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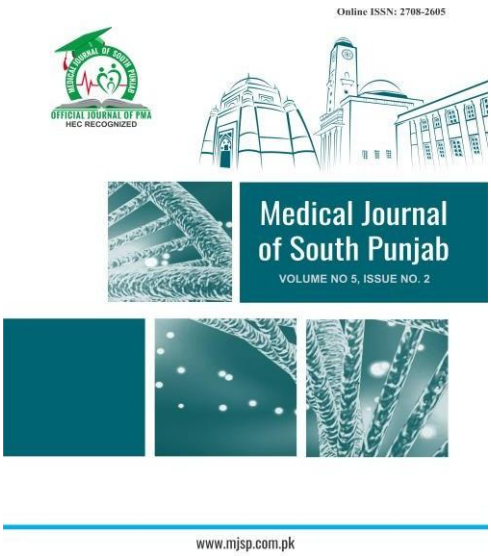

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Original Article

Comparison of efficacy of PGE2 tablets vs combination of PGE2 tablets with cervical foleys in predicting the outcome of induction of labor

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ABSTRACT

Objective: *To determine the comparison of effectiveness of PGE2 tablets alone vs combination of PGE2 tablets with cervical Foleys in predicting outcome of labor.*

Methods: *Study was conducted on 200 women enrolled according the inclusion and exclusion criteria. Simple random sampling was performed. Group 1 was induced using a vaginal prostaglandin E2 pessary, and Group 2 was induced using a combination of both PGE2 cervical Foleys catheter. The cost, the amount of time between induction and delivery, and the success rate of delivery were tracked and compared between the two approaches.*

Results: *The total of 200 female pregnant women was included. Mean age of the respondents was 25.16 + 3.3 years. PGE 2 labor induction time was 8.44+3.19 hours' vs combination use of PGE2 and cervical Foleys catheter time came as 14.67 + 6.36 hours. A statistical difference between them was found p<0.0001. PGE2 in single proved to be effective for induction of labor.*

Conclusion: *The PGE2 is simple, effective and a good substitute for traditional pharmaceutical methods of cervical ripening and labor induction.*

Keywords: *Cervical ripening, Cervical Foleys, PGE2, Labor, Cervical foleys*

1. INTRODUCTION

About 25% of term pregnancies in developing nations require the obstetric intervention known as labor induction.[1] The cervix goes through major biochemical changes over a period of anywhere from 12 hours to 6-8 weeks during the cervical ripening phase, which typically starts before labor event starts.[2] It is required to artificially ripen the cervix if this process fails in a healthy pregnancy. Since ancient times, cervical ripening and artificial labor induction have been practiced.[3] An ideal approach for inducing labor should be effective and safe for both the mother and the fetus.[4] Common indication for labor inductions include, Pre-eclampsia, early membrane rupturing, intrauterine growth limitation, postdated gestation, oligohydramnios, and issues with the mother's health.[5]

Currently, in developed countries labor induction is used to deliver close to 25% of all newborns.[6] 15% of births are artificially induced for a variety of reasons.[7] Pakistan's induction rate has been observed to range between 20 and 24%.[8] Common methods for cervical ripening and labor induction include both Pharmacological and mechanical method. Pharmacological method includes both PGE1 and PGE1 in pessary and gel form, vs mechanical method as cervical foleys.[9] Prostaglandin, oxytocin, estrogens, and mifepristone are some examples of pharmaceutical methods for inducing labour. Prostaglandins, which are cyclopentane derivatives of arachidonic acid, are extensively used in obstetrics and gynaecology.[10] Prostaglandins administered by any means for cervical ripening has been found to increases the rate of vaginal birth and lowers the rate of caesarean section and instrument births.[11] Similarly the use of cervical catheter have been found to be effective for labor induction.[12] It can mechanically dilate the cervix and stimulate the production of prostaglandins.[9]

The present study was conducted to compare the efficacy of PGE2 Tablets vs combination of PGE2 tablets with cervical foleys in Predicting the Outcome of Induction of Labor. This is the 1st study of its kind that is using both mechanical and pharmacological procedure for labor induction in a single patient.

2. METHODOLOGY

This prospective clinical cross sectional study was conducted in gynecology department of CMH Multan on 200 pregnant female patients from Nov 2022- May 2023. Ethical permission was taken from ethical review committee of CMH Multan and granted ethical permission. Inclusion criteria include cephalic presentation, primigravida $\geq$37 weeks gestation, intact membranes, and cases in which the prerequisites for vaginal delivery were met. Exclusion criteria include several pregnancies, an absent membrane, preexisting uterine bleeding, antepartum hemorrhage, comorbidities and medical conditions include heart disease or kidney failure. All respondents undergo detailed personal history, age, level of education and smoking, general body examination and all vitals were calculated, all baseline laboratory examination was performed, a digital vaginal examination was performed to determine the degree of cervical dilation, effacement, and fetal presentation. For the evaluation of fetal health, a pelvic ultrasound was performed to determine the estimated fetal weight, amniotic fluid index (AFI), and umbilical artery Doppler examination.

Pregnant women of group A were administered 3 mg of PGE2 pessary.

(repeated only after six hours). The on-call physician delivered the pessary, and if the patient was discovered to be in the active phase of labor—defined as when the cervix is >3 cm dilated and uterine contractions are 3 in 10 minutes—the medicine was withdrawn. A synthetic rupture of the amniotic membranes and an oxytocin infusion were performed if labor did not begin after three PGE2 doses.

Pregnant women in group b were exposed to both Foleys Catheter and PGE2. PGE 2 were administered same as group A and after lithotomy position, a sterile Cusco speculum was inserted to expose the cervix. With the aid of forceps that held sponges, a 22–24 G Foley catheter was inserted via the external cervical os after the cervix had been cleaned with an antiseptic solution. The balloon was inflated via an injection of 50 cc of distal water. To keep traction, the Foley catheter was affixed to the female patient's thigh. Antibiotics were given as a preventative measure and continued for 24 hours. If the catheter did not come out naturally after 24 hours, it was deflated. If the Foley catheter comes out within 24 hours, the amniotic membrane has ruptured, and oxytocin infusion for labor induction is initiated if necessary. Onset of labor and fetal monitoring was done regular after every half-hour intervals, and every four hours the progress of labor was evaluated.

3. RESULTS

The study includes 200 respondents, 100 in each group. Age group of 18-23 years had 88 (44%) of respondents, age group 24-29 years had 68 (34%) of respondents, and 30-35 had 44 (22%) of respondents. PGE2 had an average induction to delivery time interval of 8.44$\pm$3.19 hours vs combination use of PGE2 and cervical Foleys catheter time came as 14.67 $\pm$ 6.36 hours.

Out of total 100 in group A, 62.2% received 1 pessary and 37.8% received 2 pessaries and none of them required 3 pessaries. 20 (20%) of the women experienced spontaneous membrane rupture, while 80 (80%) required artificial membrane rupture. For combination of PGE2 and cervical Foleys, 8 (8%) had spontaneous membrane rupture and 92 % required artificial membrane rupture.

After 24 hours' analysis, in group A 88 % had SVD and 12 % LCS, while in group B 77% had SVD and 23% had LCS. Complications were scene in 8 patients in Group A and 16 patients Group B as shown in Table I.

Table I: Induction to labor time and complications in group A and group B

Variables	Group A	Group B
Induction to labor time (mean±SD)	8.44$\pm$ 3.19	14.67$\pm$ 6.36
Post-partum Hemorrhage n(%)	4 (4%)	8(8%)
Puerperal sepsis. n(%)	1(1%)	5(5%)
Intrapartum Pyrexia n(%)	2(2%)	3 (3%)
Tachysystole n(%)	-	-

The p-value <0.001 proves PGE2 tablet proved to be effective for induction of labor, in comparison to combination of PGE2 with cervical Foleys.

4. DISCUSSION

This study was conducted on 200 pregnant female patients after 37 weeks gestations. Divided into 2 groups, Group A had pharmacological labor induction with PGE2 while Group B had both pharmacological and mechanical labor induction with combination of PGE2 and PGE2+ cervical Foleys. Present study included high risk pregnancy, pregnancy

hypertension, and poor health for artificial labor induction. A study conducted by Sherman et al. favors out inclusion criteria where they found that pregnancy-induced hypertension was the most frequent reason for inducing labor, followed by a poor biophysical profile and intrauterine growth retardation.[13] A study conducted by Rouben DI et al. proved that hyper stimulation and induction of labor was greater in combine use of Foleys and PGE2 which contrary the present study results where only individual use of PGE2 was successful in labor induction this might be due to their small sample size. This study favors our study found that minimal complications were scene in both cases.[14] Present study explained that within 12 hr's 12 patients expelled Foleys out with mean time of 8.6hrs.

H. St. Onge. Favor our study where mean time for balloon expulsion after cervical ripening was 10hrs.[15] Wang et al. In clinical trial proved that Foleys catheter was found to be effective for labor induction then PGE2 which contradicts our results but they were not able to compare results with combine use of PGE2 and Foleys.[16] Present study proved that in group A only 1 (1%), vs group B had 2 (2%) NICU admissions which favors study conducted by Alam et al. where no statistical difference was found in group related to NICU admissions.[17]

Patabendige et al. favors our study he proved that 95% of cases had no complications when PGE2 was administered for Labor induction, our study proved that only 4% of the respondents had minimal complications.[18] Studies conducted by M Jozwiak and KWM Bloemenkamp and VL Deshmukh et al proved that PGE2 and cervical Foleys are equally effective in labors induction when used in single.[19,20]

Small sample size, observational nature, exclusion of patients with normal results, no control group, and no correlation with risk factors were studied. More study in view of above limitations can be made in future.

5. CONCLUSION

The findings of this study demonstrate that PGE2, when compared to combination of PGE2 pessary and cervical Foleys, is an equally effective technique for improving cervical ripening and induction. PGE2 gel was well-liked by the patients. When cost and storage considerations are taken into account, the individual use of Foleys catheter is a useful induction technique in underdeveloped nations. But combined use of PGE2 and Foleys proved to be costly. Antibiotics can be taken as a preventative measure to stop infections, which are a serious but mechanically avoidable problem. PGE2 have been found to be effective for the ripening of the cervix in women with low Bishop's scores.

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