Evaluation of efficacy of use of intracervical Foley's catheter with PGE1 vaginal tablet versus intracervical Foley's catheter with extra-amniotic instillation of PGF2 alpha for second trimester abortion

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Abstract:

Background: Termination of pregnancy in second trimester and more so in women with scarred uterus is a real challenge and leads to three to five times higher risk of maternal morbidity and mortality. **Objective: C**ompare effectiveness of Foley's catheter balloon and PGE2 vaginal tablet versus Foley's catheter balloon and extra amniotic instillation of PGF2α in termination of second trimester pregnancy. **Method:** Prospective study, done in the department of obstetrics and gynaecology, KGMU, Lucknow. Total of 40 patients, 20 in each group, fulfilling inclusion and exclusion criterion were recruited by simple random allocation. Group A patients were induced with Foley's catheter balloon plus vaginal PGE2 tablet, group B induced with Foley's catheter balloon with extra amniotic instillation of PGF2α. One injection of PGF2α 1ml (5mg) was diluted with 19 ml of normal saline making 2ml of the solution equal to 0.50 mg of PGF2α, 2ml was injected one hourly till the expulsion or till 48 hours have passed. Patients were observed for induction to expulsion interval. Data collected was statistically analysed. **Results:** Mean induction to products expulsion interval was significantly shorter in the group B as compared to group A (18.4±4 versus 26.2±8.4 hrs, $p<0.005$). 16 patients out of 20 in group B expelled with one ampoule and within 24 hours. **Conclusion:** The combined use of Foley's catheter balloon with extra amniotic instillation of PGF2α is safe and effective method for second trimester termination.

Keywords: Second trimester, Foley's catheter, extra-amniotic, prostaglandins.

Need for 2nd trimester termination in view of intrauterine foetal demise and congenital fetal abnormalities is a major challenge and leads to increased risk of maternal morbidity and mortality than first trimester termination.[1] Due to increased detection of fetal abnormalities by imaging, chorionic villus sampling and amniocentesis more women need termination of pregnancy.[2] Termination of pregnancy is deliberate interruption of pregnancy rather than natural onset of process irrespective of duration of pregnancy. Uterus does not respond well to induction of labour in early period of gestation as oxytocin receptors are not well developed in early gestation thus second trimester termination of pregnancy is challenging.

With liberalization of abortion laws there is urgent need for a new, reliable, effective and safe method for the termination of mid-trimester pregnancy. Worldwide rate of caesarean section is rising, making it difficult for

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obstetricians to terminate pregnancy in women with previous caesarean section. At present there is no agreement onwhich method is safe for second trimester termination. Different methods are used for 2nd trimester terminations as mechanical methods of cervical dilation with laminaria tents, Foley's catheter and use of ethacridine lactate, oxytocin infusion and prostaglandins but none of them are 100% effective and have different side effects. Present study is aimed to find some alternative, safe and effective method that can be used extra-amniotically, easy to institute and has fewer side effects.

Objectives:

1. To compare effectiveness of use of Foley's catheter balloon and PGE2 vaginal tablet and combined Foley's catheter balloon and extra amniotic instillation of PGF2α in second trimester termination.
2. To analyse causes of second trimester termination.
3. To compare effectiveness of both methods in case of previous one caesarean section.

Methodology

It is a prospective randomised control study, done in department of obstetrics and gynaecology of tertiary care institute. Approval obtained from institutional ethical committee. All women who presented between 13 to 26 weeks of gestation for therapeutic termination of pregnancy and fulfilling inclusion criteria were enrolled in the study after taking consent and proper counselling prior to induction. Patient with low lying placenta, bleeding, chorioamnionitis, DIC and in whom prostaglandins are contraindicated were excluded from study.

Patients were enrolled through random allocation into two groups. Total of 40 cases enrolled 20 in each group. The group A patients were induced with Foley's catheter balloon plus vaginal tab PGE1 400µg tablet was put in the posterior fornix aseptically every 4 hours till the expulsion or till maximum of five tablets were given and group B induced with combined Foley's catheter balloon and PGF2α infusion.

Prior to induction detailed history was taken and pervaginal examination was done to assess size of uterus and cervix. Patients haemogram, blood group, urine routine and coagulation profile was done. The women were made to lie in lithotomy position, vulva vagina cleaned with antiseptic solution. Cervix exposed using Sim's speculum, with sponge holder Foleys catheter no 14 Fr was put in the cervix into the extra amniotic space and balloon inflated with 40ml saline.

In group B Foley's catheter was put like in group A. Foleys catheter was clamped at the distal end and injection PGF2α was given. One injection of PGF2α 1ml (5mg) was diluted with 19 ml of normal saline making 20ml of the solution equal to 0.50mg of PGF2α. Three ml of this solution will be injected into the catheter, 1ml to fill the dead space and 2ml into the extra amniotic space. 2ml was injected one hourly till the expulsion or till 48 hours have passed after which it was considered treatment failure.

If no expulsion occurred after 48 hours or there were serious side effects due to which treatment was stopped than it was considered as failure of the method. The effectiveness was determined by complete expulsion, need for surgical intervention and rate of complications like infection, excessive vaginal bleeding, scar rupture. Amount of blood loss was roughly evaluated from the soaked pads and from the changes in haemoglobin percentage before and after evacuation. Any side effects of prostaglandins like chills, nausea and vomiting, diarrhoea, headache and pain were noted.

Patient's parity, gestational age in weeks, indications for termination, time taken between induction to balloon expulsion and balloon expulsion to products expulsion was noted. In group A time interval between induction with tab PGE1 and expulsion of foetus, number of tablets of PGE1 used were noted. In group B total dose of injection PGF2α and interval from start of induction till termination of pregnancy was noted.

Patient observed for induction to expulsion interval, any complications like haemorrhage, requirement of blood transfusion, post evacuation infection, placental retention any scar rupture and need to switch to other method of termination.

Data collected was statistically analysed using paired student t test and SPSS 20. $p<0.05$ was taken to be statistically significant.

Results

In the course of study period of eight months, number of cases in which first trimester abortion was done were 260, number of cases in which second trimester abortion was performed was 50 (figure 1). Average maternal age in both the groups was 23 years. All the women in both the group were para 2 or 3. Average gestational age in group A was 18 weeks and in group B was 19 weeks (table 1). Out of all 40 cases of second trimester abortion enrolled maximum 26 cases (52%) were terminated due to congenital malformation in the fetus (table 2).

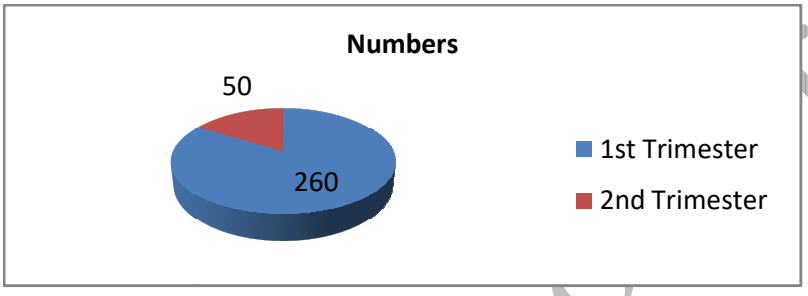

Figure1: Incidence of first and second trimester abortion during study period of eight months

Table 1: Demographic profile of study group		
Parameters	**Group**	**Mean**
Maternal age (years)	Group A	23.2
	Group B	23.4
Parity (number)	Group A	2.8
	Group B	3
Gestational age (weeks)	Group A	18
	Group B	19

Table 2: Indications of 2nd trimester termination	
Indications	**Number (%)**
Congenital malformation	26 (52%)
Rupture of membranes before fetal viability	3 (6%)
Fetal death in utero	6 (12%)
Eisenmenger's syndrome	1 (2%)
Pulmonary hypertension	1 (2%)
Proliferative diabetic retinopathy	1 (2%)
Uncontrolled hypertension	2 (4%)

Average time interval between induction to products expulsion was significantly less in the group B as compared to group A (18.4±4 versus 26.2±8.4 hrs, $p<0.005$) (figure 2). 16 patients out of 20 in group B expelled with one ampoule and within 24 hours (table 3).

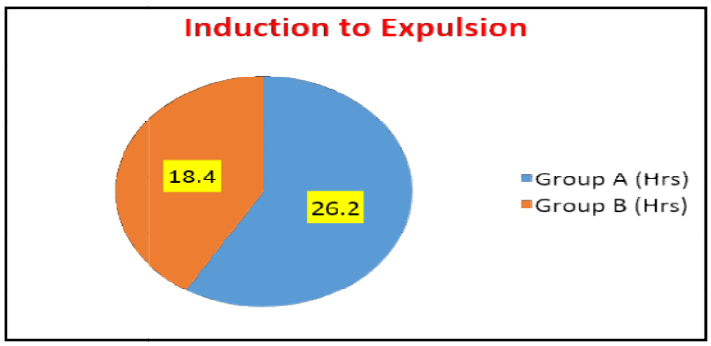

Figure 2: Inductions to expulsion interval.

Table 3: Induction to expulsion interval in both group				
Variables	**Group A (hours)**	**Group B (hours)**	**Difference (hours)**	**P value**
Mean induction to balloon expulsion interval	24	16.5	7.5	<0.005
Mean balloon expulsion to products expulsion interval	2.2	1.9	0.3	<0.05
Mean induction to products expulsion interval	26.2±8.4	18.4±4	7.8	<0.005

Table 4 shows outcome in cases of scarred uterus. Out of total 40 patient enrolled in the study six cases had previous one caesarean section, 3 cases each of previous section was enrolled in both group A and group B. Expulsion time of patient in group B was 7.8 hours less and there were no complications reported in group B while in group A one patient had excessive bleeding with incomplete evacuation and had to be terminated surgically.

Table 4: Outcome in cases of scarred uterus		
Parameters	**Group A (3 cases)**	**Group B (3 cases)**
Induction to expulsion	26.2 hours	18.4 hours
Complications	1 patient	None

In group A, one patient needed blood transfusion due to excessive bleeding; two patients had to be switched to surgical method of suction and evacuation due to incomplete expulsion. In group B, incomplete expulsion with failure of method and need to switch to other method was seen in only one patient (table 5).

Table 5: Complications		
Complications	**Group A**	**Group B**
Excessive bleeding	1 patient	None
Need of blood transfusion	1 patient	None
Incomplete expulsion	2 patient	1patient
Failure of method	2 patient	1 patient
Need to switch to other methods	2 pateint	1 patient

Discussion

Second trimester terminations of pregnancy are difficult due to unfavourable cervix. Different mechanical and pharmacological methods of cervical ripening have been used like tab PGE1, insertion of intracervical Foley's catheter, tab PGE1 combined with Foley's catheter, depending on choice of treating physician. Medical methods are often favoured for second trimester termination.[3]

Prostaglandins have opened new avenues in the management of second trimester terminations. The presence of prostaglandins helps in commencing labour and absence of prostaglandins helps continuation of pregnancy. PGE2 and PGF2α has dual action of softening the cervix prior to dilatation and initiates uterine contraction.[4] Although

PGE1 is not consented by FDA for induction of labour, termination of pregnancy and in postpartum haemorrhage but still it is being used.

FIGO 2017 recommendation for second trimester termination of pregnancy suggest use of 400mcg PGE1 tablets intravaginal/sublingually 3 hourly till maximum of 5 doses/24 hours. The induction to delivery interval of misoprostol has shown marked difference ranging from 9-33 hours in various studies [5-7]. But use of PGE1 is associated with various side effects and needs to be used with caution especially in cases of previous scarred uterus. Thus there is need to explorean alternative safe method of second trimester termination.

Krause in 1833 first narrated the role of Foley's catheter for termination of pregnancy.[9] Various studies conducted in developing countries have endorsed use of Foley's catheter either alone or along with prostaglandins as effective method for second trimester termination of pregnancy.[10-12] It has been suggested that Foley's catheter can cause mechanical dilatation of cervix and simulates release of endogenous prostaglandins which stimulates uterine contractility which can be further aided by use of prostaglandins.

Many studies have reported good outcome with theuse of extra-amniotic Foley's catheter balloon combined with extra-amniotic instillation of PGF2 alpha.[14] Various studies have suggested that Foley's catheter balloon is an effective method for ripening of cervix in second trimester of pregnancy with advantage of being cheap, and safe with no major side effects[15-17]. Results of these studies suggest that use of Foley's catheter for termination of second trimester miscarriage is efficacious and safe but at the cost of longer induction to expulsion interval but if supplementation with prostaglandins duration of termination canbe shortened.

In recent times lot of interest has been generated in use of extra-amniotic route for use of hypertonic saline and drugs for second trimester pregnancy termination. Extra-amniotic instillation of ethacridine lactate is a safe abortifacient has less side effects. With about 80% success but availability is an issue. Studies have shown that extra-amniotic instillation of prostaglandin PGF2α is an effective way of induction having minimal systemic absorption and minimal side effects.[18] In present study in cases of scarred uterus the induction to expulsion interval with use of that extra-amniotic instillation of prostaglandin PGF2α was 7.8 hours less than with Foley's and tab PGE1 group and with no side effect.

In present study remarkable differences was seen in the two groups in duration from start of induction till completion of termination. The mean induction to expulsion time required for group A patients was 26.2±8.4 hours while for group B patients it was 18.4±4 hours, the difference was statistically significant ($p<0.005$). This difference of over 7.8 hours indicates that the use of PGF2α injection as supplement to Foley's catheter for routine termination of pregnancy is good alternative method in comparison to the use of Foley'scatheter alone or combined with PGE1. PGF2α stimulates uterine contractions of adequate strength and duration, thus resulting in significant reduction in the time required fortermination of pregnancy and extra-amniotic instillation of PGF2α has advantage of uterine stimulation with least systemic absorption and side effect with desired results.

The average times for termination of pregnancy in our study is in agreement with study from Hyderabad, Pakistan [19] reported induction to abortion as 26.3 ± 8.2 hours for the Foley's catheter group (30 patients) and 32.17 ± 9.7 hours for the prostaglandin E2 group (40 patients). Result of our study are also in concordance with study from Lahore, Pakistan [20] study who in their study reported an induction to delivery interval of 19.95± 5.56 hours for the Foley's catheter group (20 patients) and 16.67 ± 6.71 hours for the PGF2α group (20 patients) the use of PGF2α injections. These two studies concluded that the use of Foley's catheter is to be preferred over prostaglandins because Foley's catheter is simple, safe, effective, convenient and economical. Although both studies have reported shorter duration of time required for termination of pregnancy with use of PGF2α and PGE1 at an expense of increased cost and side effects.

In the study by Ranjan et al, Shabana et al where they used combined Foley's catheter supplemented with the same dose of misoprostol that was used in misoprostol termination alone the abortion interval ranges between 7.5-18 hours.[21,22] The complications reported in the study were 18% of cases needed surgical evacuation for retained placenta, infection occurred in 3% of cases and uterine perforation during D and E occurred in one case followed by laparotomy and repair. In a study by Rezk et al among 100 patients, 4% had retained placenta, 13% had fever, 8 % had nausea and vomiting, and 8% developed haemorrhage.[23] Other study on 50 patients Ranjan et al, retained

placenta in 10% occurred, fever in 8%, nausea and vomiting in 18%, and 8% had haemorrhage.[21] In study by Ashok et al, uterine hyperstimulation and uterine rupture has been reported during second trimester termination using PGE1[8].

In present study in group A where we used combined Foley's catheter with PGE1 tablet one patient had excessive bleeding and needed blood transfusion in two patient methods failed and needed to be shifted to another method. In group B where we used Foley's catheter with extra-amniotic instillation of PGF2α only one patient had incomplete expulsion and needed to be switched to another method and no other major side effects were noted.

Result of our study shows that combined use of intra cervical Foley's catheter balloon along with extra-amniotic instillation of PGF2α is efficient, safe with less side effects and cost effective.

Limitation of study: It is a single centre study with limited sample size.

Conclusion

The synergistic use of Foley's catheter balloon with extra-amniotic instillation of PGF2α is safe and cost-effective method with added advantage of less time required for second trimester termination and relatively safe option in cases of scarred uterus.

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