

# FREQUENCY OF COMPLETE ABORTION WITH INTRAVAGINAL MISOPROSTOL VERSUS EXTRA AMNIOTIC CATHETER IN TERMINATION OF SECOND TRIMESTER PREGNANCY

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## ABSTRACT

Termination of pregnancy in Mid-trimester is one of the most controversial areas in gynecological practice. As a cause of maternal mortality, it is one of the major neglected health issues in Pakistan and it is the third major cause of maternal mortality in our country. The study aim was to establish safe and effective method for abortion in second trimester.

**Objectives:** The objectives of this study was to compare the frequency of complete abortion with intravaginal misoprostol versus extra amniotic catheter in termination of second trimester pregnancy.

**Main outcome measure:** It was the frequency of complete abortion in second trimester.

**Study design:** Randomized Controlled Trial

**Setting:** Obstetrics & Gynaecology Department, PGMI / AIMC/LGH, Lahore.

**Subjects:** Female patients of age range 18-35years with gestational age 13-20 weeks calculated through last menstrual period (LMP).

**Duration:** 6 months (1<sup>st</sup> November 2015 to 30<sup>th</sup> April 2016)

**Methods:** Two hundred ten patients were admitted from OPD of LGH. Informed consent. We randomly divided patients in equally two groups by lottery method. In group A, females were given misoprostol 600g vaginally followed by 400g eight hourly till expulsion of products or up to 48 hours(n=105). Group II, had Foley's catheter traction and 1ml PGF2 alpha diluted in 19cc normal saline and 1cc/hr injected extra amniotically in control group (n=105), which was removed after expulsion of products of conception or after 24 hours. Women were observed for 48 hours for spontaneous expulsion of products.

**Results:** 210 patients were included in the study. The mean age of patients was 27.50 years with standard deviation of 2.82 years with most of the patients in the age range 25-30 years. Most of women in the study group were multiparous (54.8%) with 52.9% of sample in gestational age range 17-20 weeks with mean gestational age 17.5 weeks. A total of 173 patients (82.4%) out the 210 patients included in the study had complete abortion as per the operational definition. No statistically significant difference was found when comparison was done with respect to age, gestational age and parity ( $p>0.05$ ). Frequency of complete abortion was then compared in the study groups (misoprostol versus extra amniotic catheter). It was found that patients in the misoprostol group had significantly higher complete abortion rate as compared to those who were in the extra amniotic catheter group with a p value of 0.007.

**Conclusion:** This study showed that misoprostol results in significantly higher frequency of complete abortion in second trimester compared to extra amniotic catheter. So Misoprostol is a very effective, easily useable, safe and cheap drug for second trimester termination of pregnancy.

**Keywords:** Abortion, Pregnancy, Second Trimester, Misoprostol/administration & dosage, rostaglandins/administration & dosage.

## INTRODUCTION

Abortion is a major social & health issue. Women suffer in silence, ignorance, lack of awareness & education in developing countries. In Pakistan as a cause of maternal

mortality, abortion is major neglected health issue<sup>1</sup>. It is the third major cause of maternal mortality<sup>1</sup>. About 15,000 to 20,000 women die from complications arising out of legal abortions every year<sup>1,2</sup>. Mid-trimester

termination of pregnancy is one of the most controversial areas of gynecological practice. It has moral, emotional, social and technical issues. No method is simple, safe and optimally effective. Nowadays, most of abortions in mid-trimester are done by medical means, because of the increase chances of complications due to surgical termination, especially in late part of midtrimester, like hemorrhage, pelvic infection and uterine perforation or cervical injury. There are different medical regimens with different rate of success and complications<sup>4,10</sup>. There is no consensus what is the best method. The commonly used two methods are intra-amniotic prostaglandins F (IAPG) and vaginal misoprostol. Misoprostol is widely used as it is less expensive and stable at room temperature. Misoprostol alone is best used by vaginal, oral and sublingual route.

The rates of abortion at 24 h are approximately 80%-85%<sup>1-7,11</sup>. Foley's catheters which are inflated are very popular to act as a mechanical device for cervical ripening. It has been suggested that an extra-amniotic catheter has the advantages. It is simple, reversible, low cost and do not have systemic or serious side effects. Many other studies have proved efficacy of the extra-amniotic Foley's catheter<sup>5,12,13</sup>. Ethacridine lactate (also known as Rivanol) is an organic compound based on acridine is used in extra amniotic catheter. When it is used for abortion in second trimester, it is thought to augment endogenous prostaglandin production. Up to 150-200 ml of 0.1% ethacridine is instilled extra-amniotically, using a Foley catheter<sup>6,20,21</sup>. One study reported that 92% had complete abortion with misoprostol whereas 80% of the women aborted with extra amniotic catheter in 48 hours<sup>4,18,19</sup>. Although vaginal administration of prostaglandin E2 (dinoprostone, PGE2), is a very effective method for pregnancy termination during the second trimester, it is associated with severe gastrointestinal side effects and high grade fever<sup>2,14,15</sup>. The study rationale was to observe the effectiveness and safety of misoprostol as a second trimester abortifacient and to compare it with ethacridine lactate. Abortions techniques are highly variable in different areas of country. It is evident in literature that vaginal misoprostol is more effective in termination of pregnancy with missed abortion but still some obstetricians practice extra amniotic catheter for termination in missed abortion.<sup>16,17</sup> However, extra amniotic catheter has many side effects when it is compared with misoprostol<sup>22,23,24</sup>. The previously conducted studies had sample size which was small<sup>25</sup>. We wanted to test by this study the hypothesis that intravaginal misoprostol is more effective than extra amniotic catheter and we will take large sample size in

contrast to previous studies. So that more precise results can be obtained.

**Objective of The Study:** The objective of this study was to compare the frequency of complete abortion with intravaginal misoprostol versus extra amniotic catheter in termination of second trimester pregnancy.

**Hypothesis:** With misoprostol the frequency of complete abortion is more than extra amniotic catheter in termination of second trimester pregnancy.

## MATERIALS AND METHODS

**Study Design:** Randomized controlled trial.

**Setting:** Department of Obstetrics & Gynecology, PGMI/AMC/LGH Lahore

**Duration of Study:** 6 months (01-11-2015 to 30-04-2016)

**Sample Size:** Total 210 cases; 105 in each group, was calculated with 80% power of test, 5.5% level of significance and taking expected percentage of complete abortion i.e. 92% with intravaginal misoprostol and 80% with extra amniotic catheter in termination of first and second trimester pregnancy.

**Sampling Technique:** Non probability consecutive sampling

## SAMPLE SELECTION

### Inclusion Criteria

- Patients of age range 18-35years with gestational age 13-20weeks (through LMP).
- Patients with missed abortion (through clinical examination).
- Patients who have been advised termination of pregnancy on medical grounds.
- Patients with fetal anomalies who have been advised termination.

### Exclusion Criteria

- Patients with uncontrolled hypertension (diastolic BP>110mmHg), renal disease (serum creatinine>1.2mg/dl), liver disease (ALT>40IU, AST>40IU) or jaundice, ischemic heart disease (abnormal ECG) bronchial asthma and glaucoma.
- Patients with hematological disorders, anemia (Hb<8g/dl), coagulation disorder (PT>14s, APTT>35s)
- Low lying placenta (on USG).
- Current use of long term systemic steroid
- History of allergy or intolerance to misoprostol and PGF2 alpha
- Patients with absent membranes and vaginal discharges.

## DATA COLLECTION PROCEDURE

Approval from hospital ethical committee was taken, 210 patients fulfilling the inclusion and exclusion criteria were admitted from OPD of LGH. Informed consent was obtained and patient demographic information (name, age, gestation and parity) were recorded. We randomly divided patients in two equal groups by lottery method. In group A, females were given misoprostol 600g vaginally followed by 400g eight hourly till expulsion of products or up to 48 hours (n=105). Group B, we inserted Foley's catheter, traction applied and 1ml PGF2 alpha diluted in 19cc normal saline and 1cc/hr injected extraamniotically (n=105), which was removed after expulsion of products of conception or after 24 hours. We observed patients for 48 hours for spontaneous expulsion of products of conception. Complete abortion was labeled (as per operational definition). If there is no expulsion in 48 hours, the case was considered to have failed and then we managed patient as per hospital protocol. Latent phase, active phase and induction abortion interval in both groups was noted and compared. All the information was collected on a specifically designed proforma.

### Data Analysis:

Data was entered and analyzed through SPSS 16. Quantitative variables like age, gestation and induction to abortion interval were calculated as mean+SD. Qualitative variables like

parity were calculated as percentage and frequency. We compared both groups for complete abortion by using chi-square test. P-value <0.05 was taken as significant p-value.

## RESULTS

A total of 210 patients were included in the study. The mean age of patients was 27.50 years with standard deviation of 2.82 years with most of the patients in the age range 25-30 years. Distribution of sample by gestational age shows 52.9% of sample in gestational age range 17-20 weeks with mean gestational age 17.5 weeks. Most of women in the study group were multiparous (54.8%). A total of 173 patients (82.4%) out of the 210 patients included in the study had complete abortion as per the operational definition, i.e., within 48 hours after administration of medicine.

No statistically significant difference was found when comparison was done with respect to age, gestational age and parity ( $p > 0.05$ ). Frequency of complete abortion was then compared in the study groups (misoprostol versus extra amniotic catheter) and presented in Table. Chi square test was employed to chart the difference in outcome. It was found that patients in the misoprostol group had significantly higher complete abortion rate as compared to those who were in the extra amniotic catheter group with a p value of 0.007.

**Table:** Comparison of frequency of abortion with intravaginal misoprostol versus Extra amniotic catheter (n=210)

Groups	Abortion		
	Yes	No	
Misoprostol	94	11	105
Extra Amniotic Catheter	79	26	105
<b>Total</b>	<b>173</b>	<b>37</b>	<b>210</b>

Chi Square Test Value: 7.347 Df:1 P value: 0.007

## DISCUSSION

There are few studies that have evaluated the abortion frequency with misoprostol compared with extra amniotic catheter and instillation of intra-amniotic prostaglandins F2a(IAPG)<sup>8-10</sup>. The results obtained demonstrate higher efficacy of misoprostol in attaining complete abortion in second trimester. Our study results are in consistent with some of the earlier studies with Ghorab MN et al<sup>8</sup> 85% and 65% abortion rates in misoprostol and IAPG groups respectively. A recent study by Lin Lin Su et al<sup>10</sup> showed significantly short time for induction to abortion in the misoprostol group though they could not find any significant difference in case of frequency of abortion. However, another study

by Perry et al<sup>9</sup> did not show any significant difference in the outcome between the two groups. Our literature review showed only 3 previous publications that compared the efficacy of misoprostol with extra amniotic catheter and IAPG<sup>8,9,10</sup>. Perry et al<sup>9</sup> concluded that IAPG was more effective than vaginal misoprostol in achieving successful uterine evacuations, although there was no statistically significant difference in duration from drug administration to uterine evacuation. However limitation of study was the relatively small number of cases (51 total cases) and the suboptimal doses of vaginal misoprostol used (200 mg/12 hours a part). In comparative studies of vaginal misoprostol regimens, vaginal misoprostol 400 mg administered

every 3 hours was more effective than when it was administered every 6 hours<sup>1-7</sup>. The 12-hour interval between the 2 doses of misoprostol in the study by Perry et al<sup>2</sup> is likely to be the reason of the relative ineffectiveness of misoprostol. Ghorab MN et al<sup>8</sup> reported statistically significant difference in the frequency and duration of the abortion process between vaginal misoprostol and IAPG.

Our results demonstrate that vaginal misoprostol is more effective than IAPG, in terms of a greater frequency of complete abortions. Therefore vaginal misoprostol is the recommended drug for second trimester abortions. Several factors should be considered while counseling patients with regards to the options of the termination of pregnancy. Each woman may have her own preference in terms administration route and intervention type. A study showed that the induction – abortion interval is an independent variable associated with patients’ acceptance<sup>6</sup>. One limitation of vaginal misoprostol is the need for repeated dosing and the higher chances of fever and shivering<sup>1-4</sup>.

Vaginal administration of medication may, however, be considered as minimally invasive, compared with IAPG. Misoprostol has significantly low cost. Besides the many fold higher cost of the medication, IAPG requires the expertise of medical personnel and the use of ultrasonographic facilities, which would lead to additional cost. The significantly lower cost of vaginal misoprostol has important financial implications for the individual and the health care system, and it is of particular important in the developing countries.

## CONCLUSION

In summary, vaginal misoprostol is an effective ,cheap and more safe for second trimester termination of pregnancy giving statistically significantly higher abortion rate in the study population. It should be the treatment of choice for second trimester termination of pregnancy in developing countries due to its safety, efficacy and cost effectiveness.

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