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## A randomised study to compare the efficacy of combined use of intra cervical foleys catheter followed by vaginal misoprostol with misoprostol alone in termination of second trimester pregnancy

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### Abstract

**Objective:** To assess the effectiveness of intracervical Foleys catheter and vaginal misoprostol compared to vaginal misoprostol alone in termination of second trimester pregnancy.

**Study Design:** A prospective randomised study

**Methods:** 60 women intended for termination of pregnancy between 13-20 weeks of pregnancy were randomly allocated to receive either intracervical Foleys with vaginal misoprostol (n=30) or only vaginal misoprostol 200 mcg 4<sup>th</sup> hourly (n=30). Procedure efficacy i.e., induction to abortion interval and number of doses of misoprostol required to complete abortion were assessed in both groups.

**Results:** The induction to abortion interval was 10.47 +/- 3.42 hours in combined group compared to 19.6 +/- 5.2 hours in misoprostol only group. The mean dose of vaginal misoprostol required in combined group was 544 mcg compared to 940 mcg in misoprostol alone group

**Conclusion:** Combined use of intracervical Foleys with vaginal misoprostol is a safe, effective alternative for termination of second trimester pregnancy.

**Keywords:** randomised, combined, misoprostol alone, trimester pregnancy

### Introduction

Second trimester abortions are increasing in number due to better and early diagnosis of fetal anomalies in early second trimester. Second trimester termination of pregnancy is more risky than during the first trimester [1]. The global incidence of second trimester abortion is 10-15% [2] but it accounts for 2/3<sup>rd</sup> of all abortion related complications. There is no consensus till date for the safest method for termination in second trimester. As surgical methods are associated with more morbidity, medical methods are preferred. Mechanical dilatation of cervix using Foleys was initially used to induce labour as it produces mechanical dilatation and also stimulates paracervical plexus of nerves, releases prostaglandins and increase excitability of uterus [3]. Therefore, this study is used to assess if intracervical Foleys combined with misoprostol accelerates the process of second trimester abortion compared to misoprostol alone group.

### Materials and Methods

this prospective randomized study was conducted in Navodaya medical college hospital and research centre from January 2018 to February 2019. Ethical committee approval was obtained. Pregnant women needing indicated termination of pregnancy from 14-20 weeks were enrolled.

### Inclusion Criteria

Singleton pregnancy  
Gestational age of 14 – 20 weeks

### Exclusion Criteria

2 or more previous LSCS  
PROM  
Chorioamnionitis  
Twin pregnancy  
Vaginal infection

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Antepartum hemorrhage  
Latex allergy

After satisfying the above criteria, patients were randomized to 2 groups

**Group 1** - Intracervical Foleys with vaginal misoprostol  
**Group 2** – vaginal misoprostol alone.

**In Group 1**, under aseptic precaution, 16 F Foleys catheter was placed in extra amniotic space intra cervically and inflated with 30ml normal saline. Catheter was strapped to maternal thigh. 200 mcg misoprostol was placed in posterior fornix. Dose was repeated 6<sup>th</sup> hourly till catheter was expelled or maximum 5 doses.

**In Group 2**, vaginal misoprostol 200 mcg was placed in posterior fornix for maximum 5 doses. Efficacy was determined by completion of abortion, need for surgical intervention and doses of misoprostol required.

**Results**

Total 60 women were randomly allocated to two groups. Pretreatment characteristics of both groups are described in table 1. Most of the patients were multi gravida, 17(56.6%) in group 1 and 19(63.2%) in group 2. Most of the cases were of gestational age 18-20 weeks. 16 patients in group 1 (53.3%) and 16 (53.3%) in group 2 were having gestational age between 18-20 weeks. 6 cases in group 1 and 8 cases in group 2 were a case of previous caesarean. Hence, both groups are comparable in terms of age, parity, gestational age, and pregnancy with previous caesarean cases.

As seen in table 2, the mean induction to abortion interval was 10.47 +/- 3.42 hours in the combined Foleys with misoprostol group compared to 19.6+/- 5.2 hours in misoprostol alone group. This result was found to be statistically significant. (p value<0.05)

As per table 3, the mean dose of misoprostol required in combined group was 544 mcg and dosage required in misoprostol alone group was 940 mcg. Thus there was statistically significant reduction in dose of misoprostol required in combined Foleys and misoprostol group.

**Table 1:** Pretreatment characteristics of enrolled patients.

Sl. no	Characteristics	Group 1 N=30 (Foleys with misoprostol group)		Group 2 N=30 (misoprostol alone group)
1	Mean age in years	24.4 +/- 4.2		22.6+/-3.8
2	Parity index	Primi	13 (43.3%)	11 (36.6%)
		G2	12(40%)	14(46.6%)
		G3	5 (16.6%)	5(16.6%)
3	Gestational age (weeks)	13-16	7(23.3%)	6(20%)
		16-18	7(23.3%)	8(26.6%)
		18-20	16(53.3%)	16(53.3%)
4	Previous caesarean section	Yes	6(20%)	8(26.6%)
		No	24(80%)	22(73.3%)

**Table 2:** Induction to abortion interval

Induction to abortion interval	Group 1	Group 2
< 12 hours	18(60%)	12(40%)
12-24 hours	8(26.6%)	8(26.6%)
24-48 hours	4(13.3%)	10(33.3%)

Mean  
Group 1 – 10.47 +/- 3.42 hours  
Group 2 – 19.6 +/- 5.2 hours  
P value < 0.05

**Table 3:** Misoprostol doses required

Misoprostol doses	Group 1	Group 2
200 mcg	6(20%)	4(13.3%)
400 mcg	14(46.6%)	10(33.3%)
>/- 600 mcg	10(33.3%)	16(53.3%)

Mean doses  
Group 1 – 544 mcg  
Group 2 – 940 mcg  
P value < 0.001

**Discussion**

Mid trimester abortions are more complex compared to first trimester abortion. The most effective regimen is tablet mifepristone 200 mg followed by misoprostol with a success rate of 97 – 99% in the first 24 hours [4, 5]. In low resource settings mifepristone is not available and also not affordable by the patient. There is no consensus regarding the best method for second trimester termination of pregnancy. In order to shorten the induction to abortion interval by dilating the cervix

intracervical Foleys was used in this study. In our study there was a statistically significant shortening of induction to abortion interval (p<0.05). Similar results were observed by Rezk M A *et al* [6]. The induction to abortion interval was 7.5 +/- 1.25 hours in combined Foleys and misoprostol group compared to 11.7 +/- 1.63 hours in misoprostol alone group.

A retrospective study done by Ercan *et al* showed that total dose of misoprostol required in combined group was 560 mcg compared to 1160 mcg in misoprostol alone group [7]. A similar statistically significant reduction in total dose of misoprostol required in combined Foley and misoprostol group was seen in our study too.

**Conclusion**

Combined use of intracervical Foleys catheter with vaginal misoprostol for second trimester termination of pregnancy significantly reduces the induction to abortion interval. Hence it is a safe, effective method for termination of 2<sup>nd</sup> trimester pregnancy.

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