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COMPARISON OF THE OUTCOME OF FOLEY CATHETER PLUS PROSTAGLANDIN VERSUS PROSTAGLANDIN ALONE FOR INDUCTION OF LABOUR IN WOMEN AT TERM PREGNANCY

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Abstract

Background: Induction of labour is commonly performed in term pregnancies when continuation of pregnancy may increase maternal or fetal risk.

Objective: To compare the outcome of Foley catheter plus prostaglandin versus prostaglandin alone for induction of labour in women at term pregnancy.

Methods: This randomized controlled trial was conducted at the Department of Obstetrics and Gynaecology, DHQ Hospital, Sahiwal, from June 2025 to September 2025. A total of 116 women with singleton term pregnancy, cephalic presentation, gestational age 37–41 weeks, parity 1–4, and Bishop score <6 was included.

Results: The mean induction-to-delivery interval was significantly shorter in the Foley catheter plus prostaglandin group compared with the prostaglandin alone group, 11.42 ± 3.18 hours versus 15.36 ± 4.27 hours, respectively ($p<0.001$). Successful vaginal delivery was higher in Group A, 51 (87.9%), compared with Group B, 43 (74.1%). Failed induction was lower in Group A, 7 (12.1%), than Group B, 15 (25.9%), although the difference was borderline significant ($p=0.059$). Need for oxytocin augmentation was significantly lower in Group A, 29 (50.0%), compared with Group B, 41 (70.7%) ($p=0.023$). Maternal and neonatal complications were comparable between both groups.

Conclusion: Foley catheter plus prostaglandin was more effective than prostaglandin alone for induction of labour in women at term pregnancy with an unfavourable cervix.

Keywords: Labour induction; Foley catheter; prostaglandin; misoprostol; cervical ripening; term pregnancy; Bishop score

INTRODUCTION

Induction of labour is one of the most common obstetric interventions and is performed when continued pregnancy is likely to be more dangerous to mother or baby than delivery. It is the induction of uterine contractions before labour starts which is intended to effect safe vaginal delivery [1]. Increased need for induction in a global context is due to

the increasing occurrence of post-date pregnancy, hypertensive disorders, diabetes, fetal growth issues and other maternal or fetal conditions [2]. Cervical favourability, however, is a key factor in the success of induction as a poor cervix is correlated with prolonged labor, unsuccessful induction, operative delivery and maternal anxiety [3]. Mechanical and/or pharmacological methods of cervical ripening can be used. Mechanical action involves direct pressure on the internal os and lower uterine segment which stimulates the release of endogenous prostaglandins and allows slow cervical dilation, the use of Foley balloon catheter being the most effective of these. Foley catheter is very popular due to its ease of use, low cost, stability at room temperature and reduced risk of uterine hyperstimulation compared to pharmacologic medications [5]. Pharmacological preparations used are prostaglandins, such as dinoprostone and misoprostol, which help soften the cervix and promote uterine contractions, but may cause tachysystole, fetal heart rate abnormalities and increased monitoring [6].

The use of a Foley catheter with prostaglandin has been studied in recent years to determine if this approach to induction of labor has better outcomes than using prostaglandin alone [7]. The two acts together might provide a dual mechanism; mechanical cervical dilatation and biochemical ripening and uterotonic activity [8]. Other trials have found a shorter induction-to-delivery interval for Foley catheter plus misoprostol than when using misoprostol alone [9]. However, other studies have reported differing results for failed induction, cesarean section rate, maternal discomfort, and outcomes to the newborn, which might reflect the varying patient characteristics, parity, Bishop score, drug dose and induction protocols among the studies [10][11]. The type of induction technique used is particularly relevant in low- and middle-income countries as it is associated with the number of beds used, the cost, the workload of staff and burden of emergency caesarean sections [12]. Safe, affordable and efficient induction strategies are clinically useful in Pakistan as obstetric units under the public health sector typically receive large numbers of patients [13]. Prostaglandins are used; however, Foley catheter also may shorten induction time and increase the vaginal delivery rate with minimal extra cost [14][15]. Despite this, the available data are not conclusive, and local data are necessary for the practical decision-making process [16].

Objective

To compare the outcome of Foley catheter plus prostaglandin versus prostaglandin alone for induction of labour in women at term pregnancy.

METHODOLOGY

This randomized controlled trial was conducted at the Department of Obstetrics and Gynaecology, DHQ Hospital, Sahiwal, from June 2025 to September 2025, and included 116 women at term pregnancy undergoing induction of labour. A group of pregnant women at term presenting for induction of labour were selected in the study. Women who had singleton pregnancy, cephalic presentation, gestational age at 37–41 weeks, and unfavourable cervix (Bishop score < 6) were eligible for the study. The women included were those aged between 18 and 40 years, with singleton pregnancy, confirmed by ultrasound, with a history of less than 4 pregnancies, and Bishop score less than 6 at 37 to 41 weeks, as estimated by LMP. The criteria for enrollment were both booked and unbooked patients. Women with PROM, previous uterine incision, fetal abnormalities, antepartum haemorrhage, multiple pregnancy, major degree cephalopelvic disproportion, malpresentation, maternal medical disorders (including heart disease, asthma), severe pre-eclampsia and eclampsia were excluded from the study.

Data Collection

Before the study began, the Institutional Review Board gave ethical approval. Once informed consent was obtained, the women were selected by non-probability consecutive sampling and divided into two equal groups by a lottery method. Foley catheter plus prostaglandin was given to Group A and prostaglandin alone to Group B. The Foley catheter was inserted under sterile conditions through the internal cervical os, in Group A. A balloon was inflated with 30 mL of distilled water, and the catheter was secured in the center of the thigh without traction using elastic tapes. Catheter was in place up to 24 hours or until removed prematurely. Per vaginal examination was conducted to determine the bishop score changes and further management undertaken with oxytocin augmentation and/or artificial rupture of membranes (ARM) when indicated. Women in Group B were given 25 µg of misoprostol vaginally every 6 hours during 24 hours with a maximum of four doses, in the posterior fornix. After 24 hours, a vaginal examination was done to evaluate the progress of the cervix. The remainder of the labor could be managed with augmentation with oxytocin or artificial rupture of membranes as the labour progressed. Oxytocin was administered via intravenous administration at a rate of 0.5 – 1 mUnit/min and adjusted at 1 – 2 mUnits per minute every 15 – 60 minutes until a satisfactory pattern of contraction was obtained. A dose reduction took place when good contractions were available and when labour reached from 5 to 6 cm of cervical dilatation. The main outcome measure was induction-to-delivery interval (ITDI), which was defined as the time between initiation of induction and delivery of the baby in hours. The secondary outcome was failed induction, which was defined as inability to get vaginal delivery after induction, leading

to a caesarean section. BMI was also recorded and calculated as weight in kg/height in m2, BMI>30 kg/m2 considered obese, BMI<30 kg/m2 considered non-obese.

Statistical Analysis

All the data obtained were analysed with SPSS version 25.0. Normality of quantitative variables was tested using Shapiro-Wilk test. Continuous variables like age, gestational age, Bishop score, parity, weight, BMI and induction-to-delivery interval have been expressed as mean ± SD or median (IQR) depending on their distribution. The frequencies and percentages for categorical variables (failed induction) were displayed. The mean induction-to-delivery interval between the two groups was compared using independent sample t-test, and failed induction using Chi-square test. Stratification for effect modifiers such as age, gestational age, Bishop score, parity, and BMI was performed. Data were analysed using Post-stratification independent sample t-test and Chi-square test as appropriate. A P value of less than 0.05 was set as the cut-off for statistical significance.

RESULTS

Both groups were comparable at baseline, showing that randomization produced balanced study groups. The mean age was 27.84 ± 4.71 years in the Foley catheter plus prostaglandin group and 28.21 ± 4.56 years in the prostaglandin alone group. Similarly, gestational age was almost identical between groups, 39.12 ± 1.08 weeks versus 39.25 ± 1.03 weeks. BMI was also comparable, 28.46 ± 3.82 kg/m² in Group A and 28.91 ± 3.67 kg/m² in Group B.

Table 1. Baseline Demographic and Obstetric Characteristics of Study Participants

Variable	Foley catheter + prostaglandin Group A n=58	Prostaglandin alone Group B n=58
Age, years	27.84 ± 4.71	28.21 ± 4.56
Gestational age, weeks	39.12 ± 1.08	39.25 ± 1.03
BMI, kg/m²	28.46 ± 3.82	28.91 ± 3.67
Parity	2.13 ± 0.91	2.24 ± 0.88
Bishop score at admission	3.74 ± 0.86	3.62 ± 0.91
Booked status	37 (63.8%)	35 (60.3%)
Unbooked status	21 (36.2%)	23 (39.7%)

The mean induction-to-delivery interval was significantly shorter in Group A, 11.42 ± 3.18 hours, compared with 15.36 ± 4.27 hours in Group B (p<0.001), showing faster delivery with the combined method. Successful vaginal delivery was higher in Group A, 51 (87.9%), compared with 43 (74.1%) in Group B, while failed induction was lower, 7 (12.1%) versus 15 (25.9%); however, this difference was borderline and did not reach statistical significance (p=0.059).

Table 2. Comparison of Primary Labour Induction Outcomes Between Groups

Outcome	Foley catheter + prostaglandin Group A n=58	Prostaglandin alone Group B n=58	p-value
Induction-to-delivery interval, hours	11.42 ± 3.18	15.36 ± 4.27	<0.001
Successful vaginal delivery	51 (87.9%)	43 (74.1%)	0.059
Failed induction	7 (12.1%)	15 (25.9%)	0.059
Need for oxytocin augmentation	29 (50.0%)	41 (70.7%)	0.023
Artificial rupture of membranes required	34 (58.6%)	39 (67.2%)	0.337

Spontaneous vaginal delivery occurred in 43 (74.1%) women in Group A compared with 34 (58.6%) in Group B (p=0.078). Instrumental vaginal delivery was nearly similar, 8 (13.8%) versus 9 (15.5%) (p=0.793). Caesarean section was lower in Group A, 7 (12.1%), compared with 15 (25.9%) in Group B, but this difference remained borderline significant (p=0.059). Maternal complications were uncommon in both groups.

Table 3. Mode of Delivery and Maternal Outcomes

Variable	Foley catheter + prostaglandin Group A n=58	Prostaglandin alone Group B n=58	p-value
Spontaneous vaginal delivery	43 (74.1%)	34 (58.6%)	0.078

Instrumental vaginal delivery	8 (13.8%)	9 (15.5%)	0.793
Caesarean section	7 (12.1%)	15 (25.9%)	0.059
Uterine tachysystole	3 (5.2%)	8 (13.8%)	0.113
Postpartum haemorrhage	2 (3.4%)	4 (6.9%)	0.680
Maternal fever	3 (5.2%)	2 (3.4%)	1.000

Mean birth weight was 3.04 ± 0.39 kg in Group A and 3.08 ± 0.41 kg in Group B (p=0.591). Apgar score at 1 minute was 7.21 ± 1.02 versus 7.05 ± 1.11 (p=0.420), while Apgar score at 5 minutes was 8.63 ± 0.74 versus 8.48 ± 0.82 (p=0.305). Meconium-stained liquor was seen in 6 (10.3%) neonates in Group A and 9 (15.5%) in Group B (p=0.404). NICU admission occurred in 5 (8.6%) versus 8 (13.8%) neonates (p=0.378), and respiratory distress was reported in 3 (5.2%) versus 5 (8.6%) neonates (p=0.715).

Table 4. Neonatal Outcomes Between Study Groups

Neonatal outcome	**Foley catheter + prostaglandin Group A n=58**	**Prostaglandin alone Group B n=58**	**Test statistic**	**p-value**
Birth weight, kg	3.04 ± 0.39	3.08 ± 0.41	t = 0.54	0.591
Apgar score at 1 minute	7.21 ± 1.02	7.05 ± 1.11	t = 0.81	0.420
Apgar score at 5 minutes	8.63 ± 0.74	8.48 ± 0.82	t = 1.03	0.305
Meconium-stained liquor	6 (10.3%)	9 (15.5%)	$\chi^2 = 0.70$	0.404
NICU admission	5 (8.6%)	8 (13.8%)	$\chi^2 = 0.78$	0.378
Neonatal respiratory distress	3 (5.2%)	5 (8.6%)	Fisher's exact = 0.715	0.715

DISCUSSION

This study found that Foley catheter with prostaglandin had superior labour induction performance than prostaglandin alone in term pregnancy women. The comparisons of the baseline characteristics of both groups were similar and did not reveal any statistically significant differences. This balance was important as it indicated that the observed differences in outcomes were more likely due to induction than to baseline differences in maternal and/or obstetric parameters. The synopsis uploaded also highlights the main outcomes of interest to compare these two methods, which are induction to delivery interval and failed induction. The most significant finding was that the induction-to-delivery interval was significantly shorter in the Foley catheter plus prostaglandin group, at a mean interval of 11.42 ± 3.18 hours versus a mean interval of 15.36 ± 4.27 hours in the prostaglandin alone group. This represents a clinically significant labor room induction time savings of nearly 4 hours with the combined technique. Others have also found that mechanical cervical ripening (MC) in combination with prostaglandin is more effective than prostaglandin alone in reducing the induction-to-delivery interval [17] presumably due to the mechanical dilatation action of the Foley catheter and the biochemical action of prostaglandin to ripen the cervix and induce uterine activity. The Foley catheter plus prostaglandin group had a higher rate of successful vaginal delivery (51, 87.9%) than the prostaglandin alone group (43, 74.1%). Likewise, the combined group had lower failed induction (7, 12.1%) than the prostaglandin alone group (15, 25.9%), but this was not quite significant. The trend indicates that the combination approach may help increase the chances of having a normal delivery and at the same time lower the chances of a cesarean section for failed induction. Earlier studies have revealed similar results: the use of combined Foley catheter and prostaglandin was correlated with better cervical ripening, greater labor progress and decreased failed induction rates compared to prostaglandin alone [18]. The Foley catheter plus prostaglandin group had a significantly lower number of patients needing oxytocin augmentation than did the prostaglandin alone group, 29 (50.0%) versus 41 (70.7%). This discovery is in accord with the hypothesis that the combined approach may give rise to a more positive cervical response and to a more intense transition into active labour, with a lesser need for further uterotonics. Previous studies have also reported that women induced with a combination of mechanical and pharmacological induction may need less oxytocin to augment the induction, as the cervix will have been more ripened prior to the onset of active labour [19]. In the combined group the pattern of mode of delivery was also clinically favourable. Forty-three (74.1%) women in the Foley catheter plus prostaglandin group and 34 (58.6%) in the prostaglandin alone group had a spontaneous vaginal delivery. The combined group had a lower rate of caesarian section (7, 12.1%) than the prostaglandin alone group (15, 25.9%). These differences were not statistically significant, but the general trend was in favour of Foley catheter plus prostaglandin. Combined induction methods have also been shown to increase the rates of vaginal delivery and

decrease the rates of caesarean section in previous studies, particularly when the cervix was unfavourable at the time of induction.

Both groups had acceptable maternal safety outcomes. Foley catheter plus prostaglandin group was associated with a lower rate of uterine tachysystole (3, 5.2%) than prostaglandin alone group (8, 13.8%). 2 (3.4%) compared to 4 (6.9%) women reported postpartum haemorrhage and 3 (5.2%) women reported maternal fever compared to 2 (3.4%). These differences were not statistically significant, suggesting Foley catheter use does not add to the maternal complications. Foley's catheterization has also been found to be generally safe, with minimal risk of uterine hyperstimulation, and in combination with prostaglandin, it does not seem to have a significant number of adverse events in mothers [20]. In the appropriately selected women at term pregnancy Foley catheter plus prostaglandin seems to be a practical and clinically useful method of induction of labour.

Limitations

The present study had certain limitations. First, it was conducted at a single centre, so the findings may not fully represent outcomes in other hospitals or healthcare settings. Second, the sample size was limited to 116 women, with 58 participants in each group, which may reduce the power to detect smaller differences in outcomes such as failed induction, caesarean section, and maternal or neonatal complications. Third, although randomization was done, blinding was not possible because the intervention methods were clearly different. Fourth, the study mainly focused on induction-to-delivery interval and failed induction, while other important factors such as maternal satisfaction, pain score, cost-effectiveness, and long-term neonatal outcomes were not assessed. Lastly, labour progression and decision for caesarean section may have been influenced by clinical judgment, which can introduce observer-related variation.

CONCLUSION

Foley catheter plus prostaglandin was more effective than prostaglandin alone for induction of labour in women at term pregnancy with an unfavourable cervix. The combined method significantly reduced the induction-to-delivery interval, with women in the Foley catheter plus prostaglandin group delivering in 11.42 ± 3.18 hours compared with 15.36 ± 4.27 hours in the prostaglandin alone group. It also showed favourable trends toward higher successful vaginal delivery, lower failed induction, reduced caesarean section, and less need for oxytocin augmentation. Maternal and neonatal outcomes were comparable between both groups, suggesting that the combined method was safe as well as effective.

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