

EVALUATING THE SAFETY AND EFFECTIVENESS OF DINOPROSTONE GEL AND PESSARY FOR LABOUR INDUCTION AND THEIR EFFECT ON FETOMATERNAL OUTCOMES

R. P. Patange¹, Deepashree Arbune², Manisha Laddad³, N. S. Kshirsagar⁴, Sanjay Kumar S. Patil⁵

¹Professor Department of Obstetrics and Gynecology Krishna Institute of Medical Sciences, Krishna Vishwa Vidyapeeth Deemed To Be University, Karad, Maharashtra, India. rppatange@hotmail.com

²M.B.B.S Student Department of Obstetrics and Gynecology Krishna Institute of Medical Sciences, Krishna Vishwa Vidyapeeth Deemed To Be University, Karad, Maharashtra, India.

³Professor Department of Obstetrics and Gynecology Krishna Institute of Medical Sciences, Krishna Vishwa Vidyapeeth Deemed To Be University, Karad, Maharashtra, India. drmanishald@gmail.com

⁴Professor, Department of Obstetrics and Gynecology Krishna Institute of Medical Sciences, Krishna Vishwa Vidyapeeth Deemed To Be University, Karad, Maharashtra, India. nkshirsagar49@yahoo.com

⁵Professor Department of Obstetrics and Gynecology Krishna Institute of Medical Sciences, Krishna Vishwa Vidyapeeth Deemed To Be University, Karad, Maharashtra, India. dryspmaher@gmail.com

Abstract

Introduction: A common obstetrical procedure for long-term pregnancies is labour induction, which depends on a reliable evaluation of cervical status using the Bishop score or sonographic measurement. Prostaglandins, particularly Dinoprostone, which comes in a variety of forms, including controlled-release intravaginal pessaries, are essential for cervical ripening and labour induction. In order to evaluate the effectiveness of Dinoprostone gel and vaginal pessaries for inducing labour, this study will assess the results for both mothers and newborns.

Background: Earlier research on cervical evaluation and prostaglandin delivery techniques sparked discussions over the relative effectiveness of pessaries and gels. Understanding baseline features is necessary in light of varying outcomes that can be impacted by induction indications, administration regimens, and cervical pathologies. Study group induction indication analysis contextualises the efficacy of the procedure.

Material and Methods: Dinoprostone was given intravaginally as a pessary or gel to a cohort of pregnant women who had been placed in labour. Demographics, indicators, Bishop scores, and results were among the recorded data. T-tests and chi-square testing were used in the analyses, and induction to delivery and complications were evaluated.

Results: The gel and pessary groups matched in baseline characteristics. Induction indications were dominated by post-term pregnancy. The pessary group was favoured by favourable Bishop scores. The incidence of vaginal deliveries was considerably greater in the pessary group. Lower pessary group induction failure was indicated by the primary results. There were no significant differences in secondary outcomes.

Discussion: Results highlight the effectiveness of Dinoprostone pessary, in line with previous research and highlighting the benefits of controlled-release pessary. Caution is warranted because of the increased prevalence of hyperstimulation in gel groups, which poses safety concerns.

Conclusion: In conclusion, Dinoprostone vaginal pessary emerges as a highly effective and safe method for labor induction, showcasing advantages over gel administration. The study contributes valuable insights into the nuanced differences between these two common induction methods, offering clinicians evidence to guide their decision-making process. Further research and larger-scale studies are warranted to corroborate these findings and refine clinical recommendations.

Keywords. Labor induction, Dinoprostone, Vaginal pessary, Gel administration, Cervical ripening, Obstetrical practice, Bishop score, Controlled-release, Neonatal outcomes, Hyperstimulation, Indication for induction, Prostaglandins, Maternal outcomes, Post-term pregnancy, Comparative study.

I. INTRODUCTION

Inducing labour has evolved into a widespread procedure all over the world, and it is now responsible for more than 20% of births in a number of countries [1,2]. This operation is considered necessary when the risks of continuing the pregnancy—for both the woman and the fetus—outweigh the advantages of beginning labour and delivery [3]. Induction of labour may be necessary in cases such as preeclampsia diagnosed at a gestational age of less than 37 weeks, stable

antepartum haemorrhage, chorioamnionitis, suspected foetal compromise, and prelabor rupture of the membranes at term. An induction of labour is performed with the intention of achieving a successful vaginal birth [3], which is a process that involves two fundamental elements: cervical ripening and uterine contraction stimulation to encourage cervical dilatation and foetal delivery. The primary objective of labour induction is to successfully complete a vaginal birth. The best-case scenario is to be able to give birth to the baby by vaginal

delivery without resorting to a caesarean section in the operating room.

When it comes to having a successful induction of labour, having a cervix that is in a favourable state or is already prepared for labour is one of the most important factors. This is especially true when trying to have a vaginal delivery. Prostaglandins continue to be the method of choice for cervical ripening [1,4,5], despite the fact that ripening the cervical canal has been accomplished utilising a number of methods. Dinoprostone is a prostaglandin (PGE₂) that works by preparing the cervix for labour and increasing the likelihood that a vaginal delivery will proceed smoothly. It does this by acting on the collagen structural network of the cervix. Dinoprostone is suggested to be used when the cervix has a Bishop's score of less than six since it has been demonstrated to be beneficial in raising the percentage of women who give birth vaginally within 24 hours [6].

Dinoprostone is available in two different formulations: a cerviprime gel and a vaginal pessary. Neither one is intended for oral use. The vaginal pessary is a small delivery device made of polymeric material that is flat, semi-transparent, and carries 10 milligrammes of dispersed dinoprostone inside of a retrieval system made of knit polyester. The pessary is inserted into the vaginal canal through the vaginal canal. However, factors like as cost, susceptibility to heat, and the demand for a stringent cold chain in order to sustain its efficiency may prohibit it from being utilised extensively, especially in warmer areas. Additionally, the exclusive vaginal route has its limitations due to the fact that there is an increased risk of sepsis in circumstances that involve premature rupture of membranes (PROM) [8–9]. On the other hand, cerviprime gel, which contains 0.5 mg of dinoprostone and may either be administered intravaginally or intracervically, can be used locally to stimulate cervical ripening and can be delivered either way. It is interesting to note that intra-cervical PG-E₂ gel not only ripens the cervix but also begins the labour process; about 40% of cases are likely to result in a successful induction of labour [10]. Dinoprostone comes in two forms: a gel and a pessary. The purpose of this study is to investigate whether of these forms is more effective and safe for inducing labour in a tertiary care setting.

II. LITERATURE REVIEW

LABOR INDUCTION

Labor induction (IOL) is a widely employed obstetric intervention that artificially initiates labor through various methods [21]. Since 1990, rates of labor induction have nearly doubled, with significant global variation attributed to differing guidelines and a lack of consensus on clinical practices [22].

ANATOMY AND PHYSIOLOGY

The uterus, comprising smooth muscle (body) and predominantly collagen (cervix), undergoes dynamic changes during pregnancy and labor, necessitating mechanical and pharmacological methods for labor induction [21]. These methods aim to induce physiological cervical changes such as shortening, thinning, and dilating.

INDICATIONS

Based on obstetrical and medical history, there are several situations for labour induction, including late preterm, early term, late term, and post-term [23]. A wide range of clinical

scenarios, including oligohydramnios, foetal intrauterine growth restriction, hypertension, preeclampsia, diabetes, preterm prelabor rupture of membranes (PPROM), and other conditions, are covered by the extensive recommendations provided by the American College of Obstetricians and Gynaecologists (ACOG) [24]. Induction may sometimes be necessary for logistical reasons, such as the possibility of an early labour, the distance to the hospital, or psychological issues. In these situations, it is crucial to confirm foetal lung maturity.

CONTRAINDICATIONS

Contrastingly, contraindications to labor induction include scenarios like vasa previa, placenta previa, transverse fetal presentation, umbilical cord prolapse, and a history of prior classical cesarean section, among others [22].

EQUIPMENT

Two primary methods for labor induction—mechanical and pharmacological—utilize agents such as Foley catheters, double-balloon devices, osmotic dilators, laminaria, synthetic dilators, prostaglandins, and synthetic oxytocin [22]. Amniotomy, often combined with these methods, involves the rupture of membranes.

PERSONNEL

An inpatient obstetric care team, comprising nurses, midwives, residents, obstetricians, anesthesiologists, neonatologists, pediatricians, and lactation services, collaborates to ensure a safe labor and postpartum environment [25]. Trained obstetricians capable of performing a cesarean section (CS) should be readily available during induction.

PREPARATION

Cervical evaluation using the Bishop scoring system assesses dilation characteristics, station, consistency, effacement, and position. A favorable cervix with a score of eight or more indicates a likelihood of successful vaginal delivery [22]. Informed consent from pregnant women is crucial, emphasizing the benefits, risks, and alternatives to induction.

CESAREAN SECTION RATES

Discussion of cesarean section rates and indications is vital during the consent process, addressing scenarios where induction may fail, leading to the need for cesarean delivery [26]. Recent studies, such as the ARRIVE trial, have explored elective induction at 39 weeks, demonstrating lower cesarean section rates without increased perinatal risks [29].

DINOPROSTONE

Dinoprostone, a prostaglandin E₂, is preferred for cervical ripening and labor induction, with various forms, including a controlled-release pessary [6]. Comparisons between dinoprostone gel and pessary reveal potential advantages of the pessary, such as higher rates of normal vaginal delivery and lower operative vaginal delivery rates [46].

MECHANISM OF ACTION

Dinoprostone enhances collagenase activity, promoting cervical softening and dilation. Its controlled-release pessary form disperses 10mg of dinoprostone over 24 hours, offering advantages such as single application and easy removal [46].

ADMINISTRATION

Administered vaginally as a suppository, gel, or insert, dinoprostone has specific indications and contraindications. Close monitoring is essential, with considerations for adverse effects and discontinuation if needed [37] [42].

EFFICACY OF DINOPROSTONE VAGINAL PESSARY
 Studies comparing dinoprostone vaginal pessary to other induction methods indicate favorable outcomes, including higher rates of spontaneous vaginal delivery [48] [49].

III. MATERIAL AND METHODS

STUDY DESIGN: Comparative study

STUDY SETTING: Pregnant patients hospitalised for delivery to a tertiary healthcare center's Obstetrics and Gynaecology department participated in the current study.

STUDY DURATION: 19 months

SELECTION CRITERIA FOR STUDY SUBJECTS

INCLUSION CRITERIA:

- a. pregnancy in a singleton, regardless of parity.
- b. presentation of the cephalad.
- c. Bishop had a score of less than six.
- d. Age at gestation: 37–41 weeks.
- e. no prior caesarean delivery.

EXCLUSION CRITERIA:

- a. several pregnancies.
- b. premature.
- c. prior surgery on the uterus.
- d. malpresentation of the foetus.
- e. contraindication to delivery via vagina.
- f. Dinoprostone contraindications.
- g. those unwilling to participate in a typical trial.

METHOD:

Two groups (Group (A) for Dinoprostone pessary and Group (B) for Dinoprostone gel) were randomly assigned to eligible patients.

Women were made aware of the study, and willing participants provided written informed permission. Bishop's score and a thorough history were noted.

A typical, semi-structured, pre-validated case record proforma was used to capture the clinical history, examination results, and investigation findings.

Randomization was used to assign patients who met the inclusion criteria to Group (A) and Group (B). Non-Stress Tests were performed both before and after induction, and intracervical administration of dinoprostone gel or pessary was used.

Every 30 minutes, the foetal heart rate and contractions were assessed. After six hours, the evaluation was repeated, and reinstallation was carried out if the Bishop score was still less than six. An induction was deemed unsuccessful if, following three instillations, cervical ripening did not take place.

A controlled-release vaginal pessary containing dinoprostone was inserted into the posterior fornix, delivering 0.3 mg per hour. After 24 hours, during active labour, or during membrane rupture, the pessary was withdrawn. Cervical effacement, dilatation greater than 3 cm, and at least 4 contractions within a 10-minute interval were considered indicators of active labour. If active labour could not be achieved within 24 hours, this was considered a failure of induction.

OUTCOME INDICATORS

- a. Primary results: induction success rate and induction failure rate
- b. Unexpected results:
- c. time required to reach the "active" phase after induction

d. Time between inducing labour and the beginning of labour

e. Transport strategies: Labour induction, assisted vaginal birth, and caesarean section

f. Infant Outcomes: 5 Minute APGAR, NICU Stay

STATISTICAL ANALYSIS

a. Microsoft Excel and SPSS version 22 were used for data entry and analysis, respectively.

b. Tables and charts were used to facilitate frequency analysis of the data.

c. Mean, mode, median, and standard deviation were determined for quantitative data to examine central tendency and variance.

d. Association between nominal or categorical variables was analysed using the Chi-square test.

e. To examine the relationship between continuous variables, the Student's t-test was applied.

f. Statistical significance was assumed when the p-value was less than 0.05.

IV. RESULTS

a. Baseline Demographic Characteristics

We found that the average age was 26.24 years for those in the Pessary group and 28.59 years for those in the Gel group in the present study. There were more first-time mothers in the Pessary group (78%) than in the Gel group (73%). Twenty-two percent of the Pessary group and twenty-seven percent of the Gel group were multigravida. Induction occurred between 37 and 41 weeks of gestation, on average. Table 1 shows that the average body mass index (BMI) for the first group was 23.2 2.7 (20.2-26.1), whereas the BMI for the second group was 21.2 3.1 (19.8-24.6). As a result, there weren't any significant differences between the two groups in terms of their baseline characteristics.

Table 1: Baseline Demographic Characteristics

Baseline Demographic Characteristics	Pessary Group	Gel Group	P-value
Maternal Age (mean)	26.24 years	28.59 years	0.3
Primigravida	42 (78%)	39 (73%)	0.504
Multigravida	12 (22%)	15 (27%)	
Gestational Age at Induction (median)	37–41 weeks	37–41 weeks	0.07
BMI (median)	23.2 ± 2.7 (20.2–26.1)	21.2 ± 3.1 (19.8–24.6)	0.09

b. Indication for Induction

Clinical baseline parameters were assessed in this investigation. Seventy-three percent of Pessary and sixty-four point eight one percent of Gel participants were post-term pregnant. 7.41% and 9.26% of individuals, respectively, showed signs of oligohydromnios. 9.25% of the Pessary group and 20.37% of the Gel group experienced foetal growth limitation. Diabetes afflicted 3.7% and 5.56% of patients in each group, whereas hypertensive disorders of pregnancy were detected in 11.11% and 24.07% of subjects in the respective groups.

Table 2: Indications for Induction

Indication for Induction	Pessary	Percentage	Gel	Percentage
Post-term pregnancy	38	70.37	35	64.81
Oligohydromnios	4	7.41	5	9.26
Fetal growth restriction	5	9.25	11	20.37
Intrauterine death	0	0.00	1	1.85
Hypertensive disorder of Pregnancy	6	11.11	13	24.07
Diabetes	2	3.70	3	5.56

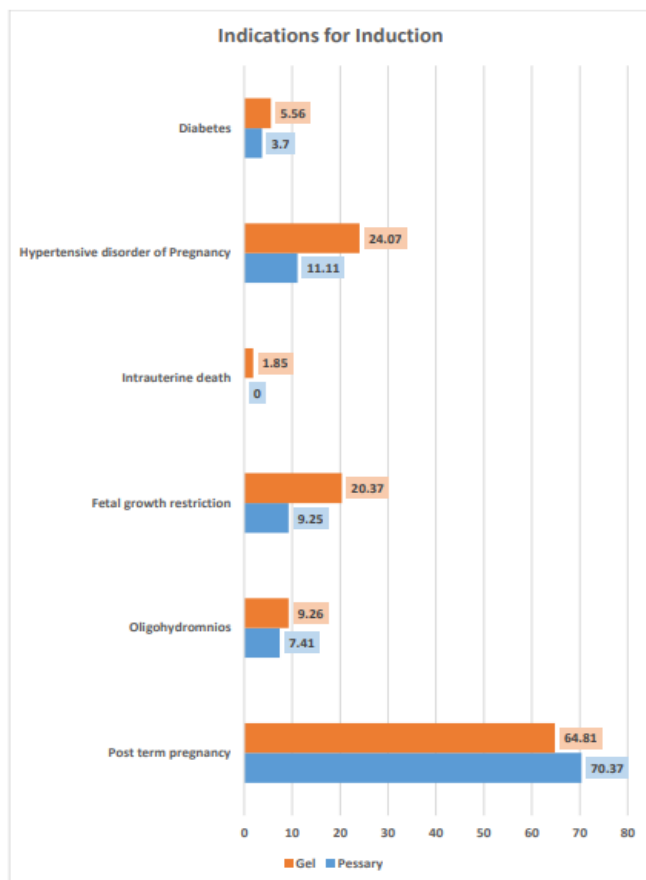


Figure 1: Indications for Induction

c. Bishops Score

The Bishop's score of the participants was calculated and analysed in this study. In the Pessary group, 79.63% of subjects had a Bishop's score more than 6, whereas 20.37% had a score less than 6. After 6 hours, 83.33% of those in the Gel group had a score of 6 or below, whereas 16.66% obtained a score of 6 or above. After 12 hours, 53.33 percent of the 45 individuals who started off with an unfavourable cervix had improved to a score of 6 or above. 16.66% had a Bishop's score of less than 6 (indicating failure of induction) after 18 hours. A total of 39 participants gave birth by vaginal delivery, while the remaining participants had caesarean sections.

Table 3: Bishop's Score

Bishops Score	Pessary Group after 24 hrs	Percentage
Less than 6	11	20.37
More than 6	43	79.63
Total	54	100.00

Table 3 (Continued): Bishop's Score

Bishops Score	Gel Group	6 hrs	12 hrs	18 hrs
Less than 6	45	21	9	
More than 6	9	24	6	

d. Delivery Outcomes in Pessary and Gel Groups

In this study, we analysed the results of the participants' deliveries. The Pessary group had a considerably higher rate of vaginal births (75%) than the Gel group (57%), according to our findings. In the Gel group, 15% of deliveries required medical intervention.

Table 4: Delivery Outcomes in Pessary and Gel Groups

Delivery Outcome	Pessary Group	Gel Group	P – value
Vaginal delivery	41 (75)	31 (57)	0.04
Operative vaginal delivery	2 (3)	8 (15)	0.04
Cesarean section	11 (22)	15 (28)	0.36

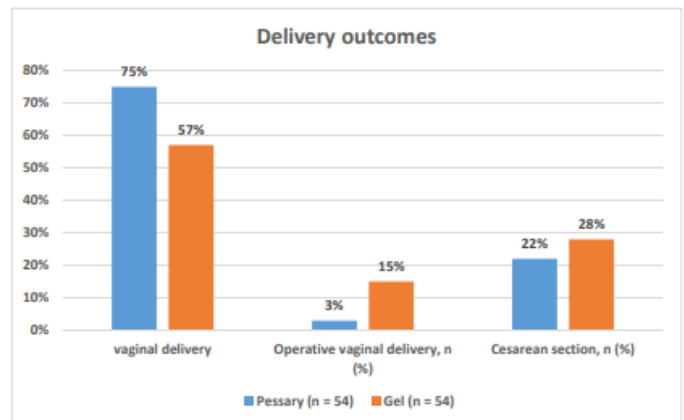


Figure 2: Delivery Outcomes in Pessary and Gel Groups

e. Primary Outcomes

The purpose of this research was to determine how effective induction was for the participants. In the Gel group, 16.66% of women claimed inability to induce labour, while just 3.7% of women in the Pessary group had this problem. There was a statistically significant correlation observed between these findings. When opposed to the use of gel, the failure rate of induction was much reduced when using a pessary.

Table 5: Primary Outcomes

Primary Outcomes	Pessary Group	Gel Group	P – value
Failure of induction	2 (3.7%)	9 (16.66%)	0.025
Success rate of Induction	52 (96.29%)	45 (83.33%)	

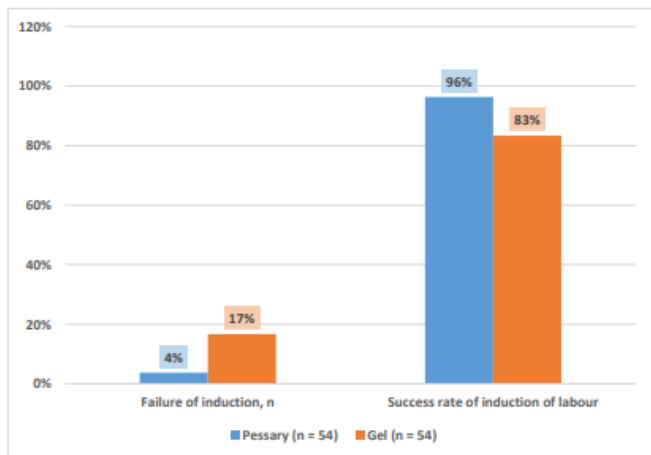


Figure 3: Primary Outcomes

f. Secondary Outcomes

Detailed observations of secondary outcomes are presented in the following table. The Gel group had a more rapid onset of labour and a shorter period between activation and delivery than the Pessary group. The data, however, did not show any statistically significant patterns.

Table 6: Secondary Outcomes

Secondary Outcome	Pessary Group	Gel Group	P – value
Induction to active phase (median)	12 h (8–31 h)	13 h (8–27 h)	0.45
Induction to delivery time (median)	15 h (11–31 h)	18 h (12–33 h)	0.38
Cesarean section for fetal distress	8 (14)	10 (18)	0.6

g. Complications

There were more cases of hyperstimulation in the Gel group (5 patients) than in the Pessary group (3 subjects). We found that more neonates in the Gel group (9.55%) exhibited respiratory distress than those in the Pessary group (5.55%). Two or three of the newborns in each group were found to have spirits tainted with meconium.

Table 7: Complications

Complications	Pessary Group	Gel Group	P – value
Hyperstimulation	3	5	0.3
Meconium-stained Liquor	2	3	NS

h. Mode of Delivery in Primigravida

The primary outcome was measured in this research of childless women. First-time mothers gave birth vaginally at a considerably higher rate (73%) in the Pessary group compared to (52% in the Gel group; p = 0.03).

Table 8: Mode of Delivery in Primigravida

Mode of Delivery	Pessary Group	Gel Group	P – value
Primigravida	42	38	0.4
Vaginal delivery	31 (73%)	20 (52%)	0.03

Operative vaginal delivery	2 (4%)	5 (13%)	0.2
Cesarean section	9 (23%)	13 (33%)	0.23

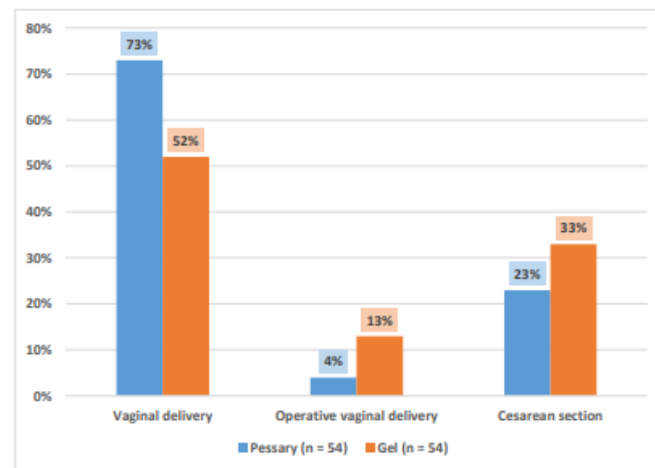


Figure 4: Mode of Delivery in Primigravida

i. Mode of Delivery in Multigravida

The key result was compared between first-time mothers and those who had already had children. When comparing primigravida women with multigravida women, we found that the proportion of primigravida women who gave birth vaginally was substantially higher (p = 0.03) than that of multigravida women (p = 0.41).

Table 9: Mode of Delivery in Multigravida

Mode of Delivery	Pessary Group	Gel Group	P – value
Multigravida	12	15	0.3
Vaginal delivery	9 (75%)	9 (60%)	0.41
Operative vaginal delivery	1 (1%)	3 (22%)	0.39
Cesarean section	2 (31%)	3 (28%)	0.75

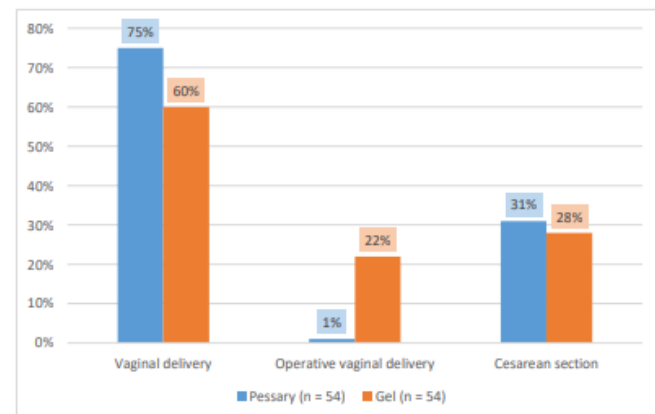


Figure 5: Mode of Delivery in Multigravida

j. Neonatal Outcomes

The purpose of this research was to evaluate the neonatal outcomes of the participants. We found that more neonates in the Gel group (9.55%) exhibited respiratory distress than those in the Pessary group (5.55%). Comparatively, just 9.55 percent of Pessary participants required admission to the NICU, whereas 20.37% of Gel subjects did. There was no statistically significant dissimilarity between the data points.

Table 10: Neonatal Outcomes

Neonatal Outcomes	Pessary Group	Gel Group	P-value
Respiratory distress	3 (5.55%)	5 (9.55%)	0.44
NICU admission	5 (9.55%)	11 (20.37)	0.104

V. DISCUSSION

An extended pregnancy is the most common reason for induction of labour, a common obstetrical procedure that can be carried out for a number of reasons. The Bishop score or sonographic measurement of cervical length can be used to determine the cervical status [5-7]. It is possible to ascertain the success of an induction using either technique. Studies comparing these two methods for vaginal birth prediction have not consistently preferred one over the other, highlighting parity as a separate predictive factor [8–11].

Synthetic prostaglandins like dinoprostone are commonly used to induce labour. It is well recognised that prostaglandins play a crucial function in the ripening of the cervical membrane and parturition process. There are several modalities of administration for this medication: oral, vaginal, intracervical, and extra- or intra-amniotic. The controlled-release intravaginal pessary formulation of dinoprostone has several advantages, such as the medication's single administration and its easy removal following the onset of labour or at the first sign of uterine hyperstimulation. Mixed findings have come from investigations that contrasted various prostaglandin formulations with the dinoprostone vaginal insert [13, 14]. This is probably because of factors including medication delivery schedules, induction causes, and cervical conditions.

a. Features of the Population at a Specific Moment in Time

The mean age of the Pessary group was 26.24 years, whereas the mean age of the Gel group was 28.59 years. Primigravida women made up 78% of the Pessary group and 73% of the Gel group, whereas multigravida women made up 22% and 27% of the groups, respectively. When induction occurred, the typical gestational age ranged from 37 to 41 weeks. When the study began, the characteristics of both groups were similar.

33% of pregnant patients using dinoprostone vaginal pessary for labour induction were multiparous, whereas 67% of patients were nulliparous, according to a study by Mamatha C et al. [50]. In addition, the majority of the patients—46 percent—had gestational diabetes, and they were mostly between the ages of 25 and 28.

b. Bishop's Score

Twenty.37 percent of the Pessary group's members had a Bishop's score below six, while 79.63% of the group's members had a score of six or higher. 53.33 percent of individuals in the Gel group who began with an unfavourable cervix ended up with a positive score after 12 hours, whereas 83.33 percent of

participants had a score of less than six after six hours. Bishop's score below 6 in 16.66% of patients at 18 hours suggested that induction was not effective. The Pessary group had a vaginal delivery rate of 75%, which was much higher than the 57% rate in the Gel group.

In a study by Maria Teresa Triglia and colleagues, it was demonstrated that using dinoprostone vaginal pessaries and gel to induce birth has no risks. With a Bishop score of less than four, women who were induced at term were much more likely to deliver their babies vaginally while taking the pessary. Ting NS and colleagues found that compared to the Pessary group, fewer individuals in the Gel group obtained positive ratings. According to Thupakula TR and colleagues' research, the vaginal insert was more effective than intracervical gel at improving Bishop's score in the range of 7-9; nevertheless, the group that got intracervical gel had a higher percentage of women who delivered normally.

c. Suggestions for the Induction Process

The most common reason cited in both the Pessary and Gel groups (70.37 percent and 64.81 percent, respectively) for inducing labour was post-term pregnancy. Other symptoms included the existence of oligohydramnios, limited foetal development, intrauterine death, hypertensive problems throughout pregnancy, or diabetes.

In Tempe A. and colleagues' study [49], the researchers discovered that postdatism was the most common cause for beginning labour. Other than postdatism, there are other causes to induce labour: intrahepatic cholestasis during pregnancy, oligohydramnios, prenatal diabetes mellitus, foetal development limitation, and hypertensive diseases.

d. The Outcomes of Distribution

The Pessary group had a significantly greater rate of vaginal delivery (75%), compared to the Gel group's comparatively lower incidence of 57%. There was a greater incidence of surgical vaginal delivery (15%) in the Gel group.

Ee Min Kho et al. [51] discovered in their study that primigravida who received the pessary had a longer induction to vaginal delivery interval than those who received intravaginal gel. Despite the fact that every group received the identical therapy, this was the case.

The whole dinoprostone pessary had a shorter induction to delivery period than the gel group, with a greater number of patients giving birth in less than 12 hours. Tempe A. and associates reported this [49].

e. The Most Significant Findings

Compared to the women in the Gel group (16.66%), the percentage of Pessary group women who were unable to successfully induce labour was significantly lower (3.7%). When comparing the percentage of vaginal births between the Pessary and Gel groups, the Pessary group had a far higher rate (73%), whereas the Gel group's percentage was 52%.

According to research by Maria Teresa Triglia and colleagues [48], the pessary group gave birth vaginally far more frequently than the gel group. Furthermore, the rate of surgical vaginal births was much lower in the pessary group.

The results of Thupakula TR and colleagues show that induction failed in 40% of women who used the intracervical gel, compared to 38% of women who utilised the vaginal implant (pessary).

f. The Incidental Effects

The Gel group was inducted into the active phase and into the delivery period later than the other groups, but the differences were not statistically significant.

Ee Min Kho and colleagues found that women who were administered the pessary to induce labour were more likely to have uterine hyperstimulation. On the other hand, ladies who received intravaginal gel to induce birth did not experience this. Maria Teresa Triglia and colleagues did not find any instances of uterine hyperstimulation or 5-minute Apgar scores less than 7 in either group.

While Hughes et al concluded that the vaginal insert is equally effective as other methods of giving prostaglandins, Sanchez-Ramos et al concluded that the vaginal insert was not as successful as other prostaglandins for cervical ripening and labour induction.

g. Issues and barriers

Three people utilised the pessary, compared to five participants in the gel-using group who had hyperstimulation. There was a notable rise in the percentage of individuals reporting respiratory pain in the Gel group (9.55%) compared to the Pessary group (5.55%). Meconium-stained liquid was given to three neonates in the Gel group and two infants in the Pessary group.

Results at Birth for Infants

There was a notable rise in the percentage of individuals reporting respiratory pain in the Gel group (9.55%) compared to the Pessary group (5.55%). In 9.55 percent of cases, patients needed to be admitted to the NICU; in 20.37 percent of cases, gel subjects needed to be admitted.

To put it briefly, the study offers a comprehensive analysis of several methods for inducing labour and shows that the dinoprostone vaginal pessary is more effective than the dinoprostone vaginal gel in terms of positive outcomes, especially for first-time moms. When making clinical decisions about labour induction strategies, comparing various criteria—such as Bishop's score, induction causes, and delivery outcomes—provides relevant data that may be used.

VI. CONCLUSIONS

The research highlights the exceptional effectiveness and superiority of the Dinoprostone vaginal pessary in achieving term labour induction. It turns out to be a very successful technique, demonstrating its potential as the go-to option for inducing labour. Although there were variations in the induction to active phase and induction to delivery periods between the Gel and Pessary groups, these differences were not statistically significant. This little detail implies that, even if labour phases may differ in length, the two approaches' total efficacy is similar. One interesting discovery concerns hyperstimulation, which was seen more often in the Gel group than in the Pessary group. Clinical consequences result from this distinction, which highlights the need to carefully assess the induction strategy that is used, especially in light of potential side effects such as hyperstimulation. There is a considerable difference in favour of primigravida women according to the primary outcome evaluation, which is stratified by these two categories. Primigravida were shown to have a significantly greater percentage of vaginal births, suggesting a possible relationship between patient features and delivery style. One important

finding about the induction failure is that the Gel group showed a greater incidence than the Pessary group. This substantial difference indicates that pessary administration yields a better result, indicating that it is a less likely technique to fail at induction. In conclusion, the study offers insightful information on the relative efficacy of gel and Dinoprostone vaginal pessaries for inducing labour. Both techniques are effective, but the pessary has certain distinct benefits that make it a better choice for obstetricians and pregnant women. These advantages include a lower rate of hyperstimulation and a decreased chance of induction failure.

References

1. van der Ham DP, van Melick MJ, Smits L, Nijhuis JG, Weiner CP, van Beek JH, Mol BW, Willekes C. *Methods for the diagnosis of rupture of the fetal membranes in equivocal cases: a systematic review. Eur J Obstet Gynecol Reprod Biol.* 2011 Aug;157(2):123-7.
2. ACOG Committee Opinion No. 766 Summary: *Approaches to Limit Intervention During Labor and Birth. Obstet Gynecol.* 2019 Feb;133(2):406-408.
3. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins—Obstetrics. *ACOG Practice Bulletin No. 209: Obstetric Analgesia and Anesthesia. Obstet Gynecol.* 2019 Mar;133(3): e208-e225.
4. ACOG Practice Bulletin No. 107: *Induction of labor. Obstet Gynecol.* 2009 Aug;114(2 Pt 1):386-397.
5. Zhang J, Troendle J, Mikolajczyk R, Sundaram R, Beaver J, Fraser W. *The natural history of the normal first stage of labor. Obstet Gynecol.* 2010 Apr;115(4):705-710.
6. Zhang J, Landy HJ, Ware Branch D, Burkman R, Haberman S, Gregory KD, Hatjis CG, Ramirez MM, Bailit JL, Gonzalez-Quintero VH, Hibbard JU, Hoffman MK, Kominiarek M, Learman LA, Van Veldhuisen P, Troendle J, Reddy UM., *Consortium on Safe Labor. Contemporary patterns of spontaneous labor with normal neonatal outcomes. Obstet Gynecol.* 2010 Dec;116(6):1281-1287.
7. Cheng YW, Caughey AB. *Defining and Managing Normal and Abnormal Second Stage of Labor. Obstet Gynecol Clin North Am.* 2017 Dec;44(4):547-566.
8. Pitkin RM, Friedman EA. *Primigravid labor: a graphicostatistical analysis. Obstet Gynecol* 1955;6:567-89. *Obstet Gynecol.* 2003 Feb;101(2):216.
9. Kilpatrick SJ, Laros RK. *Characteristics of normal labor. Obstet Gynecol.* 1989 Jul;74(1):85-7
10. Tsakiridis I, Mamopoulos A, Athanasiadis A, Dagklis T. *Induction of Labor: An Overview of Guidelines. Obstet Gynecol Surv.* 2020 Jan;75(1):61-72.
11. ACOG Practice Bulletin No. 107: *Induction of labor. Obstet Gynecol.* 2009 Aug;114(2 Pt 1):386-397.
12. Marconi AM. *Recent advances in the induction of labor. F1000Res.* 2019;8
13. ACOG committee opinion no. 560: *Medically indicated late-preterm and early-term deliveries. Obstet Gynecol.* 2013 Apr;121(4):908-910.
14. Escobar CM, Grünebaum A, Nam EY, Olson AT, Anzai Y, Benedetto-Anzai MT, Cheon T, Arslan A, McClelland WS. *Non-adherence to labor guidelines in cesarean sections done for failed induction and arrest of dilation. J Perinat Med.* 2020 Oct 12;49(1):17-22.

15. American College of Obstetricians and Gynecologists (College). Society for Maternal-Fetal Medicine. Caughey AB, Cahill AG, Guise JM, Rouse DJ. Safe prevention of the primary cesarean delivery. *Am J Obstet Gynecol.* 2014 Mar;210(3):179-93.
16. Levine LD, Downes KL, Elovitz MA, Parry S, Sammel MD, Srinivas SK. Mechanical and Pharmacologic Methods of Labor Induction: A Randomized Controlled Trial. *Obstet Gynecol.* 2016 Dec;128(6):1357-1364.
17. Kemper JI, Li W, Goni S, Flanagan M, Weeks A, Alfirovic Z, Bracken H, Mundle S, Goonewardene M, Ten Eikelder M, Bloemenkamp K, Rengerink KO, Kruit H, Mol BW, Palmer KR. Foley catheter vs oral misoprostol for induction of labor: individual participant data meta-analysis. *Ultrasound Obstet Gynecol.* 2021 Feb;57(2):215-223.