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LIST OF ABBREVIATIONS

ACOG	American College of Obstetrics and Gynaecology
ANC	Antenatal clinic
ARM	Artificial rupture of membranes
BMI	Body Mass Index
C/S	Caesarean section
CPD	Cephalo-pelvic disproportion
FIGO	International Federation of Obstetrics and Gynaecology
PGs	Prostaglandins
PGE1	Misoprostol
PGE2	Dinoprostone
RU 486	Mifepristone
RCOG	Royal College of Obstetricians and Gynaecologists
MLCK	Myosin Light Chain Kinase
WHO	World Health Organization

LIST OF NOMENCLATURE

Expected date of delivery (EDD)- 280 days or 40 completed weeks from the last menstrual period.

Post-maturity: Post-maturity or Post-maturity Syndrome (PMS) can only be diagnosed after delivery and is defined as a post-dated pregnancy accompanied with any combination of the following newborn assessments

a. No Lanugo (fine body hair)
b. Long Nails
c. Abundant Hair on Head
d. Calcified Fetal Skull
e. Hanging Or Wrinkled Skin, With the Appearance Of Weight Loss
f. Dehydrated
g. Alert Face
h. Peeling Skin
i. Little or No Vernix
j. Oligohydramnios
k. Meconium or bile staining of skin and long, thin growth retarded body with long thin limbs.

Induction of labour: Initiation of labour by artificial means prior to its spontaneous onset at a viable gestational age, with the aim of achieving vaginal delivery in a pregnant woman with intact membranes. (WHO).

Successful induction: A vaginal delivery within 24 to 48 hours of induction of labour.

Elective induction: Induction of labour in the absence of acceptable fetal or maternal indications.

Cervical ripening: The cervix becomes soft, yielding and more easily dilatable-process known as cervical ripening.

Tachysystole: >5 uterine contractions in 10 minutes over a period of 30 minutes always in relation to the presence or absence of decelerations. This is further subdivided into two categories, one with and one without fetal heart rate changes.

Hyperstimulation: Excessive uterine contractions (tachysystole or hypertonus) as a result of induction of labour with non reassuring fetal heart rate changes

Hypertonus: as a single contraction lasting longer than 2 minutes.

Amniotomy: Artificial rupture of the membranes to initiate or speed up labour.

Failed induction: Failure to achieve regular (every 3 minutes) uterine contractions and cervical change after atleast 6-8 hours of the maintenance dose of oxytocin administration, with artificial rupture of membranes.

1. Insertion of three intracervical PGE2 gel (3gm) at 6-hourly intervals, and 12-24 hours of oxytocin administration after rupture of membranes, if feasible, or
2. One PGE2 pessary (10 mg) within 24 hours.

ABSTRACT

AIM and OBJECTIVES:

Induction of labour is artificial initiation of uterine contractions before spontaneous onset of labour or after the period of viability of the fetus. Induction of labour is indicated when complications of pregnancy may have a negative impact on the health of the mother, fetus, or both. Induction of labour is therapeutic option when the benefits of the delivery outweigh the risks of continuing the pregnancy. Routine antenatal ultrasound for confirmation of EDD has been shown to reduce induction rates for post dated pregnancies after correction of dates. Prolonged pregnancy is known to be associated with significantly increased risks of perinatal and maternal complications.

Primary Objectives:

- To study the effectiveness and safety of mifepristone for cervical ripening for induction of labour in term pregnancies
- To compare the effect of mifepristone in study group with control group of same size
- To observe the improvement in cervical score as compared to control group
- To critically evaluate the effect of these drugs on primigravida and multigravida

Secondary Objectives:

- Induction to Delivery interval
- Mode of delivery
- Maternal and Fetal outcome

METHODOLOGY:

After Institutional ethical committee approval and informed written consent, 88 patients will be selected for the study based on inclusion and exclusion criteria. Patient will be randomly allocated into 2 groups (i.e. Group A and Group B) using computerized random number. A computer-generated randomization schedule will be prepared and placed into numbered opaque envelopes by an uninvolved third party before the initiation of the study.

Randomization will be done after the decision had been made that the patient required an induction of labour and after a cervical examination demonstrated a Bishop's score of <6. On admission detailed history, and complete general and obstetric examination carried out. Vaginal examination was done under strict aseptic precautions and the cervical status, fetal station are assessed. Gestational age was calculated by Naegele's rule and a routine obstetric scan for fetal maturity and wellbeing was done.

Out of 88, 44 pregnant women will be given tablet mifepristone 200mg orally and other 44 are allowed for spontaneous onset of labour.

After the waiting period of 24 hours or when the bishop's score was >6 or when the membranes ruptured or when the patient was well in labour whichever is earlier labour is accelerated with oxytocin drip,2nd dose of PGE2 gel will be given after 6 hours if there is no improvement in Bishop's score.

The efficacy was assessed by favourability of bishop's score at 24 hours, need of oxytocin for augmentation, duration of first, second, third stage of labour, drug administration to delivery interval, mode of delivery ,c-section rate, APGAR Score, neonatal complications, maternal complications.

RESULTS:

Our study included 88 patients out of which 44 were treated with Mifepristone,44 were allowed for spontaneous onset of labour with waiting period of 24 hours. Among the study group,64 women are Primigravida and 24 women are multigravida.

Out of 44 in Group A, more than half of them were belonged to 18-24 years and 29% were in 25-29 years of age group. In Group B 56% were fall in 18-24 years age category and nearly 40% (38.6%) were belonged to 25-29 years of age. Both the groups are similar in age.

The mode of delivery in the women who were enrolled in the study was found to be significant as 84% of patient in group A delivered vaginally compared to 68% in group B(Spontaneous onset of labour with waiting period of 24 hrs). 16% patients were undergone caesarean section in mifepristone group A as compared to 32% in group B. The mean duration of induction – delivery interval was found to be 25 hours in group A compared to 35 hours in group B. The incidence of Meconium stained liquor in group A was found to be 5% compared to 21% in group B. The incidence of PPH observed in the study was found to be insignificant.

CONCLUSION:

Thus, based on the results observed in our study, Tab.Mifepristone can be considered as effective in induction of labour in term pregnancy. (40 Weeks).

Keywords: Induction of labour, Mifepristone, induction-delivery interval, neonatal outcome.

INTRODUCTION

Induction of labour is defined as the stimulation of uterine contractions to bring about the delivery before the onset of spontaneous labour or after the period of viability. Induction of labour is indicated when complications of pregnancy may have a negative impact on the health of the mother, fetus, or both. Induction of labour is therapeutic option when the benefits of the delivery outweigh the risks of continuing the pregnancy.

There are many methods for induction of labour. In this study one group was induced with Tab.Mifepristone another group was allowed for spontaneous onset of labour.Induction of labour is planned for many indications. In this study induction of labour done for expected date of delivery (40 weeks of gestation) was taken into account.[1,2]

This study is done at Kilpauk medical college hospital to find the efficacy and safety of mifepristone for cervical ripening and induction of labour in full term pregnancy as a part of routine elective induction in inpatients admitted for safe confinement.

AIMS AND OBJECTIVES

To compare the safety and efficacy of mifepristone for cervical ripening and induction of labour in full term(40weeks) pregnancies.

REVIEW OF LITERATURE

1. Kanan Yelikar , Deshpande S, Deshpande R, Lone D et.zal, conducted a single blinded randomized control trial on Safety and efficacy of Oral mifepristone in pre-induction cervical ripening and induction of labour in prolonged pregnancy. 100 women with prolonged pregnancy beyond 40weeks and bishop's score < 6 are recruited and allocated into 2 groups[3]. Women who received T. Mifepristone 200mg orally were assigned in Group A(n=50) and Group B received oral placebo (n=50). It concluded that mifepristone has a modest effect on cervical ripening when given 24hr prior to labour induction and appearing to reduce need for misoprostol compared with placebo[3].

2. Athawale R, Acharya N, Samal S, Hariharan Cet.al, conducted a randomized case control study comparing the effect of mifepristone for cervical ripening in labour induction with placebo or no treatment.100 patients were included and women undergoing induction with RU486(200mg PO) were grouped in one and those with placebo control group into another[4]. Results showed that women who were induced with mifepristone 200mg PO showed drastic improvement in cervical score within 24-48hrs and decreased the caesarean rate in the study group and amount of dose requirement of augmentation of labour with misoprostol or oxytocin.

3. Oleg R.Baev, Valentina P.Rumyantseva, Oleg V.Tysyachnyu, Olga A.Kozlova, Gennady T.Sukikh et.al, conducted a randomized control trial on outcomes of mifepristone usage for cervical ripening and induction of labour in full term pregnancy, 140 women were randomized and 74 women were given mifepristone 200mg PO for cervical ripening and induction and 75 women were chosen for expectant management. It concluded that

mifepristone was efficient on inducing cervical ripening and labour in full term pregnancy[5]. There were no significant difference in main maternal and neonatal outcomes.

4. Mohapatra S and Samaprita, conducted a prospective comparative study on the role of oral mifepristone and endocervical prostaglandin as preinduction cervical ripening agent. 100 cases with bishop's score less than 6 were subjected for pre induction ripening. One group was given single dose of oral mifepristone 200mg and control group was given single dose intracervical E2 gel[6]. The results showed 90% of mifepristone group and 56% of dinoprostone group had improved bishop's score >6 after 6hrs. 32 cases required oxytocin augmentation in mifepristone group where it was 57 in dinoprostone. Drug administration to delivery interval was 19.40 hour in mifepristone group and 15 hour in dinoprostone group. Study concluded that mifepristone is an effective agent for cervical ripening with better feto maternal outcome compared to dinoprostone.

5. Sailatha R, Famida A.M., Vinoth Gnana Chellaiyan D,Vijayalakshmi K, Sathiya S, Renuka S et.al, conducted a prospective comparative study to assess and compare the efficacy, safety and feto maternal outcome of mifepristone versus dinoprostone in priming of cervix an induction of labour in term pregnancy. Group 1(n=50) were given 200mcg mifepristone orally[7]. If labour did not start at the end of 24 hrs, induction was continued with 0.5mg of dinoprostone gel at a maximum of 3 gels at 6^{th} hourly interval. Group 2(n=50) underwent induction according to routine dinoprostone gel regimen of maximum 3 gels at intervals of 6 hrs. This study concluded that mifepristone is a safe, effective and suitable alternate agent for cervical ripening and initiation of labour when given 24hr before onset of labour.

THEORETICAL BACKGROUND

Labour is a process by which the fetus after the period of viability, is expelled from the genital tract. The, World Health Organization defines ‘normal birth ’as spontaneous in onset, low -risk at the start of labour and remaining so throughout labour and delivery .The infant is born spontaneously in the vertex position between 37 and 42 completed weeks of pregnancy and the mother and infant are in good condition after birth.

Preterm labour is onset of labour before 37 weeks of gestation.

PHYSIOLOGY OF ONSET OF LABOUR

The basis of uterine contractility is the interaction between actin and myosin in myometrial smooth muscle cells. This is brought by calcium through Ca2+–calmodulin-dependent myosin light chain kinase (MLCK) activity. The calcium sensitization in smooth muscle occurs through activation of Rho kinase, a calcium-independent pathway that promotes contractility by inhibiting myosin phosphatase and probably by phosphorylating myosin on the same site as MLCK. Uterine activity can be modulated by many G-protein coupled receptors (GPCRs).

Receptors coupled to Gαq (oxytocin-, prostanoid FP and TP, endothelin-receptors) stimulate contractility by activating the phospholipase C/Ca2+ pathway

i. Receptors coupled to Gαs (β2-adrenoceptors, prostanoid EP2 and IP, some 5-hydroxytryptamine receptors e.g. 5-HT7) relax the uterus by increasing myometrial cyclic AMP levels
ii. Receptors coupled to Gαi (α2-adrenoceptors, muscarinic, 5-HT1) potentiate contractility, probably by inhibiting cAMP production.

Recent evidence showed that fetal adrenal cortisol induces prostaglandin synthase type 2 in placental trophoblast and that the resulting increase in prostaglandin E2 participates in the activation of the P450 cascade The endocrine imbalance promotes increased intrauterine production of prostaglandins, cervical softening and the onset of myometrial contractions[9]

The progress of normal labour depends upon interaction between the 3 P's

I) Passage (Birth Canal).

1. Parity of the woman, if she has ever delivered before.
2. Resistance of the soft tissues as the fetus passes through the birth canal.
3. Fetopelvic diameters.

II) Passenger (Fetus).

1. Presentation of the fetus (breech, transverse).
2. Position of the fetus (ROP, LOP).
3. Size of the fetus.

For successful vaginal delivery foetus in vertex presentation, longitudinal lie, average weight, left occipito anterior position(LOA)

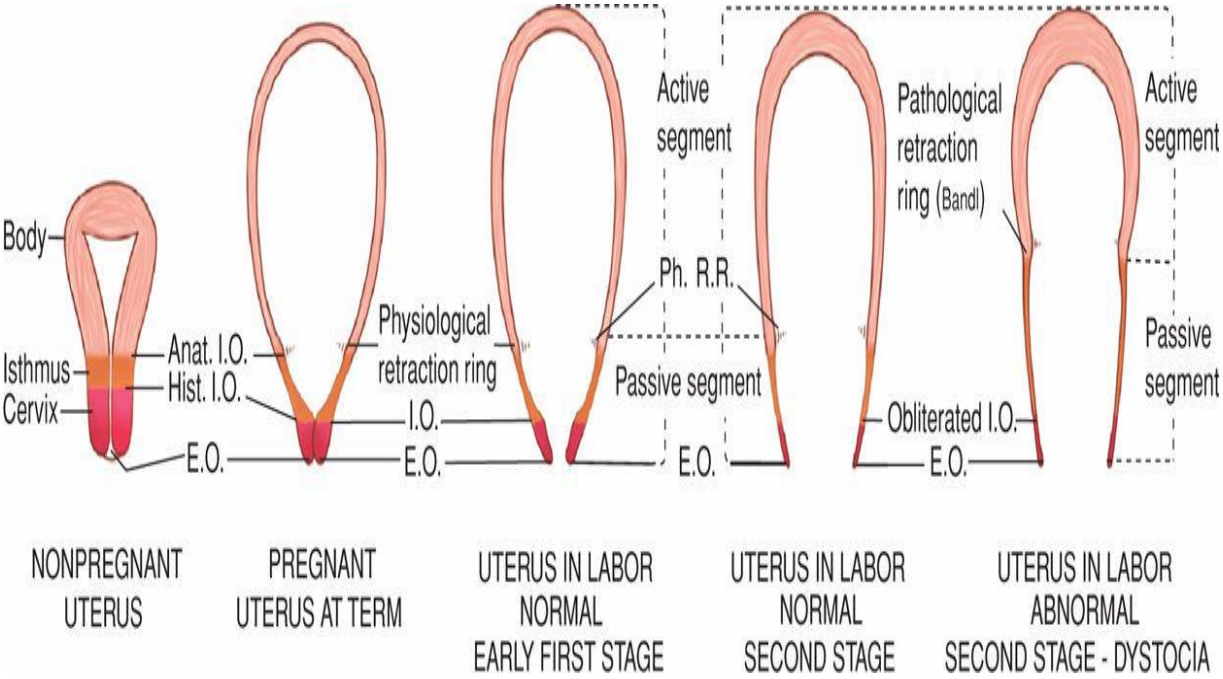
Poor prognosis for successful vaginal delivery are baby weight more than 4 kg, deflexed head, mal presentation and occipito posterior position.

III) Powers (Contractions).

1. Force of the uterine contractions.
2. Frequency of the uterine contractions.5 contractions in 10 minutes is normal.
3. Strength of uterine contractions expressed in Montevideo units

IMAGE 1

FORMATION OF PHYSIOLOGICAL AND PATHOLOGICAL RETRACTION RING



Anat.I.O. – Anatomical Internal OS

Hist .I.O. - Histological Internal OS

E.O.- External OS

MECHANISM OF NORMAL LABOUR

It is defined as the process by which the fetus maneuvers itself to the pelvic architecture, so that a safe vaginal delivery of a live fetus is effected, with minimal morbidity and no mortality to the mother and fetus, To understand the mechanism and management of labour we should first know the

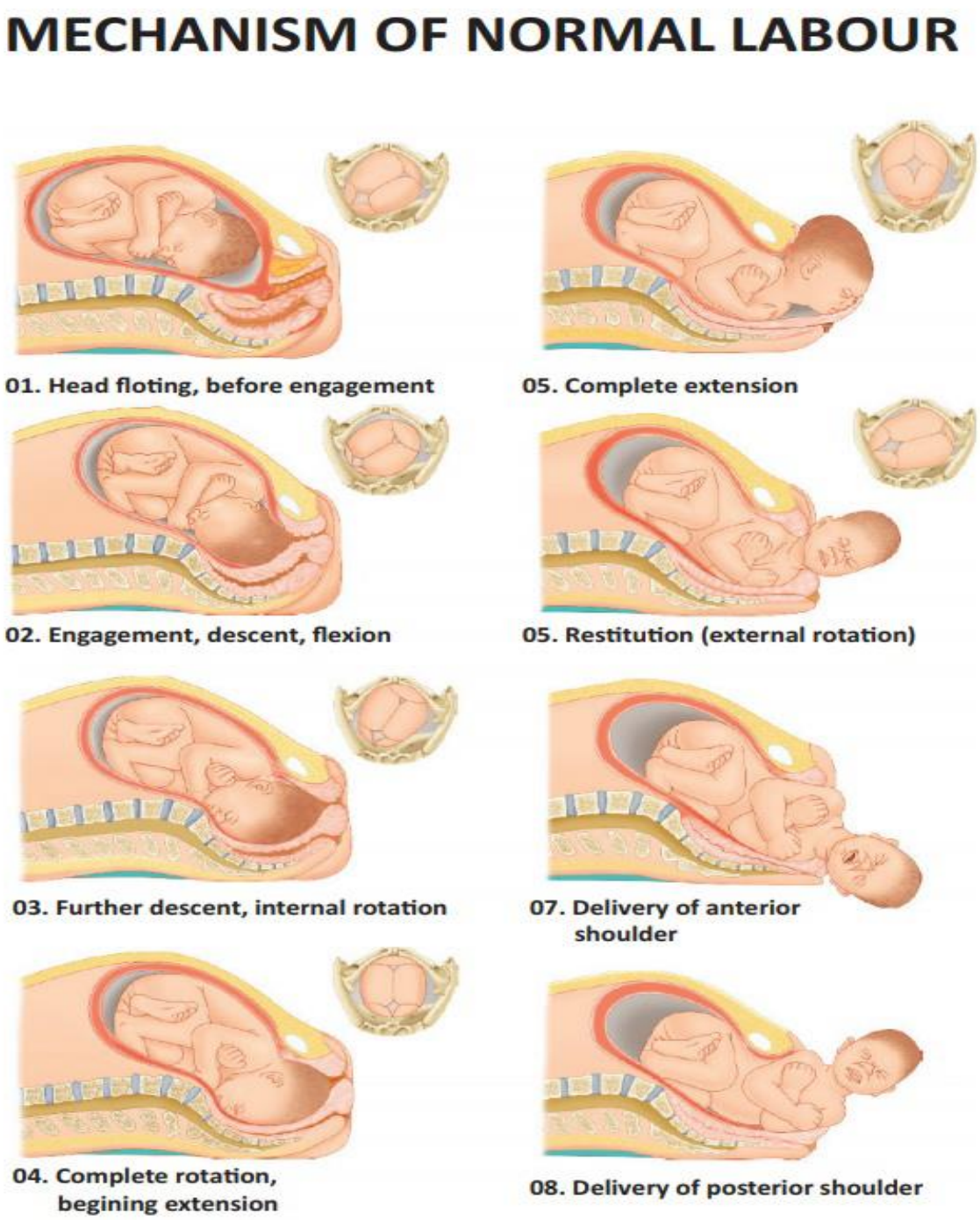
Physiological mechanisms of labour[8,9]

The cardinal movements of labour are,

- Engagement
- Descent
- Flexion
- Internal rotation
- Extension
- Restitution
- External rotation and
- expulsion

The most important movements among these is internal rotation which occurs at the level of ischial spines bringing the occiput anterior thereby extension occurs and delivery of the fetus.

IMAGE 2 MECHANISM OF LABOUR



Labour is a continuous process. It is divided into three stages.

1.First stage : Stage of dilatation

2.Second stage : Stage of expulsion of fetus

3.Third stage : Placental expulsion

4.Fourth Stage

PRELABOUR OR PREPARATORY STAGE OF LABOUR

The preparatory changes like cervical changes, engagement of the fetal head, takes place few weeks prior to onset of labour.

It begins about 2 or 3 weeks before the onset of labour in a primigravida and a few days before in a multigravida.

FIRST STAGE

onset of regular painful uterine contractions associated with progressive cervical effacement and dilatation.

Usually accompanied by

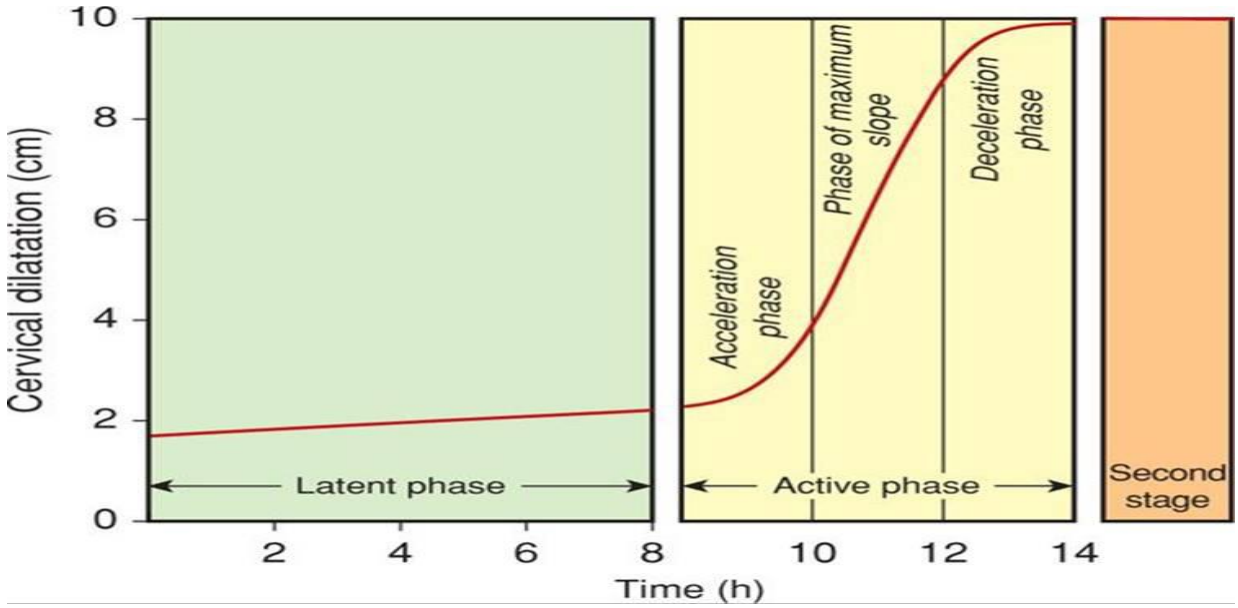
1. Uterine Contractions
2. Show (Blood Stained mucoid discharge due to dislodgement of the cervical plug of mucus
3. Effacement and dilatation of cervix

First stage further classified into two phases-

a) **latent phase (also called Prelabour)- slow cervical dilatation upto 3 -4 cm**
b) **active phase- acceleration phase,phase of maximum slope, deceleration phase**

IMAGE 3

FRIEDMAN'S CURVE FOR LABOUR MONITORING



4. Formation of Lower uterine segment
5. Descent of presenting part
6. Formation of Bag of membranes

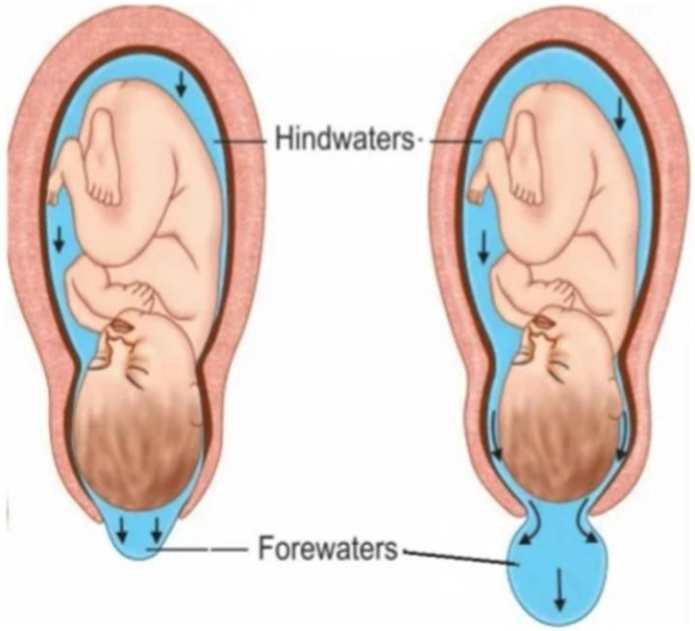
FIRST STAGE OF LABOUR : DURATION

6-8 hours for Nullipara and 4-6 hours for Multipara. Rate of cervical dilatation in the active phase 1.5cm/hr in a multipara and 1.2cm/hr in a nullipara ,a minimum dilatation of 1cm/hr. The mean duration of the active phase of labour is 3-4 hours in multipara and 5-6 hours in a nullipara.

IMAGE 4

BAG OF MEMBRANES FORMATION

- Uterine contractions→ hydrostatic pressure in forewaters→dilatation of cervix



SECOND STAGE – The stage of Expulsion

From the full dilatation of the cervix to the expulsion of fetus or fetuses.

1. It consists of two phases divided into early non-expulsive stage and late or expulsive stage

Early Non -Expulsive Stage

- Pelvic phase or phase of descent-full dilatation to the time when head reaches the pelvic floor which is identified by the bearing down efforts.

Late or Expulsive Stage

- Perineal phase or phase of expulsion-starting of bearing down efforts to delivery of fetus.

2. Uterine contractions increase in frequency and duration.
3. Bearing down efforts
4. Crowning
5. Expulsion of fetus.

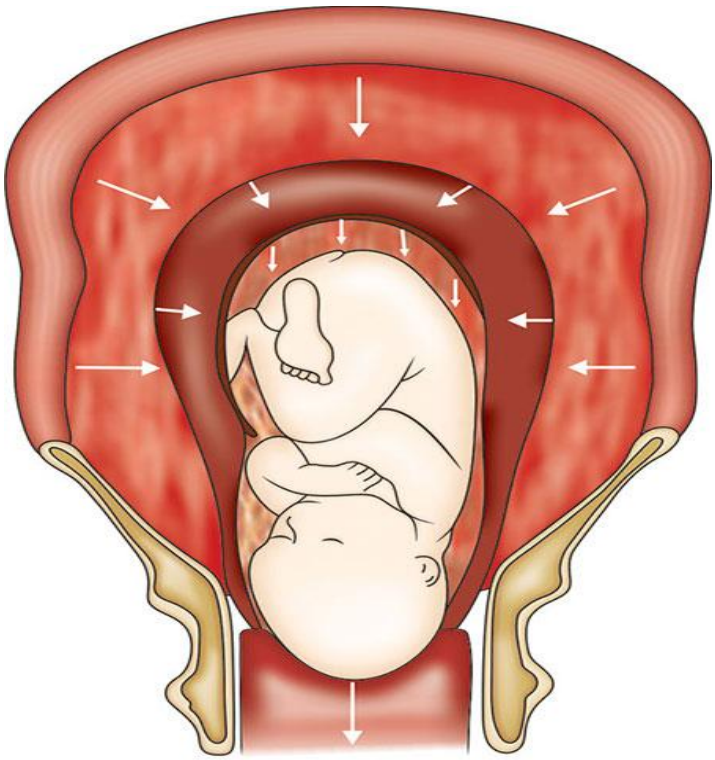
The second stage usually

1 -2 hours in **Nullipara**

0.5 -1 hour in **Multipara**

IMAGE 5

BEARING DOWN EFFORTS AND EXPULSION OF FETUS



THIRD STAGE

Stage of placental expulsion -from delivery of the fetus to delivery of the placenta

Placental separation consists of 4 phases

a) Latent phase-placenta free wall of the uterus contracts
b) Contraction phase-uterine wall at the placental site contracts
c) Detachment phase- placenta separates from the uterine wall
d) Expulsion phase-placenta expelled from the uterine cavity

SIGNS OF PLACENTAL SEPERATION

- Well contracted uterus
- Gush of blood coming from vagina indicating complete or partial separation
- Lengthening of the cord
- Placenta descends
- Uterus becomes hard, round and mobile.

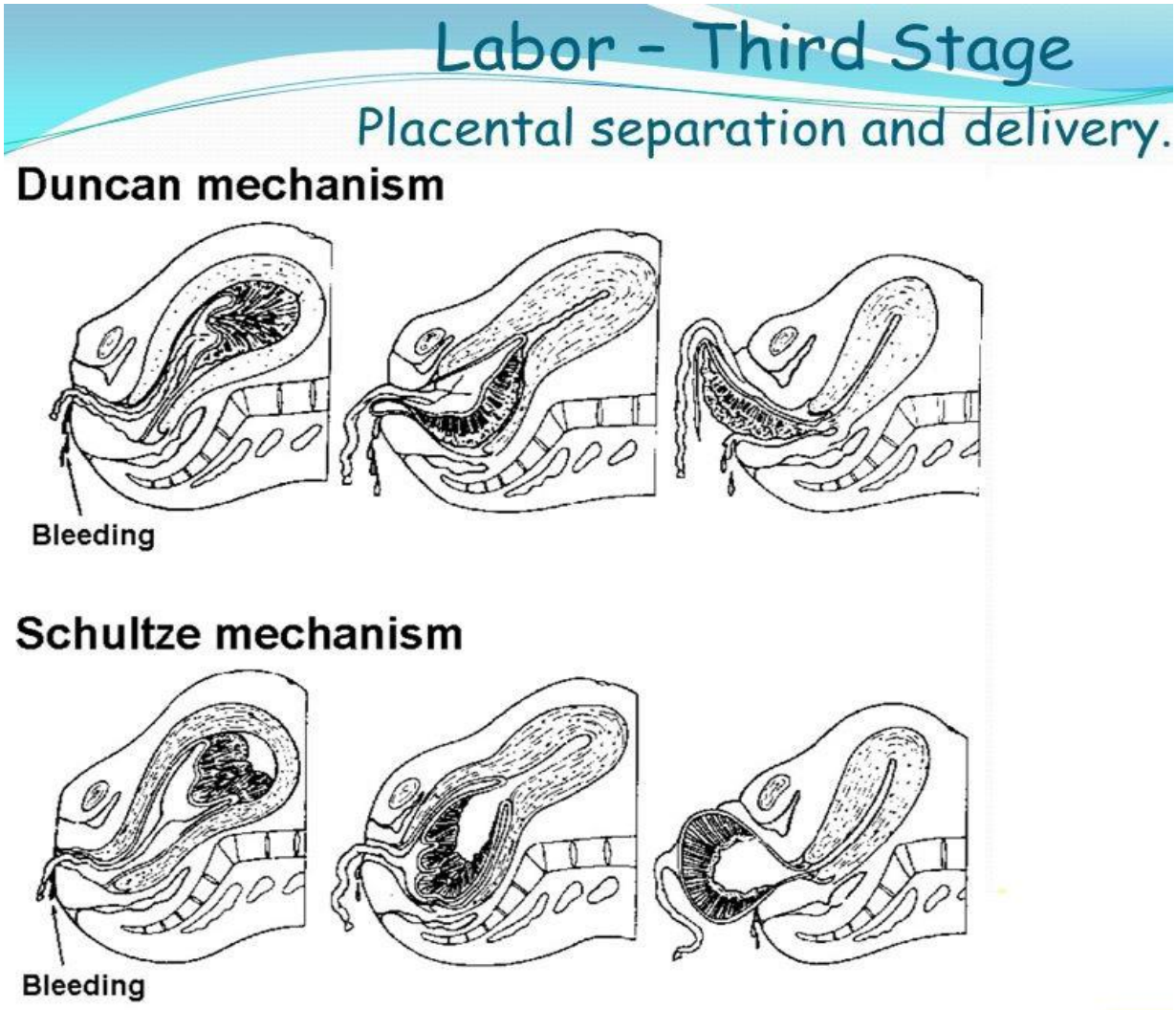
PLACENTAL SEPERATION METHODS

There are two methods,

a) Schultze-Centre of the placenta separates first and comes out as an inverted umbrella.
b) Duncan method-margins of the placenta separates first followed by the central part

IMAGE 6

METHOD OF PLACENTAL SEPARATION



After confirming the placental separation by per vaginal examination, placenta was delivered by controlled cord traction method.(Brandt Andrew method)[10].

FOURTH STAGE OF LABOUR

In this stage contraction and retraction of the uterus and arrest of bleeding occurs. The duration is 1-2 hours after delivery. PPH due to atony can occur close monitoring is needed.

Induction of labour is the iatrogenic stimulation of uterine contractions before the onset of spontaneous labour, to accomplish vaginal delivery. It is performed when the benefits of expeditious delivery to either mother or fetus outweigh the risk of continuing the pregnancy.

Labour may be induced because of maternal or fetal indications.

MATERNAL INDICATIONS

- Post dated or post term pregnancy
- Prelabour rupture of membranes(PROM)
- Preterm, prelabour rupture of membranes (PPROM)
- Diabetic complicating pregnancy
- Placental abruption
- Oligohydramnios
- Isoimmunization
- Anti-phospholipid antibody syndrome (APLA)
- Intrauterine fetal demise (IUFD)
- Hypertensive Disorder
- Gestational hypertension Pre-eclampsia
- Eclampsia
- Chronic hypertension

FETAL INDICATIONS

- Fetal growth restriction(FGR)
- Rh alloimmunization
- Fetal Malformations
- Non reassuring fetal heart rate pattern

Induction of labour is a relatively common procedure. The rate of induction of labour may differ depending on the availability of resources and population. Worldwide, the prevalence of labour induction varies greatly between countries and even between different regions of the same country. In general, however, it is higher in developed countries (at around 20%) than in developing countries[11].

In the Western world, frequency of labour induction has been increasing, with reasons including the availability of better cervical ripening agents, patient and clinicians desire to arrange a convenient time of delivery, and more relaxed attitudes toward marginal indications for induction[11]. Patient or provider concerns about the risk of fetal demise with expectant management of post-term pregnancies have also contributed to the increased rate of induction[11,12]. In the United Kingdom according to the National Health Survey (NHS), one in every five live births is induced half of which are due to post-term pregnancies [13,14].In another study in Sweden, the rate of induction in nulliparous women was as high as 40% with post-dates being the major indication[15].

From observational studies it has been found that nulliparous women have a higher failure rate than multiparas and also induction has been known to fail when the bishop's score is five or less[16]. However no such study has been carried out specifically for post-term pregnancies and the rate of successful induction of prolonged pregnancies with such factors world-wide is not known.

Prerequisites for induction of labour

1. Indication for induction of labour.

2. Cervix must be assessed for Bishop's score
3. No Cephalo pelvic disproportion
4. Estimated weight of the baby
5. Fetal presentation(Vertex Presentation)
6. Fetal well being

Successful induction is defined as (Vaginal delivery of an infant in good condition with minimum maternal discomfort and side effects, within a specified framework of time).

Predictors of successful induction

- Gestational age
- Pelvic Configuration
- Multiparity
- EFW<3.5 kg
- Normal BMI
- Favourable Bishop's score
- Tall Stature

Failed Induction:

Labour does not enter the active phase (failure to generate regular contractions and cervical change) or,in the presence of regular contractions vaginal delivery is not achieved.

Contra Indications for Induction

1. When vaginal delivery is contraindicated-
   (a) Major degrees of cephalo pelvic disproportion
   (b) Previous VVF repair

(c) Pelvic tumour

(d) Carcinoma cervix

(e) Previous uterine surgery disruption

(f) Active genital herpes infection.

2. Malpresentations.
3. Placental abnormalities like Vasa previa and Type III and IV placenta previa.
4. Appreciable macrosomia
5. Severe hydrocephalus
6. Non reassuring fetal heart rate

The etiology of post term gestation is not clearly understood.

Some of the risk factors for post term pregnancy are

- Previous post term pregnancy,
- Nulliparity,
- Maternal age > 30 years,
- Obesity[17,18].

RISKS OF INDUCTION OF LABOUR:-

Increase in caesarean Section rate:

The risk of caesarean section increased nearly threefold in primigravid women (11.8% Vs 27.9%) and doubled in multigravida women (3.4% Vs 8.5%) who were induced compared to those labouring spontaneously (RCOG 200 lb).

Uterine Hyper Contractility:-

Uterine hypertonus is defined as a single uterine contraction that lasted 2 or more minutes.

Tachysystole is defined as at least 12 contractions in 20 minutes. Hyperstimulation is defined as either hypertonus (or) tachysystole associated with abnormal FHR pattern.

Misoprostol was associated with significantly increased risk of tachysystole or hyper stimulation when compared with PGE 2 gel (WING and Coworkers 1995a, 1995b). Induced labour is associated with on increased risk of **postpartum hemorrhage.**

Prolonged induction is associated with a small increase in the risk of infectious morbidity with an estimated 10% incidence noted after 40hrs of induction (Bahn et al 1998). Oxytocin induction has been reported to increase the risk of neonatal Hyperbilirubinemia.

Iatrogenic prematurity occurs inadvertently and a review of the gestational age prior to induction is essential. The reasons for the rising rates of induction of labour can be complex and multifactorial (Rayburn and Zhang 2002).

Some of them are:

- Improved ability of physicians to determine gestational age accurately with early dating scans, thus avoiding the possibility of iatrogenic prematurity.
- Widespread availability of cervical ripening agents
- Improved knowledge of methods and indications for induction
- More relaxed attitudes towards marginal/elective indications, both of the physician and the patient
- Litigation constraints.

Counseling the couple prior to induction:

It is essential to have good communication with the woman and her family prior to induction; wherever possible this should be supported by evidence-based and preferably, written information. While counseling, the following need to be discussed (RCOG 2008):

- The indications for induction; more specifically, the risk associated with continuing the pregnancy
- The time and procedure of induction
- Arrangements for support during labour
- Pain relief measures since induced labour may be more painful.
- The need for close monitoring of the fetal heart rate (including electronic fetal monitoring in labour)
- Alternative options available to the mother if she refused induction
- The risks associated with induction of labour, specifically with the inducing agent used.
- The chances of failure of induction and the options available in case of failure

Criteria of an ideal inducing agent:

An ideal inducing agent is one which:

- Achieves onset of labour within the shortest possible time.
- Does not result in greater pain and hence does not require greater analgesics as compared to spontaneous labour
- Has a very low incidence of failure to induce labour
- Does not increase the rate of cesarean or operative vaginal deliveries as compared to spontaneous labour.
- Does not increase perinatal morbidity compared to spontaneous labour.

We are yet to find an ideal inducing agent. Hence, the decision for induction should be well thought out and communicated to the woman concerned.

Methods of Induction

There are only three existing broad approaches in induction of labour practiced in the current obstetric practice. They are:

(A) Amniotomy or Artificial rupture of membranes

(B) Use of oxytocic agents in the past

(C) Stripping of membranes or Sweeping of membranes

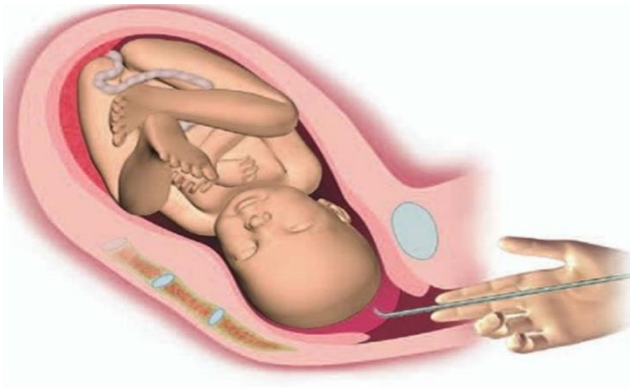
(A) AMNIOTOMY OR ARTIFICIAL RUPTURE OF MEMBRANES

Introduced by Thomas Denman more than 200 years ago, the procedure represents one of the most irrevocable interventions in pregnancy, and more than any other procedure calls for a firm commitment to delivery within a short time scale to avoid the risk of maternal and fetal infection.

Amniotomy alone often results in vaginal delivery in most women with good cervical score. However Patterson in 1971 found that 15% of Primi gravidas and 22% of multi gravidas were not in established labour

IMAGE 7

AMNIOTOMY



more than 24 hours after amniotomy. Therefore in current obstetric practice, amniotomy is usually combined with oxytocin immediately or after a variable interval.

After controlled artificial rupture of membranes without dislodging the presenting part amniotic fluid is allowed to drain, color of liquor and any cord prolapse is noted.

There are two types of rupture of membranes – ***Low rupture of membranes*** **(LARM)** done by using a kocher's artery forceps and high rupture of membranes or hind water amniotomy done by using a Drew- Smythe catheter. The low rupture of membranes is the basic procedure in induction of labour.

Prerequisites for Amniotomy

- Vertex presentation
- Cervix must be well applied to the presenting part
- High Bishop's score
- No cephalopelvic disproportion.

Mechanism of action

1. Releases endogenous prostaglandin and may result in labour.
2. Intrauterine space decreases progressively following amniotomy so that the uterine muscles contract more efficiently.

PROCEDURE

1. First to determine the position and presentation of the fetus
2. Patient should be put on electronic fetal monitoring
3. For this procedure to be effective fetal head should apply sufficient pressure on the cervix.

4. Ask the patient to lie down in dorsal position in labour room, insert a vaginal speculum, amniotomy was done by using amniotomy hook or amni hook in between the uterine contractions
5. After the rupture one hand is placed in the vagina to let the fluid come out in a controlled manner thereby preventing cord prolapse. Colour and consistency of the liquor was noted.
6. Check the fetal heart rate for one full minute before and after procedure to rule out any fetal distress.

Complications

Are mainly in the form of infection, chorioamnionitis, cord prolapse, premature separation of placenta, injury to the fetus and cervix constant drainage of liquor amni, fetal anaemia due to unrecognized vasa previa, risk for Rh iso-immunization.[19,20] .

STRIPPING OF MEMBRANES OR SWEEPING OF MEMBRANES

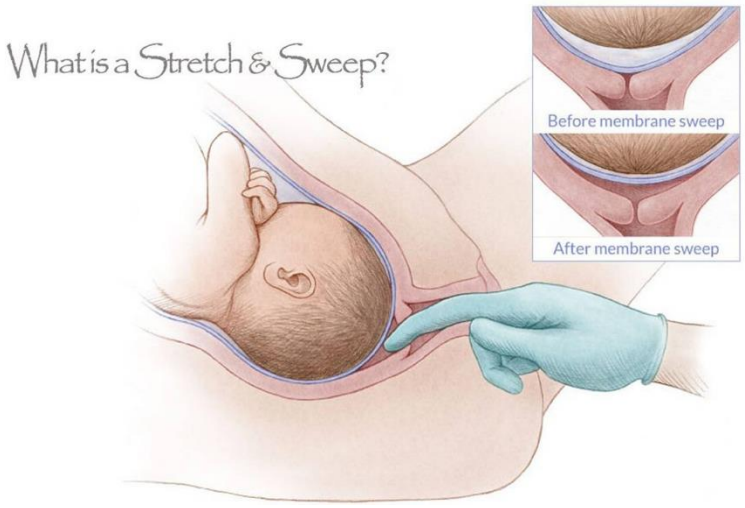
Sweeping or stripping of the membranes is an old method of inducing labour described by Hamilton in 1810. Sweeping of the membranes involve the digital separation of the membranes from the lower segment and has been widely used for many years in the belief that it reduces the need for formal induction of labour. The procedure of membrane sweeping causes an increase in the levels of prostaglandin F_2alpha (McColgin et al 1993). Several recent studies have addressed the validity of this belief and the risks associated with this procedure.

In a randomized study of 195 women beyond 40 weeks, two-thirds of women undergoing membrane sweeping laboured spontaneously within 72 hours compared to one-third of women in the control group (Allot and Palmer

1993). A recent meta-analysis concluded that sweeping membranes prior to term (38-40 weeks) does reduce the frequency of prolonged pregnancy and reduce the need for formal induction of labour from 36 per cent to 21 per cent (Boulvain et al 2001). The same review found no evidence of serious maternal or neonatal morbidity, such as infection associated with the procedure.

IMAGE 8

SWEEPING OF MEMBRANES



Technically, membrane sweeping is not possible in all women (Cammu and Haitsma 1998), usually requiring a cervical score greater than 4. Women undergoing membrane sweeping, more frequently describe discomfort during the vaginal examination, vaginal bleeding and contractions not associated with the onset of labour than women not undergoing sweeping (Boulvain et al 1999). This discomfort will not be tolerated by all women and counselling prior to membrane sweeping is needed.

Although it is presumed to be a formal method of induction, it is still employed by some obstetricians at term, especially when the indications for induction are not strong enough. The forewater is stripped by a gloved index finger passed through the cervical canal. Uterine contractions are frequently

established following the procedure resulting from the release of endogenous prostaglandins, and labour is brought about within 3 days.

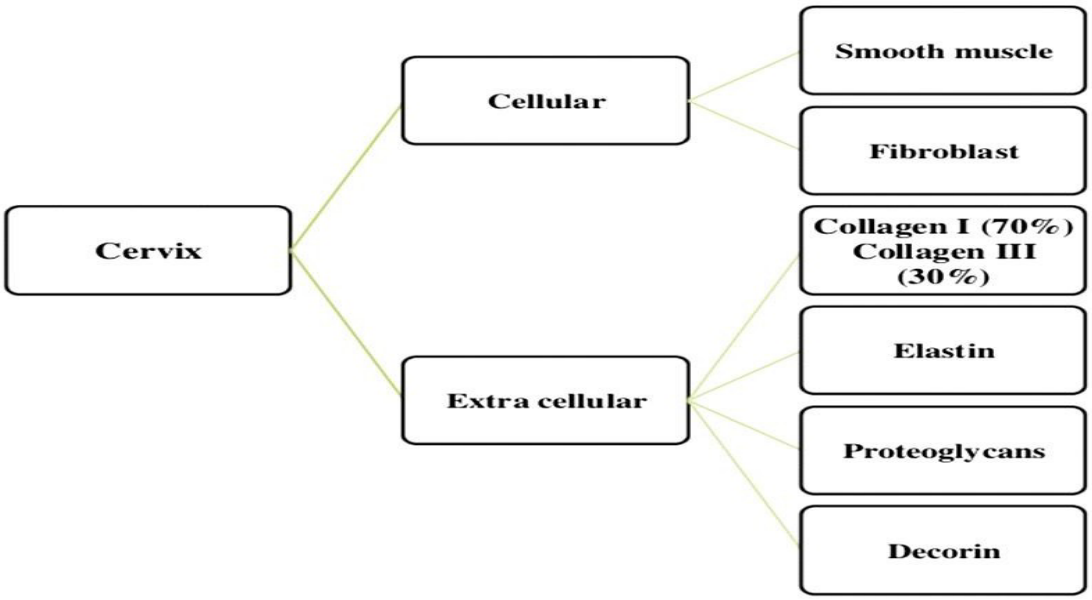
C.OXYTOCIN

Commonly used method of induction in past

CERVICAL RIPENING

Cervical ripening is a process by which the cervix becomes soft, compliant and partially dilated. It is due to a combination of biochemical, endocrine, mechanical and possibly inflammatory events.

Cervix is composed of collagen, smooth muscle and connective tissue 'ground substance' containing glycosaminoglycans. Cervix is predominantly composed of types I (66%) and type III (33%). The firmness of the cervix in the non-pregnant state is mainly due to the properties of these collagen fibrils which are bound together in the form of bundles. These bundles in turn are embedded in ground substance consisting of proteoglycans[21].



In the cervix the main glycosaminoglycan are dermatan sulphate and chondroitin sulphate both of which are highly negatively charged and hydrophobic. Hence they repel water and are responsible for the firmness of the cervix. Towards term the glycosaminoglycan concentration of the cervix alters and the dermatan and chondroitin sulphates are replaced by hyaluronic acid. Hyaluronic acid is hydrophilic and imbibes water. Accumulation of water within the substance of the cervix destabilizes the collagen fibrils contributing to cervical ripening. The water content of human cervix increases from 80% in non-pregnant state to 86% in late pregnancy. Collagenase is an enzyme that breaks down collagen types I, II and III and is produced by fibroblasts and leucocytes. Leucocyte elastase is another enzyme that that can break down elastin, collagen and proteoglycans. It is produced by macrophages, neutrophils and eosinophils. The levels of both these enzymes are found to increase with advancing gestation and are associated with progressive decline in the concentration of cervical collagen.

Cervical remodeling takes place with advancing gestation. The mature collagen, which has many crosslinks that are responsible for its tensile strength, is replaced by an immature collagen, which has few such crosslinks. Functionally the newly formed immature collagen is much weaker and is easily broken down during labour.

Cervical Ripening Methods

Non-Pharmacological methods:-

Sexual intercourse, herbal remedies, castor oil, enemas, acupuncture, baths. No Study has shown any proven benefit of these therapies for induction of labour.

Mechanical Methods:

- Laminaria tents
- Hygroscopic dilators
- Membrane stripping
- Foley catheter – Intrauterine Extra amniotic foley catheter with bulb inflation to 30ml-
- Extra amniotic saline infusion.

Pharmacologic Methods

The drugs used for cervical ripening and induction are

1. Prostaglandins – most commonly used
2. Mifepristone- now under many trials
3. Oxytocin –was used for ripening of cervix in the past, nowadays its usage for augmentation is increased rather than ripening.
4. Relaxin
5. Hyaluronidase
6. Nitric oxide donors
   - Glyceryl trinitrate
   - Isosorbide mononitrate

PROSTAGLANDINS

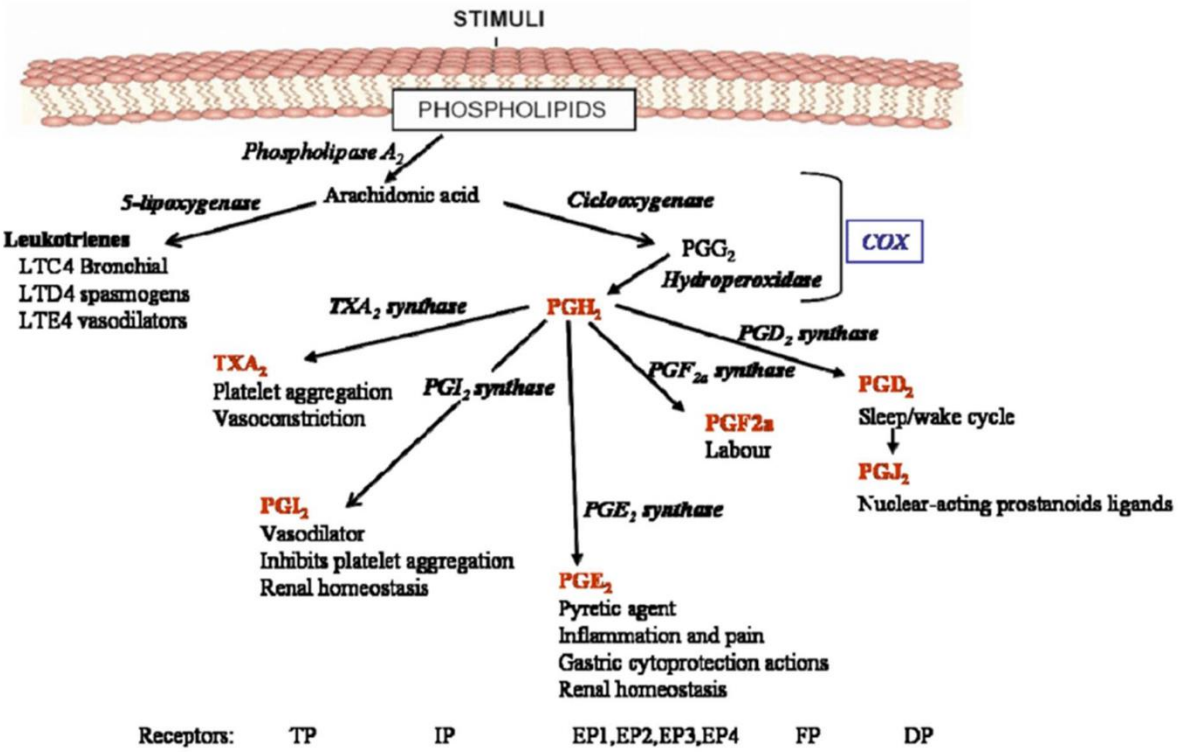
Prostaglandins are most commonly used for cervical ripening in an unscarred uterus. Prostaglandins not only improve the cervical score but also cause ripening and initiate labour. Thus the need for oxytocin to induce or augment labour is reduced.

The commonly used prostaglandins are 1.**PROSTAGLANDIN E1** (MISOPROSTOL) SYNTHESIS OF PROSTAGLANDINS:

They are mainly synthesized from phospholipids by the enzyme phospholipase A2.The flow chart was shown below

IMAGE 9

SYNTHESIS OF PROSTAGLANDINS



was first discovered by SEARL in 1973 for treating peptic ulcer patients and its effect on pregnant uterus was a major side effect. As time goes on it's effect on termination of pregnancy and induction of labour has overcome it's therapeutic value.

DOSAGE:

Vaginal route: 25 microgram of misoprostol in the posterior fornix-repeated every 3-6 hours until adequate uterine contractions[22,23].

Oral route: 50 microgram once in every 3-6 hours Interval of about 4 hours should be there after the last dose before oxytocin is started.

The side effects are

Vomitting

Diarrhoea

Hyperstimulation

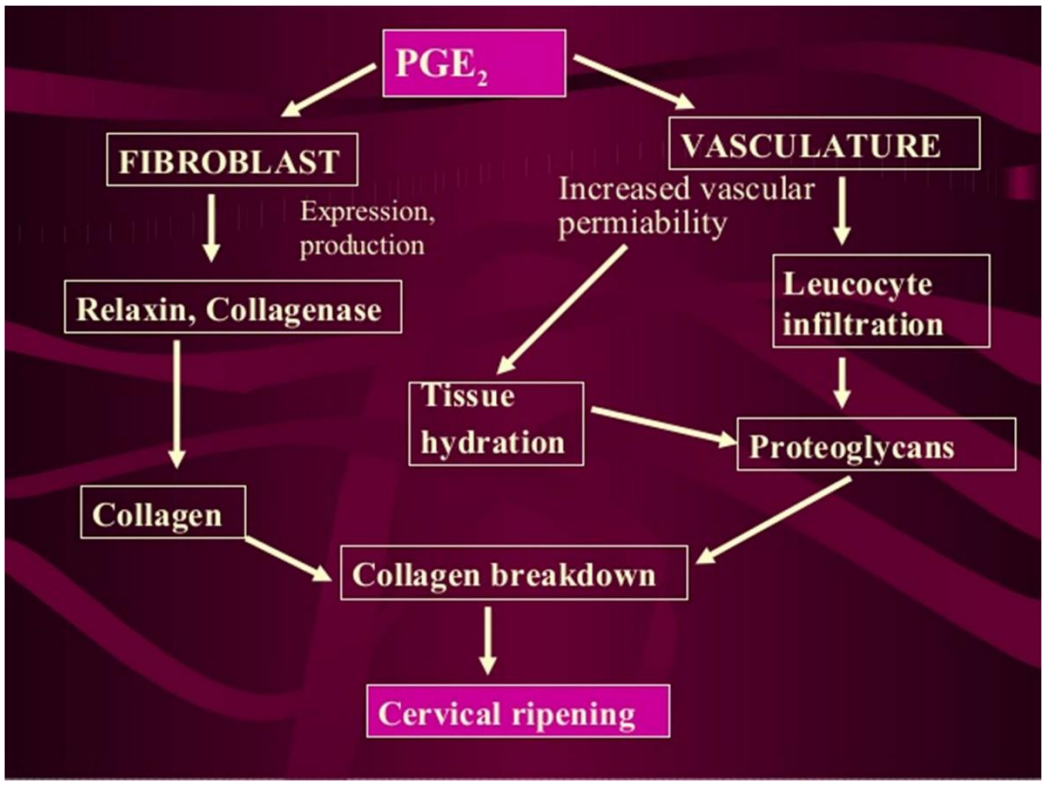
Tachysystole.

PROSTAGLANDIN E2 (DINOPROSTONE)

It induces cervical ripening.

Reduces failed induction rate and the need for oxytocin. Shortens the induction –delivery interval.

IMAGE 10 MECHANISM OF ACTION OF PG E2



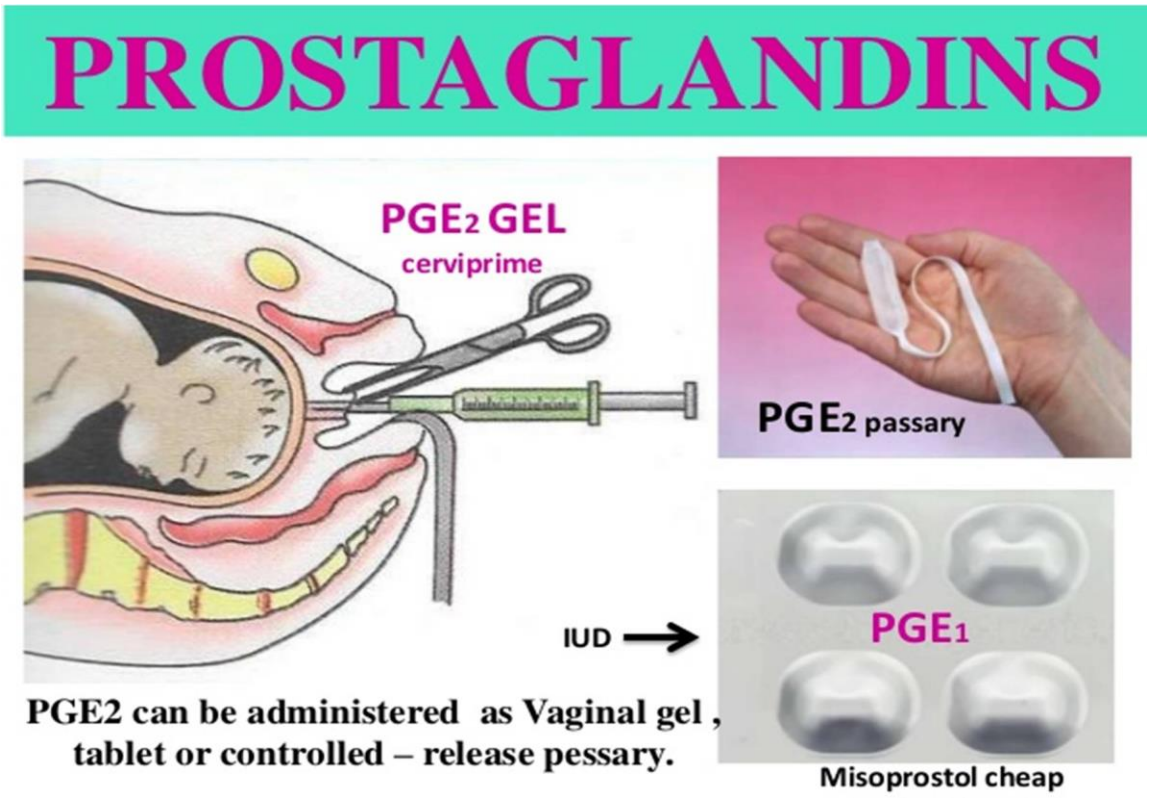
ROUTE OF ADMINISTRATION

Intracervical –is in the form of preloaded syringe(2.5 ml) with plastic insertor which contains 0.5 mg of PG E2-cervical insertion every 6 hours maximum of 3 doses in 24 hours interval.[24]

Intravaginal- is in the form of vaginal insert contains 10 mg of PGE2- easily removed in cases of tachysystole/hyperstimulation.

IMAGE 11

INTRACERVICAL APPLICATION OF PG E2 GEL



In a study comparing group A having prostaglandin E1 with group B having prostaglandin E2 with oxytocin showed the mean induction delivery interval was reduced in group A than group B. A group showed higher number of successful vaginal deliveries(82%) than B(77%).Tachysystole was more common in A group (20%) than B(5%)[25].

Methods to assess cervical ripening

- Bishop's score
- Lange score

The modified Bishop's score is now being used to assess the cervix.

This system tabulates a score based upon the station of the presenting part and four characteristics of the cervix: dilatation, cervical length (instead of effacement in the original scoring system by Bishop's), consistency, and position. A score that exceeds 8 describes the patient most likely to achieve a successful vaginal birth without cervical ripening. Bishop's scores of less than 6 usually require that a cervical ripening method be used before other methods.

TABLE -1

BISHOP'S SCORE MODIFIED

Bishop's Score (Modified)

Parameters	Score			
Cervix	0	1	2	3
Dilatation (Cm)	Closed	1-2	3-4	5+
Effacement(%) Or Cervical Length (Cm)	0-30 Or >4	40-50 or 2-4	60-70 or 1-2	≥ 80 or <1
Consistency	Firm	Medium	Soft	-
Position	Posterior	Midline	Anterior	-
Head Station	- 3	- 2	- 1, 0	+1, +2

Score <6 –unfavourable, Score >6 - favourable

The relationship between a low Bishop's score and failed induction, prolonged labour, and a high caesarean birth rate was first described prior to widespread use of cervical ripening agents .

If the cervix is unfavourable cervical ripening should be done for successful induction

A recent Cochrane review showed that routine use of membrane sweeping from 38 weeks onwards does not found to have clinically important benefits . The efficacy of membrane sweeping is found to be low at an earlier gestational age, and the major concern are pregnancies that extending beyond 41 weeks of gestation with unfavorable cervix; de Miranda et al noted that the Cochrane review included studies with relatively small sizes, and heterogeneity between the trial results outcome.

OXYTOCIN:-

In modern obstetric practice oxytocin is more commonly used in combination with amniotomy making it unsuitable for use in women who have cervical scores below 6.

When compared to induction with prostaglandins evidence suggests that oxytocin induction is associated with a lower chance of delivery within 24hours.In women with an unfavorable cervix, induction with oxytocin was associated with higher rates of caesarean section. Lower dose regimens are recommended with starting doses of 1-2 milli units / min, increased at intervals of not less than 30 minutes. The maximum dose is the minimum needed to maintain a contraction frequency of 3-4 in ten minutes (or) an absolute maximum of 32 milli units per minute.

RELAXIN:-

Relaxin has been used both vaginally and intra cervically to induce labour but studies have failed to show any benefit compared to prostaglandin (Kelly 2002b).Hyaluronidase and estrogen are of historical interest only (Thomas et al 2001).

MIFEPRISTONE{RU 486}

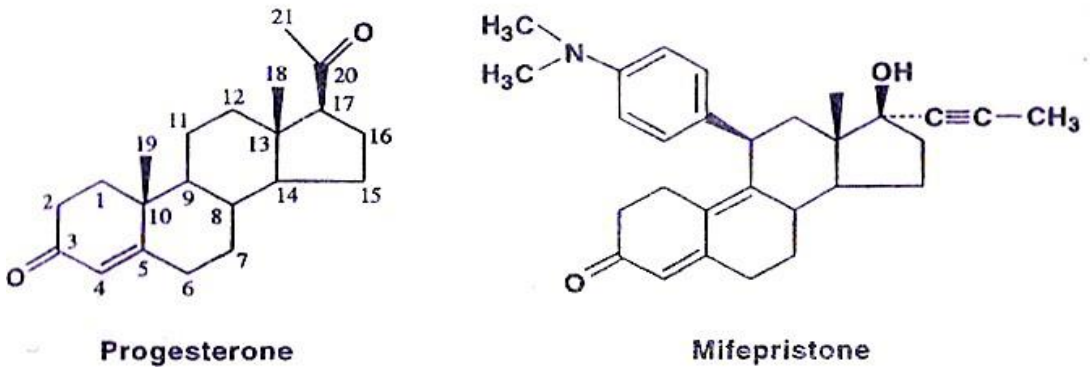
Introduction:

Mifepristone, a synthetic steroid was discovered in 1980 by Dr. Etienne – Emile Beaulieu of France. Mifepristone is an antiprogestin. There are two types of antiprogestin

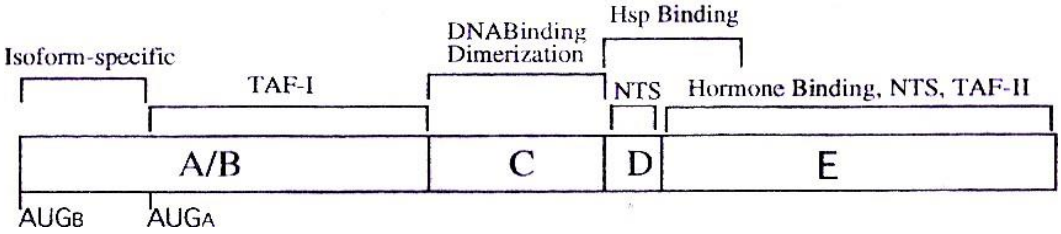
- Type I -RU486, ZK 112993
- Type II – ZK 98299.

IMAGE 12

Chemical Structure of Mifepristone



Mifepristone is a 19 nor steroid, chemically referred to as 11 beta-(4-dimethyl amino phenyl)-4, 9-dien-3-one. It is an antiprogestrone. It has a molecular formula of C19H35NO2.[26]. Its molecular weight is about 429.6. The dimethyl amino phenyl side chain at position 11, which is a hydrophilic moiety, appears to be essential for the antiprogestronic activity. It also has anti glucocorticoid and antiandrogen activity.

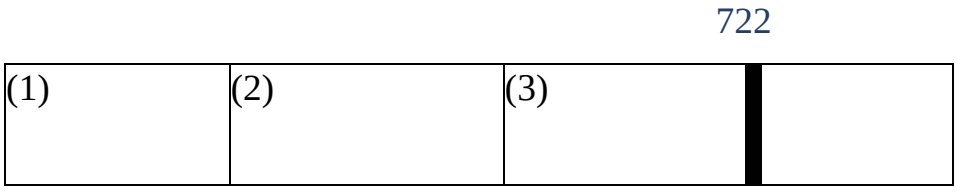


The structure of the gene encoding both isoforms (PR_A and PR_B) of the progesterone receptor includes the location of the n-terminal initiation codon for each isoform (AUG_B and AUG_A).[27] The basic structure of this gene is shared by all members of the steroid, thyroid, vitamin D, retinoic acid and orphan receptor superfamily, with five functional domains: an n-terminal transactivation domain (A/B), a DNA-binding domain (C), a hinge region (D) and a hormone-binding domain (E). Regions important for heat shock protein binding (HSP), nuclear translocation (NTS) and transcriptional activation (TAF-I, -II) are also indicated.[28].

Mifepristone acts as a competitive receptor antagonist at the progesterone receptor in the presence of progesterone and acts as partial agonist in the absence of progesterone. Mifepristone at doses greater or equal to 1mg/kg antagonize the endometrial and myometrial effects of progesterone. Anti-glucocorticoid effect of mifepristone is manifested at doses greater or equal to 5.5mg/kg and antiandrogenic effect in animals is seen with prolonged administration of very high doses of 10-100mg/kg[29].

I. Receptor binding

Progesterone receptor schematic diagram.

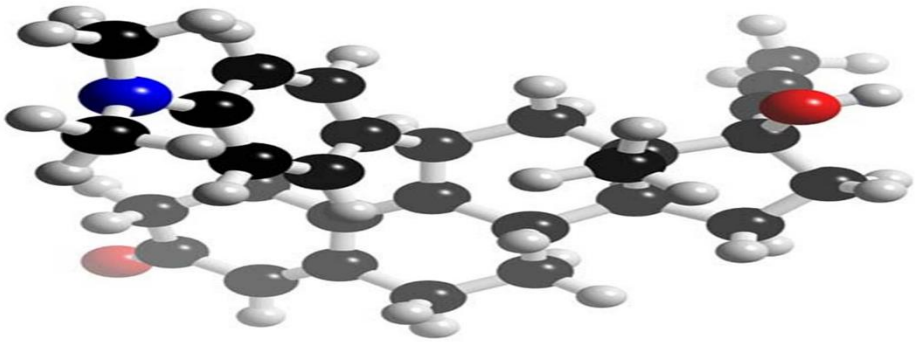


1. Transactivation domain
2. DNA binding domain
3. Hormone binding domain

The anti progestin action of mifepristone is mediated by the PR, a ligand activated transcription factor with domains for DNA binding, hormone binding and transactivation. The amino acid glycine at position 722, which is in the hormone-binding domain of the human PR, appears to be critical for mifepristone binding and action. Substitution of glycine with cysteine in the human PR generates a receptor that no longer binds mifepristone.

IMAGE 13

THREE DIMENSIONAL STRUCTURE OF MIFEPRISTONE

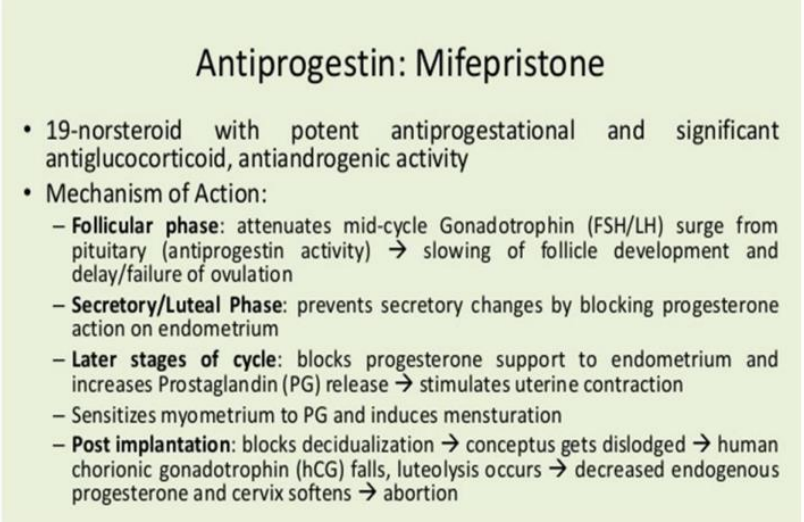


Pregnancy category: X Route of administration: oral

Drug class: anti progestogen, anti-glucocorticoid.

IMAGE 14

MECHANISM OF ACTION OF MIFEPRISTONE



PHARMACOKINETICS

*Mifepristone is absorbed rapidly after oral administration,reaching maximum serum levels within 2hours and has a half life of about 24 hours [30].

*Bioavailability:69% *Proteinbinding:98%

*Metabolism:Liver catalysed by CYP3A4 enzyme

*Excretion: feces and urine

Clinical Pharmacology

Pregnant uterus

Mifepristone acts on receptors in decidua resulting in progesterone withdrawal to endometrium, disruption of placental function and uterine bleeding. Mifepristione stimulate release of $PGEF_2\alpha$.[34,40,41]. The increase in prostaglandin is due to marked reduction in the activity and tissue concentration of prostaglandin dehydrogenase, the key enzyme involved in the control of prostaglandin catabolism by mifepristone.[31].

Mifepristone increases the sensitivity of the myometrium to prostaglandin due to increase in number of gap junctions so that synchronization of uterine muscle contractility occurs. This causes enhanced electrical activity resulting in opening of voltage dependent calcium channels, which causes calcium influx and thereby muscle contraction.[45].

Mifepristone causes cervical ripening in women undergoing termination of pregnancy. Mifepristone causes cervical ripening directly or through the blockage of progesterone receptors.[43]. Mifepristone stimulates the release of nitric oxide and the expression of inducible nitric oxide synthase in cervical cells of women. This is one of the mechanism by which mifepristone initiates cervical ripening.[44].

Other Uses

1.**First and second trimester abortion**

While in India, a combination of mifepristone and misoprostol is recommended for termination of early pregnancy up to 49 days/seven weeks from the last menstrual period (LMP); WHO recommends their use up to 63 days or nine weeks from LMP (WHO, 2003).

Mechanism of action

Mifepristone is an anti-progestin, which stops the pregnancy from growing, detaches it from the lining of the uterus and softens the cervix.

Recommended Drug Protocol		
Day 1	200mg mifepristone orally.	Anti D if Rh-ve
Day 3	400 mcg misoprostol orally/vaginally.	Analgesics
Day 15	confirm completion of abortion by USG	Contraceptive

2.For emergency contraception at low doses

Mifepristone, a novel estrogen free contraceptive when administered in low doses daily (2 to 10mg), it inhibits ovulation, menstruation and significantly suppresses effects on the endometrium.[32]But in 2003, Baird ST et al, in their study reported that mifepristone<10mg per day neither caused endometrial hyperplasia nor the significant effect on the HPA-axis. Mifepristone also maintained bone density, lipids & sense of well-being. Mifepristone as a postcoital contraceptive inhibits ovulation, blocks implantation by causing a delay in maturation of endometrium and causes regression of the corpus luteum in the majority of women when given in the middle or late luteal phase.[33,38,42].Two randomized trial have compared 600 mg of mifepristone with the Yuzpe regimen. In these trials single dose of 600mg of mifepristone given within 72 hours of unprotected intercourse was 100 percent effective as an emergency contraceptive[35].

3.Fibroid uterus-in relief from bleeding and improving quality of life.

For safe and effective non-surgical treatment of symptomatic fibroids, high-dose progestin therapy and GnRh agonists have been shown to decrease overall uterine volume by 50 percent at the end of 3 months therapy. So far no therapy has been used on a long term basis, therefore, the effect of medical therapy is temporary. On a long term basis, mifepristone blocks progesterone dependent growth factors, reduces blood supply due to vascular changes and decreases inhibition of progesterone estrogen receptor gene transcription by the progesterone receptor - A isoform, these are some of the mechanisms causing the antiproliferative activity of mifepristone. Mifepristone can be used in uterine fibroids as an alternative to GnRh analogues in the preoperative application and if the safety of long term low dose mifepristone is established, perimenopausal women with large, symptomatic fibroid could avoid hysterectomies by using mifepristone till menopause[36].

4.Endometriosis

Mifepristone through antioxidant property does not allow endometriosis to proliferate. It also preserves follicular phase levels of estradiol 5mg dose does not stabilize the endometrium and hence needs a dose of 50mg daily. However, the use of mifepristone for the treatment of endometriosis requires additional studies[37].

5.Ovarian Cancer

Mifepristone inhibits ovarian cancer cells growth by inducing G1 cell cycle arrest and blocking the G1-S phase transition without causing cell death. This growth arrest is observed by a decline in cyclin – dependent kinase 2 (cdk2) protein level and activity.[39].In 2003, Xu M et al reported that ovarian cancer cells expressed glucocorticoid receptors. Mifepristone may drive its

anticancer action by binding to glucocorticoid receptors with an affinity similar to that for progesterone receptors and as an antioxidant to drive G1 arrest through a p53 independent p21. In 2000, Rocereto TF et al in their small trial conducted with 44 patients suffering from recurrent epithelial ovarian cancer whose tumors had become resistant to standard chemotherapy, mifepristone administration showed desirable effects against some of the tumors. Thus, mifepristone is a single agent potent blocker of ovarian cancer growth, however, the feasibility of using mifepristone to enhance the efficacy of conventional chemotherapy for ovarian cancer requires further investigations.

6.Premenstrual Syndrome

The sex steroid dependency of this disorder has been well established by the absence of PMS in castrated women and women treated with GnRH agonist analogues. Because the main symptom complex occurs in the luteal phase when serum progesterone is at the highest level, it was proposed that an antiprogestin, such as RU 486, may be useful in treatment of PMS.[46]Dosing schedules such as low dose daily administration to induce a acyclic pattern may yet prove to be efficacious in the treatment of PMS.

7.For treating hyperglycemia secondary to cushing's syndrome.

8.Breast Cancer

It has been observed that estrogen and progesterone in low doses stimulates breast cancer growth but in high doses both inhibit breast cancer growth. Tamoxifen, the antiestrogen, remains the first line therapy for advanced estrogen-receptor-positive tumor because of its efficacy, safety and convenience. Antiestrogen (Tamoxifen) and antiprogestin produce tumor

regression but either agent alone only produces tumor stasis. Tamoxifen down regulates the estrogen receptor but it favors agonists activities and therefore up regulates the progesterone receptor. Mifepristone down regulates both estrogen and the progesterone receptors. The finding suggests that tamoxifen can not inhibit the progestin-mediated growth-stimulatory effects. Thus, addition of mifepristone to tamoxifen effectively reestablishes tamoxifen growth inhibition. It has been observed that eventually all advanced breast cancer become hormone independent and increasingly resistant to any subsequent therapy as a result there is limitation in potential utility of antiprogestin and other endocrine therapies for the treatment of advanced disease.

DRUG INTERACTIONS:

Enzyme inhibitors-increases the drug level Itraconazole/ketoconazole
Erythromycin macrolide Grapefruit juice

Enzyme inducers-decreases drug level
Carbamazepine/phenytoin/phenobarbitone Rifampin
Dexamethasone
Aspirin-increases risk of bleeding.
Mifepristone may inhibits the liver enzymes thereby enhancing the drugs which are going to be excreted through liver.

SIDE EFFECTS :

Side effects of short term use include abdominal pain, cramping, nausea, vomiting and headache which are dose and treatment duration dependant. Long term administration of mifepristone is associated with

adrenal insufficiency, low serum potassium levels, a slight increase in serum creatinine levels, moderate increase in hepatic enzymes and significant increase in thyrotrophins levels.

CONTRAINDICATIONS :

Mifepristone is contraindicated in the presence of an intrauterine device (IUD)

- Adrenal failure
- hemorrhagic disorders
- inherited porphyria
- anticoagulant or long term corticosteroid therapy
- Chronic Medical Disorders
- Smokers more than 10 Cigarettes/day.

MATERIALS AND METHODS

Study design - Randomized control study

Study place - Department of obstetrics and gynaecology,

Kilpauk medical college hospital, Chennai

Study duration - April 2021 to Dec 2021

INCLUSION CRITERIA :

- 40 weeks
  - ✓ Singleton pregnancy with cephalic presentation and intact membranes if labour induction was indicated and delivery could be postponed for 24 hours
- Women with unfavourable cervix(bishop's score less than 6)
- Age between 18-45yrs

EXCLUSION CRITERIA :

- Women having hypersensitivity to prostaglandins or mifepristone
- Medical problems like impaired renal ,hepatic ,adrenal function
- Cases contraindicated to vaginal delivery
- Patient refusal
- Multiple pregnancy
- Estimated fetal weight > 4kg and < 2kg.

Sample size

88

Study design

During the period from April 2021 to Dec 2021,patients coming to Obstetrics and Gynaecology department in Kilpauk medical college hospital based on the inclusion and exclusion criteria were enrolled in the study.All patients were explained about the study and informed written consent was obtained from them in the language of convenience. A detailed history including patient's age, parity, socioeconomic status, menstrual, medical history, obstetric history, past history noted. General examination, systemic and obstetric examination done. Routine investigations like complete blood count, urine routine, blood grouping,,HIV, HbsAg, VDRL, Blood sugar and Ultrasound was done.Study population were randomized into two groups. One group of patients were treated with Tab. Mifepristone 200 mg orally. Another group was allowed for spontaneous onset of labour. Based upon the results, need for further augmentation by either prostaglandin gel induction or amniotomy or oxytocin acceleration was taken into consideration for safe delivery.

The efficacy was assessed by the following criteria:

a) Favourability of Bishop's score at 24 hrs.
b) The need of oxytocin for augmentation.
c) Duration of labour.
d) Drug administration to delivery interval.
e) The mode of delivery.
f) Cesarean section rate.
g) The 5 minute Apgar score, neonatal complications and incidence of neonatal mortality.

h) Maternal complications.

Success of induction was assessed by the following criteria:

I. Patients who delivered vaginally within 24-48 hours of the start of induction.

II. Bishop's score of ≥ 6 at the end of 24 hours

Failure of induction was assessed by the following criteria:

I. Patients who delivered vaginally after 48 hours of start of induction.

II. Patients who underwent caesarean section.

OBSERVATION AND RESULTS

TABLE -2

DISTRIBUTION OF STUDY PARTICIPANTS

Group	Number	Percentage
Group A	44	50.0
Group B	44	50.0
Total	88	100.0

In my study,44 patients were induced with Tab.Mifepristone for pre induction cervical ripening ,another 44 patients(group B) were allowed for spontaneous onset of Labour.

CHART -1

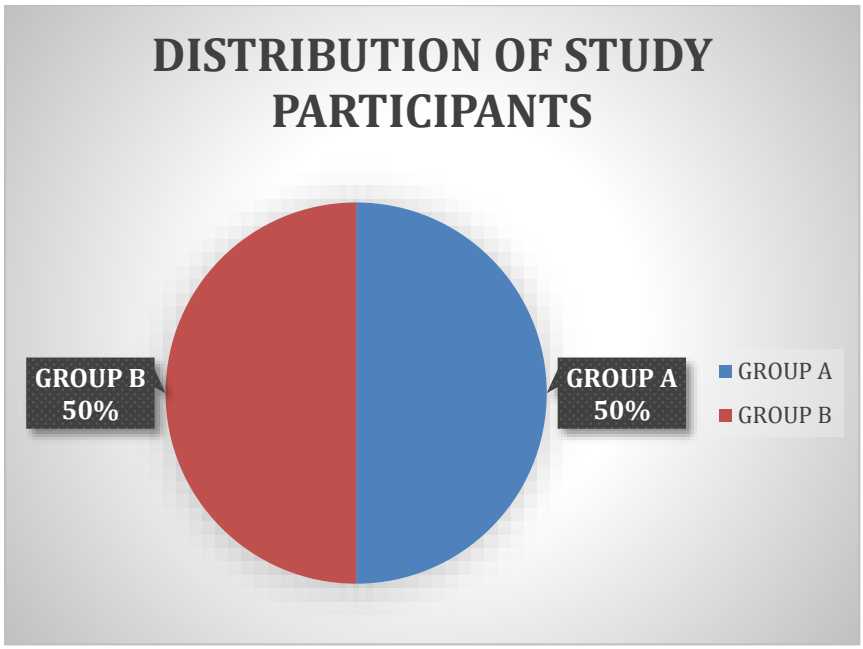


TABLE -3

AGE DISTRIBUTION OF THE STUDY GROUP

Age groups (years)	Group A		Group B	
	n	%	N	%
18-24	26	59.1	25	56.8
25-29	13	29.5	17	38.6
30 and above	5	11.4	2	4.5
Total	44	100.0	44	100.0
Chi square p value=0.39 (Not significant)				

We have included 44 women in Group A (Mifepristone) and 44 women in Group B (spontaneous onset of labour) for the purpose of our study. Both Group A and Group B more than half of them belonged to 18-24 years, with respect to age group distribution with no statistically significant difference between both groups.

CHART-2

AGE DISTRIBUTION OF THE STUDY GROUP

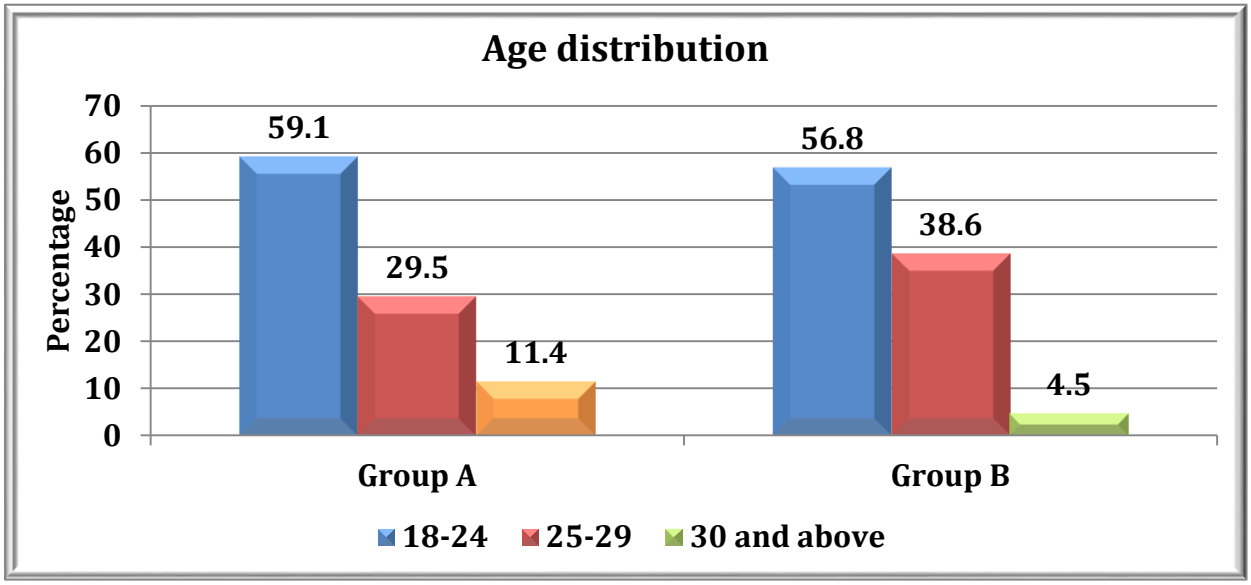


TABLE -4

PARITY

Parity	Group A		Group B	
	n	%	n	%
Primigravida	15	34.1	9	20.5
Multigravida	29	65.9	35	79.5
Total	44	100.0	44	100.0
Chi square p value=0.15 (Not significant)				

In Group A,70% were primigravida .In Group B,80% were primigravida.

CHART -3

PARITY

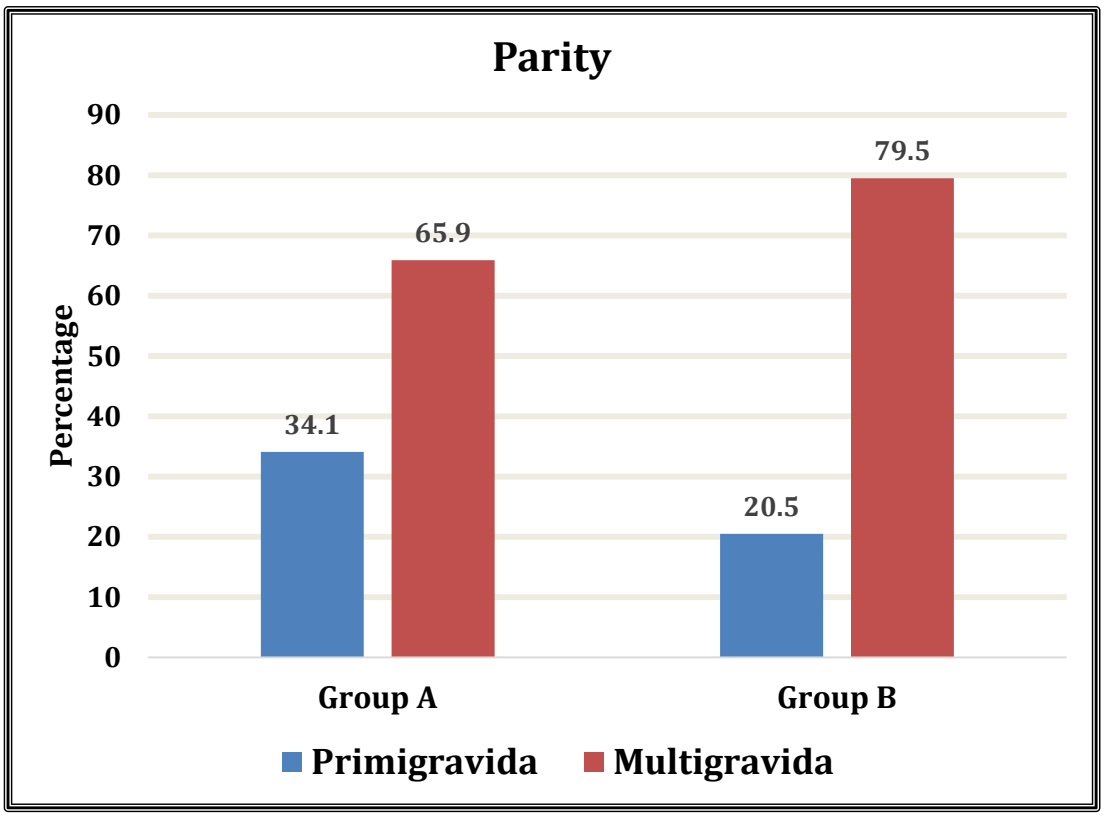


TABLE-5

SOCIO ECONOMIC STATUS

Socio economic status	Group A		Group B	
	n	%	n	%
IV	38	86.4	38	86.4
V	6	13.6	6	13.6
Total	44	100.0	44	100.0
Chi square p value=<**0.001** (Highly significant)				

Both the groups are similar in socioeconomic status. 86.4% of women belonged to Socio economic class IV and 13.6% were in Socio economic class V.

CHART -4

SOCIO ECONOMIC STATUS

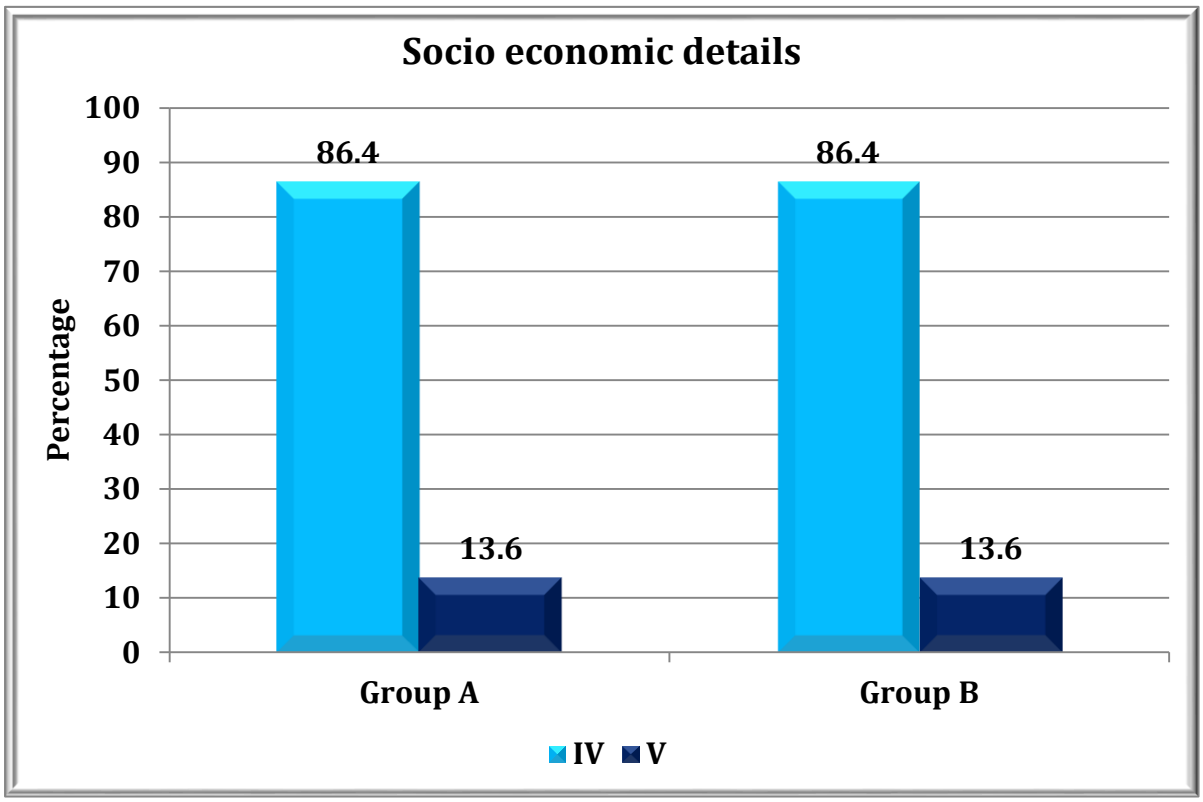


TABLE-6

COMPARISON OF BISHOP'S SCORE AT 24HRS BETWEEN THE GROUPS

Groups	Number	Mean	SD	P value
Group A	44	5.3	1.9	<**0.00**
Group B	44	2.8	1.1	**1**
Independent t-test, p value-less than 0.001				

Mean bishop's score at 24 hours was 5.3 in group A and 2.8 in group B. This difference was statistically significant with the p value of <0.001.

CHART-5

COMPARISON OF BISHOP'S SCORE AT 24HRS BETWEEN THE GROUPS

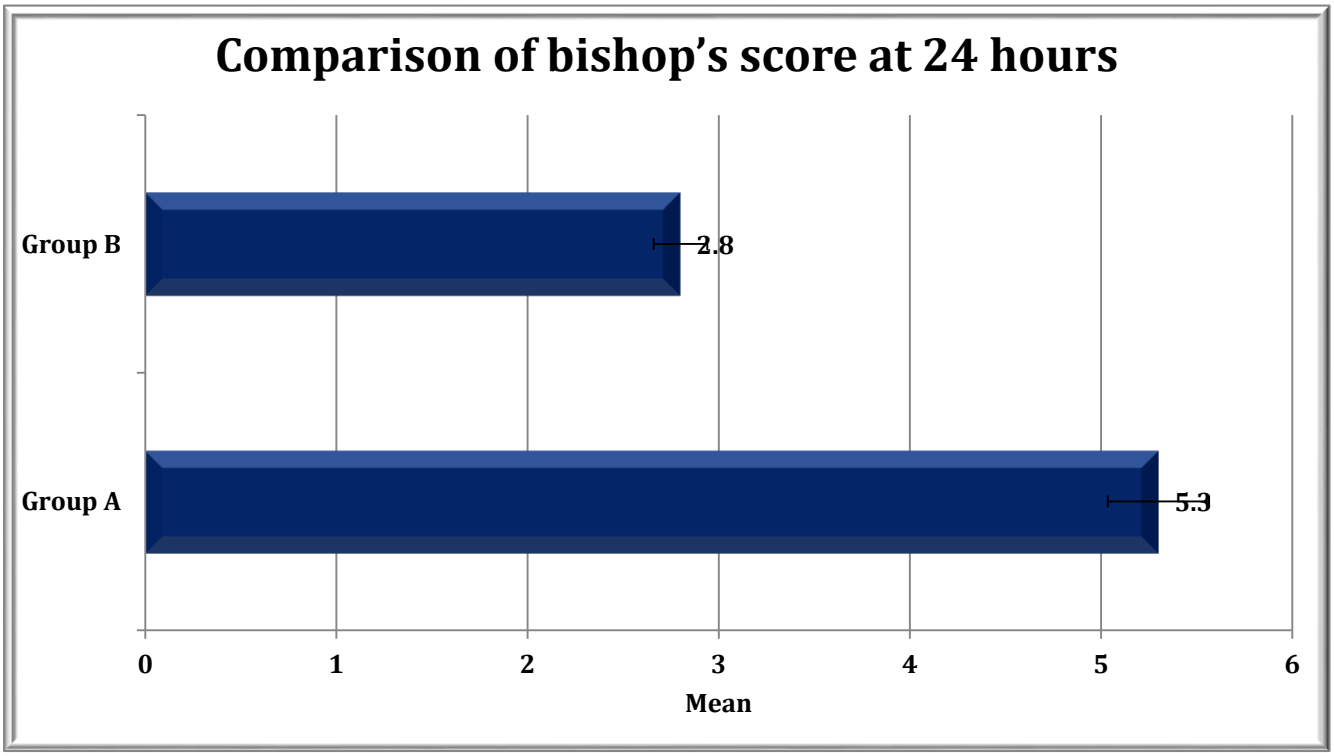


TABLE-7

AUGMENTATION WITH OXYTOCIN AMONG PRIMI AND MULTIGRAVIDA WOMEN IN BOTH THE GROUPS

Augmentation	Group A			Group B		
	Primi	Multi	Total	Primi	Multi	Total
Not required	23 (79.3)	14 (93.3)	37 (84.1)	15 (42.9)	7 (77.8)	22 (50.0)
Required	6 (20.7)	1 (6.7)	7 (15.9)	20 (57.1)	2 (22.2)	22 (50.0)
Total	29	15	44	35	9	44

Augmentation with oxytocin was comparatively higher in group B than group A. Only 16% of women required augmentation with oxytocin compared to 50 % in group B.

CHART-6

AUGMENTATION WITH OXYTOCIN AMONG PRIMI AND MULTIGRAVIDA WOMEN IN BOTH THE GROUPS

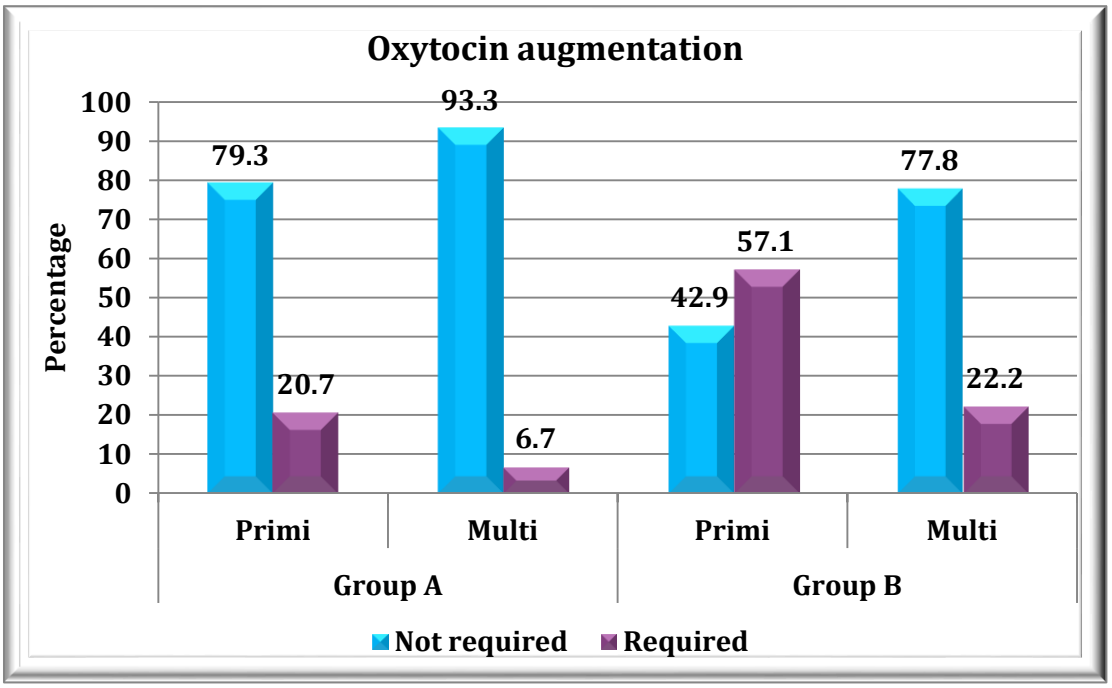


TABLE-8

ADMISSION TO DELIVERY TIME IN BOTH GROUPS

Vaginal delivery	Group A		Group B		Total
	N	%	n	%	
<24 hours	15	41.7	0	-	15
25-48 hours	21	58.3	27	100.0	48
Total	36	100.0	27	100.0	63
Chi square value: 14.8, p value=**<0.001** (Highly significant)					

Out of 63 women who had delivered vaginally, 36 belonged to group A and 27 were in group B.58.3% of the women in group A had taken more than 24 hours from admission to delivery and remaining 40% delivered within 24 hours. **In group B no women delivered within 24 hours of admission**. **So they were induced with mechanical and pharmacological method of induction for cervical ripening after which they delivered.**

CHART-7

ADMISSION TO DELIVERY TIME IN BOTH GROUPS

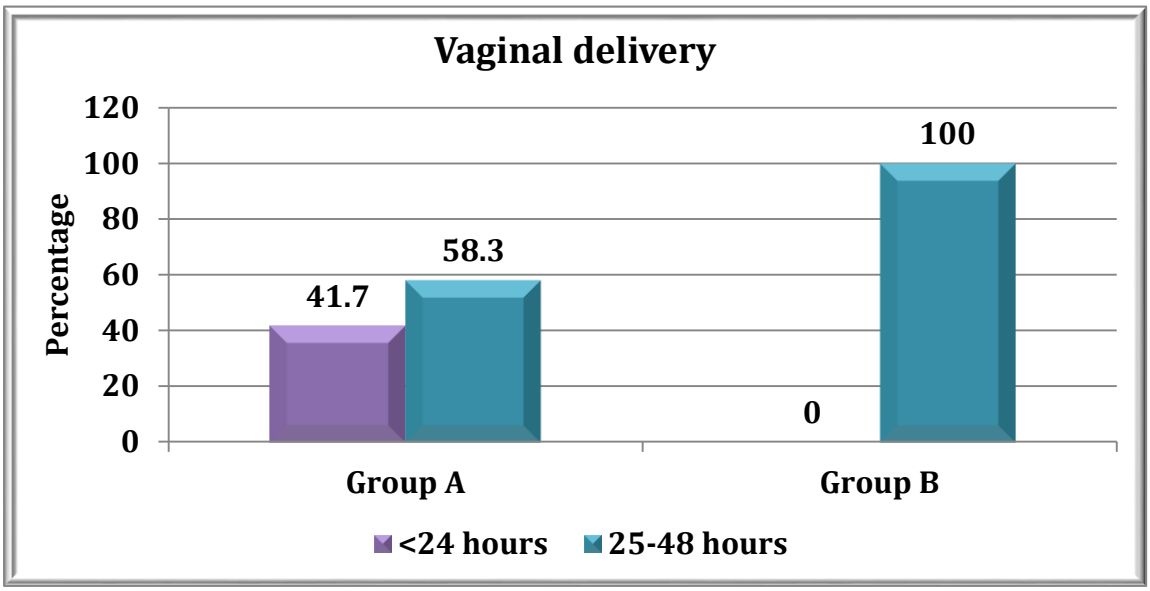


TABLE-9

COMPARISON OF MODE OF DELIVERY BETWEEN THE GROUPS

Mode of delivery	Group A		Group B	
	n	%	n	%
Vaginal	37	84.1	30	68.2
LSCS	7	15.9	14	31.8
Total	44	100.0	44	100.0
Chi square p value=0.09 (Not significant)				

In Group A more than 84.1% women had vaginal delivery and 15.9% delivered through caesarian section.

In Group B, 68.2% had vaginal delivery and 31% had LSCS. But this was not statistically significant between the groups.

CHART-8

COMPARISON OF MODE OF DELIVERY BETWEEN THE GROUPS

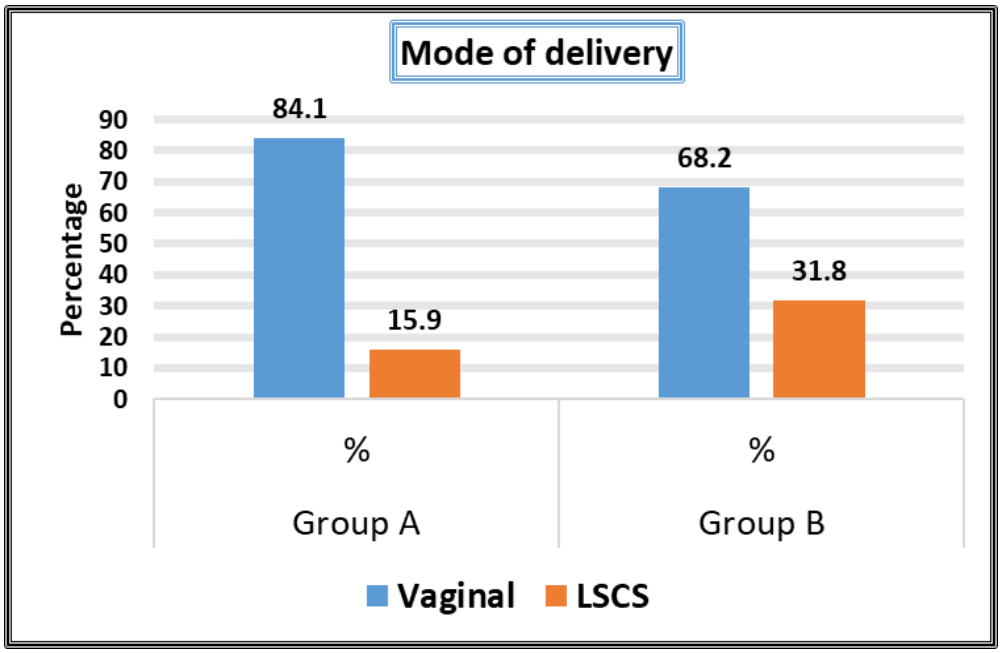


TABLE-10

COMPARISON OF MODE OF DELIVERY AND GRAVIDA IN BOTH GROUPS

Mode of delivery	Group A			Group B		
	Primi	Multi	Total	Primi	Multi	Total
Vaginal	21 (72.4)	15 (100.0)	36 (81.8)	21 (60.0)	6 (66.7)	27 (61.4)
Instrumental	1 (3.4)	0	1 (2.3)	2 (5.7)	1 (11.1)	3 (6.8)
LSCS	7 (24.1)	0	7 (15.9)	12 (34.3)	2 (22.2)	14 (31.8)
Total	29	15	44	35	9	44

Caesarian section rate was higher in group B which was 32%, when compared to mifepristone group in which it was 16%.

CHART-9

COMPARISON OF MODE OF DELIVERY AND GRAVIDA IN BOTH GROUPS

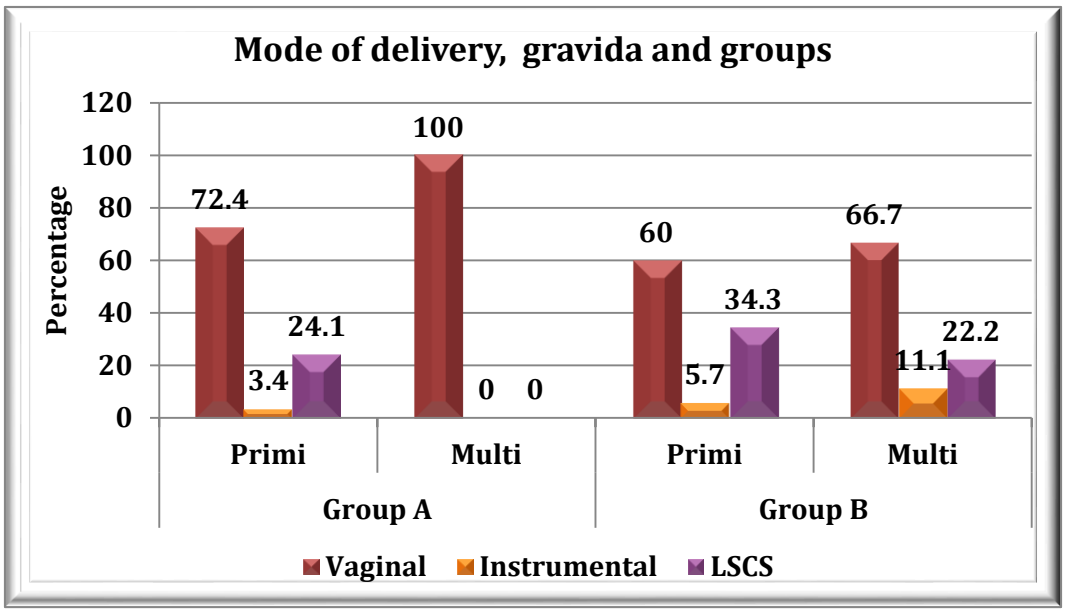


TABLE-11

INDICATION FOR LSCS

Indications for LSCS	Group A		Group B	
	N	%	n	%
FD	7	100	9	64.2
Failed Induction	0	-	3	21.4
Non reassuring CTG	0	-	2	14.3
Total	7	100.0	14	100.0
Chi square p value=0.13 (Not significant)				

In Group A , FD was the main indication for LSCS. In Group B, the indication for LSCS was Fetal distress (64.2%)followed by failed induction in 21%. There is no significant difference in both the groups.

CHART-10

INDICATION FOR LSCS

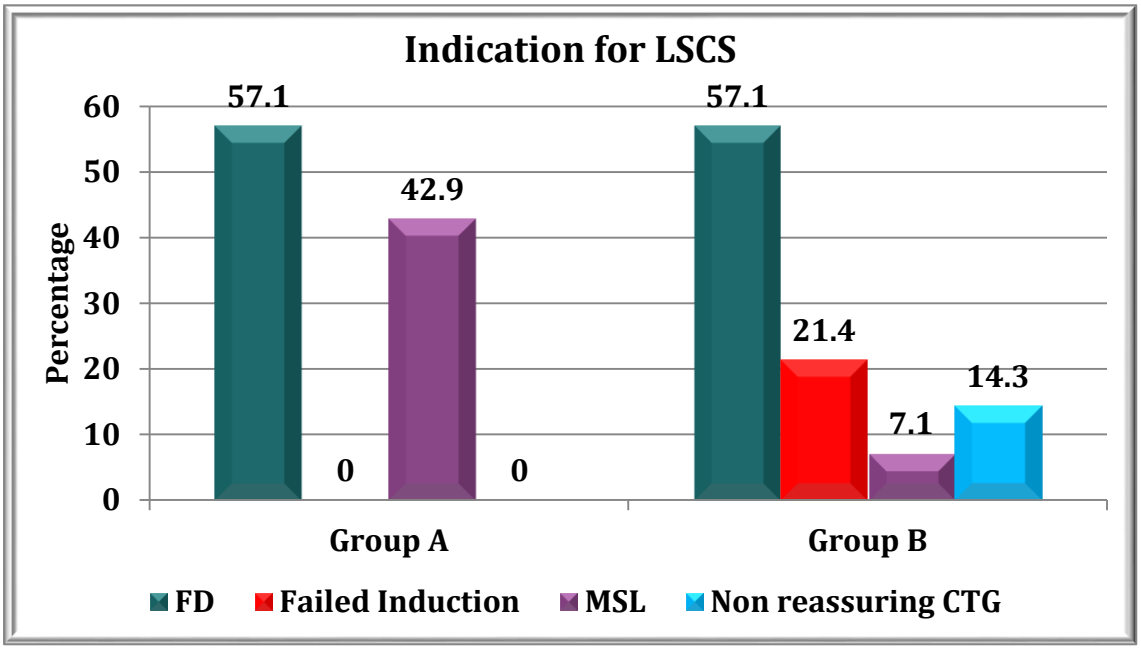


TABLE-12

COMPARISON OF APGAR SCORE AT ONE MINUTE BETWEEN THE GROUPS

Groups	Number	Mean	SD	P value
Group A	44	6.9	0.3	**<0.001**
Group B	44	5.7	1.2	
Independent t-test, p value-less than 0.001				

Mean APGAR score at one minute was 6.9 in group A and 5.7 in group B. This difference was statistically significant with the p value of <0.001.

CHART-11

COMPARISON OF APGAR SCORE AT ONE MINUTE BETWEEN THE GROUPS

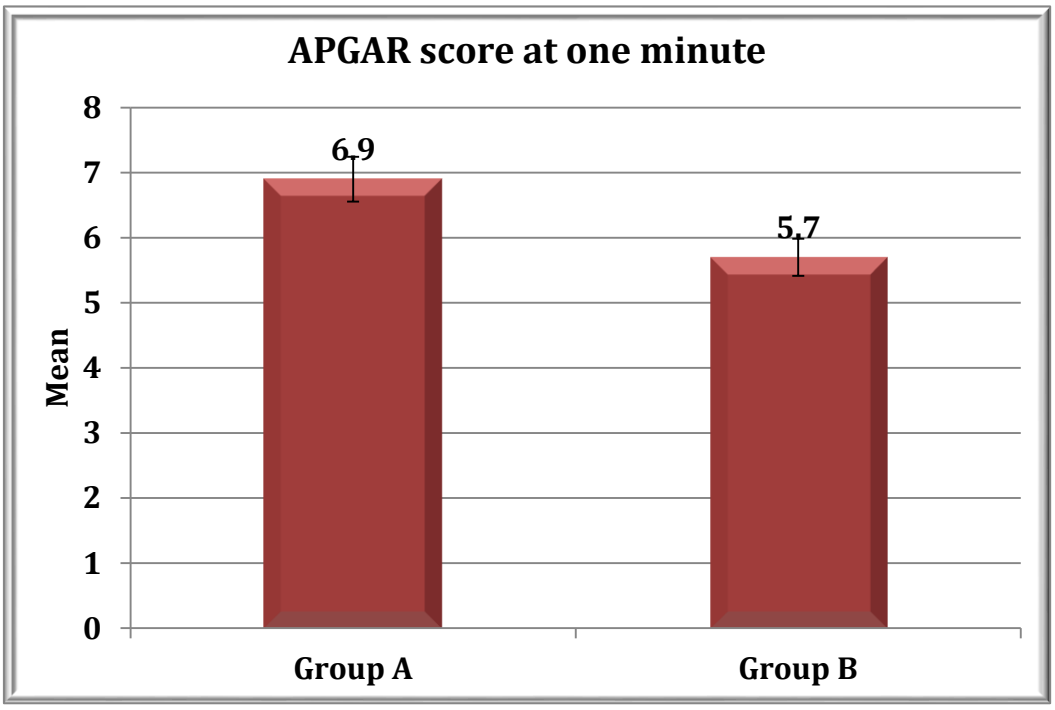


TABLE-13

COMPARISON OF APGAR SCORE AT FIVE MINUTES BETWEEN THE GROUPS

Groups	Number	Mean	SD	P value
Group A	44	8.0	0.2	**<0.001**
Group B	44	7.1	0.8	
Independent t-test, p value- less than 0.001				

Mean APGAR score at five minutes was 8.0 in group A and 7.1 in group B. This difference was statistically significant with the p value of <0.001.

CHART-12

COMPARISON OF APGAR SCORE AT FIVE MINUTES BETWEEN THE GROUPS

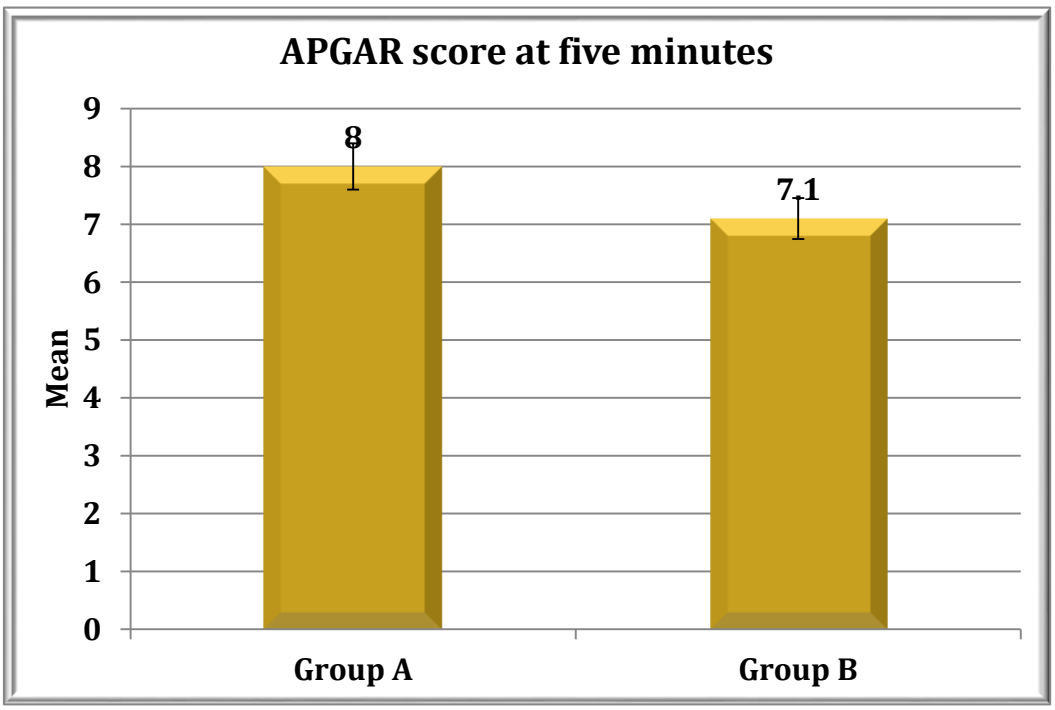


TABLE-14

THIRD STAGE COMPLICATIONS

Maternal complications	Group A		Group B	
	N	%	n	%
None	44	100.0	41	93.2
PPH	0	-	3	6.8
Total	44	100.0	44	100.0
Chi square p value=0.07 (Not significant)				

In Group A none of them developed third stage complications of pregnancy but in group B 3 (6.8%) had PPH.

CHART-13

THIRD STAGE COMPLICATIONS

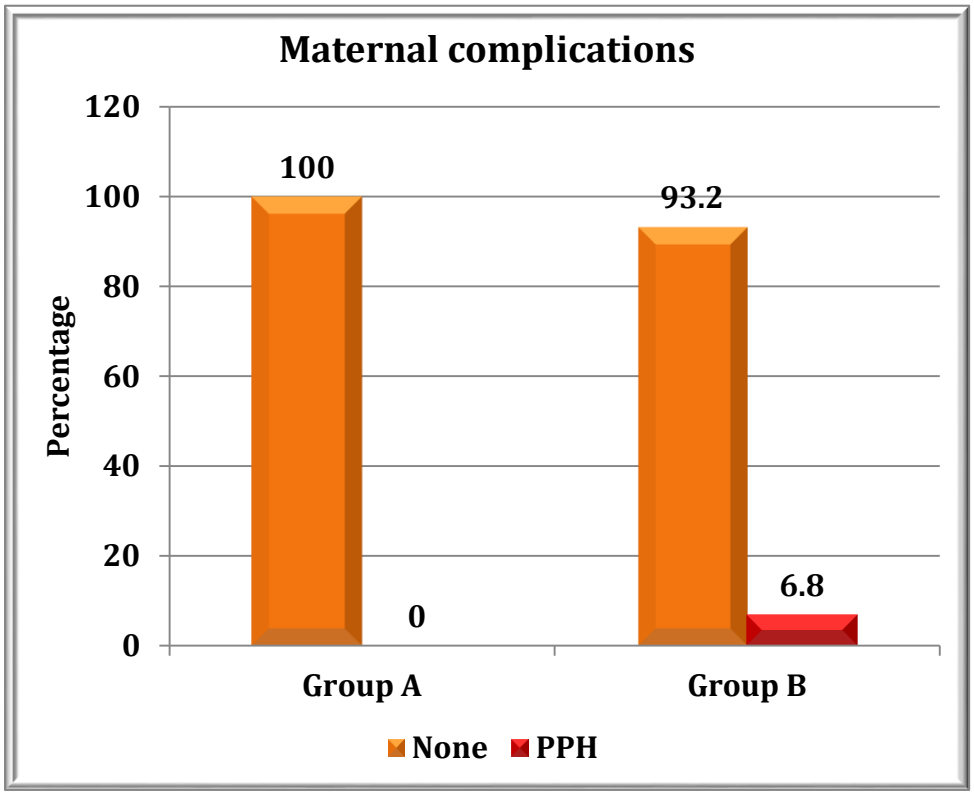


TABLE-15

FOETAL COMPLICATIONS

Foetal complications	Group A		Group B	
	N	%	n	%
None	39	88.6	32	72.7
MSL or FD	5	11.4	9	20.5
RD	0	0	3	6.8
Total	44	100.0	44	100.0
Chi square p value= <0.001 (Highly significant)				

90% of the babies born in Group A did not face any complications. In group B MSL(20.5%) was the major one followed by Respiratory distress in 6.8% of the babies. This difference was statistically significant with the p value of less than 0.001.

CHART-14

FOETAL COMPLICATIONS

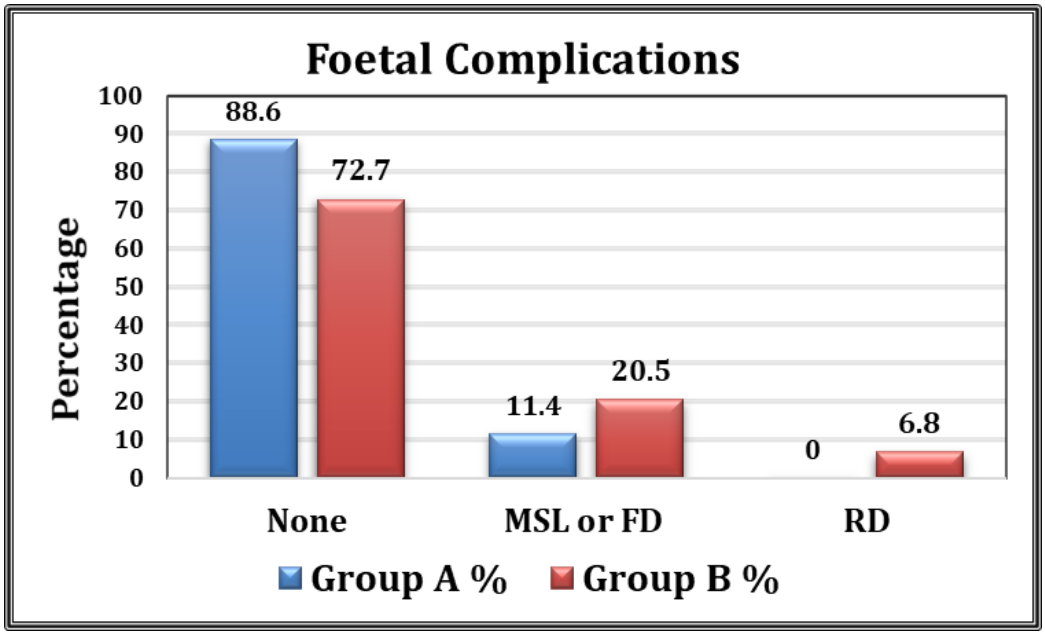


TABLE-16

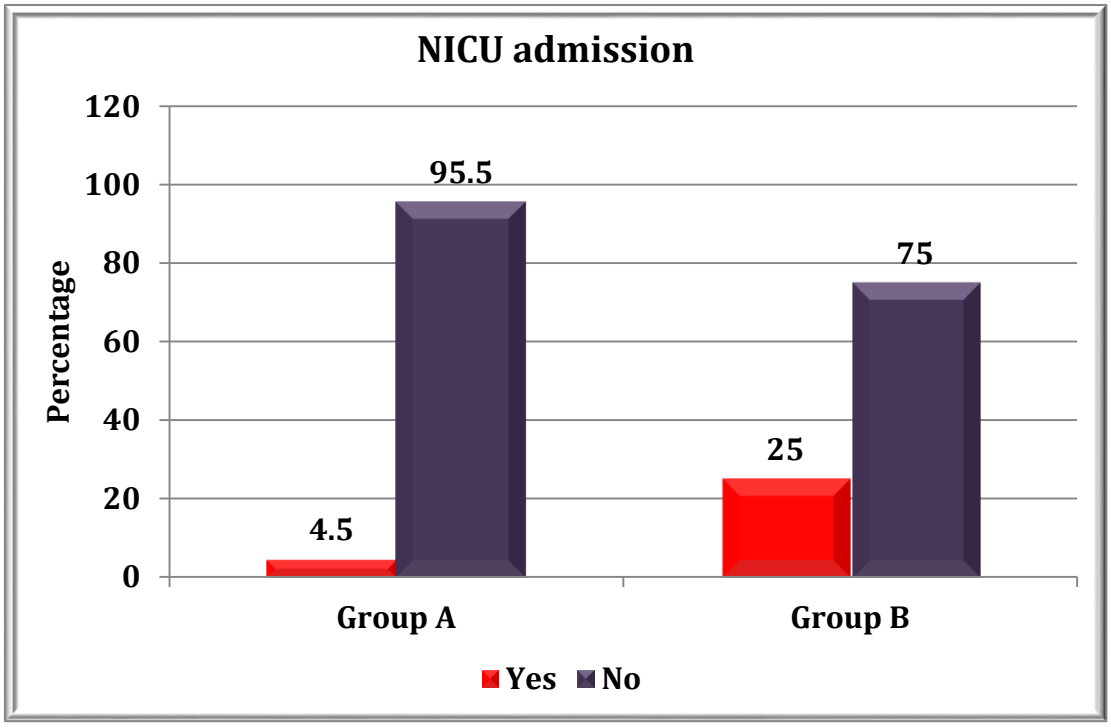
COMPARISON OF NICU ADMISSION BETWEEN THE GROUPS

NICU admission	Group A		Group B	
	N	%	n	%
Yes	2	4.5	11	25
No	42	95.5	33	75
Total	44	100.0	44	100.0
Chi square p value=**0.007** (Significant)				

NICU admission was higher in group B(25%) when compared to group A(4.5%).There was significant difference observed between the groups.

CHART-15

COMPARISON OF NICU ADMISSION BETWEEN THE GROUPS



DISCUSSION

In my study, we opted for 200mg of Mifepristone, single tablet orally for pre induction cervical ripening and observation period of 24 hours which is similar to the Wing et al ,Elliot et al and Frydam R et al study in which mifepristone was compared with placebo[47,48,49].

Out of 44 in Group A,88% of women were between the age group of 18-29 years. This study correlates with a trail conducted by Wing et al in which 88% of the patients were in the age group of 21-30 years[48].

Women with Bishop's score 0f 0-6 were included in the study group. Similar study was done by Bashutheen et al in which bishop's score of 1 to 6 were included. There was significant improvement in bishop's score in the study groups after 24 hours which showed similarities with the studies conducted by Athawale et al(82%)[4], Sanghamitra Mohapatra et al (90%)[6].

The need for Augmentation with oxytocin was 16% in mifepristone group and 22% with group B which was similar to Sailatha et al in which oxytocin requirement was less in mifepristone group (24%) as compared to another group (36%).

The mean duration of admission to delivery interval was found to be 25 hours in group A compared to 35 hours in group B.This was in accordance with study conducted by Bama et al (28 hours) and Kanan YELIKAR(30 hours)[3].

In Mifepristone group 84% of women delivered vaginally compared to 68% in group B.Similar results were observed in studies conducted by Rutuja Athawale et al (80.88%) ,Wing DA et al (87.5%) and Sanghamitra mohapatra et al (92%)[4,48,6].

16% of women needed caesarean section in group A. Most of the indication for caesarean section is fetal distress. This result was contrary to Sailatha et al(8%) study in which failed induction is the most common indication for LSCS.

Meconium passage was encountered in 5% and NICU admission was 4.5% in mifepristone group and meconium passage was 20% and NICU admission was 25% in group B. In this aspect, our study is consistent with study conducted by Gaikwad et al in which 6% NICU admission is seen in mifepristone group. It was contrast to study done by Sah et al were 10% babies admitted in mifepristone group.

In this study the success rate was determined by the time taken for induction to delivery which is ideally within 36-48 hours. Success rate was 84% in group A which was consistent with the success rate seen in wing DA at al (88%)[48] and Giacolone PL et al (80.5%)study.

In this study successful induction in relation to change in favourable Bishop's score of 6 or more was seen in 90% in group A which was consistent with Frydam R et al and Wing DA et al study[47,48].

CONCLUSION

1. Mifepristone has proved very useful for medical abortion in the first and second trimester termination of pregnancy. It has an established role as an effective cervical priming agent.
2. This effect is now utilized for cervical ripening in term pregnancies. Mifepristone is well tolerated by pregnant women and the efficacy has been proved in many trials.
3. This Study reveals that oral Mifepristone is very safe and effective drug.
    a) **For preinduction cervical ripening especially in multigravida**
    b) **It has an added advantages of ease of administration**
    c) **Better patient acceptance**
    d) **Reduced oxytocin augmentation**
    e) Shortens the duration of labour
    f) **No third stage complication like PPH**
    g) **Lesser neonatal complications and lesser neonatal admissions** with an overall success rate of 84% compared to those pregnant women was allowed for spontaneous onset of labour.
4. The drug has no untoward side effects on uterine contraction and no major maternal complications and has safe neonatal outcome.
5. The incidence of meconium stained liquor with fetal distress needs further follow up studies.

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ANNEXURES

PROFORMA

"ROLE OF ORAL MIFEPRISTONE FOR CERVICAL RIPENING AND INDUCTION OF LABOUR IN TERM PREGNANCY – Randomized Controlled Study

Name:	Age	DOA:
		DOD:
Address:	IP.No	L.M.P:
	SES	E.D.D:

HISTORY:

History of Presenting complaints Booked Case: Yes/No.

Obstetric History Gr P L A

□™ Menstrual History

□™ Past Medical / Surgical History

□™ Personal History

□Family History

GENERAL PHYSICAL EXAMINATION

Height Weight BMI

Pallor Edema

Pulse BP RR Temperature

CVS RS Breast Thyroid

Per Abdomen – Uterine Size Activity

- Lie Presentation

Position

- FHR

Per Speculum

Per Vaginum - Cx Dilatation Position Consistency

Effacement

Integrity of membranes

Presentation and Station

Pelvic Assessment

INVESTIGATIONS

1. Hb%
2. Urine-albumin

Sugar

Deposits

3. Bloodgroup&Rh typing
4. Blood-urea

   –Sugar
5. Serum creatinine
6. HIV, VDRL, HBSAG
7. Obstetric scan – single, live/dead, fetus

   Cardiac activity&fetal movements

   B.P.D- cms weeks days

   F.L cms weeks days

   Placenta - fundal anterior/posterior

   Grade maturity

   Liquor adequate/not

   Obvious congenital abnormalities

   Bishop’s score on admission-

   Indication for induction-

   Date and time of induction-

   Bishop’s score at time of induction-

   Wait period after induction

Bishop’s score at the end of 24 hrs

Need for cerviprime gel induction

Need for oxytocin

DURATION OF LABOUR

Induction to active stage(hrs)

Induction to delivery interval(hrs)

NATURE OF DELIVERY

Labour	Instrumental delivery			
Natural/labour		Low		
Natural	outlet	midcavity	vaccum	Lscs
with episiotomy	forceps	forceps	delivery	indication

Amount of blood loss at III stage

Drug administration to delivery interval

Complications-Maternal

Nausea/vomiting/diarrhea

Headache/hyperthermia/fever

Abdominal cramps

Chorioamnionitis/endometritis/puerperal sepsis,

Uterine contraction abnormalities-Tachysystole/ hypertonus/ Hyperstimulation.

Any Treatment Given

Intrapartum Fetal Complications

1. Fetal heart rate abnormalities
2. Meconium passage-thin/thick

BABY

Birth weight

Apgar 1’ 5’

Congenital anomalies if any

Neonatal resuscitation Neonatal

admissions

Fetal complications-Meconium aspiration syndrome –

Hyperbilirubinemia

-Others

PATIENT CONSENT FORM

Title of the Project :

Name : Date :

Age : IP No. :

Sex : Project Patient No. :

1. The details of the study have been provided to me in writing and explained to me in my own language or a language that I understand/speak.
2. I confirm that I have understood the above study and had the opportunity to ask questions.
3. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected.
4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
5. I have been given an information sheet giving details of the study.
6. I fully consent to participate in the above study.

(Signature of the Participant)

அனுமதியுடனான ஒப்புதல் படிவம்

-இந்த ஆய்விற்கான செயல்முறையின் நோக்கத்தை நான் புரிந்துள்ளேன் என்பதை உறுதிப்படுத்துகிறேன். எனக்கு கேள்விகளை கேட்க வாய்ப்பு உள்ளது. என்னுடைய எல்லா கேள்விகளும் சந்தேகங்களும் என் முழுதிருப்திக்கு பதில் அளித்துள்ளன.

-ஆய்வில் எனது பங்கேற்பு தன்னார்வமாக இருப்பதையும், என் சட்டஉரிமைகள் பாதிக்கப்படாமல், காரணத்தைத் தெரிவிக்காமல் எப்போது வேண்டுமானாலும் விலக்கிக்கொள்ளலாம் என்பதையும் நான் புரிந்துகொள்கிறேன்.

-ஆய்வில் இருந்து நான் விலகி வந்தாலும் கூட, ஆராய்ச்சிக்கு பொருந்தக்கூடிய என் உடல்நல ஆவணங்களைப் பார்க்க என் நெறிமுறைக்குழு மற்றும் ஒழுங்குமுறை அதிகாரிகளுக்கு எனது அனுமதி தேவையில்லை என்பதை நான் புரிந்து கொள்கிறேன். இந்தஅணுகலை நான் ஏற்கிறேன்.

-இருப்பினும், சட்டத்தின்கீழ் தேவைப்பட்டாலன்றி, மூன்றாம் தரப்பினருக்கு வெளியிடப்பட்ட அல்லது வெளியிட்ட எந்த தகவலிலும் என் அடையாளத்தை வெளிப்படுத்தமுடியாது என்பதை நான் புரிந்து கொள்கிறேன். இந்த ஆய்விலிருந்து எழும் எந்தவொரு தரவு அல்லது முடிவுகளின் பயன்பாட்டைக் கட்டுப்படுத்துவதை நான் ஏற்றுக் கொள்கிறேன்.

-மேலே உள்ள படிப்பில்கலந்துகொள்ளவும், ஆய்வின் போதுகொடுக்கப்பட்ட அறிவுறுத்தல்களுக்கு இணங்கவும், ஆய்வுக் குழுவோடு ஒத்துழைக்கவும், என் உடல்நலம் அல்லது நலம் அல்லது எந்தவொரு எதிர்பாராத அல்லது அசாதாரண அறிகுறிகளிலும் நான் பாதிக்கப்படுகையில் உடனடியாக ஆய்வு ஊழியர்களுக்கு தெரிவிக்கவும், இந்த ஆய்வில் பங்கேற்க ஒப்புக் கொள்கிறேன்.

நான் இதனுடன் முழுமையான மருத்துவ பரிசோதனை மற்றும் நோயறிதல் சோதனைகள் இரத்தம், உயிர்வேதியியல், கதிரியக்க சோதனைகள் உட்பட சிகிச்சைக்கு உட்படுத்த அனுமதிக்கிறேன்.

ஆய்வு தலைப்பு: **நிறைமாத கர்ப்பிணிகளுக்கு சுகப்பிரசவ வலி ஏற்படுத்துவதில் மீபிபிரிஸ்டோன் மாத்திரையின் பங்கு பற்றி அரசு மருத்துவ கல்லூரி மருத்துவமனையில் ஆய்வு செய்தல்.**

ஆய்வு மையம் : **கீழ்ப்பாக்கம் அரசு மருத்துவ கல்லூரி மற்றும் மருத்துவமனை**

பங்கேற்பாளரின் பெயர்:

பங்கேற்பாளரின் வயது:

நோயாளி எண்:

நோயாளியின் கையொப்பம்

நோயாளியின் பெயர் மற்றும் முகவரி: ஆராய்ச்சியாளரின் கையொப்பம்:

நோயாளியின் ஒப்புதல் படிவம்

ஆய்வின் தலைப்பு : ***நிறைமாத கர்ப்பிணிகளுக்கு சுகப்பிரசவ வலி ஏற்படுத்துவதில் மீபிபிரிஸ்டோன் மாத்திரையின் பங்கு பற்றி அரசு மருத்துவ கல்லூரி மருத்துவமனையில் ஆய்வு செய்தல்.***

முக்கிய ஆய்வாளரின் பெயர் : டாக்டர். P. லிங்கம்மாள்

நிறுவன முகவரி : கீழ்ப்பாக்கம் மருத்துவ கல்லூரி மருத்துவமனை, கீழ்ப்பாக்கம், சென்னை - 600010.

நீங்கள் இந்த ஆய்வில் பங்கு பெற வரவேற்கப்படுகிறீர்கள், இந்த தாளில் அளிக்கப்பட்டுள்ள விவரங்கள் நீங்கள் ஆய்வில் பங்கு பெறுவது குறித்து தீர்மானிக்க உதவும். சந்தேகங்கள் மற்றும் கேள்விகள் தயக்கமின்றி வரவேற்கப்படுகின்றன.

நாங்கள் இந்த ஆய்விற்காக தலைமை நெறிமுறை குழுவின் (Institutional Ethics Committee) அனுமதி பெற்றுள்ளோம்.

பகுதி - I

நோயாளியின் தகவல் படிவம்:

பொதுவாக அனைத்து கர்ப்பிணி பெண்களும், அவர்களின் கர்ப்ப காலத்திலும், கர்ப்ப கால முடிவிலும் ஆரோக்கியமான தாயும், சேயும் பெறுவதே அவர்களின் விருப்பம். அதற்கு ஏதுவாக நிறைமாத கர்ப்பிணி பெண்களுக்கு சுகப்பிரசவ வலி ஏற்படுத்துவதில் வாய்வழியாக மீபிபிரிஸ்டோன் மாத்திரையின் பங்கு குறித்து இந்த ஆய்வின் மூலமாக அறியலாம்.

உங்கள் தகவல் குறித்த நம்பிக்கை

உங்களை பற்றிய தகவல் (பரிசோதனை விவரங்கள்) எவருக்கும் தெரிவிக்கப்படமாட்டாது. இந்த ஆய்விலிருந்து அறியப்படும் விவரங்கள் கூட்டங்களில், பத்திரிக்கைகளில் இடப்படும் போது உங்களைப் பற்றிய

தனிப்பட்ட தகவல்கள் இரகசியம் காக்கப்படும்.

நீங்கள் இந்த ஆய்வில் பங்கு கொள்ளாவிட்டாலும் உங்களுடைய மருத்துவ சிகிச்சையோ அல்லது ஆய்வாளருடன், மருத்துவமனையுடன் உங்களது உறவு பாதிக்கப்படாது. இதனால் உங்களுக்கு கிடைக்கப்பெற இருக்கும் எந்த ஒரு சிகிச்சை முறையிலும் மாறுதல் ஏற்படாது. நீங்கள் இந்த ஆய்வில் பங்கு பெறுவது உங்களுடைய விருப்பம். எந்த நேரத்திலும், எந்த விளக்கமும் அளிக்காமல் நீங்கள் விலகிக் கொள்ள உரிமை உண்டு.

ஆய்வாளரின் கையொப்பம் :

பங்கேற்பவரின் பெயர் :

பங்கேற்பவரின் கையொப்பம் :

நாள் :

இடம்:

MASTER CHART

GROUP A

Sl. No.	Name	Age	IP.No	Booked /Unbooked	SES	Primi/ Multi	Gestational Age	Bishop's score		Method of Induction	Amount of Oxytocin (Units)	Duration		Mode of Delivery	Indication for LSCS	Complication		B.wt (Kg)	Apgar		NICU Admission
								At start	After 24 hours			Induction to Active Phase	Induction to Delivery			Maternal	Fetal		I"	5"	
1	Jonna	23	15700	Booked	IV	Primi	40 wks	0/13	2/13	MIFEPRISTONE	NO	-	-	LSCS	FD	-	MSL	3.04	6/10	7/10	YES
2	Nirmala	18	15789	Booked	V	Primi	40 wks	1/13	4/13	MIFEPRISTONE		-	-	LSCS	MSL		FHA	3.1	7/10	8/10	
3	Yogarani	19	15801	Unbooked	V	Primi	40 wks	1/13	6/13	MIFEPRISTONE	5	26 hrs	29 hrs	LABOUR NATURAL				3	7/10	8/10	
4	Munilakshmi	22	15864	Booked	IV	Multi	40 wks	3/13		MIFEPRISTONE		12	17 hrs 57 mts	LABOUR NATURAL				3.4	7/10	8/10	
5	sharmila	18	15862	Booked	V	Primi	40 wks	3/13	6/13	MIFEPRISTONE	5	25 hrs	29 hrs	LABOUR NATURAL				3.03	7/10	8/10	
6	Loga nayaki	27	16317	Booked	IV	Multi	40 wks	3/13	2/13	MIFEPRISTONE			8 hrs	LABOUR NATURAL				2.77	7/10	8/10	
7	Pavithra	20	16457	Booked	V	Primi	40 wks	2/13	5/13	MIFEPRISTONE		24 hrs	28 hrs	LABOUR NATURAL				3.4	6/10	8/10	YES
8	Jeyanthi	25	17270	Booked	IV	Multi	40 wks	1/13	7/13	MIFEPRISTONE			26 hrs	LABOUR NATURAL				2.53	7/10	8/10	
9	Sujithra	18	17439	Unbooked	V	Primi	40 wks	2/13		MIFEPRISTONE			14 hrs	LABOUR NATURAL				2.64	7/10	8/10	
10	Jothi Balaji	25	17438	Booked	IV	Primi	40 wks	1/13		MIFEPRISTONE				LSCS	MSL		FHA	3	6/10	7/10	
11	Ishwarya	21	19353	Booked	IV	Multi	40 wks	3/13		MIFEPRISTONE			4 hrs 1 min	LABOUR NATURAL				2.6	7/10	8/10	
12	Ranjitha	24	19357	Booked	IV	Primi	40 wks	1/13		MIFEPRISTONE			14 hrs	LABOUR NATURAL				2.56	7/10	8/10	
13	Sangeetha	23	19354	Booked	IV	Multi	40 wks	0/13	5/13	MIFEPRISTONE + Gel		25 hrs	30 hrs	LABOUR NATURAL				2.9	7/10	8/10	
14	Thangam	27	19667	Booked	IV	Multi	40 wks	1/13	7/13	MIFEPRISTONE			26 hrs	LABOUR NATURAL				2.7	7/10	8/10	
15	Mamta	26	19843	Booked	IV	Primi	40 wks	0/13	2/13	MIFEPRISTONE				LSCS	FD			2.6	7/10	8/10	
16	Thamaraiselvi	25	20937	Booked	IV	Multi	40 wks	1/13	4/13	MIFEPRISTONE	2.5	25 hrs	30 hrs	LABOUR NATURAL				3.5	7/10	8/10	
17	Ramya	23	20938	Booked	IV	Primi	40 wks	1/13	5/13	MIFEPRISTONE				LSCS	FD			3.18	7/10	8/10	

MASTER CHART - GROUP A

Sl. No.	Name	Age	IP.No	Booked /Unbooked	SES	Primi/Multi	Gestational Age	Bishop's score		Method of Induction	Amount of Oxytocin (Units)	Duration		Mode of Delivery	Indication for LSCS	Complication		B. wt (Kg)	Apgar		NICU Admission
								At start	After 24 hours			Induction to Active Phase	Induction to Delivery			Maternal	Fetal		I"	5"	
18	Deepa	30	20941	Booked	IV	Multi	40 wks	3/13		MIFEPRISTONE			10 hrs	LABOUR NATURAL				3.4	7/10	8/10	
19	Keerthana	21	21762	Booked	IV	Primi	40 wks	1/13	2/13	MIFEPRISTONE				LSCS	MSL		FHA	3.1	7/10	8/10	
20	Ashwini	18	21764	Booked	V	Primi	40 wks	3/13		MIFEPRISTONE			13 hrs	LABOUR NATURAL				3.1	7/10	8/10	
21	Bhuvaneshwari	25	21773	Booked	IV	Primi	40 wks	2/13	6/13	MIFEPRISTONE	5	22 hrs	28 hrs	LABOUR NATURAL				3.3	7/10	8/10	
22	Jamuna	24	21780	Booked	IV	Primi	40 wks	0/13	6/13	MIFEPRISTONE			26 hrs	LABOUR NATURAL				2.45	7/10	8/10	
23	Uma Maheshwari	25	22412	Booked	IV	Primi	40 wks	2/13	6/13	MIFEPRISTONE + Gel		23 hrs	29 hrs	LABOUR NATURAL				2.95	7/10	8/10	
24	Bhuvaneshwari	24	24637	Booked	IV	Multi	40 wks	2/13		MIFEPRISTONE			19 hrs	LABOUR NATURAL				2.7	7/10	8/10	
25	Bhavani	25	24354	Booked	IV	Multi	40 wks	0/13	4/13	MIFEPRISTONE		25 hrs	30 hrs	LABOUR NATURAL				3.3	7/10	8/10	
26	Priya	24	24358	Booked	IV	Multi	40 wks	2/13		MIFEPRISTONE			11 hrs	LABOUR NATURAL				2.88	7/10	8/10	
27	Abila	22	24787	Booked	IV	Primi	40 wks	2/13		MIFEPRISTONE			22 hrs	LABOUR NATURAL				2.9	7/10	8/10	
28	Priyanka	25	24368	Booked	IV	Primi	40 wks	0/13	4/13	MIFEPRISTONE + Gel		28 hrs	33 hrs	LABOUR NATURAL				2,.7	6/10	8/10	
29	Selvi	22	24404	Booked	IV	Primi	40 wks	2/13	8/13	MIFEPRISTONE	5	23 hrs	28 hrs	LABOUR NATURAL				3.1	7/10	8/10	
30	Thenmozhi	30	24450	Booked	IV	Primi	40 wks	0/13	6/13	MIFEPRISTONE		24 hrs	29 hrs	LABOUR NATURAL				2.8	7/10	8/10	

MASTER CHART - GROUP A

Sl. No.	Name	Age	IP.No	Booked /Unbooked	SES	Primi/Multi	Gestational Age	Bishop's score		Method of Induction	Amount of Oxytocin (Units)	Duration		Mode of Delivery	Indication for LSCS	Complication		B. wt (Kg)	Apgar		NICU Admission
								At start	After 24 hours			Induction to Active Phase	Induction to Delivery			Maternal	Fetal		I"	5"	
31	Parameshwari	23	24541	Booked	IV	Primi	40 wks	1/13	4/13	MIFEPRISTONE			25 hrs	LABOUR NATURAL				3.1	7/10	8/10	
32	Uma	24	24560	Booked	IV	Primi	40 wks	3/13	8/13	MIFEPRISTONE		21 hrs	27 hrs	LABOUR NATURAL				3.2	7/10	8/10	
33	Saraswathi	24	24570	Booked	IV	Primi	40 wks	0/13	4/13	MIFEPRISTONE + Gel		26 hrs	30 hrs	LABOUR NATURAL				3.3	7/10	8/10	
34	Tamilarasi	31	24590	Booked	IV	Primi	40 wks	2/13	6/13	MIFEPRISTONE	5	28 hrs	32 hrs	OUTLET				3.5	7/10	8/10	
35	Aarthi	24	24594	Booked	IV	Multi	40 wks	2/13	8/13	MIFEPRISTONE			22 hrs	LABOUR NATURAL				2.7	7/10	8/10	
36	Vidhya	24	24607	Booked	IV	Multi	40 wks	0/13	6/13	MIFEPRISTONE			24 hrs	LABOUR NATURAL				2.7	7/10	8/10	
37	Suganya	28	24613	Booked	IV	Primi	40 wks	1/13	6/13	MIFEPRISTONE		24 hrs	29 hrs	LABOUR NATURAL				2.8	7/10	8/10	
38	Pavithra	26	24704	Booked	IV	Primi	40 wks	3/13	8/13	MIFEPRISTONE			27 hrs	LABOUR NATURAL				2.6	7/10	8/10	
39	Nithya	24	24777	Booked	IV	Primi	40 wks	0/13	2/13	MIFEPRISTONE				LSCS	FD		MSL	3	7/10	8/10	
40	Jothi	30	24805	Booked	IV	Primi	40 wks	1/13	6/13	MIFEPRISTONE	5	28 hrs	32 hrs	LABOUR NATURAL				2.9	7/10	8/10	
41	Jeya	31	24818	Booked	IV	Multi	40 wks	1/13	9/13	MIFEPRISTONE			19 hrs	LABOUR NATURAL				2.5	7/10	8/10	
42	Sangeetha	26	24920	Booked	IV	Primi	40 wks	0/13	6/13	MIFEPRISTONE			24 hrs	LABOUR NATURAL				2.7	7/10	8/10	
43	Rani	24	24940	Booked	IV	Primi	40 wks	2/13	7/13	MIFEPRISTONE + Gel			24 hrs	LABOUR NATURAL				3.1	7/10	8/10	
44	Devi	24	25002	Booked	IV	Multi	40 wks	0/13	4/13	MIFEPRISTONE		24	30 hrs	LABOUR NATURAL				3.2	7/10	8/10	

MASTER CHART - GROUP B

Sl. No.	Name	Age	IP.No	Booked /Unbooked	SES	Primi/Multi	Gestational Age	Bishop's score		Method of Induction	Amount of Oxytocin (Units)	Duration		Mode of Delivery	Indication for LSCS	Complication		B. wt (Kg)	Apgar		NICU Admission
								At start	After 24 hours			Induction to Active Phase	Induction to Delivery			Maternal	Fetal		I"	5"	
1	Gomathi	29	15702	Booked	IV	Primi	40 wks	0/13	3/13	Gel (1)	NO	27 hrs	33 hrs	LABOUR NATURAL	FD	-	MSL	3.1	7/10	8/10	
2	Latha	20	15821	Booked	V	Primi	40 wks	1/13	2/13	Gel (1)	5	25 hrs	32 hrs	VACCUM Delivery			RD	3.4	4/10	5/10	YES
3	Indhumathi	20	15887	Unbooked	V	Primi	40 wks	1/13	3/13					LSCS	Non Re Assuring CTG		MEC	3.4	2/10	4/10	YES
4	Selvi	25	15902	Booked	IV	Primi	40 wks	0/13	2/13	Gel (1)	5	29 hrs	35 hrs	LABOUR NATURAL				2.8	6/10	7/10	
5	Priya	22	15928	Booked	V	Multi	40 wks	1/13	3/13			27 hrs	37 hrs	LABOUR NATURAL				3	5/10	7/10	
6	Kalpana	27	15972	Booked	IV	Primi	40 wks	2/13	4/13	Gel (1)	5	27 hrs	34 hrs	LABOUR NATURAL				3.1	6/10	7/10	
7	Rathika	21	16071	Booked	V	Primi	40 wks	0/13	2/13	Foley + Gel	5	38 hrs		LSCS			MSAF	3.5	4/10	6/10	YES
8	Aarthi	18	16174	Booked	IV	Multi	40 wks	2/13	4/13	Gel (1)		32 hrs	38 hrs	LABOUR NATURAL				2.9	7/10	8/10	
9	Amudha	30	16189	Unbooked	V	Primi	40 wks	0/13	2/13	Gel (1)				LSCS	FD		RD	2.6	5/10	7/10	
10	Sangeetha	19	17174	Booked	IV	Multi	40 wks	1/13	2/13	Gel (1)		28 hrs	34 hrs	OUTLET		PPH		3.2	4/10	7/10	YES
11	Vasanthi	19	17243	Booked	IV	Primi	40 wks	0/13	2/13	Foley + Gel		32 hrs	36 htrs	LABOUR NATURAL			MEC	3	5/10	7/10	
12	Lilly	27	17286	Booked	IV	Primi	40 wks	1/13	2/13					LSCS	FD (MSL)			3.1	5/10	7/10	YES
13	Kanmani	26	17345	Booked	IV	Primi	40 wks	1/13	2/13	Gel (1)	5	30 hrs	34 hrs	LABOUR NATURAL				3.1	6/10	7/10	
14	Lavanya	29	18306	Booked	IV	Primi	40 wks	1/13	2/13	Foley + Gel				LSCS	FD		MSAF	3.3	4/10	6/10	YES
15	Aruna	20	18415	Booked	IV	Primi	40 wks	0/13	2/13	Foley + Gel				LSCS	Non Re Assuring CTG			2.7	6/10	7/10	
16	Uma	24	19156	Booked	IV	Multi	40 wks	2/13	4/13			28 hrs	30 hrs	LABOUR NATURAL				2.8	7/10	8/10	
17	Divya	20	21704	Booked	IV	Primi	40 wks	1/13	2/13	Gel (1)		28 hrs	34 hrs	OUTLET		PPH		3.3	5/10	7/10	

MASTER CHART - GROUP B

Sl. No.	Name	Age	IP.No	Booked /Unbooked	SES	Primi/Multi	Gestational Age	Bishop's score		Method of Induction	Amount of Oxytocin (Units)	Duration		Mode of Delivery	Indication for LSCS	Complication		B.wt (Kg)	Apgar		NICU Admission
								At start	After 24 hours			Induction to Active Phase	Induction to Delivery			Maternal	Fetal		I"	5"	
18	Rani	19	21906	Booked	IV	Primi	40 wks	0/13	2/13	Foley + Gel	5	32 hrs	36 hrs	LABOUR NATURAL			MSL	3.5	4/10	7/10	yes
19	Nagamma	21	22075	Booked	IV	Multi	40 wks	2/13	2/13	Gel (1)	5			LSCS	FD			3.2	6/10	7/10	
20	Kavitha	24	22156	Booked	V	Primi	40 wks	0/13	1/13	Foley + Gel				LSCS	MSL			2.7	6/10	7/10	
21	Solai	25	22167	Booked	IV	Primi	40 wks	2/13	2/13	Foley + Gel	5	31 hrs	36 hrs	LABOUR NATURAL				2.4	6/10	7/10	
22	Pushpa	24	22256	Booked	IV	Primi	40 wks	3/13	6/13		5	28 hrs	32 hrs	LABOUR NATURAL				2.7	7/10	8/10	
23	Priyadharsini	28	22451	Booked	IV	Primi	40 wks	1/13	3/13	Gel (1)	5	30 hrs	34 hrs	LABOUR NATURAL				2.6	6/10	7/10	
24	Gowri	27	22469	Booked	IV	Multi	40 wks	2/13	2/13	Gel (1)				LSCS	FD			3.1	5/10	7/10	
25	Kamali	30	22541	Booked	IV	Primi	40 wks	0/13	2/13	Gel (1)				LSCS	FD			2.8	4/10	7/10	YES
26	Usha	29	22596	Booked	IV	Multi	40 wks	2/13	4/13	Gel (1)		30 hrs	36 hrs	LABOUR NATURAL				2.7	7/10	8/10	
27	Kalaivani	26	22655	Booked	IV	Primi	40 wks	1/13	3/13	Gel (1)	5	32 hrs	37 hrs	LABOUR NATURAL				2.8	6/10	7/10	
28	Saranya	25	22669	Booked	IV	Primi	40 wks	1/13	2/13	Foley + Gel	5			LSCS	Failed Induction		RD	3	5/10	7/10	YES
29	Vanitha	22	22756	Booked	IV	Primi	40 wks	1/13	3/13	Foley + Gel	5	30 hrs	36 hrs	LABOUR NATURAL				2.9	6/10	7/10	
30	Revathy	20	22791	Booked	IV	Primi	40 wks	0/13	2/13	Foley + Gel	5			LSCS	Failed Induction			3.2	6/10	7/10	
31	Tamil	24	22856	Booked	IV	Primi	40 wks	2/13	4/13	Gel (1)		28 hrs	34 hrs	LABOUR NATURAL				3	7/10	8/10	
32	Parameshwari	28	22951	Booked	IV	Multi	40 wks	1/13	3/13		5	24 hrs	28 hrs	LABOUR NATURAL				2.75	7/10	8/10	
33	Mangai	27	23017	Booked	IV	Primi	40 wks	0/13	2/13					LSCS	FD		MSL	2.8	6/10	7/10	
34	Poornima	22	23153	Booked	IV	Primi	40 wks	1/13	3/13	Gel (1)	5	34 hrs	40 hrs	LABOUR NATURAL				2.7	7/10	8/10	

MASTER CHART - GROUP B

Sl. No.	Name	Age	IP.No	Booked /Unbooked	SES	Primi/Multi	Gestational Age	Bishop's score		Method of Induction	Amount of Oxytocin (Units)	Duration		Mode of Delivery	Indication for LSCS	Complication		B.wt (Kg)	Apgar		NICU Admission
								At start	After 24 hours			Induction to Active Phase	Induction to Delivery			Maternal	Fetal		I"	5"	
35	Meena	24	23195	Booked	IV	Primi	40 wks	2/13	2/13	Gel (2)	5			LSCS	Failed Induction			3.1	5/10	6/10	YES
36	Vishnupriya	28	23254	Booked	IV	Multi	40 wks	1/13	3/13	Gel (1)		30 hrs	36 hrs	LABOUR NATURAL				2.7	7/10	8/10	
37	Kalai	20	23297	Booked	IV	Primi	40 wks	1/13	2/13	Foley + Gel	5	36 hrs	42 hrs	LABOUR NATURAL		PPH	MSL	3.2	6/10	7/10	
38	Lakshmi	21	23316	Booked	IV	Primi	40 wks	1/13	2/13	Foley + Gel	5	30	34hrs	LABOUR NATURAL				3.1	6/10	7/10	YES
39	Seetha	24	23378	Booked	IV	Primi	40 wks	0/13	2/13	Foley + Gel		32 hrs	36 htrs	LABOUR NATURAL			MEC	3.1	5/10	7/10	
40	Mallika	25	23419	Booked	IV	Primi	40 wks	2/13	4/13	Gel (1)		28 hrs	34 hrs	LABOUR NATURAL				3.2	7/10	8/10	
41	Vijayalakshmi	22	23476	Booked	IV	Primi	40 wks	2/13	4/13		5	26 hrs	30 hrs	LABOUR NATURAL				2.9	6/10	8/10	
42	Ramya	23	23490	Booked	IV	Primi	40 wks	3/13	6/13		5	28 hrs	32 hrs	LABOUR NATURAL				2.7	7/10	8/10	
43	Kalaiselvi	21	23514	Booked	IV	Primi	40 wks	1/13	3/13	Foley + Gel	5	30 hrs	36 hrs	LABOUR NATURAL				3.1	6/10	7/10	
44	Ilayarasi	25	23568	Booked	IV	Primi	40 wks	2/13	4/13	Gel (1)		28 hrs	34 hrs	LABOUR NATURAL				3.2	7/10	8/10	

KEY WORDS:

FD – FETAL DISTRESS

RD – RESPIRATORY DISTRESS

PPH –POST PARTUM HEMORRHAGE

MSL – MECONIUM STAINED LIQUOR

MEC - MECONIUM

PRIMI- PRIMI GRAVIDA

FHA - FETAL HEART RATE

MSAF - MECONIUM STAINED AMNIOTIC FLUID

MULTI - MULTI GRAVIDA