Original Article

# Efficacy of Misoprostol for Miscarriages using FIGO Protocol: Initial Experience at Fauji Foundation Hospital

**Naila Khurshid[1], Azra Saeed Awan[2], Nosheen Akhtar[3], Mehwish Riaz[4]**

[1]Assistant professor OBGYN, Foundation University Medical College /Fauji Foundation Hospital Rawalpindi.
[2]Professor OBGYN, Foundation University Medical College /Fauji Foundation Hospital Rawalpindi.
[3]Senior Registrar OBGYN, Foundation University Medical College /Fauji Foundation Hospital Rawalpindi.
[4]Postgraduate Trainee, Community Medicine, Foundation University Medical College

***Correspondence:*** *Dr. Naila Khurshid, Assistant Professor OBGYN*
*Foundation University Medical College/ Fauji Foundation Hospital Rawalpindi*
*drnailakhurshid5@gmail.com*

## Abstract

**Objective:** To evaluate the safety and efficacy of initiating misoprostol using latest International Federation of Gynecology and Obstetricians (FIGO) protocol in the management of first and second trimester miscarriages.

**Study Design:** A prospective observational study, conducted at Fauji foundation hospital in the department of obstetrics and gynaecology Unit 1 from 1st May 2017 to 31st Dec 2017.

**Methodology:** All patients diagnosed with first and second trimester miscarriage or undergoing termination of pregnancy < 24 weeks were given misoprostol through vaginal route only with the dose as described by FIGO. Patients with a scarred uterus were given half the dose of misoprostol for the given gestational age. The efficacy of misoprostol was considered to be a complete miscarriage up to 12 hours after completing the tablets course as an inpatient.

**Results:** Total of 55 patients diagnosed with miscarriage were included in the study. 76.4% of patients were given misoprostol for first trimester miscarriage while 23.6% were given the drug for second trimester miscarriage. The main indications for medical termination in the first trimester was 37 (67.5 %) missed miscarriage followed by 5 (9.1%) with incomplete miscarriage. While in the second trimester 8 (14.5%) cases were for a missed miscarriage and 5 patients (9.1 %) were for lethal fetal abnormality. The overall success rate as defined by competing uterine evacuation demonstrated by pelvic scan was seen in 41.8 % of cases. No serious adverse effects were seen in any of the patients.

**Conclusion:** Medical termination of pregnancy using misoprostol by FIGO protocol is a safe and effective option. Adherence to FIGO protocol maximizes success rate while keeping complication rate to the lowest level. Medical termination as outpatient procedure should be encouraged along with consistent patient counselling regarding follow up.

**Key words:** Miscarriage, misoprostol, FIGO, evacuation

Cite this article as: Khurshid N, Awan AS, Akhtar N, Riaz M. Efficacy of Misoprostol for Miscarriages using FIGO Protocol: Initial Experience at Fauji Foundation Hospital. J. Soc. Obstet. Gynaecol. Pak. 2018; Vol 8(2):76-80.

## Introduction

Miscarriage is termination of pregnancy before 24 weeks of gestation with a fetus/embryo weighing <500 g.[1] Miscarriages can be spontaneous or induced. Spontaneous miscarriage can be complete needing no treatment or can be missed or incomplete requiring treatment for uterine evacuation. Miscarriage complicates around 10% of pregnancies and is associated with significant psychological trauma for the couple.[2] According to WHO, worldwide 47,000 women die annually worldwide due to unsafe abortions and

**Authorship Contribution:** [1]Conceptualized study design Article writing, [2]Supervised and review the study. [3]Data analysis, Interpretation, [4]Data Collection

**Funding Source:** none

**Conflict of Interest:** none

**Received:** Feb 27, 2018

**Accepted:** June 29, 2018

almost all deaths are in developing countries where access to safe abortion services is limited.[3]

Management of miscarriages can be conservative, medical or surgical. Conservative management has a variable success rate of 25-57 % but it is associated with considerable anxiety.[4] The other option is medical termination of pregnancy, which is a relatively safe alternative for termination of pregnancy. The most commonly used drug for medical termination of pregnancy is misoprostol. The combination of misoprostol with mifepristone is considered more effective. However, mifepristone is costly and is not available in many countries including Pakistan. Currently international organizations like WHO, FIGO and NICE have approved misoprostol for management of miscarriages. Misoprostol is a synthetic analogue of naturally occurring prostaglandin E1. It is a cheap, heat stable drug that does not require refrigeration during transport and storage. The drug can be given by oral, sublingual, vaginal or rectal route.[5] However, it needs proper dosage protocol and careful selection of patients as incorrect dosage can lead to significant complications.[6] The patient opting for medical termination may need surgical evacuation later on due to the failure of complete evacuation of the uterus by the drug or due to heavy vaginal bleeding.

The surgical method for termination of pregnancy has been widely used and is effective in more than 99 % of cases.[7] The morbidity associated with the termination of pregnancy was more with older surgical methods of termination of pregnancy and with the advent of newer suction techniques the morbidity has been reduced. Despite this progress, the early pregnancy loss accounts for significant morbidity in the developing country.[8] According to Royal college of obstetricians and gynecologists (RCOG), the surgical evacuation of pregnancy is associated with 1-2/1000 risk of uterine perforation, 3% risk of significant pelvic infection and 5% risk of need for re-evacuation.[9] This problem gets magnified in developing countries where majority of abortions are conducted by backstreet abortionists, often with suboptimal aseptic techniques. Hence women still die due to unsafe abortion.

We conducted this study to evaluate the efficacy of misoprostol in the termination of pregnancy by introducing the dosage protocol as laid down by FIGO. The local will also help in counseling women while offering them a choice between medical and surgical methods of termination of pregnancy as well as evaluate safety in our population.

## Methodology

This study was conducted in OBGYN Unit 1 Foundation University medical college, Fauji Foundation Hospital Rawalpindi from 1st May 2017 to 31st Dec 2017. The approval of study was acquired from the hospital ethical board. All women with singleton pregnancy diagnosed with miscarriage were included in the study. Women with septic induced miscarriage or presenting with heavy vaginal bleeding were excluded from the study. Patients were explained about the process and detailed informed consent was taken beforehand. All women included in the study were admitted to the hospital and detailed history, physical examination and ultrasound examination were performed. Also, baseline investigation and coagulation study were preformed. Termination of pregnancy was done by using misoprostol according to FIGO protocol as shown in table I. Patients with scarred uterus were given half the dose of misoprostol for the given gestational age. The patient's demographic details were recorded and all patients were followed till the completion of termination of pregnancy.

**Table I: Dosage protocol for misoprostol administration**

| **Indications** | **Dose of Misoprostol** |
|---|---|
| **First Trimester** | |
| Induced abortion | 800mcg sublingually or vaginally 3hrly max. 3 doses within 12 hrs. |
| Missed miscarriage | 800mcg vaginally 3hrly max 2doses |
| Incomplete miscarriage | 400mcg sublingually single Dose |
| **Second Trimester** | |
| Induced abortion | 400mcg vaginally 3hrly max. 5 doses |
| Intrauterine fetal death | 13-17weeks: 200mcg vaginally 6hrlymax .4 doses 18-26weeks: 100mcg vaginally 6hrly max 4 doses |

In our study patients were kept under observation in the hospital due to logistic reasons as many entitled patients were referred from peripheral small health care centers. The referrals were from interior Punjab, KPK and Kashmir due to tertiary referral level status of our hospital. Such women are being managed as an in-patient to avoid any unforeseen event of heavy bleeding in which patient may not be able to reach hospital due to a far-off location. This led to an early

recourse to post termination pelvic ultrasound in an effort to reduce in-patient stay. Some of the patients were willing to go back home and return later to receive a second cycle of a drug, but the majority, didn't opt for it and preferred a surgical method during the same stay. This issue needs to be addressed by proper counselling and education of the patient. Those who are from far-off areas can be counseled to report to local health units in their localities where they can be given immediate emergency management, while those in accessible areas can be advised to reach the hospital in case they bleed heavily.

Data entry and analysis was performed using SPSS Version 23. Descriptive statistical analysis (mean, standard deviation and frequency with percentages for categorical variables) was performed for study variables. Chi square test was used to determine statistical significance between variables, and, a p value

less than 0.05 is considered to be significant. The results were presented as in percentages.

## Results

Total 55 patients diagnosed with miscarriage were included in the study after fulfilling the inclusion criteria. The mean age of the patient was 34.6 years. Urban area residence was reported by 74.5 % of the sample while 25.5 % belonged to a rural area. Regarding parity, 12 (22%) were primigravida while 43 (78%) were multigravida. Patients with a scarred uterus were 14 (25%).

The diagnoses of the patients are shown in table II. The outcome is shown in table III. The main side effect of the drug was fever, which was seen in only 3 (5.5%) of women. The post treatment ultrasound was done 6 to 12 hours after the last dose. This showed an empty uterus in 19 (34.5%) women while in 36 (65.5 %), significant retained products of conception were found. All those with retained products of conception on scan were given an option of the second cycle of drug and asked to return after one week. Seven women (13%) living in nearby areas accepted this and were given the second cycle of misoprostol, while remaining 29 (52.2%) women opted for the surgical method of evacuation during the initial inpatient stay. Total 58.2 % underwent a surgical procedure, out of which, 3(5.4%) underwent surgical evacuation prior to the completion of the first cycle of misoprostol. Moreover, n=1 (1.8%) underwent surgical termination after the second cycle of misoprostol.

**Table II: Diagnosis of patients**

| Variables | Number | Percentage |
|---|---|---|
| **First trimester** | **42** | **76.4%** |
| Missed miscarriage | 37 | 67.3% |
| Incomplete miscarriage | 05 | 9.1% |
| **Second trimester** | **13** | **23.6%** |
| Missed miscarriage | 8 | 14.5% |
| Lethal fetal anomaly | 5 | 9.1% |

**Table III: Outcome of pregnancy after misoprostol administration according to FIGO protocol**

| Outcome of Pregnancy | | FIGO protocol Cycles of Misoprostol | | | Total |
|---|---|---|---|---|---|
| | | 0* | 1 | 2 | |
| | Complete expulsion | 0 | 16 | 6 | 23 |
| | MVA | 1 | 9 | 1 | 11 |
| | E & C | 2 | 20 | 0 | 21 |
| Total | | 3 | 45 | 7 | 55 |

## Discussion

The mean age of the patient in our study was 34.6 years. In another study conducted in Qatar, 69.7% of patients were above 30 years and this finding is consistent with our study.[10] In our study the majority of patients were multiparous (78%), while in another study in Qatar 58% were multiparous. [10]

Various studies have been conducted to evaluate the efficacy of misoprostol in the termination of pregnancy. These studies vary in their dosage regimen and route of administration. The vaginal route is preferred although sublingual is an acceptable alternative for those women who refuse the vaginal route with comparable success rate.[11,12] In our study the dosage regimen was followed as described by FIGO using the vaginal route of administration.

The complete expulsion of the products of conception depends upon drug dosage, route of administration and time of follow up. The highest success rates are reported for the vaginal route followed by sublingual route, which is also associated with more side effects. Within first 12 hours after the last dose, success is reported to be around 70 %, while if this time is increased to 48 hours, success rate increased to 80 % and if patients are followed up after 72 hours, the success rate is further increased to 95 %.[13] In our study the ultrasound for confirmation of evacuation was performed 6-12 hours after last dose. This may be too early to expect complete expulsion and explain the lower success rates.

The complete expulsion as seen on post treatment ultrasound was seen in one third of patients after first cycle of misoprostol and it increased to 42% after the second cycle of misoprostol. In our study 52% women had surgical evacuation on findings of scan done 6-12 hours after the last misoprostol dose. In one study, the efficacy of 800 ug misoprostol given in 3 doses for first trimester miscarriage was shown to be 91 % when followed up after 72 hours.[14] Another study showed a success rate of 80% with 600ug misoprostol vaginally for a total of three doses.[15]

A study conducted at Hayatabad medical complex evaluating misoprostol efficacy in first trimester miscarriages showed complete expulsion in 69.44% of cases, while the surgical evacuation was required in 30.55% of cases.[16] Another study showed 80 % success rate for 400ug misoprostol administered vaginally four hours apart with a total of four doses.[17] In a study conducted by Sirimai et al the success rate of misoprostol was 74 %.[18]

Regarding side effects in one study, fever was seen in 18% of patients, and gastrointestinal side- effects in 15% of patients. Heavy vaginal bleeding was seen in 2.5% requiring a blood transfusion,[13] while in our study fever was reported in 3 (5.5%) patients. 25% of patients in our study had scarred uterus and they were given half the dose of misoprostol. No patients had any serious side effect, while in a study by Sirimai one patient had uterine rupture necessitating laparotomy. [18]

In our study the dosage regimen was the same as per FIGO protocol, our limitation was inpatient administration and need to limit the inpatient stay as desired by the patient. This may be the reason for the lower success rate in our study as compared to other studies. Although adverse effects were less common and no serious side effect was noted in any of our patients due to continuous professional care, but more of our patients underwent surgical evacuation. One of the major reasons for the high percentage of patients undergoing surgical evacuation is logistic feasibility from the patients' side. Most patients have been referred from far-flung areas and, therefore, it is not feasible for them to stay for longer period of time. This is why most patients prefer to be treated immediately, rather than accepting the standardized procedure, resulting in the higher percentage of surgical evacuation in our study (52.5%). In order to address this high percentage, such patients should have been counselled in detail to follow-up after one week for an ultrasound.

In-patient management for termination of pregnancy also increases the burden on health care services. Careful selection of patients living in accessible areas will allow adherence to the standardized protocol of FIGO, resulting in better outcome rates of complete expulsion. Detailed counselling regarding expected duration for complete expulsion will help in better compliance and follow up by patients, which will increase the number of patients being treated by the standard procedure. Another reason for early resort to the surgical evacuation of the uterus is patient's anxiety regarding bleeding. This issue needs to be thoroughly addressed before embarking on medical management.

Limitations: But another limitation is a structural limitation as Fauji Foundation Hospital is committed to providing complete health care facilities for its entitled patients. As a result, we could not provide partial treatment to our patients in case they bleed heavily, and could not reach the index hospital for management. Thus, the detailed counselling of entire process should ideally be done prior to the process of medical termination to get better compliance from those opting medical termination and avoid using this procedure among those who want an early complete treatment.

## Conclusion

Misoprostol for first and second trimester miscarriage administered according to FIGO protocol is found to be a safe, feasible and acceptable option. The success rate is lower can be improved by adopting better counselling techniques. Moving forward, out-patient management of patients undergoing medical termination of pregnancy should be the standard of care.

## References


1. Griebel CP, Halvorsen J, Golemon TB, Day AA.Management of spontaneous abortion. Am Fam Physician. 2005;72:1243–1250
2. Khan FM, Amin A, Ahmed FL, Naeem NK. Medical Termination of First Trimester Miscarriages. Annals. 2007;13(2):154-157
3. Sedgh G, Singh S, Shah IH, Ahman E, Henshaw SK, Bankole A. Induced TOP: incidence and trends worldwide from 1995 to 2008. Lancet 2012;379:625–32.
4. Jukovic, D, Ross JA. & Nicoladies KH. Expectant management of missed miscarriage. Br J Obstet Gynaecol.1998;105(6):670–71,doi:10.1111/bjo.1998.105.
5. Wong KS, Ngai CS, Yeo EL, Tang LCH, Ho PC. A comparison of two regimens of intravaginal misoprostol for termination of second trimester pregnancy: a randomized comparative trial. *Human Reproduction*.2000;15(3):709–12
6. Pourette D, Mattern C, Ratovoson R, Raharimalala P. Complications with use of misoprostol for abortion in

Madagascar: between ease of access and lack of information. Contraception.2018;97: 116–12
7. Geffen D, Doan L, et.al. Medical Compared with Surgical Abortion for Effective Pregnancy Termination in the First Trimester. Obstetrics and Gynaecology. 2015;26(2):22-28
8. Child, T.J, Thomas, J, Rees M, MacKenzie I.Z. Morbidity of first trimester aspiration termination and the seniority of the surgeon. Hum. Reprod. 2001;16:875–878 Google Scholar
9. RCOG consent advice no 10: surgical management of miscarriage and removal of persistent placental or fetal remains
10. Elsalem SA, Alsaad DT, Abdulrouf PV, Ahemd AA, Alhail MS. Misoprostol use in medical evacuation of spontaneous miscarriage: Pilot drug use evaluation study at the Women's Hospital in Qatar. Qatar Medical journal. 2016:5. doi.org/10.5339/qmj.2016.5
11. Blanchard K, Shochet T, Coyaji K, Ngoc NTN, Winiko B. Misoprostol alone for early abortion: an evaluation of sevenpotential regimens. Contraception.2005;72: 91–97
12. Tang OS, Miao BY, Lee SW, Ho PC. Pilot study on the use of repeated doses of sublingual misoprostol for the termination of pregnancy up to 12 weeks gestation: efficacy and acceptability. Hum Reprod.2002; 17: 654–58.
13. Faúndes A, Fiala C. tangos, Velasco A.Misoprostol for the termination of pregnancy up to 12 completed weeks of pregnancy. International journal of gynaecology and obstetrics. 2007; 99:172-77
14. Zikopoulos KA, Papanikolaou EG, Kalantaridou SN, TsanadisGD etal. Early pregnancy termination with vaginal misoprostol before and after 42 days gestation. Human Reproduction.2002;17(12):3079–83
15. Kafil N, Arain FR. Comparison of Efficacy of Vaginal VS Oral Prostaglandin E1 Analogue (Misoprostol) in Management of First Trimester Missed Abortion. Med Forum 2017; 28(11):45-49.
16. Tabassum S, Shamsher S, Rauf B, Sadaf R, Begum I. Efficacy of misoprostol in the termination of first trimester pregnancy failure. KJMS. 2017;10(2):213-15.
17. Deepika N, Krishna M, Inderjeet P, Navnita B. Comparative Study of Misoprostol in First and Second Trimeste Abortions by Oral, Sublingual, and Vaginal Routes. The journal of obstetric and gynaecology India. 2015;65(4):246–250
18. Sirimai K, Kiriwat O, Neungton S, Suvanichchati S. Misoprostol use for therapeutic abortion in Siriraj Hospital: The year 2000. J Med Assoc Thai. 2002;85:416–423.