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Effectiveness of Intracervical Foley's Catheter with PGE2 Versus PGE2 Alone for Induction of Labour at Term Pregnancy

Fauzia Afridi, Romana Bibi, Maimoona Qadir, Ruqia Wazir

ABSTRACT

Objective: To compare the effectiveness of intracervical foley catheter with prostaglandin E2(PGE2) and PGE2 alone in achieving vaginal delivery in a patient having full-term pregnancy and its impact on maternal and fetal outcomes.

Methodology: This Comparative cross-sectional study was conducted in the Department of Obstetrics and Gynaecology, Khyber Teaching Hospital Peshawar, and Combined Military Hospital, Peshawar from January to December 2021. It included 388 pregnant women with singleton, term,cephalic presentation, admitted for induction of labor. The patients were divided into two groups, with one group (group A) comprising patients undergoing induction of labor with a foley catheter and prostaglandinE2 combined, whereas Group B consisted of patients having ProstaglandinE2 tablet only, as the mode of induction. The primary outcome was the mode of delivery, whereas secondary outcomes were induction to delivery interval and neonatal Apgar score.

Results: In Group A, 176 (90.7%) patients showed effective results in achieving vaginal while in Group B, 172 (88.7%) patients delivered vaginally (P-value 0.504). Mean induction to delivery interval was 12.5+2.7 hours in group A and 13.6 + 3.7 hours in Group B.

(Mean difference 1.1 hr, p-value:0.04, CI :0.9-1.9). There was no significant difference in neonatal Apgar score in the two groups(p-value: 0.816).

Conclusion: This study demonstrated that intracervical foley catheter with PGE2 application resulted in a significantly shorter induction-to-delivery interval as compared to the ProstaglandinE2 tablet alone. However, regarding mode of delivery and neonatal APGAR score, although the combined Foley and PGE2 group showed better results than the PGE2 alone group, the results were not statistically significant.

Keywords: Term Pregnancy, Induction of Labour, intracervical Foley's Catheter, PGE2

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INTRODUCTION:

A frequent obstetric procedure is labor induction. It's an iatrogenic initiation of labor pains. The cervical state at the time of induction determines whether or not labor induction is successful. It is usually expected that patients with low Bishop scores (B3 or lower) may experience greater rates of induction failure. Cervical ripening can be enhanced using prostaglandin E2 and an intracervical balloon catheter.[1] A study demonstrates that the pre-induction cervical ripening effects of the Foley's Catheter and PGE2 gel are comparable.[2] Cervical ripening by whatever means is the solution to reduce induction failure. A low Bishop's score has also been linked to a higher incidence of cesarean sections, maternal fever, and fetal hypoxia, according to research.[3,4] The intracervical Foley catheter balloon was as effective as the dinoprostone on the cesarean delivery rate. In terms of maternal or neonatal safety, there were again no notable differences between the two approaches.[5] For many years, cervical ripening and labor induction have been commonly treated with dinoprostone and misoprostol, prostaglandins. While the details of their mechanics are still being worked out.[6] Combining an intracervical Foley catheter with dinoprostone (PGE2, 0.5 mg) was more effective than using a Foley catheter alone for cervical ripening.[7] Two studies evaluating the use of Foley alone, PGE2, and combined Foley and PGs found that the combined use was not more effective than the separate approaches.[8,9] While maintaining

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maternal and fetal safety, labor induction seeks to reduce the time to vaginal birth. One study showed the rate of vaginal delivery in using a Foleys catheter and PGE2 gel simultaneously versus PGE2 was 60% and 50% respectively.[10] It's crucial to explain to the patient why labor induction is necessary, the risks involved, and any potential alternatives. There are numerous techniques for inducing labor, such as mechanical and pharmacological ones that can be combined with one another or used separately. The most appropriate and efficient procedure for cervical ripening and labor induction can be difficult to choose for the proper patient because there is currently insufficient information available.

Induction of labor is an important obstetric intervention as it is the only iatrogenic method to achieve a vaginal delivery as opposed to a cesarian section. However, the optimal method of induction is still a dilemma, as every method has its own pros and cons, and studies in this regard show conflicting results. Therefore, the rationale of this study was to compare the effectiveness of combined mechanical and pharmacological(Foley catheter in combination with PGE2) and pharmacological (PGE2) alone approaches in achieving cervical ripening and vaginal delivery. Additionally compared between these two groups was the induction to delivery interval, mother and fetal outcomes.

METHODOLOGY:

This Comparative cross-sectional study was conducted in the Department of Obs & Gynae, Khyber Teaching Hospital and CMH, Peshawar in January-December 2021. The sample size for this study was based on the previously reported outcome rates for Foleys catheter and prostaglandin E2 (PGE2) gel simultaneously versus PGE2, 60% & 50 % respectively[10], taking 95% confidence interval and power of 80% by using WHO sample size calculator. It consisted of a total number of 388 patients, 194 patients in each group. Patients aged 18 Years to 40 Years with 37 weeks pregnant or more and having singleton cephalic fetuses with intact membranes were included in this study, while patients who had a previous cesarean section or other uterine surgery, fetal malpresentation, multiple gestations, had spontaneous labor (3 contractions in 10 min) presenting with fever, premature rupture of membranes (PROM) and any contraindication for vaginal delivery, Vaginal bleeding, sensitivity to either latex or PGE2 and polyhydramnios were excluded from this study. Permission was takren from the Ethical review board vide letter no: 173/DME/KMC. Informed Consent was taken from all the included patients. A detailed history of the patients was obtained, and a physical examination was performed. Patients were allocated into two groups A (cervical Foleys and PGE2) and group B (PGE2 alone). In group A the patient lay in a lithotomy position and was covered by sterile sheets. The Foley was inserted through the internal cervical os, filled with 30 ml of normal saline, and taped to the patient's thigh with gentle traction. An hour after placing the Foley bulb, a monitor was performed. If less than 3 contractions per 10 min interval appear in the monitor the patient was transferred to the delivery room and PGE2 was administrated. If 3 contractions or more appear in 10 min intervals, a further intervention was personalized according to a medical decision. The Foley catheter was removed in case of expulsion, tachysystole, and spontaneous rupture of membranes. In Group B PGE2 alone was given. It was inserted in the posterior fornix using a small amount of water-soluble lubricant. If less than 3 contractions per 10 min interval appear in the monitor the patient was transferred for observation. If 3 contractions or more appear in 10 min intervals the patient was examined and in dilatation of 3 cm or more was transferred to the delivery room/labor suite. All the data was documented on proforma.

Data were analyzed in SPSS version 22.0. Mean and standard deviation was computed for numeric variables like age, APGAR score (at 1 minute and 5 minutes), Bishop score, and gestational age. Frequencies and percentages were calculated for categorical variables like gravidity, and mode of delivery, and the two categories of APGAR score.APGAR score. The chi-square test was used to statistically compare the two groups. Differences with a P-value of <0.05 was considered statistically significant. Effect modifiers like age, bishop score, and gravidity were controlled through stratification to see their effect on the outcome. All results were presented in the form of tables.

RESULTS:

In Group A, the mean age was 25.90+3.55 years. The mean gestational age was 38.51+0.853 weeks. Mean Apgar Score at 5 min was 7.65+1.66 score. The mean bishop score was 4.62+1.36 score.In Group B, the mean age was 25.76+3.55 years. The mean gestational age was 38.50+0.835 years. The Mean Apgar score at 5 min was 7.64+1.67 score. Mean bishop score 4.69+1.342 score. In Group A, 133 (68.6%) patients were primigravida while 61 (31.4%) patients were multigravida. In Group B, 154 (79.4%) patients were primigravida while 40 (20.6%) patients were multigravida.

DISCUSSION:

According to a study done in India there was no statistically significant difference between the two groups, however, both groups showed a substantial change in the Bishop's

Table 1: Mode of Delivery in both groups

Treatment Group	Vaginal delivery	C section	P-value
Group A (n=194)	176 (90.7%)	18 (9.3%)	0.504
Group B (n=194)	172 (88.7%)	22 (11.3%)	

Group A = Cervical Foleys and PGE2 Group B = PGE2 alone

Table 2: Induction to delivery Interval in hours:

Treatment group	Mean induction-delivery interval	Standard deviation	Mean difference	Confidence interval	p-value
Group A	12.5	2.7	1.1	0.9-1.9	0.04
Group B	13.6	3.1			

Group A = Cervical Foleys and PGE2 Group B = PGE2 alone

Table.3: APGAR Score in both Groups

Treatment Group	APGAR Score >7	APGARScore <7	p-value
Group A (n=194)	145 (74.7%)	49 (25.3%)	0.816
Group B (n=194)	143 (73.7%)	51 (26.3%)	

Group A = Cervical Foleys and PGE2 Group B = PGE2 alone

score for Foley's catheter (5.54 ± 1.89) and PGE2 gel (5.44 ± 1.82) with P<0.001. Both group's rates of cesarean sections and side effects were comparable. A comparison of the two groups Apgar scores, birth weights, and NICU admissions revealed no differences.[2]

According to Lixia Zhu's meta-analysis, for this trial, eight trials were used, with 1191 women receiving the dinoprostone insert and 1199 receiving the intracervical Foley catheter balloon. In a random effect model, there was no significant difference between the two groups in terms of the time from induction to delivery (mean difference, 0.71 hours). Regarding the incidence of cesarean deliveries (relative risk, 0.91; 95% CI, 0.78-1.07; P=0.24), the Apgar score, or side effects including the prevalence of maternal infection, postpartum hemorrhage, and hyperstimulation, there was no statistically significant difference between the 2 approaches.[5]

India's study was reported. The change in Bishop Score, the need for a cesarean section, any complications, and the neonatal outcome were the additional outcomes in addition to the Induction Delivery Interval (IDI), which was the primary outcome. The combined group had a substantially lower Induction Delivery Interval(IDI) (16 hours and 16 minutes vs. 20 hours 44 minutes, p=0.002) and a significantly higher post-ripening Bishop (6.67 vs. 5.98; p=0.045). (29.1 vs. 25.5%; p=0.669) The CS rate was comparable. The newborn results were similar, and no mother experienced hyperstimulation or chorioamnionitis. As a result, co-administering a single dose of an intracervical PGE2 gel with Foley was more effective for cervical ripening and IOL than using Foley alone.[7]

In the study, which was conducted in the USA, 71 patients were induced with Foley catheter and 69 with catheter-and-gel in combination. There were no differences between the groups in terms of delivery indications, ultrasound results, labour interventions, intrapartum time interval, mode of delivery, postpartum complications and newborn outcomes.[8]

In a study published in India, 50 women were of Group A received intracervical Foley catheters and PGE2 gel at the same time. Group B had intravaginal insertion of PGE2 gel only. The mean time from induction to the active phase was 5.8 hours for Group A and 6.23 hours for Group B in both groups. Additionally, the mean time from induction to delivery in Group A was 10.085.6 hours, compared to 14.66.9 hours in Group B. This difference is substantial, favoring Group A. Although there was a modest increase in the vaginal delivery rate in Group A, it was not statistically different from Group B (66% vs. 58%, respectively).[10] These results are consistent with our findings, which showed that 176(90.7%%) and 172 (88.7% patients in Group A and Group B, respectively, had normal vaginal births(p-value:0.5)

In terms of better maternal and fetal outcomes, we can confirm that a comparison between the groups showed that no single approach offers a statistically significant advantage over the other. However, theoretical concerns about the spread of infection with the use of a Foley's catheter exist, however in this study, 49 (25.3%) and 51 (26.3%) perinatal morbidities were documented in Groups A and B with P=0.816 respectively. These results support what Deshmukh VL and Yelikar KA[11] had seen.

These results were in line with what Patabendige M. and Jayawardane A[12] had noticed.

There are several ways to induce labour induction, including mechanical and pharmacological approaches that can be employed separately or in combination. It is vital to inform the patient on the justification for labour induction, including the dangers involved and potential alternatives. There is currently inadequate knowledge regarding the most appropriate and efficient strategy for cervical ripening and labour induction, making it difficult to choose the proper method for the right patient.

Both the prostaglandin E2 gel and the foley catheter have been shown in numerous investigations to be equally efficacious in promoting pre-induction cervical softening.[8,13] For the mother and fetus, Foley's Catheter is a safe way to induce labour.[14] This is in contrast to our findings from this study, which showed that the use of an intracervical foley's catheter in combination with PGE2 on a patient's cervix during a full-term pregnancy produced significantly better and more effective results than PGE2 alone in terms of bettering maternal and fetal outcomes.

A total of 153 patients were enrolled in a different study156 (82 Foley; 71 PGE2). With the exception of the PGE2 group's lesser dilatation (16% vs. 38% 1cm dilated; P=0.05), baseline parameters were comparable. When parity, gestational age, initial dilatation, and administration of oxytocin were controlled for in the CPH model, there was no difference in time from insertion to delivery between the PGE2 and Foley catheter groups (median 27 vs. 33 hr; HR 1.13, 95% confidence interval 0.77- 1.68). Patients in the PGE2 group had a higher chance of developing uterine tachysystole (9% vs. 0%; P=0.01) and needing an additional form of CR (34%

vs. 1%; P=0.001). Negative outcomes for mothers or newborns did not differ between groups. However, in one research, we noted 51 (26.3%) perinatal morbidities in Group B compared to 49 (25.3%) in Group A, p=0.816.[15] While in our study 68.0% of Group A patients had a normal delivery with 74.7% neonates were having good Apgar Score with p=0.0002 and 0.816.

In a study published in India, In one group, intracervical Foleys catheter instillation was followed by a single dose of dinoprostone gel if necessary, and solely dinoprostone gel for ripening in the other group. The length of the induction-delivery interval, birth method, and neonatal and maternal problems were evaluated. In comparison to the other group, which had a vaginal delivery rate of 64%, the first group had an 82% rate. The change was statistically significant (p=0.0426).[16] Several other regional and international studies have shown similar results.[17-20]

Studies done in Pakistan have demonstrated the effectiveness of PGE2.[21] A recent study comparing four different types of induction showed that foley catheter with or without PGE2 is less effective as compared to PGE2 alone in achieving vaginal delivery as well well as induction to delivery interval.[22] This is in contrast to our study findings. The plausible explanation for this might be that the previous study included patients with previous c-sections in which usually mechanical induction is done and the threshold for repeat c-section in a scarred uterus is usually low.

This study's limitations include its small sample size and being a two-centered study that does not generalize its results to the overall population of Khyber Pakhtunkhwa. Therefore, large multicentered randomized control trials should be carried out across the province of Khyber Pukhtunkhwa for better and robust outcomes.

CONCLUSION

This study demonstrated that intracervical foley catheter with PGE2 application resulted in a significantly shorter induction-to-delivery interval as compared to the ProstaglandinE2 tablet alone However, regarding mode of delivery and neonatal APGAR score, although the combined Foley and PGE2 group showed better results than the PGE2 alone group, the results were not statistically significant.

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Maimoona Qadir: Result interpretation and discussion writing
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