TO DETERMINE THE EFFECT OF VAGINAL PH ON EFFICACY OF DINOPROSTONE GEL FOR LABOUR INDUCTION-PROSPECTIVE OBSERVATIONAL STUDY

By

Dr.CHINTHALA SAI LAKSHMI SHREYA, MBBS

Dissertation submitted to the

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, TAMAKA, KOLAR – 563 101

In partial fulfilment of the requirements for the degree of

MASTER OF SURGERY (MS)

IN

OBSTETRICS AND GYNAECOLOGY

Under the Guidance of

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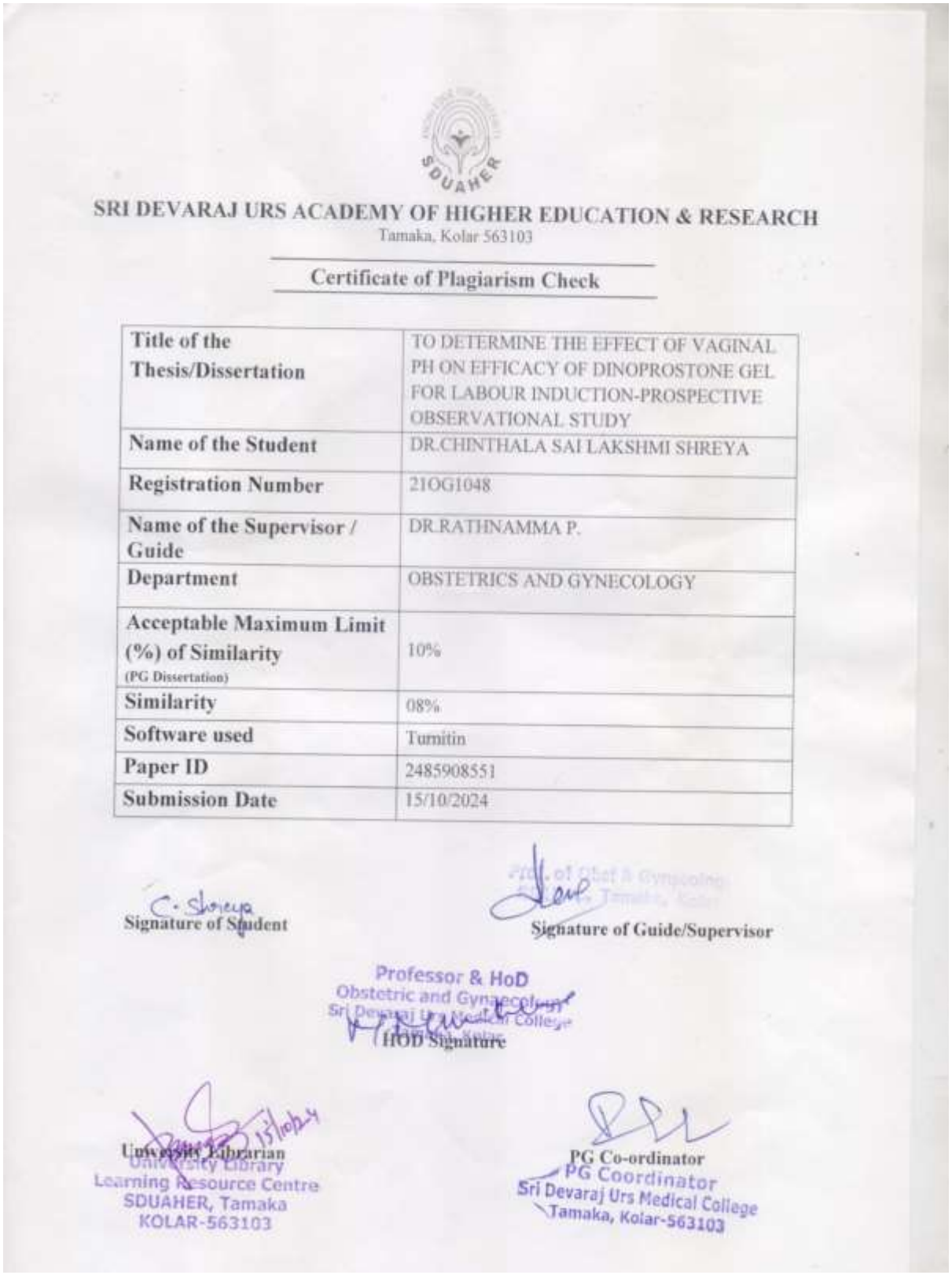

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TO DETERMINE THE EFFECT OF VAGINAL PH ON EFFICACY OF DINOPROSTONE GEL FOR LABOUR INDUCTION-PROSPECTIVE OBSERVATIONAL STUDY Abstract Introduction: Induction of labour (IOL) has shown a notable rise in the recent times. It is widely acknowledged that IOL is appropriate when the potential benefits for the fetus, or mother exceeds the risk associated with waiting for commencement of spontaneous labour. Among the many pharmacological methods of labour induction, prostaglandins like dinoprostone gel are a widely used method. The effectiveness of IOL depends on several clinical parameters. Given the complexity of these factors, this study explores the specific role of vaginal pH in modifying the effectiveness of PGE2 gel-based labour induction method. Understanding these interactions will provide critical insights into optimizing induction protocols, potentially improving maternal and fetal

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ABBREVIATIONS

AMP: Adenosine Monophosphate

ARM: Artificial Rupture of Membranes

BMI: Body Mass Index

BS: Bishop Score

cAMP: cyclic Adenosine Monophosphate

CBC: Complete Blood Count

FDA: Food and Drug Administration

GA: Gestational Age

GDM: Gestational Diabetes Mellitus

IEC: Institutional Ethics Committee

IOL: Induction of Labour

LFT: Liver Function Test

LSCS: Lower Segment Caesarean Section

NICHD: National Institutes of Child Health and Human Development

NICU: Neonatal Intensive Care Unit

NST: Non-Stress Test

OBG: Obstetrics and Gynaecology

PG: Prostaglandins

PGE1: Prostaglandin E1

PGE2: Prostaglandin E2

PGF2α: Prostaglandin F2α

PPH: Postpartum Haemorrhage

RFT: Renal Function Test

SDUAHER: Sri Devaraj Urs Academy of Higher Education and Research

SDUMC: Sri Devaraj Urs Medical College

SD: Standard Deviation

SPSS: Statistical Package for Social Sciences

WHO: World Health Organization

Abstract

ABSTRACT

Introduction: Induction of labour (IOL) has been increased significantly in the recent days. It is widely acknowledged that IOL is appropriate when the potential benefits for the fetus, mother, or both outweigh those of expectant management, which involves waiting for spontaneous labour to begin. Among the many pharmacological methods of labour induction, prostaglandins like dinoprostone gel are a widely used method. The success of IOL depends on several factors including the clinical condition of the patient at the time of induction, induction methods, pH of the vagina and other predictive factors. Given the complexity of factors influencing the success of labour induction, including biochemical, physiological, and clinical parameters, this study explores the specific role of vaginal pH in modifying the efficacy of PGE2 gel-based labour induction methods. Understanding these interactions will provide critical insights into optimizing induction protocols, potentially improving maternal and fetal outcomes.

Objectives: To determine the vaginal pH and classify as high (pH >4.5) and low vaginal pH (pH ≤4.5); and to determine if the vaginal pH has any effect on the action of PGE2 gel for cervical ripening and labour induction.

Methods: A prospective observational study was conducted in the department Obstetrics and Gynaecology of RL Jalappa Hospital, Kolar. All pregnant women underwent IOL during the study period were eligible for the study. Ninety participants with singleton pregnancy with cephalic presentation, having unfavourable modified Bishop score (≤ 5) and reactive NST were included in the study after obtaining informed consent. However, patients with known conditions including hypersensitivity to prostaglandins, placenta previa, suspected chorioamnionitis, malpresentation, cephalopelvic disproportion, previous caesarean delivery, and premature rupture of membranes were excluded from the study.

The participating patients were clinically evaluated after taking a detailed obstetric, menstrual and medical history, supported by relevant investigations. Each participant underwent speculum examination and vaginal pH was assessed by using pH indicator paper. Based on the pH, patients were divided into two groups- Group A (pH ≤4.5) and Group B (pH >4.5). Following this, Modified Bishop score is assessed at the baseline and during subsequent follow-up vaginal examinations. All clinical assessments were done by the investigators according to the standard protocol of the hospital. Standard ethical practices were followed during the study.

Results: The study included 90 term pregnant participants with equal distribution of low and high vaginal pH. The baseline characteristics of both groups like mean age, gestational age, parity, comorbidities, and pre-induction modified Bishop score was similar.

Significant differences were noted between the two groups in favour of group B. Mean Bishop score improvement in group B (4.78 ±1.72) was high compared to group A (2.5 ±1.1). The dose repetitions were less among patients having a high vaginal pH. The mean time taken enter active phase of labour was substantially higher in group A (16.2 hours) compared to the group B (9.2 hours) participants. The proportion of normal delivery was significantly higher in group B (64.5%) compared to group A (40.0%). Conversely, group A had a high rate of LSCS (60.0%) compared to group B (35.5%).

Conclusion: This study reveals that patients with higher vaginal pH (>4.5) experience better outcomes with dinoprostone-induced labour. Appreciable favourable outcomes were noted in cervical ripening, reduced induction requirements, and higher rates of normal delivery. These findings highlight the importance of examining the vaginal pH in predicting successful labour induction.

Keywords: Cervical Ripening, Dinoprostone Gel, Labour Induction (LI), Prostaglandin E2 (PGE2), Vaginal pH

Introduction

INTRODUCTION

Induction of labour is defined as an intervention designed to artificially initiate uterine contractions leading to progressive dilatation and effacement of the cervix and birth of the baby. Approximately 10-20% of expectant mothers undergo labour induction due to various medical indications.[1,2]

It is widely acknowledged that induction of labour (IOL) is appropriate if potential benefits for the fetus, and mother outweigh those of expectant management, which involves waiting for spontaneous labour to begin.[2-5] Additionally, IOL should be considered when vaginal delivery is deemed the most suitable method. IOL requires informed consent with clear communication about the risks, benefits, and the chosen method of induction.[6] Inclusion of IOL-related data is critical for any birth centre to provide a comprehensive understanding regarding the patients.

There is a common understanding that the procedure may increase the likelihood of operative deliveries and influence the overall birth experience, which can be perceived as less positive by women undergoing IOL. This perception is often linked to the obstetric risks that necessitate IOL or the eventual outcomes, such as Caesarean sections, rather than the procedure itself. In these cases, the experience of childbirth may be viewed more negatively due to the associated risks or outcomes.

Several factors influence the success of IOL, including the clinical condition at the time of induction, the characteristics of the woman, the method of induction chosen, pH of the vagina and other predictive factors that contribute to the outcome of the procedure.[7,8]

For labour induction, prostaglandins are usually used in the clinical settings.[7] Prostaglandins are types of organic acids which have low solubility in aqueous solution. The drug release can be altered by the vaginal pH; thus, resulting in variable clinical responses. The various forms

of prostaglandin E2 (Dinoprostone) available are- vaginal tablets, endocervical gel, and slow-release vaginal pessary.

The cervix is consisting of comparatively few smooth muscle cells. The collagen bundles in it surrounded by proteoglycans confers its rigidity.[7-9]

Cervical ripening commences with the breakdown of collagen fibres which is facilitated by collagenase enzymes. This remodelling occurs primarily at internal os, the narrow passage connecting the cervix to the uterus. Research has shown that neutrophils play a critical role in this process by invading the cervical tissue and releasing collagenase. These changes eventually lead to the disorganization and rearrangement of collagen bundles, ultimately preparing the cervix for labour. Prostaglandin (PGE2) primarily softens the cervix by reducing the cervical stiffness.[7,9-11]

Given the complexity of factors influencing the success of IOL, including biochemical, physiological, and clinical parameters, this study seeks to explore the specific role of vaginal pH in modifying the effectiveness of PGE_2 gel-based labour induction methods. Understanding these interactions will provide critical insights into optimizing induction protocols, potentially improving maternal and fetal outcomes.

Objectives

OBJECTIVES OF THE STUDY

1. To determine the vaginal pH and classify as high (pH >4.5) and low vaginal pH (pH ≤4.5).

2. To determine if the vaginal pH has any effect on the action of PGE2 gel for cervical ripening and labour induction.

Review of literature

REVIEW OF LITERATURE

INTRODUCTION TO LABOUR INDUCTION (IOL):

The World Health Organization (WHO) defined it as the artificial stimulation of the uterus to initiate the labour process.[12] IOL is mostly achieved through the use of medications like oxytocin or prostaglandins, or by manually rupturing the amniotic sac. Though the process is mostly safe and effective, IOL is not without risks, and many women find the procedure uncomfortable. Over the years, the frequency of labour inductions has steadily increased, particularly to shorten the pregnancy duration. In high-income countries, up to one in four term births result from labour induction. Although the proportion is generally less in the low and middle-income countries, certain regions report figures comparable to those in wealthier nations.

HISTORY OF INDUCTION OF LABOUR:

This practice has evolved significantly over centuries as medical knowledge and technology advanced. In ancient times, methods for inducing labour were often rudimentary and dangerous, with herbal remedies and physical interventions commonly employed. The concept of IOL has been traced even in the period of Hippocrates. He described methods like mechanical dilation of the cervical canal and mammary stimulation.[13] The Greek physician 'Soranus' used various labour induction methods, including artificial membrane rupture, in the 2nd century AD. Later, Moshion introduced the concept of manual cervical dilation, while Casis developed several instruments for this purpose. Ambroise Paré introduced a life-saving obstetric procedure in the mid-1500s, involving cervical stretching and fetal repositioning to

control severe bleeding during childbirth.[14] Paré's disciple, Bourgeois, expanded on these practices, utilizing strong enemas and folk medicine mixtures to induce and augment labour.[15]

James introduced amniotomy as a labour induction method in the early nineteenth century. Afterwards, amniotomy and similar mechanical techniques remained the standard approach for nearly two centuries.[16] In the early twentieth century, Henry Dale discovered that pituitary extracts have a direct role in myometrial contractions. Building on this finding, Bell conducted the first clinical trials using extract from pituitary gland for induction in 1909. However, reports of uterine rupture soon mounted, and the use of pituitary extract was restricted.[17]

It wasn't until the 20th century that safer and more reliable methods were developed.

The structure of oxytocin was identified in 1953. This was followed by introduction of synthetic oxytocin for labour induction in 1955.[18] Karim et al. first documented application of prostaglandins for IOL in the late 1960s. Since then, prostaglandins were widely used for IOL in various forms. [19,20] Afterwards, misoprostol, has also been used as a safe option in this procedure.

These innovations dramatically improved the maternal and fetal outcomes by allowing healthcare providers to intervene when necessary, such as in cases of post-term pregnancy or complications like preeclampsia. Hence there is a rise of IOL in recent decades is for managing high-risk pregnancies across the globe. However, the practice remains the subject of ongoing research and debate, if there is a balance between medical necessity and overuse in some regions, the effects of the various types of IOL methods and their choice for different types of patients.[12,21]

INCIDENCE OF INDUCTION OF LABOUR

Over the past few decades, labour induction rates have steadily increased, driven by a desire to shorten pregnancy duration. Nevertheless, there is a rising trend of labour induction across various settings.[21] The factors contributing to this upward trajectory are multifaceted.[21,22] Key drivers include:

– Easy access to cervical ripening agents.

– Enhanced understanding of induction methods and indications.

– Shifts in physician and patient attitudes, embracing more flexible elective indications.

– Growing litigation concerns.

PHYSIOLOGY OF CERVICAL RIPENING[23,24]

Cervix is primarily made up with connective tissue rich in collagen. It undergoes considerable transformations throughout the pregnancy period. The dynamic remodelling of cervix involves four distinct stages. These are softening of the cervix (Stage 1), cervical ripening (Stage 2), cervical dilation (Stage 3), and postpartum repair (Stage 4).

STAGE 1: Softening initiates as early as one-month post-conception. This stage is characterized by:

- Increased connective tissue and glands.
- Enhanced oedema and vascularity.
- Cellular growth and expansion.

STAGE 2: The second stage is cervical ripening which is marked by the following characterized by:

- Proteolytic enzymes realign and degrades the collagen cross-links.
- Disorganization of collagen bundles, facilitated by collagenase.
- Neutrophil invasion and degranulation, releasing collagenase.
- Increased cervical decorin, promoting collagen fibre separation.

STAGE 3: The third phase, dilation, occurs during active labour:

- Uterine contractions drive cervical dilation.
- With the gradual dilatation and ripening of cervix, the fetal presenting part pass through.
- Tissue fibres reorient in response to stress.
- Elastin components act as a ratchet, maintaining dilation between contractions.

STAGE 4: The last stage is known as postpartum repair. It commences immediately after birth, concluding with uterine involution.

METHODS OF LABOUR INDUCTION

There are several methods available for IOL. The most appropriate method for IOL is selected based on the medical condition and the condition of the mother and foetus.[7] The most common methods include pharmacological and mechanical techniques. The effectiveness of these methods varies considerably (Table 1).

Table 1: Methods of induction of labour

Pharmacological Methods:
Oxytocin
Prostaglandins
Mifepristone
Surgical methods
Amniotomy
Mechanical methods
Balloon Catheter (Foley Catheter)
Osmotic dilators
Natural Methods

1. PHARMACOLOGICAL METHODS:

a. OXYTOCIN:

It is one of the most widely used agents for inducing labour.

Oxytocin is used intravenously.

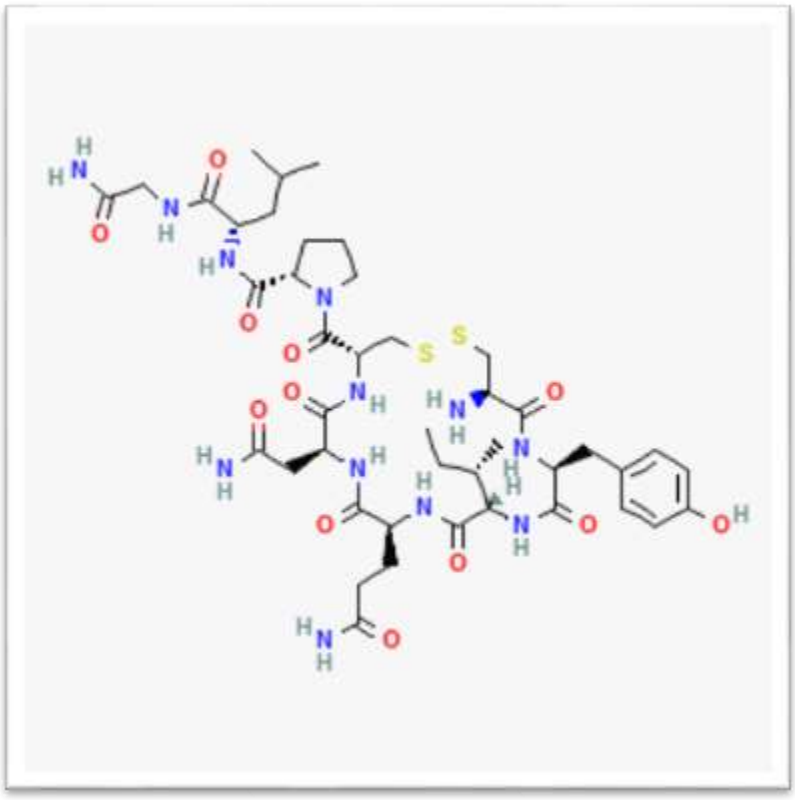
Oxytocin stimulates uterine contractions, mimicking the natural hormone's effects.

Its administration requires careful monitoring of both the mother and fetus, as excessive contractions increase the risk of fetal and maternal complications.[25,26]

Structure[25,26]:

Structurally, it is a peptide hormone, commonly referred to as a nonapeptide. It has the chemical structure $C_{43}H_{66}N_{12}O_{12}S_2$, with a molecular weight of approximately 1007 Da. The structure of oxytocin features a six-amino-acid cyclic portion, closed by a disulfide bond between two cysteine residues, and a three-amino-acid tail (Figure 1). This unique structure allows oxytocin to bind specifically to oxytocin receptors where it exerts its primary physiological effect.

Figure 1: Structure of oxytocin



Oxytocin's cyclic peptide nature increases its stability and helps regulate its interaction with receptors, making it an effective agent for stimulating uterine contractions. Once oxytocin binds to its receptors, it activates a signalling pathway that increases intracellular calcium levels, thereby enhancing the contractile strength of the uterine muscles, which is crucial for labour induction. This mechanism mimics the natural oxytocin release by the posterior pituitary, facilitating the labour process.[26]

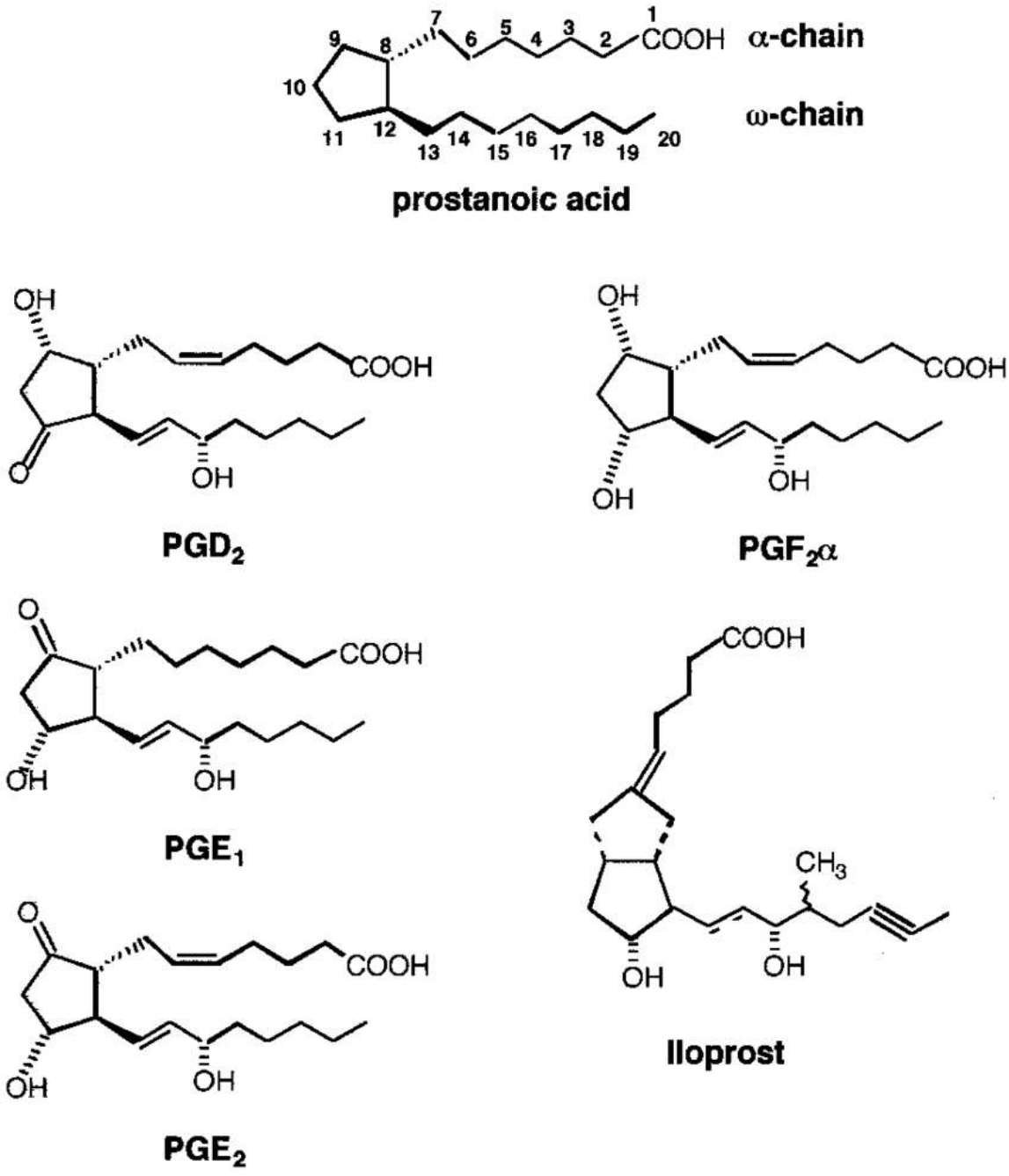
Synthetic oxytocin (Pitocin) is administered intravenously in a controlled manner to achieve a steady and manageable stimulation of uterine contractions. Its structural properties, including the disulfide bond and specific amino acid sequence, contribute to its ability to initiate labour effectively while minimizing degradation in the bloodstream.

b. PROSTAGLANDINS[9,10,27,28]

Prostaglandins, such as dinoprostone (PGE2) and misoprostol (PGE1), are another commonly used method. These drugs help to ripen the cervix, preparing it for labour by softening and dilating the tissue. Prostaglandins can be administered as vaginal gels, suppositories, or oral tablets. The effectiveness of prostaglandins in initiating labour, particularly in cases where the cervix is not yet favourable, has made them a key component in induction protocols.

Prostaglandins are a group of lipid compounds derived from fatty acids, particularly arachidonic acid. Their structure consists of a 20-carbon skeleton that forms a five-membered ring, which is essential to their biological activity. This five-carbon ring differentiates prostaglandins from other eicosanoids and gives them their distinct properties. The variations in their functional groups attached to the carbon chain define the different types of prostaglandins, such as PGE2 and PGF2α, which are relevant in labour induction (Figure 2).

Figure 2: Chemical structure of prostaglandin



Prostaglandin E2 (PGE2), commonly used in labour induction, has the chemical formula C20H32O5 and contains a hydroxyl group (-OH) at the C11 position and a ketone group (=O) at C9. This specific structure makes PGE2 highly effective in ripening the cervix and initiating uterine contractions. It interacts with prostaglandin receptors on the cervical and uterine tissues that leads to rise in intracellular calcium levels, which stimulates smooth muscle contractions and softens the cervix (Figure 3).

The softening of the cervix, also known as cervical ripening, is crucial for the labour process and is one of the primary actions of PGE2 when used in the form of gels or pessaries for induction of labour.

Prostaglandin F2α (PGF2α), another variant, has a similar structure but differs in the position of hydroxyl groups, which results in slightly different physiological effects, such as increasing uterine tone and contractility. However, PGE2 is preferred for cervical ripening due to its superior effect on the cervix. The acidity of the vaginal environment, with a pH typically ranging from 3.8 to 4.8, may influence the release and activity of these prostaglandins, altering their clinical efficacy during labour induction.

MAJOR TYPES OF PROSTAGLANDINS:

Dinoprostone:

It is a chemical replica of endogenous prostaglandin E2 (PGE2). Food and Drug Administration or FDA has given approval for its use in cervical ripening. It is found in market in two forms: vaginal insert (Available in market as Cervidil®) and cervical gel (Available in market as Primigyn®) both of which require cold storage for stability.[28,29] The vaginal insert offers a slower, more controlled release of PGE2 over 12 hours, dispensing dinoprostone 0.3 mg/ every hourly, resulting in a longer-lasting effect compared to the gel.[29,30] While a physician is required to administer the gel,[29] the vaginal insert can easily be placed or removed by any non-physician health workers also.[28] A meta-analysis based on randomized controlled trials indicated that LSCS rates significantly comes down with the use of dinoprostone vaginal insert. It also reduces

the oxytocin need among the primigravida women than repeated use of gel within the cervix.[31]

Figure 3: Dinoprostone gel

Misoprostol:

It is a structurally similar to PGE1. It is widely used for cervical ripening, terminating pregnancy <28 weeks, and management of postpartum hemorrhage.[4,30,32] It can be administered through various routes including oral, vaginal or per rectal, though absorption varies depending on the method.[33] It is typically administered through per oral or per vaginal route for IOL. Although effective, oral or vaginal tablets exhibits slow absorption and unpredictable bioavailability.[30] The need to score and divide tablets for vaginal administration near term increases the risk of inaccurate dosing.[34,35]

Misoprostol differs from dinoprostone in that it cannot be easily discontinued or removed once administered, making it challenging to promptly manage adverse effects like uterine tachysystole.[34] Its advantages over dinoprostone include lower cost and a longer shelf life, as it does not require refrigeration.[4,34]

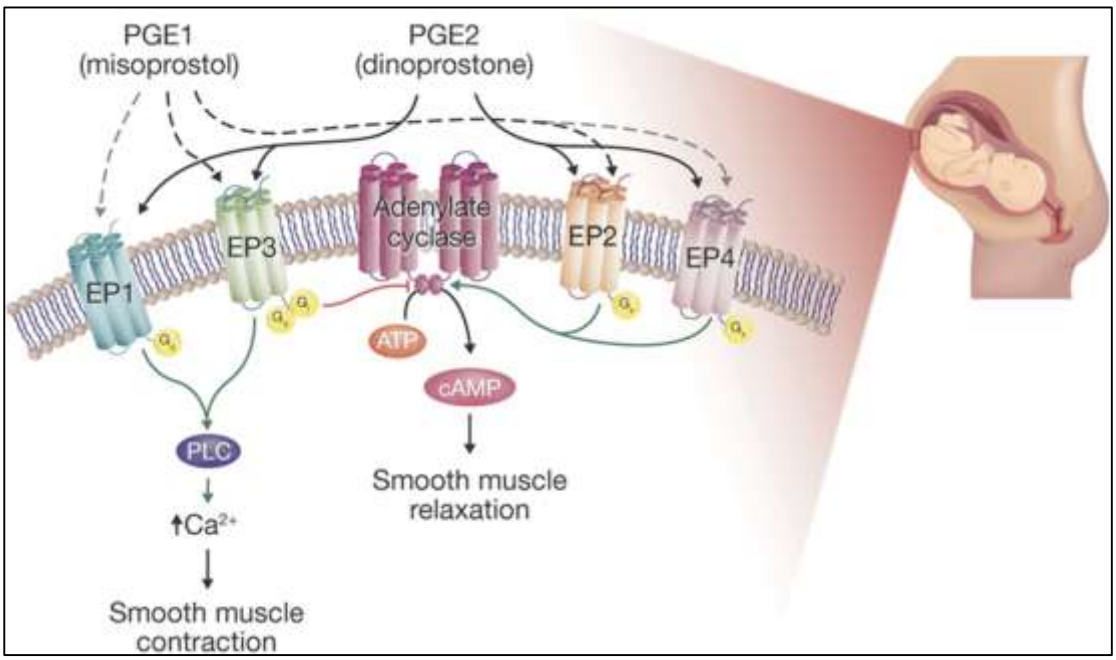
PROSTAGLANDIN METABOLISM[28]: Prostaglandins play a pivotal role in reproductive processes. Their synthesis begins with arachidonic acid, converted by Prostaglandin H Synthase. These compounds act through G protein-coupled receptors, influencing uterine tone by modulating cyclic AMP and calcium levels. Notably, PGE2 promotes cervical ripening and uterine quiescence, while PGF2α induces contractions. Metabolized by 15-OH PG dehydrogenase, prostaglandins are primarily produced by fetal membranes, with PGE2 being the dominant product. Their levels surge during labour, particularly with cervical dilatation.

Mechanism of action:

Prostaglandin E2 (PGE2) binds to four EP receptors (EP1-4) triggering two distinct signalling pathways. While EP1 receptor and EP3 receptor activation increases cellular calcium levels, EP2 receptor and EP4 receptor activation boosts cyclic adenosine monophosphate (cAMP) production.[36,37] This mechanism of action implies that cervical ripening induced by dinoprostone mirrors the natural process of cervical ripening that occurs before spontaneous labour. Misoprostol primarily targets the EP3 receptor. Besides, it also non-selectively attaches to EP2 receptors. Together, it releases endogenous PGE2 which facilitates the cervical softening and increases uterine contraction.[32,37-39] In vitro studies demonstrate that misoprostol requires relatively low dose than dinoprostone to stimulate myometrial contractions.[38,39] These findings may

explain misoprostol's link to tachysystole and uterine rupture, due to unique prostaglandin signalling pathways.[38,39] (Figure 4).

Figure 4: Mechanism of action of prostaglandins in induction of labour



The chemical structure of prostaglandins, particularly PGE2, plays a pivotal role in labour induction as it directly affects their interaction with receptors in the reproductive system, influencing cervical ripening and uterine contractions, both essential for successful labour initiation.

The characteristics of the two types of prostaglandins are described in table 2.[32]

Table 2: Comparison of Dinoprostone and Misoprostol for Labour Induction

Characteristic	Dinoprostone	Misoprostol
Description	PGE2	Synthetic PGE1 analogue
Formulation	10 mg vaginal insert placed in the posterior fornix	Tablet 25 mcg, administered vaginally or orally
Dose	0.3 mg/h released over 12 h	25–50 mcg vaginally or orally every 4–6 h
Receptor binding	EP1, EP2, EP3, EP4	EP3 (potent); possibly EP2
Pharmacologic effects	Induces cervical remodelling Inconsistent effects on uterine contractions; may be related to cervical ripening & direct myometrial effect Mild stimulation of the GI tract.	Induces cervical remodelling Generation of uterine contractions, Increased contractility Decreases total myometrial collagen and connective tissue
Pharmacokinetics	Half-life: 2.5–5 min	Half-life (oral): 20–40 min Half-life (vaginal): 60 min
Adverse effects	Tachysystole (vaginal insert: 2.0%; cervical gel: 6.6%), Chills/fever (vaginal insert: < 1%; cervical gel: 1.4%), Diarrhoea/vomiting/nausea (vaginal insert: < 1%; cervical gel: 5.7%)	Tachysystole (vaginal: 16.6%; oral: 7.0%), Chills/fever (≤ 5%), Diarrhoea/abdominal pain/nausea (≤ 5%; increased with oral administration)

Metabolism of prostaglandins[40]

In adults, PGs are quickly degraded in the liver, kidneys, myometrium, connective tissue, and lungs (Hansson and Samuelsson, 1965). Notably, during pregnancy, prostaglandin metabolism intensifies in the lungs (Bedwani and Marley, 1975) and uterus (Keirse and Turnbull, 1975), facilitating increased clearance of these compounds. This enhanced metabolic activity is crucial for maintaining optimal

prostaglandin levels, which play a vital role in pregnancy-related processes, including labour induction and uterine contractions.

2. SURGICAL METHODS:

A. AMNIOTOMY[41]:

Amniotomy, or artificial rupture of membranes (ARM), involves manually breaking the amniotic sac to stimulate labour. This is usually done with a sterile instrument during a vaginal examination. Amniotomy can be effective in triggering labour if the cervix is already partially dilated, but it is often used in conjunction with oxytocin to strengthen contractions.

A recent meta-analysis evaluated the benefits and risks of early amniotomy in labour induction. The researchers systematically reviewed studies from major databases until December 31, 2018. The researchers examined randomized controlled trials comparing early amniotomy (before active labour) to late amniotomy (after active labour onset). The authors included articles published in English that featured patients with singleton term pregnancy undergoing labour induction for various reasons.

The meta-analysis pooled data using standard methodologies and statistical analysis. While LSCS rates and time to delivery were the primary outcomes, the secondary outcomes included various labour and neonatal complications, such as intrapartum infections, operative deliveries, cord prolapse, and admissions of the newborn to neonatal intensive care unit (NICU). A separate analysis was done exclusively on nulliparous patients (women who have not given birth previously) for the primary outcomes.

The final analysis included seven studies involving a total of 1,775 patients. The study revealed that early amniotomy resulted in a significantly shorter delivery time (3.62 hours). For nulliparous women, delivery time was reduced by 5.12 hours when early amniotomy was used.

Importantly, the two groups showed no difference in LSCS rates or intrapartum infectious morbidity. Similarly, no notable differences were observed in any of the secondary outcomes, including operative delivery rates, cord prolapse, uterine hyperstimulation, and NICU admissions.

B. BALLOON CATHETER (FOLEY CATHETER)[42]:

Balloon catheter is a commonly employed method. A balloon catheter is inserted into the cervical canal and inflated, gently applying pressure to facilitate dilation.

- Once positioned, sterile saline solution is injected for the balloon inflation.
- The catheter is kept in situ for a maximum 24 hours. The balloon applies gentle pressure on the cervix during this time.
- The balloon applies pressure to soften and open the cervix, facilitating labour onset or allowing for membrane rupture.
- In addition, it enhances prostaglandin production by rubbing and stretching the cervix.
- Prostaglandin in turn shortens and softens the cervix and prepares it for labour.
- Once the cervix is ready, the doctor can break the waters to further induce labour.

3. NATURAL METHODS:

Some non-invasive, natural approaches to inducing labour are sometimes recommended, though their effectiveness is less well-documented. These include acupuncture, nipple stimulation, and certain herbal supplements.[43]

Each labour induction method has its unique advantages and potential risks. The chosen method is typically personalized to accommodate an individual's specific medical requirements

and personal preferences. In many cases, multiple methods may be combined to increase the success of induction and delivery.

CHOICE OF METHODS[4,10]

When selecting a cervical ripening method, clinicians should consider the past medical and obstetric conditions of the patients, and potential complications, particularly tachysystole. The National Institutes of Child Health and Human Development (NICHD) has defined it as tachysystole occurs when there are more than five contractions in a 10-minute window, averaged over a 30-minute period. [44] Cervical ripening techniques are tailored to individual patient needs, often combining methods for optimal results. The two primary approaches are mechanical methods (Example- Foley's catheters), and pharmacologic methods (Example- prostaglandins).[4] However, the choice is also based on the considerations on the common complications encountered during with the methods described above.[45]

ADVANTAGES OF MECHANICAL METHODS:

- More cost-effective and
- Lower risk of causing uterine tachysystole.

DISADVANTAGES OF MECHANICAL METHODS:

- Require placement by a clinician who might be unavailable in the labour room round the clock.[46]
- Correct placement of mechanical devices, which can occasionally result in failed attempts.[46]
- Patients may experience slight discomfort during the insertion process.[46]

PREREQUISITES FOR INDUCTION:

PRE-INDUCTION ASSESSMENT:

To ensure a safe and effective induction process, the following maternal parameters must be evaluated:

1. Indication Confirmation: Verify the medical necessity for induction.
2. Contraindication Review: Rule out any conditions that may preclude labour or vaginal delivery.
3. Pelvic Assessment: Evaluate the bony pelvis's shape and adequacy.
4. Cervical Status Evaluation: Determine cervical readiness using the modified Bishop score.
5. Body mass index (BMI) measurement

Table 3: Modified Bishop Score[47]

Score	**0**	**1**	**2**	**3**
Dilatation	Closed	1-2	3-4	5
Length	>4	3-4	1-2	0
Position	Posterior	Midline	Anterior	-
Consistency	Firm	Medium	Soft	-
Head station	-3	-2	-1,0	+1,+2

PREDICTING LABOUR INDUCTION OUTCOMES: BISHOP SCORE

The Bishop score, introduced by Bishop in 1964, provides a quantitative measure to predict labour induction success. This score correlates inversely with induction difficulty; lower scores indicate reduced likelihood of successful vaginal delivery. If Bishop score <5, it is considered as unfavourable cervix and induction is indicated.

FETAL PARAMETER ASSESSMENT:

To ensure optimal induction conditions, the following factors must be evaluated:

1. Gestational Age Confirmation: Verify fetal age to determine optimal induction timing.
2. Fetal Weight Estimation: Assess fetal size to anticipate potential delivery complications.
3. Fetal Position Determination: Identify fetal orientation to plan induction strategy.
4. Fetal Well-being Assessment: By non-stress test (NST) to ensure safe induction.

CONTRAINDICATIONS OF INDUCTION OF LABOUR:

1. Placenta previa
2. Vasa previa
3. Placental abruption
4. Current herpes virus infection of genitalia
5. Transverse lie of the foetus
6. Prolapse of the umbilical cord
7. Previous classic Caesarean section
8. Active pelvic infection
9. Chorioamnionitis

Table 4. COMPLICATIONS OF INDUCTION OF LABOUR[45]

MATERNAL COMPLICATIONS:

- Uterine rupture or dehiscence
- Postpartum haemorrhage (PPH)
- Cervical laceration or trauma
- Accidental haemorrhage
- Uterine hyperstimulation
- Increased risk of Caesarean delivery
- Prolonged labour
- Instrumental delivery (forceps, vacuum)

FETAL COMPLICATIONS:

- Fetal distress or heart rate abnormalities
- Umbilical cord prolapse
- Fetal trauma or injury
- Neonatal respiratory distress
- Increased risk of NICU admission
- Increased risk of instrumental delivery

OTHER COMPLICATIONS:

- Failed induction
- Prolonged hospital stay
- Increased risk of maternal anxiety and stress

NORMAL VAGINAL PH:

Vaginal pH undergoes significant changes throughout pregnancy, and by the time a woman reaches term, these changes are particularly notable in preparing the body for labour. During a healthy pregnancy, vaginal pH is generally more acidic, typically between 3.8 and 4.5, which helps maintain a balance of healthy bacteria such as Lactobacillus, essential for preventing infections.[48,49] However, as pregnancy progresses towards term, hormonal shifts mainly due to increasing oestrogen levels can alter vaginal secretions and pH levels.

At term, the vaginal pH tends to become slightly less acidic, with levels moving closer to neutral (around 4.5 to 6).[49] This shift can be attributed to factors such as increased vaginal

discharge or potential leakage of amniotic fluid as the body prepares for labour. These changes in vaginal pH might contribute to natural processes such as cervical ripening and membrane rupture, facilitating the onset of labour.[50]

While these pH changes are part of the normal physiological progression, significant deviations whether too acidic or too alkaline, can signal issues like bacterial vaginosis, which increases the risk of preterm labour or other complications.[51] Hence, monitoring vaginal pH can be a useful tool in managing maternal and fetal health at term.

EFFECT OF VAGINAL PH ON PROSTAGLANDIN EFFECTIVENESS:

The effectiveness of prostaglandins can be influenced by the vaginal pH at the time of administration. Prostaglandins, such as dinoprostone (PGE2) and misoprostol (PGE1 analogue), play an essential role in softening the cervix and stimulating uterine contractions. Vaginal pH, which changes throughout pregnancy, can affect how these prostaglandins are absorbed and activated within the vaginal environment.

At term, the change in vaginal pH can potentially impact the release and absorption of prostaglandins, particularly those administered via vaginal gels or inserts, which depend on the local environment for proper activation.[52]

Research has suggested that a pH of the vaginal environment may have a profound effect in the stability and bioavailability of prostaglandins, prominently in PGE2, as prostaglandin E receptors (EP receptors) may function optimally in higher pH conditions compared to a lower pH.[53,54]

Moreover, the altered pH near term may also affect the mucosal permeability of the vaginal epithelium, influencing the absorption rates of misoprostol and dinoprostone. For example,

studies have shown that misoprostol, which is commonly administered vaginally for labour induction, may have variable absorption based on the surrounding pH, leading to inconsistent dosing effects and a potentially higher risk of uterine hyperstimulation in some cases.[55]

Given these factors, clinicians must consider the vaginal pH when selecting the prostaglandin formulation and dosing strategy for labour induction. In cases where vaginal pH is more neutral, alternative routes of administration (e.g., oral or sublingual for misoprostol) may offer more consistent results.[56]

EVIDENCE FROM PRIOR STUDIES:

The following studies compared the outcomes in labour progression when dinoprostone is used at different vaginal pH for labour induction:

Ramsey et al. looked at the labour outcomes when dinoprostone is used for labour induction in respect to varying vaginal pH. They found that the differences were insignificant with high and low vaginal pH regarding age, number of pregnancies, gestational age, or initial cervical readiness. Women with higher vaginal pH progressed faster to active labour, full dilation, and delivery.[57]

A study by Jayashree Goswami et al. measured vaginal pH in pregnant women. They compared women with low and high vaginal pH. The baseline characteristics revealed that no significant differences. Notably, significant differences emerged after 12 hours' difference in Bishop score, duration to active labour, and proportion of normal delivery in favour of high pH suggesting vaginal pH may impact labour progression and outcomes. [53]

Singh et al. found that Bishop score change over 18 hours was considerably high among women with a higher vaginal pH. However, surprisingly, both the groups were similar in terms of time to labour onset, active labour time, full dilatation, or overall delivery time, suggesting that vaginal pH may have a limited impact on these specific labour outcomes.[58]

Poomalar et al. conducted an observational study with 150 term pregnant women undergoing IOL with intracervical PGE2. The researchers found no causal relationship between pH of the vagina and the duration between induction and active labour or delivery. Additionally, vaginal pH had no relationship with the mode of delivery or oxytocin usage during labour. Notably, the study confirmed that intracervical PGE2 remains an effective method for IOL, regardless of vaginal pH variations, making it a reliable option for labour induction.[54]

Fernandes et al. examined the relationship between pH of the vagina and the effectiveness of Dinoprostone gel for IOL. The findings from 150 participants revealed that higher vaginal pH values were linked to better labour outcomes. Specifically, patients with higher vaginal pH had improved Bishop's scores, faster progression to active labour, less delivery times, and increased rates of normal delivery, suggesting that vaginal pH may critically affect the outcome of labour induction.[59]

Kumari et al.[60] evaluated the impact on maternal and fetal outcomes in a cohort study. They recruited 500 term pregnancies over one year. They authors found that the outcomes were generally better in patients with pH>5.5. This group had higher Bishop score improvements, required fewer second doses, and experienced shorter durations to reach active labour and

delivery. The proportion of normal delivery was high in Group II. The authors concluded that a higher vaginal pH (≥5.5) significantly improves the dinoprostone efficacy in labour induction.

In a cohort study, Kurian et al.[1] followed up 200 term pregnancies. The authors found that an elevated vaginal pH correlated to a better initial Bishop score, a single induction dose requirement, and more frequent vaginal deliveries. However, vaginal pH did not significantly impact the duration to reach active labour. The authors concluded that vaginal pH, influenced by parity, plays a significant role in predicting labour outcomes IOL with PGE2.

Materials & Methods

MATERIALS AND METHODS

Study area:

The study was conducted in the department Obstetrics and Gynaecology (OBG) of Sri Devaraj URS Medical College (SDUMC), Kolar.

Study populations:

Pregnant women who completed 37 weeks to 41 weeks admitted during the study period at SDUMC hospital in the OBG department, SDUAHER.

Study design:

Prospective observational study.

Sample size:

We calculated the sample size as 90.

Maria Joseph Kurian et al.[1] reported the proportion undergoing vaginal delivery in the pH <4.5 group to be 50% and among pregnant women with pH >4.5 to be 80%.

Assuming alpha error of 0.05 (95% Confidence limit),

Power of 80% (Beta=0.20),

Ratio of pregnant women with pH>4.5 and pH<4.5 to be 1:1

- To determine the required sample size for comparing vaginal delivery proportions between two groups, researchers used the formula described by Kelsey et al.
- Calculations revealed a minimum of 45 participants per group, resulting in a total sample size of 90 for the study.

Formula used:

$$n_1 = \frac{(Z_{\alpha/2} + Z_{1-\beta})^2 \bar{p}\bar{q}(r+1)}{r(p_1 - p_2)^2}$$

Where,

n1 = Participant number in group A

n2 = Participant number in group B

Zα/2 = Z value for a desired confidence limit for a two-tailed test

Zβ = Z value for a desired power for a one-tailed test

r = Ratio of comparison groups (unexposed: exposed)

p1 = Outcome prevalence for Group A and q1 = 1-p1

p2 = Outcome prevalence for Group B and q2 = 1-p2

Study duration:

September 2022 to December 2023(16 months)

Inclusion Criteria:

1. Singleton pregnancy with cephalic presentation.
2. Unfavourable cervix (modified Bishop score ≤ 5).
3. Reactive non stress test (NST).

Exclusion Criteria:

1. History of prostaglandins-induced hypersensitivity.
2. Known case of placenta previa
3. Clinical suspicion of chorioamnionitis
4. Foetal malpresentation
5. Cephalopelvic disproportion
6. Previous LSCS or any uterine surgery
7. Premature membrane rupture

Methodology:

This study enrolled 90 women requiring labour induction, who met the specified inclusion criteria. A thorough medical, menstrual, and obstetric was obtained, supplemented by necessary investigations. All participants provided written informed consent prior to labour induction.

Speculum examination was done to assess the pH by a pH indicator strip. It was positioned against the lateral side of the vaginal wall within the speculum, and once moistened, its colour change was matched to the manufacturer's reference chart (Figure 5).

Figure 5: <u>Vaginal pH detection by test strips</u>

Participants were categorized to two groups based on vaginal pH:

- Group A: Vaginal pH measured to be ≤4.5
- Group B: Vaginal pH measured to be >4.5

Following vaginal examination, Modified Bishop score was assessed through following parameters:

- Cervical effacement
- Dilatation of cervix
- Cervix position
- Consistency of the cervix
- Presenting part's station

A score of 0-3 was assigned for all the parameters. A score ≤5 indicated an unfavourable cervix.

The study protocol dictated:

- No repeat PGE2 gel doses for women with a Bishop score ≥6 or those with a cervical dilation of 3 cm or more (active labour)
- Oxytocin augmentation for those with unsatisfactory contractions and favourable Bishop score (>8)
- Fetal well-being monitoring via cardiotocography

Induction failure was defined as no improvement in initial Bishop score after three PGE2 gel doses. The outcomes were recorded as:

- Change in Bishop score

- Labour onset time
- Time between induction commencement and onset of active labour
- Cervical dilatation completion time
- Time from induction commencement to delivery

All patients underwent a comprehensive evaluation, including:

- Routine physical examination
- Preoperative laboratory tests:
    - Complete Blood Count (CBC)
    - Renal Function Test (RFT)
    - Liver Function Test (LFT)
    - Serology
    - Ultrasonography

Relevant demographic and clinical details were recorded, including:

- Age
- Parity
- Gestational age
- Personal medical history
- Symptoms
- Duration of symptoms

Statistical analysis:

Data was entered in Microsoft Excel® and analysis was done in SPSS version 20. All continuous variables (age, pH, etc.) were presented by mean and standard deviation (SD). The categorical variables were expressed in frequency and proportions (%). Comparison of

continuous variables such as age, time taken to enter active phase, etc. will be done using independent samples t test. Comparison of categorical factors (parity, age group, failed induction, arrest of descent) were done by Chi-square test. Statistical analyses used a 5% significance level ($p < 0.05$)

Ethical considerations:

The study received prospective approval from the Institutional Ethics Committee (IEC). Participants provided informed consent before enrolment.

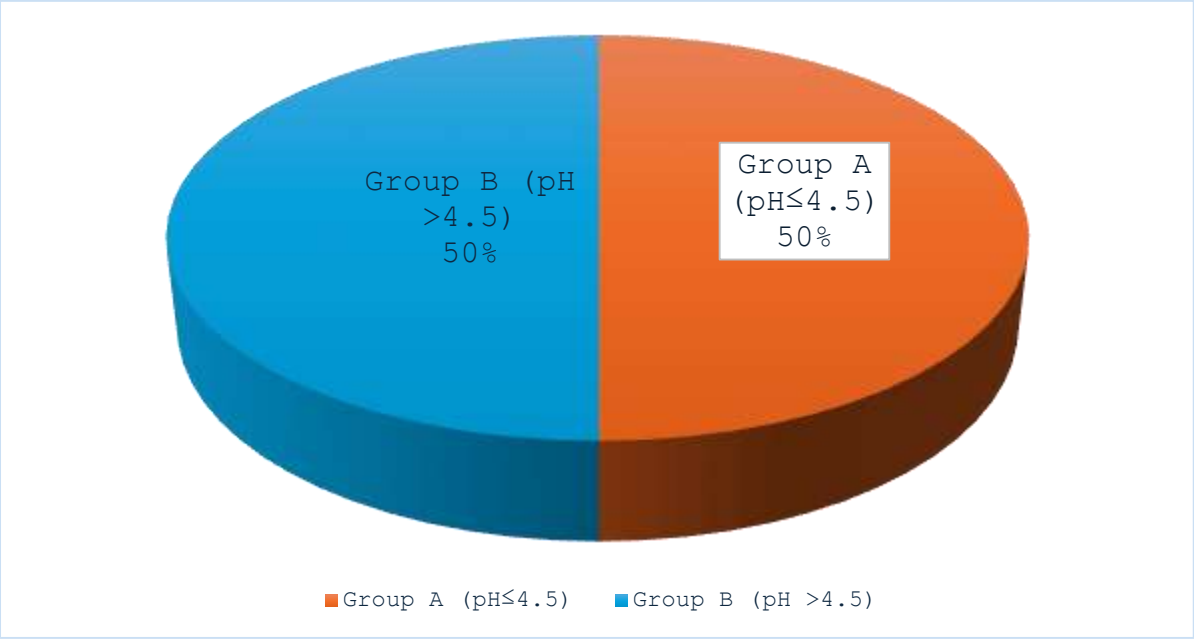
Results

We recruited a total number of 90 pregnant participants in the study. These patients presented in vertex presentation after 37 weeks of delivery. The participants were grouped into- Group A, having a vaginal pH of ≤4.5 and group B having pH > 4.5. There were 45 patients in each group. (Table 5, Figure 6)

Table 5: Distribution of the participants according to the vaginal pH.

Group	Frequency	Percentage
Group A (n=45)	45	50.0
Group B (n=45)	45	50.0
Total	90	100

Figure 6: Distribution of the participants according to the vaginal pH.



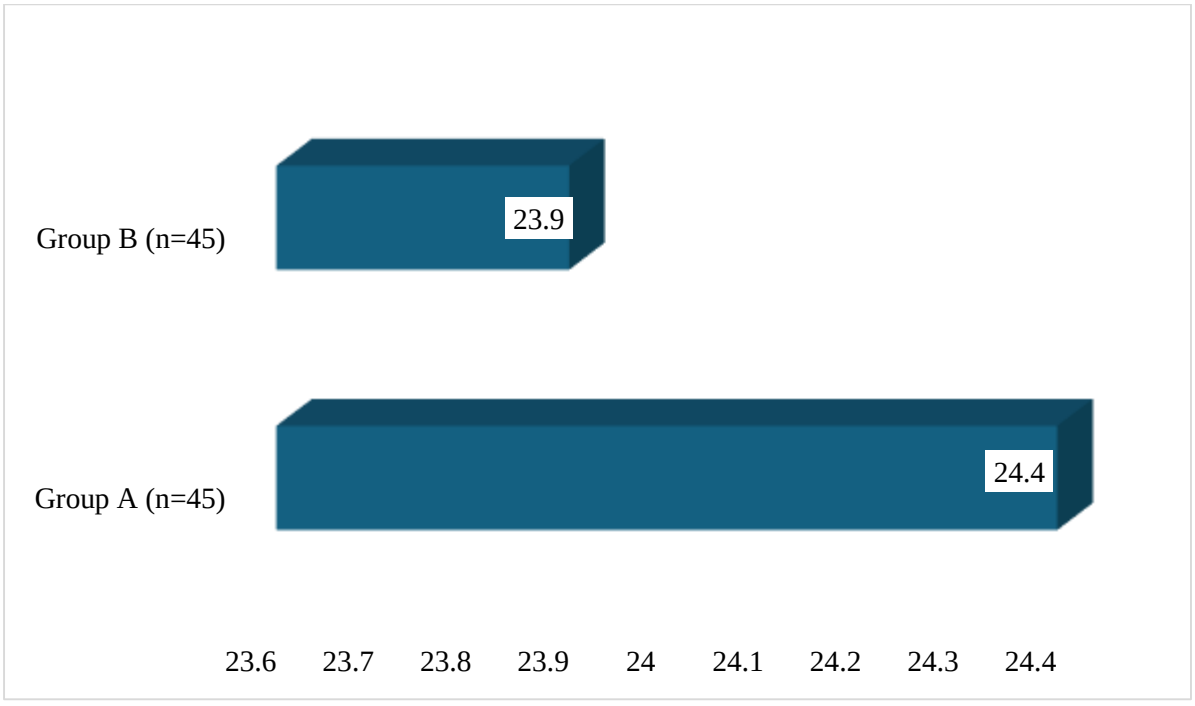
AGE DISTRIBUTION:

The mean age of the two groups was 24.4 years (±4.2 years) and 23.9 years (±3.8 years), respectively. While the age range of group A was 18-33 years, the range was 18-29 years in the other group. Statistical analysis revealed no significant difference. (p=0.5) (Table 6, figure 7).

Table 6: Distribution of age of the participants

Groups	Mean Age	SD	Range	p-value
pH≤4.5 (n=45) (Group A)	24.4	4.2	18-33 years	0.5
pH >4.5 (n=45) (Group B)	23.9	3.8	18-29 years	

Figure 7: Distribution of age of the participants



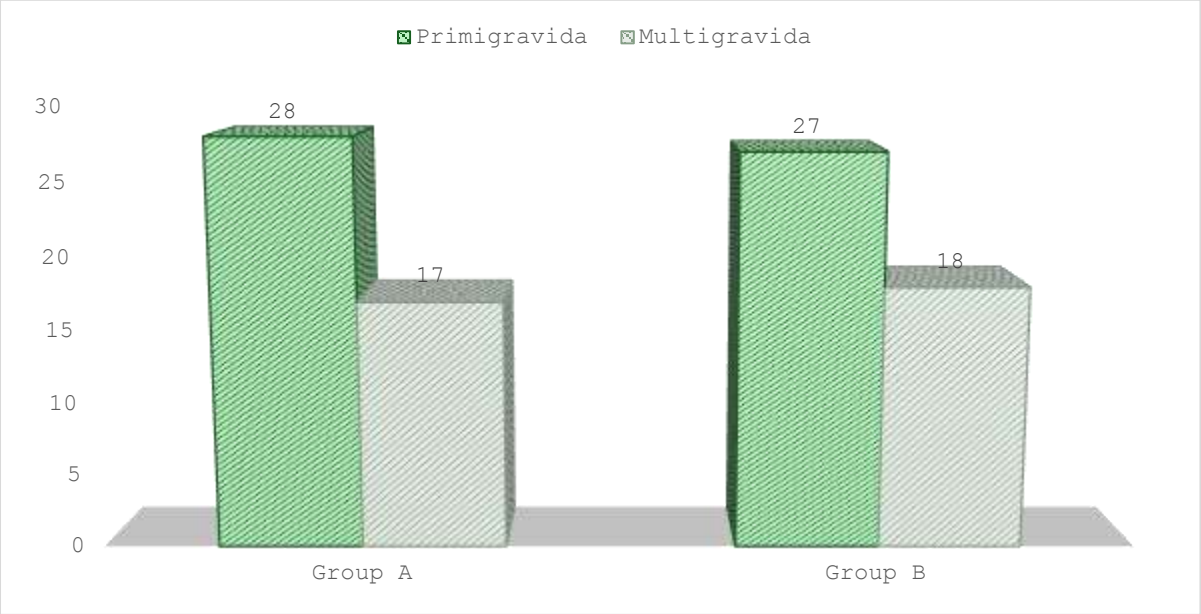
PARITY OF THE PARTICIPANTS:

There were 28 primigravida patients (62.2%) and rest of the 17 patients (37.8%) were multigravida in group A. Whereas in group B, 27 patients (60%) were primigravida and 18 patients (40%) were multigravida. (Table 7, figure 8). The groups were statistically similar (p =0.97).

Table 7: Distribution of the participants according to the parity.

Para	Group A (n=45)		Group B (n=45)		
	n	%	n	%	p-value
Primigravida	28	62.2	27	60.0	0.97
Multigravida	17	37.8	18	40.0	
Total	45	100	45	100	

Figure 8: Distribution of the participants according to the parity.



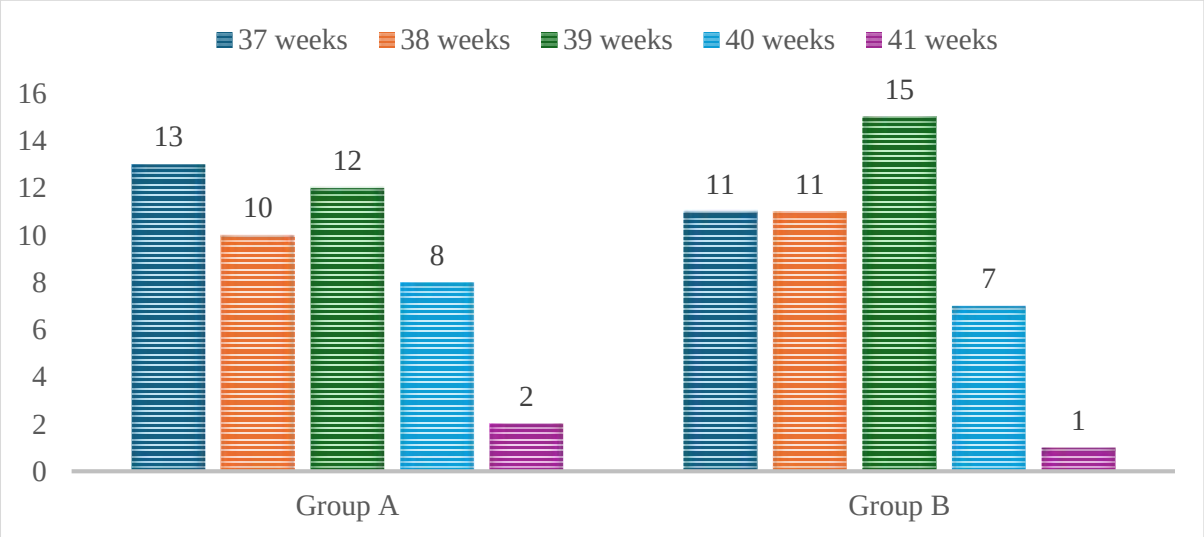
DISTRIBUTION OF GESTATIONAL AGE (GA) OF THE PARTICIPANTS:

Participants' mean gestational age was 38.39 weeks (SD 0.6 weeks) in group A. The participants in group B had a mean GA of 38.63 weeks (SD 0.7 weeks). Most of the participants belonged to 37 to 40 weeks of GA. Two women (4.4%) in group A was in 41 weeks of GA, and one (2.2%) in group B (Table 8, figure 9). The groups were statistically similar (p=0.08).

Table 8: Distribution of GA of the two groups

GA	Group A (n=45)		Group B (n=45)		
	n	%	n	%	p-value
37 weeks	13	28.9	11	24.4	0.97
38 weeks	10	22.2	11	24.4	
39 weeks	12	26.7	15	33.3	
40 weeks	8	17.8	7	15.6	
41 weeks	2	4.4	1	2.2	
Total	45	100	45	100	

Figure 9: Distribution of GA of the two groups



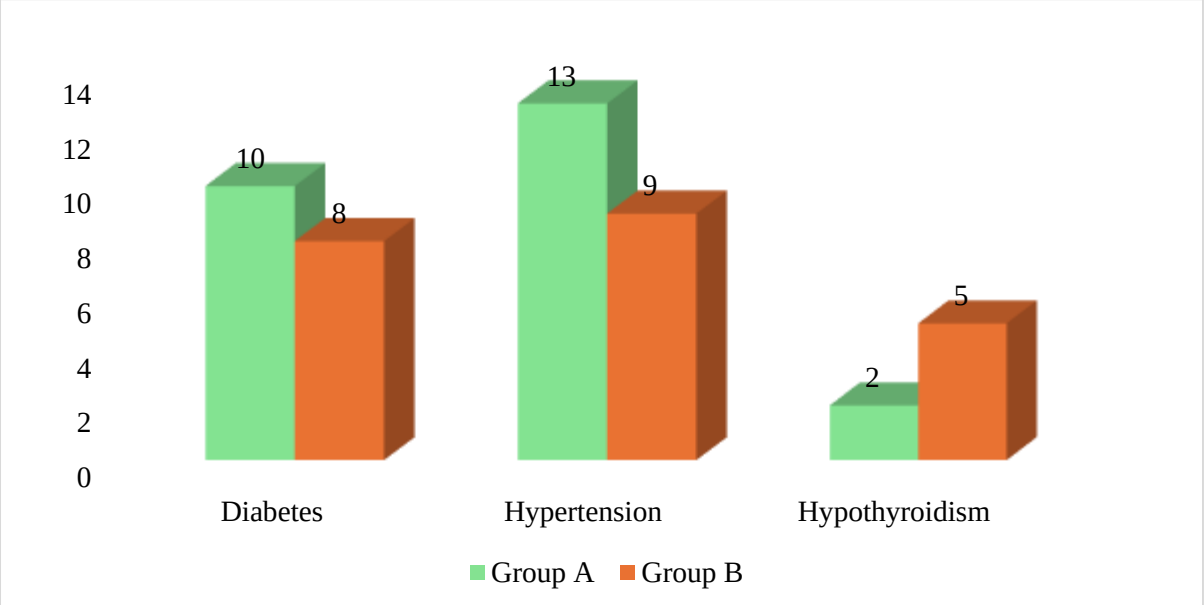
DISTRIBUTION OF COMORBIDITIES

In group A, 25 participants (55.6%) had comorbidities- 10 (22.2%) had GDM, 13 (28.9%) had hypertension, and 2 (4.4%) had hypothyroidism. In group B, 22 participants (48.9%) had comorbidities- 9 (19.57%) had GDM, 9 (20.0%) had hypertension, and 5 (11.1%) had hypothyroidism (Table 9, figure 10). The groups were statistically similar (p=0.49).

Table 9: Distribution of comorbidities of the two groups

Comorbidity	Group A (n=45)		Group B (n=45)		p-value
	n	%	n	%	
Gestational Diabetes Mellitus (GDM)	10	22.2	8	17.8	0.49
Hypertension	13	28.9	9	20.0	
Hypothyroidism	2	4.4	5	11.1	
No comorbidity	20	44.4	23	51.1	
Total	45	100	45	100	

Figure 10: Distribution of comorbidities of the two groups



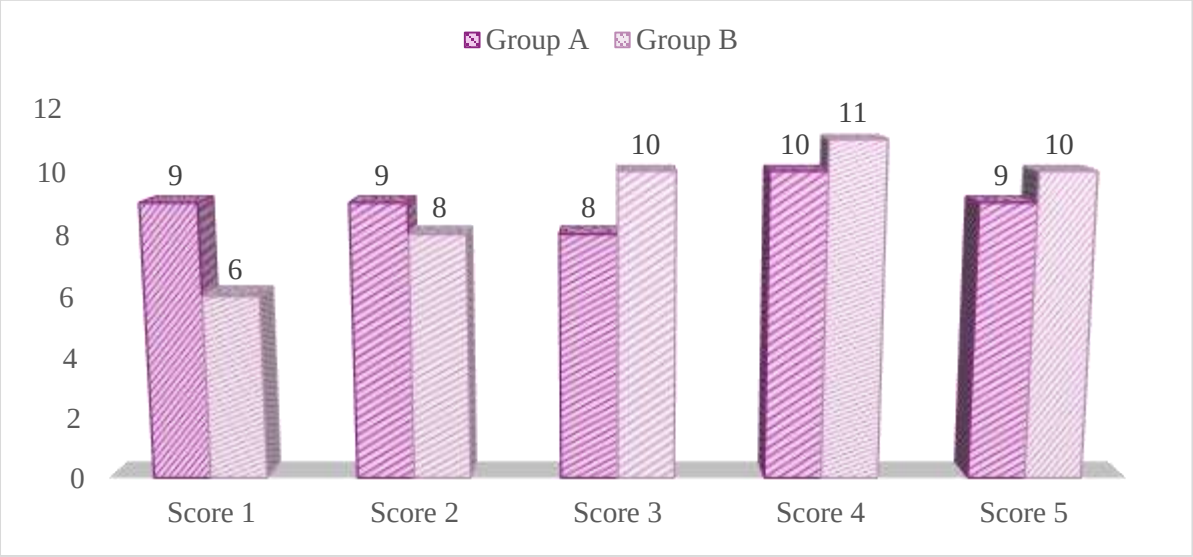
DISTRIBUTION OF BISHOP SCORE:

The mean Bishop scores were in group A was 3.0 ± 1.44 and the mean in group B was 3.5 ± 1.03. Most of the participants in group A belonged Bishop score 3-5 (n=27, 60%), whereas in group B the distribution was similar but even at a higher percentage (n=31, 68.9%). The groups were statistically similar (p=0.67). (Table 10, figure 11)

Table 10: Distribution of Bishop score of the study groups

Bishop score	Group A (n=45)		Group B (n=45)		p-value
	n	%	n	%	
Score 1	9	20	6	13.3	0.67*
Score 2	9	20	8	17.8	
Score 3	8	17.8	10	22.2	
Score 4	10	22.2	11	24.4	
Score 5	9	20	10	22.2	
Total	45	100	45	100	

Figure 11: Distribution of Bishop score in the study groups



IMPROVEMENT IN BISHOP SCORE

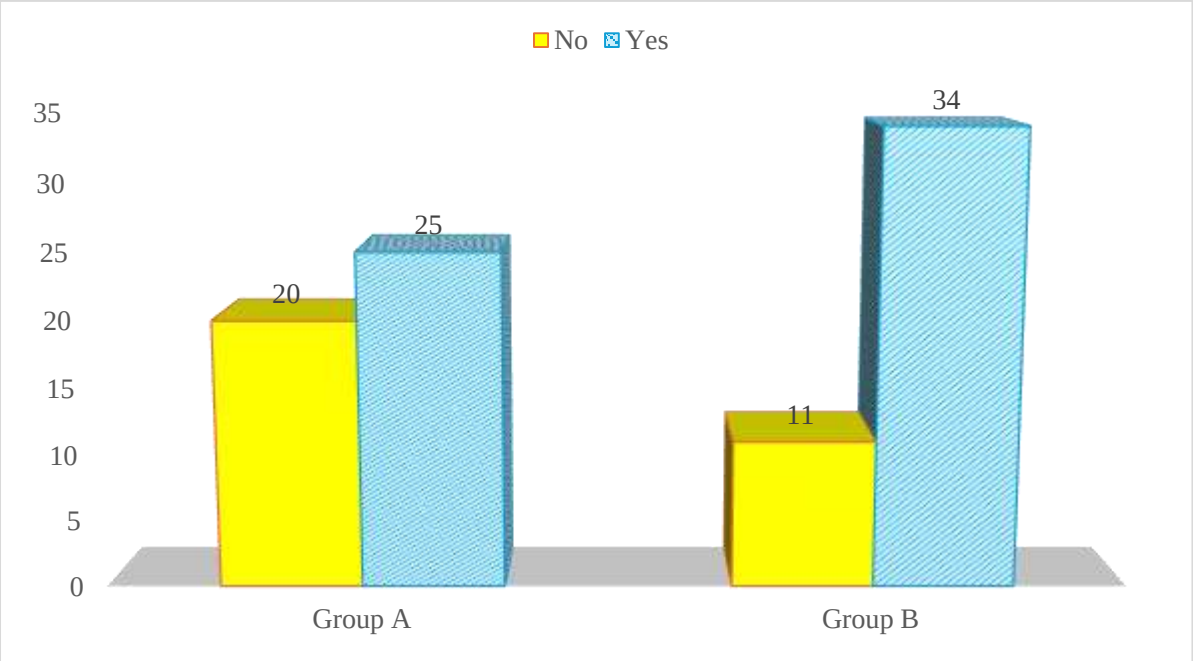
Group A showed a mean increase of 2.5 ±1.1 points in Bishop score, whereas mean increase for group B was 4.78 ±1.72. While 25 participants (45.6%) in group A had improvement in Bishop score, 34 participants (75.6%) in group B had improvement in Bishop score (Table 11, figure 12). Statistical analysis revealed a significant difference (p=0.04).

Table 11: Improvement in Bishop score in the two groups

Improvement in Bishop score	Group A (n=45)		Group B (n=45)		p-value
	n	%	n	%	
No	19	42.2	11	24.4	0.04*
Yes	26	47.8	34	75.6	
Total	45	100	45	100	

**Statistically significant*

Figure 12: Bishop score improvement in the study groups



INDUCTION NUMBER:

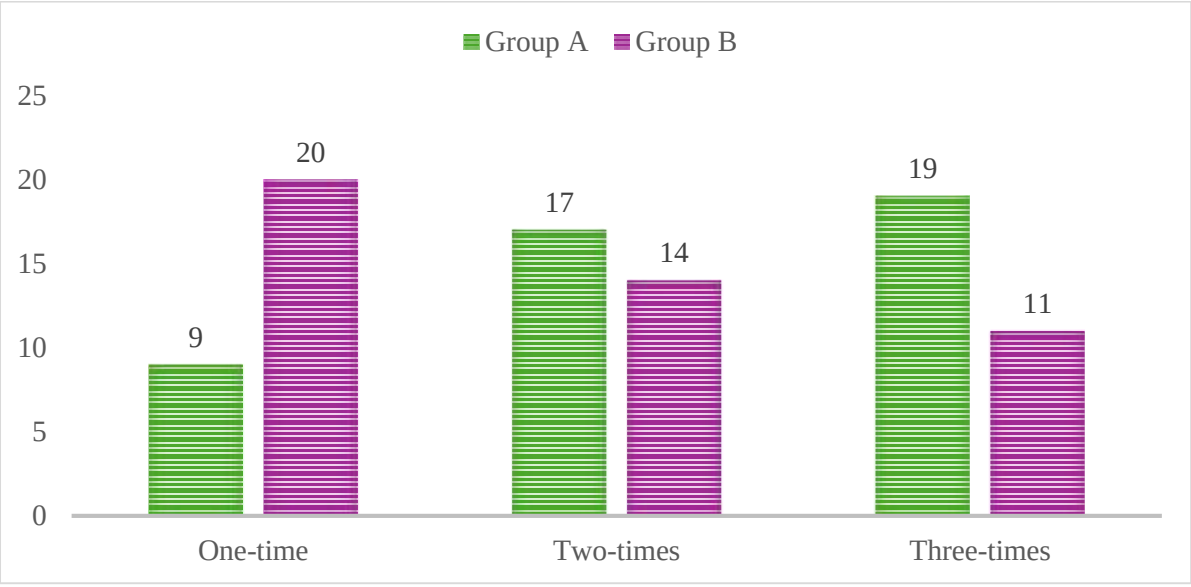
Seventeen participants (37.8%) in group A underwent induction for two times, and 19 participants (42.2%) underwent induction for three times. In group B, 14 participants (31.1%) underwent induction for two times, while 11 participants (24.4%) underwent induction for three times. While only 9 participants (20.0%) in group A had one time induction, 20 participants (44.4%) in group B had only one time induction. (Table 12, figure 13). Statistical analysis revealed a significant difference (p <0.001).

Table 12: Distribution of the participants according to number of inductions applied

Induction number	Group A (n=45)		Group B (n=45)		p-value
	n	%	n	%	
1	9	20.0	20	44.4	<0.001*
2	17	37.8	14	31.1	
3	19	42.2	11	24.4	
Total	45	100	45	100	

**Statistically significant*

Figure 13: Distribution of the participants according to number of inductions applied



PROGRESSION TO ACTIVE LABOUR

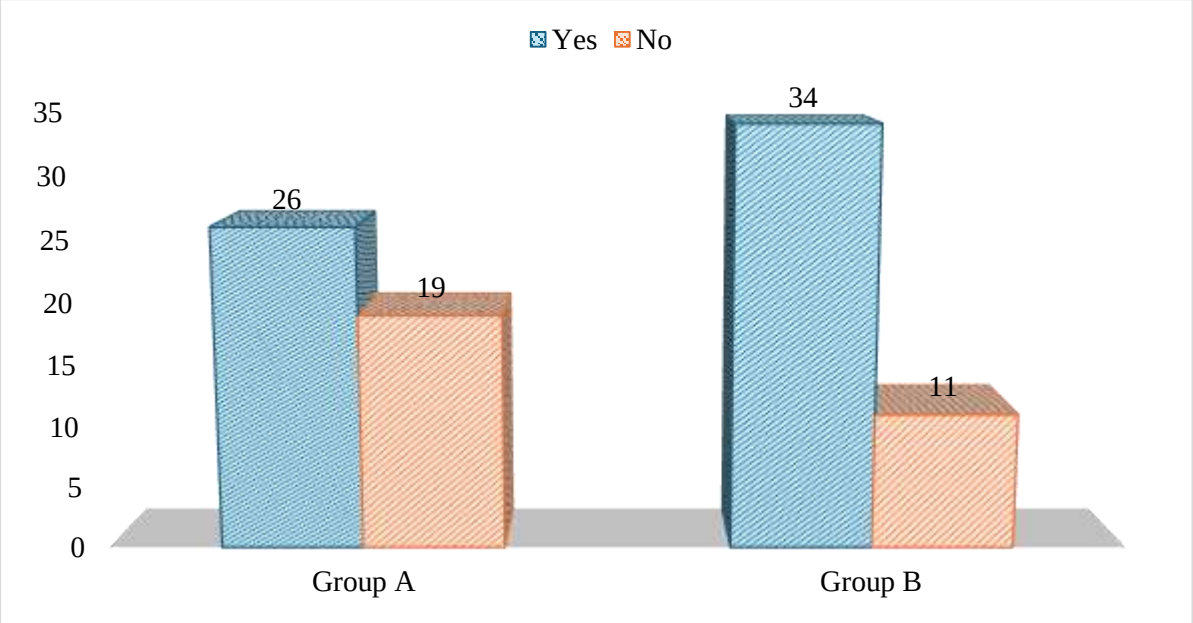
In group A, 26 participants (57.8%) progressed to the active phase of labour. On the contrary, 34 participants (77.8%) in group B progressed to the active labour (Table 13, figure 14). Statistical analysis revealed a significant difference (p= 0.04).

Table 13: Distribution of participants according to progression to active labour

Progression to active phase	Group A (n=45)		Group B (n=45)		p-value
	n	%	n	%	
Yes	26	57.8	34	75.6	0.04*
No	19	42.2	11	24.4	
Total	45	100	45	100	

**Statistically significant*

Figure 14: Distribution of participants according to advancement to active labour



TIME TO REACH ACTIVE LABOUR

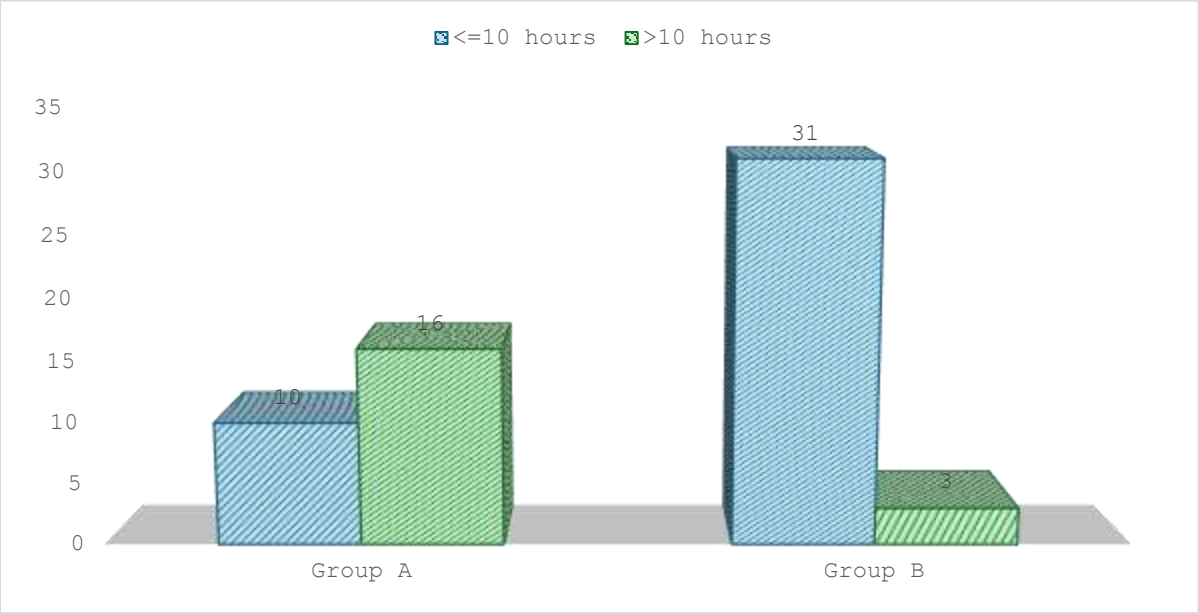
The average time taken to reach to the active labour was 16.2 ± 2.3 hours in group A participants. On the other hand, the mean duration was 9.2 ± 1.25 hours in group B. On the contrary, the figure was only 10 patients (38.5%) for group A. On the other hand, 31 (91.2%) entered active phase of labour within 10 hours (Table 14, figure 15). Statistical analysis revealed a significant difference (p<0.001).

Table 14: Participants' distribution according to time to reach to active labour

Time taken	Group A (n=26)		Group B (n=34)		p-value
	n	%	n	%	
<=10 hours	10	38.5	31	91.2	<0.001*
>10 hours	16	61.5	3	8.8	
Total	26	100	34	100	

**Statistically significant*

Figure 15: Distribution of participants according to time to reach active labour



MODE OF DELIVERY

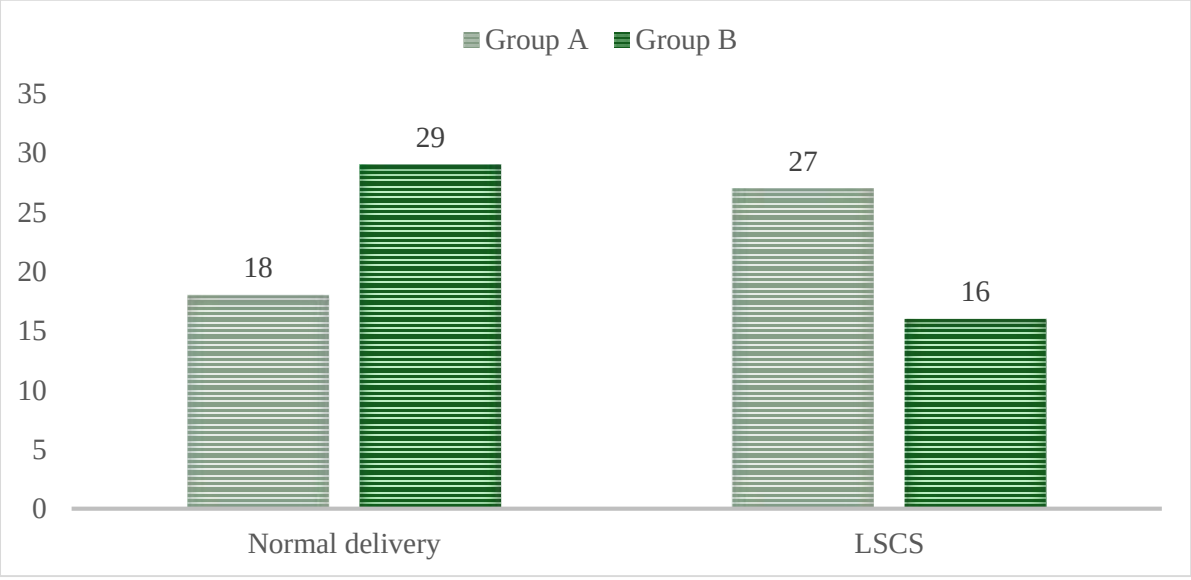
In group A, normal delivery took place for 18 participants (40.0%), while in group B, 29 participants (64.5%) underwent normal delivery. On the other hand, group A had a high rate of LSCS (n=27, 60.0%) compared to group B (n=16, 35.5%) (Table 15, figure 16). Statistical analysis revealed a significant difference (p<0.001).

Table 15: Participants' distribution based on type of delivery

	Group A (n=45)		Group B (n=45)		p-value
Type of delivery	n	%	n	%	
Normal delivery	18	40.0	29	64.5	<0.001*
LSCS	27	60.0	16	35.5	
Total	45	100	45	100	

**Statistically significant*

Figure 16: Participants' distribution based on type of delivery



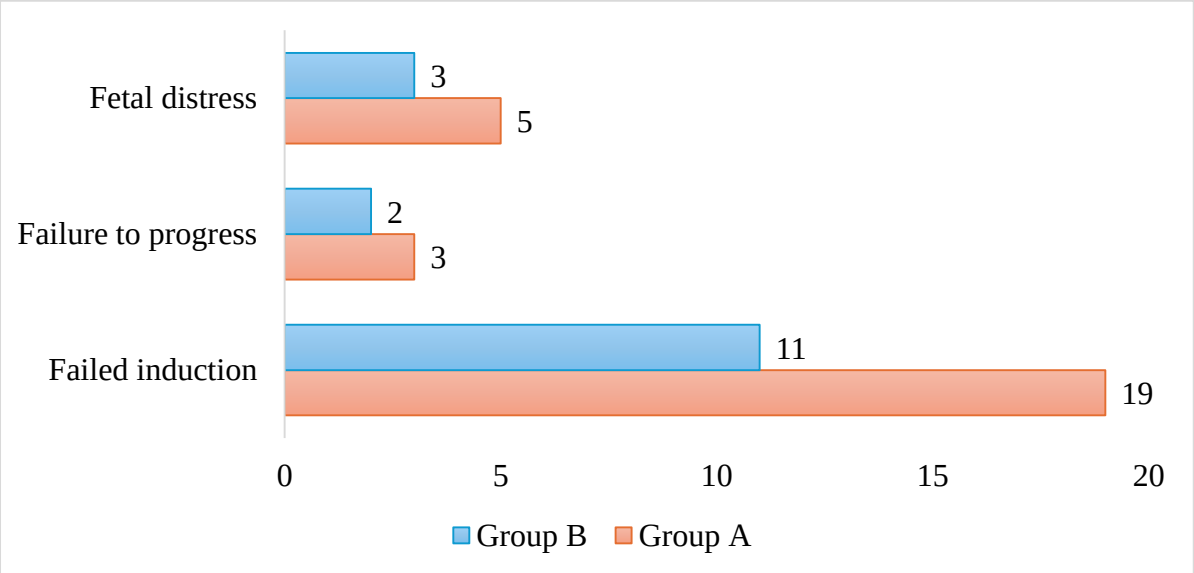
INDICATION OF LSCS

In group A, the common indications were failed induction (n=20, 74.1%) and fetal distress (5, 18.5%). In group B, common indications were- failed induction (n=11, 68.8%), and fetal distress (5, 25%). The observed difference did not reach statistical significance (p=0.42) (Table 16, figure 17).

Table 16: Distribution of participants according to Indication of LSCS

Indication of LSCS	Group A (n=45)		Group B (n=45)		p-value
	n	%	n	%	
Failed induction	19	74.1	11	68.8	0.42
Failure to progress	3	7.4	2	12.5	
Fetal distress	5	18.5	3	18.7	
Total	27	100	16	100	

Figure 17: Distribution of participants according to Indication of LSCS



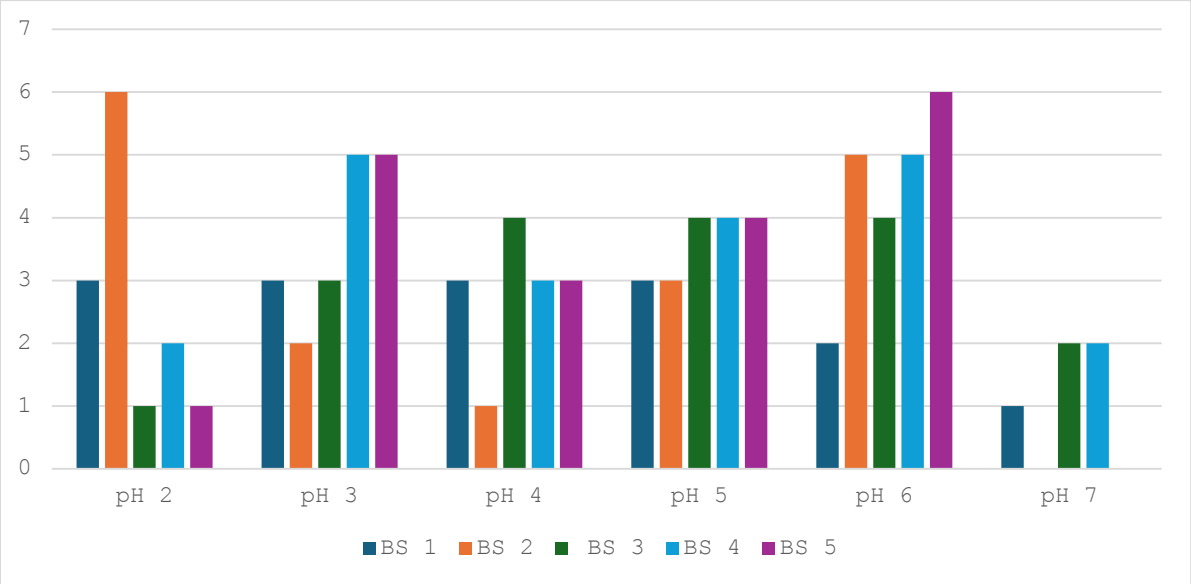
RELATIONSHIP BETWEEN VAGINAL PH AND BISHOP SCORE**:**

When Bishop score was compared with the vaginal pH, we see that at bishop score tend to be high when the vaginal pH is also high compared to the lower vaginal pH. The observed difference did not reach statistical significance (p=0.37) (Table 17, figure 18).

Table 17: Relationship between vaginal pH and Bishop score

	Bishop Score (BS)				
Vaginal pH	BS 1 (n=15)	BS 2 (n=17)	BS 3 (n=18)	BS 4 (n=21)	BS 5 (n=19)
pH 2 (n)	3	6	1	2	1
% within vaginal pH	23.1	46.2	7.7	15.4	7.7
pH 3 (n)	3	2	3	5	5
% within vaginal pH	16.7	11.1	16.7	27.8	27.8
pH 4 (n)	3	1	4	3	3
% within vaginal pH	21.4	7.1	28.6	21.4	21.4
pH 5 (n)	3	3	4	4	4
% within vaginal pH	16.7	16.7	22.2	22.2	22.2
pH 6 (n)	2	5	4	5	6
% within vaginal pH	9.1	22.7	18.2	22.7	27.3
pH 7 (n)	1	0	2	2	0
% within vaginal pH	20.0	0	40.0	40.0	40.0
Total	15	17	18	21	19
	10	18.89	26.67	23.33	21.11

Figure 18: Relationship between vaginal pH and Bishop score



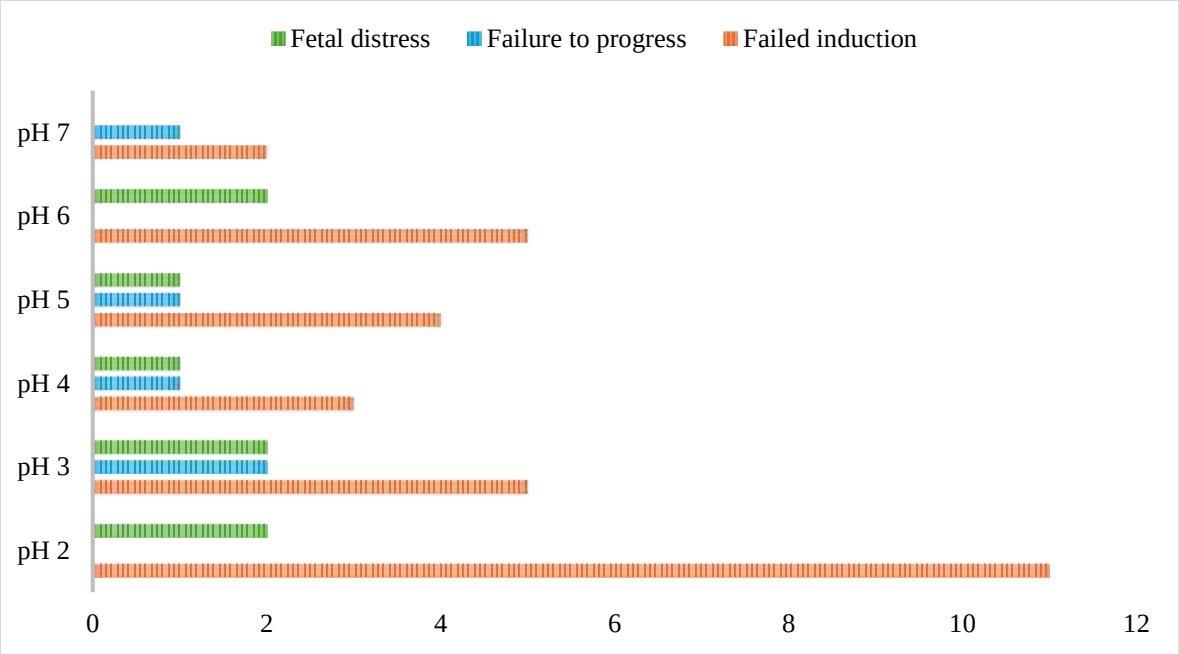
RELATIONSHIP BETWEEN VAGINAL PH AND INDICATION FOR LSCS:

When Bishop score was compared with the vaginal LSCS, we see that LSCS indication has no relationship with the vaginal pH. The observed difference did not reach statistical significance. (p=0.35) (Table 18, figure 19).

Table 18: Relationship between vaginal pH and indication for LSCS

Vaginal pH	Indication for LSCS		
	Failed induction (n=30)	Failure to progress (n=5)	Fetal distress (n=8)
pH 2 (n)	11	0	2
% within vaginal pH	84.6	0	15.4
pH 3 (n)	5	2	2
% within vaginal pH	55.6	22.2	22.2
pH 4 (n)	3	1	1
% within vaginal pH	60.0	20.0	20.0
pH 5 (n)	5	1	1
% within vaginal pH	66.7	16.7	16.7
pH 6 (n)	4	0	2
% within vaginal pH	66.7	0	33.3
pH 7 (n)	2	1	0
% within vaginal pH	66.7	33.3	0
Total	30	5	8

Figure 19: Relationship between vaginal pH and indication for LSCS



Discussion

This study recruited a total number of 90 pregnant women who underwent induction of labour by application of dinoprostone gel. Majority (n=55) were primigravida and their gestational age (GA) varied between 37 and 41 weeks. The investigator recorded the demographic, obstetric, and medical information after admission, as a usual procedure. The investigator confirmed the GA clinically and performed the routine investigations as per the hospital treatment guidelines. The investigator recorded the indications, and the methods applied. In addition, the investigator performed the general and obstetric examinations for foetal presentation, heart rate of the foetus; characteristics of uterine contractions; pelvic adequacy, the modified Bishop score; and the vaginal pH.

Obstetric scan and non-stress test (NST or cardiotocography) were performed to ensure fetal well-being. Modified Bishop score assessment was done by five parameters, and a score of 0 to 3 was assigned to each parameter. Bishop score of ≤5 indicated an unfavourable cervix. Subsequently, among patients who had a Bishop score ≥6, and entered into the active labour, PGE2 gel was not repeated for them. Their labour was augmented by Oxytocin administered for those with insufficient contractions and a Bishop score exceeding 8, according to the standard protocol. Only those participants with a reactive NST and a modified Bishop score of ≤5 were recruited and assigned to two equal groups based on the pH. The participants were grouped to- A and B, having a vaginal pH of ≤4.5 or more than 4.5, respectively. There were 45 patients in each group.

Induction failure was considered when the baseline BS remained unchanged after PGE2 gel application for three times. The study outcomes were evaluated based on improvements in Bishop score, time to labour onset, duration to reach active labour, duration for complete cervical dilatation, and delivery time.

This study mostly included pregnant women whose mean age was 24.4 years and 23.9 years in A and B groups, respectively. It indicates that most of the participants belonged to young age group. The age distribution is similar to the previous findings from the Indian context (Table 19), thereby supporting the relevance and validity of comparing the study's findings with the previous studies. Consistent age distribution enhances the applicability of the finding to similar populations in this context.

Table 19: Comparison of mean ages with prior studies

Studies	**pH ≤4.5 (Group A)**	**pH >4.5 (Group B)**
Dhivya et al	25.11 ±3.38	25.07 ±3.86
Fernandes et al	26.02	27.32
Goswami et al	24.4±3.47	23.13±3.95
Kumari et al	26.73 ± 3.39	27.84 ± 4.08
Present study	**24.4 ± 4.2**	**23.9 ± 3.8**

Comparison of gestational age across study groups revealed no significant differences, and the finding is consistent with previous findings (Table 20). This similarity across the studies justifies the comparison of findings and reinforces the present study's validity in drawing conclusions.

Table 20: Comparison of gestational age with previous studies

Studies	pH ≤4.5 (Group A)	pH >4.5 (Group B)
Dhivya et al	39.13 ± 1.28	39.25 ± 1.27
Fernandes et al	38.35	38.29
Goswami et al	40.0 ± 2.46	40.0 ± 1.97
Panagiotopoulos et al	39.37 ± 1.16	39.12 ± 1.03
Ramsey et al	39.6 ± 1.7	39.4 ± 1.3
Present study	**38.39 ± 0.6**	**38.63 ± 0.7**

PRE-INDUCTION BISHOP SCORE

The Bishop score before induction was compared between the groups. It a crucial predictor of outcomes in research examining vaginal pH's impact on dinoprostone effectiveness. We found that the pre-induction Bishop scores are comparable across the studies as shown in table 21. It substantiates the finding from our study in reaching conclusion from our study as discussed subsequently.

Table 21: Comparison of pre-induction Bishop score with previous studies

Studies	**pH ≤4.5 (Group A)**	**pH >4.5 (Group B)**
Dhivya et al	1.41 ± 0.5	2.3 ± 0.95
Fernandes et al	1.31	1.2
Goswami et al	1.74±1.597	2.33±1.379
Kumari et al	2.8 ± 0.96	3.93 ± 0.98
Panagiotopoulos et al	3.31 ± 1.43	3.54 ± 1.68
Ramsey et al	3.3 ± 1.2	2.6 ± 1.8
Present study	**3.0 ± 1.44**	**3.5 ± 1.03**

A considerable improvement in mean Bishop score was noted for the group with high vaginal pH compared to low vaginal pH across the prior studies. While the mean score improvement in group A ranged between 2.3 and 4.5, the improvement was much higher in the high pH group and ranged between 2.3 and 6.37 as shown in table 22. Poomalar et al, found that after first dose application, favourable score (>=6) was noted in more than half of the participants with a lower pH which was marginally low than participants with a high vaginal pH (>4.5). We observed that Bishop score assessment after 12 hours is the standard norm. Thus, the studies are comparable and signifies that high vaginal pH improves the effectiveness of dinoprostone gel considerably.

Table 22: Comparison of improvement in Bishop score with previous studies

Studies	**pH ≤4.5 (Group A)**	**pH >4.5 (Group B)**
Dhivya et al	2.41 ±1.01	6.37 ± 0.97
Fernandes et al	2.43 ± 1.62	4.43 ± 2.28
Goswami et al	2.57±1.8	5.71±1.4
Kumari et al	4.5	6.32
Ramsey et al	2.3 ± 2.5	2.3 ± 2.3
Present study	**2.5 ±1.1**	**4.78 ±1.72**

An important parameter in induction of labour is induction number. Overall, a significant number of participants with a vaginal pH >4.5 required only one dose of dinoprostone gel compared to the other group where the requirement of multiple doses was significantly higher (Table 23). This finding again supports the superiority of dinoprostone effectiveness when it is used in patients with a higher vaginal pH.

Table 23: Comparison of number of inductions required with previous studies

Studies	**pH ≤4.5 (Group A) Induction doses required**			**pH >4.5 (Group B) Induction doses required**		
	One	**Two**	**Three**	**One**	**Two**	**Three**
Poomalar et al	51.3%			62.2%		
Kumari et al	68.3%	31.7%	-	86.0%	14.0%	-
Present study	**20.0**	**37.8%**	**42.2%**	**44.4%**	**31.1%**	**24.4%**

Duration to reach active labour is considered as another indicator of the effectiveness of the induction. It has been noticed that in most of the studies, the average time required for patients with a low pH is considerably high than the group with high pH as shown in table 24. Most of the studies reported statistically significant differences between the two groups. Thus, it can be said that the effectiveness of dinoprostone is higher when it is used at pH >4.5.

Table 24: Comparison of time taken (In hours) to reach active labour with previous studies

Studies	**pH ≤4.5 (Group A)**	**pH >4.5 (Group B)**
Dhivya et al	21.13 ± 1.42	11.04 ± 0.93
Fernandes et al	11.35	7.55
Goswami et al	21.45±8.81	11.99±7.65
Kumari et al	6.5	7
Ramsey et al	32.7 ± 16.8	19.4 ± 9.7
Present study	**16.2 ± 2.1**	**9.2 ± 1.3**

Proportional of normal vaginal delivery is another important indication of successful labour induction. In prior studies, while the proportion of normal delivery for patients with a low (≤4.5) vaginal pH is reported to vary between 20% and 67.84%, the proportion of successful vaginal delivery varied between 64.86% and 87.7% (Table 25). Significant differences were consistently observed between groups across most studies. Our finding from the present study has also shown a significant difference between the two groups indicating that the dinoprostone gel effectiveness is high when the vaginal pH is also high.

Table 25: Comparison of proportion of normal delivery with previous studies

Studies	pH ≤4.5 (Group A)	pH >4.5 (Group B)
Dhivya et al	33.3%	85.2%
Fernandes et al	32.0%	78.8%
Goswami et al	20.0%	72.0%
Kumari et al	67.84%	87.7%
Poomalar et al	63.15%	64.86%
Present study	**40.0%**	**64.5%**

As a continuation of the above findings, we also noticed that in majority of the LSCS was due to failed induction as reported by Kumari et al. Unlike this study, Poomalar et al found that the groups were similar in terms of induction failure being the indication of LSCS (Table 26). However, considering the overall high LSCS rate in the low vaginal pH group, it is clear that high pH enhances the success of IOL with dinoprostone.

Table 26: Comparison of indication of LSCS as failed induction with previous studies

Studies	pH ≤4.5 (Group A)	pH >4.5 (Group B)
Kumari et al	17.2%	10.8%
Present study	**74.1%**	**68.8%**

Summary

The study included 90 term pregnant participants with equal distribution of low and high vaginal pH for evaluating the outcome of dinoprostone in labour induction. The groups were named as group A and group B, respectively.

The baseline characteristics of both groups were comparable. The groups were compared with appropriate statistical tests and the groups were similar in these characteristics.

The participants were clinically evaluated after taking informed consent followed by a detailed clinical and laboratory investigations. Speculum examinations were conducted for the participants. At the same time, vaginal pH was evaluated by a pH indicator paper. The participants received care according to the hospital protocol and were followed-up for the outcomes till the delivery took place.

It was noted that the average increase in Bishop score B group (4.78 ±1.72) was high compared to group A (2.5 ±1.1). While 75.6% in group B had improvement in Bishop score, the proportion was only 45.6% among the group A participants.

In group A, 37.8% required induction for two times, and 42.2% required it for three times. On the contrary, the group B participants required induction for two times for 31.1%, and three times for only 24.4% participants. Conversely, the requirement for dose repetitions were less among patients having a high vaginal pH.

Subsequently, only 57.8% of the A group participants progressed to the active labour. On the contrary, 77.8% in B group progressed to the active labour and the difference was significant. The average duration to reach active labour was substantially higher in A group (16.2 ± 2.3 hours) compared to the group B (9.2 ± 1.25 hours) participants.

The study observed that a significantly higher proportion of normal delivery took place in B group (64.5%) compared to group A (40.0%). Conversely, group A had a high rate of LSCS (60.0%) compared to group B (35.5%).

The indications of LSCS were similar in both the groups. In group A, failed induction (74.1%) and fetal distress (18.5%) were common indications. Group B also observed a same pattern-failed induction (68.8%), and fetal distress (5.25%).

Conclusion

This study reveals that pregnant women with higher vaginal pH (>4.5) experience better outcomes with dinoprostone-induced labour. Appreciable favourable outcomes were noted in cervical ripening, reduced induction requirements, and higher rates of normal delivery. The findings emphasizes the need of examining the vaginal pH in predicting successful labour induction. Reducing the chance of LSCS is expected to reduce the maternal morbidity, duration of hospital stays, and cost of care.

Limitations

The present study has a few limitations:

- LOW SAMPLE SIZE: Firstly, the study had a limited sample size and may be insufficient to generalize the findings in the larger populations.

  A large multi-centric study would be required to optimize the finding, increasing the robustness of the external validity.

  As the study has been done in a single centre, the finding of the study should be cautiously interpreted.
- SELECTION BIAS: The second important limitation is the lack of representation of heterogenous study population. It is expected that majority of the participants belonged to same socio-economic backgrounds. Thus, we expect to introduce selection bias by selecting only these populations.
- CONFOUNDING EFFECT: The effects of the potential confounders in this study like maternal health conditions, and previous obstetric history were not accounted for. The adjustment for these variables could have improved the robustness of the outcomes. However, as the baseline parameters were similar, we expect the bias due to these factors is minimized.

Recommendations

- Clinical recommendations:
    - Vaginal pH assessment should be included in pre-induction evaluations to predict labour outcomes.
    - Dinoprostone induction may be more effective in women with high vaginal pH (≥4.5).
    - Women with low vaginal pH (<4.5) may require alternative or adjunctive induction methods.
    - Cervical ripening should be monitored closely if pH is low.
- Practice-related recommendations
    - Develop hospital protocols incorporating vaginal pH assessment in induction of labour decisions.
    - Provide education on vaginal pH and its impact on labour outcomes to healthcare providers.
    - Consider individualized induction strategies based on vaginal pH and other risk factors.
- Research related:
    - Investigate optimal vaginal pH thresholds for predicting labour outcomes.
    - Explore adjunctive therapies to enhance dinoprostone efficacy in women with low vaginal pH.
    - Further validation through multicentric research is necessary.
- Patient education:
    - Inform pregnant women about the importance of vaginal pH in labour induction.

- Discuss potential benefits and risks of dinoprostone induction based on individual vaginal pH.
- Encourage open communication about labour preferences and expectations.

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Annexures

PROFORMA

Name :
IP No :
Date of admission :
Age :
Marital status :
Religion :
Address :
D/O discharge :
LMP :
EDD :
Gestational age :
Presenting complaints :
Menstrual history :
Marital history :
Obstetric history :
Past history :
General examination :
Height : weight :
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 :
Date and time of delivery :
Induction delivery interval

PATIENT INFORMATION SHEET

Study title: To determine the effect of vaginal pH on efficacy of dinoprostone gel for labour induction.

Study location: R L Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar.

Please read the following information and discuss with your family members. You can ask any question regarding the study. If you agree to participate in the study we will collect information (as per proforma) from you or from a person responsible for you or both. Relevant history will be taken. This information collected will be used only for dissertation and publication. The relevant investigations which are required others than regular investigations will be funded by me.

All information collected from you will be kept confidential and will not be disclosed to any outsider. Your identity will not be revealed. This study has been reviewed by the Institutional Ethics Committee and you are free to contact the member of the Institutional Ethics Committee. There is no compulsion to agree to this study. The care you will get will not change if you don't wish to participate. You are required to sign/ provide thumb impression only if you voluntarily agree to participate in this study.

For further information contact:

Dr. Sai Lakshmi Shreya.c

Post graduate, Department of obstetrics and Gynaecology

R L Jalappa hospital, Kolar .

INFORMED CONSENT FORM

I Mrs. _____ have been explained in my own understandable language, that I will be included in a study which is **"**To determine the effect of vaginal pH on efficacy of dinoprostone gel for labour induction**".**I have been explained that my clinical findings, investigations will be assessed and documented for study purpose.I have been explained my participation in this study is entirely voluntary, and I can withdraw from the study any time and this will not affect my relation with my doctor or the treatment for my ailment. I have been explained about the interventions needed possible benefits and adversities due to interventions, in my own understandable language. I have understood that all my details found during the study are kept confidential and while publishing or sharing of the findings, my details will be masked.I have principal investigator mobile number for enquiries.I in my sound mind give full consent to be added in the part of this study.

Signature of the patient:

Name:

Date:

Signature of the witness:

Name:

Relation to patient:

Date:

ಮಾಹಿತಿ ನೀಡಿದ ಒಪ್ಪಿಗೆ ನಮೂನೆ

ನಾನು ಶ್ರೀಮತಿ. _____ ಅನ್ನು ನನ್ನ ಸ್ವಂತ ಅರ್ಥವಾಗುವ ಭಾಷೆಯಲ್ಲಿ ವಿವರಿಸಲಾಗಿದೆ, "ಕಾರ್ಮಿಕ

ಪ್ರಚೋದನೆಗಾಗಿ ಡೈನೋಪ್ರೊಸ್ಟೋನ್

ಜೆಲ್ನ ಪರಿಣಾಮಕಾರಿತ್ವದ ಮೇಲೆ ಯೋನಿ **pH** ನ ಪರಿಣಾಮವನ್ನು ನಿರ್ಧರಿಸಲು" ಎಂಬ ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನನ್ನು

ಸೇರಿಸಲಾಗುವುದು.

ನನ್ನ ಕ್ಲಿನಿಕಲ್ ಸಂಶೋಧನೆಗಳು, ತನಿಖೆಗಳು, ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ನಂತರದ ಸಂಶೋಧನೆಗಳನ್ನು ಮೌಲ್ಯಮಾಪನ

ಮಾಡಲಾಗುತ್ತದೆ ಮತ್ತು ಅಧ್ಯಯನ

ಉದ್ದೇಶಕ್ಕಾಗಿ ದಾಖಲಿಸಲಾಗುತ್ತದೆ ಎಂದು ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ ಭಾಗವಹಿಸುವಿಕೆಯು ಸಂಪೂರ್ಣವಾಗಿ ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿದೆ ಎಂದು ನನಗೆ

ವಿವರಿಸಲಾಗಿದೆ ಮತ್ತು ನಾನು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಅಧ್ಯಯನದಿಂದ ಹಿಂದೆ ಸರಿಯಬಹುದು ಮತ್ತು ಇದು ನನ್ನ

ವೈದ್ಯರೊಂದಿಗಿನ ನನ್ನ ಸಂಬಂಧ ಅಥವಾ ನನ್ನ ಕಾಯಿಲೆಯ ಚಿಕಿತ್ಸೆಯ ಮೇಲೆ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ. ನನ್ನ

ಸ್ವಂತ ಅರ್ಥವಾಗುವ ಭಾಷೆಯಲ್ಲಿ ಮಧ್ಯಸ್ಥಿಕೆಗಳಿಂದಾಗುವ ಸಂಭವನೀಯ ಪ್ರಯೋಜನಗಳು ಮತ್ತು

ಪ್ರತಿಕೂಲತೆಗಳ ಅಗತ್ಯವಿರುವ ಮಧ್ಯಸ್ಥಿಕೆಗಳ ಬಗ್ಗೆ ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ. ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಪತ್ತೆಯಾದ

ನನ್ನ ಎಲ್ಲಾ ವಿವರಗಳನ್ನು ಗೌಪ್ಯವಾಗಿ ಇರಿಸಲಾಗಿದೆ ಮತ್ತು ಸಂಶೋಧನೆಗಳನ್ನು ಪ್ರಕಟಿಸುವಾಗ ಅಥವಾ

ಹಂಚಿಕೊಳ್ಳುವಾಗ, ನನ್ನ ವಿವರಗಳನ್ನು ಮರೆಮಾಚಲಾಗುತ್ತದೆ ಎಂದು ನಾನು

ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ.ವಿಚಾರಣೆಗಾಗಿ ನಾನು ಪ್ರಧಾನ ತನಿಖಾಧಿಕಾರಿಯ ಮೊಬೈಲ್ ಸಂಖ್ಯೆಯನ್ನು

ಹೊಂದಿದ್ದೇನೆ.

ಈ ಅಧ್ಯಯನದ ಭಾಗದಲ್ಲಿ ಸೇರಿಸಲು ನನ್ನ ಉತ್ತಮ ಮನಸ್ಸಿನಲ್ಲಿ ನಾನು ಸಂಪೂರ್ಣ ಒಪ್ಪಿಗೆಯನ್ನು ನೀಡುತ್ತೇನೆ.

ರೋಗಿಯ ಸಹಿ:

ಸಾಕ್ಷಿ ಸಹಿ:

ಹೆಸರು:

ರೋಗಿಗೆ ಸಂಬಂಧ: ದಿನಾಂಕ: ಸ್ಥಳ:

ದಿನಾಂಕ: ತನಿಖಾಧಿಕಾರಿ ಸಹಿ: .ಸಾಯಿ ಲಕ್ಷ್ಮಿ ಶ್ರೇಯಾ

Master chart

Sl no	Age	Para	GA	Comorbidity	Vaginal pH	Bishop score	Improvement Bishop score	Induction number	Time to enter active labour AL	Delivery type	Indication of LSCS
1	27	2	38	GDM	4	5	Yes	1	10	FTVD	
2	28	2	38	GDM	3	3	Yes	2	16	LSCS	Fetal distress
3	22	1	39	Hypertension	2	1	No	3	18	LSCS	Failed induction
4	18	2	38	Hypertension	2	2	No	3	12	LSCS	Failed induction
5	26	1	40	GDM	4	4	Yes	1	6	FTVD	
6	25	2	38	Hypertension	3	4	Yes	1	10	FTVD	
7	22	2	38	Hypertension	3	5	Yes	1	8	FTVS	
8	27	2	38	No comorbidity	4	1	No	3	17	LSCS	Failed induction
9	27	2	38	Hypothyroidism	6	4	Yes	1	8	FTVD	
10	30	2	38	Hypothyroidism	5	2	No	3	13	LSCS	Failed induction
11	29	1	39	GDM	3	2	No	3	19	LSCS	Failed induction
12	28	1	39	No comorbidity	6	4	Yes	1	8	FTVD	
13	29	2	38	No comorbidity	4	4	Yes	2	17	VAVD	
14	21	2	38	Hypothyroidism	3	4	Yes	2	10	FTVD	
15	22	2	38	GDM	5	3	Yes	2	6	FTVD	
16	24	2	38	No comorbidity	7	3	No	3	9	LSCS	Failed induction
17	21	1	38	Hypertension	6	3	No	3	15	LSCS	Failed induction
18	18	2	39	No comorbidity	4	3	Yes	2	18	LSCS	Fetal distress
19	26	1	40	Hypertension	2	4	Yes	1	12	FTVD	
20	28	1	39	GDM	5	4	Yes	1	6	FTVD	
21	24	2	39	No comorbidity	5	4	Yes	1	10	FTVD	
22	26	2	39	No comorbidity	5	5	Yes	1	6	FTVD	
23	33	2	39	No comorbidity	3	1	No	3	16	LSCS	Failed induction
24	22	2	39	No comorbidity	7	3	No	3	17	LSCS	Failure to progress
25	19	2	39	No comorbidity	6	3	Yes	1	7	FTVD	
26	20	1	40	No comorbidity	5	5	Yes	2	7	FTVD	
27	29	1	39	No comorbidity	3	5	Yes	2	8	FTVD	
28	19	1	40	Hypertension	6	5	Yes	1	8	FTVD	
29	29	2	38	Hypothyroidism	5	3	Yes	1	8	FTVD	
30	29	2	38	No comorbidity	3	2	No	3	15	LSCS	Failed induction
31	18	2	38	GDM	2	1	No	3	15	LSCS	Failed induction
32	29	1	39	GDM	3	1	No	3	19	LSCS	Failed induction
33	25	2	37	Hypertension	4	1	No	3	14	LSCS	Failed induction
34	24	1	40	Hypertension	6	3	Yes	1	8	VAVD	
35	20	1	38	GDM	6	5	Yes	2	9	FTVD	
36	31	2	37	No comorbidity	4	3	Yes	1	10	FTVD	
37	30	2	38	No comorbidity	6	2	No	3	14	LSCS	Failed induction

38	23	2	38	Hypothyroidism	6	4	Yes	1	9	FTVD	
39	23	1	40	Hypertension	5	3	Yes	1	7	FTVD	
40	21	2	37	No comorbidity	3	5	Yes	2	15	FTVD	
41	23	2	37	Hypertension	2	2	No	3	15	LSCS	Failed induction
42	29	1	39	No comorbidity	4	2	No	3	15	LSCS	Failed induction
43	20	2	38	No comorbidity	6	3	Yes	1	8	VAVD	
44	21	1	39	Hypothyroidism	2	2	No	3	18	LSCS	Failed induction
45	25	2	38	Hypertension	6	5	Yes	2	16	FTVD	
46	20	1	40	Hypertension	7	4	Yes	2	16	FTVD	
47	19	1	39	No comorbidity	4	5	Yes	2	12	FTVD	
48	18	1	39	GDM	5	3	Yes	3	12	LSCS	Fetal distress
49	29	2	37	Hypertension	3	4	Yes	2	11	VAVD	
50	23	1	39	No comorbidity	2	4	No	3	19	LSCS	Failed induction
51	26	2	39	GDM	5	2	No	3	12	LSCS	Failed induction
52	19	2	39	GDM	6	5	Yes	2	10	FTVD	
53	28	1	37	No comorbidity	3	3	Yes	1	11	FTVD	
54	23	1	37	No comorbidity	4	4	Yes	2	12	LSCS	Failure to progress
55	30	1	37	No comorbidity	4	5	Yes	1	11	FTVD	
56	25	1	37	No comorbidity	3	3	Yes	2	12	LSCS	Failure to progress
57	22	2	37	No comorbidity	6	5	Yes	2	8	FTVD	
58	21	1	39	No comorbidity	6	4	Yes	2	8	FTVD	
59	25	1	39	No comorbidity	6	5	Yes	1	8	FTVD	
60	28	1	37	No comorbidity	7	3	Yes	2	8	VAVD	
61	30	1	40	Hypertension	2	2	No	3	12	LSCS	Failed induction
62	18	2	37	Hypothyroidism	6	4	Yes	1	8	FTVD	
63	24	2	39	GDM	6	2	Yes	1	7	FTVD	
64	27	1	37	No comorbidity	5	5	Yes	2	7	FTVD	
65	19	1	39	No comorbidity	5	5	Yes	2	7	FTVD	
66	27	1	39	No comorbidity	5	3	Yes	1	8	FTVD	
67	30	1	37	No comorbidity	5	4	Yes	1	8	FTVD	
68	29	1	37	GDM	2	3	Yes	2	9	VAVD	
69	20	1	37	Hypertension	3	5	Yes	2	14	LSCS	Failure to progress
70	27	1	37	Hypertension	4	3	Yes	2	18	LSCS	Fetal distress
71	20	1	39	No comorbidity	6	2	No	3	12	LSCS	Fetal distress
72	25	1	37	No comorbidity	4	1	No	3	16	LSCS	Failed induction
73	29	1	39	GDM	4	3	No	3	18	LSCS	Failed induction
74	29	1	37	No comorbidity	6	2	No	3	14	LSCS	Failed induction
75	19	1	37	GDM	7	3	Yes	1	8	FTVD	
76	27	1	37	No comorbidity	5	3	Yes	2	18	FTVD	
77	19	1	40	No comorbidity	2	1	No	3	12	LSCS	Failed induction
78	19	1	39	No comorbidity	3	4	Yes	2	16	LSCS	Fetal distress
79	18	1	40	Hypertension	3	1	No	3	13	LSCS	Failed induction
80	30	1	37	No comorbidity	5	2	No	3	15	LSCS	Failed induction
81	29	1	37	Hypertension	7	4	Yes	1	9	FTVD	
82	24	1	40	No comorbidity	2	5	Yes	2	12	FTVS	
83	24	1	40	Hypertension	6	2	No	2	12	FTVD	

84	21	1	40	No comorbidity	5	4	Yes	1	6	FTVD	
85	20	1	40	GDM	2	2	No	3	18	LSCS	Failed induction
86	29	1	41	Hypertension	3	5	Yes	1	11	VAVD	
87	25	1	37	No comorbidity	6	3	No	2	13	FTVD	
88	30	1	41	GDM	2	2	Yes	2	17	LSCS	Fetal distress
89	20	1	41	Hypertension	6	3	Yes	1	7	FTVD	
90	22	1	40	No comorbidity	3	4	Yes	2	10	FTVD	