"A RANDOMIZED CONTROL TRIAL OF EXTRA-AMNIOTIC SALINE INFUSION (EASI) VERSUS INTRACERVICAL DINOPROSTONE GEL FOR INDUCTION OF LABOUR"

BY

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Dissertation

Submitted to the
KLE University, Belagavi, Karnataka

In Partial Fulfillment
of the requirements for the degree of

MASTER OF SURGERY
in
OBSTETRICS AND GYNAECOLOGY

Under the Guidance of

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Endorsement

This is to certify that the dissertation entitled **"A RANDOMIZED CONTROL TRIAL OF EXTRA-AMNIOTIC SALINE INFUSION (EASI) VERSUS INTRACERVICAL DINOPROSTONE GEL FOR INDUCTION OF LABOUR"** is a bonafide research work done by **(REG.NO. BJ0113002).**

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LIST OF ABBREVIATIONS USED

°C	-	Degrees Celsius
°F	-	Degrees Fahrenheit
ARM	-	Artificial rupture of membrane
BMI	-	Body mass index
cAMP	-	Cyclic adenosine monophosphate
cGMP	-	Cyclic guanosine monophosphate
CI	-	Confidence interval
cm	-	Centimeters
CRH	-	Corticotropin-releasing hormone
CS	-	Caesarean section
C-SECTION	-	Caesarean section
DHEA-S	-	Dehydroepiandrosterone sulfate
DTA	-	Deep transverse arrest
e.g.,	-	For example,
EASI	-	Extra amniotic saline infusion
EDD	-	Estimated date of delivery
EDFL	-	End Diastolic Fibre Length
FDA	-	Food and Drug Administration
FHR	-	Fetal heart rate
GAG	-	Glycosaminoglycan
GBS	-	Guillain-Barre syndrome
gm	-	Grams
h	-	Hours
Hrs	-	Hours

IL	-	Interleukin
IUFD	-	Intrauterine fetal death
IUGR	-	Intrauterine growth retardation
KD	-	Dissociation constant
kg	-	Kilograms
kg/m^2	-	Kilograms per square meter
Kgs	-	Kilograms
LMP	-	Last menstrual period
LSCS	-	Lower segment caesarean section
MCP	-	Monocyte chemotactic protein
mg	-	Milligrams
min	-	Minute
mL	-	Milliliters
mL/h	-	Millileter per hour
n	-	Total number
NICU	-	Neonatal intensive care unit
p	-	Probability
PAF	-	Platelet activating factor
PG	-	Prostaglandin
PROM	-	Premature rupture of membranes
RCT	-	Randomized controlled trial
RR	-	Relative risk
SD	-	Standard deviation
SOGC	-	The Society of Obstetricians and Gynaecologists of Canada

UK	-	United Kingdom
US	-	United States
USA	-	United States of America
vs.	-	Versus
WHO	-	World Health Organization

ABSTRACT

Background and objectives

Success of induction depends largely on cervical ripening and increases the likelihood of vaginal delivery. This study compared the outcomes of induction for labour using extra amniotic saline infusion versus intracervical dinoprostone gel.

Methodology

A randomized controlled trial of one year was conducted in the Department of Obstetrics and Gynaecology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi on 82 pregnant womenfrom January 2014 to December 2014. The selected women were divided into two groups of 41 each as Group A (Dinoprostone) and Group B (EASI). These women were evaluated for improvement between pre and post induction Bishop's scores, induction to delivery interval, mode of delivery and neonatal outcome**.**

Results

The mean age in group A (22.27 ± 3.11 years) and group B (22.54 ± 2.88 years) was comparable (p=0.687). The demographic characteristics, obstetric history, indications for induction and pre-induction Bishop's scores were comparable in group A and B (p>0.050). Significantly higher number of women had post induction Bishop's scores between 9 to 12 in group A (70.73%) (p<0.001) and the mean Bishop's scores in group A were significantly high (9.27±3.07 vs 8.22±2.34; p=0.086). Cervical ripening based on cut-off score of ≥6 was noted in significantly higher number of women (92.68%) in group B (p=0.241). The mean time for cervical ripening was significantly high in group A compared to group B (15.44±8.41 vs

3.88±3.67;p<0.001) but mean induction to delivery time was comparable (p=0.086). Significantly higher numbers of vaginal deliveries were noted in groupA (91.43%) (p=0.001).The neonatal outcome that is, birth weight, mean birth weight, apgar score at one and five minutes, and NICU admission were comparable (p=0.570).

Conclusion and interpretation

EASI using Foley's catheter and dinoprostone gel appear to be effective methods for cervical ripening and labour induction but dinoprostone gel yielded significantly higher rate of vaginal delivery.

Keywords:

Cervical ripening; Dinoprostone gel; Extra-amniotic saline infusion; Foley's catheter.

CONTENTS

LIST OF TABLES

LIST OF GRAPHS

LIST OF PHOTOGRAPHS

INTRODUCTION

The goal of obstetrics is a pregnancy that results in a healthy infant and a healthy mother. In Majority of women, labour starts spontaneously and it results in vaginal delivery at or when the term is near. Cervical ripening and induction of labour is often required if there is any medical or obstetric complications of pregnancy**.** Induction of labor is indicated when the benefits to either the mother or fetus outweigh those of continuing the pregnancy.[1]

Induction of labor is labor that is started artificially before its spontaneous onset for the delivery of fetoplacental unit using mechanical or pharmacologic methods.[2] Though it may be indicated by medical or obstetrical complications of pregnancy or may be requested or chosen for non-medical or social reasons.[3] Induction of labour is like a rapier or a double edged sword wherein one edge of the blade is always towards the users neck. In other words the more we try to interfere with the normal spontaneous onset of labour there are increased chances that we may land up into rough water like increased cesarean sections, increased rate of instrumental deliveries or chorioamnionitis, psychological disturbances.[4]

Induction accounts for approximately 20% of deliveries in the UK and USA and rates have been rising steadily. This has been attributed to patient and physician factors; however elective induction rates are increasing disproportionately, accounting for 10 to 30% of inductions in some countries.[5-7]

When a woman and her care provider decide that labor induction is desired, they must next choose a method of induction. Several factors may influence the

choice of method for induction of labour including cervical and membrane status, parity, and patient and provider preference.[2]

Numerous techniques have been attempted for induction of labour to ripen the unfavorable cervix and enhance the changes necessary for labor in the lower uterine segment like intravenous infusion of oxytocin, intravaginal or intracervical administration of prostaglandin and intracervical Foley's balloon catheter insertion.[8]

Induction of labour is not without risk. The World Health Organization (WHO) has recommended that induction is performed with a clear medical indication and when expected benefits outweigh potential harms. Indications that are common for labour induction include postdated pregnancy, oligohydramnios, hyperpertensive disorders, chorioamnionitis, intrauterine growth restriction, premature rupture of membranes, maternal medical problems, fetal demise, and isoimmunisation. The chief contraindications to labour induction are vaginal bleeding, multiple pregnancy, placenta praevia, malpresentation, prolapsed umbilical cord, and scarred uterus. Induction of labour is very common in obstetric practice.[5]

Success of induction largely depends on cervical status; cervix that is unripe conveys a lower likelihood of vaginal delivery.[9] Gestation that is beyond 41 weeks, induction is associated with a small reduction in perinatal deaths and meconium aspiration syndrome.[10] Induction following premature rupture of membranes (PROM) shows reduction in chorioamnionitis, endometritis, and neonatal ICU (NICU) admissions.[11]

Before a regimen is selected, cervical ripening or preparedness for induction should be assessed. Several methods have been formulated to ripen the cervix and this

process has been described as pre-induction cervical ripening. Prostaglandins and misoprostol are pharmacologic agents that are available for labour induction and cervical ripening.

Since late 1960s, local application of Prostaglandin E_2 (PGE_2 or Dinoprostone) has been used for the cervical ripening. PGE_2 administered intravaginally or intracervically, improves Bishop's score and induction to delivery time when compared to those of untreated controls. The outcome of local application of PGE_2, softens the cervix by a number of different mechanisms.[12] Uterine tachysystole and fetal distress is reported following administration of PGE_2 in 1 to 5% of women. Prostaglandins are effective agent for cervical ripening.[13, 14] Prostaglandins have been extensively studied for clinical use, for cervical ripening and labor induction, specially the PGE2.[15, 16]

The use of a cervical catheter also shows to be effective for cervical ripening and it also appears to shorten induction to delivery interval, decrease caesarean section rate and increase the rate of spontaneous vaginal delivery. Different catheter balloon volumes that range from 30 - 80 ml. and also double balloon catheter have been studied for cervical ripening. The mechanical action of the Foley's catheter strips the fetal membranes from the lower uterine segment and rupture of lysosomes in the decidual cell is caused, part of which is phospholipase A. These lytic enzymes act on phospholipase to form arachidonic acid, which is then converted to prostaglandin, thereby improving the consistency and effacement of the cervix.[12]. This method has an advantage over the pharmacological preparation, which includes simplicity of preservation, lower cost and reduction of side effects.

Nevertheless, despite the multiplicity of techniques, there is no method that is universally accepted and thus the ideal method of labor induction remains elusive. Several studies show mechanical ripening using a Foley's bulb to be at least as effective as other methods of ripening, with no increase in maternal and fetal morbidity. A number of studies describe placing the Foley's bulb beyond the internal cervical os and inflating it with sterile water, whereas others supplement Foley's bulb placement with an extra-amniotic saline infusion through the catheter.[17]

Dinoprostone is approved by the US Food and Drug Administration (FDA) and is a sustained release E_2 prostaglandin that is inserted into the cervix and left in place for up to 12 hours.[18] Dinoprostone is expensive and requires cold storage, which makes its use difficult in many settings.

Hence the study was an attempt to compare the outcomes of induction for labour using extra-amniotic saline infusion using Foley's catheter versus intracervical dinoprostone gel in terms of improvement between pre and post induction Bishop's scores, induction to delivery interval, mode of delivery and neonatal outcome.

OBJECTIVES

The objective of the present study was to compare induction of labour using extra-amniotic saline infusion versus intracervical dinoprostone gel for the following variables.

Primary

To compare improvement between pre and post induction Bishop's score in both the groups.

Secondary

To compare induction to delivery interval, mode of delivery and neonatal outcome in both the groups.

REVIEW OF LITERATURE

Fetus at term is on a springboard ready to leap into the rough sea of tough humanity. The first journey of life, which is arguably the shortest journey, may prove to be the most precarious journey ever undertaken.

The laws of nature govern uterine smooth muscles; one of which is Frank Starling's Law – which states that force of contraction of smooth muscle is directly proportional to End Diastolic Fibre Length (EDFL). Myometrial smooth muscle is inherently a contractile tissue; which is evident when isolated strips of myometrium when placed in isotonic water bath contract rhythmically without stimuli even in presence of PG synthetase inhibitor.[19]

Cellular and Biochemical Events in cervical Ripening

Ripening of the cervix is complex, and therefore the understanding of physiologic mechanisms involved in cervical ripening is far from complete. Cellular aspects of cervical maturation include presence of collagen, smooth muscle and ground substance or connective tissue. Changes, which take place in collagen and in the connective tissue matrix, appear to be the primary factors in cervical ripening. Enzymes, hormones, and collagen breakdown by-products control the changes. Various hormones have been implicated in physiology of cervical ripening, while prostaglandins appear to play an important role.

Danforth et al.[20] were the first to identify that changes in the structure and biochemistry of connective tissue are key elements of cervical ripening. They explained that during cervical ripening the ground substance becomes more

prominent, and the collagen fibrils arranged previously in an orderly fashion break up. The collagen is embedded in a ground substance comprised of large molecular weight proteoglycan complexes containing a variety of substances called glycosaminoglycans.[21]

Chemically, glycosaminoglycans are long and negatively charged disaccharides that contain one hexosamine (glucosamine or galactosamine) and one uronic acid (glucuronic or iduronic). The structure of collagen is a helix of three collagen chains of approximately 100,000 MW each.[21]

Different types of glycosaminoglycans are described, heparin; heparan sulfate, dermatan, and chondroitin sulfate. In the cervix, collagen fibrils of proteoglycans are attached by their protein core to glycosaminoglycan side chains and maintain the mechanical strength of the cervix.[21]

Even though there is an increase in the total collagen content of cervix at term, the collagen concentration is reduced by 30-50% compared with the non-pregnant cervix. Metalloproteinese-l enzymes or collagenase are responsible for collagen breakdown. Fibroblasts, macrophages, leukocytes, polymorphs, and eosinophils produce these enzymes.[21]

Also as pregnancy progresses, there are changes in the cervical proteoglycans and glycosaminoglycans. The concentration of hyaluronic acid increases 12-fold at a cervical dilatation of 2-3 cm. Hyaluronic acidbinds water, increases the tissue hydration, and decreases rigidity in the cervix. It occurs simultaneously with a decrease in tissue level of two predominant proteoglycans, i.e. chondroitin and dermatan sulfate. The changes in the process of cervical ripening is the result of

biochemical changes, which include an increase in water content, a reduction in collagen concentration, and changes in proteoglycan/glycosaminoglycan composition.[21]

The factors that control cervical ripening are complex and often not completely understood. It is speculated that inflammatory mediators play a part in cervical ripening, especially in preterm cervical dilatation. It has been shown that fibroblasts produce certain cytokines, i.e. interleukin-8, and it can induce cervical ripening in human as well as in animal models. Other cytokines like interleukin 1b and tumor necrosis factor-a, also have been shown to produce cervical ripening in animal studies.[21]

It is also speculated that nitrous oxide, which is a known inflammatory mediator, may play a role in the tissue remodeling that occurs during cervical ripening. It has been suggested that programmed cell death (apoptosis) may have a significant role in cervical ripening. Undeniably, natural and synthetic prostaglandins play a role in cervical ripening. The main prostaglandins produced by the cervix are PGE_2, PGI_2, and, to a lesser extent, PGF_2.[21]

Lately, a prostaglandin E_1 analogue, misoprostol, has received increased attention as a highly effective cervical ripening agent. Prostaglandin E_2-mediated cervical ripening which may be due to the breakdown of collagen tissue, alteration in glycosaminoglycans/proteoglycan content, or increased hyaluronic acid concentration, and cervical hydration.[21]

Clinically, estrogens like estradiol have been used to produce cervical ripening. The ripening effects of estrogen on the cervix are possibly related to the

induction of prostaglandin synthesis by estradiol that results in an influx of protease-producing leukocytes, which may be responsible for promoting cervical ripening. Unlike estrogen, progesterone appears to hinder collagenase activity and also acts as a potent anti-inflammatory agent.[21]

Human and animal studies support the observation that antiprogesterone agents helps cervical ripening, induce neutrophil influx in cervical tissue, and stimulate prostaglandin synthesis. It has been postulated that relaxin, a 6-KD dimeric peptide hormone plays a role in cervical maturation.[21]

It has been proposed that relaxin increases collagenase activity in humans via a mitotic effect on fibroblasts. While the specific role of relaxin in human pregnancy is not understood in a clear manner, there is evidence to support its role in cervical maturation and ripening.[21]

Pregnancy is maintained by (1) cervical factors and (2) uterine factors

1. Cervical factors[22]

The cervix is extremely important in maintaining uterine stability during pregnancy. To achieve this, the maintenance of cervical shape and consistency is imperative since cervical 'ripening' is a physiological process occurring throughout the later weeks of pregnancy and is completed with the beginning of labour. When delivery is necessary and ripening has not taken place, or has failed to be initiated, this natural process has to be accelerated.

The cervix has a unique construction to enable it to perform its various roles. It consists predominantly of a stroma of connective tissue which can be subdivided into a superficial loose zone and a deeper dense stromal zone.

The main components of this connective tissue are collagen together with a small amount of elastic tissue and an even smaller component of muscle fibres. The collagen is possessed of dense regular fibrils arranged in parallel bundles held together by cross-links, with a few interspersed mast cells and other cellular elements. The ground substance is composed of proteoglycan complexes, which consist of glycosaminoglycan side chains (GAGs) on core proteins linked to a hyaluronic acid chain that bind tightly. Dermatan sulphate and chondroitin sulphate, are dominant GAGs in the cervix both of which contain hyaluronic acid conferring additional binding strength and have hydrophilic properties.

Fibroblasts with numerous long cytoplasmic processes branch out from one cell body to another, possibly similar to myometrial gap junctions, infiltrate the ground substance. Along with the advance of pregnancy, increased vascularity is seen. The fibroblasts become secretory, the white cells and macrophages migrate out of vessel walls into the cervical stroma with an increase in water content. There is a reduction in collagen content and a certain increase in the glucuronic acid-containing GAG heparin sulphate that binds much less strongly. Enzymatic breakdown of collagen fibrils by collagenases/matrix metalloproteinases produced by fibroblasts and polymorphonuclear leukocytes alongside leukocyte elastase, which catabolises elastin, leads to increased cervical compliance. The precise mediation and inter-relationships remain to be elucidated, but the prostaglandins and their synthase inhibitors are closely implicated with the known increase observed as pregnancy advances. It is clear that the process of cervical ripening will occur without any detectable uterine contractions being stimulated. Cytokines, notably IL-8, or platelet activating factor (PAF), and monocyte chemotactic protein-1(MCP-1) have been

proposed as possible interactants in the remodeling process involved in cervical ripening, as nitric oxide, synthesized by macrophages, myometrium, and the cervix.

2. Uterine factors[23]

Uterus is maintained in quiescence stage throughout pregnancy probably due to following factors:

- Action of estrogen and progesterone via intracellular receptors.
- Myometrial cell plasma membrane receptor mediated increase in cAMP.
- Generation of cGMP.
- Modification of myometrial cell ion channel.

A few independent pathways maintain phase 'O' or quiescence phase. Any defect in these pathways may trigger the onset of labour.

The precise role for these agents in this physiological process remains to be elucidated.

A switch from contractions which are low frequency and low intensity but long lasting to contractions which are more frequent, with high intensity occurs before progressive cervical effacement and dilatation and regular uterine contraction.

The exact trigger for the onset of labour is unknown.

But the possible causes for onset of labour are[24]

Following theories were postulated:

Hormonal factors

- Oestrogen theory:
    - During pregnancy, most of the oestrogens are present in a binding form. During the last trimester, more free oestrogen appears, increasing the excitability of the myometrium and prostaglandins synthesis.
- Progesterone withdrawal theory:
    - Before labour, there is a drop in progesterone synthesis leading to predominance of the excitatory action of oestrogens.
- Prostaglandins theory:
    - Prostaglandins E_2 and $F_{2\alpha}$ are powerful stimulators of uterine muscle activity. $PGF_{2\alpha}$ was found to be increased in maternal and fetal blood as well as the amniotic fluid late in pregnancy and during labour.
- Oxytocin theory:
    - Although oxytocin is a powerful stimulator of uterine contraction, its natural role in onset of labour is doubtful. The secretion of oxytocinase enzyme from the placenta is decreased near term due to placental ischaemia leading to predominance of oxytocin's action.

- Fetal cortisol theory:
    - Increased cortisol production from the fetal adrenal gland before labour may influence its onset by increasing oestrogen production from the placenta.

Mechanical factors

- Uterine distension theory:
    - Like any hollow organ in the body, when the uterus in distended to a certain limit, it starts to contract to evacuate its contents. This explains the preterm labour in case of multiple pregnancy and polyhydramnios.
- Stretch of the lower uterine segment:
    - By the presenting part near term.

Most probable sequence of events is

1. Uterine stretch receptors and parturition[23]

Considerable evidence is accumulating to support this hypothesis that fetal growth is an important component in activation of onset of labour.

Fetal growth and amniotic fluid pressure acts as a common activation pathway of stretch receptors on myometrium, which in turn induces specific contractions, associated with increase gap junction protein and oxytocin receptors.

This makes the uterus more responsive to uterotonics which appear late in gestation at the time of labour.

2. Action of fetal cortisol on parturation[25]

At term, fetal adrenal glands produce 100 to 200 mg/day of steroids, which weigh the same as those in adults. Fetal cortisol level increases during last week of gestation, and also causes increase production of DHEA-S.

CRH is synthesized in maternal / fetal hypothalamus but identical CRH is synthesized in placenta in relatively large amount at term and this CRH is proposed to;

1. Fetal cortisol production, positive feedback, and CRH production.
2. High levels of cortisol modulate myometrial contractility by stimulating the membrane to increase PG synthesis.
2. CRH stimulate C-19 steroid synthesis leading to increased substrate for placental aromatization, resulting in shift in estrogen to progesterone ratio leading to loss of quiescence secondary to expression of contractile proteins.

There are instances where this natural spontaneous onset of labour need to be interfered artificially in maternal or fetal interest, a procedure called induction of labour.

The history of the induction of labor was limited by the failure of midwives and physicians to recognize the need or the desirability for it. The procedures used in the induction of labor were reviewed. Back in 1595, a Reverend Maister Alexis of Piemont was advocating a long list of medicaments said to stimulate the uterus. These included juniper berries, cinnamon, castor oil, and amber in white wine. In 1735, Dr. Henry Bracken suggested that in order to procure an early labor an unctuous application, such as oil of sweet almonds, should be applied warm and with a bunch

of feathers to "the privities and vagina." In mid 19th century edition of the works of Aristotle it is stated that the midwife should let the waters break on their own. The contributions of Denman of the Middlesex Hospital to the induction of labor at the end of the 18th century lay not so much in his advocacy of artificial rupture of the membranes as such, but for his ability to recognize the need for it and for his effort thereby to forestall disproportion and secure an easier delivery with a smaller and more premature head.[26] Denman's method has stood the test of time. They followed in the course of the last century a series of more ruthless physical attacks upon the genital tract of the expectant mother, which persisted until the 1930s.Induction protocol has undergone a dramatic change after the advent of inducing agents like oxytocin, prostaglandins, and our understanding of mechanism of labour.

A retrospective study concluded that elective induction should be discouraged in the nulliparous woman, since the rate of Caesarean delivery is increased with elective induction.[27]

A case control study did not find elective induction itself to be predictive of Caesarean delivery.[28]

However, a Meta analysis of early trials concluded that there is no benefit to elective induction and there is no place for it in term pregnancy.[29]

The American College of Obstetricians and Gynecologists suggests that labour may be induced for logistic reasons, including risk of rapid labour, distance from hospital, and psychosocial reasons.[30]

Rate of induction of labor in increasing all throughout the world and accounts for 20% of women undergoing labour.[31]

Recommendations[32]

- The indication for induction must be documented, and discussion should include reason for induction, method of induction, and risks, including failure to achieve labour and possible increased risk of Caesarean section.
- If induction of labour is unsuccessful, the indication and method of induction should be re-evaluated.
- Inductions should not be performed solely for suspected fetal macrosomia.
- Inductions should not be performed solely because of patient or care provider preference.
- Health care providers should assess the cervix (using the Bishop's score) to determine the likelihood of success and to select the appropriate method of induction.
- The Bishop's score should be documented.
- Care providers need to consider that induction of women with an unfavourable cervix is associated with a higher failure rate in nulliparous patients and a higher Caesarean section rate in nulliparous and parous patients.
- Every woman should ideally have an ultrasound, preferably in the first trimester, to confirm gestational age.
- Institutions should have quality assurance programs and induction policies, including safety tools such as checklists, to ensure that inductions are performed only for acceptable indications.

- Women should be offered induction of labour between 41+0 and 42+0 weeks as this intervention may reduce perinatal mortality and meconium aspiration syndrome without increasing the Caesarean section rate.

- Women who chose to delay induction > 41+0 weeks should undergo twice-weekly assessment for fetal well-being.

- Intracervical Foley's catheters are acceptable agents that are safe both in the setting of a vaginal birth after Caesarean section and in the outpatient setting.

- Double lumen catheters may be considered a second-line alternative.

- Prostaglandins E_2 (cervical and vaginal) should not be used in the setting of vaginal birth after Caesarean section due to the increased risk of uterine rupture.

- Vaginal prostaglandins E_2 may be considered with ruptured membranes at term and can be used in this setting.

- Misoprostol can be considered a safe and effective agent for labour induction with intact membranes and on an inpatient basis.

- Misoprostol should not be used in the setting of vaginal birth after Caesarean section due to the increased risk of uterine rupture.

Indications for induction

Induction is indicated when the risk of continuing the pregnancy, for the mother or the fetus, exceeds the risk associated with induced labour and delivery. The indication must be convincing, compelling, consented to, and documented. Based on

the recent SOGC Clinical Practice Guidelines on induction of labour, following are the indications for induction of labour (meant to be exhaustive or absolute): [32]

High Priority

- Preeclampsia ≥ 37 weeks
- Significant maternal disease not responding to treatment
- Significant but stable antepartum hemorrhage
- Chorioamnionitis
- Suspected fetal compromise
- Term pre-labour rupture of membranes with maternal GBS colonization

Other indications

- Postdates (> 41+0 weeks) or post-term (> 42+0 weeks) pregnancy
- Uncomplicated twin pregnancy ≥ 38 weeks
- Diabetes mellitus (glucose control may dictate urgency)
- Alloimmune disease at or near term
- Intrauterine growth restriction
- Oligohydramnios
- Gestational hypertension ≥ 38 weeks
- Intrauterine fetal death
- PROM at or near term, GBS negative
- Logistical problems (history of rapid labour, distance to hospital)
- Intrauterine death in a prior pregnancy (Induction may be performed to alleviate parental anxiety, but there is no known medical or outcome advantage for mother or baby.)

Unacceptable indications

- Care provider or patient convenience
- Suspected fetal macrosomia (estimated fetal weight > 4000 gm) in a non-diabetic woman is an unacceptable indication because there is no reduction in the incidence of shoulder dystocia but twice the risk of CS.

Contra-indications[32]

Induction should be avoided if there are any contraindications to labour or vaginal delivery. They include, but are not limited to the following:

- Placenta or vasa previa or cord presentation
- Abnormal fetal lie or presentation (e.g. transverse lie or footling breech)
- Prior classical or inverted T uterine incision
- Significant prior uterine surgery (e.g. full thickness myomectomy)
- Active genital herpes
- Pelvic structural deformities
- Invasive cervical carcinoma
- Previous uterine rupture

Whenever possible, for patients with prior uterine incision or surgery, the operative report or the opinion of the surgeon should be obtained and reviewed. Induction of labour using various methods may be associated with an increased risk of:

- Failure to achieve labour
- Caesarean section
- Operative vaginal delivery

- Tachysystole with or without FHR changes
- Chorioamnionitis
- Cord prolapse with ARM
- Inadvertent delivery of preterm infant in the case of inadequate dating
- Uterine rupture in scarred and unscarred uteri recommendations.

Pre-induction assessment

The goal of labour induction is to achieve a successful vaginal delivery, although induction exposes women to a higher risk of a CS than spontaneous labour. Before induction, there are several clinical elements that need to be considered to estimate the success of induction and minimize the risk of CS. Factors that have been shown to influence success rates of induction include the Bishop's score, parity (prior vaginal delivery), BMI, maternal age, estimated fetal weight, and diabetes.[32]

Bishop's score

The Bishop's score was developed in 1964 as a predictor of success for an elective induction. The initial scoring system used five determinants (dilatation, effacement, station, position, and consistency) that attributed a value of 0 to 2 or 3 points each (for a maximum score of 13). Bishop showed that women with a score of > 9 were equally likely to deliver vaginally whether induced or allowed to labour spontaneously.[33]

In 1966, Burnett modified the scoring scheme (still in use and still known as the Bishop's score) so that each variable was assigned a maximum value of 2 points (for a maximum score of 10).[34]

A favourable pre-induction Bishop's score of >6 are predictive of a successful vaginal delivery. Initial studies were limited to parous women, but the score was later found also to be applicable to nulliparous women.[32]

Modified Bishop's Scoring System Used for Assessment of Inducibility[34]

Factor	Score		
	0	**1**	**2**
Dilatation	0	1-2	3-4
Length (Cms)	>3	1-3	<1
Consistency	Firm	Medium	Soft
Position	Posterior	Mid	Anterior
Station	Sp-3 or above	Sp -2	Sp -1 or 0

Assessment of cervical status is fundamental for the clinician to estimate the likelihood of a successful vaginal delivery. Of the Bishop's score criteria for predicting successful induction, the most important is cervical dilatation, followed by effacement, station, and position, with the least important being consistency.[35,36]

Several studies have shown an increased rate of failed induction and CS when women are induced with an unfavourable cervix.[37-40]

Xenakis's prospective study of 597 pregnancies stratified by low (4 to 6) and very low (0 to 3) Bishop's scores found the highest risk of CS in both nulliparous and parous women with scores of 0 to 3 versus those with a Bishop's score > 3. Even women with a score of 4 to 6 had a significantly higher risk of CS than those with

spontaneous labour. The rate of failed induction was higher for women with a very low Bishop's score (0 to 3) in both nulliparous and parous women.[41]

The clinician may consider other non-modifiable factors in the pre-induction counselling period with the woman. Elevated BMI (> 40 kg/m^2), [37-39] maternal age > 35 years, [38,39] estimated fetal weight >4 kg,[37] and diabetes mellitus[37] have been shown to increase the CS rate when labour is induced. The presence of these negative predictive factors for a successful induction may play a role in the mutual decision to delay intervention and to allow for the opportunity of a spontaneous labour. These factors should not be used as a deterrent to vaginal delivery. In studies of women with a favourable cervix, the CS rate of induced pregnancies was equivalent to those managed expectantly.[42-44]

Several studies have compared the ability of the Bishop's score to predict successful labour induction with ultrasound assessment of the cervix with conflicting results.

Peregrine et al.[45] reported cervical length > 1 cm to be a predictor for CS with induction of labour. In contrast, Hatfield et al.[46] found that cervical length was not predictive of successful labour induction, and Rozenberg et al.[47] reported that the Bishop's score was a better predictor of time interval from induction to delivery.

Using ultrasound to assess cervical ripeness, Bartha et al.[48] found that fewer women were induced with PG with no difference in outcomes. Fetal fibronectin and transvaginal ultrasound have been shown to predict successful induction, but neither has been shown to be superior to the Bishop's score.[32]

SOGC Clinical Practice Guidelines Recommendations[32]

- Health care providers should assess the cervix (using the Bishop's score) to determine the likelihood of success and to select the appropriate method of induction.
- The Bishop's score should be documented.
- Care providers need to consider that induction of women with an unfavourable cervix is associated with a higher failure rate in nulliparous patients and a higher Caesarean section rate in nulliparous and parous patients.

Cervical ripening

The success of induction depends largely on the consistency, compliance, and configuration of the cervix. The unripe cervix thus remains a well-recognized impedent to the successful induction of labour. Therefore, cervical ripening or preparedness for induction should be assessed before a regimen is selected. Many methods have been devised to ripen the cervix and this process has been described as pre-induction cervical ripening.[21, 32]

Methods of cervical ripening and labor induction[21]

- Nipple stimulation
- Herbs: blue/black cohosh, evening primrose oil, red raspbenyleaves
- Homeopathic solutions: caulophyllum, cimicifuga, pulsatilla
- Castor oil
- Enemas
- Acupuncture

- Sweeping or stripping of the membranes
- Mechanical dilatation
    - Balloon catheters
    - Laminaria japonica
    - Synthetic osmotic dilators
- Amniotomy
- Pharmacologic hormonal preparations:
- Prostaglandin E_2 (Cervidil, Prepldil, hospital-compounded gels)
- Oxytocin
- Misoprostol (prostaglandin E_1 analogue [Cytolec]
- Mifepristone (RU-486)
- Relaxin

Considering cervical characteristics different methods have been used to improve its conditions prior to labor induction. It could be divided into biochemical or mechanical, respectively corresponding to the use of pharmacological substances through different administration or to the use of devices crossing the cervical canal. However, as the present study used Foley's catheter with extra-amniotic saline infusion and intracervical dinoprostone gel, these methods have been reviewed.

Foley's catheter with extra-amniotic saline infusion

Extra-amniotic infusion associated to the Foley's catheter for labor induction has traditionally been used. This include balloon devices (Foley's catheter with and without extra-amniotic saline infusion) that apply pressure on the internal os of the cervix to stretch the lower uterine segment and increase the release of local PG.

Simplicity of use, potential for reversibility, reduction in certain side effects such as excessive uterine activity, and low cost are advantages of these methods.[49]

Balloon devices

The first use of a balloon catheter for cervical dilation was described by Krauss in 1853.[49] The use of a transcervical Foley's catheter for labor induction was initially described by Embrey and Mollison.[50] They describe placing a 26 gauge Foley's catheter with a 50mL balloon just beyond the internal os placed either by digital examination or with a speculum. Patients were allowed to ambulate while the Foley's catheter was in place. On expulsion of the Foley's balloon, amniotomy was performed. In 100 patient case series, they were able to achieve active labor within 48 hours in 84% of patients with an unfavorable cervix. After amniotomy, active labor was accomplished within 48 hours in 94% of these patients. This rate was similar to that in their control group that presented with a favorable cervix. Of note, they only attempted placement of the Foley's catheter in patients who were at least one finger width dilated.[51]

There are numerous ways to place the Foley's catheter for cervical ripening. The most common method reported in the literature is under direct visualization during a sterile speculum examination. Although we do not perform this some practitioners, decrease local bacterial density by swabbing the cervix with povidine-iodine before placement. Forceps may be used to feed the catheter through the internal os; the catheter is inflated above the level of the internal os. The catheter is then gently withdrawn until it rests at the level of the internal os. Some practitioners place the Foley's catheter during a digital cervical examination. A urethral stent, stylet, or intrauterine pressure catheter may be center of a triple lumen Foley's to increase the

stiffness of the catheter to assist in placement through a minimally dilated cervix. The later two methods have been used in patients who are intolerant of a speculum examination. Although there is likely decreased sterility with blind placement there does not seem to be an increase risk of infection in patients who have had the catheter placed in this way. Studies of the occurrence of chorioamnionitis with blind placement are needed. It was noted that with experience and familiarity with the technique, placement with a stylet is not necessary. Furthermore, it was observed that an increased incidence of inadvertent membrane rupture on placement when a stylet is used. Foley's catheters and balloons of a variety of sizes may be used. After placement of the Foley's catheter through the cervix, many practitioners place the balloon on traction by taping it to the inner aspect of the patient's thigh or placing a weight on the catheter.[51]

Choosing a Foley's Catheter

There are reports of successful cervical ripening with catheters ranging in size from 14 to 26 gauges and using 25 to 80mL of sterile saline or water for inflation. Most studies report an inflation volume of 30 to 50mL. The question of whether inflation volume affects success was directly addressed by a randomized study of 205 women comparing inflation volume of 30 versus 80mL.[52]

The primary outcome variable in the study was cervical dilation of 3cm or more. There was a significant difference with 81.6% of patients in the 80mL inflation group achieving 3cm dilation whereas only 57.7% of patients in the 30mL group ($P<0.001$). They were also able to demonstrate a shorter mean induction to delivery interval, increased delivery within 24 hours, and a decreased requirement of oxytocin augmentation in primiparous patients. These differences were not apparent in

multiparous patients. There was no statistically significant difference between the groups in mode of delivery. Although there was a statistically significant increase in cesarean delivery due to failure to progress in the 30mL group (3% vs. 9.9%; P=0.047), this was balanced by no significant increases in cesarean delivery for cord prolapse (1% vs. 0%; p=0.31), non reassuring fetal heart rate pattern (6% vs. 1%; p=0.09), and suspected cephalopelvic disproportion (2% vs. 0%; p=0.15).

Duration of cervical ripening after placement of the Foley's catheter in most studies, the Foley's catheter is extruded through the cervix within 12 hours.[53,54] If the Foley's catheter has not extruded, some practitioners remove the Foley's catheter after a predefined time, whereas others will wait for extrusion or allow for removal with gentle traction.[51]

A prospective study demonstrated that the Foley's catheter may safely stay in the extra-amniotic space for greater than 24 hours.[53] In this series conducted in Nigeria, 39% of catheters were extruded within 12 hours, 72% within 24 hours, 88% within 48 hours, and 95% within 72 hours. These times are longer than those reported in other studies. This most likely explained by the 40% preterm induction rate in this study. For term patients the average duration of catheter placement was 19.6 hours, which contrasted sharply with the 44.8 hours required for catheter extrusion in patients between 20 to 27 weeks gestation. Four patients in that study who required 72 hours of extra-amniotic Foley's catheter before extrusion all had preterm pregnancies complicated by in utero fetal demise. All the four achieved a vaginal delivery without febrile morbidity. Although larger sample sizes are necessary to draw conclusions, these initial findings are reassuring. Several notable findings in this study are that all patients had intact membranes, the cervix was cleansed with antiseptic before catheter

insertion, and patients were placed on prophylactic antibiotics at the time of catheter placement. Clearly, data are lacking on the use of prophylactic antibiotics after transcervical Foley's catheter placement in industrialized countries.[51]

EASI (Extra- amniotic saline infusion)

The extra-amniotic saline infusion through the Foley's catheter has become a common method for induction of labor. The addition of saline through the catheter most likely separates the fetal membrane from the uterine wall causing further release of prostaglandins.[51]

In 2004, a study[54] comparing the use of a transcervical Foley's catheter with and without EASI demonstrated no decrease in induction time with the addition of EASI.[50] In this study EASI was performed at a rate of 30mL/h. Patients in this study all had concurrent administration of intravenous oxytocin. There were 49 women randomized to the Foley's catheter and 51 randomized to the Foley's catheter with EASI. After excluding women in whom the Foley's catheter could not be placed (n=13; Foley's, 7 of 49, EASI using Foley's catheter, 6 of 51), there was no difference in time from insertion to delivery (Foley's, 16.5h EASI using Foley's catheter, 17h). There was only one failed induction of labor (defined as arrest of labor before 4cm dilation). This occurred in the Foley's catheter group. Both methods were effective with 17.7% of patients in the Foley's catheter group and 18.4% of patients in the EASI group achieving vaginal delivery. The overall rate of hyper stimulation was 5% (Foley's, 3 of 49, EASI using Foley's catheter, 2 of 51). Furthermore, there was no difference in intrapartum or postpartum complications between the 2 groups.

The Cochrane review[55] of mechanical methods for labor induction reviews 5 studies with a total of 677 parturient that underwent EASI or prostaglandins. The review documents a decreased likelihood of vaginal delivery in 24 hours with an increased likelihood of caesarean delivery in the group undergoing EASI. There was no difference in hyper stimulation with fetal heart rate changes.

Effectiveness of the Foley's catheter for cervical ripening because the initial description of the Foley's catheter for pre-induction cervical ripening, numerous studies have demonstrated the effectiveness of the device for pre-induction cervical ripening. A mean change in Bishop's score of between 3.3 and 5.3 after cervical ripening with the Foley's catheter and a decrease in induction to delivery times has been demonstrated.[51]

The Foley's catheter has been especially attractive as a method for cervical ripening in developing countries where the cost of dinoprostone (PGE_2) can be prohibitive and the requirements for monitoring after the less expensive misoprostol can be daunting. The low cost, stability at room temperature and low incidence of contractile abnormalities with the transcervical Foley's catheter make it an ideal agent for use in the developing world.[51]

Case series and randomized studies in India[56] have documented the efficacy and safety of the Foley's catheter in those populations.

A prospective observational series of 187 women in India demonstrated a success rate of 25% in term nulliparous patients and 92% in multiparous patients with a mean induction to delivery interval of 8.7 hours for nulliparous patients and 5.5 hours for multiparous patients. Of note, one of the exclusion criteria in this study was

suspected cephalopelvic disproportion, which may have increased the success of the procedure.[56]

Several studies have demonstrated the Foley's catheter to be at least as effective as other methods of cervical ripening with a similar or increased safety profile. The Foley's catheter has been compared with oxytocin, PGE_2 gel, and misoprostol.[51]

A multitude of studies has compared the Foley's catheter with PGE_2 for cervical ripening. The majority of studies have found that the Foley's catheter offers an advantage to PGE_2.[57,58]

A study[57] of 149 women randomized to Foley's catheter versus transcervical PGE_2 gel demonstrated a greater change in Bishop's score (3.5 vs. 2.7; $p=0.005$), a shorter pre-induction time (9.9 vs. 17.2h; $p<0.001$) and a shorter induction time (22.4 vs. 30.4h; $p<0.001$). Although there was a 31% reduction in patient charges, there was no significant difference between the two groups in cesarean delivery rate.

Similarly, another study[58] of 224 women assigned to either pre-induction cervical ripening with the Foley's catheter or intravaginal PGE_2 gel demonstrated a greater percentage of patients with a Bishop's score of greater than 7 after 12 hours when the Foley's catheter was used (40.1% vs. 26.5%), but this did not translate into a decreased time to delivery. However, they did show a decreased caesarean delivery rate in women who had the Foley's catheter placed versus PGE_2 gel (14.7% vs. 26.5%; $p<0.05$) and in the subset of nulliparous patients (14.8% vs. 32.3%; $p<0.05$).

The Cochrane review[59] on mechanical methods for induction of labor reviewed 11 studies comparing balloon catheters with prostaglandins. They document

a reduction of risk in hyperstimulation with fetal heart rate changes when using balloon catheters; although this was only demonstrated in one study. Patients in the balloon catheter group were more likely not to achieve vaginal delivery within 24 hours. There was no difference in cesarean delivery between the two groups. It is unclear why one study was able to show a decrease in induction to delivery interval, whereas a similarly designed study did not demonstrate that effect, but did demonstrate a decreased cesarean delivery rate. However, the primary outcome of both studies was change in Bishop's score and not delivery time or mode of delivery and one study used transcervical application of PGE_2 gel as opposed to intravaginal administration. Of note, the inclusion and exclusion characteristics of the two studies were different, with the study by Sciscione et al.[57] including patients with a history of prior cesarean delivery and gestations greater than 28 weeks, whereas Ghezzi et al[57] excluded patients with prior uterine surgery and only included term gestations.

A 2009 RCT[60] of 330 term (pregnancies > 36 weeks) nulliparous women with an unfavourable cervix (Bishop 0 to 4) compared single (16F Foley's) and double balloon catheters and vaginal PGE_2.[48] The overall CS rate was high but not significantly different between groups (43% double balloon, 36% single balloon, and 37% in the PGE2 group P = 0.567). The single balloon catheter had the shortest induction to delivery interval (single balloon = 25.8 h, PGE2 = 25.8 h, double balloon = 30.6 h). Uterine tachysystole occurred in 14% (9% with normal fetal heart tracing; 4% with atypical fetal heart tracing; and 1% with abnormal fetal heart tracing requiring delivery) of the PGE2 group compared to none in the mechanical cervical ripening group. Cervical ripening with the single balloon catheter was associated with significantly less pain than the double balloon or vaginal PGE_2.

Heinemann et al.[61] systematic review of 30 RCTs showed an increased risk of both maternal infection (defined as pyrexia of 38°C, peripartum infection, or chorioamnionitis and/or endomyometritis), and neonatal infection when all (Foley's catheters, hygroscopic dilators, laminaria) mechanical methods were analyzed. Studies limited to Foley's catheters compared with pharmacological agents for cervical ripening had similar rates for maternal infection and there was no increased risk of neonatal infection.[49]The indications and methods of induction should not be altered in the case of women known to be colonized with GBS.[32]

A prospective, randomized trial[62] compared in-patient versus outpatient use of a Foley's catheter for 111 term pregnancies with an indication for induction of labour. Indications included elective (n = 48), post-dates (n = 44), macrosomia (n = 14), gestational diabetes (n = 3), and chronic hypertension (n = 2). The mean Bishop score was three for each group. There was no significant difference in the two groups for change in Bishop's score, maximum dose of oxytocin, time of oxytocin, epidural rate, induction time, 1-minute and 5-minute Apgar scores, and cord pH. The outpatient group spent an average of 9.6 hours less in hospital.

The use of a transcervical Foley's catheter for induction of labour in women who had a previous CS is not associated with an increased risk of uterine rupture. Foley's catheters have shown to be efficacious with a shorter induction to-delivery time than PG for induction of labour with an unfavourable cervix. Both agents have similar CS rates, but Foley's catheters result in increased need for oxytocin stimulation and there is more tachysystole with PG.[32]

It is recommended that, intracervical Foley's catheters are acceptable agents that are safe both in the setting of a vaginal birth after Caesarean section and in the

outpatient setting. Double lumen catheters may be considered a second-line alternative.[32]

However, it is reported that, there is an increased need for oxytocin when Foley's catheters are used. Further, in comparison with prostaglandins, Foley's catheters cause much less uterine tachysystole and are not associated with increased rates of maternal infection (chorioamnionitis and endometritis) or neonatal infection. The use of Foley's catheters does not reduce the rate of CS from that of PG.[32]

Dinoprostone (Cervidil)

According to Wing and Gaffaney,[63] dinoprostone has been the agent of choice for pre-induction cervical ripening for several decades. However, dinoprostone is both expensive and requires cold storage, which makes the use difficult in many settings. Locally administered dinoprostone is currently available in three forms. Prepidil gel contains 0.5 mg of dinoprostone in 2.5 mL of gel for intracervical administration and can be repeated every 6 to 12 hours up to three doses in a 24-hour period if needed.[64]

Prostin E_2 is a vaginal suppository containing 20 mg of dinoprostone, inserted at 3 to 5 hour intervals until abortion is complete, and is indicated for evacuation of the uterus with missed abortion or IUFD, previable termination of pregnancy, and management of benign hyaditiform mole. Controlled release dinoprostone (Cervidil) is available as a 10-mg sustained release vaginal insert that releases a dose of dinoprostone at a rate of 0.3 mg per hour for 24 hours. The advantages of this form of dinoprostone is that it is easy to apply and can be removed quickly in the event of uterine hyperstimulation.

A 2005 review by Rath[65] and a 2003 Cochrane review[66] both found dinoprostone to be highly effective as a cervical ripener. The Cochrane review of vaginal prostaglandin at term for induction of labor included 2 trials with a total of 384 women that compared vaginal prostaglandin E_2 to placebo with regard to failure to achieve vaginal delivery and found a significant reduction in failure to achieve vaginal delivery in 24 hours in the women who were in the prostaglandin arms of the trials. Eleven trials with a total of 1265 women showed a reduction in the need for oxytocin augmentation with vaginal prostaglandin E_2 over placebo.[66]

Rath's metaanalysis included three placebo-controlled trials of controlled release dinoprostone that included a total of 485 women. As in the Cochrane analysis, this analysis found a higher rate of cervical ripening, shorter interval to vaginal delivery, less use of oxytocin, and overall treatment success in the controlled release dinoprostone group. There were no significant differences in caesarean birth rates or neonatal outcomes between women induced in the dinoprostone (Cervidil) group and those undergoing no treatment in either metaanalysis.[65,66]

The most significant adverse effect of dinoprostone (Cervidil) use is uterine hyperstimulation, with an incidence of 5% to 10% above the incidence in women who did not receive this agent, which is comparable to other cervical ripening formulations, including intracervical prostaglandin gel and misoprostol.[65]

A 2003 Cochrane review of vaginal prostaglandin for induction of labor at term found an increased rate of hyperstimulation with fetal heart rate changes in women who received sustained release prostaglandin E_2 (7.5% versus 0.0%; relative risk [RR] = 10.87; 95% confidence interval [CI], 2.69-43.92 when compared to women who did not receive prostaglandin.[66]

However, a recent systematic review points out that uterine hyperstimulation and fetal heart rate abnormalities were resolved within 15 minutes of removal of the insert, and did not result in an increase in caesarean birth because of fetal distress or other adverse neonatal outcomes.[65]

There is a theoretical chance of uterine rupture in women with previous uterine scarring; dinoprostone (Cervidil) should be used with caution in a patient with previous uterine surgery.[67]

Anecdotally, clinicians have found discrepancies in the effect of dinoprostone on various women; some women needing multiple doses for cervical change, while others experiencing hyperstimulation or giving birth did so within hours after an initial dose. These differences have been attributed to many factors. Inconsistencies in the potency between batches have been noted, where an entire batch may seem ineffective in producing cervical change while the next batch works as expected. Provider preferences in insertion technique may also have an effect. For example, there are variations in provider preference of string placement. Some providers prefer to wrap the string around the insert, while others leave it loose in the posterior vagina. Some providers prefer to moisten the insert before placement with water, or sterile water, and yet others have never heard of this practice and question why this may be done. Another possible culprit is improper storage. Because dinoprostone must be kept refrigerated at a temperature between −4 °F and 14 °F (−20 °C to −10 °C) and away from light and moisture, any alteration in these conditions could affect the stability of the medication. Proper handling during shipping and receiving of the medication from the drug supply company as well as the time out of refrigeration between retrieval and insertion may vary and affect its stability to an unknown degree.

One final aspect to consider is the parity of the woman. Many providers have attributed decreased time from insertion to delivery and increased likelihood of hyperstimulation to increased parity and women who need > one dose is, more often than not, primiparous. At this time, there are no published studies regarding these differences in results.[64]

METHODOLOGY

The present study was conducted in the department of Obstetrics and Gynaecology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi during the period of January 2014 to December 2014.

Study Design

The study design was a randomized controlled trial.

Study period and duration

The present study was conducted from January 2014 to December 2014.

Place

This study was conducted at Department of Obstetrics and Gynaecology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi a teaching hospital attached to Jawaharlal Nehru Medical College, Belagavi.

Source of data

Singleton pregnancies between 37 to 42 weeks of gestations, eligible for induction of labour at Department of Obstetrics and Gynaecology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi were enrolled.

Sample size

A total of 82 pregnant women between 37 to 42 weeks of gestations, eligible for induction of labour divided into two groups of 41 each were studied.

Sampling procedure

The sample size was calculated by considering Bishop's score of ≤ 6, with type I error rate α = 0.05 and type error β =0.02 and power of 80% sample size was determined considering the following formula.

$$n = \frac{(Z_\alpha + Z_\beta)^2 \times p \times q}{(p_o - p_1)^2}$$

Where: $Z_\alpha = 1.96$

$Z_\beta = 0.84$

$P_0 = 67\%$

$P_1 = 36\%$

Hence, sample size was taken as 41 in each group totaling to a sum of 82 cases.

Selection criteria

Inclusion

- Pregnant women with singleton pregnancy and 37-42 weeks of gestation
- Cephalic presentation
- Intact membranes
- Reassuring fetal heart rate tracing
- Bishop's score less than 6

Exclusion

Pregnant women with;

- Spontaneous labour
- Multiple gestations
- Malpresentation
- Antepartum haemorrhage
- Previous cesarean delivery
- Gestational diabetes mellitus
- Pregnancy induced hypertension
- Non-reassuring fetal status
- Known sensitivity to prostaglandins
- Latex allergy

Ethical clearance

The Institutional Ethics Committee of Jawaharlal Nehru Medical College, Belagavi, approved the study.

Consent form

Pregnant women fulfilling selection criteria at Department of Obstetrics and Gynaecology at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi were briefed about the nature of the study, details of the treatment and a written informed consent was obtained (Annexure I).

Data collection

Patients were interviewed for demographic characteristics and obstetric history. Data regarding age, obstetric history and period of gestation were noted on a predesigned and pretested proforma (Annexure II).

Randomisation

Randomisation was done by computer generated random numbers assigning numbers to both groups. The women were divided into two groups 41 each as below.

- Group A – Pregnant women in this group underwent cervical ripening using dinoprostone gel.
- Group B – Pregnant women in this group underwent cervical ripening using EASI using Foley's catheter.

Intervention

Detailed speculum examination was carried out and cervix was swabbed with povidine iodine. Pre induction trace was taken for last 20 minutes.

Group A

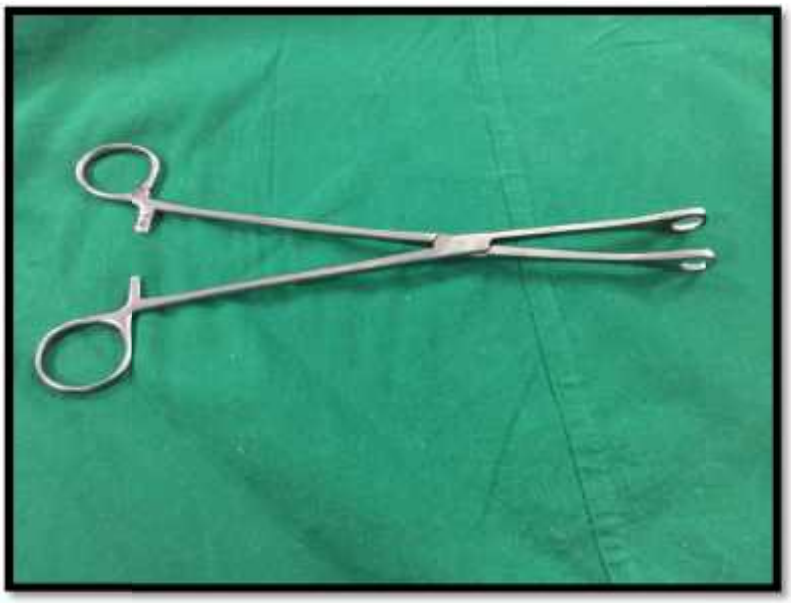
In this, Group Dinoprostone gel was injected into the endocervical canal under direct visualization and subjects remained supine for 30 minutes after administration. A post trace of at least 20 minutes was taken. A maximum of 3 doses of Dinoprostone gel was given. Amniotomy with oxytocin infusion was used to augment the labour if Bishop's score was 6 or more. Bishop's was assessed at 8 hours; 16 hours and 24 hours post induction.[32]

Group B

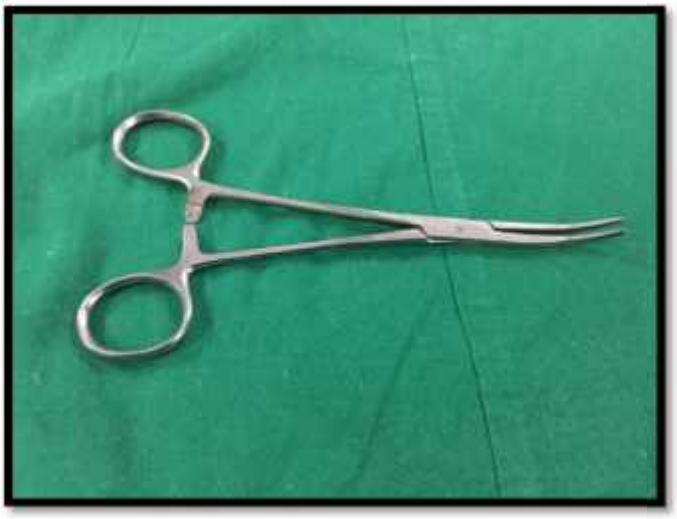
Pre-induction trace was taken for at least 20 minutes. A sterile speculum examination was done and cervix was prepared with betadine. 14 gauge Foley's catheter was inserted beyond the internal os under direct visualization. Balloon was inflated with 30 mL of sterile water, and normal saline was infused through the catheter. Totally, a maximum of 200 mL of saline was infused. The cervix was assessed for Bishop's score at 8 hours or when the catheter was expelled. If Bishop's score remained less than 6, catheter was continued for another 8 hours or until the catheter was expelled. Amniotomy with oxytocin infusion was used to augment the labour if Bishop's score was 6 or more.

Antibiotics were not given to patients unless there were any signs of infection or caesarean section was performed. For the purpose of analysis, failed induction was defined as labour arrest before 3cm of cervical dilatation. Failure to progress was defined as secondary arrest of labour at or beyond 3cm dilatation despite adequate uterine contraction of minimum of 2 hours. Fetal distress was defined as persistent non-reassuring FHS remote from delivery.

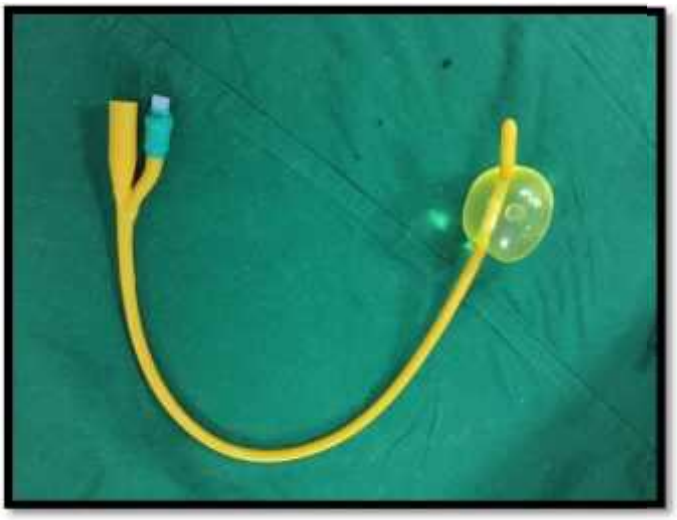
Photograph 1. Sim's speculum



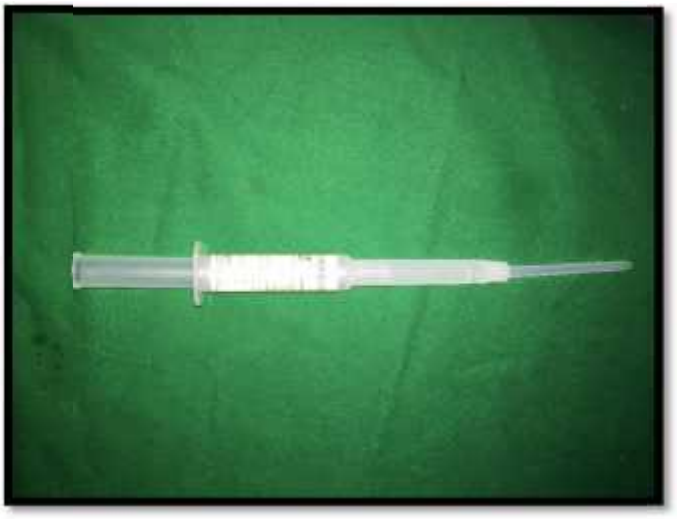
Photograph 2. Sponge holding forceps



Photograph 3. Artery forceps



Photograph 4. No. 14F Foley's catheter



Photograph 5. Dinoprostone gel

Outcome variables

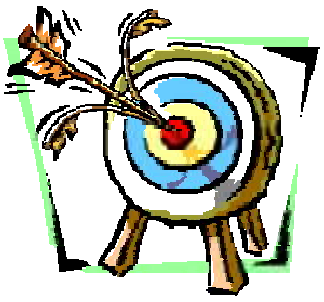
The study population was assessed for following outcomes

- Improvement between pre and post induction Bishop's score.
- Induction to delivery interval
- Mode of delivery
- Neonatal outcome

Statistical analysis

Data obtained was coded and entered into the Microsoft Excel Spreadsheet. The data was analysed using statistical software SPSS 20. The categorical data was expressed in terms of frequencies and percentages while continuous data was expressed as mean ± standard deviation (SD). The two groups were compared using chi-square test for categorical data and independent sample 't' test was used to compare the means of different parameters. A 'p' value of less than or equal to 0.05 was considered to be statistically significant.

Introduction



Objectives

Review of Literature

Methodology

Results

Discussion

Conclusion

Summary

Bibliography

Annexure-I

Annexure-II

Annexure-III

Annexure-IV

Annexure-V

RESULTS

The present one year randomized controlled trial was conducted at the Department of Obstetrics and Gynaecology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.

A total of 82 pregnant women were enrolled from January 2014 to December 2014. These women were divided into two groups of 41 each as below.

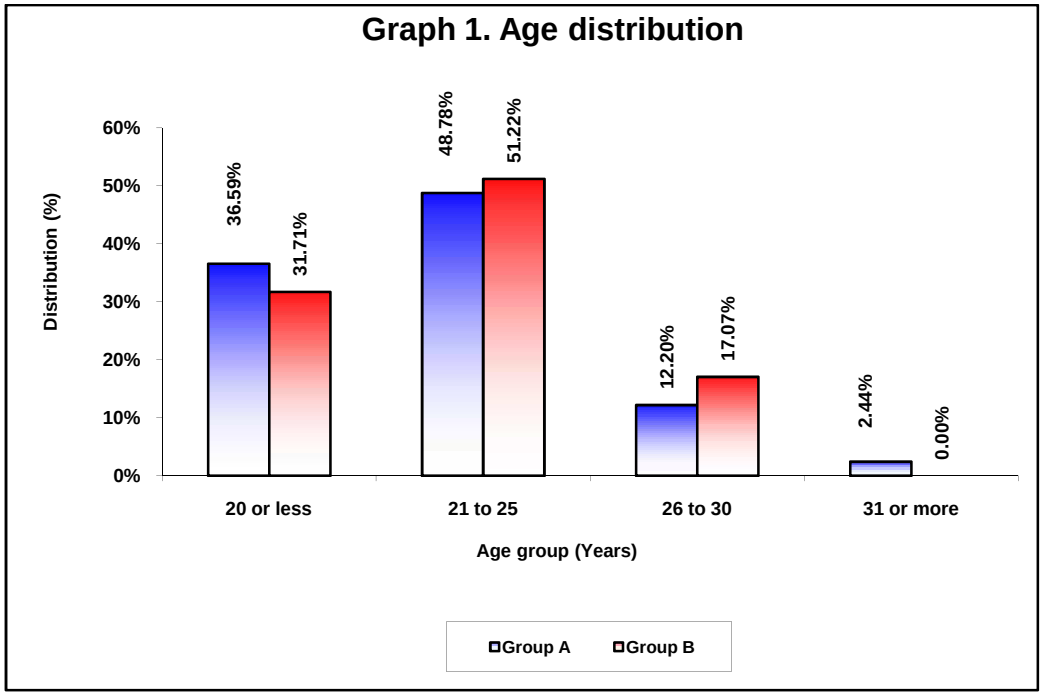
- Group A – In this group pregnant women were induced with Dinoprostone.
- Group B – Pregnant women in this group were induced with EASI.

The data obtained was analysed and the final results and observations were tabulated as below.

Table 1. Age distribution

Age group (Years)	Group A (n=41)		Group B (n=41)	
	Number	**Percentage**	**Number**	**Percentage**
20 or less	15	36.59	13	31.71
21 to 25	20	48.78	21	51.22
26 to 30	5	12.20	7	17.07
31 or more	1	2.44	0	0.00
Total	**41**	**100.00**	**41**	**100.00**

p = 0.829



In the present study, maximum women in Group A (48.78%) and Group B (51.22%) were aged between 21 to 25 years. However, age distribution in Group A and B was comparable (p=0.829).

Table 2. Mean age

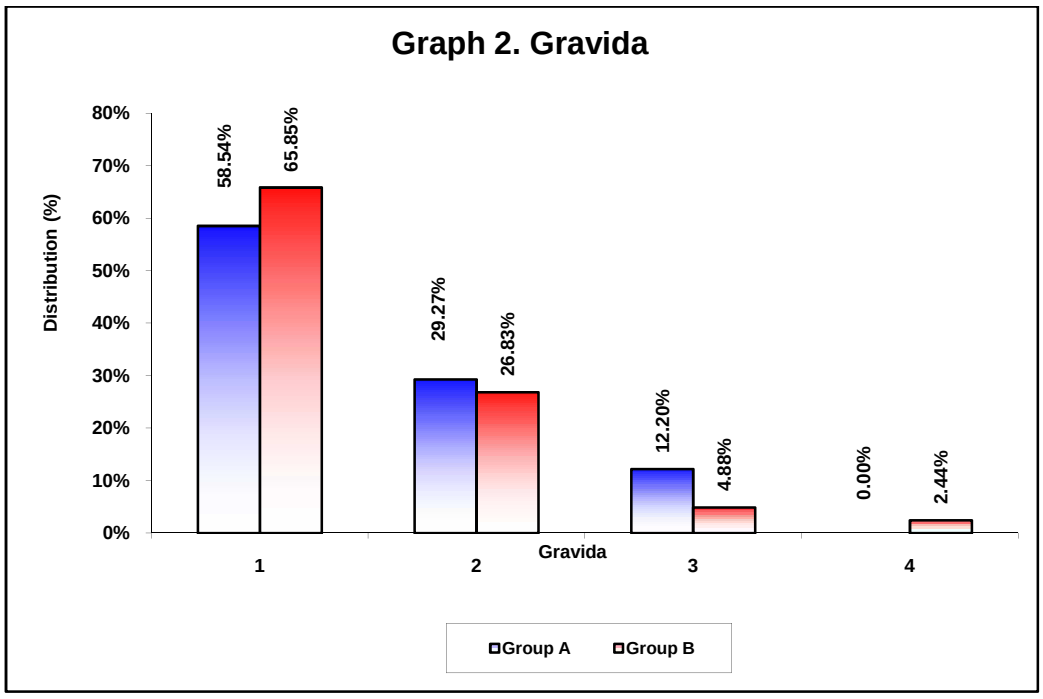
Variables	Group A (n=41)		Group B (n=41)		p value
	Mean	SD	Mean	SD	
Age (Years)	22.27	3.11	22.54	2.88	0.687

In this study, mean age in Group A (22.27 ± 3.11 years) and Group B (22.54 ± 2.88 years) was comparable (p=0.687).

Table 3. Gravida

Gravida	Group A (n=41)		Group B (n=41)	
	Number	Percentage	Number	Percentage
1	24	58.54	27	65.85
2	12	29.27	11	26.83
3	5	12.20	2	4.88
4	0	0.00	1	2.44
Total	**41**	**100.00**	**41**	**100.00**

p = 0.549

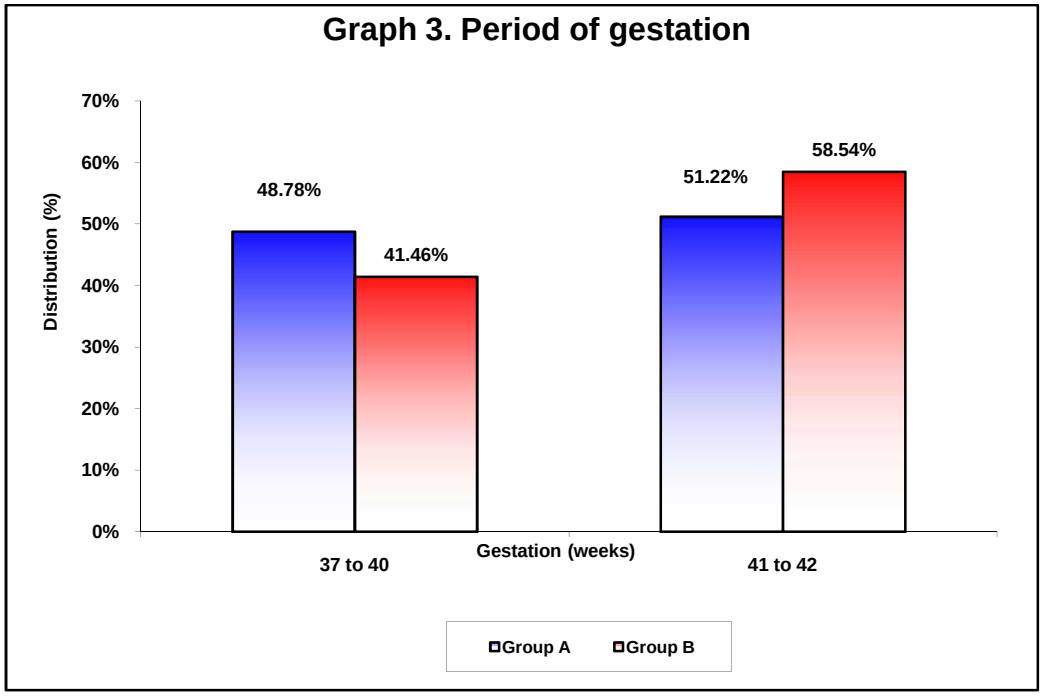


In the present study, obstetric history revealed 58.54% and 65.85% of the pregnant women were primigravida in Group A and B respectively but the difference was statistically not significant (p=0.549).

Table 4. Period of gestation

Gestation (weeks)	Group A (n=41)		Group B (n=41)	
	Number	Percentage	Number	Percentage
37 to 40	20	48.78	17	41.46
41 to 42	21	51.22	24	58.54
Total	**41**	**100.00**	**41**	**100.00**

p = 0.506



In this study 51.22% and 58.54% of the women presented with gestational age between 41 to 42 weeks in Group A and Group B respectively. However, this difference was statistically not significant (p=0.506).

Table 5. Mean period of gestation

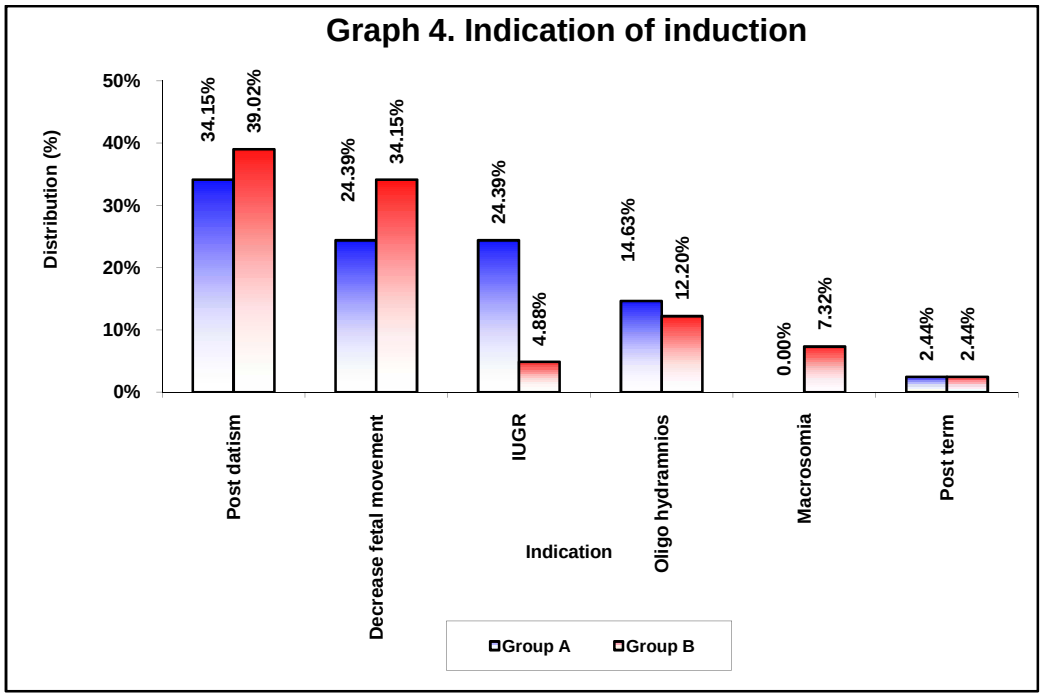
Variables	Group A (n=41)		Group B (n=41)		p value
	Mean	SD	Mean	SD	
Period of gestation (weeks)	40.01	1.31	39.85	1.38	0.599

In the present study, mean period of gestation was comparable in Group A (40.01 ± 1.31 years) and Group B (39.85 ± 1.38 years) (p=0.599).

Table 6. Indication of induction

Indication	Group A (n=41)		Group B (n=41)	
	Number	**Percentage**	**Number**	**Percentage**
Post datism	14	34.15	16	39.02
Decrease fetal movement	10	24.39	14	34.15
IUGR	10	24.39	2	4.88
Oligohydramnios	6	14.63	5	12.20
Macrosomia	0	0.00	3	7.32
Post term	1	2.44	1	2.44
Total	**41**	**100.00**	**41**	**100.00**

p = 0.075

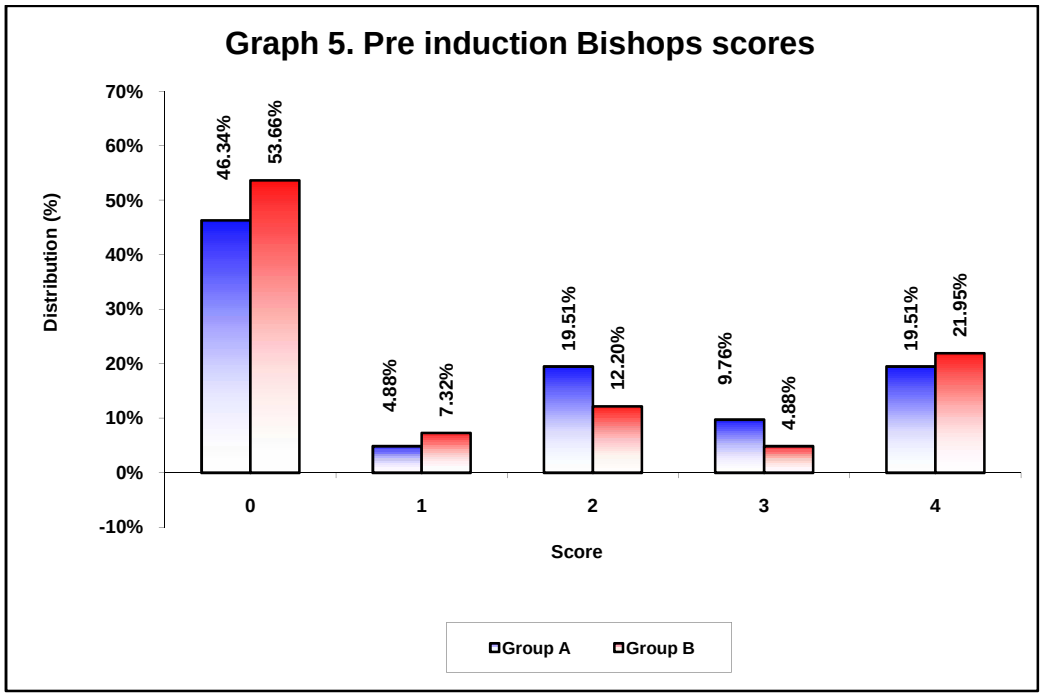


In this study, post datism was the commonest indication for induction in Group A (34.15%) as well as Group B (39.02%) (p=0.075).

Table 7. Pre-induction Bishop's scores

Score	Group A (n=41)		Group B (n=41)	
	Number	Percentage	Number	Percentage
0	19	46.34	22	53.66
1	2	4.88	3	7.32
2	8	19.51	5	12.20
3	4	9.76	2	4.88
4	8	19.51	9	21.95
Total	**41**	**100.00**	**41**	**100.00**

p = 0.780



In the present study, pre-induction Bishop's score was zero in 46.34% of the pregnant women in Group A compared to 53.66% of the pregnant women in Group B (p=0.780).

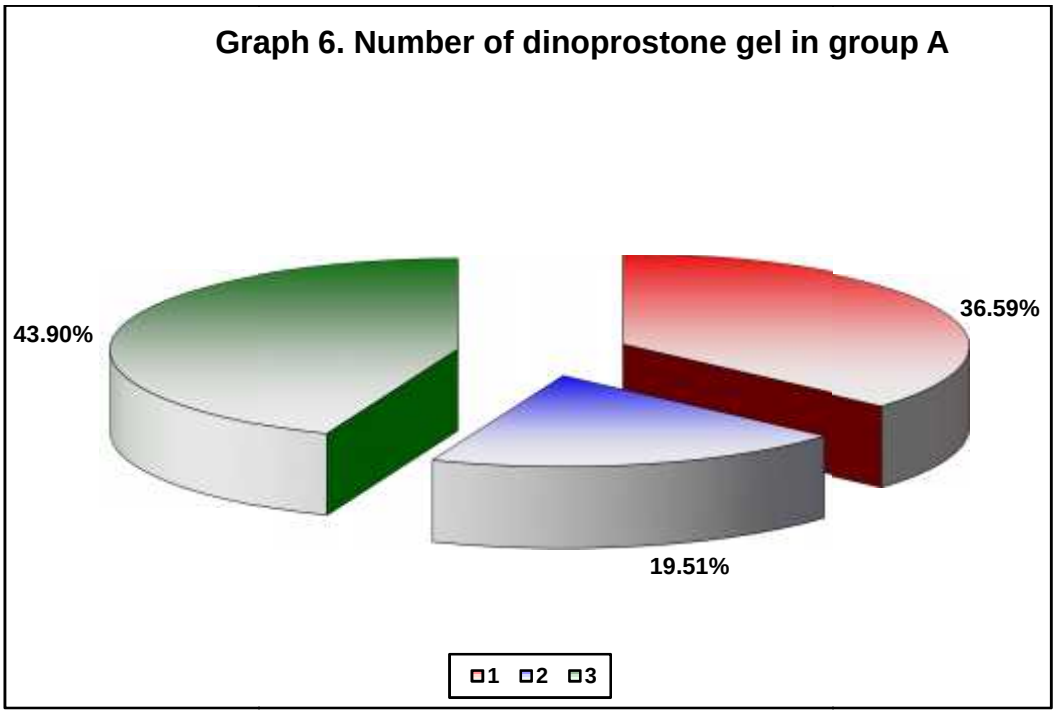
Table 8. Mean pre induction Bishop's score

Variables	Group A (n=41)		Group B (n=41)		p value
	Mean	SD	Mean	SD	
Bishop's score	1.51	1.61	1.34	1.67	0.639

In the present study, mean Bishop's score was 1.51 ± 1.61 in Group A as compared to 1.34 ± 1.67 in Group B. However, the difference was statistically not significant (p=0.639).

Table 9. Number of dinoprostone gel used in Group A patients

Number of dinoprostone gel doses	Distribution (n=41)	
	Number	**Percentage**
1	15	36.59
2	8	19.51
3	18	43.90
Total	**41**	**100.00**



In the present study, most of the women in Group A received three dinoprostone gel doses (43.90%)

Table 10. Mean number of dinoprostone gel doses and post induction time with dinoprostone gel in Group A patients

Variables	Group A (n=41)	
	Mean	**SD**
No. Of dinoprostone gel doses	2.07	0.91
Post induction time with dinoprostone gel (Hours)	15.44	8.41

In this study, in Group A patients, the mean number of dinoprostone gel doses were administered was 2.07 ± 0.91 and the mean post induction time with dinoprostone gel was 15.44 ± 8.41 hours.

Table 11. Mean bulb expulsion time in Group B

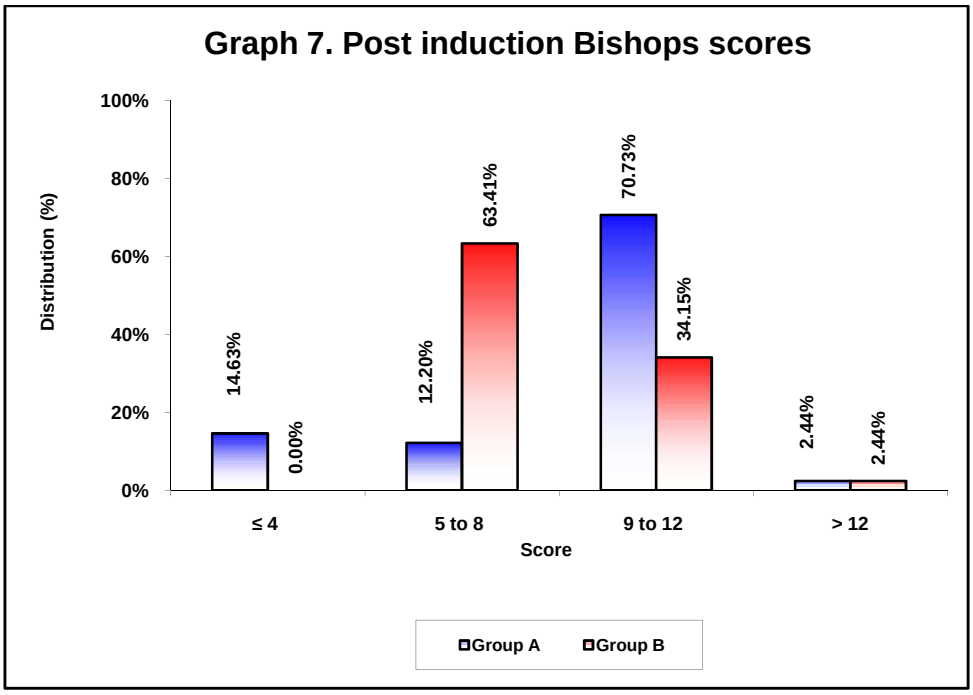
Variables	Group B (n=41)	
	Mean	**SD**
Bulb expulsion time (Hours)	3.88	3.67

In this study, in group B patients the mean bulb expulsion time was 3.88 ± 3.67.

Table 12. Post induction Bishop's scores

Score	Group A (n=41)		Group B (n=41)	
	Number	Percentage	Number	Percentage
≤ 4	6	14.63	0	0.00
5 to 8	5	12.20	26	63.41
9 to 12	29	70.73	14	34.15
> 12	1	2.44	1	2.44
Total	**41**	**100.00**	**41**	**100.00**

p<0.001



The post induction Bishop's score was between 9 to 12 among 70.73% of women in Group A compared to 34.15% of women in Group B. This difference was statistically significant (p<0.001).

Table 13. Mean post induction Bishop's score

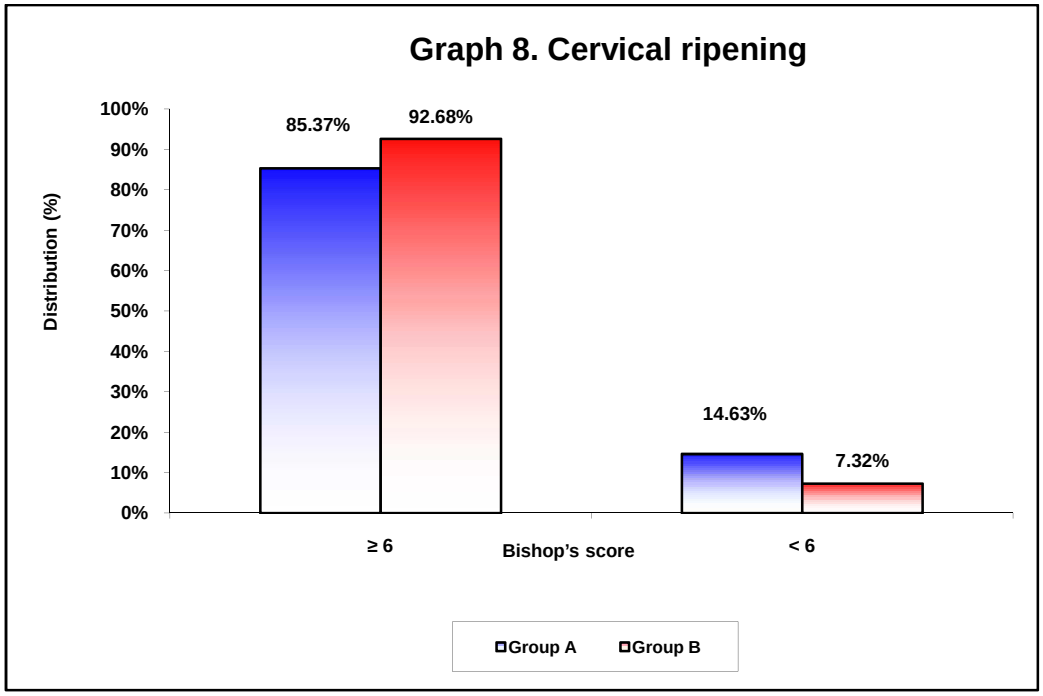
Variables	Group A (n=41)		Group B (n=41)		p value
	Mean	SD	Mean	SD	
Bishop's score	9.27	3.07	8.22	2.34	0.086

In this study, mean Bishop's score in Group A was significantly high (9.27 ± 3.07) compared to Group B (8.22 ± 2.34) (p=0.086).

Table 14. Cervical ripening

Bishop's score	Group A (n=41)		Group B (n=41)	
	Number	Percentage	Number	Percentage
≥ 6	35	85.37	38	92.68
< 6	6	14.63	3	7.32
Total	**41**	**100.00**	**41**	**100.00**

p = 0.241

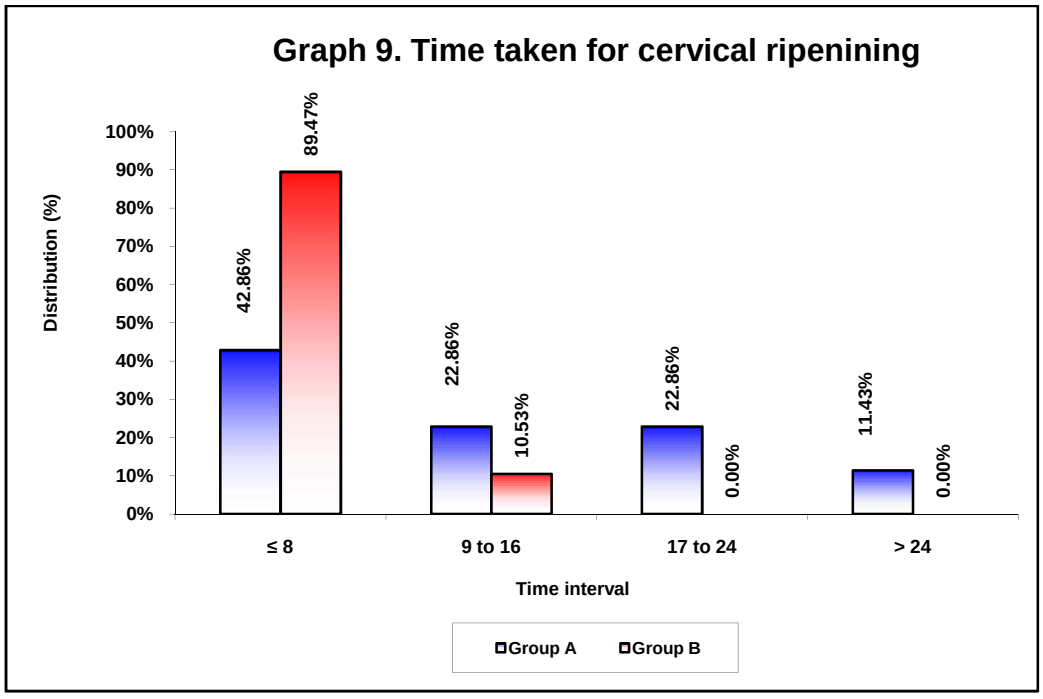


In this study, cervical ripening based on cut-off score ≥ 6 was noted in 85.37% of the women in Group A compared to 92.68% in Group B. However, the difference was statistically not significant (p=0.241).

Table 15. Time taken for cervical ripening

Time interval	Group A (n=35)		Group B (n=38)	
	Number	Percentage	Number	Percentage
≤ 8	15	42.86	34	89.47
9 to 16	8	22.86	4	10.53
17 to 24	8	22.86	0	0.00
> 24	4	11.43	0	0.00
Total	**35**	**100.00**	**38**	**100.00**

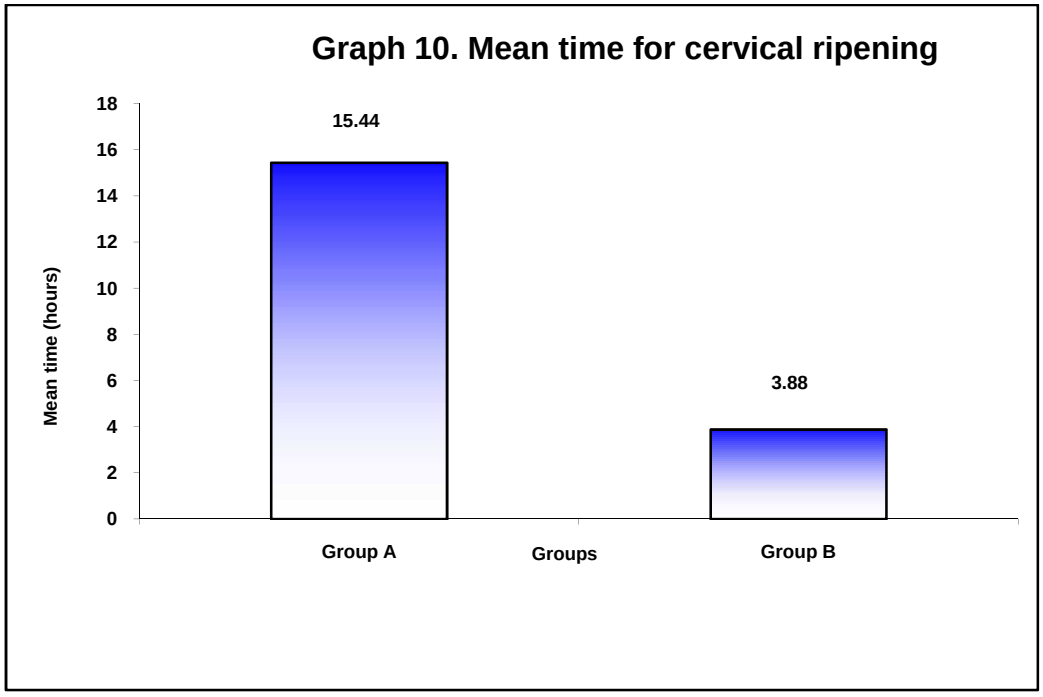
P < 0.001



In this study, significantly higher number of women in Group B (89.47%) had cervical ripening within 8 hours from the induction compared to Group A (42.86%) (p<0.001)

Table 16. Mean time for cervical ripening

Variables	Group A (n=35)		Group B (n=38)		p value
	Mean	SD	Mean	SD	
Time for cervical ripening (hours)	15.44	8.41	3.88	3.67	**<0.001**



In the present study, the mean time for cervical ripening was significantly high in Group A (15.44 ± 8.41 hours) compared to Group B (3.88 ± 3.67) ($p<0.001$).

Table 17. Mean induction to delivery time

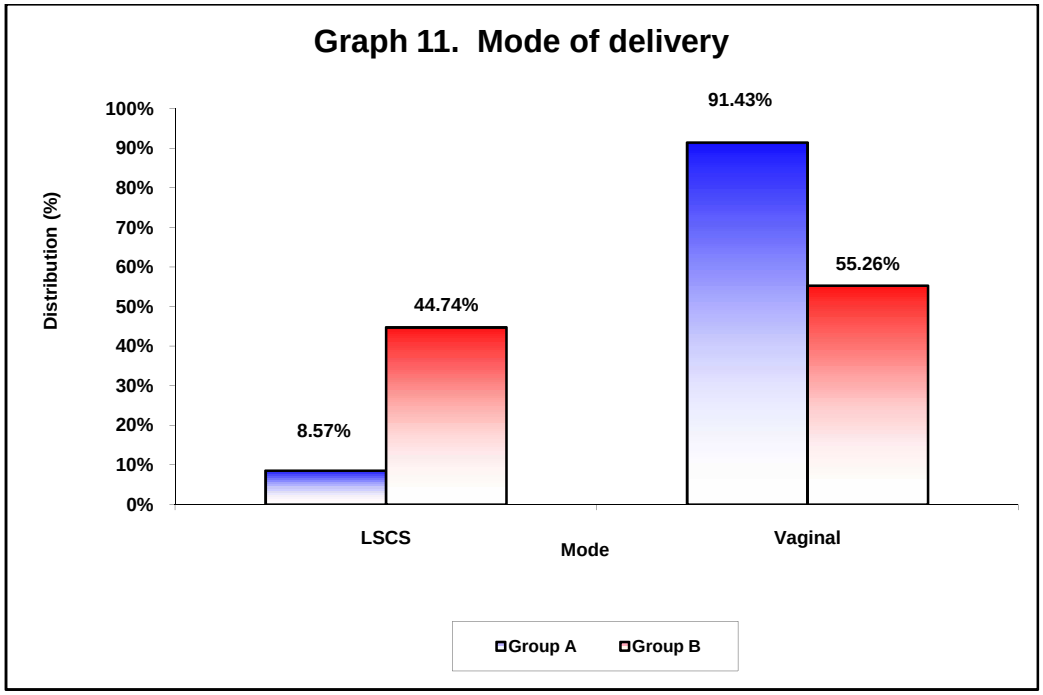
Variables	Group A (n=35)		Group B (n=38)		p value
	Mean	SD	Mean	SD	
Induction to delivery time (Hrs)	17.70	10.30	14.02	7.69	**0.086**

In this study, the mean induction to delivery time was comparable in Group A (17.70 ± 10.30 hours) and Group B (14.02 ± 7.69) (p=0.086).

Table 18. Mode of delivery

Mode	Group A (n=35)		Group B (n=38)	
	Number	Percentage	Number	Percentage
LSCS	3	8.57	17	44.74
Vaginal	32	91.43	21	55.26
Total	**35**	**100.00**	**38**	**100.00**

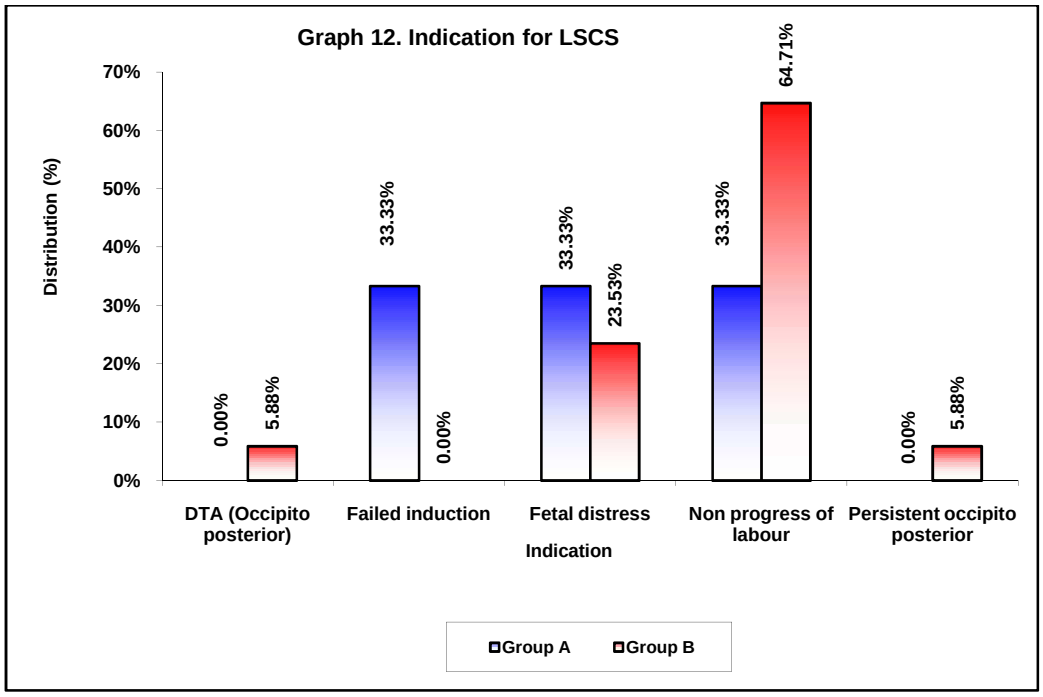
p = 0.001



In the present study, significantly higher numbers of vaginal deliveries were noted in Group A (91.43%) as compared to Group B (55.26%) (p=0.001).

Table 19. Indication for LSCS

Indication	Group A (n=35)		Group B (n=38)	
	Number	Percentage	Number	Percentage
DTA (Occipito posterior)	0	0.00	1	5.88
Failed induction	1	33.33	0	0.00
Fetal distress	1	33.33	4	23.53
Non progress of labour	1	33.33	11	64.71
Persistent occipito posterior	0	0.00	1	5.88
Total	**3**	**100.00**	**17**	**100.00**



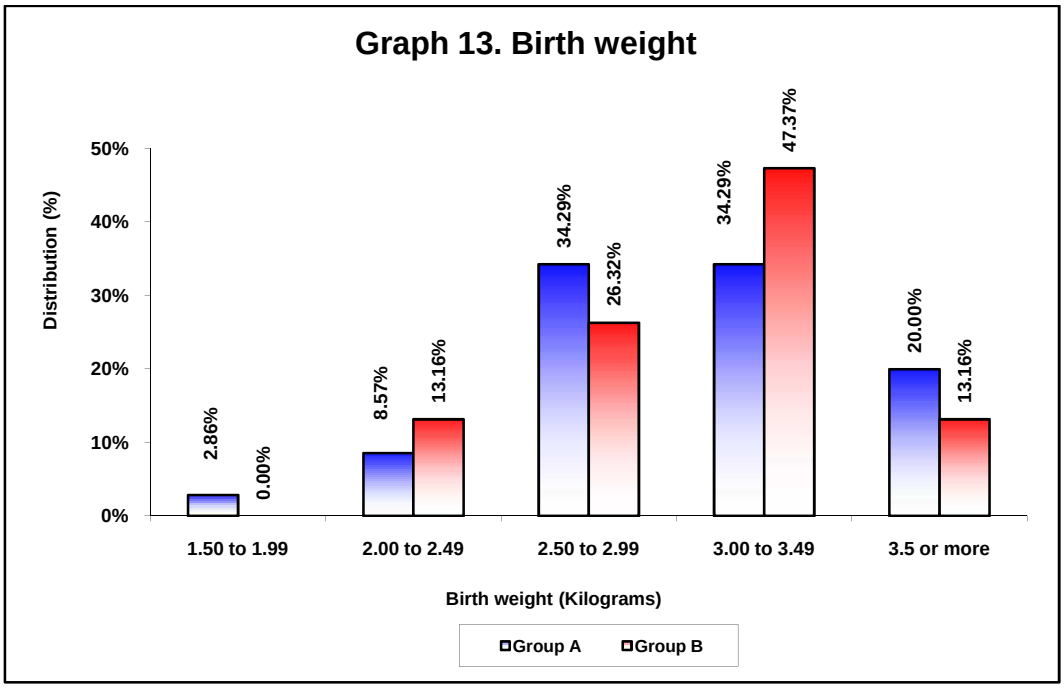
In this study non-progress of the labour was common cause of LSCS in Group B (64.71%) while in Group A failed induction, fetal distress and non progress of labour were the indications for LSCS (33.33% each).

Further, no complications were noted in both the groups.

Table 20. Birth weight

Birth weight (Kilograms)	Group A (n=35)		Group B (n=38)	
	Number	Percentage	Number	Percentage
1.50 to 1.99	1	2.86	0	0.00
2.00 to 2.49	3	8.57	5	13.16
2.50 to 2.99	12	34.29	10	26.32
3.00 to 3.49	12	34.29	18	47.37
3.5 or more	7	20.00	5	13.16
Total	**35**	**100.00**	**38**	**100.00**

p = 0.570



In the present study, no statistically significant difference was noted between Group A and B with regard to distribution of babies according to the birth weight (p=0.570).

Table 21. Mean birth weight

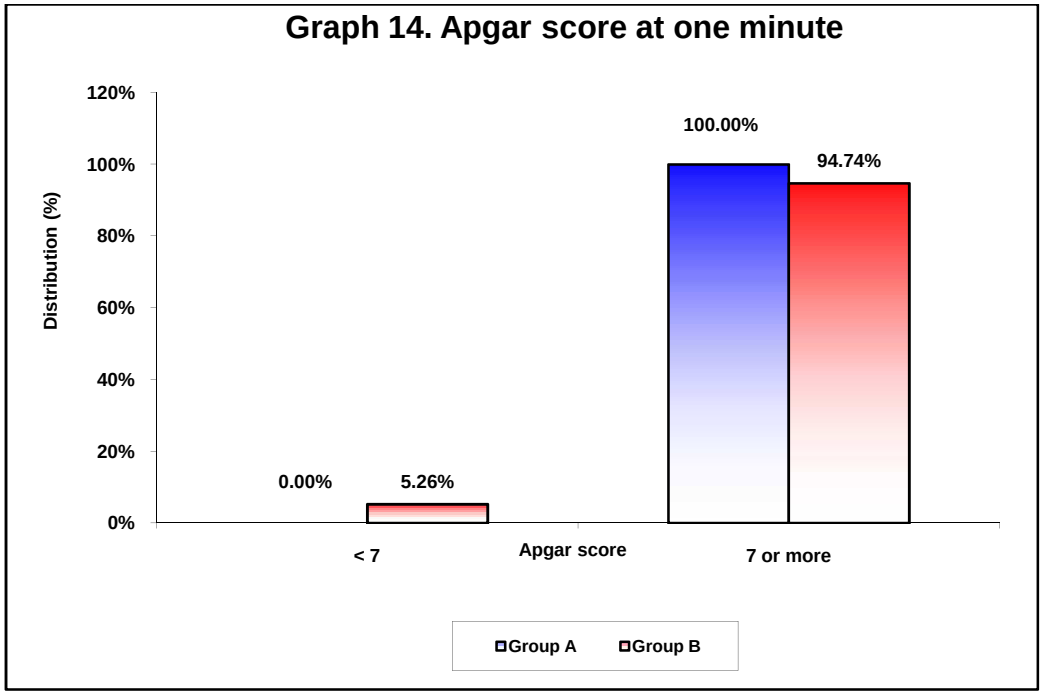
Variables	Group A (n=35)		Group B (n=38)		p value
	Mean	SD	Mean	SD	
Birth weight (Kgs)	3.02	0.50	2.98	0.41	0.739

In this study, the mean birth weight was comparable in Group A and B (3.02 ± 0.50 vs 2.98 ± 0.41 Kgs; p=0.739)

Table 22. Apgar score at one minute

Apgar	Group A (n=35)		Group B (n=38)	
	Number	**Percentage**	**Number**	**Percentage**
< 7	0	0.00	2	5.26
7 or more	35	100.00	36	94.74
Total	**35**	**100.00**	**38**	**100.00**

p = 0.268



In the present study, Apgar score at one minute was <7 in 5.26% of the babies in Group B while none of the babies had Apgar score of <7 in Group A. However, this difference was statistically not significant (p=0.268). Further all the babies in Group A and B had Apgar score of > 7 at five minutes.

Table 23. Mean Apgar score

Interval	Group A (n=35)		Group B (n=38)		p value
	Mean	SD	Mean	SD	
One minute	7.25	0.44	7.23	0.54	0.862
Five minutes	8.34	0.48	8.34	0.53	0.995

In this study, the mean APGAR score at birth (p=0.862) and at five minutes after birth (p=0.995) was comparable between Group A and B.

In the present study, no neonatal complications were observed in both the groups.

Table 24. NICU admission

NICU admission	Group A (n=35)		Group B (n=38)	
	Number	Percentage	Number	Percentage
Yes	1	2.86	2	5.26
No	34	97.14	36	94.74
Total	**35**	**100.00**	**38**	**100.00**

p = 0.531

In this study, NICU admission was required in 2.86% of the babies in Group A compared to 5.26% in Group B due to low birth weight. However, this difference was statistically not significant (p=0.531).

DISCUSSION

Mechanical methods were the first methods developed to ripen the cervix or induce labor. Among them, there are different types of catheters (including the Foley's catheter) and laminaria introduced in the cervical canal or extra-amniotic space. However, mechanical methods were never totally abandoned but extensively replaced by pharmacological methods in the last decades. There is a recent trend of reintroducing it for clinical use because of some advantages and availability of sterile devices, controlling one of the principal contraindications, i.e. infection. Potential advantages of mechanical methods in comparison with pharmacological ones include easy conservation, low cost and fewer side effects. The present study was planned to assess the outcomes of induction for labour using extra amniotic saline infusion versus intracervical dinoprostone gel with respect to improvement between pre and post induction Bishop's scores, induction to delivery interval, mode of delivery and neonatal outcome.

A randomized controlled trial for one year was carried out in the Department of Obstetrics and Gynaecology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2014 to December 2014. A total of 82 pregnant women were divided into two groups of 41 each as Group A (induced with Dinoprostone) and Group B (Using with EASI).

In the present study obstetric history including distribution maternal age (p=0.829), mean maternal age (p=0.687), gravida (p=0.549), gestational age (p=0.506), mean period of gestation (p=0.599), indication for induction (p=0.075), and pre-induction Bishop's score (p=0.780) with mean Bishop's scores (p=0.639)

were comparable in Group A and B. These findings rule the possible bias in the study results.

In this study among the pregnant women in Group A, the mean post induction time with cerviprime was high (15.44 ± 8.41 hours) and the required mean number of cerviprime doses was 2.07 ± 0.91 while in Group B, the mean expulsion time was low (3.88 ± 3.67 hours).

Extra-amniotic infusion associated to the Foley's catheter for labor induction has traditionally been used. Compared with the infusion of saline solution and PGE_2 there was a shorter permanence time with the balloon, less induction time and oxytocin need in the group using prostaglandin, however with no difference related to the type of delivery. As for the method described above, there are still many controversies.[49]

In the present study significantly higher number of women in Group A (70.73%) had post induction Bishop's scores between 9 to 12 as compared to Group B (34.15%) ($p<0.001$). Though the mean Bishop's score were high in Group A (9.27±3.07) compared to Group B (8.22 ± 2.34) statistically, the difference was not significant ($p=0.086$). These findings suggest administration of Dinoprostone gel results in favourable Bishop's score but this finding remains controversial as the mean Bishop's scores were comparable. Similar findings were described by Dahiya K. et al. [12]St. Onge et al.[68] and Ezimokhai and Nwabinelli.[69]

A randomized, prospective study was conducted by Dahiya K. et al.[12] to compare the efficacy of extra-amniotic Foley's catheter with intra cervical Dinoprostone gel for pre-induction cervical ripening. They reported mean change in

Bishop's Score as 4.18 ± 1.81 in women with intracervical extra-amniotic Foley's catheter balloon, inflated with 50 ml of normal saline as compared to 4.6 ± 1.48 in women, who received intracervical dinoprostone gel after 12 hours of initiation of process. Further, no significant difference between the mean changes in the two groups could be established.

A study by St. Onge et al.[68] has compared the Foley's catheter with a prostaglandin gel found both to be effective in changing the Bishop's score, but neither found the Foley's catheter to be more effective than gel.

Ezimokhai and Nwabinelli[69] found that ripening effect of a Foley's catheter on the cervix in 21 primigravida to be similar to that of 5 mg of PGE_2 in vaginal gel in 14 primigravida. No complication was attributable to the use of either method but the Foley's catheter was considered advantageous in its ease of use, economical and ready availability.

In the present study cervical ripening considered as Bishop's score ≥ 6 was observed in slightly higher patients who were in Group B (92.68%) compared to Group A (85.37%), but the difference was statistically not significant (p=0.241) These findings demonstrate that, the success rate of EASI using Foley's catheter is comparable with Dinoprostone gel for the induction of labour. Direct comparison of these results to other studies is limited because of reporting differences; however, some comparisons can be drawn.

Goldman JB et al.[70] also demonstrated that extra-amniotic saline infusion results in more women achieving favorable Bishop's scores than dinoprostone gel when used for pre-induction cervical ripening of an unfavorable cervix.

Schreyer et al[71] found that 67% receiving extra-amniotic saline infusion achieved a "significant change" in Bishop's score at 3 hours compared with 39% who achieved a change of 3 points or more after 6 hours of intravaginal prostaglandin E_2 tablets.

Rouben and Arias[72] also compared extra-amniotic saline infusion with intravaginal prostaglandins. In their study, 37% of women who received extra-amniotic saline infusion achieved Bishop's scores of 8 or more at 8 hours compared with 14% who received prostaglandin.

In a review of 11 reported studies, it has been suggested that ripening efficacy by catheter balloon is similar to, or better than, other methods.[73]

In this study significantly higher number of pregnant women in Group B (89.47%) had cervical ripening in ≤8 hours compared to Group A (42.86%). The duration of 9 to 16 hours was noted in only 10.53% of the pregnant women in Group B compared to 22.86% in Group A ($p<0.001$). Also the mean time taken for cervical ripening was significantly less in Group B (3.88 ± 3.67 hours) compared to Group A (15.44 ± 8.41 hours) ($p<0.001$). Furthermore, like lower mean cervical ripening time in Group B, the mean induction to delivery time was also low (14.02 ± 7.69 hours) compared to Group A (17.70 ± 10.30 hours), but the difference was statistically not significant ($p=0.086$). Hence, it may be hypothesized that, EASI using Foley's catheter requires significantly shorter duration for cervical ripening compared to Dinoprostone gel but the time required from induction to delivery is similar. Similar findings were reported in a randomized, prospective study by Dahiya K. et al.[12] where authors noted similar induction to delivery interval in both groups as 18.51 ± 8.52

hours in Foley's catheter group and 18.21 ± 11.13 hours in the prostaglandin gel group.

In the present study, cervical ripening was failed among 6 women (14.63%) of group A and 3 women (7.32%) in group B and all these women underwent LSCS. Of the 6 women in group A, 5 women (83.33%) had failed induction and one 1 woman (16.67%) had fetal distress. In group B, 2 women (66.67%) had non progress of labour and 1 woman (33.33%) had fetal distress.

Some of advantages of the Foley's catheter compared to other methods of cervical ripening and labor induction are: low cost, easy to use and principally the possibility of using it in women with prior Caesarean sections.[52]In the present study, significantly higher number of vaginal deliveries were noted in Group A (91.43%) compared to Group B (55.26%) (p=0.001). The common causes of LSCS in Group B was non progress of the labour in 11 women out of 17 women (64.71%) while in Group A failed induction, fetal distress and non progress of labour were the indications for LSCS in one women each out of 3 women (33.33% each). In contrast, Dahita K. et al.[12] reported no significant difference between Foley's catheter balloon and locally applied prostaglandin in LSCS delivery rates (10% vs 18%).

A clinical trial with over 200 pregnant women demonstrated interesting results comparing prostaglandin E2 with the Foley's catheter with similar induction time and labor time but with higher Caesarean section rates in the prostaglandin group. This difference remained significant when a group of nulliparous women was analysed, increasing the understanding that the Foley's catheter is an alternative to prostaglandin use. There was no difference on infection events between the groups.[74]

In this study, 34.29% of the newborns each had birth weight between 3.00 to 3.49 kgs and 2.50 to 2.99 kgs in Group A. In Group B, 47.37%, and 26.32% of the newborns weighed between 3.00 to 3.49 kgs and 2.50 to 2.99 kgs suggesting that the distribution of neonates according to their birth weight was comparable. The mean birth weight was also comparable in Group A and B (3.02 ± 0.50 vs 2.98 ± 0.41 Kgs; p=0.739). Further at one minute, apgar score was <7 in 5.26% of the babies in Group B while none of the baby had Apgar score of <7 in Group A and at five minutes all the babies in Group A and B had Apgar score of > 7 at five minutes. In this study the mean APGAR scores at birth (p=0.862) and at five minutes after birth (p=0.995) were comparable between Group A and B. No neonatal complications were observed in both the groups. NICU admission was required in 2.86% of the babies in Group A compared to 5.26% in Group B (p=0.531). These findings suggest that, the neonatal outcome after induction of labour with EASI using Foley's catheter was comparable to that of induction of labour with Dinoprostone gel. Similar observations were made by Dahiya K. et al.[12]who reported that, Fetal outcome data showed no significant difference between the Foley's catheter and the prostaglandin gel groups with respect to birth weight, 1-minute apgar scores and 5-minute Apgar scores. A clinical study by Rashid et al.[75] also found favourable and beneficial effect of Foley's catheter.

Overall, present study showed that both EASI using Foley's catheter and dinoprostone gel appeared to be effective agents for cervical ripening and labour induction. There was no significant difference in ripening efficacy, perinatal and neonatal outcome.

As more patients are induced for post-datism and other indications, the question of the best method of pre-induction cervical ripening remains controversial.[32]

The current study supports both the EASI using Foley's catheter and the use of exogenous prostaglandins as effective and safe. However, in specific patient populations, such as those with vaginal births after Caesarean section, the use of a Foley's catheter is a safer option. No common side effects (intrapartum or postpartum fever and vaginal bleeding, the quite-rare rupture of membranes, along with displacement of the presenting part and umbilical cord prolapse) have been seen with this simplified insertion technique in this study. Moreover, dinoprostone gel cannot be used in patients with medical disorders like bronchial asthma, epilepsy and glaucoma in which Foley's catheter can be used safely for cervical ripening. However, dinoprostone gel use is associated with higher incidence of fetal distress and hence increased chances of abdominal delivery. Therefore considering the side effects of dinoprostone gel, its irreversible effect on uterine contraction, cost and requirement of proper monitoring of foetus and mother, it is better to use Foley's catheter with EASI than dinoprostone gel. It avoids the need for continuous monitoring in health care facility. Hence, Foley's catheter is safe in contrast to dinoprostone gel.[12]

Foley's catheter causes less fetal distress. The safety profile of Foley's catheter is such that it can be used on an out patient basis, but not dinoprostone gel. These results make Foley's catheter comparable or even superior to dinoprostone gel for cervical ripening specially in developing countries. Thus, it is concluded that cervical ripening with extra-amniotic saline infusion using Foley's catheter has the advantage of simplicity, low cost, reversibility and lack of serious side effects.

CONCLUSION

Based on the findings of this study it may be concluded that, extra-amniotic saline infusion using Foley's catheter has slightly higher success rate for cervical ripening for induction of labour as determined by Bishop's score of ≥ 6 compared to intracervical dinoprostone gel. In addition, time taken for cervical ripening is significantly less with extra amniotic saline infusion using Foley's catheter. Though extra-amniotic saline infusion Foley's catheter resulted in higher success rate with less time for cervical ripening the rate of caesarean section is high.

Furthermore, the neonatal outcome in babies born to women undergoing extra-amniotic saline infusion using Foley's catheter is comparable with those who have induction of labour with intracervical dinoprostone gel.

SUMMARY

Success of induction depends largely on cervical status; an unripe cervix conveys a lower likelihood of vaginal delivery. This study compared the outcomes of induction for labour using extra-amniotic saline infusion versus intracervical dinoprostone gel in terms of improvement between pre and post induction Bishop's scores, induction to delivery interval, mode of delivery and neonatal outcome.

A randomized controlled trial for year was conducted in the Department of Obstetrics and Gynaecology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi after obtaining an approval from Institutional Ethics committee and written informed consent.

- 82 pregnant women from January 2014 to December 2014 meeting the inclusion criteria were taken for evaluation.

- The selected women were divided into two groups of 41 each as Group A (induced with Dinoprostone gel) and Group B (induced with EASI using Foley's catheter).

- Maximum women in Group A (48.78%) and Group B (51.22%) were aged between 21 to 25 years (p=0.829) and the mean age in Group A (22.27 ± 3.11 years) and Group B (22.54 ± 2.88 years) was comparable (p=0.687).

- Obstetric history revealed that 58.54% of the women were primigravida in Group A compared to 65.85% of the pregnant women in Group B (p=0.549).

- 51.22% and 58.54% of the pregnant women had gestational age between 41 to 42 weeks in Group A and Group B respectively (p=0.506).

- The demographic characteristics, obstetric history, indications for induction and pre-induction Bishop's score in Group A and B (p>0.050) were comparable.

- The post induction Bishop's scores were between 9 to 12 in significantly higher number of women in Group A (70.73%) compared to Group B (34.15%) (p<0.001).

- In addition, the mean Bishop's score in Group A were significantly high (9.27 ± 3.07) compared to Group B (8.22 ± 2.34) (p=0.086).

- Cervical ripening based on cut-off score ≥ 6 was noted in significantly higher number of women (92.68%) in Group B compared to Group A (85.37%) (p=0.241).

- Significantly higher number of women in Group B (89.47%) had cervical ripening within 8 hours from the induction compared to Group A (42.86%) (p<0.001) and the mean time for cervical ripening time was significantly high in Group A (15.44 ± 8.41 hours) compared to Group B (3.88 ± 3.67) (p<0.001).

- The mean induction to delivery time was comparable in Group A (17.70 ± 10.30 hours) and Group B (14.02 ± 7.69) (p=0.086).

- Significantly higher number of vaginal deliveries were noted in Group A (91.43%) compared to Group B (55.26%) (p=0.001).

- No statistically significant difference was noted between Group A and B with regard to distribution of babies according to the birth weight (p=0.570), mean birth weight (p=0.739), apgar score at one minute (p=0.268) and five minutes, and NICU admissions (p=0.531).

Extra-amniotic saline infusion using Foley's catheter and dinoprostone gel appeared to be effective methods for cervical ripening and labour induction, but extra amniotic saline infusion using Foley's catheter results in higher rate of caesarean section.

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ANNEXURE I – ETHICAL CLEARANCE

K.L.E.SOCIETY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
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Ref: MDC/DOME/ 76 **Date: 30/11/2013**

To,

(REG.NO. BJ0113002)

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled "**A randomized control trial of extra – amniotic saline infusion versus intracervical dinoprostone gel for induction of labour**" is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Hema Dhumale)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belgaum.

(Dr.Ganga Pilli)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belgaum.

ANNEXURE II – CONSENT FORM

INFORMED CONSENT FORM FOR PARTICIPATION IN THE RESEARCH STUDY

TITLE: A Randomized control trial of extra-amniotic saline infusion versus intracervical dinoprostone gel for induction of labour.

Mr./Mrs./Ms. _____ we are requesting you to enroll yourself in study conducted by

Your participation in this research is voluntary. Your decision whether or not to participate in the study will not affect your relationship with the institute or in the standard of care provided to you. If you decide to participate, you are free to withdraw at any time.

Purpose of the study:

This study will help to compare the effectiveness of extra-amniotic saline infusion using Foley's catheter versus commonly used intra-cervical dinoprostone gel for induction of labour.

Procedure Involved:

If you agree to enroll yourself in my study, you will be allotted into one of the two groups randomly using computer-generated software. One group will have extra-amniotic saline infusion and other will have intra-cervical dinoprostone insertion.

Risks:

Induction of labour with dinoprostone gel is associated with risk to mother and fetus. Maternal side effect includes uterine over activity, fever, nausea, vomiting, and diarrhea and also it is costly. Fetal side effects include fetal distress. While extra-amniotic saline infusion may cause infection (chorioamnionitis), rupture of membranes. In any point of induction for fetal distress your pregnancy will be terminated by cesarean section.

Benefits:

It will help to formulate local evidence based guideline to reduce induction to delivery time and hence better maternal and fetal outcome.

Voluntary Participation/Withdrawal:

Taking part in the study is voluntary. You may choose not to enroll yourself in this study. Your decision will not change present or future health care services offered to you at KLE'S DR. PRABHAKAR KORE CHARITABLE HOSPITAL.

Alternatives:

Even if you decline the participation in the study, you will get the routine line of management.

Privacy and Confidentiality:

The only people to know that you are a research subject are members of the research team. No information about you or information provided by you during the research will be disclosed to other without your written permission except:

1. In emergency to protect your rights and welfare.
2. If required by law.

Authorization to Publish Results:

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with your identity remaining confidential.

Questions:

If you have any queries about your rights as a study subject, you may call Dr. Ganga Pilli, Professor, Department of Pathology and Chairman, J.N. Medical College Institutional Ethical Committee for Human Subjects Research, Phone number-9448863866, or extension 4052 at J.N. Medical College, Belagavi.

"A RANDOMIZED CONTROL TRIAL OF EXTRA- AMNIOTIC SALINE INFUSION VERSUS INTRACERVICAL DINOPROSTONE GEL FOR INDUCTION OF LABOUR, IN KLE'S DR. PRABHAKAR KORE CHARITABLE HOSPITAL, BELAGAVI-590010

Consent for participation in research trial

I, Mr./Mrs./Ms. _____ voluntarily agree for the participation as a subject of study. By signing the consent form I am not giving up any of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read for me in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name: _____

Signature or the Left Thumb Print of Subject: _____

Date:

Witness Name: _____ Signature: _____

Date:

Investigators Name: _____ Signature: _____

Date: Place: _____

KANNADA CONSENT FORM

ಸಂಶೋಧನಾಅಧ್ಯಯನದಲ್ಲಿಪಾಲ್ಗೊಳ್ಳುವಿಕಗಾಗಿನಮಾಹಿತಿಯುಕ್ತಸಮ್ಮತಿಯನಮೂನ

ಶೀರ್ಷಿಕ: (ಟೈಟಲ್) ರಂಡಮೈಸಡ್ ಕಂಟ್ರೋಲ್ ಟ್ರೈಯಲ್ ಆಫ್ ಎಕ್ಸ್ಪ ಏಮ್ನಿಯೋಟಿಕ್ ಸಲ್ಯನ ಇನಫ್ಯುಜನ್ V/s ಪ್ರವೇಶಇಂಟ್ರಾಸವಿ ಕಲ ಡೈನೋಪ್ರೋಸ್ಟೋನ್ಜೆಲ್. ಫಾರ್ ಇಂಡಕ್ಷನ್ ಆಫ್ ಲೇಬರ

ಶ್ರೀ/ಶ್ರೀಮತಿ/ ಎಂಎಸ್._____ _____

ನಾವುಡಾಶೆಟ್ಟಿವಿರೊಡ್ರಿಗಸ್,ಸ್ನಾತಕೋತ್ತರಎಂ.ಎಸ್ನಡಸಿದಅಧ್ಯಯನದÅö ಲ್ಲಿನಿಮ್ಮನ್ನುತೊಡಗಿಸಿಕೊಳ್ಳುವದಕ್ಕೆವಿನಂತಿಸುತ್ತಿದ್ದೇವೆಡಾ. ಪ್ರೊಫೆಸರ್, ಪ್ರಸೂತಿಇಲಾಖೆಮತ್ತುಸ್ತ್ರೀ ರೋಗ, J. N. Medical ಕಾಲೇಜ್ಬೆಳಗಾವಿನೇರಮೇಲ್ವಿಚಾರಣೆಮತ್ತುಮಾಗ ದಶ ನ ಅಡಿಯಲ್ಲಿಪ್ರಸೂತಿಮತ್ತುಸ್ತ್ರೀ ರೋಗ, KLE ವಿಶ್ವವಿದ್ಯಾಲಯಬೋಧನೆಆಸ್ಪತ್ರೆ, ಬೆಳಗಾವಿವಿಭಾಗದಲ್ಲಿ.

ಅರ್ಹತಾಮಾನದಂಡಗಳನ್ನುಈಡೇರಿಸುವರೋಗಿಗಳಅಧ್ಯಯನಕ್ಕಾಗಿಸೇರಿಸಲಾಗುವುದು.

ಅಧ್ಯಯನದಸಮಯದಲ್ಲಿನಮ್ಮೆಪ್ರಸ್ತುತದೂರುಬಗ್ಗೆಕಲವುಪ್ರಶ್ನೆಗಳನ್ನುಕೇಳಲಾಗುತ್ತದೆಮತ್ತುನಮ್ಮಜ್ಞಾನದಂ ದೆಅತ್ಯುತ್ತಮಉತ್ತರಸಲುಬರಬೇಕು.

ಈಸಂಶೋಧನೆಯಲ್ಲಿನಿಮ್ಮಭಾಗವಹಿಸುವಿಕವ್ಯಯಕ್ತಿಕವಾಗಿದ್ದು.

ಅಧ್ಯಯನದಲ್ಲಿಭಾಗವಹಿಸುವುದೋಇಲ್ಲವೋಎಂಬನಿಮ್ಮನಿರ್ಧಾರವನ್ನುನೀವುಒದಗಿಸಿದಚಿಕಿತ್ಸೆಯಗುಣಮಟ್ಟವು ಇನ್ಸ್ಟಿಟ್ಯೂಟ್ ದಲ್ಲಿನಿಮ್ಮಮೇಲೆ ಪರಿಣಾಮಬೀರುವುದಿಲ್ಲ.

ನೀವುಭಾಗವಹಿಸಲುನಿರ್ಧರಿಸಿದ್ದಾರೆನೀವುಯಾವುದೇಸಮಯದಲ್ಲಿಹಿಂದಕ್ಕೆಸರಯಬಹುದು.

<u>ಅಧ್ಯಯನದಉದ್ದೇಶ:</u>

ಈಅಧ್ಯಯನವುಕಾರ್ಮಿಕರನೇಮಕಕ್ಕೆಸಾಮಾನ್ಯವಾಗಿಬಳಸಲಾಗುತ್ತದೆಆಂತರಿಕಗರ್ಭಕಂಠದdin oprostoneಜೆಲ್ವಿರುದ್ಧಫಾಲೇಕ್ಯಾತಿಟರ್ಬಳಸಿಕೊಂಡುಹೆಚ್ಚುವರಿಆಮ್ನಿಯೋಟಿಕ್ದ್ರವಣಯುಕ್ತದ್ರಾವಣಗಳನ್ನುಕ್ಷಮತೆಯನ್ನುಹೋಲಿಸಲುಸಹಾಯಮಾಡುತ್ತದ.

<u>ವಿಧಾನಒಳಗೊಂಡ:</u>

ನೀವುನನ್ನಅಧ್ಯಯನದಲ್ಲಿನಿಮ್ಮನ್ನುತೊಡಗಿಸಿಕೊಳ್ಳುವುದು ಆದಲ್ಲಿಒಪ್ಪುತ್ತೀರಿ ಎಂದರ ನಿಮ್ಮನ್ನುಕಂಪ್ಯೂಟರ್ಆಧಾರಿತತಂತ್ರಾಂಶಬಳಸಿಎರಡುಗುಂಪುಗಳಲ್ಲಿಒಂದರೊಳಗತೆಗೆದುಕೊಳ್ಳಲಾಗುತ್ತದ .ಒಂದುಗುಂಪುಹೆಚ್ಚುವರಿಆಮ್ನಿಯೋಟಿಕ್ದ್ರವಣಯುಕ್ತದ್ರಾವಣಗಳನ್ನುಹೊಂದಿರುತ್ತದಮತ್ತು ಇನ್ನೊಂದುಇತರಆಂತರಿಕಗರ್ಭಕಂಠದdinoprostoneಅಳವಡಿಕೆಹೊಂದಿರುತ್ತದೆ.

<u>ಅಪಾಯಗಳು:</u>

ಕಾಮಿ ಕನ dinoprostone ಜಲ್ಯವೇಶತಾಯಿಮತ್ತುಭ್ರೂಣಕ್ಕೆಅಪಾಯವಿದ.

ತಾಯಿಯಅಡ್ಡಪರಿಣಾಮಚಟುವಟಿಕೆಯಮೇಲೆಗರ್ಭಾಶಯದ, ಜ್ವರ, ವಾಕರಿಕೆ, ವಾಂತಿ,ಮತ್ತುಭೇದಿಮತ್ತುಇದುದುಬಾರಿ.

ಭ್ರೂಣದಅಡ್ಡಪರಿಣಾಮಗಳುಭ್ರೂಣದಒತ್ತಡ.ಹೆಚ್ಚುವರಿಆಮ್ನಿಯೋಟಿಕ್ದ್ರವಣಯುಕ್ತದ್ರಾವಣಗಳನ್ನು(chrioam nionitis) cause infectionವಿಧಿಸಬಹುದು, membranes ಆಫ್ rupture.

ಭ್ರೂಣದಯಾತನದ್ವಾರಪ್ರವೇಶಯಾವುದೇಹಂತದಲ್ಲಿ,ನಿಮ್ಮ pregnancy ವಿಭಾಗ ದಿಂದ ಅಂತ್ಯಗೊಳ್ಳುತ್ತದೆ.

ಪ್ರಯೋಜನಗಳು:

ಇದು ಡೆಲಿವರಿ (ವಿತರಣಾ)ಸಮಯಇಂಡಕ್ಷನ್‌ಆದ್ದರಿಂದಉತ್ತಮ ರೀತಿಯಿಂದ ತಾಯಿಯಹಾಗುಮಗುವಿನಫಲಿತಾಂಶ ಸ್ಥಳೀಯಸಾಕ್ಷಿಆಧಾರಿತಮಾರ್ಗದರ್ಶಿರೂಪಿಸಲುಸಹಾಯಮಾಡುತ್ತದ.

ವಾಲಂಟರಿಭಾಗವಹಿಸುವಿಕೆ/ Withdrawal:

ಅಧ್ಯಯನದಲ್ಲಿಭಾಗವಹಿಸುವುದುವ್ಯಯಕ್ತಿಕವಾಗಿದ್ದು.ಈಅಧ್ಯಯನದಲ್ಲಿನಿಮ್ಮನ್ನುತೊಡಗಿಸಿಕೊಳ್ಳುವುದೋಇಲ್ಲವೋ ಎಂಬುದನ್ನುಆಯ್ಕೆಮಾಡಬಹುದು.ನಿಮ್ಮನಿರ್ಧಾರದಿಂದ KLE'S DR.PRABHAKAR ಕೋರಚಿಕಿತ್ಸಾಲಯಲ್ಲಿನಿಮಗೆಪ್ರಸ್ತುತಅಥವಾಭವಿಷ್ಯದಆರೋಗ್ಯಸೇವಗಳುಬದಲಾಗುವುದಿಲ್ಲ

ಪರ್ಯಾಯಗಳು:

ನೀವುಅಧ್ಯಯನದಲ್ಲಿಪಾಲ್ಗೊಳ್ಳುವಿಕೆಯನ್ನು ಒಪ್ಪದಿದ್ದಲ್ಲಿನಿಮ್ಮನಿರ್ವಹಣೆಯದಿನನಿತ್ಯದವೃತ್ತಿಯನ್ನುಪಡೆಯುತ್ತಿರಿ.

ಗೌಪ್ಯತೆಮತ್ತುರಹಸ್ಯವಾದ:

ಜನರು ಮಾತ್ರನೀವುಸಂಶೋಧನಾತಂಡದಸದಸ್ಯರುಸಂಶೋಧನಾವಿ ತೊಡಗಿಸಿಕೂಂಡಿದ್ದೀರಿ ಎಂದುತಿಳಿಯಲ.

ನೀವುಅಥವಾಸಂಶೋಧನೆಯಸಮಯದಲ್ಲಿನೀವುನೀಡಿದಮಾಹಿತಿಯಬಗ್ಗೆಯಾವುದೇಮಾಹಿತಿಹೊರತುಪಡಿಸಿನಿಮ್ಮಲಿಖಿತಅನುಮತಿಇಲ್ಲದಬಹಿರಂಗಪಡಿಸಲಾಗುವುದಿಲ್ಲ:

ತುರ್ತು

1.ತುರ್ತು ಪರಿಸ್ಥಿತಿಯಲ್ಲಿನಿಮ್ಮಹಕ್ಕುಗಳುಮತ್ತುಅಭಿವೃದ್ಧಿಯನ್ನುರಕ್ಷಿಸಲು.

2.ಕಾನೂನಿನಅಗತ್ಯಗೊಳಪಟ್ಟು

ಅಧಿಕಾರಫಲಿತಾಂಶಗಳುಪ್ರಕಟಿಸಿಗೆ:

ಸಂಶೋಧನೆಯಫಲಿತಾಂಶಗಳನ್ನುಪ್ರಕಟಿಸಿಅಥವಾಕುರಿತುಚರ್ಚಿಸುವಾಗ, ಕಾನ್ಫರನ್ಸ್, ಯಾವುದೇಮಾಹಿತಿನಿಮ್ಮನ್ನು ಗುರುತಿಸಲುಬಹಿರಂಗಪಡಿಸುವುದಿಲ್ಲವಂದುಈಅಧ್ಯಯನದಲ್ಲಿಸಂಬಂಧಿಸಿದಂತಪಡಯಲಾಗುವ ಮಾಹಿತಿಯನ್ನು ಈ ವಿಷಯಕ್ಕೆ ಸಂಬಂಧಿಸಿದಂತೆನಿಮ್ಮಗುರುತನ್ನುಗೌಪ್ಯವಾಗಿಉಳಿಸುತ್ತೇವೆ.

ಪ್ರಶ್ನೆಗಳು:

ಯಾವುದೇ ಸಂದರ್ಭದಲ್ಲಿನೀವುಅಧ್ಯಯನದಸಂಬಂಧಿಸಿದಯಾವುದೇಪ್ರಶ್ನೆಗಳನ್ನುಹೊಂದಿದ್ದರ, ಭವಿಷ್ಯದಲ್ಲಿಅಥವಾಅಧ್ಯಯನಕ್ಕೆಸಂಬಂಧಿಸಿದತೊಡಕುಗಳನ್ನುಅಥವಾಅನಾರೋಗ್ಯದಸಂದರ್ಭದಲ್ಲಿ, ನೀವು

Dr.Ganga Pilli, ಪ್ರೊಫೆಸರ್ ಇವರಿಗೆಕರಮಾಡಬಹುದು, ನಿರ್ಗಮನ[ಮಾನವ ವಿಷಯಗಳ ಫಾರ್ಮಥಾಲಜಿ ಹಾಗೂಅಧ್ಯಕ್ಷರುJ.N Medicalಕಾಲೇಜ್ಆಫ್ Institute of ಎಥಿಕಲ್ Commitee ರಿಸರ್ಚ್ , ದೂರವಾಣಿಸಂಖ್ಯೆ-9448863866, ಅಥವಾವಿಸ್ತರಣೆಗೆ 4052 J.N.Medical, ಬೆಳಗಾವಿ.

ರೆಂಡಮೈಸೆಡ ಕಂಟ್ರೋಲ ಟ್ರೈಯಲ್ ಆಫ್ ಎಕ್ಸಾ ಎಮ್ಮಿಯೋಟಿಕ್ ಸಲ್ಯನ ಇನಫ್ಯುಜನ್ V/s ಇಂಟ್ರಾಸವಿ ಕಲ ಡೈನೋಪ್ರೋಸ್ಟೋನ್ಜೆಲ್. ಫಾರ್ ಇಂಡಕ್ಷನ್ ಆಫ ಲೇಬರ ಇನ "KLE'S DR.PRABHAKAR KORECHARITABLE HOSPITAL BELAGAVI-590010

ಸಂಶೋಧನಪ್ರಯೋಗದಲ್ಲಿಭಾಗವಹಿಸಲುಸಮ್ಮತಿ

ನಾನುಶ್ರೀ / ಶ್ರೀಮತಿ / _____

ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದಅಧ್ಯಯನದವಿಷಯವಾಗಿಭಾಗವಹಿಸುವಿಕಒಪ್ಪುತ್ತೇ . ನಾನು ಕಾನೂನುಹಕ್ಕುಗಳನ್ನು ಈಒಪ್ಪಿಗೆಪತ್ರಕ್ಕೆಸಹಿಮಾಡುವಮೂಲಕ ಬಿಟ್ಟುಕೊಡುವುದಿಲ್ಲಯಾವಸಮಯದಲ್ಲಾದರೂಹಿಂದಕ್ಕೆ ಸರಿಯಬಹುದು. ಓದಿದನಂತರಅಥವಾನನಗೆಅಪಾಯಗಳುಮತ್ತುಲಾಭಗಳಸೇರಿದಂತೆಮತ್ತುನನ್ನಪ್ರಶ್ನಗಳಿಗಉತ್ತರಿಸಿದ ಹೊಂದಿರುವದೇಶೀಯಭಾಷೆ, ಓದಲುಮಾಡಲಾಗಿದೆನಂತರನಾನುಒಪ್ಪಿಗೆಪತ್ರಕ್ಕೆಸಹಿಮಾಡಿರುತ್ತೇನೆ.

ವಿಷಯಹೆಸರ :_____

ಸಹಿಅಥವಾವಿಷಯವಿಡಹಬ್ಬರಳುಮುದ್ರಣ: _____

ದಿನಾಂಕ:

ವಿಟ್ನೆಸ್ಹೆಸರು:_____ಸಹಿ: _____

ದಿನಾಂಕ:

ಇನ್ವೆಸ್ಟಿಗೇಟರ್ಹೆಸರು: _____ ಸಹಿ: _____

ದಿನಾಂಕ:

ಸ್ಥಳ:_____

ANNEXURE III – PROFORMA

PROFORMA

A RANDOMIZED CONTROL TRIAL OF EXTRA-AMNIOTIC SALINE INFUSION (EASI) VERSUS INTRACERVICAL DINOPROSTONE GEL FOR INDUCTION OF LABOUR.

S.I.NO: ☐☐☐ DATE: ☐☐☐☐☐☐

OP/IP NO: ☐☐☐☐☐☐ Registered/Unregistered ☐☐

Patients Name: _____

Age: _____

Address: _____

_____

_____

Contact No: _____

Obstetric History:

G ☐ P ☐ L ☐ A ☐ D ☐

Menstrual History:

LMP: ☐☐☐☐☐☐

EDD: ☐☐☐☐☐☐

Period of Gestation:

Antenatal Complication: ☐

Indication for EASI:

Indication for DINOPROSTONE GEL:

BISHOP'S SCORE

PARAMETERSTIME						
DILATATION (CM)						
LENGTH						
CONSISTENCY						
POSITION						
HEAD: STATION						
FHS						
BISHOP'S SCORE						

Pre-treatment Bishop's Score:

EASI Insertion Time:

EASI Expulsion Time:

Post-treatment Bishop's Score:

Mode of delivery: VAGINAL

VENTOUSE

FORCEPS

C-SECTION

Indication:_____

Time of delivery:

Birth weight:

Apgar score: 1 min

5 min

Complications: _____

Induction to delivery internal:

DINOPROSTONE GEL:

Pre-treatment Bishop's Score: ☐

Dinoprostone induction time: ☐

Post-treatment Bishop's Score: ☐

Mode of delivery: VAGINAL ☐

VENTOUSE ☐

FORCEP ☐

C-SECTION ☐

Indication_____

Induction to Delivery interval: _____

Time of delivery: ☐

Birth weight: ☐

Apgar score: 1 min ☐

5 min ☐

Maternal complications:

Chorioamnionitis: Yes/ No ☐

Postpartum metritis: Yes/No ☐

Neonate complications: ☐

NICU Admission: Yes/No

Reason for admission in NICU: _____

Neonatal stay in NICU: _____

Outcome (discharge): _____

ANNEXURE IV – KEY TO MASTER CHART

LSCS	-	Lower segment caesarean section
Kgs	-	Kilograms
NICU	-	Neonatal Intensive Care Unit
Wk	-	Week
d	-	Days
IUGR	-	Intrauterine growth restriction
hrs	-	Hours
mins	-	Minutes
NPL	-	Non progress of labour
LBW	-	Low birth weight
DTA	-	Deep transverse arrest