"INDUCTION OF LABOUR USING TRANSCERVICAL FOLEY'S CATHETER WITH EXTRA AMNIOTIC SALINE INFUSION VERSUS INTRACERVICAL PROSTAGLANDIN E2 GEL AT TERM GESTATION- A COMPARATIVE STUDY"

By

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Under the Guidance of

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LIST OF ABBREVIATIONS

GLOSSARY	ABBREVIATIONS
AOP	Angle of progression
APGAR	Appearance, Pulse, Grimace, Activity, and Respiration
ARM	Artificial rupture of membranes
CTG	Cardiotocography
E2	Estradiol
EASI	Extra amniotic saline infusion
EP	Electrophysiological
HELLP	Hemolysis, elevated liver enzymes, and low platelets
LSCS	Lower segment caesarean section
NICU	Neonatal intensive care unit
OPC	Outpatient Foley Catheter
IP	In patient vaginal PGE2
PGE2	Prostaglandin E2
USG	Ultrasonography
VBACs	Vaginal birth after caesarean delivery

ABSTRACT

BACKGROUND: The intentional commencement of cervical ripening and uterine contraction for the purpose of achieving delivery prior to the onset of spontaneous parturition is known as induction of labour. When the benefits to the mother or the foetus surpass the benefits of extending the pregnancy, it is indicated.

AIM: The purpose of this study was to assess the efficacy of a transcervical foley's catheter with extra amniotic saline infusion against intra cervical prostaglandin E2 gel for inducing labour in term pregnant women.

RESEARCH MATERIALS AND METHODS: From January 2020 to June 2021, a comparative study was undertaken at R.L. Jalappa Hospital and Research Centre. The study enrolled a total of 72 individuals.

RESULTS: Prolonged gestational age, hypertensive disorders in pregnancy, and oligohydramnios were the most frequent causes for induction in the EASI group, accounting for 38.89 percent, 38.89 percent, and 22.22 percent, respectively. The dinoprostone group has 36.11 percent, 33.33 percent, and 25%, respectively. After induction, the majority of patients in the EASI group had a modified Bishop's score of 2.

CONCLUSION: Our research found that PGE2 and EASI were equally effective in inducing labour.

INTRODUCTION

INTRODUCTION:

Induction of labour is the intentional initiation of cervical ripening and uterine contractions with the goal of achieving delivery before the onset of spontaneous parturition. It is recommended when the benefits to the mother or the foetus outweigh the benefits of extending the pregnancy. Labour normally starts on its own and concludes with a vaginal birth at or near the due date. In medical or obstetric problems of pregnancy, cervical ripening and labour induction are frequently required.

Patients with hypertensive disorders of pregnancy, a prolonged period of gestation, intraamniotic infection, foetal danger, and maternal medical issues such as diabetes mellitus and chronic renal sickness are all candidates for induction of labour.[1] The ratio of progesterone to oestrogen, prostaglandin synthesis, and the condition of the cervical collagen matrix all play a role in the induction of labour success. Non-pharmacological therapies for cervical softening and labour induction include sexual intercourse, breast stimulation, medicinal herbs, homeopathic treatments, purgatives, enemas, acupuncture, and membrane stripping. Laminaria, extra amniotic Foley balloon catheter and extra amniotic sodium chloride infusion using Foley catheter are mechanical procedures for inducing labor.[2]

The act of inducing labour is linked to the dangers like prolonged labour, a high Caesarean rate, a high rate of epidural analgesia, and a low APGAR score at one minute and five minutes.[3]

In nulliparous women, it also increased the rate of operative vaginal delivery techniques. It also lowered the rate of spontaneous births, increased the rate of caesarean sections, and caused shoulder dystocia in many women.[4]

NEED OF THE STUDY:

Induction of labour can be achieved in a variety of ways, including pharmacological, surgical, combined, and mechanical methods. Each has its own set of advantages and disadvantages. Prostaglandin E2 is the most commonly recommended induction method. However, it comes with its own set of hazards, such as hyper stimulation. There are ongoing studies exploring the most effective and least painful methods of inducing labour. Mechanical induction techniques are being explored to meet the aforementioned need. The use of a foley catheter to administer extra amniotic saline infusion has gained little attention, and there are few reports on it. In India, preliminary tests suggested that it was more successful than intravaginal prostaglandins and had less side effects. The procedure of instilling sodium bicarbonate solution in the extra amniotic space has shown to be safe and to be well tolerated by women, and it should be investigated in resource-constrained places.

AIMS & OBJECTIVES

AIMS AND OBJECTIVES:

1. To compare the efficacy and safety of extra amniotic saline infusion using trans cervical foley's catheter versus administration of intracervical dinoprostone (prostaglandin E2) for induction of labour.
2. To assess fetomaternal outcome in subjects with extra amniotic saline infusion using trans cervical foley's catheter, compared to intracervical prostaglandin E2 for induction of labour.

REVIEW OF LITERATURE

REVIEW OF LITERATURE:

Induction of labour:

1. Define the term "induction of labour" and explain what it means.

The technique of artificially stimulating the uterus to trigger labour is known as induction of labour. It is done by admonishing oxytocin or prostaglandins into the pregnant woman's system by mechanically rupturing the amniotic membranes.[5]

2. Elective induction and its advantages.

When there is no medical evidence that the benefits of delivery clearly outweigh the hazards, induction of labour is typically regarded as "elective."

This will aid in the reduction of caesarean deliveries, other poor neonatal and maternal outcomes, macrosomia, and its implications, and stillbirth.

It also allows you to control the delivery timing, which is useful in some cases.

3. The stages of labour are as follows:

The First Stage of Labour:

The onset of labour is defined as a series of intense contractions that are spaced 3 to 5 minutes apart. The very first stage takes place when labour starts and ends with full cervical dilation.[6] Prostaglandins, membrane stripping, amniotomy, and intravenous oxytocin, etc., are all options for inducing labour.[6]

Using a graph of cervical dilation over time, Friedman et al.[7] discovered that typical labour had a sigmoidal curve. He deduced that labour is split up into three types based on the graph. Slow cervical dilatation, as well as significant biochemical and morphological changes, characterize the first division stage, which is a preparatory stage. It's also known as the first stage of labour's latent phase. Second division, on the other hand, is a considerably shorter and faster dilational phase that is referred to as the active phase of the first stage of labour. The third division, also known as the pelvic division phase, happens during the second stage of labour.[6]

The extent of cervical dilation is frequently used to divide the first stage of labour into two halves. The latent phase lasts between zero and six centimeters, whereas the active phase lasts between six centimeters and peaks at cervical dilatation. During the first stage, the presenting foetal component begins the process of engagement into the pelvic cavity. During the early stages of labour, along with the labour process, the presenting portion of the foetus will aid in improving cervical dilatation and effacement. The thinning of the cervix in the anterior-posterior plane results in cervical effacement. 100 percent effacement is said to be occurred if the cervix is entirely thinned down and no length remains.[6] The duration of the latent phase of labour can be extended by sedation.[8] The cervix steadily dilates to roughly around 6 cm during the latent period. In nulliparous and multiparous women, the latent phase can extend up to 20 hours and 14 hours, respectively. Until complete cervical dilatation and effacement are attained, the cervical changes are more rapid and predictable in the active phase. Active labour with rapid cervical dilation begins about 6 cms of cervical dilation. During the active phase, the cervix dilates at a pace of 1.2 to 1.5 cms per hour. Multiparas or pregnant women who have had a prior vaginal delivery have a faster cervical dilation.[6] Labour arrest occurs when

there are no cervical changes for more than 4 hours in the presence of adequate contractions or 6 hours in the absence of adequate contractions. It may require immediate intervention.

The foetus' station is determined by its location in the maternal pelvis. When the bony foetal presenting section aligns with the maternal ischial spine, the foetus is at 0 stations. Stations -1 cm to -5 cm is proximal to the ischial spines, whereas stations +1 to +5 cm are distal to the ischial spines.

Second Stage of Labour:

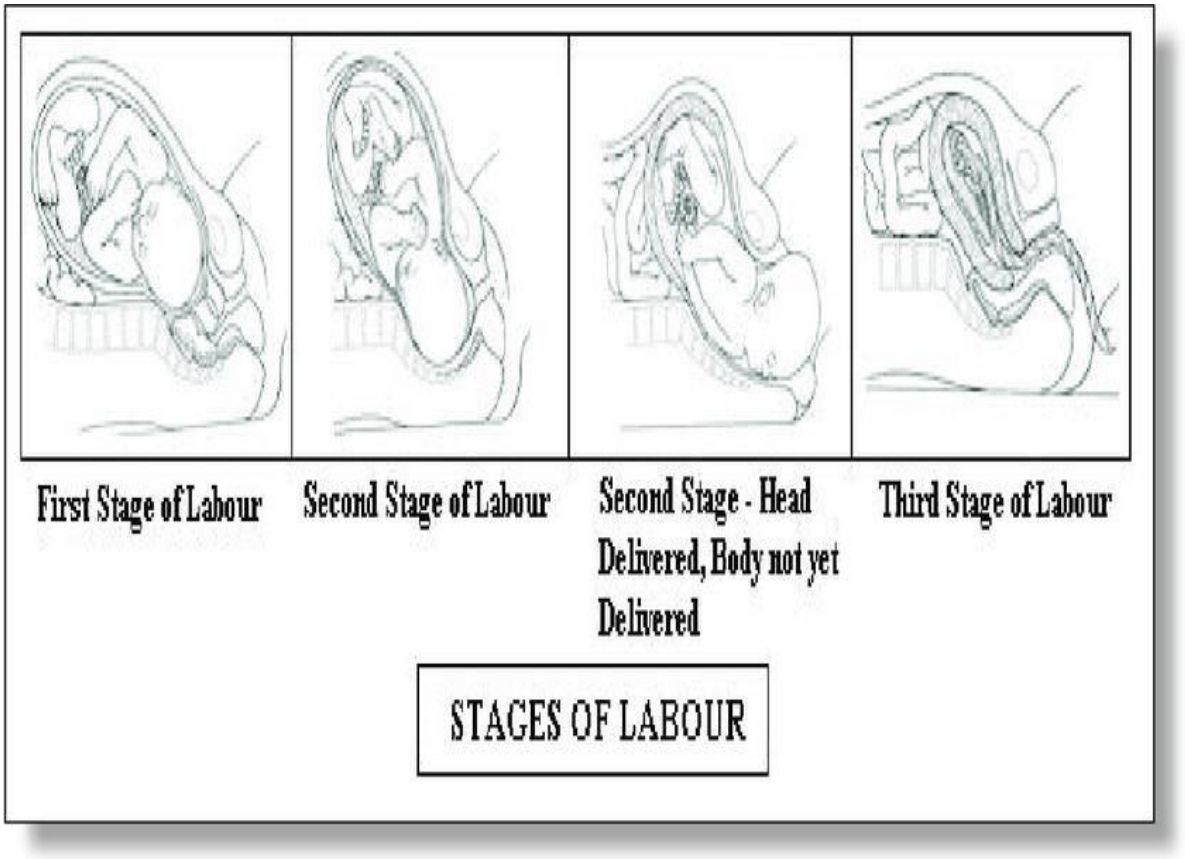
It begins with maximal cervical dilatation and terminates with the new-born's birth. Friedman also refers to it as the pelvic division episode. With or without maternal pushing, the baby falls into the canal of birth after the cervical dilatation is complete. Cardinal motions assist the foetus glide through the delivery canal. Engagement, descent, flexion, internal rotation, extension, external rotation, restitution, and expulsion are all part of it. In women who have previously delivered a baby vaginally, stage two of labour may only require a short trial, while in nulliparous women, the second stage may take much longer.

The second stage of labour in parturient without neuraxial sedation generally lasts less than 3 hours in nulliparous women and less than 2 hours in multiparous women. In this stage of labour, women who received neuraxial anaesthesia duration of the phase lasts less than 4 hours in nulliparous women and less than 3 hours in multiparous women.[6] Also, this stage two of labour is deemed extended if it lasts longer than these limits. The duration of the second stage is determined by foetal characteristics such as size and position, as well as mother factors such as pelvic shape, the intensity of expulsive efforts, comorbidities such as hypertension or diabetes, age, and previous delivery history.[9]

Third Stage of Labour:

The birth of the foetus begins stage three of labour and finishes with the delivery of the placenta. The presence of a gush of blood at the vaginal opening, apparent lengthening of the umbilical cord, and a globular-shaped uterine fundus on the inspection are all signs that the placenta has detached from the uterine interface. The placenta generally takes 5 to 30 minutes to expel on its own. A longer delivery time has been associated to a greater risk of postpartum haemorrhage, which may need manual removal or other intervention.[6] Exerting traction to the umbilical cord while applying fundal pressure to expedite placental separation is how the third stage of labour is controlled.

Figure 1: Various stages of labour.[10]



Indications:

Some of the most major causes for induction of labour are as follows:

1. Prolonged gestational age of the pregnant women.
2. Hypertensive disorders in pregnancy (Preeclampsia, eclampsia, HELLP Syndrome, etc.)
3. Oligohydramnios.
4. Medical disorders affecting mothers, such as diabetes.
5. Chronic renal disorders.
6. Prelabour rupture of membranes.
7. Intra uterine fetal demise.
8. Intra uterine growth retardation.
9. Chorioamnionitis.
10. Placental abruption.
11. Intrahepatic cholestasis of Pregnancy.
12. Alloimmunization of fetal anaemia.
13. Mental health issues of the mother.
14. Twins etc.

Contraindications of labour induction:

They are nearly identical to those for vaginal birth. Contraindications are subdivided into absolute and relative contraindications.

A. Absolute contraindications:

1. Cephalopelvic disproportion.
2. A major degree of placenta previa.

3. Vasa praevia.
4. Cord prolapses.
5. Transverse lie.
6. Active infection of herpes genitals.
7. Previous classical type of caesarean section.

B. Relative contraindications:

1. Breech presentation,
2. Triplet or high order pregnancies,
3. Two or more previous low transverse caesarean sections.

Induction techniques:

A. Non-pharmacological Procedures:

Methods that are not pharmacological used for cervical softening and initiating the labour include sexual intercourse, breast stimulation, herbal preparations, homeopathic remedies, purgatives, enemas, acupuncture, and membrane stripping.

B. Mechanical Procedures:

Mechanical approaches include amniotomy, balloon-tipped catheters, and natural and synthetic laminaria. Amniotomy, or the artificial disruption of the amniotic membranes, can cause local prostaglandin synthesis and secretion. In around 90% of term patients, it can cause labour within 6 hours. Cervical ripening and labour induction are accomplished by mechanical dilatation of unripe cervix with balloon-tipped catheters. Foley catheters with balloons of 25–50 mL is often used. The process of inducing labour will become more successful when balloon-tipped catheters and pharmacologic drugs are used together.[11] Cervical ripening is more successful with both natural and synthetic laminaria. In the second trimester, safety and

effectiveness are demonstrated. However, in pregnancy's third trimester, a significant rate of infection has been documented.[12]

C. Pharmacological approaches:

a. OXYTOCIN:

Oxytocin is a neurohormone produced by the posterior lobe of the pituitary gland and located in the hypothalamus. It's a frequent method for inducing labour. A regulated intravenous infusion, with or without an amniotomy, can induce enough uterine activity to promote cervical dilatation and birth. In such instances, 50% of inductions fail; however, using cervical ripening products prior to induction might lower the frequency of failure inductions.[13]

High expression of placental oxytocinase and its short plasma half-life, steady-state levels of the drug are obtained after 40 minutes of continuous IV infusion. The gestational age determines the dosage response to oxytocin. The presence of receptors to oxytocin in the myometrium of the uterus causes the uterus to react to oxytocin during the 20th week of pregnancy. There is no variation in sensitivity from 34 weeks to full term. The uterine sensitivity improves quickly after spontaneous labour begins.

Oxytocin is normally given at a pace of 1 mU/min for the first 20–30 minutes, then increased by 1 or 2 mU/min every 20–30 minutes until a maximum administration rate of 16–32 mU/min is attained or enough uterine activity is detected. The most common adverse effect of oxytocin infusion is foetal heart rate deceleration linked with increased uterine activity; consequently, the Fetal Heart Rate and uterine contractions should be regularly checked for tachysystole or uterine hyperstimulation and intervened when necessary.[1]

b. PROSTAGLANDINS

Prostaglandin induction has the benefit of enhancing cervical softening while also boosting myometrial contractility. In obstetrics, dinoprostone is the most extensively employed prostaglandin. In addition to the cervical ripening process, it also aids in the initiation and maintenance of labour. The two most prevalent methods of administration are intravaginal and intracervical. Dinoprostone gel in a prefilled applicator contains 0.5 mg of dinoprostone in 2.5 ml of triacetin and colloidal silicon dioxide gel. Within 30–45 minutes of administration, peak absorption occurs. Repeat doses can be given every 6 hours for a maximum dose of 1.5 mg dinoprostone in a 24-hour period.

A thin, flat polymeric hydrogel chip with rounded edges is put in a knitted polyester retrieval bag as the vaginal insert. Each insert contains 10 mg of dinoprostone in a dry polymer matrix with a regulated release rate of 0.3 mg/hour for 12 hours. By 12 hours, the insert can enhance cervical softening in pregnant ladies who are nearing or at term, resulting in a Bishop score of at least 3. Active labour and vaginal birth are most typical at this time, lowering the need for oxytocin infusion.[14]

Gel made at a hospital is also utilized. A dinoprostone suppository and a methylcellulose gel were used in many of these formulations. It's administered vaginally (2.5–5 mg) or intracervical (2.5–5 mg) (0.5 mg). Frequently associated adverse effects in women treated with PGE2 are tachysystole and uterine hyperstimulation. Uterine rupture, amniotic fluid embolism, and myocardial infarction are among the other risks. Intravaginal doses of 25 to 50 μg have been shown to shorten the induction to delivery interval, as well as the rate of caesarean section.[1]

2. What is successful labour induction, and how is it measured?

The successful vaginal delivery and the induction-to-delivery period are predicted using maternal features, obstetric history, and preinduction sonographic assessment of cervical length. Cervical length at or near term can also indicate how labour will progress the following induction. The two additional sonographic measures utilized in predicting the labour outcome are the cervical elastographic score and angle of progression. Elastography is a method that uses ultrasound to detect tissue stiffness. When opposed to hard tissue, soft tissue deforms more easily. The ultrasound signals identify the changes in deformability. The usage of a colour chart exemplifies this. The colour data are transformed into a numerical expression of average stiffness using special software.[15] Cervical elastography was used in certain studies before labour induction, and reports showed that cervical stiffness was less prominent in women. Women who had a successful induction were more likely to have this trait than those who experienced a failed induction.[16],[17],[18],[19] Angle of progression (AOP) is a sonographic measure of the head station, and a wider angle has reported to a favourable likelihood of vaginal birth in a few studies. [16],[17],[18],[19],[20] According to one study, parous women had a smaller angle of progression than nulliparous women, and a narrow-angle of advancement in nulliparous women is linked to an increased incidence of caesarean birth.[21]

3. Extra amniotic saline infusion by trans cervical foley catheter- In-inducing labour.

Extra amniotic saline infusion utilizing a transcervical Foley catheter had a higher success rate, a better bishop score, and a faster ripening period. Other benefits include fewer problems, such as uterine hyperstimulation, cost-effectiveness, and the elimination of the requirement for a cold chain in low-resource areas.[22] When compared to the spontaneous labour group, nulliparous women who were induced using Foley's catheter took longer to proceed.

When compared to foley alone, the induction to the delivery interval was considerably shorter in the additional amniotic saline infusion group.[23] The present study done was to know how successful extra amniotic saline infusion instillation using a foleys catheter and intra cervical prostaglandin E2 gel were at inducing labour at term.

Within a day span, the rate of vaginal delivery following the installation of Foley's catheter was found to be 56.1 percent, with a 1.5 percent risk rate of uterine rupture. As a result, Asghar S et al.[24] found that additional amniotic saline infusion through trans-cervical is an effective approach for inducing labour.

Varghese DP et al.[25] found that in the group given extra amniotic saline infusion using foleys catheter, the mean duration from induction to delivery was reduced, and the number of vaginal deliveries increased within 24 hours. So as per this research conducted, intra cervical Foley catheter with extra amniotic saline infusion was found to be an efficient approach in women with highly unfavourable cervices.

The advantages of cervical ripening using the Foley catheter over the Prostaglandin E2 gel include lesser cost, reversibility, and a lower chance of systemic and catastrophic adverse effects such as uterine hyperstimulation and rupture. It also causes a considerable amount of ripening, cervical dilation, and induction to the delivery interval was reduced.[26]

4. Dinoprostone (prostaglandin E2) intracervical gel for induction of labour.

Prostaglandin E2 is a chemical that is utilized to help in uterine contents evacuation and labour induction. It's a medication from the prostaglandin family. Dinoprostone is another name for prostaglandin E2.[27] Dinoprostone' s cervical gel offers a faster release than the

vaginal insert, but it's less convenient because it involves more vaginal assessments. When dinoprostone gel is administered, the risk of uterine hyperstimulation with and without foetal upset is increased.

Direct stimulation by prostaglandin E2 produces contractions in the myometrium. It interacts to G protein-coupled receptors EP1-4, which can trigger a range of downstream actions depending on EP subtype and cell type-specific expression patterns.[28] The efficiency of prostaglandin E2 during pregnancy has been connected to the expression of these receptors. Cervical dilatation, effacement, and softening are also improved by prostaglandin E2, which is identical to the natural progression of pregnancy. Increased collagenase secretion might be to blame.[29]

Labour induction using intracervical PGE2 gel is commonly used to treat postadatism, pregnancy-induced hypertension, and intrauterine growth retardation. Women who have vaginal bleeding during pregnancy, significant cephalopelvic disproportion, or multipara with 6 or more previous term pregnancies should avoid using the prostaglandin E2 gel for ripening of the cervix. It should also be avoided in situations of prolonged uterine contractions, as it might jeopardize uterine integrity and foetal safety. Women with a history of asthma, glaucoma, or cardiac problems should avoid using prostaglandin E2 for labour induction.[30]

5. Extra amniotic saline infusion through a trans cervical foley's catheter vs. intracervical dinoprostone (prostaglandin E2) for induction of labour during term gestation.

Although the mean period of augmentation and the induction delivery interval was larger in the PGE2 group, post-induction Bishop Score was enhanced in the EASI group in Kumar S, et al.[31] research. This study found that both kinds of induction are equally safe and successful in

terms of delivery method and new born APGAR score. The APGAR score of new-borns was shown to be high in PGE2-induced labour. Also, according to research by A. RA et al.[32] PGE2 and EASI had equal efficiency in inducing labour, but EASI is associated with greater adverse effects. In the Dhakal KB et al.[22] study, the mean time from induction to cervical ripening interval was shorter in Foley's catheter and EASI compared to PGE2. The majority of women using Foley catheters and EASI reached a Bishop score of 7 or above within 24 hours of induction. Induction to delivery intervals was reduced using EASI and Foley catheters.

Randomized prospective research involving 200 pregnant women was undertaken by Goswami P et al.[33] The researcher attempted to see how well transcervical extra-amniotic Foley's bulb and prostaglandin E2 gel worked for cervical softening before induction. Participants in the research ranged in age from 24 to 28 years old. The majority of the individuals were between 37- and 42-weeks gestation. In both groups, the majority of the individuals were primigravidae, with 66 percent in the Foley catheter group and 70% in the prostaglandin E2 group. In comparison to PGE2 gel, the Foley catheter was a more efficient pre-induction ripening agent for the unfavourable cervix. The foley group gave many vaginal births. The extra-amniotic Foley catheter balloon was found to be an effective, safe, easy, low-cost, reversible, non-pharmacological mechanical technique of cervical ripening prior to induction.

A survey of 80 pregnant women was conducted by Bembalgi S et al.[34] The goal of this study was to see if a Foley catheter with intra cervical PGE2 gel and a Foley catheter with PGE2 gel plus extra amniotic saline infusion for induction of labour were effective. The pre-induction Bishop score did not differ significantly across the groups. After 6 hours of introduction, the bishop score in both groups improved significantly. In group 2, the average time from

induction to delivery was shorter. The two groups had similar modes of delivery, new born and maternal morbidity and death. The Foley's with PGE2 gel and the extra amniotic saline infusion are superior for labour induction, according to the study.

Kumari KA et al.[35] analysed 200 pregnant women in a prospective and comparative study. The focus of the research was to assess if Extra amniotic Saline Instillation using a Foley Catheter trans cervically and Vaginal PGE2 was effective and safe. At zero-hour, Bishop Score of 3.92±1.49 in Group A whereas, 3.5±1.48 Group B. Cervical ripening was successful in 78% of group A patients and 94% of group B patients. The induction delivery interval in Group A was between 24 and 48 hours, while it was 37 hours in Group B. Group B had a vaginal delivery rate of 83 percent, whereas Group A had a vaginal delivery rate of 58 percent. 43 percent of Group A participants and 16 percent of Group B participants reported emergency LSCS. Uterine tachysystole was reported in 4% of participants in Group A. In 18% of Group A cases and 16% of Group B cases, NICU admissions were documented. The most prevalent reasons for NICU hospitalizations were APGAR at 5 minutes 7, Meconium-stained liquor, and respiratory distress. PGE2 was shown to be inferior to extra amniotic saline instillation through a transcervical Foley catheter.

363 pregnant women were studied by Ghanaie MM et al.[36] The aim of the trail was to see the efficacy of PGE2 suppository, intracervical foley catheter, and extra-amniotic saline infusion in inducing labour. 6 hours after administration of normal saline in the EASI group showed an enhancement of Bishop Score. The average time to active phase for the EASI, foley, and PGE2 groups was 357±135 minutes, 457±178, and 609±238 minutes, respectively. The rate of spontaneous membrane rupture was found to be greater in the EASI group. When comparing the EASI group to the other group, the mean time from the start of induction to membranes

rupture, which was spontaneous, was found to be shorter for the EASI group. For the EASI, foley, and PGE2 groups, the mean time to vaginal delivery was 14.8±6.1,11.4±4.8, and 18.9±6.4, respectively. Pre-induction cervical ripening by EASI with simultaneous oxytocin was found to be effective in this study.

A study including 106 pregnant women was done by Varghese DP. et al.[25] This trial's objective was to know if an extra amniotic saline infusion induction using a foley catheter may help with cervical ripening before using intravaginal prostaglandin E1 to induce labour. The modified Bishop score in group A improved significantly after the Foley catheter was removed, according to the findings. The duration from induction to delivery was shown to be shorter in group A, but within 24 hours span, the rate of vaginal delivery was found to be shorter in group B. No significant differences between the groups in terms of mode of delivery, intrapartum problems, rate of ARM, oxytocin usage, or neonatal outcomes. Extra amniotic saline infusion induction using transcervical Foley catheter was found to be a successful method in this trial.

A study of 150 pregnant women was done by Dhakal KB et al.[22] For cervical priming, before to induction, this study assessed the efficacy, cost-effectiveness, and safety of extra-amniotic saline infusion, Foley's catheter, and intra-cervical PGE2 gel. The majority of the cases (67.3%) were identified to be primigravida. Pregnancy after the due date was the most prominent reason for induction, accounting for 72 percent of cases. In comparison to the other groups, Foley's catheter had taken less mean time from the start of induction to cervical priming. Bishop score of 7 or above was achieved by patients induced with Foley's catheter and EASI with 88 percent and 84 percent, respectively, within 24 hours of induction. With 14.95 hours, the average duration from induction to vaginal birth is shorter in EASI. The

Foley catheter and induction using extra-amniotic saline infusion were shown to be the most effective, cost-efficient, and safe techniques of cervical priming in this research.

Sudha Pullemalla et al.[37] conducted a 120-woman comparative prospective survey. The objective of this research was to compare the efficacy of extra amniotic saline infusion and prostaglandin E2 gel was at inducing labour. The mean time from induction to active labour in primi with extra amniotic saline infusion and PGE2 gel was 6.1 hours and 8.2 hours, respectively. The mean duration from induction to active labour in multiparous women who were induced with extra amniotic saline infusion was 4.8 hours. The rate of vaginal delivery was 71.6 percent in the extra amniotic saline infusion group and 65 percent in the group induced with dinoprostone, respectively. The PGE2 gel group had a 30% LSCS rate, while the extra amniotic saline infusion group had a 25% LSCS rate. Caesarean section rates were reduced in the EASI group. In the EASI group, 1.6 percent of patients had failed induction, while in the PGE2 gel induced group was 5 percent. The NICU admission was higher in the PGE2 group with 10%. Birth asphyxia and meconium aspiration were the causes of NICU admission. The study concluded that the cervical priming was more successful in the extra Amniotic Saline Infusion group.

Jameela C. et al.[38] conducted a study in 50 women. The purpose of this study was to know if a transcervical Foley catheter with or without extra amniotic saline infusion may help induce labour. The induction to the delivery interval in the extra amniotic saline infusion group was 11.2 hours, whereas, in the Foley group, it was 11.46 hours. In terms of Bishop Score change, there were no statistically significant changes between the groups. The caesarean rate did not differ significantly between the two groups. Also found that adding extra amniotic saline to a woman's cervix did not improve the successful labour induction in women with an unfavourable cervix.

A study of 70 women was done by Ziyauddin F et al.[26] The aim of the study was to compare the safety and efficacy of the transcervical Foley catheter vs. the prostaglandin E2 gel in inducing labour. The foley catheter and the PGE2 gel had a similar effect on the bishop's score after 12 hours, as per the findings. The Foley catheter had a somewhat short mean duration induction to delivery of 18.15 hours compared to the PGE2 gel's 21.06 hours. The Foley catheter's cervical ripening impact reported as good as that of the Prostaglandin E2 gel in the study.

A randomized controlled trial was conducted in 160 women by Nusee Z et al.[26] The study's objective to know the efficacy of 750 mL traction on a Foley catheter was at inducing labour compared to no traction. In both groups, the rate of change in Bishop Score was found to be similar. The traction group had a greater rate of vaginal delivery (70%) than the control group. In terms of neonatal and maternal outcomes, there was no noticeable difference. According to the findings, using traction resulted in more vaginal deliveries and successful VBACs.

A study of 101 pregnant women was conducted by Henry A et al.[39] The study's goal was to know the feasibility, clinical efficacy, and patient acceptance of an outpatient Foley catheter vs. an inpatient vaginal PGE2 induction for term labour. The OPC group had a shorter hospital stay prior to birth, according to the study's findings. IP was 53 percent, who had a likelihood of vaginal delivery within 12 hours of coming to the Birthing Unit. Vaginal birth rates were 66 percent and 71 percent in the OPC and IP, respectively. Total time from induction to vaginal birth was 33.5 hours and 31.3 hours, respectively. During cervical preparation, the OPC group experienced less discomfort and slept more. The OPC was shown to be viable and acceptable for Labour induction in women with an unfavorable cervix at term, according to the findings.

A study of 100 pregnant women was done by Kumar S et al.[31] The researchers wanted to see how efficient extra-amniotic saline infusion was for ripening of the cervix and labour induction compared to intracervical Prostaglandin E2 gel. The EASI group had a post-induction Bishop Score, which was good, whereas the PGE2 group had a longer mean augmentation duration. In the PGE2 group, the time from induction to delivery was longer. The extra amniotic saline infusion was found to be a better solution to PGE2 gel for cervical ripening prior to induction in this trial.

A study was conducted on pregnant women by AJ K et al.[40] The researchers wanted to know how good vaginal PGE2 and PGF2- alfa compared to placebo or other vaginal prostaglandins can act for cervical ripening or labour induction in the third trimester. The inclusion of vaginal prostaglandin E2 reduced the chances of vaginal birth. With vaginal prostaglandin E2, the likelihood of the cervix staying unfavourable or unchanged was reduced by 21.6 percent. Moreover, the chance of oxytocin augmentation was lowered by 35.1 percent. With foetal heart rate variations, the chance of uterine hyperstimulation rose by 4.4 percent. The study revealed that vaginal PGE2 with a prolonged release is preferable than vaginal PGE2 gel.

J T, et al.[41] The goal of the study was to compare vaginal prostaglandins E2 and F2a affected cervical ripening or initiation of labour in the third trimester. According to the findings, as compared to placebo or no therapy, vaginal prostaglandin E2 reduces the chance of a vaginal birth not occurring within 24 hours. With foetal heart rate variations, the risk of uterine hyperstimulation increased, whereas the rate of caesarean section reduced. According to the study, the prostaglandins PGE2 increase the likelihood to deliver the baby vaginally within 24 hours.

A prospective observational study was carried by K.M et al.[42] The goal of the trial was to see if using a foley catheter with extra amniotic saline infusion may help in cervical ripening and induction of labour. The mean pre-treatment Bishop Score was found to be 2.125 ± 0.609 in the research. After EASI, there was a considerable improvement in the Bishop's Score. Vaginal birth was 76.6 percent of the time, while the caesarean section was 18.4 percent of the time. The average Induction Delivery interval was 11.02 hours, with an average Apgar score of 8.94 at 5'. According to the findings, the EASI is a simple, affordable, and easily accessible form of induction that results in a shorter induction delivery interval and a higher vaginal delivery rate.

Geetha R. et al.[43] The goal of the trial was to see if extra amniotic saline infusion through intracervical balloon catheter and Foley bulb induction were successful for inducing labour. When compared to Foley's bulb induction, the mean Bishops score rose by 6,12 hours in primigravida. The foleys group of patients with Foley bulb induction used greater oxytocin augmentation. Vaginal birth rates were 53.1 percent and 46.9 percent in the EASI and foleys bulb groups, respectively. In the EASI group, there was a significant improvement in the bishop's score. The mean time from induction to active labour was shorter in the EASI group. In both groups, the mean induction to active labour interval and the mean induction to the delivery interval was shorter in multi than in primi. In the EASI and Foleys bulb induction groups, the LSCS incidence for unsuccessful induction was 46.4 percent and 46.4 percent, respectively.

A prospective study of 100 pregnant women was undertaken by A. RA et al.[32] The researchers wanted to see how prostaglandin E2 (PGE2) compared to the extra amniotic saline infusion (EASI) for pre-labour ripening. In both groups, the majority of the individuals were between

the ages of 21 and 30. There was a substantial difference in the incidence of hyper stimulation between PGE2 and EASI in both groups. The EASI revealed a high rate of caesarean section. The APGAR score of new born new-borns was shown to be high in PGE2-induced labour. The EASI was shown to be more cost-effective than PGE2 in the study.

LITERATURE LACUNAE:

Administering extra amniotic saline using foley's catheter in inducing the labour process has been examined very infrequently. There are only a few trials in India that looked at the effectiveness of an extra amniotic saline infusion induction with transcervical catheter and intra cervical prostaglandin E2 gel for inducing labour in term pregnant women.

MATERIAL & METHODS

MATERIALS AND METHODS:

Source of data: The study will be conducted at R.L. Jalappa Hospital and research center, Tamaka, Kolar, attached to Sri Devaraj Urs medical college.

Study design: A Comparative study

Study period: January 2020 – June 2021

Sample size:

Total sample size- 72 cases (36 in transcervical foley and 36 in cervical E2 gel group) is estimated based on the induction delivery interval between two groups (transcervical foley's and Dinoprostone) as 6.9± 1.9 hours and 5.2± 2.3hours respectively from the study by Sunil kumar et al.[44] Considering these values at 1.7% alpha error and 80% power a sample size of 32 in each group is obtained from Open Epi software.

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 α/2= Z 0.05/2 = Z 0.025 = 1.96 (From Z table) at type 1 error of 5%

Zβ = 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:

Inclusion Criteria:

- Singleton pregnancy with a cephalic presentation more than 37-42 weeks of gestation visiting labour room at R.L. Jalappa Hospital.
- Intact membranes
- Bishop score <6
- Reactive Non-Stress Test.

Exclusion Criteria:

- Previous Caesarean section / scarred
- IUD
- Contraindications of labour induction.

Methodology:

Patients meeting the inclusion criteria will be enrolled and admitted to the hospital. Informed written consent will be obtained. A detailed history will be collected regarding maternal age, gestational age, parity. Baseline investigations will be done, including full blood count, blood group and Rh factor, urine routine examination, platelets count, and coagulation profile. General physical examination, per abdominal examination, non-stress test, Cardio tomogram CTG evaluation, USG will be done. Per vaginal examination will be carried out to assess Bishop's score.

By using the simple lottery method, patients will be divided into group A (Extra amniotic saline infusion group with Foley's catheter) and group B (Dinoprostone (PGE2 gel) group).

Group A: Extra amniotic saline infusion group with Foley's catheter:

All women will undergo a per speculum examination. Cervix will be prepared with betadine solution. The prophylactic antibiotic will be given to all patients before half an hour to the procedure. Foley's catheter of size 16-18F in primigravida and 18-20F in multigravida will be passed through the cervical canal past the internal OS. Foley's balloon will be inflated with 30-40ml sterile water. The catheter will be gently withdrawn until it rests at the level of the

internal OS. With moderate traction on the catheter, 200 ml of isotonic saline is infused through the catheter into the extra amniotic space. With the same traction, the catheter is taped into the inner aspect of the thigh. The catheter is blocked by putting a knot on the catheter before taping it. Catheter is left in place for 24 hrs.[14]

Pulse rate, Blood Pressure, uterine activity, fetal heart rate, respiratory rate, bleeding P/V will be monitored regularly. The catheter is removed after 24hrs. Per vaginal examination will be done when the catheter fell out or after removal at 24 hrs to assess Bishop score. Catheter is assessed every 6 hrs whether it falls out/ removed after 24 hrs to assess Bishop's score. When the cervix is favourable, i.e., the cervix is 4cm dilated, artificial rupture of membranes (ARM) is done, and Oxytocin augmentation will be done as per the protocol of the labour ward. If the cervix is unfavourable, it will be augmented with Misoprostol 25mcg every 4th hrly.

Group B – Dinoprostone (PGE2 gel) group:

For subjects assigned to this group, dinoprostone will be instilled into the endocervical canal. After 6 hours of instillation, a repeat vaginal examination is done, and the bishop score is reassigned. If no improvement in Bishop's score, a repeat dose of dinoprostone (PGE2) is done to a maximum of 3 doses. The time to achieve maximum dosing of Dinoprostone is 24hrs.

Pulse, BP, uterine contractions, fetal heart rate, bleeding P/V will be monitored regularly. If Bishop's score was found favourable, oxytocin augmentation will be done as per the protocol of the labour ward.

STATISTICAL METHODS:

Bishop's score, NICU admission, APGAR score, etc., were considered as primary outcome variables. The study group was considered as a primary explanatory variable.

For categorical data, descriptive analysis was performed using frequency and percentage. Data was also represented using appropriate diagrams like bar diagrams.

All Quantitative variables were checked for normal distribution within each category of an explanatory variable by using visual inspection of histograms and normality Q-Q plots.

Shapiro- Wilk test was also conducted to assess normal distribution. Shapiro Wilk test p-value of >0.05 was considered as a normal distribution.

Categorical outcomes were compared between study groups using the 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.).

P value < 0.05 was considered statistically significant.

Data were analysed by using SPSS software, V.22.[45]

RESULTS

OBSERVATIONS AND RESULTS:

A total of 72 people took part in the trial, with 36 in the EASI group and 36 in the Dinoprostone group.

Table 1: Descriptive analysis of study group in the study population (N=72)

Study Group	Frequency	Percentages
EASI	36	50.00%
Dinoprostone	36	50.00%

Figure 2: Bar chart of the study group in the study population (N=72)

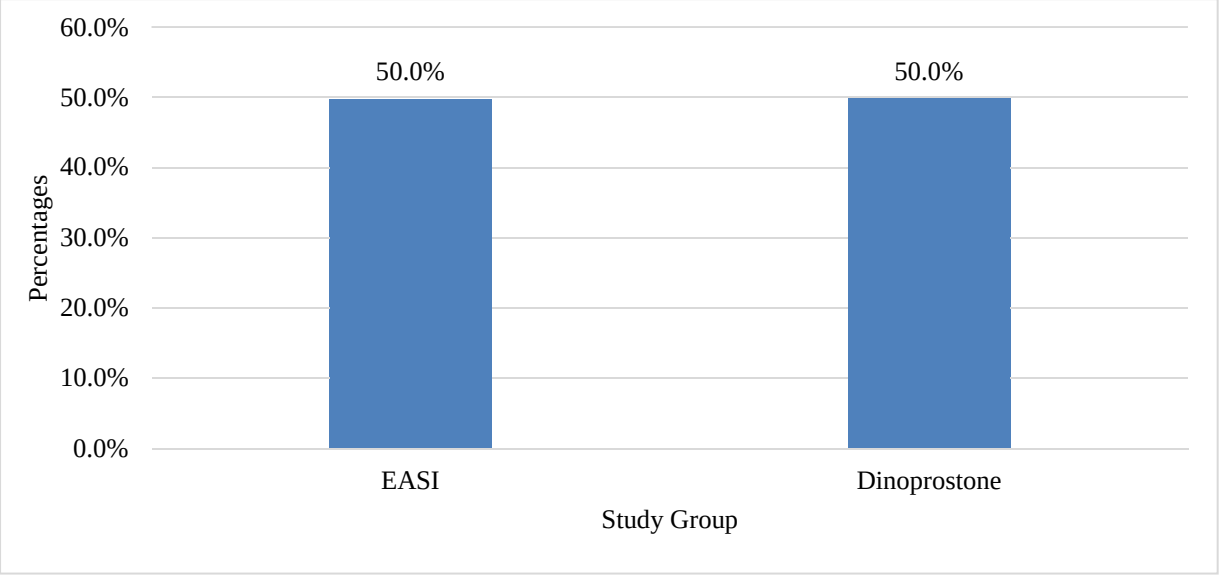


Table 2: Comparison of maternal age between study group (N=72)

Maternal Age (years)	Study Group	
	EASI (N=36)	Dinoprostone (N=36)
19-20	0 (0%)	35 (97.22%)
21-25	34 (94.44%)	1 (2.78%)
26-30	2 (5.56%)	0 (0%)

*No statistical test was applied- due to 0 subjects in the cells

There was a majority as 34(94.44%) with 21-25 years maternal age in EASI group, whereas majority 35(97.22%) reported19-20 years maternal age in dinoprostone group. (Table 2 & Figure 3)

Figure 3: Cluster bar chart of comparison of maternal age between study group (N=72)

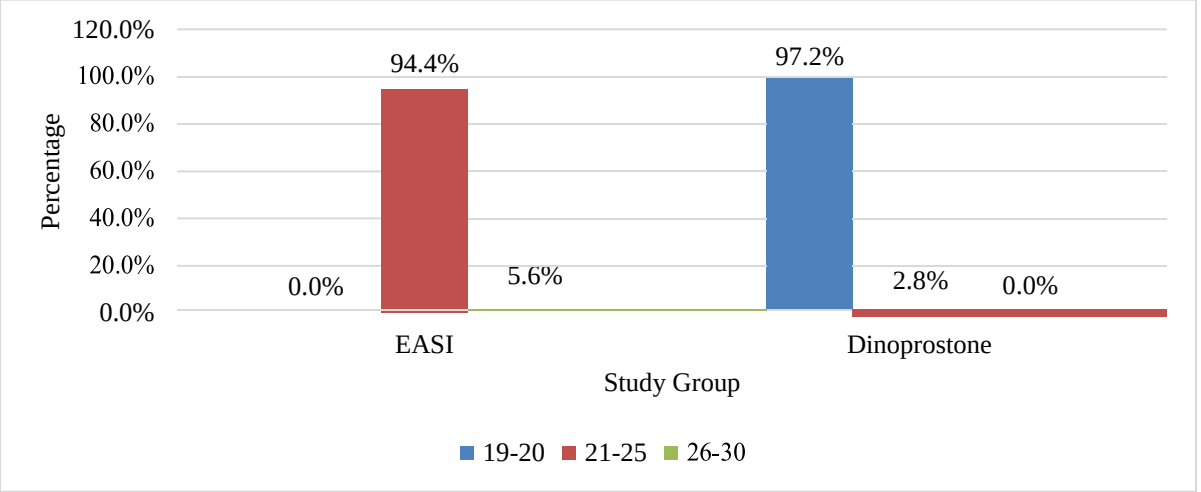


Table 3: Comparison of parity between study groups (N=72)

Parity	Study Group		Chi-square	P-value
	EASI (N=36)	Dinoprostone (N=36)		
Primi Gravida	17 (47.22%)	22 (61.11%)	1.399	0.237
Multi Gravida	19 (52.78%)	14 (38.89%)		

Primi gravida was there in 17(47.22%) in the EASI group, and it was 22(61.11%) in the dinoprostone group. The difference in Parity between study groups was statistically not significant (P-value 0.237). (Table 3)

Table 4: Comparison of gestational age between study group (N=72)

Gestational Age	Study Group		Chi-square	P-value
	EASI (N=36)	Dinoprostone (N=36)		
37W- 38+6 Days	7 (19.44%)	9 (25%)	0.740	0.864
39 W -39+6 Days	14 (38.89%)	13 (36.11%)		
40 W – 40 + 6 Days	9 (25%)	10 (27.78%)		
41 W – 41+6 Days	6 (16.67%)	4 (11.11%)		

Gestational age was 37-38+6 days in EASI group as 19.44% (7/36), 38.89% (14/36) were 39 to 39+6 days of gestational age,25% (9/36) were 40 to 40+6 days and 16.67% (6/36) were 41 to 41+6 days. In the dinoprostone group, 37 to 38+6 days gestation age was reported with 25% (9/36), 39 to 39+6 days gestation age was reported with 36.11% (13/36),40 to 40+6 days gestation age was reported with 27.78% (10/36) and 41 to 41+6 days reported with 11.11% (4/36). The difference of gestational age between study groups was statistically not significant (P-value 0.864). (Table 4 & Figure 4)

Figure 4: Cluster bar chart of comparison of gestational age between study group (N=72)

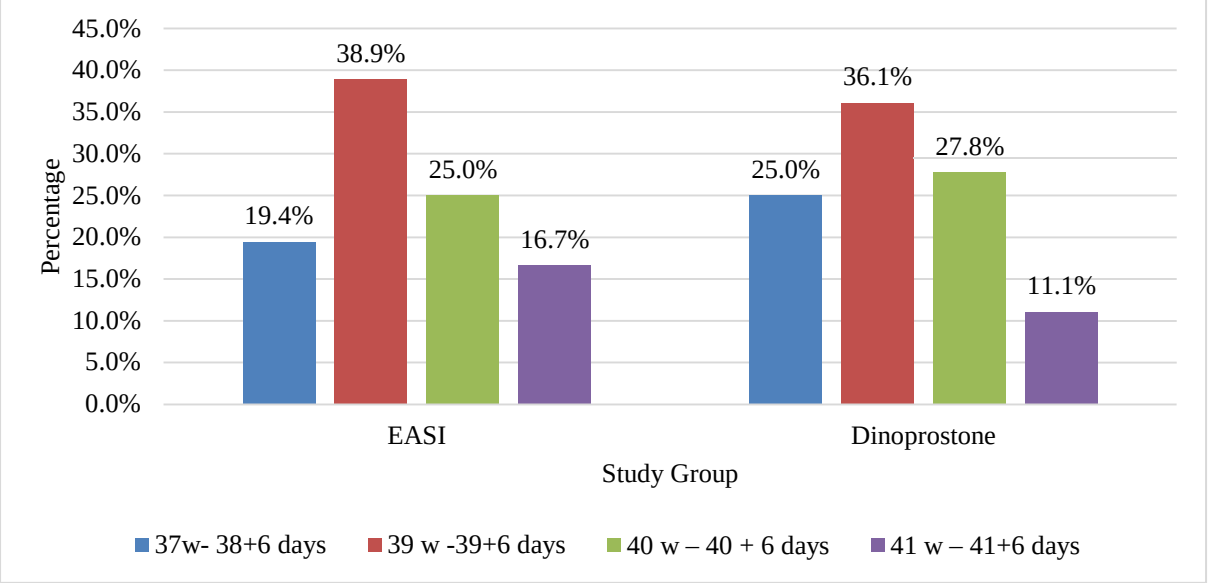


Table 5: Comparison of indication of induction between study group (N=72)

Indication Of Induction	Study Group	
	EASI (N=36)	Dinoprostone (N=36)
Post Dated	14 (38.89%)	13 (36.11%)
Preeclampsia	14 (38.89%)	12 (33.33%)
Oligohydramnios	8 (22.22%)	9 (25%)
Rh Negative Pregnancy	0 (0%)	2 (5.56%)

*No statistical test was applied- due to 0 subjects in the cells

Post-dated indication of induction was majorly reported in both the study groups as 38.89% (14/36) and 36.11% (13/36) in EASI and Dinoprostone groups, respectively. The proportion of preeclampsia was 38.89% (14/36) in the EASI group, and it was 33.33% (12/36) in the dinoprostone group. (Table 5 & Figure 5)

Figure 5: Cluster bar chart of comparison of indication of induction between study group (N=72)

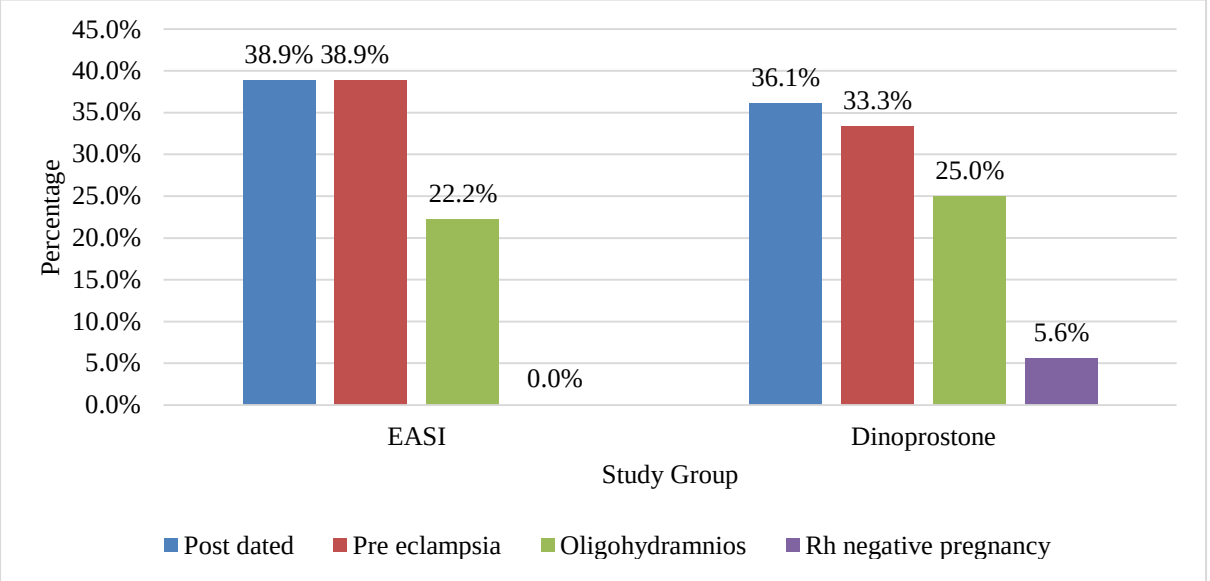


Table 6: Comparison of pre-induction modified bishop's score between study group (N=72)

Pre-Induction Modified Bishop's Score	Study Group		Chi-square	P-value
	EASI (N=36)	Dinoprostone (N=36)		
1	4 (11.11%)	5 (13.89%)	2.311	0.510
2	18 (50%)	12 (33.33%)		
3	10 (27.78%)	15 (41.67%)		
4	4 (11.11%)	4 (11.11%)		

Pre induction modified Bishop's score was 1 in 11.11%,13.89% in EASI, Dinoprostone groups respectively and similarly, it was 2 in 50%, 33.33% in two groups respectively. The proportion of score 3 was 10 (27.78%) in the EASI group and 15 (41.67%) in the dinoprostone group. 4(11.11%) was reported bishop's score as 4 in both the groups. The difference in bishop's score between study groups was statistically not significant (P-value 0.510). (Table 6 & Figure 6)

Figure 6: Cluster bar chart of comparison of pre-induction modified bishop's score between study group (N=72)

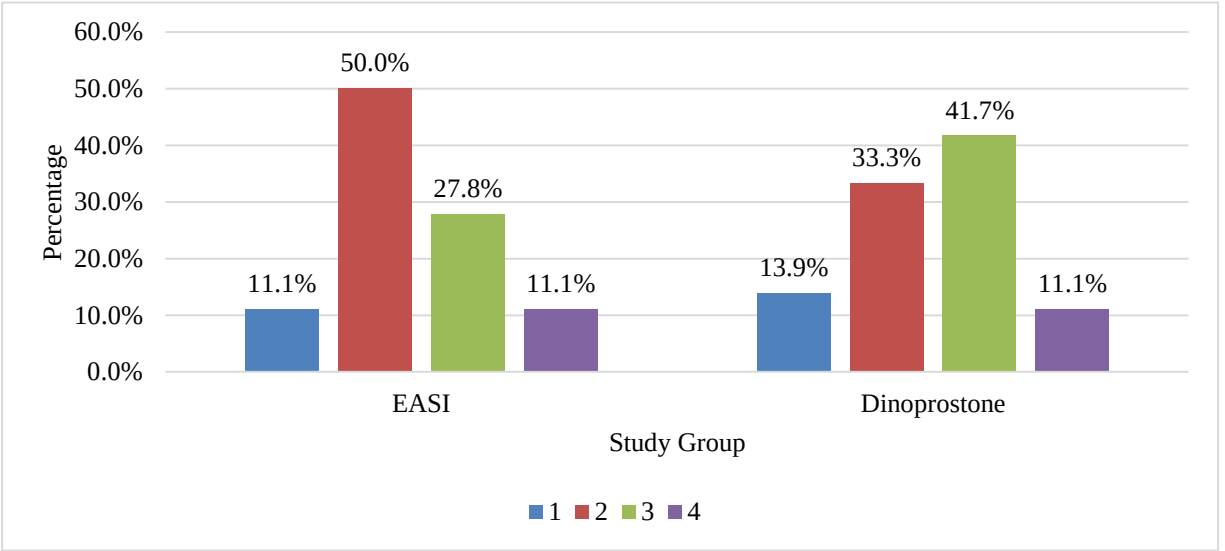


Table 7: Descriptive analysis of the number of doses in the dinoprostone group (N=36)

Number of Doses	Frequency	Percentages
1	13	36.11%
2	17	47.22%
3	6	16.67%

In the Dinoprostone group, No. of doses was 1 in 13 (36.11%), 2 doses received in 17 (47.22%), and it was 3 in 6 (16.67%). (Table 7)

Table 8: Comparison of induction to active stage interval between study group (N=72)

Induction to active stage interval	Study Group		Chi-square	P-value
	EASI (N=36)	Dinoprostone (N=36)		
4 to 6 hours	15 (41.67%)	7 (19.44%)	4.329	0.115
7 to 9 hours	12 (33.33%)	15 (41.67%)		
10 to 12 hours	9 (25%)	14 (38.89%)		

Induction to active stage interval was 4 to 6 hours in the majority as 15(41.67%) in the EASI group and it was 7 to 9 hours in the dinoprostone group as a majority with 15(41.67%). The difference in induction to active stage interval between study groups was statistically not significant between study groups (P-value 0.115). (Table 8)

Table 9: Comparison of induction to the delivery interval between study group (N=72)

Induction To Delivery Interval	Study Group		Chi-square	P-value
	EASI (N=36)	Dinoprostone (N=36)		
5 To 10 Hours	8 (22.22%)	4 (11.11%)	1.824	0.610
11 To 15 Hours	12 (33.33%)	12 (33.33%)		
16 To 20 Hours	14 (38.89%)	17 (47.22%)		
21 To 25 Hours	2 (5.56%)	3 (8.33%)		

Induction to the delivery interval was 16 – 20 hours in the EASI group as the majority in 14 (38.89%), and in the dinoprostone group, the major interval was reported in 17 (47.22%). The difference in induction to the delivery interval between study groups was statistically not significant (P value>0.05). (Table 9)

Table 10: Comparison of the mode of delivery between study group (N=72)

Mode of delivery	Study Group		Chi-square	P-value
	EASI (N=36)	Dinoprostone (N=36)		
Vaginal	17 (47.22%)	21 (58.33%)	0.988	0.610
Vacuum Assisted Vaginal	6 (16.67%)	4 (11.11%)		
Caesarean Section	13 (36.11%)	11 (30.56%)		

Vaginal delivery was done majorly in both the groups as 17(47.22%), 21(58.33%) in EASI group and dinoprostone group respectively, followed by caesarean section with 13(36.11%) and 11(30.56%) in EASI and dinoprostone groups. The difference in the mode of delivery between study groups was statistically not significant (P-value 0.610). (Table 10 & Figure 7)

Figure 7: Cluster bar chart of comparison of mode of delivery between study group (N=72)

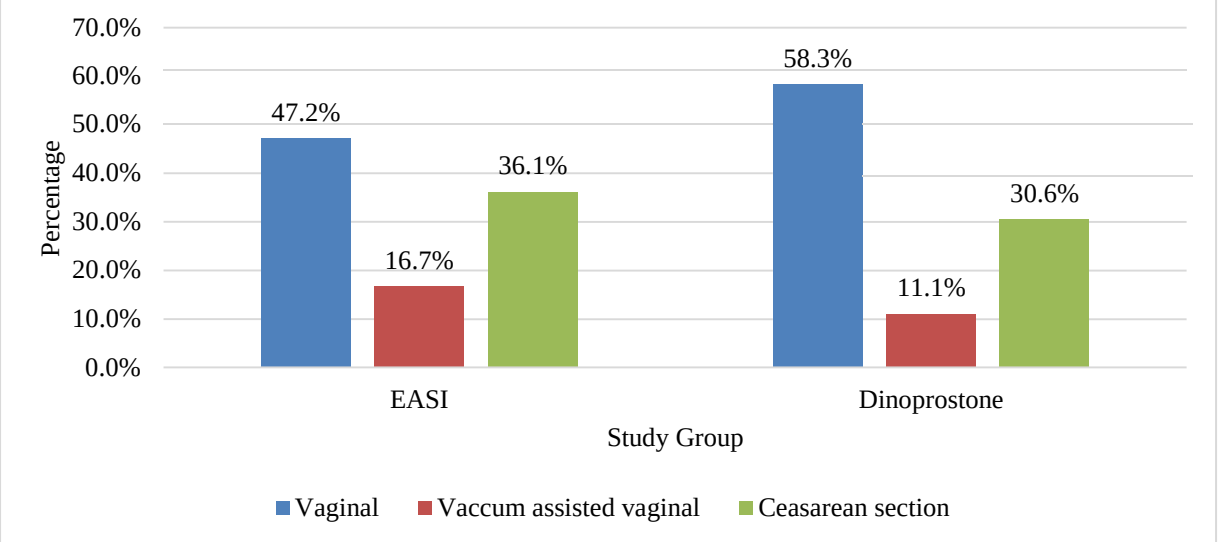


Table 11: Comparison of indication for c section between study group (N=24)

Indication For C Section	Study Group		Chi-square	P-value
	EASI (N=36)	Dinoprostone (N=11)		
Fetal distress	7 (53.85%)	6 (54.55%)	0.111	0.946
Failed induction	3 (23.08%)	2 (18.18%)		
Non-progression of labour	3 (23.08%)	3 (27.27%)		

Fetal distress was more in both the groups EASI and dinoprostone as an indication for C section with 53.85% and 54.55%, respectively. Followed by failed induction and non-progression of labour in EASI with 23.08% for each. Followed by failed induction and non-progression in the dinoprostone group as 18.18% and 27.27%. The difference in indication for the C section between study groups was statistically not significant (P-value 0.946). (Table 11)

Table 12: Comparison of oxytocin augmentation requirement between study group (N=72)

Oxytocin Augmentation Requirement	Study Group		Chi-square	P-value
	EASI (N=36)	Dinoprostone (N=36)		
Not Required	14 (38.89%)	34 (94.44%)	25.000	<0.001
Required	22 (61.11%)	2 (5.56%)		

Oxytocin augmentation requirement was present in only 22(61.11%) in the EASI group and very less people in 2(5.56%) in the dinoprostone group. The difference in Oxytocin augmentation requirement between study groups was statistically significant (P value<0.001). (Table 12 & Figure 8)

Figure 8: Cluster bar chart of comparison of oxytocin augmentation requirement between study group (N=72)

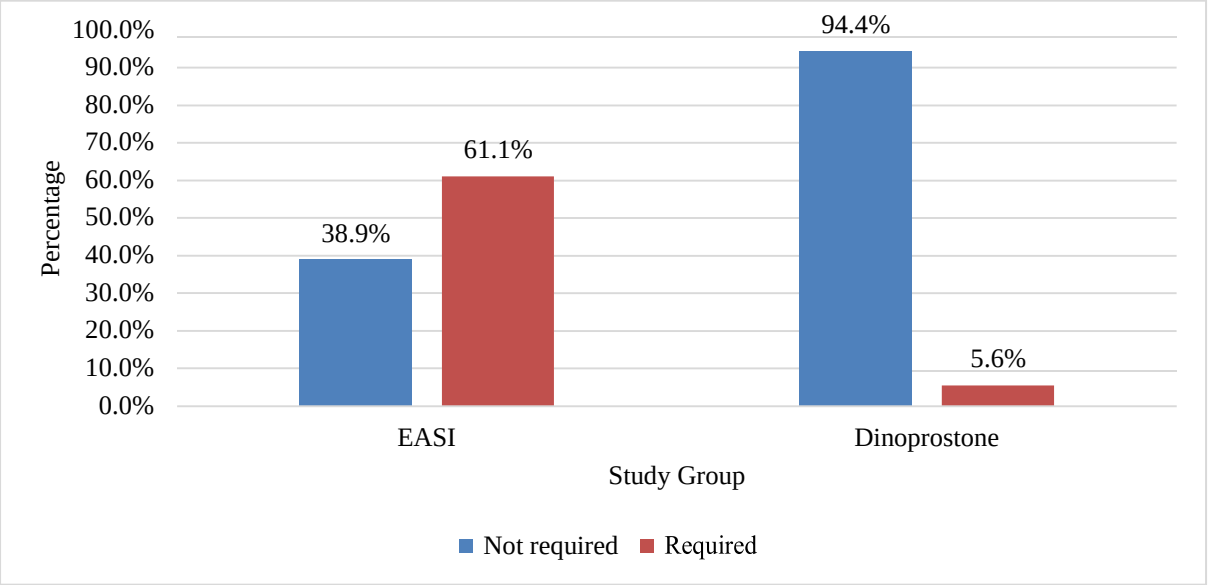


Table 13: Comparison of liquor between study group (N=72)

Liquor	Study Group		Fisher exact P-value
	EASI (N=36)	Dinoprostone (N=36)	
Clear	35 (97.22%)	33 (91.67%)	0.614
Meconium-Stained Liquor	1 (2.78%)	3 (8.33%)	

Meconium-stained liquor was present in less proportion in both groups as 1(2.78%) in the EASI group and 3(8.33%) in the dinoprostone group. The difference in liquor status between study groups was statistically not significant (P-value 0.614). (Table 13 & Figure 9)

Figure 9: Cluster bar chart of comparison of liquor between study group (N=72)

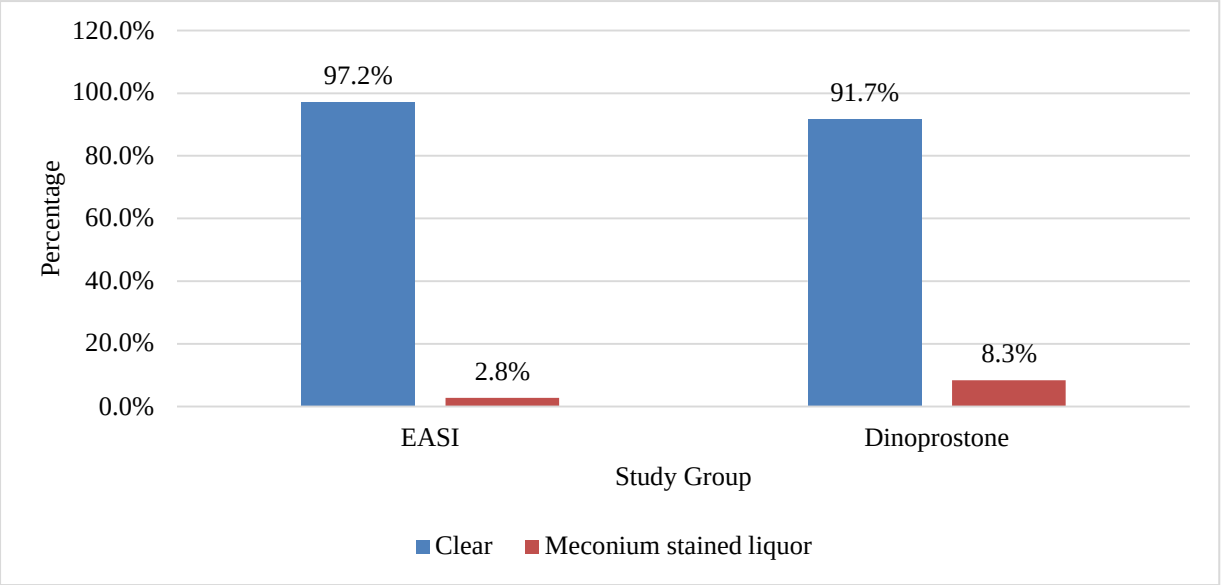


Table 14: Comparison of APGAR AT 1 minute between study group (N=72)

APGAR at 1 Minute	Study Group	
	EASI (N=36)	Dinoprostone (N=36)
>or =7	36 (100%)	36 (100%)
<7	0(0%)	0(0%)

*No statistical test was applied- due to 0 subjects in the cells.

APGAR score was >or=7 at 1 minute in both the groups was 100%. (Table 14)

Table 15: Comparison of APGAR at 5 minutes between study group (N=72)

APGAR at 5 Minute	Study Group	
	EASI (N=36)	Dinoprostone (N=36)
>or =9	36 (100%)	35 (97.22%)
<9	0 (0%)	1 (2.78%)

*No statistical test was applied- due to 0 subjects in the cells

APGAR score was >/=9 at 5 minutes in 100% EASI group, whereas it was in 97.22% in the dinoprostone group. (Table 15)

Table 16: Comparison of NICU admission between study group (N=72)

NICU Admission	Study Group		Chi-square	P-value
	EASI (N=36)	Dinoprostone (N=36)		
Yes	5 (13.88%)	7 (19.44%)	0.966	0.326
No	31 (86.11%)	29 (80.56%)		

NICU admission was reported in 5(13.88%) in the EASI group, and it was 7(19.44%) in the dinoprostone group. The difference in NICU admission between study groups was statistically not significant (P-value 0.326). (Table 16 & Figure 10)

Figure 10: Cluster bar chart of comparison of NICU admission between study group (N=72)

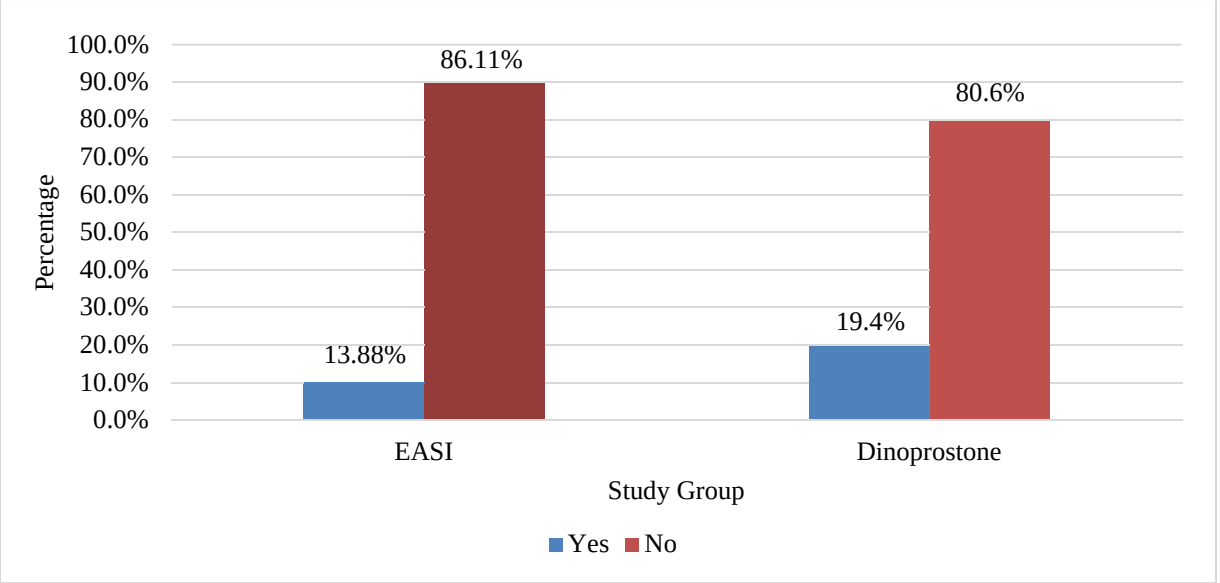


Table 17: Comparison of cause for NICU admission between study group (N=11)

Cause For NICU Admission	Study Group		Fisher exact P-value
	EASI (N=36)	Dinoprostone (N=7)	
Post Resuscitation Care	1 (20%)	1 (14.29%)	1.000
Respiratory Distress	4 (80%)	6 (85.71%)	

Respiratory distress was noted as a major cause for NICU admission in both groups as 4(80%) in EASI groups and 4(80%) 85.71% in the dinoprostone group. (Table 17)

Table 18: Comparison of maternal adverse effects between study group (N=72)

Maternal adverse effects	Study Group	
	EASI (N=36)	Dinoprostone (N=36)
No	36 (100%)	36 (100%)

No maternal adverse effects present in both the groups. (Table 18)

Note: Reassuring FHR was present in all participants in both study groups.

DISCUSSION

DISCUSSION:

The intentional initiation of ripening of the cervix and uterine contraction for the aim of achieving delivery prior to the onset of spontaneous parturition is referred to as induction of labour. When the advantages to the mother or the foetus surpass the benefits of extending the pregnancy, it is suggested. Labour usually begins on its own and ends with a vaginal birth at or near term. Cervical ripening and labour induction are frequently required in medical or obstetric problems during pregnancy. The extra amniotic saline infusion induction using foley's catheter has rarely been studied. Initial tests in India revealed that it was more successful than intravaginal prostaglandins, with less adverse effects. This method has reported to be safe, can be tolerated well by women, and should be explored in resource-constrained places. The purpose of this study was to assess the effectiveness of a transcervical Foley catheter to extra amniotic saline infusion and intra cervical prostaglandin E2. In this study, 72 people were enrolled.

In this study, 50% of each group belonged to EASI and 50% to dinoprostone, respectively. Prajakta Goswami et al.,[33] conducted a randomized prospective trial on 200 pregnant women, with 50% of them belonging to the EASI and PGE2 groups, which matches our findings. The majority of people in the EASI group were between the ages of 21 and 25, whereas the dinoprostone group included 97.22 percent of those between the ages of 19 and 20.

The bulk of women in the EASI group in the Rachel Alexander A. et al.[32] study was between the ages of 21 and 30, accounting for 71.70 percent, followed by women between the ages of 20 and 24,53 percent. Similarly, 73.47 percent of the PEG2 group belonged to the age bracket of 21-30 years, with 12.25 percent belonging to the age group of less than 20 years.

Our findings were similar to those of Steffi V Rodrigues et al.[46], Rachel Alexander A. et al.[32]

Table 19: Comparison of mean of age between various studies.

Study	Population	Mean of age	
Present study	72	EASI 19-20 (0%) 21-25 (94.44%) 26-30 (5.56%)	Dinoprostone 19-20 (97.22%) 21-25 (2.78%) 26-30 (0%)
Steffi V Rodrigues, et al.[46]	82	EASI <19 (31.71%) 21–25 (51.22%) 26–30 (17.07%) >=31 (0%)	Dinoprostone <19 (36.59%) 21–25 (48.78%) 26–30 (12.20%) >=31 (2.44%)

In the current study, the majority of the patients in the EASI group (52.78 percent) were multigravida, whereas the dinoprostone group (61.11 percent) was the primigravida. Sunil Kumar et al.[44] found that the majority of individuals in the EASI group were multigravida (34%) and primigravida (38%) in the PEG2 group, which is similar to our findings.

Another research by Prajakta Goswami et al.[33] found that the majority of individuals in the EASI and PGE2 groups were primigravida, with 66 percent and 70% respectively, which contradicted our findings.

The majority of individuals in the EASI and dinoprostone groups had a gestational age of 39 W-39+6 Days, with 38.89 percent and 36.11 percent, respectively, in the current research. Steffi V Rodrigues et al.[46] conducted a randomized controlled experiment on 82 women, finding that 51.22 percent and 58.54 percent of the pregnant women in the dinoprostone gel and extra-amniotic saline infusion groups, respectively, had gestational ages of 41 and 42 weeks.

Our findings were similar to those of Prajakta Goswami et al.[33], Rodrigues et al.[46] and Prajakta Goswami et al.[33]

Table 20: Comparison of gestational age between various studies.

Study	Population	Gestational age	
Present study	72	EASI 37W- 38+6 Days (19.44%) 39 W -39+6 Days (38.89%) 40 W – 40 + 6 Days (25%) 41 W – 41+6 Days (16.67%)	Dinoprostone 37W- 38+6 Days (25%) 39W-39+6Days 36.11%) 40W–40+6Days 27.78%) 41W–41+6Days 11.11%)
Prajakta Goswami, et al.[33]	200	EASI <37 (16%) 37-40 (40%) 37-40 (42%) ≥42 (2%)	PGE2 <37 (15%) 37-40 (38%) 37-40 (43%) ≥42 (4%)

The most frequent causes for induction in the EASI group were postdate, preeclampsia, and oligohydramnios, accounting for 38.89 percent, 38.89 percent, and 22.22 percent, respectively. With 36.11 percent, 33.33 percent, and 25% in the dinoprostone group, respectively. Postdates, mild pre-eclampsia, oligohydramnios, and gestational hypertension were the most frequent causes for induction of labour in the EASI group (64 percent, 8 percent, 6 percent, and 10%, respectively), whereas, in the PEG2 group, it was 50 percent, 16 percent, 6 percent, and 10%, respectively.

PIH, IUGR, and post-dated pregnancy - frequent indications for labour induction in the Prajakta Goswami, et al.[33] study, with 43 percent, 32 percent, and 13 percent in the EASI group, and 46 percent, 26 percent, and 10 percent in the PEG2 group, respectively.

Sunil Kumar et al.[44] found that post-dated pregnancy was the most prevalent reason for induction. Prajakta Goswami et al.[33] as well as our research.

The majority of individuals in the EASI group had a modified Bishop's score of 2 after induction, with 50%, followed by a score of 3 with 27.78 percent. The majority of individuals in the dinoprostone group had a post-induction modified Bishop's score of 3 with 41.67 percent, followed by a score of 2 with 33.33 percent. In prospective research of 80 women, Dhananjaya BS. et al.[47] found that the majority of the study population in the EASI group had a post-induction modified Bishop's score of 2 (45%) while the majority of the individuals in the dinoprostone group had a post-induction modified Bishop's score of 3 (35%).

Bhargavi B et al.[6] discovered the post-induction modified Bishop's score in another research. The pre-induction Bishop's score was determined as 0 in 46.34 percent of subjects in the dinoprostone gel by Steffi V Rodrigues et al.[46] trial followed by 2 and 4 with 19.51 percent of each. Similarly, the majority of subjects in the extra-amniotic saline infusion group had a pre-induction Bishop's score of 0 (53.66 percent), followed by 4 and 2 (21.95 percent and 12.20 percent, respectively).

Dhananjaya BS et al. Bhargavi B et al.[47] Steffi V Rodrigues, et al.[46] and our study showed similar results.

In this study, the majority of individuals in the dinoprostone group got two doses (47.22 percent), followed by one dosage (36.11 percent). Patsy Varghese et al.[48] conducted a study on 106 women in which the majority of the subjects received two doses of PGE1, with 47.2 percent receiving two doses, 32.1 percent receiving one dosage, and 20.8 percent receiving three doses, respectively.

In the current study, the majority of cases (41.67% in the EASI group) had an induction to active stage interval of 4 to 6 hours, whereas the dinoprostone group had an induction to active stage interval of 7-9 hours.

V Vijayalakshmi et al.[37] conducted a prospective randomized control study on 200 pregnant women, finding that the majority of women with extra amniotic saline infusion induction established an active stage of labour in 6 hours, while the active stage of labour in PGE2 gel established in 6-12 hours, which is similar to our findings.

The majority of patients in the EASI and dinoprostone groups (38.89 percent and 47.22 percent, respectively) identified the induction to the delivery interval as 16–20 hours in the current study. The induction to the delivery interval in the Extra-amniotic saline infusion group showed 14.02 (hours), whereas it was 17.70 (hours) in the dinoprostone group, according to Steffi V Rodrigues et al.[46] research.

Another study by V Vijayalakshmi et al.[37] found that the majority of women with extra amniotic saline infusion induction delivered within 12 hours as compared to PGE2 gel, which matches our findings.

Vaginal birth was found as the most common mode of delivery in the EASI and dinoprostone groups, with 47.22 percent and 58.33 percent, respectively, followed by caesarean section with 36.11 percent and 30.56 percent.

The majority of the subjects in the Rachel Alexander A. et al.[32] study had a spontaneous method of birth with 68.09 percent and 62.26 percent, respectively, followed by caesarean section with 19.15 percent and 30.19 percent.

Sunil Kumar et al.[44] found that the majority of women in the EASI and PEG2 groups delivered vaginally, with 66 percent and 64 percent respectively.

In another research by V Vijayalakshmi et al., the majority of individuals in the EASI and PEG2 groups (76 percent and 67 percent, respectively) had vaginal deliveries.

Sunil Kumar et al.[44] and V Vijayalakshmi et al.[37] both found that vaginal birth was the most prevalent route of delivery.

Fetal distress failed induction and non-progression of labour were found as indications for the C section in the current study, with 53.85 percent, 23.08 percent, and 23.08 percent, respectively, in the EASI group. In the case of the dinoprostone group, it was found in 54.55 percent, 18.18 percent, and 27.27 percent.

Oxytocin augmentation was seen in 61.11 percent of EASI individuals and 5.56 percent of dinoprostone subjects in this study. The majority of individuals in the EASI group (86.79 percent) required oxytocin augmentation in Rachel Alexander A. et al.[32] research. PGE2 needed oxytocin augmentation in 42.55 percent of cases.

Another research by Farah Ziyauddin et al.[26] found that 26% of PGE2 group participants needed oxytocin augmentation.

Meconium-stained liquor was found in 2.78 percent of the study population in the EASI group and 8.33 percent in the dinoprostone group in the current research. Meconium staining was seen in 4% of participants in the EASI group and 18% in the PGE2 group in prospective and comparative research of 200 women done by Aruna Kumari et al.[35] Meconium staining was

seen in 9.43 percent of the EASI group and 8.51 percent of the PGE2 group in Rachel Alexander A. et al.[32] research.

10 Aruna Kumari et al.[35], A Meconium staining was higher in the PGE2 group than in the EASI group, according to Rachel Alexander A. et al.[32] and our investigation.

In this study, all subjects in the dinoprostone group had an APGAR score of >=9 at 5 minutes, whereas the EASI group had an APGAR score of 97.22 percent. In research with 70 participants, Farah Ziyauddin et al.[26] found that 51.43 percent of the patients in the PGE2 group had an APGAR score of 9 at 5 minutes.

NICU admission was recorded in 13.88 percent of the EASI group and 19.44 percent of the dinoprostone group in the current research. NICU admission was needed by 22.64 percent in the EASI group and 8.51 percent in the PGE2 group in the Rachel Alexander A. et al.[32] research.

NICU hospitalization was recorded in 2.86 percent of dinoprostone gel participants and 5.26 percent of EASI group participants in another investigation by Steffi V Rodrigues et al.[46] study.

Respiratory distress was the leading reason of NICU hospitalization in the current trial, accounting for 80 percent and 85.71 percent of NICU admissions in the EASI and dinoprostone groups, respectively. In research by Aruna Kumari et al.[35], foetal distress was detected in 7% of the EASI group and 10% of the PGE2 group, which was a lower percentage than in our study.

SUMMARY

SUMMARY:

The process of induction of labour can be done using different methods at the term gestation. Ripening of the cervix and labour induction techniques have proved the highest chances leading to vaginal birth and reduced rate of caesarean section in most of pregnant women. When induced electively, it has been proved in many studies that it showed a better outcome of both maternal and neonatal aspects. Available evidence along with this present comparative study have helped in inducing labour in pregnant women at term gestation using extra amniotic saline infusion technique and prostaglandin E2 gel. When induced electively, using any of the induction methods it has resulted in a better outcome of both maternal and neonatal aspects. The current opted comparative study in our medical facility have shown the efficacy of dinoprostone gel and extra amniotic saline infusion induction methods in pregnant women at term gestation.

- 72 individuals were enrolled in the present study.
- Most of the women belonged to 21-25 years of maternal age in the EASI group, whereas 19-20 years of maternal age in the dinoprostone group.
- The distribution of gravidity shows the majority of a primigravida in group b where as it was multigravida in the group A.
- Distribution of gestational age showed a majority of the study population were at 39 to 39+6 weeks.
- Most of the women presented induced with the indication like prolonged gestational age, preeclampsia in both groups.
- Modified bishop scores assessed in both the groups were almost similar preinduction whereas the post-induction bishop score was increased in the dinoprostone group.

- The number of doses of dinoprostone required was 2 doses in this present study in the majority of subjects.
- Induction to active stage interval was less in Group A (EASI) than Group B (PG E2 gel).
- Induction to the delivery interval was shortened in Group A than Group B.
- Oxytocin augmentation was more necessary in Group A when compared to Group B.
- The majority of the study population in the dinoprostone gel-induced group had vaginal delivery than that of the extra amniotic saline infusion-induced group.
- Indication for caesarean section was fetal distress in both the groups with 54.55% and 46.15%, respectively.
- Meconium-stained liquor was found in a population of Group B more when compared to Group A.
- All subjects had almost a similar APGAR Score in both the groups, whereas a requirement of NICU admission was more in Group B when compared to Group A.
- Our study found that PGE2 and EASI were equally effective in inducing labour and obtaining a better outcome.

CONCLUSION

CONCLUSIONS:

Our research found that PGE2 and EASI were equally effective in inducing labour. Foley's catheter with EASI is superior than the PGE2 technique of induction in highly unfavourable cervices, especially in locations with limited resources.

LIMITATIONS:

One of the study's primary limitations is the small sample size. The study might include detailed maternal and foetal outcomes.

RECOMMENDATIONS:

With a greater sample size, more research can be done.

The results of the mother and the foetus can be carefully incorporated in future investigations.

In nulliparous women, induction of labour is connected to a greater rate of operative vaginal delivery. Utilizing a transcervical Foley's catheter saline infusion into the extra amniotic space had a higher success rate, a better bishop score, and a faster ripening period. Other benefits include fewer problems, such as uterine hyperstimulation, cost-effectiveness, and the elimination of the requirement for a cold chain in low-resource settings.

When compared to the spontaneous labour group, nulliparous women who were induced using Foley's catheter took longer to proceed.

When compared to foley alone, the induction to the delivery interval was considerably shorter in the extra amniotic saline infusion group. The purpose of this study was to evaluate how effective it was to induce labour at term using a transcervical foley's catheter, extra amniotic saline infusion, and intra cervical prostaglandin E2 gel.

Prostaglandin E2 is the most widely recommended induction technique. Hyper stimulation is a limitation. There is now research being done to find less painful and effective techniques of inducing labour. For the aforementioned need, mechanical induction is suggested.

The use of the foley catheter to administer extra amniotic saline infusion has rarely been studied. Initial studies in India reported that it was more successful than intravaginal prostaglandins, with less adverse effects. The procedure has been found to be safe, can be tolerated well by women, and should be explored in areas where resources are few.

This study which included a total of 72 individuals, had the majority of participants in the EASI group between the ages of 21 and 25, whereas 97.22 percent in the dinoprostone group were between the ages of 19 and 20.

The EASI group, i.e., Group A, included 52.78 percent of multigravida participants, whereas the dinoprostone group, i.e., group B, had 61.11 percent, primigravida people. With 38.89 percent and 36.11 percent, respectively, of the individuals in the EASI and dinoprostone groups, the gestational age was between 39 W-39+6 Days.

In the EASI group, the indications for induction were post-dated, preeclampsia, and oligohydramnios, with 38.89 percent, 38.89 percent, and 22.22 percent, respectively. With 36.11 percent, 33.33 percent, and 25% in the dinoprostone group, respectively.

Modified Bishop’s score was identified as 2 after the induction by the majority of participants in the EASI group (50 percent), followed by 3 by 27.78 percent. The majority of individuals in the dinoprostone group had a post-induction modified Bishop's score of 3 with 41.67 percent, followed by a score of 2 with 33.33 percent. In the dinoprostone group, the majority of the individuals got two doses (47.22 percent), followed by one dosage (36.11 percent). In the majority of instances, the induction to active stage interval was 4 to 6 hours in the EASI group (41.67%) and 7-9 hours in the dinoprostone group (41.67%).

In the EASI and dinoprostone groups, the induction to the delivery interval was found to be 16–20 hours in 38.89 percent and 47.22 percent, respectively. Vaginal birth was found as the most common mode of delivery in the EASI and dinoprostone groups, with 47.22 percent and 58.33 percent, respectively, followed by caesarean section with 36.11 percent and 30.56 percent.

In the EASI group, foetal distress, pre-eclampsia, and Oligohydramnios were recognized as indications for the C section with 53.85 percent, 23.08 percent, and 23.08 percent, respectively. In the dinoprostone group, it was recognized with 54.55 percent, 18.18 percent, and 27.27 percent. Oxytocin augmentation was required in 61.11 percent of the EASI individuals and 5.56 percent of the dinoprostone subjects.

In the EASI group, 2.78 percent of women had meconium-stained liquor, compared to 8.33 percent in the dinoprostone group. At 5 minutes, all of the individuals in the dinoprostone group had an APGAR score of >=9, whereas the EASI group had an APGAR score of 97.22 percent. In the EASI group, 13.88 percent of patients were admitted to the NICU, compared to 19.44 percent in the dinoprostone group. Respiratory distress was the leading reason of NICU admission in the EASI and dinoprostone groups, accounting for 80 percent and 85.71 percent, respectively. PGE2 and EASI were shown to have equivalent effectiveness in inducing labour in our study. Foley's catheter with EASI is used in severely unfavourable cervices

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ANNEXURE

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION & RESEARCH, TAMAKA, KOLAR, KARNATAKA.

ANNEXURES

STUDY PROFORMA

Name:

I.P. No:

Age:

Occupation:

Address:

Husband's Occupation:

Socio-economic Status:

History of presenting illness:

Menstrual history:

obstetric history:

Past Medical history

Family History:

Personal History: Sleep:

Appetite:

Diet:

Bowel & Bladder:

G.P.E:

Build: Nourishment:

Pallor: Icterus: Cyanosis: Clubbing:

Lymphadenopathy: Pedal edema:

Pulse: B.P.: Temp:

Breast: Thyroid:

Systemic examination:

CVS:

RS:

CNS

Abdominal Examination:

Per speculum examination:

Per vaginum examination:

Investigations:

Complete blood picture with platelet count, mean platelet volume, and platelet distribution width.

BT, CT

SEROLOGY

Random Blood sugar

LFT

Coagulation profile

LDH

Serum uric acid

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION & RESEARCH, TAMAKA, KOLAR, KARNATAKA.

PATIENT INFORMATION SHEET

INDUCTION OF LABOUR USING TRANSCERVICAL FOLEY'S CATHETER WITH EXTRA AMNIOTIC SALINE INFUSION VERSUS INTRACERVICAL PROSTAGLANDIN E2 GEL AT TERM GESTATION- A COMPARATIVE STUDY

I have read the foregoing information, or it has been read to me. 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

Participant_____

Signature/ thumb print of Participant _____

Date _____

Statement by the researcher/person taking consent:

I have accurately read out the information sheet to the potential participant and, to the best of my ability, made sure that the participant understands that the procedure done. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name of Researcher/person taking the consent: Dr. MADANA JYOTSNA PRIYA

Signature of Researcher /person taking the consent_

Date _____

Name and Address of Principal Investigator:

Dr. MADANA JYOTSNA PRIYA
R.L Jalappa Hospital, Tamaka, Kolar.

MASTER CHART

KEY TO MASTER SHEET

SI.NO.	PARAMETER	CODING
A.	**UHID NO.**	
B.	**STUDY GROUP:**	
	EASI	1
	DINOPROSTONE	2
C.	**MATERNAL AGE**	
	19-20	1
	21-25	2
	26-30	3
	31-35	4
	>35	5
D.	**Parity**	
	PRIMIGRAVIDA	1
	MULTIGRAVIDA	2
E.	**Gestational age**	
	37w- 38+6 days	1
	39 w -39+6 days	2
	40 w – 40 + 6 days	3
	41 w – 41+6 days	4

F.	**Indication of Induction**	
	Post-dated	1
	Preeclampsia	2
	Oligohydramnios	3
	Rh-negative pregnancy	4
	Thrombocytopenia	5
G.	**Pre induction modified bishop's score:**	
	1	1
	2	2
	3	3
H.	**NUMBER OF DOSES**	
	1	1
	2	2
	3	3
I.	**INDUCTION TO ACTIVE STAGE INTERVAL**	
	4 TO 6 HOURS	1
	7 TO 9 HOURS	2
	10 TO 12 HOURS	3
	12-15 HOURS	4
J.	**INDUCTION TO DELIVERY INTERVAL**	
	5 TO 10 HOURS	1

	11 TO 15 HOURS	2
	16 TO 20 HOURS	3
	21 TO 25 HOURS	4
	26 TO 30 HOURS	5
K.	**MODE OF DELIVERY**	
	VAGINAL DELIVERY	1
	VACCUM ASSISTED VAGINAL DELIVERY	2
	FORCEPS ASSISTED VAGINAL DELIVERY	3
	CEASAREAN SECTION	4
L.	**INDICATION FOR C- SECTION**	
	FETAL DISTRESS	1
	FAILED INDUCTION	2
	NON-PROGRESSION OF LABOUR	3
	ARREST OF DESCENT	4
	NOT SIGNIFICANT	0
M.	**OXYTOCIN AUGMENTATION REQUIREMENT**	
	NOT REQUIRED	1
	REQUIRED	2
N.	**LIQUOR**	
	CLEAR	1
	MECONIUM-STAINED LIQUOR	2

O	**APGAR AT 1 MINUTE**	
	>/=7	1
	<7	2
P.	**APGAR AT 5 MINUTE**	
	>/=9	1
	<9	2
Q.	**NICU ADMISSION**	
	YES	1
	NO	2
R.	**CAUSE FOR NICU ADMISSION**	
	POST RESUSCITATION CARE	1
	RESPIRATORY DISTRESS	2
	PERINATAL ASPHYXIA	3
	NOT SIGNIFICANT	0
S.	**MATERNAL ADVERSE EFFECTS**	
	YES	1
	NO	2
T.	**CAUSE FOR MATERNAL ADVERSE EFFECTS**	
	HYPERSTIMULATION	1
	PPH	2
	PRECIPITATE LABOUR	3

	TACHYSYSTOLE	4
	FEVER	5
	NOT SIGNIFICANT	0
U.	**FHR TRACING**	
	REASSURING FHR	1
	NON-REASSURING FHR	2
	NOT SIGNIFICANT	0

MASTER SHEET – EASI- GROUP A

SI.NO	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U
1	939572	1	2	2	3	2	1	0	2	2	4	1	1	1	1	1	1	2	2	0	1
2	844516	1	2	2	2	1	1	0	1	1	2	0	1	1	1	1	2	0	2	0	1
3	844345	1	2	2	4	3	2	0	3	2	2	0	1	1	1	1	2	0	2	0	1
4	844516	1	2	2	2	3	2	0	3	1	2	0	1	1	1	1	2	0	2	0	1
5	852208	1	2	2	2	3	4	0	1	2	2	0	1	1	1	1	2	0	2	0	1
6	850422	1	2	2	4	2	3	0	2	1	4	1	1	2	1	1	1	1	2	0	1
7	790000	1	2	2	2	2	4	0	1	2	1	0	1	1	1	1	2	0	2	0	1
8	855502	1	2	2	2	2	1	0	1	2	1	0	2	1	1	1	1	2	2	0	1
9	834990	1	2	2	4	1	4	0	1	3	1	0	2	1	1	1	2	0	2	0	1
10	858739	1	2	2	3	2	4	0	1	3	1	0	2	1	1	1	2	0	2	0	1
11	853486	1	2	2	2	2	3	0	1	2	4	1	1	1	1	1	2	0	2	0	1
12	868375	1	2	2	3	2	3	0	2	1	4	1	2	1	1	1	2	0	2	0	1
13	861965	1	2	1	3	1	2	0	3	4	4	3	2	1	1	1	2	0	2	0	1
14	868758	1	2	1	4	1	3	0	1	3	1	0	1	1	1	1	2	0	2	0	1
15	871793	1	2	2	2	3	1	0	1	2	1	0	2	1	1	1	2	0	2	0	1
16	884651	1	2	2	3	2	2	0	2	1	1	0	1	1	1	1	2	0	2	0	1
17	883545	1	2	2	2	3	2	0	2	1	4	1	2	1	1	1	2	0	2	0	1
18	886010	1	2	1	3	1	2	0	3	3	4	1	2	1	1	1	2	0	2	0	1
19	887738	1	2	2	2	2	3	0	1	3	1	0	2	1	1	1	2	0	2	0	1
20	889904	1	2	2	4	1	2	0	2	1	4	3	2	1	1	1	1	2	2	0	1
21	861255	1	2	2	2	2	3	0	1	2	1	0	2	1	1	1	2	0	2	0	1
22	893572	1	2	2	2	2	2	0	3	3	4	1	1	1	1	1	2	0	2	0	1
23	896559	1	2	1	3	2	2	0	2	2	1	0	1	1	1	1	2	0	2	0	1
24	900546	1	2	1	1	1	2	0	2	1	4	3	1	1	1	1	2	0	2	0	1
25	894186	1	2	1	4	1	2	0	3	3	4	2	2	1	1	1	2	0	2	0	1
26	903547	1	3	1	3	2	3	0	1	2	1	0	2	1	1	1	2	0	2	0	1
27	902610	1	2	1	1	2	2	0	3	2	1	0	2	1	1	1	2	0	2	0	1
28	898604	1	2	1	3	1	2	0	2	3	4	2	2	1	1	1	2	0	2	0	1
29	907381	1	2	1	1	3	2	0	2	4	2	0	1	1	1	1	2	0	2	0	1
30	880695	1	2	1	2	1	3	0	1	3	1	0	2	1	1	1	2	0	2	0	1
31	904627	1	2	1	2	1	2	0	3	2	1	0	2	1	1	1	2	0	2	0	1
32	876421	1	2	1	2	3	3	0	1	3	1	0	2	1	1	1	2	0	2	0	1
33	908640	1	2	1	1	1	3	0	1	3	1	0	2	1	1	1	2	0	2	0	1
34	910529	1	2	1	1	3	2	0	3	3	4	2	2	1	1	1	2	0	2	0	1
35	920028	1	2	1	1	1	2	0	2	3	2	0	2	1	1	1	2	0	2	0	1
36	920574	1	3	1	1	1	2	0	2	3	1	0	2	1	1	1	1	2	2	0	1

MASTER SHEET – DINOPROSTONE - GROUP B

SI.NO	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U
1	941671	2	1	1	3	2	2	3	2	3	4	2	2	1	1	2	1	2	2	0	1
2	727168	2	1	1	1	2	2	2	2	2	1	0	1	1	1	1	2	0	2	0	1
3	811246	2	1	1	2	2	2	2	1	2	1	0	1	1	1	1	2	0	2	0	1
4	815531	2	1	1	2	2	2	2	1	1	2	0	1	1	1	1	1	2	2	0	1
5	816886	2	1	1	4	2	1	3	2	2	1	0	1	1	1	1	2	0	2	0	1
6	817762	2	1	1	3	2	2	2	2	3	1	0	1	1	1	1	2	0	2	0	1
7	817921	2	1	2	1	2	3	2	2	2	1	0	1	1	1	1	2	0	2	0	1
8	819081	2	1	1	1	1	3	3	3	3	4	2	1	1	1	1	1	2	2	0	1
9	834094	2	1	2	1	1	4	2	2	2	1	0	1	1	1	1	2	0	2	0	1
10	834986	2	1	1	3	1	1	2	2	2	1	0	1	1	1	1	2	0	2	0	1
11	835036	2	1	1	2	3	3	1	2	2	1	0	1	1	1	1	2	0	2	0	1
12	850420	2	1	2	3	1	2	1	2	3	1	0	1	1	1	1	2	0	2	0	1
13	850933	2	1	2	4	3	3	1	3	3	1	0	1	1	1	1	2	0	2	0	1
14	849924	2	1	2	2	2	2	2	3	3	4	1	1	2	1	1	2	0	2	0	1
15	818520	2	2	2	3	1	3	1	1	3	1	0	1	1	1	1	2	0	2	0	1
16	851445	2	1	1	1	3	2	1	3	3	1	0	1	1	1	1	2	0	2	0	1
17	781216	2	1	2	2	1	1	2	2	2	4	1	1	1	1	1	2	0	2	0	1
18	872225	2	1	2	3	2	3	2	3	4	4	3	1	1	1	1	1	2	2	0	1
19	747666	2	1	1	1	3	4	2	2	3	1	0	1	1	1	1	2	0	2	0	1
20	874457	2	1	1	1	1	2	2	1	2	1	0	1	1	1	1	2	0	2	0	1
21	874705	2	1	2	3	3	3	1	1	1	2	0	1	1	1	1	2	0	2	0	1
22	881237	2	1	1	1	2	1	1	1	1	1	0	1	1	1	1	2	0	2	0	1
23	848264	2	1	2	4	1	4	1	3	3	4	1	1	1	1	1	1	2	2	0	1
24	863727	2	1	1	2	2	3	3	3	3	2	0	1	1	1	1	2	0	2	0	1
25	779343	2	1	1	2	1	1	2	1	2	1	0	1	1	1	1	2	0	2	0	1
26	897471	2	1	1	2	3	3	1	3	3	1	0	1	1	1	1	2	0	2	0	1
27	890815	2	1	2	4	1	3	3	2	3	1	0	1	1	1	1	2	0	2	0	1
28	900334	2	1	2	2	1	3	2	3	4	4	3	2	1	1	1	1	2	2	0	1
29	900233	2	1	1	1	1	3	1	3	3	4	1	1	1	1	1	1	1	2	0	1
30	931853	2	1	2	3	2	2	1	2	2	1	0	1	1	1	1	2	0	2	0	1
31	896545	2	1	1	3	3	4	3	3	3	4	1	1	1	1	1	2	0	2	0	1
32	874705	2	1	1	2	4	3	2	3	3	2	0	1	1	1	1	2	0	2	0	1
33	916086	2	1	1	2	3	2	2	2	2	1	0	1	1	1	1	2	0	2	0	1
34	924813	2	1	1	3	3	3	1	2	1	1	0	1	1	1	1	2	0	2	0	1
35	891397	2	1	2	2	1	2	2	3	3	4	1	1	2	1	1	2	0	2	0	1
36	944022	2	1	1	2	4	3	1	3	4	4	3	1	2	1	1	2	0	2	0	1