A randomised study to compare the efficacy of combined use of intracervical Foley’s 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 Foley’s 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 Foley’s with vaginal misoprostol (n=30) or only vaginal misoprostol 200 mcg 4th 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 Foley’s 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 2/3rd 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 dilation of cervix using Foley’s 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 Foley’s 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
Antepartum hemorrhage
Latex allergy

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

**Group 1 - Intracervical Foley with vaginal misoprostol**

**Group 2 – vaginal misoprostol alone.**

In **Group 1**, under aseptic precaution, 16 F Foley’s catheter was placed in extra amniotic space intra cervically and inflated with 30 ml normal saline. Catheter was strapped to maternal thigh. 200 mcg misoprostol was placed in posterior fornix. Dose was repeated 6th 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 Foley 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 Foley and misoprostol group.

**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 Foley’s 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 Foley’s 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.

**References**

3. Ezhimokhai M, Nwabinell JN. The use of Foley’s catheter in

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

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

**Table 2:** Induction to abortion interval

<table>
<thead>
<tr>
<th>Induction to abortion interval</th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 12 hours</td>
<td>18 (60%)</td>
<td>12 (40%)</td>
</tr>
<tr>
<td>12-24 hours</td>
<td>8 (26.6%)</td>
<td>8 (26.6%)</td>
</tr>
<tr>
<td>24-48 hours</td>
<td>4 (13.3%)</td>
<td>10 (33.3%)</td>
</tr>
</tbody>
</table>

Mean

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

**Table 3:** Misoprostol doses required

<table>
<thead>
<tr>
<th>Misoprostol doses</th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mcg</td>
<td>6 (20%)</td>
<td>4 (13.3%)</td>
</tr>
<tr>
<td>400 mcg</td>
<td>14 (46.6%)</td>
<td>10 (33.3%)</td>
</tr>
<tr>
<td>&gt;600 mcg</td>
<td>10 (33.3%)</td>
<td>16 (53.3%)</td>
</tr>
</tbody>
</table>

Mean doses

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

