International Journal of Reproduction, Contraception, Obstetrics and Gynecology
*Dakpe R et al. Int J Reprod Contracept Obstet Gynecol. 2023 Nov;12(11):3365-3368*
www.ijrcog.org
pISSN 2320-1770 | eISSN 2320-1789

DOI: https://dx.doi.org/10.18203/2320-1770.ijrcog20233310

**Original Research Article**

# Efficacy of single dose of misoprostol 800µg in the first trimester termination of pregnancy: a cross sectional study

**Ronald Dakpe, Namoijam Basanti*, Yanglem Ajitkumar Singh, L. Bimolchandra Singh**

Department of Obstetrics and Gynecology, Regional Institute of Medical Sciences, Lamphel, Manipur, India

**Received:** 22 September 2023
**Accepted:** 11 October 2023

***Correspondence:**
Dr. Namoijam Basanti,
E-mail: namoijambasanti116@gmail.com



## ABSTRACT

**Background:** The MTP (Amendment) Act 2021 has allowed termination of pregnancy up to 24 weeks on only certain indications. Decision of two medical practitioners are required for termination beyond 20 weeks. Misoprostol is one drug used for medical termination of pregnancy. It can be used alone in single or multiple doses, or in combination with other drugs. The study was undertaken to determine the efficacy of a single dose of 800 µg of misoprostol in the first trimester pregnancy termination.
**Methods:** It was a cross-sectional study conducted among 124 women in the first trimester who were undergoing termination of pregnancy. After administering 800 µg of misoprostol vaginally, participants were kept under observation for 48 hours. Data were collected and analysed.
**Results:** Around half of the participants (56.4%) expelled the conceptus completely by 12 hours, 78.2% by 48 hours. Seven (5.6%) out of those 27 failed cases were given further doses of misoprostol, while in the remaining 20 (16.1%), surgical intervention was undertaken.
**Conclusions:** The efficacy of a single dose of misoprostol for 1$^{st}$ trimester termination of pregnancy varies widely from study to study, but, the efficacy increases with adding further doses of the same drug or addition of mifepristone. Misoprostol is a safe, cost effective, and reasonable drug for the termination of pregnancy in first trimester.

**Keywords:** Abortion, Misoprostol, Termination

## INTRODUCTION

Abortion is defined as expulsion or extraction from its mother of an embryo or foetus weighing 500gm or less when it is not capable of independent survival (WHO). Abortion can either be spontaneous or induced.

Spontaneous abortion also called miscarriage can be caused by chromosomal anomalies of the foetus, maternal immunological, metabolic or endocrine factors, various infections, anatomical abnormalities of the uterus; while in many others, it remains unexplained.

Induced abortion is defined as the medical or surgical termination of pregnancy before the time of viability of foetus. In 2015-19, there were 121 million unintended pregnancies annually, corresponding to a global rate of 64 unintended pregnancies per 1000 women aged 15-49 years, among which, 61% ended in abortion.[1] It was estimated in another study, that 46 million pregnancies are terminated voluntarily each year globally, out of which 19 million undergo unsafe abortion.[2] In 1971, the Medical Termination of Pregnancy Act was passed in India to decrease the rate of unsafe abortions and it allowed termination of pregnancy up to 20 weeks of gestation under certain conditions- 1) when the continuance of pregnancy would involve a risk to the life of the pregnant women or of grave injury to her physical or mental health, 2) there is substantial risk that if the child were born, it would suffer from such physical or mental abnormalities

as to be seriously handicapped in life, 3) where any pregnancy is alleged by the pregnant women to have been caused by rape, 4) where any pregnancy occurs as a result of failure of any device or method used by any married women or her husband for the purpose of limiting the number of children. . In 2021, the Medical Termination of Pregnancy (Amendment) Act was passed, and it allowed termination of pregnancy up to 24 weeks and decision of two medical practitioners are required for pregnancy termination beyond 20 weeks.[3]

Termination of pregnancy in the first trimester can be done medically or surgically. Manual vacuum aspiration, suction evacuation, dilatation and evacuation, dilatation and curettage are included in the surgical methods. The drugs mainly used for medical termination are misoprostol and mifepristone. They can be used in isolation or in combination with varying doses and frequency of administration. According to WHO guidelines, mifepristone- misoprostol combination regimen is recommended for medical termination of pregnancy, while misoprostol-only is the alternate regimen.[4] The combination regimen is more effective. The dose of misoprostol-only regimen is 800 µg oral, per-vaginal or sub-lingual for pregnancies less than 12 weeks.

Misoprostol is a methyl ester of prostaglandin $E_1$. Its half-life is approximately 1-2 minutes. It stimulates the uterine contractility by changing the muscle membrane permeability to calcium ions at all periods of gestation. It is used for termination of pregnancy in first and second trimesters, ripening of cervix, and prophylaxis and treatment of post-partum haemorrhage. Abdominal pain, bleeding, tremors, nausea, vomiting, diarrhoea are the common side effects. It is generally administered vaginally, but it can also be given orally, per-rectally or sublingually. The advantages of misoprostol are its easy availability, storage, low cost, and good efficacy. Majority of the women after receiving misoprostol will abort completely by 2 weeks. Surgical evacuation is required when there is excessive or continuous bleeding, or incomplete abortion. The objective of our study was to determine the efficacy of a single dose of 800 µg of misoprostol in the first trimester pregnancy termination.

## METHODS

It was a cross-sectional study conducted in the department of Obstetrics and Gynaecology, Regional Institute of Medical Sciences, Manipur, India for a duration of 2 years from January, 2021 to December, 2022. All pregnant women up to 12 weeks of gestation seeking MTP for legally valid reasons with live intra-uterine pregnancies were included in the study. Women allergic to prostaglandins, who were haemodynamically unstable or had history of previous cervical surgery, or who did not give consent were excluded from the study. After taking a proper written consent, 800 µg of misoprostol was kept in the vagina. The time of application was noted. In the absence of excessive bleeding or haemodynamic instability, the participants were kept under observation for the next 48 hours. They were notified regarding the possible side effects and the probable surgical intervention in case the proposed medical method failed. Rh negative women were administered anti-D. Patients were monitored for complete expulsion of conceptus. Gravida of the women, last menstrual period (LMP), period of gestation, time period from the application to the complete expulsion, amount of bleeding, requirement of further medical or surgical intervention were noted. The procedure was considered successful when the conceptus got expelled completely, and the failure was regarded as the need for further doses of misoprostol or surgical intervention. The completeness of the abortion was confirmed with clinical examination and ultrasonography. Data were analysed in the SPSS v21.

## RESULTS

A total of 124 women with a mean age of 29.07 years participated in the study. Half of the study participants (50%) were primi-gravida and the other half were multigravida. Sixty women (48.38%) were within 9 weeks of pregnancy, while 64 (51.61%) were in 9-12 weeks of gestation. Among the 124 participants, 97 (78.2%) expelled completely within 48 hours, while in the remaining 27 (21.8%), the abortion was incomplete.

**Table 1: Percentage of complete abortions according to the duration of induction.**

| Duration since the induction with misoprostol | Number of participants who expelled completely | Percentage (out of 124 participants) | Cumulative percentage |
|---|---|---|---|
| **Within 6 hours** | 29 | 23.3 | 23.3 |
| **Between 6-12 hours** | 41 | 33.1 | 56.4 |
| **Between 12-24 hours** | 16 | 12.9 | 69.3 |
| **Between 24-48 hours** | 11 | 8.9 | 78.2 |
| **Total** | 97 | 78.2 | 78.2 |

Table 1 shows that 23.3% aborted completely within 6 hours of induction, 33.1% aborted between 6-12 hours, 12.9% between 12-24 hours, and 8.9% between 24-48 hours. Cumulatively, just above half of the participants

(56.4%) expelled the conceptus completely by 12 hours, 78.2% by 48 hours.

Seven (5.6%) out of those 27 failed cases were given further doses of misoprostol, while in the remaining 20 (16.1%), surgical intervention was undertaken. Five women (4%) developed excessive bleeding during the 48 hours observation period for which they were surgically intervened.

**Table 2: Duration of hospital stay.**

| Hospital stay | Number of participants | Percentage |
|---|---|---|
| **24 hours** | 79 | 63.7 |
| **24-48 hours** | 18 | 14.5 |
| **>48 hours** | 27 | 21.8 |

Majority of the participants (63.7%) got discharged within 24 hours, another 14.5% got discharged by the 2nd day, and the rest 21.8% had to stay for more than 48 hours (Table 2).

## DISCUSSION

In a similar study conducted by Narasimaiah et al, 200 women in the 1st trimester were given 800 µg of misoprostol for termination of pregnancy.[5] Seventy- six percent of the study population had complete abortion with the single dose of misoprostol, which is almost similar to the finding in our study.

Salakos et al had conducted a study among 162 women to evaluate the efficacy and safety of 800µg of misoprostol every 12 hourly for a period of 36 hours for pharmacological abortion.[6] The efficacy of the same was found to be 91%, which is much higher than the 78.2% found in our study with only a single dose.

The mean induction to abortion interval was found to be 11.38 hours. 4% had to undergo surgical curettage due to profuse bleeding, and 20% required second dose of 200µg of misoprostol.

In a different study conducted by Bugalho et al to evaluate the effectiveness of a single dose of misoprostol, observation was made for a period of 1 week, after which who had not aborted received a second dose of 800 µg.[7] Vacuum aspiration was done if not aborted even after the second dose. It was found that 71.8% of the women aborted after 24 hours of 1st dose, 87.1% aborted after 3 days. The cumulative abortion rate was 92.1% after the 2nd dose. It was also concluded from the study that there is no additional dose of misoprostol required within 72 hours of the first administration of misoprostol.

The mean hospital stay was 48 hours in another similar study conducted by Shanti SS, which is in consistent with our study.[8]

Other than the excessive bleeding associated with some of the incomplete abortions, the minor side effects of the misoprostol were only nausea, vomiting, diarrhea, fever, abdominal pain.

There were various limitations in our study. A duration of only 48 hours was given to the participants, until the next intervention; while in some studies complete abortion can occur up to 1 week or beyond post- administration.[7,9] There is no follow up after the further doses of misoprostol. Further, no consideration was given to the parity, history of previous caesarean section(s), other obstetric history, or the levels of human chorionic gonadotropin. In one study by Kobryn et al, the success of the pharmacological induction of miscarriage was found to be decreased significantly in women who had caesarean section(s).[10] The success rate according to the period of gestation was also not calculated.

## CONCLUSION

With the findings from this study on 124 pregnant with period of gestation up to 12 weeks, we can conclude that, the effectiveness for single dose of 800µg of misoprostol was notably high. From the literature review, we found the success rate to be varying a lot. So, this drug might not be always the choice for many women, as well as doctors. Combination with other drugs like mifepristone needs to be studied further in our setting. Also, a pooled analysis is required to generate more generalizable evidence in future.

## ACKNOWLEDGMENTS

Authors would like to thank Professor M. Rameswar Singh, Head of Department, Obstetrics and Gynaecology, RIMS.

*Funding: No funding sources*
*Conflict of interest: None declared*
*Ethical approval: The study was approved by the Research Ethics Board, RIMS*

## REFERENCES

1. Bearak J, Popinchalk A, Ganatra B, Moller AB, Tunçalp Ö, Beavin C, et al. Unintended pregnancy and abortion by income, region, and the legal status of abortion: estimates from a comprehensive model for 1990–2019. Lancet Global Heal. 2020;8(9):e1152-61.
2. WHO. Unsafe abortion: global and regional estimates of incidence of unsafe abortion and associated mortality in 2000, 4th edition, 2004. Available at: www.who.int/reproductivehealth/publications/unsafe_abortion/924191803/e/. Accessed 15 November 2020.
3. The Medical Termination of Pregnancy (Amendment) Act, 2021. Ministry of Law and Justice (Legislative Department), 2021. Available at: https://prsindia.org/files/bills_acts/acts_parliament/2021/Medical%20Termination%20of%20Pregnancy%

20Amendment%20Act%202021.pdf. Accessed on 15th August 2023.
4. World Health Organization. Medical management of abortion, 2018. Available at: https://iris.who.int/bitstream/handle/10665/278968/9789241550406-eng.pdf?ua=1. Accessed 15 November 2020.
5. Narasimaiah G, Pukale R, Shivanna BS, Sharma N. Effcacy of single dose of vaginal misoprostol 800ug in first trimester abortion. J Evol Med and Dental Sci. 2013;2(16):2669-74.
6. Salkos N , Kountouris A , Botsis D, Rizos D, Gregoriou O, G Detsis G, et al. First trimester pregnancy termination with 800ug of vaginal misoprostol every 12 hr. Eur J Contracept Reproduction Health Care. 2005;10(4):249-54.
7. Bugalho A, Mocumbi S, Fau A, David E. Termination of pregnancies of <6 weeks Gestation with a single dose of 800ug of vaginal misoprostol. Contraception. 2000;61(1):47-50.
8. Shanti S. Efficacy of single dose of 800ug of misoprostol in first trimester abortion. J Nobel Medi Coll. 2012;1(2):729-28.
9. Costa SH. Commercial availability of misoprostol and induced abortion in Brazil. Inter J Gynecol Obstet. 1998;63:S131-9.
10. Kobryn E, SzymusikI, Zgliczynska M, Szarla K, Kopylowska N, Piatek S, et al. The efficacy of misoprostol in the first trimester miscarriage treatment .an individual patients' data analysis. Neuro Endocrinol Lett. 2019;40(3):152-8.

**Cite this article as:** Dakpe R, Basanti N, Singh YA, Singh LB. Efficacy of single dose of misoprostol 800µg in the first trimester termination of pregnancy: a cross sectional study. Int J Reprod Contracept Obstet Gynecol 2023;12:3365-8.