to play role in human labour. These factors appear to interact in a complex fashion. The timing and exact mechanism responsible for the initiation and cessation of the remodeling process are still not clearly elucidated. Second mechanism that appear to be responsible for allowing the cervix to efface and dilate involves enzymatic degradation of collagenases, elastase and matrix metalloproteinases.

4.1.2 Layers of uterus

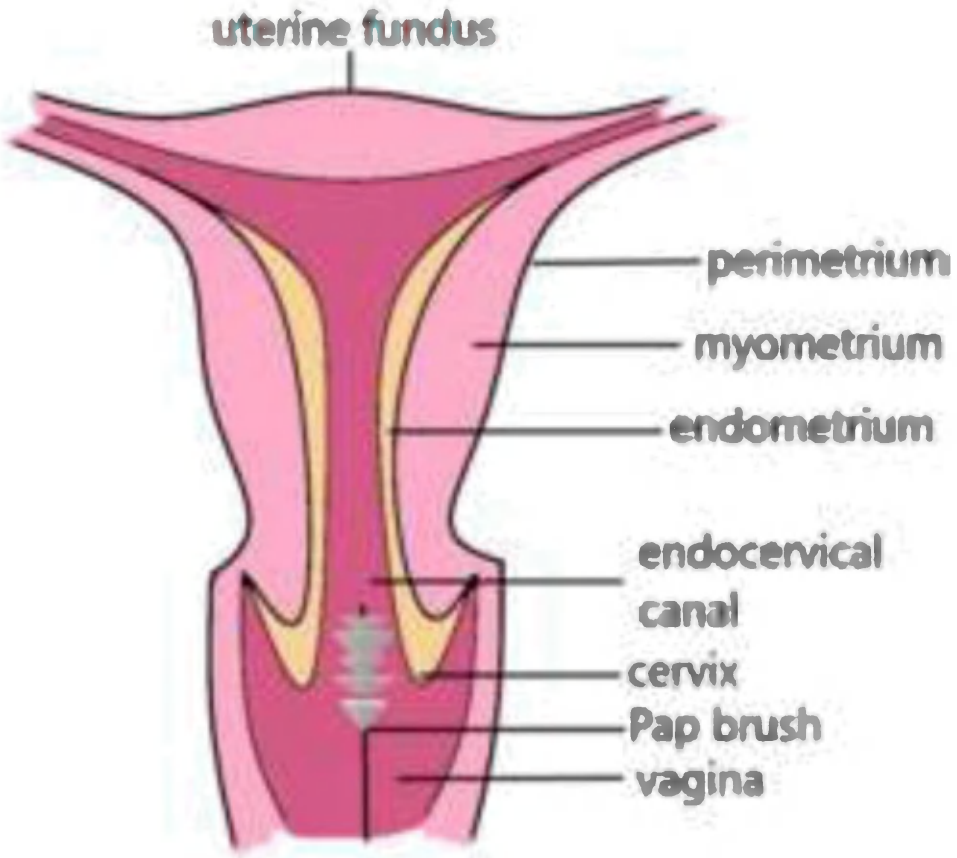

Figure 4.3 Layers of uterus

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 deciduas [20]. Vascular spaces fuse and become interconnected, forming the placenta, which supplies oxygen and nutrition to the embryo and fetus.

- Myometrium: the muscle layer and is composed of smooth muscle cells [21].
- Serosa/Perimetrium: the thin outer layer composed of epithelial cells.

4.1.3 Support of uterus

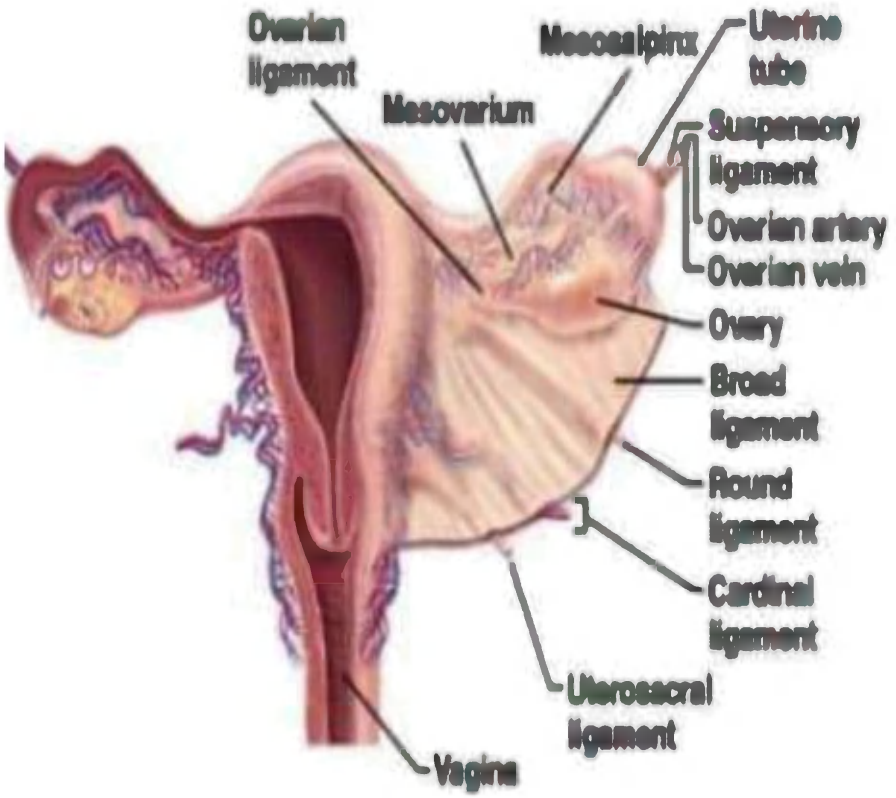

Figure 4.4 Support of uterus

The uterus is primarily supported by the pelvic diaphragm, perineal body, and urogenital diaphragm [22]. Secondarily, it is supported by ligaments, including the peritoneal ligament and the broad ligament of uterus.

4.1.4 Uterine Axis

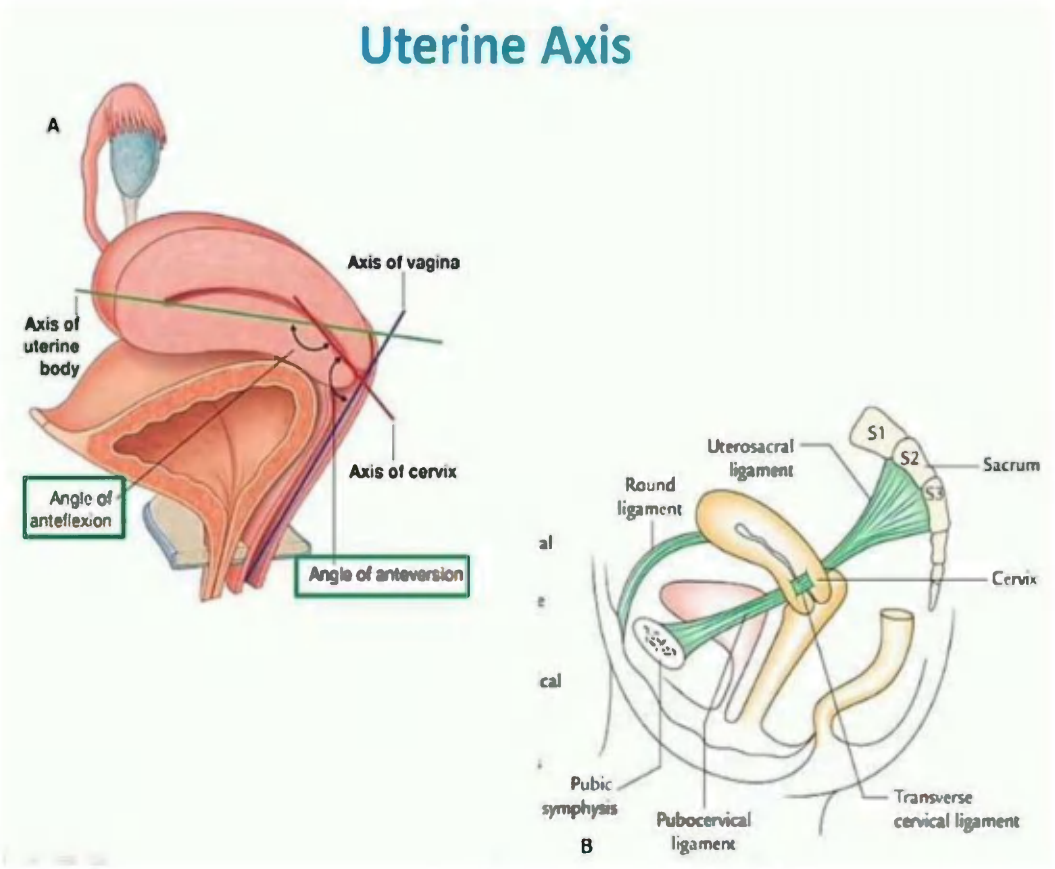

Figure 4.5 Uterine Axis

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 [23]. 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.

4.1.5 Blood 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.

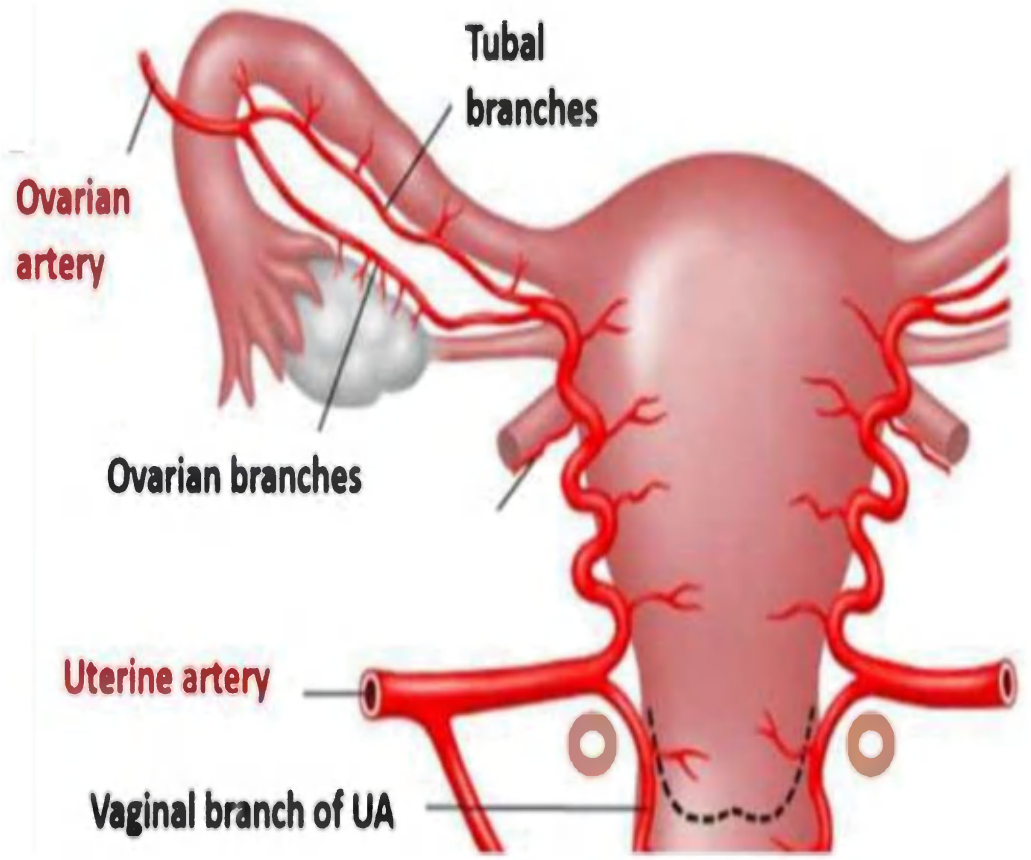

Figure 4.6 Blood supply of uterus

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.

4.1.6 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.

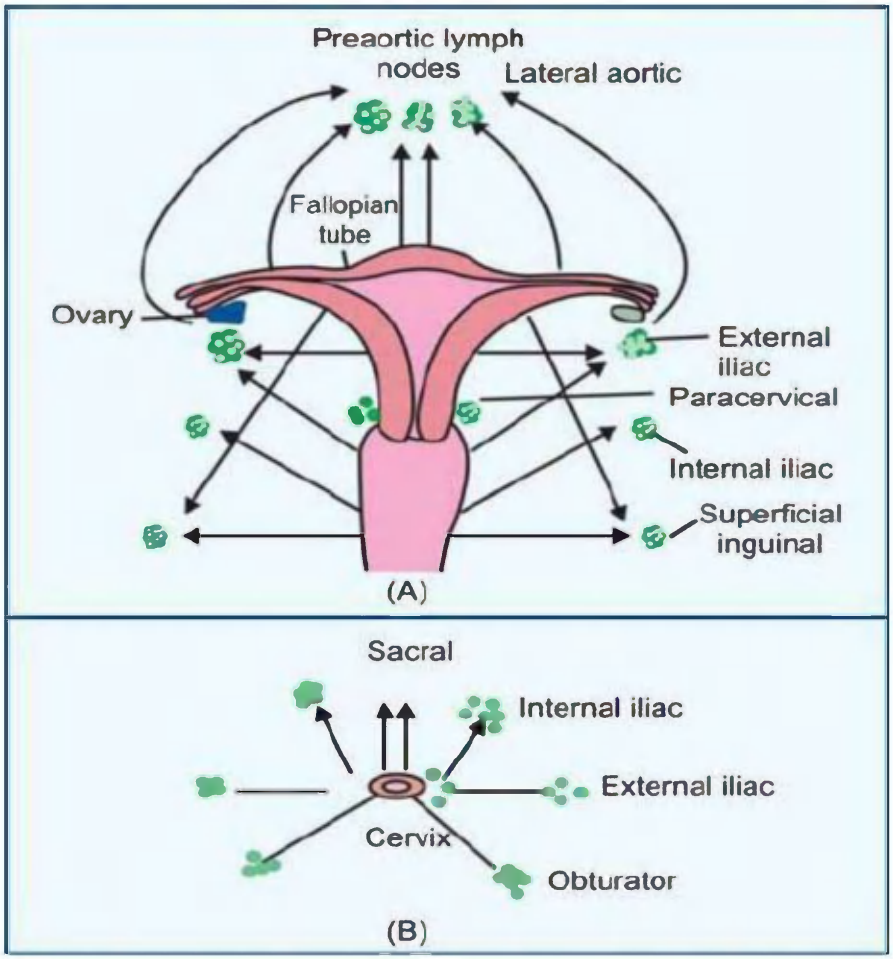

Figure 4.7 Lymphatic drainage

Lymphatic drainage

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

4.1.7 Nerve supply uterus

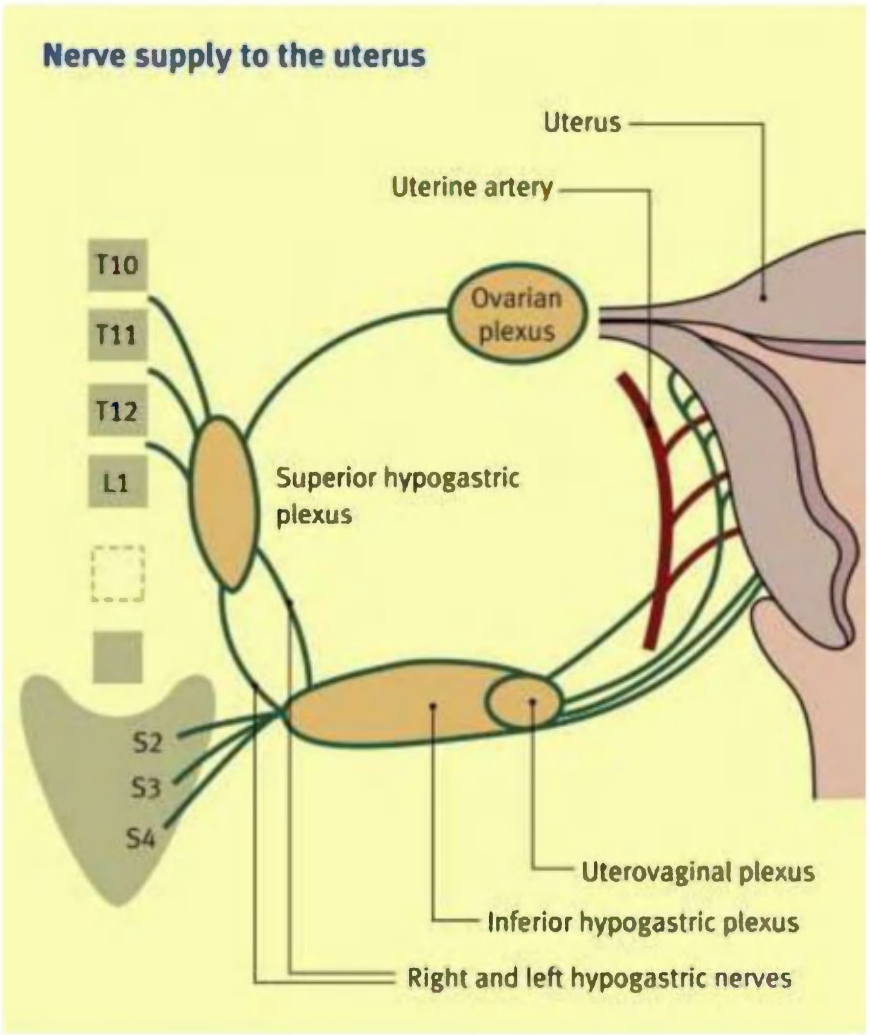

Figure 4.8 Nerve supply uterus

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."

4.2 Labour

4.2.1 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 [24]. 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.

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.

4.2.2 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.

4.2.3 Mechanism of Labor

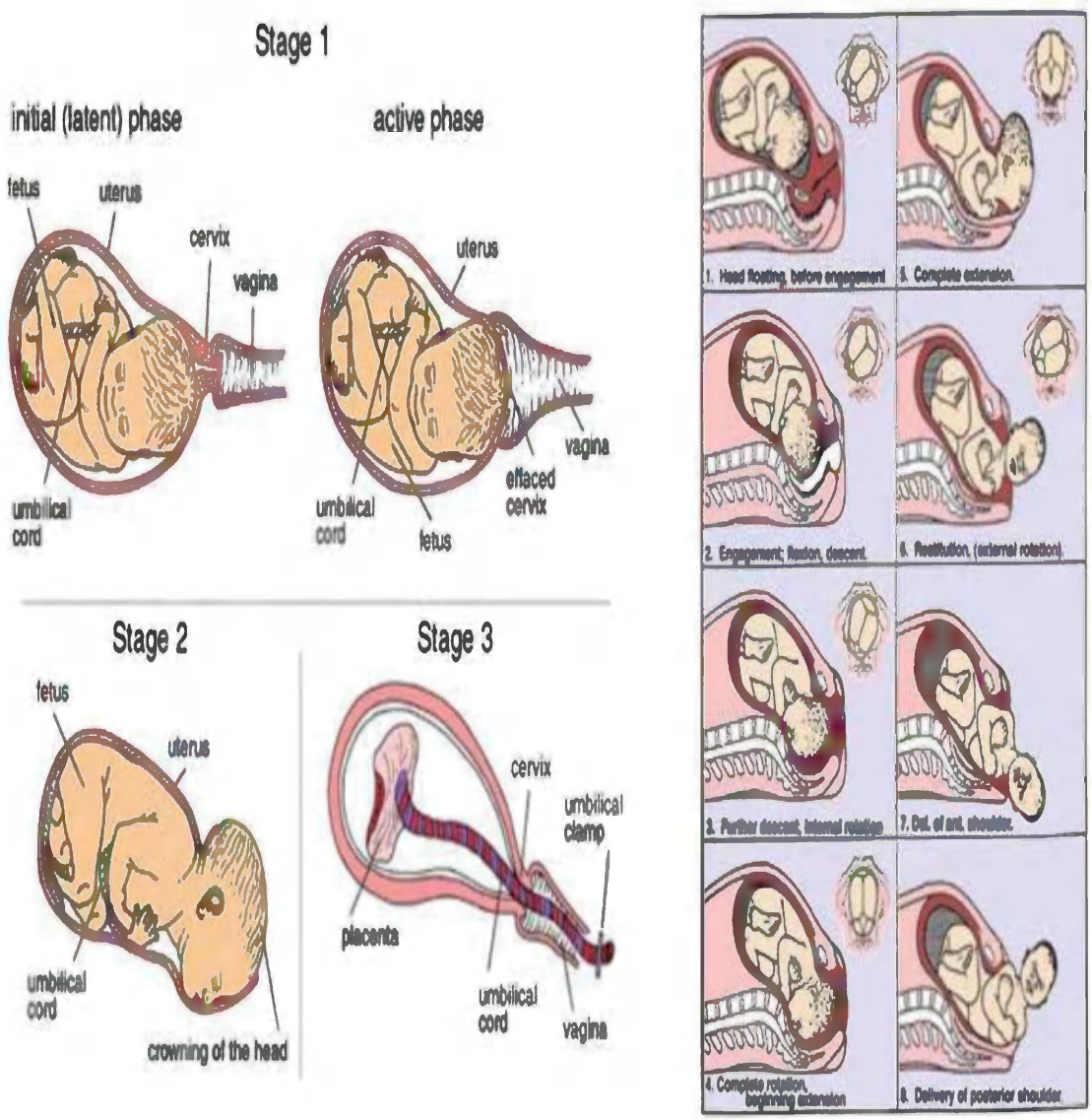

Figure 4.9 Mechanism of Labor

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 [25]. Although labor and delivery occurs in a continuous fashion, the cardinal movements are described as 7 discrete sequences, as discussed below.

4.2.3.1 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 stations, or at the level of the maternal ischial spines.

4.2.3.2 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.

4.2.3.3 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.

4.2.3.4 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.

4.2.3.5 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.

4.2.3.6 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.

4.2.3.7 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.

4.2.4 Cervical ripening

It 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 [26]. There are several methods of inducing cervical ripening which will allow the uterine contractions to effectively dilate the cervix.

Bishop Score

It indicates the changes in the cervix during the process of childbirth. In 1964, Edward Bishop set forth a criteria by parity, gestational age, fetal presentation, obstetric history ,patient consent and a pelvic scoring system for induction of labour .

Bishop scoring system:

Score	Dilation (cm)	Position of cervix	Effacement (%)	Station (-3 to +3)	Cervical Consistency
0	Closed	Posterior	0-30	-3	Firm
1	1-2	Mid position	40-50	-2	Medium
2	3-4	Anterior	60-70	-1, 0	Soft
3	5-6	–	80	+1, +2	–

Total Score-13. Unfavourable-0 to 6,Fvourable-6 to 13

MODIFIED BISHOP SCORE

In this modified pelvic scoring system, Effacement was replaced by cervical length in cm and scored as

0 for > 3cm, 1 for 2 cm, 2 for >1 cm, 3 for >3 cm

4.3 STAGES OF LABOUR

4.3.1 First stage: latent phase

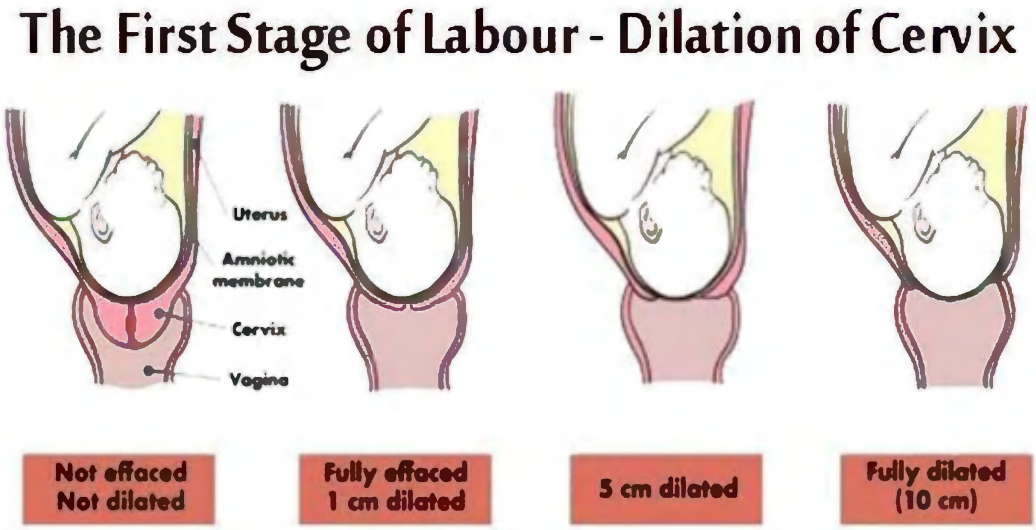

Figure 4.10 the first stage of labour

The latent phase is generally defined as beginning at the point at which the woman perceives regular uterine contractions [27]. Incontrast, 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.

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 [28]. 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.

4.3.2 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 labor [29]. 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. This was done in an effort to increase the rates of vaginal delivery.
- 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") [30]. The median duration of active first stage is four hours in first labors and three hours in second and subsequent labours.

4.3.3 Second stage: fetal expulsion

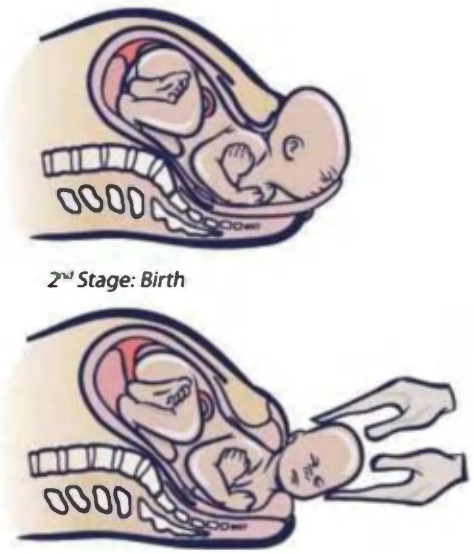

Figure 4.11 Second stage of labour

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.

- 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 [31]. 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.

4.3.4 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 [32]. 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.

4.3.5 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 [33]. 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.

4.4 Labor induction

Induction of labour is defined as stimulation of regular uterine contractions before the spontaneous onset of labour with or without rupture of membranes after 28 weeks of gestational age using mechanical or pharmacological methods in order to generate progressive cervical dilation and subsequent delivery. Induction of labour is the process of artificially stimulating the uterus to start labour [34]. It is usually performed by administering oxytocin or prostaglandins to the pregnant woman or by manually rupturing the amniotic membranes.

4.4.1 Indications of induction of labour

1. Obstetric conditions.

2. Medical conditions

Obstetric indications:

- Post dated and prolonged pregnancy,
- Pre labour rupture of membranes,
- Preterm premature rupture of membranes,
- Pre eclampsia and eclampsia,
- Fetal growth restriction,
- Rh isoimmunization,
- Oligohydramnios,
- Chorioamnionitis,
- Abruption placenta,
- Intrauterine death.

Medical indications:

- Chronic nephritis,
- Hypertension,
- Diabetes.

4.4.2 Contraindications to induction of labour

- Disproportion,
- Transverse lie,

- Major degree placenta previa, vasa previa,
- Cord presentation and prolapse,
- Previous classical caesarean section,
- Previous myomectomy entering the endometrial cavity,
- Pelvic tumors occupying the pelvis,
- Invasive carcinoma cervix,
- Maternal infections like active herpes genitalis and HIV

4.4.3 Methods used for induction of labour

1. Mechanical methods
2. Pharmacological methods
3. Non pharmacologic methods.

- Mechanical methods include sweeping of membranes, transcervical foley's catheter, extraamniotic saline infusion.
- Pharmacological methods use PGE2, oxytocin, misoprostol.
- Non-pharmacological methods include sexual intercourse and breast stimulation.

Risks of induction of labour

Need of emergency caesarean section

-due to fetal distress

-failed induction

- Hyperstimulation
- Psychological upset- more in failed induction
- Placental abruption-in case of hydramnios
- Precipitate delivery- resulting in cervical or vaginal laceration
- Uterine rupture- with injudicious use of oxytocin.

  More common with grand multiparas, those with previous uterine surgeries, fetal malpresentations, uterine overdistension.
- Infection- increased chance, if prolonged rupture of membranes
- Amniotic fluid embolism- very rare, mostly at the time of ARM.

Fetal risks:

- Iatrogenic
- Prematurity
- Hypoxia- Causes include hyperstimulation, disordered uterine action, and prolonged labour and operative interference

- Neonatal jaundice- sometimes associated with oxytocin use.

4.4.4 AMNIOTOMY/ARTIFICIAL RUPTURE OF MEMBRANES

- Also known as surgical induction in Britain
- ARM causes release of prostaglandins and convert the rigid cervix into distended one

INDICATIONS OF AMNIOTOMY

- To induce or augument the labour
- To identify the meconium stained liquor
- Internal electronic fetal heart rate monitoring

RISKS

- Injury to the fetal part/cervix
- Cord prolapse
- Amnionitis

PROSTAGLANDINS

- The evolution of prostaglandin started from Swedish physiologist von euler
- The term Prostaglandin was coined by Von Euler as this active substance is from Prostate gland

- The Prostaglandin F and E is important for labour and delivery
- The receptors for PG are always found in mypmetrial tissue
- The Prostaglandin E is more uteroselective and moreeffective in producing uterine contractions
- The PG is synthesized from essential unsaturated fatty acids
- PG s are implicated in

  -The initiation of labour

  -Cervical ripening

  - In the process of labour

  -Post partum haemostasis

Biosynthesis:-

Lenoleic acid ← **Phospholipids** → Eicosa pentanoic acid

↓ | |

PGI series AA(arachidonic acid) PG3 series

↓ |

PGE1 PG2 series

↓

PGE2

The bio-conversion of Arachidonic acid (AA) to PG (PGE2 to PGF2),prostacyclins (PGI2) and thombaxanes (TXA2) is the formation of cyclic endoperoxidases PGs G and H. PGI2 inhibitory effect on uterine contractility. Enzyme responsible for the conversion of AA to PGH2 is known "fatty acid cyclooxygenase"/ PGs endoperoxide synthetase/ PGH synthase.

Depending on the tissue, the endoperoxidases (PGE2 and PGH2) are further converted non-enzymatically into PGE2, PGF2α and TXA2. These conversions are rapid and completed within a few minutes in the in-vitro system.

Metabolism

PGE2 is metabolized by oxidation at the sites of carbon 15, and give rise to 15 keto prostaglandin, which are biologically inactive. A further reduction of double bond at carbon 13 leads to formation of 15-keto 13, 14 dehydroprostaglandin.

The enzymes involved in initial conversion of PGE2 are formed in lungs, liver and kidney.

PGE2

↓

12-keto PGE2

↓

15-keto 13, 14 dehydroprostaglandin

Physiological role of PG:

A wide range of physiological functions have been attributed to PG's, especially in the reproductive system, GI, CVS and RS. The physiological role described to PG's in the female reproductive system include sperm transport, ovulation, luteolysis, menstruation, spontaneous abortion and labour and closure of umbilical vessels at birth.

Prostaglandins act through a number of G-protein couple receptors. The final pathways involve intracellular cyclic AMP and intracellular calcium. While an increase in intracellular calcium is responsible for contraction, increase in cyclic AMP promotes relaxation. Thus, by modifying these pathways, PGE2 and PGI 2 promote uterine quiescence.

Careful monitoring of cervical dilatation and effacement is done to detect any considerable effects like hypertonic myometrial contractions or fetal distress. In the event where high tone myometrial contractions are sustained, the possibility of uterine rupture should be borne in mind.

4.4.5 Monitoring of induction

Unlike most spontaneous labor, induction of labour carries the possibility of uterine hyperstimulation. Therefore, during the induction of labour it is essential that uterine activity be monitored closely. Fetal heart rate monitoring similar to that recommended for high risk patients in active labour should be used. Properly trained nurses can monitor the induction of labour, but a specialist who has privileges to perform cesarean delivery should be readily available.

4.4.6.1 Factors to be considered during induction of labour

1. Patients informed consent: Regarding the indications, methods of induction should be explained to the patient and the possible need for a cesarean delivery or a repeat induction.
2. Estimating of fetal pulmonary maturity.
3. Gestational age.
4. Pelvic adequacy.
5. Readiness of cervix.
6. The presumed ability of fetus to tolerate the labour.
7. Stability of maternal conditions.
8. Uterine integrity

4.4.6.2 Early history of cervical assessment.

Pelvic scoring system were sought to predict the duration of induced labour and to identify the patient who would safely undergo such procedure an objective, reproducible description of the cervical state was needed. Before 1931, Calkins et al tried to identify a factor that would predict the duration of labour. They speculated that the "duration of both the first and the second stage of labour is the product of character of the labour pains on the one hand and the resistance of the soft parts on the other hand". Cervical assessment has, overtime progressed from qualitative (that is soft/not ripe/not soft and so on) to quantitative numerically based system. Later, Calkins proposed a dichotomous system for assessing cervical factor "effacement was considered present/absent." He considered the presenting part engaged when at/below the ischial spine. Consistency was also assessed in this scheme, and the cervix was called a "2" cervix, it was firmer than the nasal alae.

Calkins made these assessments of the cervix on rectal examination . Calkins's findings were later confirmed by Nixon who described two classes of cervix. Type I cervix (soft, effacing and os admits' 1 ' finger) and type II cervix(long, soft and os is closed).Sacral os was defined when the cervical os pointed towards the sacrum. He reported that type I, II and presented of sacral os was associated with prolonged labour.

To avoid the complication of prolonged labour induction in 1955, Cock's described cervices in terms of five types. Categories 1 &2 were designated as ripe, whereas 3, 4, 5 were unripe.

In Cock's experience with this classification operative delivery was more when presented unripe cervices. In 1958, Cock's findings were later confirmed by Dutton and concluded that evaluating the cervix was useful in selecting appropriate candidate for labour induction.

Cock's classification was limited to an evaluation of the ripeness of a cervix, defined by dilatation, consistency and length. All of these characteristics were adequate, quantitative measures of cervical state, but not sufficiently quantitative. Others, such as Garret (1960) and Friedman and Sachtlelen (1962) to develop a more quantitative process of cervical evaluation. These studies provided strong support for the possible role of cervical factor in the mechanism of labour to know about cervical dilatation, effacement, position, station and consistency to aid patient selection for labour induction. All of these factors would be used to develop a quantitative cervical scoring system.

Pre induction cervical assessment

The systems of quantifying and scoring the prelabor characters of cervix were sought to:

1. Predict the duration of induced labor.

2. To determine which patients may safely undergo labor induction.
3. To determine the most appropriate method for inducing labor or ripening an unfavourable cervix.

4.5 Postdated Pregnancy

Postdated pregnancy is defined as pregnancy that has extended to or beyond 40 weeks of gestation. The incidence of postdated pregnancy is about 3 to 17% . The prevalence varies depending on population characteristics and local management practices.

4.6 Transcervical Foley's Catheter

This technique is used when labour induction is indicated for women with unripe cervix. Its made up of latex rubber ,size varies from 8F TO 24F

4.6.1 Mechanism of Action

Primary effect of Foley's catheter could be through mechanical dilatation, but the cervix does not sustain permanent or significant damage [36] and it releases prostaglandins from decidual separation.

Foley's works by two mechanisms.

1. Direct pressure and over stretching of cervix and lower uterine segment, enhances uterine activity [37]. This mechanism is referred to as ferguson reflex.

2. Local secretion of prostaglandins [38]. When the cervix is extremely unfavourable, membrane stripping is often impractical and in such cases, foley's catheter use may be more reasonable for cervical ripening

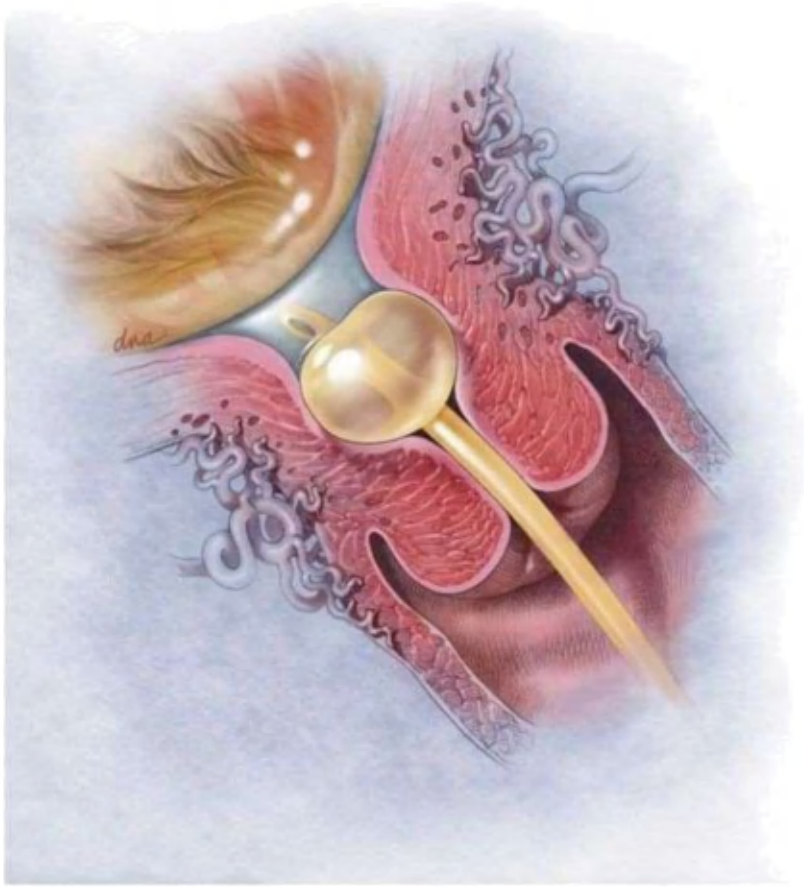

Figure 4.12 Transcervical Foley's Catheter induction

4.6.2 Advantages

- Safe
- Effective
- Inexpensive
- Lack of systemic side effects

- Fewer incidences of tachysystole and therefore continuous monitoring not required
- Improves Bishop's score rapidly
- In unripe cervices, Foley's catheter can be used with oxytocin infusion simultaneously for induction.

4.6.3 Transcervical 14-16f Foley Catheter

Safest and efficient way of inserting a Foley's catheter is under direct visualization, by retracting the posterior vaginal wall with speculum. Inflated with 30-80 ml of normal saline Pulled snugly against the internal os and the catheter is taped to the thigh under traction or by tying 500-1000ml of i.v fluid to the other end for traction. It can be combined with oxytocin infusion. Left in-situ for 12-24 hours. Expulsion correlates with cervical dilatation of 2-3 cms when amniotomy can be done.

Balloon and catheter size

The use of Foleys catheter to effect cervical ripening was first described by Embrey and Mollson in 1967. They used a 26 group catheter, modified by the removal of the tip and inflated with 50 ml of sterile water above the internal os. In most studies the balloon was inflated with 30-40ml of fluid, but values as high as 80ml have also been tested. In addition, many of these balloons assume a cylindrical, rather spherical shape when over inflated.

Theoretically, large balloon volume is more likely to displace the presenting part, but achieve only a minor increase in diameter. Foleys catheter allows a successful induction of labour and reduces the induction delivery interval from what it would have been in an unripe cervix.

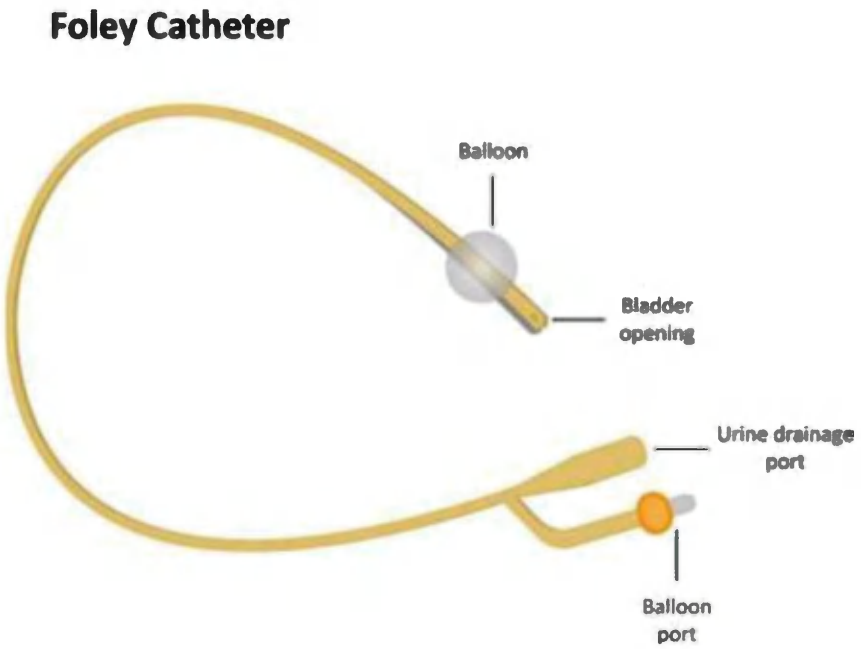

Figure 4.13 Foley Catheter

Catheter is deflated and removed if

- Membranes ruptures
- Fever
- Bleeding
- Uterine hyperstimulation
- Vasovagal syncope due to continuous traction.
- After 12-24 hours if not expelled

4.7 Cook Double Balloon Catheter

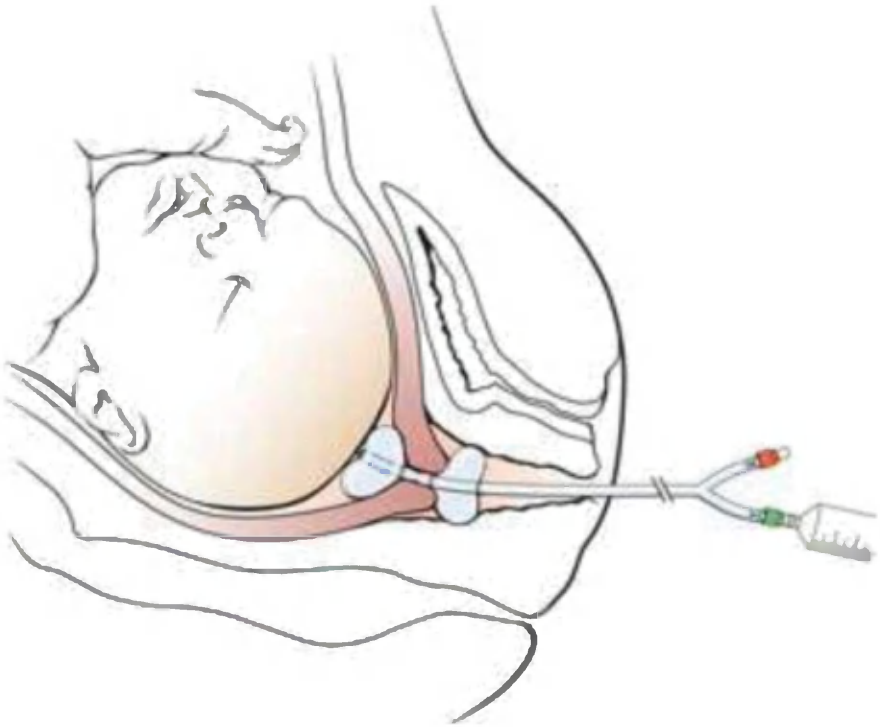

Figure 4.14 Double balloon catheters

The cook cervical ripening balloon is a silicon double balloon catheter .Maximum inflation -80ml/balloon.

MECHANISM

Insertion of a double balloon catheter for induction of labour at term in pregnant women aims to facilitate induction through causing dilation of the cervix when the cervix is unfavourable for induction. The double balloon is claimed to stimulate local prostaglandin release, which leads to cervical ripening, through the 2 balloons squeezing the cervix.

PROCEDURE

The procedure is usually done with the woman in a lithotomy or supine position. A sterile speculum is inserted into the vagina to gain access to the cervix. The cervix is then prepared by cleaning with an appropriate antiseptic solution before inserting the device. A double balloon catheter (with a uterine balloon and a vaginal balloon) is inserted through the cervical canal and into the uterus, so that the tip of the catheter lies in the extra-amniotic space. The uterine balloon is then inflated with a small amount of saline and the catheter is gently pulled back until the uterine balloon lies against the internal cervical os. The vaginal balloon is also inflated with saline so that it lies against the external cervical os. Both the balloons are inflated with alternative increments of small amounts of saline. When the balloons are fully inflated and in place on both sides of the cervix, the speculum is removed. The external end of the device is loosely taped to the woman's inner thigh.

Following the insertion of the double balloon, a fetal non-stress test is done and sometimes extra-amniotic saline is infused at the same time. The mother and fetus are monitored and the device is left in place for up to about 12 hours. If labour begins, or spontaneous device expulsion or rupture of membranes have occurred, or if fetal distress is suspected, the balloons are deflated and the device isremoved to facilitate labour management. If labour

does not begin spontaneously, the membranes are ruptured artificially and oxytocin infusion is started.

CONTRAINDICATIONS

- Patient planned for exogenous prostaglandin administration
- Ruptured membranes
- Cord prolapse
- Breech
- Multiple pregnancy
- Maternal heart disease
- Polyhydramnios
- Structural abnormality in pelvis
- Prior hysterotomy,Classical uterine incision,Myomectomy
- Active herpes infection
- Invasive cervical cancer
- Placenta previa

CHAPTER 5

MATERIALS AND METHODS

5.1 Subjects and Schemes

Study conducted in Government Theni Medical College for the duration of 12 months from OCTOBER 2020 to OCTOBER 2021.

Study design-prospective randomized case study

Study population-Postdated pregnancy

Sample size-80

Randomly allocated into two groups (each 40 patients)

Group 1- single balloon Foley catheter group.

Group 2- Double baloon catheter group.

5.2 Inclusion criteria

- Gestational age more than 40 weeks
- Singleton pregnancy
- Cephalic presentation
- Postdated pregnancy
- Bishop score of less than or equal to 3

5.3 Exclusion criteria

- Malpresentation
- Scarred uterus
- Signs of infection
- Ruptured membranes
- APH

5.4 Materials and Methods

On admission detailed history was taken ,with consent general and obstetric examination was carried out ,under aseptic precaution vaginal examination done and boshop score was assessed

After approval by ethical committee, informed consent to be obtained:

- **Group 1- single baloon catheter group.**

After getting informed consent,patient in lithotomy position under sterile aseptic precautions. Using vaginal speculum and after cleaning cervix with normal saline 18 fr foley catheter to be inserted above internal os and filled with 60 ml of normal saline. Catheter was then strapped to inner aspect of thigh.

- **Group 2. Double baloon catheter group.**

After getting informed consent, Patient in lithotomy position under sterile aseptic precautions. Using vaginal speculum, cervix is cleaned with normal saline. Double baloon catheter is inserted into cervix and advanced until both balloon has entered the cervical canal.

Uterine baloon is inflated with 40 ml normal saline. Once uterine baloon is inflated it is pulled back untill uterine baloon is against cervical internal os. Vaginal balloon is now visible outside external cervical os. Vaginal balloon is inflated with 20 ml of normal saline. Maximum of 80 ml can be inflated in both balloons.

Once both balloons are situated on each side of cervix and device has been fixed in place, speculum is removed. Proximal end of Catheter is then strapped to patient's thigh.

- A non stress test - to be conducted after catheter insertion
- Removal of catheter to be planned at 12 hrs after insertion
- If spontaneous expulsion doesnot occur in 12 hrs, it is removed
- Continuous electronic fetal monitoring should be conducted after this procedure

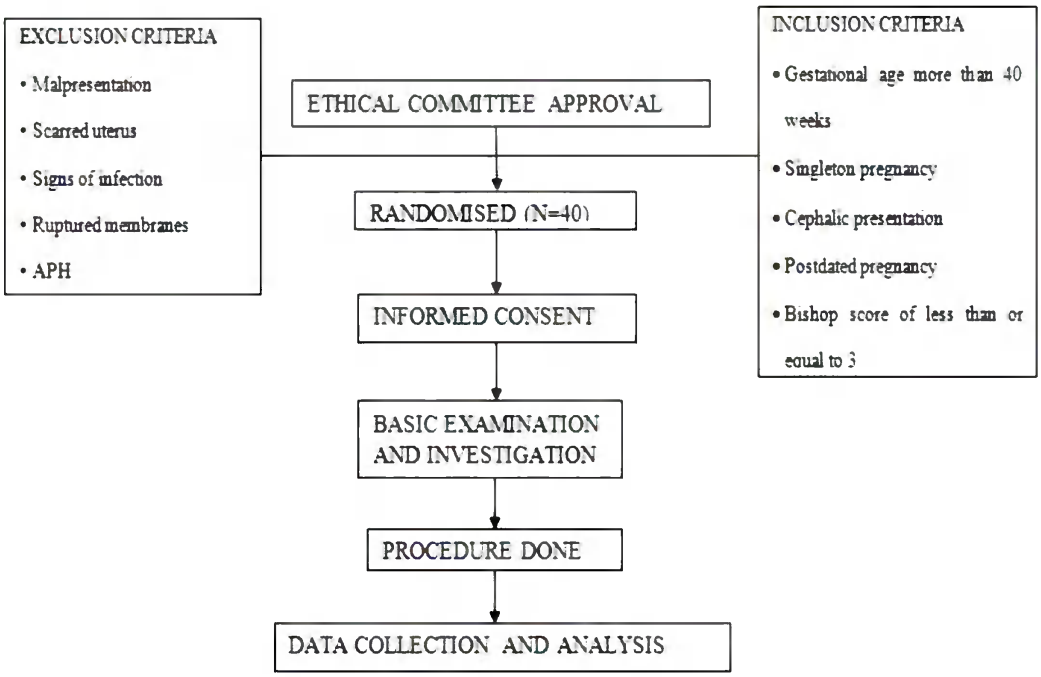

Figure 4.15 Consort diagram

5.5 Primary outcome

Change in bishop score/cervical ripening after 12 hours of labour induction in both groups

5.6 Secondary outcome

- Induction to catheter expulsion time,
- Induction to amniotomy time,
- Induction to delivery time,
- Mode of delivery, Neonatal outcome

CHAPTER 6

STATISTICAL ANALYSIS

Collected data were processed using SPSS version 16; Quantitative data were expressed as mean ± standard deviation, while qualitative data were expressed as numbers and percentages.

To test the differences between the two types of the catheters, categorical variables were analyzed by $\chi 2$ or Fisher exact tests when warranted. An independent t test or the Mann–Whitney U test, in the case of non-normally distributed variables, was used to test differences between the two types of balloon for continuous variables.

A Student's t-test was used to test the significance of difference for quantitative variables and chi-square was used to test the significance of difference for qualitative variables. A probability value of $P < 0.05$ was considered statistically significant. Data were analyzed and appropriately presented in tables and graphs.

CHAPTER 7

RESULTS AND DISCUSSION

In this chapter, discussed about the age distribution, Parity, BMI of patients, Bishop Score, Pain on catheter insertion, Catheter expulsion etc. Collected data were processed using SPSS version 16; Quantitative data were expressed as mean ± standard deviation, while qualitative data were expressed as numbers and percentages. The probability value also calculated; the p-value < 0.05 considered as a significant.

7.1 Age distribution

The mean age distribution of patients and their standard deviations were calculated and mentioned in Table 7.1. The comparisons of mean age distribution of patients among group were graphically represented in Figure 7.1. Both groups when compared with ages had the same mean value, there was no major difference observed in this study. Probability value were calculated; p-value is $0.367 > 0.05$ statistically not significant.

Table 7.1 Mean age distribution of patients and their standard deviations

Mean age	Mean	SD
Group 1	27.65	4.44
Group 2	27.87	3.32
P value	0.367	

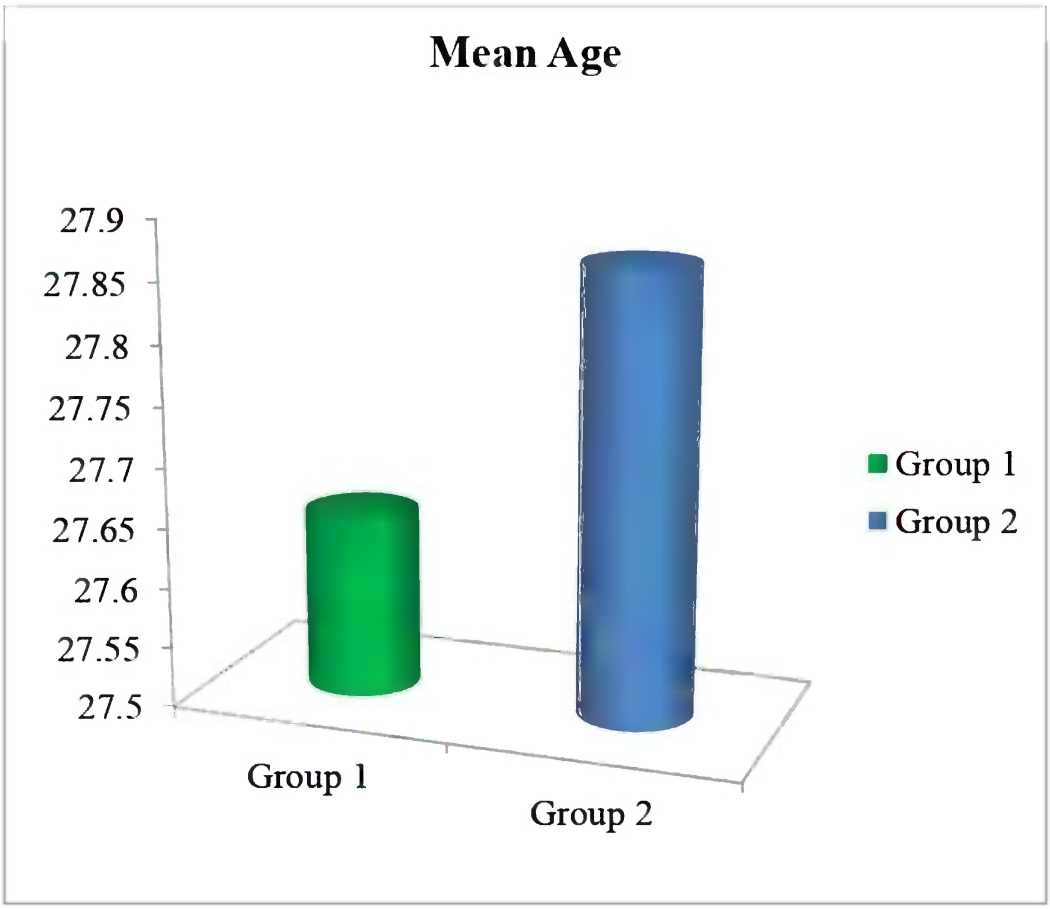

Figure 7.1 Comparison of mean age distribution of patients among group

7.2 Parity

Table 7.2 Parity of patients among groups

Parity	Primi (%)	Multi (%)
Group 1	47.5	52.5
Group 2	52.5	47.5

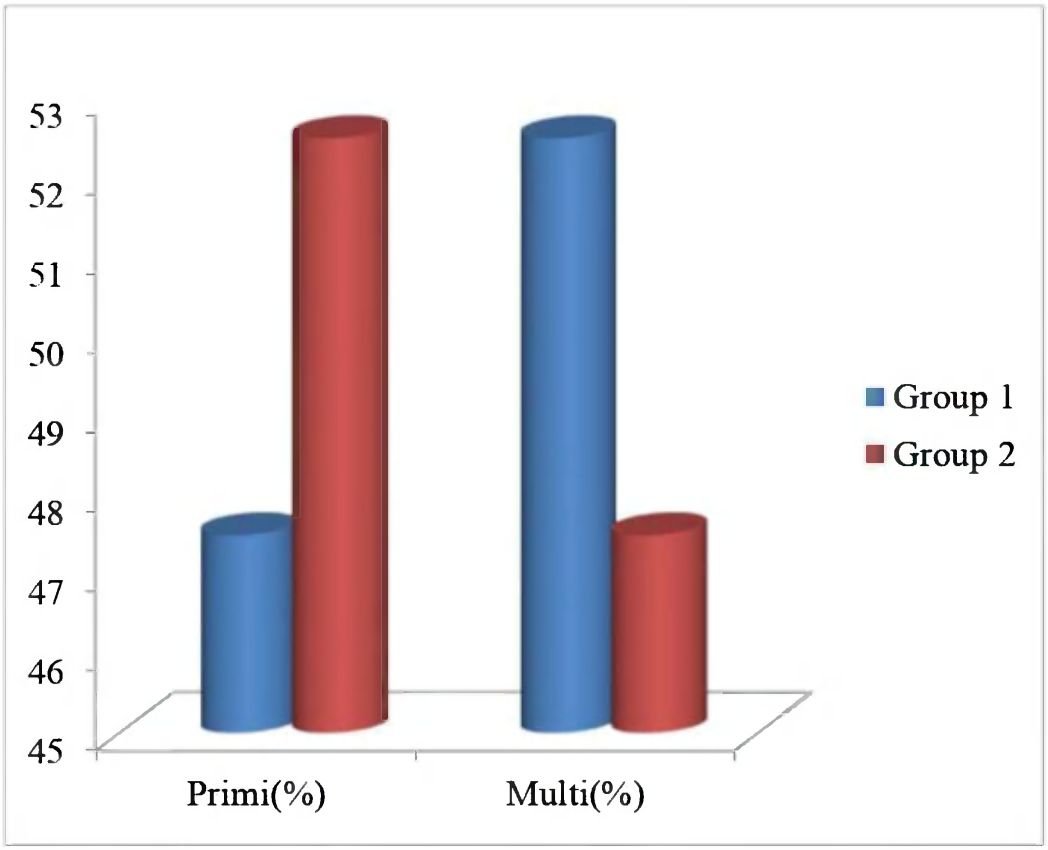

Figure 7.2 Comparison of parity among group

The parity of patients among the group have been calculated and given in Table 7.2 and graphically represented in Figure 7.2. Group 1 having higher multi = 52.5 and lower primi = 47.5. Similarly, Group 2 having higher primi= 52.5 and lower multi = 47.5.

7.3 BMI of patients

Table 7.3 BMI of patients among group

BMI	Mean	SD
Group 1	23.89	2.04
Group 2	23.78	2.09
P value	0.708	

The BMI of patients among groups were calculated and tabulated in Table 7.3. Group 1 having mean BMI of 23.89 and Groups 2 having mean BMI of 23.78. The comparison graph graphically represented in Figure 7.3. Probability value were calculated; p-value is 0.708 > 0.05 statistically not significant.

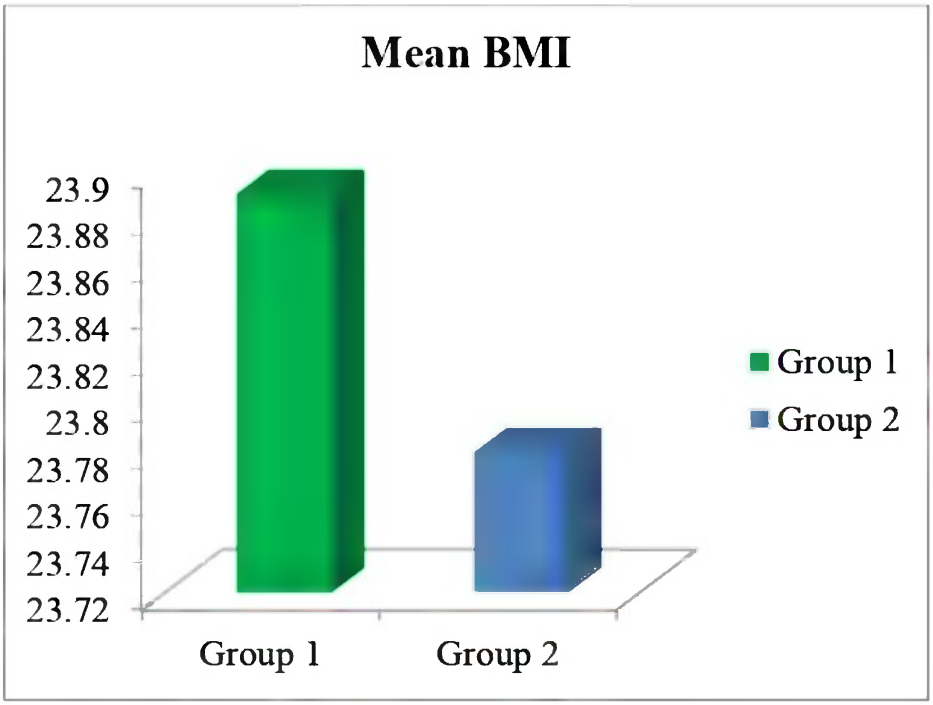

Figure 7.3 Comparison of BMI of patients among group

7.4 Bishop score

The Mean bishop score before catheter insertion were calculated and tabulated in Table 7.4 and graphically represented in Figure 7.4. Both groups having same bishop score was observed in this study. Probability value of bishop score before catheter insertion were calculated; p-value is 0.143 > 0.05 statistically not significant.

7.4 Mean bishop score before catheter insertion

Bishop score	Mean	SD
Group 1	2.75	0.44
Group 2	2.6	0.499
P value	0.143	

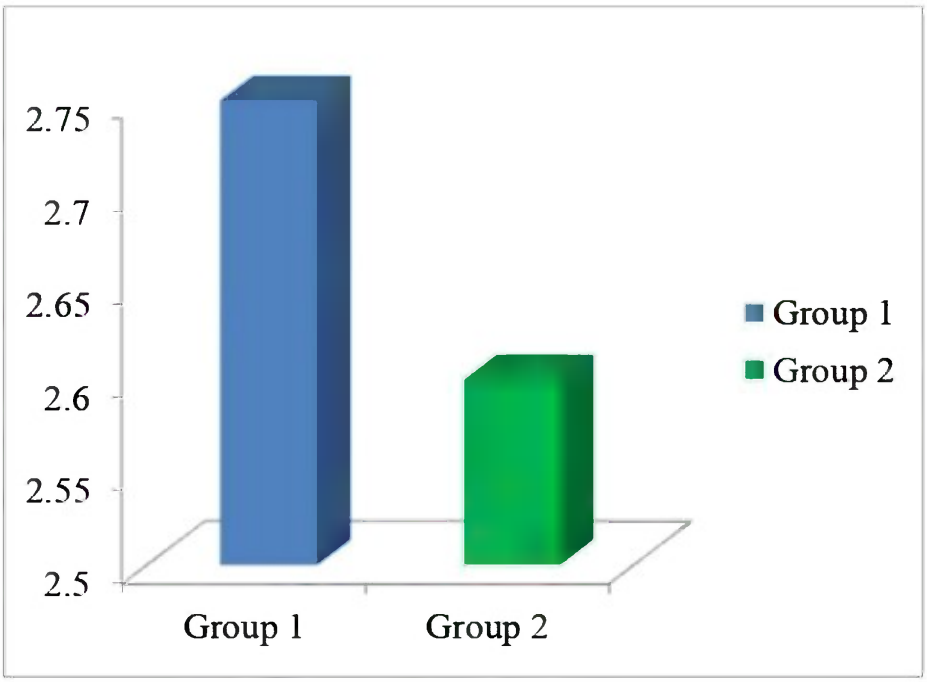

Figure 7.4 Comparison of mean bishop score before catheter insertion

7.5 Pain on catheter insertion

Table 7.5 Mean pain on catheter insertion among group

Pain on catheter insertion	Mean	SD
Group 1	4.3	0.728
Group 2	4.27	0.720
P value	0.15	

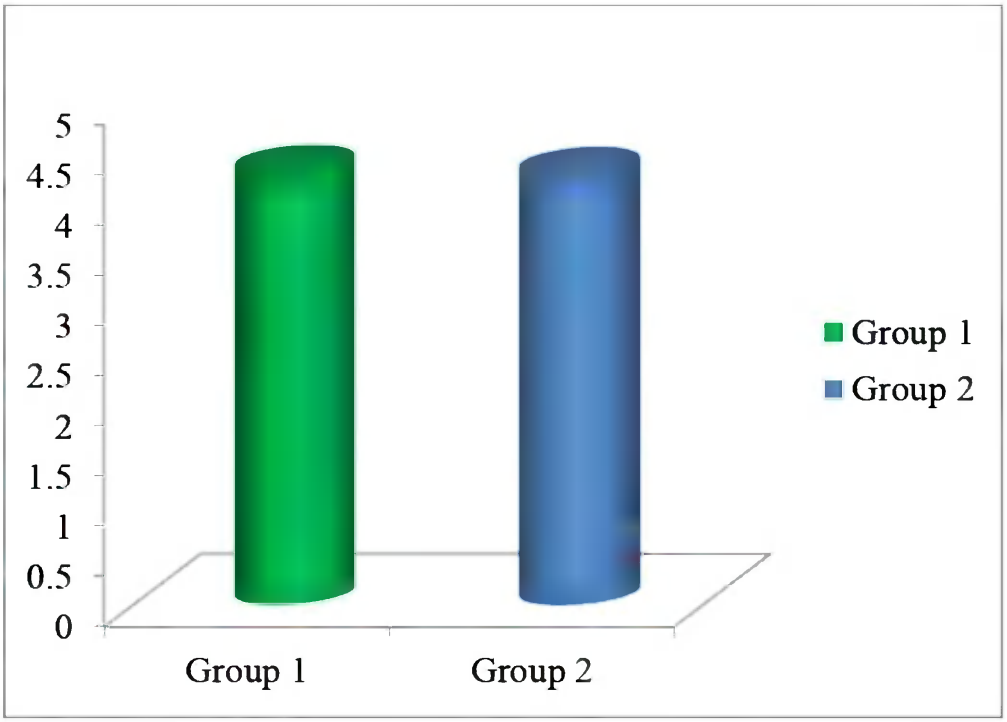

Figure 7.6 Comparison of mean pain on catheter insertion among group

The mean pain on catheter insertion have been calculated and given in Table 7.5. Slight variation was observed in mean pain on catheter insertion between group 1 and group 2 and it's clearly represented in Figure 7.5. Probability of pain on catheter insertion were calculated; p-value is $0.15 > 0.05$ statistically insignificant.

7.6 Catheter insertion

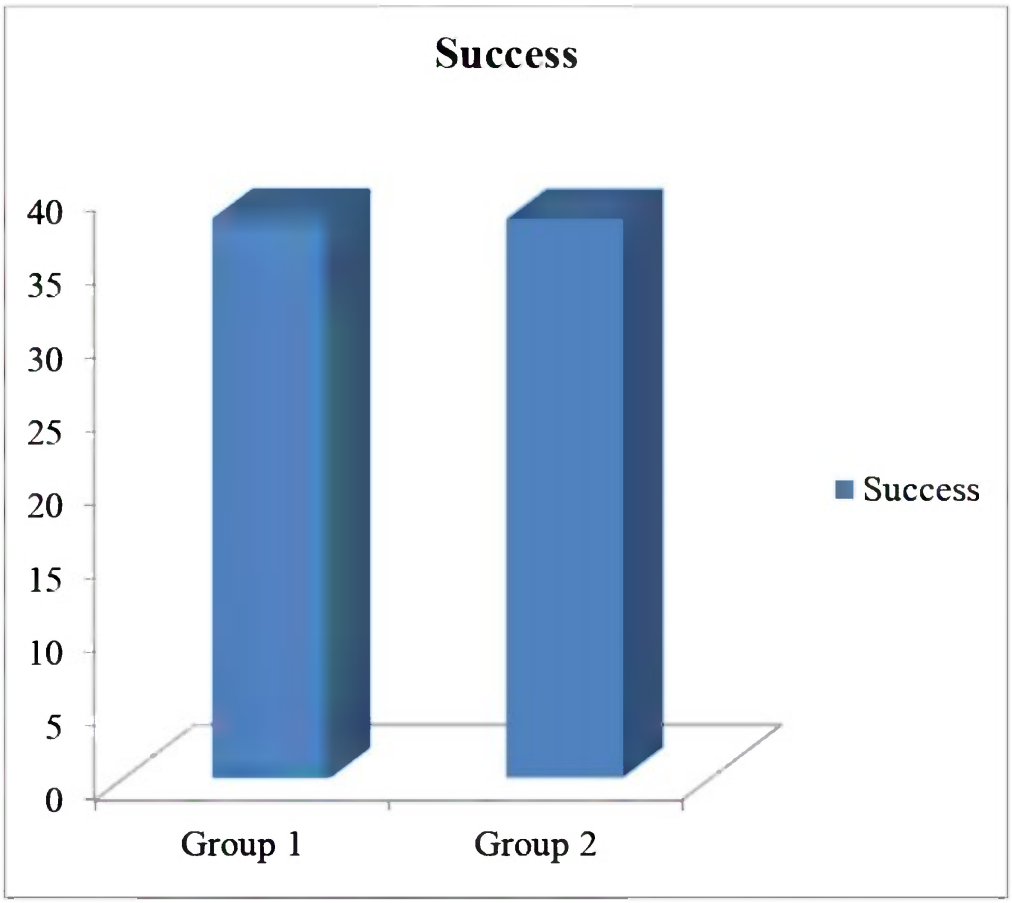

Figure 7.6 Comparison of no. of catheter insertion among group

The no. of catheter insertion among group were calculated, success rate was same in both groups

Table 7.6 No. of catheter insertion among group

Catheter insertion	Success	Failure
Group 1	40	0
Group 2	40	0

7.7 Catheter expulsion

Table 7.7 No. of Catheter expulsion

Catheter expulsion	Yes	No
Group 1	35	5
Group 2	38	2
P value 0.0001		

The no. of catheter expulsion among group were calculated and given in Table 7.7. Group 2 have higher amount of catheter expulsion ; it's clearly represented in Figure 7.7.p value 0.0001<0.05 statistically significant

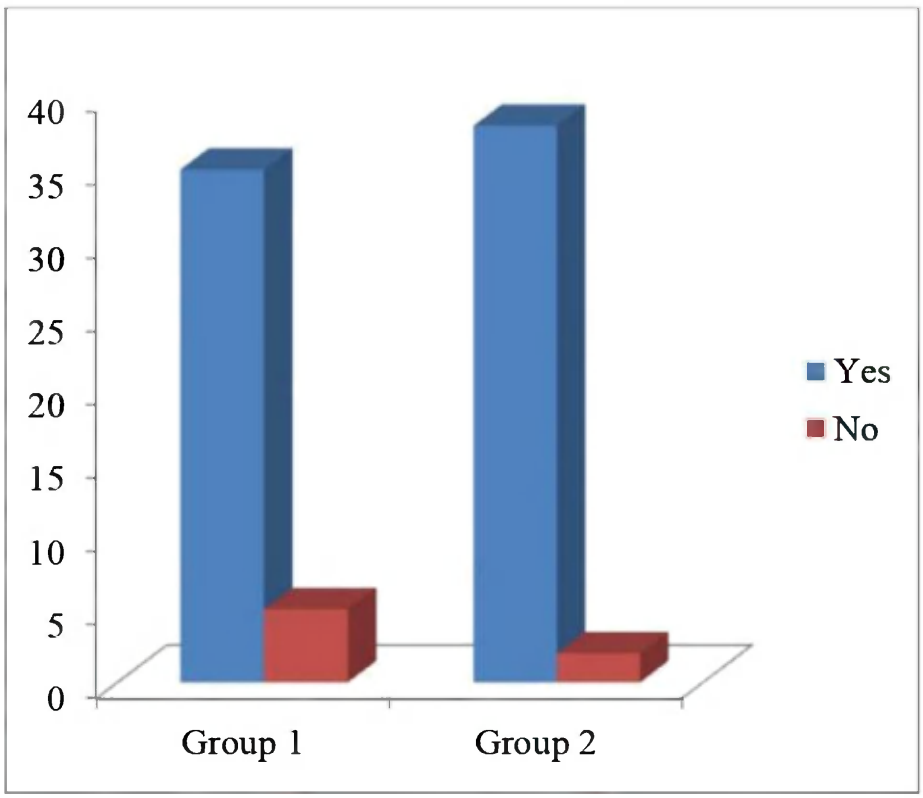

Figure 7.7 Comparison of catheter expulsion

7.8 Bishop score after catheter expulsion

The bishop score after catheter expulsion were calculated and tabulated in Table 7.8 and graphically represented in Figure 7.8. Group 2 = 6.2 ± 1.33 having higher mean bishop score after catheter expulsion among groups and it's graphically represented in Figure 7.8. Probability of Bishop score after catheter expulsion were calculated; p-value is 0.0004 < 0.05 statistically significant.

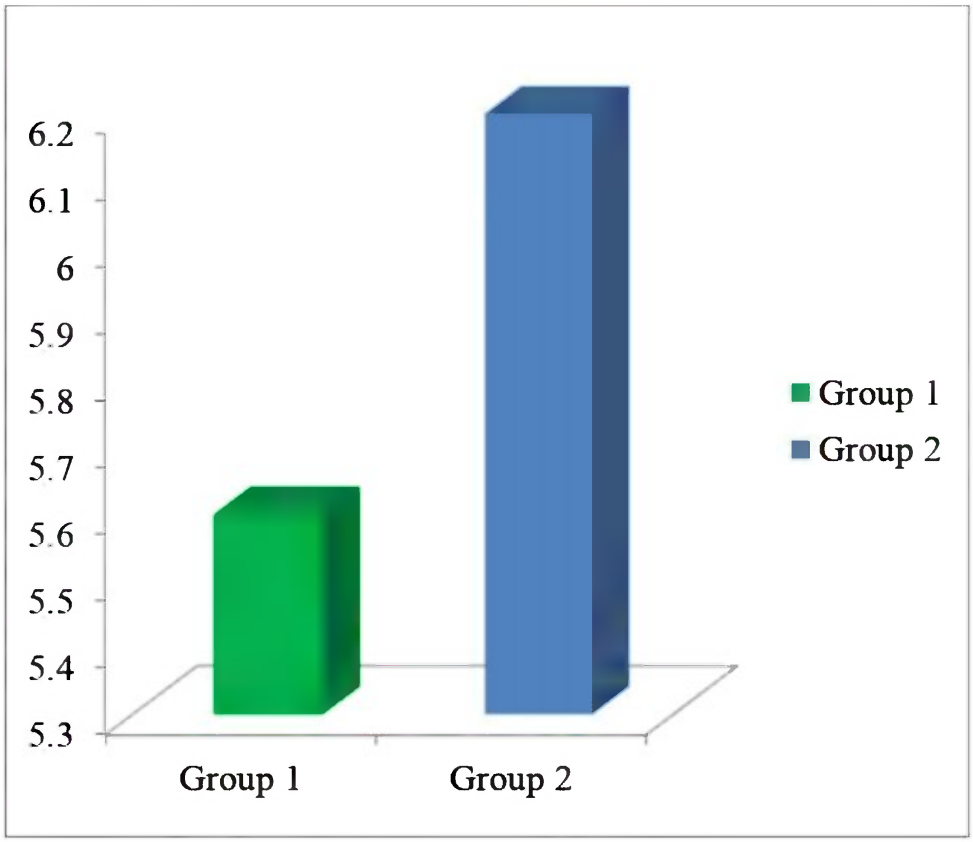

Figure 7.8 Comparison of mean bishop score after catheter expulsion

Table 7.8 Mean bishop score after catheter expulsion among groups

Bishop score after catheter expulsion	Mean	SD
Group 1	5.6	0.954
Group 2	6.2	1.33
P value	0.0004	

7.9 Insertion to Expulsion time

Table 7.9 Mean Insertion to expulsion time among groups

Insertion to Expulsion time	Mean	SD
Group 1	7.29	1.775
Group 2	7.36	1.601
P value	0.0002	

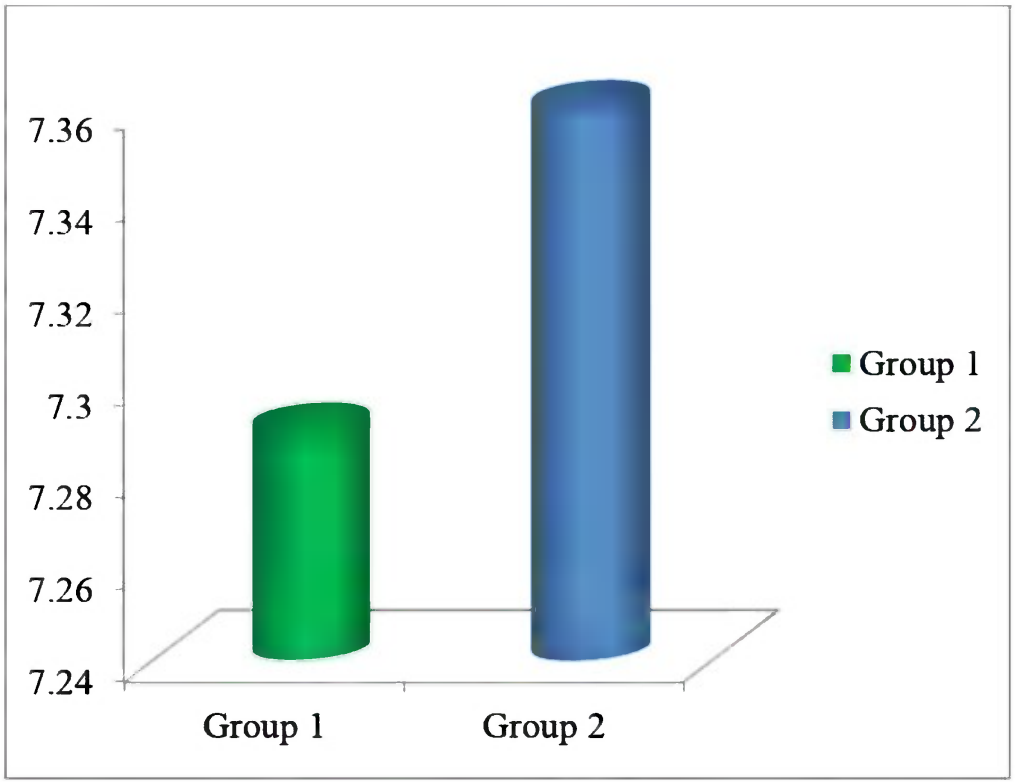

Figure 7.9 Comparison of mean Insertion to expulsion time among groups

The mean insertion to expulsion time were calculated and tabulated in Table 7.9. Both groups having same effects, slight variation were observed and graphically represented in Figure 7.9. Probability of insertion to expulsion time were calculated; p-value is $0.0002 < 0.05$ statistically significant.

7.10 Insertion to Delivery time

The mean insertion to delivery time were calculated and tabulated in Table 7.10. Group 2 having higher mean insertion to delivery time = 14.24 ± 1.81 and graphically represented in Figure 7.10. Probability of insertion to delivery time were calculated; p-value is 0.0003 < 0.05 statistically significant.

Table 7.10 Mean Insertion to Delivery time among group

Insertion to Delivery time	Mean	SD
Group 1	12.47	1.53
Group 2	14.24	1.81
P value	0.0003	

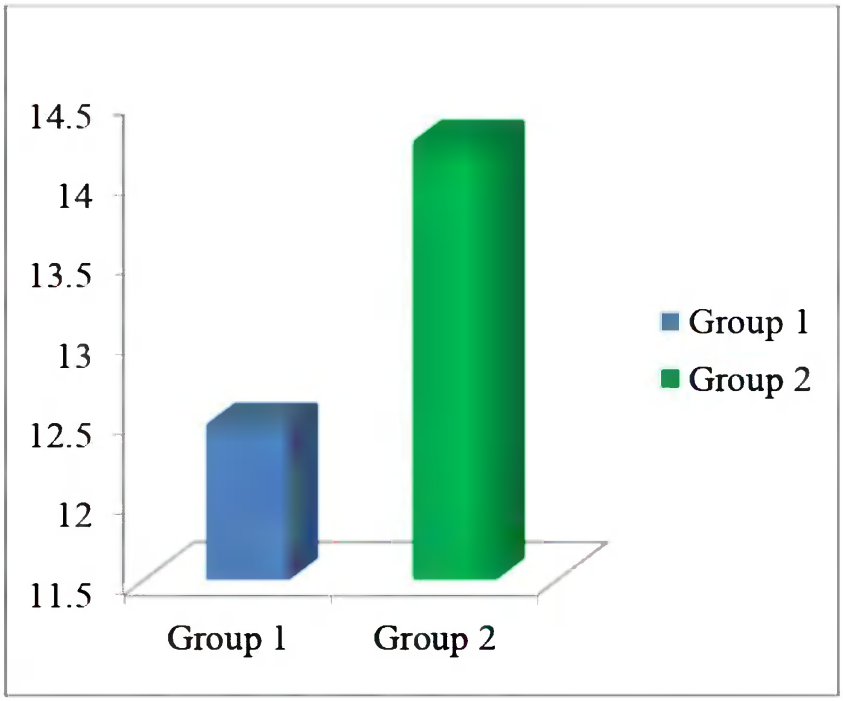

Figure 7.10 Comparison of Mean Insertion to Delivery time among group

7.11 Mode of delivery

Table 7.11 Mode of delivery

Mode of delivery	Vaginal delivery	Cesarean
Group 1	26	14
Group 2	33	7
P value	0.0005	

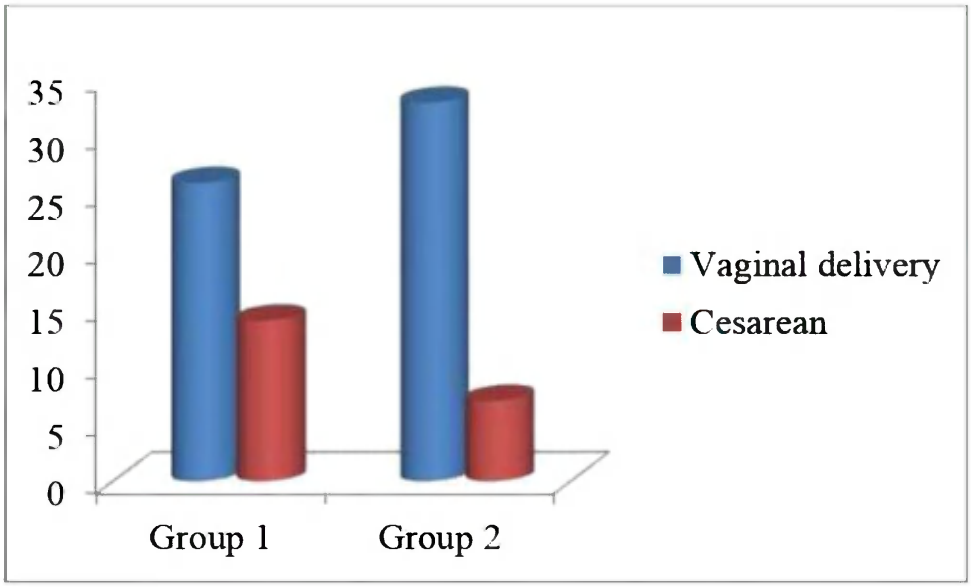

Figure 7.11 Comparison of mode of delivery

The mode of delivery were calculated and tabulated in Table 7.11. in Group 2 vaginal delivery more compared to Group 1, which was statistically significant (p= 0.0005) and it was graphically represented in Figure 7.11.

7.12 APGAR score

Table 7.12 Mean APGAR score

APGAR score	Mean	SD
Group 1	8.07	0.698
Group 2	8.1	0.676
P value	0.125	

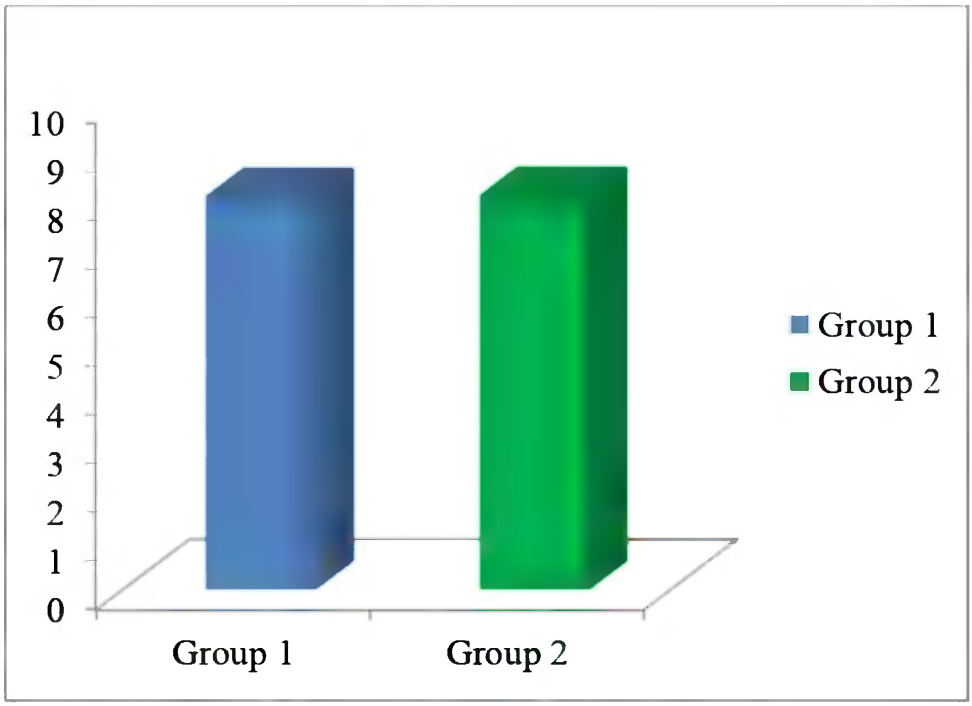

Figure 7.12 Comparison of mean APGAR score

The mean APGAR score were calculated and tabulated in Table 7.12. Group 2 having APGAR score = 8.1± 0.676 compare to group 1 (8.07±0.698) and it's graphically represented in Figure 7.12. Probability of mean APGAR score were calculated; p-value is 0.125 > 0.05 statistically insignificant.

DISCUSSION

This study is to compare the efficacy of two mechanical devices –cooks double balloon catheter versus foley catheter for preinduction of labour cervical ripening in postdated pregnancies.

AGE

Both age group having same mean value, there is no major difference observed . Probability value were calculated; p-value is 0.367 > 0.05 statistically not significant.

PARITY

Group 1 having higher multi = 52.5 and lower primi = 47.5. Similarly, Group 1 having higher primi= 52.5 and lower multi = 47.5.

BMI

Group 1 having mean BMI of patients is 23.89 and Groups 2 having mean BMI of patients is 23.78. Probability value were calculated; p-value is 0.708 > 0.05 statistically not significant.

BISHOP SCORE

Both groups having same bishop score was observed in this study. Probability value of bishop score before catheter insertion were calculated; p-value is 0.143 > 0.05 statistically not significant.

PAIN ON CATHETER INSERTION

Slight variation was observed in mean pain on catheter insertion between group 1 and group 2. Probability of pain on catheter insertion were calculated; p-value is $0.15 > 0.05$ statistically insignificant.

CATHETER INSERTION

In catheter insertion, there was no failure catheter insertion in both groups

CHANGE IN BISHOP SCORE

Group 2 having higher mean bishop score after catheter expulsion among groups. ; p-value is $0.0004 < 0.05$ statistically significant.

INSERTION TO EXPULSION TIME

In Insertion to expulsion time, slight variation was observed. Probability of insertion to expulsion time were calculated; p-value is $0.0002 < 0.05$ statistically significant.

INSERTION TO DELIVERY TIME

Group 2 having higher mean insertion to delivery time = 14.24 ± 1.81 compared to group 1. Probability of insertion to delivery time were calculated; p-value is $0.0003 < 0.05$ statistically significant.

MODE OF DELIVERY

In mode of delivery, Group 2 had more vaginal deliveries compared to group 1, p value is 0.0005<0.05 ,statistically significant

APGAR SCORE

Probability of mean APGAR score were calculated; p-value is 0.125 >0.05 statistically insignificant.

The study goes well with the study conducted by Ahmed et al that cervical ripening is faster with double balloon catheter than foley catheter

CONCLUSION

1. In this study ,double balloon catheter is associated with faster cervical ripening compared with foley catheter
2. The success of catheter insertion is equal in both groups
3. The induction to delivery interval is shorter with double balloon catheter
4. vaginal delivery is more with double balloon catheter
5. Double balloon catheter decreases the primary cesarean section rate
6. Both methods of induction is safe as no case had APGAR<7 score in both groups and no case of tachysystole was observed during the study

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PROFORMA

Name: IP no:

Age:

DOA dmission: DO Delivery: DO Discharge:

Parity: Ht: Wt: BMI:

LMP EDD: GA:

1st trimester USG GA:

Type of admission: Emergency Booked

Education:

Ante-natal Visits:

Residence:

Socio-Economic Status:

Complaints:

Past History:

Menstrual History:

Marital History:

Obstetric History:

General Examination:

P/A:

P/V:

USG:

AFI:

Investigations:

Hb	PLT	URE
RBS	RFT	LFT

Pre-Induction Bishop's: Pre-Induction CTG:

Time of Catheter Insertion Post-Induction CTG:

Insertion to expulsion time

Induction Delivery Interval

Outcome:

LN LSCS

Neonatal outcome:

APGAR SCORE

ABBREVIATIONS

ARM	Artificial Rupture of Membranes
BMI	Body mass index
CVS	Cardiovascular System
CCRB	Cook Cervical Ripening Balloon
DBC	Double Balloon Catheter
EDD	Estimated Date of Delivery
F	French Catheter
FHR	Fetal Heart Rate
IOL	Induction of Labour
IV	Intravenous
LN	Labour Natural
LSCS	Lower Section Caesarean Section
OG	Obstetrics & Gynaecology
PG	Prostaglandin
PROM	Premature Rupture of Membranes
RR	RISK RATIO
SD	Standard Deviation
SBC	SINGLE BALLOON CATHETER
USG	Ultrasonogram
WHO	World Health Organization

ETHICAL COMMITTEE APPROVAL CERTIFICATE

Ref. No.1515/ME III/21

Government Theni Medical College
Theni. Dated: 19.03.2021

Institutional Ethical Committee

Convener:

Dr. R. Balajinathan, M.D., FICP.,
Dean
Govt. Theni Medical College
Theni

Sub: Medical Education – Govt. Theni Medical College, Theni – Ethical Committee – Minutes – Communicated – Reg.

The Ethical Committee Meeting of the Govt. Theni Medical College, Theni was held at 11.00 A.M. on 19.03.2021 at Conference Hall, Administrative Block, Government Theni Medical College, Theni.

The following Members of the Committee have attended the Meeting.

1.	Convenor	:	Dr. R. Balajinathan, M.D., FICP., Dean
2.	Member Secretary	:	Dr. M. Rangovan, M.S., Medical Superintendent
3.	Members		
	Vice Principal	:	Dr. S. Ezhilarasan, M.S.,
	Professor of Medicine	:	Dr. S.M. Thirunavukkarasu, M.D.,
	Professor of Surgery	:	Dr. F. Celine Fousina mary, M.S.,
	Professor of Obs. & Gynaec.	:	Dr. B. Shanthirani, M.D., D.G.,
	Professor of Micro Biology	:	Dr. S. Lalitha, M.D.,
4.	Chairman (Private Consultant)	:	Dr. Paulraj, M.D., Ramya Clinic, Periyakulam Road, Theni.
5	Lawyer	:	Thiru.K.Murugesan, B.Com., B.L., S/o.Kamaraj, Ambedkar Nagar, Varusanadu, Theni District.
6.	Public	:	Mr. P. Deenadhayalan, M.A., Land Lord, Koduvilarpatti, Theni District.

The following Project was approved by the Committee:

Name of the Project	Name and Designation	Remarks
Comparison of double balloon catheter versus foley catheter for Cervical ripening in post dated pregnancy	Dr. T. S. Abirami II Year PG Dept. of Obs. & Gynaec.	Approved

Please note that the investigator should adhere the following: He/she should get a detailed informed consent from the Patients/participants and maintain Confidentially.

1. He/she should carry out the work without detrimental to regular activities as well as without extra expenditure to the institution.
2. He/she should inform the Institution Ethical Committee in case of any change of study procedure site and investigation or guide.
3. He/she should not deviate for the area of the work for which applied for Ethical Clearance. He/She should inform the Institution Ethical Committee immediately, in case of any adverse events or any serious adverse reactions.
4. He/she should abide to the rules and regulations of the institution.
5. He/she should complete the work within the specific period and apply for if any extension of time is required. He/she should apply for permission again and do the work.
6. He/she should submit the summary of the research work to the Ethical Committee on completion of the work.
7. He/she should not claim any funds from the institution while doing the work or on completion.
8. He/she should understand that the members of Institutional Ethical Committee have the right to monitor the work with prior intimation.
9. He/she should follow the existing Biomedical Wastes 2010 guidelines in samples collections, sample storage and sample disposals off.

Chairman
Dr.M. PALRAJ,M.D.,
Civil Surgeon Retd.,

To
The above individual through the Head of the Department concerned

DEAN
GOVT. THENI MEDICAL COLLEGE
THENI

CONSENT FORM

PATIENT NAME:

IP NO.:

STUDY TITLE: "COMPARISON OF DOUBLE BALLOON CATHETER VERSUS FOLEY CATHETER FOR CERVICAL RIPENING IN POSTDATED PREGNANCY"

I agree to participate in the study entitled and have been informed about the details of the study in my own language.

I have completely understood the details of the study.

I am aware of the possible risks and benefits, while taking part in the study.

I understand that I can withdraw from the study at any point of time and even then, I can receive the medical treatment as usual.

I understand that I will not get any money for taking part in the study.

I will not object if the results of this study are getting published in any medical journal, provided my personal identity is not revealed.

I know what I am supposed to do by taking part in this study and I assure that I would extend my full cooperation for this study

Name of the participant :

Signature / Left thumb print:

Date :

Name of the investigator: Dr. T.S.ABIRAMI

Signature of investigator:

Date:

PATIENT INFORMATION SHEET

Confidentiality:

Utmost priority will be given to protect the privacy and confidentiality of your personal information. The collected information will not be shared with anyone not involved in the study and reporting will be done in aggregate form only

Voluntary participation:

Your participation in this study is voluntary and you have the right to withdraw your participation at any time during the interview without any explanation. Refusal to participate will not involve any penalty or loss of benefits to which you are otherwise entitled. There might be certain questions which you may not wish to answer. You can choose to decline answering these questions

ஆராய்ச்சிஒப்புதல்படிவம்

ஆராய்ச்சியாளர்பெயர் : மருத்துவர். DR. T.S.ABIRAMI

பங்கேற்பாளர்பெயர்:

பங்கேற்பாளர்எண் :

மேலேகுறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது .என்னுடைய சந்தேகங்களைகேட்கவும், அதற்கானதகுந்த விளக்கங்களை பெறவும்வாய்ப்பளிக்கப்பட்டது. நான் இவ்வாய்வில் தன்னிச்சையாகத்தான் பங்கேற்கிறேன் .எந்த காரணத்தினாலோ எந்த கட்டத்திலும்எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகிகொள்ளலாம் என்றும் அறிந்து கொண்டேன்.

இந்தஆய்வு சம்மந்தமாகவோ இதை சார்ந்த மேலும் ஆய்வுமேற்கொள்ளும் போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளைபார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன் .நான் ஆய்வில் இருந்து விலகிகொண்டாலும் இது பொருந்தும் என அறிகிறேன்.

இந்தஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பானதகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயப்படுத்திக்கொள்ளவும் அதை பிரசுரிக்கவும்என் முழுமனதுடன் சம்மதிக்கின்றேன்

இந்தஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன்.எனக்கு கொடுக்கப்பட்ட அறிவுரைகளின்படி நடந்துகொள்வதுடன் இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்று உறுதியளிக்கிறேன்.

ஆராய்ச்சியாளர் கையொப்பம் பங்கேற்பாளர் கையொப்பம்

தேதி

<u>தகவல்நகல்</u>

இந்த ஆராய்ச்சியில் உங்களிடம் கேட்கப்படும் கேள்விகளுக்கு உங்கள் முழுமனதுடன் பதிலளிக்கவேண்டும்.

இந்த ஆராய்ச்சியில் உங்களுக்கு எந்த பின்விளைவும் ஏற்படாது என்பதை நான் உறுதியளிக்கிறேன்.

உங்களுக்கு பணம் எதுவும் அளிக்கப்படாது என்பதை இதன் மூலம் தெரிவிக்கிறேன்.

இந்த ஆய்வில் உங்களுக்கு எந்த நேரடி பயன்எதுவும் இல்லை. நீங்கள் அளிக்கும் தகவல் மூலம் புதுயுக்திகள் வகுக்கப்படலாம்.

அதன் மூலம் வருங்காலத்தில் உங்களுக்கோ அல்லது உங்களை போன்ற மக்களுக்கு பயன்படலாம்.

நீங்கள் எப்போது வேண்டுமானாலும் இந்த ஆய்விலிருந்து விலகிக்கொள்ளலாம் .அதனால் உங்களின் விபரங்கள் எதுவும் தெரிவிக்கப்படாது என்பதை உறுதியளிக்கிறேன்.

இந்த ஆராய்ச்சியின் முடிவுகள் பத்திரிக்கைகளில் பிரசுரிக்கப்படலாம். ஆனால் உங்களின் அடையாளம் எதுவும் தெரிவிக்கப்படாது.

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Analysis address	abitamil94.mgmru@analysis.urkund.com

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Dr. B.SHANTHIRANI M.D., DGO.,

Professor & Head of the Department,

Department of O&G

Govt. Theni Medical College & Hospital,

Theni.

MASTER CHART

S.No	Name	Age	Parity	BMI	GA	Bishop score	Pain	Catheter insertion	Catheter expulsion	score expulsion	Expulsion time	Delivery time	Mode of delivery	APGAR score
1	RAMA	27	G2A1	22.7	41 w+1	3	5	success	yes	5	7.00	13:15	normal	8
2	SUJATHA	29	G2P1L1	26.8	40w+1d	3	5	success	yes	5	7.30	10:20	normal	8
3	JOTHI	25	PRIMI	21.1	40w+1d	3	4	success	No	5	6.00	15:20	cesarean	9
4	SURIYA	28	PRIMI	21.9	40w+1d	3	4	success	yes	6	6.00	08:15	normal	7
5	ASHA	25	PRIMI	25.4	40w+2d	3	4	success	Yes	6	8.10	12:15	normal	8
6	BARGATH NI	32	PRIMI	25.1	40w+2d	3	4	success	No	6	6.25	11:25	normal	7
7	SUSILA	28	PRIMI	27.9	40w+1d	3	4	success	yes	5	6.00	14:10	cesarean	7
8	TAMIL	24	G2P1L1	25.4	40w+2d	3	5	success	yes	5	5.00	18:15	normal	7
9	SUNITHA	27	PRIMI	24.1	41w	3	4	success	No	5	8.00	12:15	normal	7
10	VENKI	24	G2P1L1	21.4	40w+2d	3	5	success	yes	5	7.15	13:15	normal	7
11	SONIA	31	PRIMI	24.8	40w+1d	2	3	success	yes	6	6.00	14:20	normal	8
12	KANIKA	25	G2P1L1	21.1	40w+2d	3	6	success	yes	5	10.00	15:20	cesarean	8
13	ANJALI	26	G2P1L1	22.4	40w+2d	3	6	success	yes	8	12.00	08:25	cesarean	8
14	LAVANYA	22	G2P1L1	25	40w+2d	3	5	success	yes	6	8.00	12:15	normal	8
15	SNEKA	23	PRIMI	27	40w+2d	3	4	success	yes	5	6.00	10:25	normal	8
16	BARGAVI	27	G5P1L1A3	22	40w+2d	2	4	success	yes	6	8.00	14:10	normal	9
17	ILAVARASI	24	G3P1L1A1	24.8	40w+2d	2	4	success	yes	5	6.15	15:20	normal	9
18	RENUKA	26	PRIMI	25.7	40w+2d	2	4	success	yes	5	6.15	09:30	cesarean	9
19	SNEKADEVI	25	G2A1	27.1	40w+2d	3	4	success	yes	5	9.00	12:15	normal	9
20	LAKSHMI	27	PRIMI	21.6	40w+2d	3	4	success	yes	6	6.00	10:25	normal	9
21	REENA	30	PRIMI	22.2	40w+2d	3	4	success	yes	6	8.00	14:10	normal	9
22	POOJA	35	G3P1L1A1	23.9	40w+1d	3	4	success	yes	6	9.00	18:15	cesarean	9
23	RAJINI DEVI	28	G2P1L1	21.1	41w	3	4	success	yes	5	10.00	10:10	normal	9
24	NADHIYA	32	PRIMI	21.6	40w+1d	3	5	success	yes	5	12.20	13:15	cesarean	8
25	MEENAKSHI	27	G3P2L2	23.2	40w+1d	3	5	success	yes	5	8.00	14:20	normal	8
26	RADHA	24	G3P2L2	26.4	40w+2d	3	4	success	Yes	8	6.00	15:20	cesarean	8
27	SHALINI	25	PRIMI	22.2	40w+1d	3	4	success	yes	5	8.00	09:15	cesarean	8
28	KARUTHAMN	28	PRIMI	24.1	40w+2d	2	4	success	yes	6	7.00	08:15	normal	8
29	RAGINI	29	G4A3	22.4	40w+1d	2	5	success	yes	6	6.00	19:15	normal	8
30	PRIYANKA	32	PRIMI	21.6	40w+1d	2	6	success	yes	4	9.00	13:15	cesarean	8
31	Roja	34	G2P1L1	21.4	40w+2d	3	4	success	no	6	6.00	14:20	normal	8
32	AMBIKA	28	G5P1L1A3	21.6	40w+2d	2	3	success	yes	5	7.20	15:20	normal	8

33	KANIKUTTY	26	PRIMI	22.4	40w+1d	2	4	success	yes	5	9.00	08:15	cesarean	7
34	PRAMILA	30	PRIMI	25.4	40w+2d	3	4	success	yes	6	6.00	12:15	normal	7
35	INDHU	26	PRIMI	26.7	40w+1d	3	4	success	yes	6	6.00	14:25	cesarean	8
36	RADHA	35	G3P2L2	24.4	40w+2d	3	4	success	yes	8	5.00	14:10	normal	8
37	DEEPIKA	29	PRIMI	21.9	40w+1d	3	4	success	yes	8	6.10	15:20	cesarean	8
38	SOWMIYA	32	G2P1L1	23	40w+2d	3	4	success	yes	5	6.00	08:15	normal	8
39	NEHA	28	PRIMI	25.9	40w+1d	2	4	success	No	6	6.15	12:15	cesarean	9
40	MEENAKSHI	32	PRIMI	26.8	40w+2d	3	3	success	yes	6	7.00	10:25	normal	9
						2.75				5.675	7.29	12:47		8.075

S.No	Name	Age	Parity	BMI	GA	Bishop score	Pain	Catheter insertion	Catheter expulsion	expulsion Score	Expulsion time	Delivery time	Mode of delivery	APGAR score
1	MAHALAKSHI	18	PRIMI	26.7	40w+1d	3	4	success	yes	6	6.00	13.15	normal	7
2	KALAIVANI	35	G2P1L1	25.5	40w+2d	2	5	success	yes	6	5.15	14:30	normal	9
3	RENA	25	G3P1L1A1	25.5	40w+2d	3	5	success	yes	5	6.00	15:20	normal	7
4	THOULATH	22	PRIMI	23.4	40w+1d	2	4	success	yes	6	7.00	08.15	normal	8
5	PAVITHRA	20	PRIMI	23.8	40w+2d	2	4	success	No	6	8.00	12.15	normal	8
6	BARGATH NIS	19	PRIMI	23.6	40w+2d	3	4	success	Yes	4	6.30	11.25	normal	8
7	USHA	23	PRIMI	22.5	40w+2d	3	5	success	yes	5	6.00	14:10	normal	8
8	SUJIPRIYA	38	G2P1L1	21	40w+2d	2	4	success	yes	6	5.00	18.15	normal	8
9	MEENAKSHI	32	PRIMI	21.2	40w+2d	2	4	success	No	6	10.10	12.15	cesarean	9
10	BHAVANA	28	G2A1	22.5	40w+2d	2	3	success	yes	6	9.00	13.15	normal	9
11	ANITHA	28	G3P1L1A1	24.4	40w+2d	2	4	success	yes	5	8.00	14:20	normal	9
12	AFRIN	26	PRIMI	24	40w+2 d	3	5	success	yes	5	7.30	15:30	cesarean	8
13	MENAKA	37	G3P1L1A1	28.8	40W+1D	3	5	success	yes	5	7.20	20:15	normal	8
14	KANCHANA	24	PRIMI	25.5	40W+2D	2	4	success	yes	6	7.30	12:15	normal	9
15	RAKSHANA	26	G3P2L2	26	40W+2D	2	4	success	yes	6	7.30	10:25	normal	7
16	SATHYA	32	G3P1L1A1	22.1	40W+1D	2	4	success	yes	6	7.25	14.10	cesarean	8
17	RANI	23	PRIMI	23.1	40W+1d	3	4	success	yes	5	6.00	15.20	normal	9
18	SHANTHI	31	PRIMI	25.4	40W+2D	3	4	success	yes	5	8.05	20:15	normal	9
19	KOWSALYA	25	G2P1L1	26.6	40W+1D	3	5	success	yes	5	9.00	12:15	normal	9
20	KRISHNA	30	G2A1	25.9	40W+1D	3	4	success	yes	8	10.00	10:25	normal	7
21	PADMINI	28	PRIMI	26.4	40W+2D	2	5	success	yes	5	12.00	14.10	cesarean	8
22	UMA	34	G2A1	21.9	40W+1D	3	3	success	yes	6	8.00	18.15	normal	8
23	VIJAYA	28	PRIMI	23	40W+2D	2	6	success	yes	7	6.00	18.15	normal	8
24	RENU	33	G4P1L1A2	35	40W+2D	3	6	success	yes	8	7.00	13:15	cesarean	8
25	RASHMI	30	G2P1L1	23	40W+2D	2	5	success	Yes	8	6.30	14:30	normal	8
26	REKHA	26	G3P1L1A1	25.2	40W+1D	3	4	success	yes	6	7.00	15:20	normal	7
27	KATTAMAL	22	PRIMI	22.1	40W+2D	3	4	success	yes	6	6.00	09:15	cesarean	7
28	RANI	28	G3P1L1A1	27	40W+2D	3	4	success	yes	5	5.00	18.15	normal	8
29	DHIVYA	31	PRIMI	21.6	40W+1D	3	4	success	yes	5	6.00	19.15	cesarean	8
30	SHILPA	27	PRIMI	26.7	40W+2D	3	4	success	yes	6	7.00	13:15	normal	8
31	PINKY	30	PRIMI	21.8	40W+1D	2	4	success	yes	8	8.45	14:20	normal	8
32	SHAILAJA	26	G2P1L1	23.2	40W+1D	3	4	success	yes	6	6.00	15.20	normal	9
33	KANDEA	31	G2P1L1	26	40W+2D	3	4	success	yes	6	6.00	18.15	normal	9
34	ASHA	34	G2P1L1	22.1	40W+1D	2	3	success	yes	8	5.15	12:15	normal	8
35	SUSAN	30	G3P1L1A1	22	40W+2D	3	4	success	yes	5	6.00	14:25	normal	7
36	PALLAVI	24	PRIMI	23.9	40W+1D	3	5	success	yes	8	9.00	14:30	normal	8
37	JAYA	26	G3A2	21.8	40W+1D	3	4	success	yes	9	8.00	15:20	normal	8
38	RANI	31	PRIMI	23	40W+2D	2	4	success	yes	10	8.00	18.15	normal	8
39	TAULATH	32	G3P2L2	20	40W+2D	3	4	success	yes	8	6.00	12.15	normal	8
40	NISHA	28	PRIMI	22.5	40W+1D	3	4	success	yes	6	7.00	10:25	normal	9
						2.6				6.2	7.36	14:24		8.1