

# Comparison of Misoprostol and PGF2 Alpha for Second Trimester Termination of Pregnancy

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## ABSTRACT

**Background:** Termination of pregnancy for various, maternal as well as foetal conditions, is a common obstetrical problem. The main concern of obstetrician is to provide the most effective and safest regimen which combines the shortest expulsion interval with least side effects.

**Aim:** To compare the efficacy of Misoprostol versus PGF2alpha for termination of pregnancy.

**Study design:** Randomized controlled trial

**Setting:** Department of Obstetrics and Gynaecology, Unit-II, Lady Willingdon Hospital, Lahore.

**Duration:** From 09-05-2013 to 08-11-2015.

**Methods:** 150 patients fulfilling the inclusion criteria were selected from labour room requiring termination of pregnancy. 75 patients were randomly assigned to receive either tablet misoprostol intravaginally or extra-amniotic injection of prostaglandin F2alpha. Efficacy of drugs was assessed by complete abortion by ultrasound at 12 hours after giving the respective treatment.

**Results:** Regarding age distribution, 42 patients (28%) were between 18-25 years old, 45 patients (30%) were between 26-30 years of age while 42 patients (28%) were having 31 to 35 years of age and 21 patients (14%) were having 36 to 40 years of age. Mean age of patients was 27.9 with standard deviation 7.1. Efficacy of Misoprostol was proved in 47 patients (62.66%) and of PGF2 Alpha in 31 patients (41.33%). The Mean Interval hours from treatment to abortion are less in case of Misoprostol than PGF2 Alpha that highlights the efficacy of Misoprostol.

**Conclusion:** Misoprostol is an effective method for termination of second trimester pregnancy than PGF2 Alpha, is easy to use and has no serious maternal side effects.

**Keywords:** Efficacy, Second trimester abortion, Misoprostol, PGF2 Alpha

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## INTRODUCTION

Many women need access to abortion care in the second trimester<sup>1</sup>. Termination of pregnancy for various, maternal as well as foetal conditions, is a common obstetrical problem. Induction of abortion needs meticulous and effective care, as do women in labour with childbirth<sup>2</sup>.

Termination of pregnancy (TOP) in the second trimester is associated with three to five times higher risk of maternal morbidity and mortality than termination, during first trimester. The main concern of obstetrician is to provide the most effective and safest regimen which combines the shortest expulsion interval with least side effects.<sup>3</sup> Prostaglandins are now commonly used to achieve termination of pregnancy. PGF2-a have potent oxytocic action and have combined effects of priming or ripening the cervix prior to dilatation and inducing uterine contraction<sup>4</sup>. Termination of pregnancy in the second trimester with misoprostol is safe and

effective. Misoprostol does not require special storage conditions<sup>5</sup>.

In a study by Quddusi and Anwar carried out at Nishter Medical College and Hospital, Multan. Induction expulsion interval was <12 hrs in 80% patients in misoprostol group and 60% in PGF2a group<sup>6</sup>. This was a significant difference (P<0.05). In another study it was found that oral misoprostol is as effective as intra-amniotic PGF2 alpha for second trimester pregnancy termination when laminaria is inserted before treatment<sup>7</sup>. (p=0.04)

Ultrasonography and latest modern parental diagnostic methods are very helpful in identifying the fetal abnormalities at an early stage of pregnancy, resulting into the increased number of women who are requiring termination of pregnancy (TOP). It has been observed that second trimester termination of pregnancy is mostly used in case of missed abortion and congenitally abnormal fetus. Different methods have been used for second trimester termination of pregnancy like cervical dilatation with laminaria tents, use of prostaglandins through different routes, infusion of oxytocin etc. It is important for obstetrician to give the safest and the most effective regimen that can result into shortest expulsion interval with no or least side effects. Second trimester TOP is safe and

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effective with misoprostol but unfortunately the published material of its use in women is very limited particularly those who are having fetal abnormalities or missed abortion. Misoprostol and oxytocin can be used for Second trimester TOP but that might lead to rupturing of uterine of women who are having fetal abnormalities or missed abortion. The studies have shown that case-studies analysis have been conducted on women with various congenitally abnormal fetus and missed abortion, in which misoprostol has been used for second trimester TOP. The studies have concluded that different doses of misoprostol with various protocols at proper intervals between the doses should be used. The second trimester TOP should be analyzed on case-by case basis, and the treatment should be implemented on the basis of analyses. It is important to give considerable importance to the factors like gestational age, congenitally abnormal fetus and previous history of cesarean sections with careful labor monitoring of these patients.

In the light of above mentioned discussion, it is important to conduct comparative analysis on this issue, as this will add to the existing literature and will also be helpful in finding out which drug is better than other. In most of the studies it is found that Misoprostol is as effective as PGF2 alpha, therefore the researcher want to assess on the patients that which drug is more effective in second trimester termination. The study will be useful for all females who are coming for the second trimester TOP in various gynae centers and hospitals. Similar study has also been conducted by some other local researchers but their sample size is 50, therefore the current study with a sample size of 150 will yield more useful results. Moreover, the study will be conducted in Lady Willingdon Hospital which is the Asia's largest obstetrics and Gynaecological hospital; hence the current study will generate useful insights about the females requiring Termination of pregnancy. Moreover, the study can also be helpful in conducting more large scale quantitative studies at other hospitals of Lahore with larger sample size with focusing on other uterus and fetus problems.

## MATERIAL AND METHODS

Objective of the study is to compare the efficacy of Misoprostol versus PGF2alpha for termination of pregnancy. It was a randomized controlled trial carried out in the department of Obstetrics and Gynaecology, Unit-II, Lady Willingdon Hospital, Lahore for a period of six months from 9-05-2013 to 08-11-2013. Sample size of 150 cases, 75 cases in each group is calculated with 80 % power of test, 6.5% level of significance and taking expected

percentage of efficacy i.e., 80% with Misoprostol and 60% with PGF2 alpha for termination of pregnancy. Sampling technique was non-probability purposive sampling.

Inclusion criteria were:

1. Age 18 – 40 years, parity
2. At 13 to 28 weeks of gestation (by dating scan)
3. Indications of termination of 2nd trimester pregnancy (IUD, missed abortion assessed through scan.)

Exclusion criteria were:

1. Patients with medical disease like diabetes mellitus (BSR>180 mg/dl), hypertension (BP >140/90), asthma, (Through record).
2. History of previous uterine surgery.
3. Patients with infected vaginal discharge ( per speculum )

**Data Collection:** One hundred and fifty patients fulfilling the inclusion criteria were selected from labour room requiring termination of pregnancy. The Demographic history were recorded including age, gestational age, address and after that informed consent forms were subdivided into two groups, 75 patients in each group using random numbers table. After informed consent, the data were collected. A detailed history was taken followed by clinical examination. Seventy five patients were randomly assigned to receive either tablet misoprostol intravaginally or extra-amniotic injection of prostaglandin F2alpha. Induction-expulsion interval was noted in each patient. Efficacy of drugs was assessed by complete abortion through ultrasound at 12 hours after giving the respective treatment.

The collected information was entered into SPSS version 17.0 and analyzed statistically. The variables to be analyzed quantitative age, gestational age were presented in the form of mean & standard deviation and qualitative variable, parity and efficacy were presented in the form of frequency and percentages of both treatments to assess which treatment is better for termination of second trimester pregnancy.

## RESULTS

Study was carried out during a period of six months from 09-05-2013 to 08-11-2013. Regarding age distribution, 42 patients (28%) were between 18-25 years old, 45 patients (30%) were between 26-30 years of age while 42 patients (28%) were having 31 to 35 years of age and 21 patients (14%) were having 36 to 40 years of age. Mean age of patients was 27.9 with standard deviation 7.1. Out of 75 patients who were given Misoprostol Treatment, 47 patients reported that it was effective and 31 of the 75 patients who were given PGF2 Alpha reported that it

was effective. Efficacy of Misoprostol was proved in 47 patients (62.66%) and of PGF2 Alpha in 31 patients (41.33%). Cross tabulation results clearly shows the efficacy of Misoprostol is higher than PGF2 Alpha for termination of second trimester pregnancy. The efficacy results have supported the hypothesis of the study that there is some difference between Misoprostol & PGF2 alpha for termination of second trimester pregnancy to achieve efficacy in patients with Misoprostol. The Mean Interval hours from treatment to abortion are less in case of Misoprostol than PGF2 Alpha that highlights the efficacy of Misoprostol. Out of the 30 patients whose indications of start of termination of 2nd trimester pregnancy is Intra Uterine Death, 17 reported that Misoprostol was effective compared with 13 patients who reported PGF2 was effective. Out of the 48 patients whose indications of start of termination of 2nd trimester pregnancy is Missed Abortion, 30 reported that Misoprostol was effective compared with 18 patients who reported PGF2 was effective. It has been concluded that in both indications, IUD and Missed abortion, Misoprostol was effective than PGF2 Alpha.

Table 1: Distribution of cases by age

Age in years	n	%age
18-25	42	28
26-30	45	30
31-35	42	28
36-40	21	14
Total	150	100

Mean±SD 27.9±7.1

Table 2: Treatment \* Efficacy Cross tabulation

Treatment	n	%age	Total
Misoprostol	47	28	75
PGF2 Alpha	31	44	75
Total	78	72	150

Table 3: Efficacy of Misoprostol

Efficacy	n	%age
Yes	47	63
No	28	37
Total	75	100

Table 4: Efficacy of PGF2 Alpha

Efficacy	n	%age
Yes	31	41
No	44	59
Total	75	100

Table 5: Comparison of Mean Interval Hours

Treatment	Mean Interval Hours From Treatment To Abortion (Hrs)
Misoprostol	7.11
PGF2 Alpha	9.46

Table 6: Efficacy \* Treatment \* Indications Cross tabulation

Indications		Misoprostol	PGF2 Alpha	Total
IUD				
Efficacy	Yes	17	13	30
	No	23	27	50
Total		40	40	80
Missed abortion				
Efficacy	Yes	30	18	48
	No	5	17	22
Total		35	35	70

## DISCUSSION

There are multiples of methods used for second trimester pregnancy. Many studies have proved that Misoprostol is the effective and safest treatment for this purpose. Other prostaglandins like PGF2 Alpha injections are also successful but those may results into different side effects like diarrhea, fever and nausea vomiting etc<sup>8,9</sup>. Previous studies have concluded that in second trimester termination of pregnancy, the side effects of Misoprostol treatment were better borne as compared to PFG2 alpha<sup>9</sup>.

Similarly, some studies have been undertaken to find out the most favorable route of administration and dosage of Misoprostol treatment. The results have shown that vaginal administration route was better compared with oral administration route due to the reason of its pharmacokinetics<sup>10,11</sup>. The other studies conducted to compare the vaginal treatment of Misoprostol 600, 400 and 200 g for every 12 hours for the purpose of second trimester termination of pregnancy have shown that the efficacy rate increased with increasing the dosage with abortion within 48 hours but at the same time the rate of side effects also increased<sup>7</sup>. The Royal Thai College of Obstetricians and Gynecologists (RTCOG) has recommended the vaginal use of Misoprostol treatment after every 12 hours for second trimester termination of pregnancy<sup>12</sup>.

The current study has concluded that efficacy of Misoprostol was proved in 47 patients (62.66%) and of PGF2 Alpha in 31 patients (41.33%). The efficacy rate of Misoprostol was higher than PDF2 Alpha. The mean interval hours from treatment to abortion were 7.11 in case of Misoprostol and 9.46 in case of PGF2 Alpha that highlights the efficacy of Misoprostol. The Mean Interval hours from treatment to abortion in case of Misoprostol were shorter than a previous study conducted by University of Connecticut Health Center that demonstrated the mean interval hours of 14.5 of using Misoprostol 400ug every 12 hours for termination of second trimester pregnancy<sup>12</sup>.

Out of the 48 patients whose indications of start of termination of 2nd trimester pregnancy is Missed Abortion, 30 reported that Misoprostol was effective

compared with 18 patients who reported PGF2 was effective. It has been concluded that in both indications, IUD and Missed abortion, Misoprostol was effective than PGF2 Alpha. During second trimester pregnancy with Misoprostol treatment, the uterine rupture incident is uncertain as such cases with prior cesarean sections or uterine surgery have not been included in this study. However, many previous studies have demonstrated no uterine rupture from the use of Misoprostol for termination of second trimester pregnancy among the cases of patients having cesarean history<sup>13,14</sup>. Similar study was conducted by Friel in the form of a meta analysis of published studies, that demonstrated that Misoprostol is the effective and safest for termination of second trimester pregnancy between 13 to 28 weeks of gestation period among women having previous cesarean history<sup>15</sup>. It can be said that extreme precautionary measures must be taken care off in such cases and uterine contractions must be continuously and carefully monitored. Moreover, future studies should be conducted to find out the efficacy rate of Misoprostol and PGF2 Alpha with live fetuses compared with dead fetuses. Similarly, further studies can be conducted to find out the possible side effects of both of the treatments.

## CONCLUSION

In conclusion, Misoprostol is an effective method for termination of second trimester pregnancy than PGF2 Alpha, is easy to use and has no serious maternal side effects. The Mean Interval hours from treatment to abortion are less in case of Misoprostol than PGF2 Alpha that highlights the efficacy of Misoprostol. Furthermore, it has been concluded that in both indications, Intra Uterine Death and Missed Abortion, Misoprostol was effective than PGF2 Alpha.

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