

Comparative Efficacy of Vaginal Dinoprostone And Cervical Foley's Catheter For Induction of Labour In Women with One Previous Caesarean Section

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ABSTRACT

Objective: To compare the efficacy of Vaginal Dinoprostone and Cervical Foley's Catheter for Induction of Labour In Women With One Previous Caesarean Section.

Study Design: Quasi-Experimental Study

Setting and Duration of Study: Department of Gynecology and Obstetrics, PAF Hospital Mushaf, Sargodha, Pakistan, from Mar to Nov 2023.

Methodology: A total of 120 women having a previous cesarean section undergoing the induction of labor with a gestational age of 37-41 weeks were included. Patients with multiple pregnancies, preterm labor, rupture of membranes, intrauterine fetal death, polyhydramnios, placenta previa, PIH, and GDM were excluded. All the included participants were randomly divided into two equal groups, i.e., Group-B (transcervical Foley's catheter) & Group-A (vaginal Dinoprostone), by using the lottery method (randomization process). In both groups, the efficacy was noted.

Results: The study included individuals aged between 20 and 45 years, with an average age of 27.53 ± 4.31 years. Group-A women had an average age of 27.60 ± 5.12 years, while Group-B women had 27.40 ± 3.99 years. 20 to 30 years was the common age among most of the patients, 78 (65.0%). In this study, vaginal delivery within 24 hours was significantly higher in Group-A (Dinoprostone group) (96.67% vs. 76.67%, $p = 0.0013$) as compared to Group-B (Intracervical Foley's catheter group).

Conclusion: This study concluded that the efficacy (in terms of vaginal delivery) of vaginal Dinoprostone is higher as compared to intracervical Foley's catheter for the initiation of labor in prior one-scar pregnancies.

Keywords: Induction of labor, Intracervical Foley's catheter, Vaginal Dinoprostone

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INTRODUCTION

The use of labor induction has increased significantly in obstetrics. In the past 20 years, its prevalence has more than doubled, with about 25% of pregnant women now undergoing this procedure.¹ One challenge faced by healthcare providers involved in labor induction is determining whether it is beneficial to let a woman continue laboring when she remains in the early stage for a long time. Sometimes, if a cesarean delivery is performed during this early stage, it is categorized as a "failed" induction. However, there is no consensus on the criteria for this classification, leading to different approaches to managing the early stage of labor induction among healthcare providers and institutions.² One study attempted to define a failed induction by considering

specific factors.³ They defined the early stage as starting when each Oxytocin was administered, and the rupturing of membranes ruptured. It ended either at 4-cm dilation and 90% effacement or at 5-cm dilation, irrespective of effacement. The researchers then analyzed the impact of the duration of the early stage on obstetric outcomes in induced labor. They concluded that the early stage could be extended for up to 12 hours without an increased risk of obstetric complications. Three other studies approached the diagnosis of a failed induction from a similar perspective, but each had its limitations in terms of methodology.⁴

Prostaglandins modify the substance surrounding the cervix, leading to the maturation of the cervix.⁵ They additionally boost the function of the collagenase in the cervix. Additionally, prostaglandins promote an increase in the levels of calcium inside cells, which causes contractions in the muscles of the uterine lining.⁶ In April 2002, the FDA updated the

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indications for using Misoprostol, changing it from "not recommended during pregnancy" to "contraindicated during the pregnancy period for the prevention and treatment of ulcers caused by NSAIDs".⁵

Both Misoprostol and Dinoprostone are considered safe and efficient methods for cervical ripening and labor induction. In terms of cost, Misoprostol is more affordable than Dinoprostone.⁷ In one study, the normal vaginal delivery rate is 74% in cases with Dinoprostone induction as compared to 88% in Misoprostol induction. Failure of induction was 7% in patients with Dinoprostone induction compared to 2% in patients with Misoprostol induction.⁸

Induction of Labour in women with one previous caesarean section requires a method that promotes vaginal delivery while minimizing maternal and fetal risks. Vaginal dinoprostone and the cervical Foley catheter are commonly used for cervical ripening, but their comparative effectiveness remains uncertain. Limited local evidence makes it difficult to select the most effective induction method for women attempting vaginal birth after caesarean section. Therefore, this study aimed to compare both methods in terms of successful vaginal delivery within 24 hours to guide evidence-based clinical practice.

METHODOLOGY

This Quasi-experimental study was conducted at the Department of Gynecology and Obstetrics, PAF Hospital Mushaf, Sargodha, Pakistan, from Mar to Nov 2023. The sample size was calculated using the "Calculator of sensitivity and specificity (CPSP)". The calculated sample size was 120, i.e., 60 cases per group, assigned by the randomization process (lottery method), as shown in the patient flow diagram (Figure)

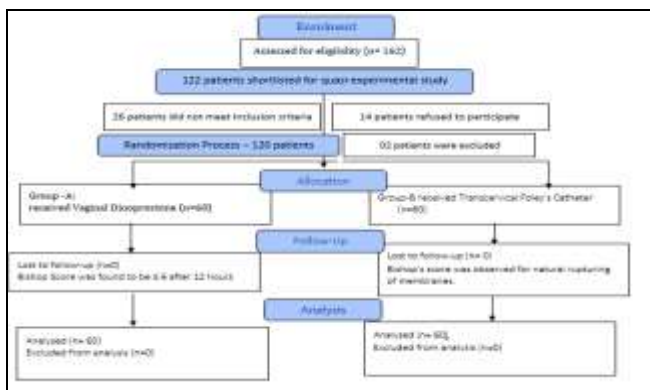


Figure: Patient Flow Diagram

With a 5% level of significance and 80% power, the study assumed an efficacy of 60.0% for vaginal Dinoprostone and 37.14% for cervical Foley's for induction of labor in the previous cesarean section. The non-probability consecutive sampling technique was used to gather the sample.

Inclusion Criteria: All the women having a previous cesarean section undergoing the induction of Labour with the age group of 20 -45 years, having gestational age between 37-41 weeks (assessed on LMP), Bishop's score of ≤ 6 , and parity 2-5 were included

Exclusion Criteria: women with preterm labor, rupture of membrane (assessed on clinical examination), >1 previous cesarean section and multiple pregnancies (assessed on ultrasonography), with breech presentation (assessed on USG), placenta previa and/or any other contraindication for the labor induction, polyhydramnios, pregnancy-induced hypertension, gestational diabetes mellitus, patients with intrauterine fetal death, and cardiac disease were excluded.

After receiving approval from the Ethical Review Committee, a total of 120 women who met the specified criteria were selected for the study. Informed written consent was obtained from each participant before dividing them randomly into two equal groups: Group-B (transcervical Foley's catheter) and Group-A (vaginal Dinoprostone). The randomization process utilized a lottery method.

For Group-B, a sterile Foley's catheter No. 16 Fr was used to soften and dilate the cervix.⁹ The procedure was performed with the patient lying in the lithotomy position while maintaining aseptic measures. The Bishop's scoring system was used to examine the status of the cervix.¹⁰ A Foley catheter with a 30 mL balloon was inserted beyond the internal os into the endocervical canal and then inflated with 30 milliliters of sterile water. After that, the catheter was either withdrawn after 12 hours or discharged spontaneously. Throughout this period, our focus was on observing if there were any positive changes in the altered Bishop's score or if the membranes ruptured naturally. After intentionally breaking the membranes, we started administering Oxytocin intravenously. The Oxytocin infusion consisted of 2.5 units in 500ml of 5% dextrose, delivered at a rate of 10 drops per minute. The dosage progressively increased every 10 minutes until it approached the maximum of 60 drops in one minute, or until the requisite uterine contractions occurred.

In Group-A, a dose of 0.5mg Dinoprostone PGE₂ was administered vaginally under aseptic conditions. The PGE₂ was injected into the posterior fornix. If the Bishop Score was found to be ≤ 6 after 12 hours, a repeat dose was given. Following ARM, Oxytocin infusion was initiated once there was improvement in Bishop's score. Efficacy in both groups was evaluated according to predefined criteria. All necessary data were collected using a specially developed proforma.

Statistical Package for Social Sciences version 24.0 was used to input and analyze all the data. Age, BMI, bishop score, gestational age, and parity were presented as mean and standard deviation (SD). Efficacy (yes/no) was presented as frequency and percentage. Chi-square was applied to evaluate the efficacy of both groups and a p -value of ≤ 0.05 to be statistically significant.

RESULTS

The study included individuals aged between 20 and 45 years, with an average age of 27.53 ± 4.31 years. Group-A women had an average age of 27.60 ± 5.12 years, while Group-B women had 27.40 ± 3.99 years. 20 to 30 years was the common age among most of the patients, 78(65.0%).

The gestational age of the included participants was between 37 and 41 weeks, with the mean gestational age of 38.35 ± 1.32 weeks. Group-A participants had a mean gestational age of 38.33 ± 1.28 weeks, and Group-B participants had 38.60 ± 1.34 weeks. The mean parity was 3.29 ± 1.17 , while the mean BMI was 28.39 ± 2.71 kg/m². The mean bishop score in Group-A was 4.20 ± 1.12 and in Group-B was 4.18 ± 1.07 . The vaginal delivery rate was higher during 24 hours in the Dinoprostone group (96.67% vs. 76.67%, $p = 0.0013$) as compared to the intracervical Foley's catheter group.

Stratification details of efficacy in Groups A and B for age group, gestational age, parity, BMI, and bishop score are shown in Table.

DISCUSSION

This study tested the efficacy of vaginal Dinoprostone vs cervical Foley's for initiating the process of labor in prior cesarean surgery, with a mean age of 27.53 ± 4.31 years, having an age range of 20 to 45 years. Group-A women had a mean age of 27.60 ± 5.12 years, while Group-B women had a mean age of 27.40 ± 3.99 years. 20 to 30 years was the common age among most of the patients, 78 (65.0%). In this study, vaginal delivery within 24 hours was significantly

higher in the Dinoprostone group (96.67% vs. 76.67%, $p = 0.0013$) as compared to intracervical Foley's catheter. The study has shown 60.0% efficacy (Regarding vaginal delivery in 24 hours) of vaginal Dinoprostone and 37.14% of cervical Foley's in the prior section of cesarean for the induction of labor.^{Error!} Reference source not found. In another study by Weeks et al., there was no significant variation in efficacy between the two drugs (62.0% vs 80.0%) was found.^{Error!} Reference source not found.

Table: Stratification Analysis of Efficacy in Groups A and B for age group, gestational age, parity, BMI, and bishop score (n=120)

Age of patients (years)	Group-A (n=60)		Group-B (n=60)		p-value
	Efficacy		Efficacy		
	Yes	No	Yes	No	
20-30	32 (94.12%)	02 (5.88%)	36 (81.82%)	08 (18.18%)	0.107
31-40	26 (100.00%)	00 (0.00%)	10 (62.50%)	06 (37.50%)	0.0007
Gestational Age (weeks)					
37-39	48 (96.00%)	02 (4.00%)	34 (77.27%)	10 (22.73%)	0.007
40-41	10 (100.00%)	00 (0.00%)	12 (75.0%)	04 (25.00%)	0.086
Parity					
2-3	32 (94.12%)	02 (5.88%)	36 (81.82%)	08 (18.18%)	0.107
4-5	26 (100.00%)	00 (0.00%)	10 (62.50%)	06 (37.50%)	0.0007
Body Mass Index (kg/m2)					
≤30	18 (29.23%)	08 (30.77%)	26(100.00%)	00 (0.00%)	0.002
>30	28 (82.35%)	06 (17.65%)	32 (94.12%)	02 (5.88%)	0.132
Bishop Score					
0-2	38 (95.00%)	02 (5.00%)	28 (70.00%)	12 (30.00%)	0.003
3-5	20 (100.00%)	00 (0.00%)	18 (90.00%)	02 (10.00%)	0.147

The rate of labor induction has increased significantly during the previous ten years. Obstetricians today face the challenge of ensuring successful vaginal delivery for women who require induced labor.² The choice to induce labor is usually made when the hazards of prolonging the pregnancy exceed the advantages of waiting. Immediate circumstances for labor induction include severe preeclampsia and ruptured membranes alongside chorioamnionitis.⁶ Other significant obstetric and medical causes include membrane rupture without contractions, postdated pregnancy, gestational hypertension, non-reassuring fetal condition, chronic hypertension, diabetes, limited fetal growth, and low amniotic fluid level as reported by Kerr et al.¹⁰ It is important to note that the success of vaginal delivery is closely tied to the process of cervical ripening. Labor induction techniques vary, but none are without danger. Therefore, induction should only be considered when the risks associated with continuing the pregnancy outweigh the risks of the induction process. Ideally, the agents used to induce labor should replicate the natural process of labor without producing extensive uterine activity.⁷ The most common methods used for labor induction when the

cervix is unfavorable involve intravaginal administration of Misoprostol or Dinoprostone, the application of prostaglandin gel, and transcervical placement of Foley's catheter. On the other hand, if the cervix is ripe, Oxytocin may be administered intravenously.¹¹

Kehl *et al.*, conducted a study on cervical ripening using two methods: PGE2 alone and DBC followed by PGE2 if needed. Interestingly, their study did not find a significant difference in cesarean rates between the two methods.¹² However, one limitation of their study was the lack of explanation regarding the rationale behind choosing either PGE2 or DBC. In another study by Sangram *et al.*, cervical ripening achieved through prostaglandins was compared with ripening achieved through the Foley catheter.¹³ The results demonstrated a significantly higher cesarean rate in the group using the Foley catheter. Nonetheless, this study had its limitations, such as a small sample size, inadequate information about the cervical characteristics at the beginning and end of the ripening process, and the duration of time until ripening occurred, which unfortunately was not specified.

Another study by Mathuriya *et al.*, has found that using intracervical PGE2 instead of a Foley's catheter is more successful in terms of cervical ripening during labor induction. It also leads to a shorter ripening time, as well as shorter times for labor induction, delivery, and reaching the active phase of labor, in cases where the cervix is unfavorable. Importantly, this method does not increase the rate of cesarean section due to fetal distress or failure to progress.¹⁴ These findings align with a Cochrane review by West *et al.*, which also concluded that the efficacy of the catheter procedure is similar to that of PGE1 administration but lower than that of PGE2.¹⁵

Elasz *et al.*, conducted a study involving 21 first-time pregnant women to determine the impact of a Foley catheter on cervical ripening.¹⁶ Their findings indicated that the results were similar to those achieved with a 5 mg dosage of PGE2 in vaginal gel, which was tested on 14 first-time pregnant women. No complications were observed with either method. However, the Foley catheter was considered advantageous due to its ease of use, cost-effectiveness, and wide availability.¹⁷ Another study by Chowdhary *et al.*, compared the effectiveness of prostaglandin gel and Foley catheter in changing the Bishop score. Both methods were found to be effective, with no significant difference observed.¹⁸

LIMITATION OF STUDY

The study was conducted at a single center, which may limit the generalizability of the findings to other obstetric populations and healthcare settings. The relatively small sample size may have reduced the statistical power to detect differences in secondary maternal and neonatal outcomes. Additionally, potential confounding factors, including baseline cervical characteristics, indication for induction, and variations in induction protocols, may have influenced the observed efficacy of the two methods.

CONCLUSION

Vaginal Dinoprostone demonstrated significantly higher efficacy than intracervical Foley's catheter for achieving vaginal delivery within 24 hours in women with a previous cesarean section undergoing induction of labor. Dinoprostone was associated with a greater likelihood of successful vaginal delivery within the specified timeframe. These findings suggest that vaginal Dinoprostone may be a more effective option for cervical ripening and labor induction in carefully selected women with a previous cesarean delivery. However, the choice of induction method should be individualized according to cervical favorability, maternal and fetal status, and institutional protocols. Further multicenter studies with larger sample sizes are warranted to confirm these findings and evaluate maternal and neonatal safety outcomes.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

MNBT & RA: Data acquisition, data analysis, critical review, approval of the final version to be published.

HA & MYS: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

MA & JTB: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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