COMPARISON OF ORAL MIFEPRISTONE WITH INTRACERVICAL FOLEYS CATHETERISATION FOR INDUCTION OF LABOUR AND FETOMATERNAL OUTCOME

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STRUCTURED ABSTRACT

Background: Induction of labor (IOL) is a critical obstetric intervention employed when the benefits of early delivery outweigh the risks of continuing pregnancy. While both mechanical and pharmacological methods exist, their relative safety, effectiveness, and comfort for term pregnancies remain under evaluation.

Objective: This study aims to compare the efficacy and fetomaternal outcomes of oral mifepristone versus transcervical Foley catheterization for cervical ripening and labor induction in term pregnancies with an unfavorable cervix.

Methods: In a prospective study conducted over 18 months at RL Jalappa Hospital, 50 term pregnant women with unfavorable cervices were randomized into two groups: Group A received 200 mg oral mifepristone, and Group B underwent Foley catheter insertion. Labor induction success, Bishop score changes, induction-delivery intervals, mode of delivery, and neonatal outcomes were evaluated. Statistical analysis was performed using SPSS version 26.0.

Results: There were no statistically significant differences between groups in terms of age, parity, gestational age, or baseline Bishop scores. Although vaginal delivery rates were slightly higher in the mifepristone group (88% vs. 76%), this difference was not significant. However, the induction-to-delivery interval was significantly shorter in the Foley group (13.66 ± 5.36 hrs) compared to the mifepristone group (21.14 ± 8.39 hrs, P = 0.001). Neonatal APGAR scores and failed induction rates showed no significant differences.

Conclusion: Both mifepristone and Foley catheter are effective for cervical ripening and induction of labor in term pregnancies. While Foley catheterization leads to faster deliveries, mifepristone offers a non-invasive alternative with comparable safety and

delivery outcomes. Method selection should be individualized based on patient comfort, resource availability, and clinical circumstances.

Keywords: *Mifepristone, Foley catheter, cervical ripening, labor induction, term pregnancy, Bishop score, vaginal delivery, maternal outcomes, neonatal outcomes.*

INTRODUCTION:

Obstetrics is a field of medicine dedicated to the care of women duringg pregnancy, childbirth, and postpaartum periodd, involving a delicate balance of maternal annd fetal well-being. While most pregnancies progress without complication, certain medical or obstetric conditions necessitate intervention before spontaaneous onset of labour. In such cases, Induction of laabour (IOL) becomes a critical tool, allowing clinicians to safely initiate labor when prolongation of pregnancy may lead to adverse outcomes.

Induuction of labourr is clinically iindicated wheen the benefitss off timely deliverry outweighs thee Rissks associated with continuation of the pregnancy[1]. Common indications include Hyperrtensive disorders, Diabetes mellitus, Prremature rupture of membranes, Inntrauterine growth restriction of baby, oligohydramnios, fetal death, and posst-term pregnancy[2] . While medically indicated induction is widely accepted, **elective inductions**—those performed without a medical necessity—have increased in recent years and remain controversial due to their association with increased cesarean section (CS) rates and maternal morbidity[3]

The global rise in IOL is evident, with the overalll induction raate is climbing from 8.5 % in the year 1990 to twenty three percentage in 2009 [4]. Among parous women, this rate is even higher—up to 38%[4–6] . Elective inductions now account for nearly one-third of

total births in some settings, often leading to unnecessary interventions, healthcare cost escalation, and increased maternal and neonatal complications[4–10]

A crucial determinant of IOL success is the **state of the cervix** at initiation. In cases with a unfavorrable cervix, induction before cervical ripening is necessary. Two methods—**pharmacological (e.g., mifepristone)** and **mechanical (e.g., Foley catheterization)**—are widely used. Mechanical methods exert pressure to induce local prostaglandin release, whereas pharmacologic agents act via hormonal modulation[11]

Among pharmacologic agents, mifepristone has emerged as promising cerrvical ripenning and labour-induction agent. Alsoo knoown as RUU:486, mifepristone iss aa 19-norrsteroid wiith pottent aanti-proogestogenic, antii-gluccocorticoid, andd mild antii-androgeenic effects[12]. It works by blocking progesterone receptors, increasing uterine sensitivity to prostaglandins, and facilitating cervical softening and dilatation. It is characteriized by rapiid absorpttion and a longer half-liffe of 25–30 hours, making it suitable even for outpatient settings.

While mechanical methods like the Foley catheter are commonly used, especially in women with prior cesarean sections, their **invasive nature**, potential for discomfort, and risk of infection have led to greater interest in non-invasive pharmacologic alternatives. Mifepristone offers a **less invasive** approach with potential for outpatient use and **favorable outcomes**, including **higher rates of spontaneous labor onset**, **improved Bishop scores**, and **lower cesarean section rates** in several studies[13,14].

Despite growing interest in mifepristone, clinical data remain insufficient, particularly regarding its comparative efficacy and safety in term pregnancies. According to a Cochrane review by Hapangama and Neilson (2009), while mifepristone shows

potential as a labor induction agent, more clinical studies are needed to substantiate its widespread use.

This study is focused on evaluating the effectiveness and fetomaternal outcomes of oral mifeepristone ass ann agent for the induction of labour in the term pregnancies with a unnfavorable cerrvix, comparing its performance with that of the commonly used Foleyy's catheter. As labour inducttion in an unripened cervix can be prolonged and stressful for both mother and fetus, optimizing the method of induction is crucial for improving birth outcomes. Through this study, we aim to assess whether mifepristone offers a safer, more efficient, and more comfortable alternative for cervical ripening and inducttion of labour.

STUDY OBJECTIVES:

1. Determination of thee effectiiveness annd saffety of Mifeepristone aand foleys ballooon catheterization in inducction of labour at term pregnancy.
2. Too assess feetal andd obstetric outcoome

REVIEWW OFF LITERRATURE

NORMAL LABOUR

Labour is a series of coordinated physiological processes that enable the fetus to transition from the intrauterine environment to the external world. In a typical singleton pregnancy, gestation lasts an average of 40 weeeks (280 daays), calculated from the firrst day of the laast noormal menstruual cycle. A pregnancy iss considered "term" when it reaches between 37 weeeks (259 daays) and 42 weeeks (294 daays) of gestaation.

DEFINITION:

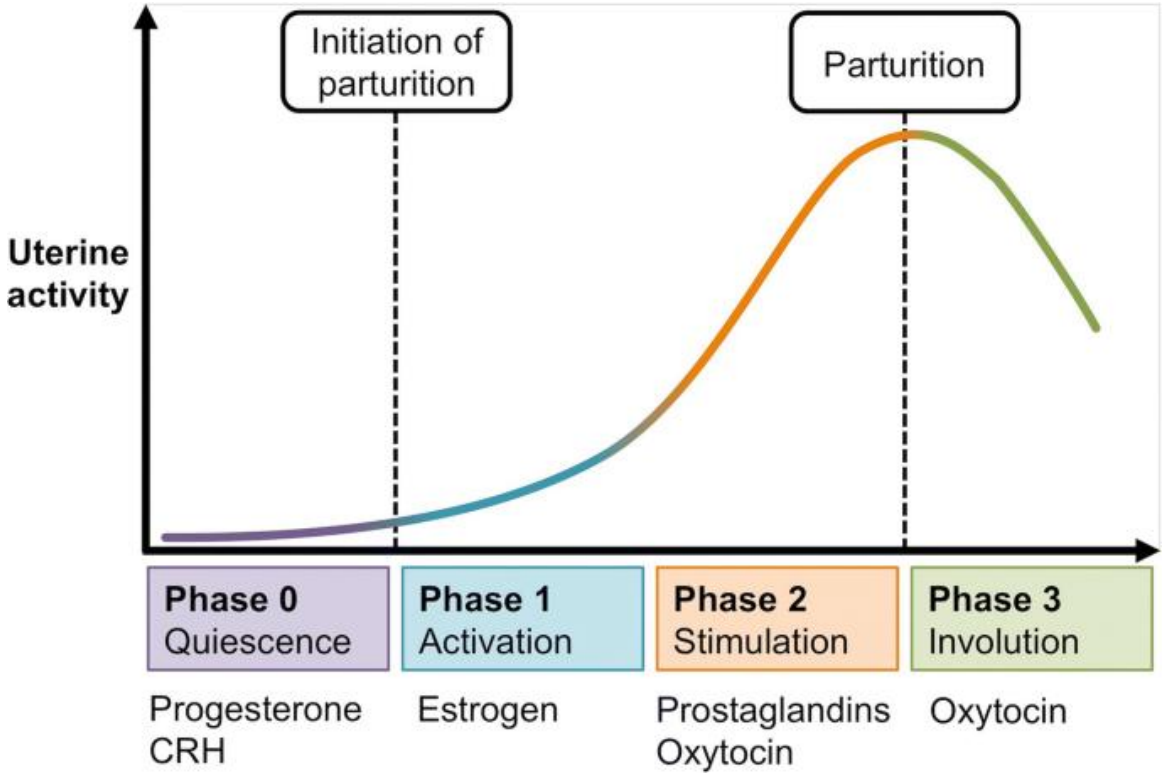
Clinically, labour iss defined by the presence of consistent, painfful uteriine contractioons thaat progressively increaase inn both strength andd frequency, accompanied

by cerviccal efffacement or dilaation. A hallmark of true labor is the shift in myometrial activity from irregular, prolonged, low-frequency contractions ("contractures") to more powerful and frequent contractions ("contractions")[15]. It is important to distinguish that contractions without cervical changes do not qualify as labor. The presence of a blooddy mucus discharge, commonly referred aas a "show," may occur in the days leading up to labor but is not essential for diagnosis. Typically, in spontaneous term labor, cervical softening and remodeling occur before uterine contractions, which are then followed by cervical dilation. Rupture of the fetal membranes usually happens during labor, although in some instances, it may precede thhe onsett off contractiions and result in leakagee of amniiotic fluiid.

THEE ONSETT OF LABOUR:

Physiologically, thee initiation of labour at term is better understood as the withdrawal of pregnancy-induced inhibition of myometrial contractility rather than a response to direct uterine stimulation[15]. There are four recognized phases of uterine activity that characterize this progression (Fig. 1).

FIGURE 1



Duringg pregnancy uterus remains in a state of functionall dormancay—referred to aas Phase o due to the influence of several inhibitory substances suchh as progesterne, prostacycliin, relaxiin, nitriic oxide, and various peptides including parathyroiid hormone related peptiide, calciitonin gene related peptiide, adrenomedullin, and vasoactive intestinal peptide. As pregnancy advances toward term the uterus undergoes a preparatory transformation Phase 1 driven by uterotropins like estrogen. This leads to increased production of contractionn associated proteiins, including receptors forr oxytoocin and prostaglandiins, enhanced expression of ion channels, and upregulation of connexiin 43, which is vital for gaap junctiion communication.

Following this preparatory stage uteruss becoomes responsive to utero tonins such as oxytoocin and prostaglandins E2 and F2α, triggering contractions (Phase 2). Since no single molecule has been identified as the definitive trigger, the term "promoters of labor onset" is more appropriate than "initiators." After delivery, uterine involution—Phase 3—is primarily mediated by oxytocin and possiibly thrombiin.

Thee Endoocrine Control of Labour

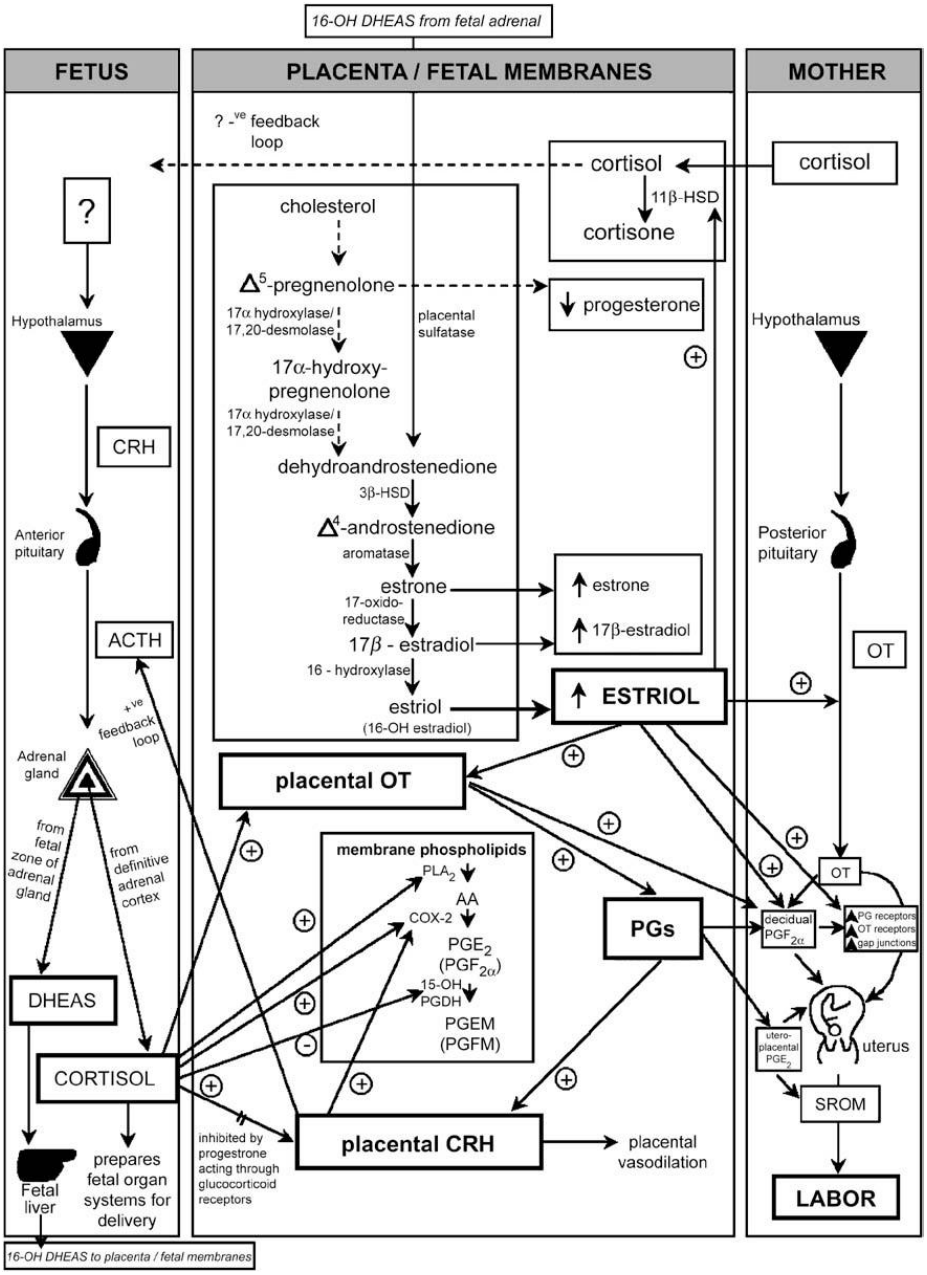
Substantial evidennce suggests the foetus has a central roole in determining the timing of labor. Ancient beliefs speculated that fetal movements-initiated labor, and although we now understand labor more intricately, the idea that the fetus contributes to initiating labor is supported by data from various mammalian species. Mid-20th-century cross-breeding studies in equines demonstrated intermediate gestational lengths, implying fetal genetics influence labor timing. In domestic ruminants like sheep, fetal cortisol triggers placental enzyme activation—specifically 17 alpha hydroxylase/ 17,20-lyase which converts progesterone too estradiol-17β, leading to increased uterine prostaglandin production and subsequent labor. Surfaactant protein-A relase from foetal lungs into amniotiic fluid has also been implicated in labour initiation in mice. However, these mechanisms do not fully translate to humans; for example, the human placenta lacks the enzyme activated by glucocorticoids in ruminants.

The slow progress in elucidating human parturition biochemistry is largely due to the complexity and species-specific nature of labour mechanisms. In humans labor is controlled predominantly through paracriine and autocriine signalling within the uterrus, which complicates direct study. Still most consistent mechanism appears to be activation of the foetal hypothalamic pituiitary-adrenal axiis, common across viviparus specis. In humans this activation results in the release of dehydroepiandrosterone (DHEA), a C-19 steroiid precursor necessary for placental estriol synthesis[16,17]. Studies in rhesuss monkeys have shown thaat whiile direect adminiistration of ostrogen does not induce preterm labor, administration of its precursor does. Furthermore, aromatase inhibition prevents this effect, confirming the necessity of precursor conversion to estrogen for labor initiation[18,19]

Regardles of whether labour signaling originates in the moother or foetus, the final pathway converges in the maternaal uteriine tissues. Myometrial contractions, like those in other smooth muscle types, rely on ATP-mediated bindiing of musin to actiin. Unliike vascular smoth muscle, uteriine muscle has minimal nerve supply, which diminishes further during pregnancy. Thus, uterine contractility is mainly regulated by hormonal signals and intrinsic cellular mechanisms. As the uterus transitions from quiescence to contractility, enhanced gap junction formation between myometrial cells ensures electrical coordination of contractions. Notablyy expression of connexin-43 mRNA a critical gap junction component iincreases as labour begins[20]

It is proposed that labour in humans results from a cascading sequence of interconnected signals—referred to as the "parturition cascade" (Fig. 2)—which progressively removes factors that maintain uterine quiescence and introduces those promoting uterine activity. This sequence integrates maternal, placental, and foetal pathways, ensuriing redundancy and resilience. Labour ultiimatelly emerges as a complex, multi-phase physiological process that reflects cumulative changes across the myometrium, decidua, and cervix. These changes include heightened prostaglandin production, increased gapp juunction fformation, annd upregulattion off oxyttocin recepttors. Once the uterus annd cerrvix arre sufficiently primed, hormonal annd mechanical stimuli from the fetus and placenta facilitate the shift from uterine contractures to effective contractions. The fetus likely contributes to this switch thrrough itss iinfluence onn pllacental horrmone prroduction, mecchanical stretching off thhe uterus, and release of hormoones that stimulate prostaglandin synthesis

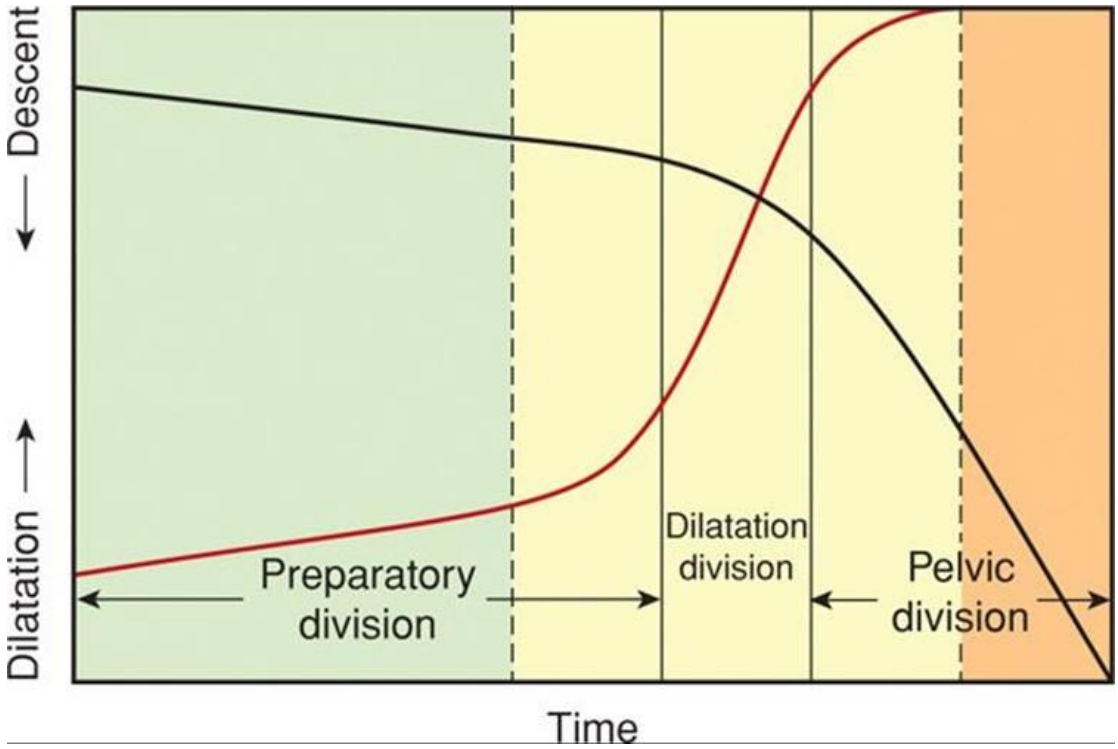
FIGURE 2. ‘‘parturition cascade’’ in spontaneous labor.



STAGEES AND DRATION OF NRMAL LABOUR

Altthough labour iis aa coontinuous proceess, itt trraditionally hass beeen diivided intto threee stagees tto facilitatte stuudy annd assisst iin cliniical managementt.

FIGURE 3



Firstt Sttage oOf LaboUr

Thee fiirst stagee marks the tiime from thee begining of labour until the cervix reaches full dilation. It is commonly divided into three phases based on cervical dilation rates[21]

1. **Lateent Phaase:** This early phase involves slow, gradual dilation of the cervix and varies widely in duration.
2. **Activee Phaase:** Diilation accelerates, typically starting around 2–4 cm. Although this phase can be further subdivided (e.g., acceleration, peak slope, deceleration), such distinctions are now rarely used.
3. **Descent Phase:** Whiile descnt of the foetus typicaly aligns with the secondd stge, some early frameworks included it here. However this classification is debated.

Labour progressiion paterns are generally consistent across ethnic groups but differ significantly between women giving birth for the first time and those with previous deliveries. Friedman's classic work quantified average labor durations and defined thresholds for delay as two standard deviations beyond the mean. For example, 1.2 cm/hr dilation in a nullipara was considered slow, though the average was closer to 3 cm/hr. Labor progression can be tracked using a partogram—a chart mapping cervical dilation over time—to quickly identify abnormalities and respond accordingly[21]

Second Staage of Labour

The secoond stage begiins at full cervical dilation (10 cm) aand endss with the biirth of the baby. It involves descent of the fetal presennting paart throuh the pelvis and eventual delivery. Signs of entering this stage include increased vaginal bleeding, maternal urge to bear down, rctal pressure, and sometimes nausea or vomiting. Women often take a more active role by pushing during contractions. For nulliparous patients, pushing may continue for up to 2 hours (3 hours with epidural), and for multiparas, up to 1–2 hours is acceptable. If both maternal and fetal conditions remain stable, longer pushing times may be permitted without increased risk[21]

Thirdd Stage of Labour

Thiis staage extennds from the baby's birth to the delivery of the placentaa and membrans. Classical indicators of placental separatin include:

1. Lengthenng of the umblical cord
2. Vaginal bleeding indicating placental detachment, and
3. Uterine fundus becoming firm, elevated, and globular.

Postpartum hemorrhage is the primary concern during this stage, as it contributes significantly to maternal complications. Normal blood loss is around 500 mL. While there's no universal timeline for this stage, retained placenta is typically diagnosed if it remains undelivered after 30 minutes. The WHO uses a 60-minute threshold as the definition[22]

Cardiinal Moovements of Labour

These are the speciific posiitional changess of the foetal head required too navigatee the birth canaal due too anatomical a symmetry. The seven movements are: **Engagment, Dscent, Flexon, Internl Rotaion, Extenson, Externl Rotatin (Restittion),** and **Explsion** (Fig. 4).

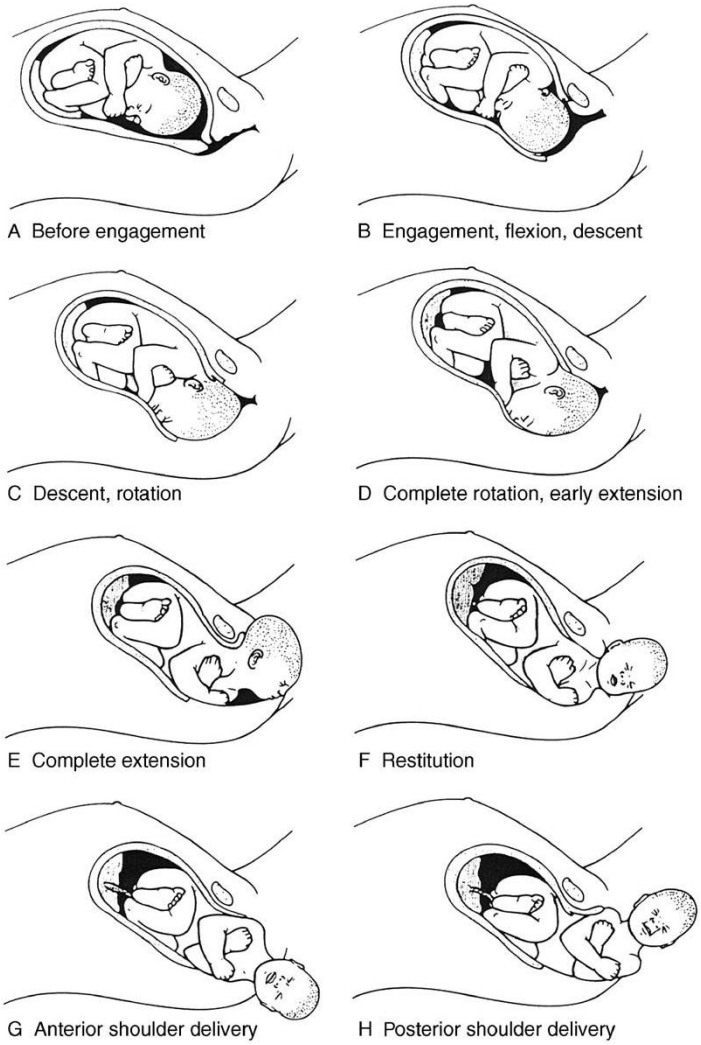
- **Engagment** occurs when the widest part of the foetal head (usually thee biparetal dimeter in cephalc presentation) passes the pelviic iinlet. Clinically, it's confirmed either by abdominal palpation (when only two-fifths of the head are felt) or vaginal examination (when the head is at or below the ischiiial spiines). This is a key marker of labour progresion. In multiparas engagement caan ocur later, even duriing labour, but in nuliparas, lack oof engagement by 36 weeks may suggest cephalopellvic diisproportion

- **Descent:** This refers to the donward movment of the preseting foetal part throughh the maternal pelvis. It occurs intermittently, accelerating during the late first stage and throughout the secoond stage oof labuor.

- **Flexion:** As the fetal head moves downward, it flexes due to pelvic anatomy and resistance from pelvic soft tissues. While some flexion exists before labuor, full flexion—presenting the smallest head diameter (suboccipito-bregmatic)—typically occurs during labuor, allowing easier passage.

- **Internal Rotation:** This movement shifts the fetal presenting part, usually from a transverse to an anteroposterior orientation, aligning the feotal ociput with the maternall symphysiis pubis. Initially, the head may descend slightly off-center (asynclitic) but usually corrects as it rotates, guided passively by the pelvic shape and musculature.

FIGURE 4



- **Extension:** Once foetal head reaches the vulvar opening, the occiput meets the underside off thee symphysiis pubiis. The birth canal then curvs upward, and thee head is deliverd by extending and pivting around the symphysis, propelled by contractions and maternal pushing against pelviic flor resistance.

- **Externaal Rotaton (Restution):** After delivery of the head, it passively rotats to realign with thee shoulders and torso. This movement releases built-up rotational tension and reflects the fetal head returning to its natural alignment.
- **Expulsion:** Final delivery of the fetus occurs as the anteriior shoullder slides beneath the symphysiis pubiis, folowed by the posterior shoulder and the rest off the body, typiclly with minimal resistance.

INDUCTIN OFF LABUOR

Historic Perspectives

The practice of labor induction began in the late 18th century, originally applied in select high-risk cases. Over time, it expanded to include a broader range of maternal and fetal indications, including overdue pregnancies, leading to the modern concepts of "post-term" and "post-dates." Today, induction is common even in low-risk pregnancies when continuation poses potential risks[23]

Historically, both mechanical and chemical methods of induction have evolved across cultures. Ancient practices are sparsely documented but include intriguing ethnobotanical and spiritual techniques. Native Americans reportedly used powdered rattlesnake rattles, bear claw scrapings, and herbal teas for induction. A medicine man was even observed using smoke and rhythmic rattles as part of the ritual[23]

In ancient Greece and Rome, physicians like Hippocrates advocated methods such as nipple stimulation, while Soranus of Ephesus described interventions for women with contracted pelvises, including enemas and topical applications to relax the cervix. Mechanical approaches like digital cervical dilation were used widely, though often with risk of trauma. Over time, devices like balloon dilators were introduced—Tarnier's device

in 1862, followed by the Champetier de Ribes' “metreurynter” in 1878, which later evolved into the Voorhees version. In 1890, Treub proposed using a urinary catheter fitted with a condom. By 1947, Kloosterman still favored this method, though complications like fetal malposition and cord prolapse were concerns. The usse off thee FoleEy catheter for cervical ripening emergd in thee late 1960s[23]

Pharmacological induction began with the use of ergot, quinine, and posterior pituitary extracts. Sir Henry Dale's discovery that pituitary extracts could stimulate the uterus was groundbreaking, although associated side effects limited its application. By 1928, oxytocin and vasopressin were identified separately, and in 1949, Vigneaud discovered and later synthesized oxytocin, revolutionizing modern induction techniques [23]

Prostaglandins became relevant in the 1930s when Kurzoak and Lieb observed that semen stimulated uterine contractions. Von Euler named them “prostaglandins” in 1935. In 1968, Karim introduced labor induction using intravenous PGF2α, followed by successful use of PGE2 by Calder and Embrey in 1973 via extra-amniotic infusion. Their findings confirmed PGE2's role in cervical ripening and spurred extensive trials to determine optimal use. Since the 1980s, two main strategies have dominated: amniotomy with oxytocin in favorable cervices, and prostaglandin-based cervical ripening followed by augmentation for unfavorable cases[23]

INDICATIONS

Labour iis indiicated wheen deliivery off the foetus will b beneficial to the health of fetus or mother or booth. The indicatiions for thee induction of labuor may be oone of the belw causes[24]

MATERAL CAUES

- Pregnancyy iinduced hyperttension

- Uncontroled dabetes
- Abruptio placente
- Coaguopathy
- Chorioamnionitiis
- Prematuere rupture oof membraness
- Cholestasiis of pregnanccy
- Acute fattty liveer off pregnancy
- Acute hydramniios
- Maternaal request

FEToAL CAUSES

- Intrauteriine growth restrictiion
- Diabetess
- Rh incompatibiility
- Unstable liie
- Proloonged pregnanncy
- Ruptureed membraanes

CONTRINDICATIONS fOR LABuR INDUcCTION

The contraindcations to labor innduction are tthe saame as thse foor spontaneus labuor and vagiinal deliivery[25]. They include, but are noot limited the folowing situations:

ABSOLUUTE CONTRAIINDICATIONS

- Vasa previia oor complete plaacenta preevia
- Transveerse or obliique fetoal lie
- Umbiliical coord proolapse

- Prior classical uteriine inciision or tranns fundall uteriine surgeery
- Activve geenital herrpes infecction
- Absollute cephaloopelvic dissproportion
- Contraccted pellvis
- Previous Myomeectomy enteering the endoometrial cavityy

RELATVE CONTRAIDICATIONS

- Mallpresentation (breech)
- Cervical carrcinoma

CRITERIA FOOR INDUCCTION OOF LABOUR

Maternal criteriia:

- Confiirm indiication
- Rulee oout contrraindications
- Performm cliniical pelviimetry to rulle out CPD
- Assess Bishop's score
- Disscuss riisks annd benefiits wiith patiient andd relativees

Fetal criteriia:

- Confiirm gestational age
- Assess fettal lunng maturiity statuus if requiired
- Estimatte feotal weight (clinically or USG)
- Confiirm fetaal presenntatioon and liie
- Cofirm feotal welll beiing

METHOODS OF INNDUCING LAABOUR

Thee choiice of labUor inductIion metthod is inflenced byy mulltiple facctors, such as gestational age, maternaal parity and overall health, the underlying reason for induction, any existing pregnancy complications, fetal wellbeing and position, previous delivery history, cervical status, maternal preferences, and available healthcare resources[26]. Among these, cervical readiness—assessed by features like consistency, dilation, and effacement—playss a critiical role in prediicting the sucess of inductiion and guiiding the selecion of the most suitable method. Mechanical approaches often suffice when the cervix is already somewhat favorable, especially if labor is imminent. In contrast, less favorable cervices may require pharmacologic interventions, sometimes in combination with mechanical techniques, and often involve more than one agent.

Naturall Meethods:

- Breasst/niple stimmulation
- Membane seeeping
- Amnniotomy
- Acuupuncture

Mechaniical Techniques:

- Balloon catheters (e.g., Foley catheter)
- Lamiinaria stems
- Synthetiic osmoytic dilattors

Chemicall Methods:

Non-Hormonall Agents:

- Herbaal remediies: blue/black coohosh, red raspberry leaf, evening primrose oil

- Castor oil
- Enemas

Hormonal Agents:

- Prostaglandiin E2 (PGE2)
- Misoprostol (PGE1 analogue)
- Oxytocin
- Mifepristone
- Relaxin
- Estrogen
- Nitric oxide donors
- Fetal fibronectin

PREPARATION

Before initiating induction of labor (IOL), the cervix should be assessed usiing thee Biishop scorring system, whiich evaluates dilation, effacement, consistency, position, and fetal station. A score of ≥8 suggests favorable conditions for vaginal delivery, whereas a score ≤3 is associated with reduced success. Discussing these findings with the patient helps inform her expectations[24]

Informed consent must include a clear explanation of the benefits, risks, alternatives, and possible outcomes of IOL. Risks associated with IOL are similar to those of spontaneous labuor and include cesrean delivery, operative vaginal birth, infection (chorioamnionitis), abnormal fetal heart patterns, and postpartum hemurrhage. Cesarean delivery may be necessary when indduction fails—defined by inadequate cervical dilation

despite medications or membrane rupture. According to ACOG, oxytocin should be administered for 12–18 hours post-amniotomy before labelling IOL as unsuccssful[24]

Providers should also outline available induction methods—mechanical, pharmacological, or a combination. A 2016 RCT showed that using combined methods (e.g., Foley catheter with misoprostol or syntocinon) led to faster delivery than single-method approaches, though differences diminished when adjusting for confounding variables[28] Cochrane reviews comparing amniotomy, prostaglandins, and mechanical options indicate that balloon catheters may be as effective as vaginal PGE2, with potential safety advantages for the neonate. Although oral misoprostol may be more effective, its safety profile is less clear. Future research should focus on maternal satisfaction and neonatal safety[24].

The ARRRIVE triial (NEJM) foound thaat ellective induuction att 39 weeeks iin low-rissk nulliparas resulteed iin a loweer cesarean rate without increased adverse neonatal outcomes. Similarly, a 2013 retrospective study suggested elective IOL between 37–40 weeks did not elevate maternal risks and was associated with reduced cesarean odds[24]. Regarding neonatal risks, that same 2013 California study found no significant differences in NICU admissions or respiratory distress between groups. However, a 2009 NEJM study noted increased complications in neonattes deliivered at 37 weeeks byy cesareaan compared to those born at 38–39 weeks[24]

Techniquee

Mechanical dilaation may be achieved using a Foley catheter, double-balloon catheter, or osmotic dilators (e.g., laminaria). A Foley catheter is inserted past the cervical os and inflaated wiith 30–80 mL oof saaline, applying pressure too promote dilation. A double-balloon system applies pressure internally and externally. These are typically

removed once the cervix reaches 3–4 cm . Pharmacologic agents such as misoprostol (PGE1 analog) caan bee admiinistered orally, vaaginally, orr subliingually in 25–50 mcg doses[27]. In caases off inttrauterine feetal demiise, higher misoprostol doses (e.g., 400 mcg every 3 hours) are used[28]. Dinoprostone (PGE2) iis avvailable ass aa gell (0.5 mg) or vagiinal iinsert (10 mg)[27] . Oxytocin (syntocinon) is administered IV, titrated to achieve contractions every 2–3 minutes. Hospitals may cap dosages in women undergoing trial of labor after cesarean (TOLAC). Amniotomy may be performed at the clinician's discretion, considering fetal station, engagement, and maternal preference.

Complications

As IOL becomes more common, especially for non-urgent reasons, the focus on safety increases. Mechanical methods are often safer and cost-effective, with fewer side effects like uterine hyperstimulation. Excessive uterine activity, particularly from pharmacologic agents like prostaglandins, can lead to fetal bradycardia or decelerations due to reduced oxygenation[29]

Other possible complications include:

- Vagiinal bleeeding
- Mecoonium-staiined amniiotic fluiid
- Umbiliical corrd prolapsee
- Inadequate paain control
- Peerineal trauma
- Posstpartum heemorrhage
- Infections like chorioamnionitis or endometritis[27]

Advantages and Disadvantages of Elective Induction[29]

Advantages:

- Reduces anxiety about prolonged pregnancy
- Facilitates planned delivery
- Beneficial in certain medical or logistical situations (e.g., history of stillbirth, remote living, maternal comorbidities)

Disadvantages:

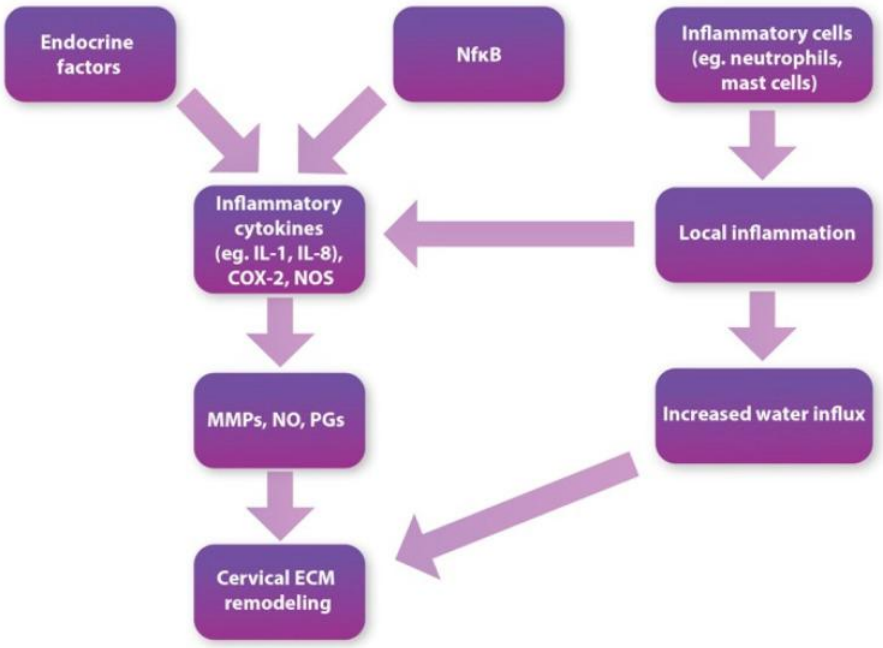
- Potential increase in cesarean or operative deliveries
- Possible rise in perinatal complications (fetal distress, asphyxia)
- Higher epidural use and pain perception
- Limited maternal mobility during labor

While elective IOL isn't universally advised, it may be justified for select clinical or logistical reasons when appropriately counseled.

CERVICAL RIPENING

The cervix undergoes profound remodeling, primarily involving alterations to the extracellular matrix. These changes intensify as term approaches, resulting in a shift from a firm, clOosed struccture to oone thaat is sofft and compliiant. Key histological and biochemical features of cervical ripening include the breakdown of collagen and elastin fibers, increased hydration of cervical tissue, and activation of localized inflammatory processes (Figure 1).

FIGURE 5



Glycosaminoglyycans (GAGs) annd Cerviical Riipening

During cervical remodeling, there is a marked increase in hyaluronan (HA) production, coupled with reduced collagen gene expression and heightened immune cell presence[30] HA, the most abundant GAG in the cervical matrix near term, increases gradually through parturition due to elevated transcription of the enzyme HAS2[31]. Its hydrophilic nature draws water into the tissue, contributing to cervical hydration and dispersion of collagen and elastin fibers—ultimately reducing cervical collagen content by approximately 70%. Interestingly, while total proteoglycan (PG) levels drop, specific types like PG-S1 and PG-L increase. These variants have weaker collagen-binding affinities, further promoting collagen fiber disorganization and tissue softening[32]

Matrix Metalloproteinases (MMPs)

MMPs, secreted by cervical stromal and inflammatory cells, are central to cervical ECM degradation[33]. Neutrophils and macrophages produce MMP-8 and MMP-1—key enzymes that break down collagen[34]. MMPs also act on other structural proteins such as laminin, fibronectin, and proteoglycans. These enzymes are initially secreted as inactive zymogens and require proteolytic cleavage for activation. Their expression is upregulated by cytokines and growth factors, while hormones like progesterone and glucocorticoids suppress their activity[35]

Specific MMPs invollved iin cervicall ripeening include MMP-1, MMP-2 (gellatinase A), MMP-8, and MMP-9 (gelatinase B). These enzymes target various types of collagen (I, II, III, IV), reorganizing the collagen architecture into looser, disordered bundles[36,37] . MMP levels and enzymatic activity rise in both thee cerrvix and loower uteriine segmeent during labor[35]. Nitricc oxiide (NO), an effective cerviical ripeening agent, also enhances MMP activity[38].

MMP activity is regulated by natural inhibiitors suuch as β2-macrroglobulin and tisssue inhibitors oof metalloproteinases (TIMPs). TIMPs inhibit enzymes like MMP-2 and MMP-9 by binding to their active sites[38,39]. The presence of TIMPs in the cervix during pregnancy suggests a regulatory mechanism for collagen breakdown, and their therapeutic potential for preventing preterm cervical ripening warrants further investigation[40]

Inflammatory Response and Immune Cell Infiltration

Cervical ripening exhibits characteristics similar to an inflammatory response, including vasodilation and increased vascular permeability, which contribute to tissue edema[41] . Immune cell infiltration—particularly neutrophils, macrophages, and mast cells—becomes prominent near term[42]. Chemokines and adhesion molecules guide

granulocyte migration into cervical tissue[43], with higher CXCL8 mRNA levels noted during labor[44].

Neutrophils are key contributors, releasing cytokines and MMPs that drive ECM remodeling[45]. Macrophages support this process through secretion of MMPs, interrleukins (IL-1, IL-6), TNF-α, and NO[46]. Mast cells (MCs) also have a regulatory role in cervical remodeling and labor. Their degranulation releases various mediators, including histamine, serotonin, PGs, proteases, and interleeukins (IL-1β, IL-3, IL-6, TNF-α), which influence myometrial and cervical contractility[47,48]. Histamine stimulates the phospholipase C pathway via H1 receptors, promoting muscle contractions[49]. Furthermore, allergen-triggered MC activation can lead to preterm labour via type I hypersensitivity.

MIFEPRISTONE

Mifepriistone (RUU-486) iis aa proggesterone reeceptor antagonist thaat facilitates cervical softening and dilation in early pregnancy and enhances uterine contractility. It has long been utilized for medical termination of early pregnancies[50]. Due to its physiological effects, mifepristone is considered a promising agent for ceervical ripeniing annd iinduction off labour.

A Coochrane reviiew published iin 2009 analyzed 10 randomized clinical trials encompassing 1108 participants, comparing mifepristone to placebo in women undergoing labor induction[51]. The review found that mifepristone significantly improved cervical favorability att 48 hourrs (RR 2.41; 95% CI, 1.70–3.42), reduced the neeed for oxytoccin auugmentation (RR 0.80; 95% CI, 0.66–0.97), and lowered the riisk off ceesarean deliivery

duee too failed iinduction (RR 0.40; 95% CI, 0.20–0.80). The review suggested that a single 200 mg oral dose was the minimal effective amount, with maximal benefit observed by 72 hours. Although abnormal fetal heart rate patterns occurred more frequently with mifepristone, no adverse neonatal outcomes were reported[51]

Further comparisons between mifepristone and mechanical methods such as laminaria and Foley catheters have also been studied. In one trial, mifepristone significantly shortened both the meann (10 vs 16 hourrs, $P = .01$) and mediian (7.5 vs 13.4 hours, $P = .01$) induction-to-delivery intervals, and reduced pain during cervical ripening (median pain score 1 vs 6, $P = .001$) compared to laminaria[52]. Outcomes such as delivery mode were similar in both groups.

In women with prior cesarean sections and post-term pregnancies, mifepristone (400 mg oral dose) was compared to Foley catheter insertion. Mifepristone use resulted in a shorter time to labor onset, higher Biishop scorres att 24 hourrs, reduceed oxytoocin requirement, annd feewer cases of faiiled induuction, with noo significant diifference in cesarean delivery rates[53].

When directly compared with other pharmacologic agents, mifepristone appears somewhat less effective. In a prospective trial, Jindal et al. compared 200 mg oral mifepristone to 0.5 mg endocervical dinoprostone gel[53]. Dinoprostone showed a greater improvement in Biishop scorre (mean±SD: 6.00±1.83 vs 5.33±1.62; $P = .007$) and significantly reduceed the time from iinduction tto actiive labour (meean±SD: 8.94±3.35 vs 50.98±3.35; $P < .0001$). Delivery outcomes were similar between both groups.

Overall, mifepristone is an effective cervical ripening agent and can serve as a useful adjunct to both mechanical and pharmacological methods, particularly in women

with an unfavorable cervix[54]. Its lonng hallf-liife (12–72 hourrs) makes it suitable for pretreatment before active induction begins.

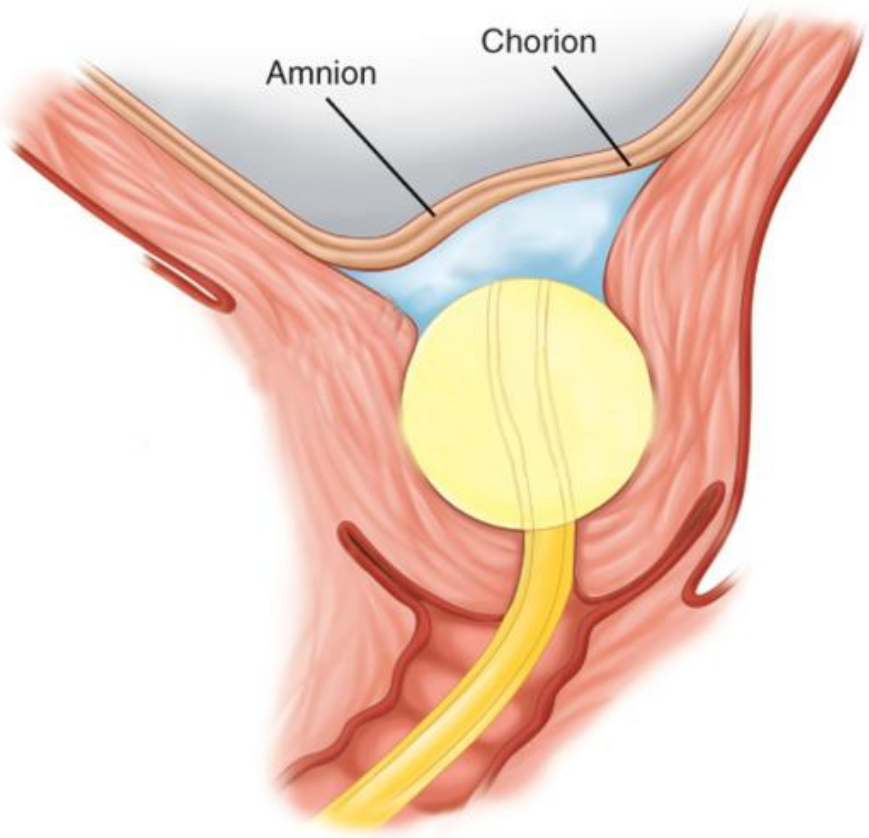
FOLEY CATHETER

Thee Folley catheterr wass initially introduced forr outpaatient cerrvical riipening inn 2001 (Figure 6)[55]. It typically comes in gauges ranging from 16 to 26 and can be inflated with ballloon vollumes between 30 to 80 mL. The catheter is usually made from lattex or silicone rubbber, while the Cookk cattheter, a double-balloon version, is constructed from silicone.

Cervical ripening using mechanical methods like the Foley catheter involves the application of physical pressure to dilate the cervix. This can occur through downward traction or circumferential expansion, depending on the type of device. Additionally, mechanical dilation may stimulate local inflammation and the releease off prostaaglandins, which contribute further too cerviical softening[56].

One modification to enhance this method includes **extra-amniotic saline infusion (EASI)** through the catheter. This technique may help further separate thee deciidua frrom tthe uterinne walll, incrreasing endogenous prrostaglandin rellease. Coombining EASI with aa Foleey catheteer has shown promise in reducing both thhe tiime too vaaginal dellivery aand thee likelihood off caesarean section[57].

Figure 6. Singgle-ballloon trranscervical Fooley cathetter



Adminiistration annd Appllication of Folley Cattheter

The Foley catheter caan bee innserted either usiing aa speeculum or via diigital examiination. Studies indicate that diigital insertion teends tto be leess painful for the patient, while both techniques demonstrate comparable effectiveness in achieving cervical ripening . Thee usse off aa sttylet during innsertion has not shown improved success rates and is generally not necessary . After placement, traction is often applied by taping the catheterr too thee patient's innerr thighh. Howeever, evidence suggests that thiis praactice does not enhancce the effiicacy of cerviical riipening or reduce laborr duration [58]

Efficacy, Cost, and Safety Profile

The Foleys cathetter remains aa preferred method for cerviical ripening due to its affordability and comparable efficacy to more expensive devices like the double-balloon

catheter. Although it is used "off-label" for cervical ripening, it is widely accepted in clinical practice due to its effectiveness and clinician familiarity.

Infection Risk

Concerns have been raised about the potential for mechanical methods to increase infection risk due to their invasive nature. However, the Foley catheter has demonstrated a strong safety profile in this regard. A systematic review and meta-analysis of 26 randomized controlled trials (RCTs) found no significant increase in infection risk with the Foley catheter compared to prostaglandins (8.8% vs. 9%; RR, 0.95; 95% CI, 0.81–1.12)[59]

Use in Ruptured Membranes

Thhe usse off tthe Folley cattheter iin patients wiith rruptured meembranes haas shown mixeed reesults. Twwo rrandomized trrials found it effective forr cerviical rippening and innduction in this setting. However, one trial reported no elevated riisk off choriioamnionitis while the otheer noted ann inncreased risk[60.]

Impact on Future Pregnancies

Given the physical dilation involved, concerns exist about whether Foley catheter use coulld leead tto cervical daamage, iincreasing thee risk of miscarriage or prreterm biirth in future pregnancies. However, three studies have found no such correlation, supporting its safety in this context[55,61]

RELATED STUDIES:

1. In a study conducted to compare two methods of labour induction—one involving oral Mifepristone followed by vaginal Misoprostol, and the other using intracervical Foley's catheterization followed by vaginal Misoprostol—the researchers aimed to evaluate the induction-to-delivery interval as the primary outcome, along with

secondary outcomes like mode of delivery, cesarean indications, and neonatal results. The findings indicated a significantly shorter induction-to-delivery interval with the Foley catheter method compared to oral Mifepristone. However, there was no notable difference between the groups regarding delivery route, cesarean rates, or neonatal outcomes. The researchers concluded that while Mifepristone is a viable option for inducing term pregnancies, it does not reduce the induction-delivery time, and its fetal safety profile is similar to that of the Foley catheter method[62].

2. Inn aa raandomized coontrolled triial by aiimed att comparing thhe effectiveness off oral mifepristone with intracervical Foley balloon catheter for outpatient cervical ripening in term pregnancies, the goal was to assess whether mifepristone was not inferior in inducing labour or achieving a favorable Bishop's score within 24 hours. The results showed that 33.3% of women in the mifepristone group and 30.2% in the Foley catheter group reached the primary outcome, but the confidence interval failed to demonstrate non-inferiority. The study concluded that although both methods yielded similar rates of labor onset or cervical ripening, mifepristone could not be confirmed as non-inferior to the Foley balloon catheter[62].
3. In a retrospective study connducted tto coompare thee safeety and effectiveness of twoo induuction methoods for midtrimester abortion—one usiing a coombination off intraccervical Fooley's caatheter annd missoprostol, and the other using mifepristone with misoprostol—the goal was to evaluate procedural outcomes and patient factors affecting success. Complete fetal expulsion occurred in all Foley catheter cases, while the mifepristone group had an 89.47% success rate. Additionally, the induction-to-abortion interval was significantly shorter with the mechanical-pharmacologic combination. The study concluded that combining Foley's catheter with misoprostol is a safe, effective, and more cost-efficient

alternative that reduces misoprostol dosage, shortens the procedure time, and improves patient comfort.

4. In a retrospective cohort study conducted, the objective wass too coompare thhe effectiveness of intracervical balloon catheter and oral mifepristone for labor induction, specifically in women with a Bishop score ≤5. The findings revealed that while overall vaginal delivery rates were slightly higher with mifepristone (76.5%) compared to Foley catheter (74.5%), a greater proportion of patients in the Foley catheter groups delivered within 24 hours of induction initiation. The study concluded that both methods are effective, but Foley catheter may lead to quicker delivery in the early induction window, and overall success is closely tied to cervical ripening status and parity[14].
5. In a random study conducted recently ,the objective was to assess whether the use of a stylette during Foley catheter insertion influenced insertion time, patient-reported pain, and insertion failure rates. The findings showed no significant differences between groups in terms of patient demographics or primary outcomes. Although stylette use did not significantly affect outcomes, it showed a trend toward reducing pain variability and insertion failures. The study concluded that Foley catheter placement with or without a stylette results in comparable performance, and both methods are effective[63].
6. Inn aa ranndomized contrrolled triial , the study aimed too deteermine wheether using an 80 mL transcervical Foley catheter alongside vaginal misoprostol would reduce the induction-to-delivery interval compared to a 60 mL Foley catheter in nulliparous term pregnancies with an unfavorable cervix. The results showed a significantly shorter induction-to-delivery interval and quicker onset of labor in the 80 mL group. Although there were no statistically significant differences in the

mode of delivery or maternal and neonatal morbidity, the likelihood of delivering within 12 hours was significantly higher with the 80 mL catheter. The study concluded that using a larger-volume Foley catheter more effectively shortens labor induction time[64].

7. In recent randomized controlled trial the objective was to evaluate whether Foley catheter balloon volume—30 mL versus 60 mL—impacts the effectiveness of labor induction in term pregnancies. While overall delivery rates within eight hours after amniotomy did not differ significantly between groups, sub-analyses revealed that multiparous women using the 60 mL catheter had a higher likelihood of early delivery, and nulliparous women in the 30 mL group had a greater cesarean rate. The study concluded that while both catheter volumes were comparable for the primary outcome, the 60 mL volume may offer advantages in certain subgroups, though findings should be interpreted cautiously[65].
8. In a meeta-analyysis, the objeective was too comppare thee efffectiveness aand safetty oof Foleey catheterr versus orral misoproostol for inducing labour in women with viable singleton pregnancies. The results indicated that Foley catheter use was slightly less effective in achieving vaginal birth compared to oral misoprostol. However, there was a trend toward fewer adverse perinatal outcomes in the Foleuey group, allthough noot sttatistically siignificant. Maaternal outtcomes were similar across both groups. The study concluded that while oral misoprostol is more effective for vaginal delivery, Foley catheter induction may be associated with improved perinatal safety[66].

MATERIALS AND METHDS

STUDY DESIIGN: Prospectiive study

DURATIOON OF STUDY: 18 moonths (JULY 2023 TO DECEMBER 2024)

STUDY POPULATION: Pregnant women in labour attending department of OBG, RL Jalappa Hospital, Kolar during the study period.

STUDY AREA: RL Jalappa Hospital, Kolar.

SAMPLING METHDS: Consecutiive sampliing

INCLUSION CRITERIA:

- Terrm pregnanncy
- cephaliic presentatiion.
- Intacct membrranes.
- Adequate pelvis.
- Hypertension, Diabetes mellitus, Ov patients.
- Previous caesarean section.
- Singleton pregnancy
- Delivery cann be postpooned for 24 houurs
- Reactivee NSsT
- Women with unfavourable cervix.

EXCLUSION CRITERIA:

- Intra uterine fetal demise.
- Intra uterine growth restriction.
- Oligohydramnios.

- Malpresentations.
- Associated medical disorders such as heart disease, Anaemia, thyroid, epilepsy, asthma
- Prematuure ruptuure of mmembranes.
- Placental insufficiency.
- Cephallo pelviic disproporrtion.
- Impaiired reenal, hepatiic, or adreenal funcction and antepartum hemorrhage.

METHOD OF DATA COLLECTION

A prospective study which is hospital based and is conducted in women whoo mett thee iinclusion criiteria werre eenrolled forr thee sttudy which is done iin department off obstetrics and gynaecology at R L JALLAPPA HOSPIITAL TAAMAKA KOLAR attached to SRI DEVRAJA URS MEDICAAL COLLGE under SRI DEVARAJ URS ACADEMY OF HIGHER EDUCCATION AND RESEARrCH frrom Juuly 2023 tto December 2024. A total of 50 pregNnant womeen selected through convenience sampling constituted the study population. Upon admission, detailed medical, surgiical, and obsstetric histories were recorded, and eligible participants were enrolled after confirmation of gestational age based on their last mennstrual peiriod and ultrasoound findings. Inforrmed writteen conseent wass obttained frrom alll partiicipants after clearly explaining thee risks and benefits of thee stuudy. A comprehensive obstetric examination was performed to assess foetal lie, presentation, gestatioonal agge, and fetal heart rate. Per vaginal examination was done to evaluate the Modified Bishop's score and pelvic adequacy. All enrolled patiennts undderwent baaseline iinvestigations iincluding coomplete bloood counnt, liiver annd reenal fuunction tessts, and fetal ultrasound.

Following consent, participants meeting the inclussion criiteria weree raandomly diivided into twoo groups: Grooup A reeceived ooral Mifepristone 200 mg, while Group B underwent intracervical Foley's balloon catheter insertion for labor induction. Assessment in Group A was done either afterr 24 hoours orr upon iniitiation of coontractions, whhichever occurred earllier. Iff the Biishop's scoore remained less than 8, labor was induced using misoprostol tablets (25 mccg or 50 mccg depeending on paarity), whereas if the Bishop's scoore was ≥8, labour was auggmented using intravenous oxytocin. In Group B, patients werre asseessed afteer expuulsion off the Foley catheter. Iff the Biishop's scoore wass <8 post-expulsion, misoprostol was administered similarly, while a score ≥8 warranted augmentation with oxytocin. In both groups, a maximum of four doses of misooprostol was used. If adequate contractions did not begin thereafter, patients were offered the choice between proceeding with a cesarean section or waiting further for the onset of labor.

STATISTICAL METHODS

Dataa was coollected and coompiled in MS Excl. Statistiical analyysis wasa performed usiing SPSS for winddows version 26.0. The description of data will be in the form of mean (±) SD foor quantitatiive daata and freequency and proportion for qualitative data. Student t test/ANOVA was used to compare continuoous variaables and $\chi 2$ teest used to coompare cateegorical variaables. P vaalue <0.05 was considered statistically significant**.**

SAMPLE SIZE CALCULATION

Waas eestimated by ussing thhe diifference inn Meean Doose oof Mifeepristone betweeen stuudy grooup annd coontrol grroup frrom thhe stuudy Dr.shivikaa et.al.as 2.14 ± 0.63 annd 1.4 ± 0.8. Usiing theese vaalues att 95% Coonfidence liimit annd 90% poower

sammple siize oof 22 was oobtained in eaach groupp by usiing the beelow mentiioned forrmula and Medd calcu sammple siize softtware. Witth 10% nonresponse sammple siize off 22 + 2.22 ≈ 25 minimum subjects willl bee inncluded in eaach grroup.

Sammple Siize Esstimation Foormula:

$$N = 2\,SD^2(Z_{\alpha/2} + Z_{\beta})^2/\,d^2$$

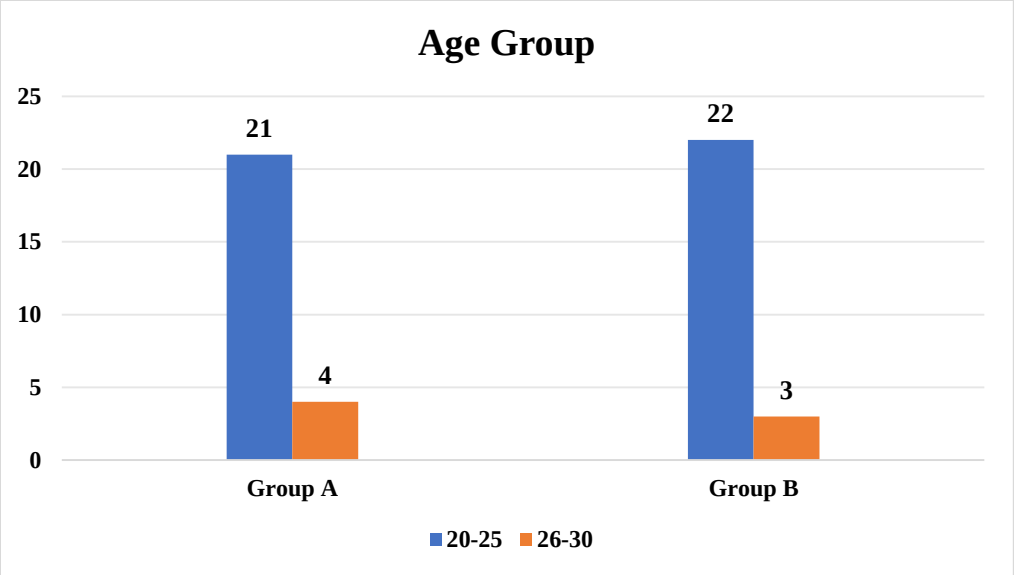
- Wheere $Z\alpha/2$ iss critiical vaalue of thhe Noormal diistribution att $_{\alpha/2}$ (e.g. for the
- confidennce leevel oof 95%, ***α*** is 0.05 annd thhe criitical valuue iis 01.96).
- $Z\beta$ iss thhe criitical vaalue oof thhe Noormal diistribution att β (e.g. forr power of 80%, ß iss 0.2 annd thhe criitical vaalue iis 0.84),
- Sd iss thhe sttandard deeviation frrom preevious stuudy poopulation vaariance, and the
- d iis thhe largest diifference beetween ttwo meean

RESULTS:

TABLE 1: AGE CATEGORY

Agge Group	**Grooup A**	**Grouup B**	**P Vaalue**
20-**25**	21 (84%)	22 (88%)	**0.684**
26-30	4 (16%)	3 (12%)	
Total	**25 (100%)**	**25 (100%)**	

FIGURE 7: AGE CATEGORY

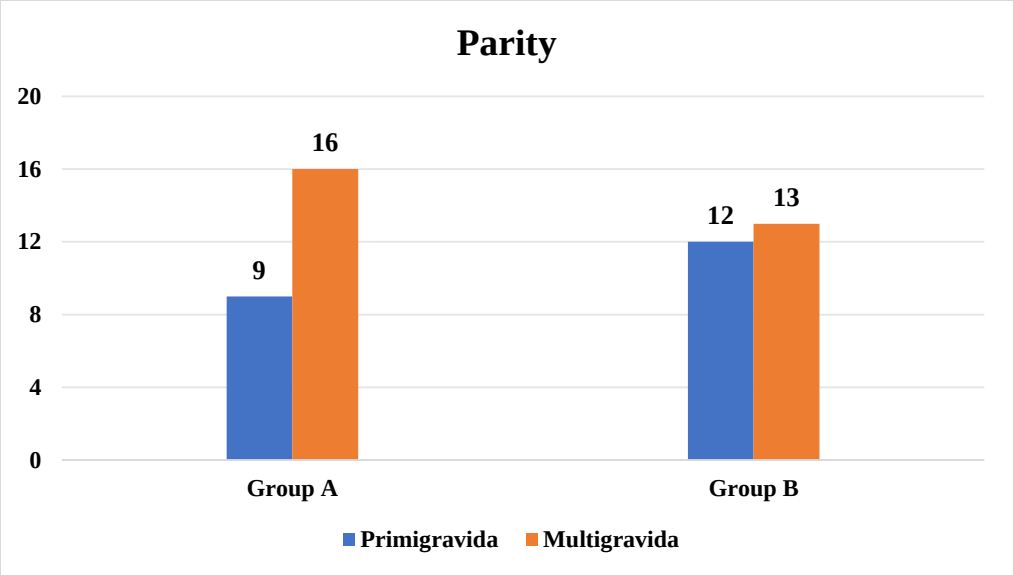


This table categorizes participants by age group. In Group A, which received Mifepristone 200mg orally, 84% (21 participants) were aged between 20–25 years, while 16% (4 participants) were in the 26–30 age range. Similarly, in Group B, which underwent Foley's balloon catheterisation, 88% (22 participants) were aged 20–25 and 12% (3 participants) were in the 26–30 age group. Thee *P* vaalue oof *0.684* indicates noo statistically signiificant diifference in thee age diistribution betweeen thee twoo grroups.

TABLE 2. Parity

Pariity	**Grroup A**	**Grroup B**	**P Value**
Priimigravida	9 (36%)	12 (48%)	
Multigravida	16 (64%)	13 (52%)	**0.39**
Total	**25 (100%)**	**25 (100%)**	

FIGURE 8. Parity

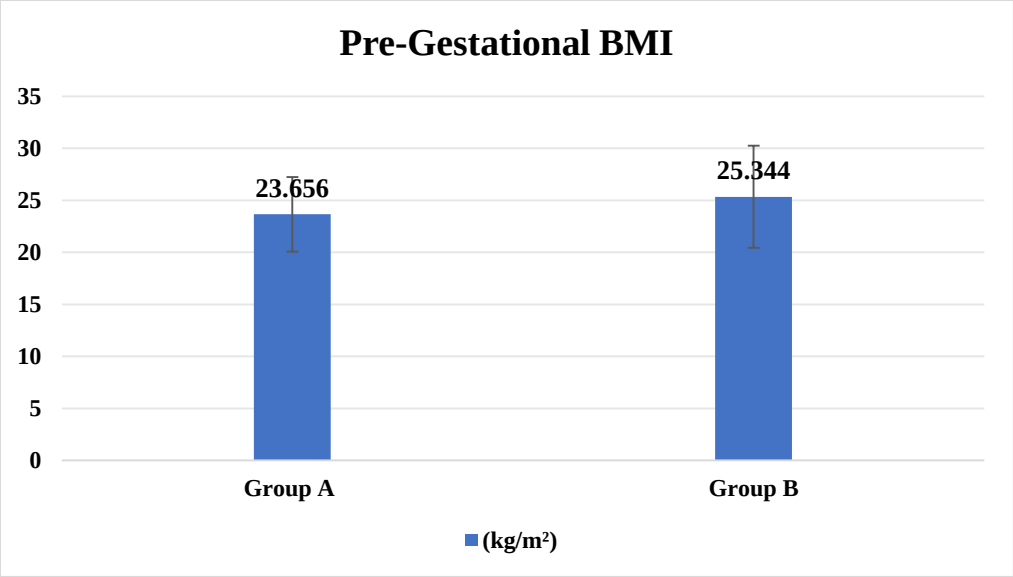


Parity data reveals that in Group A, 64% (16 participants) were multigravida and 36% (9 participants) were primigravida. In Group B, multigravida constituted 52% (13 participants) and primigravida 48% (12 participants). The P value of 0.39 suggests that parity distribution waas nott siignificantly diffeerent beetween thee grroups.

TABLEE 3. Pre-Gestational BMI

	Grroup A (MEEAN + SD)	**Grroup B (MEAAN + SD)**	**P VAALUE**
Pree-Gestational BMI (kg/m²)	23.656 ± 3.58	25.344 ± 4.91	**0.172**

FIGURE 9. Pre-Gestational BMI

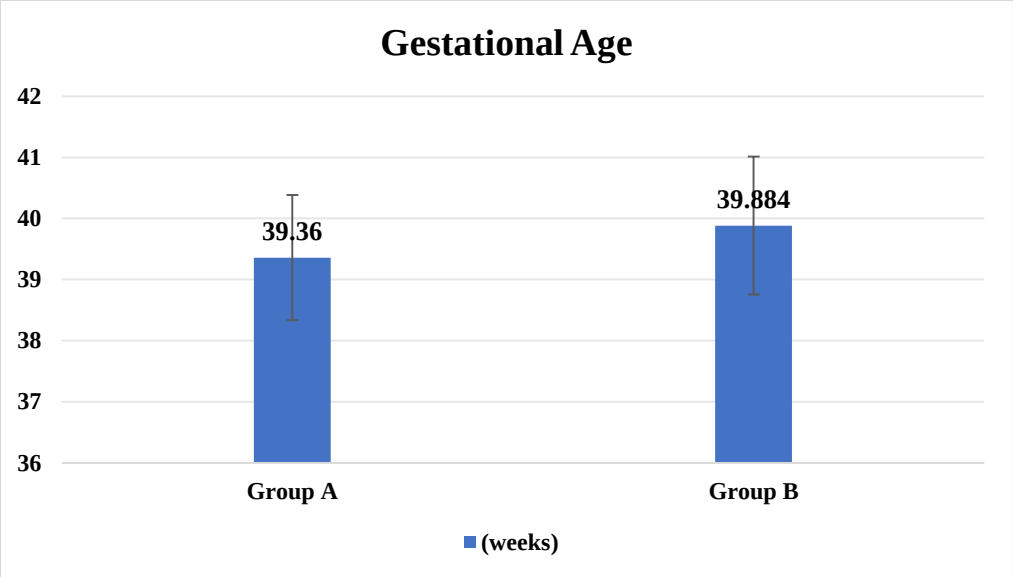


Grroup A haad aa meean prre-geestational bmi off 23.656 ± *3.58* kgg/m², whiile Grroup B's meean wass slightly higher att 25.344 ± 4.91 kg/m². The P vaalue off 0.172 indiicates noo signifiicant diffeerence iin baaseline BMI betweeen grroups.

TABLE 4. Geestational Agee

	Grroup A (MEAAN + SD)	**Group B (MEAAN + SD)**	**P VAALUE**
Geestational Agee (weeeks)	*39.36 ± 1.023*	*39.884 ± 1.13*	*0.983*

FIGURE 10. Geestational Agee

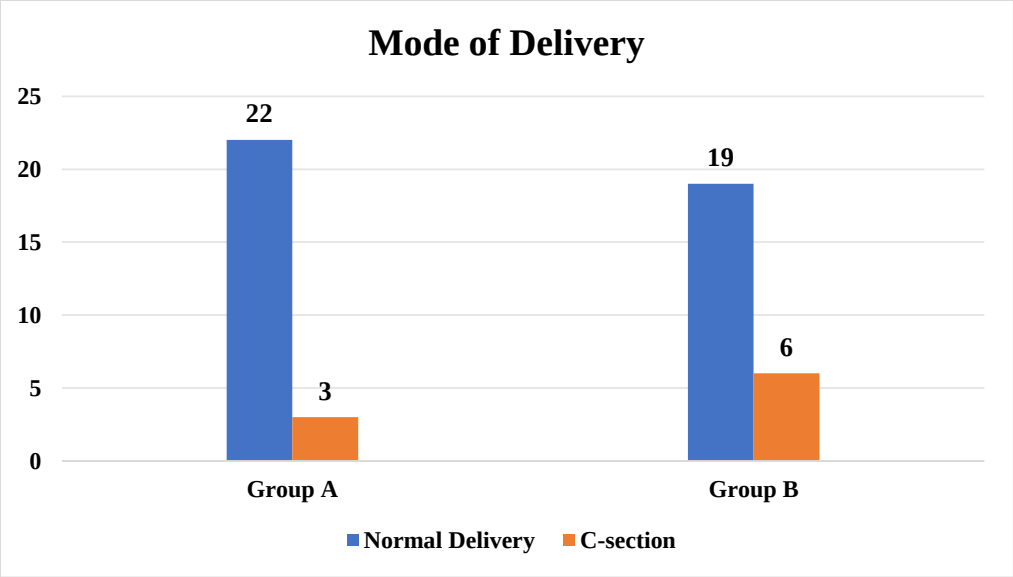


The meaan gestaational agee was *39.36 ± 1.023* weeeks iin Grroup A annd *39.884 ± 1.13* weeeks iin Grroup B. Thee P vaalue of *0.983* demonstrates that theere iis noo signiificant variiation iin geestational agee at thee tiime of intertrventiion.

TABLE 5. Moode off Deliivery

Moode off Deliivery	**Grroup A**	**Grroup B**	**P Vaalue**
Normal Delivery	22 (88%)	19 (76%)	**0.269**
C-section	3 (12%)	6 (24%)	
Total	**25 (100%)**	**25 (100%)**	

FIGURE 11. Mode of Delivery

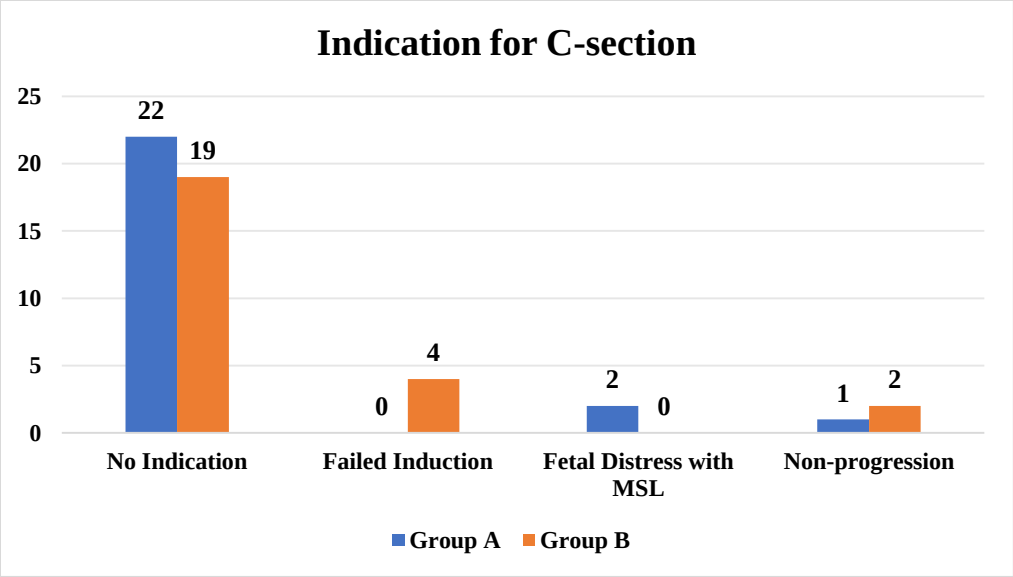


The mode of delivery indicates that 88% (22 participants) in Grouup A hadd normaal deliiveries compaared to 76% (19 participants) in Group B. C-section rates were higher in Group B at 24% (6 participants) compared to 12% (3 participants) in Group A. The P value of 0.269 shoows that thiis difference iis not statisticaly significant.

TABLLE 6. Indiication forr C-sectiion

Indiication forr Caesarean section	**Grroup A**	**Grroup B**	**P Vaalue**
No Indication	22 (88%)	19 (76%)	
Failed Induction	0 (0%)	4 (16%)	
Fetal Distress with MSL	2 (8%)	0 (0%)	**0.088**
Non-progression	1 (4%)	2 (8%)	
Total	**25 (100%)**	**25 (100%)**	

FIGURE 12. Indication for Caesarean section

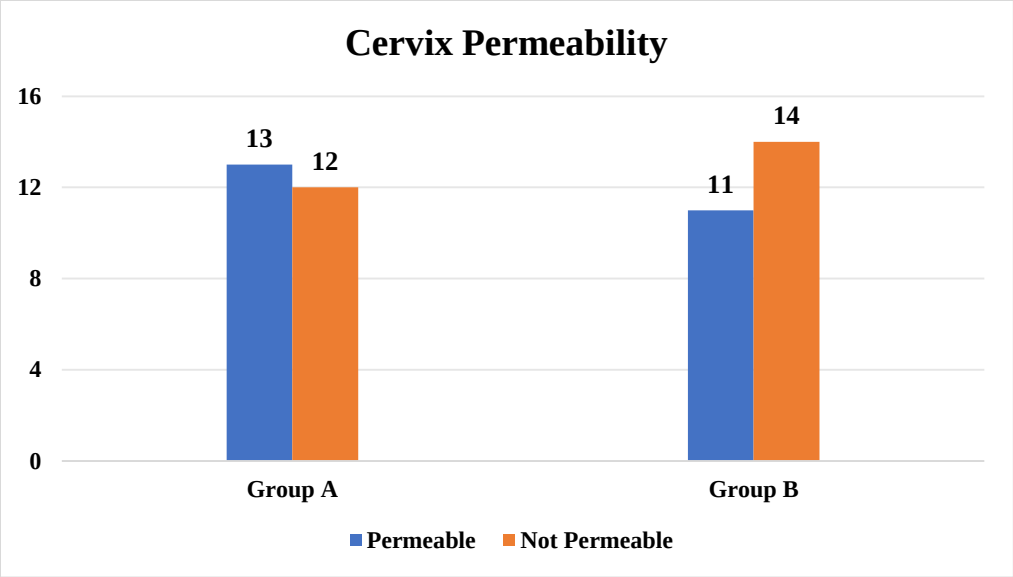


This table breaks down the specific indications for cesarean section. Group A had no cases of failed induction, two cases (8%) of fetal distreess wiith meconium staiined liquor (MSL), and one case (4%) of non-progression. In Group B, failed induction accounted for 16% (4 cases), non-progression was 8% (2 cases), and there were no cases of fetal distress with MSL. The proportion of participants with no indication for C-section was higher in Groupp A (88%) than Grouup B (76%), witth a P vallue of 0.088, showing borderline significance.

TABLE 7. Cervix Permeability

Cervix Permeability	**Group A**	**Group B**	**P Value**
Permeable	13 (52%)	11 (44%)	
Not Permeable	12 (48%)	14 (56%)	**0.571**
Total	**25 (100%)**	**25 (100%)**	

FIGURE 13. Cervix Permeability

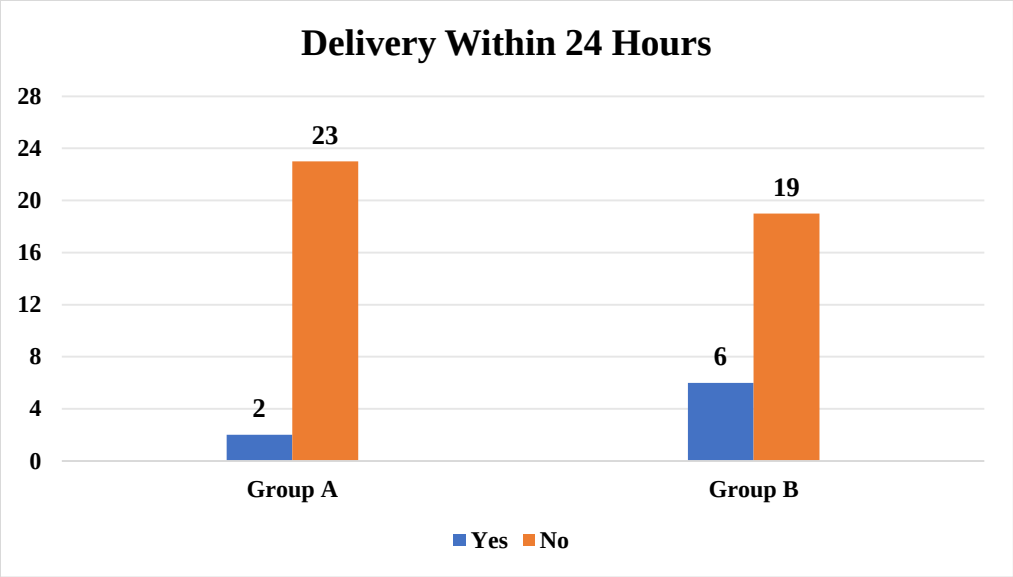


Permeability of the cervix was comparable between groups, with Group A having 52% permeability (13 participants) and Group B slightly lower at 44% (11 participants). Non-permeability was recorded in 48% off Grroup A aand 56% off Grroup B. The P valuee off 0.571 implies no significant difference in cervical status before induction.

TABLE 8. Delivery Within 24 Hours

Delivery Within 24 Hoours	**Grroup A**	**Grroup B**	**P Vaalue**
Yes	2 (8%)	6 (24%)	
No	23 (92%)	19 (76%)	**0.023**
Total	**25 (100%)**	**25 (100%)**	

TABLE 14. Delivery Within 24 Hours

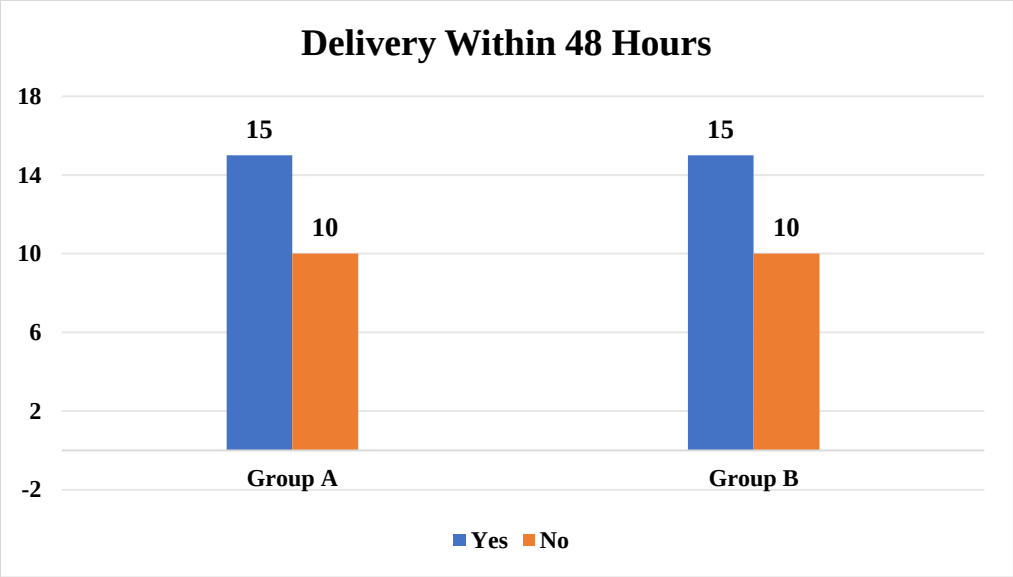


Only 8% (2 participants) of Group A deliivered witthin 24 hoours, compaared too 24% (6 participants) iin Group B. Thee majority in Groupp A (92%) and a slightly lower proportion in Group B (76%) did not deliver within this period. The P value of 0.023 indicates a non-significant difference.

TABLE 9. Delivery Within 48 Hours

Delivery Within 48 Hoours	**Grouup A**	**Gruoup B**	**P Value**
Yes	15 (60%)	15 (60%)	**1.000**
No	10 (40%)	10 (40%)	
Total	**25 (100%)**	**25 (100%)**	

FIGURE 15. Deliveery Within 48 Hours

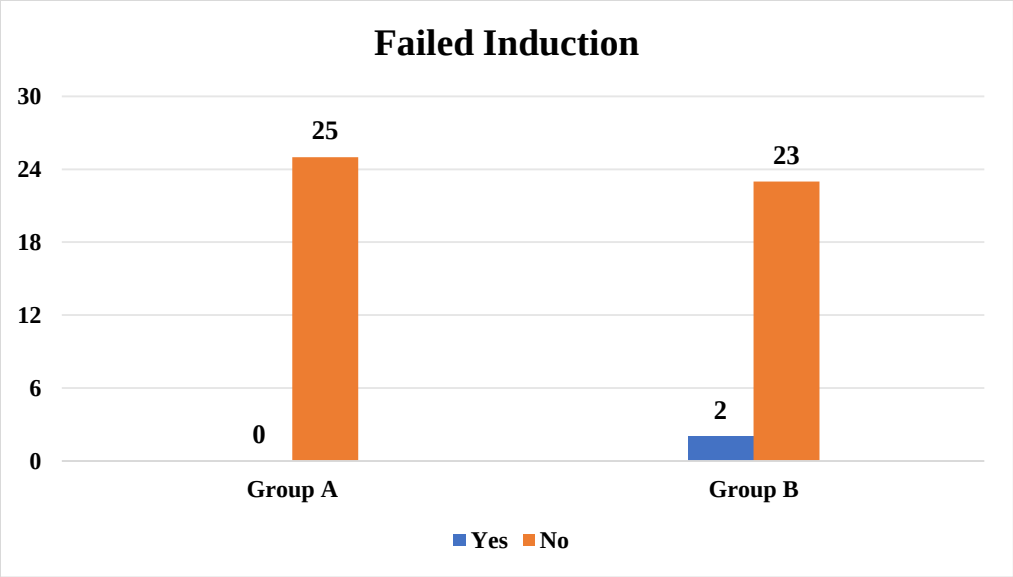


Both groups had identical outcomes for delivery within 48 hours, with 60% (15 participants) in each group delivering in this timeframe. The P value of 1 reflects no statistical difference between the groups in this regard.

TABLE 10. Failed Induction

Failed Induction	Group A	Group B	P Value
Yes	0 (0%)	2 (8%)	
No	25 (100%)	23 (92%)	**0.149**
Total	**25 (100%)**	**25 (100%)**	

FIGURE 16. Failed Induction

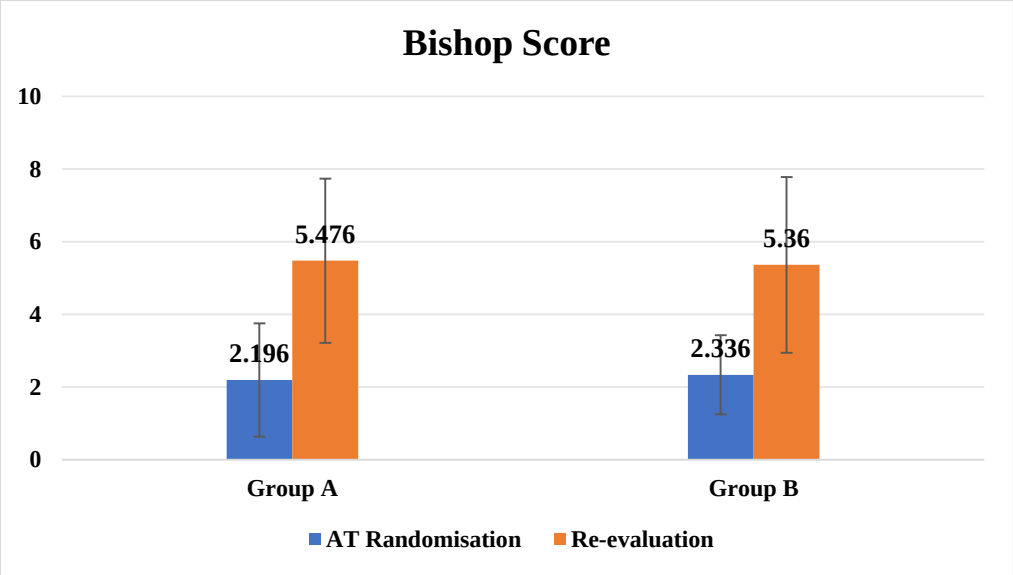


There were no cases of failed inducction in Grouup A, whiile Grouup B had 2 cases (8%). All 25 particiipants in Group A succesfully proceded to deliivery, whereas 92% (23 participants) did so in Grroup B. Thhe diifference is not staatistically siignificant wiith aa P vaalue oof 0.149.

TABLE 11. Bishop Score

Bishop Score	**Grooup A (MEEAN + SD)**	**Grouup B (MEEAN + SD)**	**P VAALUE**
AAT Randomisation	2.196 ± 1.56	2.336 ± 1.09	**0.716**
Re-evaluation	5.476 ± 2.26	5.36 ± 2.42	**0.862**

FIGURE 17. Bishop Score

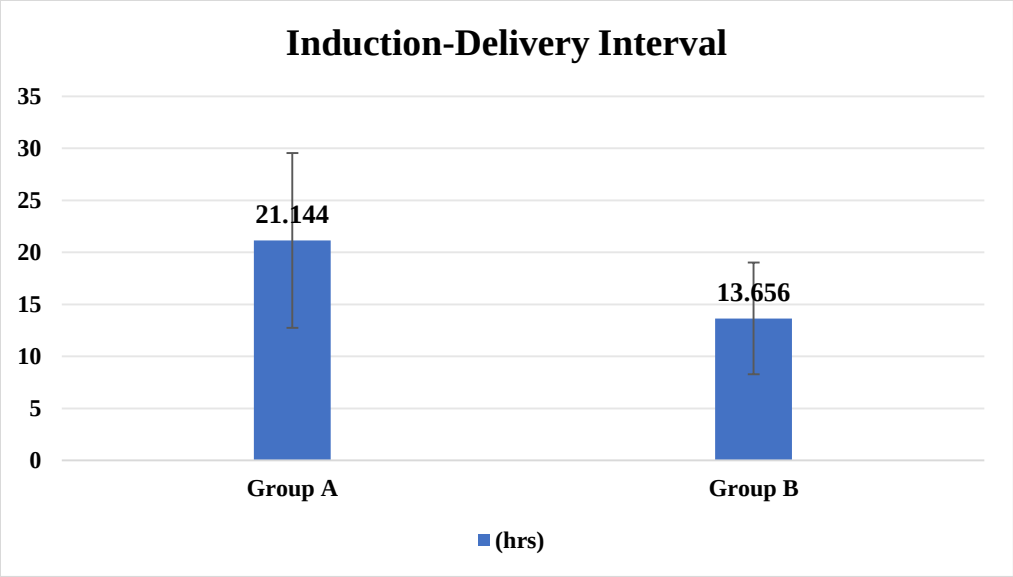


Initiial Bishop scores were 2.196 ± 1.56 foor Group A and 2.336 ± 1.09 for Group B. Upon re-evaluation, the scores improved to 5.476 ± 2.26 inn Grouup A and 5.36 ± 2.42 in Grouup B. The P values (0.716 foor initial and 0.862 for re-evaluation) show no significant difference iin cervical ripening progress between the groups.

TABLE 12. Induction-Delivery Interval

	Grooup A (MEAAN + SD)	**Grooup B (MEEAN + SD)**	**P VAALUE**
Induction-Delivery Interval (hrs)	21.144 ± 8.39	13.656 ± 5.36	**0.001**

FIGURE 18. Induction-Delivery Interval

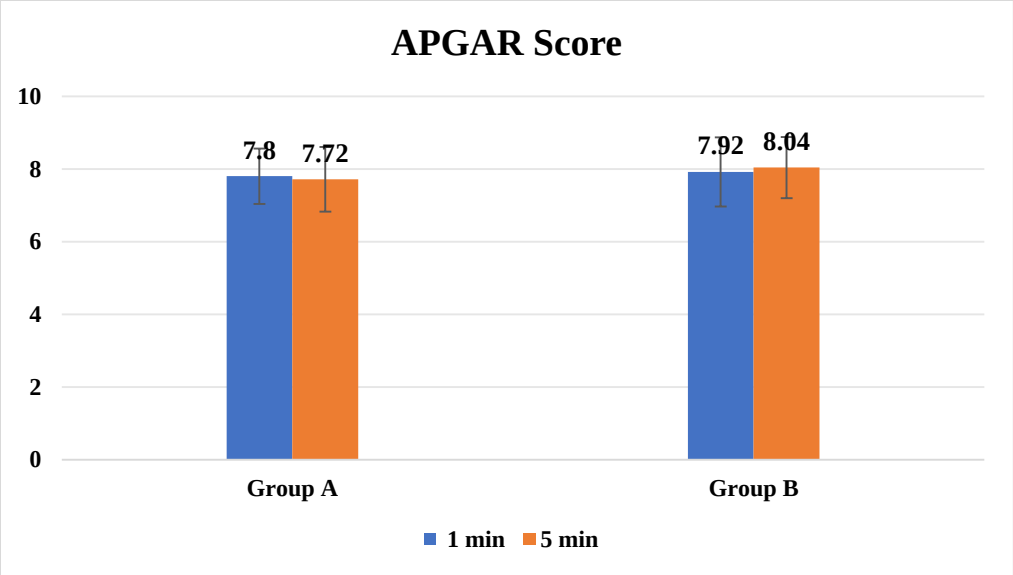


Group A had a significantly longer induction-to-delivery interval of 21.144 ± 8.39 hours, compared to 13.656 ± 5.36 hours in Grooup B. This diffeerence waas statisticallly signiificant wiith aa P vallue oof 0.001, suggesting that Foley's catheterization resulted in a quicker delivery process.

TABLE 13. APGAR Score

APGAR Scoore	**Grooup A (MEEAN + SD)**	**Grooup B (MEEAN + SD)**	**P VAALUE**
1 min	7.8 ± 0.76	7.92 ± 0.95	**0.626**
5 min	7.72 ± 0.89	8.04 ± 0.84	**0.198**

FIGURE 19. APGAR Score

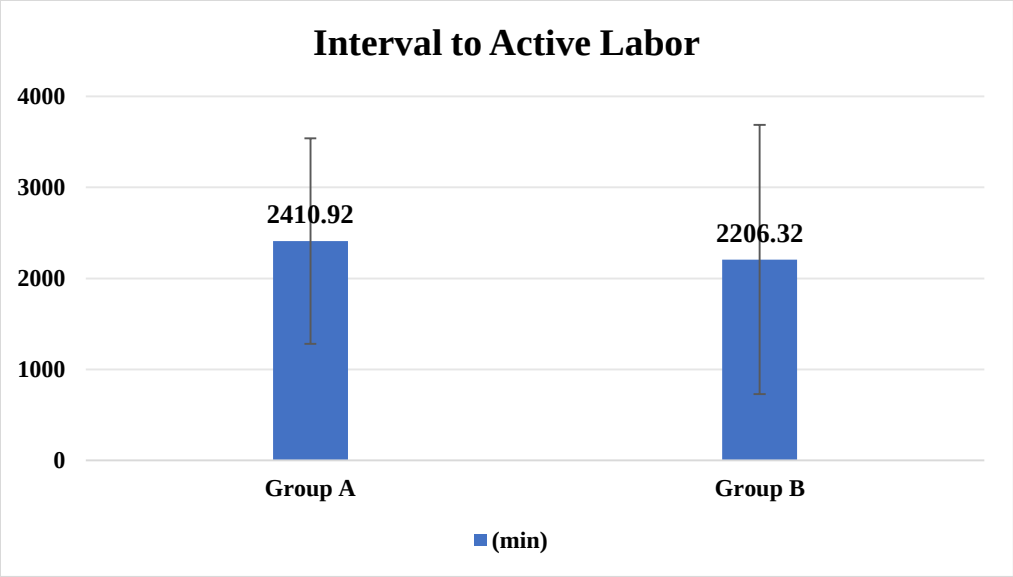


The average 1 minute APGAR score wass 7.8 ± 0.76 iin Grooup A aand 7.92 ± 0.95 inn Grroup B. Att 5 miinutes, scores were 7.72 ± 0.89 aand 8.04 ± 0.84 respectively. Neither time poiint showed significant differences, with P values of 0.626 and 0.198, indicating similar neonatal outcomes.

TABLE 14. Interval to Active Labor

	Grooup A (MEEAN + SD)	**Grroup B (MEEAN + SD)**	**P VAALUE**
Interval to Active Labor (min)	2410.92 ± 1128.7	2206.32 ± 1478.59	**0.585**

FIGURE 20. Interval to Active Labor



The time to reach active labor was 2410.92 ± 1128.7 miinutes in Group A and 2206.32 ± 1478.59 miinutes in Group B. The P value of 0.585 indicates noo significant difference in this inteerval between the twoo groups.

DISCUSSION

The preseent stuudy was under taken too evalluate and compare the efficacy and safety of oral mifepristone and transcervical Fooley cattheter in cerviical ripening and labor induccttion at term. Given the ongoing debate over optimal induction methods—especially in low-resource and VBAC-eligible populations—this study aimed to assess not only clinical effectiveness (in terms of delivery rates, induction intervals, and cervical readiness) but also maternal and neonatal safety outcomes. The findings were interpreted within the broader context of available literature to better understand how our data align with or differ from existing evidence.

To ensure the validity and clinical applicability of our results, comparisons were made with a range of contemporary studies—both randomized controlled trials and observational cohorts—where similar methodologies, outcome measures, and patient profiles were used. Each core parameter has been evaluated against these external sources

to identify trends, discrepancies, and potential explanatory factors. This comparative approach enhances the robustness of our conclusions and provides a multidimensional view of the relative benefits and limitations of both induction methods.

Baseline Characteristics

Age Distribution

In our study, the majority of particiipants were ageed between 20 to 25 years in both groups (84% inn thhe mifepristone grroup annd 88% inn thhe Foley catheter grroup), wiith nno statistically siignificant diifference (P = 0.684). Comparatively,the study reported a slightly older population, with mean ages of 28.65 ± 5.47 years in the mifepristone group and 27.71 ± 4.22 years in the Foley group[67].Anotherr study conducted where it is observed even higher mean ages around 31 years in both arms[62]. Similarly,anotherr studyy found mean ages ranging from 25 to 31 years across parity groups[68]. Later studies also documented mean ages in the late twenties across study groups[69]. Across all these studies, age was well-balanced and showed no significant influence on induction outcomes—consistent with our findings.

Parity

Our study demonstrated a higher proportion of multigravida women in the mifepristone group (64%) compareed too thee Fooley grroup (52%), although thiis diffference waas nott stattistically significant (P = 0.39). This trend aligns with findings from various studies, who reported 62.22% multigravidas in the mifepristone group and 52.22% in the Foley group[70]. Recent studies reveelaed presented a different pattern, with more nulliparous women in the mifepristone group (79.2%) than in the Foley group (67.9%)SStudies reported a median parity of one in both arms. Taken together, these

studies indicate that parity was adequately balanced and unlikely to confound induction outcomes across cohorts[68].

Pre-Gestational BMI

The average pre-gestational BMI in our study was 23.656 ± 3.58 kg/m² in the mifepristone group and 25.344 ± 4.91 kg/m² in the Foley group, with no statistical significance (P = 0.172). Similar findings were observed in a study conducted ,where BMI was comparable between groups (24.2 vs. 25.1 kg/m², P = 0.88), suggesting that BMI does not significantly influence the choice or efficacy of induction methods[62].

Gestational Age

Gestational age at induction in our study was comparable between groups—39.36 ± 1.02 weeks in the mifepristone group and 39.88 ± 1.13 weeks in the Foley group (P = 0.983). Many studiies later reported similar gestational ages in both arms (39.46 vs. 39.51 weeks), and observed that medians of 40.7 and 40.5 weeks[62]. These consistent gestational parameters across studies help confirm the internal comparability of intervention outcomes.

Labor Outcomes and Delivery

Mode of Delivery

In our study, normal vaginal delivery waas moore freequent iin tthe mifepristone grouup (88%) compareed to the Foley grooup (76%), though this diifference waas not statisticallly signifiicant (P = 0.269). Many studies found nearly identical trends[70] (87.78% vs. 77.78%), whereas few observers identified a statistically significant advantage in vaginal deliveries with mifepristone [71](61.53% vs. 32.3%, P < 0.001). Contrarily,reported higher vaginal delivery rates in the Foley group[72] (71.7% vs. 56.2%), although this was

not statistically significant. Notably, Radzinsky emphasized that all multiparous women in the mifepristone group delivered vaginally, compared to 69.3% in the Foley group—highlighting a possible advantage for mifepristone in multigravida women[17]. Meta-analytic evidence from further supported a slightly reduced likelihood of vaginal delivery with Foley catheter use (RR = 0.95, 95% CI: 0.91–0.99), aligning with our study's direction[66].

Indications for Cesarean Section

Our study noted that failed inductions occurred exclusively inn thee Foley group (16%), while fetal distress with meconium-stained liquor (MSL) was seen only in the mifepristone groupp (8%). Thhe overall diifference waas nott statisstically siignificant (P = 0.088).other studies documented more cesareans for failed induction and pathological CTG in the Foley group, and found higher rates of scar tenderness (13.33% vs. 3.33%) in the Foley arm[70]. These results suggest that while mifepristone may increase risk of fetal distress, Foley is more often associated with mechanical failure or prolonged induction.

Cervical Permeability

Inn ourr stuudy, 52% off participants iin the mifepristone grroup and 44% inn the Foley grooup haad a permeable cervix, with no significant difference (P = 0.571). Later similarly found near-identical rates (47.2% vs. 47.9%), reinforcing the notion that both methods are comparable in their initial mechanical effect on the cervix[62].

Time-Based Delivery Metrics

Delivery Within 24 Hours

A significantly higgher prroportion oof woomen inn thhe Foley grooup delivered withiin 24 hours (24%) commpared too only 8% in thhe mifepristone group (P = 0.023).

This is supported by other researches ,[14]who found 55.7–63.6% 24-hour delivery rates with Foley versus 20.7–23.1% with mifepristone[14].various reports also reported higher 24-hour delivery rates with misoprostol than Foley (57% vs. 47%, P = 0.0136), reinforcing Foley's advantage in shorter induction intervals.

Delivery Within 48 Hours

Both groups in our study had equal 48-hour delivery rates (60%, P = 1.000). local studies reported similar findings, with slightly higher rates in the Foley group (62.3% vs. 54.2%, P = 0.410), showing that over extended intervals, the differences between methods tend to diminish[62].

Failed Induction

In our study, no failed inductions were observed in the mifepristone group, whereas 8% of Foley cases failed to progress (P = 0.149). Previous studies similarly reported higher failure rates with Foley catheter. This supports the notion that mifepristone may provide more consistent induction outcomes, especially in cases where mechanical ripening alone may be insufficient[62].

Induction-to-Delivery Interval

Thee meean inducction-tto-dellivery interrval waas signiificantly shoorter inn tthe Foley grooup (13.65 ± 5.36 hrs) compared to the mifepristone group (21.14 ± 8.39 hrs), with statistical significance (P = 0.001). This was corroborated by prevuous studies who also found significantly shorter intervals with Foley catheter[72], though studying second-trimester terminations, reported similar findings in favor of Foley in combination settings[71].

Interval to Active Labor

The time to active labor was comparable in our study (2410.92 mins in Group A vs. 2206.32 mins in Group B, P = 0.585), and not statistically significant. This aligns with suggestive reported similar times (2422 vs. 2194 mins, P = 0.381), reinforcing that while Foley may slightly expedite labor onset, the difference may not always translate into clinical relevance[73].

Cervical Readiness

Bishop Score

Our study showed improvements in Bishop scores in both groups, but without significant intergroup difference at baseline or re-evaluation (P = 0.716 and 0.862, respectively). Laterr studies found a significantly higher Bishop score at 12 hours with Foley (P = 0.039), but by 24–36 hours, differences evened out. in contrast, it is found better improvements with mifepristone (P = 0.002), along with a higher proportion achieving favorable scores (P = 0.050). similar studies noted improved cervical favorability in Foley-treated primigravidae[68]. These mixed findings suggest that while both agents enhance cervical readiness, their optimal timing and mechanism may differ.

Neonatal Outcome

APGAR Scores

In our study, APGAAR scoores att 1 annd 5 miinutes were comparable acrross grooups and not statistically different (P = 0.626 and 0.198, respectively). Priimary stuudies reported similar neonatal scores, confirming both methods are safe in terms of immediate neonatal outcomes[69]. Reports showedd fewer abnormal 5-minute APGARs and NICU admissions in the Foley + misoprostol group, suggesting a potential advantage with mechanical support in high-risk contexts[74].

NICU Admission and Neonatal Safety

We observed no NICU admissions or significant complications.

Our findings align closely with current literature, reaffirming that both mifepristone and Foley catheter are effective and safe for cervical ripening and labor induction. Mifeprristone iis associated with higher rates of vaginal delivery and fewer induction failures, while Foley catheter offers faster onset of labor and shorter induction-to-delivery intervals. Neonatal outcomes remain comparable between methods. The choice between the two should thus consider clinical urgency, maternal parity, and logistical factors such as time constraints or prior cesarean status.

LIMITATIIONS

Whille thee fiindings off thiis study contriibute meaningfully to thee ongoing evaluation oof cervical ripening agents, seeveral liimitations shhould bee ackknowledged:

1. **Sample Size**: The study involved a relatively small cohort, which, while statistically powered for primary outcomes, may not capture rare maternal or neonatal complications or allow robust subgroup analysis (e.g., VBAC, post-term, or primigravida-only cohorts).
2. **Single-Center Design**: As a single-institution study, findings may not be universally generalizable across populations with differing maternal demographics, induction protocols, or health care infrastructure.
3. **Lack of Blinding**: Due to the nature of interventions, blinding was not feasible, potentially introducing observational bias, particularly in subjective outcomes like Bishop score evaluation and pain perception.

4. **Exclusion of Combination Regimens**: Only single-agent regimens (mifepristone alone or Foley alone) were studied. Combination methods, which are increasingly supported in recent literature, were not evaluated.

5. **Neonatal Follow-up**: While immediate neonatal outcomes (e.g., APGAR score, NICU admission) were assessed, long-term neonatal morbidity was not included, limiting comprehensive safety profiling.

RECOOMMENDATIONS

Baased oon thhe fiindings aand liimitations off thiis stuudy, thee folloowing recoommendations aare prooposed:

1. **Larger, Multicenter Trials**: To validate these findings, future studies should involve larger, multicenter cohorts, ideally incorporating diverse patient populations and clinical settings.

2. **Evaluation of Combination Protocols**: Future trials should compare single-agent methods with combination regimens (e.g., Foley + mifepristone or Foley + misoprostol), which have shown synergistic effects in other studies.

3. **Stratified Analysis by Parity and Cervical Status**: Outcomes may differ significantly between primigravidas and multigravidas or based on pre-induction Bishop scores; thus, stratified or subgroup analyses are warranted.

4. **Patient-Centered Outcomes**: Future studies should incorporate patient-reported outcomes, including pain scores, satisfaction, and ease of ambulation during cervical ripening.

5. **Long-Term Neonatal Outcomes**: Incorporating follow-up data on neonatal development and morbidity could provide a more comprehensive safety assessment of these induction methods.

CONCLUSION

This study demonstrated that **oral mifepristone (200 mg)** and **transcervical Foley catheter** are both effective and safe methods foor cervvical riipening aand labor induction aat teerm. **Mifepristone was associiated witth higher rates oof vaaginal deelivery and fewer induction failures**, while **Foley catheter offered a faster inductioon-too-deliveery iinterval aand aa significantly hiigher raate off delivery wiithin 24 hoours**. Cervical readiness and neonatal outcoomes werre comparable betweeen the twwo grooups, with noo signiificant diifference in APGAR scores or NICU admissions. The findings support the clinical utility of both methods, with the choice of agent potentially tailored to individual patient factors such as urgency of induction, prior cesarean, or institutional resources. However, the observed trends and limitations underscore the need for further robust comparative studies, particularly those assessing combination protocols and longer-term maternal and neonatal outcomes.

SUMMARY

This prospective, comparative study was conducted to evaluate and compare the efficacy, cervical ripening potential, delivery outcomes, and neonatal safety of **oral mifepristone (200 mg)** versus **transcervical Foley catheterisation** in term pregnancies requiring labor induction.

Key Findings

- **Age & Demographics**:
    - Most participants in both groups were aged 20–25 years (84% in Group A, 88% in Group B).
    - No significant difference in age, parity, gestational age, or BMI between groups, ensuring well-matched cohorts.
- **Cervical Readiness**:
    - Initial and post-intervention Bishop scorees impproved signiificantly iin bothh grooups.
    - Noo statiistically signifiicant intergroup diffeerence in Bishop scores at re-evaluation (P = 0.862).
- **Induction Efficiency**:
    - **Foley catheter group** had a **shorter induction-to-delivery interval** (13.65 hrs vs. 21.14 hrs; *P = 0.001*).
    - **More womeen deliveered withiin 24 hoours** in the Foley group (24% vs. 8%; *P = 0.023*).
    - **Failed induction occurred only** in the Foley group (8%); none in the mifepristone group.
- **Mode of Delivery**:
    - Vaginal delivery was more frequent in the mifepristone group (88% vs. 76%), but not statistically significant (*P = 0.269*).

- Ceasarean seection duee too faileed inductionn was exclusive to thee Foleys groupp.

- **Cervical Permeability**:
  - Comparable between both groups (52% iin Groupp A vs. 44% iin Groupp B; *P = 0.571*).

- **Neonatal Outcomes**:
  - Mean APPGAR scoores att 1 andd 5 minutes weere **siimilar between grroups** (*P = 0.626, P = 0.198*).
  - **No NICU admissions** were reported in either group.

REFERENCES

1. Babu S ML. Elective induction versus spontaneous labor at term: prospective study of outcome and complications. Int J Reprod Contracept Obstet Gynecol. 2017 Oct;6(11):4899.

2. Sande HA, Tuveng J, Fønstelien T. A prospective randomized study of induction of labor. International Journal of Gynecology & Obstetrics. 1983 Aug 22;21(4):333–6.

3. Knutzen VK, Tanneberger U, Davey DA. Complications and outcome of induced labour. S Afr Med J. 1977 Sep 10;52(12):482–5.

4. Swamy GK. Current Methods of Labor Induction. Semin Perinatol. 2012 Oct;36(5):348–52.

5. Zhang J, Troendle J, Reddy UM, Laughon SK, Branch DW, Burkman R, et al. Contemporary cesarean delivery practice in the United States. Am J Obstet Gynecol. 2010 Oct;203(4):326.e1-326.e10.

6. Battista L, Chung JH, Lagrew DC, Wing DA. Complications of labor induction among multiparous women in a community-based hospital system. Am J Obstet Gynecol. 2007 Sep;197(3):241.e1-241.e7.

7. Clark SL, Miller DD, Belfort MA, Dildy GA, Frye DK, Meyers JA. Neonatal and maternal outcomes associated with elective term delivery. Am J Obstet Gynecol. 2009 Feb;200(2):156.e1-156.e4.

8. Hoffman MK, Vahratian A, Sciscione AC, Troendle JF, Zhang J. Comparison of Labor Progression Between Induced and Noninduced Multiparous Women. Obstetrics & Gynecology. 2006 May;107(5):1029–34.

9. Yeast JD, Jones A, Poskin M. Induction of labor and the relationship to cesarean delivery: A review of 7001 consecutive inductions. Am J Obstet Gynecol. 1999 Mar;180(3):628–33.

10. Kaufman KE, Bailit JL, Grobman W. Elective induction: An analysis of economic and health consequences. Am J Obstet Gynecol. 2002 Oct;187(4):858–63.

11. Gallot D, de Lapasse C, Houlle C, Sapin V, Laurichesse-Delmas H, Saulnier JP, et al. Pronostic obstétrical du déclenchement artificiel du travail au-delà de 41 semaines d'aménorrhée en fonction de la réponse à la mifépristone. Gynecol Obstet Fertil. 2004 Sep;32(9):708–12.

12. Heikinheimo O. Clinical Pharmacokinetics of Mifepristone. Clin Pharmacokinet. 1997 Jul;33(1):7–17.

13. Amrutha V Mbbs BA. "COMPARATIVE STUDY OF EFFICACY AND SAFETY OF MIFEPRISTONE AND FOLEY'S CATHETER IN INDUCTION OF LABOUR". Karnataka in partial fulfilment of the requirements for the degree of MASTER OF SURGERY IN OBSTETRICS AND GYNAECOLOGY ASSOCIATE PROFESSOR DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY VIJAYANAGAR INSTITUTE OF MEDICAL SCIENCES.

14. Radzinsky VE, Startseva NM, Doronina OK, Teplov K V., Borisova A V. Mifepristone versus balloon catheter for labor induction: a cohort study. The Journal of Maternal-Fetal & Neonatal Medicine. 2022 Nov 30;35(25):9331–5.

15. Kilpatrick S, Garrison E. Normal and problem pregnancies. 17th ed. 2017. 246–270 p.

16. Creasy RK, Resnik R. Creasy and Resnik Maternal -fetal medicine: principles and practice. 7th ed. 2014. 1294 p.

17. Madden JD, Gant NF, MacDonald PC. Study of the kinetics of conversion of maternal plasma dehydroisoandrosterone sulfate to 16α-hydroxydehydroisoandrosterone sulfate, estradiol, and estriol. Am J Obstet Gynecol. 1978 Oct;132(4):392–5.

18. Mecenas CA, Giussani DA, Owiny JR, Jenkins SL, Wu WX, Honnebier BO, et al. Production of premature delivery in pregnant rhesus monkeys by androstenedione infusion. Nat Med. 1996 Apr;2(4):443–8.

19. Nathanielsz PW, Jenkins SL, Tame JD, Winter JA, Guller S, Giussani DA. Local paracrine effects of estradiol are central to parturition in the rhesus monkey. Nat Med. 1998 Apr;4(4):456–9.

20. Garfield RE, Sims S, Daniel EE. Gap Junctions: Their Presence and Necessity in Myometrium During Parturition. Science (1979). 1977 Dec 2;198(4320):958–60.

21. Julia Hutchison;Jenkins;, Heba Mahdy, Suzanne M. Normal Labor: Physiology, Evaluation, and Management.

22. Perlman NC, Carusi DA. Retained placenta after vaginal delivery: risk factors and management . Int J Womens Health. 2019 Oct;Volume 11:527–34.

23. W. Arage M. Labor Induction. In: New Aspects in Cesarean Sections. IntechOpen; 2023.

24. jenkins SN, van hook JW. indcution of labour. may. 2025.

25. labour induction -acog. may. 2025.

26. arias MD, fernand. arias practical guide to high risk pregnancy and delivery. 2019.

27. Practice Bulletin No. 135. Obstetrics & Gynecology. 2013 Jun;121(6):1394–406.

28. Kumar N, Haas DM, Weeks AD. Misoprostol for labour induction. Best Pract Res Clin Obstet Gynaecol. 2021 Nov;77:53–63.

29. Levine LD, Downes KL, Elovitz MA, Parry S, Sammel MD, Srinivas SK. Mechanical and Pharmacologic Methods of Labor Induction. Obstetrics & Gynecology. 2016 Dec;128(6):1357–64.

30. Ruscheinsky M, De la Motte C, Mahendroo M. Hyaluronan and its binding proteins during cervical ripening and parturition: Dynamic changes in size, distribution and temporal sequence. Matrix Biology. 2008 Jun;27(5):487–97.

31. El Maradny E, Kanayama N, Kobayashi H, Hossain B, Khatun S, Liping S, et al. The role of hyaluronic acid as a mediator and regulator of cervical ripening. Human Reproduction. 1997 May 1;12(5):1080–8.

32. Norman M, Ekman G, Malmström A. Changed proteoglycan metabolism in human cervix immediately after spontaneous vaginal delivery. Obstetrics and gynecology. 1993 Feb;81(2):217–23.

33. Socha MW, Flis W, Pietrus M, Wartęga M, Stankiewicz M. Signaling Pathways Regulating Human Cervical Ripening in Preterm and Term Delivery. Cells. 2022 Nov 21;11(22):3690.

34. Osmers R, Rath W, Adelmann-Grill BC, Fittkow C, Kuloczik M, Szeverényi M, et al. Origin of cervical collagenase during parturition. Am J Obstet Gynecol. 1992 May;166(5):1455–60.

35. Visse R, Nagase H. Matrix Metalloproteinases and Tissue Inhibitors of Metalloproteinases. Circ Res. 2003 May 2;92(8):827–39.

36. Uldbjerg N, Ekman G, Malmström A, Olsson K, Ulmsten U. Ripening of the human uterine cervix related to changes in collagen, glycosaminoglycans, and collagenolytic activity. Am J Obstet Gynecol. 1983 Nov;147(6):662–6.

37. Ledingham MA, Denison FC, Riley SC, Norman JE. Matrix metalloproteinases-2 and -9 and their inhibitors are produced by the human uterine cervix but their secretion is not regulated by nitric oxide donors. Human Reproduction. 1999 Aug;14(8):2089–96.

38. Bollopragada S, Youssef R, Jordan F, Greer I, Norman J, Nelson S. Term labor is associated with a core inflammatory response in human fetal membranes, myometrium, and cervix. Am J Obstet Gynecol. 2009 Jan;200(1):104.e1-104.e11.

39. Gomez-Lopez N, Guilbert LJ, Olson DM. Invasion of the leukocytes into the fetal-maternal interface during pregnancy. J Leukoc Biol. 2010 Jun 2;88(4):625–33.

40. Helmig BR, Romero R, Espinoza J, Chaiworapongsa T, Bujold E, Gomez R, et al. Neutrophil elastase and secretory leukocyte protease inhibitor in prelabor rupture of membranes, parturition and intra-amniotic infection. The Journal of Maternal-Fetal & Neonatal Medicine. 2002 Jan 7;12(4):237–46.

41. Junqueira LCU, Zugaib M, Montes GS, Toledo OMS, Krisztán RM, Shigihara KM. Morphologic and histochemical evidence for the occurrence of collagenolysis and for the role of neutrophilic polymorphonuclear leukocytes during cervical dilation. Am J Obstet Gynecol. 1980 Oct;138(3):273–81.

42. Pavlov O, Pavlova O, Ailamazyan E, Selkov S. ORIGINAL ARTICLE: Characterization of Cytokine Production by Human Term Placenta Macrophages *In Vitro*. American Journal of Reproductive Immunology. 2008 Dec 6;60(6):556–67.

43. Menzies FM, Shepherd MC, Nibbs RJ, Nelson SM. The role of mast cells and their mediators in reproduction, pregnancy and labour. Hum Reprod Update. 2011 May 1;17(3):383–96.

44. Gomez-Lopez N, Galaz J, Miller D, Farias-Jofre M, Liu Z, Arenas-Hernandez M, et al. The immunobiology of preterm labor and birth: intra-amniotic inflammation or breakdown of maternal–fetal homeostasis. Reproduction. 2022 Aug 1;164(2):R11–45.

45. Juremalm M, Nilssin G. Chemokine receptor expression by mast cells: chemical immunology. In 2025. p. 130–44.

46. Rudolph MI, Reinicke K, Cruz MA, Gallardo V, Gonzalez C, Bardisa L. Distribution of mast cells and the effect of their mediators on contractility in human myometrium. BJOG. 1993 Dec 19;100(12):1125–30.

47. Bytautiene E, Romero R, Vedernikov YP, El-Zeky F, Saade GR, Garfield RE. Induction of premature labor and delivery by allergic reaction and prevention by histamine H1 receptor antagonist. Am J Obstet Gynecol. 2004 Oct;191(4):1356–61.

48. Willets JM, Taylor AH, Shaw H, Konje JC, Challiss RAJ. Selective Regulation of H 1 Histamine Receptor Signaling by G Protein-Coupled Receptor Kinase 2 in Uterine Smooth Muscle Cells. Molecular Endocrinology. 2008 Aug;22(8):1893–907.

49. Breyer RM, Bagdassarian CK, Myers SA, Breyer MD. Prostanoid Receptors: Subtypes and Signaling. Annu Rev Pharmacol Toxicol. 2001 Apr;41(1):661–90.

50. ACOG Committee Opinion #67: Medical Management of Abortion. Obstetrics & Gynecology. 2005 Oct;106(4):871–82.

51. Hapangama D, Neilson JP. Mifepristone for induction of labour. Cochrane Database of Systematic Reviews. 2009 Jul 8;

52. Prairie BA, Lauria MR, Kapp N, MacKenzie T, Baker ER, George KE. Mifepristone versus laminaria: a randomized controlled trial of cervical ripening in midtrimester termination. Contraception. 2007 Nov;76(5):383–8.

53. Jindal N, Rao R, Dhiman B, Kandoria M, Jamwal A. Safety and efficacy of mifepristone versus dinoprostone gel in induction of labor: A randomized controlled trial. Journal of Obstetrics and Gynaecology Research. 2019 Aug 7;45(8):1530–5.

54. McGill J, Shetty A. Mifepristone and misoprostol in the induction of labor at term. International Journal of Gynecology & Obstetrics. 2007 Feb;96(2):80–4.

55. Sciscione A, Larkin M, O'Shea A, Pollock M, Hoffman M, Colmorgen G. Preinduction cervical ripening with the Foley catheter and the risk of subsequent preterm birth. Am J Obstet Gynecol. 2004 Mar;190(3):751–4.

56. Burgio K. Risk factors for fecal and urinary incontinence after childbirth: The childbirth and pelvic symptoms study. Am J Obstet Gynecol. 2006 Dec;195(6):S102.

57. Lyndrup J, Nickelsen C, Weber T, Mølnitz E, Guldbæk E. Induction of labour by balloon catheter with extra-amniotic saline infusion (BCEAS): a randomised comparison with PGE2 vaginal pessaries. European Journal of Obstetrics & Gynecology and Reproductive Biology. 1994 Mar;53(3):189–97.

58. Schoen CN, Saccone G, Berghella V, Baker EG. Traction vs no traction in Foley catheter use for induction of labor: a systematic review and meta-analysis of randomized trials. Am J Obstet Gynecol MFM. 2022 Jul;4(4):100610.

59. McMaster K, Sanchez-Ramos L, Kaunitz AM. Evaluation of a Transcervical Foley Catheter as a Source of Infection. Obstetrics & Gynecology. 2015 Sep;126(3):539–51.

60. Mackeen AD, Durie DE, Lin M, Huls CK, Qureshey E, Paglia MJ, et al. Foley Plus Oxytocin Compared With Oxytocin for Induction After Membrane Rupture. Obstetrics & Gynecology. 2018 Jan;131(1):4–11.

61. KARL E. MILLER MD. Ripening of the Cervix and Risk for Later Preterm Birth. 2005. 157–163 p.

62. Carvalho-Afonso M, Antunes M, Fonseca A, Ayres-de-Campos D. Mifepristone versus Foley balloon catheter for outpatient cervical ripening at term: A non-inferiority randomised controlled trial. European Journal of Obstetrics & Gynecology and Reproductive Biology. 2025 Feb;305:253–9.

63. Forgie MM, Greer DM, Kram JJF, Vander Wyst KB, Salvo NP, Siddiqui DS. Foley catheter placement for induction of labor with or without stylette: a randomized clinical trial. Am J Obstet Gynecol. 2016 Mar;214(3):397.e1-397.e10.

64. Sharma C, Jaryal S, Soni A. Foley catheter (80 vs 60 mL) and misoprostol for labor induction in nulliparous women: a randomized controlled trial. Am J Obstet Gynecol MFM. 2023 Aug;5(8):101026.

65. Sandberg EM, Schepers EM, Sitter RL van, Huisman CMA, Wijngaarden WJ van. Foley catheter for induction of labour filled with 30 mL or 60 mL: A randomized controlled trial. European Journal of Obstetrics & Gynecology and Reproductive Biology. 2017 Apr;211:150–5.

66. Kemper JI, Li W, Goni S, Flanagan M, Weeks A, Alfirevic Z, et al. Foley catheter *vs* oral misoprostol for induction of labor: individual participant data meta-analysis. Ultrasound in Obstetrics & Gynecology. 2021 Feb;57(2):215–23.

67. tomar, yugantika. Effectiveness of mifepristone versus balloon catheter in induction of labour in women with previous caesarean sections: a randomised comparative study.

68. Goonewardene M, Kumara DMA, Ziard MH, Bhabu B. Intra Cervical Foley Catheter vs oral misoprostol for pre induction cervical ripening of postdated pregnancies. Sri Lanka Journal of Obstetrics and Gynaecology. 2014 Dec 1;36(3):66.

69. Beyrami S, Noorzadeh M, Naemi M. Safety and Efficacy of Combined Oral Misoprostol and Foley Catheter Treatment in Comparison with Oral Misoprostol Alone for Labor Induction: A Randomized Clinical Trial study. Biomedical Research and Therapy. 2024 Oct 31;11(10):6852–8.

70. Amin JV, Gokhale AV, Shah VH, Rajani AJ. Comparison of oral mifepristone with intracervical foleys catheterisation for induction of labour in term pregnancy: A randomized control trial. Indian Journal of Obstetrics and Gynecology Research. 2023 Aug 28;10(3):242–6.

71. dahiya k, yadav N. study of mifepristone versus balloon catheter.

72. Dasgupta S, Dasgupta J, Goswami B, Mondal J. Randomized controlled trial comparing efficacy of a combination regime containing two cervical sensitizers (mifepristone + Foley's catheter) versus single agent mifepristone or Foley's catheter for labor induction in women attempting <scp>TOLAC</scp> at late third

trimester with a dead fetus in utero. Journal of Obstetrics and Gynaecology Research. 2023 Nov 7;49(11):2671–9.

73. Rezk MAA, Sanad Z, Dawood R, Emarh M, Masood A. Comparison of intravaginal misoprostol and intracervical Foley catheter alone or in combination for termination of second trimester pregnancy. The Journal of Maternal-Fetal & Neonatal Medicine. 2015 Jan 2;28(1):93–6.

74. yadav M, mahala U. prospective study to compare combined use of intravaginal misoprostol and intracervical foleys catheter versus intravaginal misoprostol for termination of mid trimester pregnancy.