

Clinical observation of first trimester abortion induced by mifepristone and misoprostol in pregnant women in terms of success, side effects and acceptability

Prathibha Raju^{1*}, Merugu Padma Latha², A Mohathasim Billah³

¹Assistant Professor, Department of Obstetrics & Gynaecology, Government General Hospital, Nizamabad, INDIA.

²Assistant Professor, Department of Pharmacology, Kamineni Academy of Medical Sciences & Research Centre, Hyderabad, Telangana, INDIA

³Principal, Department Of Pharmacy, Sri Indu Institute of Pharmacy, Hyderabad, Telangana, INDIA.

Email: drprathibha2019@gmail.com

Abstract

Background: This study assessed the efficacy and side effects of first trimester medical abortion using mifepristone and vaginally administered misoprostol. **Objective:** To compare mifepristone and misoprostol in abortion. **No. of patients:** 77 women willing to undergo MTP in early first trimester. **Methodology:** After detailed clinical history and clinical evaluation of the patients. The dose of mifepristone 600 mg and misoprostol 400mcg respectively for the termination in early first trimester pregnancy was prescribed. However different dosage regimen was followed in different hospitals. Reduced dose of mifepristone 200mg and misoprostol 800mcg was recommended for the termination of late first trimester pregnancy recommended in the American journal of obstetrics and Gynaecology **Results:** The patient coming under the age group of 15 to 25 shown 100% success rate. Whereas in the age group of 26 to 30 and 31 to 35 were found to be decreasing as 87.90% and 83.3% respectively. There were 28 subjects treated with the standard dosage regimens, i.e. 600mg of mifepristone and 400 mcg of misoprostol. The result found as a success rate of 96.43% ranging the gestational age <63 days. Out of above-mentioned subjects two are the failure cases. In alteration of standard dosage regimen advised by the manufactures, is 400 mg mifepristone and 400 mcg of misoprostol. There were three failure cases among 22 patients have been treated. The success rate was calculated as 86.36% A second modification in standard dosage form advised by the company. Further reduction of mifepristone to 200mg and no change in the misoprostol have shown a 100% success out of 22 number of patients. This dosage regimen was found to be cost effective and improved success rate. **Conclusions:** Early medical abortion with mifepristone followed by misoprostol is highly effective and safe. **Key Words:** Induced Abortion, Mifepristone, Misoprostol, MTP.

*Address for Correspondence:

Dr Prathibha Raju, Assistant Professor, Department of Obstetrics & Gynaecology, Government General Hospital, Nizamabad, INDIA.

Email: drprathibha2019@gmail.com

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INTRODUCTION

Millions of women every year have an unwanted pregnancy throughout the world. So unwanted pregnancies are carried to term, other end in a spontaneous abortion. Yet others end in an induced abortion. Induced abortion is restricted by law in many countries. In other pregnancy termination is legal on board medical and social grounds. Even though induced abortion is constitutionally permissible Often facilities are not equipped or adequate to meet demand, particularly. Alternatively, women may be unaware of their availability. Despite restrictive laws and

lack of adequate services, women continue to seek to terminate unwanted pregnancies. In order to discourage abortion, the state should recommend appropriate steps that are not marketed as a family planning tool in any situation and whenever possible to provide for the humane treatment and counselling of women have for the recourse to abortion. All couples and individuals have the basic human right to decide freely, responsibly and without coercion, the number and the spacing of their children. Everyone has the human right to reproductive health, choice and dignity; women must enjoy self-determination in their sexual and reproductive lives; and every child should be a wanted child. The unwanted pregnancy and unsafe abortion are major public health and social problems. Preventing unintended pregnancy has always been a key concern, so therefore efforts should be made to prevent the possibility of unsafe abortion. When abortion is not accessible or unavailable, many unintended pregnancies may eventually arise. Furthermore, even if services are available and accessible, proportion of unwanted pregnancies arise following contraceptive failure and women may resort to unsafe abortion to terminate these pregnancies, putting their lives and health at risk. It is therefore important that government, intergovernmental and non-governmental deal openly with unsafe abortion as a major public health concern. Government shall assess the health consequences of unsafe abortion, minimize the demand for abortion by improved Family Planning and Provision Abortion Laws and Policies on the grounds of responsibility to the wellbeing and wellness of women, and not on criminal codes and disciplinary acts. Preventing unintended pregnancy has also been a key concern, so therefore efforts should be taken to remove the risk of unsafe abortion. Women seeking to terminate their pregnancy would have ready access to reliable information, supportive counselling and complementary resources for the prevention of unintended pregnancy and for the treatment of complications. Unsafe abortion is a significant issue for women during their reproductive years and is a major underestimated health challenge for developed countries. Unlike traditional belief, most people who want abortion are married or live in healthy relationships with many kids. Abortion is used to restrict the family dimension or timing of conception. They may resort to abortion in the event of all abortion seekers. According to the conditions to which the unsafe abortion is performed and the method used, a variety of severe complications may occur. Complications such as sepsis, haemorrhage, genital and abdominal trauma, perforation of uterus or poisoning may be from secondary complications such as gas gangrene and acute renal failure. Abortion was legalized in India on broad socio-medical grounds through the Medical Termination of Pregnancies

(MTP) Act, 1971, which allowed a woman to opt out of an unwanted or unintended pregnancy in certain specific circumstances. Abortion was permitted with certain provisions and safeguards, up to 20 weeks gestation. The shah committee (1971) placed the incidence of sepsis occurs in abortion in India at 5 to 20%, which made septic abortion a major cause of maternal mortality in India then (Shah committee, 1971). A significant number of medical practitioners engage in the practice of abortion that do actually follow the standards set down in the MTP Act. Besides non-allopathic too involved in abortion practice. As a result, women face problems getting a sap and legal abortion done. Worldwide, for many years the starch was on for simpler methods for early abortion. The termination of unwanted pregnancies has been practical since antiquities and historically been a concern of women and health care provides. In the past several centuries, many agents and modalities have been touted for their "abortion inducing" properties. While certain cultures support this custom, others condemn it and may even find it as a felony. In India, the most popular methods of terminating pregnancy are surgical, primarily vacuum aspiration, which is easier and less traumatic than dilation and curettage. Every year throughout the world, an approximate 26 million births are lawfully terminated and over 20 million are unlawfully terminated, with over 78,000 deaths.¹ Many people come for confirmation of pregnancy quite soon after they have a missed menstrual cycle. That treatment option of medical abortion should be a very welcome addition to the therapeutic armamentarium of the physician treating women in the reproductive age group. A site medical method would save many lives. It would also go a king a way in casing the problem of failed contraception and unwanted pregnancy often faced by the Indian women. Medical abortion has now opened a new era in fertility control, and the pace of research has again accelerated. Investigators explored early medical abortion with prostaglandins alone, but this approach proved unsatisfactory. A voluminous literature now documents the safety and efficacy of mifepristone abortion regimens. Another by-product of medical abortion research has been interesting in the therapeutic uses of misoprostol as an adjunct to abortion.

Surgical Abortion:

The method generally used today to affect an early abortion is surgical, consisting of dilatation of the cervix followed by evacuation of the uterus, performed under local anaesthesia, sedation or general anaesthesia. Surgical abortion can be performed throughout the first trimester. In general, the surgical methods used consists of two steps.

1. Dilatation of the cervix:

- The commonest method used to dilate the cervix today is rapid mechanical dilatation using graded cervical dilators made of metal or plastic.
- Sometimes, a drug like prostaglandins may be used to soften the cervix prior to mechanical dilatation.
- The other methods available are slow dilatation of the cervix using substances like laminaria tents or similar devices.

2. The methods employed to evacuate, the uterus are:

- Blunt curettage 111 which he pregnancy is scraped off the uterine walls. This is minable for an early pregnancy.
- Vacuum aspiration (suction evacuation, suction curettage) using suction front an electrical or foot/hand operated suction apparatus, or a large plastic syringe (Karman syringe). This is especially useful in early pregnancy.
- Piece-meal evacuation using ovum forceps. This may be used in late first trimester or sometimes early second trimester pregnancies.
- A combination of the above.

Medical abortions are effective mainly in early first trimester of pregnancy, and are attempted usually up to 4, days from the last menstrual period, sometimes up to 56 days, with 63 clays being the outer Many hospitals are yet to adopt these procedures since they prefer dilatation and curettage surgical technique only. To validate the new drug regimen the drug was freely supplied by Sun Pharmaceuticals Industries limited to practice on pregnant ladies in and around chidambaram. About this drug, the author joint with the medical representative of the company on explaining the new regimen to the doctors. The drug was used in the hospitals for pregnant ladies in first trimester. The outcome of the dosage regimen is observed and reported in terms of safety, side effects and acceptability among patient and doctors. The most commonly used method today for a first trimester termination in India is probably vacuum aspiration, though general anaesthesia may be used less often especially in rural areas.

Medical abortion:

The current Indian environment has created a situation in which majority of the helpless women live in areas where there is no surgical abortion provider and are thus footed to seek resource to illegally induced abortion with crude, homemade, remedies. Medical abortion promises sees' non-surgical option to such women seeking early pregnancy lamination. Medical abortion is the induction of early abortion by means of medications alone, without the

need for any surgical procedure. A medical abortion is said to be successful when the medications used achieves complete evacuation without incomplete abortion or excessive bleeding.

METHODOLOGY

Source of data:

Subjects presenting to outpatient (OPD) or main department between April 2019 to October 2019, at Rajah Muthiah Medical Collage Hospital and selected hospitals.

Participants:

77 women willing to undergo MTP in early first trimester.

Inclusion criteria:

- All women decided to have MTP
- Gestational age < 63 days.

Exclusion criteria:

- Asthma patients
- Women presenting with bleeding per vaginum and missed abortion.
- Women with IUD.

Sample size: 77 cases

Statistical Analysis: Data were presented in the form of statistical tables and charts. SPSS software version 20 was used for statistical analysis.

Procedure:

1. Monitoring the patients being treated with medical abortion regimens.
2. The side effects experienced by the patient are being monitored.
3. The safety will be assured for using the medical abortion regimen for its use
4. Reporting of the success rate of the medical abortion regimen used
5. Informed and written consent regarding the procedure from the patient,

The following scheme was adopted for the monitor., of medical abortion regimens.

1. Record of Name, age, address etc.,
2. Detailed obstetric history: -
 - a) regarding the number of prior pregnancies
 - b) number of living issues
 - c) previous abortions
3. History of present pregnancy
4. History of medical illness -Hypertension, cardiac disorder and other complications
5. Drug history (previous)
6. Menstrual history
7. Pelvic examination to assess uterine size and any other pathology in genital tract.
8. Routine laboratory investigations
9. Post medications and post procedure
10. Monitoring the side effects
11. Treatment given when discharge or during the follow up visit

12. Confirmations of complete abortion

Hospitals identified for the Project:

1. Rajah Muthiah Medical College hospital, Annamalai nagar, Tamil nadu.
2. Arul Nursing Home, South-car street, Chidambaram-608001.
3. Sri Venkatesa Nursing Home, S.P Koil street, Chidambaram-608001.
4. Shivprasad Nursing Home, I E Yadawa street, Kattumannar koil-608301.
5. Rajesh Clinic, Saidapet, Chennai.

Dose

- a. The dose of mifepristone and misoprostol as 600mg² and 400mcg respectively for the termination in early first trimester pregnancy.
- b. However different dosage regimen was followed in different hospitals. e) Reduced dose of mifepristone as 200g and misoprostol as 800mcg was recommended for the termination of late first trimester pregnancy recommended in the American journal of obstetrics and Gynaecology.^{3,4,5,6,7,8,9}

OBSERVATION AND RESULTS

Different dosage regimens

Table 1: tables of different dosage regimen

| Gestational age in days | No. of patients | Complete abortion | % Success | Incomplete abortion | % Failure | Overall success rate |
|-------------------------|-----------------|-------------------|-----------|---------------------|-----------|----------------------|
| 30 - 39 | 2 | 2 | 100% | 0 | 0% | 96.43% |
| 40 - 49 | 10 | 9 | 90% | 1 | 10% | |
| 50 - 59 | 12 | 12 | 100% | 0 | 0% | |
| >60 | 4 | 4 | 100% | 0 | 0% | |

600 mg of mifepristone + 400 mcg of misoprostol

There were 28 subjects treated with the standard dosage regimens which was advised by the manufacturer, i.e., 600mg of mifepristone and 400 mcg of misoprostol. The result found as a success rate of 96.43% ranging the gestational age <63 days. Out of above-mentioned subjects two are the failure cases

Table 2: 400 mg of mifepristone + 400 mcg of misoprostol

| Gestational age in days | No. of patients | Complete abortion | % Success | Incomplete abortion | % Failure | Overall success rate |
|-------------------------|-----------------|-------------------|-----------|---------------------|-----------|----------------------|
| 30 - 39 | 0 | 0 | 0 | 0 | 0% | 86.36% |
| 40 - 49 | 12 | 10 | 83.33% | 2 | 16.67% | |
| 50 - 59 | 7 | 6 | 85.71% | 1 | 14.29% | |
| >60 | 3 | 3 | 100% | 0 | 0% | |

In alteration of standard dosage regimen advised by the manufactures, i.e. 400 mg mifepristone and 400 mcg of misoprostol. There were three failure cases among 22 patients have been treated. The success rate was calculated as 86.36%

Table 3: 200 mg of mifepristone + 400 mcg of misoprostol

| Gestational age in days | No. of patients | Complete abortion | % Success | Incomplete abortion | % Failure | Overall success rate |
|-------------------------|-----------------|-------------------|-----------|---------------------|-----------|----------------------|
| 30 - 39 | 1 | 1 | 100% | 0 | 0% | 100% |
| 40 - 49 | 19 | 19 | 100% | 0 | 0% | |
| 50 - 59 | 1 | 1 | 100% | 0 | 0% | |
| >60 | 1 | 1 | 100% | 0 | 0% | |

A second modification in standard dosage form advised by the company. Further reduction of mifepristone to 200mg and no change in the misoprostol have shown a 100% success out of 22 number of patients. This dosage regimen was found to be cost effective and improved success rate.

Table 4: 200 mg of mifepristone + 800 mcg of misoprostol

| Gestational age in days | No. of patients | Complete abortion | % Success | Incomplete abortion | % Failure | Overall success rate |
|-------------------------|-----------------|-------------------|-----------|---------------------|-----------|----------------------|
| 30 - 39 | 0 | 0 | 0% | 0 | 0% | 60% |
| 40 - 49 | 2 | 1 | 50% | 1 | 50% | |
| 50 - 59 | 0 | 0 | 0% | 0 | 0% | |
| >60 | 3 | 2 | 66.67% | 1 | 33.33% | |

According to regimen published in American Journal of Obstetrics and Gynaecology, lowering the dose of mifepristone to 200mg and offering 800mcg of misoprostol to extend the use of medical abortion to extreme limit of gestational age of the foetus. Five subjects were treated with above regimen and the result found to be 60% success rate. The subject of gestation age range 42 and 45 days were treated the earlier regime and an incomplete result was found, so they were given another dose of 400mcg of misoprostol and one among them shown positive result

Tables according to parity variations

Table 5: In case of gravida 1

| Gestational age in days | No. of patients | Complete abortion | % Success | Incomplete abortion | % Failure | Overall success rate |
|-------------------------|-----------------|-------------------|-----------|---------------------|-----------|----------------------|
| 30 - 39 | 0 | - | - | - | - | 100% |
| 40 - 49 | 6 | 6 | 100% | 0 | 0% | |
| 50 - 59 | 4 | 4 | 100% | 0 | 0% | |
| >60 | 2 | 2 | 100% | 0 | 0% | |

In case of 12 number of subjects treated in the prime gravida and the success rate was found to be 100%.

Table 6: In case of gravida 2

| Gestational age in days | No. of patients | Complete abortion | % Success | Incomplete abortion | % Failure | Overall success rate |
|-------------------------|-----------------|-------------------|-----------|---------------------|-----------|----------------------|
| 30 - 39 | 2 | 2 | 100% | 0 | 0% | 96.30% |
| 40 - 49 | 17 | 17 | 100% | 0 | 0% | |
| 50 - 59 | 6 | 6 | 100% | 0 | 0% | |
| >60 | 2 | 2 | 50% | 1 | 50% | |

The study in second gravida in which 27 subjects were treated and the result found to be 96.30% as success rate.

Table 7: In case of gravida 3

| Gestational age in days | No. of patients | Complete abortion | % Success | Incomplete abortion | % Failure | Overall success rate |
|-------------------------|-----------------|-------------------|-----------|---------------------|-----------|----------------------|
| 30 - 39 | 0 | - | - | - | - | 95.24% |
| 40 - 49 | 13 | 12 | 92.31% | 1 | 7.69% | |
| 50 - 59 | 4 | 4 | 100% | 0 | 0% | |
| >60 | 4 | 4 | 100% | 0 | 0% | |

The result from third gravida in which 21 subjects were treated found to be 95.24% as success rate.

Table 8: In case of gravida 4,5 and 6

| Gestational age in days | No. of patients | Complete abortion | % Success | Incomplete abortion | % Failure | Overall success rate |
|-------------------------|-----------------|-------------------|-----------|---------------------|-----------|----------------------|
| 30 - 39 | 1 | 1 | 100% | 0 | 0% | 76.47% |
| 40 - 49 | 7 | 4 | 57.4% | 3 | 42.86% | |
| 50 - 59 | 6 | 5 | 83.33% | 1 | 16.67% | |
| >60 | 3 | 3 | 100% | 0 | 0% | |

In case of grand multi gravida 17 subjects were treated and the success was found in 76.47% of the cases.

Result concerned with period of gestation:

Table 9: According to period of gestation

| Gestation age in days | No. of patients | Success rate |
|-----------------------|-----------------|--------------|
| 35 - 40 | 10 | 100% |
| 41 - 45 | 30 | 90% |
| 46 - 50 | 13 | 84.62% |
| 51 - 55 | 7 | 100% |
| 56 - 60 | 13 | 92.31% |
| 61 - 65 | 4 | 100% |

Patients with gestational period of 35 to 40 days and 56 to 60 days and more than 60 days i.e. 61 to 65 days, 100% successful outcome was seen, In 41 – 45 days and 56 – 60 days of gestation the positive outcome was around 90% and 92.31% respectively. In the patients with 46 – 50 days of gestation, successful outcome was 84.62%.

Results concerned with the age of the pregnant women:

Table 10: According to age of the women

| Age in years | Number of patients | Success rate |
|--------------|--------------------|--------------|
| 15 - 20 | 11 | 100% |
| 21 - 25 | 21 | 100% |
| 26 - 30 | 33 | 87.90% |
| 31 - 35 | 12 | 83.3% |

It Is found that the age of pregnant women from 15 to 25 years shows 100% result and in this range 32 patients were treated. The result in the age group from 26 to 30 years found to be 97.9%, and in this range 33 subjects were treated Twelve subjects were treated in the age group of 31 to 35 years and the success rate obtained was 83.3%

Patients with previous history of abortion:

Table 11: patients with previous history of abortion

| Previous abortion | No. of patient | Success rate |
|-------------------|----------------|--------------|
| 1 st | 71 | 100% |
| 2 nd | 3 | 66.67% |
| 3 rd | 2 | 50% |
| 4 th | 1 | 0% |

Here the subjects experiencing the abortion for the first time are concerned. Seventy-one subjects were treated and the success rate was found to be 100%. Three patients experiencing the abortion for the second time were treated and result found to be 66.7% as one of the patients among those had incomplete abortion. There are two patients experiencing the abortion for the third time and one among them shown positive result. A subject experiencing abortion for fourth time was treated and the result found to be 0% as success rate.

Side effects experienced by the patients:

Table 12: Side effects experienced by the patients

| Side effects | Number of patients | Percentage |
|-----------------------|--------------------|------------|
| Pain | 62 | 80.52% |
| Bleeding | 49 | 63.64% |
| Heavy bleeding | 19 | 24.68% |
| Vomiting | 36 | 46.75% |
| Head ache / dizziness | 35 | 45.45% |

Pain / cramp was experienced by 80.52% of patients. 63.64% patients experienced bleeding. 24.68% patients experienced heavy bleeding. 46.75% patients experienced Vomiting. Headache / dizziness was experienced by 45.45% patients.

DISCUSSION

Medical Abortion is revolutionary addition to women's health can. Its introduction in to general medical practice will teach us much about the practical aspects of service provision and acceptability. Medical abortion is a safe and effective alteration to surgical abortion. The major side effects with any-many medical abortion regimes are gastrointestinal and are more commonly related to the prostaglandin analogy. With appropriately trained clinician and well-informed patients, medical abortion can provide a safe and effective method of early pregnancy termination that can result in increased access and options for reproductive health care Abortion using mifepristone is free from the risk of uterine perforation and complication associated with anaesthesia because it is a non-invasive procedure and does not require anaesthesia. (Anquillanne and tyrer, 1995).¹⁰ No death has been reported as a result of the use of mifepristone. The present study was undertaken for clinical observation of first trimester abortion induced by mifepristone and misoprostol in pregnant women in terms of success, side effects and

acceptability. Here we Observe for the various dosage regimens, which used in the different hospital Settings. The variation in the dosage regimen was altered under the therapeutic range. Reducing the dosage of mifepristone from 600mg to 400mg and then to 200mg and the misoprostol being unaltered as 400mcg (Table 1,2 and 3). There were five cases, which were treated by lowering the dose of mifepristone to 200mg and offering 800mcg of misoprostol to extend the use of medical abortion to its extreme limit of gestational age of the foetus. The result shows 60% success rate even though the number of subjects was minimum as five, The study shows the result in relation to the parity variation as the success rate gradually decreases when the gravida increases. However, the number of subjects in gravida 5 and 6 were very less as 4 and 2 respectively. As the age of the subject increases the success rate found to be decreases. The age of the pregnant women also plays a significant role in the abortion success rate. The patient coming under the age group of 15 to 25 shown 100% success rate. Whereas in the age group of 26 to 30 and 31 to 35 were found to be decreasing as 87.90%

and 83.3% respectively. The patients who experience the abortion first time were large in number and the success rate was observed as 100%. In case of second abortion only three subjects were treated and out of which one had incomplete abortion. Further in third abortion the success was only half the rate and only two subjects are presented, one among shown incomplete abortion. There was only shown the negative result. one subject presented for fourth abortion and Reports of side effects of medical abortion were fairly lent and tolerable, majority of the patients have experienced the side effects. The combination of mifepristone and misoprostol for induction of trimester termination of pregnancy is an effective and safe regimen. Women can safely and effectively self-administer misoprostol at home as part of a medical abortion regimen.^{11,12,13} Since medical abortion are available only at an early stage of the pregnancy. this may encourage women to present earlier for termination. In general, earlier abortions (whichever method is used) are safer than later (surgical) abortions, owing to the increasing size of the pregnancy, which requires mere cervical dilatation and increases then technical difficulty of the surgical procedure. Reports of side effects of medical abortion were fairly consistent and tolerable. Majority of the patients have experienced the expected side effect.

CONCLUSION

The combination of mifepristone and misoprostol for induction of trimester termination of pregnancy is an effective and safe regimen. Mifepristone administered in a 200 mg dose in a highly effective and with high patient acceptability and fewer side effects compared with the higher doses. In short. medical abortion is among the safest possible outcomes of unwanted pregnancy in early first trimester. The availability of medical abortion should be done in all urban and rural areas to sustain the health of women and preventing them from unsafe abortion. Our study and observation revealed that for termination of 1st trimester abortion, mifepristone and misoprostol is found to be safest drug and non-complained adverse effects. Hence it is the preferred method of choice for abortion instead of complicated methods like surgical abortion.

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