A RANDOMISED CONTROLLED TRIAL COMPARING INTRAVAGINAL MISOPROSTOL ALONE VERSUS COMBINATION OF CERVICAL FOLEYS CATHETER AND INTRAVAGINAL MISOPROSTOL FOR INDUCTION OF LABOUR

By

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DISSERTATION SUBMITTED TO SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, KOLAR, KARNATAKA IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE

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Under the Guidance of

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Dr TEJASHREE N R

LIST OF ABBREVIATIONS USED

ACOG	: The American College of Obstetricians and Gynecologists
APGAR	: Activity, pulse, Grimace, Appearance, Respiration
DTA	: Deep Transverse Arrest
FDA	: U.S. Food & Drug Administration
FHR	: Fetal Heart Rate
IAI	: Induction to active phase interval
IDI	: Induction to delivery interval
IL	: Interleukin
MCP	: Monocyte Chemotactic protein.
MPA	: Misoprostol acid
NICU	: Neonatal Intensive Care Unit
NST	: Non stress test
PGE2	: Prostaglandin E2
RCOG	: The Royal College of Obstetricians and Gynaecologists
RCT	: Randomized controlled trial
WHO	: World Health Organization

ABSTRACT

A RANDOMISED CONTROLLED TRIAL COMPARING INTRAVAGINAL MISOPROSTOL ALONE VERSUS COMBINATION OF CERVICAL FOLEYS CATHETER AND INTRAVAGINAL MISOPROSTOL FOR INDUCTION OF LABOUR

INTRODUCTION

Induction of labour is commonly performed in the obstetric department. now a days which indicates the need of effective methods for the induction of labour. Around 20% of deliveries are initiated using induction methods.When the risk of continuing the pregnancy is more than benefits of delivery an induction for labour is preferred.

Common indication for induction of labour include maternal medical conditions like hypertension or diabetes mellitus, premature rupture of membranes, chorioamnionitis, placental abruption or foetal conditions like foetal growth restriction or oligohydramnios and post term pregnancy.

Cervical ripening has a major in successful induction of labour and vaginal delivery. It is the first component of induction of labour where in cervix is softened in preparation of labour. Mechanical methods like Foley's catheter or pharmacologic methods are used for the cervical ripening. Cervical ripening takes place with a series of biochemical processes which cause many changes in cervix like collagen fibril rearrangement and realignment, glycosaminoglycan composition changes, increased production of cytokine and infiltration of white blood cells.

Balloon catheters and hygroscopic dilators are mechanical methods of cervical ripening. Balloon catheters like Foley's catheter cause cervical ripening by stimulating endogenous

release of prostaglandins through physical and mechanical stretching of cervix. Foley's catheter induces changes in biochemical mediators resulting in cervical ripening.

OBJECTIVES OF THE STUDY

1. To determine the safety and efficacy of 25 microgram intravaginal misoprostol for induction of labor in primigravida with term pregnancy.
2. To determine the safety and efficacy of combined intracervical foleys- intravaginal misoprostol for induction of labor in primigravida with term pregnancy.
3. To compare the maternal and fetal outcomes between the groups.

STUDY DESIGN: It is a randomised controlled trail conducted on Primigravida at term gestation who are admitted in labour ward for induction of labour at RL Jalappa Hospital, Kolar during the study period.

MATERIALS AND METHODS:200 pregnant women included in the study. They were alternatively divided into 2 groups(combined group and misoprostol group).In combined group , 16F foleys catheter inserted aseptically into cervix with concurrent intravaginal administration of 25 microgram misoprostol 6^{th} hourly for a maximum of 4 doses. In misoprostol group 25 micrograms misoprostol inserted into the posterior fornix of vagina every 6 hours until the cervix was favourable(Bishop score >/- 6). Progress of labour is monitored by a partogram and in all cases fetal heart was monitored by continuos CTG.Outcome measures such as rate of vaginal delivery , induction to active stage interval , induction to delivery interval, NICU admissions , maternal complications were recorded.

RESULTS: Two hundred women were included in the final analysis. The combined group and misoprostol group showed a mean age of 24.85 ± 4.93 and 24.55 ± 4.35 years. Pre-induction modified bishop score 2, 3, 4 and 5 were identified in the combined group with 34%, 31%, 29% and 6% whereas, in misoprostol group with 33%, 46%, 12% and 9% respectively. In the combined group, APGAR at 1 minutes were >=7 and <7 in 83% and 17% of participants whereas, in misoprostol group identified with 71% and 29%. Similarly, APGAR at 5 minutes in combined group were >=9 in in 84% and <9 in 16% of participants whereas, in misoprostol group identified with 72% and 28%.

CONCLUSION:

The combined use of foleys catheter plus misoprostol is associated with shorter duration of cervical ripening , shorter induction to delivery interval . The combined use of foleys catheter and misoprostol also appears to cause less hyperstimulation and tachysystole compared with misoprostol alone. Perinatal outcome was similar between between the two groups.

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INTRODUCTION

Artificial termination of pregnancy after completion of viable gestational age before onset of labour naturally is called induction of labour.[1] Induction methods are used in 20% of deliveries . When the risk of continuing the pregnancy is more than benefits of delivery an induction for labour is preferred. Common indication for induction of labour include maternal medical conditions like hypertension or diabetes mellitus, premature rupture of membranes, chorioamnionitis, placental abruption or foetal conditions like foetal growth restriction or oligohydramnios and post term pregnancy.[3]

Cervical ripening has a major role in successful induction of labour and vaginal delivery.[4] It is the first component of induction of labour where in cervix is softened in preparation of labour. Mechanical methods like Foley's catheter or pharmacologic methods are used for the cervical ripening.[3] Cervical ripening takes place with a series of biochemical processes which cause many changes in cervix like collagen fibril rearrangement and realignment, glycosaminoglycan composition changes, increased production of cytokine and infiltration of white blood cells. All these changes together result in thinning and softening of cervix. Cervical ripening is determined as favourable or unfavourable depending on the extent of modifications occurring and is given by Bishop's score. Favourable cervical ripening is important to be achieved to enhance the efficacy of exogenous oxytocin used to stimulate uterine contractions.[3] Cervical ripening method is usually selected depending on patient's medical and obstetric history, clinical findings and risk of adverse effects like tachysystole. Sometimes even combination methods are used for cervical ripening.[3]

Cervical ripening are identified with advantages in terms of cost and reduced adverse effects particularly tachysystole but also have some disadvantages like failed placement and discomfort to patient. The alternative methods used for cervical ripening in place of mechanical methods include pharmacologic methods where prostaglandin preparations are administered.[3]

Prostaglandins are mediators of cervical ripening and are naturally produced by cervix when there is natural onset of labour. For induction of labour these can be administered exogenously. Prostaglandins cause collagenase activation, remodelling of extracellular matrix and initiation of uterine contractions. Exogenous administration of prostaglandins results in variable outcomes and can lead to adverse effects and this depends on type of prostaglandin preparation used. Prostaglandins used for exogenous administration are available in two forms misoprostol (PGE1) and dinoprostone (PGE2). Misoprostol can be given through different routes of administration including oral, sublingual or vaginal.[5] Misoprostol is synthetic analog of PGE 1 approved by FDA mainly for prevention and treatment of gastrointestinal ulcers and peptic ulcer disease. But it is also widely used for cervical ripening in induction of labour.[3] Misoprostol is the most widely used pharmacologic agent for cervical ripening because of various advantages associated with its usage which include easy storage due to its thermostability, cheaper in terms of cost and it is the only synthetic prostaglandin widely available in market. The disadvantage associated with misoprostol is the hyper stimulation of uterus. It can avoided with the use of low doses in every 4-6 hours.[6]

Balloon catheters and hygroscopic dilators are mechanical methods of cervical ripening. Balloon catheters like Foley's catheter cause cervical ripening by stimulating endogenous release of prostaglandins through physical and mechanical stretching of cervix. Foley's catheter induces changes in biochemical mediators resulting in cervical ripening. It increases levels of interleukins (IL-6, IL-8), matrix metalloproteinase (MMP)-8, nitric oxide synthetase (NOS) and hyaluronic acid synthetase (HAS-1).[7]

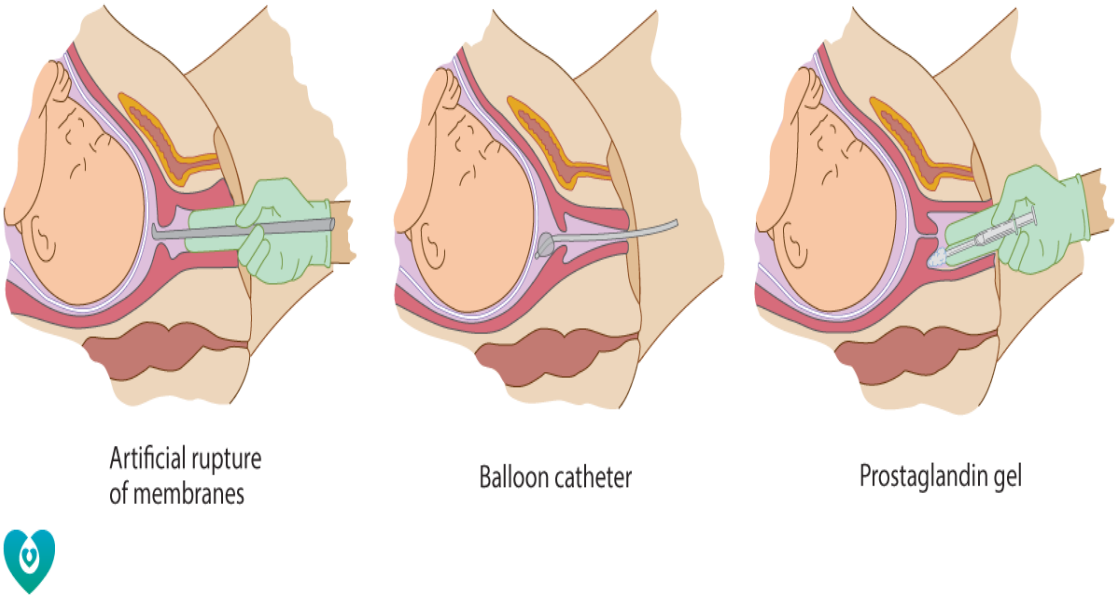
Safe and timely vaginal delivery is the main goal of induction of labour and it is believed that combination method of used of mechanical device and administration of chemical agent is more advantageous than using either of the methods in isolation. This study aims to compare efficacy of use of intravaginal misoprostol alone and combination of use of cervical Foley's catheter along with intravaginal misoprostol for induction of labour.

INDUCTION OF LABOUR

a) Definition

Induction of labour can be defined as the initiation of contractions in a pregnant woman who is not in labour before spontaneous onset. It also helps to achieve a vaginal birth within 24 to 48 hours.[8] It can be done with or without ruptured membranes.

Figure: Induction of labour



b) Epidemiology- global, India– Induction rates

The induction of labour incidence varies from 5% to 22% and it varies from setting to setting.[9-11] Around 23% of all deliveries are conducted by induction of labor in United States of America and the United kingdom. Latin America was reported with 11.4% of deliveries.[12-14] In US, the prevalence of labour induction was 23.2% in the year

2011.[15] Elective induction rate identified in Sri Lanka, Thailand, Japan, India and China are 77.2%, 44.6%, 41.0%, 32.1% and 20.4% respectively.[16-17]

c) Cervical ripening and induction of labour

Cervical ripening is the utilization of pharmacological or other means in order to soften, efface or dilate the cervix that can increase the likelihood of a vaginal delivery. Whereas, induction of labour can be defined as the initiation of contractions in a pregnant woman who is not in labour. It also helps to achieve a vaginal birth within 24 to 48 hours.[8]

d) Indications of labour induction

Induction of labour is preferred when the risk of pregnancy continuing exceeds the risk related with induced labour. The need for the induction of labour is categorized by the doctors based on the urgency of the condition and resources availability.

Indications of induction of labours is as follow:

Absolute indications

- Preeclampsia /eclampsia
- Maternal diseases – Diabetes mellitus , Renal disease , Chronic pulmonary disease
- Antepartum hemorrhage
- Chorioamnionitis
- Intrauterine fetal demise

Other Indications of labour induction includes

- Postdates (> 40+0 weeks) or post-term (> 42+0 weeks) pregnancy

- Maternal medical disorders- SLE ,Gestational diabetes, cholestatis of pregnancy
- Intrauterine growth restriction
- Oligohydramnios
- Gestational hypertension ≥ 38 weeks
- Polyhydramnios
- PROM at or near term
- Logistical problems such as history of rapid labour, distance to hospital
- Intrauterine death in a prior pregnancy

Indications that are unacceptable for induction of labour includes

- Care provider or patient convenience
- Suspected fetal macrosomia (estimated fetal weight > 4000 gm) in a non-diabetic women.

e) Contra indications

Induction of labour using various methods can enhance the 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.

Induction of labour should be avoided in the following situations

- Placenta previa or vasa previa or cord presentation
- Abnormal fetal lie or presentation such as Transverse lie or footling breech
- Prior classical or inverted T uterine incision
- Significant prior uterine surgery such as full thickness myomectomy)

- Active genital herpes
- Pelvic structural deformities
- Invasive cervical carcinoma
- Contracted pelvis
- Previous uterine rupture

EVALUATION BEFORE INDUCTION OF LABOUR

Before inducing labour , the obstetrician should review carefully the indications for terminating the pregnancy and obtain informed consent .Assessment of gestational age and consideration of any potential risks to the mother or fetus are of para amount importance for appropriate evaluation and counselling before initiating cervical ripening or labour induction. The patient should be counselled regarding inidcations for induction , the agents and methods of labour stimulation and the possible need for repeat induction or caesarean delivery. Maternal pelvis should be assessed as to its adequacy for vaginal delivery. Fetal weight and presentation should be determined.[11,12]

Because of increased risk of caesarean delivery with failed labour induction , great efforts have been made to identify predictors of the success or failure of induction and to develop interventions that may reduce these events. The favourability of uterine cervix is one of the most significant predictors of induction success. Cervical dilatation is also inversely associated with caesarean delivery.

MATERNAL PARAMETERS:

- Confirm indication for induction
- Review contraindications to labour and / or vaginal delivery.
- Perform clinical pelvimetry to assess pelvic shape and adequacy of bony pelvis.
- Assess cervical condition

Review risks, benefits and alternatives of induction of labour with patient.

FETAL PARAMETERS:

- Confirm gestational age
- Assess need to document fetal lung maturity status.
- Estimate fetal weight.
- Determine fetal presentation and lie.
- Confirm fetal well being.

DIFFERENT METHODS OF INDUCTION OF LABOUR

NON PHARMACOLOGICAL METHODS

- Membrane stripping
- Acupuncture
- Castor oil,enema
- Sexual intercourse
- Breast stimulation

SURGICAL METHODS

- Amniotomy
- Mechanical methods(intracervical foleys catheter ,laminaria stent)

PHARMACOLOGICAL METHODS

- Prostaglandins
- Oxytocin
- Mifepristone

PHYSIOLOGY OF CERVICAL RIPENING

Cervical transformartion is a dynamic process in which it transforms from a rigid closed structure to one that softens and dilates sufficiently. It is divided as four distinct overlapping phases in cervical remodelling-softening , ripening , dilatation and postpartum repair.A decrease in tensile strength and tissue compliance as compared with non pregnant cervix is known as softening .Greater loss of cervical tissue integrity and compliance is defined as cervical ripening.A ripened cervix undergoes dilatation and effacement as labour progresses with progressive increase in contractions.Phase of remodeling and repair of cervix with restoration of tissue integrity follows this in postpartum period.[28]

Fibrous connective tissue , an extracellular matrix consisting mainly collagen (type I and type III) along with elastin and proteoglycans , a cellular portion concsisting of fibroblasts , smooth muscle , epithelium and blood vessels is the composition of cervix.[29]

The total amount and composition of proteoglycans and glycosaminoglycans within the matrix are altered during this process.Width of collagen fibrils and the space between them is increased .Loss of tissue integrity accounts due to separation of collagen fibrils.[25]

Production of glycosaminoglycans are increased during cervical ripening.Within the extracellular matrix,inflammatory cells invade stoma .Inflammatory cells are attracted by cervical chemoattractants. Inturn proteases are released which causes degradation of collagen and matrix components , thus it has been concluded that cervical ripening is a inflammatory process.[22]

Chemokines such as IL- 8 and monocyte chemotactic protein-1 are responsible for release of collagenolytic enzymes which cause degradation of cervical collagen and finally ripening of cervix.Estrogen is responsible for collagenase production in pregnant cervix and progesterone inhibits IL-8 production by cervical tissue.

TIMING OF INDUCTION OF LABOUR

Evaluation of optimal timing for induction of labour is crucial in minimizing the feto-maternal risks. The ACOG, Society for Maternal-Fetal Medicine (SMFM), March of Dimes have all discouraged induction of labour in late preterm and early term gestations without maternal or fetal indication.[32]

ACOG recommends that the gestational age of the fetus to be at least 39 weeks or that the fetal lung maturity be established prior to induction.

f) Methods of induction of labour

Mechanical and pharmacologic options are the effective cervical ripening methods used to increase the success of a vaginal delivery with an unfavourable cervix.

MECHANICAL METHODS

The release of prostaglandins can be triggered by the mechanical stimulation of the endocervical canal. Amniotomy, balloon-tipped catheters, and natural and synthetic laminaria are the popular mechanical methods used for the induction of labour. Local synthesis and prostaglandins release is caused by amniotomy or artificial rupture of the amniotic membranes. It can induce labor within 6 hours in almost 90% of term cases. Turnbull and Anderson concluded that amniotomy without any additional drug therapy can successfully induce labor in a 75% of patients within 24 hours.

Figure: Diagram of (18)foley catheter(18)

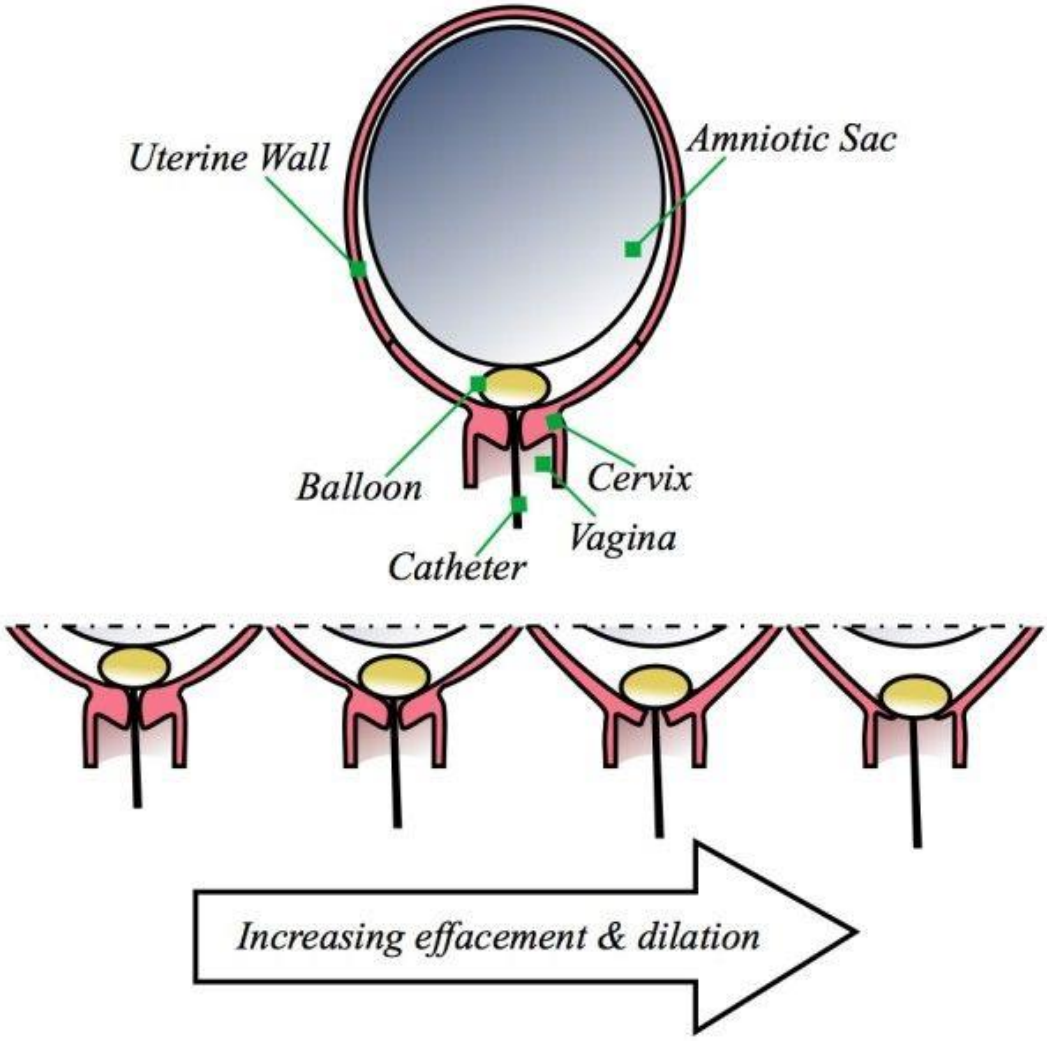
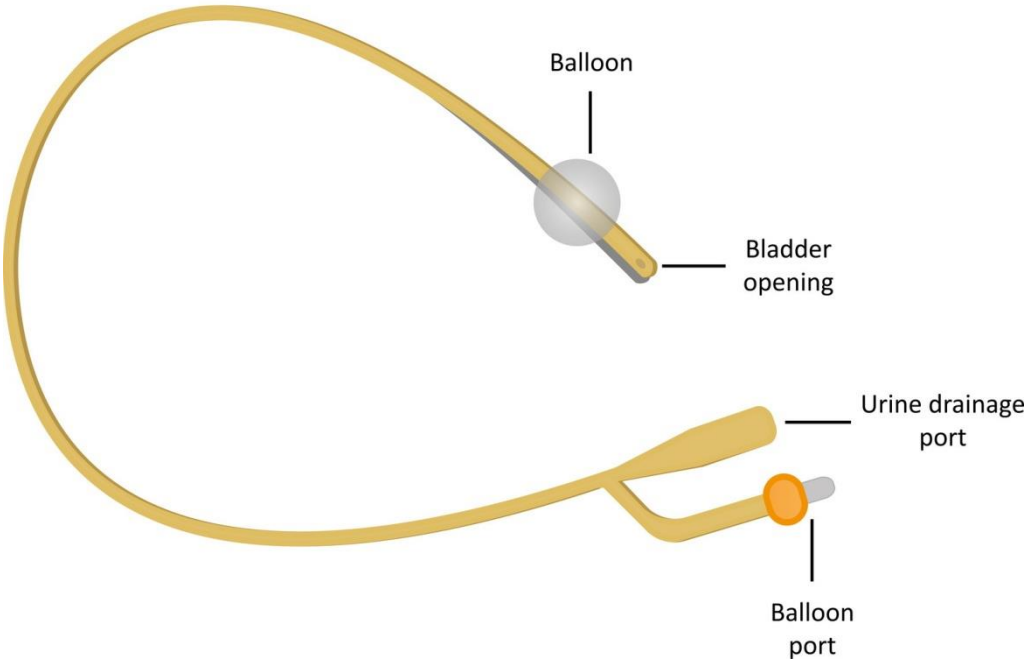


Figure: Balloon catheter

Foley Catheter



The mechanical dilation of the unripe cervix using balloon-tipped catheters can be performed with cervical ripening and labor induction . As the catheter tends to come out as cervix opens, these techniques are best when cervix is unfavourable. Foley catheters with 25–50-ml balloons is the frequently used catheter. Concomitant use of balloon-tipped catheters and pharmacologic agents are identified effective in the induction of labour,[19]

Induction with Foleys catheter led to a decrease in fetal acidosis when used in women with high risk for fetal hypoxemia in conditions such as sickle cell disease, fetal growth retriction, post term pregnancy , pregnancy induced hypertension.

Easy storage , low cost and less stringent monitoring of uterine contractions are advantages of induction with foleys catheter .

Natural and synthetic laminaria is more effective in cervical ripening as compared with labor induction. The safety and efficacy of natural and synthetic laminaria is

identified in the second trimester. The incidence of infection related with the laminaria is observed to be high in the third trimester .[20]

PHARMACOLOGICAL METHODS

PROSTAGLANDINS

The most commonly used prostaglandins is the dinoprostone (PGE_2). Intravaginal and intracervical are the two preferred routes of administration for PGE_2.[21-23] Dinoprostone gel contains 0.5 mg of dinoprostone in 2.5 ml of triacetin and colloidal silicon dioxide gel in a prefilled applicator. Peak absorption of the drug takes place within 30–45 minutes. Repeat doses can be given at an interval of 6-hours, with a maximum 24-hour dose of 1.5mg dinoprostone.

The vaginal insert of 10-mg dinoprostone consists of a thin, flat, polymeric hydrogel chip (29 × 9.5 × 0.8 mm) with rounded corners placed in a knitted polyester retrieval pouch. Each insert contains 10 mg of dinoprostone in a dried polymer matrix. When rehydrated on exposure to the vaginal mucosa dinoprostone releases at a controlled rate of 0.3 mg/hour for 12 hours. The insert can promote cervical ripening in pregnant women at or near term,. It produces a Bishop score of at least three by twelve hours. Active labor and vaginal delivery may occur within this 12-hour period. It reduces the requirement for oxytocin infusion.

Mifepristone, Relaxin, Cytokines and Nitric Oxide were considered as the other pharmacological agents used for the induction of labour.

OXYTOCIN

Oxytocin is considered as a neurohormone that originates in the hypothalamus. It is secreted by the posterior lobe of the pituitary gland. The most frequently used agent for labor induction is the oxytocin. A controlled intravenous infusion with or without amniotomy can enhance the uterine activity that leads to cervical dilation and can effect delivery. The plasma half-life of oxytocin is short because of the high activity of placental oxytocinase and the steady-state levels can be achieved after 40 minutes of continuous intravenous infusion.[24]

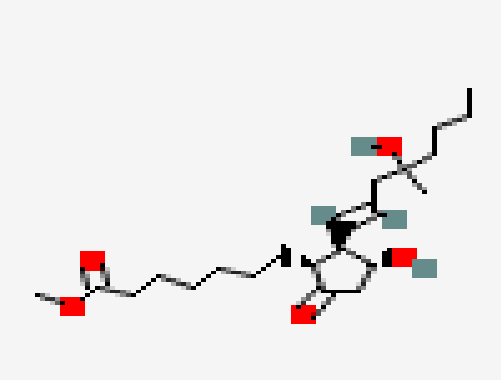
The uterus starts to respond to oxytocin at 20 weeks' gestation due to the appearance of oxytocin receptors in the myometrium. Whereas, from 34 weeks' gestation until term, there is no change in the sensitivity but once spontaneous labor begins the uterine sensitivity increases rapidly. Usually, oxytocin is initiated at a dosage of 1 mU/minute with an increases of 1 or 2 mU/minute every 20–30 minutes until a maximum administration rate of 16–32 mU/minute is reached or adequate uterine activity is present. Also, a starting dose of 0.5 mU/minute with similar dose increases at intervals of 60 minutes. Both 20 and 40 minute dosage intervals are safe and efficient when using oxytocin at starting doses of 6 mU/minute with equal increases.

INTRAVAGINAL MISOPROSTOL IN INDUCTION OF LABOUR

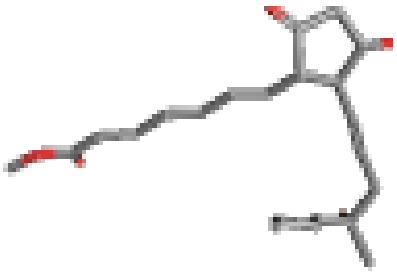
Misoprostol is also called as cytotec or glefos that belongs to the organic compounds class known as prostaglandins and related compounds. The dose of misoprostol is 50 mcg orally or 25 mcg vaginally. It may be repeated every 4 – 6 hours if contractions are absent .[24]

Structure of misoprostol

2D



3D



Oral, vaginal, sublingual, buccal or rectal are the routes of misoprostol administration. Vaginal misoprostol is associated with slower absorption and slower clearance as compared to oral misoprostol. Overall exposure to the drug, effects on the cervix and uterus are observed greater with the vaginal misoprostol.[25]

After the intravaginal administration of misoprostol the plasma concentration gradually increases and reaches its maximum level after 70-80 minutes before declining slowly with the detectable drug levels still present after 6 hours. The peak

concentration is achieved higher with oral administration as compared with the intravaginal administration. Whereas, the area under the curve is higher with the vaginal administration. [26]

Contractions of uterine smooth muscle can be caused by misoprostol. It produces softening of the cervix, promoting enhanced dilation that can facilitates both the intra-uterine procedures and expulsion of contents of the uterus.[27] Diarrhea, nausea, abdominal pain and headache. are the adverse effects reported with misoprostol Whereas, fatigue, rash, vomiting and body ache are less frequently reported adverse effects. [28]

The use of misoprostol is avoided in the third trimester in women with previous c-section. Because it can enhance the uterine rupture and other adverse effects. Women with multiple gestation or women who have had 6 or more previous pregnancies are not considered as the appropriate candidates for labor induction with prostaglandin analogs.

A -dose of 25 mcg intravaginal misoprostol is considered as safe and effective for the cervical ripening in case of term pregnancy for patients without a history of cesarean section.

EFFECTS OF MISOPROSTOL ON THE UTERUS AND THE CERVIX

Misoprostol acts an effective myometrial stimulant of the gravid uterus by selective binding to EP-2/EP-3 prostaglandin receptors.[59]

Misoprostol, has uterotonic and cervical softening effects in the female genital tract. It causes an increase in uterine tonus. It causes disintegration and dissolution of the collagen in the cervix causing cervical softening .

Misoprostol has a cervical priming effect. Less force was required for mechanical dilatation of the cervix following use of misoprostol. Along with increasing uterine contractions misoprostol also has a direct softening effect on the cervix[51]

CERVICAL SCORING SYSTEMS :

In 1964, a cervical scoring system, referred to as the Bishop's score was developed to assess the cervical status prior to induction of labour. This method is used to assess the readiness for onset of labour. This system considered the position, consistency, effacement, and the dilatation of the cervix, also the station of the presenting part of the fetus was taken into account. A modified Bishop's score that replaces effacement with cervical length has been developed. In these scoring systems, each component is assigned a score from 0 to 3, with a total maximum score of 13.[36,37]

BISHOPS SCORE

CERVICAL FEATURES	0	1	2	3
DILATATION(cm)	0	1-2	3-4	5-6
EFFACEMENT(%)	0-30	40-60	60-70	=/>80
STATION(cm)	-3	-2	-1/0	+1/ +2
CONSISTENCY	Firm	medium	soft	
POSITION	Posterior	Midposition	Anterior	

MODIFIED BISHOP SCORE

CERVICAL FEATURES	0	1	2	3
DILATATION(cm)	0	1-2	3-4	5-6
LENGTH OF THE CERVIX (cm)	3	2	1	<1
STATION(cm)	-3	-2	-1/0	+1/ +2
CONSISTENCY	Firm	medium	soft	
POSITION	Posterior	Midposition	Anterior	

A higher score reflects a "favourable" cervix for induction. Routinely, a score of ≤ 6 is classified as an "unfavourable" cervix, and that would benefit from cervical ripening agents during labour induction.[39]

Bishop's score is also used to predict the likelihood of vaginal delivery with induction of labour. A score of ≤ 6 is associated with a higher probability of failed induction, while a score of > 8 probability of a vaginal delivery is same for induced or spontaneous labour.[36]

Dilatation of the cervix at the initiation of induction is the best independent predictor of success of induction of labour.[29]

Studies have suggested that cervical dilatation is inversely proportional to cesarean delivery. In a primiparous woman, a closed cervix is associated with a 50% caesarean section rate, whereas at 4 cm dilatation the risk for caesarean section was < 10%.39

AIMS & OBJECTIVES

OBJECTIVES OF THE STUDY

1. To determine the safety and efficacy of 25 microgram intravaginal misoprostol for induction of labor in primigravida with term pregnancy.
2. To determine the safety and efficacy of combined intracervical foleys-intravaginal misoprostol for induction of labor in primigravida with term pregnancy.
3. To compare the maternal and fetal outcomes between the groups.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

HISTORY

The history of induction of labour dates back to Hippocrates descriptions of mammary stimulation and mechanical dilation of the cervical canal.

In the early 100's, Soranus of Ephese described rupture of membranes, administration of an enema containing oil, water, andhoney, and pouring egg whites into the vagina to soften and relax the cervix along with mechanical dilation of the cervix.[1]

Moshion described manual dilation of the cervix, and Casis invented several instruments for cervical dilation. From, the 2nd through the 17th centuries, mechanical methods to induce labour came into more common practice. In 1756, at a meeting held in London, physicians discussed the efficacy and ethics of early delivery by rupturing the membranes to induce labor.[2]

In 1810, James was the first in the United States to use amniotomy to induce labour. Amniotomy and other mechanical methods remained the most commonly employed methods for induction of labour until the 20th century.[3] In 1856, Scanzoni used hot carbolic acid douche for induction of labour.[4]

In the late 1800s, several balloon devices were described. In 1862, Tarnier described a balloon device for stretching of the cervix and uterus through introduction of the device into the lower uterine segment.[1]

In 1906, Sir Henry Dale observed that extracts from the infundibular lobe of the pituitary gland caused myometrial contractions.[5] Three years later, Bell reported the experience with use of a pituitary extract for labour induction.[6] With the introduction

of pituitary extract as a hormonal method of labour induction in 1913, the use of this method gained acceptance among obstetricians. However, due to the use of large doses and the impurity of the extract, numerous adverse effects were reported. Gradually, the number of reported cases of uterine rupture increased with the use of pituitary extract thus discrediting its use. Initially, oxytocin (pituitary extract) was administered via intramuscular or subcutaneous routes.

REVIEW

Comparison of vaginal misoprostol and Foley catheter for cervical ripening were performed in Adeniji *et al.* study. They concluded that the cervical length score and consistency can be improved more with vaginal misoprostol, whereas the cervical os dilatation score during the pre-induction cervical ripening can be improved more effectively with foley catheter[30]

Chen et al., performed a meta analysis study in the year 2015 in which it was concluded the mean time to delivery and tachysystole were reduced with the combined use of Foley catheter plus misoprostol[32]

Aduloju OP, et al.,conducted a study in which the women in the combined Foley's catheter and vaginal misoprostol group was identified with higher post cervical ripening Bishop's score as compared with Foley's catheter group and vaginal misoprostol alone group. Also, the combined group was observed with lesser time for cervical ripening, induction of delivery and cervical ripening-delivery interval. Similarly, the combined group was required with lesser oxytocin augmentation as compared with the other groups[34]

In a population of 123 women Carbone JF, et al.,performed a study in which the mean induction-to-delivery time and induction to complete cervical dilation time were

identified shorter with the combination group. The neonatal and maternal adverse outcomes were observed similar in both the groups[35].

Chung JH, et al. conducted a prospective, randomized controlled study in 146 women in which the vaginal delivery rates identified in women administered with intravaginal misoprostol 25 mug every 3 hours, intracervical 16F Foley catheter or combination misoprostol-Foley catheter were 63.3%, 57.4% and 58.1% respectively[36].

The labor induction and cervical ripening can be done with cervical foley catheter and vaginal misoprostol (prostaglandin E1). Kashanian M, et al. concluded in his study that the foley catheter can be considered as safe and suitable method in patients with an unfavorable cervix. It can also decrease the time of labor and enhance the chances of deliveries within 24 hours[29].

In a randomized controlled study conducted by Al-Ibraheemi Z, et al. in which the combined misoprostol- transcervical Foley group was observed with shorter time to delivery interval when compared with the misoprostol- alone group. The rate for cesarean delivery, estimated blood loss, rate of tachysystole, chorioamnionitis and neonatal outcomes were identified to be similar between the two groups[33].

Fekrat, et al.study indicated that the duration between induction of labor and delivery was lower with misoprostol group as compared with the other groups. Also, stated that the combination does not have a high efficacy on cervical ripening[31].

Vahid Roudsari, F. et al. conducted a study in 108 women in which the vaginal misoprostol with Foley catheter was compared for cervical ripening and induction of labor. This randomized clinical trial was performed on 108 pregnant women randomly divided into two groups. One batch was given misoprostol and another group was administered Foley's catheter for induction of labour. Vaginal delivery was significantly higher in misoprostol group. Misoprostol group was identified with

shorter mean of delivery time. misoprostol and Foley catheter were identified as suitable for the pregnancy termination and unripe cervix[4].

Bhatiyani, B. R., et al. compared the efficacy of vaginal misoprostol alone with vaginal misoprostol in combination with Foley catheter for labour induction. 105 women with singleton viable pregnancies of 28 weeks or more gestation with cephalic presentation, intact membranes and an unfavourable cervix (Bishops score less than 6) were randomly assigned to induction of labor using vaginal misoprostol or Foley catheter in combination with vaginal misoprostol. This study suggested that the misoprostol alone was more efficacious for ripening and inducing agent as compared to Foley in combination with misoprostol[37].

Noor, N., et al. al. compared the efficacy of intravaginal misoprostol with transcervical Foley catheter for labour induction. One hundred and four women with term gestation, with Bishop score < 4, and with various indications for labour induction were randomly divided into two groups. In Group I, 25 μg of misoprostol tablet was placed intravaginally, 4 hourly Whereas, . In Group II, Foley catheter 16F was placed in the cervix under aseptic condition. The study concluded that intravaginal misoprostol is identified with a shorter induction to delivery interval as compared to Foley's catheter. Also, increases the rate of vaginal delivery in unripe cervix cases . Transcervical Foley catheter is associated with a lower incidence of uterine hyperstimulation during labour [38].

Chung, J. H., et al. determined the efficacy of combination intravaginal misoprostol and intracervical Foley catheter for pre-labor cervical ripening. Among 146 patients, 49 patients were assigned to misoprostol, 54 patients were assigned to Foley catheter, and 43 patients were assigned to combination therapy. This indicated that

intravaginal misoprostol and intracervical Foley catheter are comparable for preinduction cervical ripening. Also, the combination methods did not provide additional efficacy[39].

Aduloju, P. et al. condicted a study in 210 women in which the efficacy of combination of Foley's catheter and vaginal misoprostol with Foley's catheter or low-dose vaginal misoprostol alone were compared for cervical ripening. The post-cervical ripening Bishop's score was higher in the combined group. Whereas, Cervical ripening time, induction-delivery time and cervical ripening-delivery interval were less in the combined group. Hereby, it suggested the combination method for the cervical ripening[22].

Ornat, L. et al. conducted a study in which the effect of misoprostol with a cervical single or double-balloon catheter versus misoprostol alone were compared for the labor induction of singleton pregnancies with an unfavourable cervix. This suggested that the combined use of misoprostol and a cervical balloon catheter reduces the intervention to delivery time interval and number of NICU admissions in women induced with an unfavourable cervix[35].

Carbone, J. F., et al. compared the utilization of the Foley bulb plus vaginal misoprostol will result in shorter induction-to-delivery time compared with vaginal misoprostol alone. 123 women with singleton pregnancies at 24 weeks of gestation or greater with an unfavourable cervix (Bishop score 6 or lower) were randomized to Foley bulb plus vaginal misoprostol (n=56) or vaginal misoprostol alone groups. Combination group was identified with less mean induction to delivery time when compared with vaginal misoprostol alone. This indicated that the combination group can show shorter induction-to-delivery time without increasing labor complications[35].

Moraes Filho, O. B.,et al. conducted a study in which 25 microg vaginal misoprostol versus Foley catheter and oxytocin were compared for cervical ripening and labor induction . Induction of labour was identified more effective with misoprostol. Also misoprostol group was identified with short mean induction to vaginal delivery time . Misoprostol group was observed with more vaginal deliveries. This indicated that the vaginal misoprostol is more effective for the induction of labour in pregnant women[42].

Owolabi, A. T., et al. compared the safety and efficacy of intravaginal misoprostol and an intracervical Foley's balloon catheter for pre-induction cervical ripening and labour induction. A total of 120 patients requiring indicated induction of labour with an unfavourable cervix (Bishop's score < or =4) were randomised prospectively to receive either 50 mug intravaginal misoprostol every 6 h or an intracervical Foley balloon catheter for 12 h followed by an intravenous oxytocin infusion. The study concluded that the maternal and perinatal outcomes confirming the efficacy and safety of both methods were similar in both the groups, however a decrease in the induction-to-delivery interval was observed when misoprostol is used for this purpose[43].

Abramovici, D. et al. conducted a study in which the efficacy of oral misoprostol administered to patients with the efficacy and safety in a control group treated with a Foley catheter and oxytocin for induction of labor. Two hundred patients requiring induction of labor at term with a Bishop score of </=5 were randomized to receive oral misoprostol or a cervical Foley catheter plus oxytocin. This indicates that the oral misoprostol is effective for inducing labor in multiparous women. Misoprostol appears less efficacious in nulliparous patients[45].

Fox, N., et al. compared misoprostol and transcervical Foley catheter placement for induction of labour. Prospective, randomised trials comparing the use of intravaginal misoprostol and transcervical Foley catheter for the purpose of cervical ripening and induction of labour were included. Metanalysis concluded that intravaginal misoprostol and transcervical Foley catheter have similar effectiveness as induction agents. Transcervical Foley catheter is related with a lower incidence of tachysystole[46].

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MATERIALS AND METHODS

MATERIALS AND METHODS

SOURCES OF DATA

The study was conducted on Primigravida at term gestation who were admitted in labour ward requiring induction of labour for any medical or obstetric indication at RL Jalappa Hospital, Kolar during the study period

STUDY DESIGN: RANDOMISED CONTROLLED TRIAL

STUDY PERIOD : October 2018 to June 2020

INCLUSION CRITERIA

- Gestational age between 37 to 42 weeks
- Primigravida
- Age between 19-35 years
- Singleton foetus
- Cephalic presentation
- Intact Membranes
- Bishop score less than 6
- Reactive Non stress test

EXCLUSION CRITERIA

- Multigravida
- Intrauterine fetal death
- Previous LSCS
- Prelabour rupture of membranes
- Malpresentations
- Placenta previa, Vasa previa, active genital herpes
- Any contraindication to vaginal deliveries ,Hysterotomy /myotomy scar

SAMPLE SIZE

200 cases (100 in combined group and 100 in misoprostol group), was estimated based on induction delivery interval between two groups as 20+/-8.4 and 22.09+/-7 hours respectively from the study by levine ld et al .considering these values at 10% alpha error and 85% power a sample size of 100 in each group was obtained from open epi software.

CONFIDENCE INTERVAL 90%

POWER 85%

	COMBINED GROUP	MISOPROSTOL GROUP
MEAN	22.09	20
SD	7	8.4

SAMPLE SIZE OF COMBINED GROUP – 100

SAMPLE SIZE OF MISOPROSTOL GROUP – 100

THE SAMPLE SIZE WAS CALCULATED BY THE FORMULA

$$\text{Sample size} = \frac{2SD^2(Z_{\alpha/2} + Z_{\beta})^2}{d^2}$$

SD – Standard deviation = From previous studies or pilot study

$Z_{\alpha/2} = Z_{0.05/2} = Z_{0.025} = 1.96$ (From Z table) at type 1 error of 5%

$Z_{\beta} = Z_{0.20} = 0.842$ (From Z table) at 80% power

d = effect size = difference between mean values

So now formula will be

$$\text{Sample size} = \frac{2SD^2(1.96 + 0.84)^2}{d^2}$$

METHOD OF COLLECTION OF DATA

A total of 200 primigravida(100 in combined group and 100 in misoprostol group) fullfilling the inclusion criteria for induction of labour were included into the study after explaining the method of study and obtaining an informed consent.

Detailed history regarding age, parity, period of gestation, menstrual history , obstetric history , past history and any complications in present pregnancy were taken

Indication for induction of labour was recorded.

General clinical examination and complete obstetric examination was perfomed. Abdominal examination was done to find out presentation, fetal heart rate and uterine contractions. Pervaginal examination was done to assess adequacy of pelvis and modified bishop score.

Obstetric scan and NST was done to find out fetal well being.

Following reactive NST and confirmation of modified bishop score </=5 , patients were alternatively divided into 2 groups (combined group and misoprostol group).

Combined group (100 patients)- The participants assigned to this group had a 16F foleys catheter inserted aseptically into cervix. Patient was placed in lithotomy position, a sterile cusco's speculum was introduced into vagina to visualise cervix. The anterior lip of cervix was held with sponge holding forceps and the foleys catheter which is held with another sponge holding forceps was advanced upto endocervical canal. The ballon of catheter was inflated with 40ml of sterile normal saline and then the catheter is tapped with traction to inner thighs until it is expelled spontaneously or removed after 12 hours with concurrently intravaginal administration of 25 microgram misoprostol 6^{th} hourly inserted for a maximum of 4 doses.

Misoprostol group(100 patients)- The participants assigned to this group recieved 25 micrograms misoprostol inserted into the posterior fornix of vagina every 6 hours until the cervix was favourable(Bishop score >/- 6) or to a maximum of 100mcg(4 doses.)

ANALYSIS OF PROGRESSION

The cervix was assessed every 6 hours to determine the bishops score .Progress of labour was monitored by a Partogram in active stage of labour .

In all cases fetal heart rate was monitored by continuous CTG and oxytocin infusion was given for augmentation of labour if needed .

Outcome measures that were observed was Rate of vaginal delivery, Induction to active phase interval. Others include induction to delivery interval ,need for oxytocin augmentation , mode of delivery ,APGAR SCORES at 1 and 5 min ,admission into NICU, indication of NICU admission ,occurrence of maternal complications which includes hyperstimulation 1.Tachysystole- 6 contractions in 10 minutes, 2.uterine hypertonus- single contraction more than 60 seconds, fetal heart rate abnormalities .

Failed induction is defined as if the modified bishop score remains unfaourable / no adequate uterine contractions were initiated even after 4 doses of misoprostol in both the groups.In such cases , further patient was considered for augmentation with oxytocin / decision for caesarean section was made.

Non progression of labour includes prolonged latent phase and protracted active phase dilatation and descent.

STATISTICAL METHODS:

Apgar 1 min, Apgar at 5 min, NICU admission, cause for NICU admission, maternal adverse effects, cause for maternal adverse effects Were considered as primary outcome variable Study group (combined and Misoprostol) was considered as Primary explanatory variable. Gestational age, age, indication for induction modified bishop score, number of doses, induction to active stage interval, induction to delivery interval, mode of delivery, indication for LSCS, oxytocin augmentation requirement, liquor tracing was considered as other study relevant variable.

For normally distributed Quantitative parameters the mean values were compared between study groups using Independent sample t-test Study group (combined and Misoprostol)

Categorical outcomes were compared between Study group (combined and Misoprostol) using Chi square test /Fisher's Exact test (If the overall sample size was < 20 or if the expected number in any one of the cells is < 5, Fisher's exact test was used.) Data also represent by like Cluster bar diagram and stacked bar diagram.

P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.

RESULTS & OBSERVATION

RESULT

A total of 200 subjects were included in the final analysis. 100(50%) participants were in combined group and remaining 100(50%) participants were in misoprostol group.

Table 1: Comparison of age group between study groups (N=200)

Age Group(years)	Study Groups		Chi square	P value
	Combined Group (N=100)	Misoprostol Group (N=100)		
19 to 20	31 (31%)	27 (27%)	5.165	0.160
21 to 25	28 (28%)	39 (39%)		
26 to 30	23 (23%)	25 (25%)		
31 and above	18 (18%)	9 (9%)		

In the combined group,31 (31%) cases were aged between 19 to 20 years, 28 (28%) cases were aged between 21 to 25 years, 23 (23%) cases were aged between 26 to 30 years and 18 (18%) cases were aged 31 years and above. In the misoprostol group,27 (27%) cases were aged between 19 to 20 years, 39 (39%) cases were aged between 21 to 25 years, 25 (25%) cases were aged between 26 to 30 years and 9 (9%) cases were aged 31 years and above. The difference in the proportion of age group between study groups was statistically not significant (p value 0.160) (Table 1&Figure 1)

Figure 1: Staked bar chart of comparison of age group between study groups (N=200)

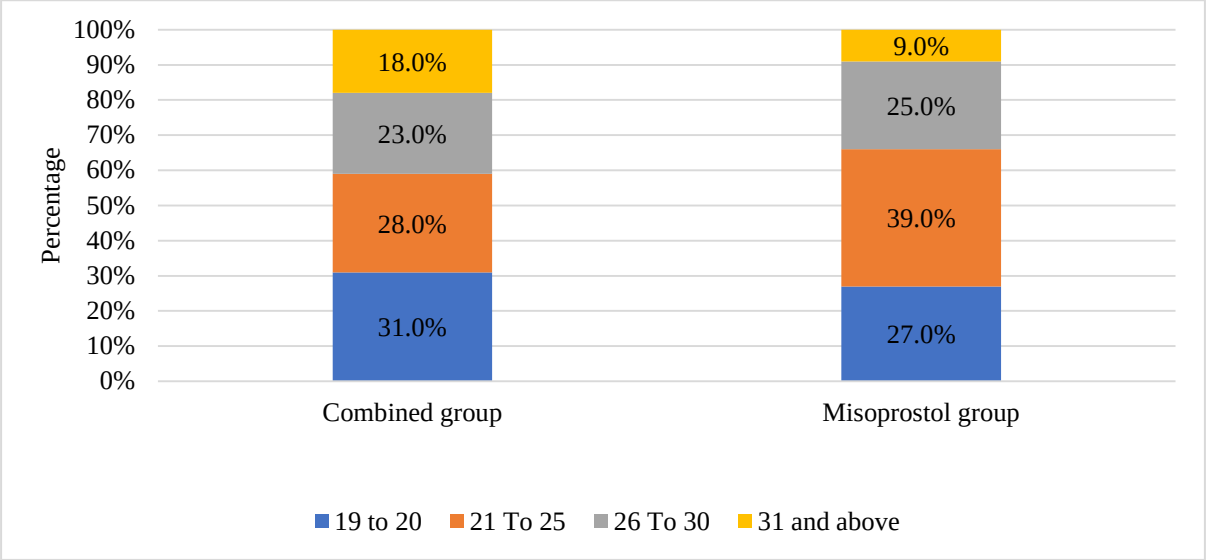


Table 2: Comparison of mean age group between study groups(N=200)

Parameter	Study group (Mean± SD)		P value
	Combined group (N=100)	Misoprostol group (N=100)	
Age	24.85 ± 4.93	24.55 ± 4.35	0.648

The mean age was 24.85 ± 4.93 years in combined group and it was 24.55 ± 4.35 years in misoprostol group, the difference of age between study group was statistically not significant (P value 0.648). (Table 2)

Table 3: Comparison of gestational age between study groups (N=200)

Gestational Age	Study Group		Chi square	P value
	Combined group (N=100)	Misoprostol group (N=100)		
37-38 Weeks+6Days	25 (25%)	18 (18%)	1.716	0.633
39- 39Weeks+6Days	19 (19%)	19 (19%)		
40- 40Weeks+6Days	39 (39%)	46 (46%)		
41-41Weeks+6Days	17 (17%)	17 (17%)		

In the combined group, 25 (25%) cases were in gestational age 37 to 38 weeks+6days, 19 (19%) cases were in 39 to 39 weeks+6days, 39 (39%) cases were in 40 to 40 weeks+6days and 17 (17%) cases were in 41 to 41 weeks+6days.In the misoprostol group, 18 (18%) cases were in gestational age 37 to 38 weeks+6days, 19 (19%) cases were in 39 to 39 weeks+6days, 46 (46%) cases were in 40 to 40 weeks+6days and 17 (17%) cases were in 41 to 41 weeks+6days.The difference in the proportion of gestational age between study groups was statistically not significant (p value 0.633) (Table 3&Figure 2)

Figure 2: Staked bar chart of comparison of gestational age between study groups (N=200)

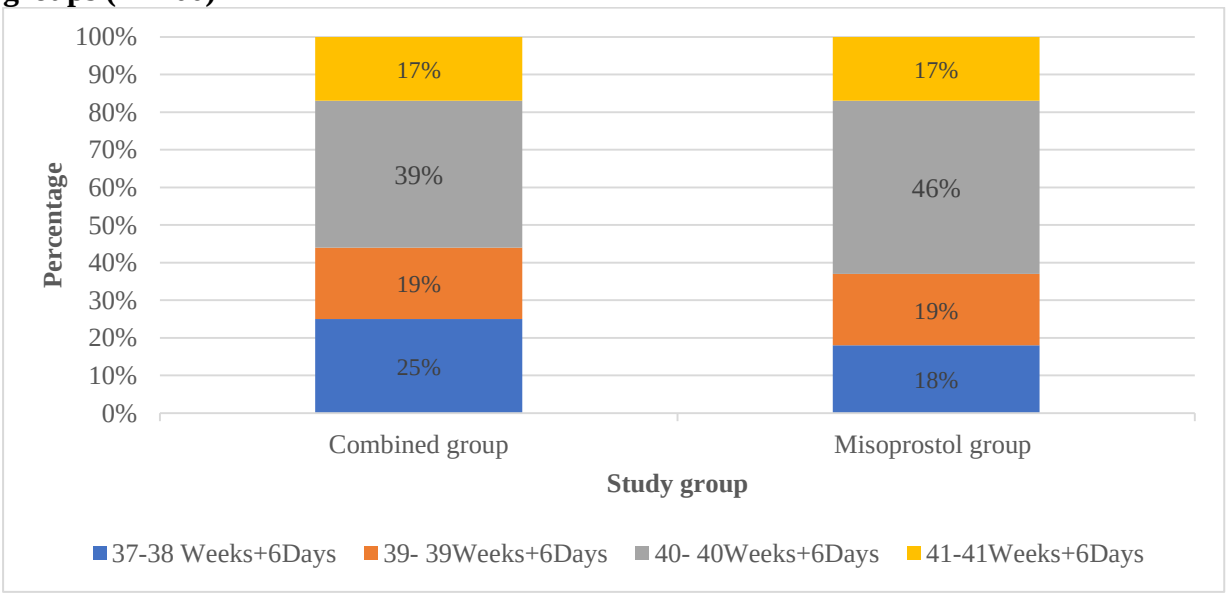


Table 4: Comparison of indication for induction of labour between study groups (N=200)

Indication for Induction	Study Group		Chi square	P value
	Combined group (N=100)	Misoprostol group (N=100)		
Prolonged Pregnancy	49 (49%)	61 (61%)	3.585	0.167
Pre-eclampsia – eclampsia	20 (20%)	12 (12%)		
Oligohydramnios	31 (31%)	27 (27%)		

In the combined group, 49 (49%) cases had prolonged pregnancy as indication and 20 (20%) cases had pre-eclampsia-eclampsia and 31(31%) cases had oligohydramnios.In the misoprostol group, 61 (61%) cases had prolonged pregnancy and 12 (12%) cases had pre-eclampsia-eclampsia and 27 (27%) cases had oligohydramnios as indication. The difference in the proportion of indication for induction between study group was statistically not significant (p value 0.167) (Table 4&Figure 3)

Figure 3: Staked bar chart of comparison of indication for induction between study groups (N=200)

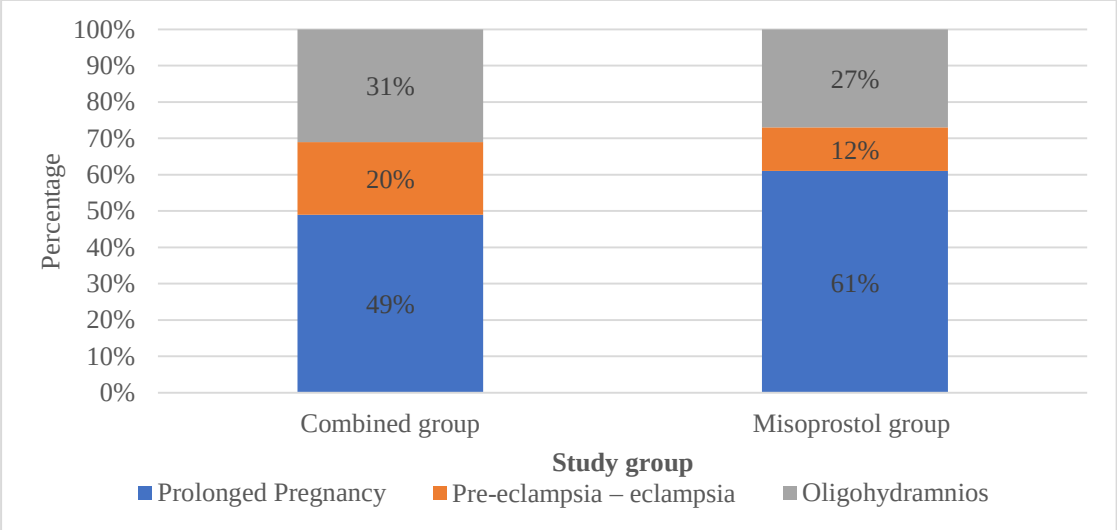


Table 5: Comparison of pre induction modified bishop score between study groups (N=200)

Pre-Induction Modified Bishop Score	Study Group		Chi square	P value
	Combined group (N=100)	Misoprostol group (N=100)		
2	34 (34%)	33 (33%)	0.967	0.809
3	40 (40%)	46 (46%)		
4	15 (15%)	12 (12%)		
5	11 (11%)	9 (9%)		

Among the cases in combined group, 34 (34%) cases had a pre-induction modified bishop score 2, 40 (40%) had a score of 3, 15 (15%) had a score of 4 and 11 (11%) had a score of 5.Among the cases in misoprostol group, 33 (33%) had a score of 2, 46 (46%) had a score of 3, 12 (12%) had a score of 4 and 9 (9%) had a score of 5. The difference in the proportion of pre-induction modified bishop score between study group was statistically not significant (p value 0.809) (Table 5&Figure 4)

Figure 4: Staked bar chart of comparison of pre induction modified bishop score between study groups (N=200)

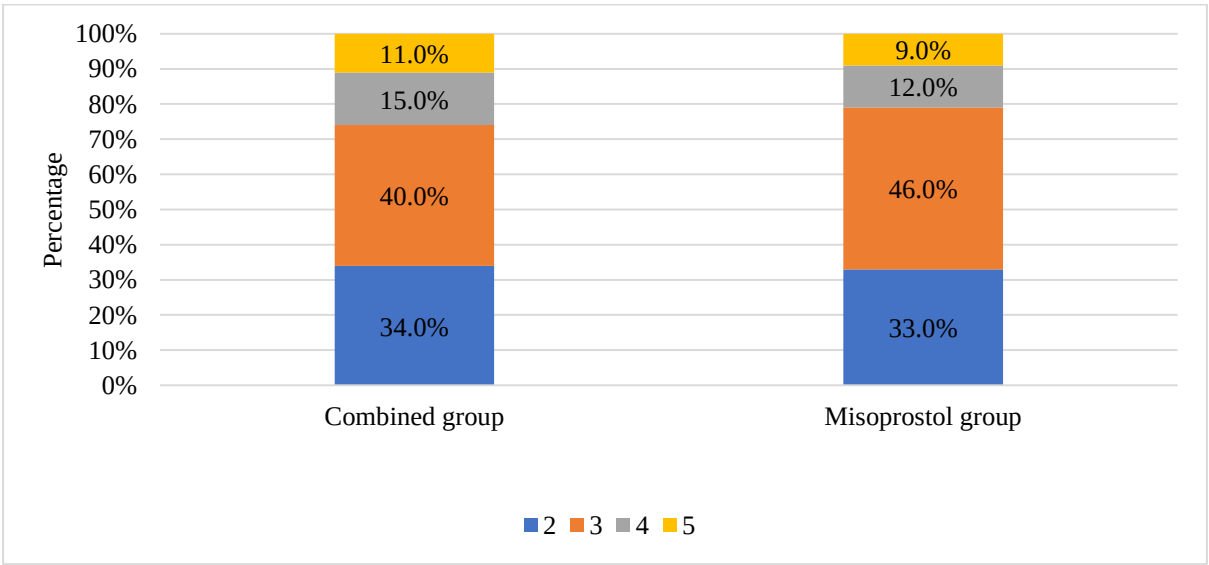


Table 6: Comparison of number of doses of doses of misoprostol used between study groups (N=200)

Number of Doses of misoprostol	Study Group		Chi square	P value
	Combined Group (N=100)	Misoprostol Group (N=100)		
1	39 (39%)	22 (22%)	21.956	<0.001
2	39 (39%)	27 (27%)		
3	18 (18%)	29 (29%)		
4	4 (4%)	22 (22%)		

In combined group, 39 (39%) cases required 1 dose ,39(39%) cases required 2 doses ,18(18%) cases required 3 doses and 4(4%) cases required 4 doses. In misoprostol group, 22 (22%) cases required 1 dose, 27 (27%) cases required 2 doses, 29 (29%) cases required 3 doses and 22 (22%) cases required 4 doses. The difference in the proportion of number of doses between study group was statistically significant (p value<0.001) (Table 6&Figure 5)

Figure 5: Staked bar chart of comparison of number of doses between study groups (N=200)

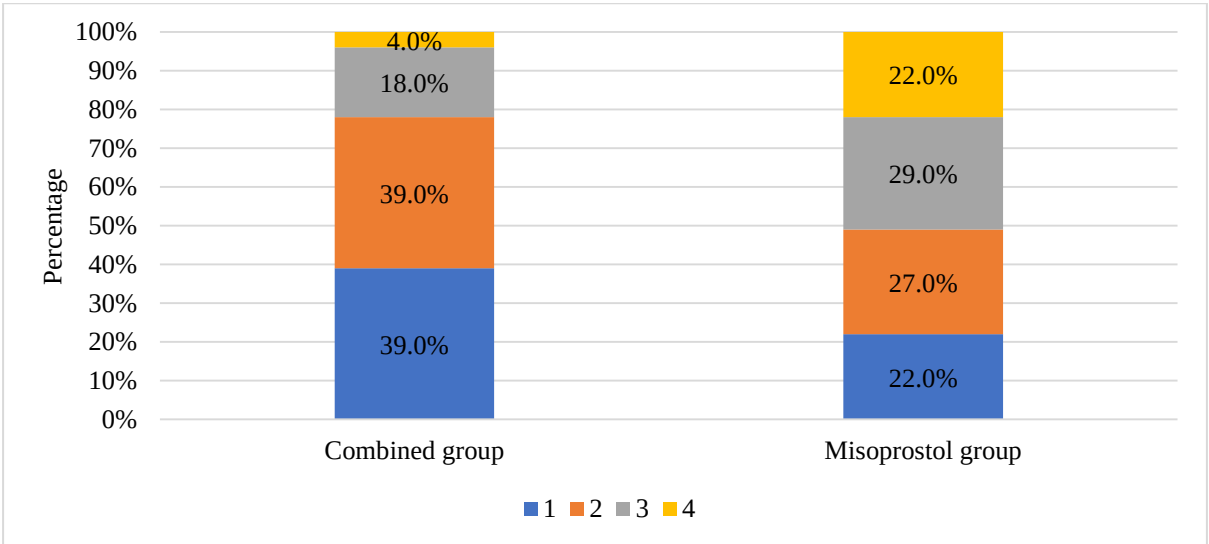


Table 7: Comparison of Induction to active stage interval between study groups (N=200)

Induction to active stage interval	Study Group		Chi square	P value
	Combined Group (N=100)	Misoprostol Group (N=100)		
1 to 6 Hrs	29 (29%)	17 (17%)	5.895	0.052
7 to12 Hrs	65 (65%)	70 (70%)		
12 and above	6 (6%)	13 (13%)		

Among the cases in combined group, duration of induction to active stage was 1 to 6 hours in 29 (29%) cases, 7 to 12 hours in 65(65%) cases, 12 and above hours in 6(6%) cases. Among the cases in misoprostol group, duration of induction to active stage was 1 to 6 hours in 17(17%) cases, 7 to 12 hours in 70 (70%) cases, 12 and above hours in 13(13%) cases. The difference in the proportion of timing of induction to favourable bishops score between study group was statistically significant (p value0.052) (Table 7&Figure 6)

Figure 6: Cluster bar chart of comparison of induction to active stage interval between study groups (N=200)

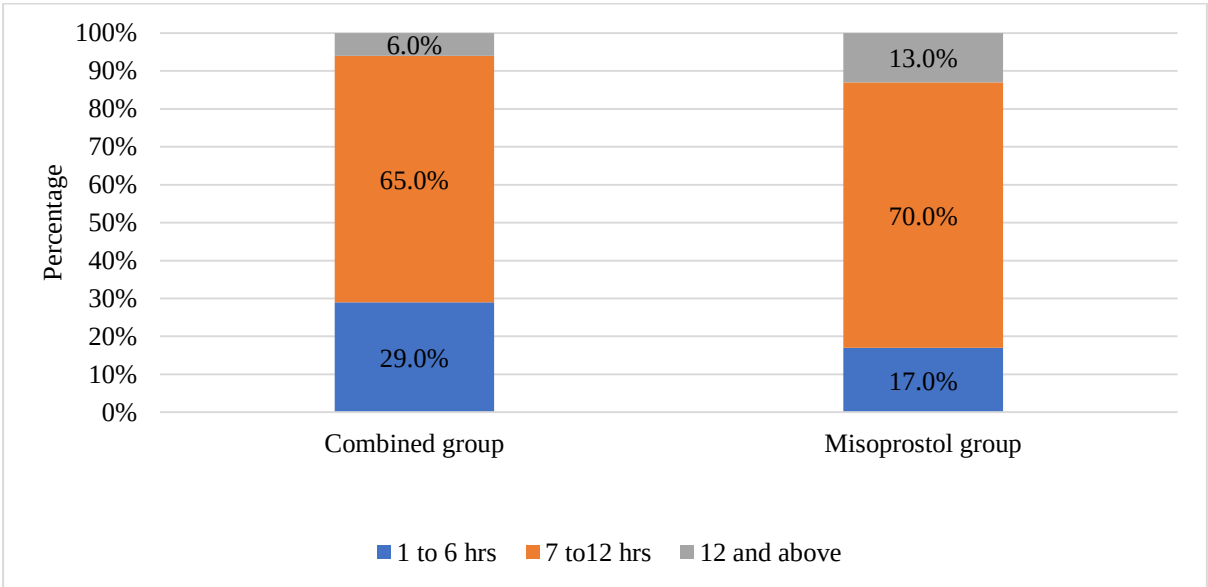


Table 8: Comparison of induction to delivery interval between study groups (N=200)

Induction to Delivery Interval	Study Group		Chi square	P value
	Combined Group (N=100)	Misoprostol Group (N=100)		
Upto 12Hrs	40 (40%)	13 (13%)	62.670	<0.001
13 to 24 Hrs	57 (57%)	35 (35%)		
25 to 36	3 (3%)	52 (52%)		

In the combined group, 40 (40%) cases had induction to delivery interval upto 12hrs, 57 (57%) cases had 13 to 24 hrs, and 3 (3%) cases had 25 to 36hrs.In the misoprostol group, 13 (13%) cases had induction to delivery interval upto 12hrs, 35 (35%) cases had 13 to 24 hrs, and 52 (52%)cases had 25 to 36hrs. The difference in the proportion of induction to active stage interval between study group was statistically significant (p value<0.001) (Table 8&Figure 7)

Figure 7: Staked bar chart of comparison of induction to delivery interval between study groups (N=200)

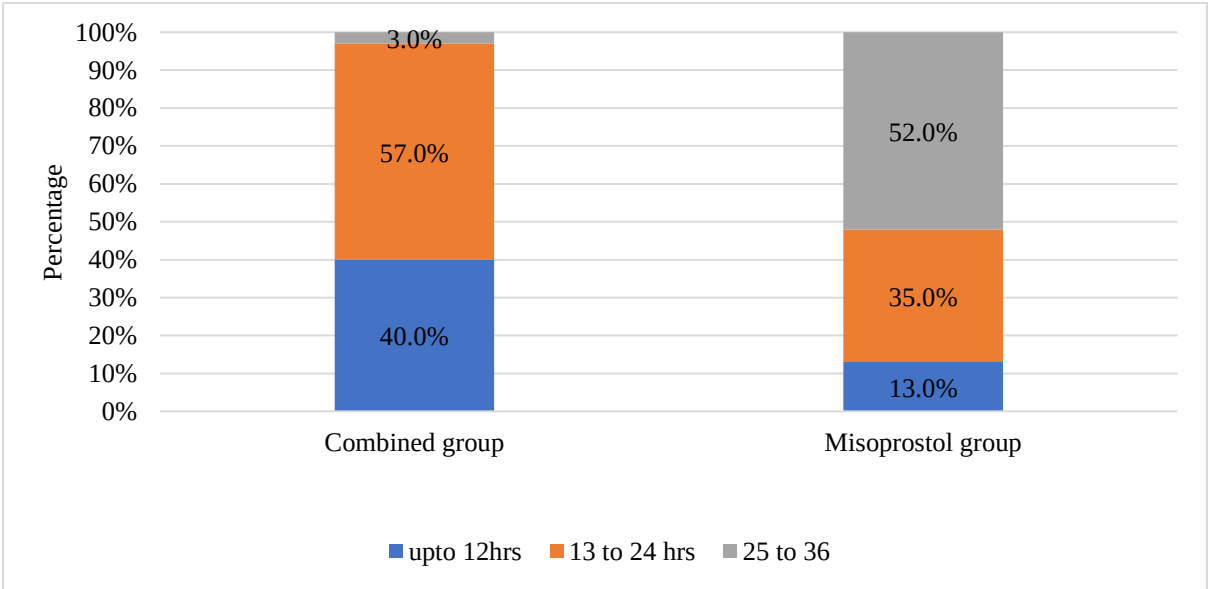


Table 9: Comparison of mode of delivery between study groups (N=200)

Mode of Delivery	Study Group		Chi square	P value
	Combined Group (N=100)100%	Misoprostol Group (N=100)100%		
Vaginal Delivery	58 (58%)	37 (37%)	10.683	0.005
Assisted Vaginal Delivery	16 (16%)	16 (16%)		
Caesarean Section	26 (26%)	47 (47%)		

In the combined group, 58 (58%) women delivered vaginally, 16 (16%) cases had assisted vaginal delivery, and 26 (26%) women underwent caesarean section. In the misoprostol group, 37 (37%) women delivered vaginally, 16 (16%) women had assisted vaginal delivery, and 47 (47%) women underwent caesarean section. The difference in the proportion of mode of delivery between study group was statistically significant (p value0.005) (Table 9&Figure 8)

Figure 8: Staked bar chart of comparison of mode of delivery between study groups (N=200)

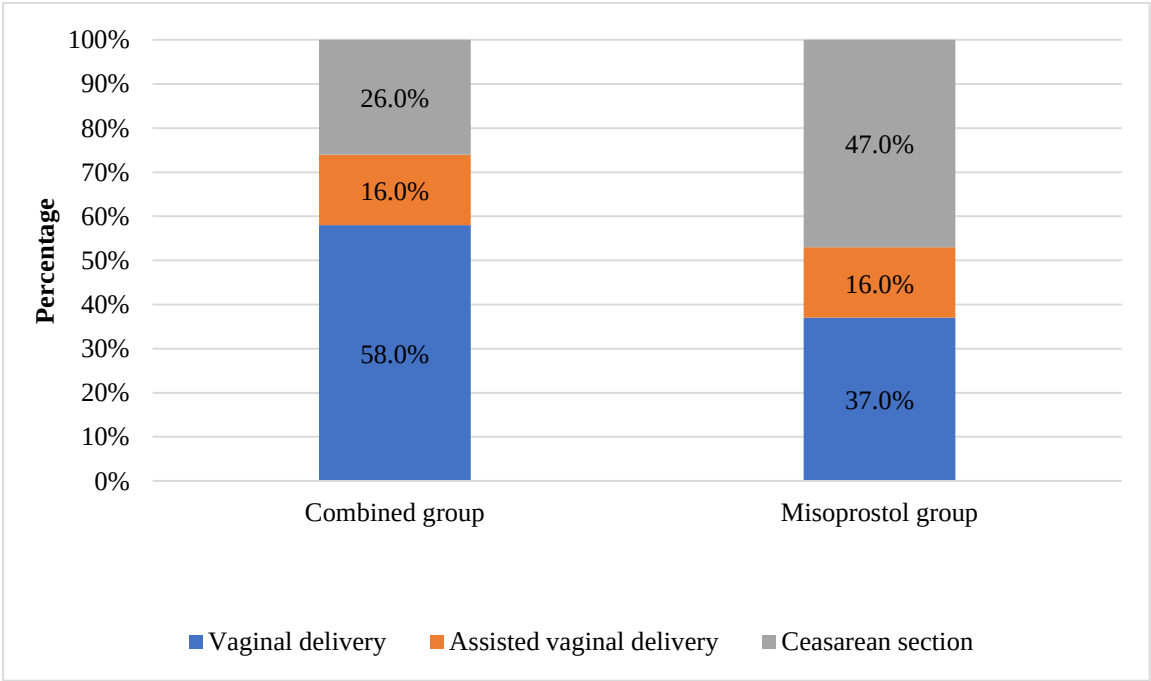


Table 10: Comparison of indication for Caesarean section between study group (N=73)

Indication for caesarean section	Study Group		Chi square	P value
	Combined Group (N=26)	Misoprostol Group (N=47)		
Fetal Distress	10 (38.46%)	24 (51.06%)	1.100	0.577
Failed Induction	6 (23.08%)	8 (17.02%)		
Non-Progression of Labour	10 (38.46%)	15 (31.91%)		

Among the cases in combined group, the indication for caesarean section was fetal distress in 10 (38.46%) cases, failed induction in 6 (23.08%) cases, non-progression of labour in 10(38%) cases. Among the cases in misoprostol group, the indication for caesarean section was fetal distress in 24 (51.06%) cases, failed induction in 8(17.02%) cases, non-progression of labour in 15 (31.91./.) The difference in the proportion of indication for Caesarean section between study group was statistically not significant (p value0.577) (Table 10 &Figure 9)

Figure 9: Staked bar chart of comparison of indication for Caesarean section between study groups (N=73)

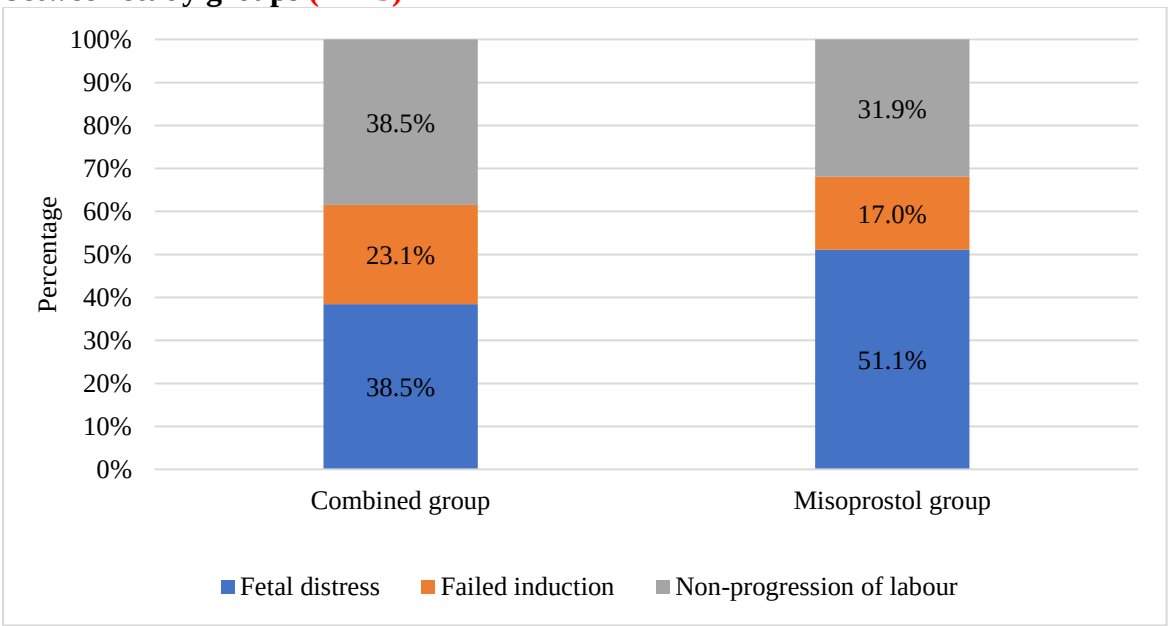


Table 11: Comparison of oxytocin augmentation requirement between study groups (N=200)

Oxytocin augmentation requirement	Study Group		Chi square	P value
	Combined group (N=100)100%	Misoprostol group (N=100)100%		
Required	35 (35%)	42 (42%)	1.035	0.309
Not Required	65 (65%)	58 (58%)		

In combined group, 35 (35%) cases required oxytocin augmentation. In the misoprostol group, 42 (42%) cases required oxytocin augmentation. The difference in the proportion of oxytocin augmentation between study groups was statistically not significant (p value0.309) (Table 11&Figure 10)

Figure 10: Staked bar chart of comparison of oxytocin augmentation requirement between study groups(N=200)

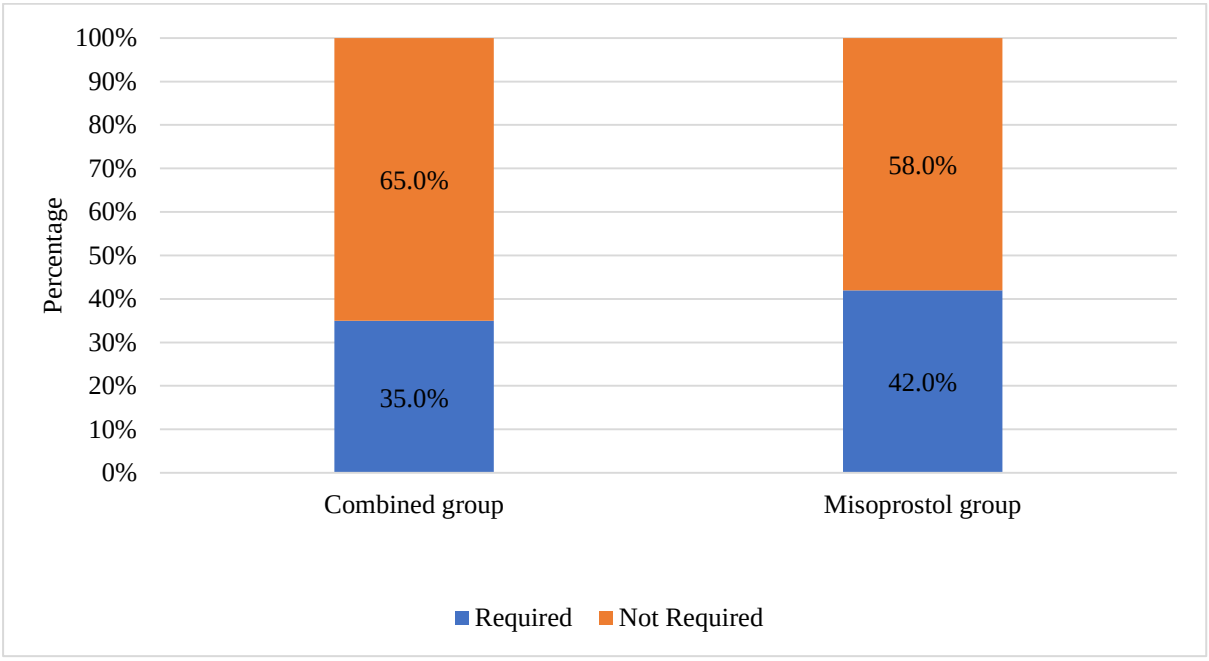


Table 12: Comparison of liquor between study group (N=200)

Liquor	Study Group		Chi square	P value
	Combined group (N=100)	Misoprostol group (N=100)		
Meconium stained liquor	37 (37%)	55 (55%)	6.522	0.078
Clear	63 (63%)	45 (45%)		

Among the cases in combined group, 63 (63%) cases had clear liquor and 37 (37%) cases had meconium stained liquor. Among the cases in misoprostol group, 45 (45%) cases had clear liquor and 55 (55%) cases had meconium-stained liquor. The difference in the proportion of liquor between study group was statistically not significant (p value0.078) (Table 12&Figure 11)

Figure 11: Staked bar chart of comparison of liquor between study groups (N=200)

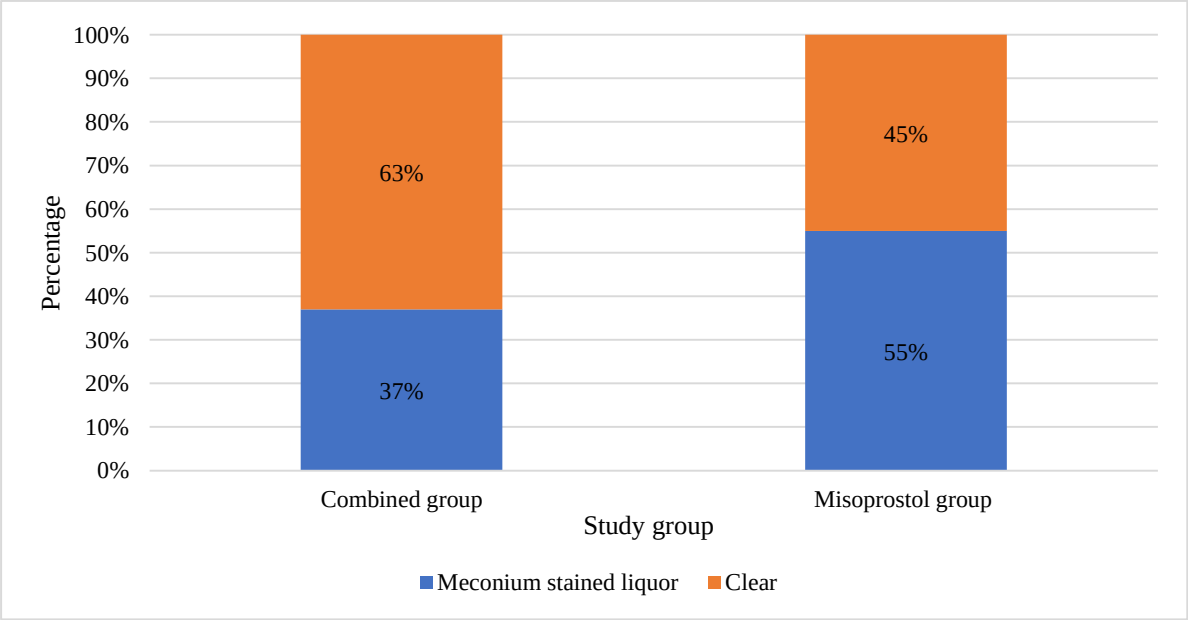


Table 13: Comparison of maternal adverse effects between study groups (N=200)

Maternal Adverse Effects	Study Group		Chi square	P value
	Combined group (N=100)	Misoprostol group (N=100)		
Yes	8 (8%)	19 (19%)	5.181	0.023
No	92 (92%)	81 (81%)		

Among the cases in combined group, 8 (8%) women had maternal adverse effect and 19 (19%) women had maternal adverse effects in misoprostol group .The difference in the proportion of maternal adverse effects between study groups was statistically significant (p value 0.023) (Table 13&Figure 12)

Figure 12: Cluster bar chart of comparison of maternal adverse effects between study groups (N=200)

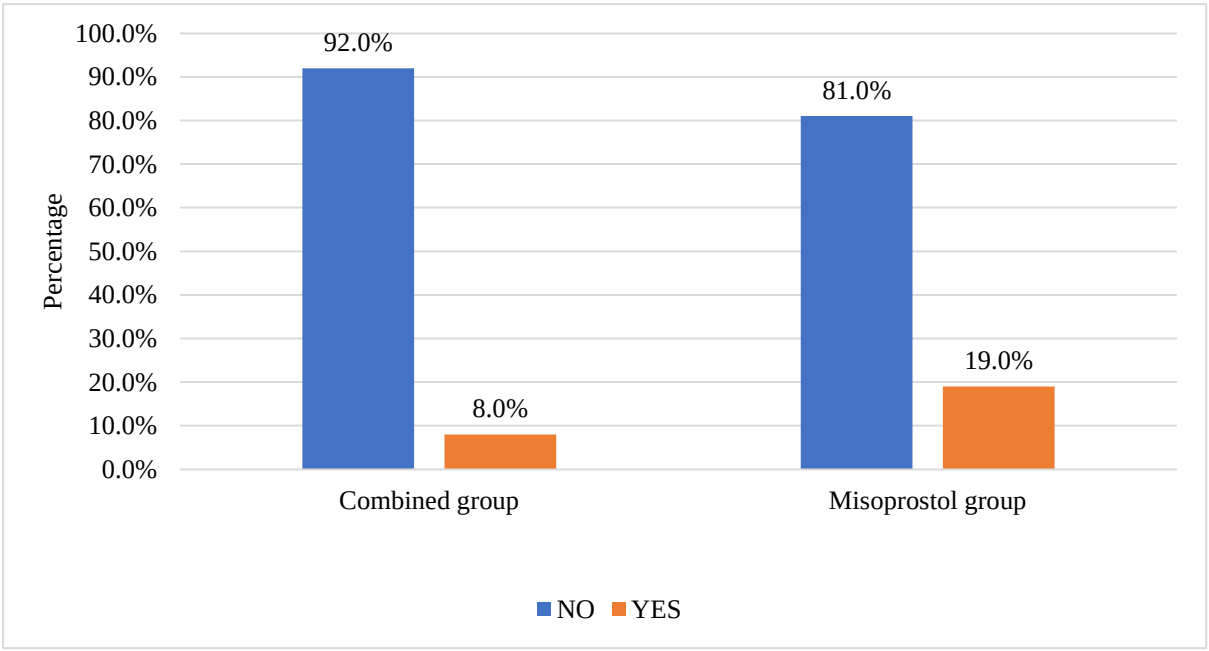


Table 14: Comparison of cause for maternal adverse effects between study groups (N=27)

Cause for Maternal Adverse Effects	Study Group	
	Combined group (N=8)	Misoprostol group (N=19)
Hyperstimulation	0 (0%)	3 (15.79%)
PPH	6 (75%)	7 (36.84%)
Precipitate Labour	1 (12.5%)	5 (26.32%)
Tachysystole	1 (12.5%)	2 (10.53%)
Fever	0 (0%)	2 (10.53%)

In the combined group, 6 (75%) women had PPH,1 (12.5%) woman had precipitate labour and 1 (12.5%) woman had tachysystole. In the misoprostol group, 3 (15.79%) women had hyperstimulation, 7 (36.84%) women had PPH, 5 (26.32%) women had precipitate labour, 2 (10.53%) women had tachysystole and 2 (10.53%) women had fever.(Table 14&Figure 13)

Figure 13: Staked bar chart of comparison of cause for maternal adverse effects between study groups (N=27)

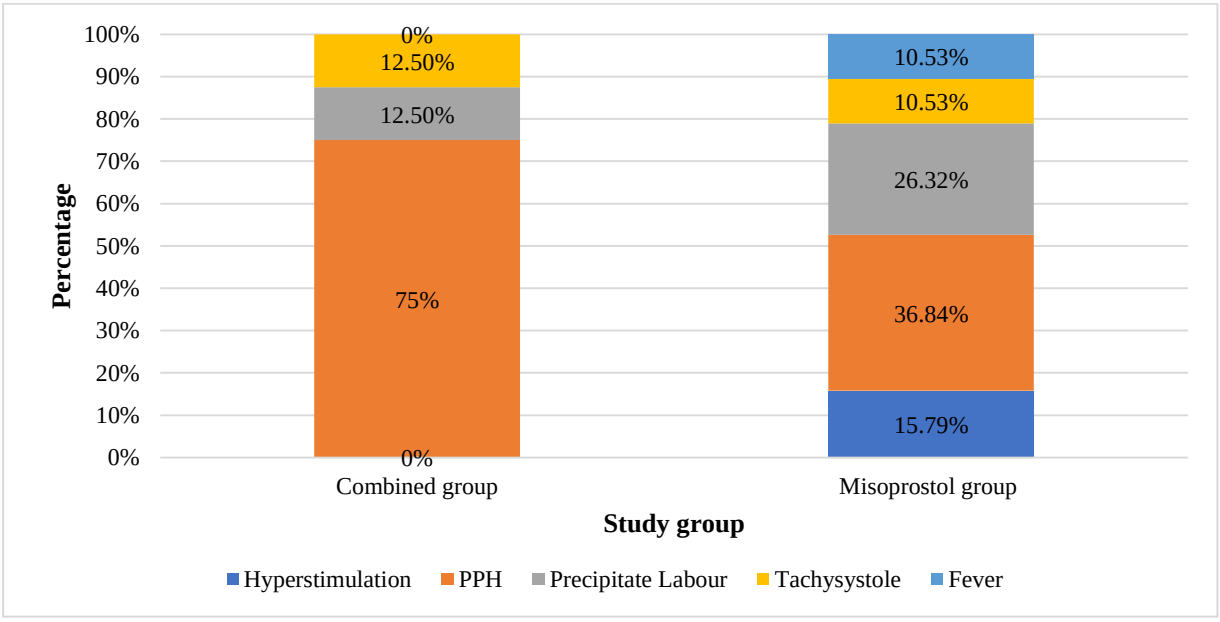


Table 15: Comparison of Apgar score at 1min between study groups (N=200)

Apgar score at 1 minute	Study Group		Chi square	P value
	Combined group (N=100)	Misoprostol group (N=100)		
>=7	83 (83%)	71 (71%)	4.065	0.056
<7	17 (17%)	29 (29%)		

Among the cases in combined group, 83 (83%) babies were with Apgar score >7/= 7 and 17 (17%) babies were with Apgar score <7. Among the cases in misoprostol group, 71 (71%) babies were with APGAR score >7/=7 and 29 (29%) babies were with Apgar score <7. The difference in the proportion of Apgar score at 1 minute between study groups was not statistically significant (p value0.056) (Table 15&Figure 14)

Figure 14: Staked bar chart of comparison of APGAR score at 1 min between study groups (N=200)

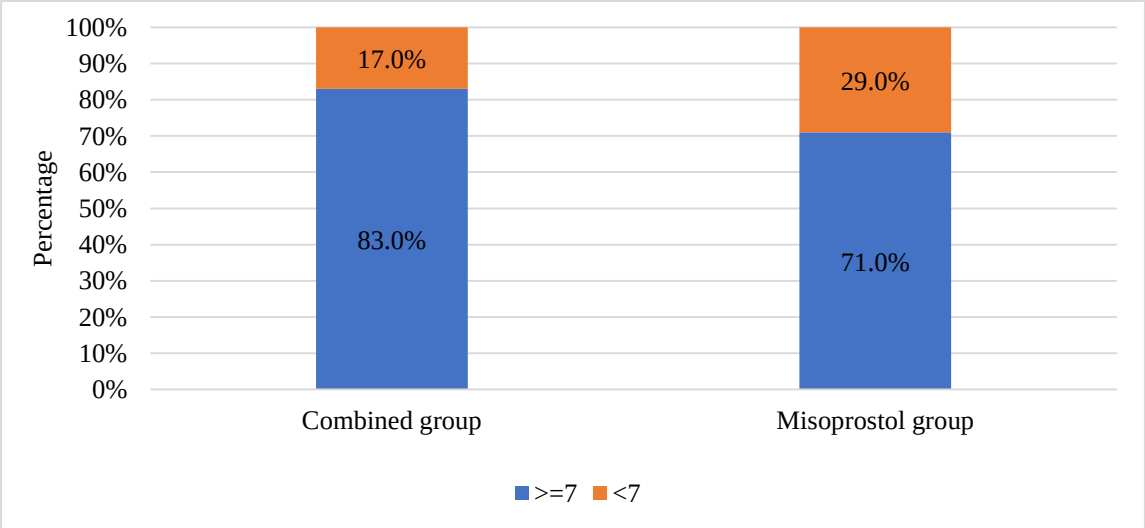


Table 16: Comparison of Apgar score at 5min between study groups (N=200)

Apgar score at 5 minutes	Study Group		Chi square	P value
	Combined group (N=100)	Misoprostol group (N=100)		
>=9	84 (84%)	72 (72%)	4.196	0.078
<9	16 (16%)	28 (28%)		

Among the cases in combined group, 84 (84%) babies were with Apgar score = >9, and 16 (16%) babies were with Apgar score <9. Among the cases in misoprostol group, 72 (72%) babies were with Apgar score = >9 and 28 (28%) babies were with Apgar score <9. The difference in the proportion of Apgar score at 5 minutes between study group was not statistically significant (p value0.078) (Table 15&Figure 13)

Figure 15: Staked bar chart of comparison of Apgar score at 5min between study groups (N=200)

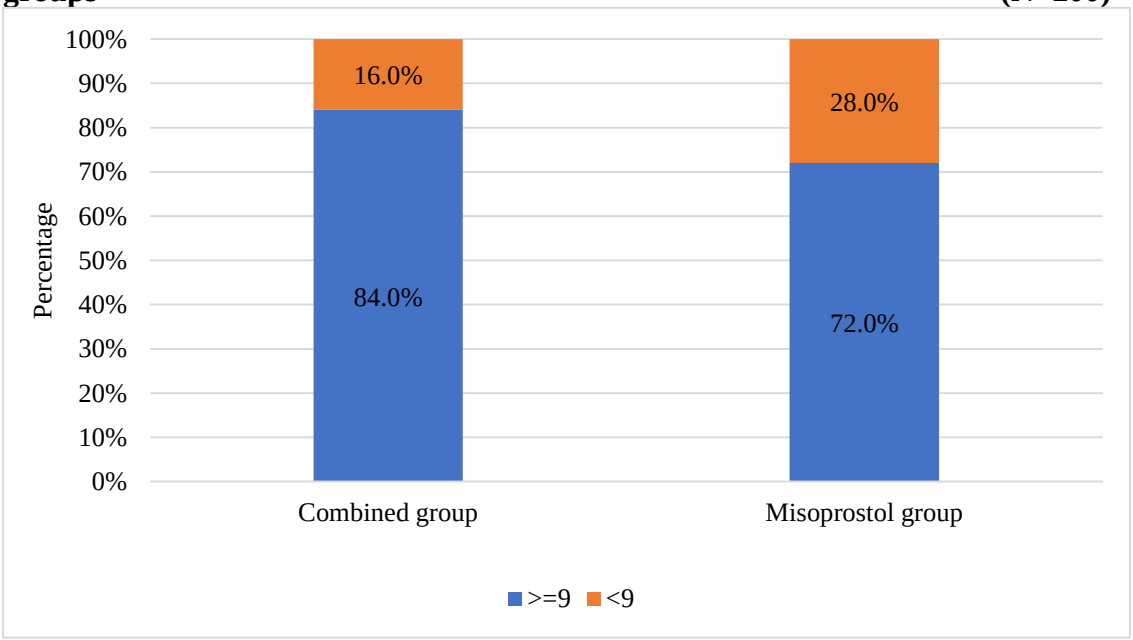


Table 17: Comparison of NICU admission between study groups (N=200)

NICU Admission	Study Group		Chi square	P value
	Combined group (N=100)	Misoprostol group (N=100)		
Yes	28 (28%)	39 (39%)	2.716	0.099
No	72 (72%)	61 (61%)		

In the combined group, 28 (28%) babies admitted in NICU, whereas in misoprostol group, 39 (39%) babies admitted to NICU. The difference in the proportion of NICU admission between study group was statistically not significant (p value0.099) (Table 16&Figure 14)

Figure 16: Cluster bar chart of comparison of NICU admission between study groups (N=200)

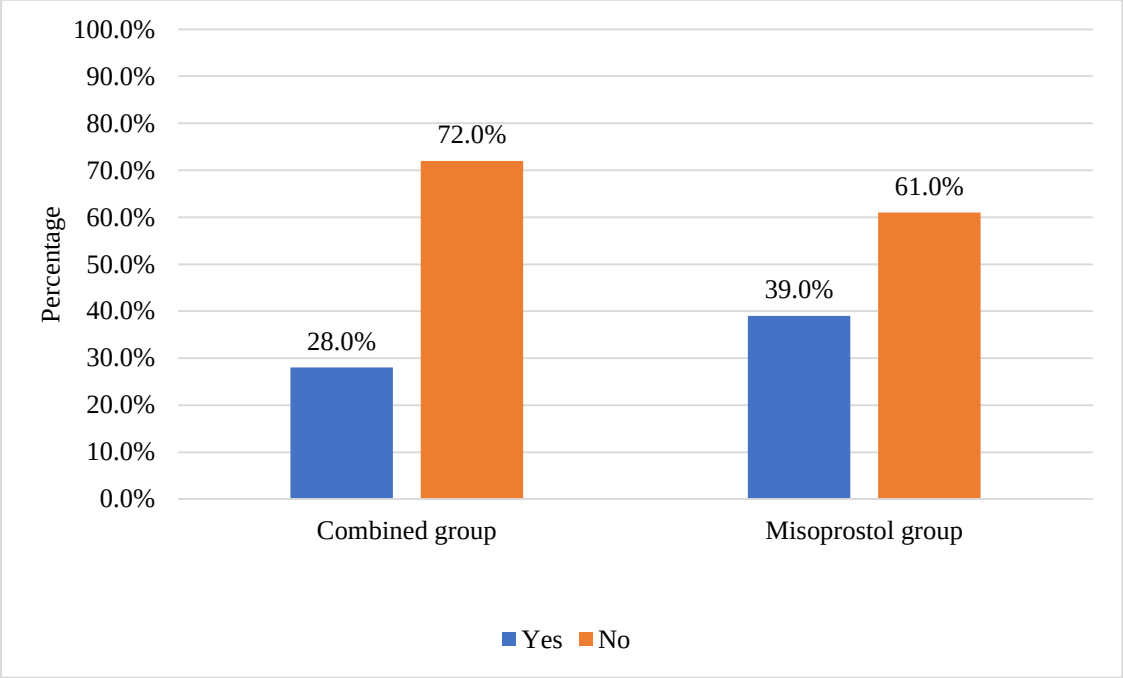
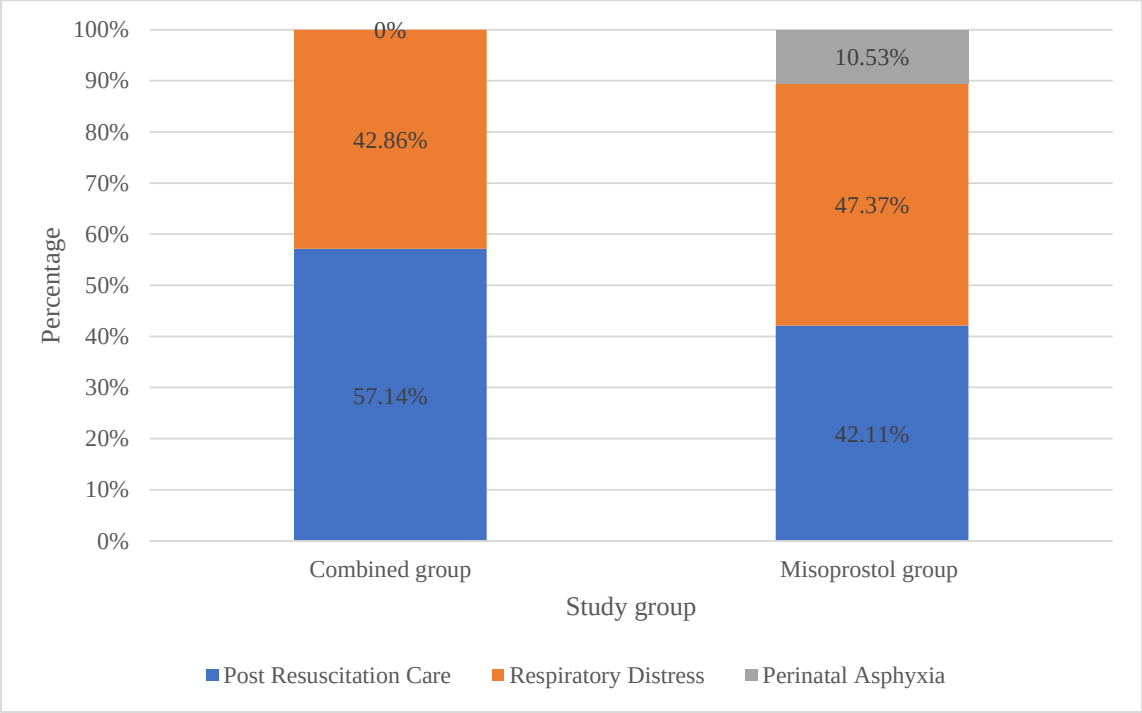


Table 18: Comparison of Indication for NICU admission between study groups (N=66)

Indication for NICU Admission	Study Group	
	Combined group (N=28)	Misoprostol group (N=38)
Post Resuscitation Care	16 (57.14%)	16 (42.11%)
Respiratory Distress	12 (42.86%)	18 (47.37%)
Perinatal Asphyxia	0 (0%)	4 (10.53%)

Among the cases in combined group, the Indication for NICU admission was post resuscitation care in 16 (57.14%) babies and respiratory distress in 12 (42.86%) babies. Among the cases in misoprostol group, the indication for NICU admission was post resuscitation care in 16 (42.11%) babies, respiratory distress in 18 (47.37%) babies and perinatal asphyxia in 4(10.53%) babies (Table 18&Figure 17)

Figure 17: Staked bar chart of comparison of indication for NICU admission between study groups (N=66)



DISCUSSION

DISCUSSION

Induction of labour is being increasingly used to prevent many complications of pregnancy including perinatal death. Various factors like fetal size and presentation, gestational age, membrane status, cervical favorability influence successful vaginal delivery through induction. Some studies have established biological efficacy of use of combination of mechanical and pharmacologic agents which include administration of synthetic prostaglandin along with use of catheter. Hence, the present study was conducted to compare the efficacy of use of intravaginal misoprostol alone and combination of use of cervical Foley's catheter along with intravaginal misoprostol for induction of labour.

A total of 200 women were enrolled in the study. The subjects were divided in to two equal groups of 100, with the one where intravaginal misoprostol alone was used and the other where combination of use of cervical Foley's catheter along with intravaginal misoprostol for induction of labour was used.

Baseline demographic and obstetric characteristics of study participants

AGE RATIO:

In the present study, 24.85 ± 4.93 years was the mean age of participants in combined group and 24.55 ± 4.35 years in misoprostol group. In a prospective, randomized controlled trial conducted by Chung JH, et al. in 146 patients the mean of age in the combined and misoprostol group were 26.4 ± 6.61 and 26.3 ± 6.82 respectively which is similar to our study results.[34]

Table: Comparison of mean of age in various studies.

Study	Number of cases	Mean of age
Present study	200	Combined group (24.85 ± 4.93) Misoprostol group (24.55 ± 4.35)
Chung JH, et al., [34]	146	Combined group (26.4 ± 6.61) Misoprostol group (26.3 ± 6.82)

The majority of subjects in the present study were between 20-30 years of age in both the groups. There was no statistically significant age group change in both the groups indicating that the age group bias was also considered in our study. Similarly no statistically significant change in the gestation period was noted in a study between the groups, where the majority of the subjects were at 40 weeks of gestational age.[23]

The present study is in accordance with the study of Chung JH, et al., where the gestational age was approximately 40 weeks in both the groups[34.]However in the study of Ramchandra KR., et al. who conducted a hospital based comparative study among 200 women in whom 63% of women in combined group had gestational age between 35-37 weeks, 19% between 37-40 and 18% >41. Whereas in misoprostol group, 52% between 35-37 years, 21% between 37-40 and 27% > 41 years which is contrasting to our study results[45]

In the present study, prolonged pregnancy, pre-eclampsia-eclampsia and oligohydramnious were the indication for induction of labour identified in the combined group with 49%, 20% and 31% whereas, in misoprostol group with 61%, 12% and 27% respectively. In both the groups the major indication of the induction of

the labour was prolonged pregnancy and no statistically significant difference was observed between the groups regarding the indications of the induction[33]

The observations of our study are contradicting the study conducted by Bhatiyani BR, et al., in which postdatism, PIH, IUGR and oligohydramnios are the indications identified for induction in combined group with 40.7%, 44.4%, 11.1% and 3.7% while in misoprostol group with 49%, 27.5%, 9.8% and 13.7% [35].

According to the Modified Bishop's pre-induction cervical scoring system, effacement has been replaced by cervical length in cm, with scores as follows: 0 for >3 cm, 1 for >2 cm, 2 for >1 cm, 3 for >0 cm. Cervical length may be easier and more accurate to measure and have less inter-examiner variability. In the present study, the pre-induction Bishop's Score distribution was similar in both the groups with a p value of 0.809.

NUMBER OF DOSES

In the present study, most women (39%) in the combined group achieved a favourable Bishop's score with one dose; while in the misoprostol group, 22 % cases achieved favourable bishops with one dose.

In a study of 237 pregnant women done by Osoti A, et al. 1, 2, 3 and 4 doses were administered with 100%, 66.7%, 26.7% and 8.9% whereas, in misoprostol group with 100%, 88.9%, 46.7% and 17.6% respectively which is contrasting to our study results[46]

However, by Mandal A et al single dose of misoprostol was required to achieve favourable score in both combined group (63.73%) and misoprostol (79.78%) group[23]

INDUCTION TO ACTIVE STAGE INTERVAL

In the present study the induction to active phase interval in the combined group was significantly shorter than in the misoprostol group with a p value of 0.052.

Similar results were obtained in a study by Aduloju D et al, the induction to active phase was shorter in the combined group than in the misoprostol group (1 hour 57 minutes versus 4 hours 25 minutes) with a p value of 0.006[12]

These results were also comparable to a study by Leduc P et al, interval from induction of labour to onset of active labour was significantly shorter in the Combined group as compared to the misoprostol group (464.35 ± 253.61 minutes versus 617.57 ± 242.72 minutes, $p<0.001$)[33]

INDUCTION TO DELIVERY INTERVAL

In the current study, the interval from induction to delivery in combined group was upto 12 hours in 40./. whereas 13-24 hours in 57./. and 25-36 hours in 3./. While in misoprostol group , the interval from induction to delivery was upto 12 hours in 13./. while 13 – 24 hours in 35./. and 25-36 hours in 52./. of cases, which was statistically significant between the groups.

Santosh PK, et al. conducted prospective randomized study in 200 patients in which the induction to delivery interval was 6-16 hours in 50% of women in combined

group followed by 12-24 hours and > 24 hours with 41.67% and 8.53% whereas, in misoprostol group 29.55% had induction to delivery interval between 6-12 hours followed by 12-24 hours and > 24 hours with 47.72% and 22.73% respectively which is similar to our study results[44]

Table : Comparison of induction to delivery interval between various studies

Study	Population	Induction to delivery interval
Present study	200	Combined group <12 hrs (40%) 13-24 hrs (57%) 25-36 hrs (3%) Misoprostol group <12 hours (13%) 13-24 hrs (35%) 25-36hrs (52%)
Santosh PK, et al.,[44]	200	Combined group 6-16 hrs (50%) 12-24 hrs (41.67%) > 24 hrs (8.535) Misoprostol group 6-16 hrs (29.55%) 12-24 hrs (47.72%) >24 hrs (22.73%)

MODE OF DELIVERY

In the present study, the mode of delivery was vaginal in 58%whereas assisted vaginal delivery and caesarean delivery in 16% and 26% of participants and in misoprostol group vaginal delivery , assisted vaginal delivery and caesarean section

were identified with 37% , 16% and 47% respectively which was statistically significant between the groups where the majority underwent vaginal delivery in combined group, where as in misoprostol group it was by caesarean section.

In a prospective, randomized controlled trial conducted by Chung JH, et al., in 146 patients in which vaginal delivery, assisted delivery and caesarean section were identified in the combined group with 58.1%, 11.6% and 41.9% whereas, in misoprostol group with 63.3%, 6.1% and 36.7% respectively which is similar to our study results[32]

INDICATION FOR CAESAREAN SECTION

In the current study, in combined group ,38.46% had fetal distress , whereas 23.08.% had failed induction and 38.46 % had non progression of labour as indication for LSCS .Similarly in misoprostol group , 52.06% had fetal distress , 17.03% had failed induction and 31.91% had non progression of labour as indication. The commonest indication for caesarean section in both the groups was fetal distress, though the absolute number of cases with fetal distress was greater in the misoprostol group 52.06% as compared to combined group 38.46%, this difference did not achieve statistical significance.

Similar results were obtained in the study by El- Kelani et al, fetal distress followed by failure of induction were the commonest indications for caesarean section and there was no statistically significant difference between the groups[14]

OXYTOCIN AUGMENTATION

In the present study ,35% cases required oxytocin augmentation in combined group , while in misoprostol group , 42 % cases required .Though not significant more subjects in the misoprostol group required oxytocin augmentation in the present study.

Ande AB., et al.performed a study in 100 women in which 44% of participants in the combined group required oxytocin augmentation whereas, 64% in misoprostol group required oxytocin augmentation which is similar to our study results[48]

Table: Comparison of oxytocin augmentation in various studies.

Study	Population	Oxytocin augmentation
Present study	200	Combined group (35%) Misoprostol group (65%)
Carbone JF, et al., [33]	123	Combined group (82%) Misoprostol group(88.5%)
Ande AB., et al.[48]	100	Combined group (44%) Misoprostol group (64%)

MECONIUM STAINED LIQUOR

In the present study, 63 % in the combined group had clear liquor and 37% had meconium stained liquor . Whereas in misoprostol group , 45% had clear liquor and 55% had meconium stained liquor. The difference was not statistically significant (P = 0.078).

Aduloju et al observed that the rate of meconium passage was 17.4% in misoprostol group and 13.9% in the combined group, and the difference was not statistically significant[12]

MATERNAL ADVERSE EFFECTS

In the present study, maternal side effects were identified in combined and misoprostol groups with 8% and 19% respectively. Hyperstimulation, PPH, precipitate labour, tachysystole and fever were the causes identified for maternal adverse effects . In misoprostol group , hyperstimulation was noted in 3 cases and fever in 2 cases and no cases of hyperstimulation and fever were reported in combined group. Compared to combined group , a relatively higher frequency of precipitate labour and tachysystole is noted in misoprostol group which was statistically sifnificant(p=0.023) In a study of 237 pregnant women done by Osoti A, et al., 4.4% of participants in combined group had maternal adverse effects whereas, 8.9% in misoprostol group had maternal adverse effects which is a dissimilar to our study[45]

Table: Comparison of maternal adverse effects between various studies.

Study	Population	Maternal side effects
Present study	200	Combined group (9%) Misoprostol group (19%)
Osoti A, et al.,[46]	237	Combined group (4.4%) Misoprostol group (8.9%)

NEONATAL ADVERSE EFFECTS

In the present study 83% of participants were Apgar score at 1 minute = >7 in combined group and 17% were Apgar score at 1 minute <7. Whereas, in misoprostol group, 71% were Apgar score at 1 minute = >7 and 29% were Apgar score at 1 minute <7.There was no statistical significant difference between the groups.

In a prospective, randomized controlled trial conducted by Chung JH, et al. in 146 patients in which 31.5% of participants in the combined group had Apgar score ≤7 whereas, 24.5% in misoprostol group[34]

Ramchandra KR., et al. conducted a hospital based comparative study in 200 women in which Apgar score at 1 minutes <7 and > 7 were identified with 20% and 80% in combined group while in misoprostol group with 20% and 80% respectively which is dissimilar to our study results [45]

Table: Comparison of Apgar score at 1 min between various studies.

Study	Population	Apgar at 1 minute
Present study	200	Combined group = >7 (83%) <7 (17%) Misoprostol group = >7 (71%) <7 (29%)
Ramchandra KR., et al.,[45]	146	Combined group <7 (20%) > 7 (80%) Misoprostol group <7 (20%) > 7 (80%)

In the current study, 84% had Apgar score at 5 minute = >9 in combined group and 16% had Apgar score at 5 minute <9. While in misoprostol group, 72% had Apgar

score at 5 minute = >9 and 28% had Apgar score at 5 minutes <9 which was not statistically significant between the groups.

Ramchandra KR., et al. conducted a hospital based comparative study in 200 women in which Apgar score at 5 mins <9 and > 9 were identified with 4% and 96% in combined group while in misoprostol group with 7% and 93% respectively which is dissimilar to our study[45]

Table: Comparison of Apgar score at 5min between various studies

Study	Population	Apgar at 5 minute
Present study	200	Combined group = >9 (84%) <9 (16%) Misoprostol group = >9 (72%) <9 (28%)
Ramchandra KR., et al.,[45]	200	Combined group <7 (4%) > 7 (96%) Misoprostol group <7 (7%) > 7 (93%)

In the present study, 8% of babies had NICU admission in combined group whereas, in misoprostol group, 39% had NICU admission but it is not statistically significant(p =0.009).

Bhatiyani BR, et al., performed a study in 105 participants in which NICU admission was required by 7% in combined group and 11% in misoprostol group which is similar to our study results[35]

In the current study, post resuscitation care, respiratory distress and perinatal asphyxia are the causes identified for NICU admission in combined group with 57.14%, 42.86% and 0% whereas, in misoprostol group with 42.11%, 47.37% and 10.53% respectively. The commonest cause for neonatal NICU admission was respiratory distress in both the groups. There was four cases of perinatal asphyxia in misoprostol group and no cases of perinatal asphyxia reported in combined group.

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SUMMARY

SUMMARY

- A total of 200 subjects were included in the final analysis (100 in combined group and misoprostol group).
- The mean age of the participants in the combined group and misoprostol group were 24.85 ± 4.93 years and 24.55 ± 4.35 years respectively.
- Among the cases with combined group, majority of the cases were aged upto 20 years with 31% followed by 28% cases between 21 to 25 years and 23% cases between 26 to 30 years Whereas, Among the cases with misoprostol group, majority of the case were aged between 21 to 25 years with 39% followed by 27% cases aged upto 20 years and 25% cases 26 to 30 years.
- Among the combined group, 25% of the participants were gestational age 37 to 38 weeks+6days, 19% were 39 to 39 weeks+6days, 39% were 40 to 40 weeks+6days and 17% were 41 to 41 weeks+6days. Similarly, with misoprostol group, 18% people were gestational age 37 to 38 weeks+6days, 19% were 39 to 39 weeks+6days, 46% were 40 to 40 weeks+6days and 17% people were 41 to 41 weeks+6days.
- In combined group, prolonged pregnancy, pre-eclampsia-eclampsia and oligohydramnious were the indication for induction identified with 49%, 20% and 31% whereas, in misoprostol group with 61%, 12% and 27% respectively.
- Pre-induction modified bishop score 2, 3, 4 and 5 were identified in the combined group with 34%, 40%, 15% and 11% whereas, in misoprostol group with 33%, 46%, 12% and 9% respectively.
- Majority of the participants in the combined group was administered with one and two doses with 39% of each followed by three and four doses with 18%

and 4%. Whereas, among misoprostol group, majority were administered with 3 doses with 29% followed by two doses with 27%.

- Among the combined group, the interval between induction and active stage was 1-6 hours in 29% whereas, 7-12 hours in 65% and above 12 hours in 6% where as in misoprostol group, the interval between induction and active stage was 1-6 hours in 17% while 7-12 hours in 70% and above 12hours in 13%.
- Among the combined group, the interval from induction to delivery was up to 12 hours in 40% whereas, 13-24 hours in 57% and 25-36 hours in 3%. Where as, among the misoprostol group, the interval from induction to delivery was up to 12 hours in 13% while 13-24 hours in 35% and 25-36 hours in 52% of participants.
- In combined group, the mode of delivery was vaginal in 58% whereas, assisted vaginal delivery and caesarean delivery in 16% and 26% of participants. Where as, in misoprostol group vaginal delivery, assisted vaginal delivery and caesarean section were identified with 37%, 16% and 47% respectively.
- Fetal distress, failed induction, non-progression of labour were the indication for LSCS identified in the combined group with 38.46%, 23.08%, 38.46./. Similarly identified in the misoprostol group with 51.06%, 17.02% and 31.91% respectively.
- Oxytocin augmentation requirement was identified in combined group and misoprostol group with 35% and 42% respectively.
- Among the cases with combined group, 63% had clear required and 37% had meconium stained liquor. Whereas, Among the cases with misoprostol group, 45% had clear required, and 55% had meconium stained liquor.

- Among the combined group, APGAR score at 1 minutes were >=7 and <7 in 83% and 17% of participants whereas, in misoprostol group identified with 71% and 29% respectively.
- Among the combined group, APGAR score at 5 minutes were >=9 and <9 in 84% and 16% of participants whereas, in misoprostol group identified with 72% and 28% respectively.
- Around 28% had NICU admission in combined group whereas, 39% in misoprostol.
- Among the combined group, post resuscitation care, respiratory distress and perinatal asphyxia are the causes identified for NICU admission with 57.14%, 42.86% and 0% whereas, in misoprostol group with 42.11%, 47.37% and 10.53% respectively.
- Maternal side effects were identified in combined and misoprostol groups with 8% and 19% respectively.
- Hyperstimulation, PPH, precipitate labour, tachysystole and fever were the causes identified for maternal adverse effects in combined group with 0%, 75%, 12.5%, 12.5% and 0% whereas, in misoprostol group with 15.79%, 36.84%, 26.32%, 10.53% and 10.53% respectively.

CONCLUSION

CONCLUSION

The combined use of foleys catheter plus misoprostol is associated with shorter duration of cervical ripening , shorter induction to delivery interval . The combination of foleys catheter and misoprostol also appears to cause less hyperstimulation and tachysystole when compared with misoprostol alone. Perinatal outcome was similar between the two groups.

BIBLIOGRAPHY

BIBLIOGRAPHY

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ANNEXURES

ANNEXURES

PATIENT INFORMATION SHEET

Study title: **A RANDOMISED CONTROLLED TRIAL COMPARING INTRAVAGINAL MISOPROSTOL ALONE VERSUS COMBINATION OF CERVICAL FOLEYS CATHETER AND INTRAVAGINAL MISOPROSTOL FOR INDUCTION OF LABOUR**

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

Details-

In primigravida patients beyond 37 weeks gestation, induction of labour will be done with either intravaginal misoprostol alone or with combination of cervical foleys catheter and misoprostol .

Patients in this study will have to undergo complete general physical examination, obstetric examination, routine blood investigations such as complete blood count, viral serology, urine routine and random blood sugar levels. To assess the fetal wellbeing a cardiotocograph and an obstetric ultrasound with biophysical profile will also be done.

Please read the following information and discuss with your family members. You can ask any question regarding the study. If you agree to participate in the study, we will collect information (as per proforma) from you or a person responsible for you or both. Relevant history will be taken. This information collected will be used only for dissertation and publication.

All information collected from you will be kept confidential and will not be disclosed to any outsider. Your identity will not be revealed. This study has been reviewed by the Institutional Ethics Committee and you are free to contact the member of the

Institutional Ethics Committee. There is no compulsion to agree to this study. The care you will get will not change if you don't wish to participate. You are required to sign/ provide thumb impression only if you voluntarily agree to participate in this study.

For further information contact

Dr. Tejashree.N.R.

Post graduate,

Department of obstetrics and gynecology,

Sri Devaraj Urs Medical College,

Kolar.

CASE PROFORMA

NAME: **IP NO:**

AGE: **DOA:**

OCCUPATION: **DOD:**

ADDRESS:

EDUCATION:

HUSBANDS

OCCUPATION:

SOCIOECONOMIC

STATUS:

CHIEF COMPLAINTS:

HISTORY OF PRESENT ILLNESS:

OBSTETRIC HISTORY:

Marital life: Consanguinity:

Gravida: Para: living: Abortion: Dead: Details of previous pregnancy:

Details of present pregnancy:

MENSTRUAL HISTORY:

Last menstrual period: Age of menarche: Expected delivery date:

Period of gestation:

Period of gestation according to early scan:

Past menstrual cycles:

PAST HISTORY:

Hypertension /Diabetes Mellitus/Bronchial Asthma/Tuberculosis /Blood

Dyscrasias/ Epilepsy/ Thyroid Disorder/ Cardiac Disease/Allergy

H/O blood transfusions:

H/O Surgeries or hospitalization:

PERSONAL HISTORY:

Sleep and appetite:

Diet:

Bowel and bladder:

FAMILY HISTORY:

DRUG HISTORY:

GENERAL EXAMINATION:

General condition:

Fair/ moderate/ Poor

Built: Nourishment:

Ht: cms Wt: kgs BMI: Pallor: Icterus:

Cyanosis:

Clubbing:

Lymphadenopathy:

Edema:

VITALS:

Pulse rate: Respiratory rate:

Blood pressure : Temperature:

Breast : Spine : Thyroid :

SYSTEMIC EXAMINATION:

Cardiovascular system: Respiratory system: Central nervous system:

Per abdomen: Uterus size:

Relaxed / Irritable / Acting Presentation: cephalic/

Breech/ other FHS:

LOCAL EXAMINATION:

Per Speculum:

Per Vaginum: Effacement:

Dilatation:

Station:

Membranes:

Pelvis:

Modified Bishop Score:

DIAGNOSIS:

Total dose of induction:

Number of doses:

Induction to active stage interval:

Induction to delivery interval:

Mode of delivery:

Indication for cesarean section:

Need for oxytocin augmentation:

Maternal adverse effects:

APGAR score at 1 minute & 5 minutes:

Meconium stained liquor:

Fetal heart rate tracing (Non stress test and cardiotocograph findings) :

DETAILS OF THE NEONATE:

Sex: Date: Time: Birth weight:

APGAR score: 1'- 5'-

Admission to NICU:

Neonatal

resuscitation

Perinatal

morbidity/mortality

:

INVESTIGATIONS:

Blood group and Rh typing:

CBC: HB: HIV:

PCV: HbsAG:

RBC: VDRL:

WBC:

PLT: RBS:

Urine analysis: Albumin-

Su

ga

r-

Microscopy-

OBSTETRICS SCAN:

SRI DEVARAJ URS MEDICAL COLLEGE & RESEARCH CENTRE, TAMAKA, KOLAR

PATIENT CONSENT FORM

Case no:

I have read the foregoing information, or it has been read to me and has been explained to me in my own understanding language. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I have understood that I have the right to refuse consent or withdraw it at any time during the study and this will not affect my treatment in any way. I consent voluntarily to participate in this study

"A RANDOMISED CONTROLLED TRIAL COMPARING INTRAVAGINAL MISOPROSTOL ALONE VERSUS COMBINATION OF CERVICAL FOLEYS CATHETER AND INTRAVAGINAL MISOPROSTOL FOR INDUCTION OF LABOUR"

Name of Participant_____

Signature/ thumb print of Participant _____

Date _____

R.L Jalappa Hospital Tamaka, Kolar.

TO MASTER CHART

B.STUDY GROUP

1.COMBINED GROUP

2.MISOPROSTOL GROUP

C.GESTATIONAL AGE

1. 37 -38+6

2.39- 39+6

3.40- 40+6

4.41-41+6

D.AGE GROUOP

E.INDICATION FOR INDUCTION

1.PROLONGED PREGNANCY

2.HYPERTENSIVE DISORDER

3.OLIGOHYDRAMNIOS

F.PRE INDUCTION MODIFIED BISHOP SCORE

1.2

2.3

3.4

4.5

G.NUMBER OF DOSES

1.1

2.2

3.3

4.4

H.INDUCTION TO ACTIVE STAGE INTERVAL

1. upto 12 hours

2.13 to 24 hours

3.25 to 36 hours

I.INDUCTION TO DELIVERT INTERVAL

1. upto 12 hours

2.13 to 24 hours

3.25 to 36 hours

J.MODE OF DELIVERY

1.VAGINAL DELIVERY

2.ASSISTED VAGINAL DELIVERY

3.CEASAREAN SECTION

K.INDICATION FOR LSCS

1.FETAL DISTRESS

2.FAILED INDUCTION

3.NON PROGRESSION OF LABOUR

L.OXYTOCIN AUGMENTATION REQUIREMENT

1.NOT REQUIRED

2.REQUIRED

M..LIQUOR

1.CLEAR

2.MECONIUM STAINED LIQUOR

N.APGAR AT 1 MINUTE

1.>/=7

2.<7

0.APGAR AT 5 MINUTE

1.>/=9

2.<9

P.NICU ADMISSION

1.YES

2.NO

Q.INDICATION FOR NICU ADMISSION

1.POST RESUSCITATION CARE

2.RESPIRATORY DISTRESS

3.PERINATAL ASPHYXIA

R.MATERNAL ADVERSE EFFECTS

1.YES

2.NO

S.CAUSE FOR MATERNAL ADVERSE EFFECTS

1.HYPERSTIMULATION

2.PPH

3.PRECIPITATE LABOUR

4.TACHYSYSTOLE

5.FEVER

736130	1	1	20	1	2	1	2	1	2		2	1	7	9	2		NO	
728167	2	2	22	1	2	1	1	2	4	2	2	1	6	8	1	1	YES	2
737062	1	2	19	2	4	2	1	2	1		1	1	7	9	1	1	NO	
729636	2	2	21	2	2	3	2	3	2		1	2	2	9	2		NO	
727453	1	3	21	1	2	2	1	1	4	1	1	2	5	9	1	2	NO	
795965	2	2	22	1	3	4	2	2	4	3	2	2	6	8	1	2	NO	
701615	1	1	20	1	4	3	2	2	1		2	1	7	9	2		NO	
719905	2	2	22	1	3	2	1	5	4	1	2	1	7	8	2		NO	
663993	1	2	22	2	4	2	2	1	1		1	1	7	9	2		NO	
597389	2	2	22	1	3	1	2	5	2		1	2	5	6	1	1	NO	
737544	1	1	20	1	3	1	2	2	4	4	1	2	7	9	2		NO	
597389	2	2	27	3	2	3	1	2	1		2	1	7	8	2		YES	2
737525	1	2	23	3	4	2	1	2	2		1	2	5	8	1	1	NO	
731313	2	2	28	1	3	2	2	3	4	2	1	2	6	8	1	2	NO	
702534	1	1	27	1	2	1	1	1	3		1	1	7	9	1	1	NO	
731216	2	3	20	1	3	1	1	5	2		1	1	7	9	1	1	NO	
738476	1	3	24	1	3	2	1	2	4	1	1	2	7	9	2		NO	
792253	2	2	25	1	3	3	1	5	1		2	2	6	9	1	2	NO	
738488	1	1	19	2	4	3	1	4	1		2	2	7	9	2		YES	2
732993	2	3	27	1	2	1	2	2	4	3	1	1	7	9	2		YES	1
738484	1	2	25	1	2	2	2	1	1		1	1	7	9	2		NO	
733350	2	3	20	3	3	2	2	3	1		2	2	6	8	1	1	NO	
738459	1	1	28	3	4	3	1	3	4	4	1	2	7	9	2		NO	
733905	2	2	20	2	2	2	2	2	4	2	1	1	5	9	2		NO	
740414	1	3	19	1	3	1	1	1	2		1	2	7	9	1	1	NO	
654014	2	3	25	1	2	3	2	3	1		2	2	6	8	2		NO	
776060	1	1	25	2	2	2	2	2	1		2	2	6	8	1	2	NO	
717196	2	3	26	1	3	1	2	5	4	3	1	1	7	9	2	1	YES	5
775504	1	3	28	1	4	1	1	2	1		1	1	7	9	2		NO	
700255	2	3	29	1	3	3	2	2	1		2	2	7	8	1	2	NO	
77405	1	1	19	2	2	2	2	2	4	1	1	1	7	9	2		NO	
736501	2	2	19	1	3	2	1	5	4	1	1	1	6	8	1	2	NO	
777782	1	3	29	1	3	1	2	2	2		1	1	7	9	2		NO	
675762	2	3	25	1	2	2	2	2	1		2	2	7	9	2		NO	
795096	1	1	24	3	4	1	1	1	4	3	2	2	7	9	2		NO	
760074	2	3	29	1	2	1	1	5	4	1	1	1	6	8	1	2	NO	
777492	1	3	19	1	2	1	2	2	1		1	2	7	9	2		NO	
833824	2	3	19	2	3	3	1	3	1		2	2	7	9	1		NO	
795036	1	1	30	3	3	1	1	3	1		1	1	7	9	1	1	NO	
765353	2	2	20	3	3	1	2	4	1		1	1	7	9	2		NO	
741205	1	3	20	1	2	1	2	1	1		2	1	7	9	2		NO	
685252	2	3	25	1	2	2	1	2	4	2	2	2	6	7	2		NO	
796384	1	1	22	3	4	1	2	2	4	1	2	2	6	8	1	1	NO	
700591	2	3	29	1	3	3	1	3	1		1	1	7	9	1	2	NO	
788354	1	3	20	1	4	1	1	1	2		1	1	7	9	2		NO	
720478	2	2	24	1	2	4	2	4	4	1	2	2	7	9	2		YES	2
781641	1	1	28	2	2	1	1	2	1		1	1	7	9	2		NO	
760016	2	3	19	1	3	3	1	2	2		1	1	5	7	2		NO	

710345	1	3	29	1	3	2	2	1	1		1	1	7	9	2		NO	
801292	2	3	30	1	2	1	1	4	4	3	2	2	7	9	2		NO	
801270	1	1	28	3	4	1	2	2	1		1	1	7	9	2		NO	
782759	2	2	22	1	3	2	2	3	3		1	1	6	7	2		NO	
805029	1	3	20	3	2	3	1	1	4	3	2	1	7	9	2		YES	4
788258	2	3	19	1	2	2	1	4	4	2	1	2	7	9	1	1	NO	
801292	1	1	22	1	3	2	2	2	1		1	2	7	9	2		NO	
745563	2	3	24	2	3	1	1	3	4	1	2	1	5	7	1	2	YES	4
801578	1	2	19	2	2	5	1	2	1		1	1	7	9	2		NO	
774178	2	2	23	3	2	3	2	2	4	1	1	2	7	9	2		NO	
805876	1	1	26	2	3	2	2	2	2		1	1	7	9	2		NO	
662827	2	3	20	1	3	2	3	4	2		2	1	7	9	1	2	NO	
817302	1	3	24	1	2	1	1	2	1		1	1	6	8	1	1	NO	
788359	2	3	23	1	2	3	3	3	1		1	2	6	9	2		NO	
805481	1	1	28	3	4	2	2	2	4	1	2	2	7	9	2		NO	
690851	2	2	30	1	3	1	2	2	1		2	1	7	9	2		NO	
816810	1	2	31	2	4	3	1	2	2		1	1	7	9	2		NO	
801270	2	3	20	1	2	2	3	4	4	2	1	2	5	7	2		YES	4
721298	1	1	19	1	2	1	2	2	1		1	1	7	9	2		NO	
677592	2	3	19	1	4	3	2	3	1		2	1	7	9	1	1	NO	
811392	1	2	28	1	4	1	1	3	4	3	1	2	6	8	1	2	YES	2
675746	2	2	24	1	2	4	3	2	4	1	1	2	7	9	2		NO	
803122	1	1	25	1	2	1	2	2	1		1	1	7	9	1	2	NO	
789289	2	3	24	2	3	1	3	4	4	3	2	1	7	9	2		NO	
832468	1	3	33	1	3	2	4	2	1		2	1	7	9	2		NO	
729636	2	3	25	1	2	2	2	2	1		1	2	6	9	1	2	NO	
832858	1	1	34	2	4	3	2	2	2		2	2	7	9	2		NO	
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