COMPARATIVE STUDY OF HYGROSCOPIC DILATORS VERSUS FOLEYS BALLOON CATHETER FOR INDUCTION OF LABOUR AND ITS OUTCOME- PROSPECTIVE STUDY

A Dissertation Submitted to

THE TAMILNADU DR. M.G.R MEDICAL UNIVERSITY

CHENNAI

In Partial fulfilments of the Regulations

for the Award of the Degree of

M.S. (OBSTETRICS & GYNAECOLOGY)

BRANCH – II

Reg. No. 221716055

GOVERNMENT STANLEY MEDICAL COLLEGE

CHENNAI

MAY 2020

CERTIFICATE BY THE INSTITUTION

This is to certify that the dissertation entitled **"COMPARATIVE STUDY OF HYGROSCOPIC DILATORS VERSUS FOLEYS BALLOON CATHETER FOR INDUCTION OF LABOUR AND ITS OUTCOME- PROSPECTIVE STUDY"** is a bonafide work done by **Dr. S. SARANYA** at R.S.R.M Lying in Hospital, Stanley Medical College, Chennai. This dissertation is submitted to Tamilnadu Dr. M.G.R. Medical University in partial fulfilment of university rules and regulations for the award of M.S. Degree in Obstetrics and Gynaecology.

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This is to certify that this dissertation entitled **"COMPARATIVE STUDY OF HYGROSCOPIC DILATORS VERSUS FOLEYS BALLOON CATHETER FOR INDUCTION OF LABOUR AND ITS OUTCOME - PROSPECTIVE STUDY"** submitted by **Dr. S. SARANYA,** appearing for Part II MS, Branch II Obstetrics and Gynaecology Degree Examination in May 2019, is a bonafide record of work done by her, under my direct guidance and supervision as per the rules and regulations of the Tamil Nadu Dr. MGR Medical university, Chennai, Tamil Nadu, India. I forward this dissertation to the Tamil Nadu Dr. MGR Medical University Chennai, India.

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DECLARATION

I, **Dr. S. SARANYA**, solemnly declare that the dissertation titled, **"COMPARATIVE STUDY OF HYGROSCOPIC DILATORS VERSUS FOLEYS BALLOON CATHETER FOR INDUCTION OF LABOUR AND ITS OUTCOME - PROSPECTIVE STUDY"** is a bonafide work done by me at R.S.R.M. Lying in Hospital. Stanley Medical College, Chennai – during December 2018–to September 2019 under the guidance and supervision of Prof. Dr.SUGANTHI M.D., D.G.O., Professor of Obstetrics and Gynaecology. The dissertation is submitted to the Tamilnadu Dr. M.G.R. Medical University, in partial fulfilment of University rules and regulations for the award of M.S. Degree in obstetrics and Gynaecology.

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ACKNOWLEDGMENT

I am grateful to **Prof. Dr. R. SHANTHIMALAR, M.D., D.A.,** Dean, Govt. Stanley Medical College for granting me permission to undertake this study. I take this opportunity to express my sincere and humble gratitude to **Dr. K. KALAIVANI, M.D., D.G.O., DNB.,** Superintendent, Govt. R.S.R.M. Lying in Hospital who not only gave me the opportunity and necessary facilities to carry out this work but also gave me encouragement and valuable guidance to complete the task I had undertaken. I am deeply indebted to **Prof. Dr. SUGANTHI, M.D., D.G.O.,** the mover behind this study for her able guidance and inspiration and constant support without which this would not have been possible.

I am very grateful to **Prof. Dr.SUGANTH., M.D., D.G.O.,** and RMO **Dr.H.ANITHA VIRGIN KUMARI M.D.,D.G.O** and Assistant Professor **Dr.KAMALI, M.D.,D.G.O.,** for their valuable advice, constant guidance and supervision during this study.

I am extremely grateful to all our Assistant Professors, for their advice and support during this study.

I sincerely thank my fellow postgraduates and friends for their support and cooperation.

I owe a great many thanks to all my patients without whom this study would not have been possible.

Finally, I thank Lord Almighty, who gave me the will power and showered blessings to complete my dissertation work.

PLAGIARISM CERTIFICATE

This is to certify that this dissertation work titled **"COMPARATIVE STUDY OF HYGROSCOPIC DILATORS VERSUS FOLEYS BALLOON CATHETER FOR INDUCTION OF LABOUR AND ITS OUTCOME-PROSPECTIVE STUDY"** of the candidate **Dr. S. SARANYA** with Registration Number 221716055 for the award of **MASTER OF SURGERY** in the branch of **OBSTETRICS AND GYNAECOLOGY**.

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ABBREVIATIONS

CODE	DESCRIPTION
S.NO	SERIAL NUMBER
IP.NO	IN PATIENT NUMBER
GA	GESTATIONAL AGE
40W2D	40 WEEKS 2 DAYS
5H 10M	5 HOURS 10 MINUTES
LSCS	LOWER SEGMENT CAESAREAN SECTION
B.WT	BIRTH WEIGHT
OLIGO	OLIGOHYDRAMNIOS
RH NEG	RH NEGATIVE COMPLICATING PREGNANCY
GDM	GESTATIONAL DIABETES MELLITUS
GHTN	GESTATIONAL HYPERTENSION

PGE 2	PROSTAGLANDIN E 2
IUD	INTRAUTERINE DEATH
RCOG	ROYAL COLLEGE OF OBSTETRICS AND GYNAECOLOGY
ACOG	AMERICAN COLLEGE OF OBSTETRICS AND GYNAECOLOGY
HIV	HUMAN IMMUNODEFICIENCY VIRUS
NST	NON STRESS TEST
AFI	AMNIOTIC FLUID INDEX
LN	LABOUR NATURAL
EPI	EPISIOTOMY

INTRODUCTION

INTRODUCTION

Induction of labour can be defined as an intervention intended to artificially initiate uterine contractions resulting in progressive effacement and dilation of cervix. This should ideally result in the birth of the baby through vaginal route.

The more common indications include post term pregnancy, premature rupture of membrane, gestational hypertension, oligohydramnios, non reassuring fetal status and various maternal medical conditions such as chronic hypertension and diabetes (American College of Obstetricians and Gynaecologists, 2013b). Before induction one must ensure that the gestational age and fetal lung maturity is confirmed.

Induction of labour is one of the most common interventions practiced in modern world. Overall throughout the world, up to 20 per cent of women have labour induced by one method or the other. Induction rates vary with practices and cultural backgrounds. The availability of newer oxytocics and induction techniques which are safer, more effective and predictable than the older techniques has made the process of induction more easier.

AIMS OF THE STUDY

AIM OF STUDY

1. To estimate the effects of Hygroscopic dilators in ripening of uterine cervix .
2. To study the course and outcome of labour when induced with Hygroscopic dilators.
3. To estimate the effects of Foley catheter in the ripening of uterine cervix.
4. To study the course and outcome of labour when induced with Foley catheter.
5. To compare the effects of Hygroscopic dilators and Foley catheter in the induction of labour in terms of cervical dilatation, induction delivery interval , maternal and fetal outcome.

MATERIALS AND METHODS

MATERIALS AND METHODS

The Prospective study was conducted in Govt. RSRM Lying In Hospital, Chennai during the period of December 2018 to September 2019 after getting approval from the Institutional Ethical Committee.

120 patients who were term antenatal mothers eligible for induction of labour were selected in the labour ward .

A vaginal examination was performed to assess the bischop score for these patients.

Bishop score was assessed

Cervical dilatation, cervical effacement/length, Cervical consistency, Cervical position, Fetal station. Each component is given a score of 0-2 or 0-3. The highest possible score is 13 and <6 is unfavourable that needs induction.

If the bischop score was less than 6 ,they were divided into two groups randomly .

Group A was induced with Hygroscopic dilators. Patient was put in lithotomy position , under per speculum vision Dilapan S hygroscopic dilator rods were inserted intracervically .

Group B was induced with Foley balloon catheter with 60ml distilled water instilled and the catheter taped to the medial side of thigh with traction. The course of labour and outcome was monitored.

Inclusion criteria

1) An unfavourable cervical Bishop score of ≤ 6
2) Singleton pregnancy with vertex presentation and no contraindication to vaginal delivery.
3) Assuring fetal heart rate.
4) Maternal and/or fetal indication for labour induction.

Exclusion criteria

1) Multiple pregnancies , non cephalic presentation
2) Gestational age less than 37 weeks
3) Placenta previa
4) Suspected chorioamnionitis
5) Parity of >3

6) A previous caesarean delivery or a history of uterine surgery

7) Previous attempted induction of labour for this pregnancy

8) Cephalopelvic disproportion.

The differences between the groups with respect to age, parity, Bishop score prior and after induction, need for a second induction, induction delivery interval and the final mode of delivery were compared and analysed. The Caesarean section rates and indications, Birth weight and APGAR score of the babies were noted and tabulated. Statistical analysis was done and P value <0.05 was considered significant.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

INDUCTION OF LABOUR

Induction of labour is the initiation of contractions in a pregnant woman who is not in labour to help her achieve a vaginal birth within 24 to 48 hours.

Successful induction is defined as a vaginal delivery within 24 to 48 hours of induction of labour.

Elective induction is the induction of labour in the absence of acceptable fetal or maternal indications.

Cervical ripening is the use of pharmacological or other means to soften, efface, or dilate the cervix to increase the likelihood of a vaginal delivery.

PATIENT PREREQUISITE FOR INDUCTION

Assessment of maternal parameters

- Confirm the indication for induction
- Review for contraindication to labour and/or vaginal delivery
- Assess the shape and adequacy of bony pelvis
- Assess the cervical status by Bishop score
- Review risk and benefit of induction of labour with patient and the family

Assessment of fetal parameter

- Confirm the gestational age
- Estimate fetal weight
- Determine fetal position
- Determine fetal well being

INDICATIONS OF INDUCTION

OBSTETRIC INDICATIONS :

- Post term pregnancy
- Preeclampsia, eclampsia
- Previous unexplained IUD
- Fetal compromise (eg,Fetal growth restriction, isoimmunization)
- Preterm Premature rupture of membranes (PPROM)
- Prelabour rupture of membranes(PROM)
- Malformed fetus
- Polyhydraminos
- Oligo hydraminos
- Gestational diabetes mellitus
- Abruption placentae
- Chorioamnionitis
- Fetal demise
- Cholestasis of pregnancy

MATERNAL MEDICAL CONDITIONS AGGRAVATED BY PREGNANCY :

- Diabetes mellitus
- Chronic renal disease
- Chronic pulmonary disease
- Chronic hypertension

CONTRAINDICATIONS
ABSOLUTE

Active genital herpes infection

Serious chronic medical condition

Pelvic abnormality

Cephalopelvic disproportion major degree

Abnormal fetal lie [transverse lie, oblique lie]

Umbilical cord prolapse and cord presentation

Placenta previa and vasa previa

Previous classical Caesarean section .

Previous Myomectomy

Invasive cervical cancer.

RELATIVE

- Uterine overdistension [multiple pregnancy, polyhydraminos]
- Breech
- Fetal macrosomia
- Low lying placenta
- Abnormal fetal heart pattern

METHODS OF LABOUR INDUCTION

I-NON PHARMACOLOGIC METHODS NATURAL METHODS

- Sexual intercourse
- Nipple stimulation
- Hot Bath / Castor oil / Enemas
- Cumin Tea
- Several herbs
- Acupressure
- Acupuncture

MECHANICAL METHODS

- Osmotic dilators- Laminaria tent and Dilapan
- Balloon devices - Foleys .

SURGICAL METHODS

- Stripping the membranes
- Amniotomy

II- PHARMACOLOGICAL METHODS

- Oxytocin
- Prostaglandins
- Misoprostol [E1]
- Dinoprostone [E2]
- Mifepristone

COMPLICATIONS OF INDUCTION

MATERNAL

- Uterine tachysystole
- Uterine Rupture
- Failed Induction and Increased Caesarean Delivery Rate Sepsis
- Postpartum Haemorrhage
- Accidental Haemorrhage
- Amniotic Fluid Embolism

FETAL

- Iatrogenic prematurity
- Fetal Distress

INDUCTION OF LABOUR

Induction of labour is defined as the process of artificially stimulating the labour. It is usually performed by administering oxytocin or prostaglandins to the pregnant woman or by manually rupturing the amniotic membranes. This should ideally result in the delivery of the baby through the vaginal route[1] (RCOG 2001). Ideally, most pregnancies should be allowed to reach term, the onset of spontaneous labour being the sign of physiologic termination of pregnancy. It is one of the most common interventions practiced in modern obstetrics. Overall, throughout the world, up to 20 per cent of women have labour induced by one method or the other. Induction rates vary with practices and cultural backgrounds. Cervical ripening greatly facilitates labour and augments the chances of vaginal birth. The cervical state is related to the success of labour induction, duration of labour, and likelihood of vaginal delivery.

Elective inductions for the convenience of either the obstetrician or the patient are on the rise. Due to the attendant risk of severe, though infrequent, adverse maternal outcomes, elective inductions are not routinely recommended.

Recent opinions, however, tend to veer towards the idea that elective inductions before 41 weeks may not be as bad as obstetricians have traditionally believed[2] (Macones 2009)

HISTORY OF INDUCTION OF LABOUR

Since antiquity various methods, many bizarre and some frankly dangerous, have been used in an attempt to bring on labour. Massage of the breasts and uterus are very old but inefficient methods. Something approaching the use of tents dates back to the sixth century, and stretching of the cervix digitally has been long employed. The last century brought with it more ingenuity and at one time electricity was thought of. Scanzoni used a hot carbolic acid douche in 1856, and at this time Kraus introduced his bougies, which fell into disuse by the 1930s because of their relative inefficiency, high sepsis rate and the often countered risk of harpooning or detaching the placenta.

Artificial rupture of the membranes stands in a class by itself, for it has stood a prolonged test of time, being first used by Denman in 1756 for cases of contracted pelvis, and being known since then as the "English method". It remains to this day a widely used method in spite of the sacrifice of an intact amniotic sac that it entails. Hind water rupture with Drew Smythe catheter was introduced in 1931, but what it gains in safety, in terms of fore water preservation with reduced risk of amniotic fluid infection and cord prolapse, it loses in efficiency when compared with fore water rupture.

Prostaglandin was first isolated from seminal fluid of monkeys, sheep and goat, by Ulf von Euler at the Karolinska Institute in Stockholm in 1935. It was believed to be part of prostatic secretions and was therefore called prostaglandin.

Elias Corey synthesized dinoprostone in 1970 at the Harvard University. Three biochemists, Bergstrom, Samuelsson and Vane jointly received the 1982 Nobel Prize for their discovery of prostaglandins.

The reasons for the rising rates of induction of labour can be complex and multifactorial[3] (Rayburn and Zhang 2002)

Some of them are: -

- Improved ability of physicians to determine gestational age accurately with early dating scans, thus avoiding the possibility of iatrogenic prematurity.
- Widespread availability of cervical ripening agents.
- Improved knowledge of methods and indications for induction.
- More relaxed attitudes towards marginal/elective indications, both of the physician and the patient.
- Litigation constraints.

GENERAL PRINCIPLES RELATED TO INDUCTION

- The Induction of labour should be performed only when there is a clear medical indication for it and the expected benefits outweigh its potential harms.
- Induction of labour should be performed with caution since the procedure carries the risk of uterine hyperstimulation and rupture and fetal distress.
- Induction of labour is carried out, facilities should be available for assessing maternal and fetal well-being.
- Women receiving oxytocin, misoprostol or other prostaglandins should be monitored meticulously.
- Failed induction of labour does not necessarily indicate caesarean section.
- Wherever possible, induction of labour should be carried out in facilities where caesarean section can be performed.

Criteria of an ideal inducing agent

An ideal inducing agent is one which:

- Achieves onset of labour within the shortest possible time.
- Should not result in greater pain .
- Has low failure rate.

- Does not increase the rate of caesarean delivery or operative vaginal deliveries as compared to spontaneous labour.
- There should be a less perinatal morbidity.
- We are yet to find an ideal inducing agent. Hence, the decision for induction should be well thought out and communicated to the woman concerned.

PRE INDUCTION COUNSELLING FOR THE COUPLE

It is essential to have good communication with the woman and her family prior to induction; wherever possible this should be supported by evidence-based and preferably, written information. During induction of labour, the woman has restricted mobility and the procedure itself can cause discomfort to her. To avoid potential risks associated with the procedure, the woman and her baby need to be monitored closely. According to[4] (RCOG 2008):

- Explain the indications for induction; more specifically, the consequences associated with continuing the pregnancy
- Explain the time and procedure of induction
- Arrangements for support during labour
- Pain relief measures should be taken
- The need for close monitoring of the fetal heart rate (including electronic fetal monitoring in labour)

- Should give multiple options.
- The risks associated with inducing agent used should be explained.
- The chances of failure of induction and the options available in case of failure.

In summary, the woman and her partner should be offered to be made a part of the decision-making process. A positive attitude imparted to the woman when she is actively involved in the decision making, not only increases the chances of success of induction but also enables her to better face the consequences[5] (Nuutila et al 1999).

WOMEN'S ATTITUDE TOWARDS INDUCTION

One study showed that 76 per cent of women following an induction prefer not to be induced in the next pregnancy[6] (Cartwright 1977). More recent studies show a better response. Roberts and Yound (1991) found that when perception after the event was compared with anxieties of continuing the pregnancy beyond term in uncomplicated pregnancies, more women opted for elective induction than conservative management. They also said that most pregnant women are unwilling to accept the conservative management of prolonged pregnancy and more so if undelivered by 41 weeks gestation. Women today would not prefer conservative management of pregnancy beyond term.

INDICATIONS AND CONTRAINDICATIONS FOR INDUCTION

The indications can be divided under the following headings:

1) Obstetrical conditions;
2) Medical conditions aggravated by pregnancy.

The correct selection of cases in itself predisposes certainty as to the child's maturity. The best paediatric unit in the world is no substitute for a healthy intrauterine environment up to the time of adequate maturity.

COMMONLY ACCEPTED INDICATIONS FOR INDUCTION OF LABOUR

- Pregnancy-induced hypertension
- Premature rupture of membranes
- Severe intrauterine growth restriction
- Rhesus Iso immunization
- Maternal medical problems (diabetes mellitus, lupus, renal disease)
- Intrauterine fetal demise
- Postdated pregnancy
- Oligohydramnios
- Logistic factors (distance from hospital)

OBSTETRIC INDICATIONS

INDUCTION OF LABOUR IN WOMEN AT OR BEYOND TERM

Pregnancies that reach beyond 42 gestational weeks are defined as post-term. This is the commonest indication for induction of labour worldwide.

Evidence related to induction of labour at term and beyond term was extracted from one Cochrane systematic review of 22 randomized controlled trials[7] (cochrane review 2011). Most of the trials were judged by the Cochrane review authors to likely have a moderate risk of bias, largely due to unclear concealment of allocation and generation of the sequence of randomization.

The trials had evaluated the effect of inducing labour at 37–40 weeks, 41 completed weeks, and 42 completed weeks of gestation, and the intervention was compared with expectant management with fetal monitoring at varying intervals. There were no statistical and clinical differences in the priority comparisons and outcomes, except for a reduction in perinatal deaths when labour was induced at 41 completed weeks.

Recommendations

Induction of labour is recommended for women who are known with certainty to have reached 41 weeks (> 40 weeks + 7 days) of gestation. (Low-quality evidence. Weak recommendation.)

Induction of labour is not recommended for women with an uncomplicated pregnancy at gestational age less than 41 weeks. (Low-quality evidence. Weak recommendation.)

A recent systematic review[8] (Caughey et al 2009) showed that women who completed 41 weeks of gestation or more who were managed expectantly had a higher risk of caesarean section. It also suggested that elective induction of labour at 41 weeks of gestation and beyond is associated with a decreased risk of caesarean section and meconium staining of the amniotic fluid. Fetal monitoring should begin at 41 weeks of gestation. In their study of expectant management versus induction of labour in post-term pregnancies[9], James et al (2001) found that 57 per cent of women went into spontaneous labour by 41 weeks and 4 days (291 days) of gestation and only 14 per cent developed fetal compromise before that. However, when the gestational age was more than this period, the incidence of meconium stained amniotic fluid and evidence of uteroplacental insufficiency was increased significantly. There was no significant difference in the rate of caesarean section, instrumental

delivery, fetal distress and duration of labour between the two groups. The American College of Obstetricians and Gynaecologists recommends that women who are post-term and also have unfavourable cervices can either undergo labour induction or be allowed to be managed expectantly. Many studies recommend prompt delivery in an uncomplicated post-term patient with a favourable cervix (ACOG 2004). The Department of Obstetrics and Gynaecology and Reproductive Biology at Harvard Medical School recommends routine induction at 41 weeks gestation[10] (Rand et al 2000).

INTRAUTERINE GROWTH RESTRICTION

Chronic placental insufficiency leads to intrauterine growth restriction. Infants with growth restriction have a higher risk of perinatal morbidity and mortality, which usually results from placental insufficiency. The placental insufficiency is likely to be aggravated by labour. Due to low placental reserve as compared to normal fetus, these fetuses, as a group, might require induction of labour prior to their expected date of delivery.

PRE-ECLAMPSIA AND ECLAMPSIA

The more severe pre-eclampsia is, the greater risk of serious complications to both mother and baby. The exact cause of cause of pre-eclampsia is uncertain but it is thought to be due to a problem with the

placenta. Hence delivering the baby is the only way to cure pre-eclampsia and eclampsia.

PREVIOUS UNEXPLAINED INTRAUTERINE FETAL DEATH

This peculiar entity, said to be due to placental insufficiency may, by the warning history, provide an opportunity to forestall disaster by timely induction which is usually done at 38 weeks, but may be done earlier if indicated by fetal monitoring tests.

PRELABOUR RUPTURE OF MEMBRANES

(PROM) at term complicates about 8-10% pregnancies. It has been a matter of great controversy whether women with term PROM should be induced or managed with an expectant policy, and if the latter course is opted, how long is it safe to await spontaneous labour. Results from many randomized trial to date demonstrate that expectant management was associated with an increased incidence of clinical chorioamnionitis, postpartum fever, longer hospital stay for the mother and a long stay for the baby in the neonatal intensive care unit; induction therefore seems to be a reasonable choice.

RH ISO-IMMUNISATION

Rh Negative women are carefully monitored with MCA Doppler and antibody titres for the early detection of fetal anemia. The prolongation of

pregnancy beyond term leads to increased placental insufficiency , hence Rh negative pregnancies are induced at 40weeks and not allowed for Post Datism.

MALFORMED FETUSES

The prolongation of pregnancy has a great impact on the psychology of the mother and on grounds of humanity as well, pregnancy is better terminated. It is a maternal indication for termination of pregnancy under the MTP act .

HYDRAMNIOS

Severe hydramnios producing marked pressure symptoms may call for relief. There is the danger of accidental haemorrhage following artificial rupture of the membranes in these cases.

ABRUPTIO PLACENTA

Minor degrees of placental abruption without any signs of fetal distress are best managed by amniotomy and oxytocin infusion.

INTRAUTERINE DEATH OF THE FETUS.

Spontaneous labour will always start eventually, but the patient can often be spared some very wretched weeks of waiting if labour is induced. Drug induction is both safe and usually efficacious.

MEDICAL INDICATIONS

CHRONIC RENAL DISEASE.

Pregnancy has no known beneficial effects whatever on the healthy kidney, and where renal function is already damaged the effects of pregnancy vary between bad and disastrous. The decision and the timing of intervention must be taken considering both maternal and fetal interests.

HYPERTENSION

The risks of fetal prematurity have to be weighed against the risk of superimposed pre-eclampsia and abruption placenta.

DIABETES

Whether or not pre-eclampsia is added to this complication, induction of labour is often called for to forestall intrauterine fetal death, which is a very real risk in the third trimester, particularly in the uncontrolled diabetics and those associated with hypertension.

CONTRAINDICATIONS TO LABOUR INDUCTION

- Placenta or vasa previa
- Fetal malpresentations
- Prior classic uterine incision

- Active genital herpes infection or any other lower genital tract infections and tumors.
- Pelvic deformities and major degree cephalopelvic disproportions.

1. Where the lie is other than longitudinal, for obvious reasons.
2. In cases of previous caesarean section for contracted pelvis or who have failed in previous trial of labour for disproportion. However, it may be added that a pelvic examination must be done to confirm the presence of cephalopelvic disproportion, as some of these cases may have been mistakenly labeled or in some cases the baby may be smaller than it was in the previous pregnancy.
3. Where a tumour occupies the pelvis.
4. When vaginal delivery is contraindicated. These include placenta previa, vasa previa, cord presentation and prolapsed, carcinoma cervix, and infections like active herpes genitalis and HIV.
5. Previous classical caesarean section. Some conditions which are considered to be relative contraindications include maternal heart disease, multiple pregnancy, borderline clinical pelvimetry, grand multiparity, non-reassuring fetal testing not requiring emergency delivery.

Though not a contraindication, extreme caution is required in grand multipara because of the precipitate labour that can follow, and cases of previous caesarean section or myomectomy because of the danger of uterine rupture.

PREINDUCTION CERVICAL RIPENING

Starting with a favourable cervix ensures the success of labour induction. Further, the time taken for labour induction is affected by parity and to a small degree by baseline uterine activity and sensitivity to oxytocic drugs. The goal of cervical ripening is to facilitate the process of cervical softening, effacement and dilatation, thus reducing the induction to-delivery time. When there is an indication for induction and the cervix is unfavourable, agents for cervical ripening may be used.

Cervical ripening is the process that culminates in the softening and distensibility of the cervix, which facilitates labour and delivery. The cervix contains relatively few smooth muscle cells and derives its rigidity from collagen bundles surrounded by proteoglycans.

In pregnancy nearing term, there are various factors that induce certain changes in the cervix leading to cervical ripening. There are agents that can artificially induce these changes if it has not occurred. It is difficult to separate methods of cervical ripening and labour induction

Cervical ripening is associated with the disorganization of collagen bundles which is likely to be effected by collagenase. The active area of cervical tissue remodelling is at the internal OS. The collagenase found in the cervix has been identified as neutrophil derived and the invading neutrophil plays an important role in the tissue rearrangements associated with cervical ripening.

Neutrophils represent a readily available source of collagenase, present in specific granules, which can be made available by degranulation rearrangement of extracellular matrix.

Another change is an increase in cervical decorin (dermatan sulfate proteoglycan 2), leading to collagen fiber separation.

These changes together lead to softening of the cervix. As uterine contractions ensue, the ripened cervix dilates as the presenting fetal part descends, thus leading to reorientation of the tissue fibers in the direction of the stress. The cervix passively dilates and is pulled over the presenting part.

Evidence also says that the elastin component of the cervix acts like a ratchet so that dilatation is maintained even after the contraction ceases.

In summary, cervical ripening is the realignment of collagen and degradation of collagen cross-linking due to proteolytic enzymes. Cervical

dilation results from these processes along with uterine contractions. In this complicated series of events many changes may occur both simultaneously and sequentially.

ROLE OF THE VARIOUS HORMONES IN CERVICAL RIPENING

The hormones stimulate the complex series of chemical reactions critical for the process.

- Dilation of all the tiny vascular channels of the cervix
- A rise in degradation of collagen
- Increase in hyaluronic acid
- A rise in leukocyte, chemotaxis which is the cause for collagen degradation
- And an increase in the release of interleukin (IL)

The process is associated with an increase in the activity of matrix metalloproteinases 2 and 9. Cervical collagenase and elastase also rise. At term, the degradation of collagen fibres increases, leading to a decrease in collagen content of the cervix.

Calkins and colleagues were the first to carry out systematic studies of the factors influencing the duration of the first stage of labour. The authors concluded that the length, thickness, and particularly, the consistency of the cervix are important parameters.

PROSTAGLANDINS IN LABOUR

Since their discovery in the early 1970s, prostaglandins (PGs) have contributed significantly to the practice of obstetrics. Over the years, many PG compounds have been discovered and the importance of the role of prostaglandins in several reproductive processes including menstruation, ovulation and parturition has become apparent.

Prostaglandins are important mediators of uterine activity and play an important role in the contraction of the smooth muscle of the uterus and the biophysical changes associated with cervical ripening. It can be even said that prostaglandins seem to play a much larger role in labour than oxytocin.

Almost every tissue in the body produces prostaglandins which serve as important messengers in a wide variety of functions. When efforts are made to accelerate or inhibit the effects of prostaglandins in labour, we also have to deal with their effects on other organs and systems. Attempts to decrease the production of prostaglandins in an effort to reduce myometrial contractility are limited because of the important role prostaglandins play in the maintenance of fetal ductal flow and renal blood flow. Likewise, administration of prostaglandins for inducing labour or ripening an unfavourable cervix has to be balanced against their effects on

other systems, including the gastrointestinal tract and brain[11] (O'Brien et al 1995).

The F and E series Prostaglandins are the most important for labour, delivery and the postpartum period. In contrast to oxytocin, which requires an induction of receptors that does not usually occur until the later part of pregnancy, prostaglandin receptors are always present in myometrial tissue. Thus, the use of prostaglandins remains throughout pregnancy.

Although both the F and E series Prostaglandins result in uterine contractions, the E series of Prostaglandins are relatively more uteroselective and are more effective in producing cervical ripening.

The naturally-occurring prostaglandins were modified to result in products that are longer acting and effective at lower concentrations, with the potential for significant savings in cost. This has allowed their widespread use in developing countries. Problems such as intrauterine fetal death and hemorrhage from postpartum uterine atony, which earlier required surgical intervention, can be managed with prostaglandins today. Currently, all prostaglandins used in clinical practice are synthetic.

Those like PGE2and PGF2α which retain the molecular structure present in nature, are called Natural, while those synthesised with a different structure are called analogues.

LABOUR

The process of labour is regulated by endocrine factors such as corticotropin-releasing hormone (CRH), oxytocin as well as paracrine and autocrine factors and cytokines, such as platelet activating factor, endothelin-1 and angiotensin II. Near term, there is a striking increase in the number of oxytocin receptors in the myometrium leading to an increased sensitivity to oxytocin. Therefore, even a small increase in oxytocin is sufficient to initiate uterine contractions. Oxytocin also acts on decidual tissue to promote prostaglandin release. At term, free levels of CRH increase in maternal blood, fetal blood, amniotic fluid and the umbilical cord. CRH modulates myometrial response to PGF2α. CRH also enhances the fetal production of cortisol, which stimulates the membranes to increase prostaglandin synthesis. Prostaglandins modulate myometrial cell contractility by utilizing extracellular calcium.

Prostaglandins soften the cervix, induce gap junctions and further sensitise the action of oxytocin on the myometrium, causing progressive dilatation of the cervix. At the end of the first stage of labour, there is rupture of membranes, further increasing prostaglandin synthesis, thus making it an irreversible process.

THE THIRD STAGE OF LABOUR

After the delivery of the fetus, the uterus remains tonically contracted. This helps in separation of the placenta and also prevents postpartum hemorrhage.

There is some evidence that there is considerable production of PGF2 in the decidua and the myometrium in the early postpartum period after expulsion of the fetus and placenta[12]. (Husslein et al 1983).

PRE-INDUCTION ASSESSMENT

The goal of labour induction is to achieve a successful vaginal delivery, although induction exposes women to a higher risk of a CS than spontaneous labour. Before induction, there are several clinical elements that need to be considered to estimate the success of induction and minimize the risk of CS.

Factors that have been shown to influence success rates of induction include the Bishop score, parity (prior vaginal delivery), BMI, maternal age, estimated fetal weight, and diabetes. The Bishop score was developed in 1964 as a predictor of success for an elective induction[13] (Bishop 1964). The initial scoring system used 5 determinants (dilatation, effacement, station, position, and consistency) that attributed a value of 0 to 2 or 3 points each (for a maximum score of 13).

He determined that when the total score was at least 9, the likelihood of vaginal delivery following labour induction was similar to that observed in patients with spontaneous onset of labour. Although several modifications have been suggested, the Bishop score has become a classic parameter in obstetrics and has since been applied to a much wider group of patients.

Nulliparous women with a Bishop score no greater than 3 have a 23-fold increased risk of induction failure and a 2- to 4- fold increased risk of caesarean delivery compared with nulliparous women with a Bishop score of at least 4. Similarly, multiparous women with a Bishop score of no greater than 3 have a 6-fold increased risk of failed induction and a 2-fold increased risk of caesarean birth compared with women with higher Bishop scores.

BISHOP 'S SCORE

	0	1	2	3
Dilatation (cm)	0	1-2	3-4	5-6
Effacement (%)	0 - 30	40-60	60-70	>80
Station	-3	-2	-1 / 0	+1/+2
Consistency	Firm	Medium	Soft	
Position	Posterior	Mid position	Anterior	

MODIFIED BISHOP SCORE (CALDER 1974)

	0	1	2	3
Dilatation (cm)	0	1-2	2-4	5-6
Length (cm)	>4	2-4	1-2	<1
Station	-3	-2	-1 / 0	+1/+2
Consistency	Firm	Medium	Soft	
Position	Posterior	Mid position Anterior		

Other scoring systems

1. Field system
2. Burnett modifications of bishops score.
3. Weighted Bishops score by Freidman.
4. Pelvic score by Lange

The Bishop score has become the most commonly employed pre-induction scoring system.

HISTORICAL MECHANICAL DILATORS

Mechanical forces to dilate the cervix have been used since primitive times, most often to aid in the removal of uterine contents during pregnancy termination. Rigid cervical dilators were primarily used, with numerous variations of surgical instruments. In the late 1800s, mechanical techniques were developed, these included boogies, the Braun's colpeurynter and the champetier de ribes metreurynter; the latter two using rubber balloons inserted into the lower uterine segment and attached to external weight.

Over time this process was extrapolated for cervical ripening prior to labour , with today's version being the Foley catheter.

In 1863, Sloan described the use of seaweed, specifically the dried stem of laminaria digitata, as a tent that expanded in length and diameter with absorption of water. Early uses of seaweed included the treatment of

dysmenorrhea, primary infertility, and pyometria and prior to uterine exploration.

Over time however the natural seaweed tents became associated with high rate of sepsis due to poor packaging, pollution of the areas where the seaweed was harvested, porous nature making it difficult to sterilize and blockage of tissue secretions. Subsequently, synthetic tents were designed to imitate the properties of Laminaria but without the risk of infections. Modern-day sterilization techniques have eliminated the infectious morbidity of Laminaria.

Mechanical cervical ripening—mechanisms of action

Cervical ripening occurs throughout gestation, with progressive softening of the cervix secondary to remodeling of the extracellular matrix [14.] Closer to term, there is a breakdown of the cervical collagen that results in effacement of the cervix. This allows the cervix to dilate in response to uterine contractions[15]. This process is likely regulated by both endocrine factors (estrogen, progesterone, relaxin, androgens, and prostaglandins) and inflammatory responses[16].

Mechanical methods lead to cervical ripening both by direct mechanical dilation of the cervix and stimulation of prostaglandin release from the amnion, chorion, and decidua. Myometrial stretching has been shown to increase the production of COX-2, which is a prostaglandin

precursor[17]. Another potential mechanism is the production of an inflammatory reaction at the level of the cervix that leads to cervical remodeling by release of inflammatory cytokines (such as IL-1 and IL-8) and matrix metalloproteases[18].

Osmotic dilators

Osmotic cervical dilators are made of hygroscopic materials that readily absorb water resulting in their swelling. When placed in the cervix, they swell and lengthen, thereby progressively dilating the cervix. They are

made from sea- weeds (Laminaria japonica or Laminaria digitata) or from synthetic hydrophilic materials. Synthetic dilators include Lamicel (Medtronic Xomed, Inc; Jacksonville, FL) and Dilapan-S (JCEC Company, Inc; Kendall Park, NJ).

Osmotic dilators are inserted into the cervical canal under direct visualization during a sterile speculum examination. The cervix should be cleansed with a sterile solution prior to insertion. Using sponge forceps, the dilators should be inserted such that the tip is just inside the internal os and

the string is still visible in the vagina[19]. Osmotic dilators range in size from 2 to 10 mm. Often the maximum number of dilators that can be inserted without causing significant pressure to the cervical wall are used.

Laminaria are hygroscopic rods made from the stem of sterile seaweed (Laminaria japonica or Laminaria digitata).

Dilapan-S is a synthetic hygroscopic dilator made of polyacrylonitrile sponges. Both Laminaria and Dilapan-S function by active and passive cervical dilation. They absorb water from the cervix thereby increasing their diameter by which in turn stretches the cervix. The cervical stretching also stimulates the release of prostaglandins, aiding in the ripening process.

Most of the increment in size of Laminaria occurs in the first 6 h, however it can be used for 12–24 h for maximum expansion. Dilapan-S exerts a greater mechanical force on the cervix compared to Laminaria, as well as acts significantly faster, reaching two to three times its original diameter within 2–4 h.

Lamicel is composed of compressed polyvinyl acetal sponges containing up to 500mg of magnesium. It also works by extracting fluid from the cervical tissue and softening the cervix, but has an additional property of magnesium- induced cervical stroma collagenolysis[20]. It may also increase the sensitivity of the cervix to prostaglandin E2 (PGE2)[21].

Lamicel can increase up to three to four times its diameter in the first 2–4 h, while exerting significantly less mechanical force on the cervix compared to Laminaria. Lamicel is currently not approved for use beyond gestational age of 23 weeks and 6 days in the United States.

Effectiveness of osmotic dilators

Osmotic dilators versus placebo

A 2012 Cochrane review on methods of mechanical dilation for induction of labor found no significant difference in risk of cesarean section between Laminaria and placebo (RR 1⁄4 0.98, 95% CI: 0.74–1.30)[22]. A randomized, controlled, double-blind study evaluated the safety and efficacy of pre-induction cervical ripening with Laminaria japonica

versus no ripening prior to amniotomy on day 2. Laminaria use did not improve rates of cesarean delivery or mean length of induction[23]. In a comparison of Dilapan and no pretreatment before oxytocin induction, Dilapan resulted in a significant difference in median Bishop score but no significant difference in length of labor or in the cesarean section rate were observed[24].

Laminaria versus Dilapan

In a randomized study comparing Dilapan to Laminaria japonicum, fewer Dilapan diliators were needed to achieve significant cervical ripening than Laminaria. Dilapan was also associated with a trend towards a shorter induction to delivery interval; however, there were no differences in mode of delivery[25].

Osmotic dilators versus prostaglandins

There are a number of studies that compare osmotic dilators to different prostaglandins for cervical ripening (vaginal PGE2, intracervical PGE2, or misoprostol). One consistent finding was a similar rate of cesarean delivery for both methods[26].The results are mixed with respect to cervical ripening to delivery interval, with one report finding no significant difference[27] and another noting a longer induction time to delivery with Laminaria.

Osmotic dilators have been consistently associated with lower rates of hyper stimulation, both with and without change in the fetal heart rate; however, no differences in operative delivery for fetal distress have been reported[28].

A 2012 Cochrane Review on methods of mechanical cervical ripening included 11 studies (1397 women) and found no difference in rates of cesarean delivery or time to delivery, but reported higher rates of hyper stimulation with prostaglandins.

Several studies compared the use of prostaglandin E2 gel with and without an osmotic dilator. There were no differences in rates of vaginal delivery within 24 h,27 need for oxytocin admin- istration, hyperstimulation, or cesarean delivery[29,30].

Osmotic dilators versus oxytocin

There are only a few studies that have evaluated Laminaria with and without oxytocin to oxytocin alone, and these consistently found no differences in rate of cesarean delivery[31]. However, Jagani et al.29 noted that Laminaria alone was associated with a longer induction to delivery time compared to oxytocin alone, whereas Lyndrup et al found similar efficacy with Lamicel and oxytocin versus oxytocin alone[32].

Osmotic dilators versus Foley balloon

There are no reports of osmotic dilators versus the intra- cervical Foley balloon alone. Lin et al compared Laminaria followed by oxytocin to the cervical Foley with extra-amniotic saline infusion (EASI) and oxytocin[33]. This was a small study (26 subjects per arm); however, they found a significantly shorter induction to delivery time by 4 h in the EASI and oxytocin group. There were no significant differences in the rate of cesarean delivery; however, fewer cesarean deliveries were performed for failed induction in the EASI group.

Safety of osmotic dilators

Historically, Laminaria use was associated with an increased risk of sepsis; however, recent sterilization techniques have significantly reduced this risk. Currently, osmotic dilators are most often used for cervical ripening prior to first and second trimester dilation and evacuation (D&E) procedures. This process has been associated with decreased risk of cervical laceration and uterine perforation, without significant risks other than pain with insertion.

The data regarding risk of infection with osmotic dilators for pre-induction cervical ripening is more mixed. A Cochrane review on cervical ripening found increased odds of chorioamnionitis or endometritis with

osmotic dilators, but when the outcomes were assessed individually, these results were not significant.

Another systematic review included randomized controlled trials using Laminaria or other hygroscopic dilators, as well as other mechanical methods of cervical ripening. When outcomes were individually assessed, the only significant finding was an increase in risk of endometritis with other hygroscopic dilator use[34]. Two other reports comparing osmotic dilators to pharmacologic methods found increased risk of infections with osmotic dilator use, specifically endometritis , chorioamnionitis, and neonatal sepsis[35].

Other potential complications of osmotic dilators include hypersensitivity/anaphylaxis and retention of whole or fragmented product. A recent case series outlined a total of 10 cases of hypersensitivity, of which eight met criteria for true anaphylaxis. In these cases, the reaction time ranged from immediate to 3 h after placement, almost all patients had prior exposure to Laminaria[36] .

There are no reports of hyper- sensitivity related to synthetic osmotic dilator use. There are a number of reports of retained fragments of Dilapan, which can occur as the result of mechanical stress. This occurred more frequently with an earlier version of Dilapan, which was removed from the market in 1995. Dilapan became available for use again in 2002 with a

significantly lower rate of complications. Laminaria can also be retained, but this is less common as they are less likely to fragment.

Double-balloon catheter

A cervical double-balloon catheter was first described by Atad et al[37] in 1991, as a method to ensure that the intracervical PGE2 gel remained in place. In this study, the authors found that the use of a double-balloon catheter was associated with improved cervical ripening and a shorter induction to delivery time when compared to PGE2 gel, without benefit of adding intracervical PGE2 gel through the device. The authors proposed that the mechanism was superior to that of a single balloon Foley catheter because the force of dilation occurs from both the internal and external cervical os, whereas the Foley can only exert force on the internal os when placed on traction.

The original double-balloon catheter was marketed as the "Atad Ripener Device" and approved by the FDA in 2005 (Atad Developments and Medical Services Ltd; Israel). The device is an 18-French natural latex, 3-lumen catheter with double balloons 2-cm apart at the distal end. These balloons each have a capacity of 80 ml. The catheter is inserted into the cervix such that both balloons are within the cervix. The internal balloon is then partially inflated, followed by traction to appropriately place this balloon at the internal os. The external balloon is then partially inflated in

a similar fashion. Both balloons are then inflated to their capacity, and the device taped to the patient's leg. The device can be left in place for up to 12 h.

The Cook Cervical Ripening Balloon (Cook Inc; Bloomington, IN) was approved by the FDA in 2013. This is an 18-French silicone double-balloon catheter that comes with an optional stylet to aid with insertion. These balloons also have a capacity of 80 ml, and insertion is identical to that of the Atad catheter.

Effectiveness of the double-balloon catheter

Double-balloon catheter versus PGE2

In the initial study by Atad et al. the double-balloon catheter resulted in shorter induction to delivery times. In a subsequent study, Atad et al. compared the double-balloon catheter, PGE2, and oxytocin. They found that the double- balloon catheter and PGE2 were equivalent in terms of change in Bishop score, time to delivery, and rate of vaginal delivery, but both were superior to oxytocin alone for these outcomes[38] .

Two recent reports found that the double- balloon catheter was associated with a higher rate of delivery within 24 h, without a difference in mode of delivery[39] · In contrast, one report examining PGE2 and the double-balloon catheter in patients with oligohydramnios found a shorter

induction to delivery time in the PGE2 group; however, they did not assess time to vaginal delivery as an outcome[40].

Double-balloon catheter versus single balloon catheter

Pennell et al. compared the single balloon catheter, double- balloon catheter, and PGE2 gel. The double-balloon catheter resulted in a 1-h longer induction to delivery time due to a longer time to active labor, but there were no differences in mode of delivery. The authors also found that the single balloon catheter was associated with the lowest pain scores, as well as the lowest cost (attributed to the cost of the ripening device, with no differences in length of stay or postnatal complications)[41] .

Another randomized controlled trial comparing the single and double-balloon catheters found no differences in induction to delivery times or rates of cesarean delivery regardless of parity; however, there was a higher rate of operative delivery (vacuum or cesarean section) in the double-balloon catheter group. This group also had a higher rate of the composite adverse neonatal outcome that included intrapartum fever, malpresentation, and cord prolapse[42] . In summary, the double-balloon catheter appears to be comparable to the single balloon catheter in terms of efficacy; however, it has a significantly higher cost, has been associated with increase pain scores, and may be associated with an increased risk of adverse labor outcomes.

RESULTS AND ANALYSIS

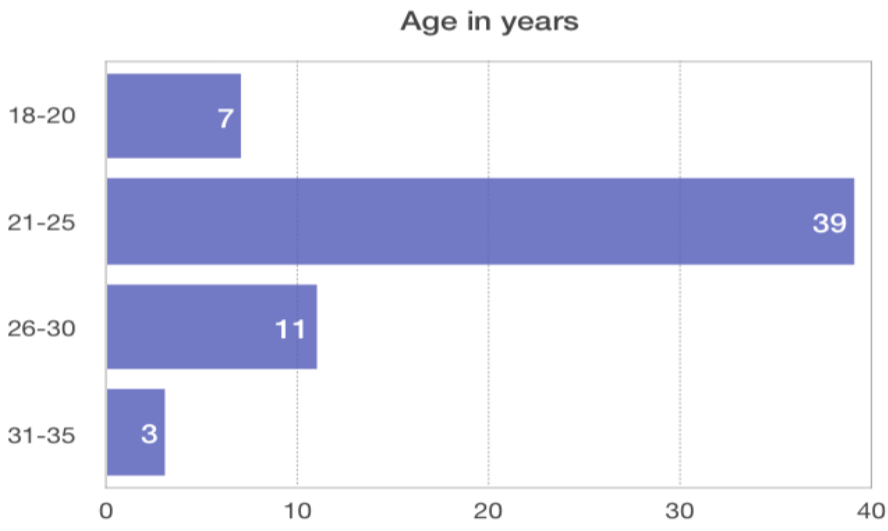
RESULTS AND ANALYSIS

During the study period 120 cases were taken up for the study based on inclusion criteria which were randomly assigned to two groups containing 60 each. Among hygroscopic group, 65% of patients belong to age group of 21 to 25 years. The mean age of the study group was 23.49 years.

Table 1 : Age Group

AGE IN YEARS			
		No of patients	Percent
Age	18-20	7	11.7
	21-25	39	65.0
	26-30	11	18.3
	31-35	3	5.0
	Total	60	100.0

Chart 1 : Age Group



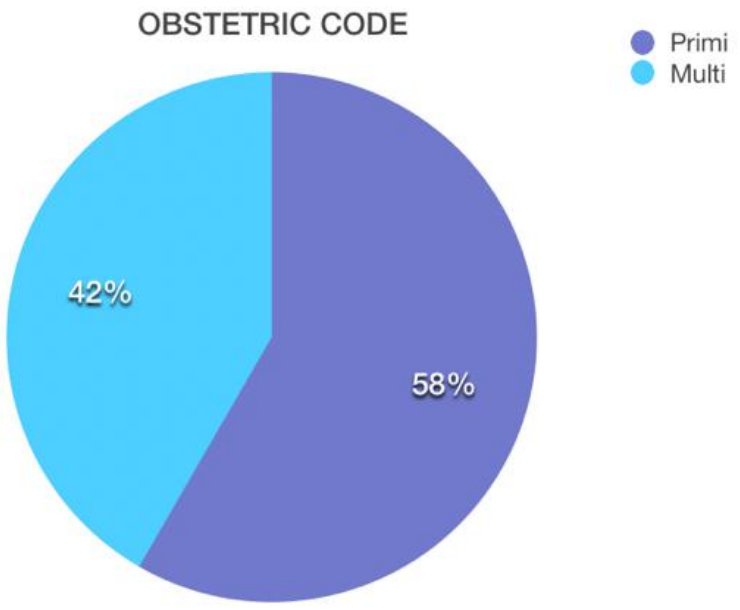
Obstetric code

Among hygroscopic group, 58% of patients were primigravida and remaining 42% were multigravida.

Table 2 : Obstetric Code

	No. of Patients	Percent
Primi	35	58.3
Multi	25	41.7
Total	60	100.0

Chart 2 : Obstetric Code



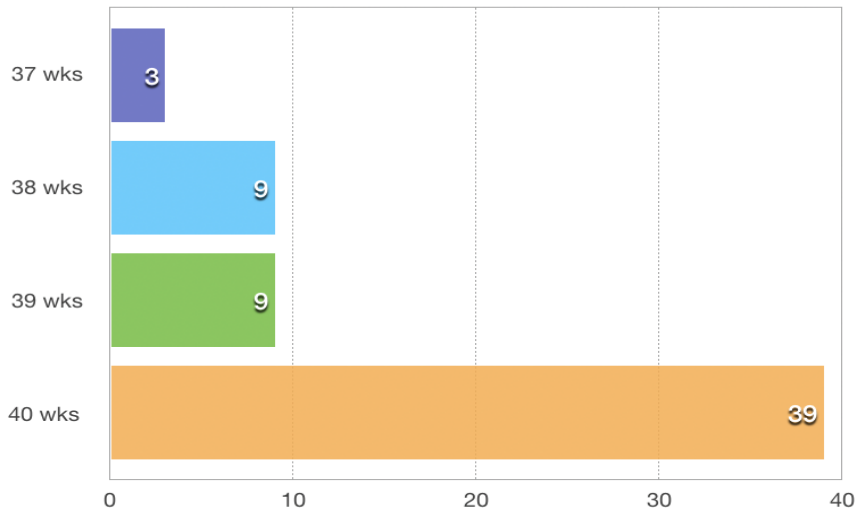
Gestational age in weeks

Gestational age distribution of the study group is shown in following table. About 65% of patients in study group were induced at the gestational age of 40 weeks to 40 weeks 6 days interval. If the NST and AFI monitoring is normal routine induction was done at 40 weeks 3 days.

Table 3 : Gestational age in weeks

	No. of Patients	Percent
37 weeks	3	5.0
38weeks	9	15.0
39 weeks	9	15.0
40 weeks	39	65.0
Total	60	100.0

Chart 3 : Gestational age in weeks



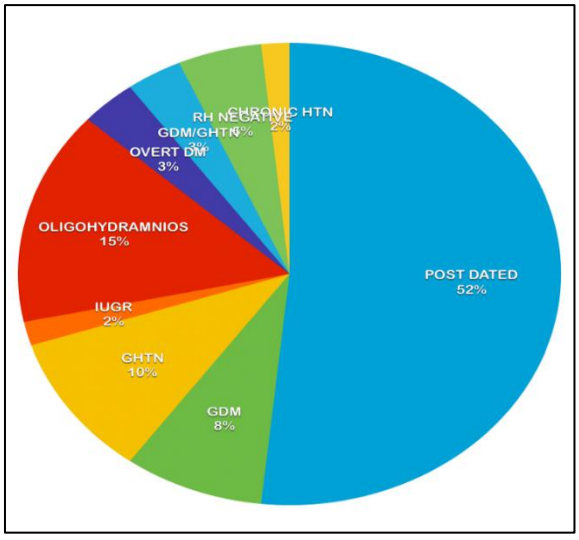
Indication for Induction

The most common indication for induction was postdatism(51.7%). The other two indications were Oligohydramnios (15%)and Gestational Hypertension complicating pregnancy(10%).

Table 4 : Indication for Induction

	No. of Patients	Percent
Post Dated	31	51.7
GDM	5	8.3
GHTN	6	10.0
IUGR	1	1.7
Oligohydramnios	9	15.0
Overt DM	2	3.3
GDM/GHTN	2	3.3
RH Negative	3	5.0
Chronic HTN	1	1.7
Total	60	100.0

Chart 4 : Indication for Induction



Modified bishop score

Pre insertion score

This table shows the distribution of Modified Bishop's Score in the study group. 29 patients had a Modified Bishop's Score of 2 prior to the insertion of hygroscopic dilator. The median Modified Bishop's Score was 2.

Table 5 : Bishops score- Pre Insertion

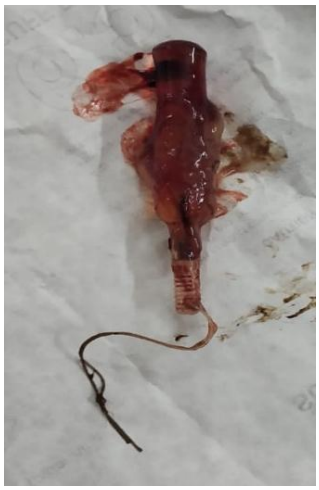
		No. of Patients	Percent
Score	1	8	13.3
	2	29	48.3
	3	15	25.0
	4	7	11.7
	5	1	1.7
	Total	60	100.0

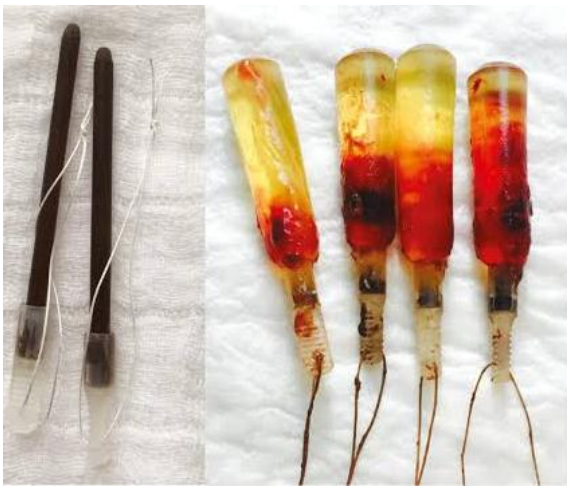
Post insertion score

Modified Bishop's Score 12 hours after the insertion of hygroscopic dilator are shown in following table. 36 patients (60%) had a modified bishop score of 5 following 12 hours of Dilapan S insertion.

Table 6 : Bishops score- Post Insertion (After 12 hours)

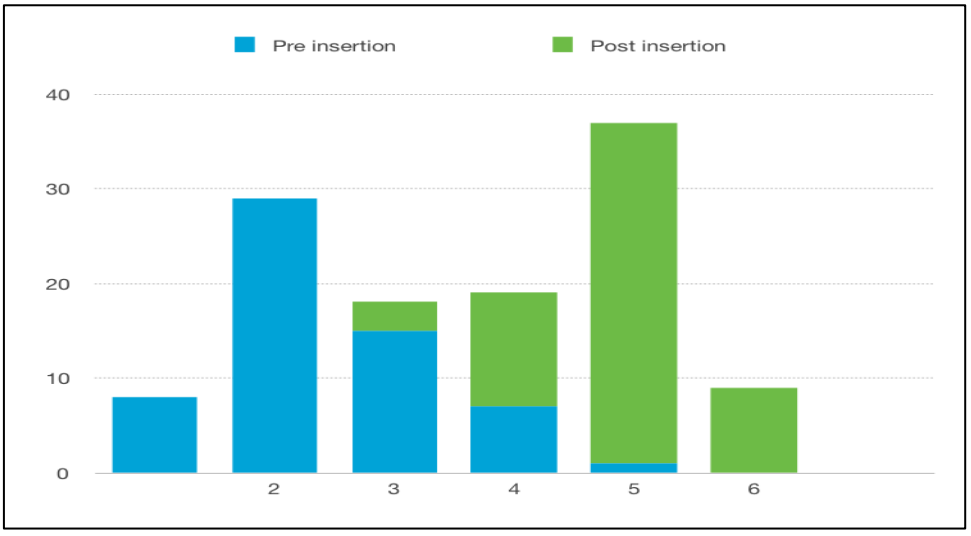
		No. of Patients	Percent
Score	3	3	5
	4	12	20
	5	36	60
	6	9	15
	Total	60	100.0





Improvement in score

Post insertion improvement in the score by 3 occurred due to increase in dilation of cervix , effacement and decrease in the length of the cervix.



Charts 5 & 6 : Improvement in Score

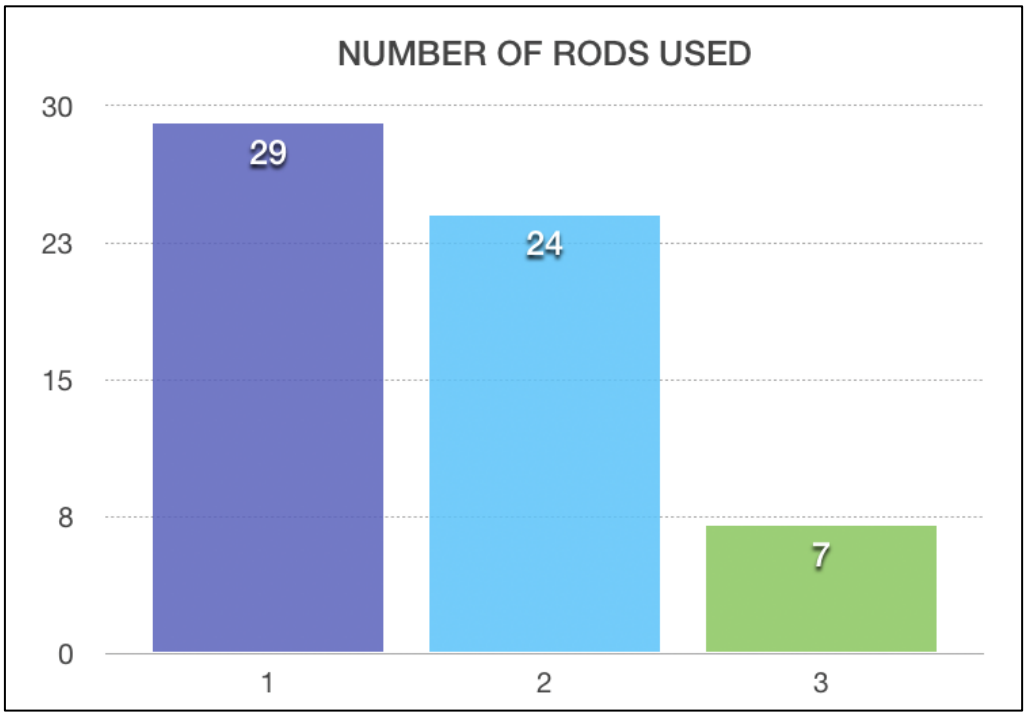
NUMBER OF RODS USED

This table shows the number of dilapan S rods used for cervical ripening. In 29 patients , 1 rod was used and in 24 patients , 2 rods were used. 3 rods were used in only 7 patients .

Table 7 : Number of Rods Used

No. of Rods	No. of Patients	Percent
1	29	48.3
2	24	40.0
3	7	11.7
	60	100.0

Chart 7 : Number of Rods Used



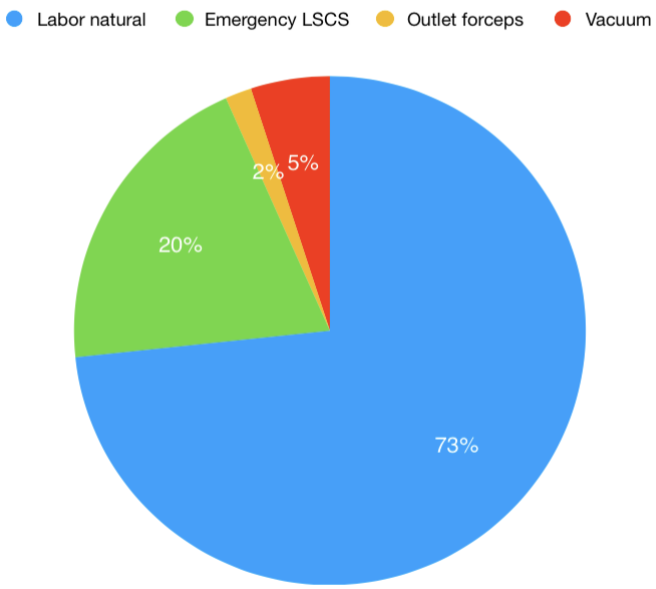
Mode of delivery

Among 60 patients in the study group, 44(73%) patients had normal vaginal delivery and 12(20%) patients underwent LSCS. 1 (1.7%) patient delivered with Outlet forceps with episiotomy and 3(5%) patients with vacuum with episiotomy. Overall vaginal delivery rate was 80%.

Table 8 : Mode of Delivery – hygroscopic group

Mode of Delivery	No. of Patients	Percent
Labour Natural	44	73.3
Emergency LSCS	12	20.0
Outlet Forceps	1	1.7
Vaccum	3	5.0
Total	60	100.0

Chart 8 : Mode of Delivery – hygroscopic group



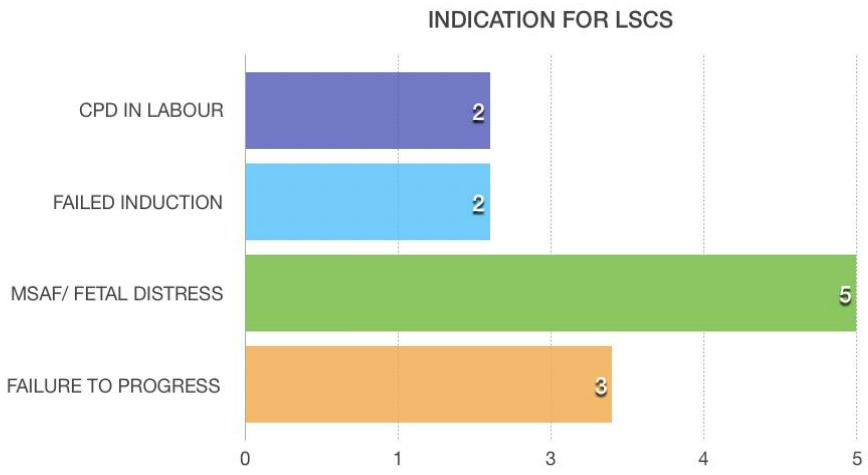
Indication of LSCS

Twenty percent of cases were delivered by LSCS in study group. Five (8.3%) cases were done for fetal distress and 2(3.3%) cases for failed induction. 3(5%) cases were done for failure to progress.

Table 9 : Indication of LSCS

	No. of Patients	Percent
NA	48	80.0
CPD In labour	2	3.3
Failed Induction	2	3.3
MSAF/Fetal Distress	5	8.3
Failure to Progress	3	5.0
Total	60	100.0

Chart 9 : Indication of LSCS



Neonatal outcome – Apgar score

In this study 76.7% of babies delivered with a 1 minute apgar of 7. The 5 minute apgar was 8 in 81.7% of babies. The 5 babies who had a lower apgar were mainly due to respiratory distress, perinatal depression and birth asphyxia. They were admitted in the NICU and recovered.

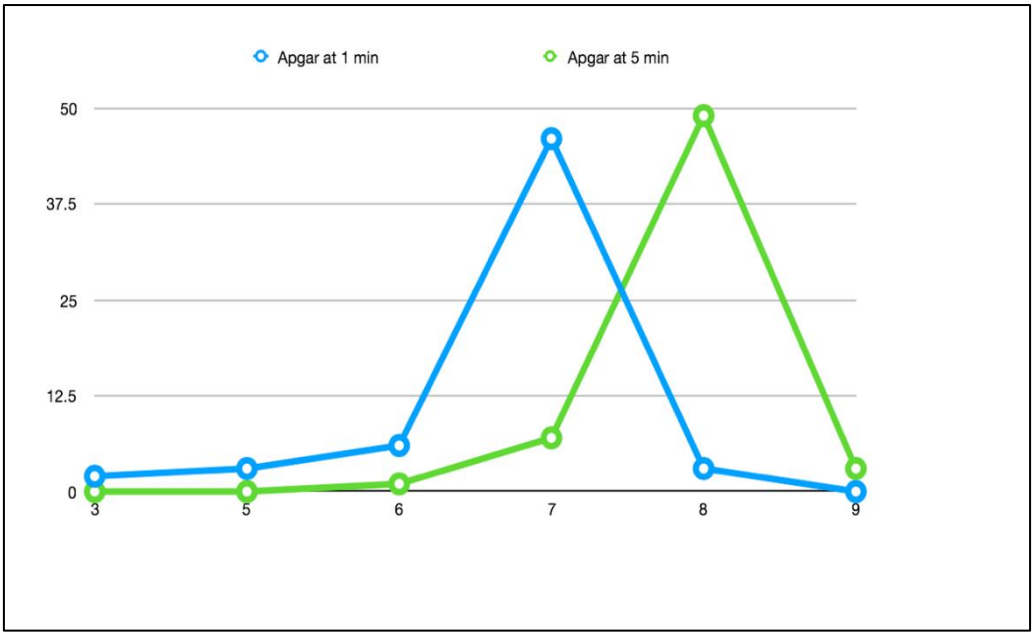
Table 10a : Apgar at 1 Minute

		No of cases	Percent
Score	3	2	3.3
	5	3	5.0
	6	6	10.0
	7	46	76.7
	8	3	5.0
	Total	60	100.0

Table 10b : Apgar at 5 Minute

		No of cases	Percent
Score	6	1	1.7
	7	7	11.7
	8	49	81.7
	9	3	5.0
	Total	60	100.0

Chart 10 : Apgar Score



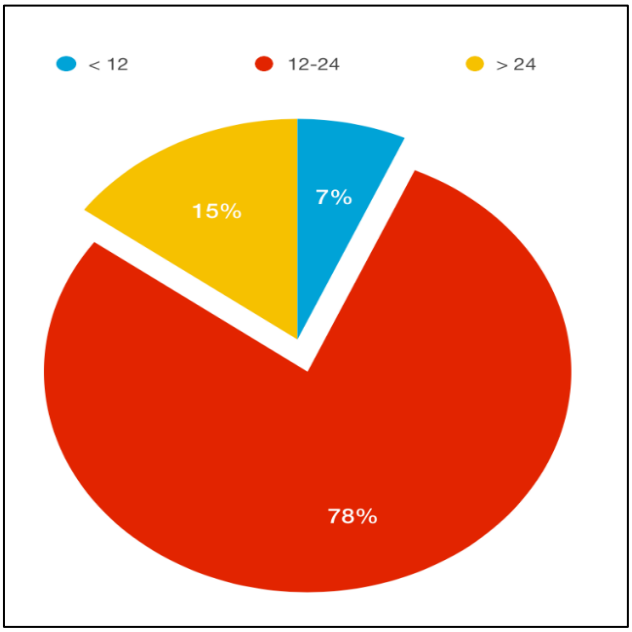
Induction Delivery Interval

Induction delivery interval is 12- 24 hours in majority of cases. The average time taken for patients to deliver from the time of insertion of Dilapan S in our study group was 19 hours . 78.3% of cases delivered in 12-24hours. Following table shows induction delivery interval in the study group.

Table 11 : Induction Delivery Interval

		No. of Patients	Percent
Hours	< 12	4	6.7
	12-24	47	78.3
	> 24	9	15.0
	Total	60	100.0

Chart 11 : Induction Delivery Interval



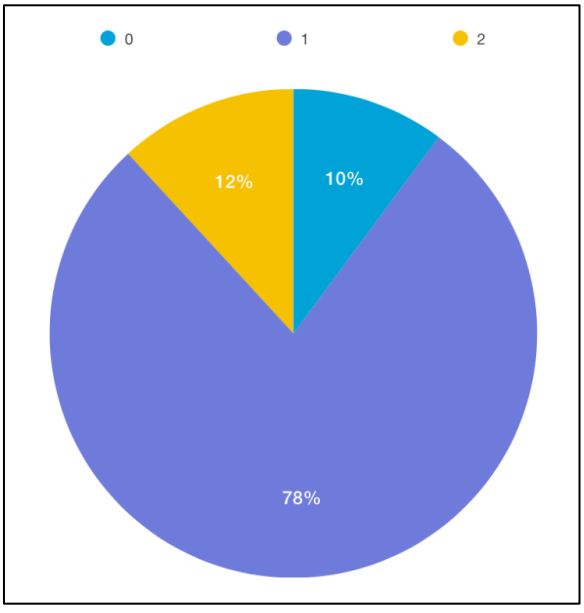
Requirement of PGE2 GEL

The number of PGE 2 Gel doses used in the study group is shown in the following table. Of 60 patients, 46 patients received a single dose of PGE 2 gel and 7 Patients received 2 doses of PGE 2 gel . 1 patient received 3 doses of PGE2 gel and was delivered by LSCS because of failure to progress . Of the 7 patients who received 2 doses , 2 delivered vaginally and 4 cases by LSCS for failed induction , failure to progress and CPD In labour. Out of 60 cases , 6 cases (10%) did not require induction with PGE2 gel after extraction of Dilapan S and had delivered with oxytocin augmentation.

Table 12 : PGE2 GEL DOSE

		No. of Patients	Percent
Unit	1	46	76.7
	2	7	11.7
	3	1	1.7
	Total	54	90.0
No Gel	0	6	10.0
Total		60	100.0

Chart 12 : PGE2 GEL DOSE



Complications:

Complications associated with inducing agents during insertion are

- Cervical injury
- Bleeding during insertion or removal
- Spontaneous expulsion
- Retraction into cavity
- Dilator entrapment
- Dilator fragmentation

In our study there was no complications encountered during the insertion of Dilapan S. Rupture of membranes occurred in 2 patients during insertion

Safety profile:

Maternal infection defined as maternal temperature greater than 38 °C, endometritis, chorioamnionitis or antibiotic usage following Dilapan S insertion was not seen in the study group.

Maternal hyperstimulation defined as greater than five contractions in 15 min at any time following study allocation was not seen.

There was better patient satisfaction with Dilapan S.

COMPARISON BETWEEN THE STUDY AND CONTROL GROUP

Patient characteristics and outcome were analysed and compared between hygroscopic group and foleys group. In both group, majority of patients were in the age group of 21 to 25 years. Among control group, 63.3 % were primigravida and 36.7 % were multi gravida whereas 58.3% were primigravida and 41.7% were multi gravida in the study group.

Chart 13 : Comparison of Age Group between Study and Control Groups

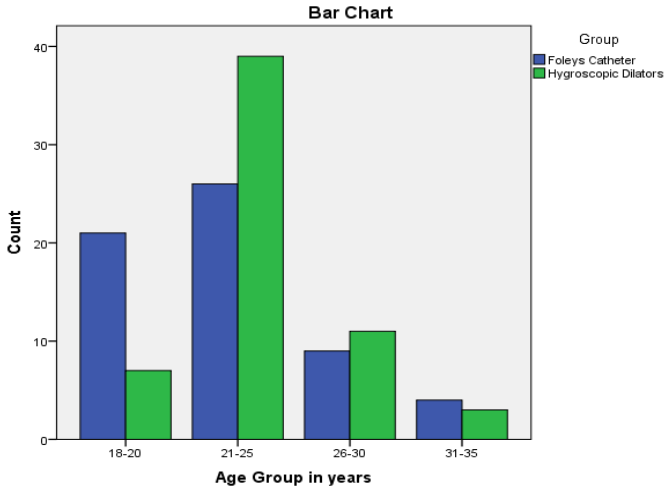
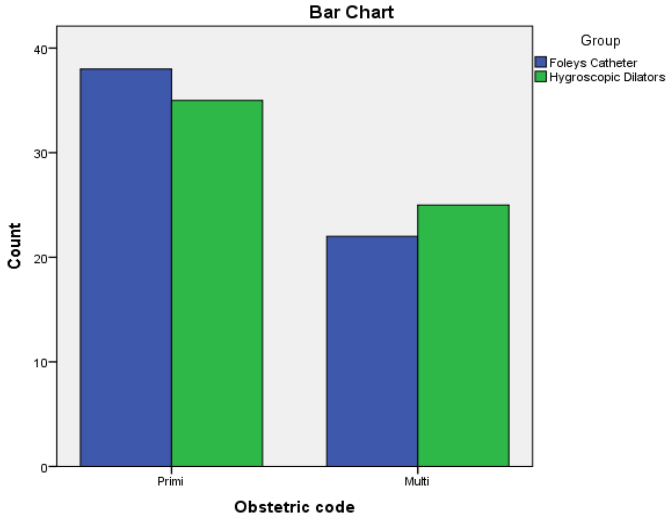


Chart 14 : Comparison of Obstetric Code between Study and Control Groups



Gestational age

Majority of cases were 40 weeks of gestational age in the study group (65%) whereas in the control group 46.7 % belong to 40 weeks and 35 % of patients belong to 38 weeks of gestation. Patient demographics were given in following table.

Chart 15 : Comparison of Gestational Age between Study and Control Groups

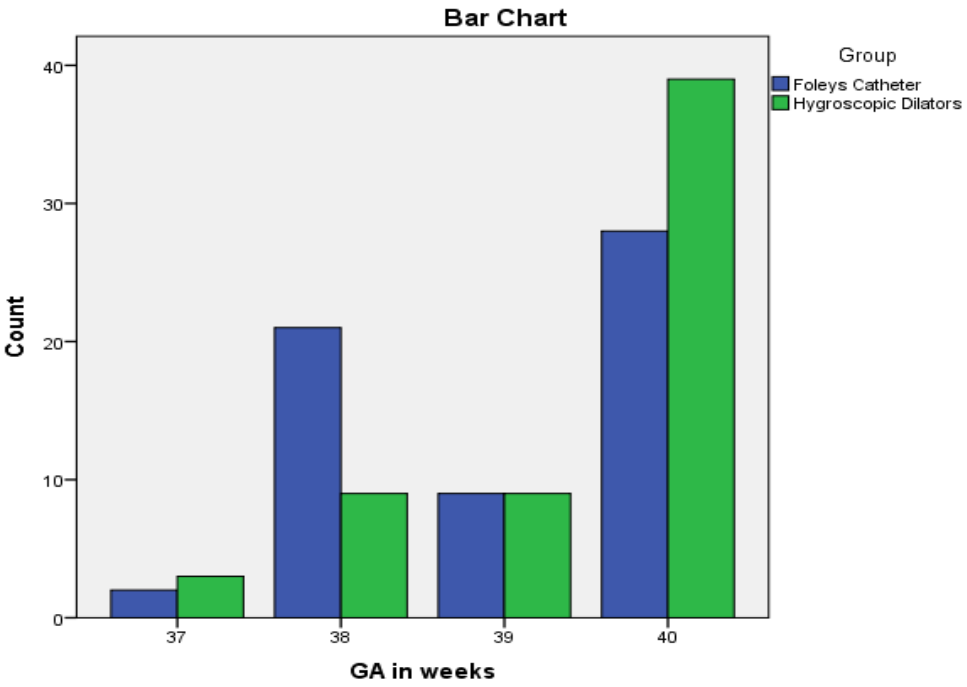


Table 13 : Patient demographics

Patient characteristics	Foley's group (n = 60)	Hygroscopic group (n =60)
Age group		
18-20	21(35)	7 (11.7)
21-25	26 (43.3)	39 (65)
26-30	9 (15)	11(18.3)
31-35	4 (6.7)	3 (5)
Obstetric code		
Primi gravida	38(63.3)	35(58.3)
Multi gravida	22(36.7)	25(41.7)
Gestational age		
37	2(3.3)	3(5.0)
38	21(35.0)	9(15)
39	9(15)	9(15)
40	28(46.7)	39(65)

Values in Parentheses are in Percentage

Obstetric and neonatal outcome

Mode of delivery

Primary outcome of this study was mode of delivery. Among the study group 73.3% of patients had labour natural whereas 71.7% had labour natural in the control group (p value = 0.838).. Around 20% patients underwent emergency LSCS in the study group whereas 26% patients underwent emergency LSCS in the control group (p value = 0.387). Hence there is no statistically significant difference in primary outcome between study group and control group. In each group, 1.7 % patients underwent outlet forceps delivery. Five percent of patients in study group delivered by vacuum assisted delivery whereas no vacuum assisted delivery in control group. Overall vaginal delivery rate was 80% in Study group and 73.4% in Control group.

Chart 16 : Comparison of Mode of Delivery between Study and Control Groups

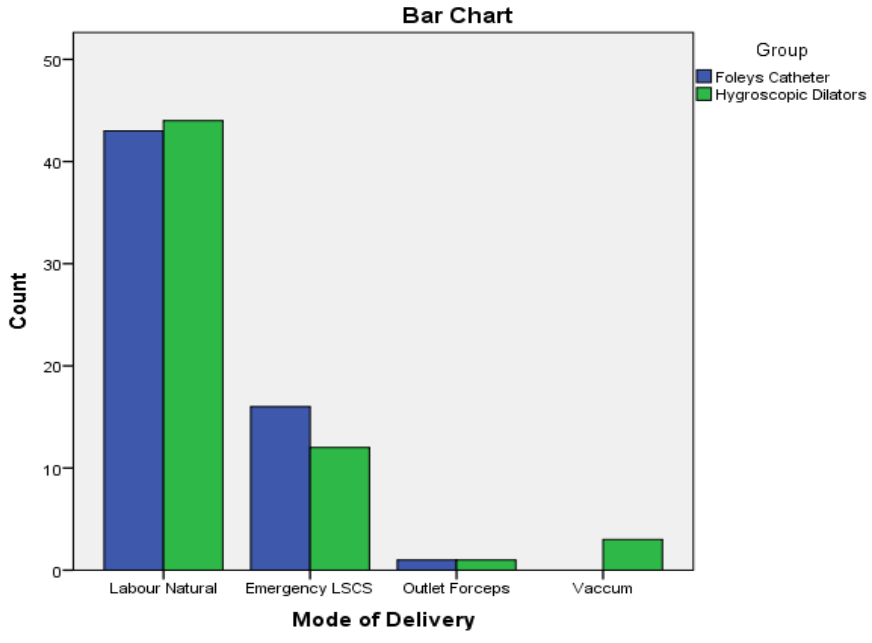


Table 14 : Primary outcome – Foleys vs Hygroscopic dilator group

Outcome	Foley's (n = 60)	Hygroscopic (n = 60)
Mode of delivery		
Labour Natural	43(71.7)	44(73.3)
Emergency LSCS	16(26.7)	12(20.0)
Outlet Forceps	1(1.7)	1(1.7)
Vacuum	0(0)	3(5.0)
Indication for LSCS		
CPD in labour	3(5)	2(3.3)
Failed induction	4(6.7)	2(3.3)
MSAF/fetal distress	3(5)	5(8.3)
Failure to progress	4(6.7)	3(5)
Fetal alarm signal	2(3.3)	-

Values in Parentheses are in Percentage

In the study group 3.3% underwent emergency LSCS for failed induction whereas in the control group 6.7% underwent emergency LSCS for failed induction. The other common indications for LSCS were MSAF/ fetal distress and failure to progress. Since there are various confounding factors , the indication for LSCS between both groups is statistically not significant.

Table 15 : Secondary outcomes – Foleys vs Hygroscopic dilator group

Outcome	Foley's (n = 60)	Hygroscopic (n = 60)
Bishop Score		
Pre insertion score		
1	9(15)	8(13.3)
2	36(60)	29(48.3)
3	14(23.3)	15(28)
4	1(1.7)	1(1.7)
5	0	1(1.7)
Post insertion score		
3	0	3(5)
4	17(28.3)	12(20)
5	27(45)	36(60)
6	9(15)	9(15)
7	6(10)	0
8	1(1.7)	0
Induction delivery interval		
Primi gravida		
< 12	5(13.2)	1(2.9)
12-24	10(26.3)	27(77.1)
> 24	23(60.5)	7(20)
Multi gravida		
< 12	4(18.2)	3(12)
12-24	9(40.9)	20(80)
> 24	9(40.9)	2(8)
PGE2 gel requirement		
0	19(31.7)	6(10)
1	36(60)	46(76.7)
2	5(8.3)	7(11.7)
3	0	1(1.7)

Values in parentheses are in percentages

Induction delivery interval

Induction delivery interval for primigravida was 12 to 24 hours in majority of cases in study group (77.1%) whereas more than 24 hours in control group (60.5%) which is statistically significant (p value = 0.025).

Induction delivery interval for multigravida is 12 to 24 hours in study group in 80 % cases whereas in the control group 12 to 24 hours in 40.9 % cases and more than 24 hours in 40.9 % cases.

Induction delivery interval is shorter among the study group with majority of cases delivering in less than 24 hours when compared with the control group were majority cases delivering in more than 24 hours.

Chart 17 : Comparison of Induction Delivery Interval between Study Group and Control Group

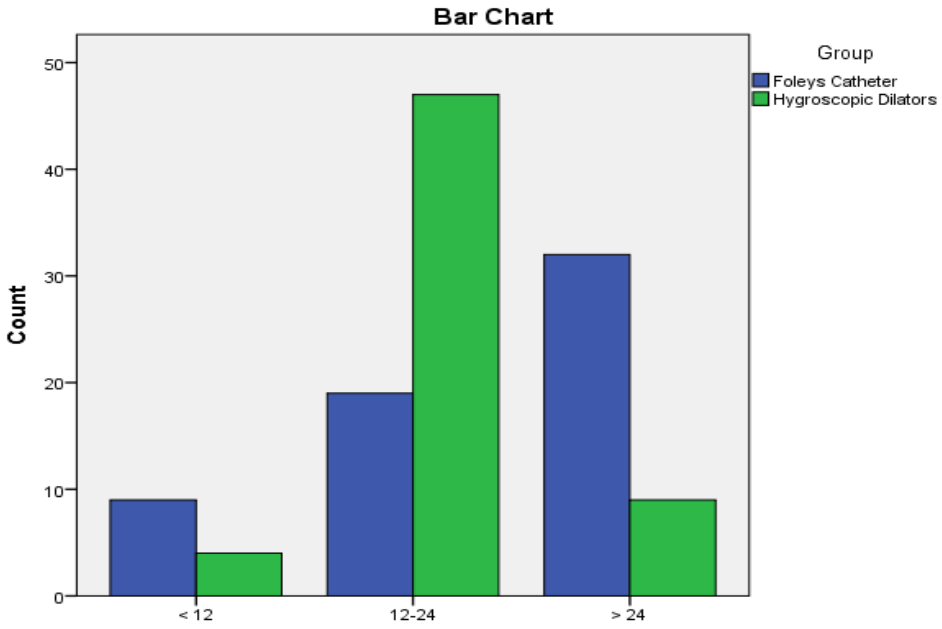


Chart 18 : Comparison of Induction Delivery Interval between Primi and Multi in Foley Group

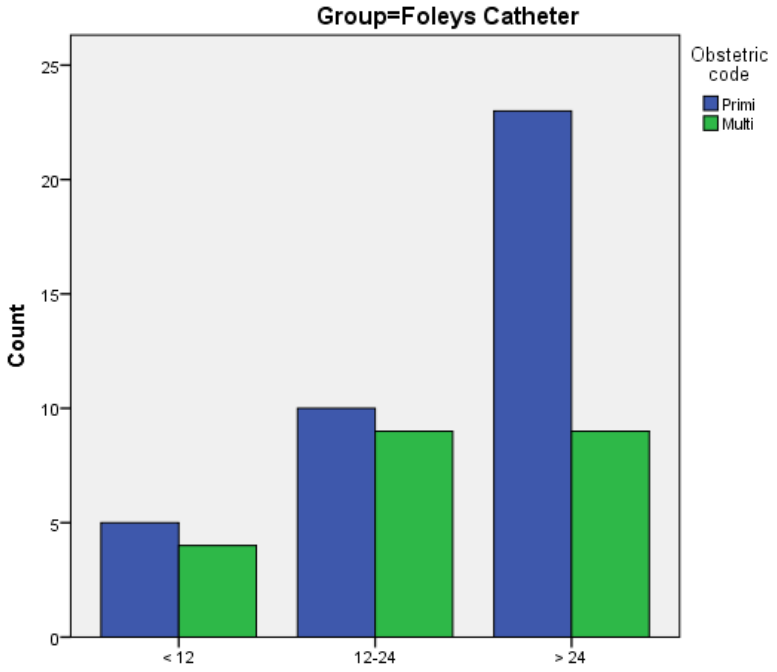
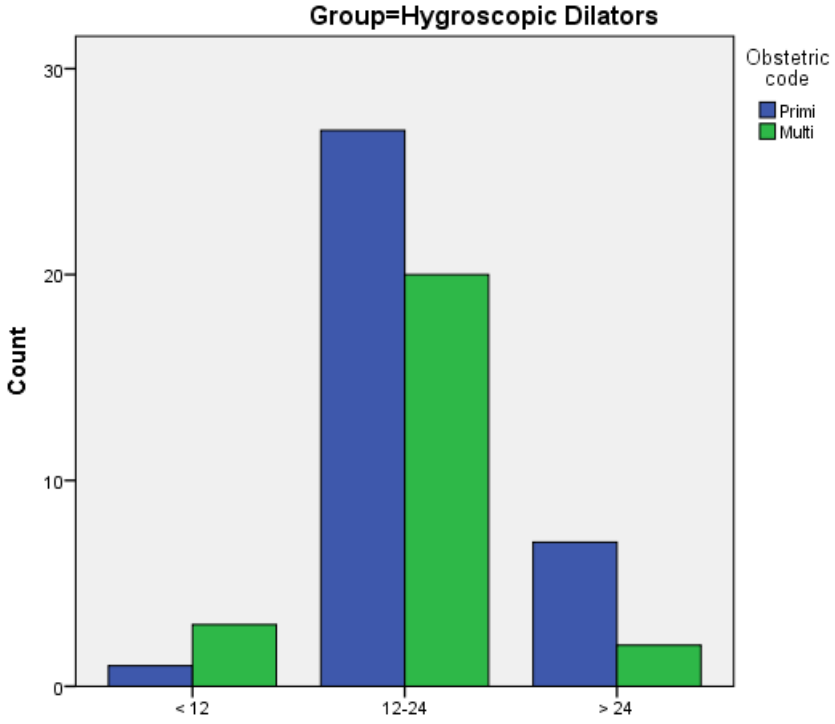


Chart 19 : Comparison of Induction Delivery Interval between Primi and Multi in Hygroscopic Dilators Group

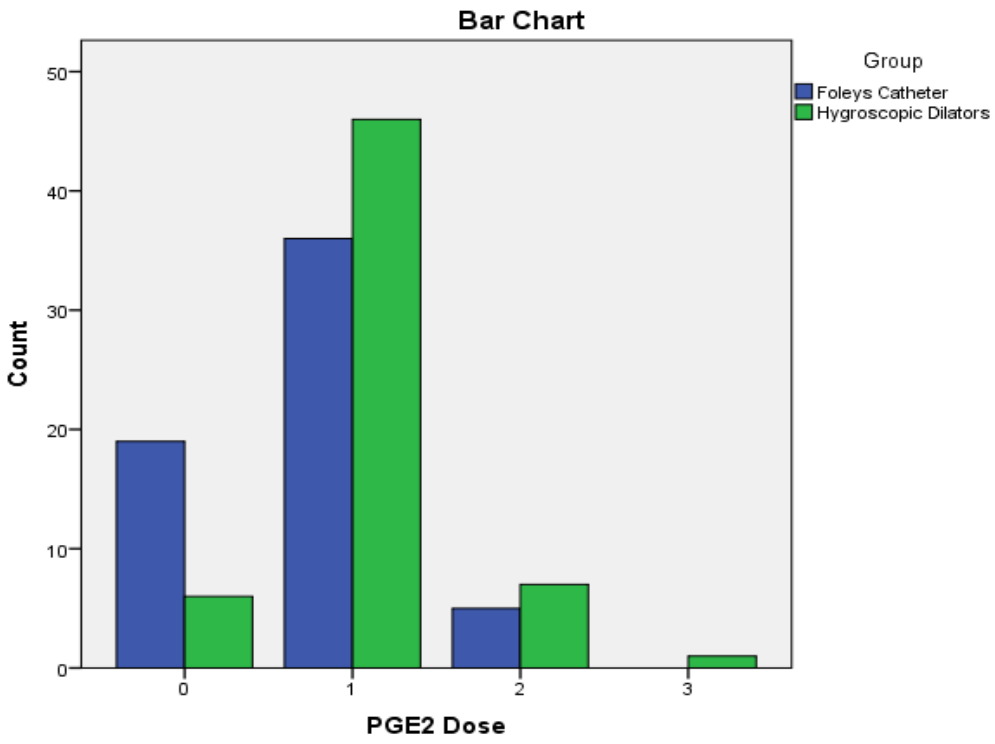


Requirement of PGE2 Gel

No PGE 2 gel was used in 31.7 % of cases in control group and 10 % cases in study group. In study group 1 gel was used in 76.7%, two gel were used in 11.7 % cases and 3 gel were used in 1.7% cases. In control group, 1 gel was used in 36% cases, two gel were used in 5 % cases.

Requirement for PGE 2 gel is higher in study group than control group which is statistically significant.

Chart 20 : Comparison of Requirement of PGE2 Gel between Study Group and Control Group



There is no statistically significant difference in 1 min and 5 min apgar score between study group and control group (p value = 0.120).

Chart 21 : Comparison of Apgar score at 1 min between Study and Control Groups

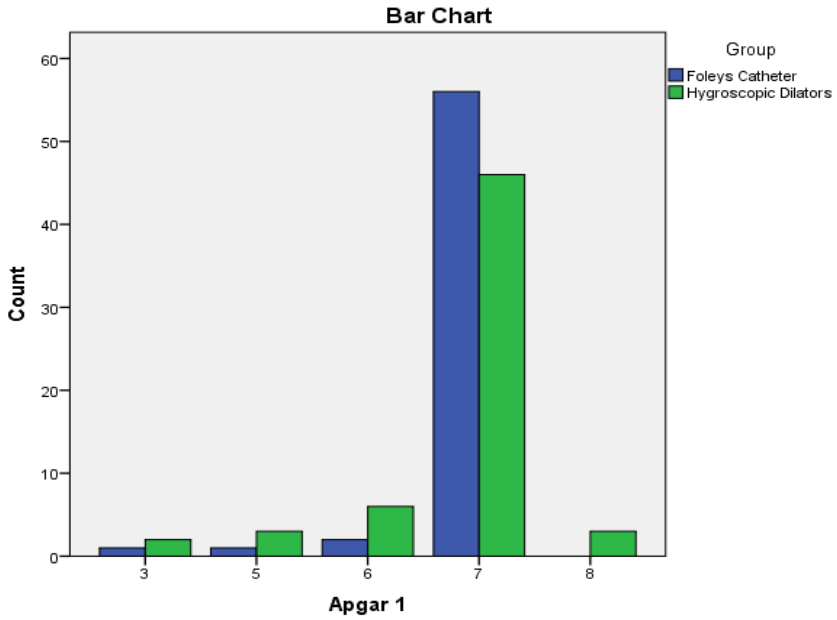
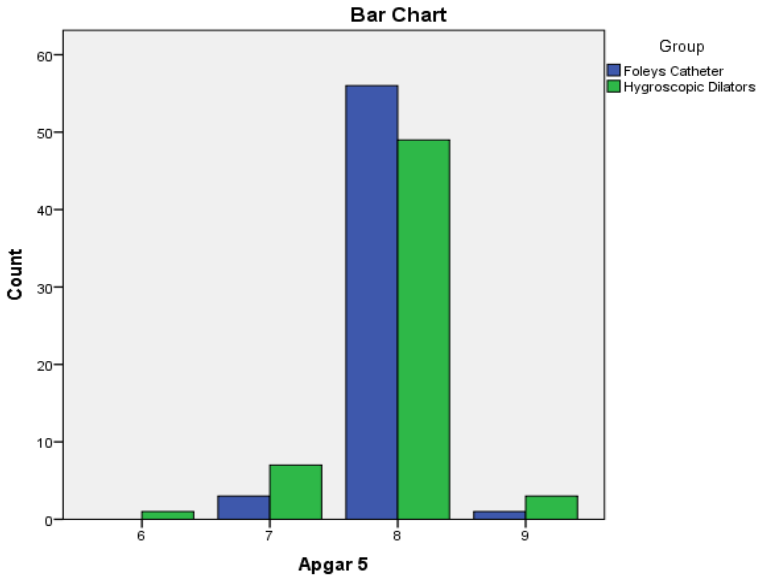


Chart 22 : Comparison of Apgar score at 5 mins between Study and Control Groups



Bishop score

In the study group the mean pre induction bishop score is 2.4 with standard deviation of 0.924 and mean post induction bishop score is 4.85 with standard deviation of 0.732.

The mean change in bishop score is 2.4 with standard deviation of 0.982.

In the control group the mean pre induction bishop score is 2.12 with standard deviation of 0.666 and mean post induction bishop score is 5.12 with standard deviation of 0.993.

The mean change in bishop score is 3 with standard deviation of 1.135.

There is no statistically significant difference in pre insertion bishop score in study group compared to control group (p value = 0.175) .

However there is statistically significant difference in higher post insertion bishop score in control group compared to study group (p value = 0.033) .

Chart 23 : Comparison of Pre induction score between Study and Control Groups

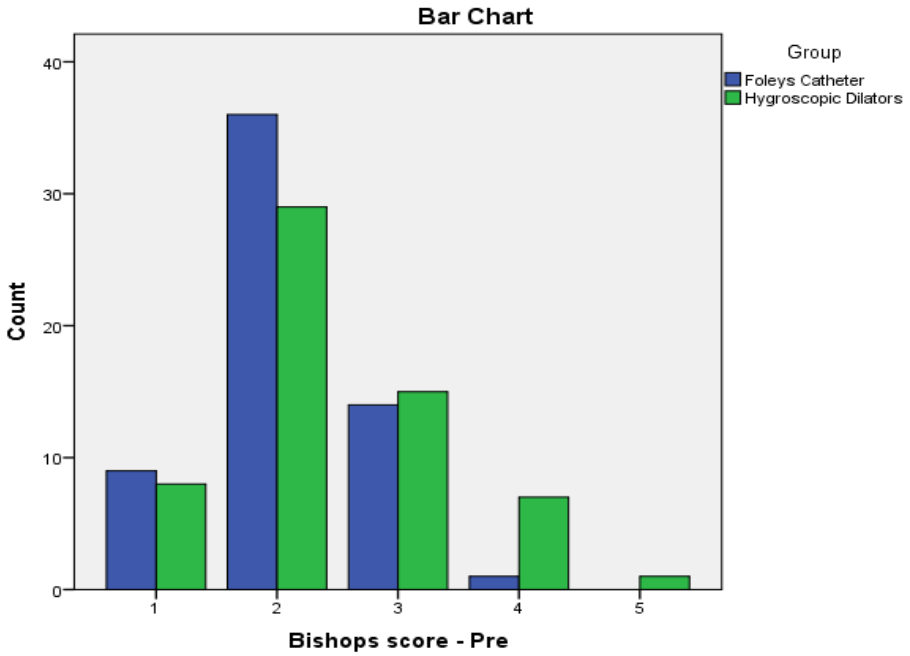
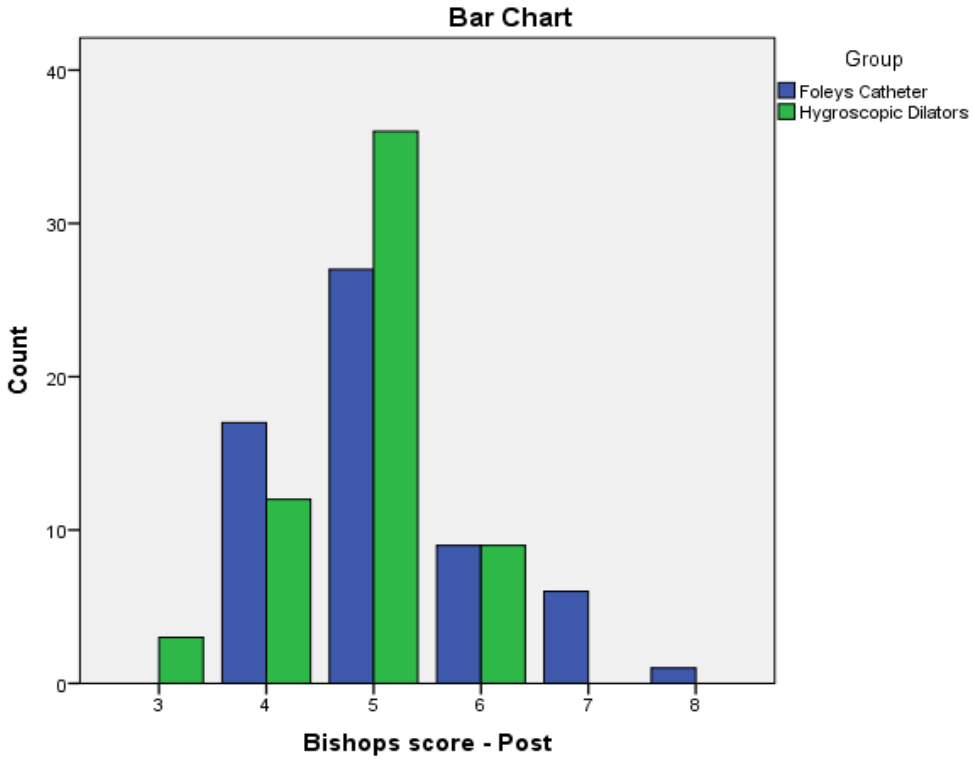


Chart 24 : Comparison of Post induction score between Study and Control Groups



DISCUSSION

DISCUSSION

Mechanical dilators are very commonly used methods for cervical ripening. Safety profile and cost effectiveness of these dilators make them ideal preinduction agents of choice. The Foley balloon catheter is the gold standard method of preinduction for decades. After the publication of ARRIVE trial by Grobman et al[43], there is increasing rate of induction of labour since it is beneficial than expectant management.

In 2012, Cochrane review of all mechanical methods for induction of labour reveals that mechanical methods do not increase the overall number of women not delivered in 24 h when compared to intravaginal prostaglandins (three studies; 586 women RR 1.72; 95% CI 0.90 to 3.27). Risk of hyperstimulation with fetal heart rate (FHR) changes in eight studies of 1203 women (RR 0.16; 95% CI 0.06–0.39) were low with mechanical methods. No difference in Serious neonatal and maternal morbidity noted between the groups.

Even though Dilapan-S use for cervical ripening is well established in early pregnancy, there are very few literature evidence for dilapan use at term due to limited clinical experience with its use at term.

Saad et al reported noninferiority of dilapan versus foleys balloon for preinduction of labour in a randomized controlled trial(DILAFOL TRIAL)[44], eventhough there is no statistically significant difference in

outcome. In our study, there is no statistically significant difference in mode of delivery and requirement of LSCS with the use of dilapan versus foleys catheter induction . But there is statistically significant difference in secondary outcome parameters like post induction bishop score and induction delivery interval. Moreover, dilapan use has more patient satisfaction and compliance than foleys for induction of labour.

In a recent study, Gupta et al published overall vaginal delivery rate of 77%, with up to 12 h of dilator use, statistically significantly falls to 65% beyond 12 h of insertion. The vaginal delivery rate within a 24-h period was 46% and increased to 76% within a 48-h period[45].

Another advantage of dilapan as well as foleys induction are low rate of hyper stimulation as there is no case of hyperstimulation in our study.

In many studies, Foley balloon catheters are equivalent to pharmacologic methods with rates of failed induction of labor and cesarean section. Due to their low cost and lower rates of uterine hyperstimulation, they are an excellent tool to use both in prospering and developing countries However, their safety profile makes them an attractive alternative, even as an option for out patient preinduction cervical ripening.

R shindo et al.reported comparable rate of vaginal delivery with use of hygroscopic versus foley balloon catheters[46]. In their study, number of

vaginal instrumental delivery, intrapartum hemorrhage and PPH were low in hygroscopic dilator group compare to other methods.

Following table compares the outcome of various methods of induction of labour.

Table 16 : Comparison between present study and previous studies

Study	Rate of vaginal delivery	Rate of LSCS	Change in bishop score
Gupata et al (Dilapan)	69.8%	30.1%	3.6
Crosby et al (Dilapan vs dinoprostone)	74%	26.9%	3.3
Saad et al (Dilapan vs foleys)	81.3%	18.8%	3
Present study (Dilapan vs foleys)	80%	20%	3

CONCLUSION

CONCLUSION

Dilapan S is safe, effective induction method at term with outcome comparable to foleys balloon catheter in the induction of labour. Both Dilapan S and foleys catheter have good safety profile.

They have equivalent efficacy, lower risk of hyperstimulation and no clear evidence of increased infection risk.

While both Dilapan S and Foley's catheter have minimal adverse events , the advantages of Dilapan S over Foley's Catheter include no protrusion from the introitus, no need to keep under tension and improve the patient satisfaction. It is easy to insert and remove. Insertion of Dilapan S does not require a skilled medical personnel where as insertion of Foley's Catheter requires skill.

Dilapan S has better patient satisfaction with patients feeling more comfortable without any traction or tension. Dilapan S use of <12 hours results in overall vaginal delivery rate of 80% with decreased induction delivery interval compared to Foley's Catheter use for 24 hours with overall vaginal rate of 73.4%.

The rate of Cesarean Section was slightly higher (26.7%) in Foley's group compared to Dilapan S group (20%).

Dilapan S being equally effective as the Foley's Catheter in cervical ripening and induction of labour, is a good alternative to Foley's Balloon Catheter with good safety profile and patient satisfaction rate.

SUMMARY

SUMMARY

Introduction

Induction of labour can be defined as an intervention intended to artificially initiate uterine contractions resulting in progressive effacement and dilation of cervix to enable vaginal delivery. The more common indications include post term pregnancy, gestational hypertension, oligohydramnios etc.

Aim of Study

The aim of the study is to estimate the effects of Hygroscopic dilators in ripening of uterine cervix and to compare the effects of Hygroscopic dilators and Foley catheter in the induction of labour in terms of cervical dilatation, induction delivery interval, maternal and fetal outcome.

Materials and Methods

The Prospective study was conducted in Govt. RSRM Lying In Hospital, Chennai during the period of December 2018 to September 2019. 120 patients who were term antenatal mothers eligible for induction of labour were selected and bishop score assessed. If the bishop score was less than 6, they were divided into hygroscopic dilator group and foleys group randomly. Patient characteristics and outcome were analyzed and

compared between hygroscopic group and foleys group. Primary outcome of this study was mode of delivery. Secondary outcome like post induction bishop score, induction delivery interval, apgar at 1 min and 5 min, requirement of PGE2 gel were measured and analyzed.

Results

Among the study group 73.3% of patients had labour natural compare to 71.7% in the control group (p value = 0.838). Overall vaginal delivery rate including operative vaginal delivery was 80% in Study group and 73.4% in Control group. Emergency LSCS done in 20 % in study group whereas 26.7% in control group (p value = 0.387). Hence there is no statistically significant difference in primary outcome between study group and control group.

Induction delivery interval for primigravida was 12 to 24 hours in 77.1% cases in study group and more than 24 hours in 60.5% cases in control group (p value = 0.025).

Induction delivery interval for multigravida is 12 to 24 hours in study group in 80 % cases whereas in study group 12 to 24 hours in 40.9 % cases and more than 24 hours in 40.9 % cases.

No PGE 2 gel was used in 31.7 % of cases in control group and 10 % cases in study group. In study group 1 gel was used in 76.7%, two gel were used in 11.7 % cases and 3 gel were used in 1.7% cases. In control

group, 1 gel was used in 36% cases, two gel were used in 5 % cases. Requirement for PGE 2 gel is higher in study group than control group which is statistically significant.There is no statistically significant difference in 1 min and 5 min apgar score between study group and control group (p value = 0.120).There is statistically significant difference in higher post insertion bishop score in study group compared to control group (p value = 0.033) .

Conclusion

Dilapan S is safe, effective induction method at term with outcome comparable to foleys balloon catheter in the induction of labour.

Key Words

Hygroscopic Dilators, Dilapan S, Foley's Balloon Catheter, Induction of Labour, Cervical ripening, Mechanical Methods of Induction, Pregnancy Outcome.

BIBLIOGRAPHY

REFERENCES

1. Induction of labour. Evidence based clinical guideline No 9. Royal College of Obstetricians and Gynaecologists, 2001. Pp39-40.

2. Macones GA. Elective induction of labor: waking the sleeping dogma?. Annals of internal medicine. 2009 Aug 18;151(4):281-2.

3. Rayburn WF, Zhang J. Rising rates of labor induction: present concerns and future strategies. Obstetrics & Gynecology. 2002 Jul 1;100(1):164-7.

4. RCOG. Royal College of Obstetricians and Gynaecologists. Induction of labour. 2008;1:1-12,5:45-68

5. Nuutila M, Halmesmäki E, Hiilesmaa V, Ylikorkala O. Women's anticipations of and experiences with induction of labor. Acta obstetricia et gynecologica Scandinavica. 1999 Jan 1;78(8):704-9.

6. Out JJ, Vierhout ME, Verhage F, Duivenvoorden HJ, Wallenburg HC. Characteristics and motives of women choosing elective induction of labour. Journal of psychosomatic research. 1986 Jan 1;30(3):375-80.

7. Mozurkewich EL, Chilimigras JL, Berman DR, Perni UC, Romero VC, King VJ, Keeton KL. Methods of induction of labour: a

systematic review. BMC pregnancy and childbirth. 2011 Dec;11(1):84.

8. Caughey AB, Sundaram V, Kaimal AJ, Gienger A, Cheng YW, McDonald KM, Shaffer BL, Owens DK, Bravata DM. Systematic review: elective induction of labor versus expectant management of pregnancy. Annals of internal medicine. 2009 Aug 18;151(4):252-63.

9. Alexander JM, MCIntire DD, Leveno KJ. Prolonged pregnancy: induction of labor and cesarean births. Obstetrics & Gynecology. 2001 Jun 1;97(6):911-5.

10. Rand L, Robinson JN, Economy KE, Norwitz ER. Post-term induction of labor revisited. Obstetrics & Gynecology. 2000 Nov 1;96(5):779-83.

11. O'Brien WF. The role of prostaglandins in labor and delivery. Clinics in perinatology. 1995 Dec 1;22(4):973-84.

12. Fuchs AR, Goeschen K, Husslein P, Rasmussen AB, Fuchs F. Oxytocin and the initiation of human parturition: III. Plasma concentrations of oxytocin and 13, 14-dihydro-15-keto-prostaglandin F2α in spontaneous and oxytocin-induced labor at term. American journal of obstetrics and gynecology. 1983 Nov 1;147(5):497-502.

13. Bishop EH. Pelvic scoring for elective induction. Obstet Gynecol 1964; 24: 266-268

14. Maul H, Mackay L, Garfield RE. Cervical ripening: biochemical, molecular, and clinical considerations. Clin Obstet Gynecol. 2006;49(3):551–563.

15. Sciscione AC. Methods of cervical ripening and labor induction: mechanical. Clinical obstetrics and gynecology. 2014 Jun 1;57(2):369-7

16. Rayburn WF. Preinduction cervical ripening: basis and methods of current practice. Obstetrical & gynecological survey. 2002 Oct 1;57(10):683-92.

17. Sooranna SR, Lee Y, Kim LU, Mohan AR, Bennett PR, Johnson MR. Mechanical stretch activates type 2 cyclooxygenase via activator protein-1 transcription factor in human myometrial cells. Molecular human reproduction. 2004 Feb 1;10(2):109-13.

18. Mohan AR, Sooranna SR, Lindstrom TM, Johnson MR, Bennett PR. The effect of mechanical stretch on cyclooxygenase type 2 expression and activator protein-1 and nuclear factor-κB activity in human amnion cells. Endocrinology. 2007 Apr 1;148(4):1850-7.

19. Johnson N. Intracervical tents: usage and mode of action. Obstet Gynecol Surv. 1989;44(6):410–420

20. Norström A1, Bryman I, Hansson HA. Cervical dilatation by Lamicel before first trimester abortion: a clinical and exper- imental study. Br J Obstet Gynaecol. 1988;95(4):372–376.

21. Gelber S, Sciscione A. Mechanical methods of cervical ripening and labor induction. Clin Obstet Gynecol. 2006;49(3):642–657

22. Jozwiak M, Bloemenkamp KW, Kelly AJ, Mol BW, Irion O, Boulvain M. Mechanical methods for induction of labor. Cochrane Database Syst Rev. 2012:3:CD001233.

23. Gower RH, Toraya J, Miller JM Jr. Laminaria for preinduction cervical ripening. Obstet Gynecol. 1982;60(5):617–619

24. Gilson GJ, Russell DJ, Izquierdo LA, Qualls CR, Curet LB. A prospective randomized evaluation of a hygroscopic cervical dilator, dilapan, in the preinduction ripening of patients undergoing induction of labor. Am J Obstet Gynecol. 1996;175 (1):145–149

25. Blumenthal PD, Ramanauskas R. Randomized trial of dilapan and laminaria as cervical ripening agents before induction of labor. Obstet Gynecol. 1990;75(3):365–368.

26. Chua S, Arulkumaran S, Vanaja K, Ratnam SS. Preinduction cervical ripening: prostaglandin E2 gel vs hygroscopic mechanical dilator. J Obstet Gynaecol Res. 1997;23(2):171–177.

27. Johnson IR, Macpherson MB, Welch CC, Filshie GM. A comparison of Lamicel and prostaglandin E2 vaginal gel for cervical ripening before induction of labor. Am J Obstet Gynecol. 1985;151(5):604–607.

28. Sanchez-Ramos L, Kaunitz AM, Connor PM. Hygroscopic cervical dilators and prostaglandin E2 gel for preinduction cervical ripening. A randomized, prospective comparison. J Reprod Med. 1992;37(4):355–359.

29. Hibbard JU, Shashoua A, Adamczyk C, Ismail M. Cervical ripening with prostaglandin gel and hygroscopic dilators. Infect Dis Obstet Gynecol. 1998;6(1):18–24.

30. Turnquest MA, Lemke MD, Brown HL. Cervical ripening: randomized comparison of intravaginal prostaglandin E2 gel with prostaglandin E2 gel plus Laminaria tents. J Matern Fetal Med. 1997;6(5):260–263.

31. Roberts WE, North DH, Speed JE, Martin JN, Palmer SM, Morrison JC. Comparative study of prostaglandin, laminaria, and minidose oxytocin for ripening of the unfavorable cervix prior to induction of labor. J Perinatol. 1986;6:16–19.

32. Lyndrup J, Legarth J, Dahl C, Philipsen T, Eriksen PS. Lamicel does not promote induction of labour. A randomized con- trolled study. Eur J Obstet Gynecol Reprod Biol. 1989;30(3): 205–208.

33. Lin A, Kupferminc M, Dooley SL. A randomized trial of extra-amniotic saline infusion versus laminaria for cervical ripening. Obstet Gynecol. 1995;86(4):545–549.

34. Heinemann J, Gillen G, Sanchez-Ramos L, Kaunitz AM. Do mechanical methods of cervical ripening increase infectious morbidity? A systematic review. Am J Obstet Gynecol. 2008;199 (2):177–187.

35. Kazzi GM, Bottoms SF, Rosen MG. Efficacy and safety of laminaria digitata for preinduction ripening of the cervix. Obstet Gynecol. 1982;60(4):440–443.

36. Sierra T, Figueroa MM, Chen KT, Lunde B, Jacobs A. Hyper-sensitivity to laminaria: a case report and review of literature. Contraception. 2015;91(4):353–355.

37. Atad J, Bornstein J, Calderon I, Petrikovsky BM, Sorokin Y, Abramovici H. Nonpharmaceutical ripening of the unfavorable cervix and induction of labor by a novel double balloon device. Obstet Gynecol. 1991;77(1):146–152.

38. Atad J, Hallak M, Auslender R, Porat-Packer T, Zarfati D, Abramovici H. A randomized comparison of prostaglandin E2, oxytocin, and the double balloon device in inducing labor. Obstet Gynecol. 1996;87(2):223–227.

39. Suffecool K, Rosenn B, Kam S, Mushi J, Foroutan J, Herrera K. Labor induction in nulliparous women with an unfavorable cervix: double balloon catheter versus dinoprostone. J Perinat Med. 2014;42(2):213–218.

40. Shechter-Maor G, Haran G, Sadeh-Mestechkin D, Ganor-Paz Y, Fejgin MD, Biron-Shental T. Intra-vaginal prostaglandin E2 versus double balloon catheter for labor induction in term oligohydramnios. J Perinat. 2015;35(2):95–98.

41. Pennell CE, Henderson JJ, O'Neill MJ, McCleery S, Doherty DA, Dickinson JE. Induction of labour in nulliparous women with an ufavourable cervix: a randomised controlled trial compar- ing double and single balloon catheters and PGE2 gel. BJOG. 2009;116(11):1443–1452.

42. Salim R, Zafran N, Nachum Z, Garmi G, Kraiem N, Shalev E. Single balloon compared with double balloon catheters for induction of labor. Obstet Gynecol. 2011;118(1):79–86.

43. Grobman WA, Rice MM, Reddy UM, Tita AT, Silver RM, Mallett G, Hill K, Thom EA, El-Sayed YY, Perez-Delboy A, Rouse DJ. Labor induction versus expectant management in low-risk nulliparous women. New England Journal of Medicine. 2018 Aug 9;379(6):513-23.

44. Saad AF, Villarreal J, Eid J, Spencer N, Ellis V, Hankins GD, Saade GR. A randomized controlled trial of Dilapan-S vs Foley balloon for preinduction cervical ripening (DILAFOL trial). American journal of obstetrics and gynecology. 2019 Mar 1;220(3):275-e1.

45. Gupta J, Chodankar R, Baev O, Bahlmann F, Brega E, Gala A, Hellmeyer L, Hruban L, Maier J, Mehta P, Murthy A. Synthetic osmotic dilators in the induction of labour—An international multicentre observational study. European Journal of Obstetrics & Gynecology and Reproductive Biology. 2018 Oct 1;229:70-5.

46. Shindo R, Aoki S, Yonemoto N, Yamamoto Y, Kasai J, Kasai M, Miyagi E. Hygroscopic dilators vs balloon catheter ripening of the cervix for induction of labor in nulliparous women at term: Retrospective study. PloS one. 2017 Dec 22;12(12):e0189665.

ANNEXURES

ANNEXURE 1 : ETHICAL COMMITTEE APPROVAL FORM

GOVERNMENT STANLEY MEDICAL COLLEGE & HOSPITAL,CHENNAI -01

INSTITUTIONAL ETHICS COMMITTEE

TITLE OF THE WORK	: COMPARATIVE STUDY OF HYGROSCOPIC DILATORS VERSUS FOLEYS BALLOON CATHETER FOR INDUCTION OF LABOUR AND ITS OUTCOME - PROSPECTIVE STUDY
PRINCIPAL INVESTIGATOR	: DR. S. SARANYA,
DESIGNATION	: PG IN MS (O&G),
DEPARTMENT	: DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY , GOVT. STANLEY MEDICAL COLLEGE.

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 07.12.2018 at the Council Hall, Stanley Medical College, Chennai-1 at 10am.

The members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.

The Principal investigator and their team are directed to adhere to the guidelines given below:

1. You should inform the IEC in case of changes in study procedure, site investigator investigation or guide or any other changes.
2. You should not deviate from the area of the work for which you applied for ethical clearance.
3. You should inform the IEC immediately, in case of any adverse events or serious adverse reaction.
4. You should abide to the rules and regulation of the institution(s).
5. You should complete the work within the specified period and if any extension of time is required, you should apply for permission again and do the work.
6. You should submit the summary of the work to the ethical committee on completion of the work.

MEMBER SECRETARY
IEC, SMC, CHENNAI
12/12/18

ANNEXURE II : PROFORMA

NAME	:
AGE	:
IP NO	:
D.O.A	:
D.O.DELIVERY	:
D.O.DISCHARGE	:
LMP	:
EDD	:
OBSTETRIC CODE	:
GESTATIONAL AGE	:
ADDRESS AND CONTACT NO	:
PRESENTING COMPLAINTS	:
MODIFIED BISHOP'S SCORE	:
DATE AND TIME OF INDUCTION	:
INDICATION FOR INDUCTION	:
HYGROSCOPIC DILATORS/ FOLEYS	:
OUTCOME OF INDUCTION	:
MODE OF DELIVERY	:
IF LSCS INDICATION FOR LSCS	:
BABY WEIGHT	:
BABY SEX	:
APGAR	:
DATE AND TIME OF DELIVERY	:
INDUCTION DELIVERY INTERVAL	:

ANNEXURE III : CONSENT FORM

I agree to participate in the study entitled

COMPARATIVE STUDY OF HYGROSCOPIC DILATORS VERSUS FOLEYS BALLOON CATHETER FOR INDUCTION OF LABOUR AND ITS OUTCOME- PROSPECTIVE STUDY

I confirm that I have been told about this study in my mother tongue and have had the opportunity to clarify my doubts.

I understand that my participation is voluntary and I may refuse to participate at any time without giving any reasons and without affecting my benefits.

I agree not to restrict the use of any data or results that arise from this study.

Name of the Participant :

Sign / Thumb Print :

Name of the Investigator : **Dr. S. SARANYA**

Sign of Investigator :

தகவல் படிவம்

ஸ்டான்லி மருத்துவமனையின் ஆர்.எஸ்.ஆர்.எம். மருத்துவமனையில் மகப்பேறு மற்றும் பெண்கள் நல மருத்துவ துறையில் மேற்கொள்ளப்படும் ஆய்வு தொடர்பான தகவல் படிவம் இது.

இந்த ஆய்வு, அனுபவம் வாய்ந்த மருத்துவர்களின் உதவியோடு நடத்தப்படுகிறது. கர்ப்பிணிப் பெண்களுக்கு ஹைக்ரோஸ்பிக் டையலேட்டர் (Hygroscopic Dilator) அல்லது ஃபோலி கெத்தீட்டர் (Foley Catheter) மூலம் பிரசவ வலி உண்டாக்கி ஆய்வு மேற்கொள்ளப்பட்டது.

ஒப்புதல் படிவம்

நான் _____ யாரிடமிருந்தும் எந்தவொரு நிர்ப்பந்தமும் இல்லாமல் எனது இயல்பான மனநிலையில் முழுமனதுடன் ஆய்வின் ஒரு பகுதியாக இருப்பதற்கு எனது சம்மதத்தை அளிக்கிறேன். ஆய்வு மற்றும் அதன் தாக்கம் குறித்து எனக்கு விளக்கமளிக்கப்பட்டது. இந்த படிவத்தில் கையொப்பமிடுவதன் மூலம் இந்த ஆய்வில் பங்கேற்க ஒப்புக்கொள்கிறேன்.

மருத்துவரின் அடையாளம்:

நோயாளியின் அடையாளம்:

நாள்:

ANNEXURE – IV : MASTER CHART FOR FOLEY'S CATHETER

S.NO	NAME	AGE	OBSTETRIC CODE	GA	INDICATION FOR INDUCTION	MODE OF DELIVERY	INDICATION OF LSCS	B.WT	APGAR 1' 5'	PRE INSERTION BISHOP SCORE	INSERTION DELIVERY INTERVAL	INDUCTION DELIVERY INTERVAL	POST INSERTION BISCHOP SCORE	PGE2 DOSE
1	MAHESWARI	20	G2A1	40W2D	POST DATED	LABOUR NATURAL		2.700KG	7/10 8/10	3	34 HRS 42MIN	8 HRS 22 MIN	5	1
2	NIVETHA	20	G3P2L2	38W2D	TERM/GDM	LABOUR NATURAL		2.785KG	7/10 8/10	4	18HRS 24 MIN	3 HRS 25 MIN	6	1
3	AMUDHA	19	PRIMI	40W	OLIGO	LABOUR NATURAL		3.215KG	7/10 8/10	2	41 HRS 14 MIN	17 HRS 14 MIN	5	2
4	DEEPA	25	PRIMI	37W6D	GHTN	EMERGENCY LSCS	FAILURE TO PROGRESS	2.980 KG	7/10 8/10	2'	13HRS 53MIN		7'	-
5	MAHA	22	PRIMI	40W	OLIGO	EMERGENCY LSCS	CPD IN LABOUR	2.590KG	5/10 8/10	1	37 HRS 15MIN	22HRS 15MIN	5	2
6	MAHALAKSHMI	24	PRIMI	39W2D	OLIGO	LABOUR NATURAL	-	3.015 KG	7/10 8/10	2	11 HRS 29 MIN		5	-
7	KAVITHA SELVI	18	PRIMI	40W2D	GHTN	LABOUR NATURAL	-	3.270KG	7/10 8/10	1	26 HRS 22MIN	-	6	-
8	VIJAYALAKSHMI	22	G2P1L1	39W2D	OLIGO	LABOUR NATURAL	-	2.960KG	7/10 8/10	2	26 HRS 22MIN	-	6	-
9	GAYATHRI	22	PRIMI	40W3D	POST DATED	LABOUR NATURAL		3.5KG	7/10 8/10	1	25 HRS 25MIN	7 HRS 55MIN	4	1
10	ROSY	25	PRIMI	39W3D	OLIGO	EMERGENCY LSCS	FETAL ALARM SIGNAL /IUGR/ OLIGO	1.785 KG	7/10 8/10	2	10 HRS 52MIN	-		-
11	SALMA	19	G5P1L1A3	40W2D	POST DATED / GDM ON MEALPLAN	LABOUR NATURAL		3.110 KG	7/10 8/10	2	16 HRS 20MIN	-	7	-

S.NO	NAME	AGE	OBSTETRIC CODE	GA	INDICATION FOR INDUCTION	MODE OF DELIVERY	INDICATION OF LSCS	B.WT	APGAR 1' 5'	PRE INSERTION BISHOP SCORE	INSERTION DELIVERY INTERVAL	INDUCTION DELIVERY INTERVAL	POST INSERTION BISCHOP SCORE	PGE2 DOSE
12	SURYA	23	PRIMI	38W5D	OLIGO	LABOUR NATURAL	-	2.01KG	7/10 8/10	1	33 HRS 40MIN	9 HR 40 MIN	5	1
13	RATHI MEENA	21	G2A1	38W2D	GHTN	LABOUR NATURAL	-	3.045 KG	7/10 8/10	2	28 HRS 15MIN	-	6	-
14	LOGESHWARI	20	PRIMI	38W3D	GHTN/ OLIGO	LABOUR NATURAL		2.40 KG	7/10 8/10	1	28 HRS 18 MIN	4 HRS 18 MIN	5	1
15	JEYALAKSHMI	32	PRIMI	38W4D	PRIM / OLIGO	EMERGENCY LSCS	FETAL ALAM SIGNAL / OLIGO	2.860KG	7/10 8/10	2	15 HRS 44 MIN	-	6	-
16	DHIVYA	20	PRIMI	40W2D	POST DATED	LABOUR NATURAL		2.685KG	7/10 8/10	3	18 HRS 25 MIN	8HRS 39MIN	5	1
17	VIJAYALAKSHMI	25	PRIMI	40W3D	POST DATED	LABOUR NATURAL	-	2.870KG	7/10 8/10	2	22 HRS 30MIN	7HRS 40 MIN	4	1
18	ABIRAMI	27	PRIMI	38W2D	OLIGO	EMERGENCY LSCS	PRIMI / FAILED INDUCTION	2.490 KG	7/10 8/10	2	32 HRS 3 MIN	7 HRS 30MIN	5	1
19	REVATHI	24	PRIMI	37W6D	GHTN / IUGR	EMERGENCY LSCS	FAILED INDUCTION	1.835 KG	7/10 8/10	2	36HRS 40MIN	10 HRS 30 MIN	5	1
20	HEMAVATHY	26	G2A1	39W2D	OLIGO	LABOUR NATURAL		3.065 KG	7/10 8/10	1	33 HRS 58 MIN	8 HRS 58 MIN	5	1
21	SIVASANKARI	23	PRIMI	40W2D	POST DATED	OUTLET FORCEPS	-	4.120 KG	7/10 8/10	2	26HRS 50MIN	6 HRS 50 MIN	4	1
22	RAMYA	22	PRIMI	40W3D	TERM / POST DATED	EMERGENCY LSCS	PRIMI/ FAILURE TO PROGREES	3.23KG	7/10 9/10	2	38 HRS 30 MIN	14 HRS 15MIN	5	2
23	RADHIKA	22	G2P1L1	40W2D	POST DATED	LABOUR NATURAL		2.520KG	7/10 8/10	3	24 HRS 58 MIN	5 HRS 58 MIN	5	1

S.NO	NAME	AGE	OBSTETRIC CODE	GA	INDICATION FOR INDUCTION	MODE OF DELIVERY	INDICATION OF LSCS	B.WT	APGAR 1' 5'	PRE INSERTION BISHOP SCORE	INSERTION DELIVERY INTERVAL	INDUCTION DELIVERY INTERVAL	POST INSERTION BISCHOP SCORE	PGE2 DOSE
24	SARITHA	24	PRIMI	38W25D	GHTN	EMERGENCY LSCS	FAILED INDUCTION	2.97 KG	7/10 8/10	2	28 HRS 20 MIN	7 HRS 20 MIN	4	1
25	KANAGESHWARI	18	PRIMI	39W	GHTN	LABOUR NATURAL		2.630 KG	7/10 8/10	2	5 HRS 47MIN	-	8	-
26	RADHA	20	PRIMI	39W2D	OLIGO	LABOUR NATURAL	-	2.92 KG	7/10 8/10	2	31 HRS 37 MIN	11 HRS 37 MIN	4	1
27	NIRMALA	22	G3P2L2A1	40W2D	POST DATED	LABOUR NATURAL	-	2.740 KG	7/10 8/10	2	7 HRS 46MIN	-	6	-
28	RESHMA	19	PRIMI	40W3D	POST DATED	EMERGENCY LSCS	FAILURE TO PROGRESS	3.175KG	7/10 8/10	3	46 HRS 39MIN	24 HRS 15 MIN	5	2
29	ISHWARYA	19	PRIMI	38W6D	OLIGO	LABOUR NATURAL	-	2.375 KG	7/10 8/10	2	29 HRS 17MIN	5 HRS 17 MIN	5	1
30	SHARMILA	23	PRIMI	38W2D	GDM	LABOUR NATURAL	-	2.320 KG	7/10 8/10	3	41 HRS 20MIN	17 HRS 20MIN	4	2
31	MOHANA	20	G2A1	38W3D	GHTN	EMERGENCY LSCS	FAILURE TO PROGRASS	3.240 KG	6/10 7/10	2	32 HRS 39MIN	8HRS 39MIN	4	1
32	SANDHYA	33	G3P1L1A1	38W	GDM ON INSULIN	LABOUR NATURAL	-	2.835KG	3/10 7/10	2	23 HRS 49MIN	10 HRS 49 MIN	5	1
33	FARITHA	29	PRIMI	38W2D	GHTN	EMERGENCY LSCS	MSAF / FETAL DISTRESS	2.455 KG	6/10 7/10	2	6 HRS 59MIN	-	7	-
34	DEEPA	19	G2P1L1	40W3D	POST DATED	LABOUR NATURAL	-	2.070KG	7/10 8/10	2	17 HRS 30MIN	7 HRS 30MIN	5	1
35	SANMUGAPRIYA	30	PRIMI	39W2D	OLIGO	LABOUR NATURAL	-	3.245KG	7/10 8/10	3	26 HRS 49MIN	-	6	-
36	SANGEETHA	26	PRIMI	38W3D	GHTN	LABOUR NATURAL	-	3.010 KG	7/10 8/10	1	28HRS 38MIN	11 HRS 20 MIN	4	1

S.NO	NAME	AGE	OBSTETRIC CODE	GA	INDICATION FOR INDUCTION	MODE OF DELIVERY	INDICATION OF LSCS	B.WT	APGAR 1' 5'	PRE INSERTION BISHOP SCORE	INSERTION DELIVERY INTERVAL	INDUCTION DELIVERY INTERVAL	POST INSERTION BISCHOP SCORE	PGE2 DOSE
37	NAGAVALLI	20	PRIMI	38W5D	OLIGO	LABOUR NATURAL	-	2.570 KG	7/10 8/10	3	26 HRS 40MIN	7HRS 40 MIN	4	1
38	SHENBAGAVALLI	20	PRIMI	38W4D	OLIGO	LABOUR NATURAL	-	2.8KG	7/10 8/10	2	30HRS 5MIN	6 HRS 35 MIN	5	1
39	CHARUMATHY	26	PRIMI	38W	GHTN	EMERGENCY LSCS	FAILED INDUCTION	3.670 KG	7/10 8/10	2	24 HRS 36MIN	9 HRS 36MIN	5	1
40	PRIYA	20	PRIMI	38W2D	OLIGO	LABOUR NATURAL	-	2.745KG	7/10 8/10	3	24 HRS	11 HRS 30 MIN	4	1
41	VELLAKSHMI	21	G2P1L1	40W3D	POST DATED	LABOUR NATURAL	-	2.390 KG	7/10 8/10	2	12 HRS 15MIN		5	-
42	BANU	30	G2P1L1	39W	OLIGO	LABOUR NATURAL	-	2.650 KG	7/10 8/10	2	9 HRS 26MIN		7	-
43	VINODHINI	24	PRIMI	40W2D	POST DATED	LABOUR NATURAL		3.510 KG	7/10 8/10	2	26 HRS 10 MIN	4 HRS 2 MIN	5	1
44	GANDHIMATHI	32	G2P1L1	38W3D	GHTN	LABOUR NATURAL		1.985KG	7/10 8/10	2	18 HRS 6MIN	8 HRS 2 MIN	5	1
45	RAMYA	26	G2P1L1	38W3D	OLIGO	LABOUR NATURAL	-	3.245KG	7/10 8/10	2	28 HRS 6MIN	6 HRS 14 MIN	5	1
46	KOKILA	30	G3A2	38W2D	GDM	LABOUR NATURAL	-	2.400KG	7/10 8/10	3	26 HRS 14MIN	7 HRS 8 MIN	4	1
47	AYESHA	21	G2P1L1	38W	GDM	LABOUR NATURAL	-	3.045KG	7/10 8/10	2	23 HRS 49MIN	5HRS 17 MIN	5	1
48	DHIYABARATHY	20	PRIMI	40W3D	POST DATED	LABOUR NATURAL	-	2.670 KG	7/10 8/10	2	24 HRS 17MIN	6HRS 42MIN	5	1
49	DURGADEVI	25	PRIMI	40W3D	POST DATED	EMERGENCY LSCS	THICK MSAF	3.350 KG	7/10 8/10	2	23 HRS 12MIN	9 HRS	4	1
50	JAYALAKSHMI	21	G2P1L1	40W3D	POST DATED	LABOUR NATURAL	-	2.850 KG	7/10 8/10	3	9 HRS 35MIN	-	7	-

S.NO	NAME	AGE	OBSTETRIC CODE	GA	INDICATION FOR INDUCTION	MODE OF DELIVERY	INDICATION OF LSCS	B.WT	APGAR 1' 5'	PRE INSERTION BISHOP SCORE	INSERTION DELIVERY INTERVAL	INDUCTION DELIVERY INTERVAL	POST INSERTION BISCHOP SCORE	PGE2 DOSE
51	RESHMA	20	G2A1	40W3D	POST DATED	LABOUR NATURAL	-	2.850 KG	7/10 8/10	2	29HRS 20MIN	5HRS 20MIN	5	1
52	MALATHY	31	G3P2L2	40W3D	POST DATED	LABOUR NATURAL	-	3.275 KG	7/10 8/10	3	18 HRS 10MIN		6	-
53	THILAGAVATHY	22	PRIMI	40W3D	POST DATED	LABOUR NATURAL	-	1.9 KG	7/10 8/10	3	20 HRS 5MIN	8HRS 12MIN	5	1
54	MANJULA	22	G2A1	40W3D	POST DATED	LABOUR NATURAL	-	2.735KG	7/10 8/10	1	40 HRS 5MIN	10HRS	4	1
55	HEMALATHA	20	PRIMI	40W3D	POST DATED	EMERGENCY LSCS	THICK MSAF	3.035KG	7/10 8/10	1	31 HRS 55MIN	9 HRS 15MIN	4	1
56	NAGEEMA	18	G2P1L1	39W	OLIGO	LABOUR NATURAL	-	3.33 KG	7/10 8/10	2	19 HRS 56MIN	6 HRS 15 MIN	4	1
57	DEEPIKA	23	PRIMI	40W3D	POST DATED	LABOUR NATURAL	-	2.20 KG	7/10 8/10	2	28 HRS 15MIN	-	4	-
58	BANU	21	PRIMI	40W3D	POST DATED	EMERGENCY LSCS	CPD IN LABOUR	2.79 KG	7/10 8/10	2	9 HRS 21MIN	-	7	-
59	KAVITHA SELVI	20	PRIMI	40W3D	POST DATED	LABOUR NATURAL	-	3.5 KG	7/10 8/10	3	30 HRS 10MIN	8 HRS 30 MIN	5	1
60	NIVETHA	21	PRIMI	40W3D	POST DATED	EMERGENCY LSCS	CPD IN LABOUR	3.145 KG	7/10 8/10	3	23 HRS 55MIN	-	6	-

ANNEXURE V – MASTER CHART FOR HYGROSCOPIC CATHETER

S.NO	NAME	AGE	OBSTETRIC CODE	GA	INDICATION FOR INDUCTION	MODE OF DELIVERY	INDICATION OF LSCS	B.WT	APGAR 1' 5'	PRE INSERTION BISHOP SCORE	NO OF RODS	INSERTION DELIVERY INTERVAL	INDUCTION DELIVERY INTERVAL	POST INSERTION BISHOP SCORE	PGE2
1	BAGYASHREE	21	G2A1	40W+1 D	POST DATED/GDM	LABOUR NATURAL	-	2.715 KG	7/10 8/10	2/13'	2’	24 HRS	10 HRS 34 MIN	5/13’	1
2	SANDHYA	24	G2P1L1	40W+3 D	POST DATED	LABOUR NATURAL	-	3.57KG	7/10 8/10	2/13'	2’	19HRS	4 HRS 5IN	5/13’	1
3	YASOODA	22	PRIMI	37W+5 D	GDM ON INSULIN /GHTN	EMERGENCY LSCS	CPD IN LABOUR	3.58KG	6/10 8/10	2/13'	1’	26 HRS	-	5/13’	2
4	KUMARI	23	PRIMI	37W+5 D	TERM / IUGR	EMERGENCY LSCS	FAILED INDUCTION	2.095KG	7/10 8/10	1/13'	1’	37 HRS	18 HRS	5/13’	2 -
5	MAHALAKSHMI	24	G2P1L1	40W+3 D	POST DATED	LABOUR NATURAL	-	3.09KG	6/10 8/10	3/13'	2	4HRS	-	5/13’	-
6	SHALINI	25	PRIMI	40W	RH NEG	LABOUR NATURAL	-	2.84KG	8/10 9/10	2/13'	1	20 HRS	-	6/13’	-
7	DIVYA	29	G2P1L1	37W	OLIGO/ GHTN	LABOUR NATURAL	-	2.47KG	7/10 8/10	2/13'	1	21HRS 33MIN	6HRS 33MIN	5/13’	1
8	SANDHIYA	24	G2P1L1	40W	RH REG	LABOUR NATURAL	-	2.81KG	7/10 8/10	2/13'	2	26HRS 28MIN	8 HRS 23 MIN	5/13’	1
9	PRIYA	24	PRIMI	40W+3 D	POST DATED	VACCUM DELIVERY	-	2.9KG	3/10 7/10	1/13'	1	37HRS	22 HRS	4/13’	2
10	ANAND JOTHI	30	G3P2L2	40W+3 D	POST DATED	LABOUR NATURAL	-	3.958KG	7/10 8/10	2/13'	2	15HRS 15MIN	-	6/13’	-
11	MARIYAMMA	22	PRIMI	40W+3 D	POST DATED	LABOUR NATURAL	-	3.515KG	7/10 8/10	2/13'	1	28 HRS 15MIN	9 HRS 17 MIN	4/13’	1

S.NO	NAME	AGE	OBSTETRIC CODE	GA	INDICATION FOR INDUCTION	MODE OF DELIVERY	INDICATION OF LSCS	B.WT	APGAR 1' 5'	PRE INSERTION BISHOP SCORE	NO OF RODS	INSERTION DELIVERY INTERVAL	INDUCTION DELIVERY INTERVAL	POST INSERTION BISHOP SCORE	PGE2
12	KOWSALYA	22	PRIMI	40W+3 D	POST DATED	LABOUR NATURAL	-	3.05KG	7/10 8/10	2/13'	1	16 HRS 15MIN	4HRS 14 MIN	5/13 '	1
13	PRIYANKA	23	PRIMI	40W+3 D	POST DATED	LABOUR NATURAL	-	2.71KG	7/10 8/10	5/13'	2	18 HRS	6 HRS 17 MIN	5/13 '	1
14	SHARMILA	24	PRIMI	40W+3 D	POST DATED	EMERGENCY LSCS	MSAF/ FETAL DISTRESS	2.85KG	7/10 8/10	2/13'	1	20 HRS	2 HRS 19 MIN	5/13 '	1
15	PRIYA	24	G2P1L1	40W+3 D	POST DATED	LABOUR NATURAL	-	3.035K G	7/10 8/10	2/13'	3	17HRS 47MIN	3 HRS 47MIN	6/13 '	1
16	SYED ALI FATHIMA	23	G2P1L1	40W+1 D	OLIGO/POST DATED	OUTLET FORCEPS	-	3.035K G	7/10 8/10	2/13'	3	21 HRS54MIN	6HRS 54 MIN	5/13 '	1
17	VASANTHA	30	G3P1L1	39W	OLIGO	LABOUR NATURAL	-	2.785K G	7/10 8/10	3/13'	3	19 HRS 54 MIN	7 HRS 54 MIN	5/13 '	1
18	RAJAESWARI	24	G2A1	38W	OVERT DM	EMERGENCY LSCS	FAILURE TO PROGRESS	3.33KG	7/10 8/10	1/13'	1	33 HRS	21 HRS	4/13 '	3
19	KARTHIGA	26	G2P1L1	40W 3D	POST DATED	LABOUR NATURAL	-	3.485K G	7/10 8/10	2/13'	2	20 HRS	8 HRS	5/13 '	1
20	CHARUMATHI	26	PRIMI	39W	GDM/GHTN	EMERGENCY LSCS	FAILED INDUCTION	3.67KG	7/10 8/10	2/13'	1	27HRS	15 HRS	3/13 '	2
21	DEEPA	21	G2P1L1	38W	OVERT DM	LABOUR NATURAL	-	2.63KG	7/10 8/10	3/13'	3	17 HRS	-	6/13 '	-
22	YASODHA	22	PRIMI	40W+3	POST DATED	EMERGENCY LSCS	FAILURE TO PROGRESS	3.38KG	7/10 8/10	2/13'	1	28HRS	16HRS	4/13 '	2
23	ANANDHI	21	G2P1L1	40W+3 D	POST DATED	LABOUR NATURAL		3.18KG	7/10 8/10	2/13'	1	20 HRS	8HRS	4/13 '	1
24	SIVAGAMI	28	G3P2L2	39W	GHTN	LABOUR NATURAL	-	2.94KG	7/10 8/10	3/13'	3	21 HRS	9 HRS	5/13 '	1

S.NO	NAME	AGE	OBSTETRIC CODE	GA	INDICATION FOR INDUCTION	MODE OF DELIVERY	INDICATION OF LSCS	B.WT	APGAR 1' 5'	PRE INSERTION BISHOP SCORE	NO OF RODS	INSERTION DELIVERY INTERVAL	INDUCTION DELIVERY INTERVAL	POST INSERTION BISHOP SCORE	PGE2
25	PREMA	25	G3P1L1A1	40W+3D	POST DATED	LABOUR NATURAL	-	2.91KG	7/10 8/10	3/13'	2	8 HRS 30MIN	-	5/13,	-
26	SUBULAKSHMI	31	G3A2	39W	OLIGO	LN	-	2.845	7/10 8/10	2/13.	2	15HR 30MITS	3HR 30MIT	5/13,	-
27	KALAISELVI	25	PRIMI	40+3	POST DATED	LN	-	3.065	6/10 7/10	1/13.	1	18HR	6HR 15MIN	3/13,	1
28	RAJALAKSHMI	20	PRIMI	40W	OLIGO	LN	-	2.805	7/10 8/10	2/13.	2	19HR 20MIN	7HR 10MIN	5/13,	1
29	SHAIBU NISHA	22	PRIMI	40+3	POST DATED	LN	-	2.805	7/10 8/10	2/13.	2	18HR 40MITS	6HR 57MIT	5/13,	1
30	SUNDARI	20	G2A1	38W	GHTN	LN	-	2.385	7/10 8/10	1/13.	1	23HR 47MITS	11HR 47MIT	3/13,	1
31	JAMUNA	23	PRIMI	40+3	POST DATED	VACCUM	-	2.46	7/10 8/10	1/13.	1	24HR 59MIT	12HR 59MIT	4/13,	2
32	SANDHIYA	33	G3P1L1A1	38+3	GDM ON INSULIN	LN	-	2.835	3/10 7/10	2/13.	2	23HR 49 MITS	9HR 49MIT	5/13,	1
33	ARIYAL	29	G4P1L1A2	39	OLIGO	LN	-	2.385	7/10 8/10	4/13.	3	21HR 30MITS	9HR 10MITS	6/13,	1
34	MARIYAL	24	PRIMI	40+3	POST DATED	LN	-	2.91	7/10 8/10	2/13.	1	19HR 50MITS	7HR 58MIT	4/13,	1
35	GRACY	27	PRIMI	40+3	POST DATED	LN	-	2.41	7/10 8/10	3/13.	1	20HR	8HR 45MIT	5/13,	1
36	GIRIJA	22	PRIMI	40	RH NEG	LN	-	2.22	7/10 8/10	4/13.	1	19HR	7HR 50MIT	4/13,	1
37	PRIYANKA	24	PRIMI	40+3	POST DATED	LN	-	2.75	7/10 8/10	3/13.	2	15HR 20MIT	3HR 18MITS	5/13,	1

S.NO	NAME	AGE	OBSTETRIC CODE	GA	INDICATION FOR INDUCTION	MODE OF DELIVERY	INDICATION OF LSCS	B.WT	APGAR 1' 5'	PRE INSERTION BISHOP SCORE	NO OF RODS	INSERTION DELIVERY INTERVAL	INDUCTION DELIVERY INTERVAL	POST INSERTION BISHOP SCORE	PGE2
38	GEETHA	24	PRIMI	40W	OLIGO	EMERGENCY LSCS	MSAF/ FETAL DISTRESS	2.31	7/10 8/10	2/13.	2	18HR	6H	5/13 '	1
39	RAMYA	31	G2P1L1	40+3	POST DATED	LN	-	2.9	7/10 8/10	4/13.	1	18HR 40MITS	10HR 37MIT	4/13 '	1
40	JAYAPRIYA	25	PRIMI	39W	OLIGO	LN	-	3.015	7/10 8/10	3/13.	1	19HR	7HR	6/13 '	1
41	PARAMESHWARI	21	PRIMI	40+3	POST DATED	EMERGENCY LSCS	FAILURE TO PROGRESS	2.54	7/10 8/10	2/13.	2	28HR	16HR	5/13 '	2
42	DANUJA	23	G2A1	39	OLIGO	LN	-	2.94	7/10 8/10	2/13.	2	21HR	9HR 5MITS	4/13 '	1
43	NANDHINI	25	PRIMI	40+3	POST DATED	EMERGENCY LSCS	CPD IN LABOUR	2.23	7/10 8/10	3/13.	2	19HR 11MIT	7HR 11MIT	4/13 '	1
44	SHYMALA	19	PRIMI	40+3	POST DATED	LN	-	2.715	7/10 8/10	4/13.	2	16HR	4HR 17MIT	5/13 '	1
45	SARANYA	26	PRIMI	40+3	POST DATED	LN	-	3.13	7/10 8/10	3/13.	1	17HR 45MIT	5HR 46MIT	6/13 '	1
46	DEVIKA	23	PRIMI	39	OLIGO	LN	-	2.43	6/10 7/10	3/13.	1	21 HR	9HR	5/13 '	1
47	MEENATCHI	24	PRIMI	40+3	POST DATED	LN	-	2.5	7/10 8/10	2/13.	1	19HR 27HR	7H 27MIT	5/13 '	1
48	PAVITHRA	23	PRIMI	40	OLIGO/GDM	LN	-	2.62	6/10 8/10	2/13.	1	23HR	11HR 22MIT	5/13 '	1
49	REKHA	19	PRIMI	38	GHTN	LN	-	2.44	7/10 8/10	3/13.	2	7HR 25MIT	5HR 25MIT	4/13 '	1
50	LAKSHMI	21	PRIMI	38	CHRONIC HTN	LN	-	3.08	7/10 8/10	3/13.	2	18HR 20 MITS	6HR 16MIT	5/13 '	1

S.NO	NAME	AGE	OBSTETRIC CODE	GA	INDICATION FOR INDUCTION	MODE OF DELIVERY	INDICATION OF LSCS	B.WT	APGAR 1' 5'	PRE INSERTION BISHOP SCORE	NO OF RODS	INSERTION DELIVERY INTERVAL	INDUCTION DELIVERY INTERVAL	POST INSERTION BISHOP SCORE	PGE2
51	KEERTHANA	19	PRIMI	40+3	POST DATED	LN		2.86	7/10 8/10	2/13.	1	21HR	9HR 46MIT	5/13,	1
52	INDIRA	26	PRIMI	40+3	POST DATED	LN		2.59	7/10 8/10	4/13.	2	16HR	4HR 35MIT	5/13,	1
53	HEMALATHA	20	PRIMI	38	GDM ON INSULIN	VACCUM	-	3.34	6/10 7/10	2./13.	1	19.HR 30MITS	7HR 30MIT	5/13,	1
54	MICHAEL SELVI	23	PRIMI	40+3	POST DATED	EMERGENCY LSCS	MSAF/ FETAL DISTRESS	2.265	5/10 7/10	3/13.	2	15HR	5HR	5/13,	1
55	JANCY	18	PRIMI	38	GHTN	LN		3.47	8/10 9/10	2/13.	1	19HR	7HR 15MIT	6/13,	1
56	LOGESHWARI	23	G2P1L1	40+3	POST DATED	LN	-	3.25	7/10 8/10	3/13.	2	13HR	7HR 34.MIT	5/13,	1
57	SUGANYA	21	G2A1	39	GDM	EMERGENCY LSCS	MSAF/ FETAL DISTRESS	2.3	5/10 7/10	4/13.	3	16HR	4HR 50MIT S	5/13,	1
58	SARASWATHI	26	G3P2L1A 1	38W	GHTN	LN		2.53	8/10 9/10	3/13.	1	18HR	6HR 15MIT	6/13,	1
59	MEENA	23	G2P1L1	40+3	POST DATED	LN	-	2.75	7/10 8/10	4/13.	2	10HR	4HR	5/13,	1
60	NAGALAKSHMI	24	PRIMI	40+3	POST DATED	EMERGENCY LSCS	MSAF/ FETAL DISTRESS	3.055	5/10 6/10	1/13.	1	19HR	7HR 30MIT	5/13,	1