EFFECT OF VAGINAL PH ON EFFICACY OF DINOPROSTONE GEL FOR LABOUR INDUCTION

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Prof. Dr. PONNAMBALA NAMASIVAYAM, MD., D.A., DNB.
Dean
Prof & Head of Department,
Stanley Medical College & Hospital,
Chennai – 600 001

Dr. K. KALAIVANI,
M.D., D.G.O., DNB.
Prof. & Head of the Department
Superintendent
Dept. of Obstetrics and Gynaecology
Government RSRM Lying In Hospital,
Stanley Medical College,
Chennai- 600 013

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This is to certify that this dissertation entitled "**EFFECT OF VAGINAL PH ON EFFICACY OF DINOPROSTONE GEL FOR LABOUR INDUCTION"** submitted by **Dr.H.HUMAIRA SAFRIN,** appearing for Part II MS, Branch II Obstetrics and Gynaecology Degree Examination in May 2018, 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.

Dr.V.RAJALAKSHMI, M.D.,D.G.O.
Associate Professor,
Dept. of Obstetrics and Gynecology
Government RSRM Lying In Hospital
Stanley Medical College, Chennai

DECLARATION

I, Dr. H. HUMAIRA SAFRIN, solemnly declare that the dissertation titled, "**EFFECT OF VAGINAL PH ON EFFICACY OF DINOPROSTONE GEL FOR LABOUR INDUCTION"** is a bonafide work done by me at R.S.R.M. Lying in Hospital. Stanley Medical College, Chennai – during December 2016–to September 2017 under the guidance and supervision of **Prof. Dr. K. Kalaivani M.D., D.G.O., DNB.,** Professor and Head of the department , 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.

Dr.H.HUMAIRA SAFRIN

Place : Chennai

Date :

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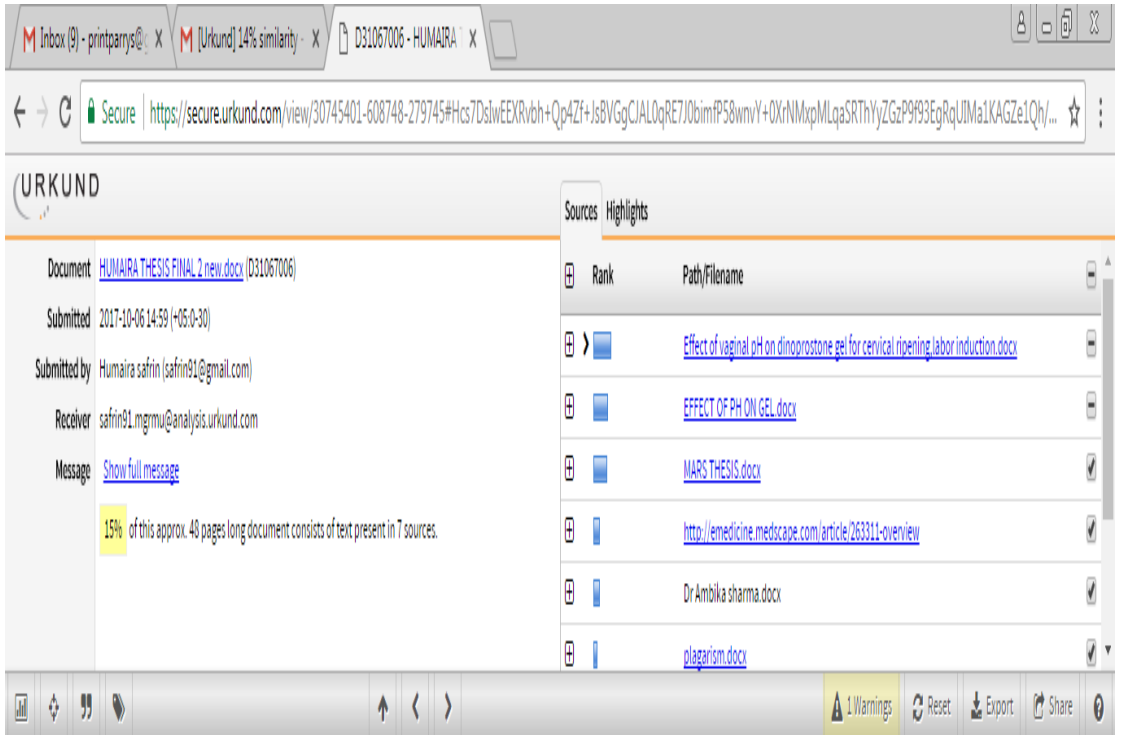
CONTENTS

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
E	EFFACEMENT
D	DILATATION
C	CONSISTENCY
P	POSITION
S	STATION
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 NATURALE
LSCS	LOWER SEGMENT CAESAREAN SECTION
EPI	EPISIOTOMY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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, membrane rupture without labour, 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.

AIM OF THE STUDY

1. To evaluate the influence of vaginal pH on the efficacy of PGE2 gel for cervical ripening/labour induction

2. To improve patient selection for PGE2 induction and reduce the incidence of failed induction with PGE2 gel.

3. To asses the labour outcome in induction with PGE2 by knowing the vaginal pH prior induction.

4. To asses whether vaginal pH itself has a significant effect on the Bishop score prior induction or not.

MATERIALS AND METHODS

METHODOLOGY

The Prospective study was conducted in Govt. RSRM Lying In Hospital, Chennai during the period of December 2016 to September 2017 after getting approval from the Institutional Ethical Committee.

100 patients who underwent induction of labour for various reasons were selected for the study and examined.

Before other examinations were performed, each participant underwent a speculum examination and **vaginal pH value was assessed by using pH indicator paper** (both broad & narrow spectrum).

The indicator paper was placed on the lateral vaginal wall between the two valves of Cusco's speculum until it became wet.

Colour change of the strip was immediately compared with the manufacturer's colorimetric scale and the finding was recorded.

A vaginal examination was then performed to determine the Bishop's score.

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 <5 is unfavourable that needs induction. All received intracervically placed PGE2 gel 0.5 mg

After ruling out all contraindications, All received intracervically placed PGE2 gel 0.5 mg . Following application the patient is instructed to remain recumbent for at least 30 minutes. The patient is then continuously monitored.

After 6 hrs depending on Bishop Score and uterine contraction either PGE2 gel was repeated (maximum 2 doses) or labour was augmented as per labour theatre protocol.

The differences between the groups with respect to age, parity, Bishop score prior induction, need for a second induction, time to enter into active phase of labour and the final mode of delivery were compared and analysed. The induction delivery interval, 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.

Inclusion criteria

(1) An unfavourable cervical Bishop score of ≤ 5,

(2) Singleton pregnancy with vertex presentation and no contraindication to vaginal delivery.

(3) Assuring fetal heart rate.

Exclusion criteria

(1) Known hypersensitivity to prostaglandins

(2) Placenta previa

(3) Suspected chorioamnionitis

(4) Parity of >3

(5) A previous caesarean delivery or a history of uterine surgery

(6) Previous attempted induction of labour for this pregnancy

(7) Cephalopelvic disproportion.

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 parameters

- 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
- Severe hydraminos
- Oligo hydraminos
- Gestational diabetes mellitus

- Abruptio 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 Structural abnormality
- Cephalopelvic disproportion major degree
- Abnormal fetal lie [transverse lie, oblique lie]
- Umbilical cord prolapse and cord presentation
- Placenta previa of major degree and vasa previa

- Previous classical Caesarean section or other transfundal uterine surgery.
- Previous Myomectomy entering the endometrial cavity.
- Contraindication specific to the inducing drug used.
- 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

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

MECHANICAL METHODS

- Osmotic dilators Laminaria 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
- ❖ Umbilical Cord Prolapse
- ❖ Hyperbilirubinemia

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 (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 (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 (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 never be left unattended.
- 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 (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 inducing agent used.
- 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 (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 (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 and there is now no excuse for being in doubt about this, thanks to the precision afforded by modern sonar techniques.

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 (10). 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 (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, 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 (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

In moderately or severely affected cases, where pregnancy has already reached the 34th week, induction of labour and delivery of the child in spite of prematurity is safer and more likely to be successful than intrauterine transfusion. The object of the induction is to get the child delivered so that it is available for exchange transfusion after birth and the timing will depend upon the likely severity of the disease.

MALFORMED FETUSES

The prolongation of pregnancy is profitless, and on grounds of humanity as well, pregnancy is better terminated. Besides it is better to deliver a small monster than a large one.

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 structural deformities and major degree cephalopelvic disproportions.

Disproportion that is more than borderline. It must have been made abundantly clear already that such treatment is little short of wanton folly rewarded with a high failure rate, a prohibitive fetal mortality and the likelihood of maternal morbidity.

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 major degree placenta previa, vasa previa, cord presentation and prolapsed, invasive 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 tumultuous 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 of 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 caeses.

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 (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.

STRUCTURE AND CLASSIFICATION

Prostaglandins are members of the eicosanoid family. They are synthesized from arachidonic acid. Each molecule has 20 carbon atoms with a cyclopentane ring and two side chains. The position of the side chain and number of multiple bonds determines the group identity and its action. Prostaglandins were designated PG1, PG2, PG3, based on the number of double bonds in the polyunsaturated fatty acids from which they are formed. They were initially divided into classes E and F because of their solubility in ether and phosphate buffer. Subsequently, they have been divided into ten main groups, A to I. The subscripts (alpha, beta) were then added (Van Dorp et al 1964; Bergstrom et al 1964).

METABOLISM

Arachidonic acid is metabolised by the enzyme Prostaglandin H Synthase (PGHS), formerly called fatty-acid cyclooxygenase. The release of arachidonic acid from glycerophospholipids in the plasma membrane has generally been regarded as being the rate-limiting step in prostaglandin biosynthesis (Rice 1995). Prostaglandins act through a number of G-protein coupled receptors. The final pathways involve intracellular cyclic AMP and intracellular calcium. While an increase in intracellular calcium is responsible for contraction, increase in cyclic AMP promotes relaxation. Thus, by modifying these pathways, PGE2 and PGI2 promote uterine quiescence. PGE2 in particular causes cervical ripening. On the other

hand, PGF2α causes uterine contractions. Prostaglandin is catabolised by the enzyme 15-OH PG dehydrogenase to its metabolites, several of which are bioactive. This enzyme is mainly localised in the chorion and prevents the prostaglandins from reaching the myometrium in the non-labouring state.

DISTRIBUTION IN NORMAL TISSUES

PGE2 is the main prostaglandin product of the fetal membranes. The inner membrane, the amnion, has the highest production rate (Olson et al 1993). PGE2 production by the amnion, chorion, and decidua is increased during labour (Olson et al 1993). Though PGE2 and F2α are detected in the amniotic fluid in all stages of gestation, the major increase occurs with the start of labour, and they continue to increase with dilatation of the cervix (MacDonald and Casey 1993). It has been shown that prostaglandin concentrations in amniotic fluid increase early in labour (<3 cm dilatation) before the active stage of labour is reached (Romero 1994).

Properties and clinical effects

In the same doses, compared to PGF2, PGE2 is 10 times more potent on the pregnant uterus (Keirse 1992). Because PGF2α needs to be administered in larger doses, it causes more side effects, gastrointestinal in

particular. Side effects include nausea, vomiting, diarrhoea, abdominal pain, chills and fever.

Preparations and dosages of prostaglandins currently available

PGE2	Vaginal gel	1 and 2 mg
	Endocervical gel	0.5 mg
	Timed-release vaginal insert	3 and 10mg
PGF2α	IM injection	250/125 mcg
Misoprostol	Oral, vaginal, rectal administration	25, 100 and 200 mcg

ROLE OF PROSTAGLANDINS IN LABOUR

The role of prostaglandins in labour includes softening of the cervix, induction of gap junctions (communication between smooth muscle cells through which conduction of electrophysiological stimuli occur) and direct stimulation of uterine contractions.

CERVICAL RIPENING

The first report of the use of prostaglandins in labour was the use of PGF2α by Karim et al in 1968. Embrey pioneered the use of PGE2 for induction of labour (Embrey 1969) and cervical ripening (Calder and Embrey 1971).

A number of functional and biochemical changes happen in the cervical connective tissue during pregnancy (Leppert 1995). Prostaglandins take part in this cervical ripening process, forming a complex network of pathways.

Prostaglandins act synergistically with interleukin-8 to stimulate the fibroblasts to produce hyaluronic acid (Ogawa et al 1998), which in turn alters the composition and structure of the cervix. Besides this, prostaglandins also have an effect on the uterine muscle, inducing contractions. Thus, prostaglandins are involved both in cervical ripening and subsequently, the process of labour.

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. (Husslein et al 1983).

PROSTAGLANDIN E2

ROUTES OF ADMINISTRATION

EXTRA-AMNIOTIC

The effects of prostaglandins on the cervix were initially studied by extra-amniotic infusion of prostaglandins. As less invasive and equally

effective routes of administration came into use, this route for administering prostaglandins has been abandoned.

ORAL TABLETS

Oral prostaglandin E2 is no more effective than oxytocin for induction of labour but the gastrointestinal side effects, particularly vomiting, has been shown to be higher (Keirse and van Oppen 1989).

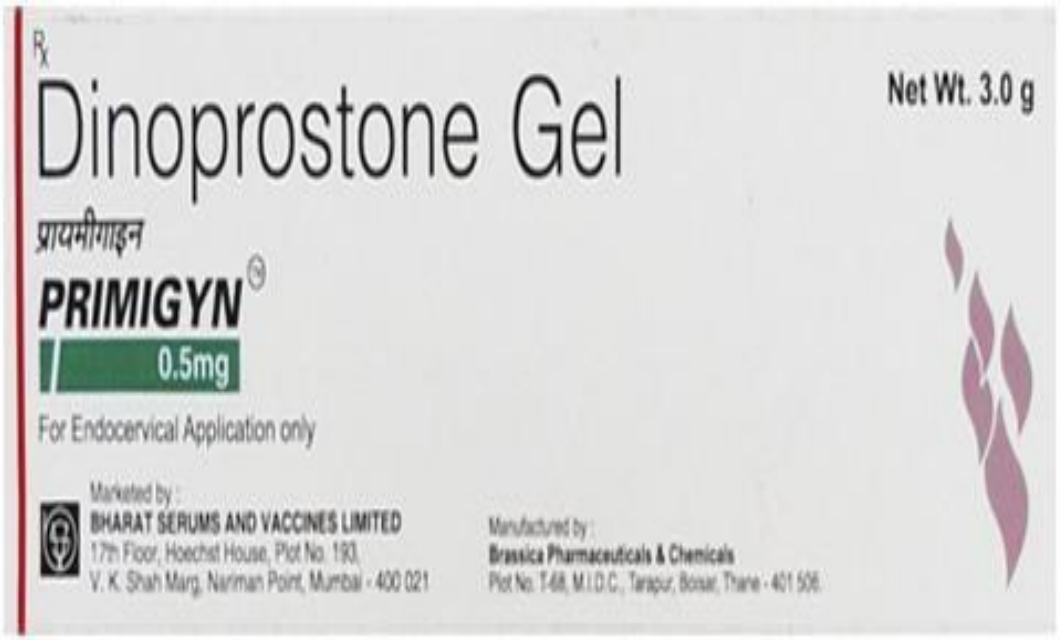
This route is no longer used for the induction of labour.

INTRACERVICAL PGE2

As gel preparation has been widely used and studied. Its usage for cervical ripening is widespread (ACOG 2009). The gel from is available in a 2.5 ml pre-loaded syringe for intracervical application. It contains 0.5 mg of dinoprostone. With the woman in a dorsolithotomy position, the cervix is exposed. The tip of the cannula, which is attached to the prefilled syringe, is inserted gently into the internal os. The gel is then instilled into the cervix. The patient is kept in a reclining position for the next 30 minutes. The dose is repeated every 6 hours. A maximum cumulative dose of 1.5 mg of dinoprostone is recommended (three doses or 7.5 ml of gel) within a 24-hour period. It is good clinical practice to perform a pelvic examination and assess the state of the cervix before the next dose is instilled.

After inserting the gel, oxytocin infusion should be delayed for 6-12 hours, because the effect of prostaglandins may be heightened with oxytocin (ACOG 2009).

Intracervical PGE2 gel not only ripens the cervix, but also induces labour and reduces the risk of failed induction. About 40 percent of women do not need further induction of labour.



A COMPARATIVE STUDY OF INTRACEVICAL PGE2 WITH PLACEBO OR NO TREATMENT

In a metanalysis (Boulvain et al 2008), it was shown that compared to placebo, there was an increased chance of achieving vaginal delivery within 24 hours and a small but statistically insignificant reduction in the caesarean section rates when PGE2 was used. The finding was statistically

significant in a subgroup of women with intact membranes and unfavourable cervix. While there was an increase in hyper stimulation rate, there was no significant increase in fetal heart rate changes.

COMPARISON OF TWO DIFFERENT REGIMENS OF PROSTAGLANDIN E2 IN PREINDUCTION

CERVICAL RIPENING

Trials were too small to provide data for evidence of effectiveness between low and high dose of gels. In a study by Robert et al, a randomized clinical study was done to test the relative efficacy of 0.25 mg prostaglandin E2 (PGE2), repeated if necessary (group 1) compared to 0.50 mg PGE2 single dose(group 2) for cervical ripening. In group 1 (42 patients), the ripening process was repeated every day until spontaneous onset of labour occurred or augmentation with oxytocin was decided upon (for improved Bishop Score above 5, or maternal or fetal distress). In group 2 (42patients) the ones who had not got into labour 12 hours after the procedure were induced with oxytocin, irrespective of their cervical bishops score. In group 1, 28 patients experienced repeated maturations. Thirty patients had an induction of labour with oxytocin in group 2 and only 12 in group 1 ($P < 0.0001$). There were four failures of induction of labour in group 2 and none in group 1 ($P < 0.05$).

Three episodes of myometrial hyperstimulation occurred which required an emergency caesarean section for acute fetal distress in group 2 and none in group 1.

There were 8 caesarean sections in group 1and 13 in groups 2. The outcome of pregnancy was otherwise similar in both groups. When comparing induction of labour using either oxytocin versus PGE2 (vaginal or intracervical), induction with PGE2 was associated with (RCOG 2001):

- Increase in successful vaginal delivery within 24 hours
- Reduced caesarean section rate
- Reduced risk of the cervix remaining unfavourable at 24-48 hours post induction.
- Reduced use of epidural analgesia
- An increase in the number of women satisfied with the method.

MODIFIED BISHOP'S SCORE AND VAGINAL PH

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. 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'S SCORE (CALDER 1974)

	0	1	2	3
Dilatation(cm)	<1	1-2	2-4	>4
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.

VAGINAL PH

In general vagina maintains a pH between 3.8-4.8, which is influenced by frequency of coitus, presence of cervical mucus and the amount of vaginal transudate. The lactic acid produced from glycogen by lactobacillus present in vagina plays an important role in maintaining acidic Ph environment. A variety of factors can alter the normal vaginal pH. Several factors such as lower genital tract infection; bacterial vaginosis, rupture of membrane, douching etc can alter the vaginal pH. The acidity of the vagina may alter the release of the drug and this could result in variable clinical response. Prostaglandins are organic acids that have diminished solubility in aqueous solution with a low pH.

To summarize, the complex interactions of various cytokines bring about profound changes in the proteoglycans in the cervix which eventually leads to cervical ripening.

Recently, vaginal pH has been investigated as a potential factor influencing the efficacy of prostaglandins for cervical ripening and labour induction but the results have been conflicting. Studies have been conducted on the effects of vaginal pH on the efficacy of controlled-release PGE2 vaginal insert and PGE2 gel for cervical priming/labour induction in which overall vaginal pH seemed to influence the PGE2 release.

Nonetheless, the effect of vaginal pH on overall efficacy of the cervical ripening/labour induction with PGE2 has not been well studied.

The vaginal pH in pregnancy is known to be acidic and not much is known about the variations in vaginal pH throughout pregnancy. There are studies that mention that pH may change the degree of ionization of a drug and affect the absorption of the drug resulting in variable clinical responses.

Vaginal pH changes also has a role in preterm delivery which suggests that it has a role in influencing cervical ripening.

The purpose of this study is to evaluate the influence of vaginal pH on the efficacy of PGE2 gel for cervical ripening/labour induction which would improve patient selection for PGE2 induction and reduce the incidence of failed induction with PGE2.

PH INDICATOR STRIPS

RESULTS AND ANALYSIS

AGE

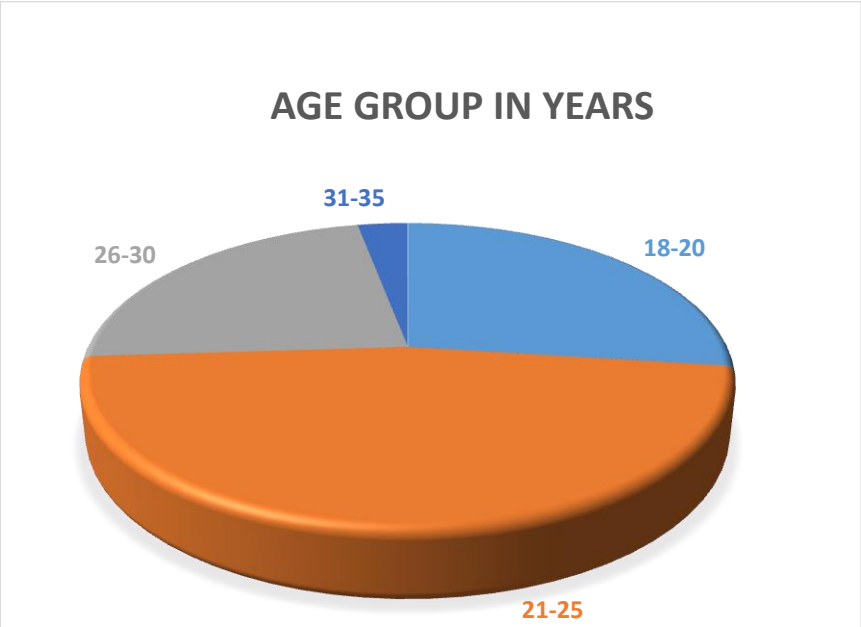
TABLE 1 : AGE DISTRIBUTION OF THE STUDY GROUP

Age Group in years	Frequency	Percent
18-20	27	27.0
21-25	47	47.0
26-30	23	23.0
31-35	3	3.0
Total	100	100.0

This table shows the age wise distribution of the study group. Majority (47 %)of the patients were in the age group of 21 to 25 years. The mean age of the study group was 23.49 years

CHART - 1

AGE DISTRIBUTION OF THE STUDY GROUP



GESTATIONAL AGE

TABLE : 2 GESTATIONAL AGE DISTRIBUTION OF THE STUDY GROUP

GESTATIONAL AGE IN WEEKS	FREQUENCY	PERCENT
UP TO 38	29	29.0
38-40	25	25.0
Above 40	46	46.0
Total	100	100.0

This table depicts the gestational age distribution of the study group. About 58 patients 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.

CHART - 2

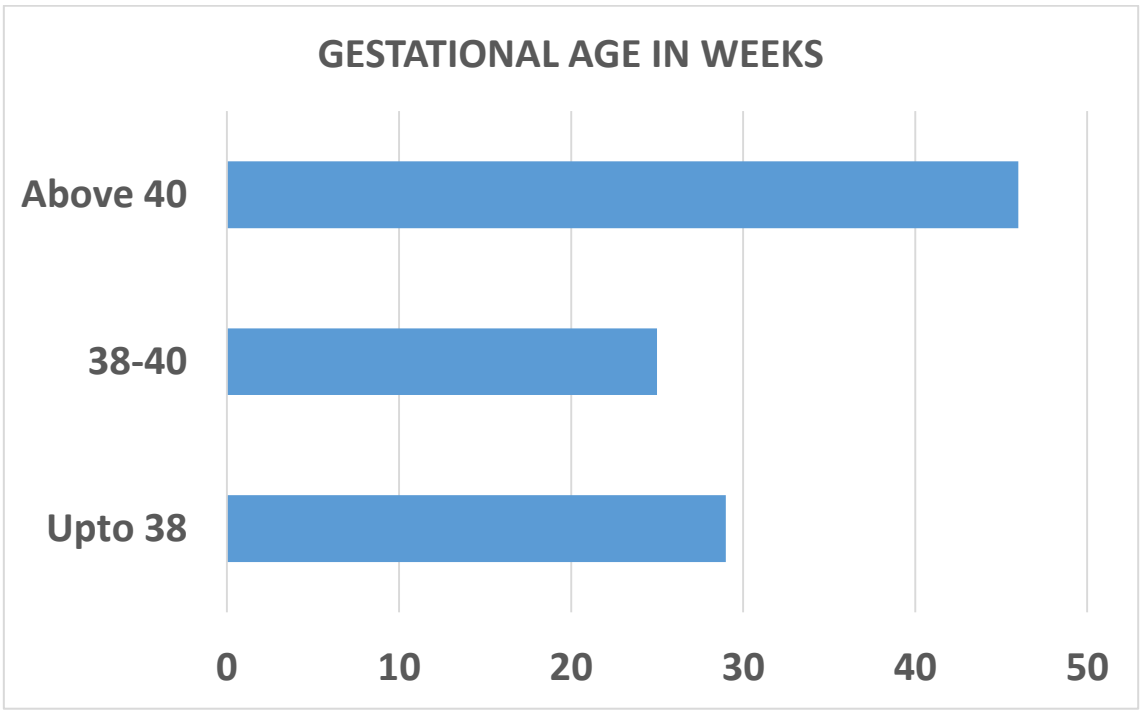


TABLE : 3 MODIFIED BISHOP'S SCORE DISTRIBUTION IN THE STUDY GROUP

Bishop Score	Frequency	Percent
1	7	7.0
2	32	32.0
3	43	43.0
4	17	17.0
5	1	1.0
Total	100	100.0

This table shows the distribution of Modified Bishop's Score in the study group. 43 patients had a pre-induction Modified Bishop's Score of 3. The median Modified Bishop's Score was 3.

CHART : 3

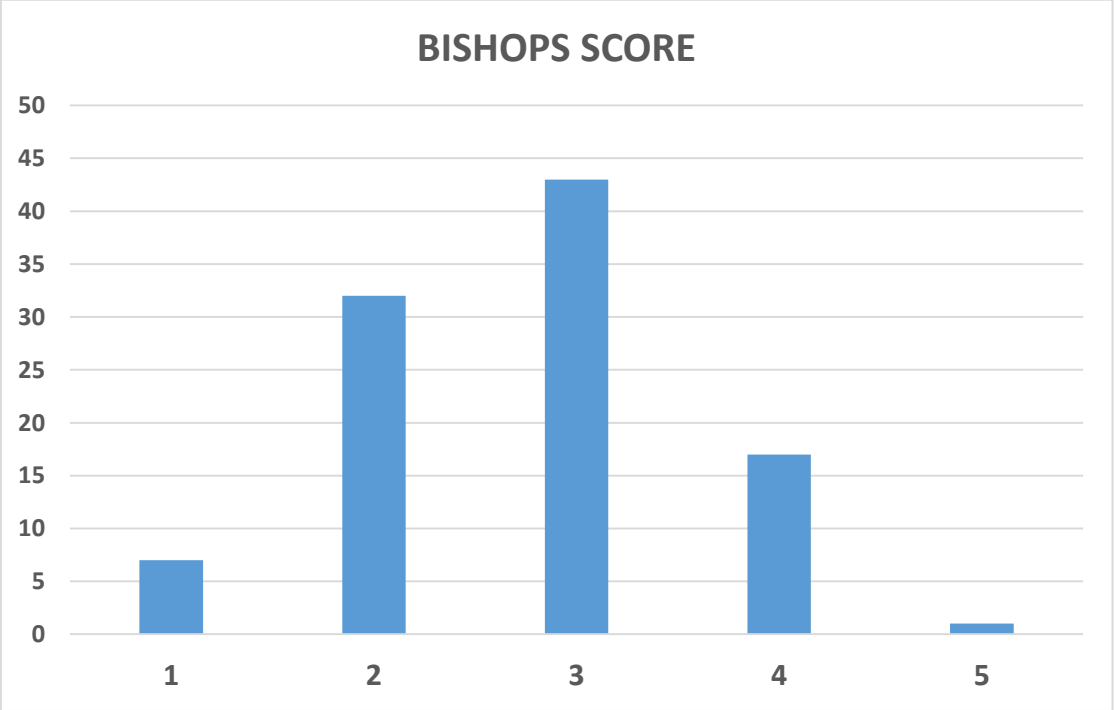


TABLE : 4

VAGINAL pH DISTRIBUTION AMONG THE STUDY GROUP

VAGINAL pH	Frequency	Percent
4.0	12	12.0
4.5	28	28.0
5.0	24	24.0
5.5	32	32.0
6.0	4	4.0
Total	100	100.0

The patients in the study group had vaginal pH in the range of 4 to 6.60 patients had a vaginal pH of more than 5. The mean vaginal pH in the study group was 5. In the study conducted by Ramsey et al the median vaginal pH was 5.5

CHART : 4

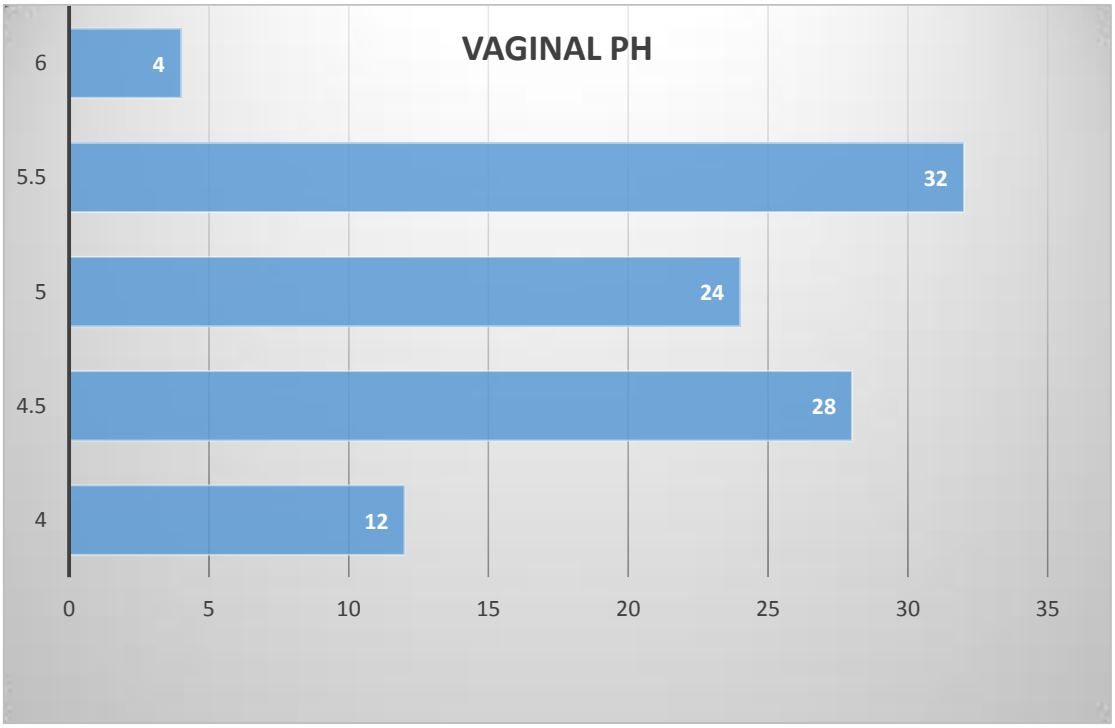


TABLE : 5 PARITY

PARITY	Frequency	Percent
Primi	63	63.0
Multi	37	37.0
Total	100	100.0

CHART : 5 PARITY

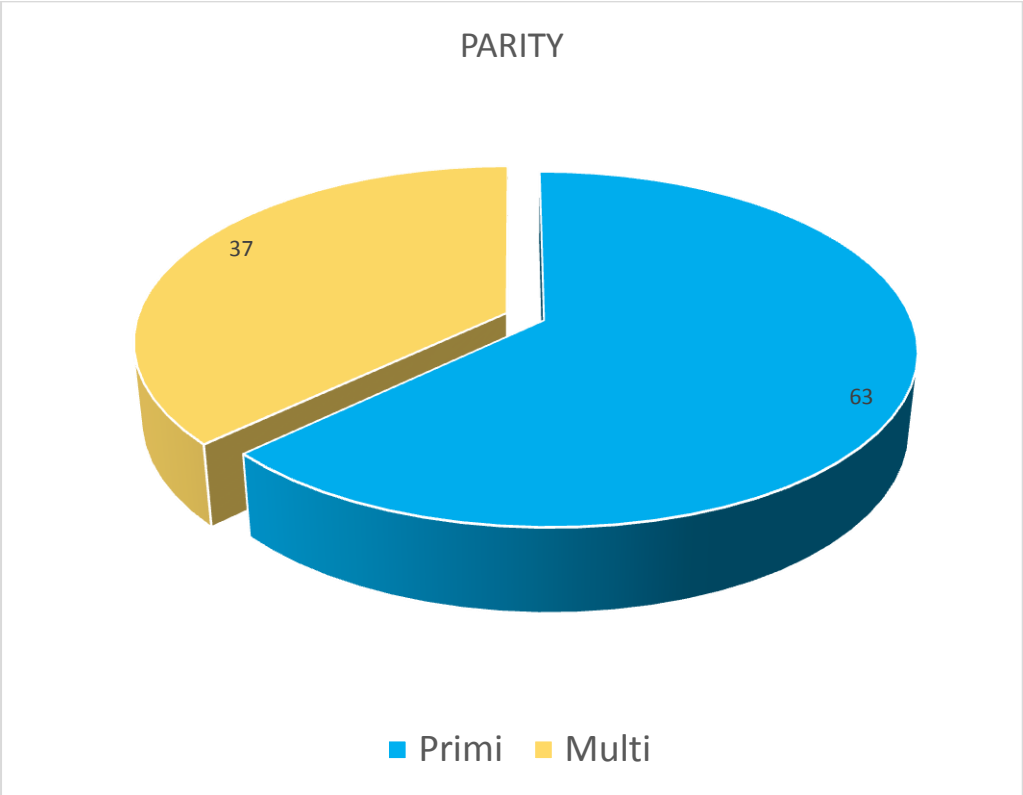


TABLE – 6

INDICATION FOR INDUCTION DISTRIBUTION IN THE STUDY GROUP

Indication for Induction	Frequency	Percent
Postdated	**53**	**53.0**
Oligohydramnios	**11**	**11.0**
GHTN	**25**	**25.0**
GDM	**9**	**9.0**
RH Negative	**2**	**2.0**
Total	**100**	**100.0**

- The most common indication for induction was postdatism. The other two indications were Oligohydramnios and Gestational Hypertension complicating pregnancy.

CHART – 6 : INDICATION FOR INDUCTION DISTRIBUTION IN THE STUDY GROUP

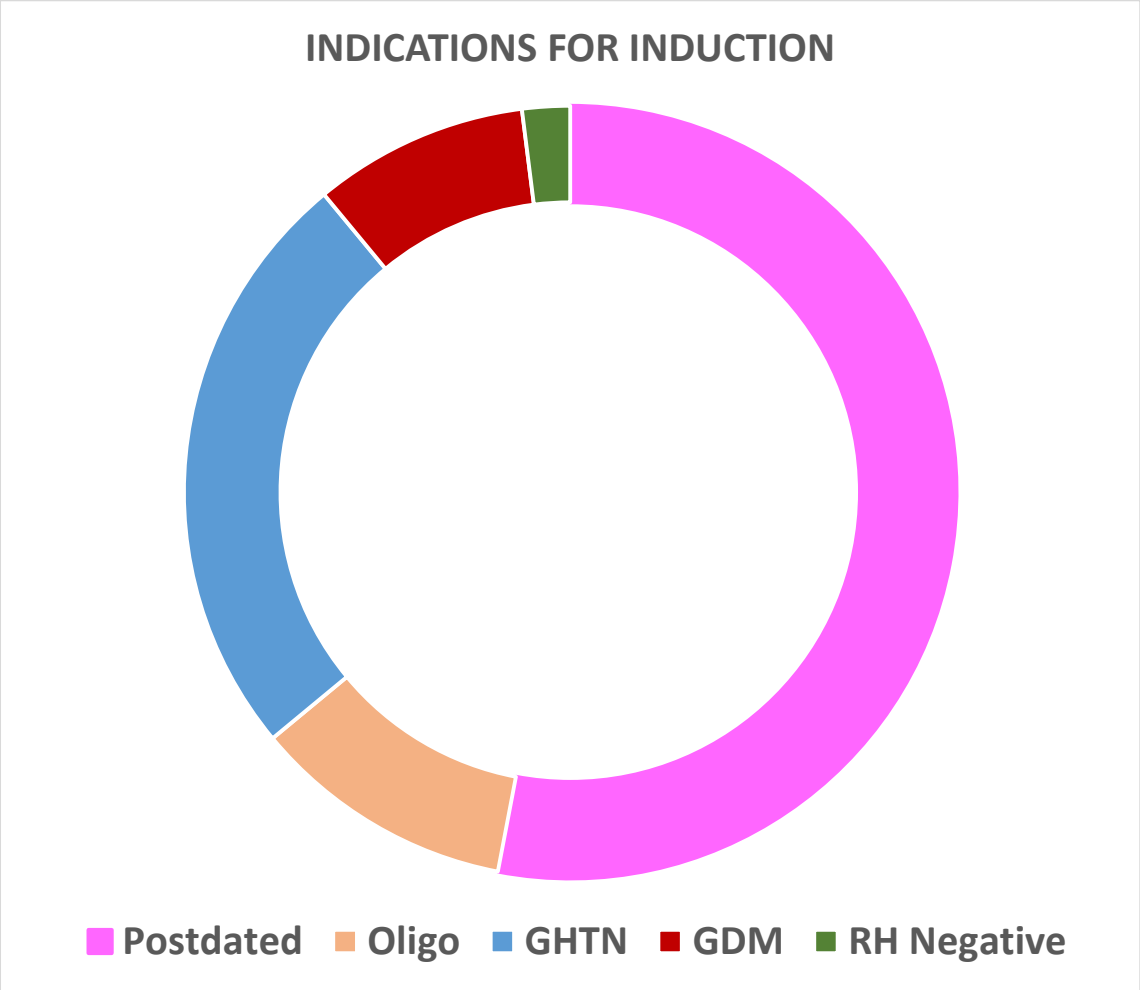


TABLE 7 : PGE2 GEL DOSE DISTRIBUTION IN THE STUDY GROUP

PGE2 GEL DOSE	Frequency	Percent
1	**95**	**95.0**
2	**5**	**5.0**
Total	**100**	**100.0**

This table shows the number of PGE 2 Gel doses used in the study patients.95 patients received a single dose of PGE 2 gel and 5 Patients received 2 doses of PGE 2 gel. Of these 5 patients, 1 delivered vaginally and 4 delivered by LSCS for failed induction

CHART – 7 : PGE2 GEL DOSE DISTRIBUTION IN THE STUDY GROUP

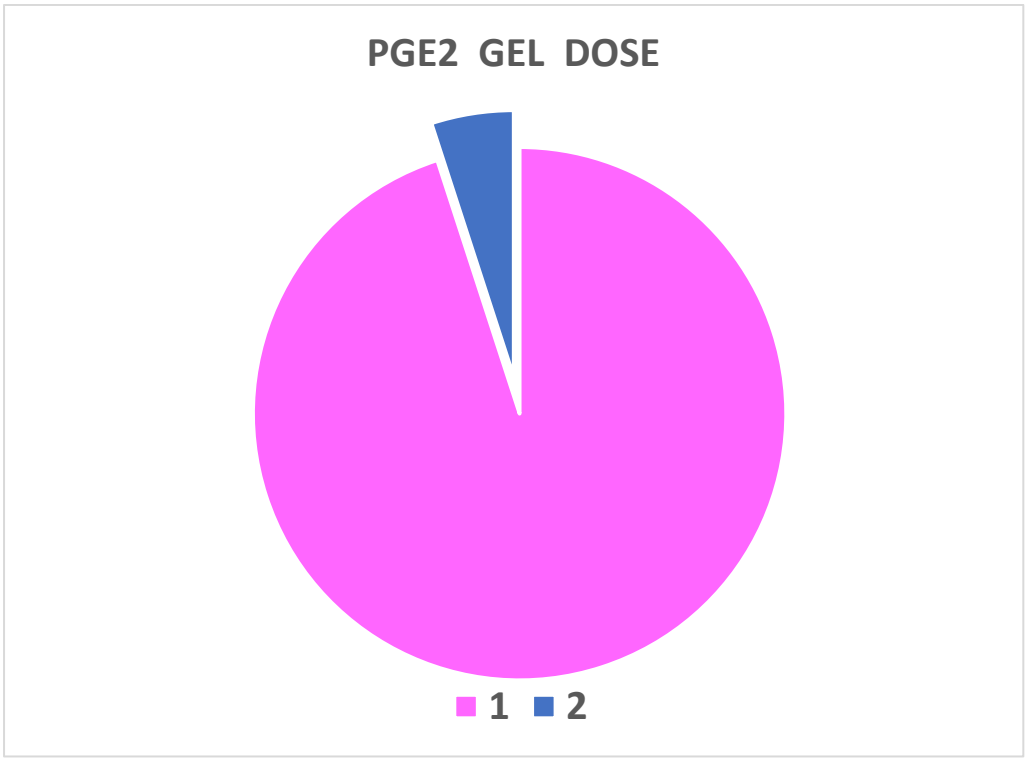


TABLE 8 : MODE OF DELIVERY DISTRIBUTION IN THE STUDY GROUP

Mode of Delivery	Frequency	Percent
LSCS	44	44.0
LN with EPI	49	49.0
Outlet with EPI	3	3.0
Vacuum with EPI	4	4.0
Total	100	100.0

This table shows the distribution of mode of delivery in the study group. 56 patients had normal vaginal delivery and 44 patients underwent LSCS. 3 patients delivered with Outlet forceps with episiotomy and 4 patients with vacuum with episiotomy.

CHART 8 : MODE OF DELIVERY DISTRIBUTION IN THE STUDY GROUP

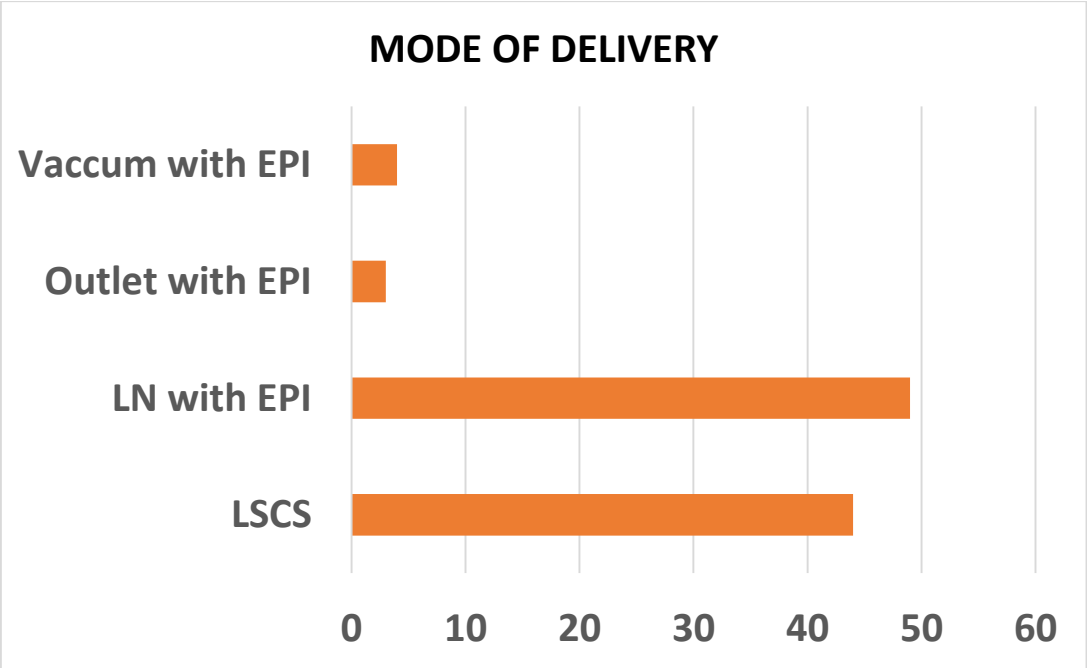


TABLE - 9

INDICATION FOR LSCS DISTRIBUTION

INDICATION FOR LSCS	Frequency	Percent
Failed Induction	30	30.0
Failure to progress	6	6.0
Fetal Distress	7	7.0
Imminent Eclampsia	1	1.0
Total LSCS	44	44.0
Normal Delivery	56	56.0
Total	**100**	**100.0**

Out of the total 100 cases, 44 cases delivered by LSCS. 7 cases were done for fetal distress and 30 cases for failed induction

CHART - 9

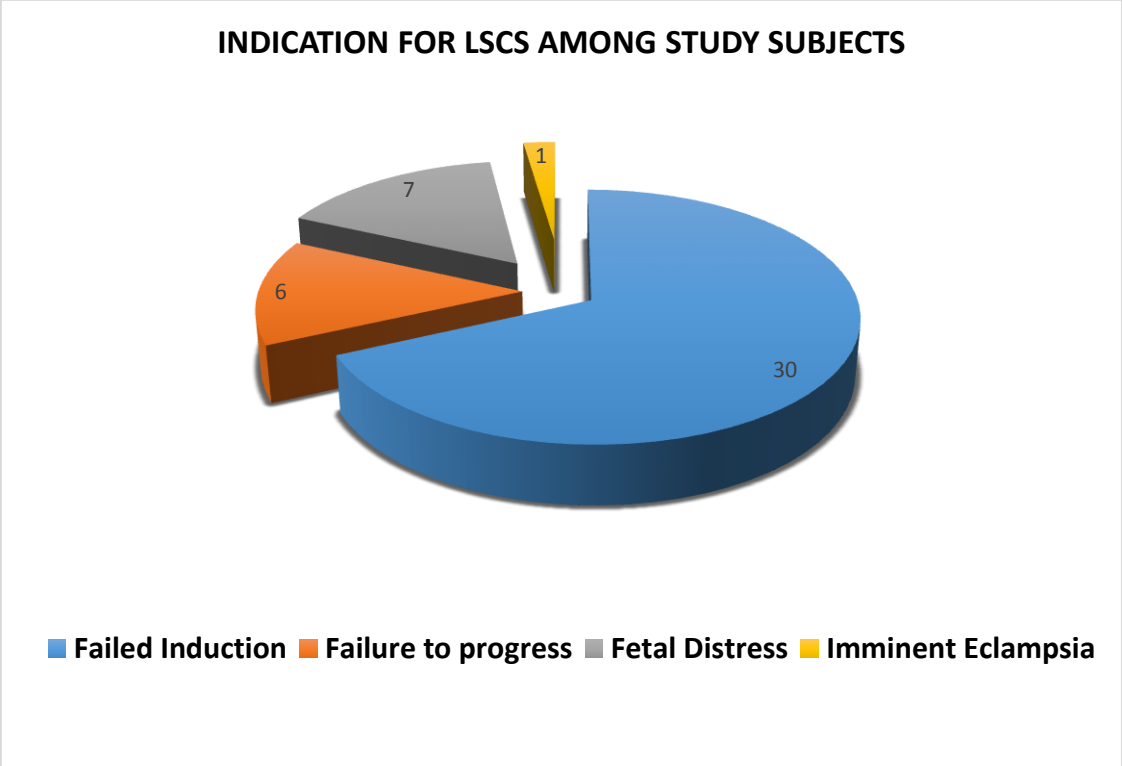


TABLE - 10 : BABY WEIGHT IN KG DISTRIBUTION IN THE STUDY GROUP

Weight in Kg	Frequency	Percent
Upto 2.5	22	22.0
2.5-3.0	43	43.0
3.0-3.5	29	29.0
Above 3.5	6	6.0
Total	100	100.0

In this study the mean birth weight of the babies born was found to be 2.9 kg. About 43 babies were in the range of 2.5 to 3.0 kg

CHART- 10 : BABY WEIGHT IN KG DISTRIBUTION IN THE STUDY GROUP

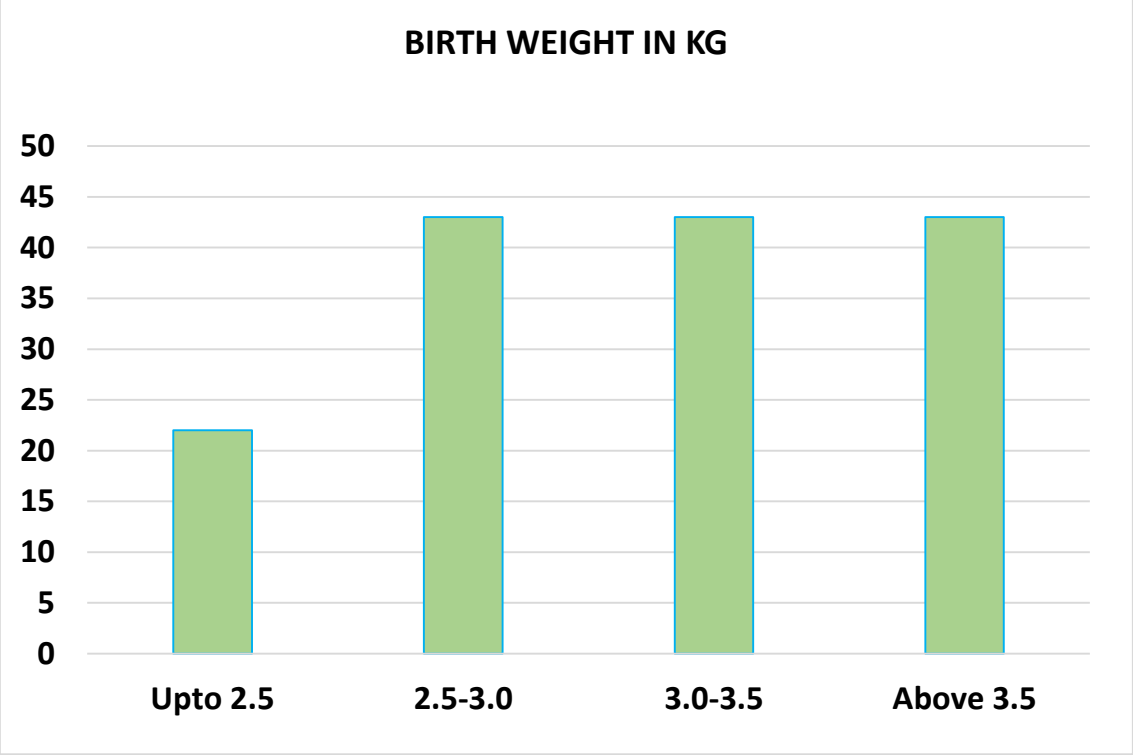


TABLE 11 : ONE MINUTE APGAR DISTRIBUTION IN THE STUDY GROUP

	Frequency	Percent
6	3	3.0
7	95	95.0
8	1	1.0
9	1	1.0
Total	100	100.0

In this study 95% of the babies had a 1 minute APGAR of 7.

CHART 11 : ONE MINUTE APGAR DISTRIBUTION IN THE STUDY GROUP

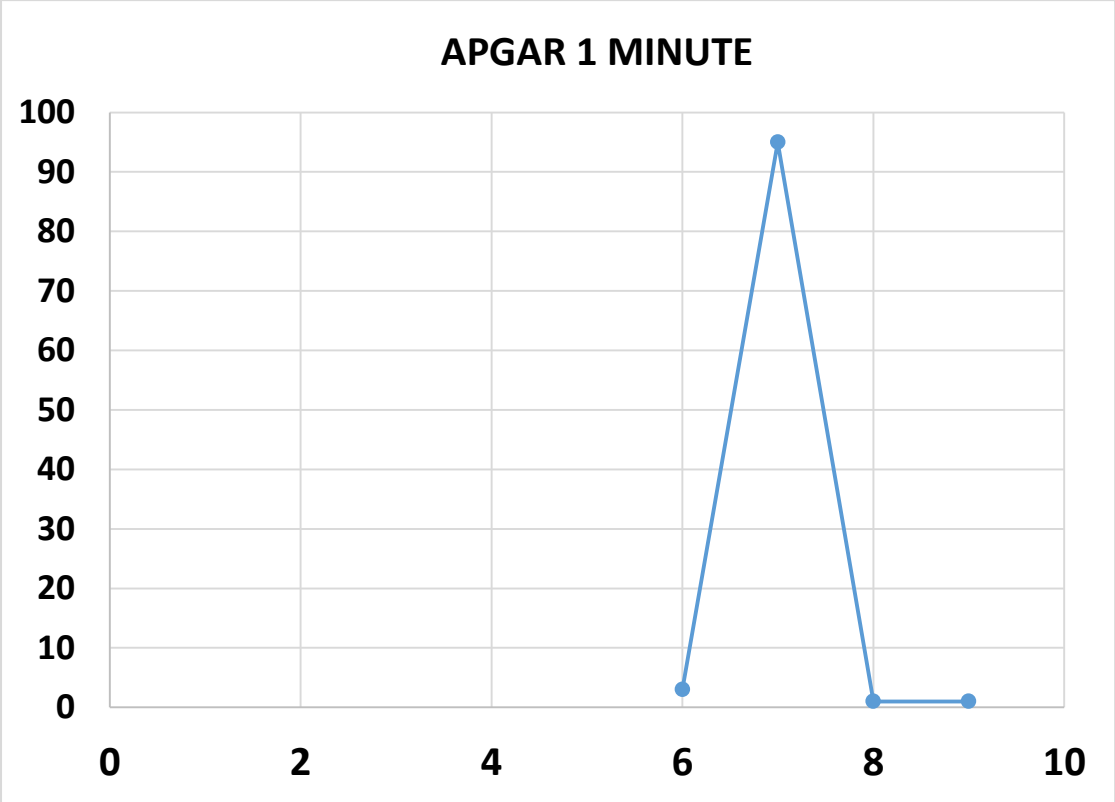


TABLE 12 : 5 MINUTE APGAR DISTRIBUTION IN THE STUDY GROUP

5 MIN APGAR	Frequency	Percent
7	4	4.0
8	94	94.0
9	2	2.0
Total	100	100.0

In this study 94 % of the babies delivered had a 5 minute APGAR of 8.

CHART 12 : 5 MINUTE APGAR DISTRIBUTION IN THE STUDY GROUP

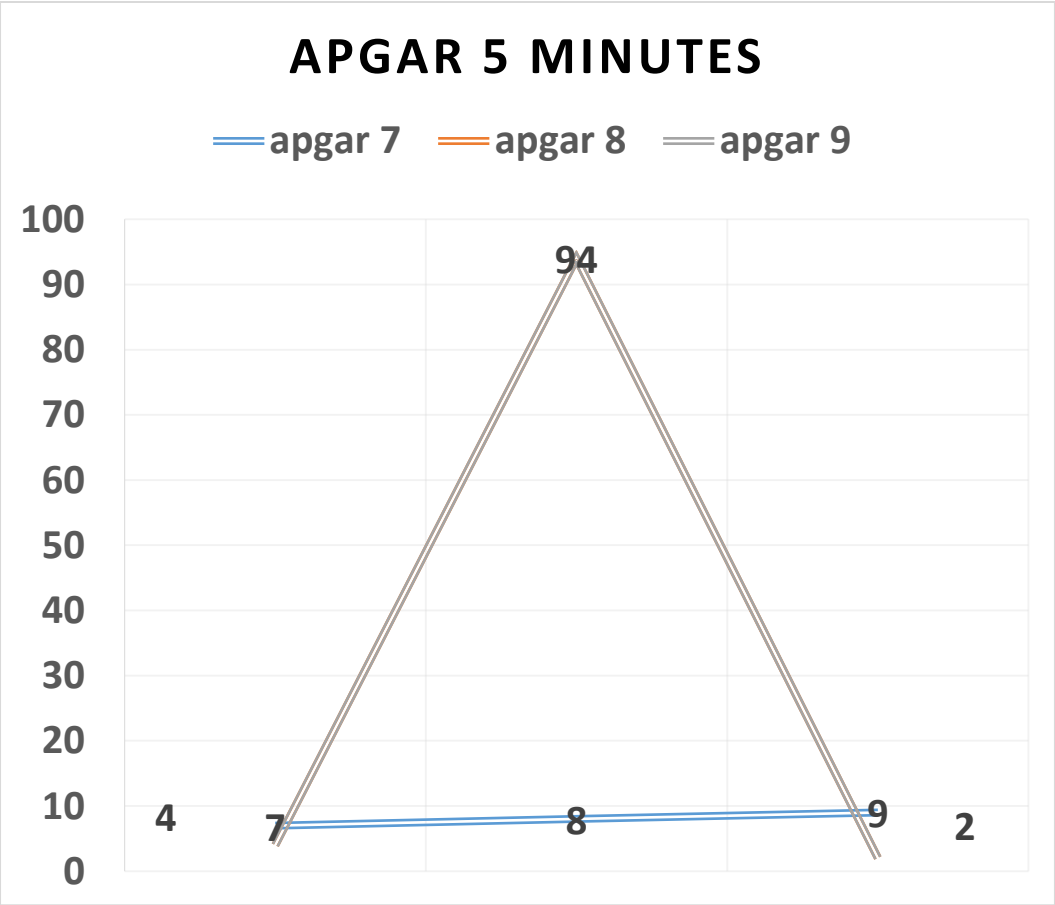


TABLE – 13 : INDUCTION DELIVERY INTERVAL DISTRIBUTION IN THE STUDY GROUP

INDUCTION DELIVERY INTERVAL	Frequency	Percent
<6 hours	14	14.0
6-10 hours	55	55.0
>10 hours	31	31.0
Total	100	100.0

This table shows induction delivery interval in the study group. The maximum induction delivery interval is around 6 – 10 hours. The average induction to delivery interval in our study group was 9 hours 52 minutes.

CHART – 13 : INDUCTION DELIVERY INTERVAL DISTRIBUTION IN THE STUDY GROUP

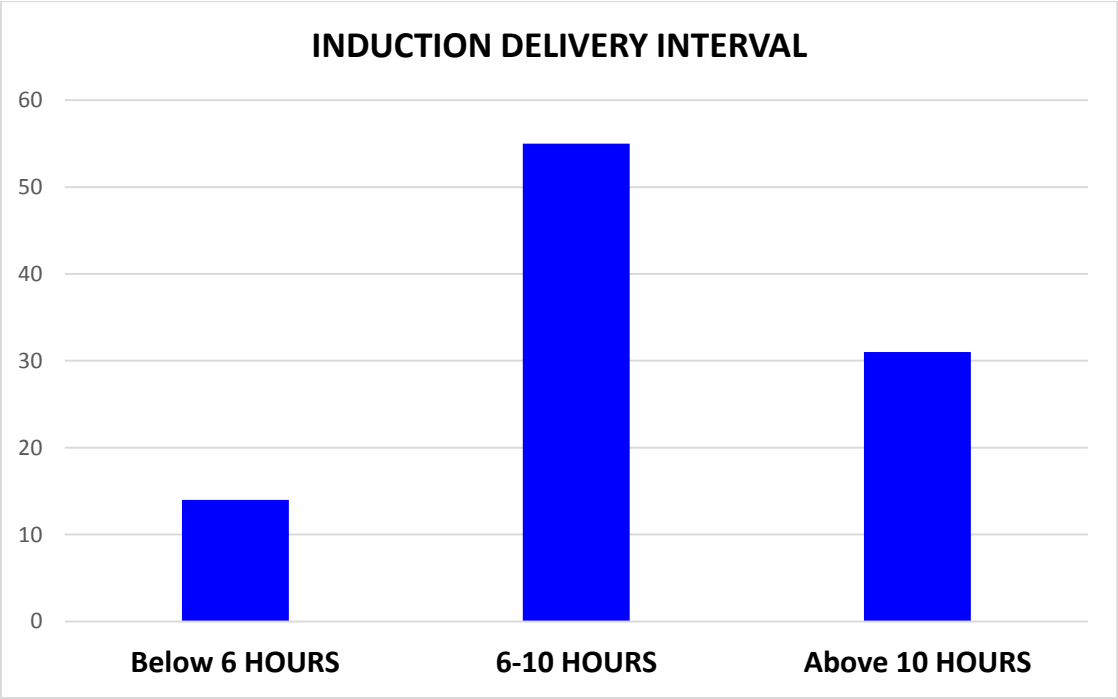


TABLE – 15 : TIME TO ENTRY INTO ACTIVE PHASE OF LABOUR IN HOURS AMONG OUR STUDY GROUP

Time taken to enter into active phase of labour	Frequency	Percent
Upto 10	52	52.0
Above 10	4	4.0
Total	56	56.0

This table shows time to entry into active phase of labour in hours among our study group. The average time to entry into active phase of labour in our study group was 7 hours 50 minutes

CHART – 15

TIME TAKEN TO ENTER INTO ACTIVE PHASE OF LABOUR IN HOURS AMONG OUR STUDY GROUP

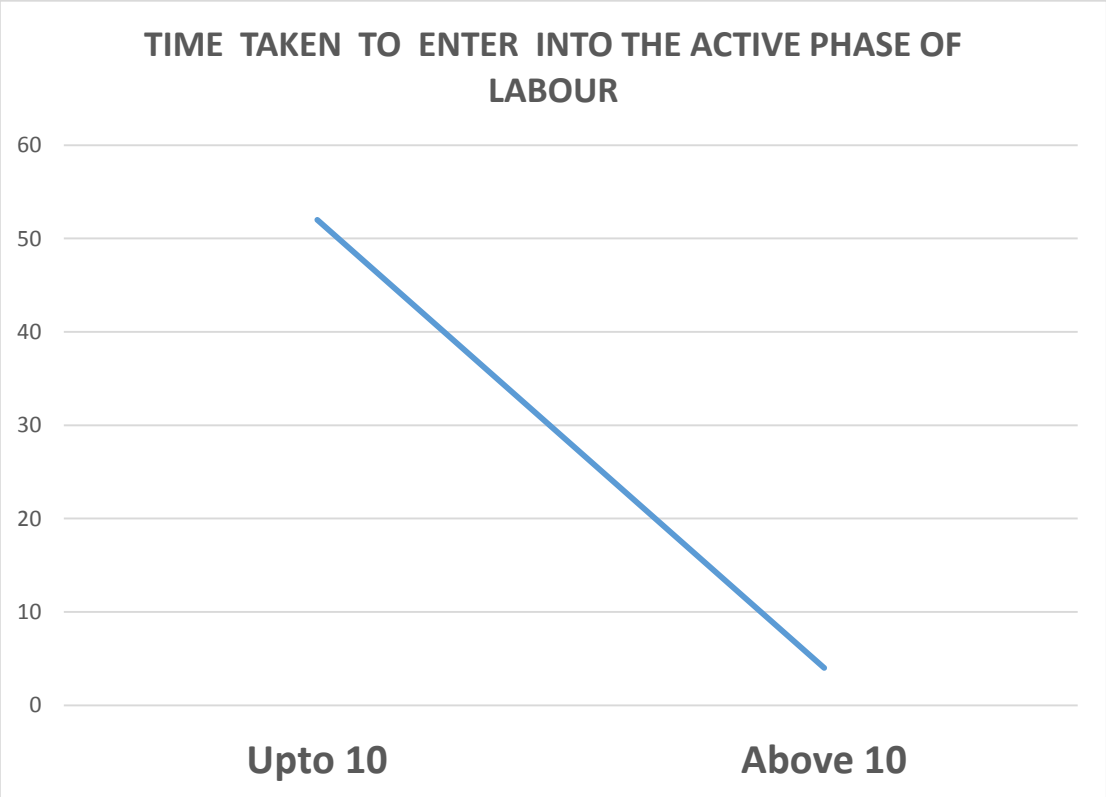


TABLE 16: COMPARISON OF VAGINAL pH AND AGE GROUP IN YEARS.

Vaginal pH		Age Group in years				Total	P value
		18-20	21-25	26-30	31-35		
4.0	Count	6	3	3	0	12	0.828
	% within Vaginal pH	50.0%	25.0%	25.0%	.0%	100.0%	
	% within Age Group in years	22.2%	6.4%	13.0%	.0%	12.0%	
4.5	Count	5	15	7	1	28	
	% within Vaginal pH	17.9%	53.6%	25.0%	3.6%	100.0%	
	% within Age Group in years	18.5%	31.9%	30.4%	33.3%	28.0%	
5.0	Count	8	9	6	1	24	
	% within Vaginal pH	33.3%	37.5%	25.0%	4.2%	100.0%	
	% within Age Group in years	29.6%	19.1%	26.1%	33.3%	24.0%	
5.5	Count	7	18	6	1	32	
	% within Vaginal pH	21.9%	56.3%	18.8%	3.1%	100.0%	
	% within Age Group in years	25.9%	38.3%	26.1%	33.3%	32.0%	
6.0	Count	1	2	1	0	4	
	% within Vaginal pH	25.0%	50.0%	25.0%	.0%	100.0%	
	% within Age Group in years	3.7%	4.3%	4.3%	.0%	4.0%	
Total	Count	27	47	23	3	100	
	% within Vaginal pH	27.0%	47.0%	23.0%	3.0%	100.0%	
	% within Age Group in years	100.0%	100.0%	100.0 %	100.0%	100.0%	

This table shows the comparison of vaginal pH and age group of the study group patients which is not statistically significant (p value-0.828)

CHART : 16 : COMPARISON OF VAGINAL pH AND AGE GROUP IN YEARS.

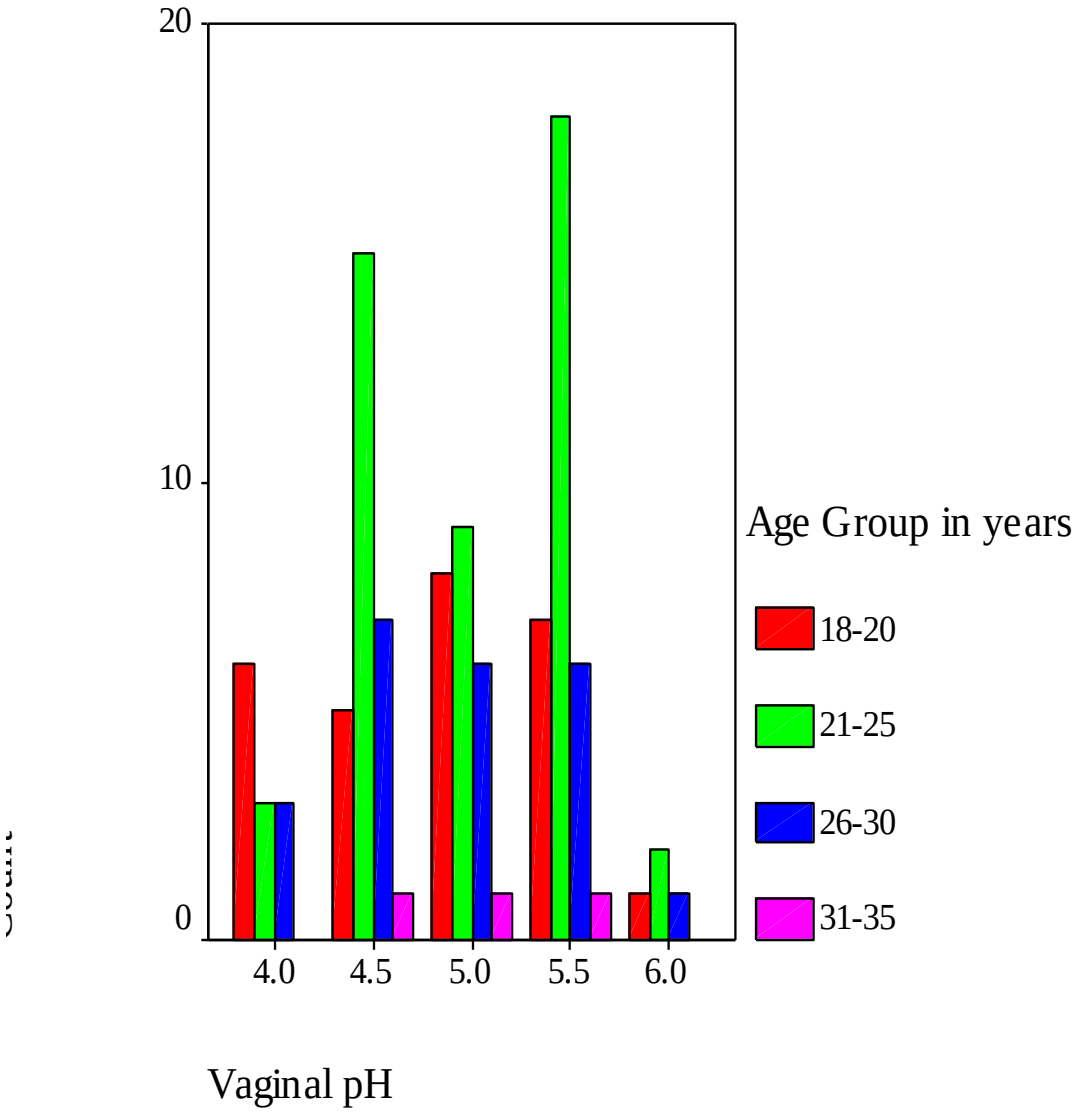


TABLE 17 : COMPARISON OF VAGINAL pH AND BISHOP SCORE

Vaginal pH		Bishops score					P value
			2	6	2	2	
4.0	Count	16.7%	50.0%	16.7%	16.7%	.0%	
	% within Vaginal pH	28.6%	18.8%	4.7%	11.8%	.0%	
	% within Bishops score	3	11	13	1	0	
4.5	Count	10.7%	39.3%	46.4%	3.6%	.0%	
	% within Vaginal Ph						
	% within Bishops score	42.9%	34.4%	30.2%	5.9%	.0%	
5.0	Count	2	5	15	2	0	
	% within Vaginal pH	8.3%	20.8%	62.5%	8.3%	.0%	<0.05*
	% within Bishops score	28.6%	15.6%	34.9%	11.8%	.0%	
5.5	Count	0	9	13	9	1	
	% within Vaginal pH	.0%	28.1%	40.6%	28.1%	3.1%	
	% within Bishops score	.0%	28.1%	30.2%	52.9%	100.0%	
6.0	Count	0	1	0	3	0	
	% within Vaginal pH	.0%	25.0%	.0%	75.0%	.0%	
	% within Bishops score	.0%	3.1%	.0%	17.6%	.0%	

This table shows the comparison of vaginal pH and mode of delivery which is statistically significant (p value-0.019). 76.5 % of patients with a Bishops score of 4 delivered vaginally and 23.5% had LSCS. 100 % of patients with a Bishops Score of 5 delivered vaginally only 30 % of patients with a Bishops score of 3 delivered vaginally. Bishops score appears to reliably predict vaginal delivery only at values of 4 and above. For patients with a Bishops score of 3 and less than that it was difficult to predict normal vaginal delivery.

CHART : 17 COMPARISON OF VAGINAL pH AND BISHOP SCORE

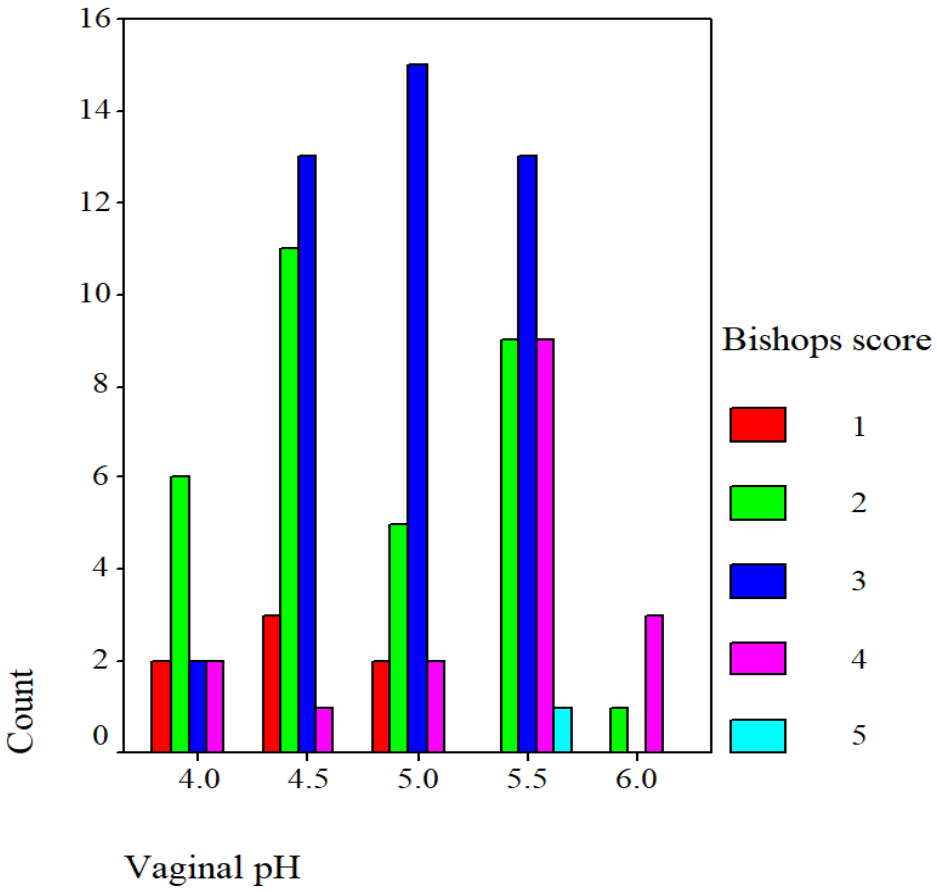


TABLE : 18 Vaginal pH * PGE 2 Dose

Vaginal pH		PGE 2		Total	P value
		1	2		
4.0	Count	11	1	12	
	% within Vaginal pH	91.7%	8.3%	100.0%	
	% within PGE 2	11.6%	20.0%	12.0%	
4.5	Count	27	1	28	
	% within Vaginal pH	96.4%	3.6%	100.0%	
	% within PGE 2	28.4%	20.0%	28.0%	
5.0	Count	21	3	24	
	% within Vaginal pH	87.5%	12.5%	100.0%	0.273
	% within PGE 2	22.1%	60.0%	24.0%	
5.5	Count	32	0	32	
	% within Vaginal pH	100.0%	.0%	100.0%	
	% within PGE 2	33.7%	.0%	32.0%	
6.0	Count	4	0	4	
	% within Vaginal pH	100.0%	.0%	100.0%	
	% within PGE 2	4.2%	.0%	4.0%	

In our study 95 patients received a single dose of PGE 2 gel and 5 Patients received 2 doses of PGE 2 gel. Of these 5 patients, 3 delivered vaginally and 2 delivered by LSCS for failed induction. The comparison between vaginal pH and number of times induced by PGE2 (p value-0.273) which is not statistically significant.

CHART : 18 Vaginal pH * PGE 2 Dose

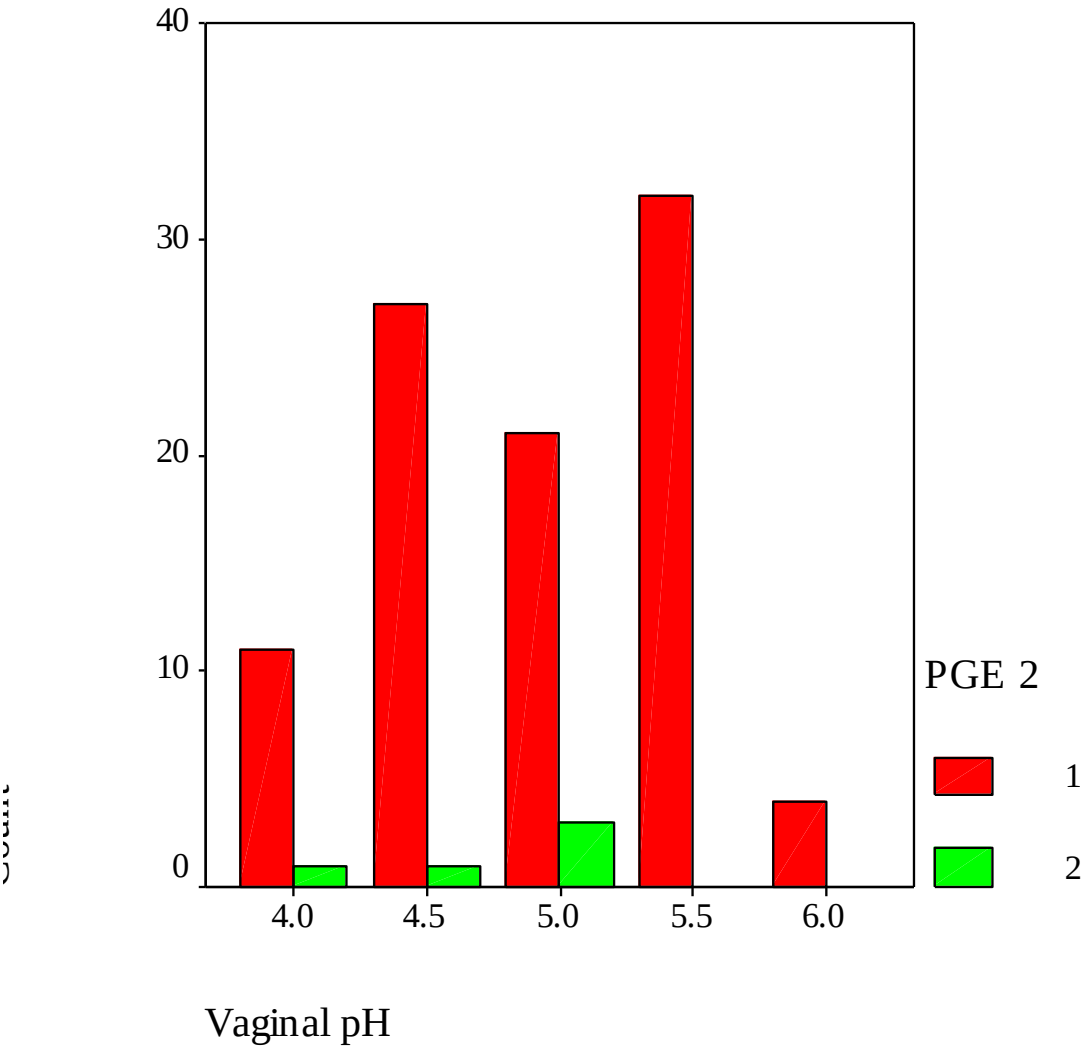


TABLE 19 : COMPARISON OF VAGINAL pH AND MODE OF DELIVERY.

	Mode of Delivery					P Value
Vaginal pH		LSCS	LN with EPI	Outlet with EPI	Vacuum with EPI	
4.0	Count	12	0	0	0	<0.001**
	% within Vaginal pH	100.0 %	.0%	.0%	.0%	
	% within Mode of Delivery	27.3%	.0%	.0%	.0%	
4.5	Count	19	8	0	1	
	% within Vaginal pH	67.9%	28.6%	.0%	3.6%	
	% within Mode of Delivery	43.2%	16.3%	.0%	25.0%	
5.0	Count	8	14	0	2	
	% within Vaginal pH	33.3%	58.3%	.0%	8.3%	
	% within Mode of Delivery	18.2%	28.6%	.0%	50.0%	
5.5	Count	5	23	3	1	
	% within Vaginal pH	15.6%	71.9%	9.4%	3.1%	
	% within Mode of Delivery	11.4%	46.9%	100.0%	25.0%	
6.0	Count	0	4	0	0	
	% within Vaginal pH	.0%	100.0%	.0%	.0%	
	% within Mode of Delivery	.0%	8.2%	.0%	.0%	
	Count	44	49	3	4	
	% within Vaginal pH	44.0%	49.0%	3.0%	4.0%	
	% within Mode of Delivery	100.0 %	100.0%	100.0%	100.0%	

This table shows the Comparison of vaginal pH and mode of delivery in the study group patients which is statistically significant.

100% of patients with a vaginal pH of 6 delivered vaginally. 83.4% of patients with vaginal pH 5.5, delivered vaginally and 15.6% underwent LSCS. 67.9% of patients with vaginal pH underwent LSCS, only 32.1% delivered vaginally. 100% of patients with vaginal pH of 4 underwent LSCS.

Vaginal pH in the range of 5-6 appears to predict vaginal delivery more reliably and it is a better predictor of success of induction.

Hence this study concludes that higher the vaginal pH higher chances of normal delivery when inducing with PGE2 gel. (p value <0.001) which is statistically significant.

CHART – 19 : : COMPARISON OF VAGINAL pH AND MODE OF DELIVERY.

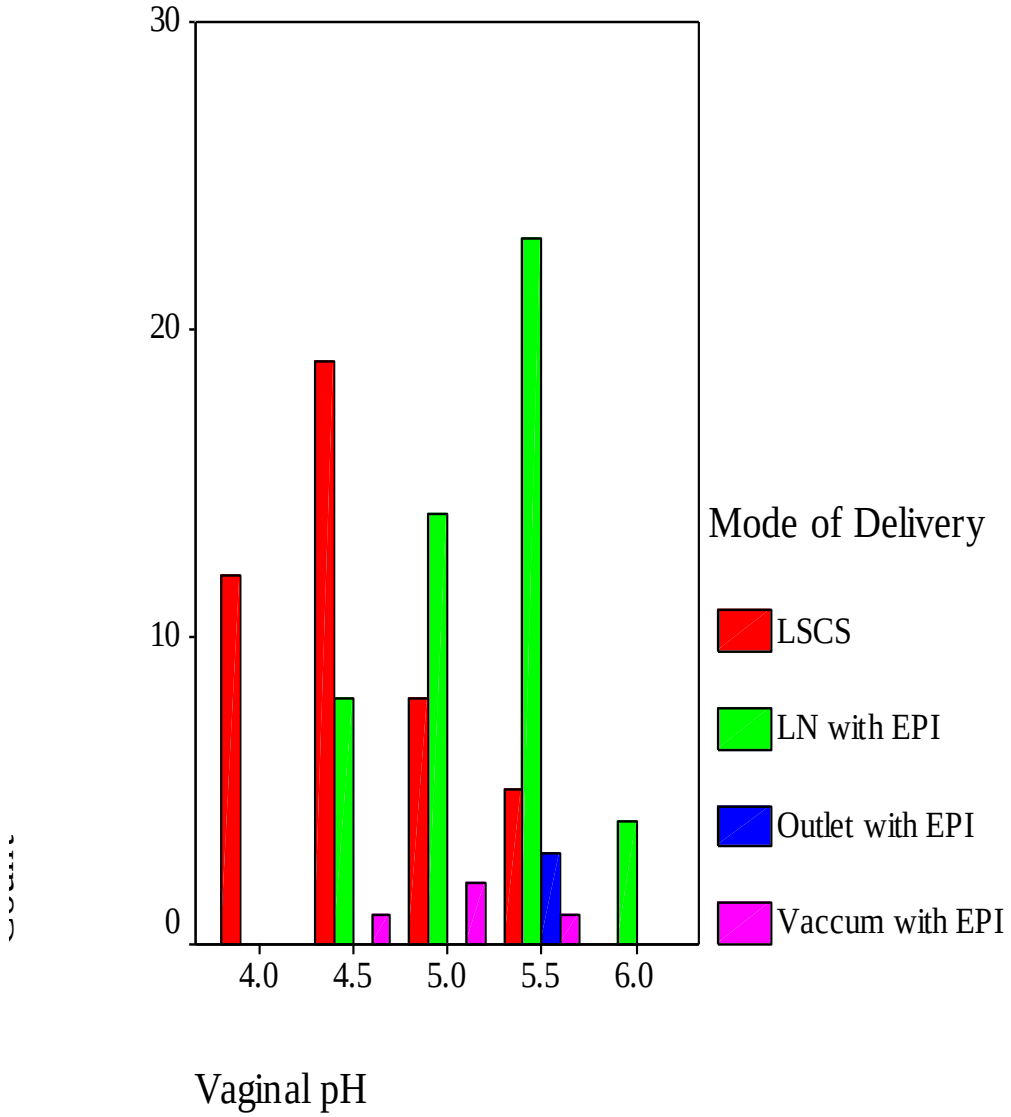


TABLE – 20: Vaginal pH * Indication for LSCS

	Vaginal pH	Indication for LSCS				Total	P value
		Failed Induction	Failure to progress	Fetal Distress	Imminent Eclampsia		
4.0	Count	11	0	1	0	12	0.448
	% within Vaginal pH	91.7%	.0%	8.3%	.0%	100.0%	
	% within Indication for LSCS	36.7%	.0%	14.3%	.0%	27.3%	
4.5	Count	13	3	2	1	19	
	% within Vaginal pH	68.4%	15.8%	10.5%	5.3%	100.0%	
	% within Indication for LSCS	43.3%	50.0%	28.6%	100.0%	43.2%	
5.0	Count	4	2	2	0	8	
	% within Vaginal pH	50.0%	25.0%	25.0%	.0%	100.0%	
	% within Indication for LSCS	13.3%	33.3%	28.6%	.0%	18.2%	
5.5	Count	2	1	2	0	5	
	% within Vaginal pH	40.0%	20.0%	40.0%	.0%	100.0%	
		6.7%	16.7%	28.6%	.0%	11.4%	

6	% within Vaginal pH	30	6	7	1	44	
	% within Indication for LSCS	68.2%	13.6%	15.9%	2.3%	100.0%	
	Total	100.0%	100.0%	100.0%	100.0%	100.0%	

There was no statistical significance between vaginal pH and indication for LSCS. (p value > 0.05). Most of the subjects who underwent LSCS for failed induction had lower vaginal Ph.

CHART – 20: : Vaginal pH * Indication for LSCS

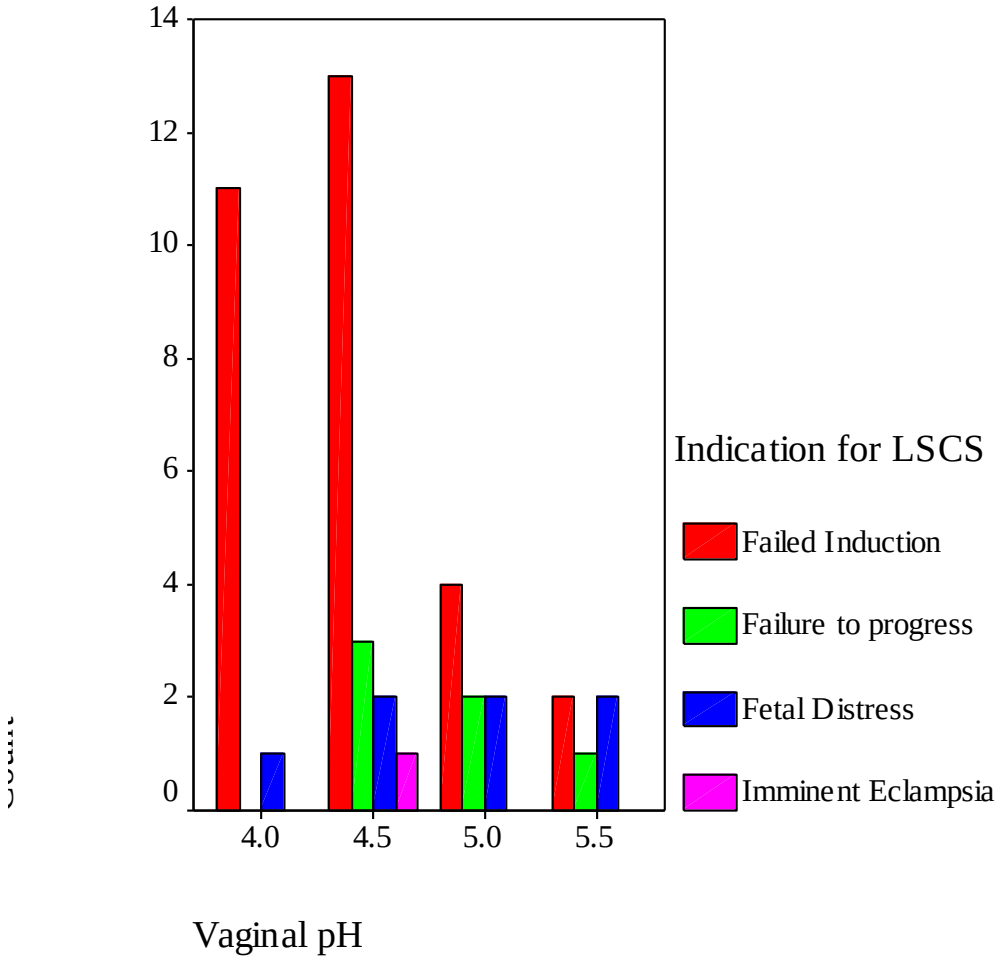


TABLE – 21: Vaginal pH * Time Taken to enter into Active Phase of Labour in hours

Vaginal pH		Time taken to enter into Active Phase of Labour in hours		Total	P Value
		Upto 10	Above 10		
4.5	Count	8	1	9	0.909
	% within Vaginal pH	88.9%	11.1%	100.0%	
	% within Time taken to enter into Active Phase of Labour in hours	15.4%	25.0%	16.1%	
5.0	Count	15	1	16	
	% within Vaginal pH	93.8%	6.3%	100.0%	
	% within Time taken to enter into Active Phase of Labour in hours	28.8%	25.0%	28.6%	
5.5	Count	25	2	27	
	% within Vaginal pH	92.6%	7.4%	100.0%	
	% within Time taken to enter into Active Phase of Labour in hours	48.1%	50.0%	48.2%	
6.0	Count	4	0	4	
	% within Vaginal pH	100.0%	.0%	100.0%	
	% within Time taken to enter into Active Phase of Labour in hours	7.7%	.0%	7.1%	
	Count	52	4	56	
	% within Vaginal pH	92.9%	7.1%	100.0%	
	% within Time taken to enter into Active Phase of Labour in hours	100.0%	100.0%	100.0%	

There was no significant association found in vaginal pH influencing the time taken to enter active phase of labour. (p value > 0.05).

CHART – 21: Vaginal pH * Time Taken to enter into Active Phase of Labour in hours

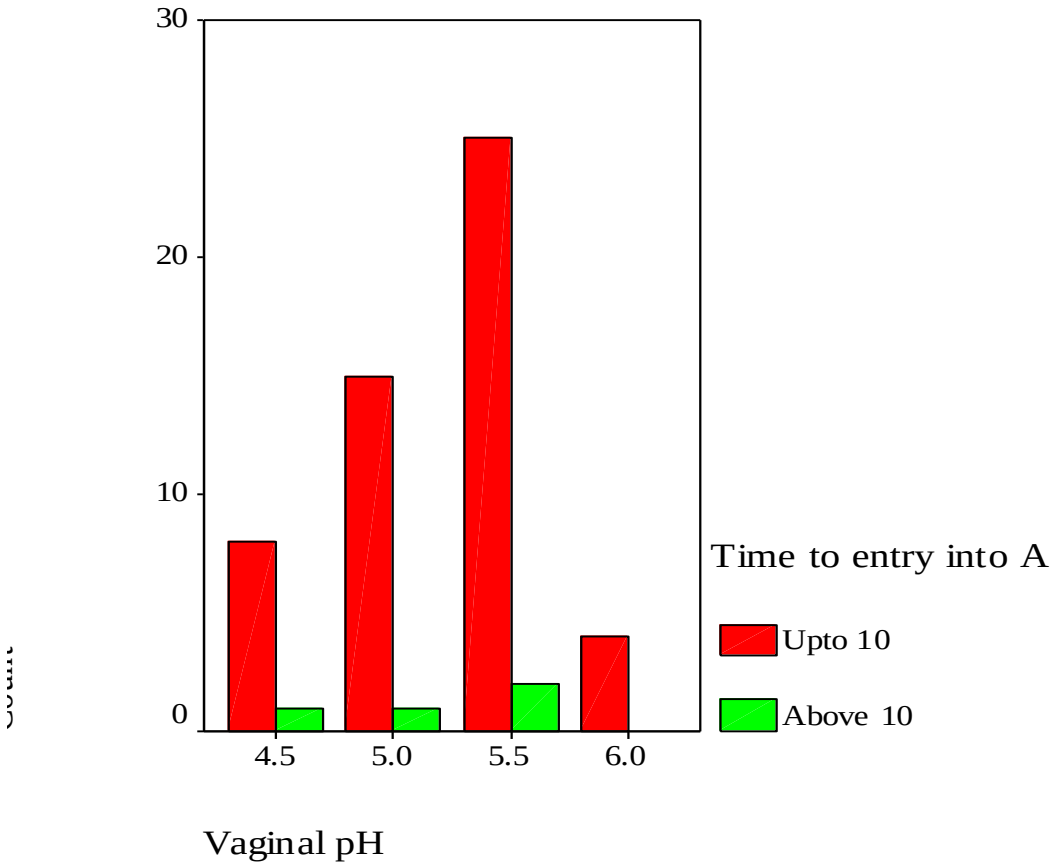


TABLE – 22: Vaginal pH * Parity

Vaginal pH		Parity		Total	P value
		Primi	Multi		
4.0	Count	10	2	12	<0.05*
	% within Vaginal pH	83.3%	16.7%	100.0%	
	% within Parity	15.9%	5.4%	12.0%	
4.5	Count	19	9	28	
	% within Vaginal pH	67.9%	32.1%	100.0%	
	% within Parity	30.2%	24.3%	28.0%	
5.0	Count	17	7	24	
	% within Vaginal pH	70.8%	29.2%	100.0%	
	% within Parity	27.0%	18.9%	24.0%	
5.5	Count	17	15	32	
	% within Vaginal pH	53.1%	46.9%	100.0%	
	% within Parity	27.0%	40.5%	32.0%	
6.0	Count	0	4	4	
	% within Vaginal pH	.0%	100.0%	100.0%	
	% within Parity	.0%	10.8%	4.0%	
Total	Count	63	37	100	
	% within Vaginal pH	63.0%	37.0%	100.0%	
	% within Parity	100.0%	100.0%	100.0%	

In this observational study there was a significant association between vaginal pH and parity (p value – 0.024). Subjects with higher parity had a higher vaginal pH (>5).

CHART – 22: Vaginal pH * Parity

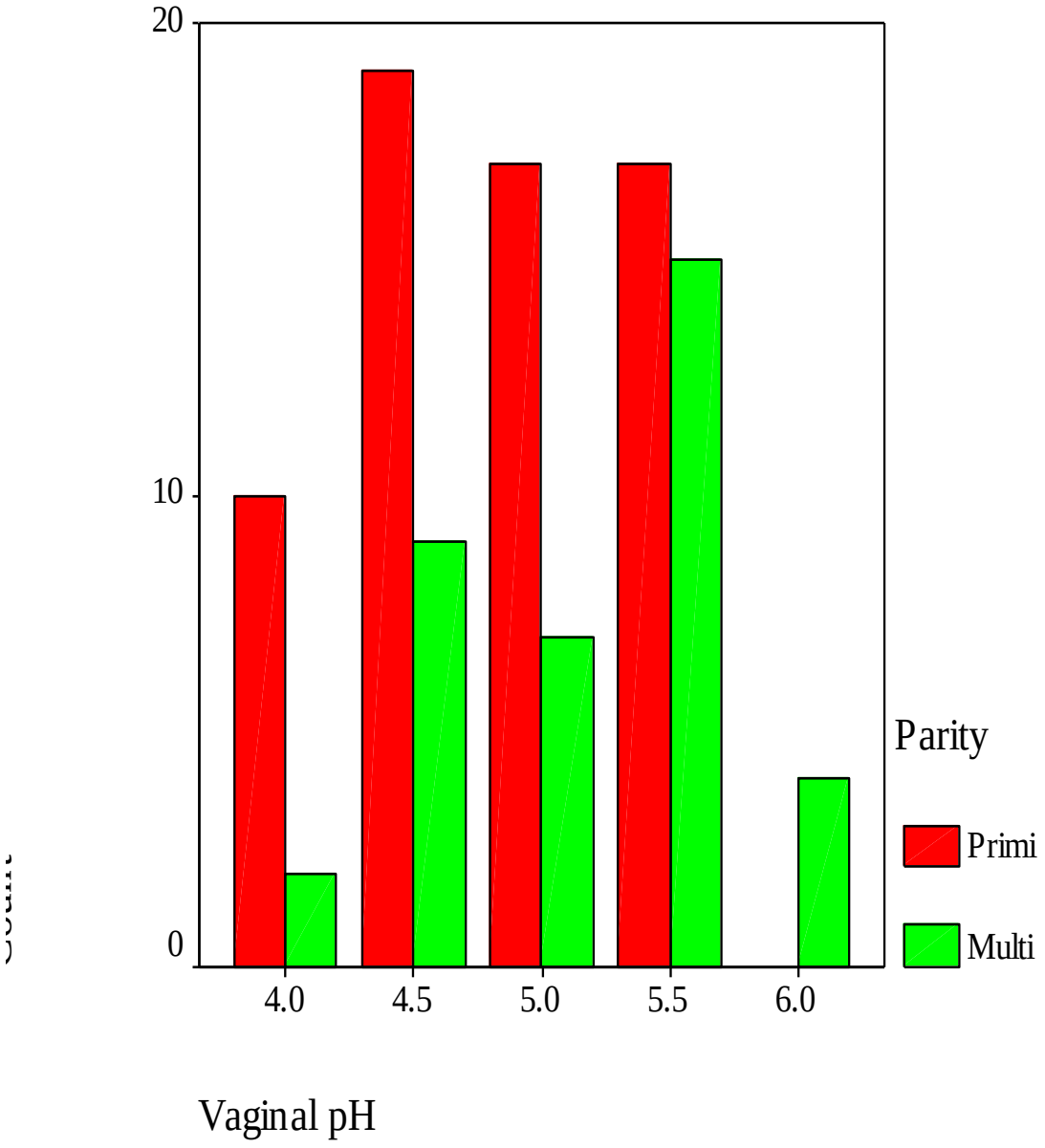
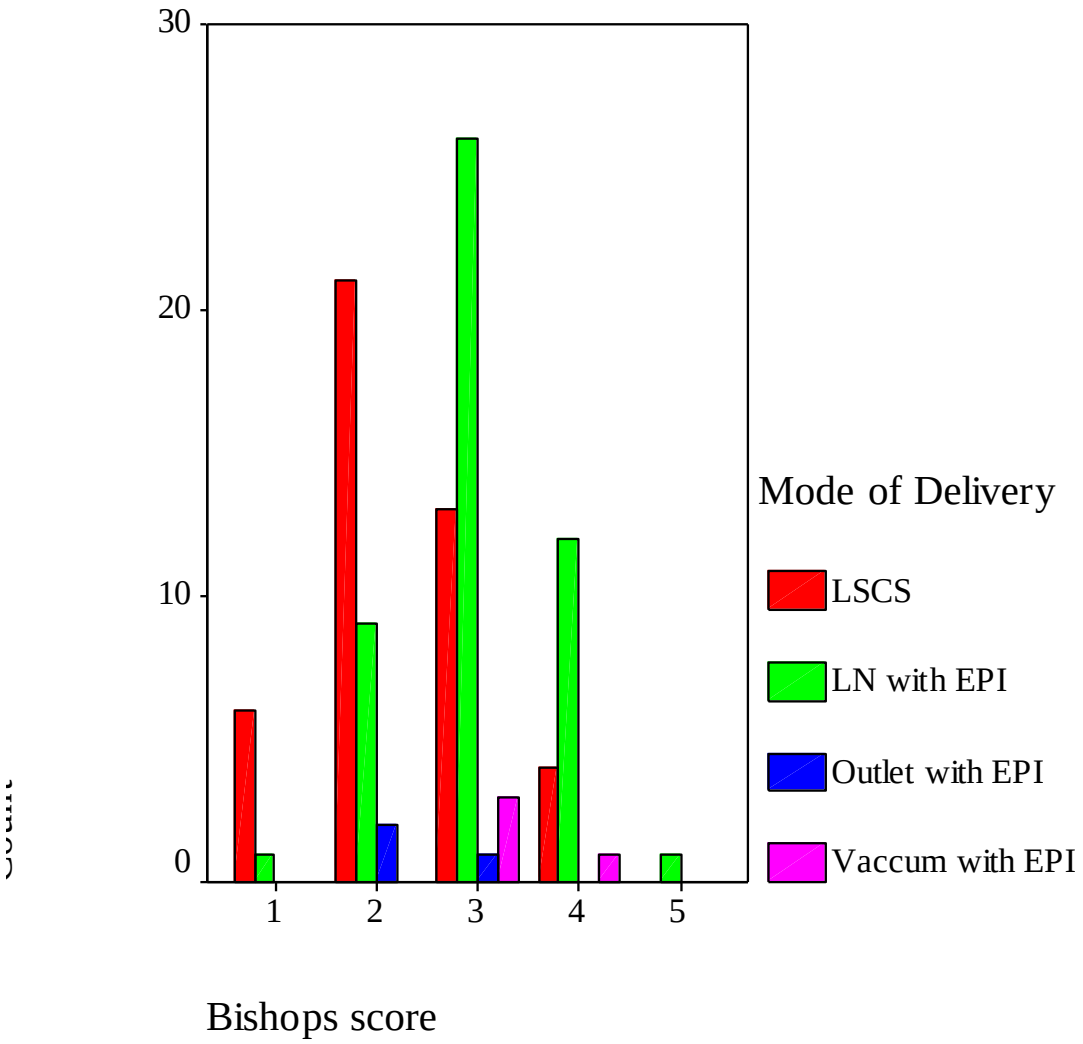


TABLE – 23: Bishop score*Mode of delivery

Bishops score		Mode of Delivery				Total	P value
		LSCS	LN with EPI	Outlet with EPI	Vacuum with EPI		
1	Count	6	1	0	0	7	<0.05*
	% within Bishops score	85.7%	14.3%	.0%	.0%	100.0 %	
	% within Mode of Delivery	13.6%	2.0%	.0%	.0%	7.0%	
2	Count	21	9	2	0	32	
	% within Bishops score	65.6%	28.1%	6.3%	.0%	100.0 %	
	% within Mode of Delivery	47.7%	18.4%	66.7%	.0%	32.0%	
3	Count	13	26	1	3	43	
	% within Bishops score	30.2%	60.5%	2.3%	7.0%	100.0 %	
	% within Mode of Delivery	29.5%	53.1%	33.3%	75.0%	43.0%	
4	Count	4	12	0	1	17	
	% within Bishops score	23.5%	70.6%	.0%	5.9%	100.0 %	
	% within Mode of Delivery	9.1%	24.5%	.0%	25.0%	17.0%	
5	Count	0	1	0	0	1	
	% within Bishops score	.0%	100.0%	.0%	.0%	100.0 %	
	% within Mode of Delivery	.0%	2.0%	.0%	.0%	1.0%	
Total	Count	44	49	3	4	100	
	% within Bishops score	44.0%	49.0%	3.0%	4.0%	100.0 %	
	% within Mode of Delivery	100.0%	100.0%	100.0%	100.0%	100.0 %	

76.5 % of patients with a Bishops score of 4 delivered vaginally and 23.5% had LSCS. 100 % of patients with a Bishops Score of 5 delivered vaginally. Only 30 % of patients with a Bishops score of 3 delivered vaginally. Bishops score appears to reliably predict vaginal delivery only at values of 4 and above .For patients with a Bishops score of 3 and less than that it was difficult to predict normal vaginal delivery. (P value – 0.031)

CHART – 23: Bishop score*Mode of delivery



DISCUSSION

100 patients were included in this study in the age group of 18 to 35 years. The mean age of the study group being 23.49 years. The most common indication for induction was postdatism. The other two indications were Oligohydramnios and Gestational hypertension complicating pregnancy.

In a similar study by Ramsey et al the indications for induction were prolonged pregnancy, gestational hypertension, diabetes mellitus, maternal cholestasis, pruritus, hypothyroidism, maternal renal disease, suspected fetal growth restriction, oligohydramnios, polyhydramnios etc.

The patients in the study group were induced from 37 to 42 weeks gestational age. About 58 patients 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. In the study conducted by Ramsey et al the mean gestational age at induction was 41 weeks

The patients in the study group had a pre induction Bishop's score of 1,2.3,4 or 5.32 patients had a pre induction Modified Bishops Score of 3 and 17 patients had a pre induction Modified Bishops Score of 4. The median. Modified Bishops Score was 3. In the study of Ramsey et al also the median Bishops score was 3.

The patients in the study group had vaginal pH in the range of 4 to 6. 60 patients had a vaginal pH of more than 5.5. The mean vaginal pH in the study group was 5. In the study conducted by Ramsey et al the median vaginal pH was 5.5

In our study 95 patients received a single dose of PGE 2 gel and 5 Patients received 2 doses of PGE 2 gel. Of these 5 patients, 3 delivered vaginally and 2 delivered by LSCS for failed induction.

On analyzing the mode of delivery in our study 56 patients had normal vaginal delivery and 44 patients underwent LSCS. 3 patients delivered with Outlet forceps, 4 patients delivered with vacuum. 7 cases of LSCS were done for fetal distress, 6 cases for failure to progress and 30 cases for failed induction.

In this study the mean birth weight of the babies born was found to be 2.9 kg. About 36 babies were in the range of 2.5 to 3.0 kg.

The average induction to delivery interval in our study group was 9 hours 52 minutes.

76.5 % of patients with a Bishops score of 4 delivered vaginally and 23.5% had LSCS. 100 % of patients with a Bishops Score of 5 delivered vaginally. Only 30 % of patients with a Bishops score of 3 delivered vaginally. Bishops score appears to reliably predict vaginal delivery only at values of 4 and above .For patients with a Bishops score of 3 and less than that it was difficult to predict normal vaginal delivery.

The study of Kanwar et al showed that 73.25 % cases with Bishop's score > 6 delivered vaginally and 26.74% underwent LSCS. On the other hand cases with Bishop's score of < 6 had to undergo LSCS and only 20.83 % delivered vaginally

100 % of patients with a vaginal pH of 6 delivered vaginally. 83.4% of patients with vaginal pH of 5.5 delivered vaginally and 15.6% underwent LSCS. 67.9% of patients with vaginal pH underwent Lscs, only 32.1% delivered vaginally. 100 % of patients with vaginal pH of 4 underwent Lscs. Vaginal pH in the range of 5-6 appears to predict vaginal delivery more reliably and it is a better predictor of success of induction.

According to the study of Ramsey et al, vaginally delivered cases were more compared to LSCS when vaginal pH of more than 5.

There was no statistically significant association between vaginal pH with respect to maternal age, parity, gestational age, time taken to enter into active phase of labour and induction delivery interval but there was statistically significant difference between vaginal pH of 5 or more with initial Bishop score prior to induction and mode of delivery. Normal vaginal delivery is considered as successful induction.

SUMMARY

The present study was done at Govt RSRM Lying In hospital to study vaginal pH has an effect on the efficacy of the Dinoprostone gel for cervical ripening. Hence vaginal pH as a predictor of successful induction which denotes normal vaginal delivery.

- 100 patients were included in this study in the age group of 18 to 35 years. The mean age of the study group being 23.49 years. The most common indication for induction was postdatism. The other two indications were Oligohydramnios and Gestational Hypertension complicating pregnancy.

- About 58 patients were induced at the gestational age of 40 weeks to 40 weeks 6 days interval.

- 32 patients had a pre induction Modified Bishops Score of 3. The median Modified Bishops Score was 3.

- 60 patients had a vaginal pH of more than 5.5. The mean vaginal pH in the study group was 5.

- 95 patients received a single dose of PGE2 gel and 5 Patients received 2 doses of PGE 2 gel. Of these 5 patients, 3 delivered vaginally and 2 delivered by LSCS for failed induction.

- On analysing the mode of delivery in our study 56 patients had normal vaginal delivery and 44 patients underwent LSCS. 3 patients delivered with Outlet forceps, 4 patients with vacuum delivery. 7 cases of LSCS were done for fetal distress and 30 cases for failed induction.

- In this study the mean birth weight of the babies born was found to be 2.9 kg. About 36 babies were in the range of 2.5 to 3.0 kg.

- In our study the average induction delivery interval was 9 hours and 52 minutes

- 76.5 % of patients with a Bishops score of 4 delivered vaginally and 23.5% had LSCS. 100 % of patients with a Bishops Score of 5 delivered vaginally. Only 30 % of patients with a Bishops score of 3 delivered vaginally. Bishops score appears to reliably predict vaginal delivery only at values of 4 and above .For patients with a Bishops score of 3 and less than that it was difficult to predict normal vaginal delivery.

- 100 % of patients with a vaginal pH of 6 delivered vaginally. 83.4% of patients with vaginal pH of 5.5 delivered vaginally and 15.6% underwent LSCS. 67.9% of patients with vaginal pH underwent Lscs, only 32.1% delivered vaginally. 100 % of

patients with vaginal pH of 4 underwent Lscs. Vaginal pH in the range of 5-6 appears to predict vaginal delivery more reliably and it is a better predictor of success of induction.

- Among the previous studies in the literature; there are three studies investigating the effect of vaginal pH on efficacy of PGE2 gel and the another three investigating the effect of vaginal pH on the efficacy of slow-release PGE2 vaginal insert in vivo but giving conflicting results.

- Ramsey et al studies conducted in 2002 and 2003 conflict each other. The study in 2002 conducted with PGE2 gel showed significant association between higher vaginal pH and the shorter time taken to enter into active phase, time to full dilatation and time to delivery while the study in 2003 conducted with PGE2 vaginal insert showed no significance. The present study also showed no significant change in the time to enter active phase of labour.

- In the present study conducted there was a significant association found between the vaginal pH and the Bishop score prior induction but the change in the Bishop score over 6-8 hours of induction could not be assessed. In the studies conducted by Ramsey et al and Basirat et al, there was no significant association found between vaginal pH and the initial Bishop score prior induction and the change in the Bishop score over 12 hours in contrast to the study

conducted by Singh u et al where there was significant association found between the vaginal pH and the change in the Bishop score over 18 hours which may be due to the difference in the duration (in hours) of assessment of Bishop score after an induction.

- Basirat et al also found that the incidence of Caesarean section was lower in women with high vaginal pH as in the present study but was not statistically significant.

SUMMARY OF COMPARISON OF THE PRESENT STUDY WITH PREVIOUS CONDUCTED STUDIES

Year of study	Study conducted by	PGE2 form used in the study	Number of subjects in the study	Association of vaginal pH and age	Association pf vaginal pH and parity	Association of vaginal pH and bishop score prior induction	Association of vaginal pH and time taken to enter in to active phase of labour
2002	Ramsey et al	Gel	32	A	A	A	B
2003	Ramsey et al	Insert	34	A	A	A	A
2008	Onen et al	Insert	63	A	A	A	A
2011	Basirat et al	Gel	45	A	A	A	A
	Present study	Gel	100	A	A	A	B

A- Significant association; B- No significant association

CONCLUSION

Induction of labour is one of the most common obstetric practices carried out in the world. Compared to spontaneous onset of labour, induction of labour is complicated by a higher rate of Caesareansection. This difference is greater for nulliparous women with unfavourable cervix.

The pH is important in terms of the design and the efficacy of vaginal drug delivery systems.

To assess the pre induction favorability of the cervix vaginal pH appears to be better tool. Vaginal pH measurement is easy to do.

So this study was conducted with 100 patients who underwent induction of labour at 37 to 40weeks 6 days in our hospital. The most common indication for induction was postdated pregnancy. PGE2 gel induction was done and the results were tabulated and analysed.

Vaginal pH in the range of 5 to 6 was found to be a better predictor of normal vaginal delivery than Modified Bishop's Score. This is a objective, more reproducible and quantitative method which can be performed easily anywhere. Therefore more liberal use of vaginal pH for pre induction cervical assessment in term pregnancy would enable obstetricians to predict the outcome of labour induction and to select a safe and more efficient policy of induction

Hence, findings of the present study suggest that parity influences vaginal pH and vaginal pH itself has a significant effect on cervical ripening and the Bishop Score prior induction. Higher vaginal pH more often responds to a single induction and is more often associated with vaginal deliveries than LSCS.

Hence knowing the vaginal pH prior induction could prove to be a useful tool in assessing the labour outcome of a patient undergoing labour induction with PGE2 gel. Further research is required to find various agents that would increase the vaginal pH thereby creating a favorable environment for PGE2 gel induction.

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CONSENT FORM

I agree to participate in the study entitled **"EFFECT OF VAGINAL PH ON EFFICACY OF DINOPROSTONE GEL FOR LABOUR INDUCTION"**

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. HUMAIRA SAFRIN H**

Sign of Investigator :

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 :

MENSTRUAL HISTORY :

MARITAL HISTORY :

OBSTETRIC HISTORY :

PAST HISTORY :

GENERAL EXAMINATION :

HEIGHT :

WEIGHT :

ANAEMIA :

EDEMA :

PULSE RATE :

BP :

CVS :

RS :

OBSTETRIC EXAMINATION :

P/A EXAMINATION :

P/V EXAMINATION :

MODIFIED BISHOP'S SCORE :

VAGINAL PH :

DATE AND TIME OF INDUCTION :

INDICATION FOR INDUCTION :

PGE2 GEL DOSE :

OUTCOME OF INDUCTION :

MODE OF DELIVERY :

TIME TAKEN TO ENTER IN TO ACTIVE PHASE OF LABOUR :

IF LSCS INDICATION FOR LSCS :

BABY WEIGHT :

BABY SEX :

APGAR :

DATE AND TIME OF DELIVERY :

INDUCTION DELIVERY INTERVAL :

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.

கர்ப்பிணி பெண்களுக்கு டைனோபராஸ்டோன் (DINOPROSTONE GEL) கூழ்மம் மூலம் பிரசவ வலி உண்டாக்குதலுக்கு முன்பு யோனியின் காரத்தண்மை (VAGINAL PH) பற்றிய ஆய்வு மேற்கொள்ளப்படுகிறது.

யோனியின் காரத்தண்மையை கண்டறிய காரத்தண்மை அறியும் காகிதத்தை யோனியில் வைத்து பரிசோதனை செய்யப்படும்.

இந்த ஆய்வு கர்ப்பிணி பெண்கள் தங்கள் சுய விருப்பத்துடன் முன்வந்தால் மட்டுமே மேற்கொள்ளப்படும்.

இந்த ஆய்வில் எனக்கு எவ்விதமான பரிசோதனைகளையும் சிகிச்சைகளையும் மேற்கொள்ள நான் முழுமனதுடன் சம்மதிக்கிறேன்.

இப்படிக்கு,

நோயாளியின் கையொப்பம் ஆய்வாளரின் கையொப்பம்

MASTER CHART

S.NO	NAME	AGE	IP.NO	GA (WEEKS)	BISHOPS SCORE	VAGINAL PH	OBSTETRIC CODE	INDICATION FOR INDUCTION	PGE 2 GEL DOSE	MODE OF DELIVERY	INDICAION FOR LSCS	B.WT	AP GAR	INDUCTION DELIVERY INTERVAL	TIME TAKEN TO ENTER IN TO ACTIVE PHASE OF LABOUR
1	SWAPNA	28	841	40W	2	5.5	G2P1L1	PD	1	LN WITH EPI		3.4	7,8	10 H 50 M	8H
2	MOHANAVALLI	25	869	38W	4	5.5	G2P1L1	PD	1	LN WITH EPI		2.5	7,8	8 H 41 M	7H
3	ARCHANA	28	1047	38W	4	5.5	G4P1L1A2	GHTN	1	LSCS	FAILURE TO PROGRESS	3.39	7,9	13 H	
4	KRANTHIDEVI	22	633	38W	2	5.5	G2P1L0	PREV NO LIVE CHILD	1	LN WITH EPI		3.1	6,7	5 H	4H
5	RASHEEDA BEGUM	23	1160	40W5D	3	5.5	G2P1L1	POSTDATED	1	LN WITH EPI		2.5	8,9	3 H 19 M	2H
6	MYTHILI	27	1183	38W5D	3	5.0	G2P1L1	GHTN	2	LN WITH EPI		3.39	7,8	15 H	12H

S.NO	NAME	AGE	IP.NO	GA (WEEKS)	BISHOPS SCORE	VAGINAL PH	OBSTETRIC CODE	INDICATION FOR INDUCTION	PGE 2 GEL DOSE	MODE OF DELIVERY	INDICAION FOR LSCS	B.WT	AP GAR	INDUCTION DELIVERY INTERVAL	TIME TAKEN TO ENTER IN TO ACTIVE PHASE OF LABOUR
7	MANIMEGALAI	26	1226	38W1D	3	4.5	G3P1L0A1	PREV IUD	2	LN WITH EPI		3.08	7,8	16 H	9H
8	VANITHA	26	1262	39W	3	4.5	G2P1L1	GDM IN MEALPLAN	1	LSCS	FAILED INDUCTION	3.2	7,8	7 H	
9	AKALYA	22	1330	38W	1	5.0	PRIMI	GDM	1	LSCS	FAILED INDUCTION	2.3	7,8	10 H	
10	PRABAVATHY	25	1373	38W2D	2	5.5	PRIMI GDM		1	LSCS	FAILED INDUCTION	2.105	7,8	10 H	
11	SANGEETHA	22	1253	38W1D	2	4.5	SHORT PRIMI GHTN		1	LSCS	FAILED INDUCTION	2.62	7,8	8 H	
12	SHANMUGATHAI	30	1184	39W	3	5.0	G2P1L1	GHTN	2	LN WITH EPI		2.52	7,8	12 H	9H
13	VAIJANTHI	25	1465	40W3D	2	5.5	G3P1L1A1	POSTDATED	1	LN WITH EPI		3.15	7,8	7 H 50 M	6H
14	RADHIKA	25	1507	40W	3	5.0	PRIMI	POSTDATED	1	LSCS	FAILED	3.5	7,8	8H 16 M	

S.NO	NAME	AGE	IP.NO	GA (WEEKS)	BISHOPS SCORE	VAGINAL PH	OBSTETRIC CODE	INDICATION FOR INDUCTION	PGE 2 GEL DOSE	MODE OF DELIVERY	INDICAION FOR LSCS	B.WT	AP GAR	INDUCTION DELIVERY INTERVAL	TIME TAKEN TO ENTER IN TO ACTIVE PHASE OF LABOUR
											INDUCTION				
15	DIVYA	24	1559	39W	3	5.5	PRIMI	OLIGO	1	OUTLET WITH EPI		2.8	7,8	10 H	7H30M
16	MANJULA	23	1629	37W5D	2	5	PRIMI	GHTN	1	LSCS	FETAL BRADY CARDIA	3.2	7,8	7 H	4H
17	THOOYAMATH	23	1182	37W	1	4.5	G2P1L1	GHTN	1	LSCS	FAILED INDUCTION	2.8	7,8	8 H 30 M	
18	SHANTHY	23	1176	37W1D	2	5	PRIMI	GHTN	2	LSCS	FAILED INDUCTION	2.5	7,8	13H	
19	DEVI	31	1864	37W	2	5	G2P1L1	OLIGO	1	LN WITH EPI		2.26	7,8	5 H 5 M	4H
20	PRIYA	21	1765	37W1D	3	4.5	PRIMI	OLIGO	1	LSCS	IMMINENT ECLAMPSIA	3	7,8	8H	
21	SANDHYA	20	1719	40W2D	2	5.5	PRIMI	POSTDATED	1	LN WITH		2.9	6,7	12H	10 H

S.NO	NAME	AGE	IP.NO	GA (WEEKS)	BISHOPS SCORE	VAGINAL PH	OBSTETRIC CODE	INDICATION FOR INDUCTION	PGE 2 GEL DOSE	MODE OF DELIVERY	INDICAION FOR LSCS	B.WT	AP GAR	INDUCTION DELIVERY INTERVAL	TIME TAKEN TO ENTER IN TO ACTIVE PHASE OF LABOUR
										EPI					
22	MEENAKSHI	21	1876	40W3D	1	4.5	PRIMI	POSTDATED	1	LSCS	FAILED INDUCTION	3.5	7,8	8H	
23	SUMITHRA	20	1160	40W3D	2	5.5	PRIMI	POSTDATED	1	OUT LET FORCEPS WITH EPI		3.4	7,8	13H	**10H30M**
24	BHUVENESHWARI	24	1180	38W	2	4.5	PRIMI	GHTN	1	LSCS	FAILED INDUCTION	2.8	7,8	8H	
25	NANDHINI	24	1854	39W6D	2	4.5	G2A1	GHTN	1	LN WITH EPI		3.6	7,8	10 H 58 M	9H
26	ANITHA	23	1856	38W	3	5	PRIMI	GHTN	1	LSCS	FAILED INDUCTION	2.6	7,8	10H	
27	SANDHYA	26	1936	40W5D	4	5.5	PRIMI	POSTDATED	1	LN WITH EPI		2.8	7,8	12H15M	10H
28	REKHA	25	2056	40W	2	4.5	PRIMI	RH NEG	1	LSCS	FETAL DISTRES	2.8	7,8	5H	

S.NO	NAME	AGE	IP.NO	GA (WEEKS)	BISHOPS SCORE	VAGINAL PH	OBSTETRIC CODE	INDICATION FOR INDUCTION	PGE 2 GEL DOSE	MODE OF DELIVERY	INDICAION FOR LSCS	B.WT	AP GAR	INDUCTION DELIVERY INTERVAL	TIME TAKEN TO ENTER IN TO ACTIVE PHASE OF LABOUR
											S				
29	PRABHA	22	1845	40W5D	4	5.5	PRIMI	POSTDATED	I	LN WITH EPI		3	7,8	12H	9H
30	KALPANA	27	1926	40W3D	3	4.5	PRIMI	POSTDATED	1	LSCS	FAILED INDUCTION	2.95	6,7	7H	
31	NALINI	22	1856	40W 6D	4	5	PRIMI	POSTDATED	1	LN WITH EPI		3.26	7,8	12 H 15 M	10H
32	AMBIKA	23	1956	39W	3	4.5	PRIMI	OLIGO	1	LN WITH EPI		2.89	7,8	10 H 5 M	8H30M
33	SUMAYA	26	1958	40W4D	2	4.5	PRIMI	POSTDATED	1	LSCS	FAILED INDUCTION	3.1	7,8	7H30M	
34	HEMALATHA	29	2034	38W	4	6	G3P2L2	GDM	1	LN WITH EPI		3.25	7,8	5 H 15 M	4H15M
35	SHANTHI	24	1880	37W	2	4.5	PRIMI	OLIGO	1	LSCS	FAILED INDUCTION	2.56	7,8	7 H 45 M	
36	NANDHINI	20	1860	40W	3	4.5	PRIMI	OLIGO	1	LSCS	FAILED INDUCTI	2.6	7,8	12H	

S.NO	NAME	AGE	IP.NO	GA (WEEKS)	BISHOPS SCORE	VAGINAL PH	OBSTETRIC CODE	INDICATION FOR INDUCTION	PGE 2 GEL DOSE	MODE OF DELIVERY	INDICAION FOR LSCS	B.WT	AP GAR	INDUCTION DELIVERY INTERVAL	TIME TAKEN TO ENTER IN TO ACTIVE PHASE OF LABOUR
											ON				
37	THULASI	27	1880	38W	2	4.5	PRIMI	OLIGO	1	LSCS	FAILURE TO PROGRESS	3.2	7,8	16H	
38	PRIYA	33	1170	38W	2	5.5	G3A2 POSTDATED		1	LSCS	FETAL DISTRESS	2.5	7,8	5 H 16 M	
39	SURYA	25	1860	40 W4D	3	5.5	PRIMI	POSTDATED	1	LN WITH EPI		3.26	7,8	11H	
40	RESHMA	20	1160	40W 4D	2	5.5	PRIMI	POSTDATED	1	OUT LET FORCEPS WITH EPI		2.56	7,8	13 H 6 M	11H
41	DHIVYA	23	1180	40 W 1 D	2	5.5	PRIMI GHTN		1	LSCS	FAILED INDUCTION	2.2	7,8	6H30M	
42	NITHYA	18	1160	40 W 1 D	2	4.5	PRIMI	POSTDATED	1	LN WITH EPI		3.6	7,8	12H	9H48M
43	KEERTHANA	23	1264	40 W 5D	2	4	PRIMI	POSTDATED	1	LSCS	FAILED	3.6	7,8	8 H	

S.NO	NAME	AGE	IP.NO	GA (WEEKS)	BISHOPS SCORE	VAGINAL PH	OBSTETRIC CODE	INDICATION FOR INDUCTION	PGE 2 GEL DOSE	MODE OF DELIVERY	INDICAION FOR LSCS	B.WT	AP GAR	INDUCTION DELIVERY INTERVAL	TIME TAKEN TO ENTER IN TO ACTIVE PHASE OF LABOUR
											INDUCTION				
44	ABITHA	20	1987	37 W 5D	1	4	PRIMI	PREECLAMPSIA	1	LSCS	FAILED INDUCTION	1.3	7,8	8 H	
45	MUNIYAMMAL	24	2624	40 W3D	4	5.5	G2P1L1	POSTDATED	1	LSCS	FETAL DISTRESS	2.7	7,8	6H 17 M	
46	AMIRTHAVALLI	26	2965	40 W	2	4.5	PRIMI	POSTDATED	1	LSCS	FAILED INDUCTION	2.8	7,8	7H35 M	
47	DEEPIKA	22	1265	37W	1	4.5	PRIMI	GHTN	1	LSCS	MSAF/FETAL DISTRESS	2.5	7,8	4H 50M	
48	DIVYABHARATHI	21	5356	39W 2D	3	5.5	PRIMI	PROM	1	LN WITH EPI		2.8	7,8	8 H 30 M	6H
49	PAVITHRA	18	5288	40 W 3D	4	5.5	PRIMI	POSTDATED	1	LN WITH E87PI		2.89	7,8	8H	6H
50	GOMATHY	21	5142	40 W 6D	1	4			1	LSCS	FETAL DISTRESS	2.6	7,8	2H 40M	

S.NO	NAME	AGE	IP.NO	GA (WEEKS)	BISHOPS SCORE	VAGINAL PH	OBSTETRIC CODE	INDICATION FOR INDUCTION	PGE 2 GEL DOSE	MODE OF DELIVERY	INDICAION FOR LSCS	B.WT	AP GAR	INDUCTION DELIVERY INTERVAL	TIME TAKEN TO ENTER IN TO ACTIVE PHASE OF LABOUR
51	VASANTHI	26	53124	0 W 1D	3	5.5	G2A1	POSTDATED	1	LN WITH EPI		2.5	7,8	11H 50M	9H
56	KEERTHI		40W2D	2	4	PRIMI	POSTDATED	1	FAILED INDUCTION	2.9			7,8	8 H	
57	GOWTHAMI		38W	3	5	PRIMI	GHTN	1		2.08			7,8	8H 10M	
58	GAYATHR		40W 3D	3	5.5	G3P2L2	POSTDATED	1		3.4			7,8	3H	

S.NO	NAME	AGE	IP.NO	GA (WEEKS)	BISHOPS SCORE	VAGINAL PH	OBSTETRIC CODE	INDICATION FOR INDUCTION	PGE 2 GEL DOSE	MODE OF DELIVERY	INDICAION FOR LSCS	B.WT	AP GAR	INDUCTION DELIVERY INTERVAL	TIME TAKEN TO ENTER IN TO ACTIVE PHASE OF LABOUR
															6M
59	AKILA			38W	3	5	PRIMI	GHTN	1		2.8			7,8	8 H 30 M
60	PARVEEN			38W	2	4	PRIMI	GHTN	1	FAILURE TO	2.9			7,8	12H

S.NO	NAME	AGE	IP.NO	GA (WEEKS)	BISHOPS SCORE	VAGINAL PH	OBSTETRIC CODE	INDICATION FOR INDUCTION	PGE 2 GEL DOSE	MODE OF DELIVERY	INDICAION FOR LSCS	B.WT	AP GAR	INDUCTION DELIVERY INTERVAL	TIME TAKEN TO ENTER IN TO ACTIVE PHASE OF LABOUR
										PROGRESS					
61	GEETHA PRASANAKUMAR			38W	3	5	PRIMI	GHTN	1		3			7,8	12H 33M
62	NEELA			40 W 2D	3	4.5	PRIMI	POSTDATED	1		2.7			7,8	10H

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63	SYED MEENA		40 W	4	5	PRIMI	GHTN POSTDATED	1			3.1		7,8	9H 55M	
64	JANSI		40 W 6D	3	5.5	G3P2L2	POSTDATED	1			2.9		7,8	5H 55M	

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65	DESARANI			40 W	3	4	PRIMI	POSTDATED	1	FAILEDINDUCTION	2.8			7,8	8H
66	GNANASUDA			39W6D	3	5.5	G3P1L1A1	OLIGO	1		3.025			7,8	10H 20M
67	KAVITHA			40 W	4	6	G2P1L1	POSTDATED	1		2.3			7,8	4H 30M

S.NO	NAME	AGE	IP.NO	GA (WEEKS)	BISHOPS SCORE	VAGINAL PH	OBSTETRIC CODE	INDICATION FOR INDUCTION	PGE 2 GEL DOSE	MODE OF DELIVERY	INDICAION FOR LSCS	B.WT	AP GAR	INDUCTION DELIVERY INTERVAL	TIME TAKEN TO ENTER IN TO ACTIVE PHASE OF LABOUR
68	JEBENA			40 W 2D	3	4.5	PRIMI	POSTDATED	1	CPD IN LABOUR	3.02			7,8	8 H 15M
69	ARCHANA			40 W 3D	4	4	PRIMI	POSTDATED	1	FAILED INDUCTION	2.9			7,8	8H 40M
70	NADHIYA			40 W	3	5.5	PRIMI	POSTDATED GHTN	1		2.3			7,8	8H

S.NO	NAME	AGE	IP.NO	GA (WEEKS)	BISHOPS SCORE	VAGINAL PH	OBSTETRIC CODE	INDICATION FOR INDUCTION	PGE 2 GEL DOSE	MODE OF DELIVERY	INDICAION FOR LSCS	B.WT	AP GAR	INDUCTION DELIVERY INTERVAL	TIME TAKEN TO ENTER IN TO ACTIVE PHASE OF LABOUR
71	ESWARI			40W1D	4	6	G3P2L2	POSTDATED	1				2	7,8	5H
72	SRIMATHI			40 W 2 D	3	5	PRIMI	POSTDATED	1	FETAL DISTRESS			3.2	7,8	10H
73	SANGAVI			40 W 1D	3	5	PRIMI	POSTDATED	1				3.3	7,8	12H

S.NO	NAME	AGE	IP.NO	GA (WEEKS)	BISHOPS SCORE	VAGINAL PH	OBSTETRIC CODE	INDICATION FOR INDUCTION	PGE 2 GEL DOSE	MODE OF DELIVERY	INDICAION FOR LSCS	B.WT	AP GAR	INDUCTION DELIVERY INTERVAL	TIME TAKEN TO ENTER IN TO ACTIVE PHASE OF LABOUR
74	KANCHAN DEVI		40 W 2D		4	5.5	G2P1L1	POSTDATED	1		2.8			7,8	8H
75	SWAPNA		39W 3D		3	5	G2P1L1	OLIGO	1		3.6			7,8	7H

S.NO	NAME	AGE	IP.NO	GA (WEEKS)	BISHOPS SCORE	VAGINAL PH	OBSTETRIC CODE	INDICATION FOR INDUCTION	PGE 2 GEL DOSE	MODE OF DELIVERY	INDICAION FOR LSCS	B.WT	AP GAR	INDUCTION DELIVERY INTERVAL	TIME TAKEN TO ENTER IN TO ACTIVE PHASE OF LABOUR
76	PAVITHRA		38W	3	4.5		PRIMI	OLIGO	1		2.5			7,8	14H
77	SUGANYA		40W 1D	2	4		PRIMI	POSTDATED	1	FAILED INDUCTION	3.00			7,8	8H
78	TAMILSELVI		38W	2	4		PRIMI	POSTDATED	1	FAIL	2.3			7,8	7H

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										ED NDUCTION					
79	HEMALATHA			39W	3	4.5	PRIMI	GHTN	1	FAILED INDUCTION	2.5			7,8	14H
80	MUTHULAKSHMI	19	10500	38W	3	5	PRIMI	GDM	1	LN WITH EPI		2.1	7,8	12H	
81	PAVITHRAA	20	10417	40W 2D	2	4	PRIMI	POSTDATED	1	LSCS	FAILED INDUCTION	2.5	7,8	8H	
82	GAYATHRI	25	10537	40W 4D	2	5	PRIMI	POSTDATED	1	LSCS	FAILURE TO PROGRESS	2.8	7,8	10H	
83	DIVYA	22	10511	40 W 2D	3	4.5	PRIMI	POSTDATED	1	LSCS	FAILED INDUCTION	3.0	7,8	8H	
84	KOWSALYA	20	19601	40 W 2D	3	4	PRIMI	POSTDATED	2	LSCS	FAILED INDUCTION	2.8	7,8	14H	
85	HASEENA BEGAM	27	10609	40 W 1	2	4.5	G2P1L1	POSTDATED	1	LSCS	FAILURE TO	3.6	7,8	12H	

S.NO	NAME	AGE	IP.NO	GA (WEEKS)	BISHOPS SCORE	VAGINAL PH	OBSTETRIC CODE	INDICATION FOR INDUCTION	PGE 2 GEL DOSE	MODE OF DELIVERY	INDICAION FOR LSCS	B.WT	AP GAR	INDUCTION DELIVERY INTERVAL	TIME TAKEN TO ENTER IN TO ACTIVE PHASE OF LABOUR
				D							PROGRESS				
86	THENMOZHI	20	9438	40 W 2D	4	5.5	PRIMI	POSTDATED	1	VACCUM		2.6	7,8		10H
87	AARTHI	19	9253	38W	3	5	PRIMI	GTHN	1	LN WITH EPI		3.1	7,8		12H
88	NANDHINI	19	9461	40W 3D	3	5.5	PRIMI	POSTDATED	1	LN WITH EPI		3	7,8		8H
89	BHARATHI	20	9561	40 W 3D	2	5	PRIMI	POSTDATED	1	LN WITH EPI		2.7	7,8		10H
90	MAHALAKSHM	20	9508	40	2	4		POSTDATED	1	LSCS	FAILED	2.8	7,8		9 H

S.NO	NAME	AGE	IP.NO	GA (WEEKS)	BISHOPS SCORE	VAGINAL PH	OBSTETRIC CODE	INDICATION FOR INDUCTION	PGE 2 GEL DOSE	MODE OF DELIVERY	INDICAION FOR LSCS	B.WT	AP GAR	INDUCTION DELIVERY INTERVAL	TIME TAKEN TO ENTER IN TO ACTIVE PHASE OF LABOUR
	I			W 2D			PRIMI				INDUCTION				
91	NIRMALA	25	9582	37W	3	5.5	G2P1L1	GDM ON INSULIN	1	LN WITH EPI		3.3	7,8	8H	
92	SHARMILA	21	9485	40 W 2D	3	4.5	G2P1L1	POSTDATED	1	LN WITH EPI		2.9	7,8	10H 30M	
93	ANUSIYA	22	9881	40 W 1D	3	5	G2A1	POSTDATED	1	LN WITH EPI		3.1	7,8	8H 30M	
94	POONGODI	26	9203	38 W	3	5	PRIMI	GDM	1	LSCS	FAILURE TO PROGRESS	3.1	7,8	11 H 6 M	
95	SELVI	24	9206	40 W 3D	3	5.5	PRIMI	POSTDATED	1	LN WITH EPI		2.9	7,8	8H	
96	SIVARANJANI	23	9210	37W	4	4.5	G2P1L1	GHTN	1	LN WITH EPI		3.1	7,8	8H 45 M	

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97	RUBINI	25	9510	38W 3D	3	5.5	PRIMI	OLIGO	1	LN WITH EPI		2.3	7,8	6H 30M	
98	AALIYA	23	9673	40 W	4	4	PRIMI	RH NEG	1	LSCS	FAILED INDUCTION	3.6	7,8	7H	
99	INDUMATHY	27	9532	40 W 5 D	4	5.5	PRIMI	POSTDATED	1	LN WITH EPI		2.89	7,8	7 H 18 M	
100	AARTHI	29	9158	40 W 4 D	3	5	G2P1L1	POSTDATED	1	LN WITH EPI		3.12	7,8	6 H 43 M	

INSTITUTIONAL ETHICAL COMMITTEE, STANLEY MEDICAL COLLEGE, CHENNAI-1

Title of the Work : Effect of Vaginal PH on Efficacy of Dinoprostone Gel for Labour induction.

Principal Investigator : Dr. H Humaira Safrin

Designation : PG M S (O & G)

Department : Department of O & G,
Government Stanley Medical College,
Chennai-01

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 26.09.2016 at the Council Hall, Stanley Medical College, Chennai-1 at 2PM

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, 27/9/16.
IEC, SMC, CHENNAI