THE JOURNAL OF OBSTETRICS AND GYNECOLOGY OF INDIA

The Journal of Obstetrics and Gynecology of India (November–December 2013) 63(6):370–372
DOI 10.1007/s13224-013-0407-1

ORIGINAL ARTICLE

A Prospective Trial Using Mifepristone and Vaginal Misoprostol in Termination of Pregnancies up to 63 Days of Gestation

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Received: 27 February 2012 / Accepted: 18 April 2013 / Published online: 12 June 2013

Abstract
Purpose According to the Consortium on National Consensus for Medical Abortion in India, on average about 11 million abortions take place annually, and around 20,000 women die every year due to abortion-related complications. This study was undertaken to determine the efficacy and the side effect profile of a regime of 200 mg of mifepristone administered orally followed by 800 mcg of vaginal misoprostol after 48 h.
Methods 50 cases of medical abortion meeting the inclusion criteria were included. On day 1, 200 mg of oral mifepristone was given. On day 3, the patient was called back, and 800 mcg of Misoprostol administered per vaginum and was observed for 6 h. The patients were then called back for review after two weeks to make sure that the abortion was complete. Although, in most cases, this was clinically evident, an ultrasonography was repeated to confirm the completion.
Results Out of the 50 patients, four were lost to follow up, and of the remaining 46 patients, abortions were complete in 44 (95.65 %), while two (4.35 %) patients required surgical intervention.
Conclusions Medical abortion with 200 mg oral mifepristone and 800 mcg vaginal misoprostol is an effective, safe, reliable, and noninvasive method with a success rate of 95.65 %. The availability of this low-cost medical treatment using agents which do not require special cold storage and transport facilities and negligible operating theater time makes this provision of safe abortion feasible in settings especially of developing countries, like India, where medical facilities are limited.

Keywords Mifepristone · Misoprostol · Abortion · MTP

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Introduction

> No woman can call herself free who does not own and control her body. No woman can call herself free until she can choose consciously whether she will or will not be a mother.—Margaret Sanger.

According to the Consortium on National Consensus for Medical Abortion in India, every year on average about 11 million abortions take place, and around 20,000 women die every year due to abortion-related complications [1].

Most abortion-related maternal deaths are attributable to illegal abortions [2].

Number of Abortions reported annually [3]

Years	1972	1975	1980	1985	1990	1995	2000
No. of abortions reported	24,300	214,197	388,405	583,704	581,215	570,914	723,142

In the following table, the number of abortions reported includes legally reported induced abortions.

Various regimens have been proposed for the administration of the mifepristone/misoprostol combination. Numerous studies have overwhelmingly demonstrated the efficacy and safety of the mifepristone/misoprostol regimens [4].

This study was undertaken to determine the efficacy and the side effect profile of a regime of 200 mg of mifepristone administered orally followed by 800 mcg of vaginal misoprostol after 48 h.

Materials and Methods

50 cases of medical abortion meeting the inclusion criteria were admitted, and a detailed present and past history was recorded. Vital baseline parameters like pulse, BP, temperature, etc. were recorded. Detailed per abdomen, per speculum, and per vaginal examination were done.

The hematological investigations included hemogram, blood grouping and typing, urine routine examination, blood sugar level (R), Australia antigen, VDRL and HIV. An ultrasonography was performed to confirm the period of gestation.

Written informed consent regarding the dose of the drug, the side effects, the number of visits required, and the need for surgical intervention in case of failure was taken. All norms as per the MTP Act 1972 by the Government of India were adhered to.

On day 1: 200 mg of oral mifepristone was given.
On day 3: The patient was called back, and 800 mcg of Misoprostol (four tablets of 200 mcg each) was administered per vaginum and was observed for 6 h.
The patients were then called back for review after 2 weeks to make sure the abortion was complete. Although, in most cases, this was clinically evident, an ultrasonography was repeated to confirm the completion of the process.

Abortion failure was defined as a need for evacuation of the uterus by a surgical technique for any reason, including the presence of

- Persistent gestational sac seen sonographically.
- Excessive or prolonged uterine bleeding.
- Incomplete abortion.

Inclusion criteria were a confirmed pregnancy of less than 63 days of gestation in patients of 18 years of age or older who were willing to come back to the hospital for 1–3 follow-up appointments and agreed to have a surgical abortion if the medical abortion fails.

Exclusion criteria included patients with suspected ectopic pregnancy, history of allergy to either Mifepristone or Misoprostol, hypertension, severe hepatic or renal disease, severe anaemia, chronic systemic use of corticosteroids, chronic adrenal failure, coagulopathies, current therapy with anticoagulants, and inherited porphyrias.

Results

70 % of the patients were $\leq$30 years of age. Mean age was 26.44 years. (range 18–42 years), and 52 % of the patients were primigravidas. The mean time interval from the administration of misoprostol to the onset of bleeding was 5.34 h in primigravidas and 4.42 h in multigravidas. In the current study, the mean induction–abortion interval was 4.9 h.

There was a statistically significant difference in the onset of bleeding among primigravidas (5.34 ± 0.51 h) and multigravidas (4.42 ± 0.55 h) ($p < 0.0001$).

There were no cases that started bleeding with mifepristone alone. Bleeding started only after administration of misoprostol. Although there were two cases of incomplete abortion, all the patients responded to Misoprostol with bleeding per vaginum, on the same day of administration. Serious hemorrhage requiring surgical intervention or blood transfusion was not observed in any of the subjects.

The most common side effects were abdominal cramps (74 %), nausea (42 %), and vomiting (22 %). Another common side effect was chills (70 %). Dizziness was seen in 10 % of the patients.

Out of the 50 patients, four were lost to follow up, and of the remaining 46 patients, abortions were complete in 44 (95.65 %), and two (4.35 %) patients required surgical intervention.

The two patients who required a surgical intervention in the current study were in the gestational age group of 49–56 days of gestation. There was a statistically significant association between age $\leq$30 years, and there were side effects like abdominal cramps ($p < 0.01$), fever ($p < 0.01$), nausea ($p < 0.05$), and dizziness ($p < 0.05$).

Discussion

An estimated 41.6 million abortions occur annually and nearly 19 million (55 %) of them are unsafe [5]. Almost there is one unsafe abortion for every ten pregnancies or one abortion every seven life births world wide [6]. The MTP practices have undergone a sea change over the years.

Medical abortion has a great potential of being the modern, reliable, safe and noninvasive method of termination of pregnancy which can serve large number of women particularly in developing countries like India. The safety of the procedure is therefore of global public health importance.

As seen in the present study and various other multicenter trials it is evident that one needs to provide a safe, reliable method of abortion for these young women coming from diverse cultures especially in developing countries like India where surgical facilities and adequately trained personnel are in shortage.

The incidence of primigravidas is probably on the rise on account of the current socioeconomic scenario where the Woman of today is more career oriented. Medical abortion provides a safe and effective alternative without subjecting the woman to the trauma and complication of a surgical intervention.

As vaginal administration of misoprostol results in sustained blood level of drug, rather than a quick peak level and rapid metabolism noted after oral administration, a profile that might explain the greater effectiveness in patients with advanced gestational age [7].

The two patients who required a surgical intervention in the current study were in the gestational age group of 49–56 days of gestation. This is contradictory to the existing literature as it is suggested that there is an inverse relation between increasing gestational age and outcome of medical abortion. This could be attributable to the fact that all failures were seen in primigravidas.

Although the literature does not indicate a significant association between age of the patient and the incidence of side effects, in the current study, there was a statistically significant association between age $\leq$30 years and side effects like abdominal cramps ($p < 0.01$), fever ($p < 0.01$), nausea ($p < 0.05$). and dizziness ($p < 0.05$). However, this may be attributed to the patients in this group, who were predominantly primigravidas.

Contrary to the various available studies in the literature, in the current study all the failures were seen in primigravida patients.

Although various regimes of medical abortion with variable doses of Mifepristone and Misoprostol have been advocated, the current, low dose regime of 200 mg of oral Mifepristone with 800 mcg of vaginal misoprostol represents a cost-effective alternative for medical abortion up to 63 days of gestation.

Conclusions

Medical abortion with 200 mg oral mifepristone and 800 mcg vaginal misoprostol has proven to be an effective, safe, reliable, and noninvasive method with a success rate of 95.65 %. The most common side effect was abdominal cramps (74 %) followed by chills (70 %) and nausea (42 %). Inspite of these unpleasant sequeale, women seemed to accept this method better because of lack of surgical intervention and avoidance of general anesthesia.

Medical abortion by its nature has liberated 95 % of women from rare but serious complications of infection, genital trauma, and anaesthetic mishaps, and thereby has a positive implication on reproductive health of women seeking abortion services.

The drug is licensed for its use up to 9 weeks of gestation; this prompts earlier referral and reduces the morbidity associated with increasing gestation. The mandatory follow-up visit provides an excellent opportunity for reenforcing contraceptive counseling.

The availability of this low-cost medical treatment using agents which do not require special cold storage and transport facilities and negligible operating theater time makes this provision of safe abortion feasible in settings especially of developing countries, like India, where medical facilities are limited.

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