"SUBLINGUAL MISOPROSTOL VERSUS INTRACERVICAL DINOPROSTONE GEL FOR INDUCTION OF LABOUR-A RANDOMIZED TRIAL"

By

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ABBREVATIONS

S.No	ABBREVATION	EXPANSION
1	IOL	INDUCTION OF LABOUR
2	PG	PROSTAGLANDINS
3	PGE1	PROSTAGLANDIN E1
4	PGE2	PROSTAGLANDIN E2
5	WHO	WORLD HEALTH ORGANIZATION
6	FIGO	INTERNATIONAL FEDERATION OF OBSTETRICS AND GYNAECOLOGY
7	SL	SUB LINGUAL
8	IUFD	INTRA UTERINE FETAL DEMISE
9	FGR	FETAL GROWTH RESTRICTION
10	PROM	PREMATURE RUPTURE OF MEMBRANES
11	GDM	GESTATIONAL DIABETES MELLITUS
12	COPD	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
13	CPD	CEPHALOPELVIC DISPROPORTION
14	NST	NON-STRESS TEST
15	RU 486	ROUSSEL UCLAF DRUG NUMBER 486
16	ACOG	AMERICAN COLLEGE OF OBSTETRICS AND GYNAECOLOGY
17	NSAID'S	NON-STEROIDAL ANTI-INFLAMMATORY DRUGS
18	PPH	POST PARTUM HEMORRHAGE

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INTRODUCTION

INTRODUCTION

In modern obstetrics, inducing labour in women remains a big challenge. Until recently, fetal death was the only reason for inducing labour. In today's world, the percent of labour induction varies in different nations and is around 20%[1]. The ideal agent for this purpose has yet to be identified, despite of multiple researches on the topic.

Natural, mechanical, surgical, and pharmaceutical methods of induction of labour are all available. The preference for a particular procedure has not yet been fully established, and it is dependent on the protocol of each institute. Oxytocin, misoprostol, mifepristone, dinoprostone, and other pharmacological techniques are used. Induction in the presence of an unfavorable cervix is linked to a higher risk of failed induction and caesarean section[2]. As a result, cervical ripening is required to improve the chances of a successful induction and reduce the danger of a caesarean delivery. The use of prostaglandins with or without oxytocin as infusion is a conventional approach for cervical ripening and IOL was generally acknowledged and accepted[3]. Natural prostaglandins, on the other hand, are cumbersome to use, expensive, and difficult to store because they need to be refrigerated[4].

Misoprostol is a prostaglandin E1 analogue that has been used as a cytoprotective drug in the stomach since 1988. It was previously used for IOL with a live fetus in 1991, and following multiple studies, it has acquired widespread support for labour induction. Misoprostol has been tested in a variety of ways, including orally, per vaginally, per rectal, buccal route, and sublingually[5]. Vaginal route is the common route of

administration of misoprostol for IOL, but it has a greater risk of unwanted side effects, such as uterine hyperstimulation syndrome (UHS), as well as vaginal administration being inconvenient[6]. Studies on the oral route of misoprostol were conducted to avoid this unfavorable effect and the inconvenience of vaginal administration. Many clinical trials have revealed that vaginal misoprostol is more effective than oral misoprostol because the systemic bioavailability of vaginal misoprostol is three times that of oral misoprostol[7]. An alternative technique was sought to overcome the hyperstimulation syndrome and discomfort of vaginal administration of vaginal misoprostol, as well as the lower bioavailability of oral misoprostol. Theoretically, the sublingual route of administration could be an alternative since it combines the increased efficiency of the vaginal route with lower hyperstimulation rates by avoiding a direct influence on the cervix by avoiding gastrointestinal and hepatic metabolism. Sublingual misoprostol has similar advantages to oral misoprostol, such as ease of administration, greater freedom of position following insertion, and less number of vaginal examinations[8].

With vaginal delivery occurring in 73 percent of cases and hyperstimulation syndrome occurring in 3.6% of women, the first dose of vaginal misoprostol given was 50 μg for every 2 hours to a maximum dose of 600 micrograms[9,10]. Since then, smaller dosages for induction of labour have been advocated in an attempt to lessen side effects[6,11]. WHO and FIGO approved a vaginal misoprostol dosage of 25 microgram every 4 hours for a maximum of 6 doses after multiple research[12]. Prior to 2001[8], there were no studies on the use of S.L misoprostol for IOL with a viable pregnancy had been published. A pharmacokinetics study of misoprostol taken by multiple routes revealed

that the sublingual route had higher bioavailability than the vaginal route[5].

OBJECTIVES

Primary objective:

To evaluate the safety and efficacy of sublingual misoprostol vs intracervical dinoprostone gel for induction of labor.

Secondary objectives:

(1) The induction –delivery interval between the two study groups to be compared.

(2) To compare the intrapartum complication rate between the two study groups.

(3) To compare factors affecting the performance of labour during induction with misoprostol and oxytocin titration.

(4) To compare the maternal and neonatal outcome.

REVIEW OF THE LITERATURE

REVIEW OF THE LITERATURE

INDUCTION OF LABOUR

Definition

Stimulation of uterine contractions before the commencement of spontaneous labour, at any time following fetal viability, with or without membrane breach, in order to achieve delivery vaginally [13,14].

Prerequisite for induction

- Assessment of maternal parameters
    - Confirm that induction is required.
    - Rule out contraindications of labour and/or vaginal delivery.
    - Pelvic assessment
    - favorability of the cervix
    - Weigh and explain benefit and risk of induction of labour to patient and the family

- Assessment of fetal parameters

    - Period of gestation
    - EFW calculation
    - Position of the Fetus
    - Assess fetal status

Indication[15]

- Obstetric indication**:**

    - Post-dated pregnancy
    - Mild and severe preeclampsia, eclampsia
    - Previous history of unexplained IUFD
    - Fetal compromise (Severe FGR, isoimmunization)
    - PROM
    - Fetal malformations
    - Polyhydramnios
    - Oligo hydramnios

- GDM
- Abruptio placentae
- Chorioamnionitis
- Intra Uterine Fetal Demise

- **Maternal medical conditions**

  - Diabetes mellitus Type I/II
  - Chronic renal disease
  - COPD
  - Chronic hypertension

Contraindication[16]

- Absolute
  - Herpes genitalis active lesions
  - A serious, long-term medical illness
  - Contracted pelvis or rhactic pelvis

- CPD
- If lie of the fetus is abnormal [transverse lie, oblique lie]
- Occult cord prolapse
- Placenta previa – grade IIb, III, IV and vasa previa
- Previous classical C-section or other trans fundal uterine surgery
- Contraindication to the inducing drug.

- **Relative**

- Carcinoma cervix
- Overdistension of uterus [twins, triplets, quatraplets, polyhydramnios]
- Malpresentation [breech]
- Macrosomia of the Fetus
- Placenta - Low lying
- Unexplained pv bleeding
- Presentation - Cord
- Myomectomy involving uterine cavity
- Non reassuring NST

Methods of Labor Induction[18]

Non-pharmacologic methods

- **Natural method**
    - Relaxation methods
    - Coitus
    - Tactile stimulation of Nipples
    - Enema
    - Cumin Tea
    - Herbs
    - Acupressure

- **Mechanical methods**
    - Osmotic dilators
        - Laminaria
        - dilapan
    - Balloon devices
        - Foleys
        - Bougie

II- Surgical methods

- stripping the membranes
- Amniotomy

III- Pharmacological methods

- Oxytocin
- Prostaglandin
    - Misoprostol(15deoxy-16hydroxyl-6methyl-prostaglandinE1)
    - Dinoprostone [E2]
- Mifepristone / RU 486

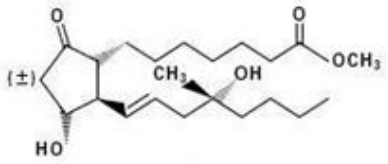
In a randomized controlled trial, oxytocin coupled with the Foley's catheter for IOL did not appear to reduce delivery time[19]. Studies comparing the period from induction to birth with additional amniotic saline given through the Foley catheter vs the Foley catheter with contemporaneous oxytocin administration had inconsistent results[20]. Discrepancies in findings could be explained by differences in approach. For cervical ripening and initiating labour, the Foley catheter proved a realistic and effective alternative. PGE2 was often utilized intracervical or intravaginal, and it was found to be superior to placebo or no treatment in cervical ripening[21]. PGE1 (misoprostol) was found to be an effective treatment for cervical ripening in several prospective randomized clinical trials and two meta-analyses[22]. Misoprostol used intravaginally has been shown to be as effective as or better than dinoprostone gel[23] in cervical ripening[21]. PGE1 (misoprostol) was found to be an effective therapy for cervical ripening in several prospective randomized clinical trials and two meta-analyses[22]. Misoprostol used intravaginally has been than when compared to

dinoprostone gel, vaginal misoprostol was reported to be equally effective or better[23]. When compared to dinoprostone and oxytocin, vaginal misoprostol was associated with less use of epidural analgesia, more vaginal deliveries within 24 hours, and more uterine tachysystole with or without FHR changes. Endpoints as Bishop Score, labour time, total oxytocin use, successful induction, and caesarean delivery rate[24] make it hard to compare misoprostol research outcomes. The use of pharmacological cervical ripening treatments had no effect on the likelihood of a caesarean section.

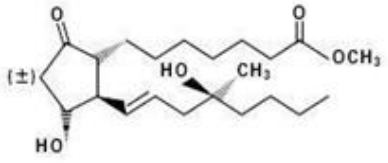
The ACOG reiterated their recommendation for the drug's usage in December 2000, citing its demonstrated safety and efficacy[25]. When compared to intracervical prostaglandin E2 gel, misoprostol tablets administered in the vagina were either superior to or similar in efficacy[26]. Misoprostol administration may lower the requirement for oxytocin, increase the rate of vaginal birth within 24 hours of induction, as well as reducing the time between induction and delivery Misoprostol costs cheaper than dinoprostone gel and doesn't need to be refrigerated.

Misoprostol - Clinical Pharmacology

Misoprostol is an analogue of prostaglandin E1. Misoprostol has almost equal proportions of the 2 diastereomers as shown below, and enantiomers are denoted by (±):



and



$C_{22}H_{38}O_5$ M.W. = 382.5

(±) methyl 11α,16-dihydroxy-16-methyl-9-oxoprost-13E-en-1-oate

Pharmacokinetics[27]

Misoprostol is a soluble in water. Unlike the parent molecule[28], misoprostol is absorbed rapidly and de-esterified to its free acid (Misoprostolic acid), which provides therapeutic efficacy and is detected in plasma. The alpha side chain is beta oxidized, while the beta side chain is omega oxidized, followed by ketone reduction to produce prostaglandin F analogues. Misoprostol is rapidly absorbed in healthy volunteers, with

a Tmax of Misoprostolic acid being12 ± 3 minutes and a terminal half-life of 20–40 minutes.

Route[5]	**Onset ofaction**[5]	**Duration of action**[5]
Oral *	8 min	~ 2 h
Sublingual	11 min	~ 3 h
Vaginal	20 min	~ 4 h
Rectal	100 min	~ 4 h

Pharmacodynamics[27]

Misoprostol prevents gastric acid secretion in animals, and is mucosal protective. P.G synthesis is decreased by NSAIDs; hence they cause mucosal damage due to lack of prostaglandins in the gastric mucosa, which in turn can reduce bicarbonate and mucus secretion, contributing to the mucosal damage induced by these medications. Misoprostol has been demonstrated in humans to enhance bicarbonate and mucus production, but at dosages of 200 micrograms and above, it is also antisecretory.

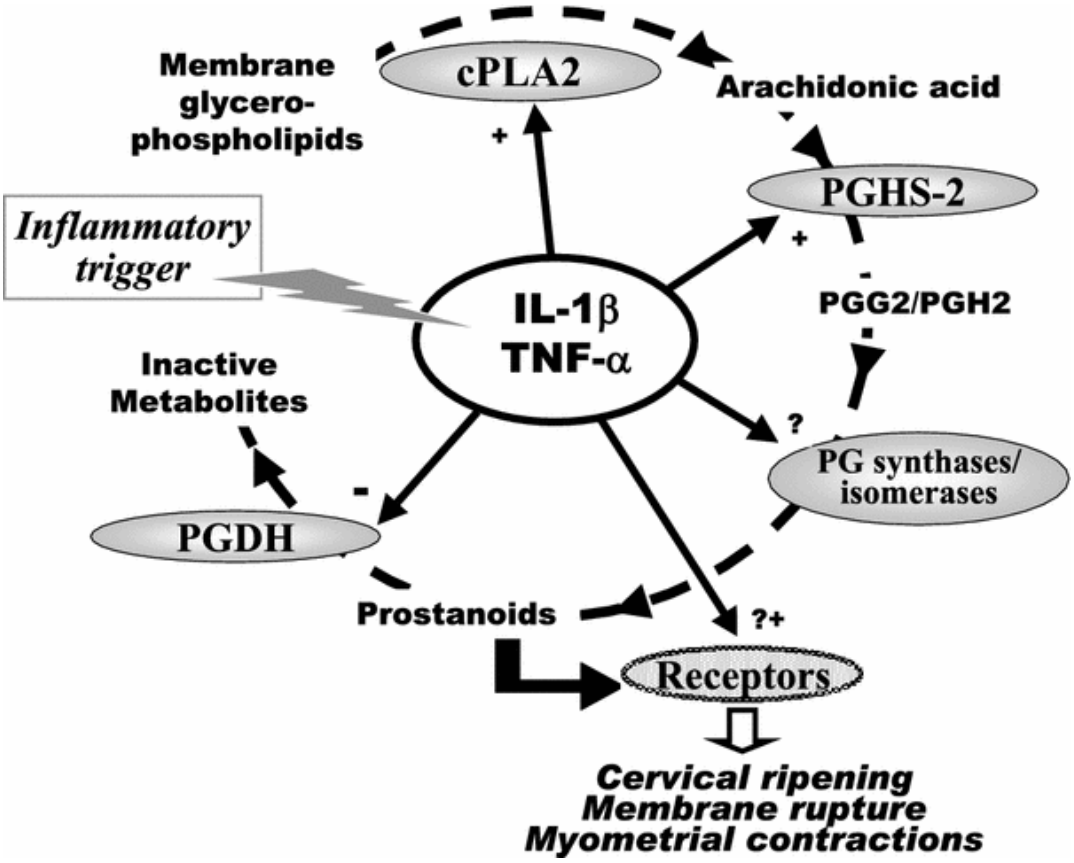
Uterine Effects

Use of misoprostol in pregnancy is risky as it is known to cause uterine contractions.

Indications and Usage for Misoprostol

1. Misoprostol is used to prevent gastric ulcers caused by nonsteroidal anti-inflammatory drugs (NSAIDs), in patients with concomitant disease or those at high risk of developing gastric ulceration, such as those who have had a previous ulcer, such as the elderly, and, such as those who have had a previous ulcer, such as those who have taken aspirin[29].
2. Mifepristone in combination with misoprostol has been shown to be effective and tolerable in the termination of a pregnancy in its early stages (up to 49 days of amenorrhea).[30]
3. Misoprostol was a fantastically effective and safe method of inducing labour at very low doses.[31]

FIG 2: THE ROLE OF PROSTAGLANDINS IN CERVICAL RIPENING AND THE INDUCTION OF LABOR



Advantages of sub-lingual misoprostol

Pregnancy: Teratogenic effects

Misoprostol use during the first trimester of pregnancy has been linked to skull deformities, cranial nerve palsies, facial malformations, and limb problems in several studies.[33]

Nonteratogenic effects

When given to a pregnant woman, misoprostol may put the pregnancy at risk (cause abortion) and hence harm the foetus.[34]

Labor and delivery

Uterine contractions can either be induced or augmented. Misoprostol has been used as a cervical ripening agent, for induction of labour, and for the treatment of significant postpartum haemorrhage in the presence of uterine atony[35], outside of its recognized indications. Hyperstimulation of the uterus, which may proceed to uterine tetany with substantial impairment of uteroplacental blood flow, uterine rupture (requiring surgical repair, hysterectomy, and/or salpingo-oophorectomy), or amniotic fluid embolism, is a major side effect of Misoprostol in obstetrics. Pelvic pain, a retained placenta, acute vaginal bleeding, shock, fetal bradycardia, and fetal and maternal death are some of the symptoms that can occur.[27]

With the use of greater dosages of misoprostol, there may be an increased risk of uterine tachysystole, uterine rupture, meconium passage, meconium staining of amniotic fluid, and caesarean delivery[36] due to uterine hyperstimulation. The risk of uterine rupture increases with advancing gestational ages and with prior uterine surgery, including cesarean delivery.[37] Grand multiparity also appears to be a risk factor for

uterine rupture.

Misoprostol when used for cervical ripening or induction of labour, the effect on the child's later growth, development, and functional maturation has yet to be determined. There is no information on the impact of misoprostol on the requirement for forceps delivery or other interventions.

Nursing mothers

Misoprostol should be used with caution in nursing mothers.[27]

Adverse Reactions

1. Diarrhea
2. Pain Abdomen
3. Nausea
4. Flatulence
5. Headache
6. Dyspepsia
7. Constipation
8. Vomiting

9. Cramps
10. Spotting
11. Hypermenorrhea
12. Dysmenorrhea

Misoprostol Dosage and Administration[38]

Indication	Dosage
NSAID's ulcer prophylaxis	200 µg x 4 times
Induced abortion (0-12 weeks)	800 µg vaginally 12-hrly x3
Missed abortion (0-12 weeks)	800 µg vaginal3-hrly *or sublingual* 600mcg 3-hourly
Incomplete abortion (0-12weeks)	600 µg single oral dose
Induced abortion (13-22 weeks)	400 µg vaginally 3-hrly x5
Intrauterine fetal death	13-17 wks: 200 µg pv 6-hrly. 18-26 wks: 100 µg pv 6-hrly. 27+ wks: 25-50 µg pv 4-hrly
Induction of labour	25 µg vaginally 4-hrly *or* 50 µg orally 4-hrly *or* 20 µg oral solution 2-hrly
PPH prophylaxis	600 µg orally or sublingually stat
PPH treatment	600 µg orally or sublingually stat
Cervical ripening	400 µg vaginally 3h before procedure

Overdosage

Misoprostol's hazardous dose in humans has yet to be established. Only gastrointestinal discomfort was noted after cumulative total daily dosages of 1600 mcg were given.

Contraindications

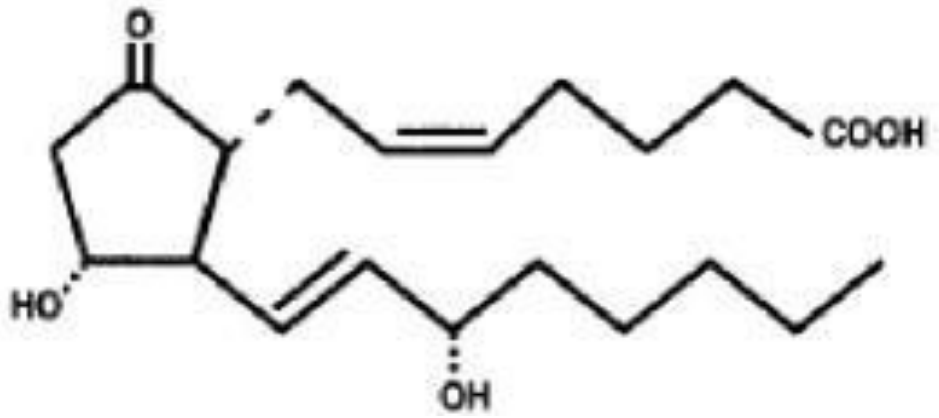
To avoid the risk of ulcers caused by non-steroidal anti-inflammatory medicines, pregnant women should not take misoprostol (NSAIDs). Anyone who has ever had a reaction to prostaglandins should avoid misoprostol.

Precautions

Caution should be employed when administering misoprostol to patients with pre-existing cardiovascular disease.

Dinoprostone (PGE_2)- CLINICAL PHARMACOLOGY

Dinoprostone (also known as prostaglandin E2 or PGE2) has the chemical name 11, 15S-dihydroxy-9-oxo-prosta-5Z,13E-dien-1-oic acid and the structural formula is as follows:



Only prostaglandin E2 Dinoprostone (PGE2) is currently approved for labour induction in healthy pregnancies. This prostaglandin is involved in the cervical ripening process as well as the initiation and maintenance of labour. PGE2 is continually released by the foetal membranes and placenta during pregnancy, and it plays a vital role in cervical ripening without altering uterine contractions in the final events prior to labour start. PGE2 increases the formation of PGF2, which then sensitises the myometrium to endogenous or exogenously given oxytocin, which can start uterine contractions in the early stages of labour. This distinction allows cervical ripening and inducement of

labour (typically with the use of oxytocin) to be treated as two different processes.

A dry vaginal pill, a viscous gel, and a nonbiodegradable hydrogel pessary are all commercially available vaginal PGE2 formulations. Treatment plans range from a single dose of the hydrogel pessary 10 mg or viscous gel 1 mg or 2 mg to recurrent treatments of the gel at six-hourly intervals for a maximum of two doses or three doses of the dry tablet 3 mg. In general, intravaginal and intracervical modes of administration have been used. Approximately two-thirds of reported clinical trials approved for commercial use by the Food and Drug Administration employed the intracervical route (FDA).

The dinoprostone gel comprises 0.5 mg of dinoprostone in 2.5 ml of triacetin and colloidal silicon dioxide gel in a prefilled applicator, with maximal absorption rate of 30–45 minutes and repeat doses at 6-hrly, with a maximum 24-hour dose of 1.5 mg dinoprostone. Macer, J., et al., 1984, conducted placebo-controlled experiments and found that intracervical PGE2 treatment more often leads to effective cervical softening and labour induction in patients with equivalent Bishop scores[40].

A thin, flat, polymeric hydrogel chip (29x9.5x0.8 mm) with rounded edges is commercially available as a sustained-release 10-mg dinoprostone vaginal insert with FDA approval and is inserted in a knitted polyester retrieval pouch. When rehydrated on exposure to the vaginal mucosa, each insert contains 10 mg of dinoprostone in a dry polymer matrix that releases at a controlled rate of 0.3 mg/hour for 12 hours. The insert has been proven to induce cervical ripening in pregnant women who are at or near term, resulting in a Bishop score of at least 3 after 12 hours. This 12-hour period is more likely to result in active labour and vaginal birth, lowering the requirement for oxytocin infusion. Nearly three-quarters of patients only require a single application, according

to Rayburn, W. F., et al., (1992)[41.] Prior to the FDA's approval of intracervical and vaginal insert dinoprostone preparations, hospital-prepared gel was commonly used as a mixed dinoprostone suppository (Prostin E2) and methylcellulose gel (K-Y Jelly) administered vaginally (2.5–5 mg) or intracervically (0.5 mg). Stempel, J. E., et al., (1997) conducted comparative tests and found no benefit of the FDA-approved product over hospital-prepared gels.[42]The most common side effects in patients treated with PGE2 for cervical ripening and labour induction have been tachysystole and uterine hyperstimulation, both of which are dose-dependent and very rarely seen in individuals receiving low dosages (0.5 mg). Other risks associated with PGE2 induction include uterine rupture, amniotic fluid embolism, and myocardial infarction, all of which are serious but uncommon consequences.

The American College of Obstetricians and Gynaecologists recommends that the foetal heart rate and uterine activity be electronically monitored for the length of the insert insertion and for 15 minutes after it is removed.

Contraindications: -

Patients who have a known allergy to prostaglandins should avoid PGE2.

* Patients who have a clinical suspicion or definite proof of foetal distress and are about to deliver, as well as those who are currently on I.v oxytocic medications.

* Pregnant women who have experienced unexplained vaginal bleeding.

* Multipara with 6 or more previous term pregnancies or primi with high suspicion of substantial cephalopelvic disproportion. Patients who are contraindicated for oxytocic medications or in whom prolonged uterine contractions may be harmful to fetal safety or uterine integrity, such as those who have had a

previous caesarean section or severe uterine surgery.

PGE2 should only be used by trained obstetrical workers in a hospital setting with suitable obstetrical care facilities, according to the warnings.

General Precautions: Because prostaglandins increase the potency of oxytocin, they must be eliminated before oxytocin is given or an amniotomy is performed, and the patient's uterine activity must be closely watched for uterine hyperstimulation. When labour begins, the vaginal insert/gel should be removed if uterine hyperstimulation, fetal distress, or other fetal or maternal adverse responses occur. In patients with ruptured membranes, non-vertex or non-singleton presentation, and a history of previous uterine hypertony, glaucoma, or a history of childhood asthma, even if there have been no asthma attacks in adulthood, caution should be exercised in the administration of PG E2 for cervical ripening. When using the PGE2 vaginal insert/gel, keep a close eye on uterine activity, fetal condition, and the course of cervical dilatation and effacement.

Drug Interactions: PGE_2 has synergistic effect with oxytocin and their concomitant use is not recommended. The successive administration of oxytocin after the removal of the dinoprostone vaginal insert/gel is indicated with a dosage interval of at least 30 minutes.

Teratogenic Effects: Pregnancy Category C.

Recommendations by ACOG Review: Consider induction of labour before ripening the cervix, if the cervix is unfavourable (II-2 A). Prostaglandin gel should be given every six to twelve hourly up to maximum of three doses; however, some studies have indicated further dosages (I- II-3). While ACOG recommends intracervical

administration (in addition to vaginal administration), NICE exclusively recommends vaginal administration and discourages oral, intravenous, extra-amniotic, and intracervical administration of PGE2.

Comparison of available literature:

The availability of literature that compares intra-cervical dinoprostone and sub-lingual misoprostol is limited and is mainly confined to the Indian Sub-continent. While there are numerous reports that look at other modes of administration of these agents such as orally and intra-vaginally, the dearth of a head-to-head comparison of these agents sub-lingually and intra-cervically makes the necessity of the present study all the more important. The available literature is carefully examined and summarized below.

A. The effect of misoprostol delivered via various routes on pregnant uterine contractility was investigated by Aronsson et al[43]. They noticed an increase in uterine tonus after oral (7.8 min) and sublingual ((10.7±11.5 min) treatment, but it took a lot less time than vaginal (19.4 min) treatment. The time to maximal tonus elevation was also significantly shorter in all three groups (39.5, 47.1±51.7 and 62.2 min for the three groups respectively). After sublingual and vaginal administration, all participants experienced regular uterine contractions, but not after oral administration. After 2 hours, the rise in uterine activity assessed in Montevideo Units was much higher.

B. Patient satisfaction with two methods of misoprostol for term labour induction was evaluated by AH Nassar et al[8.] Despite the fact that both groups reported the labour induction as being more painful than expected, the sublingual group reported a considerably lower number of pelvic examinations as being extremely painful (19.7% versus 36.1 percent, relative risk [RR] 0.5, 95 percent CI 0.3–0.9). Both groups had comparable requests for analgesia. Most of the women in the sublingual group felt their labour experience was better than expected (RR 2.0, 95 percent CI 1.2–3.3), wanted induction in subsequent pregnancies (RR 1.6, 95 percent CI 1.1–2.3), and preferred sublingual method in next pregnancies (RR 1.6, 95 percent CI 1.1–2.3), and preferred the same route in subsequent pregnancies (RR 1.6, 95 percent CI 1.1–2.3).

C. A study by Bartusevicius et al.4 looked at the efficacy and safety of combining 50 g of sublingual misoprostol with 25 g of vaginal misoprostol for term labour induction. They discovered that the time between induction and vaginal birth was significantly shorter in the sublingual group (15.0 3.7 hours, P = 0.03) than in the vaginal group (16.7 4.1 hours, P = 0.03). Although not statistically significant, the sublingual group exhibited a three-fold higher rate of tachysystole than the vaginal group (14 versus 4.3 percent; RR 3.3, 95 percent CI 0.9–11.6). The incidence of hypertonus or hyperstimulation syndrome, mode of delivery, interventions for fetal distress or neonatal outcomes

between the two groups were not significant.

D. Veena et al [19] from Karnataka in 2015 conducted a randomized control trial on 190 cases where they compared sub-lingual Misoprostol versus intra-cervical Dinoprostone gel for induction of Labour. They found that post-induction mean Bishop's score in misoprostol group was significant. They further found that failed induction rate and need for augmentation were significantly lower with misoprostol when compared to dinoprostone. Significantly higher rates of normal vaginal delivery, lower LSCS rates, and lower incidence of fetal complications were seen with misoprostol. Misoprostol was also significantly more cost effective. Based on these findings, they concluded that sub-lingual misoprostol was a better cervical ripening agent as compared to intra-cervical dinoprostone.

E. Jha et al [44] from Puducherry in 2015 conducted a study on 188 women where they compared the efficacy and safety of sub-lingual misoprostol versus intra-cervical dinoprostone gel for cervical ripening in patients with prelabour rupture of membranes (PROM) after 34 weeks of pregnancy. They found that there was a significantly shorter induction to delivery interval in the sub-lingual misoprostol group versus the intra-cervical dinoprostone. They also found that there was a significantly lower

lower duration of rupture of membrane to delivery interval and a shorter 1st stage of labour in sub-lingual misoprostol group. However, they failed to demonstrate a difference in spontaneous vaginal delivery between misoprostol and dinoprostone. The requirement of oxytocin was significantly higher in the dinoprostone group. Misoprostol was found to have more frequent maternal adverse effects but safety profiles were comparable in neonates.

F. However, Raghavan et al[45] from Chennai in 2017 conducted a study comparing intra-cervical dinoprostone versus sublingual misoprostol for the pre-induction cervical ripening in 410 cases and they had opposing findings in many regards. They found no significant difference in mean number of doses required with respect to the bishop's score with misoprostol but significant difference with dinoprostone was used. This was in direct contrast contrast to Veena et al's [46] findings. Raghavan et al further found that there was no statistically significant difference noted in the induction to active phase interval or induction to delivery interval or in the neonatal outcomes between misoprostol and dinoprostone. In the dinoprostone group, there was however significantly higher failed induction while in the misoprostol group, there was significantly lesser oxytocin requirement. Their main

point of interest was in the comparison of cost and they found that that the mean cost was 37.75 times higher when using dinoprostone. They concluded that based on their findings, the biggest advantage of misoprostol over dinoprostone was in terms terms of cost rather than clinical advantages, or rather misoprostol was non-inferior with better cost effectiveness[47].

G. In 2019, Deepika et al[48] from Karnataka conducted a comparative comparative study between sub-lingual misoprostol and intra-cervical dinoprostone Gel in labour induction using 200 participants. They found no significant difference in induction to delivery time between the groups. They found that stage II of labor significantly shorter in the misoprostol group. Normal vaginal delivery was higher with misoprostol although not statistically significant. Apgar score (≥7) at 1 min was comparable comparable across both groups. The requirement of labour augmentation by artificial rupture of the membrane was significantly lower with misoprostol as compared to dinoprostone. The need of NICU admission was similar across the groups. They They concluded that misoprostol showed an overall shorter IDI, greater number of vaginal deliveries with fewer cesarean sections sections when compared to the dinoprostone group. Combined with other results, their final conclusion was that misoprostol was

more efficacious than dinoprostone.

H. In 2019 again, Jahangir et al[49] from Hyderabad conducted a study on sub-lingual misoprostol compared to dinoprostone gel in induction of labour in 100 cases. They found that the average time for labour onset was lower in the misoprostol group. Similarly, similar shorter time intervals in misoprostol use were seen across the induction phase to the active phase and the active phase at the time of administration to delivery. They further found that the rate of LSCS was lower in the misoprostol group. Maternal side effects and the neonatal outcomes were comparable across the two groups. In keeping with the previous reports, they found that the cost was much lower with misoprostol use. They concluded that misoprostol was a safe, economical, and effective agent that was suitable for the induction of labour.

I. In 2019 again, Panchal et al[50] from Ahmadabad compared misoprostol sub-lingually with dinoprostone gel intra-cervically for cervical ripening and induction of labour in 200 women. They found shorter induction to delivery time, higher vaginal delivery rate, less requirement of oxytocin augmentation, and lower LSCS in the misoprostol group. However, they also found that the incidence of tachysystole was greater with misoprostol use. Other maternal and neonatal complications were

comparable between misoprostol and dinoprostone. They concluded that lower dose misoprostol was a safe and economical method for labour induction and cervical ripening.

MATERIALS AND METHODS

MATERIALS AND METHODS

STUDY SETTING:

- Patients admitted in Department of OBSTERTICS AND GYNAECOLOGY in B.L.D.E. (DEEMED TO BE UNIVERSITY) Shri B.M.Patil's Medical College Hospital and Research Centre, Vijayapura for induction of labour fulfilling the inclusion exclusion criteria.
- The patients will be informed about study in all respects and informed written consent will be obtained.
- Period of study will be from Novemeber 2019- 31stAPRIL 2021.

STUDY DESIGN:

Prospective observational Study

PATIENT SELECTION:

A set of patients, who satisfied the inclusion criteria were selected from the departments of Obstetrics and Gynaecology. In total, 84 patients were selected to be part of the study.

INCLUSION CRITERIA

1. Singleton pregnancy
2. Cephalic presentation
3. BISHOP SCORE<6
4. Post maturity
5. FGR
6. Oligohydromnios and polyhydromnios
7. Rh isoimmunization
8. Premature rupture of membranes
9. IUD

EXCLUSION CRITERIA

1.Absolute contracted pelvis and cephalopelvic disproportion

2.Pre-Existing Cardiac Disorders

3.Malpresentation (breech, transverse, oblique lie)

4.Previous lscs or hysterotomy

5.Vasa previa, placenta previa

6.Acute genital herpes.

7.umbilical cord prolapse

8.abruptio placenta

9.cervical carcinoma

METHODS OF DATA COLLECTION:

Patients will be assigned to a randomized trial using a computer-generated randomization sequence and will be administered sublingual Misoprostol and Intracervical Dinoprostone gel for induction of labour.They will be assessed and Bishop score will be evaluated.

Group A: Patients in group A will be given 50micrograms of sublingual misoprostol which is to be repeated at 4hourly interval with 25micrigrams of misoprostol. until uterine activity or favourable score is attained. Participant will be reassessed using the modified bishop's score after 4hours and routine protocol is followed.

Group B: 0.5mg of dinoprostone is administered intracervically under aseptic conditions, and the patient is examined after 6 hours and is to be repeated upto 3 maximum doses. If the bishop's score remains less than 6, routine protocol is followed.

The hospital protocol will be followed if the bishop's score remained 6 following the maximum dosages of sublingual misoprostol or dinoprostone in both groups. The progress and outcome of the labour will be evaluated.

As per the hospital protocol, if the induction of labour fails even after the maximum doses of induction of labour, caesarean section to be considered

DEFINITIONS AND TECHNIQUES

MODIFIED BISHOP SCORE [25]:

FACTOR	0	1	2	3

DILATATION	0	1-2	3-4	5+
CERVICAL LENGTH	>4	2-4	1-2	<1
STATION	-3 OR HIGHER	-2	-1,0	+1,+2
CONSISTENCY	FIRM	INTERMEDIATE	SOFT	
POSITION	POSTERIOR	MID	ANTERIOR	

TOTAL SCORE: 13

FAVOURABLE SCORE : 6.

UNFAVOURABLE SCORES : 1-5

STATISTICAL METHODS

SAMPLE SIZE:

- On the basis of a study Braganza e.tal the anticipated Mean±SD of post

induction mean Bishop's score inPGE1and PGE2 8.59±1.59 and 6.77±2.19 The minimum sample size is 42 per group with 5% level of significance and 95% power.

Formula used is

$$N=2\left[(Z\alpha+Z\beta\times S)\div d\right]^2$$

- Level of significance=95%
- power of the study=90%
- d=clinically significant difference between two parameters
- SD= Common standard deviation

STATISTICAL ANALYSIS:

- Numerical variables will be presented as Mean ±SD, and categorical variables will be presented as frequency (%) and diagrams
- Comparison of numerical variables between groups will be found using unpaired t test/ Mann
- Whitney U test, and categorical variables by Chi square or Fisher's Exact test.

RESULTS

RESULTS

A total of 84 patients who met the pre-determined criteria who presented to labour room, BLDE hospital, vijayapura were included in the study.

Analysis was done under following headings:

- Descriptive Statistics

- Clinical details of the patient

AGE WISE DISTRIBUTION

Age(Years)	Sublingual Misoprostol		Dinoprostone	
	No. of patients	%	No. of patients	%
< 25	21	50.0	18	42.9
25 - 29	16	38.1	17	40.5
30+	5	11.9	7	16.7
Total	42	100.0	42	100.0

TABLE 1 SHOWS DISTRIBUTION OF CASES ACCORDING TO MATERNAL AGE IN BOTH THE GROUPS.

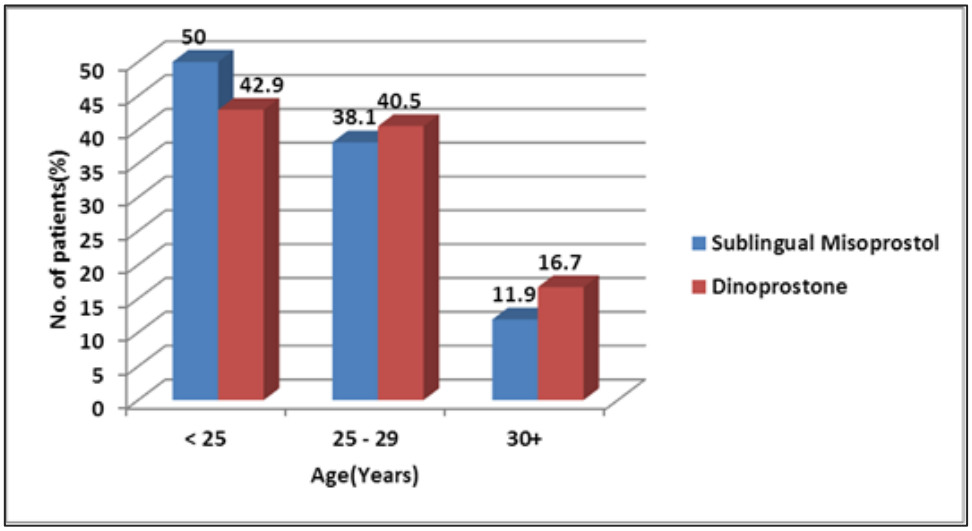


FIGURE1: AGE DISTRIBUTION BAR CHART

TABLE 2: SHOWS DISTRIBUTION OF PARITY IN BOTH THE STUDY GROUPS

PARITY	Sublingual Misoprostol		Dinoprostone		Chi square test	P value
	No. of patients	%	No. of patients	%		
Multi gravida	27	64.3	27	64.3	0.000	1.000
PRIMI	15	35.7	15	35.7		
Total	42	100.0	42	100.0		
STATISTICALLY NOT SIGNIFICANT						

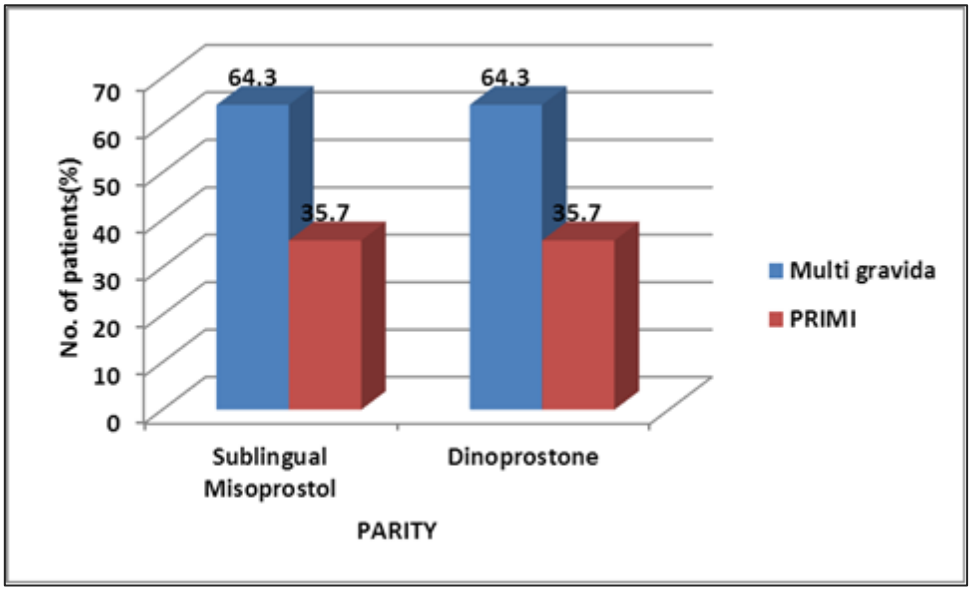


FIGURE 2: PARITY DISTRIBUTION BAR CHART

TABLE 3: POG(WEEKS)

POG(weeks)	Sublingual Misoprostol		Dinoprostone		Chi square test	P value
	No. of patients	%	No. of patients	%		
< 38	6	14.3	8	19.0	0.5444	0.7677
38 - 40	32	76.2	29	69.0		
41+	4	9.5	5	11.9		
Total	42	100.0	42	100.0		
STATISTICALLY NOT SIGNIFICANT						

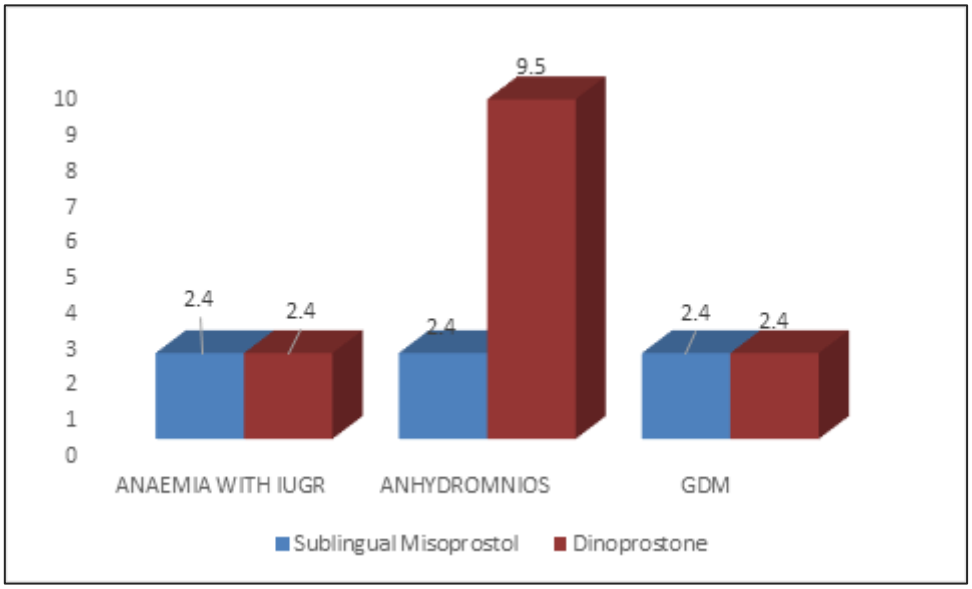


FIGURE 3: POG(WEEKS) DISTRIBUTION BAR CHART

TABLE 4: INDICATION FOR INDUCTION

INDICATION FOR INDUCTION	Sublingual Misoprostol		Dinoprostone		Chi square test	P value
	No. of patients	%	No. of patients	%		
ANAEMIA WITH IUGR	1	2.4	1	2.4	10.002	0.6158
ANHYDROMNIOS	1	2.4	4	9.5		
GDM	1	2.4	1	2.4		
GHTN	1	2.4	5	11.9		

HELLP SYNDROME	**4**	**9.5**	**1**	**2.4**		
IMMINENT ECLAMPSIA WITH IUGR	**1**	**2.4**	**1**	**2.4**		
IUD	**4**	**9.5**	**3**	**7.1**		
OLIGO	**4**	**9.5**	**8**	**19.0**		
OLIGOHYDOMNIOS WITH PROM	**1**	**2.4**	**1**	**2.4**		
POSTDATED	**17**	**40.4**	**10**	**23.8**		
SEVERE OLIGO	**1**	**2.4**	**1**	**2.4**		
SEVERE PE	**4**	**9.5**	**5**	**11.9**		
SEVERE PE WITH IUGR WITH OLIGO	**2**	**4.8**	**1**	**2.4**		
Total	**42**	**100.0**	**42**	**100.0**		
STATISTICALLY NOT SIGNIFICANT						

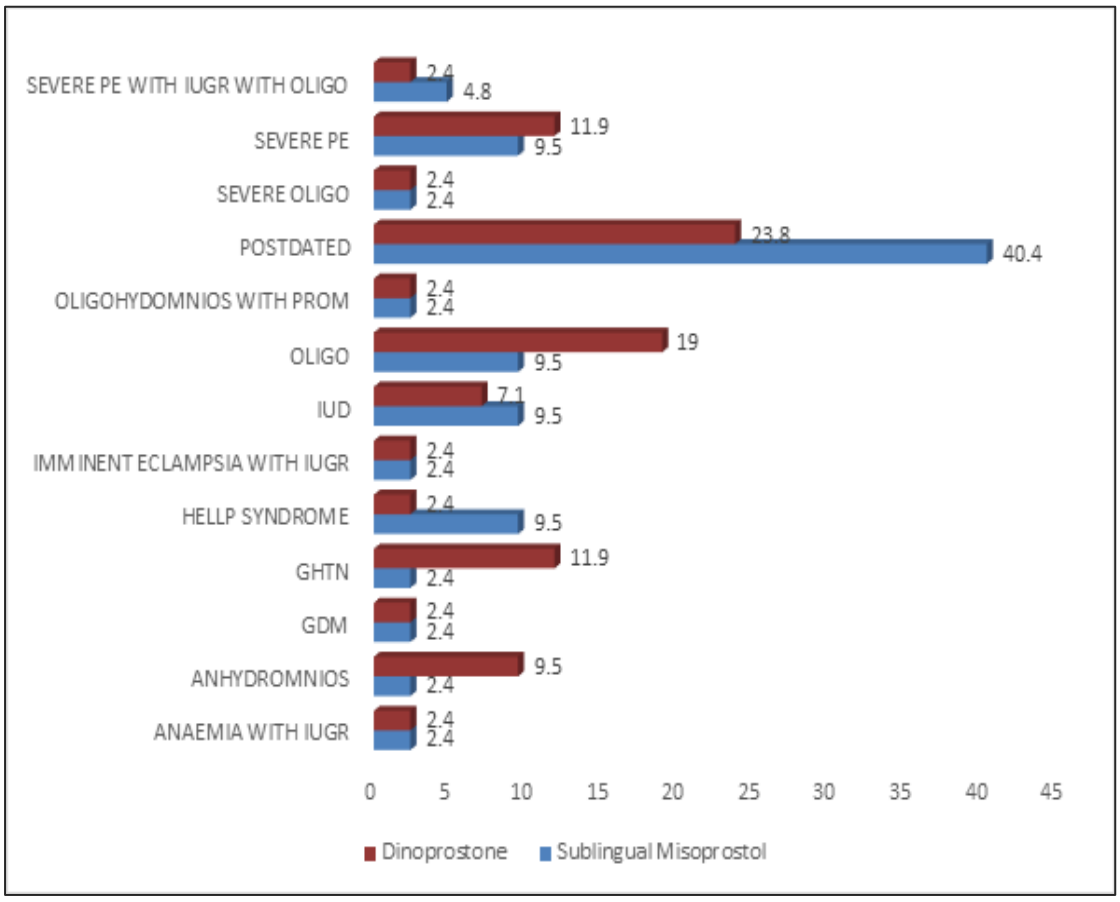


FIGURE 4: INDICATION FOR INDUCTION BAR CHART

TABLE 5: MODIFIED BISHOP'S SCORE AFTER INDUCTION

M.BISHOP'S SCORE AFTER INDUCTION	Sublingual Misoprostol		Dinoprostone		Chi square test	P value
	No. of patients	%	No. of patients	%		
5.	1	2.4	0	0	30.774	0.002
6.	3	7.1	1	2.4		
7.	1	2.4	2	4.8		
8.	20	47.6	13	31.0		
9.	4	9.5	6	14.3		
10.	1	2.4	17	40.5		
11.	1	2.4	2	4.8		
12	0	0	1	2.4		
NOT ASSESSED	11	26.2	0	0		
Total	42	100.0	42	100.0		
STATISTICALLY SIGNIFICANT						

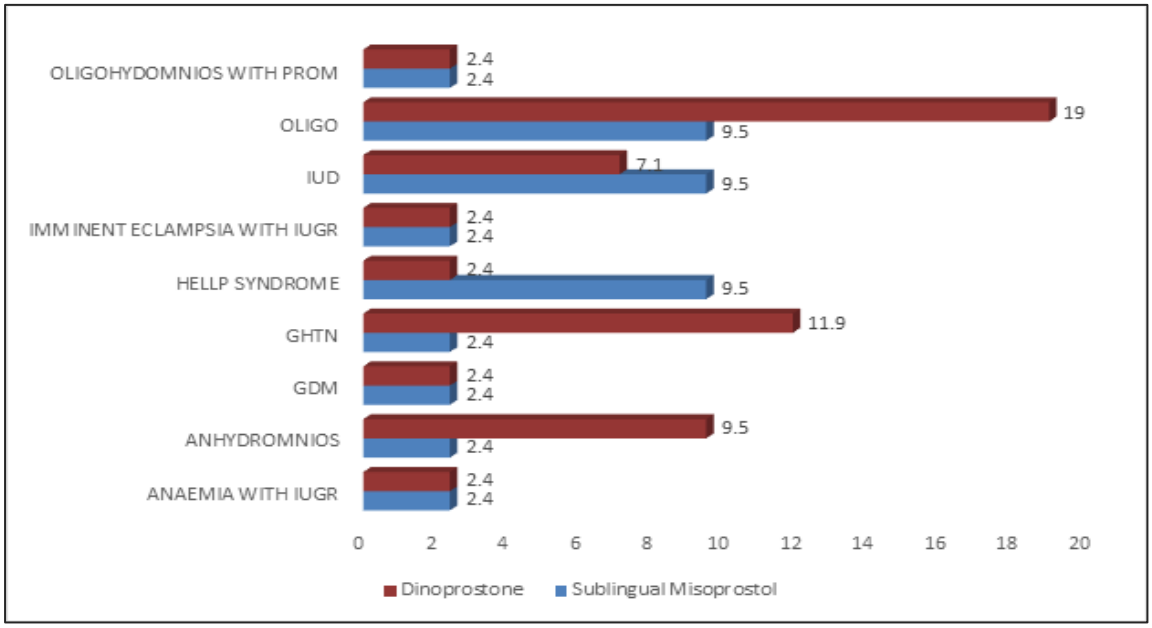


FIGURE 5: MODIFIED BISHOP'S SCORE AFTER INDUCTION

BAR CHART

TABLE 6: COLOR OF LIQOUR

COLOR OF LIQOUR	Sublingual Misoprostol		Dinoprostone		Chi square test	P value
	No. of patients	%	No. of patients	%		
CLEAR	12	28.6	32	76.2	21.891	0.0001
DARK BROWN	2	4.8	3	7.1		
MECONIUM	28	66.7	7	16.7		
Total	42	100.0	42	100.0		
STATISTICALLY SIGNIFICANT						

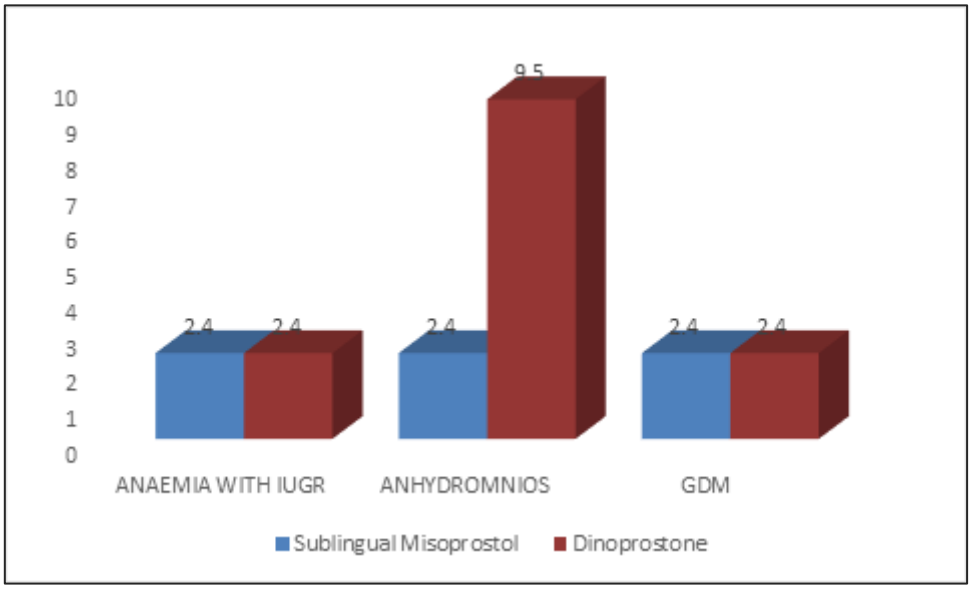


FIGURE 6: COLOR OF LIQOUR DISTRIBUTION BAR CHART

TABLE 7: MODE OF DELIVERY

COLOR OF LIQOUR	Sublingual Misoprostol		Dinoprostone		Chi square test	P value
	No. of patients	%	No. of patients	%		
NVD	27	64.3	38	90.5	14.209	0.0026
LSCS IN VIEW OF FETAL DISTRESS	15	35.7	4	9.5		
Total	42	100.0	42	100.0		
STATISTICALLY SIGNIFICANT						

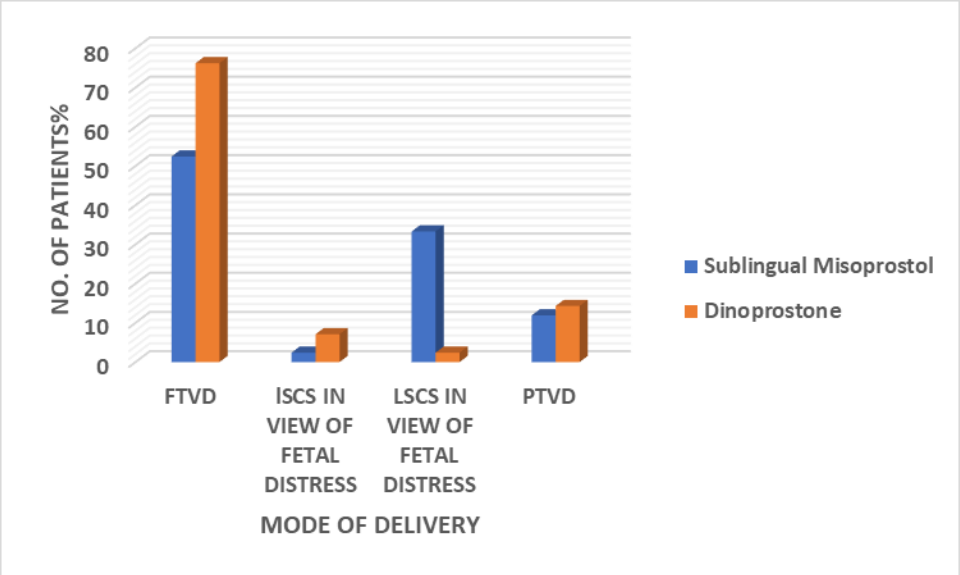


FIGURE 7: MODE OF DELIVERY BAR CHART

TABLE 8: PERINATAL OUTCOME

PERINATAL OUTCOME	Sublingual Misoprostol		Dinoprostone		Chi square test	P value
	No. of patients	%	No. of patients	%		
IUD	4	9.5	6	14.3	41.248	0.0001
MOTHER SIDE	6	14.3	32	76.2		
NICU ADMISSION,RDS	32	76.2	4	9.5		
Total	42	100.0	42	100.0		
STATISTICALLY SIGNIFICANT						

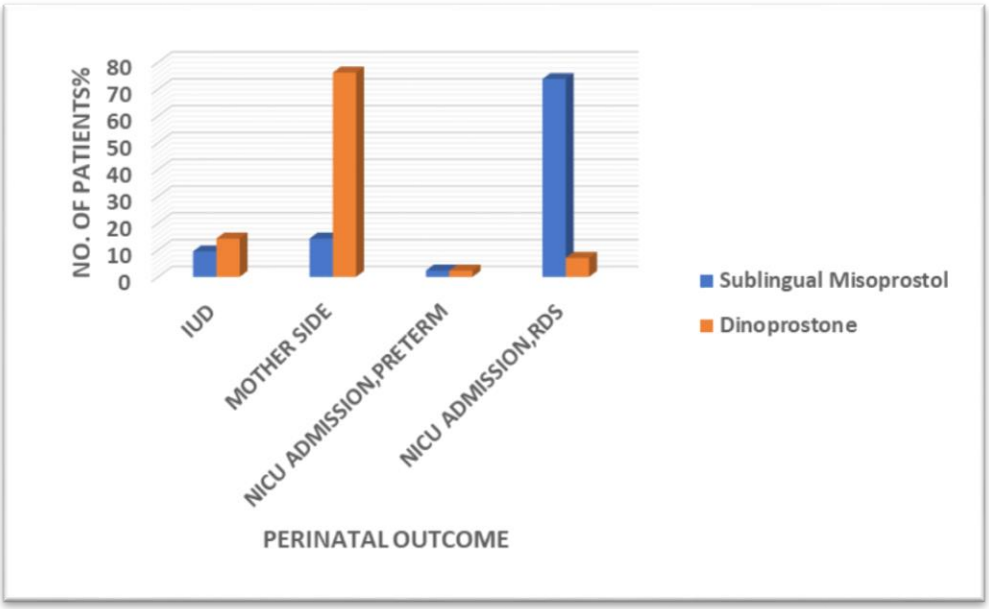


FIGURE 8: PERINATAL OUTCOME BAR CHART

TABLE 9: ADVERSE EFFECTS

ADVERSE EFFECTS	Sublingual Misoprostol		Dinoprostone		Chi square test	P value
	No. of patients	%	No. of patients	%		
FETAL DISTRESS	2	4.8	1	2.4	65.716	0.0001
NIL	1	2.4	36	85.7		
SHIVERING	15	35.7	2	4.8		
SHIVERING AND FEVER	1	2.4	1	2.4		

SHIVERING,FETAL DISTRESS	**1**	**2.4**	**2**	**4.8**		
SHIVERING,FEVER AND FETAL DISTRESS	**12**	**28.6**	**0**	**0**		
SHIVERING,FEVER AND UTERINE HYPERSTIMULATION	**5**	**11.9**	**0**	**0**		
SHIVERING,FEVER,FETAL DISTRESS,UTERINE HYPERSTIMULATION	**2**	**4.8**	**0**	**0**		
SHIVERING,FEVER,UTERINE HYPERSTIMULATION AND FETAL DISTRESS	**1**	**2.4**	**0**	**0**		
SHIVERING,TACHYSYSTOLE AND FEVER--	**1**	**2.4**	**0**	**0**		
SHIVERING,UTERINE HYPERSTIMULATION	**1**	**2.4**	**0**	**0**		
Total	**42**	**100.0**	**42**	**100.0**		
STATISTICALLY SIGNIFICANT						

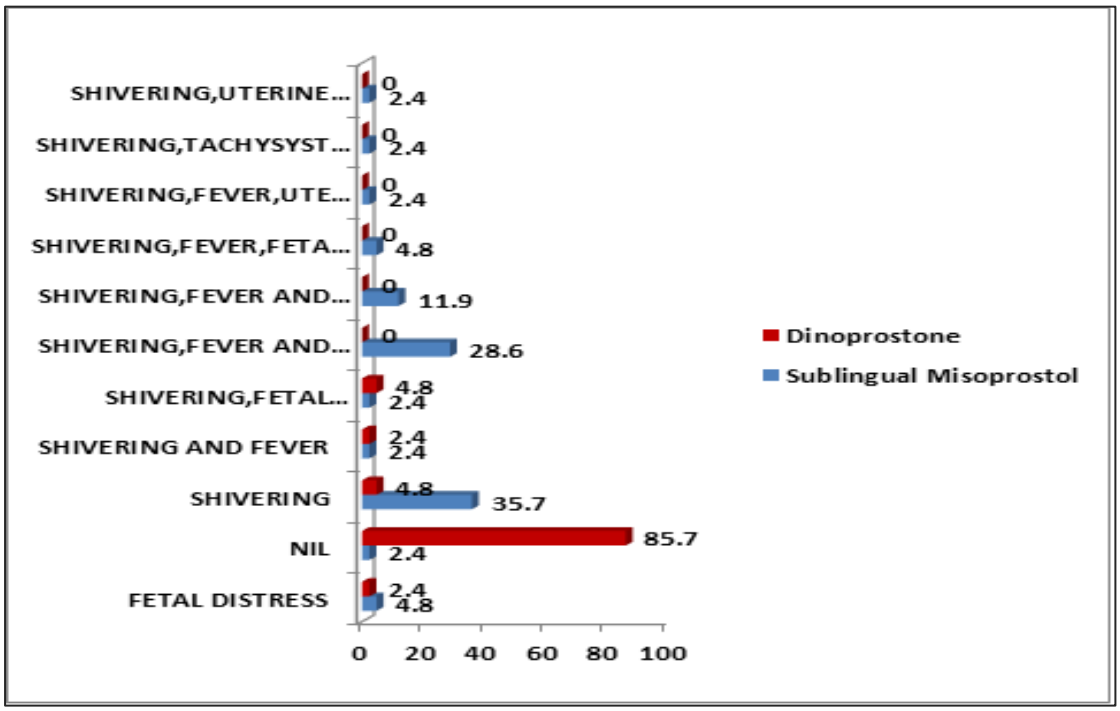


FIGURE 9: ADVERSE EFFECTS DISTRIBUTION BAR CHART

TABLE 10: NO. OF DOSES

NO. OF DOSES	Sublingual Misoprostol		Dinoprostone		Chi square test	P value
	No. of patients	%	No. of patients	%		
<= 1	24	57.1	21	50.0	0.4308	0.5116
2+	18	42.9	21	50.0		
Total	42	100.0	42	100.0		
STATISTICALLY NOT SIGNIFICANT						

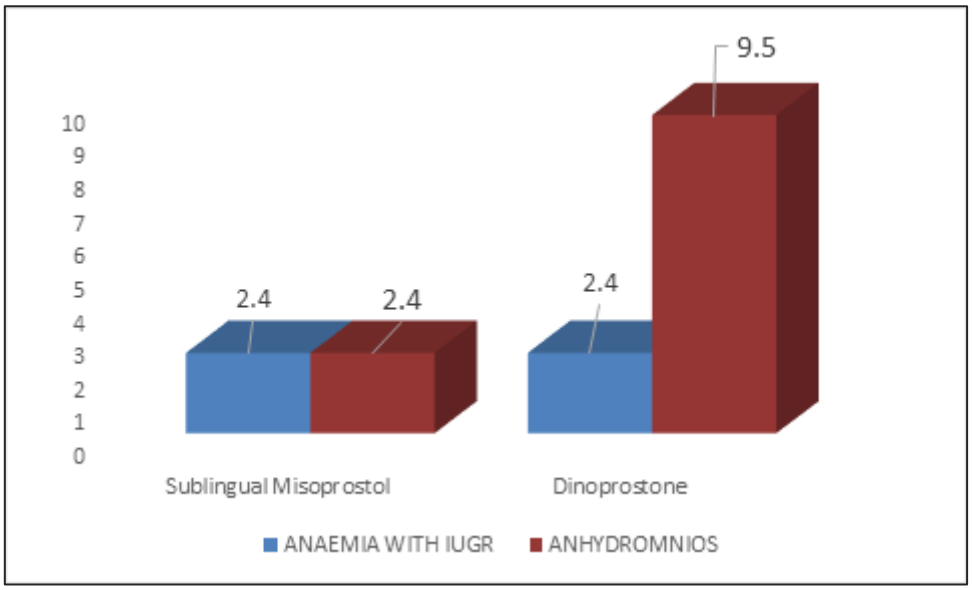


FIGURE 10 : NO. OF DOSES DISTRIBUTION BAR CHART

Table 11: INDUCTION TO NORMAL DELIVERY

INDUCTION TO NORMAL DELIVERY	Sublingual Misoprostol		Dinoprostone		Chi square test	P value
	No. of patients	%	No. of patients	%		
<= 12	19	45.2	32	76.2	11.380	0.0034
13+	8	19.0	7	16.7		
LSCS	15	35.7	3	7.14		
Total	42	100	42	100		
STATISTICALLY SIGNIFICANT						

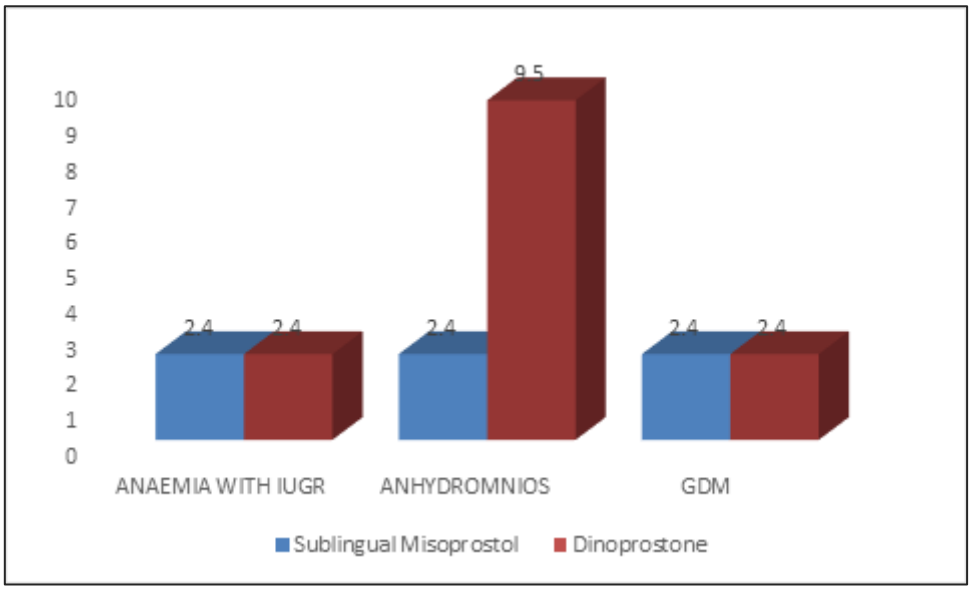


FIGURE 11:INDUCTION TO NORMAL DELIVERY

DISTRIBUTION BAR CHART

TABLE 12: INDUCTION TO ACTIVE LABOUR

INDUCTION TO ACTIVE LABOUR	Sublingual Misoprostol		Dinoprostone		Chi square test	P value
	No. of patients	%	No. of patients	%		
<= 8	18	42.9	28	66.7	13.211	0.0014
9+	13	31.0	14	33.3		
LSCS	11	26.1	-	-		
Total	42	100	42	100.0		
STATISTICALLY SIGNIFICANT						

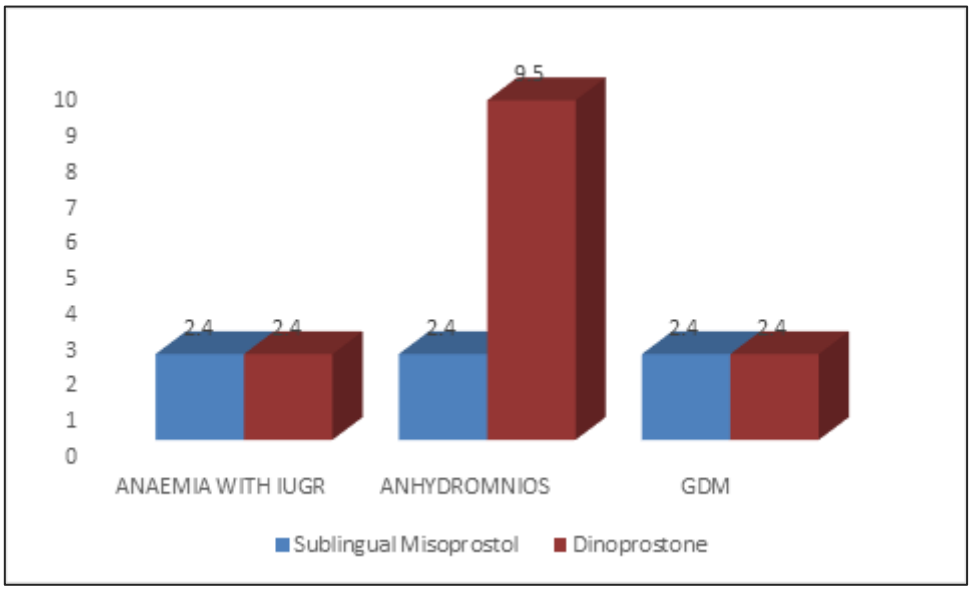


FIGURE12 :INDUCTION TO ACTIVE LABOUR DISTRIBUTION BAR CHART

TABLE 13: DESCRIPTIVES OF SUBLINGUAL MISOPROSTOL

Descriptive Statistics	N	Minimum	Maximum	Mean	Std. Deviation
AGE	42	20	35	24.79	3.579
POG	42	29	42	38.50	2.973
M.BISHOP'S AFTER	31	5	11	7.97	1.140

INDUCTION					
INDUCTION TO ACTIVE LABOUR	**31**	**1**	**20**	**7.52**	**5.691**
INDUCTION TO	**27**	**2**	**22**	**9.78**	**5.905**
NO. OF DOSES	**42**	**1**	**4**	**1.86**	**1.138**

TABLE 14: DESCRIPTIVES OF DINOPROSTONE

Descriptive Statistics	N	Minimum	Maximum	Mean	Std. Deviation
AGE	**42**	**19**	**34**	**25.15**	**3.518**
POG(weeks)	**42**	**30**	**42**	**38.76**	**2.477**
ON ADMISSION M.BISHOP'S	**42**	**6**	**12**	**9.10**	**1.246**
INDUCTION TO ACTIVE LABOUR	**42**	**5**	**16**	**8.00**	**2.518**
INDUCTION TO	**39**	**8**	**20**	**10.69**	**2.839**
NO. OF DOSES	**42**	**1**	**3**	**1.55**	**.593**

DISCUSSION

DISCUSSION

Patients were chosen as eligible candidates for our study, and 84 patients were involved.

In our study, there was no difference in age, parity, gestational age, number of dosages, or indication of induction between the two groups. In comparison to those given 25 μg of sublingual misoprostol, intracervical dinoprostone gel administration

resulted in a good modified bishop's score, significantly shorter duration of induction to active labour, and significantly shorter duration of induction to delivery interval [p0.05], fewer side effects, and fewer pelvic examinations required.

Misoprostol serum peak concentrations were substantially higher after sublingual administration than after oral or vaginal administration, according to Tang et al.[5.] Furthermore, after sublingual treatment, the area under the curve for plasma levels throughout 4 and 6 hours was significantly higher than after oral or vaginal administration. A recent study42 looked at the effects of misoprostol on uterine contractility when given through various methods of administration. In terms of effects on the myometrium, sublingual misoprostol had the same quick effect on uterine contractility as oral misoprostol, and the bioavailability was similar.

In their investigation, Bartusevicius et al[4] found the same outcome. In contrast to our investigation, they used 50 μg of sublingual misoprostol instead of 25 μg. Our research found that 25 μg delivered sublingually had the same effect as 25 μg administered vaginally in terms of induction delivery time and the number of misoprostol tablets used for induction. It has the potential to lower management costs. Vaginal birth rates were 57 percent in the sublingual group and 69 percent in the vaginal group, according to Feitossa et al.43. The sublingual group had 11 occurrences of fetal discomfort, while the vaginal group had four. They had been taking 25 μg of misoprostol sublingually every 6 hours. Though they found a substantial difference in value between the groups, the percentage of vaginal deliveries was relatively low [57

percent and 69 percent vs 81.7 percent and 75 percent in our study]. It could be because their dosage interval was longer [6 hours vs. 4 hours] than ours.

Tang et al.[5] discovered that the blood levels of MPA in the vaginal groups were greater at the end of 6 hours than those in the sublingual and oral groups after analyzing the pharmacokinetics of misoprostol in different routes of administration. To achieve significant plasma levels, the sublingual dosing interval should be less than this period. Feitossa et al.43 found a lower percentage of vaginal deliveries, which could be attributed to their longer dose interval [6 hours vs 4 hours]. As a result, we chose a 4-hour repeat dose interval in our research.

Induction active labour interval and delivery interval measurement was shorter in dinoprostone group compared to sublingual misoprostol group and was significant.

The number of pelvic examinations performed prior to delivery was significantly reduced in our study. When the number of pelvic examinations is reduced, the patient feels more at ease. We didn't include a satisfaction metric in our analysis because it was outside of our scope. Nasser et al[8] looked at patient satisfaction and found that sublingual misoprostol was a better method of delivery than vaginal misoprostol. Because fewer vaginal inspections are required, this form of delivery may lower the risk of infection, especially in PROM patients. Given these facts and our observation of a considerable reduction in the number of pelvic examinations, the sublingual route of misoprostol administration may be a viable option.

There was a significant difference in mode of delivery in our study. When

compared to intracervical dinoprostone gel, the number of lscs in the sublingual misoprostol group increased. The indication for a caesarean delivery did not differ much. In comparison, the dinoprostone group had a higher number of vaginal deliveries.

The benefits (shorter time to delivery) and risks (different routes of misoprostol administration for labour induction) must be carefully balanced (uterine hyperstimulation, adverse neonatal and maternal outcomes). In our investigation, the prevalence of tachysystole, hypertonus, and hyperstimulation syndrome was reported but not statistically significant. Tachysystole was 3 times higher in the 50 μg sublingual group than in the vaginal group in a recent study[4]. There were no significant changes in the number of women who had hyperstimulation syndrome, the mode of delivery, or the neonatal outcome between the two groups. We found no significant value for tachysystole with an initial dose of 50 μg and a repeat dose of 25 μg of sublingual misoprostol in our trial, but due to the small sample size, we cannot infer on an unfavorable effect. As previously stated, excessive uterine activity was not lessened due to the direct effect on the cervix. But, according to our findings, reducing the dose can reduce this risk without jeopardizing our primary goal.

In our trial, the newborn outcomes in the dinoprostone arm were better than the sublingual misoprostol group. When compared to dinoprostone gel, NICU admissions were observed to be higher in the sublingual misoprostol arm. Despite the fact that our study found no substantial prenatal morbidity or mortality. We cannot draw definitive

conclusions on the safety of sublingual misoprostol in this setting due to the small sample size of our study.

Sublingual dosage for labour induction is appealing since it is simple to administer, requires less frequent vaginal examination, gives you more flexibility of movement, and can be used even if you have vaginal bleeding or torn membranes. When compared to alternative forms of induction, the cost of management was also cheap. Despite the fact that this was not tested in the current study, we believe that the sublingual route has a greater patient acceptability rate than oral administration when compared to vaginal administration.

CONCLUSIONS

CONCLUSIONS

we conclude that 0.5mg of dinoprostone gel administered intacervically every 6th hourly for maximum of 3 doses was more effective for induction of labour than 50 μg of sublingual misoprostol followed by 25micrograms administered every 4th hourly for maximum of 6 doses in terms of shortened induction to active labour interval, colour of liqour, perinatal outcome, mode of delivery and less number of pelvic examinations required. Sublingual misoprostol group had decreased vaginal delivery rate and increased caesarean section producing significant complications like hypertonus, tachysystole and hyperstimulation syndrome, meconium stained liqour than intracervical dinoprostone gel group. NICU admissions were very less in intracervical dinoprostone gel group compared to sublingual misoprostol group. Need of oxytocin augmentation was more with sublingual misoprostol group. Fever with chills was seen in sublingual misoprostol group

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BIBLIOGRAPHY

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APPENDIX

CONSENT FORM

B.L.D.E. (DEEMED TO BE UNIVERSITY)

SHRI B.M.PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTER, VIJAYAPURA-586103

INFORMED CONSENT FOR PARTICIPATION IN DISSERTATION/RESEARCH

I, the undersigned, _____, S/O D/O W/O _____, aged ____years, ordinarily resident of _____ do hereby state/declare that Dr. POLISETTY S.V.S.N.M.M. LAKSHMI PRIYA of Shri. B. M. Patil Medical College Hospital and Research Centre has examined me thoroughly on _____ at _____ Further Dr. POLISETTY S.V.S.N.M.M. LAKSHMI PRIYA informed me that he/she is conducting dissertation/research titled "A Randomized trial of sublingual misoprostol versus intracervical dinoprostone gel for induction of labour" under the guidance of Dr. P.B.JAJU requesting my participation in the study. According to this I will be assigned to a parallel randomized trial. I will be administered either of the drugs and evaluated for the induction of labour and outcomes of the pregnancy. Further Doctor has informed me that my participation in this study help in evaluation of the results of the study which is useful reference to treatment of other similar cases in near future.

The Doctor has also informed me that information given by me, observations made/ photographs/ video graphs taken upon me by the investigator will be kept secret and not assessed by the person other than me or my legal hirer except for academic purposes.

The Doctor did inform me that though my participation is purely voluntary, based on information given by me, I can ask any clarification during the course of treatment / study related to diagnosis. At the same time, I have been informed that I can withdraw from my participation in this study at any time if I want or the investigator can terminate me from the study at any time from the study but not the procedure of treatment and follow-up unless I request to be discharged.

After understanding the nature of dissertation or research, diagnosis made, mode of treatment. I am giving consent for the blood investigations and also for the follow up.

I the undersigned Shri/Smt _____ under my full conscious state of mind agree to participate in the said research/dissertation.

Signature of patient:

Signature of doctor:

Witness: 1.

2.

Date:

Place

PROFORMA

Name: IPNo:

Age:

Case.no:

Address:

Occupation:

DOA:

Contact no: 1.

DO Study:

Mobile no : 2.

1.Obstetric History :

1. ML:

2.Obstetric score: G P L A

2.MENSTRUAL HISTORY:

1: LMP:

2: EDD:

3: POG:

2.Past History:

3.Family Hisory

4.PERSONAL HISTORY:

5.GENERAL PHYSICAL EXAMINATION

PR: RR:

BP: TEMPERATURE:

SYSTEMIC EXAMINATION

CVS:

RS:

P/A:

P/S:

P/V:

DIAGNOSIS:

INDICATION FOR INDUCTION OF LABOUR:

STUDY PARAMETERS :

INDUCTION TO ACTIVE LABOUR INTERVAL

BISHOPS SCORE

1. On admission:

2. After induction:

AUGMENTATION WITH OXYTOCIN OR ARM

INDUCTION TO DELIVERY INTERVAL

COLOR OF LIQOUR

. MODE OF DELIVERY:

- Vaginal delivery:
- Instrumental delivery:
- LSCS: Indication:

9.PERINATAL OUTCOME:

- Mother side:
- NICU:

- Mortality:

10.FOLLOWUP:

CBC:

11.ADVERSE EFFECTS:

SHIVERING

FEVER

UTERINE HYPERSTIMULATION

FETAL DISTRESS

MATERNAL INFECTION

REMARKS:

MASTERCHART

SL NO	GROUP	NAME	IP NO	AGE	DOA	PARI	POG	CERVICAL ON ADMISSION M BISHOP'S SCO	INDICATION FOR INDUCTION	INDUCTION TO ACTIVE LABOUR	M.BISHOP'S SCORE AFTER INDUCTION	DUCTION DELIVERY	NO. OF DOSES	COLOUR OF LIQOUR	MODE OF DELIVERY	PERINATAL OUTCOME	ADVERSE EFFECTS
1	S.L MISOPRPSTOL	MEENAXI	43708	27	28-12-2019	G4P3L3	35W 1D	3CM 3	OLIGOHYDOMNIOS	1HR	8	4HRS	1	CLEAR	PTVD	NICU ADMISSI	SHIVERING
																LOW BIRTH WEIGHT	
2	S.L MISOPRPSTOL	BHARATI	3731	22	31-01-2020	PRIMI	42WKS	3CM 2	POSTDATED WITH O	NON REACTIVE	NOT ASSESSED	LSCS	1	CLEAR	LSCS IN VI	NICU ADMISSI	SHIVERING,FETAL DI
																	DISTRESS
3	DINOPROSTONE	LAXMI SAVADI	41749	25	01-02-2020	G2P1L1	35WKS	3CM 4	IUD WITH SEVERE PI	6HRS	10	10HRS	1	DARK BROWN	PTVD	IUD	NIL
4	DINOPROSTONE	BAGAMMA	43776	20	02-02-2020	PRIMI	39WK 1D	3CM 3	OLIGO	10HRS	9	12HRS	2	CLEAR	FTVD	MOTHER SIDE	NIL
5	DINOPROSTONE	GAYATRI	979	32	08-02-2020	G3P2L2	41WK 2D	3CM 4	POSTDATED WITH O	6HRS	8	8HRS	1	CLEAR	FTVD	MOTHER SIDE	NIL
6	DINOPROSTONE	NEELAMMA	1382	30	12-02-2020	G2P1L1	35WK 4D	3CM 3	IUD	9HRS	8	11HRS	2	CLEAR	PTVD	IUD	NIL
7	S.L MISOPRPSTOL	VEENA RAMESH	41047	25	14-02-2020	PRIMI	40WKS	4CM 0	POSTDATED	10HRS	8	12HRS	2	CLEAR	FTVD	NICU ADMISSI	SHIVERING,FEVER
																	TACHYSYSTOLE
8	DINOPROSTONE	LAXMI ALABAL	4141	23	16-02-2020	PRIMI	39WK 6D	3CM 3	SEVERE PE	6HRS	10	8HRS	1	CLEAR	FTVD	MOTHER SIDE	NIL
9	S.L MISOPRPSTOL	REKHA	40974	25	18-02-2020	G3P2L2	40WK 5D	3CM 4	POSTDATED WITH O	2HRS	9	4HRS	1	MECONIUM	FTVD	NICU ADMISSI	SHIVERING,FEVER
10	S.L MISOPRPSTOL	MAHANANDA	41185	24	18-02-2020	G2P1L1	38WKS	4CM 4	SEVERE PE	2HRS	9	4HRS	1	MECONIUM	FTVD	NICU ADMISSI	SHIVERING,UTERINE
																	HYPERSTIMULATION
11	S.L MISOPRPSTOL	SAVITA	5	22	01-01-2020	PRIMI	39WK 1D	2CM 5	IUD	5HRS	11	6HRS	1	DARK BROWN	FTVD	IUD	SHIVERING,FEVER AN
																	UTERINE HYPERSTIM
12	S.L MISOPRPSTOL	LAILABEEMULL	42266	30	20-02-2020	G3P2L2	38WKS	2CM 5	IUD	10HRS	8	12HRS	3	DARK BROWN	FTVD	IUD	SHIVERING,FEVER
																	UTERINE HYPERSTIM
13	DINOPROSTONE	NAGAMMA	4614	22	17-02-2020	PRIMI	40WK 5D	3CM 3	POSTDATED WITH O	6HRS	9	8HRS	1	CLEAR	FTVD	MOTHER SIDE	NIL

14	S.L MISOPRPSTOL	MAYAVVA	3591	20	21-02-2020	PRIMI	40WKS	4CM	0	POSTDATED WITH O	12HRS	6	14HRS	3	MECONIUM	FTVD	NICU ADMISSI	SHIVERING,FEVER
																		UTERINE HYPERSTIM
15	DINOPROSTONE	BHAGYASHREE	5375	27	22-02-2020	PRIMI	33WK	4CM	0	IUD	16HRS	9	20HRS	3	DARK BROWN	PTVD	IUD	SHIVERING AND FEV
16	S.L MISOPRPSTOL	LAXMI MINAJA(	5394	30	24-02-2020	G3P2L2	41WK 2D	3CM	3	POSTDATED	2HRS	8	4HRS	1	MECONIUM	FTVD	NICU ADMISSI	SHIVERING,FEVER
																		FETAL DISTRESS
17	DINOPROSTONE	MAHANANDA	5380	26	26-02-2020	G2P1L1	40WK 5D	4CM	4	POSTDATED WITH O	6HRS	10	8HRS	1	CLEAR	FTVD	MOTHER SIDE	NIL
18	S.L MISOPRPSTOL	KAVERI	4094	26	03-03-2020	G2P1L1	40WK 3D	4CM	2	POSTDATED WITH PI	2HRS	5	LSCS	1	MECONIUM	LSCS IN VI	NICU ADMISSI	SHIVERING
19	S.L MISOPRPSTOL	SHALUBAI	4855	32	08-03-2020	G3P2L2	39WK 1D	4CM	3	HELLP SYNDROME	NON REACTIVE I	NOT ASSESSED	LSCS	1	MECONIUM	LSCS IN VI	NICU ADMISSI	SHIVERING,FEVER
																		FETAL DISTRESS
20	DINOPROSTONE	ASMA NADAF	6634	20	10-03-2020	PRIMI	40WK 3D	4CM	4	POSTDATED	7HRS	9	10HRS	2	MECONIUM	LSCS IN VI	NICU ADMISSI	SHIVERING
21	S.L MISOPRPSTOL	MALLAMMA	6571	22	12-03-2020	PRIMI	41WK 2D	4CM	0	POSTDATED	NON REACTIVE I	NOT ASSESSED	LSCS	1	MECONIUM	LSCS IN VI	NICU ADMISSI	SHIVERING,FEVER
																		FETAL DISTRESS
22	DINOPROSTONE	VIJAYALAXMI	7022	19	26-03-2020	G2P1L1	30WKS	4CM	1	SEVERE IUGR WITH (	6HRS	7	8HRS	1	CLEAR	PTVD	NICU ADMISSI	SHIVERING,FEVER
																		FETAL DISTRESS
23	DINOPROSTONE	DEEPA	6998	24	25-03-2020	G2P1L1	38WKS	2CM	5	GDM	8HRS	10	12HRS	2	CLEAR	FTVD	MOTHER SIDE	NIL
24	S.L MISOPRPSTOL	LAXMI MALAPP	7025	26	26-03-2020	G3P2L2	39WK 1D	3CM	2	SEVERE OLIGO	NON REACTIVE I	NOT ASSESSED	LSCS	1	MECONIUM	LSCS IN VI	NICU ADMISSI	SHIVERING,FEVER
																		FETAL DISTRESS
25	DINOPROSTONE	HEMA	7171	24	28-03-2020	G2P1L1	41WK 2D	2CM	4	POSTDATED WITH O	8HRS	10	LSCS	1	MECONIUM	LSCS IN VI	NICU ADMISSI	FETAL DISTRESS
26	S.L MISOPRPSTOL	ANJALI	7213	25	29-03-2020	G3P2L2	40WKS	4CM	1	POSTDATED	4HRS	8	7HRS	1	CLEAR	FTVD	NICU ADMISSI	SHIVERING,FEVER
																		FETAL DISTRESS
27	DINOPROSTONE	CHAYA	7282	27	29-03-2020	G2P1L1	40WKS	2CM	2	IUGR,HELLP	6HRS	10	8HRS	1	CLEAR	FTVD	MOTHER SIDE	NIL

28	DINOPROSTONE	SUNITA	7212	26	29-03-2020	G2P1L1	39WK 1D	3CM	2	SEVERE PE	6HRS	8	8HRS	1	CLEAR	FTVD	MOTHER SIDE	NIL
29	DINOPROSTONE	GODAVARI	7285	28	30-03-2020	G2P1L1	38WK 6D	2CM	5	IUD	6HRS	10	8HRS	1	CLEAR	FTVD	IUD	NIL
30	S.L MISOPRPSTOL	AMBIKA	7793	28	30-03-2020	G3P2L2	40WKS	4CM	3	GHTN	3HRS	8	LSCS	1	MECONIUM	LSCS IN VI	MOTHER SIDE	NIL
31	S.L MISOPRPSTOL	BHUVANESHWA	7824	22	31-03-2020	PRIMI	38WKS	4CM	4	OLIGO	NON REACTIVE I	NOT ASSESSED	LSCS	1	CLEAR	LSCS IN VI	NICU ADMISSI	FETAL DISTRESS
32	DINOPROSTONE	ANITA	8780	23	05-04-2020	G2P1L1	39WK 1D	3CM	2	GHTN	5HRS	6	-	1	MECONIUM	LSCS IN VI	MOTHER SIDE	SHIVERING,FEVER
																		FETAL DISTRESS
33	S.L MISOPRPSTOL	LAXMI BIDRI	8195	20	06-04-2020	PRIMI	39WK 1D	3CM	3	SEVERE PE	6HRS	8	8HRS	2	CLEAR	FTVD	NICU ADMISSI	SHIVERING
34	DINOPROSTONE	BASAMMA	8192	25	07-04-2020	G2P1L1	40WK 3D	4CM	0	POSTDATED WITH O	8HRS	10	12HRS	2	CLEAR	FTVD	MOTHER SIDE	NIL
35	S.L MISOPRPSTOL	SHAHEEN	7607	22	08-04-2020	G2P1L1	36WK	3CM	2	HELLP SYNDROME	NON REACTIVE I	NOT ASSESSED	LSCS	1	MECONIUM	LSCS IN VI	NICU ADMISSI	SHIVERING,FEVER
																		FETAL DISTRESS
36	S.L MISOPRPSTOL	RADHIKA	8399	25	09-04-2020	G3P2L2	40WK 3D	3CM	3	POSTDATED WITH O	4HRS	8	6HRS	1	MECONIUM	FTVD	NICU ADMISSI	SHIVERING,FEVER
																		FETAL DISTRESS
37	DINOPROSTONE	MAMTAZ	8403	20	10-04-2020	PRIMI	34WKS	4CM	0	SEVERE PE WITH AN	10HRS	10	12HRS	2	MECONIUM	PTVD	NICU ADMISSI	NIL
38	DINOPROSTONE	ASHWINI	8540	23	10-04-2020	G3P2L2	40WK 3D	3CM	2	POSTDATED WITH G	6HRS	7	LSCS	1	MECONIUM	LSCS IN VI	MOTHER SIDE	NIL
39	DINOPROSTONE	BHARATI	8598	24	15-04-2020	G2P1L1	39WK 1D	3CM	3	SEVERE PE	8HRS	8	12HRS	2	CLEAR	FTVD	MOTHER SIDE	NIL
40	DINOPROSTONE	SANDYA RAHUI	8675	26	17-04-2020	G3P2L2	40WK 3D	3CM	4	POSTDATED WITH O	8HRS	10	11HRS	2	CLEAR	FTVD	MOTHER SIDE	NIL
41	S.L MISOPRPSTOL	SUCHITRA	10831	29	04-05-2020	PRIMI	40WKS	3CM	2	POSTDATED WITH O	6HRS	7	10HRS	2	CLEAR	FTVD	MOTHER SIDE	SHIVERING

42	S.L MISOPRPSTOL	VIDYASHREE	10866	28	05-05-2020	G2P1L1	41WKS	3CM	3	POSTDATED	2HRS	6	4HRS	2	MECONIUM	FTVD	NICU ADMISSI	FETAL DISTRESS
43	DINOPROSTONE	SOUMYA	10923	23	06-05-2020	PRIMI	39WK 1D	3CM	2	OLIGO	10HRS	8	12HRS	2	CLEAR	FTVD	MOTHER SIDE	NIL
44	S.L MISOPRPSTOL	REAYANA NADA	10990	29	07-05-2020	PRIMI	38WK 6D	4CM	0	SEVERE PE	NON REACTIVE I	NOT ASSESSED	LSCS	1	MECONIUM	LSCS IN VI	MOTHER SIDE	SHIVERING
45	S.L MISOPRPSTOL	ANITA BIRADAR	11015	25	09-05-2020	G3P2L2	40WK 3D	3CM	4	POSTDATED WITH O	3HRS	8	5HRS	1	MECONIUM	FTVD	MOTHER SIDE	SHIVERING
46	DINOPROSTONE	SHILPA	11031	25	10-05-2020	G2P1L1	40WKS	3CM	1	ANAEMIA WITH IUG	6HRS	8	8HRS	1	CLEAR	FTVD	MOTHER SIDE	NIL
47	S.L MISOPRPSTOL	RAJESHRI	11050	28	12-05-2020	G3A2	38WKS	4CM	2	GDM	14HRS	6	LSCS	3	MECONIUM	LSCS IN VI	NICU ADMISSI	SHIVERING,FEVER
																AND NPOL		FETAL DISTRESS
48	S.L MISOPRPSTOL	SHRIDEVI	11067	35	13-05-2020	G3P2L1	34WKS 3	3CM	4	SEVERE PE WITH IUG	3HRS	9	5HRS	2	MECONIUM	PTVD	NICU,RDS,PRE	SHIVERING
49	DINOPROSTONE	RUKSANA	11072	22	14-05-2020	PRIMI	40WK 1D	3CM	3	POSTDATED	10HRS	10	12HRS	2	CLEAR	FTVD	MOTHER SIDE	NIL
50	S.L MISOPRPSTOL	INDURANI	11112	30	15-05-2020	G4P2L2	39WK2D	3CM	3	OLIGO	NON REACTIVE I	NOT ASSESSED	LSCS	1	MECONIUM	LSCS IN VI	MOTHER SIDE	SHIVERING
51	S.L MISOPRPSTOL	SIDDAMMA	11233	22	16-05-2020	G2P1L1	39WKS 5/	4CM	0	ANAEMIA WITH IUG	2HRS	8	5HRS	1	MECONIUM	FTVD	NICU ADMISSI	SHIVERING,FEVER
																		FETAL DISTRESS
52	S.L MISOPRPSTOL	PRIYANKA	11283	20	17-05-2020	PRIMI	39WKS 5/	3CM	3	OLIGO	12HRS	8	16HRS	4	MECONIUM	FTVD	NICU ADMISSI	SHIVERING,FEVER
																		FETAL DISTRESS
53	S.L MISOPRPSTOL	NEELAMMA	11278	26	18-05-2020	PRIMI	39WK2D	3cm	2	OLIGO	NON REACTIVE I	NOT ASSESSED	LSCS	1	mECONIUM	ISCS IN VI	NICU ADMISSI	SHIVERING
54	DINOPROSTONE	BHAGYASHREE	11183	23	20-05-2020	PRIMI	39WK 2D	4CM	0	GDM	10HRS	8	14HRS	2	CLEAR	FTVD	MOTHER SIDE	NIL
55	S.L MISOPRPSTOL	RESHMA	11282	20	22-05-2020	PRIMI	39WK 1D	3CM	2	HELLP SYNDROME	6HRS	8	8HRS	2	MECONIUM	FTVD	MOTHER SIDE	SHIVERING

56	S.L MISOPRPSTOL	RAJASHRI	11343	24	24-05-2020	G2P1L1	38WKS	4CM	0	IMMINENT ECLAMP	NON REACTIVE	NOT ASSESSED	LSCS	1	CLEAR	LSCS IN VI	NICU,RDS,PRE	SHIVERING
57	DINOPROSTONE	KAVITA	11367	28	25-05-2020	G2P1L1	40WK 1D	3CM	3	POSTDATED	6HRS	10	8HRS	1	CLEAR	FTVD	MOTHER SIDE	NIL
58	s.L MISOPRPSTOL	laxmibai	11352	21	26-05-2020	G2P1L1	39WK 2D	3CM	3	SEVERE PE WITH IUG	16HRS	8	LSCS	4	CLEAR	LSCS IN VI	NICU,RDS,PRE	SHIVERING,FEVER
																		FETAL DISTRESS
59	DINOPROSTONE	RESHMA	11469	26	30-05-2020	PRIMI	40WK 1D	3CM	2	POSTDATED WITH O	14HRS	11	16HRS	3	CLEAR	FTVD	MOTHER SIDE	SHIVERING
60	DINOPROSTONE	PRIYANKA	11458	22	31-05-2020	PRIMI	41WKS	4CM	1	POSTDATED	8HRS	10	10HRS	2	CLEAR	FTVD	MOTHER SIDE	NIL
61	S.L MISOPRPSTOL	SARASWATI	11474	21	12-06-2020	PRIMI	30WKS	4CM	0	ANHYDROMNIOS	20HRS	8	22HRS	4	CLEAR	PTVD	NICU,RDS,PRE	SHIVERING,FEVER A
62	S.L MISOPRPSTOL	ROOPA	11498	24	14-06-2020	G4P2L2	40WK 5D	3CM	4	POSTDATED WITH O	3HRS	9	6H	1	MECONIUM	FTVD	NICU ADMISSI	SHIVERING
63	DINOPROSTONE	LAXMI	11433	21	15-06-2020	PRIMI	42WKS	4CM	2	POSTDATED WITH O	12HRS	10	15HRS	2	MECONIUM	FTVD	MOTHER SIDE	NIL
64	S.L MISOPRPSTOL	SHRIDEVI	11582	25	16-06-2020	G3P1D	38WKS 6	3CM	3	SEVERE PE	NON REACTIVE	NOT ASSESSED	LSCS	1	MECONIUM	LSCS IN VI	NICU ADMISSI	SHIVERING
65	DINOPROSTONE	SUMITRA	11816	30	20-06-2020	G4P2L2	38WKS 6	3CM	3	IUD	6HRS	11	8HRS	1	DARK BROWN	FTVD	IUD	NIL
66	S.L MISOPRPSTOL	PARVATI	11849	21	21-06-2020	G2P1L1	39WK 2D	3CM	2	HELLP SYNDROME W	12HRS	8	16HRS	3	MECONIUM	FTVD	NICU ADMISSI	SHIVERING
67	S.L MISOPRPSTOL	VANUJA	11863	24	21-06-2020	G2P1L1	40WK 1D	4CM	0	POSTDATED	16HRS	8	20HRS	4	MECONIUM	FTVD	NICU ADMISSI	SHIVERING,FEVER
																		FETAL DISTRESS
68	S.L MISOPRPSTOL	RESHMA	11838	24	21-06-2020	PRIMI	29WKS	4CM	0	IUD	16HRS	8	20HRS	4	CLEAR	PTVD	IUD	SHIVERING,FEVER
																		FETAL DISTRESS
69	S.L MISOPRPSTOL	CHANNAMMA	11872	22	22-06-2020	G2P1L1	28WK 4D	4CM	1	IUD	12HRS	8	14HRS	3	CLEAR	PTVD	IUD	SHIVERING,FEVER
																		FETAL DISTRESS

70	DINOPROSTONE	SHALIN	11890	34YR	22-06-2020	G5P4L3	40WK 5D	3CM	4	POSTDATED	10HRS	12	14HRS	2	CLEAR	FTVD	MOTHER SIDE	NIL
71	DINOPROSTONE	PARREEN	11901	27	23-06-2020	G3P2L2	39WKS 6	3CM	4	GDM	8HRS	10	12HRS	2	CLEAR	FTVD	MOTHER SIDE	NIL
72	S.L MISOPRPSTOL	SHASHIKALA	12037	23	24-06-2020	G2P1L1	40WK 5D	4CM	0	POSTDATED	10HRS	8	12HRS	3	MECONIUM	FTVD	NICU ADMISSI	SHIVERING,FEVER
																		FETAL DISTRESS
73	DINOPROSTONE	VIDYASHREE	12071	25	25-06-2020	G3P1L1	39WK 2D	3CM	3	SEVERE PE	6HRS	8	8HRS	1	CLEAR	FTVD	MOTHER SIDE	NIL
74	S.L MISOPRPSTOL	LAXMI	12110	21	26-06-2020	PRIMI	40WK 1D	3CM	3	POSTDATED	16HRS	10	18HRS	4	MECONIUM	FTVD	NICU ADMISSI	SHIVERING,FEVER
																		FETAL DISTRESS
75	DINOPROSTONE	SAVITRI	12154	27	28-06-2020	G4P3L2	40WK 5D	3CM	3	POSTDATED	6HRS	10	8HRS	1	CLEAR	FTVD	MOTHER SIDE	NIL
76	DINOPROSTONE	SUNITA	12135	32	28-06-2020	PRIMI	35WK	4CM	0	IUD	6HRS	8	8HRS	1	CLEAR	PTVD	IUD	NIL
77	DINOPROSTONE	KAVITA	12185	28	28-06-2020	G3P1L1	39WK 2D	3CM	2	OLIGO	12HRS	8	14HRS	2	CLEAR	FTVD	MOTHER SIDE	NIL
78	S.L MISOPRPSTOL	AMENABABU	12292	26	01-07-2020	G3P2L2	40WK 1D	3CM	3	POSTDATED WITH O	1HRS	8	2HRS	1	MECONIUM	FTVD	NICU ADMISSI	SHIVERING
79	DINOPROSTONE	TARABAI	12323	25	02-07-2020	G2P1L1	40WK 5D	3CM	1	POSTDATED	11HRS	9	13HRS	2	MECONIUM	FTVD	MOTHER SIDE	NIL
80	DINOPROSTONE	MAMTAZ LONI	12354	22	03-07-2020	PRIMI	40WK 1D	4CM	0	POSTDATED WITH O	6HRS	8	8HRS	1	CLEAR	FTVD	MOTHER SIDE	NIL
81	DINOPROSTONE	SHEELA	12554	34	04-07-2020	G4P3L2	37WK	3CM	2	GDM	10HRS	8	12HRS	2	CLEAR	FTVD	MOTHER SIDE	NIL
82	DINOPROSTONE	TANYA	12654	22	04-07-2020	G2P1L1	41WK	3CM	2	POSTDATED WITH O	6HRS	9	11HRS	1	CLEAR	FTVD	MOTHER SIDE	NIL
83	DINOPROSTONE	SOWMYA	12754	30	04-07-2020	G3P1L1	35WK	4CM	1	SEVERE PE	10HRS	10	12HRS	2	CLEAR	FTVD	MOTHER SIDE	NIL
84	DINOPROSTONE	RAMYA	12884	25	04-07-2020	PRIMI	40WK 5D	3CM	2	POSTDATED	6HRS	8	8HRS	1	CLEAR	FTVD	MOTHER SIDE	NIL