

Study on Safety, Efficacy and Complication of Medical Abortion

Atima Bharti¹, Anjali Tuddu²

ABSTRACT

Introduction: The term abortion has been derived from the Latin word “ABORIRI” which means to detach from its proper place. “ab” means abnormal and it indicates premature expulsion. “ORIRI” means to be born or to arise. Aim of the present study was to evaluate the role of combination of Mifepristone and Misoprostol in pregnancy termination up to 63 days. Safety, efficacy, cost effectiveness and complications have been evaluated.

Material and Methods: This study was carried out at Rajendra Institute of Medical Sciences, Ranchi in the department of Obstetrics & Gynaecology from June 2016 to Oct 2017. 200 cases were selected from outpatient department and labour room of Obstetrics & Gynaecology.

Result: In my study 93% of women had successful abortion and 7% had to undergo surgical evacuation. It was observed that majority 98% of the cases were between 21-30 years of age and most of them 56.5% came from urban areas. 65.5% of the cases belonged to literate groups. In majority of the cases 76.5% the indication for pregnancy termination was unwanted pregnancy followed by contraceptive failure. 18.5% of the cases were primigravida and 56% of the cases were gravida two.

Conclusion: Unrestricted use and over the counter purchase of drugs for medical abortion is detrimental for maternal health. Proper dosing, timing, route and counseling by the medical professionals can prevent serious complications.

Keywords: Mifepristone, Misoprostol, Medical Abortion.

INTRODUCTION

Abortion is defined as termination of pregnancy by any means before the fetus is Viable. Governments all over the world have liberalized “Abortion laws” in keeping with changing time, accepting the recognition of the right of the individual to bear a child at her chosen time and helping to curb the malpractices accompanying illegal abortion.

A medical abortion, also known as medication abortion, occurs when pills are used to bring about an abortion. The recommended regimen consists of a combination of medications, starting with mifepristone followed after at least a day by misoprostol. Mifepristone followed by misoprostol for abortion is considered both safe and effective throughout a range of gestational ages. When mifepristone is not available, misoprostol may be used.

In India, the MTP act was adopted as a health measure, way back in 1972 to avoid death due to criminal abortion. The Indian act permits the willful termination of pregnancy before the age of fetal viability (20 weeks of gestation) for well defined indication. It has to be performed by recognized medical practitioners in a recognized place approved by the

competent authority under the act.

It has been estimated that total number of abortions performed globally is approximately 46 million annually. Of these 26 million takes place in countries where abortions are legalized. In India 6.7 million MTP takes place, out of which 40% pregnancies are unplanned and 25% are unwanted. Termination of such unwanted pregnancy has been legal for several years in India ever since MTP act of 1971. The aim of the act was to reduce maternal morbidity and mortality due to illegal, unsafe abortions which accounts for 12% of maternal death.

There are different surgical and medical methods of abortion since ancient times. A matter of great concern in the past was that, there were no safe drugs for inducing an abortion. Women have used various herbs, salt douches and purgatives all with questionable success to achieve pregnancy termination. Among the methods listed as outdated by WHO but still commonly used in several developing countries e.g. India, China and until recently Mongolia is intra or extra-amniotic administration of ethacridine lactate especially to terminate second trimester pregnancies.² Medical abortions, the termination of pregnancy through the use of a drug or a combination of drugs, have the potential to reduce complication and to expand access to abortion provided by specially trained clinicians. Drawback of older methods include hospitalization for several days, long duration of labour and the need for curettage with the introduction of prostaglandins and later prostaglandin analogues, the efficacy of medical abortion has improved while the risk of complication and side effects are reduced. Medically induced abortion was further improved when mifepristone become available in the 1980s.³⁻⁷ Since the introduction of mifepristone in the 1980s its combination with Misoprostol for pregnancy termination has been subjected to substantial research internationally.^{8,9} Mifepristone was found to influence the human luteal phase endometrium by reducing stromal edema, increasing venular diameter, causing erythrocyte and leukocyte diapedesis, focal haemorrhage and degeneration of the stromal extracellular Matrix, thus initiating the eventual degradation of the endometrium.^{10,11}

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The current standard protocol for medical abortion calls for Misoprostol to be administered in a hospital setting under medical staff supervision, in where women can leave if they are not experiencing severe discomfort.¹²

Mifepristone and Misoprostol given in a combined manner are the most commonly used drugs for medical abortion. In India the combination was approved for clinical use in 2001. Medical abortion during early pregnancy was first approved in France in 1988 for up to 49 days of amenorrhea followed by approval in UK in 1991 and Sweden 1992 for up to 63 days of amenorrhea in both the countries. Few years later approval followed in these countries for second trimester medical abortion. However it was only in 1992-2000 that both early first and second trimester medical abortion with mifepristone and a prostaglandin analogue were approved in several other European countries.

Combination of mifepristone and Misoprostol is now widely used method for the first trimester abortion. Priming of the uterus with mifepristone makes it more sensitive to prostaglandin. It binds with progesterone receptor and antagonizes the action of progesterone. It induces cervical softening thus enhancing the efficacy of prostaglandin as an abortifacient. Therefore this combination is widely used now a days as a method of termination of pregnancy up to 63 days because it is easier and non invasive when compared to surgical method and it does not require anaesthesia.

Drugs are easily available and can be kept at room temperature. However over the counters purchase of MTP Kit has led to many detrimental effects on maternal health. Patients are unaware of the proper dosage, timing, route and complication of drugs. Improper use of these drugs can lead to serious complications. On the other hand supervised use of the drugs is an easy and cost effective way of termination of pregnancy.

Our study is designed to correlate the "Safety, efficacy, acceptability and complication" of medical abortion with Mifepristone and Misoprostol in pregnancy up to 63 days of gestation.

In December 2008 Mifepristone and Misoprostol (1 tab of Mifepristone 200mg + Misoprostol 4 tabs of 200µg each) combi pack 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.¹³

Aim of present study was to evaluate the role of combination of mifepristone and Misoprostol in first trimester of pregnancy regarding-

Safety- Unsafe abortion accounts for 12% of maternal death which is significant with advent of this combination drug, the concept of medical abortion emerged as one of the safe and effective method for termination of pregnancy.

Efficacy- To evaluate the efficacy by the success rate.

Acceptability- To study its acceptability among women regarding its simplicity and convenience of use.

Cost effectiveness.

MATERIAL AND METHODS

Present study was carried out at Rajendra Institute of Medical Sciences, Ranchi in department of Obstetrics and Gynaecology from June 2016 to October 2017. 200 cases were selected from outpatient and labour room of Obstetrics & Gynaecology department.

All patients underwent either pelvic examination or an ultrasound for pregnancy dating prior to abortion. Gestational age was calculated using a Hadlock scale by ultrasound. Our medical abortion regimen consisted of 200mg of Mifepristone followed by 800µg of buccal Misoprostol use by the patient at home 36-48 hours later. Gestational age limit for this regimen was up to 63 days. All patients were counselled to return after a fortnight for post-abortion evaluation. Record was kept of adverse events including continuation of pregnancy, aspiration for retained product of conception, infection and haemorrhage requiring admission. Primary outcome was successful abortion were pregnancy was expelled without any intervention. Women were counselled that they will experience cramping pain for several hours and bleeding for few days. Moreover they were explained about the possibility of failure and complications that may arise. Women were not given any medication to control pain and bleeding. They were asked the reason for seeking abortion. In most of the cases the reason was unwanted pregnancy. Teratogenicity of medical abortion becomes an important issue if the pregnancy continues, so the patients were counselled before the treatment, of need for surgical evacuation in the event of a continuing pregnancy.

Inclusion criteria

1. Pregnant women in a good general health from outdoor taking MTP Pills under supervision.
2. Patients admitted in emergency taking medicines without prescription and reporting with complications like-
 - Continuous heavy bleeding per vagina.
 - Severe pain abdomen.
 - Intractable vomiting.
 - Bleeding P/V on & off since long period.
3. Pregnancy of <63 days of gestation based on last menstrual date, clinical examination with or without USG.
4. No contraindication to Mifepristone and Misoprostol.
5. Informed consent was taken after proper counseling regarding its failure and complication.

Exclusion criteria

- Pregnancy of >63 days of gestation.
- Allergy or contraindication to Misoprostol or Mifepristone.
- Ectopic pregnancy diagnosed.
- Patients with bronchial asthma, heart disease, coagulation disorder, renal disease and jaundice.
- Haemoglobin <9gm/dl.

RESULT

Distribution of cases according to age of the patient. 98%

of cases were between 21-30 yrs. 33% were between 31-40 yrs (fig-I).

Distribution of cases according to residential status 56.5% of the patients came from urban areas and rest 43.5% from rural areas (fig-II). Based on literacy 65.5% of cases were literate and 34.5% of cases were illiterate (Table-III). Distribution of cases according to the indications for termination of

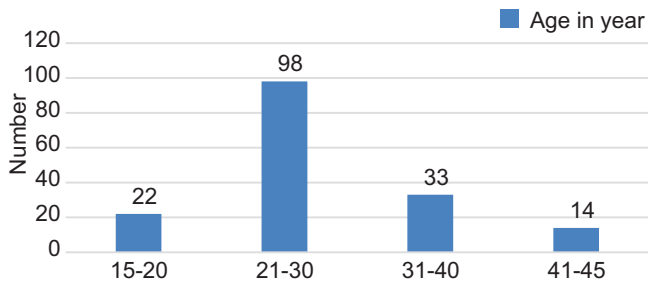


Figure-1: Age

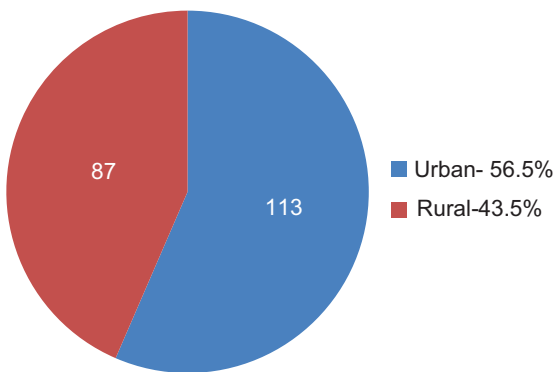


Figure-2: Residential status

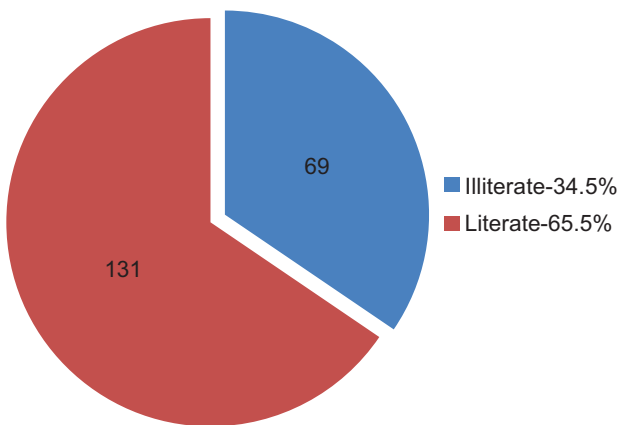


Figure-3: Literacy

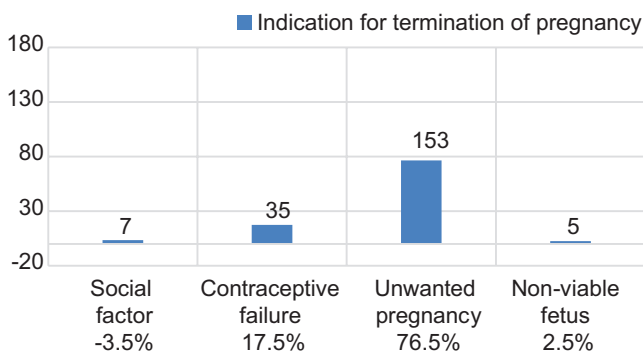


Figure-4: Indication for termination of pregnancy

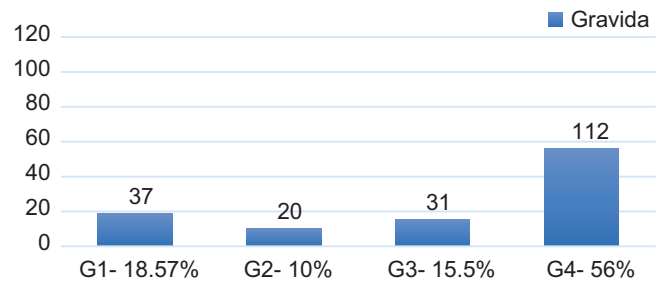


Figure-5: Gravida

pregnancy. In 76.5% of cases the indication for pregnancy termination was unwanted pregnancy followed by contraceptive failure 17.5%. Other cases were social factors and non viable fetus (fig-IV). Distribution of cases according to gravida. 37 cases (18.5%) were primigravida followed by 20 (10%), 31 (15.5%) and 112 (56%) for G₂, G₃ and >G₄ respectively (fig-V).

Side effects of the drug like fever occurred in 12.5% cases, nausea 9% cases, diarrhea 7.5%, rigor 6.5%, headache 6% and vomiting in 5% of cases. However 53.5% of cases did not have any side effect. Complications included anaemia, shock, sepsis and D & E had to be done in 14 cases.

DISCUSSION

The present study was carried out with Mifepristone and Misoprostol in 200 cases. Maximum numbers of cases (49%) were between 21-30 years, 56.5% belonged to urban areas. Cases from urban area were aware of the abortion caused by drugs. Majority of women (65.5%) were literate.

72.5% were married whereas 22% were unmarried pregnancy. High percentage in married cases were due to the fact that they either came to seek treatment for failed contraception or with ultrasound diagnosed non viable pregnancy or had some medical problem were continuation of pregnancy would endanger their life. Indication for termination was unwanted pregnancy in majority of cases 76.5% followed by contraception failure. Late decision making for termination of pregnancy was also one of the reasons why women came late for medical advice. 83 (41.5%) of cases were prescribed the drug for termination out of which 72 cases had complete abortion and 10 cases had incomplete and 1 case failed. 117 (58.5%) case were of non prescribed group out of which 62 cases had complete abortion and 54 cases had incomplete and 1 case failed. So the success rate in women with pregnancy of <63 days was 93%. Anaemia and incomplete abortion leading to blood transfusion and surgical evacuation respectively was one of the common complications in our study.

This medical abortion regimen has proved to be acceptable to women and safe when provided under proper conditions.¹⁴ Current evidence supports the home use of mifepristone and misoprostol up to 70 days gestation and emphasizes the need for routine repeated Misoprostol dosing beyond 70 days. But the systematic review, published in the journal CONTRACEPTION says more research is needed to strengthen that body of evidence.

Medical abortion is one of the most significant developments in the field of reproduction health, both in countries where abortion is permitted on broad grounds or on request and in others where it is highly restricted. Where abortion is permitted and medical abortion has been approved, it provides a safe, effective and noninvasive alternative to surgical abortion and is highly acceptable to women whether it was induced by Misoprostol only or by the combined regimen.¹⁵

The success rate of Mifepristone followed by Misoprostol through 10 weeks pregnancy is 96.6%.¹⁶ In another review of patient up to 9 weeks gestation Mifepristone followed by various routes of Misoprostol was associated with a successful abortion rate of over 95%, 1.1% experienced ongoing pregnancy.¹⁷ If mifepristone is not available the WHO recommends 800µgm inside the cheek, under the tongue or in the vagina.¹⁸ The success rate of Misoprostol alone for first trimester abortion is 78%.¹⁹ Medical abortion regimens using Mifepristone in combination with a prostaglandin analog are the most common methods used to induce second trimester abortion in Canada, most of the Europe, China and India.²⁰

CONCLUSION

Unsafe abortion is the cause of one woman dying every seven minutes worldwide and in India one woman dies every 2 hours. So safe abortion services needs to be accessible to every woman and provided by well trained health personnel. Unrestricted use and over the counter purchase of drugs for medical abortion is detrimental for maternal health leading to maternal mortality and morbidity. There is few potential risk of medical abortion-

- Incomplete abortion which may need to be followed by surgical abortion.
- An ongoing unwanted pregnancy if the procedure doesn't work.
- Heavy and prolonged bleeding
- Infection
- Fever

Proper dose, timing, route and counseling can prevent serious complications. It is cost effective, easy to use and patient privacy is maintained. Women undergoing medical abortion should be educated about contraception and made aware of hazards of unsafe abortion. Our study shows that mifepristone 200mg orally and Misoprostol 800µgm is safe, convenient to use, cost effective if taken under proper guidance of a health personnel.

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