

Efficacy and acceptability of outpatient, single-visit, medical abortion up to 59 days of gestation

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Abstract: This study evaluated the efficacy and acceptability of medical abortion by a modified, single-visit treatment regimen for termination of early (up to 59 days) pregnancy. The study population included 160 women. They were vaginally administered misoprostol 600 mg six hours after oral administration of mifepristone 200 µg. Patients' symptoms were evaluated by telephone, and they were counseled accordingly. Follow-up sonography was performed two weeks later. The reasons patients chose this method were to avoid hospitalization, preference for a natural and noninvasive method, and confidentiality (55%). Side effects were mainly mild abdominal cramps (45%) and prolonged bleeding (2.4%). The success rate of complete abortion was 98.12%, with 1.25% of these patients needing a second vaginal dose to complete the treatment. The single-visit medical abortion method is acceptable and efficacious for women in developing countries.

Keywords: medical abortion, mifepristone, misoprostol, administration, intravaginal

Introduction

In India, 3.9–6.0 million abortions are conducted annually. However, this number is probably a gross underestimate, given that most abortions are either not reported or are performed illegally.¹ Termination of pregnancy has been legalized in India under the Medical Termination of Pregnancy (MTP) Act, 1971. Two methods, ie, surgical abortion and medical abortion, are generally preferred for early termination of pregnancy.

Surgical evacuation is the traditional method. However, this approach has disadvantages, including need for admission to hospital, administration of anesthesia, instrumentation, immediate procedural morbidity, absence from work and loss of manpower, and long-term consequences affecting future pregnancy. These disadvantages can be overcome by employing medical abortion. This is a simple method, involving use of mifepristone with misoprostol as an abortifacient. The combination of these drugs was approved for medical abortion in India in April 2002. Combined with appropriate counseling and supervision, it is safe and acceptable for termination of pregnancy. Since April 2002, various doses of the drugs and routes of administration have been tried and tested. However, the ideal route and dose are yet to be determined. Vaginal administration of misoprostol minimizes gastrointestinal side effects and is more effective locally in the uterus. A strictly supervised procedure and several visits to the clinic are barriers to acceptability of this method. However, lately, self-administration of the drug with telephone evaluation of symptoms and less frequent hospital visits has improved its acceptability. The aim of this study was to ensure more effective

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utilization of this important advancement to maximize the reproductive health of women and maintain women's right to high quality health care services.

Methods

This prospective cross-sectional study was conducted in women seeking termination of pregnancy up to 59 days of gestation and was carried out between January 2007 and May 2008 in the Green Cross Hospital and Sakriti Clinic in Lucknow, India. The women in the study were counseled to help them decide on the method of abortion. As required by the MTP Act, patients were identified and gestational age was confirmed by scanning. A total of 160 patients volunteered to participate in this single-visit treatment study, and written informed consent was obtained from every patient. An emergency contact number and instructions were given to each patient as per protocol. The first 200 µg dose of oral mifepristone was administered to the patients in the outpatient department followed by vaginal administration of 600 mg of misoprostol by the patient at home or by hospital staff six hours later. All patients were instructed to report onset of bleeding/abortion, side effects, and discontinuation of medication by telephone, and these issues were then managed accordingly. A follow-up visit was scheduled on the 14th day after administration of the first dose. To confirm complete abortion, scanning was performed. Every patient filled out a questionnaire regarding choice of method and satisfaction level before and after the abortion. In addition, they also underwent counseling for family planning. The primary outcome was success, ie, complete abortion, after the first dose of vaginal misoprostol and the secondary outcome was complete abortion after the second dose.

Results

The mean age and parity of the patients was 26.28 years and one, respectively. Of the 160 women, 90% were married and 10% were unmarried. In addition, 49.4% patients had one child, while 27.5% had two or more children. Primigravida patients comprised 23.15% of the total study population. Thirty-five percent of the women had undergone termination of pregnancy previously (23.85% once and 11.3% more than once). The proportion of women at weeks 7–8 of gestation was 65%, while those at ≤6 weeks of gestation comprised 10.6% (Table 1).

The success rate in terms of complete abortion was 98.12%, with 1.25% of patients aborting after the second vaginal dose of misoprostol 400 µg. The failure rate was

Table 1 Participants characteristics (n = 160)

Age (years)	Number	Percentage
20–25	74	46.25%
25–30	50	31.25%
30–35	27	16.87%
35–40	9	5.62%
Mean age	26.28 years	
Married	144	90%
Unmarried	16	10%
Parity		
0	44	27.50%
1	79	49.37%
>2	37	23.13%
Mean parity	1	
Prior termination of pregnancy		
1	28	23.8%
>1	18	11.3%
Gestational age		
<6 weeks	17	10.6%
6 weeks	39	24.4%
7 weeks	51	31.9%
8 weeks	53	33.1%

1.88%, with 0.65% requiring surgical evacuation. In 86.9% of patients, vaginal bleeding began within 12 hours of vaginal misoprostol administration, while in 13.1% women bleeding began 12 hours after administration (Table 2).

Discussion

The combination of mifepristone and misoprostol has been shown to be effective for early termination of pregnancy of up to 63 days' gestation.^{2,3} There are various regimens and routes for medical abortion. The usual regimen is the administration of mifepristone followed by oral misoprostol 36–48 hours later.^{4,5,13} Previous studies have revealed that the success rate of complete abortion is very similar in cases where mifepristone doses of 200–600 µg are administered.⁸ Hence, we used the lower dose (200 µg) of mifepristone in our study, followed by administration of a 600 mg misoprostol vaginal tablet six hours later. Vaginal

Table 2 Outcome of medical abortion

Outcome	Number	Percentage
Success rate	157	98.12%
Primary	155	96.87%
Secondary	2	1.25%
Failure rate	3	1.88%
Surgical intervention	1	0.65%
Vaginal bleeding	139	86.9%
<12 hours	21	13.1%
>12 hours		
Not confirmed by ultrasound	36	22.5%
Confirmed by ultrasound	124	77.5%

administration of misoprostol is highly effective because its bioavailability is route-dependent.⁹ By evaluating the questionnaires filled out by the patients in this study before and after abortion, we found that the percentage of women who had previously terminated pregnancy, either by the surgical or medical method, was 35.1%, and 18% of these women preferred this modified regimen. This finding indicates that, given a choice, patients deem surgical abortion to be unacceptable.^{6,7} Furthermore, 92% of our patients chose the medical method offered to avoid hospitalization and because they preferred a noninvasive, natural method, such as a heavy menstrual period. No loss of work, complete privacy and confidentiality, and convenience were the other reasons cited for their preference.^{6,11} In our study, the success rate, ie, complete abortion, was 98.1%, which is comparable with that reported in other studies.^{7,10} However, our findings do not coincide with those of another similar study.¹³ In that study, administration of vaginal tablets six hours after the first dose on the same day was not effective. However, the bioavailability of vaginal misoprostol is three times higher than that of oral misoprostol; hence, the rate of incomplete abortion is lower when misoprostol is administered via the vaginal route than when it is administered via the oral route.⁵ The 1.88% incomplete abortion rate in the current study is comparable with that reported in other studies.¹⁰ The decrease in efficacy with increasing gestational age¹¹ may be the reason why 1.25% patients required a second dose of misoprostol. Our results are better than those of a previous study,¹² and only one patient required surgical evacuation because of excessive vaginal bleeding on the second day after administration of the treatment dose. The mean abortion interval was 7.2 hours, which is comparable with that reported in a similar study.¹³ Side effects, such as nausea, vomiting, diarrhea, abdominal pain, and fever, are dose- and route-dependent,¹⁰ although vaginal administration of the drugs enhances their effects in the reproductive tract and minimizes their effects in the gastrointestinal tract. No such side effects were noted in this study, except for mild abdominal cramps and prolonged bleeding beyond 14 days. The most common disadvantages of our study method were prolonged spotting for more than 14 days, as observed in four patients (2.5%), and the time lag between administration of the drugs and complete abortion.⁶ The procedure acceptability of 96.2% was better than that in another study.⁶ Ninety-three percent of patients preferred this method, would undergo the same procedure if needed again in the future, and will recommend it to others. There were several reasons for this preference, ie, no hospitalization, noninvasive procedure employing natural

methods (heavy menstruation), confidentiality, privacy, convenience, no absence from work, and no frequent hospital visits.⁶ We conclude from our study that, because women do not need frequent hospital visits and strict supervision, they can administer the vaginal dose of the treatment regimen by themselves at home, and telephone evaluation of symptoms with a single consultation visit is appropriate for follow-up. Furthermore, as stated in other studies, home-based medical abortion under limited supervision is an acceptable and effective method for early termination of pregnancy.¹⁴ Further study of this method is now needed in a larger population of women.

Conclusion

Medical termination of pregnancy is a promising alternative to surgical abortion. In our study, women given the options to choose were certain about this method. Only a single visit was required for treatment, and the follow-up visit was replaced by telephone evaluation of symptoms, which is acceptable in terms of safety. This method is highly preferred and efficacious, and maintains women's right to high quality health care services. This method for abortion promises to revolutionize reproductive health care, especially in developing countries, which would also benefit from awareness about the dangers of unsafe abortions and the availability of safe abortion services.

Disclosure

The author reports no conflict of interest in this work.

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