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Medical abortion by Mifepristone with vaginal Misoprostol in women in tertiary care hospital of North India: A comparative study

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Abstract

Introduction: According to the World Health Organization (WHO), every 8 minutes a woman in developing nation die due to complications arising from an unsafe abortion. Abortion is one of the most fundamental healthcare needs of a woman. In spite of legislation of abortion, the incidences of illegal & unsafe abortion have not come down in our Country & quality & coverage of MTP services remain poor. Medical abortion with a combination of Mifepristone and Misoprostol is safe and effective alternative to Suction & Evacuation upto 9 weeks of gestation.

Methods and Material: All 200 patients attending outpatient and emergency department of obstetrics and gynaecology, a tertiary care center with history of intake of abortion pill (mifepristone and misoprostol). And all the patients were divided into two groups, Group A: 100 Women with Amenorrhea ≤ 49 days. Group B: 100 Women with Amenorrhea 50-63 days. After confirming gestational age by ultrasound, and after written informed consent, following regimen was followed while prescribing the study drugs. Mifepristone standard regimen.

Results: The baseline data of the 200 women enrolled in the study. The two groups were comparable in age, parity, previous MTP and previous LSCS. 80% women in group A and 68% women in group B aborted within 4 hours. The difference was not found to be statistically significant. The requirement of additional dose of Misoprostol in both the groups. 20(20%) women in group A and 32(32%) women in group B required additional dose. The difference was not statistically significant. The average duration of bleeding was significantly longer in women with 50-63 days of gestation (7.33 ± 2.32) days as compared with women with gestational age ≤ 49 days (6.50 ± 2.49), $P < 0.5$. Adverse effects observed in the two groups.

Conclusion: Medical abortion is effective and safe when carried out under medical supervision. Our study has demonstrated that the use of this combination can be effectively and safely extended for inducing abortions in women with amenorrhoea upto 63 days (9 weeks gestation).

Keywords: Mifepristone, vaginal Misoprostol, Suction & Evacuation

Introduction

According to the World Health Organization (WHO), every 8 minutes a woman in developing nation die due to complications arising from an unsafe abortion. In India there is an unmet need of contraception. Women use abortion pill as an alternative to contraception which results in morbidity and mortality. Medical abortion is a safe method of termination of pregnancy when performed as per guidelines with success rate of 95 to 99%.^[1] Commonly used drugs for medical methods of abortion are a combination of mifepristone and misoprostol. Drug Controller General of India approved the use of Mifepristone (in April 2002) and Misoprostol (in December 2006) for termination of pregnancy up to 49 days gestation period. In December 2008, Mifepristone + 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^[2]. 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^[3]. Despite this, it has been perceived by the society that, medical abortions are extremely safe option even in hands of untrained personnel, leading to it's over the counter dispensing and possibly increase in unsupervised terminations and life threatening complications^[4, 5].

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Abortion is one of the most fundamental healthcare needs of a woman. In spite of legislation of abortion, the incidences of illegal & unsafe abortion have not come down in our Country & quality & coverage of MTP services remain poor. Septic abortion contributes to 10% of maternal mortality. So high quality safe abortion services should be available even at grass root levels to avoid the risk of women turning to un-authorized personnel. Significant advances have occurred during last 15 years in the development of medical methods for pregnancy termination. Use of drugs to induce abortion is safe and non-invasive alternative. The training is simpler and complications are minimum. This can be an attractive option for healthcare systems of developing countries where limited resources and trained personnel are available to carry out surgical abortions. Medical abortion with a combination of Mefipristone and Misoprostol is safe and effective alternative to Suction & Evacuation upto 9 weeks of gestation. The present study aims to conduct prospective comparative clinical study using Mefipristone and vaginal misoprostol combination in women.

Methods and Material

All 200 patients attending outpatient and emergency department of obstetrics and gynaecology, a tertiary care center with history of intake of abortion pill (mifepristone and misoprostol). And all the patients were divided into two groups, Group A: 100 Women with Amenorrhea ≤ 49 days. Group B: 100 Women with Amenorrhea 50-63 days. Anemia, Hb $< 8\text{gm\%}$, Suspected/confirmed Ectopic pregnancy/ undiagnosed adnexal mass, Coagulopathy or anticoagulant therapy, Chronic adrenal failure or steroid therapy, Cardiovascular, renal, liver, respiratory disease, Glaucoma, uncontrolled seizure disorder, Lack of access to emergency services. After confirming gestational age by ultrasound, and after written informed consent, following regimen was followed while prescribing the study drugs. Mifepristone standard regimen.

Day 1: Women 200 mg Mifepristone orally. Anti-D was given to Rh negative mothers.

Day 3: 400 μg Misoprostol vaginally. Schedule was completed even if the woman aborted with mifepristone only. At the end of 4hrs if patient didn't abort re-instillation of 400 μg vaginally. Women were asked to note onset of bleeding, timing of passage of product of conception, duration of bleeding and side effects.

Day 14: Women were called for follow-up and clinical and ultrasound evaluation was done.

Results

The baseline data of the 200 women enrolled in the study. The two groups were comparable in age, parity, previous MTP and previous LSCS. 80% women in group A and 68% women in group B aborted within 4 hours. The difference was not found to be statistically significant. The requirement of additional dose of Misoprostol in both the groups. 20(20%) women in group A and 32(32%) women in group B required additional dose. The difference was not statistically significant. The average duration of bleeding was significantly longer in women with 50-63 days of gestation (7.33 ± 2.32) days as compared with women with gestational age ≤ 49 days (6.50 ± 2.49), $P < 0.5$. Adverse effects observed in the two groups.

Table 1: Baseline Characteristics

	Gestational age ≤ 49 days (Group A) (n=100)	Gestational age 50-63 days (Group B) (n=100)	'P' value
Age in years Mean \pm SD Range	28 ± 4.59 20-40	29 ± 5.41 20-40	> 0.05
Parity Primigravidas Multigravidas	11(11%) 89(89%)	7(7%) 93(93%)	> 0.05
Previous MTP	7(7%)	7(7%)	> 0.05
Previous LSCS	6(6%)	5(5%)	> 0.05

Table 2: Induction abortion Interval.

Induction Abortion Interval (In Hours)	Gestational age ≤ 49 Days (Group A) (n=100)	Gestational age 50-63 Days (Group B) (n=100)	'P' Value
≤ 4	80(80%)	68(68%)	> 0.05
≤ 4	20(20%)	32(32%)	> 0.05

Table 3: Additional Dose of Misoprostol

Gestational age (In Days)	Women required Additional Dose of Misoprostol	'P' Value
≤ 49 (Group A)	20(20%)	> 0.05
$> 50-63$ (Group B)	32(32%)	> 0.05

Table 4: Average duration of bleeding

Gestational age (In Days)	Average duration of bleeding	'P' Value
≤ 49 (Group A)	6.50 SD ± 2.49	> 0.05
$> 50-63$ (Group B)	7.33 SD ± 2.32	> 0.05

Discussion

In worldwide each year 42 million pregnancies end in induce abortion and in which 20 million are unsafe and 95% of these occur in developing countries.^[6] In India MTP Act was passed in 1971, As per the central health management and information (HMIS) system of national rural health mission, a total of 11.06 lakh abortions were recorded in the year of 2008-09 in India to prevent unsafe and illegal abortion with the aim of reducing the number of maternal morbidity and mortality due to unsafe abortion.^[7, 8] Women take the abortion pill at any gestational age and are not aware about possibility of serious life threatening condition like hemorrhagic shock, ectopic pregnancy. Researchers continue to modify medical abortion regimens to provide optimal alternatives for women seeking early pregnancy termination. The addition of vaginal misoprostol may extend the use of medical abortion up to 9 weeks. The complete abortion rate in our study is in agreement with that of Peyron *et al.*^[9] They found a success rate of 98.7% with additional dose of misoprostol. However, they conclude that the addition of second dose of misoprostol does not necessarily increase the overall efficacy. Ashok *et al* reported a high (96.7%) rate of abortion in 1072 women with 50 to 63 days of gestation.^[10] Schaff *et al* in their study of 933 women at less than or equal to 56 days of gestation reported a success rate of 97%.^[11] Pyamar and Creinin proved the efficacy of vaginal misoprostol in achieving complete abortion between 7 to 9 weeks of gestation.^[12] There was no statistically significant difference in induction-abortion

interval and requirement of additional dose of misoprostol between both the groups in our study. Aubeny *et al* reported in his study that the second dose of misoprostol did not improve the efficacy in comparison with the standard regimen. ^[13] In our study, the average duration of bleeding was found to be statistically significantly higher in women with higher gestational age. None of the women required blood transfusion. Complications like excessive bleeding per vaginum, rupture ectopic and rupture uterus can be life threatening in already anaemic patient. When drugs are given under medical supervision, in most of the studies, women bled for median 9 to 13 days yet total blood loss was clinically insignificant. Hemorrhage requiring transfusions occurs in only about 1 in 1000 cases of medical abortions as reported due to heavy bleeding. ^[13, 14] only 1-2 per thousand may need blood transfusion. In a study by Deshpande *et al*, no woman required blood transfusion when drugs were given under medical supervision. ^[15] There are no reports in the literature of laparotomy or hysterectomy for hemostasis after medical abortions. ^[16] However, the possibility of hemorrhage with medical abortion highlights the need for vigilance and early access to medical help.

Conclusion

In India, unsafe abortion is one of the cause of increasing maternal mortality and morbidity, unintended pregnancy is one of the leading cause for which women go for termination of pregnancy in unauthorized condition and such unintended pregnancy can be due to lack of knowledge, apprehension, poverty, denial, and ignorance of contraceptive use. Medical abortion is effective and safe when carried out under medical supervision. Unsupervised use of medical abortion pills was associated with many complications like higher chances of incomplete abortion, hemorrhage, ectopic pregnancy and rupture uterus necessitating blood transfusion. The combination of oral mifepristone and vaginal misoprostol is currently approved for medical abortion in women with amenorrhoea upto 49 days (7 weeks gestation). Our study has demonstrated that the use of this combination can be effectively and safely extended for inducing abortions in women with amenorrhoea upto 63 days (9 weeks gestation).

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