Original Article

Comparison of Efficacy of Foleys Catheter with Prostaglandin E2 Gel for Induction of Labor in Women with Previous One Caesarean Section for Non-Recurrent Cause

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ABSTRACT

Objective: To compare the efficacy of Foley's Catheter versus Prostaglandin E 2 GEL for IOL in women with previous one Caesarean Section for a non-recurrent cause.

Study Design: Randomized controlled trial study

Place and Duration of Study: This study was conducted at the in Gynae B unit MTI, LRH, Peshawar from 4th December 2019 to 3rd June 2020.

Materials and Methods: Ninety (90) women undergoing IOL at term pregnancy with previous one cesarean section for non-recurrent causes were included. They were grouped randomly as group A (Foley catheter group) & group B (prostaglandin E2 (PGE2) gel group) by using the lottery method. Patients in both groups were analyzed for successful induction, induction delivery interval, and complications like hyper stimulation, fetal distress, and scar dehiscence. Data was entered in a structured proforma and analyzed using SPSS version 19.

Results: Mean age of women in group A was 28.68 ± 3.26 years and mean gestational age was 38.62 ±1.26 weeks. In group B mean age was 27.577± 3.07 years and mean gestational age was 38.777±1.49 weeks. The delivery interval after induction was16.04 hrs. in group A and 20.84 hrs. in group B. In group A, the delivery within 24 hours was seen in ales (89%) women who were > 39 weeks pregnant. Delivery within 24 hours was seen in 36(80%) patients in group A as compared to 22(48.9%) in Group B (P 0.002).

Conclusion: In this study, both the methods of induction in the women with a previous cesarean section were safe and effective. The cervical ripening effect of the Foley catheter was as good as that of the Prostaglandin E2 gel.

Key Words: Foley catheter, Induction of labor. Prostaglandins E2 gel.

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INTRODUCTION

Obstetricians are reluctant to give Trial of Labor to women who have had a previous cesarean section because there is a risk of uterine rupture, which might pose a threat to the mother and the fetus, as well as the possibility of subsequent litigation.[1,2] Although the trial of labor is safe, but it is not without risk and should be done with caution[3]. According to studies on vaginal birth after cesarean section, 60–80 percent of women who are allowed to labor after a previous cesarean section would deliver vaginally.

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The majority of studies on prostaglandin E2 gel (PGE2) induction have been conducted on women with simple obstetric histories, and there has been little research on the outcome and safety of vaginal prostaglandin for labor induction in individuals who have undergone previous caesarean section. The American College of Obstetricians and Gynecologists (ACOG) is not recommending the use of prostaglandins for labour induction.[4] However Prostaglandins are recommended by the Royal College of Obstetricians and Gynecologists even in situations of a trial of labor in women with previous cesarean section. [5-6]

In vaginal births with a history of Cesarean section, uterine rupture is a well-known but uncommon complication. In women with previous one CS, the incidence of uterine rupture was 0.5–0.9 percent, compared to 0.2 percent in women who have never had a CS. [7]Although in women with a previous CS the overall incidence of UR is low. Among women attempting vaginal birth after a previous cesarean section, labour is induced in 18%-27%. Previous studies have shown that 60%-80% of women with one previous cesarean section will deliver vaginally if a trial of labor is allowed, even when induced. [8]

Pharmacological agent (such as prostaglandins (PGE), oxytocin, estrogens, mifepristone) and non-pharmacological techniques (such as a transcervical Foley catheter, bougies and fore waters amniotomy) are used to ripen the unfavorable cervices.[9] The intracervical Foleys balloon catheter for cervical softening is gaining popularity for IOL in previous scars, with results comparable to pharmacological agents.[10,11] Prostaglandins given externally promote cervical ripening and expedite the delivery , but these also increase uterine hyper stimulation and lead to an abnormal fetal heart rate changes. In addition to maternal issues, uterine rupture can result in neonatal morbidity and stillbirth.[12] So, in women who have had a previous cesarean section, a cautious strategy for labor induction may be used.

MATERIALS AND METHODS

This Randomized controlled trial was conducted in Department of Obstetrics and Gynecology "B" Unit; Lady Reading Hospital Peshawar from 4th December 2019 to 3rd June 2020.Aproval was taken from hospital Ethical board. Sample size was 90 i.e. 45 in each group. P1 success of Foley catheter for labor induction being 84% & P2 success of Prostaglandin E2 for induction of labor being 50 % based on previous study. Significance level was 5% and power was 80% under WHO sample size calculation formula.

Sampling technique was Consecutive non-probability sampling. Inclusion criteria included women aged 18 to 35 years with previous one cesarean section for non-recurrent causes, Gestational age of ≥ 37 weeks assessed by early ultrasound, Singleton pregnancies with a cephalic presentation and Bishop's score of ≤ 6 were included. Women with controlled gestational diabetes mellitus and mild pregnancy induced hypertension were also included. While patients with previous one classical caesarean section, relative cephalopelvic disproportion, polyhydramnios, placenta previa, estimated fetal weight > 4.2 kg and positive scar tenderness were excluded. All women admitted to Department of Obstetrics and Gynecology "B" unit, Lady Reading Hospital Peshawar were included in the study that fulfilled the inclusion criteria. A written informed consent was taken from them for including them in the study. A detailed history, examination and investigations were done. A CTG was done before starting IOL. They were grouped randomly as group A (Foley catheter group) & group B (prostaglandin E2 (PGE2) gel group) by using lottery method. In group A, a 16-18 French Foley catheter with a 30-40ml balloon was inserted into the endocervical canal and the balloon was inflated with 30-40ml of sterile water to ripen the cervix under aseptic conditions. The catheter was strapped to the thigh with gentle traction. The catheter was checked for its position and the traction at 4-6 hours intervals. The time limit for catheter was 24 hours if it was not expelled spontaneously and whether the modified Bishop's score had improved or spontaneous rupture of the membranes had occurred. Patient was put on I/V antibiotics. In group B 0.5 mg Dinoprostone PGE2 gel was used. The next dose was repeated at 6 hours if the Bishop's score ≤ 6. In both groups if bishop score was improved then artificial Rupture of the Membranes (ARM) was done, followed by the starting with an intravenous oxytocin infusion of 2.5 units of oxytocin in 500ml of 5% dextrose at 10 drops/minute. The dose was increased at 10 drops/minute interval up to a maximum of 60 drops/ minute, or till the desired uterine contractions achieved. Meanwhile all the women in both groups were monitored for scar tenderness. Pulse was recorded after every 15-30 minutes in active stage of labour. Fetal wellbeing was checked by intermittent auscultation and one hourly Cardiotocography (CTG). Labour progress was monitored on Partogram. In case of failure to deliver within 24 hours or complication like fetal distress, uterine rupture, scar dehiscence, Category I cesarean section was done. All the information obtained including demographic details was entered in predesigned proforma. Statiscal analysis was done in SPSS 19. Mean and standard deviation were calculated for numeric variables like maternal age, gestational age, modified Bishop Score at induction and after 12 hours of induction, delivery interval after induction and parity in both groups.

Frequency and percentages were calculated for both groups for categorical factors such as delivery within 24 hours after induction. Successful induction was stratified by maternal age, gestational age, parity, and the modified Bishop Score at the time of induction in both groups. The Chi-square test was performed to evaluate outcomes in both groups after stratification, with a p-value ≤0.05 deemed significant.

RESULTS

Table No.1: Demographics of Both Groups (mean values)

Demographics	Group A (N=45)	Group B (N=45)
Patients' mean age in years	28.68± 3.26	27.57±3.07
Patients' mean gestational age in weeks	38.62 ±1.26	38.77±1.49
Score of Bishop Scale (at induction)	3.62 ±1.46	3.35 ±1.43
Bishop score after 12 hours of induction	8.62 ±1.91	6.86 ±2.41
Delivery interval after induction(hours)	16.04 ±5.89	20.84 ±6.60
Parity	1.64±1.02	1.57 ±1.01

The demographics of Group A and B are given in Table 1. The two groups were almost similar in maternal age, gestational age, and Bishop score at the time of induction, but differed in the Bishop score after 12 hours of induction (8.62 versus 6.86) and in the delivery interval after induction considerably.

In Table 2, the A and B groups were further divided based on induction to the delivery interval. Delivery within 24 hrs. (P-value of 0.005), occurred in the 18-27-year age group.

Table No.2: Induction delivery interval in different age groups

Age Range	Groups	Delivery within 24 hours		P-value
		YES	NO	
18-27 Years	A	16 (84.2%)	31 (5.8%)	0.005 (signi-ficant result)
	B	11 (42.3%)	15 (57.7%)	
28-35 Years	A	20 (76.9%)	6 (23.1%)	0.173
	B	11 (57.9%)	8 (42.1%)	

Table 3 Shows the delivery intervals in two gestational age groups. In group A, the delivery within 24 hours was seen in the maximum number of females (89%) that were greater than 39 weeks pregnant. There existed a significant difference (p-value: 0.008) between two groups A and B, with a gestational age of 37-39 weeks.

Table No.3: Delivery Interval with Respect to Gestational Age

Gestational age	Groups	Delivery within 24 hours		P-value
		Yes	No	
37-39 weeks	A	28 (77.8%)	8 (22.2%)	0.008 (signi ficant result)
	B	16 (47.1%)	18 (52.9%)	
>39weeks	A	8 (88.9%)	1 (11.1%)	0.095
	B	6 (54.5%)	5 (45.5%)	

A significant number (78%) of women in group A with parity between 1-3, delivered in 24 hours (p value= 0.008). While, in another category (parity >3), 100% females of group A had delivery within 24 hours. 95.2% of women in group A with Modified Bishop Score of 0-3, delivered within 24 hours, and 4.8% delivered after 24 hours with significant difference (p-value 0.000). 66.7% of Group A and 100% of Group B females with Modified Bishop Score of 4-6, delivered within 24 hours, with a significant result (p-value= 0.005).

Table 4 shows, 80% of Group A females delivered within 24 hours, while females of Group B delivered almost equally before 24 hours (48.9%), and after 24 hours (51.1%). There existed a significant difference (p-value: 0.002) between groups A and B for delivery time within 24 hours.

Table No.4: Comparison of Delivery within 24 Hours in Both Groups

Delivery within 24 hours	A	B	P-value
Yes	36(80%)	22(48.9%)	0.002 (significant result)
No	9(20%)	23(51.1%)	
Total	45(100%)	45(100%)	

DISCUSSION

Inducing labor in women who have had a previous cesarean section increases the risk of uterine rupture, especially when prostaglandins are used.[13] Balloon catheters have been shown to be effective and safe in women who have had a previous caesarean section, with vaginal birth rates ranging from 55.7 % to 71% and uterine rupture rates ranging from 0.3 percent to 1.6 percent. Some studies discourage the use of prostaglandins for cervical ripening and instead recommend using a balloon catheter.[14] Geeta P et al observed that using Prostaglandin E2 vaginal gel is both safe and effective, resulting in a successful vaginal delivery without a risk of scar rupture.[15]

In our study, the Foley catheter and the PGE2 gel had similar effects on cervical ripening in women with previous one lower segment cesarean section, which is comparable to Jhakar S et al.[16]. There are various advantages of the Foley catheter over prostaglandin E2 gel, including a lower cost, a shorter induction delivery interval, a greater rate of VBAC, and decreased risk of uterine hyper tonicity or tachysystole.

According to Masood A's study Foley catheter induction was associated with the lowest rupture rate in the induced group, which was comparable to the results in the spontaneous trial of the labor group. [17] In the large MEDICS research [18], the use of prostaglandins to induce labor was linked with a negligible increase in the risk of uterine rupture when compared to mechanical methods of induction. According to a randomized control trial done by the PROBAAT study group, the results of labour induction with a Foley catheter was similar to the induction of labour with the Prostaglandin E2 gel, with fewer maternal and neonatal side effects.[19]

The use of a Foley catheter over prostaglandins was preferred in this study because the method more closely matched the physiology of labor onset, resulting in a lesser risk of hyper stimulation, fetal heart rate abnormalities, and postpartum hemorrhage. Multiple techniques for IOL in the previous scar were evaluated

in a large database systematic analysis by West HM et al, and found equivalent outcomes in terms of safety and effectiveness of induction of labor using Prostaglandins and Foleys catheter.[20] In terms of delivery within 24 hours of IOL in both groups, the results of our study are comparable to Zhu et al's meta-analysis.[21] The effectiveness and safety of Foleys balloon catheter and prostaglandin E 2gel for IOL were compared in an Indian study by Ziyauddin F et al., who discovered that the Foleys catheter group had a slightly shorter induction to delivery time. In neither group, scar dehiscence was detected.[22] Furthermore, the Foleys catheter group had a shorter time from induction to delivery and no incidences of scar dehiscence.

CONCLUSION

Both techniques of induction were shown to be safe, simple, and effective in women with previous cesarean section in this research. The Foley catheter has several advantages over the prostaglandin E2 gel, such as lower costs, reversibility, and a lower risk of systemic and serious side effects such as uterine hyper stimulation and rupture, as well as significant cervical ripening and dilatation and a shorter induction to delivery interval.

Author's Contribution:

Concept & Design of Study:	Laila Zeb
Drafting:	Tanveer Shafqat
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Conflict of Interest: The study has no conflict of interest to declare by any author.

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