ORIGINAL ARTICLE

Comparison of Outcome of Intracervical Foley Catheter Versus E2 in **Primigravida Women for Induction of Labour**

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ABSTRACT

Background: Labour induction refers to the artificial initiation of the childbirth process before it begins naturally. The Foley catheter serves as a reliable option for cervical ripening and labour induction, offering an effective alternative to prostaglandins. Objective: To compare the outcome of intracervical Foley's catheter versus prostaglandin E2 in primigravida women for induction of labour.

Study Design: Randomized controlled trial

Place and Duration of Study: Department of Obstetrics & Gynaecology, Sughra Shafi Medical Complex, Narowal from 15-03-

Methodology: A total of 70 eligible women were randomly divided into two groups of 35 in the Foley catheter group and 35 in the PGE2 group by the lottery method. Intracervical Foley's catheter versus prostaglandin E2 effectiveness was measured as successful labour induction and mean labour duration. SPSS version 21 was used to analyze data.

Results: Group A had a mean age of 25.8±3.0 years, and Group B had a mean age of 25.7±4.6 years. Success rate of induction of labour between Group A, Foley Catheter and Group B, Prostaglandin E2 was compared. In Group A, 13 (37.1%) successful induction and 22 (62.9%) failed induction. But in Group B, the success rate was quite high as 25 patients (71.4%) had successful induction (p=0.004). Group A (Foley Catheter) and Group B (Prostaglandin E2) mean labour time was statistically compared. Group A recorded increased mean labour time of 402.31± 34.01 minutes whereas Group B recorded smaller mean time of 357.60± 38.43 minutes. The p-value of 0.001 is statistically significant and signifies quicker advancement of labour in the patients induced with Prostaglandin E2 than in the patients induced with Foley catheter.

Conclusion: In conclusion, prostaglandin E2 tablets proved to be significantly more effective than Foley catheters in achieving vaginal delivery within 24-48 hours among primigravida women and quicker labour progress was noted in the Prostaglandin E2induced patients than in Foley catheter-induced patients.

Keywords: Induction of labour, Primigravida, Foley catheter, PGE₂

INTRODUCTION

Induction of labour refers to the process of initiating uterine contractions in pregnant women who are yet to enter labour and helping with vaginal delivery in 24 to 48 hours. 1 Induction takes place at more than 20% of all births in most countries.² Khan et al.³ in Pakistan determined that it is up to 40% in some health centers.3 When the Bishop score is below 6, ripening of the cervix has to be performed to achieve a successful induction. In these cases, medically induced cervical ripening is usually performed.4

A number of approaches, pharmacological and mechanical, are utilized in cervical ripening to minimize caesarean delivery risk among women with an unfavourable cervix.5

A randomised controlled trial by Eser et al⁶ proved that in primiparous women, the use of prostaglandin E2 (PGE2) with a Foley catheter had a significantly shorter induction-to-delivery interval (1001±608 vs. 1386±474 minutes; p <0.051) compared to when PGE2 was used with no difference in caesarean delivery rate (19.7% vs. 23.8%; p >0.05). Conversely, in women with multiple previous pregnancies, combination protocol had slightly lower but not statistically significant induction-to-delivery interval (777±634 vs. 933±532 minutes; p >0.05) with similar caesarean delivery rates (7.8% vs. 13.3%; p >0.05). On the other hand, one study done in Quetta by Arshad et al7 revealed that outcomes with the delivery within 24 hours were better in PGE2-gel group than in Foley catheter group with a value of 66.6% (50/75) vs 34.6% (26/75) in post-term pregnancy. Retrospective comparison by Manly et al8 indicated that the Foley catheter group had a much shorter time from ripening to delivery (16.2±9.2 vs. 27.0±14.8 hours; p <0.001) than the PGE2-CR group but that caesarean delivery rates were virtually the same (9.5% vs. 9.6%; p=0.970).

But compared to the PGE2-gel group, the Foley catheter group only experienced a reduction but not statistically significant delivery rates (9.5% vs. 11.8%; p = 0.664) [8]. Further, Fatima et al., in their Peshawar descriptive study, have presented that

 $(16.2\pm9.2 \text{ vs. } 17.5\pm10.6 \text{ hours}; p = 0.429), \text{ with equal caesarean}$

induction with a combination of PGE2 and Foley catheter resulted in an induction-to-delivery interval of 12.38 hours (range: 10-24 hours) and a rate of emergency caesarean section of 16.67%, thereby establishing its efficacy and safety in women with previous caesarean section history.9

MATERIALS AND METHODS

This randomised controlled trial was carried out in the Department of Obstetrics & Gynaecology, Sughra Shafi Medical Complex, Narowal from $15^{\rm th}$ March 2023 to $14^{\rm th}$ September 2023, Using the WHO sample size calculator, 70 (35 in each of the groups) sample was calculated on the expected success rate of delivery in 24 hours (66.6% in PGE2 and 34.6% in Foley's catheter group), with 95.0% confidence level and 80.0% test power.7 Non-probability consecutive sampling technique was used in the selection of the patients. Primigravida women, as per the operational definition, between 18-40 years of age, gestational age ≥ 37 weeks, Bishop score < 4 and EFW < 4 kg on USG were taken into the study. History of more than one pregnancy, non-cephalic presentation, contraindication for prostaglandin E2, placenta previa, placental abruption and congenital foetal anomalies, severe anaemia, severe hypertension, uncontrolled diabetes, coagulopathy, and any contraindication for labour induction and vaginal delivery were excluded. Ethical approval was provided by ERC of Sughra Shafi Medical Complex, Narowal. Written informed consent was taken from all the participants and demographic and clinical data were collected. In the Foley catheter group, 16F latex Foley catheter was inserted high above the internal cervical os, filled with 30 ml sterile water, and secured with little traction. 3 mg PGE2 tablet was placed in the vagina at the posterior fornix, followed by a 30-minute CTG in the PGE2 group. Foley catheters were compared with PGE2 in the study for labour duration and induction. If there was no improvement in Bishop score in six hours, then repeat dose was given. Successful induction was thus vaginal delivery between 24 and 48 hours, and labour duration was measured from the start of the active phase to delivery. The effectiveness of the intracervical Foley catheter compared to prostaglandin E2 was evaluated based on the success of labour induction and the mean

Received on 05-10-2023 Accepted on 06-12-2023 duration of labour. Labour induction was considered successful if vaginal delivery occurred within 24 to 48 hours following the initiation of induction. The length of labour was assessed by measuring the time elapsed, in minutes, from the start of the active phase of labour (i.e., 4 cm cervical dilation) until the birth of the foetus.

RESULTS

Group A (Foley catheter) and Group B (Prostaglandin E2) age category of the patients were compared. In 16 (45.7%) patients were of age 25 years and less, and in 19 patients (54.3%) were of age between 26-40 years in Group A. In Group B, 19 (54.3%) patients aged 25 years or less and 16 (45.7%) patients aged 26-40 years. Group A had a mean age of 25.8±3.0 years, and Group B had a mean age of 25.7±4.6 years. This indicates that the groups have comparable age distribution (Table 1).

A comparison of the success rate of labour induction between the two groups (Group A, Foley Catheter, and Group B, Prostaglandin E2) was done. In Group A, there were 13 (37.1%) successful induction patients and 22 (62.9%) failed induction patients. But with Group B, the success rate was very good, as 25 patients (71.4%) had undergone successful induction, whereas 10 patients (28.6%) failed induction. The Chi-square test shows the value to be 8.289 with a p-value of 0.004, which is a statistically significant value and suggests that there is a difference between the two. These results show that Prostaglandin E2 is in a better position to have a successful labour than Foley catheter (Table 2).

Group A (Foley Catheter) and Group B (Prostaglandin E2) mean time of labour were statistically compared. Group A contained a higher mean labour time of 402.31± 34.01 minutes compared to Group B having lesser mean time of 357.60± 38.43 minutes. The p-value of 0.001 is statistically significant, which indicates faster labour progress among the patients induced with Prostaglandin E2 than those induced with Foley catheter (Table 3).

Table-1: Distribution of patients by age

Table 1. Distribution of patients by age							
Age (Year)	Group-A		Group-B				
	(Foley Catheter)		(Prostaglandin E2)				
	No.	%	No.	%			
≤ 25	16	45.7	19	54.3			
26-40	19	54.3	16	45.7			
Total	35	100.0	35	100.0			
Mean ±SD	25.8±3.0		25.7±4.6				

Table-2: Successful induction of labour

Table 2: Caccocial induction of labour							
Successful induction	Group-A (Foley Catheter)		Group-B (Prostaglandin E2)				
	No.	%	No.	%			
Yes	13	37.1	25	71.4			
No	22	62.9	10	28.6			
Total	35	100.0	35	100.0			
Chi square = 8.289 P value = 0.004							

Table 3: Comparison of mean duration of labour

Craus	Duration of labour (min)		P value	
Group	Mean	SD	r value	
Group-A (Foley Catheter)	402.31	34.01	P=0.001	
Group-B (Prostaglandin E2)	357.60	38.43		

DISCUSSION

In current study, comparison of labour induction techniques between Group A (Foley Catheter) and Group B (Prostaglandin E2) shows a statistically significant higher induction success rate in the Prostaglandin E2 group. To be specific, 71.4% of Group B patients were successful in induction, whereas 37.1% of Group A patients were successful, with chi-square being 8.289 and p-value being 0.004, showing that it is significantly in favour of Prostaglandin E2.

The present study concurs with previous literature endorsing the effectiveness of Prostaglandin E2 for labour induction. Our findings are in agreement with the research by Arshad et al⁷, which

reported that 66.6% of patients in the Prostaglandin E2 group delivered within 24 hours, a figure significantly higher than the 34.6% in the Foley catheter group.

A study in the American Journal of Obstetrics and Gynecology compared Prostaglandin E2 vaginal inserts with Foley catheter and concluded that although both are effective, prostaglandin E2 has a greater rate of successful inductions. ¹⁰

A further randomized controlled trial also concluded that Foley catheter was less effective than Prostaglandin E2 gel for pre-induction cervical ripening with higher successful induction of labour.¹¹

Similarly, another study conducted by Henry et al. also reported the same result as in the current study. In their study, 53% of the patients (n=51) in the PGE2 group were found to have delivered vaginally at 24 hours compared to a mere 28% of the patients (n=50) who received the Foley catheter. It was statistically significant, i.e., PGE2 is better than Foley catheter for induction (p=0.011). 12

A multicenter randomized trial contrasted intra-cervical Foley catheter utilization with prostaglandins for labour induction and noted considerably higher failure of induction in the Foley catheter group compared with the prostaglandin group.¹³

The findings from this research confirm that labour proceeded faster in induced patients with Prostaglandin E2 (PGE2) than it did for Foley catheter-induced patients. Specifically, the duration of mean labour was appreciably lower among the PGE2 group patients (357.60±38.43 minutes) than that among Foley catheter patients (402.31±34.01 minutes) and was of statistical significance (p=0.001). This result is consistent with other studies that have proved PGE2 to be successful at shortening the induction-to-delivery interval. For example, in one study, the mean induction-to-delivery interval for PGE2 was 15.77±7.37 hours, which was less than that of the Foley catheter group (17.31±7.19 hours). 14

A study by Manly et al.8 showed that the Foley catheter group had a significantly shorter interval between ripening and delivery (16.2±9.2 vs. 27.0±14.8 hours; p <0.001) compared to the PGE2 group.

Prostaglandin E2 has the potential to advance ripening of the cervix and induce labour efficiently, thereby tending to accelerate the labour process. 15,16

Use of PGE2 has been linked with higher Bishop scores making the induction easier and less oxytocin augmentation required. 15

Conversely, Foley catheters are mechanical instruments utilized for cervical ripening and induction of labour. They are effective and safe but might not always lead to as quick an advancement of labour as PGE2.^{17,18}

The findings of the current study are consistent with the current evidence that Prostaglandin E2 is superior to the Foley catheter for labour induction. However, clinical practice should be tailored, taking into consideration both the safety and efficacy profiles of both approaches.

CONCLUSION

In conclusion, prostaglandin E2 tablets were dramatically better than Foley catheters to accomplish vaginal delivery within 24–48 hours in primigravida patients. Additionally, patients induced by Prostaglandin E2 had the labour much more advanced compared to patients induced by a Foley catheter.

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