International Journal of Medical and Health Research
ISSN: 2454-9142
Received: 08-08-2018; Accepted: 09-09-2018
www.medicalsciencejournal.com
Volume 4; Issue 10; October 2018; Page No. 35-38

Safety, efficacy, acceptability & complication of Medical Abortion with mifepristone (200mg) & misoprostol (800micrograms) in pregnancy with gestation up to 63 days: A prospective observational study

Anjali Tudu[1], Mirja Tudu[2]
[1] MD OBS and Gynae RIMS Ranchi, Jharkhand, India
[2] MD PSM, Associate professor MGM Medical College Jamshedpur, Jharkhand, India

Abstract
Aim: The aim of this study is to evaluate the role of combination of mifepristone and misoprostol in first trimester termination of pregnancy, regarding safety, efficacy, acceptability and complication.
Materials and Method: The study was conducted at Rajendra Institute of Medical Sciences, Ranchi in department of Obstetrics & Gynaecology from December 2016 to February 2017.
The cases were selected from 200 patients (prescribed and non-prescribed) attending OPD & Labour Room of the department of Obstetrics & Gynaecology.
Results: In my study, 83(41.5%) cases were prescribed out of which 72 and 10 were complete and incomplete respectively, followed by 1 case of failure.
To this 117 (58.5%) out of total were non-prescribed out of which 62 and 54 were complete and incomplete respectively followed by 1 case of failure. In my study, side effects like fever occurred in 12.5% cases, nausea 9% cases, diarrhea 7.5% cases, rigor 6.5%, headache 6%, and vomiting 5% cases.
Conclusion: Unsafe abortion has a shocking picture of one women dying every seven minutes world-wide and in India one women every 2hrs. Unsafe abortion has a shocking picture of one women dying every seven minutes world-wide and in India one women every 2hrs.

Keywords: first trimester termination, mifepristone, misoprostol, unsafe abortion

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 [1]. Abortion is defined as termination of pregnancy by any means before the fetus is viable.
Willful termination of pregnancy prior to the age of fetal viability has been controversial at all times. However, many governments, the world over have liberalized "Abortion laws" in keeping with changing times, 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.
In India, the MTP Act was adopted as a health measure, way back in 1972 to avoid death due to criminal abortion [2].
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 abortion performed globally is approximately 46 million annually; of these 26 Million take place in countries where abortions are legalized. In India, 6.7 million MTPs take, place out of which 40% pregnancies are unplanned and 25% are unwanted [2, 3, 4].
Despite the law,40-50% abortions are unsafe termination of pregnancy done by an unqualified person under unhygienic conditions.
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 the maternal morbidity and mortality due to illegal, unsafe abortions [6, 7].
Such unsafe abortions lead to much complication, which is a drain on scarce resources. Unsafe abortion leads to prolonged morbidity and also a major cause of maternal mortality, accounting for about 12% of maternal deaths [7].
Medical abortions, the termination of pregnancy through the use of a drug or a combination of drugs, has the potential to reduce complications and to expand access to abortion provided by specially trained clinicians. Today, in most cases, safe and efficient medical abortion services can be offered or improved by minor changes in existing health care facilities.

Materials and Method
The present prospective study was conducted at Rajendra Institute of Medical Sciences, Ranchi in department of Obstetrics & Gynaecology from December 2016 to February 2017.
The cases were selected from 200 patients attending OPD & Labour Room of the department of Obstetrics & Gynaecology.
Indication for performing a medical termination of pregnancy were as per guidelines of MTP Act of India. Termination was done for one or more of the following reasons: in order to save

the life of the women, in view of substantial risk if child was born and it would suffer from such mental and physical health of women, in view of substantial risk if child was born and it would suffer from mental and physical abnormalities, pregnancy due to rape or it are caused due to failure of contraception.

History and physical examination was recorded and an ultrasonographic evaluation was done to confirm the gestational age and ectopic pregnancy. On day 1-tab Mifepristone(200mg) and day 3-tab Misoprostol (800microgram) is given After 15 days of intake of mifepristone patient called for follow up with USG Report to rule out any retained product of conception.

Inclusion criteria

a) Patients selection:-In this study two types of patients will be included.
   1. Outdoor patients: -Patients taking MTP pills under our supervision.
   2. Indoor patients: -Patients taking MTP pills without prescription & coming to hospital with complications.
      - continues heavy bleeding per vagina
      - severe pain abdomen
      - intractable vomiting
      - shock

b) Pregnancy of <63 days of gestation were selected based on menstrual history and clinical examination with or without USG.

c) Selected cases were able to give consent to the procedure, either by reading consent document or by having consent document read to her.

d) Selected cases were willing to follow study procedure.

e) Patient were able to speak and understand.

f) No contraindication to mifepristone and misoprostol.

Exclusion criteria

a) Pregnancy of > 63 days of gestation.

b) Allergy or contraindication to misoprostol or mifepristone.

c) ectopic pregnancy

d) Patient with diagnosed bronchial asthma, heart disease, coagulation disorder, renal disease, jaundice.

Results

In this study total 200 cases were studied and the result have been presented in table form and graphs as follows:

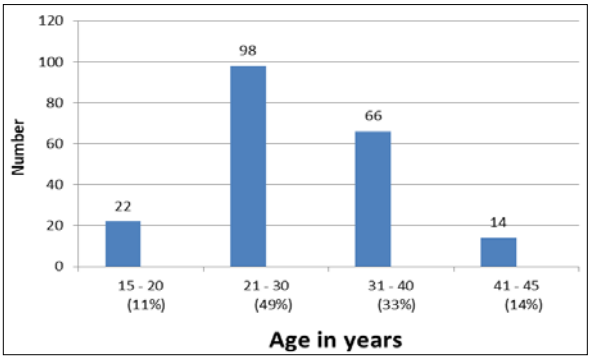

Fig 1

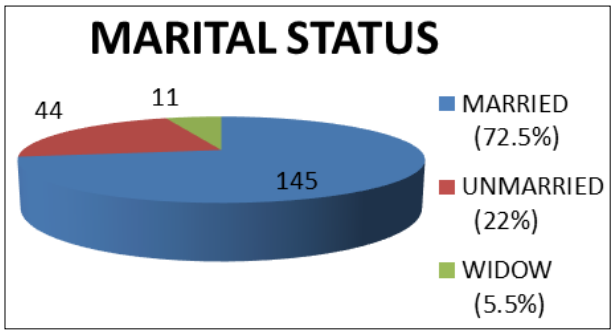

Fig 2

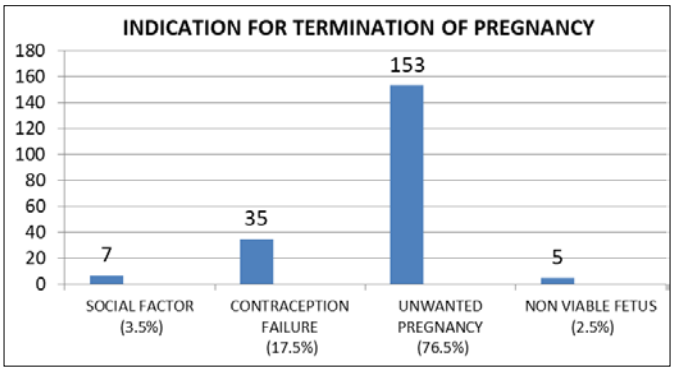

Fig 3

Table 1: Distribution of cases according to use of the drug

	Total	Complete abortion	Incomplete abortion	Failure
Prescribed	83 (41.5%)	72	10	1
Non-prescribed	117(58.5%)	62	54	1
Total	200	134	64	1

Table 2: Severity of side effects

Side effects	No. Of patients	Percentage (%)
Nausea	18	9
Fever	25	12.5
Vomiting	10	5
Diarhhoea	15	7.5
Headache	12	6
Rigor	13	6.5
Total	93	46.5%

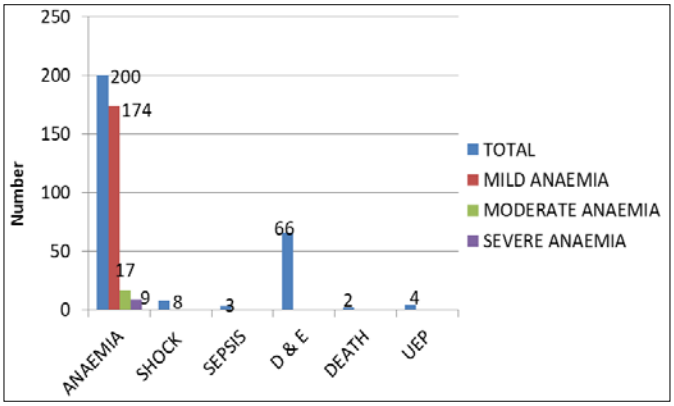

Fig 6: Complications

In my study, total of 200 cases were included, 83(41.5%) cases were prescribed out of which 72 and 10 were complete and incomplete respectively, followed by 1 case of failure.
To this 117 (58.5%) out of total were non-prescribed out of which 62 and 54 were complete and incomplete respectively followed by 1 case of failure in my study, side effects like fever occurred in 12.5% cases, nausea 9% cases, diarrhea 7.5% cases, rigor 6.5%, headache 6% and vomiting 5% cases.
However, 53.5% of cases did not have any side effects.
Incidence of fever was little higher in our study. In the present study group complication was anaemia WHO classification (Mild anaemia 87%, moderate anaemia 8.5% and severe anaemia 4.5% of cases respectively.
12.5% cases needed blood transfusion, 27% cases injectable iron was given, and 52% cases oral iron was given.
Other complication like D&E 33%, Shock 4%, sepsis 1.5% which was managed with higher injectable antibiotics, undiagnosed ectopic pregnancy 2% which further landed into laparotomy, and death occurred in 1% cases respectively.
The success rate with this regime was 88%, failure rate was 1%, complication 3%. There were no major side effects with Mifepristone. The average bleeding after misoprostol insertion was 10 days and 80% women had more bleeding than normal period. All of them had pain. Only 13.3% needed analgesic. women (96%) were satisfied with the method. It is observed that failure rate and complications are less in prescribed patients as compared to non-prescribed ones.

Discussion

The present study was carried out with mifepristone and misoprostol. Study included 200 cases.
In the present study, maximum number of cases, (49%) were between 21-30 yrs. next common group (33%) were between 31-40 yrs. followed by (11%) 15-20 yrs. and (7%) 41-45 yrs of age.
These women due to fear, ignorance, hesitation, and less awareness seek medical help late.
Fox *et al* (2002) also reported maximum number of patients i.e. 49% belonged to 21- 30 yrs in series of 80 patients. EI Refacy Rajasekar D. *et al*. (!1995) reported that 36% of patients were in age group of 26-30 years in series of 263 patients.
Eric A. Schaff *et al*. (2002) reported that 46% of patients were in the age group of 26-30 years in series of 1045 women. Data from the study of Eric A. Schaff, M.C. Fox are similar to our study.
In the present study majority of the patients were from the rural (56.5%) and rest (43.5%) were from urban area**.**
The high percentage of cases in my study from urban area may be explained by the fact that women from Ranchi and surrounding districts are coming here or referred to RIMS as RIMS is Tertiary Centre with better facilities.
Less than 43% of cases coming from rural area may be due to lack of awareness and poverty preventing them to come this institution.
In my study, majority of patients are from lower class (58%) & (41.5%) are from middle class.
The high incidence of first trimester abortion in lower class is due to ignorance, illiteracy, hesitation to come at time to seek treatment at hospital and also RIMS is a Govt. Hospital with facilities so more ladies from these classes come to seek treatment here.
In my study, majority of women 65.5% cases were literate and 34.5% cases were illiterate
In the present study 72.5% were married 22% were unmarried and 5.5% were widow.
The high percentage of married women is due to the fact that they either come to seek treatment for failed contraception or with ultrasound diagnosed non-viable pregnancy or they had some medical problems where continuation of pregnancy would endanger their life.
The percentage of unmarried and widow is also high due to ignorance, poverty, social taboo, lack of proper sex education and lack of knowledge of proper use of contraception.
Michelle. C. Fox *et al*. (2002) however reported that 37% were having 1 child. In another study of 40 women they reported that 43% of patients were having no child and unwanted pregnancy was the commonest indication for MTP. Schaff *et al*. (2002) observed that 40% of patients were having 1 child and they resorted for medical abortion for spacing purposes.
In my study most of the women had completed their family whereas in their study, primiparous and nulliparous women were more in number because of planned family practice, which exist there.
In the present study, majority of cases 76.5% had their termination of pregnancy due to unwanted pregnancy followed by contraception failure 17.5% cases, followed by 3.5% for social factors and by 2.5% for non-viable fetus.
The cause for high percentage of termination of pregnancy due to unwanted pregnancy is due to the fact that many of them are unmarried or widow, ignorant, poor with least sense of sexual awareness.
Michell C Fox *et al*. (2002) observed that maximum number of women (35%) in 40 women series came forward for termination of pregnancy due to having small children. This data is comparable to my study.
Michelle C Fox (2002) observed in another study of 40 women that 43% patients were unmarried. It was the reason for seeking abortion. So, number of unmarried patients was more in our study.
In the present study majority 18.5% of cases were primigravida followed by G3 15.5%, G2 10% and >G4 56%.
The high percentage of primi cases is because of the reason as many of them were unmarried and due to fear, anxiety, and ignorance they come late for termination whereas others had ultrasound diagnosed non-viability of fetus.
The incidence of multigravidae is also high either due to failed contraception or as method of family planning.
In my study, majority of patients were of gestational age 7 to 9 weeks 53%, followed by 5 to 7 weeks 45.5% followed by <5 weeks 1.5%.
E.A. Scaff (2002) *et al*. observed that mean gestation period was 47 days in series of 1011 women. Savita Desai *et al*. (2003) reported that 50% patients were of 6weeks pregnancy 27.7% were of 5weeks and 22.2% were of 7 weeks pregnancy. The duration of pregnancy in present study is almost similar to other studies except 53% for 7-9 weeks which may be due to late decision making for the termination of pregnancy.
In my study, 83(41.5%) cases were prescribed out of which 72

and 10 were complete and incomplete respectively, followed by 1 case of failure.

To this 117 (58.5%) out of total were non-prescribed out of which 62 and 54 were complete and incomplete respectively followed by 1 case of failure.

Eric A Schaff *et al*., (2002) reported 92% success rate up to 63 days gestation.

Aubney *et al*., (1995) reported that success rate in women at <63 days gestation with standard regimen were 97.6% at <42 days gestation and 94.8% between 43-49 days gestation.

In 1998 Spitz IM *et al*., reported that success rate in women <63 days gestation was 93%.

In 1993 Mc Kenley reported success rates at less than 49 days gestation was 96.7% and 89.8% at 50-63 days gestation.

Success rate of these studies is almost similar to my study.

These data of incomplete abortion requiring surgical evacuation was almost similar to our study.

In my study, side effects like fever occurred in 12.5% cases, nausea 9% cases, diarrhea 7.5% cases, rigor 6.5%, headache 6%, and vomiting 5% cases.

However, 53.5% of cases did not have any side effects.

Savita Desai *et al*. (2003) reported nausea and vomiting in 8.3% of cases in a series of 48 patients. It was comparable to present study.

EA Schaff *et al*., 2002 reported diarrhea in 32% case. Incidence of diarrhea was lesser in my study.

H Honkanen *et al*. (2004) reported fever in 4.7% of cases.

EI Refacy *et al*. (1995) reported incidence of fever to be 9%.

Incidence of fever was little higher in our study.

In the present study group complication was anaemia WHO classification (Mild anaemia 87%, moderate anaemia 8.5% and severe anaemia 4.5% of cases respectively.

12.5% cases needed blood transfusion, 27% cases injectable iron was given, and 52% cases oral iron was given.

Other complication like D&E 33%, Shock 4%, sepsis 1.5% which was managed with higher injectable antibiotics, undiagnosed ectopic pregnancy 2% which further landed into laparotomy, and death occurred in 1% cases respectively.

Conclusion

Unsafe abortion has a shocking picture of one women dying every seven minutes worldwide and in India one women every 2hrs. So, safe abortion services which has been legalized, therefore need to be easily available and should be provided by well-trained health personnel. Health system infrastructure, including equipment &supplies should be easily available, convenient & effective so that women can have rapid access to these services.

Over the counter purchase of the MTPKIT has led to many detrimental effect on maternal health. Patients are unaware of the proper dosage, timing, route and complication of the drug.

Unrestricted use of these drugs has led to serious complication like maternal mortality and many co morbidities.

in the other hand supervised use of the drug is an easy and cost-effective way of termination of pregnancy and maintaining patient privacy.

The women undergoing MTP should be educated about contraception. There should be programme for proper sex education, contraception & benefits of early termination of pregnancy.

This study shows that lower dose of Tab Mifepristone 200mg orally & Tab Misoprostol 800 microgram orally is quite safe, convenient and cost effective if taken under proper guidance of a doctor.

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