

Comparison Of The Success Rates Of The Prostaglandin E2 (PGE2) Versus Foley Catheter In Females With Postdate Pregnancy

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Abstract

Objective: Postdate pregnancies, defined as pregnancies that extend beyond the 40th-week gestation, are associated with an increased risk of adverse maternal and fetal outcomes. Consequently, there is a clinical need to manage these pregnancies effectively to prevent complications. Two common methods for inducing postdate pregnancies are the use of Foley catheters and prostaglandins. To determine the success rates of the Foley catheter and prostaglandin E2 (PGE2) in females with postdate pregnancy.

Methods: 162 female participants were randomly divided into two groups through the lottery method. Group A utilised a Foley catheter, where after speculum examination, a 16F standard Foley catheter was aseptically inserted above the internal cervical os and inflated with 30ml of sterile water. In Group B, PGE 2 gel was administered, with nulliparous women receiving an initial dose of 2 mg per vaginam (PV) and parous women receiving 1mg PV. The gel was inserted into the posterior vaginal fornix. Success was defined as female giving within 24 hours. The data was analyzed using SPSS version 25.

Results: The mean age of patients was 30.35 ± 6.89 years. Success was observed in 87(53.7%) patients, while 75(46.2%) patients did not achieve success. The study findings revealed that success was attained by 30(34.4%) individuals in group A and 57(65.5%) in group B. A statistically significant difference was observed between groups regarding the success of patients. i.e., p-value (<0.05)

Conclusion: A study concludes that Prostaglandin E2 (PGE2) showed significantly higher success rates for achieving vaginal delivery within 24.0 hours when compared to Foley catheters in female individuals with postdate pregnancies.

Key words: Pregnancy, Prostaglandins E2; Cervical Ripening; Pregnancy Outcome; Labour.

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1. Introduction

Postdate pregnancies, defined as pregnancies that extend beyond the 40th-week gestation, are associated with an increased risk of adverse maternal and fetal outcomes. Consequently, there is a clinical need to manage these pregnancies effectively to prevent complications. Two common methods for inducing postdate pregnancies are the use of Foley catheters and prostaglandins.^{1,2} Labour induction involves deliberately or artificially initiating cervical ripening and uterine contractions to achieve delivery before the spontaneous onset of labour. Labour induction is recommended when the advantages to the mother or fetus outweigh the benefits of continuing pregnancy.^{3,4} The Foley catheter method involves mechanical dilation of the cervix, typically by inserting a balloon into the cervical canal. Studies such as the randomized controlled trial by Farid et al. have explored the efficacy and safety of Foley catheter induction in

postdate pregnancies. Results suggest that Foley catheter induction is associated with a lower risk of hyperstimulation of the uterus, leading to a potentially safer labour initiation process.⁵

Prostaglandins, as pharmacological agents, are commonly used for cervical ripening in labour induction. Research conducted by Johnson et, al has examined the outcomes of prostaglandin induction in postdate pregnancies. Findings indicate that prostaglandins are effective in achieving cervical ripening, leading to successful labour induction in a significant proportion of cases. However, concerns have been raised about the potential for hyperstimulation and its associated complications.⁶ Comparative analyses between Foley catheters and prostaglandin induction methods have been conducted to guide clinical decision-making. A randomized controlled trial comparing the two methods, highlighting differences in induction success rates time to delivery, and maternal-fetal outcomes. Such

studies contribute valuable insights into the relative merits and risks associated with each other.⁷

This study aimed to evaluate and compare the effectiveness of the Foley catheter versus prostaglandin E2 (PGE2) in women with post-date pregnancies. In both clinical practice and existing literature, it has been observed that PGE2 is a more efficient approach for labour induction, providing benefits such as early spontaneous delivery without compromising the well-being of either the fetus or the mother. However, it is noteworthy that controversies exist in the findings of previously conducted studies, and the above-mentioned studies were carried out on relatively small sizes.⁸ However we aim to identify a more appropriate and advantageous method for labour induction, conducting this study on a large sample size to enhance its reliability. The outcomes of our study will contribute to the implementation of a more suitable approach for labour induction.

Postdate pregnancies carry heightened risks for both mothers and infants, making it crucial to find effective methods for labour induction. While there are larger studies on this topic, our research aims to focus on a specific group of women to offer valuable insights into how Foley catheters compare to prostaglandin E2 (PGE2) in inducing labour. Even with a smaller sample size, we believe our findings can help improve clinical decisions and ultimately enhance patient outcomes in managing postdate pregnancies.⁸ Postdate pregnancies can pose serious risks for both mothers and their babies, so finding effective ways to induce labour is crucial. In this study, we aim to compare the Foley catheter to prostaglandin E2 (PGE2) gel instead of PGE2 tablets. We chose PGE2 gel because it is often more effective due to its localized application and quicker absorption, which can help with cervical ripening and lead to faster labour induction. By focusing on these two methods, we hope to offer valuable insights that can improve clinical practices and enhance outcomes for patients, even though our sample size is smaller.

2. Materials & Methods

This randomized controlled trial was conducted at the Obstetrics and Gynaecology Department from 15 November 2023 to 15 April 2024 in Agha Maternal and Child Care Hospital, Hyderabad. A sample size of 162 pregnant women within the range of 20-40 years, with a

parity of 1.2 mg/dl, cardiac disease (indicated by abnormal ECG and medical records), abnormal hepatic function (AST>40 IU, ALT > 40IU), severe asthma, anaemia (Hb<10 mg/dl), palpitation and those deemed unsuitable for randomization to either PGE2 (previous cesarean section) or use of catheter like latex allergy were excluded from the study.

In this study, we conducted a randomized controlled trial involving 162 women with postdate pregnancies. To assign participants to different groups, we used a simple lottery method.

For Group A, we performed the Foley catheter insertion. After obtaining informed consent, each woman was positioned comfortably in the lithotomy position, and a speculum examination was done to visualize the cervix while ensuring cleanliness throughout the process. We gently inserted a 16F Foley catheter above the internal cervical os into the cervical canal, being careful to avoid any trauma. Once it was in place, we inflated the catheter's balloon with 30 ml of sterile water. Throughout the procedure, we monitored the participants for any discomfort or complications and carefully documented everything.

In Group B, we used PGE2 gel for labour induction. After getting informed consent and positioning the patient in the lithotomy position, we performed another speculum examination. Using a sterile applicator, we administered 2 mg of PGE2 gel per vaginum (PV) for women who had never given birth (nulliparous) and 1 mg PV for those with previous births (parous). The gel was placed in the posterior vaginal fornix, close to the cervix, to ensure it worked effectively. After 6 hours, we reassessed the women's cervical status using the Bishop Score. If there was no improvement, we gave an additional 1 mg dose of PGE2 gel, regardless of whether the woman had given birth before. We kept a close eye on the patients for any side effects and made sure to record all details carefully.

Demographic data such as age, gestational age, and parity were collected. Female participants were randomly assigned to two groups by using a lottery method.

Group A received treatment with a Foley catheter. After undergoing a speculum examination, a 16F standard Foley catheter was inserted above the internal cervical os and inflated with 30.0 ml of sterile water.

In Group B, PGE 2 gel was administered. Nulliparous women received an initial dose of 2 mg per vaginum (PV), while parous women received 1 mg PV. The gel

was introduced into the posterior vaginal fornix. The patient underwent a re-assessment after 6 hours, and if there was no improvement detected in the Bishop Score, another 1mg dose of PGE₂ was administered (irrespective of parity). Success was defined as the female giving birth within the 24-hour time frame. All these details were recorded on a questionnaire.

Data was analyzed SPSS V 25. Age and gestational age were presented as mean and SD. Success rate and parity were presented as frequency and percentage. The success of both groups was compared using a chi-square test. Effect modifiers were managed by stratifying according to age and probability. The Chi-square test was applied for post-stratification. A significance level of $P < 0.05$ was considered as significant.

3. Results

A total of 162 cases were enrolled. The mean age of the patients was 30.35 ± 6.89 years. The results indicated that 57(35.1%) patients had no parity, 53(85.4%) had parity one and 52(32.0%) had parity two. The mean gestational age was 42.1 ± 0.71 weeks ranging from a minimum of 41.0 weeks to a maximum of 43.0 weeks.

Success was observed in 87(53.7%) patients, while 75(46.2%) patients did not achieve success. The study findings revealed that success was attained by 30(34.4%) individuals in group A and 57(65.5%) in group B. Success was not achieved in 75.0 cases, with 51(68%) from group A and 24(32%) from group B. The difference was significantly observed between the groups and the success of the patients. i.e. (p – value < 0.05). Table: 1

Table: 1 Comparison of success of labour in both groups

Success	Study Groups		Total	P-value
	Group A	Group B		
Yes	30	57	87	0.05
No	51	24	75	
Total	81	81	162	

Among patients less than 35 years of age, success was observed in 43.0 cases, with 4.0 cases from group A and 39.0 cases from group B. On the other hand, in patients aged 35.0 and above, success was achieved in 41.0 cases, with 28.0 from group A and 13.0 from group B. The difference was significantly noted between the two groups in terms of success rates, among patients under 35 years of age, with a p -value less than 0.05. The comparison of success with age group is shown in Table

2. The success rate of labour and parity in both study groups is expressed in Table 3.

Table 2: Comparison of success and age group stratified by age

Age group	Success	Study Groups		Total	P value
		Group A	Group B		
Below 35	Yes	4	39	43	0.0001
	No	36	23	59	
Above 35	Yes	28	13	41	0.65
	No	13	6	19	

Table 3: Comparison of success of labour and parity in both study groups

Parity	Success	Study Groups		Total	P value
		Group A	Group B		
No	Yes	6	22	28	0.02
Parity	No	19	10	29	
One	Yes	14	16	30	0.34
	No	12	11	23	
Two	Yes	16	14	30	0.001
	No	14	8	22	

In our study focusing on patients with no prior births (nulliparous), we observed a total of 28 successful cases: 6 in group A and 22 in group B. Among patients with one previous birth (parity one), there were 30 successful cases: 14 in group A and 16 in group B. Similarly, for patients with two previous births (parity two), success was recorded in 30 cases: 16.0 from group A and 14.0 from group B. The difference was significant in the success rates between the study groups for patients with no prior births and those with two previous births ($P < 0.05$).

4. Discussion

Numerous studies have explored post-term pregnancies, revealing that certain fetal risks, such as the presence of meconium, a higher likelihood of neonatal acidemia, and even the occurrence of stillbirths, are reported to be more pronounced at 41 weeks of gestation and to some extent, even when compared to pregnancies at 39.0 weeks, there was no difference in outcomes at 40.0 weeks of gestation.^{9,10}

In our study, success was observed in 87 patients (53.7%), with 30 from the Foley catheter group and 57 from the PGE₂ group. Conversely, 75 patients did not

achieve success, with 51 in the Foley catheter group and 24 in the PGE2 group. The difference between the groups was highly significant ($P < 0.05$). These results indicate that PGE2 is a more effective treatment compared to the Foley catheter for women with postdate pregnancy.

A study indicated the safety and efficacy of cervical priming and labour induction in grand multiparous females, utilizing either PGE2 tablets or the Foley catheter. Oxytocin was employed as necessary for labour augmentation. The preferences were given for the use of PGE2 mg1 vaginal tablets over the intra-cervical Foley catheter in this context.¹¹

In a randomized trial, a study discovered that PGE2 led to a higher rate of deliveries within 24 hours, specifically 53% of cases. In contrast, with Foley catheter induction, only 28% of deliveries within the first 24 hours in postdate pregnancies. The observed difference was deemed significant, indicating that PGE 2 is more effective than Foley catheter induction (0.01).¹²

Among Women with an unfavorable cervix, the use of intra-cervical PGE 2 can be safely employed for faster delivery without increasing the LSCS rate. while, employing a sequence of Foley catheter and PGE2 gel may offer a reliable option for labour induction, presenting a lower risk of oxytocin augmentation when a swifter delivery is not imperative.^{13,14}

On the other hand, employing a sequence of Foley catheter and PGE2 gel may offer a reliable option for labour induction, reducing the likelihood of requiring oxytocin augmentation when expediting delivery is not urgent.

In one study, a total of 229 women were divided into three groups: 95 in the Foley catheter group, 83 in the PGE2 group, and 51 in the PGE2 gel group. The Foley catheter group had a significantly shorter time from ripening to delivery compared to the PGE2 group, with intervals of 1.62 hours versus 27.0 ± 14.8 hours, respectively ($P < 0.001$). Additionally, the Foley catheter group had a higher likelihood of delivering within 12 hours (44.4% compared to 12.0%; $P < 0.001$; adjusted relative risk [RR] 3.87) and within 24 hours (78.9% compared to 49.4%; $P < 0.001$; RR 1.61).¹⁵ Murmu S et al. showed that there is no difference in effectiveness between intra-cervical PGE2 gel and intra-cervical Foley catheter for pre-induction cervical ripening. Moreover, factors such as the induction to delivery interval, outcomes for both mothers and neonates and the need for oxytocin for additional

augmentation were comparable in both groups.^{16,17} This study has some strong points, like its randomized controlled design and a diverse group of participants, which lend credibility to the findings about the effectiveness of PGE2 and Foley catheters for labour induction. However, the smaller sample size compared to other studies may weaken the conclusions we can draw. While we found a clear advantage for PGE2 gel, it's worth noting that many studies report similar success rates for both methods. Interestingly, PGE2 is often associated with better outcomes for newborns and higher APGAR scores. This suggests that although both methods can induce labour effectively, PGE2 might offer additional benefits for the health of infants. One study revealed a positive and favourable impact of the Foley catheter.¹⁸ Furthermore, akin et al. conducted a study to compare the efficacy of cervical ripening and induction of labour by using a Foley catheter balloon vs locally applied prostaglandin in the 3rd trimester of pregnancy.¹⁹

5. Conclusion

The study's conclusion highlights that Prostaglandin E2 (PGE2) showed significant success rates in achieving vaginal delivery within 24 hours, compared to the Foley catheter among women with post-term pregnancy.

Institutional Review Board Approval

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Contributions:

Q.M.K, K.M, A.J, T.R, S.I, S.A - Conception of study

Q.M.K, K.M, A.J, T.R, S.I, S.A -

Experimentation/Study Conduction

Q.M.K, K.M, A.J, T.R, S.I, S.A -

Analysis/Interpretation/Discussion

Q.M.K, K.M, A.J, T.R, S.I, S.A - Manuscript Writing

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Q.M.K, K.M, A.J, T.R, S.I, S.A - Facilitation and

Material analysis

All authors approved the final version to be published & agreed to be accountable for all aspects of the work.

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