

Comparison of Extra Amniotic Foleys Catheter Balloon with Traction Versus the Combined Use of Foleys Catheter Balloon Plus Extra-Amniotic Instillation of Pgf2 Alpha in Termination of Second-Trimester Pregnancy

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ABSTRACT

Objective: To compare the efficacy of intracervical catheter balloon with traction versus intracervical catheter and instillation of pgf2 alpha for termination of mid trimester pregnancy.

Study Design: Randomized controlled trial study

Place and Duration of Study: This study was conducted at the Department of Gynae and Obstetrics, Mardan Medical Complex Teaching Hospital Mardan for 6 months from January 2016 to June, 2016.

Materials and Methods: Consecutive non-probability sampling technique was used. Patients were grouped randomly into two groups by simple lottery method. The group 1 patients were induced with intracervical catheter balloon with traction while patients in group 2 were induced with intracervical catheter balloon and instillation of PGF2-alpha extra-amniotic space. The duration required for expulsion and efficacy of treatment was noted.

Results: The mean age of the patients was 29.68 ± 6.46 years with the mean gestational age of 20.63 ± 4.01 weeks. The need for E&C was found in 17.24% patients and efficacy was observed in 56.90% patients. Statistically, there is a significant difference between the efficacy in study groups of the patients i.e. $p\text{-value}=0.004$.

Conclusion: Foley+PGF2 is found to have more effective and satisfactory results as compared to Foleys catheter alone for termination of second-trimester pregnancy.

Key Words: Efficacy, Foleys catheter balloon, PGF2 alpha, Trimester, Pregnancy

Citation of articles: Gul H, Khan N, Jadoon S. Comparison of Extra Amniotic Foleys Catheter Balloon with Traction Versus the Combined Use of Foleys Catheter Balloon Plus Extra-Amniotic Instillation of Pgf2 Alpha in Termination of Second-Trimester Pregnancy. Med Forum 2019;30(2):2-5.

INTRODUCTION

Therapeutic miscarriage is one of the commonly practiced gynecological procedures in UK.¹ There is no exact data regarding induced abortion in this region. A majority (90%) miscarriages take place in early pregnancies. Worldwide second trimester abortion constitutes 10–15% of all therapeutic miscarriage but is responsible for more than 60% of all major complications.² Although the majority of therapeutic miscarriage are performed in the early pregnancies but there is still a gradual increase in mid trimester miscarriage because of the wide-scale introduction of

prenatal screening programs that detects women whose pregnancies are complicated by serious congenital anomalies' such as cardiovascular and skeletal malformation. Achieving the termination of pregnancy in mid trimester is a challenge facing by the obstetricians today. Disseminated intravascular coagulation disorder is an important complication if a dead fetus is retained in uterus for four weeks of the estimated fetal demise.³

It is also a psychological problem for the mother once she knows that she is having a dead or an abnormal fetus, in such circumstances, pregnancy has to be terminated. Both medical and surgical abortion procedures are used in the second trimester.^{4,5} The complication rates with surgical evacuation are between 4 and 10% and consist of uterine perforation, cervical injury, infection and hemorrhage.⁶ These complications in the form of hemorrhage and sepsis, associated with the surgical evacuation when performed by unskilled personal; in low resource countries have changed the focus towards non-surgical management with an economic advantage as well. Non-surgical methods for second trimester miscarriage have shown a considerable development during the last decade and have become more safe and considerable.⁷

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Received: August, 2018

Accepted: November, 2018

Printed: February, 2019

A variety of methods for termination pregnancy in second trimester can be used like induction with mifepristone and misoprostol, misoprostol or extra-amniotic instillation of PGF2 alfa and cervical dilatation with Foleys catheter with different efficacy in terms of induction to expulsion time ,need for surgical evacuation and rate of complications.⁸ Use of the intracervical catheter for therapeutic miscarriage was first described by Krause in 1833.⁹ The mechanical dilatation and endogenous Prostaglandin release are the mechanisms of cervical ripening by Foleys catheter and this effect is exaggerated when traction is added.¹⁰ The rationale of my study is to find out an effective and safes method for therapeutic termination of mid-trimester pregnancy, which have a short induction to expulsion time, cost-effective and with less complication rate. This study will help in finding efficacy of PGF2 alpha instillation via Foley's catheter in extra-amniotic space for therapeutic miscarriage in mid-trimester pregnancy as compared to catheter insertion and traction alone.

MATERIALS AND METHODS

It was a Randomized Controlled Trial study, conducted at Department of and Gynea and Obstetrics in Mardan Medical Complex Teaching Hospital Mardan; it took six month to conduct the study. The sample size was 58 in each group while taking 76% efficacy of Foleys catheter Balloon with traction and 50% efficacy of PGF2 alpha in Foleys catheter for therapeutic termination of second-trimester pregnancy, confidence interval 95%, power of test 90%. According to WHO formula for sample size calculation. Consecutive non-probability sampling, The Inclusion Criteria were the Women undergoing therapeutic termination of pregnancy with 14-28 weeks of gestation for maternal medical condition including intrauterine fetal death (missed abortion), lethal congenital malformations like anencephaly, gross hydrocephalus and fetal hydrops. Patients with placenta previa, unexplained vaginal bleeding and vaginal discharges, vaginal bleeding, absent membrane, previous lower segment cesarean section, previous myomectomy or patients presenting with labour pains were excluded. *Data Collection* Approval was taken from the ethical committee of the hospital before starting the project. Patients meeting the inclusion criteria were enrolled and admitted to the hospital. Informed written consent was obtained. A detailed history was recorded. General physical examination, per abdominal and per vaginal, was carried out to assess cervical score and uterine size. Data was collected regarding maternal age, gestational age, parity and indications for termination of 2nd-trimester pregnancy. All baseline investigations have done including Full blood count, blood group and Rh factor, urine routine examination, platelets count and coagulation profile. Patients were divided into two

groups randomly by simple lottery method. The group 1 patients were induced with intracervical catheter balloon with traction while group 2 patients were induced with combined intra cervical catheter balloon and instillation of PGF2-alpha in extra-amniotic space. Using sterile techniques in both groups a 20 French gauge Foleys catheter was inserted through the internalos. The balloon of catheter was inflated with 40 ml distilled water and gentle traction was applied by using a urinary bag filled with half liter water. To the patients in group 2 PGF2-alpha injection was instilled in the extra amniotic space through the same catheter. One injection of PGF2-alpha was diluted with 19 ml normal saline. 2 ml of the diluted solution was instilled through the catheter immediately after insertion of the catheter and then 1 ml per hour till expulsion of the balloon. After achieving the cervical ripening, intravenous oxytocin infusion was used for augmentation in both groups. Induction to catheter expulsion interval and catheter expulsion to fetus expulsion interval was recorded. Complete expulsion was confirmed on pelvic examination as closed OS and Ultrasound scan. Evacuation of product of conception and curettage were performed under short general anesthesia when required. Efficacy is defined as complete expulsion of a product of conception within 24 hours. Data was analyzed using suitable statistical tools by SPSS software version 21. Chi-square test was applied to compare the efficacy in both groups. P<0.05 was considered significant. All the results were presented as charts and graphs.

RESULTS

The mean age of the patients was 29.68±6.46 years. The mean gestational age was 20.63±4.01 weeks. In this study, the mean induction of expulsion time was 22.17±5.49 hours. Table 1

Table No.1: Demographics of patients

N	116
Age (years)	29.68±6.46
Gestational age (weeks)	20.63±4.01
Induction of Expulsion time (hours)	22.17±5.49

Table No.2: comparison of outcome in both groups

		Study groups		Total	P-value
		Foley+PGF2	Foleys catheter		
Need for E&C	Yes	7 (12.1%)	13 (22.4%)	20	0.07
	No	51 (87.9%)	45 (77.6%)	96	
Efficacy	Yes	40 (69.0%)	26 (44.8%)	66	0.004
	No	18 (31.0%)	32 (55.2%)	50	

The need of E&C was observed in 20 cases in which 7 (12.1%) were from group A and 13 (22.4%) were from group B. statistically insignificant difference was found between both study groups i.e. p-value=0.07. The efficacy was observed in 66 cases in which 40 (69%)

were from group A and 26 (44.8%) were from group B. Statistically a significant difference was found between the two study groups i.e. p-value=0.004. Table 2

DISCUSSION

Termination of pregnancy in the second trimester due to intrauterine fetal death and fetal abnormalities is one of the big challenges faced by the obstetricians today. There was no statistically significant difference in side effects and major complications developed in both groups. In our study, the overall efficacy was observed in 66 (56.90%) patients. Out of 66 patients 40 were from group A and 26 were from group B, similarly efficacy was not found in 50 patients in which 18 patients belonged to group A and 32 patients were from group B. Group A showed statistically more effective results as compared to group B patients.

With the use of intracervical catheter balloon and administration of extra amniotic PGF2-alpha at regular interval, successful termination of pregnancy has been achieved in 76 to 94%.^{8, 11, 12} Eileen K Hutton et al¹³ demonstrated in their study that when extra-amniotic instillation PGE2 was compared to intracervical catheter only, the only difference between groups was that there were fewer cases of unfavorable cervix at 12 to 24 hours following treatment (RR 0.59; 95% CI 0.41 to 0.86). Patient satisfaction rate was higher in those patients who received extra-amniotic prostaglandin. (mean difference 4.40; 95% CI 3.50 to 5.30) and these patients were less likely to be embarrassed by the treatment compared to vaginal PGE2 (RR 8.91; 95% CI 2.26 to 35.02).

Musarrat Halimi et al¹⁴ described that the combined use of Foley's catheter balloon and extra amniotic PGF2-alpha is more rapid, safe and cost-effective method for induction of therapeutic termination of second-trimester pregnancy, resulting in greater number of successful uterine evacuation within 24 hours than the Folley's catheter balloon alone. The efficacy and safety of the combined use of balloon catheter and extra-amniotic instillation of PEGF2-alpha has been studied with favorable results,^{15,16} but studies comparing the combined use of Foley's catheter balloon and extra-amniotic instillation of PEGF2-alpha with the use of extra-amniotic Foley's catheter balloon alone are limited.

Muhammad Shoaib et al¹⁷ also concluded in their study that the combined use of intracervical catheter balloon with instillation of PGF2-alpha is more efficacious than the catheter balloon with traction alone. H.S Liu et al¹⁸ mentioned in their study that the catheter balloon with intracervical PGE2 is more efficient in decreasing the induction-to-delivery interval for dissolution of second trimester pregnancies than the extra-ovular catheter with intrauterine PGF2 α .

In our study, the mean induction of expulsion time was 22.17 \pm 5.49 hours with minimum and maximum time of

12 & 30 hours respectively. the need for E&C was found in 17.24% patients. Statistically, there is insignificant difference was found between the need for E&C and study groups of the patients. i.e p-value=0.07 One study revealed that the group 1 patients were induced with intracervical catheter balloon alone with traction while patients in group 2 ,were induced with combined catheter balloon and PGF2-alpha. Mean induction to expulsion of the products of conception time was significantly shorter in group 2 as compared to patients in group 1 (16.7 \pm 4 versus 26.2 \pm 11.019 hrs, p<0.005). The combined use of catheter balloon with instillation of PGF2-alpha is more efficacious than the catheter balloon with traction alone.⁸

Shoab et al¹⁷ demonstrated in their study that the mean induction to expulsion of the products of conception interval was considerably shorter in group 2 as compared to group 1 (16.7 \pm 4 versus 26.2 \pm 11.019 hrs, p<0.005). One study also presented that the balloon of the Foley catheter can safely remain in the extra-amniotic space for more than 24 hours if the cervix is not favorable, provided the membranes are intact and there is clinical evidence of satisfactory fetomaternal well-being.¹⁹

Instillation of PGF2 alpha in extra-amniotic space significantly reduces mean induction to products expulsion interval as compared to Foleys Cather and traction alone (17 hours and 27 hours respectively)⁸ and in more than 50% of cases termination can be achieved in 24 hours.¹¹

CONCLUSION

Foley+PGF2 is found to have more effective and satisfactory results as compared to Foleys catheter alone for termination of second-trimester pregnancy.

Author's Contribution:

Concept & Design of Study:	Hemasa Gul
Drafting:	Nabeela Khan
Data Analysis:	Samina Jadoon
Revisiting Critically:	Hemasa Gul, Nabeela Khan
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Conflict of Interest: The study has no conflict of interest to declare by any author.

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