

## Research Article



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## COMPARISON OF INTRACERVICAL FOLEYS CATHETER WITH EXTRA AMNIOTIC PGF2 ALPHA INSTILLATION AND INTRACERVICAL FOLEYS CATHETER WITH PGE1 VAGINAL PILLS FOR SECOND-TRIMESTER ABORTION

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### ABSTRACT

**Background:** Pregnancy termination in the second trimester, or more specifically in women with scarred uteruses, is a very difficult scenario that is linked to a three to five times increased risk of maternal morbidity and death.

**Aim:** Using an intracervical foleys catheter with additional amniotic PGF2 alpha instillation against an intracervical foleys catheter with PGE1 vaginal tablets for pregnancy termination starting in the second trimester was the goal of the current investigation.

**Methods:** In order to meet inclusion and exclusion criteria, 80 subjects were randomly assigned to two groups of 40 subjects each. Group I subjects were induced using a Foley's catheter balloon and a vaginal PGE2 tablet, while Group II females were induced using a Foley's catheter balloon and extra amniotic instillation of PGF2 $\alpha$ . In order to create a 2 ml solution equivalent to 0.50 mg PGF2 $\alpha$ , 5 mg of 1 ml PGF2 $\alpha$  was injected every hour for 48 hours or until expulsion. The injection was made with 19 ml of normal saline. The subjects' readiness for expulsion or induction was evaluated.

**Results:** The mean product expulsion interval for Group II females was 18.2 $\pm$ 3.8 hours, considerably shorter than that of Group I females (26.0 $\pm$ 8.2 hours), with a p-value of <0.005. Additionally, it was observed that 32 out of 40 Group II participants had expulsion within 24 hours and using just one ampoule.

**Conclusion:** The current study comes to the conclusion that the combination of Foley's catheter balloon and additional amniotic instillation of PGF2 $\alpha$  is a safe and efficient way to end second-trimester pregnancies in women.

**Keywords:** prostaglandins, Foley's catheter, extra-amniotic, and second trimester

### INTRODUCTION

The need of terminating a pregnancy in the second trimester due to congenital fetal abnormalities and intrauterine fetal death is one of the biggest problems addressed by obstetricians and gynecologists. When compared to first-trimester pregnancy termination, this difficulty is associated with a three to five-fold higher risk of maternal morbidity and death. One More females are needing pregnancy termination in the second trimester as a result of the greater discovery of fetal abnormalities brought about by different breakthroughs in amniocentesis, chronic villus sampling, and imaging.

Regardless of the length of the pregnancy, pregnancy termination is a purposeful disruption of the natural onset process. Because oxytocin receptors are not fully established in the early stages of pregnancy, the uterus does not react well to labor induction during this time, making second-trimester pregnancy difficult.<sup>2</sup>

Given India's easy legislation and abortion rights, a novel, safe, and dependable technique of mid-trimester pregnancy termination is necessary. Obstetricians and gynecologists find it challenging to end a pregnancy in women who have had

a previous cesarean section due to the significant rise in the prevalence of cesarean sections worldwide. There is currently no agreed-upon safe technique for terminating a pregnancy in the second trimester.<sup>3</sup>

Nowadays, a number of techniques are employed to end a pregnancy in the second trimester, such as the use of oxytocin infusion, prostaglandins, cervical dilatation using laminaria tents, Foley's catheter, and ethacridine lactate. But since none of these techniques are 100% effective and come with a number of negative consequences, it is crucial to thoroughly evaluate the options for ending a pregnancy starting in the second trimester.<sup>4</sup> Therefore, the purpose of the study was to evaluate any safe, effective, and alternative technique of second-trimester pregnancy termination that was easier to use, had less side effects, and could be utilized extra-amniotically.

Using an intracervical foleys catheter with additional amniotic PGF2 alpha instillation against an intracervical foleys catheter with PGE1 vaginal tablets for pregnancy termination starting in the second trimester was the goal of the current investigation.

## **MATERIALS AND METHODS**

In order to compare the effectiveness of intracervical foleys catheter with extra amniotic PGF2 alpha instillation and intracervical foleys catheter with PGE1 vaginal pills for pregnancy termination starting in the second trimester, the current prospective randomized-controlled trial was conducted.

The research participants came from the Institute's outpatient department. Prior to their involvement in the study, all individuals gave their written and verbal informed consent. The study evaluated 80 women who sought therapeutic pregnancy termination between 13 and 26 weeks of gestation, met all inclusion requirements, and received appropriate counseling prior to induction. Females with DIC, chorioamnionitis, hemorrhage, low-lying placenta, and prostaglandin contraindications were excluded from the trial.

The 80 participants were split into two groups of 40 each. Group I participants were induced using a Foley's catheter balloon and a 400µg vaginal PGE2 tablet, which was aseptically inserted into the posterior fornix every 4 hours for a maximum of 5 tablets or until expulsion was seen. Using Foley's catheter balloon and extra amniotic instillation of PGF2α, Group II females were induced. All females had a thorough medical history taken prior to induction, and a per-vaginal examination was performed to measure the uterus and cervix's sizes. Laboratory tests included coagulation profiles, regular urine evaluation, blood group analysis, and hemograms for each female.

The vulva vagina was washed with an antiseptic solution while the females were in a lithotomy posture. Using a sponge folder, Sim's speculum was used to expose the cervix. After inserting Foley's catheter number 14 Fr into the excess amniotic space in the cervix, 40 milliliters of saline were used to inflate the balloon.

Similar to Group I, Group II also had Foley's catheter inserted. The distal end of Foley's catheter was clamped, and an injection of PGF2α was administered. 20 ml of solution, or 0.50 mg PGF2α, was created by diluting 1 ml of 5 mg PGF2α injection with 19 ml of regular saline.

Three millilitres of this 20 millilitre solution were injected into the catheter, two millilitres into the extra-amniotic space, one millilitre filled the dead space, and two millilitres were administered every hour until the 48-hour mark or expulsion. It was considered a therapeutic failure after 48 hours.

It was deemed a technique failure when there was no expulsion within 48 hours or when there were severe adverse effects that led to the cessation of therapy. Scar rupture, severe vaginal bleeding, the rate of complications such as infection, the necessity for surgery, and total expulsion were used to evaluate the effectiveness. The amount of blood lost was estimated using pads that had been soaked and changes in hemoglobin % before and after evacuation. Prostaglandin-related adverse symptoms, such as pain, headache, diarrhea, nausea, vomiting, and/or chills, were noted.

The participants' parity, gestational age in weeks, termination induction, and the interval between induction and balloon expulsion and balloon expulsion to product expulsion were measured in all of the females. The amount of PGE1 pills taken and the duration between the fetus's induction and ejection were noted in Group I. The whole PGF2α injection dosage and the time between the beginning of induction and the end of the pregnancy were noted in Group II. The subjects were evaluated for any problems such as bleeding, induction to expulsion interval, placental retention, scar rupture, post-evacuation infection, requirement for blood transfusion, and the necessity to transition to other form of termination.

The chi-square test, Fisher's exact test, Mann Whitney U test, and SPSS (Statistical Package for the Social Sciences) software version 24.0 (IBM Corp., Armonk, NY, USA) with ANOVA and student's t-test were used to statistically analyze the collected data. A p-value of less than 0.05 was taken into consideration for the significance threshold.

## **RESULTS**

In order to compare the effectiveness of intracervical foleys catheter with extra amniotic PGF2 alpha instillation and

intracervical foleys catheter with PGE1 vaginal pills for pregnancy termination starting in the second trimester, the current prospective randomized-controlled trial was conducted.

Using inclusion and exclusion criteria, 80 subjects were randomly assigned to two groups of 40 each. Group I subjects were induced using a Foley's catheter balloon and a vaginal PGE2 tablet, while Group II females were induced using a Foley's catheter balloon and extra amniotic instillation of PGF2 $\alpha$ . 520 abortions were performed in the first trimester and 100 in the second throughout the research period. The females in Group I and II were 16 and 17 weeks along in their gestation, had parities of 2.6 and 2.8, and were 23.0 and 23.2 years old, respectively (Table 1).

Abortion was indicated in 4, 2, 2, 2, 12, 6, and 52% of participants, respectively, for uncontrolled hypertension, proliferative diabetic retinopathy, pulmonary hypertension, Eisenmenger's syndrome, fetal mortality in utero, membrane rupture prior to fetal viability, and congenital deformities (Table 2).

It was found that on comparing the induction to expulsion interval in two study groups, the mean induction to products expulsion interval was  $26\pm 8.2$  hours in Group I which was substantially greater compared to Group II where it was  $26\pm 8.2$  hours indicating a difference of 7.6 hours with  $p < 0.005$ . Group I saw a substantially greater mean balloon expulsion to products expulsion interval (2.0) than Group II (1.7), with a difference of 0.1 and a p-value of less than 0.005. Additionally, with a difference of 7.3 and a p-value of  $> 0.005$ , Group I's mean induction to balloon expulsion interval was 23.8, substantially larger than Group II's 16.3 (Table 3).

The study's findings demonstrated that, of the 80 participants, two underwent cesarean sections, and both groups I and II comprised six instances each for the preceding section. In Group I, two participants experienced severe bleeding with incomplete evacuation, and the fetus was surgically terminated; in Group II, the expulsion time was 7.6 hours shorter and there were no complications (Table 4).

Regarding the issues in two research subject groups, two and four people in Groups I and II reported technique failure, incomplete expulsion, and the necessity to transition to alternative ways. Two Group I participants required a blood transfusion, and two Group I subjects experienced severe bleeding (Table 5).

## DISCUSSION

Using inclusion and exclusion criteria, 80 subjects were randomly assigned to two groups of 40 each. Group I subjects were induced using a Foley's catheter balloon and a vaginal PGE2 tablet, while Group II females were induced using a Foley's catheter balloon and extra amniotic instillation of PGF2 $\alpha$ . 520 abortions were performed in the first trimester and 100 in the second throughout the research period.

The females in Group I and II were 16 and 17 weeks along in their gestation, had parities of 2.6 and 2.8, and were 23.0 and 23.2 years old, respectively. Abortion was indicated in 4, 2, 2, 2, 12, 6, and 52% of participants, respectively, for uncontrolled hypertension, proliferative diabetic retinopathy, pulmonary hypertension, Eisenmenger's syndrome, fetal mortality in utero, membrane rupture prior to fetal viability, and congenital deformities. These findings were similar to those of the 2015 and 2016 investigations by Rezk MA et al. and Ranjan S et al., whose authors reported comparable illness data and demographics in their research participants.

When comparing the induction to expulsion intervals of the two study groups, the mean induction to products expulsion interval for Group I was  $26\pm 8.2$  hours, which was significantly longer than that of Group II, which was  $26\pm 8.2$  hours. This difference was 7.6 hours, with a p-value of less than 0.005.

Group I saw a substantially greater mean balloon expulsion to products expulsion interval (2.0) than Group II (1.7), with a difference of 0.1 and a p-value of less than 0.005. Additionally, with a difference of 7.3 and a p-value of  $> 0.005$ , the mean induction to balloon expulsion interval in Group I was 23.8, substantially larger than that in Group II, which was 16.3.

The results of Halimi M7 (2004) and Ashok PW et al. (2004), who evaluated the induction to expulsion interval in two research groups and found a mean induction to products ejection interval comparable to the current study, were in agreement with these findings.

Out of the 80 study participants, two underwent cesarean sections, and both groups I and II comprised six instances each for the preceding section. These results were seen for the two study subject groups.

In contrast to Group I, where two participants experienced significant bleeding with incomplete evacuation and the fetus was surgically killed, Group II subjects had an expulsion time that was 7.6 hours shorter and without complications. These results were consistent with those of Henry A. et al. (2013) and Kosinska-Kaczynska K. et al. (2015), whose findings on the consequences of second-trimester pregnancy termination were similarly seen in the current study.

Additionally, two and four patients in Groups I and II had to resort to other procedures, reported method failure, and had incomplete expulsion because to the problems in two groups of research participants. Two of the Group I participants required blood transfusions, while two of the Group I subjects experienced severe bleeding. These results were consistent with those of Roudsaria FV et al. (2011) and Tabowei TO et al. (2003), who also reported similar complications in their studies involving Foley's catheter balloon with vaginal PGE2 tablet and Foley's catheter balloon with extra amniotic instillation of PGF2 $\alpha$ .

### CONCLUSION

Considering its limitations, the present study concludes that the combined use of extra amniotic instillation of PGF2 $\alpha$  along with the Foley's catheter balloon is an effective and safe method for the termination of second-trimester pregnancies of females. Further studies with larger sample sizes and multi-institutional setup are needed to reach a definitive conclusion.

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S. No	Parameters	Group I (mean)	Group II (mean)
1.	Gestational age (weeks)	16	17
2.	Parity (number)	2.6	2.8
3.	Maternal age (years)	23.0	23.2

Table 1: Demographic data in two groups of study subjects

S. No	Parameters	Number (n)	Percentage (%)
1.	Uncontrolled hypertension	4	4
2.	Proliferative diabetic retinopathy	2	2
3.	Pulmonary hypertension	2	2
4.	Eisenmenger's syndrome	2	2
5.	Fetal death in utero	12	12
6.	Rupture of membranes before fetal viability	6	6
7.	Congenital malformation	52	52

Table 2: Indications for abortion in 2<sup>nd</sup> trimester in study subjects

Variables	Group I (hours)	Group II (hours)	Difference (hours)	p-value
Mean induction to products expulsion interval	26±8.2	18.2±3.8	7.6	<0.005
Mean balloon expulsion to product expulsion interval	2.0	1.7	0.1	<0.05
Mean induction to balloon expulsion interval	23.8	16.3	7.3	<0.005

Table 3: Induction to expulsion interval in two study groups

S. No	Parameters	Group I (n=6)	Group II (n=6)
1.	Induction to expulsion	26	18.2
2.	Complications	2	0

Table 4: Outcomes in subjects with scarred uterus

S. No	Complications	Group I	Group II
1.	Need to switch to other methods	4	2
2.	Method failure	4	2
3.	Incomplete expulsion	4	2
4.	Blood transfusion needed	2	0
5.	Excessive bleeding	2	0

Table 5: Complications in two groups of study subjects