"COMPARATIVE STUDY BETWEEN INTRACERVICAL DOUBLE FOLEYS CATHETER PLUS MISOPROSTOL AND INTRAVAGINAL MISOPROSTOL ALONE FOR INDUCTION OF LABOUR"

By

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Dissertation Submitted to the

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In partial fulfilment of the requirements for the degree of

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In

OBSTETRICS AND GYNECOLOGY

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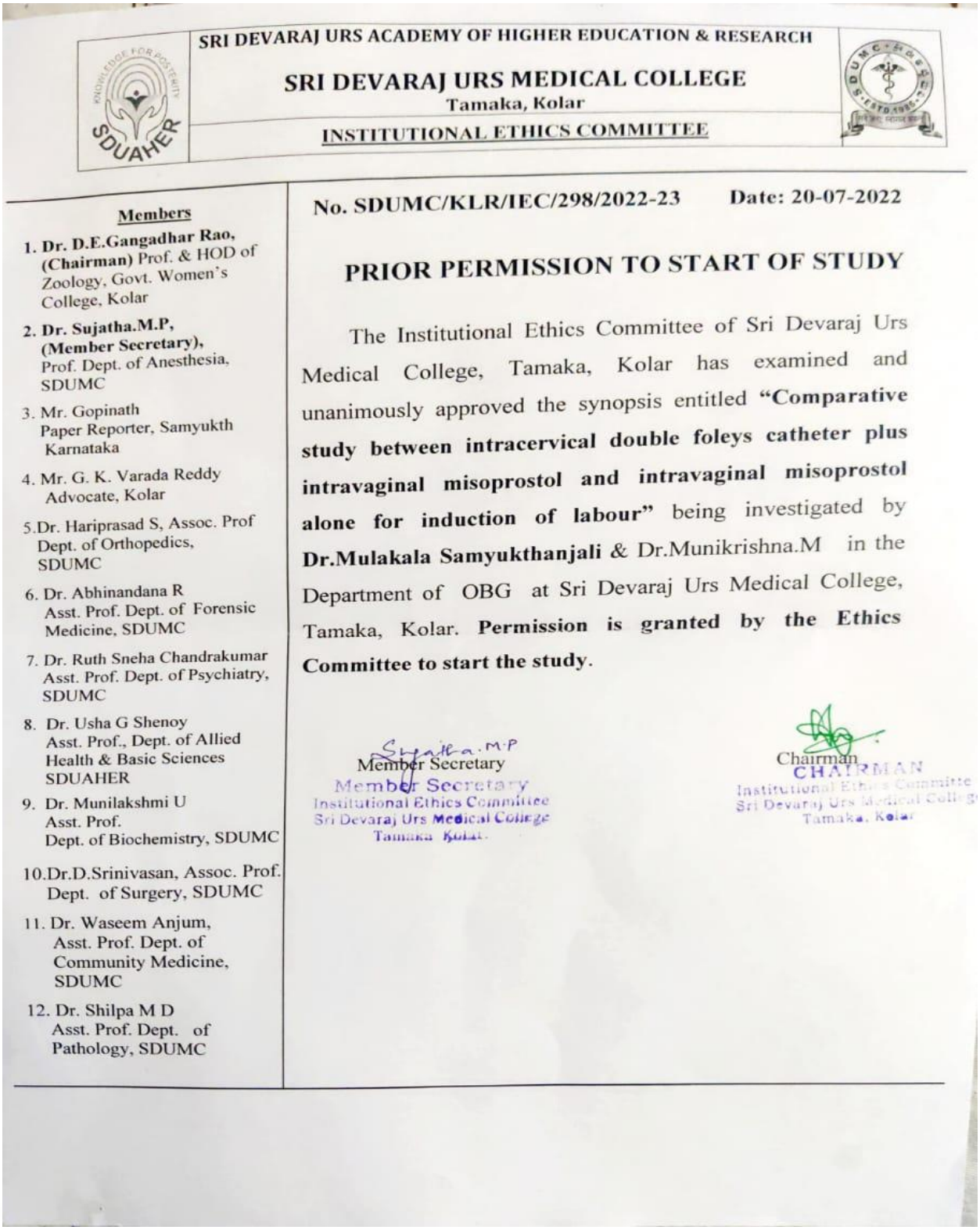

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Arezoo shayan, Seyedeh Zahra Masoumi, Farideh Kazemi, Mansoureh Refaee, Maryam Ahmadi, Hadis Sourinezhad, Minoo Hamoun. "Effect of Evening Primrose Vaginal Capsule on Cervix Preparation and Duration of First Stage of Labor in Nulliparous Women Referred to Fatemieh Hospital in Hamadan, Iran: A Single-blind Randomized Controlled Trial", Current Drug Research Reviews, 2022

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ACOG	American College of Obstetricians and Gynaecologists
AJOG	American Journal of Obstetrics and Gynaecology
BMI	Body Mass Index
FDA	Food and Drug Administration
GDM	Gestational Diabetes Mellitus
HELLP	Haemolysis, Elevated Liver Enzyme Levels, and Low Platelet Levels
IOL	Induction of Labor
NEJM	New England Journal of Medicine's
NICU	Neonatal Intensive Care Unit
NSAIDs	Nonsteroidal Anti-Inflammatory Drugs
PPH	Postpartum Haemorrhage
PROM	Premature Rupture of Membranes
RCOG	Royal College of Obstetricians & Gynaecologists
UTI	Urinary Tract Infection
WHO	World Health Organization

ABSTRACT

"COMPARATIVE STUDY BETWEEN INTRACERVICAL DOUBLE FOLEYS CATHETER PLUS MISOPROSTOL AND INTRAVAGINAL MISOPROSTOL ALONE FOR INDUCTION OF LABOUR"

ABSTRACT

Background

Labour induction, constituting approximately 25% of deliveries, involves stimulating uterine contractions to initiate vaginal delivery. One of the approaches involves the use of pharmacological drugs, which include prostaglandins like dinoprostone, misoprostol, and oxytocin, as well as medical equipment, which include saline drip and balloon catheters. Treatments that do not include the use of pharmaceuticals include amniotomy and membrane peeling. The cervix's initial condition significantly impacts induction success, with optimal outcomes seen in already softened and effaced cervices. The Foley balloon catheter is effective for cervical ripening, offering advantages such as lower uterine tachysystole risk, reduced cost, and easy reversibility. A comparison was made between the usage of 25 micrograms of intravaginal misoprostol and the usage of intracervical twin Foley catheters paired with misoprostol to induce labor. The research also compared the results for both the mother and the fetus.

Materials and Methodology

At the RLJH hospital, the research comprised 166 women who were experiencing their first pregnancy and had gestational ages ranging from 37 to 42 weeks. Comprehensive demographic, obstetric, and medical histories were recorded. Gestational age was clinically confirmed, and routine investigations were conducted. Two groups of women were blindly randomized to obtain either a

Double Foley's Catheter with Misoprostol or Misoprostol alone. These women had a reactive NST and a modified Bishop score of just five. In the Double Foley group, two inflated catheters and intravaginal misoprostol were administered every six hours (up to four doses). On the other hand, the Misoprostol group was given 25 micrograms of misoprostol every six hours until the cervix was favorable. The following were some of the outcomes that were measured: vaginal birth rates, induction-to-active-phase and delivery intervals, oxytocin augmentation, delivery mode, APGAR ratings, NICU admissions, anomalies in fetal heart rate, and maternal problems such as uterine hyperstimulation.

Results

The mean age of participants was similar between groups (25.78 years for the combined group and 24.91 years for the misoprostol group), with most participants aged 21-25 years. Gestational ages were comparable, with more early-term pregnancies in the combined group and more full-term pregnancies in the misoprostol group. Prolonged pregnancy was the most common induction reason. The combined group required fewer misoprostol doses and had shorter induction-to-active-phase (mean 7.24 hours) and delivery times (mean 13.13 hours) compared to the misoprostol group (16.28 and 18.14 hours, respectively). The vaginal delivery was more usual in the combined group (59. 0% vs. 38. 6%) while caesarean sections were less frequent (28. 9% vs. 46. 9%). There were no noteworthy differences in neonatal results and maternal adverse events, although postpartum hemorrhage appeared slightly higher in the misoprostol group. These outcomes suggest that the coordinated treatment strategy is efficient, thus reducing the labor and enhancing the vaginal delivery proportions.

Conclusion

Based on the study, it can be suggested that the effectiveness of the treatment regimens of induction of labor with misoprostol only is lower than the effectiveness of the treatment regimens with the Double Foley's Catheter and misoprostol combined, therefore giving better outcomes in shorter induction time, increased rates of vaginal delivery and lower rates of CS - Caesarean section. Since the two groups did not vary in terms of newborn outcomes or maternal problems, the combination approach was superior.

Keywords

Comparative Study, Intracervical Double Foleys Catheter Plus Misoprostol, Intravaginal Misoprostol, Induction of Labour

INTRODUCTION

INTRODUCTION

The process of labor is now one of the most commonly used and sought-after obstetric care that is used in approximately one-quarter of all births. [1] It encompasses the induction of contractions of the uterus with a view of commencing vaginal birth irrespective of whether the membranes are intact or not. Because there were no variations between the groups in terms of newborn outcomes or maternal problems, the combined technique was evaluated as being superior. [2]

The state that the cervix is in is crucial in cases of labour induction because when the cervix is ripe it is softer and thinned out, which will give the best results. In mechanical methods, the most effective technique as regards cervical maturation is the Foley balloon catheter which is performed with the Foley balloon device. This method compares well with prostaglandin treatment in terms of induction success, offering advantages like a lower risk of uterine tachysystole, reduced cost, and easier reversibility.[3,4]

Labour induction is essential in obstetric care, especially for pregnancies requiring timely delivery for maternal or fetal health reasons. Prostaglandins are frequently used for their ability to alter collagen and glycosaminoglycan concentrations in the cervix, facilitating its ripening.[5] Mechanical treatments can also be reversed and are generally cheaper and easier to perform; hence their popularity; examples include the Foley catheter which by applying mechanical pressure encourages synthesis of prostaglandin and cervical dilation.[6]

The research that fills a noteworthy gap in comparative studies of induction techniques via the use of a double balloon catheter in conjunction with misoprostol to induce labor is a noteworthy step

forward. While both mechanical methods like the Foley catheter and pharmacological agents like misoprostol are individually validated, their combined efficacy and safety have not been thoroughly explored.[7] Because there is a dearth of data, the development of optimum induction techniques is hampered, which may affect the results for both the mother and the new baby.

Current research mainly focuses on the effectiveness of single methods, lacking comprehensive comparisons. By examining the double balloon plus misoprostol method against intravaginal misoprostol alone, this study aims to provide clearer insights into their comparative effectiveness, side effect profiles, and overall health outcomes. The present study is conducted to show the method of induction by combined method have better outcomes like lesser misoprostol dose , lesser induction to delivery interval with lesser maternal complications and similar neonatal outcomes. These findings are vital for improving clinical practices, ensuring efficient resource use, and minimizing risks, thereby enhancing the safety and well-being of both mother and child during delivery.

OBJECTIVES

OBJECTIVES OF THE STUDY

OBJECTIVES

The purpose of this research is to evaluate the safety and effectiveness of using intracervical double Foley catheters in conjunction with misoprostol to use 25 micrograms of intravaginal misoprostol to induce labor.

To compare the maternal and fetal outcomes, between the two induction methods.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

LABOR

Childbirth and expulsion of the placenta through the uterine cavity by way of the birth canal is referred to as labor. A successful labor is dependent on three essential elements: the movements and movements of the mother, the characteristics of the fetus, and the structure of the birth canal, known as the 'passenger, power, passage''.[8]

In this regard, there are different ways that clinicians use to monitor labor. They keep on performing cervical checks that tell the extent of cervical dilation, the degree of cervical effacement, and fetal station. Fetal heart rate assessment examines the baby's health while monitoring the contractions of the uterus through tools such as a cardiotocograph. The information derived from these methods is used in identifying the labor stage and in fact, the rate of progress. 9 This makes it easier to handle any complications that arise thus making the delivery to be safer for both the mother and the baby.

INITIAL EVALUATION AND PRESENTATION OF LABOR [10,11]

When women present at obstetrical triage complaining of contractions and fearing that labor has begun, the clinician should then assess the symptoms to determine the truth. Some of the common signs include; bleeding from the vagina or bloody show, painful contractions, and the release of a fluid. Labour is defined as being rhythmic, and there is a visible cervical change or effacement.

Assessments are done on admission when a woman is admitted into the labor and delivery unit, to ensure that both the woman and the baby are healthy. Temperature, HR, saturation of oxygen,

respiration rate, and BP of the patient are taken and checked for any change that may have occurred. The general well-being of the fetus is assessed with the help of a process referred to as cardiotocographic monitoring.

Evaluation of the patient records from the prenatal period: obstetrics, surgical, medical records, laboratory data, and imaging can help in the assessment of the patient's health and possible risk factors if any. The next steps are to take an extensive history of the present illness, a review of systems, and a general examination in which a bimanual pelvic examination is done using a sterile speculum.

It is the recurrent laryngeal nerve that gives sensation to the subglottic area which is just below the vocal cords and the trachea while the superior laryngeal nerve which arises from the vagus nerve supplies the supraglottic area just above the vocal cords. Also, the vagus nerve (X) has a contribution to the blood vessels of the trachea. Amniotic fluid alt pH is slightly higher than that of normal vaginal secretion, it lies between pH 7. 0 to 7. 5.

A sterile gloved exam is used to determine cervical dilatation and effacement. Estimating the centimeter-long distance between two fingers splayed out in a 'V' shape at the external cervical OS is the normal method for measuring dilation. The amount of cervix that has been effaced may be measured by comparing the residual cervical length to the uneffaced one. In situations of breech presentation, there is an increased risk of fetal morbidity and death compared to cephalic presentation, hence it is vital to establish the presenting fetal component during the cervical exam and, if required, perform a bedside ultrasound.

NORMAL LABOR MANAGEMENT [12,13]

Although labor is a normal process, complications may arise that require clinical intervention. Managing low-risk labor involves balancing the natural progression with the need to minimize complications. Clinicians may detect fetal discomfort and evaluate the efficacy of contractions with the use of cardiotocographic monitoring, which tracks the fetal heart rate in addition to the contractions of the uterus. Maternal vital signs are regularly checked, with adjustments made as necessary.

Laboratory tests, including hemoglobin, hematocrit, and platelet counts, are conducted and often repeated postpartum if there is substantial blood loss. Cervical assessments, executed every 2 to 3 hours, can increase infection risk, particularly after membrane rupture. Women are encouraged to move and vary positions freely, and an intravenous catheter is inserted for administering medications or fluids. Oral intake is generally allowed, with intravenous fluids given if fasting is prolonged.

Opioids administered intravenously, nitrous oxide sighed, and neuraxial analgesia are all alternatives for those who qualify for pain relief. The use of amniotomy is discouraged for normal procedures and is reserved for certain cases such as fetal scalp screening or labor stimulation. Weak contractions may be strengthened by the administration of oxytocin.

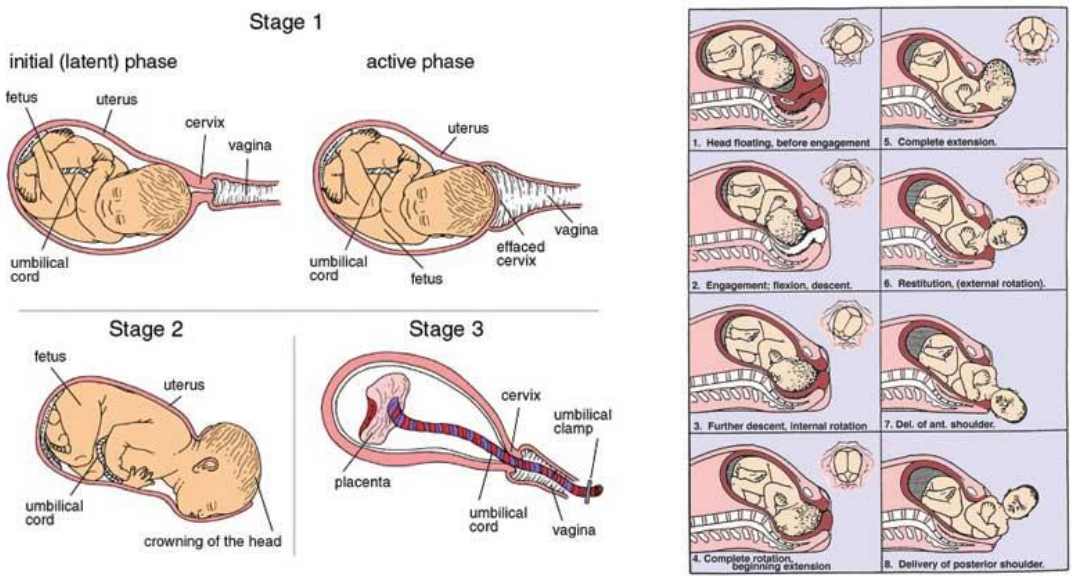

Figure 1: Stages of labor

First Stage of Labor [14]

It starts when the contractions start and stops when the cervical opening is fully dilated (10 centimeters).

Induction methods include prostaglandin cervical ripening, membrane stripping, amniotomy, and intravenous oxytocin.

Labor onset is typically characterized by sturdy, consistent contractions (3 to 5 minutes apart).

Friedman et al. described three categorizations of labor: preparatory, dilational, and pelvic division phases.

Subdivided into latent (0-6 cm) and active (6 cm to full dilation) phases.

The fetal location, cervical dilation, and effacement are monitored with serial cervical examinations.

The cervix has completely thinned down when there is cervical effacement.

The fetal station is assessed relative to the maternal pelvis.

The unprecedented length of time that the latent phase lasts—up to twenty hours in women who have never given birth and fourteen hours in those who have given birth more than once—is not a reason for alarm.

Active labor normally starts at a dilation of around 6 centimeters and continues at a rate of 1.2 to 1.5 centimeters each hour.

The lack of cervical change for more than four hours is considered to be the point at which labor has begun.

SECOND STAGE OF LABOR [15]

Begins with the completion of the cervical dilatation and completes with the birth of the newborn.

Seven cardinal motions are performed by the fetus as it descends into the vaginal canal.

The following are examples of cardinal movements: expulsion, engagement, descent, stretching, inner rotation, expansion, and external rotation.

Parity and the use of anaesthetic both have an impact on the duration of the procedure.

Nulliparous women who do not get anaesthesia often have a duration of less than three hours.

In women who have never given birth and are under neuraxial anaesthesia, the duration of the procedure is shorter than four hours.

There is a possibility that fetal and maternal variables might have a role in the prolonged second stage.

THIRD STAGE OF LABOR [16]

Starts the process following the birth of the fetus and ends with the delivery of the placenta.

A gush of blood, a stretch of the umbilical cord, and a globular uterine fundus are the three cardinal indications that are characteristic of this condition.

The time it takes for spontaneous placental ejection to occur ranges from five to thirty minutes.

If the delivery duration is more than thirty minutes, there is an increased likelihood of postpartum haemorrhage.

The management consists of applying fundal pressure and traction to the umbilical cord to facilitate more rapid delivery of the placenta.

INDUCTION OF LABOR

Induction of labor is a common procedure that is often used in the field of obstetrics, accounting for twenty percent of all successful births. A number of reasons, including as the availability of cervical maturing drugs, patient preferences, the accessibility of the medical professional, logistical factors, psychological aspects, and medicolegal concerns, all contribute to the occurrence of this condition. Labor entails painful uterine contractions that lead to cervical dilation and fetal descent through the birth canal, culminating in delivery. Preceding this process, extensive cervical changes occur, involving remodeling, increased myometrial responsiveness, ripening, effacement, and cervical integrity loss, initiated weeks before contractions.[17]

Key cervical changes include alterations in proteoglycans, glycosaminoglycans, collagen composition, and infiltration by inflammatory cells, facilitating softening—a phenomenon termed cervical ripening. Induction of labor refers to artificially terminating pregnancy post-viability but pre-spontaneous labor onset, with or without ruptured membranes. Induction is warranted when it promises a better outcome than allowing the process to proceed naturally.[18]

Throughout history, the purpose of inducing labor was to either deliver a fetus that was not viable or to prevent cephalopelvic disproportion. Mechanical procedures and the artificial rupture of membranes were among the early applications of this approach. Beginning in the middle of the 20th century, oxytocin and, subsequently, prostaglandins have emerged as key agents, which complement the ways that have been developed.[19] These advancements reflect evolving obstetrical practices, aiming to optimize maternal and fetal outcomes during labor induction procedures.

INDUCTION OF LABOR RATES

Analyzing the tendencies of the last several decades, one can notice that there is a certain increase in the rates of induction of labor. This upward trend could be due to several factors such as; medical advancement in the field and the changes in procedures that are used during childbirth. One factor that defines induction rates is the access to resources especially agents for cervical ripening. The increase in the use of medications in preparing the cervix has also boosted the incidence of inductions since it has provided clinicians with various ways to follow when they need to start labor.

Inequalities in induction are also identifiable between developed and developing countries because of the variations in healthcare systems and standards. Countries that are categorized as having a developed healthcare system normally have higher levels of use of labor induction compared to developing countries due to the availability of health facilities and technologies. For example, in the US and the UK, it is shown that the induction rate is approximately 20%, which, however, points to the fact that this obstetrical intervention is widespread in the conditions of the affluent health care systems. [20]

However, induction rates in developing countries such as India depict a relative fluctuation where the rates depend on the type of facility and the intensity of care offered. Induction rates may vary significantly in the private and government healthcare settings and between the teaching/tertiary care and nonteaching hospitals in India. For instance, within the state of Maharashtra, induction rates varied between 6. 59% to 23. 9% indicating a variation in the practices and resources in use in various healthcare facilities within the same region. [21]

Being aware of factors behind the differences in the induction rates is essential for the effective development of healthcare strategies and guidelines that will allow for improving maternal and fetal

outcomes. Measures such as attempting to control the ways induction is carried out, the availability of materials, and optimizing the methods of delivering obstetrical care universally can assist in the proper use of induction of labor to address intended goals without incurring a whole lot of hazards.

INDICATIONS FOR INDUCTION OF LABOR [22-25]

It is also important to note that while some countries and institutions may use the process of induction, they may do it in different ways. PROM, fetal death, chorioamnionitis, placental abruption, chronic lung disorder, diabetes mellitus, high blood pressure, renal illness, HELLP syndrome, preeclampsia, eclampsia, gestational hypertension, and anti-phospholipid syndrome are some of the causes in mothers. Some of the fetal causes include oligohydramnios, Rh iso-immunization, and severe growth restriction.

POST-TERM PREGNANCY

Defined as pregnancy exceeding 42 weeks.

Requires termination due to risks like uteroplacental insufficiency leading to fetomaternal complications.

The “United States College of Obstetricians and Gynecologists (ACOG), the Royal College of Obstetricians and Gynecologists (RCOG), and the World Health Organization (WHO)” all agree that induction should begin at 41 weeks to decrease the likelihood of complications like meconium aspiration, poor Apgar scores, neonatal acidaemia, and birth traumas.

Risks grow with each successive week of pregnancy length: the perinatal death rate quadruples at 43 weeks, climb 5- to 7-fold at 44 weeks, and then doubles again at 42 weeks.

PREMATURE RUPTURE OF MEMBRANES (PROM)

The amniotic sac bursts spontaneously just before labor begins.

Term PROM occurs after 37 weeks; preterm PROM (PPROM) occurs before 37 weeks.

Conditions such as UTIs, GTIs, polyhydramnios, many pregnancies, cervical inadequacy previa placenta, abruptio placentae, amniocentesis, and nutritional inadequacies might increase the risk of complications during pregnancy.

Complications include maternal sepsis, postpartum endometritis, fetal/neonatal sepsis, distress, meningitis, and pneumonia.

Induction is advised if labor does not commence within 4-6 hours post-PROM to prevent complications.

OLIGOHYDRAMNIOS

Defined as an amniotic fluid index <8 cm or absence of fluid pocket 2-3 cm deep.

Caused by reduced fetal urine production, leading to fetal compression and pulmonary hypoplasia.

Incidence: 0.5-5%.

Meconium-stained fluid, uteroplacental deficiency, and compression of the umbilical cord are all conditions that come together.

Considered a solid indication for induction due to the threat of caesarean delivery from fetal distress.

HYPERTENSIVE DISORDERS IN THE PREGNANCY

The third leading cause of maternal mortality in India.

Including preeclampsia, eclampsia, chronic hypertension, and gestational hypertension.

Connected to problems such as low birth weight, gestational diabetes, and fetal mortality in the womb.

Induction is recommended after 37 weeks to mitigate maternal and fetal risks.

GESTATIONAL DIABETES MELLITUS (GDM)

Affects 3-5% of pregnancies, increased by obesity, hypertension, and advanced maternal age.

The hazards are higher in cases of untreated diabetes and fetal macrosomia.

Induction at 38 weeks is advised for positive outcomes.

Induction at 37-39 weeks is supported by studies for improved results in GDM cases.

CONTRAINDICATIONS FOR INDUCTION OF LABOR

The risk involved with inducing labor makes it inappropriate in some clinical situations. Fetal abnormalities such as transverse lying, footling breech, cord presentation, placenta previa, vasa previa, and gross cephalopelvic discrepancy (CPD) are examples of these. Additional factors that can prevent the procedure from being performed include a history of uterine rupture, a previous traditional or inverted T uterine incision, extensive prior uterine surgery such as a full-thickness myomectomy, active sexually transmitted infections, invasive cervical cancer, inability to induce active labor, tachysystole, anomalies in the fetal heart rate, cord protrusion, chorioamnionitis, higher rates of vaginal operation deliveries and cesarean sections, and, rarely, uterine break, especially in a scarred uterus.[26,27]

PROCEDURE [28-30]

Equipment

Induction of labor (IOL) can be attained through two primary methods: mechanical and pharmacological. These methods are selected based on the patient's cervical readiness, often assessed using the bishop score.

1. **Mechanical methods**

   Foley catheter

   A balloon catheter is positioned through the endocervical canal to promote cervical dilation.

   Double-balloon device (cook catheter)

   Utilizes two balloons to mechanically dilate the cervix.

   Osmotic dilators

   Such as laminaria and synthetic dilators, placed in the cervical os to absorb fluid and expand, facilitating cervical ripening.

2. **Pharmacological methods**

   Synthetic Prostaglandins

   Used primarily for cervical ripening. Women who have had a low transverse cesarean delivery before should exercise care while using prostaglandins because of the risk of rupture of the uterus.

   Misoprostol (PGE1)

   Administered in various doses and routes.

   Dinoprostone (PGE2)

   Also used in different forms to soften and dilate the cervix.

Oxytocin

Administered intravenously to stimulate uterine contractions and augment labor.

3. Combined Methods

Amniotomy

The artificial rupture of membranes, is often combined with mechanical or pharmacological methods to enhance labor induction effectiveness.

Personnel

The members of an inpatient obstetric care team may include lactation specialists, medical professionals, neonatal specialists, obstetricians, residents, midwives, and nurses. Collaboration among these specialists ensures a safe environment for mother and baby during labor and postpartum. An obstetrician trained to perform a cesarean section (CS) must be available whenever labor induction (IOL) is used, to address complications requiring a CS. It becomes fundamental to apply a multidisciplinary perspective to the complexity of labor and work processes to obtain the best results.

Preparation

The cervix is assessed using the Bishop scoring system, which takes into account the following factors: position, obsolescence, homogeneity increase, and post. Helping in estimating the likelihood of vaginal birth, this score is assessed in the late third trimester and at the beginning of IOL. When the score is eight and above, the possibility of achieving a vaginal birth is good while when the score

is three and below; it is poor. Every expectant lady should discuss these with her medical practitioner so that they can understand the IOL procedure.

Before they can consent, women are obliged to learn the prospects of gain, loss, and options They need to comprehend the risks and benefits of IOL. Like with the risks of preterm labour, the risks of IOL, are chorioamnionitis, surgical vaginal delivery, postpartum haemorrhage, an upsetting fetal HR, and the requirement of a CS. The possible grounds for operational births and cesarean operations should be discussed before presenting an intraoperative lens (IOL). IOL failure is one of the signs; it is where medications and amniotomy fail to push the cervical dilatation any further. According to the "American College of Obstetricians and Gynecologists", the cesarean section is advised 12 to 18 hours after the intraocular lens operation in case the treatment is ineffective.

Reviewing different IOL approaches should be done throughout the consent procedure. You have the option to apply mechanical and pharmacological approaches together or separately. Patients with a singleton pregnancy and a Bishop score below six who were given a combination of induction treatments, such as a Foley catheter with syntocinon or misoprostol, had a quicker time to delivery compared to those who were given either medication alone. This was determined in a randomized controlled experiment that took place in 2016. After controlling for other factors, however, the syntocinon and Foley combination did not outperform either approach alone.

Amniotomy alone is compared to mechanical and pharmacological approaches in other research and Cochrane reviews. Balloon mechanical induction seems to be safer for the infant than vaginal PGE2, yet it is just as effective. Although the effects on the baby's safety are not yet known, research indicates that a balloon catheter may be somewhat less successful than oral misoprostol. The infant is likely to be safer with the balloon catheter, even if it may be less successful than low-dose vaginal

misoprostol. Babies' well-being and mothers' contentment should be the primary goals of future studies.

Before an IOL is consented to, pregnant women should be informed about the rates and indications of cesarean sections. In American medical journals and online communities, the frequency of caesarean sections is a prominent topic. In a study published in the NEJM, researchers compared the perinatal outcomes and cesarean rates of nulliparous women who had elective intraocular lens (IOL) implantation at 39 weeks to those of women who received expectant care. The induction group had a lower incidence of cesarean sections without significantly higher rates of adverse perinatal outcomes, according to the study. A lot of people are paying attention to this study because it could change the way induction works.

A retrospective study conducted in 2013 found that the frequency of cesarean sections, serious lacerations, and surgical deliveries was lower among multiparous and nulliparous women who were electively induced between 37 and 40 weeks of pregnancy. Cesarean sections are examined in this research and others examine cesarean sections about maternal variables, gestational age, and parity.

Neonatal hazards may be a worry for women with certain reasons for intraocular lenses (IOLs), such as fetal growth limitation. Fetal mortality, hospitalizations to the newborn intensive care unit (NICU), and respiratory distress were not different among gestational ages and parity in the 2013 California retrospective research. Nevertheless, there may be variations in neonatal outcomes for babies born prematurely, according to previous research. Babies born by cesarean section at 37 weeks of gestation had a greater risk of respiratory and non-respiratory problems than those born at 38 or 39 weeks, according to a 2009 NEJM research that used data from the Eunice Kennedy Shriver National Institute.

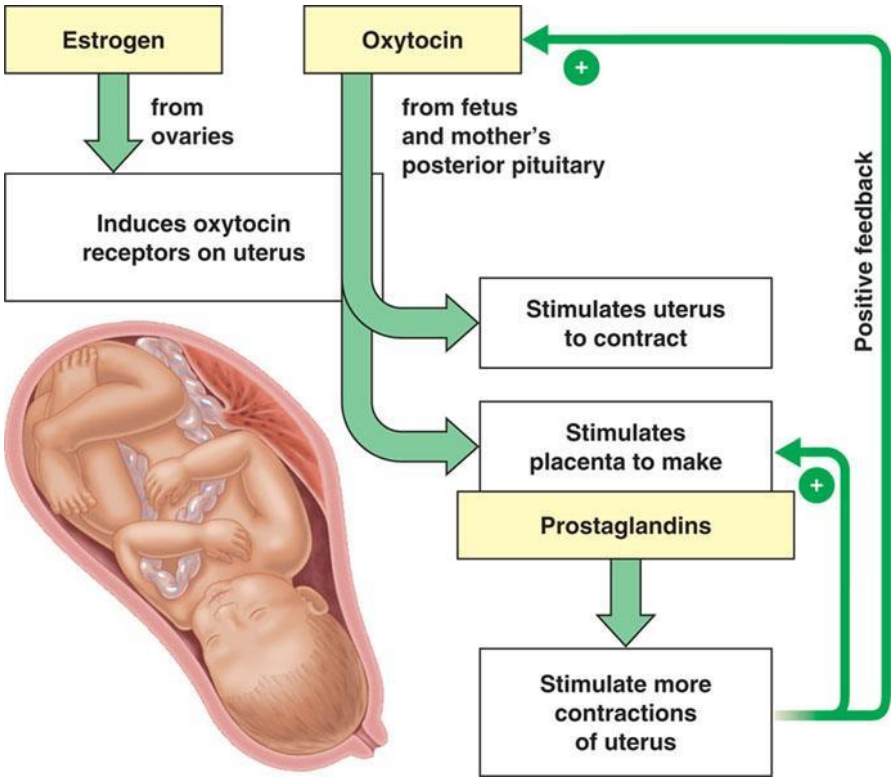

Figure 2: Induction of labor

Treatment

Foley catheters, double-balloon catheters, or laminaria may all be used to mechanically dilate the catheter during induction. The external and internal cervical OS are used to implant the Foley catheter, which is then inflated with 30 to 80 mL of normal saline. Cervical dilatation is facilitated by the pressure exerted on the internal OS by this inflation.

In 2012, the AJOG released research that indicated a decrease in the requirement for syntocinon and speedier induction using an 80 mL inflated volume instead of a 30 mL volume. With a double-balloon catheter, you may adjust the pressure applied to the internal OS and the exterior OS using two separate balloons filled with different quantities of saline. When the cervical dilatation measures

three or four centimeters, the Foley or Cook catheters are usually withdrawn. Another option for dilatation of the cervical OS is the use of osmotic dilators, which come in a range of sizes.

Oral, vaginal, or sublingual administration of 25–50 mcg of misoprostol is recommended for cervical ripening. More frequent dosing, up to 400 mcg every three hours, with a maximum of five doses, may be recommended by the ACOG if the fetus dies inside the mother during the second trimester. Dinoprostone, which stands for prostaglandin E2 (PGE2), is available as a gel and an implant for placement in the vagina. The gel is usually available in quantities of 0.5 mg, while the insert is available in doses of 10 mg.

As a further pharmaceutical option, intravenous syntocinon may be administered at a dose that induces contractions every two to three minutes, thereby expanding the cervical opening. For women experiencing trial labor after a cesarean section, hospitals may have special regulations regarding the maximum dosage of oxytocin.

An amniotomy, which involves the use of an "amnio hook," may be carried out when the cervix has been dilated enough. The fetal position, head engagement, patient preference, and the level of pain experienced by the patient are some of the factors that are considered while making judgments about amniotomy. The decision to perform this technique to induce labor is left to the discretion of the clinician.

PREDICTORS OF SUCCESSFUL INDUCTION OF LABOR

Maternal maturity, parity, induction gestational period, BMI, and cervical condition are some of the variables that affect the effectiveness of labor induction. To what extent an induction is likely to be effective depends on each of these factors. [31-33]

Maternal Age

Numerous research has shown that there is a connection between the age of the mother and the results of labor induction measures. The higher the age of the mother, the greater the risk that she will have a cesarean section. As an example, Rayamajhi et al. found that women above the age of 30 had a greater risk of unsuccessful labor induction attempts. One study reported a 51.32% rate of vaginal delivery among women with an average age of 22.3 years. Conversely, another study confirmed that advanced maternal age is linked to an increased proportion of cesarean sections.

Parity

The success of labor induction is also significantly influenced by parity, as concluded by Bueno et al. Nulliparous women had a much greater risk of cesarean sections, according to the research. Previous childbearing experience favorably affects the chance of effective induction, as shown by the higher rates of vaginal delivery among multiparous women compared to primiparous women (Admani et al., 2015).

Gestational Age

The timing of labor induction is another crucial factor. Park observed higher cesarean section rates at earlier gestational ages. However, some studies have noted increased cesarean rates at later gestational ages, suggesting that the timing of induction is strongly influenced by gestational age, but the exact effect may differ from one case to the next.

Body Mass Index

It is more probable that women who are overweight will need a cesarean section, and they also have a higher risk of experiencing an unsuccessful induction of labor. According to the findings of Crane et al., a greater body mass index is linked to an increased likelihood of induction failure as well as subsequent cesarean sections. Other studies have shown that women with lower BMI tend to have more successful inductions, highlighting the influence of body weight on labor outcomes.

Cervical Status

Perhaps the most important factor in determining whether or not an induction will be successful is the state of the cervix. A commonly used measure to determine cervical preparation for labor is the Bishop score, which was created by Bishop in 1964. Five dimensions were assessed in the first "Bishop score: cervical position, uniformity, effacement, expansion, and the station of the presenting section". Now often used is the modified Bishop score, which measures cervical length in centimeters to more objectively determine effacement; it has a maximum potential score of 13. Another method employed to forecast the success of labour induction is transvaginal ultrasonography, which assesses the cervical length.

Cervical Assessment Methods

Bishop initially established a scoring system in the year 1964 to predict the likelihood of successful inducement of labor. At first, there were five parts to this method, and each one was given a score between zero and three: “Cervical positioning, rhythm, evolution, dilation, and station of the presenting part”. After that, the change in Bishop's score enhanced the assessment since effacement was quantified in centimeters of cervical length with a maximum score of 13 points. This rating system has been used vigorously in clinical practice. In addition, labor induction outcomes could be predicted by estimating cervical length by transvaginal ultrasonography.

Modified Bishop Score [34]

In obstetrics, the Bishop Score is an important tool that is employed for the identification of the preparedness of the cervix for the induction of labor as well as for deciding the chances of a successful vaginal birth. Certain characteristics of the cervix may be utilized by healthcare providers to make a more informed decision concerning the management of inducing labour.

The Bishop Score assesses five cervical parameters: These are the five key indicators which are as follows dilation, effacement, station, consistency, and position. For every parameter, a score is given on how prepared each is for labor, and the higher the score the better the cervix. The scores usually lie between 0 and 13; the score of 8 and above gives a hint that cervix is favorable for induction while if it is 6 or below, it means that cervix is unfavorable for induction and requires other methods of ripening before the induction can take place.

Cervical feature	*Modified Bishop score*			
	0	1	2	3
Dilatation (cm)	<1	1–2	2–4	>4
Length of cervix (cm)	>4	2–4	1–2	<1
Station	−3	−2	−1/0	+1/+2
Consistency	Firm	Average	Soft	–
Position	Posterior	Mid/anterior	–	–

Figure 3: Modified Bishop Score

The Modified Bishop Score is more useful in the process of evaluating the situation since it includes other factors, such as cervical length and fetal station. Due to the incorporation of these extra parameters, the Modified Bishop Score gives a better insight into the cervix for induction, thus improving the success rate of induction and vaginal birth.

Each scoring system is useful in obstetric practice, helping the clinician to choose the most appropriate time and the best protocol of labor induction considering the patient's characteristics. Pap smear scoring systems are useful in the evaluation and follow-up of the cervix which helps in developing an effective management plan for the woman and her fetus. From the cervical characteristics assessment, it is possible to avoid necessary additional manipulations and complications in labor induction process, so, achieve a safe childbirth.

COMPLICATIONS OF INDUCTION OF LABOR [35-37]

Maternal Complications

Caesarean Delivery

There were no noteworthy variances in the rate of caesarean sections among women who were expectantly handled and women who had labor induction as concluded by a Cochrane review of RCTs in 2009. Therefore, if a woman had a pregnancy of longer duration or if her cervix was unfavourable, she was very likely to be delivered by Caesarean section.

Operative Vaginal Delivery

This 2009 Cochrane study also revealed that there was no variance in the rates of instrumental deliveries between the induction group and the expectant group.

Length of Labor

Greenberg et al. established that work duration varies from one ethnic group to the other. It has been noted in many research works that the causes may include the age of the mother, the age of the pregnancy, the body mass index (BMI) as well as the weight of the woman may influence the duration of labour.

Maternal Infections

Hannah et al. (1996) found that vaginal PGE2 treatment was related to a greater risk of maternal infection than oxytocin infusion, most likely as a result of the increased frequency of vaginal exams. Chorioamnionitis is more likely to occur during an induction.

Postpartum Haemorrhage

There was no statistically noteworthy variance in the occurrence of postpartum haemorrhage (PPH) between the induction and expectant management groups, according to a 2009 Cochrane study. PPH was more likely to occur in women who had been in latent phases for longer periods, had been receiving lengthy oxytocin infusions, and had been having many children.

Uterine Hyperstimulation

Women induced with prostaglandins may have uterine hyperstimulation; tocolytics may help treat this condition. If hyperstimulation occurs when using oxytocin infusions, the infusions should be halted. A low-dose oxytocin infusion started while the patient is under close observation for uterine contractions may help alleviate this situation.

Fetal Complications

Meconium-stained Liquor

This condition is normal in postdated pregnancies and prolonged latent phases of labor, as well as in cases of uterine hyperstimulation. Careful monitoring of contractions can help prevent this issue.

Fetal Distress

Fetal distress may occur in cases of meconium-stained liquor and uterine hyperstimulation. Statistically speaking, there is no substantial difference in the level of fetal distress between women who are receiving induction and those who are handled expectantly.

Neonatal Jaundice

Those women who are handled expectantly and those who receive labor induction do not significantly vary from one another in terms of the prevalence of newborn jaundice.

RISKS IN INDUCTION OF LABOR [38-40]

Maternal risks

A higher level of pain and a greater need for analgesia are among the hazards that mothers face. The possibility of an unsuccessful induction, which would need surgical delivery, is another possibility. Thus, when taking oxytocin for a long time, a woman might have to face consequences like water retention and hyponatremia, uterine rupture, abruption of the placenta, and bleeding after delivery.

Fetal risks

The possible adverse effects include uterine hyperstimulation and iatrogenic prematurity for the developing baby. Oxytocin use is associated with even more risks such as cord prolapse, chorioamnionitis, and newborn jaundice in case of long-term use.

MISOPROSTOL [41-45]

The FDA of the United States has approved misoprostol, a synthetic prostaglandin E1 analog, for use in the prevention and treatment of gastrointestinal ulcers that result from the use of NSAIDs. PGE1 receptors in stomach parietal cells are directly activated by this substance and findings of the effects of this drug show that it leads to a decrease in gastric acid secretion during the day and at night.

INDICATIONS

Misoprostol is known by the FDA primarily for use in the prevention and treatment of gastrointestinal ulcers resulting from NSAIDS in those patients who are susceptible to ulceration. Misoprostol is acknowledged to prevent damage to the mucosal lining of the gastrointestinal tract in addition to having uterotonic properties; however, it may result in diarrhea and stomach pain which are considered to be side effects. Further, it is employed for the temporary treatment of those active duodenal or gastric ulcers that are generated by other factors even if the preparation is not the FDA-approved one.

Consistent with the guidelines set forth by the American College of Gastroenterology, misoprostol cannot be used because of side effects experienced on the gastrointestinal system as well as the fact that the doses must be frequently administered. The preferred treatment for the prevention of recurrent ulcer bleeding in patients on NSAIDs and Helicobacter pylori infection is omeprazole. Hence, most PPIs are given for the prevention and management of upper gastrointestinal lesions resulting from NSAIDs.

In medical abortions, the use of misoprostol combined with mifepristone has been approved by the FDA. This combination is characterized by high levels of efficacy and acceptable toxicity. Both of them are recommended by the American College of Obstetricians and Gynecologists (ACOG) for the intention of carrying out medication abortions up to seventy days of pregnancy. If for any reason mifepristone cannot be used, the recommended backup regimen is a regimen with only misoprostol. New prescription and dispensing measures were added to the Mifepristone REMS program when the FDA revised it in January 2023. Misoprostol-only regimens remain an option, even though there have been some restrictions regarding mifepristone.

Off-Label Uses

Misoprostol is known by the FDA primarily for use in the inhibition and treatment of stomach ulcers resulting from NSAIDS in those patients who are susceptible to ulceration. Misoprostol is acknowledged to prevent damage to the mucosal lining of the gastrointestinal tract in addition to having uterotonic properties; however, it may result in diarrhea and stomach pain which are considered to be side effects. Further, it is employed for the short-term treatment of active duodenal or gastric ulcers that are generated by other factors even if the preparation is not FDA-approved.

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MECHANISM OF ACTION

Misoprostol is a prostaglandin E1 analogue that when administered directly to the parietal cells of the stomach can reduce the secretion of gastric acid both normally as well as during the night. This activity has a dose-dependent impact on the reduction of stomach acid production, which is caused by food, alcohol, nonsteroidal anti-inflammatory drugs (NSAIDs), histamine, and caffeine.

The mucosal bilayer is thickened and the backflow of hydrogen ions is reduced by the production of bicarbonate and mucus by misoprostol. This maintains the mucosa's regenerative capacity and improves control of mucosal blood flow.

Inducing labor and cervical ripening, misoprostol works by binding prostaglandin to uterine smooth muscle cells, which gives it its uterotonic effects. The breakdown of collagen in the cervical stroma and an increase in the frequency of uterine contractions are the main causes of cervical dilatation. Additionally, characteristics of uterotonic aid in minimizing postpartum hemorrhage.

PHARMACOKINETICS

Absorption

Misoprostol reaches its maximal plasma concentration in about 12 ± 3 minutes after being administered orally since it is quickly absorbed. Inhibition of stomach acid secretion begins around 30 minutes after oral ingestion and continues for about three hours.

Distribution

Misoprostol acid, the active metabolite, has less than 90% plasma protein binding and is excreted in breast milk.

Metabolism

Through the process of de-esterification, the prodrug misoprostol is converted into the active ingredient misoprostol acid.

Elimination

Its main form of excretion is as inert metabolites in the urine.

ADMINISTRATION

Oral and buccal delivery methods are both authorized by the FDA for the use of misoprostol in conjunction with mifepristone. Additional administration options include sublingual, vaginal, or rectal administration.

NSAID-induced ulcers

To avoid or treat gastric ulcers caused by nonsteroidal anti-inflammatory drugs (NSAIDs), the suggested dose is 200 mcg, given four times a day with food to keep stomach disturbance to a minimum. For stomach ulcers, a daily dosage of 800 mcg is more helpful, but it also comes with greater side effects.

Medical abortion up to 70 days

Confirming pregnancy and determining gestational age are recommended by ACOG recommendations. The recommended dosage is 200 mg of mifepristone once a day, with 800 mcg of buccal misoprostol given either once every two or three days. It is recommended to hold the cheek pouches containing misoprostol for 30 minutes before taking it within 24 to 48 hours after taking mifepristone.

Misoprostol-only regimen (off-label)

According to ACOG, the recommended dosage of misoprostol is 800 mcg, which may be taken vaginally, sublingually, or buccally. The recommended intervals between doses are three hours. A dose of 800 mcg sublingually every three hours may terminate pregnancies up to thirteen weeks, according to FIGO recommendations. You may also take 800 mcg orally or by buccal or vaginal injection every three to twelve hours for a maximum of three doses; however, you should not inject it intravaginally if you are bleeding or have an infection.

Cervical ripening and induction of labor

ACOG recommends vaginal misoprostol for labor induction before 28 weeks gestation at a dose of 25 mcg. The administration frequency should not exceed every three to six hours, and sublingual or buccal routes should be avoided.

Early pregnancy loss

The ACOG recommends a dosage of 800 mcg of vaginal misoprostol if a nonviable intrauterine pregnancy occurs before 13 weeks of gestation. The effectiveness of the medication may be improved by administering 200 milligrams of mifepristone orally twenty-four hours before misoprostol.

Postpartum haemorrhage

Misoprostol is usually combined with oxytocin. However, if oxytocin is unavailable, misoprostol monotherapy can be used at a dose of 600 mcg to 1000 mcg as a single dose via oral, sublingual, or rectal routes.

ADVERSE EFFECTS

Mild side effects are the most often reported when using misoprostol. Fevers, chills, diarrhea, stomach pains, fever, queasy stomach, vomiting, flatulence, bloating, indigestion, migraines abnormal periods, and breakthrough bleeding are among the symptoms that might be experienced. Mild adverse effects such as vertigo, weakness, lethargy, and syncope are less prevalent.

Rare but serious side effects include low blood pressure, sinus tachycardia, fetal bradycardia, vaginal hemorrhage, swelling, uterine rupture, cervical lacerations, fetal mortality, teratogenesis, pulmonary edema, anaphylactoid consequences, and thrombosis.

The most common side effects are self-limiting diarrhea and stomach discomfort, which are mainly caused by the misoprostol acid that is generated during metabolism. Misoprostol acid's peak plasma concentration is inversely proportional to the intensity of these side effects.

Another prominent adverse effect of prostaglandin is its influence on the hypothalamus, which may cause fever and chills. Misoprostol is used to treat postpartum hemorrhage, and when given in relatively high dosages, these moderate side effects are common.

Adverse birth defects are more common in babies whose mothers' used misoprostol throughout their pregnancies. Having said that, there is zero proof that misoprostol causes harm to developing embryos or teratogenic consequences. Research on mutagenicity has shown poor results. The abnormalities that were seen are probably because the fetal blood supply was diminished during the contractions caused by the misoprostol. It seems that the time of exposure is also connected to the spectrum of abnormalities. The central nervous system and limbs are the most typical areas affected by these abnormalities.

Fetal hypoxemia, non-reassuring heart rates, and tachysystole are all risks that are raised when prostaglandins are used to ripen the cervical mucosa.

Drug-Drug Interactions

When magnesium-containing antacids are taken at the same time as misoprostol, the likelihood of experiencing diarrhea is increased.

CONTRAINDICATIONS

Using misoprostol during pregnancy has been associated with a higher risk of preterm delivery, congenital defects, and abortion.

If a woman has a history of cesarean sections or is otherwise at high risk, she should not take misoprostol for labor induction beyond eight weeks of pregnancy. Urine rupture after medical abortion in the first trimester is very uncommon, but it might cause infection in the uterus afterward.

When treating NSAID-induced ulcers in pregnant women, misoprostol should not be utilized. Misoprostol must be started no later than two weeks after a negative serum pregnancy test has been administered to individuals at high risk of problems. In addition, patients must use effective methods of birth control. Misoprostol and contraceptive failure are serious dangers that patients should be informed of both verbally and in writing by their healthcare professionals. Patients should wait until the second or third day of their subsequent regular menstrual cycle to begin taking misoprostol.

Warnings and Precautions

People who have an allergy or reactivity to prostaglandins should not use misoprostol. Because of the possibility of unfavorable effects during pregnancy, it should not be taken by pregnant women or those at risk for stomach ulcers caused by NSAIDs. Each patient's risk factors should be considered while developing a list of pharmacological contraindications. Medical abortion patients with a history of cesarean sections should not use misoprostol because of the elevated risk of uterine rupture.

MONITORING

Patients with cardiovascular disorders should exercise care while using misoprostol since it might induce coronary vasospasm, even though it is often safe and well-tolerated. Regular checkups, including a review of medical records, a physical exam, an hCG test, and an ultrasound, should be part of any medical abortion protocol. For individuals whose Rh status is uncertain, it is advised to undergo Rh testing before a medical abortion. If necessary, Rh D immunoglobulin may be delivered.

Although some data shows outpatient usage might be possible, fetal monitoring is still recommended for labor induction.

TOXICITY

Misoprostol is generally safe at doses between 400 to 800 mcg. On the other hand, serious side effects from overdosing have occurred in very rare instances. In one case, the mother passed away after suffering from upper gastrointestinal hemorrhage, hemodynamic dysfunction, and multiorgan malfunction as a result of an oral dosage of 12 mg, which was meant for medical abortion. Despite attempts to resuscitate the patient, emergency surgery showed stomach and esophageal destruction, and the patient finally died of cardiac arrest.

DOUBLE FOLEY CATHETER [46-50]

The Double Foley catheter is an advancement of the traditional Foley catheter, aimed at improving labor induction by enhancing cervical ripening. Originally invented by Dr. Frederic Foley in the 1930s for urinary catheterization, its application expanded to obstetrics for mechanical cervical ripening.

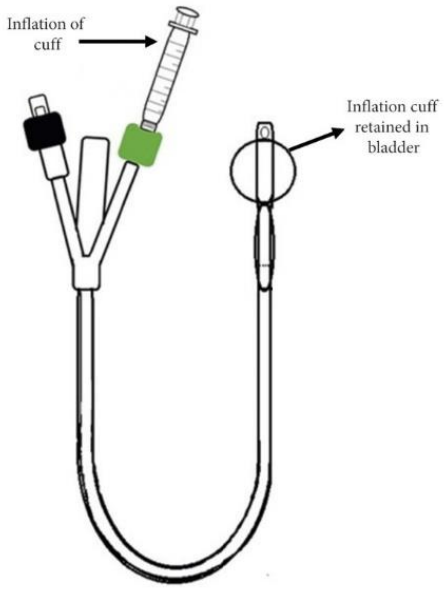

Figure 4: Double Foley catheter

The Double Foley catheter is a two-balloon procedure; one balloon is at the internal cervical OS while the other is at the cervicovaginal area. This design ensures better and even distributed mechanical pressure that facilitates cervical dilation as well as preparing for labor induction.

INDICATIONS

The usage of a Double Foley catheter is for cervical ripening and labor induction in several clinical situations.

Post-term Pregnancy

When pregnancy has gone beyond 42 weeks without the onset of labor on its own.

Premature Rupture of Membranes (PROM)

With premature rupture of the membranes in cases where the cervix is unfavourable, and there is no onset of labor.

Preeclampsia or Hypertension

To help in handling pregnancies with hypertension: when early delivery is required.

Diabetes Mellitus

When maternal or gestational diabetes requires early delivery, for some reason.

Fetal Growth Restriction

When the fetus is not developing properly there are complications if the pregnancy is carried out.

Maternal Medical Conditions

As in hypertension, chronic renal disease, or any other disease that may necessitate early delivery.

MECHANISM OF ACTION

The Double Foley catheter promotes cervical ripening and dilation through mechanical pressure. Its mechanism involves several key actions;

Mechanical Dilation

The catheter's balloons exert direct pressure on the cervix, aiding physical dilation. The first balloon, placed at the internal OS, helps open the cervix from within, while the second, at the cervicovaginal junction, applies external pressure.

Prostaglandin Release

Mechanical dilation stimulates the release of local prostaglandins, which aid in softening and effacing the cervix. These natural chemicals are crucial in preparing the cervix for labor.

Enhanced Blood Flow

The pressure applied by the catheter improves blood flow to the cervix, facilitating the biochemical processes necessary for cervical ripening.

The dual-balloon design allows for more consistent and controlled dilation compared to single-balloon catheters, potentially reducing induction time and improving outcomes.

CONTRAINDICATIONS

The Double Foley catheter is contraindicated in several situations;

Placenta Previa

Where the placenta covers the cervical OS, as using the catheter can cause severe bleeding.

Vasa Previa

The existence of fetal blood vessels near the cervical OS increases the risk of vessel rupture and fetal haemorrhage.

Active Genital Herpes

Risk of transmitting herpes to the newborn during delivery.

Severe Fetal Distress

Immediate delivery may be required, making induction inappropriate.

Significant Antepartum Haemorrhage

Unexplained vaginal bleeding could indicate underlying complications that contraindicate mechanical induction.

Unstable Maternal Conditions

Such as severe hypertension or heart disease, where induction poses additional risks.

Severe Cephalopelvic Disproportion

When mechanical induction is not expected to be successful because the foetal head is too big for the mother's pelvis.

ADVERSE EFFECTS

While generally considered safe, the Double Foley catheter can be associated with several adverse effects;

Discomfort and Pain

The insertion and presence of the catheter can cause noteworthy discomfort and pain for the patient.

Infection

Invasive procedures carry a risk of introducing infections into the uterus or cervix, potentially leading to chorioamnionitis or endometritis.

Bleeding

Mechanical pressure can sometimes cause cervical or vaginal bleeding. This is typically minor but can occasionally be noteworthy.

Uterine Hyperstimulation

Excessive uterine contractions can occur, leading to fetal distress. This is a particular concern if the catheter is used alongside other induction agents like prostaglandins or oxytocin.

Premature Rupture of Membranes

While sometimes intended as part of the induction process, premature rupture can increase the risk of infection and other complications if not carefully managed.

Uterine Perforation

Although rare, improper placement or excessive pressure can cause perforation of the uterine wall, leading to noteworthy maternal morbidity.

Fetal Complications

Increased uterine activity and hyperstimulation can result in fetal heart rate abnormalities, requiring close monitoring and potentially urgent intervention.

REVIEW OF PREVIOUS STUDIES

1. Santhosh et al[51] performed prospective randomized research on two hundred singleton pregnancies that were full-term at the Government Medical College and Rajindra Hospital Patiala between November 2014 and July 2016. Patients who had a Bishop score that was equal to or less than four were randomly allocated to one of two groups. In Group A, which consisted of one hundred women, an intracervical 16F Foley catheter and 25 micrograms of intravaginal misoprostol were administered. A single dose of 25 micrograms of misoprostol was administered intravaginally to all 100 women in Group B. Up to five doses of misoprostol were given at regular intervals of four hours. Eighty-six percent of the women in Group A and eighty-eight percent of the women in Group B gave birth vaginally. There was a statistically noteworthy difference between Group A (14.58±6.67 hours) and Group B (19.11±10.20 hours) in terms of the induction-delivery interval. Group A had a shorter time. A combination of misoprostol and Foley's catheter was shown to be safer and more successful for cervical maturing and labor induction than misoprostol alone, according to the findings of the research.

2. Lee HH et al[52] compared the efficacy of intravaginal misoprostol alone with that of an intracervical Foley catheter as part of a randomized controlled trial (RCT) that was searched for in the databases Embase, Pubmed, and the Cochrane Collaboration up to January 29, 2019. Two independent reviewers extracted and analysed data on study characteristics, induction time, caesarean section rates, chorioamnionitis, uterine tachysystole, meconium staining, and NICU admissions. Pooled analysis from eight studies (1,110 women) showed that combining the Foley catheter with misoprostol reduced induction time by 2.71 hours and decreased risks of uterine tachysystole and meconium staining. However, there were no differences in caesarean section rates or chorioamnionitis between the groups. This combination appears advantageous for shortening induction time and reducing certain risks.

3. Aregeb ZA et al[53] conducted a study on 72 pregnant women at the Maternity Hospital, Faculty of Medicine, "Zagazig University Hospitals", to evaluate labor induction methods. For 36 women in Group A, the only intervention was intravaginal misoprostol; for the same number of patients in Group B, the combination of intravaginal misoprostol and an intracervical Foley catheter was administered. A complete medical history and physical examination were given to every individual. Parity, gestational age, and birth weight were not significantly different across groups when primary and secondary outcomes were evaluated. Group B differed significantly from Group A in terms of complications, dystocia, tachysystole, vomiting, and the number of misoprostol doses needed for induction and delivery. The research found that the induction to delivery time was shortened when the Foley catheter was used in conjunction with misoprostol.

4. Swidan KH et al[54] undertook research with 120 patients at the "Ain Shams University Maternity Hospital" from May to October 2017. Fifty patients were divided into two groups: one that got vaginal misoprostol and another that received it via a trans-cervical Foley catheter. The rate of natural vaginal birth increased to 88.3% from 78.3% and the rate of caesarean section decreased to 11.7% from 21.7% as a consequence of the combination technique. Plus, whereas only 59.5% of women in the misoprostol-alone group gave birth within 12 hours, 81.6% of those in the combination group did. In the combined group, tachysystole was more prevalent (28.3% vs. 13.3%), and non-reassuring heart rates in the fetus were more common (8.3% vs. 1.7%). Nevertheless, the combined group had a lower incidence of dystocia (3.3% vs. 15%). Researchers found that although the combination technique did reduce the time it took from induction to delivery, misoprostol by itself was safer for the woman and the baby.

5. A randomized comparative study by Toshniwal SM et al[55] included 110 women who were expected to give birth vaginally, had a singleton gestation, were more than 39 weeks along in their pregnancies, had a Bishop's score below 6, and were not in any way unable to do so. Group A patients were given 25 μg of misoprostol and Group B patients were given 25 μg of misoprostol in addition to Foley's catheter No. 16. The purpose of the examinations was to record the Bishop's score and pelvic adequacy. Group B had a substantially shorter induction-to-delivery period (14.6 ± 2.26 hours) than Group A (17.9 ± 2.82 hours) ($p = 0.05$). There was no difference in the incidences of aberrant HR, meconium-stained liquor, neonatal outcomes, or problems during or after delivery between the groups. When used together, Foley's catheter and vaginal misoprostol shorten the time it takes to induce labor and enhance the Bishop score. Both methods were equally effective regarding delivery mode, caesarean indications, complications, and neonatal outcomes.

6. Rafiq M et al.,[56] carried out a controlled experiment with 96 female subjects from 2020 to 2021. They were randomly assigned to one of two groups: one group got sublingual misoprostol in addition to a cervical Foley catheter, while the other group received sublingual misoprostol alone (0). Both groups had 48 patients each. The average age was 25.80 years, and gestation was 39.51 weeks. Group 1 had a higher rate of normal vaginal delivery (35.4% vs. 26%) and a shorter induction-to-delivery time (13.93 vs. 17.89 hours). The study concluded that combining misoprostol with a Foley catheter led to more vaginal deliveries and shorter delivery times.

7. Elpo JA et al[57] conducted a non-blinded, block randomized controlled trial in southern Brazil, evaluating labor induction methods in 230 normal-risk pregnant women. One hundred and seventy-seven patients were assigned to the combination group that got both a transcervical Foley catheter and 25 μg of vaginal misoprostol, whereas one hundred and thirty-three patients were assigned to the misoprostol group that received just 25 μg of the drug. Shorter labor induction times ($p=0.008$) and fewer doses of misoprostol needed for cervical softening ($p<0.001$) were seen in the combined group. Members of the combined group were also less likely to need more misoprostol pills. The rates of induction failure, caesarean sections, and perinatal outcomes were not significantly different.

8. Kadu NA et al[58] performed a controlled experiment with 148 women randomly assigned to two groups: Group A had 25 µg of vaginal misoprostol in addition to intracervical Foley catheter insertion, whereas Group B got 25 µg of misoprostol administered intravaginally solely. The study compared induction to delivery time, caesarean rates, chorioamnionitis, puerperal infection, uterine tachysystole, neonatal outcomes, and NICU admissions. Group B had noteworthily higher rates of puerperal infection (48.6% vs. 27.0%, p=0.0066), meconium-stained amniotic fluid (60.8% vs. 33.8%, p=0.0009), and NICU admissions (63.5% vs. 40.5%, p=0.0051). Researchers found that compared to using misoprostol alone, inducing labor using a Foley catheter and misoprostol was more successful.

9. Kadar N et al[59] conducted a quasi-experimental study with 100 patients, divided into two groups. The first group, A, had foley's catheter induction with misoprostol, whereas the second, B, got misoprostol alone. Hyperstimulation, tachysystole, caesarean rates, neonatal outcomes, labor outcomes, induction to active phase duration, and induction to delivery time were all documented in the research. The beginning BISHOP scores, gestational age, parity, and mother age were all similar in the two groups. Group A had a significantly shorter time to active phase (7.4 vs. 9.3 hours) and induction to delivery (11 vs. 13.7 hours). Vaginal delivery rates were higher, and caesarean rates were lower, in Group A. There were no maternal or neonatal complications in either group.

10. Yin J et al[60] to determine the effectiveness of intracervical Foley catheter paired with intravaginal misoprostol against intravaginal misoprostol alone for cervical ripening, a systematic review was successfully carried out. The researchers conducted a comprehensive search of several databases, such as Medline, EMBASE, ClinicalTrials.gov, PROSPERO, Scopus, and the Cochrane Collaboration, to identify randomized controlled trials that included patients who were undergoing labor induction and had an unfavourable cervix (Bishop ≤6). Thirteen studies, with a total of 2,978 individuals, conformed to the conditions. Both groups had a comparable rate of caesarean delivery (relative risk = 0.90, 95% confidence interval = 0.72–1.14). In the combination group, the time to vaginal birth was shorter (mean minus 3.49 hours), the number of admissions to the neonatal intensive care unit (NICU) was lower (relative risk = 0.72), the amount of meconium-stained fluid was decreased (relative risk = 0.48), and there were fewer instances of tachysystole with fetal cardiac abnormalities (relative risk = 0.49). No noteworthy differences were found in terbutaline use, endometritis, or chorioamnionitis rates.

METHODOLOGY

METHODOLOGY

Study Area

Department of Obstetrics and Gynaecology, Sri Devaraj Urs Medical College, Tamaka, Kolar.

Study Population

All primigravida with gestational age of completed 37 weeks to 42 weeks, who admitted at RLJH hospital, in the department of obstetrics and gynaecology, SDUAHER, Kolar, during the proposed study period.

Study Design

Prospective comparative study

Sample Size

The sample size was estimated based on the difference in the proportion of vaginal delivery between the Foley catheter group and the Misoprostol group. The proportion of vaginal delivery in the Foley catheter group was 60.8% and, in the Misoprostol, groups was 81.6% from the study by Mini Mohan et al[61]. Using these values in the below-mentioned formula;

$$N = \frac{2 (Z_{\alpha/2} + Z_{\beta})^2 P (1-P)}{(p_1 - p_2)^2}$$

Where,

$Z_{\alpha/2=} Z_{0.05/2}=Z_{0.025} = 1.96$ at type 1 error of 5%

$Z_{\beta}=Z_{0.20}= 1.28$= At 80% power

$p_1 - p_2$= Difference in proportion in the two differentc groups = 20.8%

$\bar{p}$= Pooled prevalence = [Proportion in Foley catheter group (p_1) + Proportion in Direct Misoprostol groups (p_2)]/2 = [60.8 + 81.6]/2 = 71.2.

$$N = \frac{2 \times 71.2 \times 28.8 (1.96 + 0.84)^2}{20.8 \times 20.8} = 75 \text{ in each group}$$

Considering Non response rate of 10%, 75 + 7.5 = 82.5 ≈ **83 minimum subjects** will be included in each group.

Sampling Method

Simple random sampling

Study Duration

July 2022 to December 2023 for 18 months

Inclusion Criteria

Primigravida aged between 19 and 35 years, with gestational age 37 to 42 weeks

Singleton pregnancy

Cephalic presentation of fetus

with intact membranes

Bishop score less than 6

Reactive to non-stress test

Exclusion Criteria

Multigravida women

Pregnant women with intrauterine fetal death

Pregnant women with previous LSCS

Pregnant women with malpresentation of fetus

Refusal of consent

Hypersensitivity to prostaglandins

Methodology

After obtaining informed permission and providing an explanation of the research methodology, a total of 166 women who were experiencing their first pregnancy were enrolled in the study. Of these, 83 were in the combination group, while the other 83 were in the misoprostol group. Detailed histories were collected regarding age, parity, gestation period, menstrual and obstetric history, past medical history, and any complications in the current pregnancy. The reasons for labor induction were documented.

A thorough clinical and obstetric examination was conducted. Abdominal exams assessed presentation, fetal heart rate, and uterine contractions, while pervaginal exams evaluated pelvic adequacy and the modified Bishop score. Fetal well-being was confirmed through obstetric scans and NST.

Participants with a reactive NST and a modified Bishop score ≤6 were alternately assigned to either the combined group or the misoprostol group.

Combined Group (83 patients): Double Foley's Catheter and Misoprostol Group

Two Foley catheters (FCs) that were attached were introduced into the cervix with the assistance of long forceps and then progressed to the internal OS for this particular group. The first Foley balloon was filled with 80 milliliters of saline and then inflated. The second Foley catheter was positioned in the cervicovaginal region, and once the balloon was visualized, it was gently tugged until it was visible. once that, 20 milliliters of saline was used to balloon the balloon. The cervico-vaginal balloon was filled to a total of 80 ml of saline after the vaginal speculum was removed during the procedure. A modest amount of stress was applied to the catheters in order to adhere them to the inner thigh. Twenty-five micrograms of misoprostol were given intravaginally every six hours, with a maximum of four doses being provided at the same time. Continuous NST monitoring was performed following device insertion. If the balloon device did not spontaneously expel within 12 hours, it was deflated and removed. The Bishop score was reassessed before and after the balloon's expulsion or withdrawal.

Misoprostol Group (83 patients)

Participants were given 25 micrograms of misoprostol every 6 hours until a Bishop score of ≥6 was achieved, or up to a maximum of 100 micrograms (four doses).

Progression Analysis

The cervix was assessed every 6 hours to determine the Bishop score, and labor progress was monitored with a partogram during the active stage. Continuous CTG monitored fetal heart rate, and oxytocin infusion was administered if needed for labor augmentation.

Outcome Measures

The rate of vaginal delivery, the time between induction and active phase, the delay between induction and delivery, the extent to which oxytocin augmentation was required, and the method of delivery were the primary end measures.

The APGAR scores at 1 and 5 minutes, admissions to the neonatal intensive care unit (NICU), the causes for admission to the NICU, and maternal problems such as hyperstimulation, tachysystole (more than six contractions in ten minutes), uterine hypertonus (contraction lasting more than sixty seconds), and anomalies in the fetal heart rate were the secondary outcome criteria.

Failed induction was defined as an unfavorable modified Bishop score or lack of adequate uterine contractions after four doses of misoprostol in both groups. In such cases, further intervention with oxytocin augmentation or a decision for cesarean section was made. Non-progression of labor included prolonged latent phase and protracted active phase dilation and descent.

Statistical analysis

The data was obtained by entering it into a data sheet created in Microsoft Excel and then analyzing it using the SPSS 26 edition program.

Frequencies and proportions were used to depict the categorical data that was collected. The Chi-square test was used as a statistical method for determining the importance of qualitative data. For qualitative data that does not meet the requirements for the Chi-square test (only for two-by-two tables), Fischer's exact test was used as a determination of significance. In cases where the chi-

square criteria were not satisfied, Yates adjustment was done (this occurred only for tables with dimensions of 2 by 2).

To determine whether or not the continuous data were normal, the Kolmogorov–Smirnov test and the Shapiro–Wilk test were used. Mean and standard deviation were the two measures that were used to describe continuous data. The significance of the difference between the two quantitative variables was determined by using the independent t-test as the test of significance. To determine the median variation between two quantitative parameters that had a skewed distribution, the Mann-Whitney U test was used as a test of relevance.

Graphical representation of data

Several kinds of graphs, including bar charts, line graphs, pie diagrams, and scatter plots, were generated using Microsoft Excel and Word. A p-value (the likelihood that this finding is true) below 0.05 was deemed statistically noteworthy after the assumption of all statistical test procedures.

Statistical software

MS Excel and SPSS version 26 **(**IBM SPSS Statistics, Somers NY, USA) were used to analyze data.

RESULTS

RESULTS

Table 1: Comparison of maternal age between study groups

Subjects (N=166)	Groups				p-value#
	Combined (N=83)		Misoprostol (N=83)		
	N	%	N	%	
19 - 20 years	15	18.1%	17	20.5%	0.634
21 to 25 years	27	32.5%	32	38.6%	
26 to 30 years	27	32.5%	25	30.1%	
>30 years	14	16.9%	9	10.8%	

Chi-square test

Table 2: Comparison of mean ages of the mothers between study groups

Subjects (N=166)	Groups				p-value#
	Combined (N=83)		Misoprostol (N=83)		
	Mean	SD	Mean	SD	
Age (in years)	25.78	4.47	24.91	4.60	0.218

Independent t-test

In the study, the mean age of the mothers was 25.78 ± 4.47 years in the Combined group and 24.91 ± 4.60 years in the Misoprostol group. Most participants were aged between 21 and 25 years in both groups, followed by those aged 26 to 30 years, and those under 20 years. The least common age group was mothers above 30 years. Statistical analysis revealed no noteworthy variance between the two groups concerning age distribution, indicating that maternal age was comparable across both induction methods.

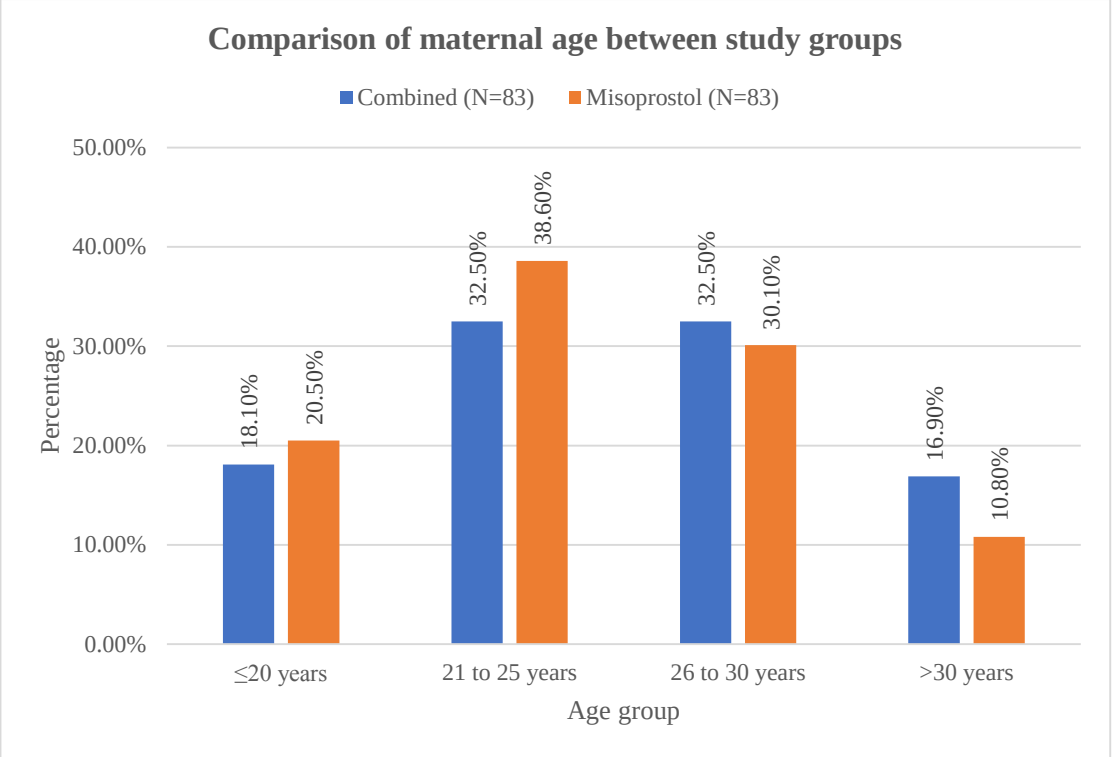

Figure 5: Comparison of maternal age between study groups

Table 3: Comparison of booking status between study groups

Subjects (N=166)	Groups				p-value#
	Combined (N=83)		Misoprostol (N=83)		
	N	%	N	%	
)OKED	80	96.4%	83	100.0%	0.080
NOT BOOKED	3	3.6%	0	0.0%	

Chi-square test

Most mothers in the study had regular antenatal checkups, with 96.4% in the Combined group and 100% in the Misoprostol group. There was no noteworthy variance in pregnancy registration rates between the groups, ensuring consistent antenatal care. This consistency means the outcomes of the two induction methods can be compared fairly, without being affected by differences in prenatal care.

Figure 6: Comparison of pregnancy registration between study groups

Table 4: Comparison of gestational age of mothers between study groups

Subjects (N=166)	Groups				p-value#
	Combined (N=83)		Misoprostol (N=83)		
	N	%	N	%	
37-38 weeks + 6 days	46	55.4%	33	39.8%	0.129
39-40 weeks + 6 days	33	39.8%	45	54.2%	
41-42 weeks	4	4.8%	5	6.0%	

Chi-square test

Table 5: Comparison of mean gestational ages between study groups

Subjects (N=166)	Groups				p-value#
	Combined (N=83)		Misoprostol (N=83)		
	Mean	SD	Mean	SD	
GA (in weeks)	39.30	1.20	39.46	1.16	0.383

Independent t-test

In the study, the mean gestational age of the mothers was 39.30 ± 1.20 weeks in the Combined group and 39.46 ± 1.16 weeks in the Misoprostol group. The majority of mothers in the Combined group had a gestational age of 37 to 38 weeks + 6 days, classified as early term (55.4%). In contrast, most mothers in the Misoprostol group had a gestational age of 39 to 40 weeks + 6 days, considered full term (54.2%). Despite these variations in gestational age distribution, a comparative analysis revealed no statistically noteworthy variance between the groups. This indicates that the timing of gestation at induction was similar across both groups, allowing for a fair comparison of the induction methods.

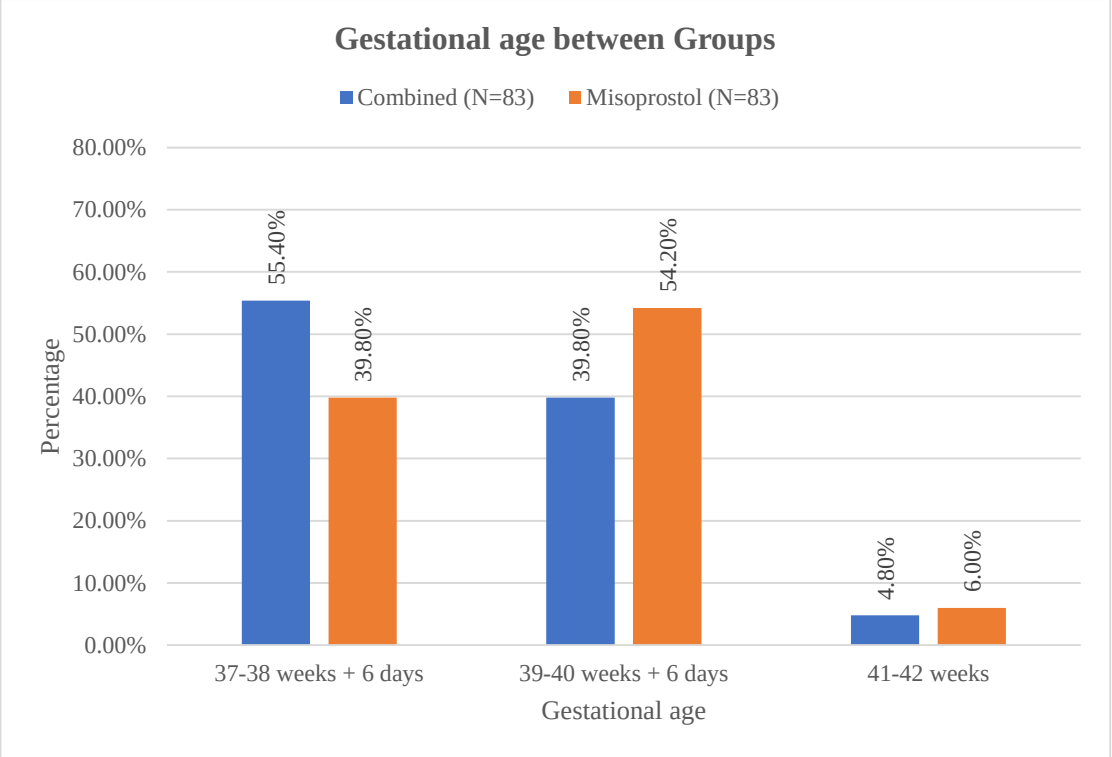

Figure 7: Comparison of gestational age of mothers between study groups

Table 6: Comparison of indications for induction between study groups

Subjects (N=166)	Groups				p-value[#]
	Combined (N=83)		Misoprostol (N=83)		
	N	%	N	%	
reeclampsia & Eclampsia	27	32.5%	19	22.9%	0.093
Oligohydramnios	17	20.5%	29	34.9%	
Prolonged pregnancy	39	47.0%	35	42.2%	

Chi-square test

In the combined group, a lengthy pregnancy was the leading cause for labor induction, accounting for 47.0% of cases, followed by preeclampsia & eclampsia at 32.5%, and oligohydramnios at 20.5%. In the Misoprostol group, the commonest indication was prolonged pregnancy at 42.2%, with oligohydramnios at 34.9%, and preeclampsia & eclampsia at 22.9%. Comparative analysis revealed no statistically noteworthy variances between the groups regarding the indications for induction.

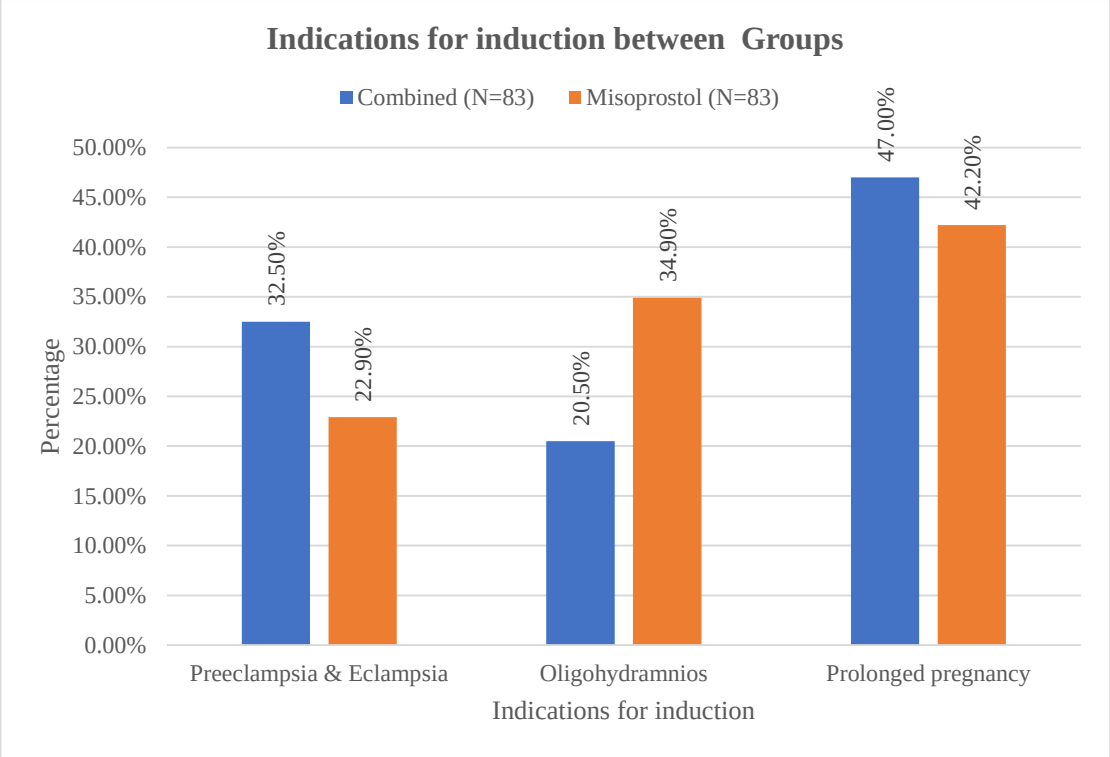

Figure 8: Comparison of indications for induction between study groups

Table 7: Comparison of preinduction modified Bishop score between study groups

Subjects (N=166)	Groups				p-value#
	Combined (N=83)		Misoprostol (N=83)		
	N	%	N	%	
1	9	10.8%	7	8.4%	0.799
2	20	24.1%	25	30.1%	
3	19	22.9%	22	26.5%	
4	18	21.7%	14	16.9%	
5	17	20.5%	15	18.1%	

Chi-square test

The distribution of Bishop scores shows that the scores were alike between the two groups, with no noteworthy variance. Specifically, 24.1% of the combined group had a score of 2 compared to 30.1% in the Misoprostol group. Scores of 3 and 4 were also comparable between the groups, indicating that the efficacy of cervical ripening was similar regardless of the treatment approach used.

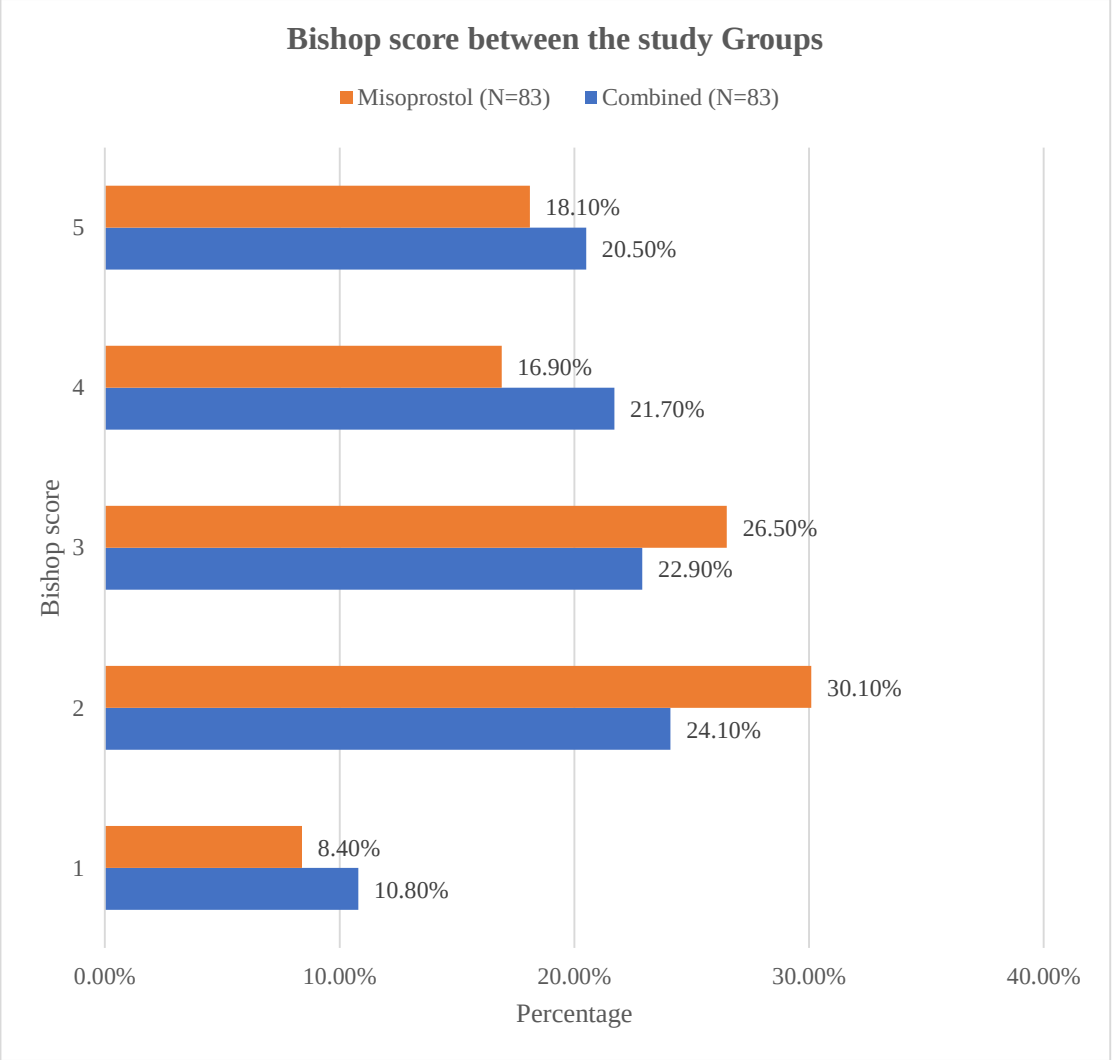

Figure 9: Comparison of Bishop score during active phase between study groups

Table 8: Comparison of need for augmentation of labor with oxytocin between study groups

Subjects (N=166) Augmentation with oxytocin)	Groups				p-value#
	Combined (N=83)		Misoprostol (N=83)		
	N	%	N	%	
Yes	74	89.2%	70	84.3%	0.360
No	9	10.8%	13	15.7%	

Chi-square test

The study showed that most participants in both groups needed oxytocin to augment labor, with 89.2% in the Combined group and 84.3% in the Misoprostol group. This high rate indicates a common need for additional labor support with oxytocin in both methods. The necessity for oxytocin was similarly distributed across both groups, regardless of the induction method.

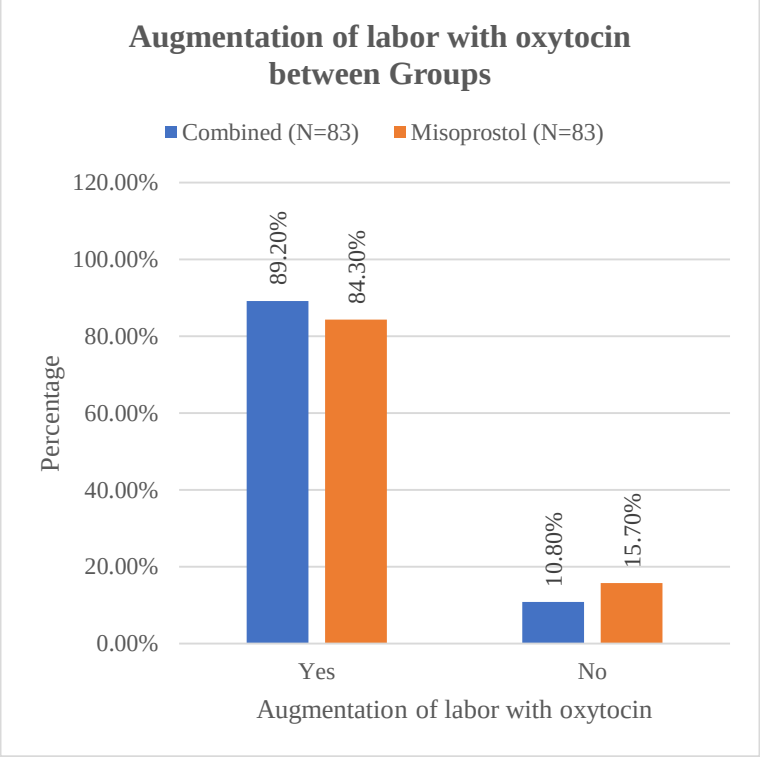

Figure 10: Comparison of need for augmentation of labor with oxytocin between study groups

Table 9: Comparison of number of misoprostol doses used between study groups

Subjects (N=166) Misoprostol doses	Groups				p-value#
	Combined (N=83)		Misoprostol (N=83)		
	N	%	N	%	
1	42	50.6%	16	19.3%	<0.001*
2	31	37.3%	39	59.0%	
3	10	12.1%	28	21.7%	
4	0	0%	0	0%	

Chi-square test
* Statistically significant

The data reveals a statistically noteworthy variance between the groups. In the Combined group, 50.6% of subjects required only one dose, compared to 19.3% in the Misoprostol group. Conversely, 59.0% of the Misoprostol group required two doses, compared to 37.3% in the Combined group. These findings point to the Combined therapy as the superior method for decreasing misoprostol dosages.

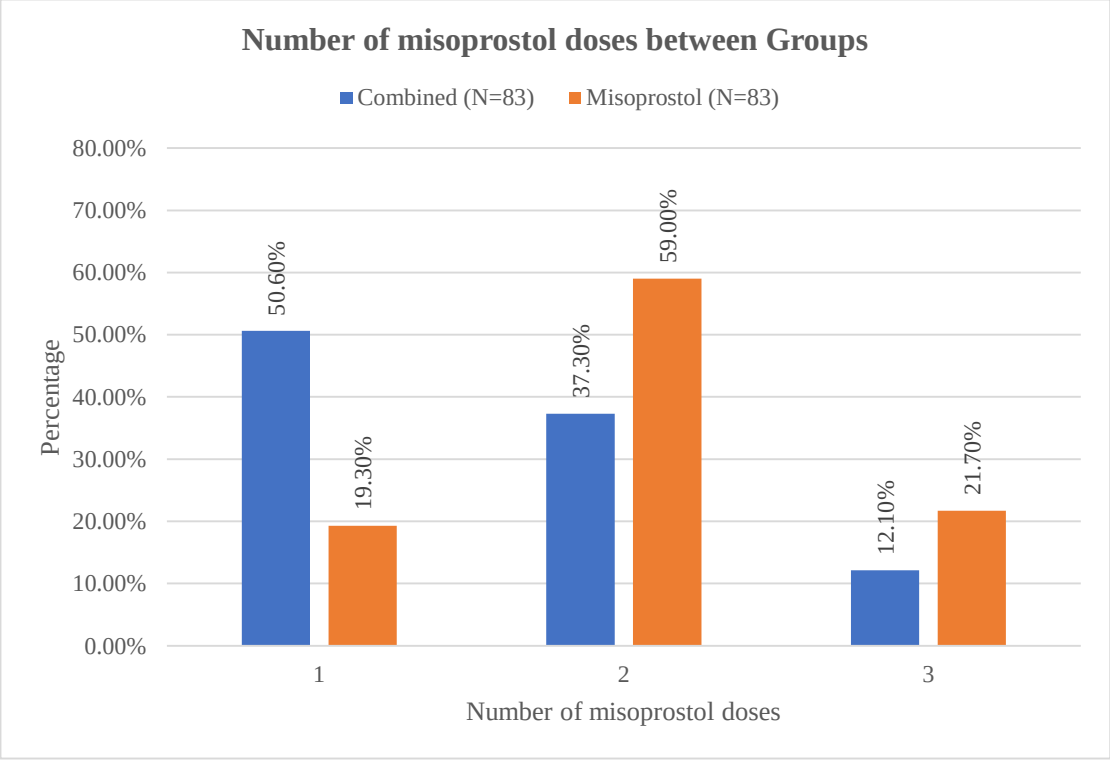

Figure 11: Comparison of number of misoprostol doses used between study groups

Table 10: Comparison of duration from induction to active phase between study groups

Subjects (N=166) luction to active phase	Groups				p-value#
	Combined (N=83)		Misoprostol (N=83)		
	N	%	N	%	
<6 hours	39	47.0%	0	0.0%	<0.001*
6-12 hours	43	51.8%	3	3.6%	
12-24 hours	1	1.2%	80	96.4%	

Chi-square test
* Statistically significant

Table 11: Comparison of mean duration from induction to active phase between study groups

Subjects (N=166) duction to active phase	Groups				p-value#
	Combined (N=83)		Misoprostol (N=83)		
	Mean	SD	Mean	SD	
Duration (in hours)	7.24	2.93	16.28	2.46	<0.001*

Independent t-test
* Statistically significant

A statistically noteworthy variance was observed in the groups. In the Combined group, 47.0% of subjects reached the active phase in less than 6 hours, while none in the Misoprostol group did. Additionally, 51.8% of the Combined group transitioned to the active phase within 6-12 hours, compared to only 3.6% in the Misoprostol group. Conversely, 96.4% of the Misoprostol group required 12-24 hours to reach the active phase, whereas only 1.2% in the Combined group needed this duration. The mean duration for the Combined group was significantly shorter, at 7.24 ± 2.93 hours, compared to 16.28 ± 2.46 hours for the Misoprostol group. These results indicate that the Combined method is more effective in reducing the time needed to reach the active phase of labor, thus potentially improving labor outcomes and efficiency. The significantly shorter induction-to-active phase duration in the combined group highlights the benefit of using a Combined approach over Misoprostol alone for labor induction.

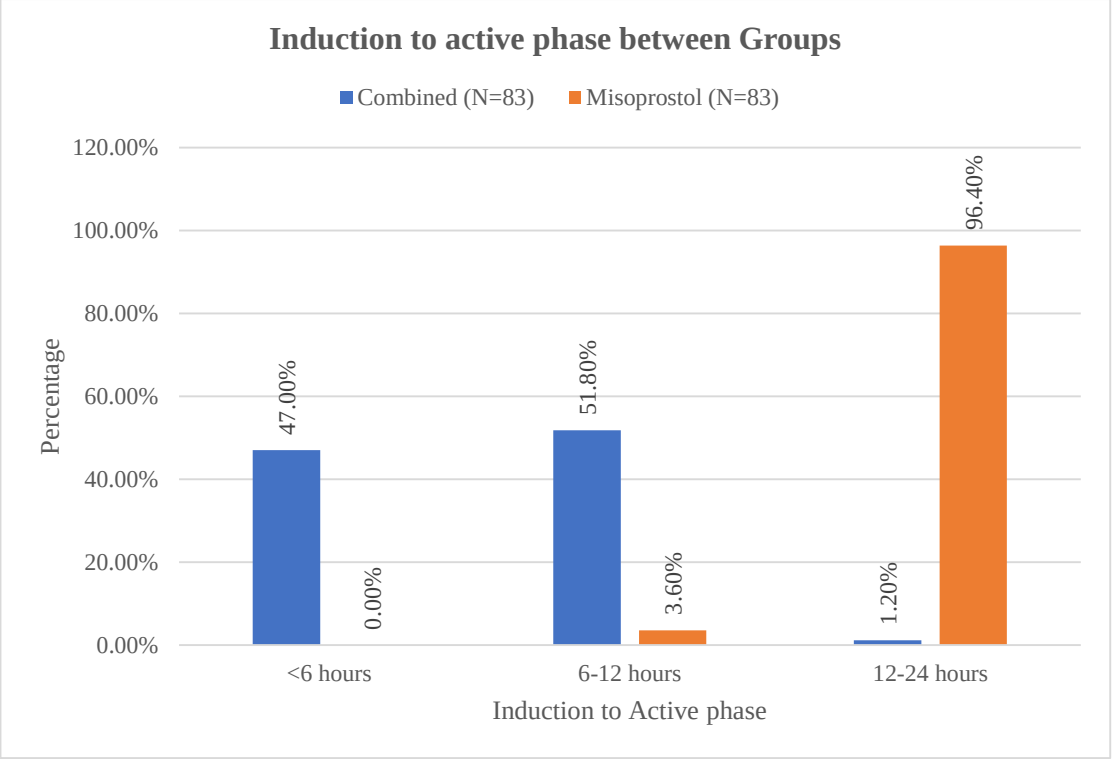

Figure 12: Comparison of duration from induction to active phase between study groups

Table 12: Comparison of duration from induction to delivery interval between study groups

Subjects (N=166) nduction to delivery interval	Groups				p-value#
	Combined (N=83)		Misoprostol (N=83)		
	N	%	N	%	
<12 hours	33	39.8%	10	12.0%	<0.001*
13-24 hours	50	60.2%	41	49.4%	
25-36 hours	0	0.0%	32	38.6%	

Chi-square test
* Statistically significant

Table 13: **Comparison of mean duration from induction to delivery interval between study groups**

Subjects (N=166) nduction to delivery interval	Groups				p-value#
	Combined (N=83)		Misoprostol (N=83)		
	Mean	SD	Mean	SD	
Duration (in hours)	13.13	3.01	18.14	7.33	<0.001*

Independent t-test
* Statistically significant

A statistically noteworthy variance was observed. In the Combined group, 39.8% of subjects delivered within 12 hours of induction, compared to only 12.0% in the Misoprostol group. Additionally, 60.2% of the Combined group delivered within 13-24 hours, whereas 49.4% in the Misoprostol group did. No one of the subjects in the Combined group took 25-36 hours to deliver, while 38.6% of the Misoprostol group did. The mean duration for the Combined group was significantly shorter, at 13.13 ± 3.01 hours, compared to 18.14 ± 7.33 hours for the Misoprostol group. These results demonstrate that the Combined treatment is more operative in reducing the total time from induction to delivery, potentially leading to better maternal and neonatal outcomes. The meaningfully shorter induction-to-delivery duration in the Combined group underscores the benefit of using a Combined approach over Misoprostol alone for labor induction, making it a more efficient option for facilitating timely deliveries.

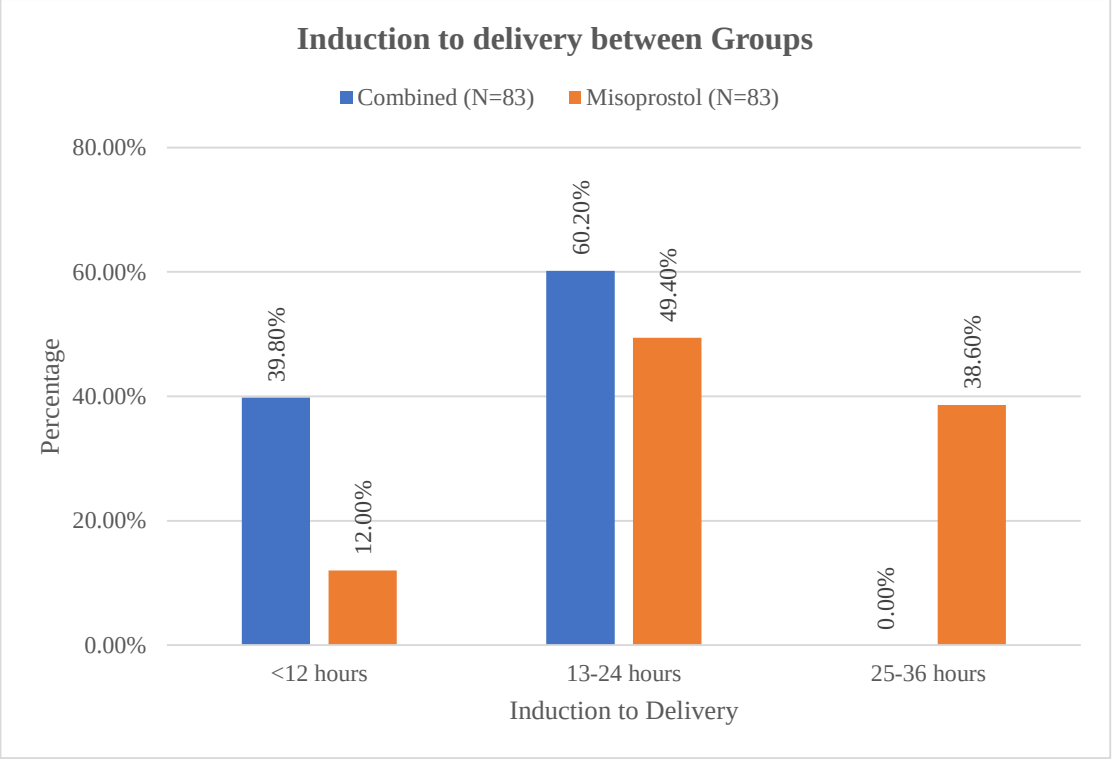

Figure 13: Comparison of duration from induction to delivery between study groups

Table 14: Comparison of mode of delivery between study groups

Subjects (N=166)	Groups				p-value#
	Combined (N=83)		Misoprostol (N=83)		
	N	%	N	%	
Vaginal delivery	49	59.0%	32	38.6%	0.025*
ssisted vaginal delivery	10	12.1%	12	14.5%	
Caesarean section	24	28.9%	39	46.9%	

Chi-square test
* Statistically significant

There is a statistically noteworthy variance in the mode of delivery between the groups. Compared to the Misoprostol group, which had a 39.6% rate of vaginal birth, the Combined group had a 59.0% rate of vaginal delivery. The percentages of women who were assisted in giving birth were comparable between the two groups (12.1% and 14.5%, respectively). When compared to the combined group, the Misoprostol group had a considerably greater rate of caesarean sections (46.9%) than the combined group had (28.9%). These results suggest that the Combined treatment may reduce the need for caesarean sections.

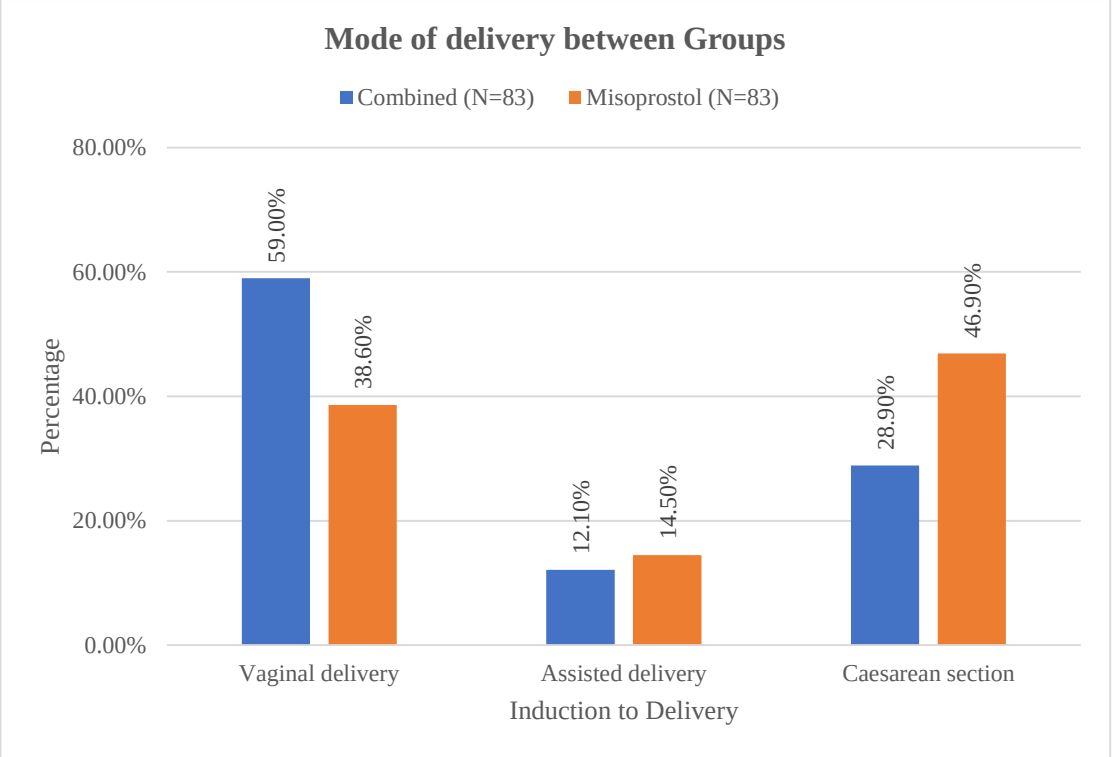

Figure 14: Comparison of mode of delivery between study groups

Table 15: Comparison of indications for caesarean section between study groups

Subjects (N=63)	Groups				p-value#
	Combined (N=24)		Misoprostol (N=39)		
	N	%	N	%	
Fetal distress	11	45.8%	15	38.5%	0.807
Failed induction	5	20.8%	8	20.5%	
ɔn-progression of labour	8	33.4%	16	41.0%	

Chi-square test

The highest frequency of occurrence in both groups was fetal distress, accounting for 45.8% in the Combined group and 38.5% in the Misoprostol group. Failed induction was similar between the groups, with 20.8% in the Combined group and 20.5% in the Misoprostol group. Non-progression was slightly higher in the Misoprostol group (41.0%) compared to the Combined group (33.4%). There was no statistically noteworthy variance between the groups for any of these indications.

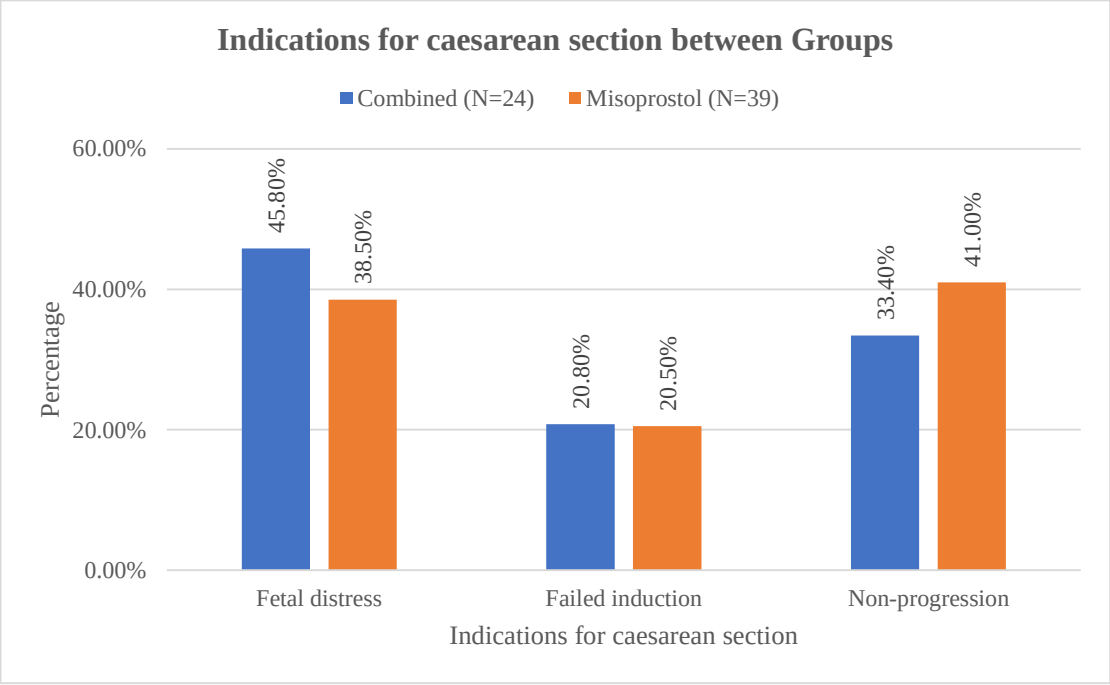

Figure 15: Comparison of indications for caesarean section between study groups

Table 16: Comparison of APGAR score at 1 and 5 minutes between study groups

Subjects (N=166) APGAR SCORE		Groups				p-value#
		Combined (N=83)		Misoprostol (N=83)		
		N	%	N	%	
At 1 minute	<7	28	33.7%	33	39.8%	0.420
	≥7	55	66.3%	50	60.2%	
At 5 minutes	<9	33	39.8%	29	10.8%	0.521
	≥9	50	60.2%	54	89.2%	

Chi-square test

At 1 minute, 33.7% of neonates in the Combined group had an APGAR score <7, compared to 39.8% in the Misoprostol group. At 5 minutes, 39.8% of neonates in the Combined group had an APGAR score <9, compared to 34.9% in the Misoprostol group. There was no statistically noteworthy distinction between the groups according to either the APGAR score at one minute or the APGAR score at five minutes, which indicates that the neonatal outcomes of the two groups were comparable.

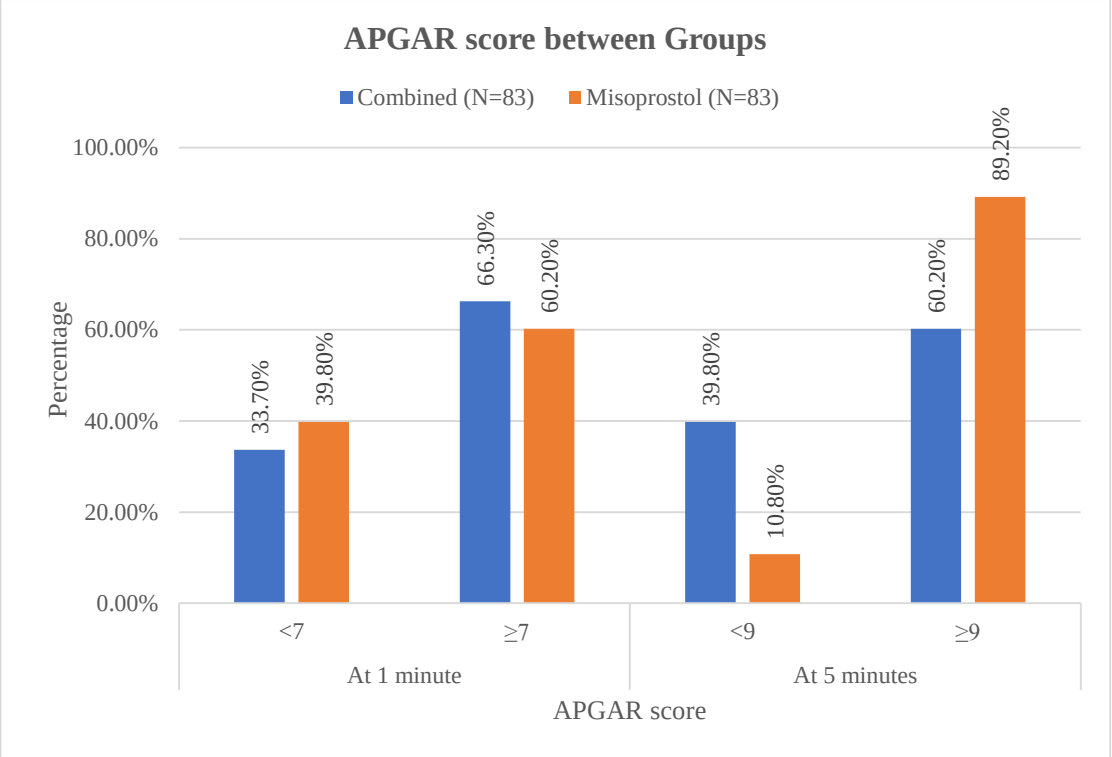

Figure 16: Comparison of APGAR score at 1 and 5 minutes between study groups

Table 17: Comparison of NICU admission rates between study groups

Subjects (N=166) NICU	Groups				p-value#
	Combined (N=83)		Misoprostol (N=83)		
	N	%	N	%	
Yes	13	15.7%	17	20.5%	0.420
No	70	84.3%	66	79.5%	

Chi-square test

The study analysed NICU admission rates, which were 15.7% in the Combined group and 20.5% in the Misoprostol group. Statistical analysis indicated no noteworthy variance between the groups concerning NICU admission rates. These findings suggest that both induction methods had similar rates of neonates requiring NICU admission, emphasizing the importance of monitoring neonatal health regardless of the induction method used, and ensuring appropriate care for neonates requiring intensive care.

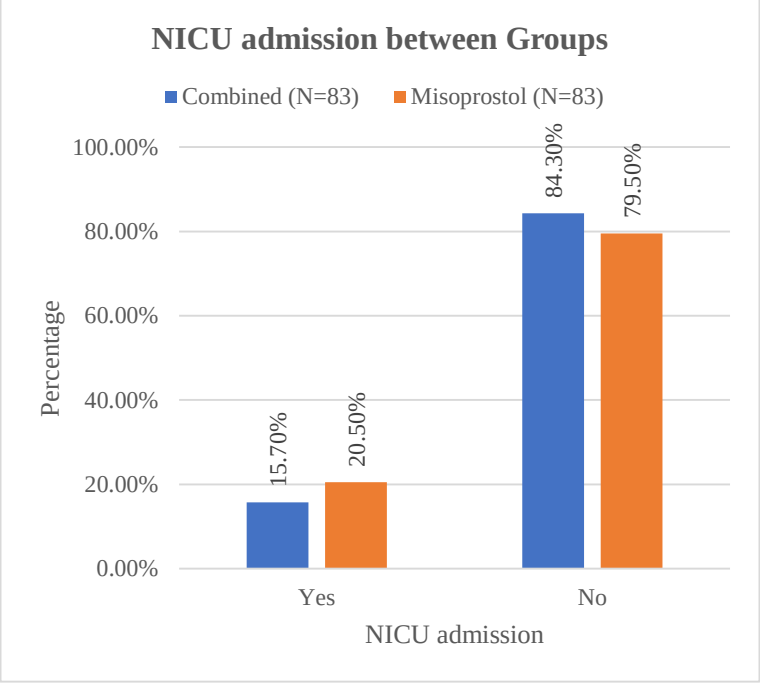

Figure 17: Comparison of NICU admission rates between study groups

Table 18: Comparison of maternal adverse effects between the groups

Subjects (N=166)	Groups				p-value#
	Combined (N=83)		Misoprostol (N=83)		
	N	%	N	%	
None	77	92.8%	75	90.4%	0.423
PPH	6	7.2%	8	9.6%	

Chi-square test

The majority of subjects in both groups experienced no complications, with 92.8% in the combined group and 90.4% in the Misoprostol group. Postpartum hemorrhage (PPH) occurred in 7.2% of the Combined group and 9.6% of the Misoprostol group. There was no statistically noteworthy variance in complications, indicating that both treatments have similar safety profiles.

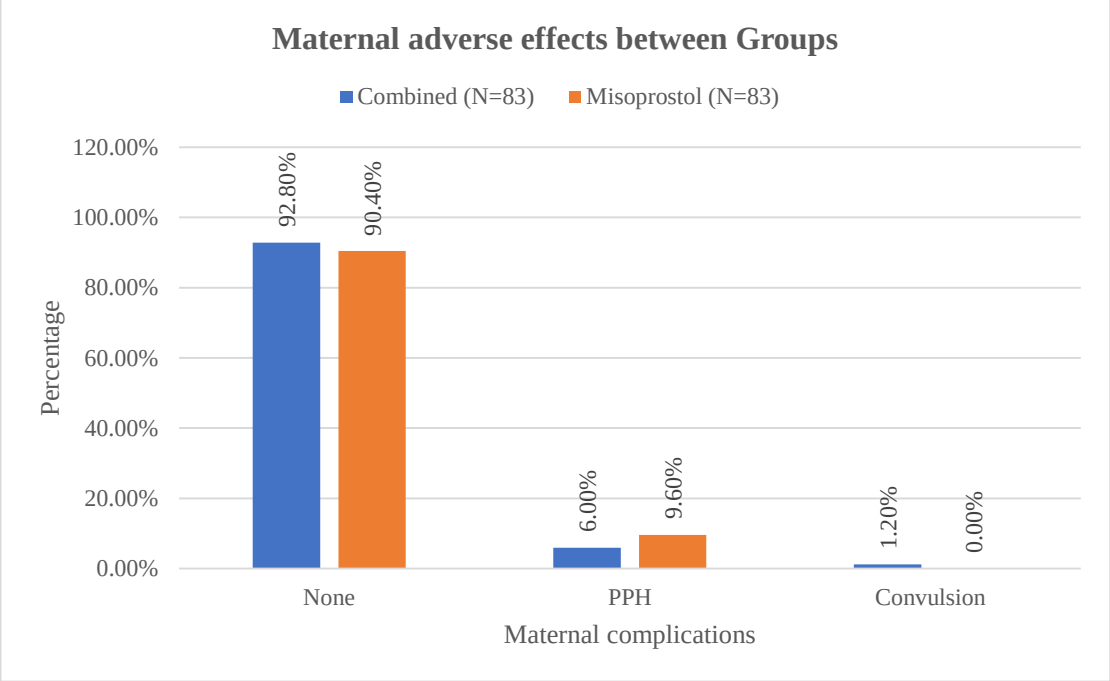

Figure 18: Comparison of maternal complications between study groups

DISCUSSION

DISCUSSION

The present study included 166 primigravida women with gestational ages between 37 and 42 weeks at RLJH hospital, who met the eligibility criteria and provided informed consent. Comprehensive demographic, obstetric, and medical histories were recorded upon admission. Gestational age was confirmed clinically, and routine investigations were conducted. Indications for labor induction were documented to select the appropriate method. General and obstetric examinations assessed fetal presentation, heart rate, uterine contractions, pelvic adequacy, and the modified Bishop score. To ensure fetal well-being, an obstetric scan and non-stress test (NST) were performed. Patients with a reactive NST and a modified Bishop score of ≤5 were included and randomly assigned to two equal groups for different induction methods.

In the Double Foley's Catheter and Misoprostol Group, two connected Foley catheters were inserted and inflated, with misoprostol administered intravaginally every 6 hours, up to four doses. Continuous NST monitoring was performed, and the Bishop score was reassessed post-expulsion or withdrawal of the balloon. Misoprostol was given in dosages of 25 micrograms every six hours to the Misoprostol Group until the cervix became favorable, or until a total of four doses were provided. Ongoing monitoring of the fetal heart rate was carried out using cardiotocography, and a partogram was used to track the progression of labor. APGAR scores, fetal heart rate anomalies, maternal problems such as uterine hyperstimulation, and the rate of vaginal delivery were among the key outcome measures. Other important indicators were the intervals between induction and active phase and induction and delivery, the requirement for oxytocin augmentation, the method of delivery, and the APGAR scores.

The present study predominantly included mothers aged 21 to 25 years in both groups, with the next largest age group being 26 to 30 years. This age distribution aligns with previous research findings,

as shown in the accompanying table, thereby supporting the validity and relevance of comparing this study's results with prior studies. This consistency in age demographics enhances the reliability of the study's conclusions and its applicability to similar populations.

Table 19: Comparison of mean ages with the previous literatures

Studies	Combined group	Misoprostol group
Santosh et al	24.32 ± 3.35 years	24.35 ± 3.30 years
Rafiq M et al[56]	25.75 ± 5.45 years	25.85 ± 6.05 years
Elpo JA et al[57]	27.75 ± 6.82 years	26.90 ± 6.11 years
Kadu NA et al[58]	25.29 ± 4.10 years	25.37 ± 4.10 years
Present Study	**25.78 ± 4.47 years**	**24.91 ± 4.60 years**

Comparing the gestational age of mothers between the groups in the present study revealed no noteworthy variances, mirroring the gestational age distribution seen in most previous studies, as detailed in the accompanying table. This similarity justifies the comparison of findings, reinforcing the study's validity and allowing for meaningful conclusions to be drawn from the data, consistent with established research in the field.

Table 20: Comparison of mean gestational ages with the previous literatures

Studies	Combined group	Misoprostol group
Santosh et al	39.07 ± 1.59 weeks	39.16 ± 1.60 weeks
Aregeb ZA et al[53]	37.86 ± 0.87 weeks	38.00 ± 0.76 weeks
Rafiq M et al[56]	39.66 ± 1.19 weeks	39.35 ± 1.06 weeks
Kadu NA et al[58]	39.26 ± 1.00 weeks	39.28 ± 1.13 weeks
Present Study	**39.30 ± 1.20 weeks**	**39.46 ± 1.16 weeks**

In this particular research, the most prevalent reason for inducing labor in the Combined group was extended pregnancy (47.0% of cases), followed by preeclampsia and eclampsia (32.5% of cases), and then oligohydramnios (20.5% of cases). In the Misoprostol group, prolonged pregnancy was the

most frequent indication (42.2%), followed by oligohydramnios (34.9%), and preeclampsia & eclampsia (22.9%). Comparison between the groups revealed no statistically noteworthy variances in the indications for induction, indicating that both groups had similar clinical reasons for initiating labor induction.

In furtherance of the study findings, it could be deduced from the table below that the Bishop scores were also almost similar between the two groups and no difference could be distinguished between the two groups. Therefore, the comparison of the outcomes of the studies can be justified since the Bishop score distribution of the current study is similar to the findings of other investigations. Therefore, showing that the Bishop scores are comparable, supports the practice of comparing the efficacy and safety of the two induction procedures that were examined in this study.

Based on the conclusion of this study, the combined group had a significantly lesser interval between the initiation of labor and the active phase of labor as compared to the misoprostol group. In this case, the Combined group had a remarkable decrease in the time between the induction of labor and the actual birth of the baby as compared to the Misoprostol group. The findings shown here are in agreement with the findings of prior research, which are presented in the table that is attached to this article. These data highlight the effectiveness of using a combination of misoprostol and a double Foley catheter technique. This combined strategy exhibits a strong benefit in lowering the total time from induction to delivery, which reinforces its potential as a preferred way in labor induction procedures. There is a clear advantage in reducing the overall duration as well.

Table 21: Comparison of mean duration from induction to delivery with the previous literatures

Studies	Combined group	Misoprostol group
Santosh et al	14.58 ± 6.67 hours	19.11 ± 10.20 hours
Toshniwal SM et al[55]	14.60 ± 2.26 hours	17.90 ± 2.82 hours
Rafiq M et al[56]	13.93 ± 1.47 hours	17.89 ± 1.05 hours
Kadar N et al[59]	11.00 ± 3.60 hours	13.70 ± 3.60 hours
Present Study	**13.13 ± 3.01 hours**	**18.14 ± 7.33 hours**

There was a statistically noteworthy variance in the mode of delivery between the groups in the present study. Caesarean sections were significantly more in the Misoprostol group to the Combined group. However, findings from previous studies, as detailed in the accompanying table, showed varied rates of cesarean section.

Table 22: Comparison of caesarean section rates with the previous literatures

Studies	Combined group	Misoprostol group
Toshniwal SM et al[55]	21.8%	27.3%
Rafiq M et al[56]	14.6%	24.0%
Elpo JA et al[57]	17.8%	16.3%
Kadu NA et al[58]	37.8%	39.2%
Present Study	**28.9%**	**46.9%**

The primary indication for cesarean section was fetal distress, in both the Combined and Misoprostol groups, with no statistically noteworthy differences between them in the present study. This finding is consistent with previous studies by Lee HH et al[52], Swidan KH et al[54], Kadar N et al[59], and Yin J et al[60], which also identified these indications as predominant. These results reinforce the commonality of these indications for LSCS across various studies.

The APGAR scores in the current research revealed that the Combined group had a significantly greater incidence of newborn respiratory depression compared to the Misoprostol group at both 1 and 5 minutes after delivery. This was the case regardless of whether the group was given Misoprostol or Combined. In particular, the rates were 66.3% and 60.2% at 1 and 5 minutes, respectively, in the group that received Combined, but in the group that received Misoprostol, the rates were 39.8% and 10.85%, respectively. The rates of admission to the Neonatal Intensive Care Unit (NICU) did not vary substantially across the groups, with the Combined group having a rate of 15.7% and the Misoprostol group having a rate of 20.5%. The earlier research has painted a picture of a somewhat more pessimistic picture, but our findings were in agreement that Misoprostol had adverse effects on neonatal health. Such outcomes enhance the need to monitor the infants, especially in the neonatal period regardless the type of induction used, and to effectively intervene for the sick newborns.

Table 23: Comparison of NICU admission rates with the previous literatures

Studies	Combined group	Misoprostol group
Toshniwal SM et al[55]	10.9%	16.4%
Elpo JA et al[57]	0.0%	3.2%
Kadu NA et al[58]	40.5%	63.5%
Kadar N et al[59]	4.0%	6.0%
Present Study	**15.7%**	**20.5%**

The findings on the occurrence of complications among mothers in the two groups in the present study were generally low. Nonetheless, for women who had complications, the most common one was PPH, which implies postpartum hemorrhage. Such a trend was also observed in several previous studies by Santosh et al., Aregeb ZA et al. 53 Elpo JA et al. 57, Kadu NA et al. 58, Yin J et al. 60. The fact that PPH has always been reported in the studies as a primary complication confirms its

importance to the investigation of maternal health and the necessity of focusing on the further identification of the methods that can help to minimize the severity of the consequences as much as possible.

SUMMARY

SUMMARY

The study included 166 primigravida women divided into two groups: 83 receiving combined treatment with Double Foley's Catheter and Misoprostol, and 83 receiving misoprostol only.

The mean age was similar between groups (25.78 years for combined, 24.91 years for misoprostol), with most participants aged 21-25 years. Both groups had similar antenatal care. Gestational ages were comparable, with the combined group having more early-term pregnancies and the misoprostol group having more full-term pregnancies.

• In all groups, the most prevalent cause for induction was a pregnancy that had been going on for a long time. It was shown that both groups had a high need for oxytocin enhancement, with the combined group having a slightly greater requirement.

The combined group required fewer doses of misoprostol and had significantly shorter times from induction to active phase (mean 7.24 hours) and delivery (mean 13.13 hours) compared to the misoprostol group (mean 16.28 hours and 18.14 hours, respectively).

Vaginal delivery rates were higher in the combined group (59.0% vs. 38.6%), and caesarean sections were less frequent (28.9% vs. 46.9%).

Neonatal outcomes, measured by APGAR scores and NICU admissions, were similar between groups. Maternal complications were low and comparable, with slightly higher rates of postpartum haemorrhage in the misoprostol group.

These findings suggest that the combined treatment approach is more efficient, leading to shorter labor and higher vaginal delivery rates, making it a preferable method for labor induction.

CONCLUSION

CONCLUSION

The combined method i.e. double foleys with misoprostol when compared to misoprostol alone led to significantly shorter induction to active phase duration and induction to deliver interval with usage of lesser doses of misoprostol and higher vaginal rates and fewer ceaseran sections. Neonatal outcomes and maternal complications are similar in both groups.The present study shows that intracervical double foleys catheter plus misoprostol is more effective than intravagimal misoprostol alone for induction of labour

Limitations

The study investigating the efficacy of labor induction methods among 166 pregnant women presents several limitations that should be considered when interpreting the results. Firstly, the sample size, while relatively substantial, may still be insufficient to generalize the findings across broader populations. Larger multi-center studies would be necessary to confirm these results and enhance their external validity. Additionally, the study was conducted in a single institution, which may limit the applicability of the findings to other settings with different demographic, socio-economic, and healthcare delivery contexts.

Another limitation is the lack of diversity in the study population. Most participants were likely from similar socio-economic backgrounds, which could introduce selection bias. This homogeneity might not reflect the variations in outcomes that could occur in more diverse populations. Moreover, the study did not account for potential confounding factors such as maternal health conditions, previous obstetric history, and lifestyle factors that could influence labor induction outcomes. The exclusion of these variables may affect the robustness and comprehensiveness of the findings.

The reliance on self-reported data for some aspects of the study, such as medical and obstetric history, introduces the potential for recall bias, which can affect the accuracy of the collected data. Additionally, the study design did not include a follow-up period to assess long-term maternal and neonatal outcomes, limiting the ability to evaluate the sustained efficacy and safety of the induction methods.

Recommendations

To address these limitations, future research should aim to include larger and more diverse sample sizes, encompassing multiple centers to enhance the generalizability of the findings. Conducting multi-center studies would provide a more comprehensive understanding of labor induction methods across different populations and healthcare settings. Additionally, incorporating a longitudinal design with extended follow-up periods would allow for the assessment of long-term maternal and neonatal outcomes, providing a more holistic view of the efficacy and safety of the induction methods.

It is also recommended to control for potential confounding factors more rigorously. Including detailed assessments of maternal health conditions, previous obstetric history, and lifestyle factors would provide a more nuanced understanding of the factors influencing labor induction outcomes. Advanced statistical methods should be employed to adjust for these confounders, enhancing the validity of the findings.

Furthermore, future studies should consider the impact of various induction methods on maternal satisfaction and psychological outcomes. Incorporating patient-reported outcome measures would provide valuable insights into the patient experience and preferences, which are crucial for informed decision-making in clinical practice. Collaborative efforts across different healthcare institutions and regions would be beneficial in achieving more diverse and representative samples, ultimately leading to more reliable and applicable results.

REFERENCES

REFERENCES

1. Marconi AM. Recent advances in the induction of labor. F1000Research. 2019;8.

2. Ryan RM, McCarthy FP. Induction of labour. Obstetrics, Gynaecology & Reproductive Medicine. 2019 Dec 1;29(12):351-8.

3. Mackenzie IZ. Induction of labour at the start of the new millennium. Reproduction. 2006 Jun 1;131(6):989-98.

4. Summers L. Methods of cervical ripening and labor induction. Journal of Nurse- Midwifery. 1997 Mar 4;42(2):71-85.

5. Yellon SM. Immunobiology of cervix ripening. Frontiers in Immunology. 2020 Jan 24;10:3156.

6. Pierce S, Bakker R, Myers DA, Edwards RK. Clinical insights for cervical ripening and labor induction using prostaglandins. American Journal of Perinatology Reports. 2018 Oct;8(04):e307-14.

7. Juncu V, Vaso E, Cernețchi O, Căpîlna ME. Comparative analysis of pharmacologic and mechanical methods for labor induction in patients at full-term pregnancy—A systematic review. F1000Research. 2023 Dec 14;12:1586.

8. Muhunthan K. Pelvic fetal cranial Anatomy and the stages and mechanism of labor. Best Practice in Labour and Delivery. 2016 Nov 24;1.

9. Ibrahim EA, Al Awar S, Balayah ZH, Hadjileontiadis LJ, Khandoker AH. A comparative study on fetal heart rates estimated from fetal phonography and cardiotocography. Frontiers in physiology. 2017 Oct 17;8:764.

10. Howard E. Labor evaluation. Obstetric triage and emergency care protocols. 2013:159-67.

11. Cohen WR, Friedman EA. Clinical evaluation of labor: an evidence-and experience-based approach. Journal of Perinatal Medicine. 2021 Mar 26;49(3):241-53.

12. Funai EF, Norwitz ER, Lockwood CJ, Barss VA. Management of normal labor and delivery. UpToDate [Internet]. 2012 Mar.

13. Iravani M, Janghorbani M, Zarean E, Bahrami M. An overview of systematic reviews of normal labor and delivery management. Iranian journal of nursing and midwifery research. 2015 May 1;20(3):293-303.

14. Zhang J, Troendle J, Mikolajczyk R, Sundaram R, Beaver J, Fraser W. The natural history of the normal first stage of labor. Obstetrics & Gynecology. 2010 Apr 1;115(4):705-10.

15. Motherhood FS, Committee NH. Management of the second stage of labor. International Journal of Gynecology & Obstetrics. 2012 Nov 1;119(2):111-6.

16. Magann EF, Lanneau GS. Third stage of labor. Obstetrics and Gynecology Clinics. 2005 Jun 1;32(2):323-32.

17. Word RA, Li XH, Hnat M, Carrick K. Dynamics of cervical remodeling during pregnancy and parturition: mechanisms and current concepts. InSeminars in reproductive medicine 2007 Jan (Vol. 25, No. 01, pp. 069-079). Copyright© 2007 by Thieme Publishers, Inc., 333 Seventh Avenue, New York, NY 10001, USA.

18. Tew M. Safer childbirth?: a critical history of maternity care. Springer; 2013 Nov 11.

19. Hofmeyr GJ. Obstructed labor: using better technologies to reduce mortality. International Journal of Gynecology & Obstetrics. 2004 Jun;85:S62-72.

20. Taylor B, Cross-Sudworth F, Rimmer M, Quinn L, Morris RK, Johnston T, et al, UK Audit and Research Collaborative in Obstetrics and Gynaecology (UKARCOG) Members. Induction of labour care in the UK: A cross-sectional survey of maternity units. Plos one. 2024 Feb 28;19(2):e0297857.

21. USAID MOMENTUM. Induction and Augmentation of Labor in India: Excessive and Inappropriate Use of Uterotonics In and Out of Health Facilities [Internet]. 2023 Apr [cited 2024 Jun 25]. Available from: https://usaidmomentum.org/resource/induction-and-augmentation-of-labor-in-india-excessive-and-inappropriate-use-of-uterotonics-in-and-out-of-health-facilities/

22. Gabbay-Benziv R, Hadar E, Ashwal E, Chen R, Wiznitzer A, Hiersch L. Induction of labor: does indication matter?. Archives of gynecology and obstetrics. 2016 Dec;294:1195-201.

23. Parkes I, Kabiri D, Hants Y, Ezra Y. The indication for induction of labor impacts the risk of cesarean delivery. The Journal of Maternal-Fetal & Neonatal Medicine. 2016 Jan 17;29(2):224-8.

24. Brouillard-Pierce C. Indications for induction of labor. MCN: The American Journal of Maternal/Child Nursing. 1993 Sep 1;18:14-22.

25. Mozurkewich E, Chilimigras J, Koepke E, Keeton K, King VJ. Indications for induction of labour: a best- evidence review. BJOG: An International Journal of Obstetrics & Gynaecology. 2009 Apr;116(5):626-36.

26. Mauldin JG, Newman RB. Prior cesarean: a contraindication to labor induction?. Clinical obstetrics and gynecology. 2006 Sep 1;49(3):684-97.

27. Berghella V, Bellussi F, Schoen CN. Evidence-based labor management: induction of labor (part 2). American Journal of Obstetrics & Gynecology MFM. 2020 Aug 1;2(3):100136.

28. ACOG Practice Bulletin No. 107: Induction of labor. Obstet Gynecol. 2009 Aug;114(2 Pt 1):386-397.

29. Escobar CM, Grünebaum A, Nam EY, Olson AT, Anzai Y, Benedetto-Anzai MT, et al. Non-adherence to labor guidelines in cesarean sections done for failed induction and arrest of dilation. J Perinat Med. 2020 Oct 12;49(1):17-22.

30. American College of Obstetricians and Gynecologists (College). Society for Maternal-Fetal Medicine. Caughey AB, Cahill AG, Guise JM, Rouse DJ. Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol. 2014 Mar;210(3):179-93.

31. Gibson KS, Waters TP. Measures of success: Prediction of successful labor induction. InSeminars in perinatology 2015 Oct 1 (Vol. 39, No. 6, pp. 475-482). WB Saunders.

32. Watson WJ, Stevens D, Welter S, Day D. Factors predicting successful labor induction. Obstetrics & Gynecology. 1996 Dec 1;88(6):990-2.

33. Crane JM. Factors predicting labor induction success: a critical analysis. Clinical obstetrics and gynecology. 2006 Sep 1;49(3):573-84.

34. Dutta DC. Text Book of Obstetrics. 6ed. New Central Book Agency. 2001. ISBN 978-81-7381-142-5.

35. Battista L, Chung JH, Lagrew DC, Wing DA. Complications of labor induction among multiparous women in a community-based hospital system. American journal of obstetrics and gynecology. 2007 Sep 1;197(3):241-e1.

36. Alhazmi AA, Al Hajlan MA, Al Haider AS, Alhamami YM, Al Harthi NN, Alasmari MH, et al. Rules of induction of labor, complication and benefits. The Egyptian Journal of Hospital Medicine. 2018 Oct 1;73(5):6767-72.

37. Grivell RM, Reilly AJ, Oakey H, Chan A, Dodd JM. Maternal and neonatal outcomes following induction of labor: a cohort study. Acta obstetricia et gynecologica Scandinavica. 2012 Feb;91(2):198-203.

38. Yogev Y, Hiersch L, Yariv O, Peled Y, Wiznitzer A, Melamed N. Association and risk factors between induction of labor and cesarean section. The Journal of Maternal-Fetal & Neonatal Medicine. 2013 Nov 1;26(17):1733-6.

39. Triebwasser JE, VanArtsdalen J, Kobernik EK, Seiler K, Langen ES. Assessing maternal and fetal risks associated with prolonged induction of labor. American Journal of Perinatology. 2019 Apr;36(05):455-9.

40. Smith LP, Nagourney BA, McLean FH, Usher RH. Hazards and benefits of elective induction of labor. American journal of obstetrics and gynecology. 1984 Mar 1;148(5):579-85.

41. Alfirevic Z, Aflaifel N, Weeks A. Oral misoprostol for induction of labour. Cochrane Database Syst Rev. 2014 Jun 13;2014(6):CD001338.

42. Turner JV, Agatonovic-Kustrn S, Ward H. Off-label use of misoprostol in gynaecology. Facts Views Vis Obgyn. 2015 Dec 28;7(4):261-264.

43. Tang OS, Gemzell-Danielsson K, Ho PC. Misoprostol: pharmacokinetic profiles, effects on the uterus and side-effects. Int J Gynaecol Obstet. 2007 Dec;99 Suppl 2:S160-7.

44. Das R, Panda S, Sharma N, Deb P. A rare case of misoprostol hypersensitivity. J Family Med Prim Care. 2022 May;11(5):2226-2227.

45. Henriques A, Lourenço AV, Ribeirinho A, Ferreira H, Graça LM. Maternal death related to misoprostol overdose. Obstet Gynecol. 2007 Feb;109(2 Pt2):489-90.

46. Obut M, Balsak D, Sarsmaz K, Tolunay HE, Varlı EN, Şahin D, et al. Double Foley catheter for labor induction: An alternative method. International Journal of Gynecology & Obstetrics. 2021 Dec;155(3):496-504.

47. Gu N, Ru T, Wang Z, Dai Y, Zheng M, Xu B, et al. Foley catheter for induction of labor at term: an open-label, randomized controlled trial. PloS one. 2015 Aug 31;10(8):e0136856.

48. Kruit H, Heikinheimo O, Ulander VM, Aitokallio-Tallberg A, Nupponen I, Paavonen J, et al. Foley catheter induction of labor as an outpatient procedure. Journal of Perinatology. 2016 Aug;36(8):618-22.

49. Salim R, Zafran N, Nachum Z, Garmi G, Kraiem N, Shalev E. Single-balloon compared with double-balloon catheters for induction of labor: a randomized controlled trial. Obstetrics & Gynecology. 2011 Jul 1;118(1):79-86.

50. Ausbeck EB, Jauk VC, Xue Y, Files P, Kuper SG, Subramaniam A, et al. Outpatient Foley catheter for induction of labor in nulliparous women: a randomized controlled trial. Obstetrics & Gynecology. 2020 Sep 1;136(3):597-606.

51. Santosh KP, Kaur A, Kaur M, Garg R. A comparative study of combination of intracervical foley's catheter and intravaginal misoprostol versus intravaginal misoprostol alone for induction of labour. Indian J Obstet Gynecol Res. 2020 Dec 15;5(1):131-5.

52. Lee HH, Huang BS, Cheng M, Yeh CC, Lin IC, Horng HC, et al. Intracervical Foley catheter plus intravaginal misoprostol vs intravaginal misoprostol alone for cervical ripening: a meta-analysis. International journal of environmental research and public health. 2020 Mar;17(6):1825.

53. Aregeb ZA, Albromboly W, Abdelhameid AA, Helal KF, Badr MS. Induction of Labor Using Vaginal Misoprostol Alone or Combined with Intracervical Foley Catheter. The Egyptian Journal of Hospital Medicine. 2021 Oct 1;85(1):3125-9.

54. Swidan KH, El-Shahawy AA, Abbass AM, Mohamed HM. Combined Use of Vaginal Misoprostol with Intracervical Foley Catheter Versus Vaginal Misoprostol alone in Induction of Labor at Term Pregnancy. QJM: An International Journal of Medicine. 2021 Oct 1;114(Supplement_1):hcab115-018.

55. Toshniwal SM, Inamdar S, Sharma SR. Foley's Catheter and Vaginal Misoprostol vs Vaginal Misoprostol Alone for Labor Induction. Journal of South Asian Federation of Obstetrics and Gynaecology. 2022 Aug 22;14:381-6.

56. Rafiq M, Salman SG. Comparison of Foley's Catheter and Misoprostol Versus Misoprostol Alone on Labour Induction. Hamdan Medical Journal. 2022 Apr 1;15(2):93-6.

57. Elpo JA, Araújo BD, Volpato LK. Foley catheter plus misoprostol versus misoprostol alone for labor induction. Revista da Associação Médica Brasileira. 2023 Jan 9;69(1):119-23.

58. Kadu NA, Shiragur S. Comparison of Intracervical Foley's Catheter With Vaginal Misoprostol Versus Intravaginal Misoprostol Alone for Cervical Ripening and Induction of Labor. Cureus. 2023 Sep;15(9).

59. Kadar N, BA AM. Foley's Catheter with Misoprostol Versus Misoprostol Alone for Induction of Labour-A Comparative Study in Mysuru. European Journal of Cardiovascular Medicine. 2023 Apr 1;13(2).

60. Yin J, Li Y, Chen Y, Wang C, Song X. Intracervical Foley catheter plus intravaginal misoprostol compared to intravaginal misoprostol-only for cervical ripening: A systematic review and meta-analysis. European Journal of Obstetrics & Gynecology and Reproductive Biology. 2023 Feb 1;281:76-84.

61. Mohan M. Comparative Study of Efficacy of Intracervical Foley Catheter with Intravaginal Misoprostol in Induction of Labour in Primigravida with Term Pregnancy. Indian Obstetrics and Gynaecology. 2020 May 22;10(1).

ANNEXURES

PROFORMA

Personal Details:

NAME:

AGE:

IP NO.:

ADDRESS:

PHONE NO:

DATE OF ADMISSION:

DATE OF DELIVERY:

DATE OF DISCHARGE:

BOOKED/ UNBOOKED:

OBSTETRIC CODE:

LMP: **EDD:**

GESTATIONAL AGE:

COMORBIDITIES:

PAST H/O:

MENSTRUAL H/O:

MARITAL H/O:

OBSTETRIC H/O:

GENERAL EXAMINATION:

SYSTEMIC EXAMINATION:

VITALS:

PR-

BP-

PER ABDOMINAL EXAMINATION:

DIAGNOSIS:

INDICATION FOR INDUCTION:

DATE & TIME OF INDUCTION:

PV & BISHOP SCORE:

REVIEW PV & BISHOP SCORE:

CERVIPRIME GEL: YES/NO

OXYTOCIN ACCELERATION: YES/NO

DATE & TIME OF DELIVERY:

INDUCTION- DELIVERY INTERVAL:

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

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

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

BABY DETAILS:

MALE/ FEMALE

BIRTH WEIGHT:

APGAR: 1' - 5' –

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

PN STAY AND FOLLOW UP:

SIGNS OF CERVICAL ISCHEMIA:

INFORMED CONSENT FORM

I Mr./Mrs. _____ have been explained in my own understandable language, that I will be included in a study "COMPARATIVE STUY BETWEEN INTRACERVICALDOUBLE FOLEYS CATHETER PLUS MISOPROSTOL AND INTRAVAGINAL MISOPROSTOL FOR INDUCTION OF LABOUR"

I have been explained that my clinical findings, investigations, postoperative findings 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 – 8095607780

I in my sound mind give full consent to be added in the part of this study.

Name of the patient Name of the witness

Signature of the patient Signature of the witness

Date: Relation to the patient

Place: Kolar

Investigator signature

ಮಾಹಿತಿ ನೀಡಿದ ಒಪ್ಪಿಗೆ ನಮೂನೆ

ನಾನು ಶ್ರೀ/ಶ್ರೀಮತಿ. _____ "ಲೇಬರ್ ಪ್ರಚೋದನೆಗಾಗಿ ಇಂಟ್ರಾಸರ್ವಿಕಲ್ಡಬಲ್ ಫೋಲೀಸ್ ಕ್ಯಾಥೆಟರ್ ಪ್ಲಸ್ ಮಿಸೊಪ್ರೊಸ್ಟೋಲ್ ಮತ್ತು ಇಂಟ್ರಾವಾಜಿನಲ್ ಮಿಸೊಪ್ರೊಸ್ಟೋಲ್ ನಡುವಿನ ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನ"ದಲ್ಲಿ 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 ಸಂಪ್ರತ ಅರ್ಥವಾಗುವ ಭಾಷೆಯಲ್ಲಿ ಮಧ್ಯಸ್ಥಿಕೆಗಳಿಂದಾಗಬಹುದಾದ 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 – 8095607780

ಈ ಅಧ್ಯಯನದ ಭಾಗದಲ್ಲಿ ಸೇರಿಸಲು ನನ್ನ ಮನಸ್ಸಿನಲ್ಲಿ ನಾನು ಸಂಪೂರ್ಣ ಒಪ್ಪಿಗೆಯನ್ನು ನೀಡುತ್ತೇನೆ.

ರೋಗಿಯ ಹೆಸರು

ಸಾಕ್ಷಿಯ ಹೆಸರು

ರೋಗಿಯ ಸಹಿ

ಸಾಕ್ಷಿಯ ಸಹಿ

ದಿನಾಂಕ:

ರೋಗಿಗೆ ಸಂಬಂಧ

ಸ್ಥಳ: ಕೋಲಾರ

ತನಿಖಾಧಿಕಾರಿ ಸಹಿ

PATIENT INFORMATION SHEET

Study title

COMPARATIVE STUY BETWEEN INTRACERVICALDOUBLE FOLEYS CATHETER PLUS MISOPROSTOL AND INTRAVAGINAL MISOPROSTOL FOR INDUCTION OF LABOUR

Name of the Investigator:

Dr. MULAKALA SAMYUKTHANJALI

Name of the Participant:

Name of the Institution:

SRI DEVRAJ URS MEDICAL COLLEGE TAMAKA KOLAR, KARNATAKA

I am over 18 years of age and, exercising my free power of choice, hereby give my consent to be included as a participant in this study. I was free to ask any questions and they have been answered.

1. I have read and understood this consent form and the information provided to me. I have had the consent document explained to me. I have been explained about the nature of the study.
2. I have been explained about my rights and responsibilities by the investigator.
3. I have informed the investigator of all the treatments I am taking or have taken in the past months/years including any native (alternative) treatments.
4. I have been advised about the risks associated with my participation in the study.*
5. I have not participated in any research study within the past _____ month(s).*
6. I have been explained about the cost of the study and that is 600 Rs

7. I have been also explained about the cost and also the amount required to get serum ferritin levels will be taken care by the priniciple investigator.

8. I am aware of the fact that I can opt out of the study at any time without having to give any reasoned this will not affect my future treatment in this hospital.*

9. I am also aware that the investigators may terminate my participation in the study at any time, for any reason, without my consent.

10. I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, Govt. agencies, and IEC if required\. I understand that my identity will be kept confidential if my data are publicly presented.

11. I have had my questions answered to my satisfaction

I consent voluntarily to participate in the research/study. I am aware that if I have any question during this study, I should contact the investigator. By signing this consent form, I attest that the information given in this document has been clearly explained to me and understood by me. I will be given a copy of this consent document.

For any further information contact

Dr MULAKALA SAMYUKTHANJALI (Ph: 8095607780)

Signature/thumb impression of the patient

ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆ

ಅಧ್ಯಯನದ ಶೀರ್ಷಿಕೆ

ಲೇಬರ್ ಪ್ರಚೋದನೆಗಾಗಿ ಇಂಟ್ರಾಸರ್ವಿಕಲ್ಡಬಲ್ ಫೋಲೀಸ್ ಕ್ಯಾಥೆಟರ್ ಪ್ಲಸ್ ಮಿಸೊಪ್ರೊಸ್ಟೋಲ್ ಮತ್ತು ಇಂಟ್ರಾವಾಜಿನಲ್ ಮಿಸೊಪ್ರೊಸ್ಟೋಲ್ ನಡುವಿನ ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನ

ತನಿಖಾಧಿಕಾರಿಯ ಹೆಸರು:

ಡಾ. ಮುಲಕಲ ಸಂಯುಕ್ತಾಂಜಲಿ

ಭಾಗವಹಿಸುವವರ ಹೆಸರು:

ಸಂಸ್ಥೆಯ ಹೆಸರು:

ಶ್ರೀ ದೇವರಾಜ್ ಅರಸು ವೈದ್ಯಕೀಯ ಕಾಲೇಜು ತಮಕ ಕೋಲಾರ, ಕರ್ನಾಟಕ

ನಾನು 18 ವರ್ಷಕ್ಕಿಂತ ಮೇಲ್ಪಟ್ಟವನಾಗಿದ್ದೇನೆ ಮತ್ತು ನನ್ನ ಆಯ್ಕೆಯ ಮುಕ್ತ ಅಧಿಕಾರವನ್ನು ಚಲಾಯಿಸುತ್ತಿದ್ದೇನೆ, ಈ ಮೂಲಕ ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವವನಾಗಿ ಸೇರಿಸಿಕೊಳ್ಳಲು ನನ್ನ ಒಪ್ಪಿಗೆಯನ್ನು ನೀಡುತ್ತೇನೆ. ನಾನು ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ಸ್ವತಂತ್ರನಾಗಿದ್ದೆ ಮತ್ತು ಅವುಗಳಿಗೆ ಉತ್ತರಿಸಲಾಗಿದೆ.

1. ನಾನು ಈ ಒಪ್ಪಿಗೆ ನಮೂನೆ ಮತ್ತು ನನಗೆ ಒದಗಿಸಿದ ಮಾಹಿತಿಯನ್ನು ಓದಿದ್ದೇನೆ ಮತ್ತು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ. ನಾನು ಒಪ್ಪಿಗೆಯ ದಾಖಲೆಯನ್ನು ನನಗೆ ವಿವರಿಸಿದ್ದೇನೆ. ಅಧ್ಯಯನದ ಸ್ವರೂಪದ ಬಗ್ಗೆ ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ.

2. ತನಿಖಾಧಿಕಾರಿಯಿಂದ ನನ್ನ ಹಕ್ಕುಗಳು ಮತ್ತು ಜವಾಬ್ದಾರಿಗಳ ಬಗ್ಗೆ ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ.

3. ಯಾವುದೇ ಸ್ಥಳೀಯ (ಪರ್ಯಾಯ) ಚಿಕಿತ್ಸೆಗಳನ್ನು ಒಳಗೊಂಡಂತೆ ಕಳೆದ ತಿಂಗಳು/ವರ್ಷಗಳಲ್ಲಿ ನಾನು ತೆಗೆದುಕೊಳ್ಳುತ್ತಿರುವ ಅಥವಾ ತೆಗೆದುಕೊಂಡಿರುವ ಎಲ್ಲಾ ಚಿಕಿತ್ಸೆಗಳ ಕುರಿತು ತನಿಖಾಧಿಕಾರಿಗೆ ತಿಳಿಸಿದ್ದೇನೆ.

4. ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ ಭಾಗವಹಿಸುವಿಕೆಗೆ ಸಂಬಂಧಿಸಿದ ಅಪಾಯಗಳ ಕುರಿತು ನನಗೆ ಸಲಹೆ ನೀಡಲಾಗಿದೆ.*

5. ನಾನು ಕಳೆದ _____ ತಿಂಗಳು(ಗಳು) ಒಳಗೆ ಯಾವುದೇ ಸಂಶೋಧನಾ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಿಲ್ಲ.*

6. ಅಧ್ಯಯನದ ವೆಚ್ಚದ ಬಗ್ಗೆ ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ ಮತ್ತು ಅದು 600 ರೂ

7. ವೆಚ್ಚದ ಬಗ್ಗೆಯೂ ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ ಮತ್ತು ಸೀರಮ್ ಫೆರಿಟಿನ್ ಮಟ್ಟವನ್ನು ಪಡೆಯಲು ಅಗತ್ಯವಿರುವ ಮೊತ್ತವನ್ನು ತತ್ಪ ತನಿಖಾಧಿಕಾರಿಗಳು ನೋಡಿಕೊಳ್ಳುತ್ತಾರೆ.

8. ಯಾವುದೇ ಕಾರಣವನ್ನು ನೀಡದೆಯೇ ನಾನು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಅಧ್ಯಯನದಿಂದ ಹೊರಗುಳಿಯಬಹುದು ಎಂಬ ಸತ್ಯದ ಬಗ್ಗೆ ನನಗೆ ತಿಳಿದಿದೆ, ಇದು ಈ ಆಸ್ಪತ್ರೆಯಲ್ಲಿ ನನ್ನ ಭವಿಷ್ಯದ ಚಿಕಿತ್ಸೆಯ ಮೇಲೆ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ.*

9. ತನಿಖಾಧಿಕಾರಿಗಳು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ, ಯಾವುದೇ ಕಾರಣಕ್ಕಾಗಿ, ನನ್ನ ಒಪ್ಪಿಗೆಯಿಲ್ಲದೆ ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ ಭಾಗವಹಿಸುವಿಕೆಯನ್ನು ಕೊನೆಗೊಳಿಸಬಹುದು ಎಂದು ನನಗೆ ತಿಳಿದಿದೆ.

10. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಿದ ಪರಿಣಾಮವಾಗಿ ನನ್ನಿಂದ ಪಡೆದ ಮಾಹಿತಿಯನ್ನು ಪ್ರಾಯೋಜಕರು, ನಿಯಂತ್ರಣ ಪ್ರಾಧಿಕಾರಗಳು, ಸರ್ಕಾರಕ್ಕೆ ಬಿಡುಗಡೆ ಮಾಡಲು ತನಿಖಾಧಿಕಾರಿಗಳಿಗೆ ನಾನು ಈ ಮೂಲಕ ಅನುಮತಿ ನೀಡುತ್ತೇನೆ. ಏಜೆನ್ಸಿಗಳು, ಮತ್ತು

ಅಗತ್ಯವಿದ್ದರೆ IEC\. ನನ್ನ ಡೇಟಾವನ್ನು ಸಾರ್ವಜನಿಕವಾಗಿ ಪ್ರಸ್ತುತಪಡಿಸಿದರೆ ನನ್ನ ಗುರುತನ್ನು ಗೌಪ್ಯವಾಗಿ ಇರಿಸಲಾಗುವುದು ಎಂದು ನಾನು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ.

11. ನನ್ನ ಪ್ರಶ್ನೆಗಳಿಗೆ ನನ್ನ ತೃಪ್ತಿಗೆ ಉತ್ತರ ಸಿಕ್ಕಿದೆ

ಸಂಶೋಧನೆ/ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಾನು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಸಮ್ಮತಿಸುತ್ತೇನೆ. ಈ ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ನಾನು ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳನ್ನು ಹೊಂದಿದ್ದರೆ, ನಾನು ತನಿಖಾಧಿಕಾರಿಯನ್ನು ಸಂಪರ್ಕಿಸಬೇಕು ಎಂದು ನನಗೆ ತಿಳಿದಿದೆ. ಈ ಸಮ್ಮತಿಯ ನಮೂನೆಗೆ ಸಹಿ ಮಾಡುವ ಮೂಲಕ, ಈ ಡಾಕ್ಯುಮೆಂಟ್‌ನಲ್ಲಿ ನೀಡಲಾದ ಮಾಹಿತಿಯನ್ನು ನನಗೆ ಸ್ಪಷ್ಟವಾಗಿ ವಿವರಿಸಲಾಗಿದೆ ಮತ್ತು ನನಗೆ ಅರ್ಥವಾಗಿದೆ ಎಂದು ನಾನು ದೃಢೀಕರಿಸುತ್ತೇನೆ. ಈ ಒಪ್ಪಿಗೆಯ ದಾಖಲೆಯ ಪ್ರತಿಯನ್ನು ನನಗೆ ನೀಡಲಾಗುವುದು.

ಯಾವುದೇ ಹೆಚ್ಚಿನ ಮಾಹಿತಿಗಾಗಿ ಸಂಪರ್ಕಿಸಿ

ಡಾ ಮುಲಕಲ ಸಂಯುಕ್ತಾಂಜಲಿ (Ph: 8095607780)

ರೋಗಿಯ ಸಹಿ/ಹೆಬ್ಬೆರಳಿನ ಗುರುತು

MASTER CHART

Combined group

Sl No	Age (in years)	Booked	Gestational age (in weeks)	Comorbidities	Indication for Induction	BISHOP Score (Active Phase)	Oxytocin Acceleration	Induction - Active (in hour) Phase Interval	Induction -(in hour) Delivery Interval	Mode of Delivery	Indication for LSCS	Maternal Complications	Gender of the Child	Birth Weight (in kg)	APGAR (At 1 min)	APGAR (At 5 min)	NICU Admission	Stay at Hospital
1	19	yes	37	No	PROM	2	Yes	16	10	formal		None	M	1.9	7	8	No	3
2	32	yes	38	Eclampsia	Eclampsia	3	Yes	18	8	LSCS	Eclampsia	nvulsion	F	2.1	4	6	No	2
3	20	yes	39	No	None	5	Yes	17	6	formal		None	M	2.5	5	7	No	3
4	25	yes	40	No	None	4	Yes	15	4	formal		None	F	3	6	8	No	1
5	26	yes	37	No	None	1	Yes	20	7	formal		None	F	3.1	7	9	No	1
6	27	yes	38	No	fetal distress	5	Yes	18	9	LSCS	Fetal distress	PPH	F	1.4	3	4	Yes	2
7	24	yes	39	No	None	4	Yes	14	10	formal		None	M	2.4	4	5	No	3
8	23	yes	40	estational DM	Oligoyroaminos	2	Yes	16	8	LSCS	oligoydroaminos	None	F	2.5	5	6	No	10
9	22	yes	36	No	None	3	Yes	13	6	formal		None	M	2.1	6	7	No	3
10	29	yes	37	No	None	2	Yes	19	4	LSCS	Fetal distress	None	F	1.26	2	4	Yes	3
11	31	yes	38	No	PROM	3	Yes	17	5	formal		None	F	2.6	3	5	No	7
12	34	yes	39	No	None	5	Yes	15	7	formal		None	M	2.9	7	8	No	8
13	35	yes	40	No	None	4	No	13	9	formal		None	M	3	4	6	No	3
14	19	yes	37	No	fetal distress	1	Yes	14	10	LSCS	Fetal distress	PPH	F	1.46	3	5	Yes	4
15	20	yes	38	No	fetal distress	5	Yes	15	8	LSCS	ephalopelvic disproportion	None	M	3.1	7	8	No	5
16	24	yes	39	No	None	4	Yes	16	6	formal		None	F	3.2	4	6	No	1
17	28	yes	40	No	None	2	No	17	4	formal		None	F	1.9	5	7	No	3
18	27	yes	36	No	None	3	Yes	18	7	formal		None	F	2.1	6	8	No	2
19	26	yes	37	No	None	2	Yes	19	9	formal		None	M	2.5	7	9	No	2
20	25	no	38	Eclampsia	Eclampsia	3	Yes	20	10	LSCS	Eclampsia	None	F	3	3	5	No	3
21	19	yes	39	No	None	5	Yes	22	8	formal		None	M	3.1	7	8	No	4

22	32	yes	40	No	None	4	No	14	6	formal		None	F	1.4	4	6	No	5
23	20	yes	37	No	None	1	Yes	15	4	formal		None	F	2.4	3	5	No	8
24	25	yes	38	No	None	5	Yes	16	5	formal		None	M	2.5	7	8	No	3
25	26	yes	39	No	None	4	Yes	17	7	formal		None	M	2.1	4	6	No	2
26	27	yes	40	No	None	2	Yes	12	9	Normal		None	F	1.26	3	5	No	5
27	24	yes	37	Gestational DM	Gestational DM	3	No	14	10	LSCS	Gestational DM	None	M	2.6	7	8	No	12
28	23	yes	37	No	None	2	Yes	13	8	Normal		None	F	2	4	6	No	1
29	22	yes	38	No	fetal distress	3	Yes	18	6	LSCS	Fetal distress	None	F	1.12	2	5	Yes	4
30	29	no	39	No	None	5	Yes	15	4	Normal		None	F	2	7	8	No	2
31	31	yes	40	No	PROM	4	Yes	14	7	Normal		None	M	2.2	4	6	No	3
32	34	yes	37	No	fetal distress	1	Yes	16	9	LSCS	Fetal distress	PPH	F	2.2	2	4	Yes	4
33	35	yes	38	Eclampsia	Meconiuum stained Liquor	5	Yes	13	10	LSCS	Meconium stain liquor	None	M	3.2	1	3	Yes	5
34	19	yes	39	No	PROM	4	Yes	19	8	Normal		None	F	2	3	5	No	5
35	20	yes	40	No	None	2	Yes	17	6	Normal		None	F	1.12	7	8	No	6
36	24	yes	37	No	None	3	Yes	15	4	Normal		None	M	2	4	6	No	7
37	28	yes	37	No	fetal distress	2	Yes	13	5	LSCS	Fetal distress	None	M	1.67	2	5	Yes	8
38	27	yes	38	No	None	3	Yes	14	7	Normal		None	F	3.1	3	5	No	2
39	26	yes	39	No	None	5	Yes	15	9	Normal		None	M	1.4	7	8	No	3
40	25	yes	40	No	None	4	Yes	16	10	Normal		None	F	2.4	4	6	No	5
41	30	yes	37	No	None	1	Yes	17	8	Normal		None	F	2.5	2	5	No	1
42	20	yes	38	No	None	5	No	18	6	Normal		None	F	2.1	7	8	No	4
43	25	yes	39	Eclampsia	Eclampsia	4	Yes	19	4	Normal		None	M	1.26	3	5	No	2
44	26	yes	40	No	None	2	Yes	20	7	Normal		None	F	2.6	7	8	No	3
45	27	yes	37	No	None	3	Yes	22	9	Normal		None	M	3.6	4	6	No	4
46	24	yes	37	No	None	2	Yes	14	10	Normal		None	F	2.6	2	5	No	6
47	23	yes	38	No	fetal distress	3	Yes	15	8	LSCS	Fetal distress	None	F	1.8	1	3	Yes	7
48	22	yes	39	No	None	5	Yes	16	6	Normal		None	M	2	4	6	No	8
49	29	yes	40	No	Meconiuum stained Liquor	4	Yes	17	4	LSCS	Meconium stain liquor	None	M	1.9	2	4	Yes	2
50	31	no	37	No	PROM	1	Yes	12	5	LSCS	Fetal distress	None	F	2	7	8	No	3
51	34	yes	38	No	None	5	Yes	14	7	Normal		None	M	1.12	3	5	No	5
52	35	yes	39	No	None	4	Yes	16	9	Normal		None	F	2	7	8	No	1
53	19	yes	40	No	None	2	Yes	13	10	Normal		None	F	2.2	4	6	No	4
54	20	yes	37	No	Oligoyroaminos	3	Yes	19	8	LSCS	oligoydroaminos	PPH	F	2.1	2	2	Yes	2
55	24	yes	37	No	None	2	Yes	17	6	Normal		None	M	2	7	8	No	3
56	28	yes	38	No	None	3	No	15	4	Normal		None	F	1.12	3	5	No	4
57	27	yes	39	No	fetal distress	5	Yes	13	7	LSCS	Fetal distress	None	M	2	7	8	No	6
58	26	yes	40	No	Meconiuum stained Liquor	4	Yes	14	9	LSCS	cephalopelvic disproportion	None	F	2.6	4	6	No	7
59	25	yes	37	No	fetal distress	1	Yes	15	10	LSCS	Fetal distress	None	F	2.2	3	4	Yes	8

60	30	yes	38	No	None	5	Yes	16	8	Normal		None	M	1.9	7	8	No	2
61	20	yes	39	No	None	4	Yes	17	6	Normal		None	M	2	3	5	No	3
62	25	yes	40	No	None	2	Yes	18	4	Normal		None	F	1.12	7	8	No	5
63	26	yes	37	No	None	3	Yes	19	5	Normal		None	M	2	4	6	No	1
64	27	yes	37	No	None	2	Yes	20	7	Normal		None	F	2.2	7	8	No	4
65	24	yes	38	No	None	3	Yes	22	9	Normal		None	F	2.1	3	5	No	2
66	23	yes	39	No	None	5	Yes	14	10	Normal		None	F	2	7	8	No	3
67	22	yes	40	No	None	4	No	15	8	Normal		None	M	1.12	4	6	No	4
68	29	yes	37	No	None	1	Yes	16	6	Normal		None	F	2	7	8	No	6
69	31	yes	38	No	None	5	Yes	17	4	Normal		None	M	2.6	3	5	No	7
70	34	yes	39	No	PROM	4	Yes	12	7	LSCS	Fetal distress	None	F	2.2	7	8	No	8
71	35	yes	40	No	None	2	Yes	14	9	Normal		None	F	1.12	4	6	No	2
72	19	yes	37	No	fetal distress	3	Yes	15	10	LSCS	Fetal distress	None	M	2	2	4	Yes	3
73	20	yes	37	Gestational DM	Gestational DM	2	Yes	16	8	LSCS	Gestational DM	None	F	2.2	3	6	No	5
74	24	yes	38	No	Oligoyroaminos	2	No	17	6	LSCS	oligoydroaminos	PPH	F	2.1	7	8	No	1
75	28	yes	39	No	Meconiuum stained Liquor	3	Yes	18	4	LSCS	Meconium stain liquor	None	F	2	3	5	Yes	4
76	20	yes	39	No	None	4	Yes	17	6	Normal		None	M	2	3	5	No	3
77	25	yes	40	No	None	2	Yes	18	4	Normal		None	F	1.12	7	8	No	5
78	26	yes	37	No	None	3	Yes	19	5	Normal		None	M	2	4	6	No	1
79	27	yes	37	No	None	2	Yes	20	7	Normal		None	F	2.2	7	8	No	4
80	24	yes	38	No	None	3	Yes	22	9	Normal		None	F	2.1	3	5	No	2
81	23	yes	39	No	None	5	Yes	14	10	Normal		None	F	2	7	8	No	3
82	22	yes	40	No	None	4	No	15	8	Normal		None	M	1.12	4	6	No	4
83	29	yes	37	No	None	1	Yes	16	6	Normal		None	F	2	7	8	No	6

Misoprostol group

Sl No	Age (in years)	Booked	Gestational age (in weeks)	Comorbidities	Indication for Induction	BISHOP Score (Active Phase)	Oxytocin Acceleration	INDUCTION TO DELIVERY INTERVAL	INDUCTION TO ACTIVE PHASE INTERVAL	Mode of Delivery	Indication for LSCS	Maternal Complications	Gender of the Child	Birth Weight (in kg)	APGAR (At 1 min)	APGAR (At 5 min)	NICU Admission	Stay at Hospital	total misprostol dose	number of doses
1	23	yes	40	No	None	2	Yes	13	6	Normal		None	M	3.1	7	9	No	4	50	2
2	26	yes	37	No	Oligoyroaminos	3	Yes	6	4	Normal		PPH	M	2.52	7	9	Yes	2	25	1
3	19	yes	39	No	None	2	Yes	14	4	Normal		None	M	2.4	7	8	No	3	50	2
4	30	yes	39	No	None	3	No	12	8	Normal		None	M	2.42	6	8	No	4	50	2
5	27	yes	39	No		5	Yes	8	4	Normal		None	F	3.2	7	8	No	6	25	1
6	23	yes	41	No		4	Yes	12	10	Normal		None	M	2.78	7	9	No	7	50	2
7	24	yes	39	No		1	Yes	10	4	Normal		None	F	3.42	7	9	Yes	8	25	1
8	29	yes	39	No	None	5	Yes	8	4	Normal		None	M	3.3	7	8	No	2	25	1
9	19	yes	40	No	None	4	Yes	10	5	Normal		None	F	2.96	7	9	No	3	25	1
10	20	yes	39	No	None	2	Yes	19	8	Normal		None	M	3.8	7	9	No	5	50	2
11	26	yes	37	No	None	3	Yes	19	5	Normal		None	M	2	7	9	No	1	25	1
12	25	yes	39	No	None	2	Yes	12	6	Normal		None	M	3.54	7	9	No	4	25	1
13	22	yes	39	No	None	3	Yes	11	5	Normal		None	M	2.64	7	9	No	2	25	1
14	29	yes	39	No	None	5	Yes	16	8	Normal		None	F	2.34	7	9	No	3	50	2
15	23	yes	39	No	None	4	No	12	6	Normal		None	F	2.92	6	8	No	4	25	1
16	24	yes	38	No	None	1	Yes	12	5	Normal		None	M	2.34	7	9	No	6	25	1
17	27	yes	39	No	None	5	Yes	10	4	Normal		None	M	3.08	6	8	No	7	25	1
18	25	yes	41	No	PROM	4	Yes	12	8	Normal		None	M	2.86	7	8	No	8	50	2
19	20	yes	39	No	None	2	Yes	10	4	Normal		None	F	2.54	6	8	No	2	25	1
20	23	yes	40	No		3	Yes	14	8	Normal		None	F	2.76	6	8	Yes	3	50	2
21	27	yes	39	Gestational DM	Gestational DM	2	Yes	8	4	Normal	Gestational DM	None	M	3.18	7	9	No	5	25	1
22	26	yes	39	No	Oligoyroaminos	2	No	14	6	Normal	oligoydroaminos	PPH	M	3.1	7	9	No	1	50	2
23	24	yes	40	No	Meconiuum stained Liquor	3	Yes	12	5	Normal	Meconium stain liquor	None	M	2.92	7	9	Yes	4	25	1
24	26	yes	40	No	None	2	Yes	8	4	Normal		None	F	2.92	6	8	No	4	25	1

25	26	yes	40	No		3	Yes	10	4	Normal	oligoydroaminos	None	F	3.34	6	8	Yes	2	25	1
26	19	yes	40	No	None	2	Yes	8	4	Normal		None	M	2.82	7	8	No	3	25	1
27	19	yes	38	No	None	3	No	15	7	LSCS	Meconium stain liquor	None	M	2.42	5	7	Yes	4	50	2
28	29	yes	39	No	fetal distress	5	Yes	13	8	LSCS	Fetal distress	None	M	3.14	7	8	No	6	50	2
29	23	yes	37	No	Meconiuum stained Liquor	4	Yes	14	9	LSCS	Fetal distress	None	M	2.54	6	8	YES	7	50	2
30	20	yes	38	No	fetal distress	1	Yes	15	10	LSCS	Fetal distress	None	M	3.1	6	8	Yes	8	50	2
31	23	yes	38	No	None	5	Yes	8	4	LSCS	Fetal distress	None	F	3.54	7	8	No	2	50	2
32	20	yes	39	No	None	4	Yes	10	6	Normal		None	M	3.14	6	8	No	3	25	1
33	21	yes	40	No	None	2	Yes	12	8	Normal		None	F	2.96	7	8	No	5	50	2
34	26	yes	37	No	None	3	Yes	10	6	Normal		None	M	3	6	8	No	1	25	1
35	27	yes	37	No	None	2	Yes	20	12	Normal		None	F	3.56	7	8	No	4	50	2
36	24	yes	38	No	None	3	Yes	12	6	Normal		None	F	2.4	3	5	No	2	25	1
37	23	yes	39	No	None	5	Yes	12	7	Normal		None	F	2.92	7	8	No	3	25	1
38	22	yes	40	No	None	4	No	15	8	Normal		None	M	3	6	8	No	4	50	2
39	29	yes	37	No	None	1	Yes	10	4	Normal		None	F	2.34	7	8	No	6	25	1
40	31	yes	38	No	None	5	Yes	16	10	Normal		None	M	2.6	6	8	No	7	50	2
41	34	yes	39	No	PROM	4	Yes	10	6	Normal		None	F	3.4	7	8	No	8	25	1
42	35	yes	40	No	None	2	Yes	14	9	Normal		None	F	3	6	8	No	2	50	2
43	19	yes	37	No	fetal distress	3	Yes	15	10	LSCS	Fetal distress	None	M	3.4	5	7	Yes	3	50	2
44	22	yes	40	Gestational DM	Gestational DM	2	Yes	6	4	Normal	Gestational DM	None	M	2.42	6	8	Yes	5	25	1
45	18	yes	40	No	Oligoyroaminos	2	No	16	10	Normal	oligoydroaminos	PPH	F	3.14	7	9	No	1	50	2
46	26	yes	41	No	Meconiuum stained Liquor	3	Yes	8	4	LSCS	Meconium stain liquor	None	M	2.68	6	8	Yes	4	25	1
47	26	yes	38	No	None	2	Yes	6	4	Normal		None	M	2.64	6	8	No	4	25	1
48	22	yes	40	No	Oligoyroaminos	3	Yes	11	4	Normal	oligoydroaminos	PPH	F	3.18	6	8	Yes	2	25	1
49	19	yes	38	No	None	2	Yes	10	4	Normal		None	M	2.34	7	9	No	3	25	1
50	21	yes	40	No	None	3	No	12	6	Normal		None	F	2.5	7	9	No	4	25	1
51	22	yes	39	No	fetal distress	5	Yes	16	8	Normal		None	F	2.88	7	9	No	6	50	2
52	23	yes	39	No	Meconiuum stained Liquor	4	Yes	9	6	Normal		None	M	2.2	6	8	No	7	25	1
53	19	yes	40	No		1	Yes	10	6	Normal		None	M	2.94	7	8	Yes	8	25	1
54	25	yes	39	No	None	5	Yes	10	6	Normal		None	M	3.04	7	8	No	2	25	1
55	22	yes	40	No	None	4	Yes	11	6	Normal		None	F	1.81	5	7	Yes	3	25	1
56	25	yes	38	No	None	2	Yes	6	4	LSCS	oligoydroaminos	None	F	2.28	7	8	No	5	25	1
57	26	yes	40	No	None	3	Yes	8	4	Normal		None	F	2.74	6	8	No	1	25	1
58	21	yes	37	No	None	2	Yes	8	4	LSCS	FETAL DISTRESS	None	F	2.91	7	8	No	4	25	1
59	27	yes	40	No	None	3	Yes	11	4	Normal		None	F	3.14	6	8	No	2	25	1
60	25	yes	37	No	None	5	Yes	6	4	Normal		None	M	2.72	7	8	No	3	25	1
61	26	yes	40	No	None	4	No	12	8	LSCS	Fetal distress	None	M	2.74	6	8	No	4	25	1
62	23	yes	40	No	None	1	Yes	18	10	LSCS	Fetal distress	None	M	3.1	7	8	No	6	50	2

63	30	yes	38	No	None	5	Yes	16	8	Normal		None	M	3.084	6	8	No	7	50	2
64	27	yes	40	No	PROM	4	Yes	10	6	Normal		None	M	3.24	7	8	No	8	25	1
65	25	yes	39	No	None	2	Yes	10	4	Normal		None	F	2.6	6	8	No	2	25	1
66	29	yes	37	No		3	Yes	8	4	Normal		None	M	3.56	6	8	Yes	3	25	1
67	30	yes	39	Gestational DM	Gestational DM	2	Yes	12	5	Normal	Gestational DM	None	M	2.6	6	8	No	5	25	1
68	23	yes	38	No	Oligoyroaminos	2	No	6	4	Normal	oligoydroaminos	PPH	F	3.06	7	8	No	1	25	1
69	21	yes	39	No	Meconiuum stained Liquor	3	Yes	14	8	LSCS	Meconium stain liquor	None	M	2.78	6	8	Yes	4	50	2
70	20	yes	38	No	None	5	Yes	12	8	Normal		None	F	2.7	7	8	No	2	50	2
71	27	yes	38	No	None	4	Yes	12	6	Normal		None	F	3	7	9	No	3	25	1
72	29	yes	40	No	None	2	Yes	11	8	Normal		None	F	3.11	7	8	No	5	50	2
73	25	yes	41	No	None	3	Yes	7	4	Normal		None	M	3.2	7	8	No	1	25	1
74	25	yes	39	No	None	2	Yes	4	3	Normal		None	M	2.04	7	8	No	4	25	1
75	24	yes	39	No	None	3	Yes	12	8	Normal		None	F	2.74	6	8	No	2	50	2
76	35	yes	38	No	None	2	Yes	6	4	Normal		None	F	3	7	8	No	5	25	1
77	28	yes	39	No	None	3	Yes	8	4	Normal		None	F	2.84	7	9	No	1	25	1
78	31	yes	40	No	None	2	Yes	11	8	Normal		None	M	3.34	7	8	No	4	50	2
79	22	yes	38	No	None	3	Yes	16	8	Normal		None	M	3.08	6	8	No	2	50	2
80	19	yes	40	No	None	5	Yes	8	4	Normal		None	M	2.68	7	8	No	3	25	1
81	25	yes	39	No	None	4	No	8	4	Normal		None	F	2.26	6	8	No	4	25	1
82	22	yes	41	No	None	1	Yes	8	4	Normal		None	M	2.45	7	8	No	6	25	1
83	20	yes	37	No	None	5	Yes	10	6	Normal		None	F	2.6	6	8	No	7	25	1