

DOI: <http://dx.doi.org/10.18203/2320-1770.ijrcog20183763>

Original Research Article

## Use of MTP kit (Mifepristone and Misoprostol combination pack) for 1st trimester MTP (up to 63 days) at GMERS Dharpur, Patan, Gujarat, India

Parul S. Jani\*

Department of Obstetrics and Gynecology, GMERS Medical College, Dharpur, Patan, Gujarat, India

**Received:** 15 June 2018

**Accepted:** 24 July 2018

**\*Correspondence:**

Dr. Parul S. Jani,

E-mail: [paruparelia@yahoo.in](mailto:paruparelia@yahoo.in)

**Copyright:** © the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

### ABSTRACT

**Background:** MTP has been legalized in India since 1971. MTP pill (Medical abortion) refers for early pregnancy termination (usually before 9 week gestation) performed without any primary surgical interventions. This study was called out to measure its effectiveness and safety as an abortifacient drug.

**Methods:** This is a prospective study of 57 cases, conducted at OBSTETRIC and GYNECOLOGY Department, GMERS Medical College, Dharpur, Patan (N.G.) from April 2017 to April 2018.

**Results:** In present study, 61.4% women are of 20-30 years of age. Majority of women are (82.5%) of 2<sup>nd</sup> and 3<sup>rd</sup> para. Complete abortion was found in 91.2%. Incomplete abortion was in 7%. And there was no effect in 1.8%. Major side effects were bleeding (84.2%), abdominal pain (85.9%). Misoprostol related side effects are minimal.

**Conclusions:** The present observational study demonstrates that mifepristone and misoprostol combined therapy is an effective and well tolerated medication in Indian adult women ( $\geq 18$  years) requiring medical termination of intrauterine pregnancy (MTP) up to 63 days' gestation.

**Keywords:** Mifepristone and Misoprostol, MTP, MTP pill

### INTRODUCTION

Abortion is the termination of a pregnancy before the fetus has attained viability, i.e. becomes capable of independent extra-uterine life. The term medical abortion refers to early pregnancy termination (usually before 9 weeks' gestation) performed without primary surgical intervention and resulting from the use of abortion-inducing medications. When performed as per guidelines with success rate of 95 to 99%.<sup>1</sup>

Drug Controller General of India approved the use of Mifepristone (in April 2002) and Misoprostole (in December 2006) for termination of pregnancy up to 49 days gestation period. In December 2008, Mifepristion +

Misoprostol (1 tab of mifepristone 200mg and 4 tab of misoprostol 200 mcg each). Combipack was approved by the Central Drugs Standard Control Organization, Directorate General of Health Services for the medical termination of intrauterine pregnancy (MTP) for up to 63 days gestation.<sup>2</sup>

Federation of Obstetrics and Gynecological Societies of India (FOGSI) recommends close monitoring of distribution of drugs that are used for medical abortion and that the medical profession and pharmaceutical industry should exercise due diligence in the promotion and usage of drugs that are used for medical abortion.<sup>3</sup> As per the MTP law of India, abortion pills can only be prescribed by registered medical practitioner.<sup>4</sup>

Mifepristone acts by binding to the progesterone receptor, thus inhibiting the effect of progesterone. The sensitivity of myometrium to exogenous prostaglandins is also increased by administration of Mifepristone. Thus, in early pregnancy, administration of Mifepristone results in regular uterine contractility and increased sensitivity of prostaglandins.<sup>5</sup> Misoprostol is a synthetic prostaglandins E1 analogue and because of its uterotonic and cervical-ripening actions, Misoprostol is also widely used for various gynecological and obstetrical purposes, such as cervical ripening and induction of labour, for pretreatment of the cervix prior to surgical termination of pregnancy and, in combination with Mifepristone for medical abortion.<sup>6</sup> Prostaglandins causes powerful contraction of uterus.<sup>7</sup>

**METHODS**

This study was carried out at Obstetric and Gynecology Department, GMERS Medical college, Dharpur, Patan, (N.G.) from April 2017 to April 2018.

**Inclusion criteria**

Women who needed termination of pregnancy with live intrauterine pregnancy up to 63 days gestation, confirmed by ultrasound.

**Exclusion criteria**

- Pregnant women more than 63 days of gestation
- Previous allergic reaction to the drugs involved
- Severe anemia
- Pre-existing heart disease
- Undiagnosed adenexal mass
- Intrauterine device in place
- Chronic adrenal failure
- Renal or hepatic failure
- Porphyria and Hemorrhagic disorders
- With concurrent anticoagulant therapy
- Long-term corticosteroid therapy.

All the women were explained about the bleeding and some abdominal pain after taking the drug and all the women were explain about the surgical evacuation in case of incomplete abortion or if there is no effect of the drug. All women had timely access to appropriate emergency medical facilities, if arises.

Day 1 Tab. Mefipristone 200mg. orally

Follow up on Day 2 Tab. Misoprost 400mcg orally given and advised to take another 400 mcg after 12 hours at home.

Follow up on day 14- for final confirmation by clinical examination and ultrasonographic scan that a complete termination of pregnancy had occurred.

Efficacy rates were determined as complete abortion rate, incomplete abortion rate or no response rate observed at Day 14. Based on the outcome of the treatment for each patient.

**RESULTS**

Table 1 shows majority of women seeking for MTP pill are of 20-35 years of age accounting for 80% of case study. Whereas 12.3% of women were between 15-19 years and 7% were 35-39 years.

**Table 1: Age distribution.**

Age of women	No. (n=57)	%
15-19	07	12.3
20-24	20	35.1
25-29	15	26.3
30-34	11	19.3
35-39	04	7

**Table 2: Parity.**

Parity of women	No. (n=57)	%
1	07	12.3
2	25	43.9
3	22	38.6
4 or more	03	5.3

In Table 2, majority of women are 2<sup>nd</sup> and 3<sup>rd</sup> para about 82.5% of case study and about 12.3% cases are para 1 and 5.35% are having 4 or more children.

**Table 3: Gestational age.**

Age of gestation (days)	No. (n=57)	%
30-39	14	24.6
40-49	23	40.1
50-63	20	35.1

According to Table 3, age of gestation at the time of taking pill shows 40-49 days gestation carries 40% of case study and 50-63 days of gestation carries 35%. Early hospital visit (30-39days) consist of 24.6% of case study.

**Table 4: Success rate.**

Success rate	No. (n=57)	%
Complete abortion	52	91.2
Incomplete abortion	04	7.0
no effect	01	1.8

Table 4 of success rate shows about 91.2% of cases all completely aborted when followed up on 14th day, confirmed by ultrasound scanning, only 7% of cases need surgical intervention due to incomplete abortion and only 1.8% cases have no effect, so surgical evacuation done.

**Table 5: Side effects.**

Side effects	No. (n=57)	%
Bleeding	48	84.2
Abdominal pain	49	85.9
Nausea	18	31.5
Vomiting	11	19.2
Headache	03	5.2
Backache	11	19.2
Anxiety	04	7
Sleeplessness	02	3.5
Loss of appetite	05	8.7
Diarrhoea	06	10.5

According to Table 5, in present study, the main side effect is bleeding (84.2%) and pain related effects –Abd. Pain (85.9%), backache (19.2%), headache (5.2%). With nausea (31.5%), and vomiting (19.2%). 7% had anxiety and 3.5% had sleeplessness may be due abortion related fear and nervousness. Loss of appetite in 8.7 and and diarrhea was in 10.5% of cases.

## DISCUSSION

In India, MTP act was passed in 1971 to prevent unsafe and illegal abortion with the aim of reducing the maternal mortality and morbidity due to unsafe abortion.<sup>4</sup> As per the guidelines for medical abortion in India, medical abortion is only offered only to those patients, who are ready for minimum three follow-up visits, can understand the instruction, ready for surgical procedure if failure or excessive bleeding, good family support and easy access to appropriate healthcare facility.<sup>8</sup>

Present study shows majority of woman seeking for MTP pill are of 20-35yr ages accounting for 80% of case study. Whereas 12.3% patients were less than 20 years, compare to study by Sarojini et al 3.8% patients were less than 19 years of age.<sup>9</sup> Majority of woman are 2nd and 3rd para about 82.5% of case study about 12.3% case are para 1 and 5.35% are having 4 or more children. Where in a study by Sarojini majority of patients were multigravida.<sup>9</sup> Age of gestation shows 40-49day gestation carries 40% of case study and 50-63 day of gestation comprise of 35%. Early hospital visit (30-39days) consists of 24.6% case. Thus, majority of patients having 40-63 days consist of 75% cases.

In success rate, Present study Suggest about 91.2% of case all completely aborted when follow up on 14th day, confirm by ultrasound scanning. In a study by Ashok et al, overall success rate was 97.5% our success rate is comparable to study by Shivastava in 2006 in Nepal.<sup>6,10</sup> success rate was 92.6%. Kathleen et al, in 2011 performed similar study and found success rate of 80%.<sup>11</sup> Similarly Schaff et al reported success rate of 97% with 200mg mifepristone followed by 800 microgram misoprostol vaginally.<sup>12</sup>

In present study, only 7% of case need surgical intervention due to incomplete abortion which is slightly higher than 2-5% reported by Ashok et al. In a study by Sarojini et al, surgical evacuation required in 90.4% and 1-2% required surgical evacuation for heavy bleeding and 2-3% need surgical evacuation due to incomplete abortion.<sup>6,9</sup> Schaff et al reported 2.4% surgical evacuation rate and spitz IM, and Bardin CW reported 14.65% surgical evacuation rate respectively.<sup>12,13</sup>

In present study, only 1.8% case have no effect. which is higher than the 0.6% rate reported by Ashok et al Schaff et al reported 0.3% of cases have no effect at all.<sup>6,12</sup> Ongoing pregnancy rate with a range of 0.8% to 1.5% has been reported by Spitz IM et al.<sup>13</sup>

In side effects, endogenous prostaglandins induce uterine contractility and increase sensitivity of prostaglandins and leads to the uterine bleeding and disruption of placental function.<sup>5</sup> present study Shows excessive bleeding 84.2%, abdominal pain 85.9%, nausea 31.5%, vomiting 19.2%, backache 19.2%, other side effects are very minimal. In a study by Sarojini et al, 69.3% patients reported bleeding.<sup>9</sup> Vaginal bleeding and Uterine cramping are expected.<sup>10</sup> In present study, pain related side effects are about abdominal pain 85.9%, backache 19.2% and headache 5.2%. where as in study of Schaff et al, the abdominal cramping c was reported 36.9% - 91.8%.<sup>12</sup> Pain related side effects like abdominal pain, backache, headache were experienced due to uterine contraction and misoprostol related side effects.<sup>14</sup>

About Nausea and vomiting and diarrhoea, our study reported 31.5% and 19.2% and 10.5% respectively, in the study of Schaff et al, nausea was reported in 44.6 and 91.8%.<sup>12</sup> where as in study of El-Refaey et al, its incidence reported was 70%, 44%, and 36% respectively.<sup>15</sup> These were attributed due to misoprostol. The most frequent side effects reported in some studies are abdominal pain or discomfort (56%), nausea (54%), tiredness (50%) and breast pain (28%).<sup>16</sup>

In present study, Anxiety, sleeplessness, and loss of appetite were experienced by many number of women. This could be due to mental health of women undergoing the abortion.

## CONCLUSION

Medical abortion is effective and safe if carried out under medical supervision. The standard protocol followed by the hospital was oral administration of 200 mg Mifepristone followed by (24 hours later) oral administration of Misoprostol 800 mcg. The success rate of the combination was excellent and was found to be significantly associated with gestational age. Misoprostol related gastrointestinal side effects were minimal. Unwanted pregnancies due to failure of contraception were one of the noticeable reasons which was intervened and counselled properly.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the Institutional Ethics Committee*

## REFERENCES

1. Use of RU-486 with Misoprostol for early abortions in India. Guidelines for Medical Officers, WHO-CCR in Human Reproduction. All India Institute of Medical Sciences, Ministry of Health and Family Welfare, Government of India and India Council of Medical Research 2003.
2. Handbook on medical methods of abortion. Available at <http://www.health.mp.gov.in/mtp/MMAReference%20Manual.pdf>
3. The Federation of Obstetric and Gynecological Societies of India. Available at [http://www.fogsi.org/index.php?option=com\\_content&view=article&id=97&Itemid=16](http://www.fogsi.org/index.php?option=com_content&view=article&id=97&Itemid=16)
4. Government of India. The medical termination of pregnancy rules (amendment). 2003. Ministry of Health and Family Welfare. Department of Family Welfare: notification, New Delhi, the 13th June 2003. Available at <http://mohfw.nic.in/index1.php?sublinkid=3618&andlevel=4&andlid=26020&andlang=1>.
5. Cadepond F, Ulman A, Baulieu E. RU486 (mifepristone) Mechanism of action and clinical uses. *Annual Rev Med.* 1997;48:129-56.
6. Ashok PW, Flet GM and Templeton A. Mifepristone versus vaginally administered misoprostol for cervical priming before first trimester termination of pregnancy: A randomised, controlled study. *American Journal of obstetrics and gynecology* 2000;183(4); 998-1002.
7. Van der Veen N, Brouns J, Doornbos J and Van Wijngaarden W. Misoprostol and termination of pregnancy: is there a need for ultrasound screening in a general population to assess the risk for adverse outcome in cases of uterine anomaly. *Arch Gynecol Obstet.* 2011;283(1):1-5.
8. Refresher course of medical abortion services. Available at [www.ipas.org/-/media/files/Ipas%20Publications/REFMAINDE09.ASHX](http://www.ipas.org/-/media/files/Ipas%20Publications/REFMAINDE09.ASHX).
9. Sarojini TR, Ashakiran BT Bhanu, Radhika. Over-the-counter MTP pills and its impact on women's health. *J Obstet Gynecol India.* 2017;67(1):37-41.
10. Shrivastava V. Safety, efficacy and acceptability of medical abortion with mifepristone and misoprostol in Nepalese women. *Nepal J Obstet Gynecol.* 2007;2(2):54-8.
11. Kathleen K, Leslie M, Patricia L, Mithcell D. Mifepristone and Misoprostol for early pregnancy failure: a cohort analysis. *Am J Obstet Gynecol.* 2011;204(5):386.e1-6.
12. Schaff EA, Eisinger SH, Stadalius LS, Franks P, Gore BZ, Poppema S. Low dose mifepristone 200mg and vaginal misoprostol for abortion. *Contraception.* 1999 Jan 1;59(1):1-6.
13. Spitz IM, Bardin CW, Benton L, Robbins A. Early pregnancy termination with mifepristone and misoprostol in the United States. *N Engl J Med.* 1998 Apr 30;338(18):1241-7.
14. Kruse B, Poppema S, Creinin MD, Paul M. Management of side effects and complications in medical abortion. *Am J Obstet Gynecol.* 2000;183(2):S65-S75.
15. El-Refaey H, Rajasekar D, Abadalia M, Calder L, Templeton A. Induction of abortion with Mifepristone (RU 486) and oral or vaginal Misoprostol. *New Engl J Medic.* 2008;332:983-8.
16. Urquhart DR, Templeton AA, Shinewi F. The efficacy and tolerance of mifepristone and prostaglandin in termination of pregnancy of less than 63 days gestation; UK multicenter study-final results. *Contraception.* 1997;55:1-5.

**Cite this article as:** Jani PS. Use of MTP kit (Mifepristone and Misoprostol combination pack) for 1st trimester MTP (up to 63 days) at GMERS Dharpur, Patan, Gujarat, India. *Int J Reprod Contracept Obstet Gynecol* 2018;7:3615-8.