■ *Original Article*

Feasibility and Acceptability of Medical Abortion at BPKIHS

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Abstract

Objective: To test the feasibility and acceptability of a simplified mifepristone-misoprostol regimen for early abortion at BPKIHS. **Methods:** Pregnant women (n=100) with amenorrhea of 56 days or less seeking termination of pregnancy received 200mg of oral mifepristone followed 48hours later by 400 μg of oral misoprostol, administered either at home or at the clinic. Prospective data were collected to determine the women's experience, abortion outcome, and the operational requirement for providing the method. *Result*: Most (91%) of the 88 women with known outcomes had successful medical abortions. Given the option, most (95.4%) women elected to administer the misoprostol at home. **Conclusion:** A simplified medical abortion protocol, including home administration of misoprostol, is highly safe, effective acceptable and feasible in our setting.

Keywords: medical abortion, mifepristone, misoprostol

Introduction

Abortion was legalized in Nepal in September 2002 and services in public sector facilities were started in early 2004[1]. Comprehensive abortion services are now available in country's 75 districts. Over 200 000 women have received safe abortion services since the change in legislation. Before this time Nepal had one of the highest maternal mortality ratios (MMR) in Asia, at 539 per 100000 live births[2], and clandestine abortions contributed significantly to it. According to ministry of health figure, 54% of all maternal deaths occurring in the hospitals were due to unsafe abortion[3]. But even in post-legalization era unsafe abortion continue to occur in a large scale. Between 2005 April to 2008 September (3.5years) there were 1071 abortion related admissions in gynecology unit of BPKIHS, out of which 70 were unsafe abortions[4]. This may be result of difficult access to safe abortion for many Nepali women. The absence of provider trained in surgical methods or lack of equipments or infrastructure may limit access to abortion particularly in rural areas[1].

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Mifepristone-misoprostol regimen for early abortion promises a new nonsurgical option to women seeking early pregnancy termination. Indeed, this combination regimen for early abortion is established as safe, effective, and acceptable to woman and health care provider in Europe and in several developing countries[5,6]. Studies show that medical abortion is effective in settings lacking surgical abortion services[7].

This study assessed the feasibility and acceptability of provision of a simplified medical abortion protocol, including home administration of misoprostol among women coming to BPKIHS. It aims to document the experience of the women and the operational requirements for the provision of medical abortion.

Methods

The study population was recruited from women seeking pregnancy termination at BPKIHS between February 2007 and January 2008. Approval and permission to conduct the study was taken from BPKIHS Ethics Committee. Women were eligible to participate if they had an intrauterine pregnancy of 56 days or less since their last menstrual period; lived or worked within a reasonable distance *(please specify in approx. km.)* of the study site and/or were

willing to provide their telephone number and/or address for follow-up; were in good general health; had no contraindications to mifepristone or misoprostol; and were willing to return for a follow-up visit. Women who agreed to participate were enrolled in the study after taking written informed consent. Women were not compensated for their study participation.

Women enrolled in the study were required to make at least 2 clinic visits. At the first visit, women were given 200 mg of oral mifepristone after which they were given the choice either to take the misoprostol at home or at the clinic. All women were counseled to expect bleeding and/or pain at the time of misoprostol administration and were given a mild analgesic (500 mg of paracetamol) to be taken as needed. Women who elected to take the misoprostol at home were counseled to take the misoprostol tablets even if they believed the abortion had occurred after mifepristone administration and to administer misoprostol when someone is available to assist them, if needed.

Women returned for follow-up at the clinic 12 days after misoprostol administration. At the follow-up visit, a pelvic examination and case interview were performed to assess abortion status. Women who had had a complete abortion were discharged from the study. If a complete abortion had not taken place, it was determined whether the pregnancy was ongoing and viable (i.e. either a fetal cardiac activity on ultrasnogram or 2 weeks of fetal growth). Women with ongoing viable pregnancies were offered a surgical evacuation. Women with nonviable pregnancies or incomplete abortions at the follow-up visit were given the option of waiting another week before surgical intervention. Women who elected to wait an additional week were asked to return to the clinic 1week later for a final clinical assessment. At both the initial and follow-up visit, ultrasound was used to confirm the gestational age and to assess the abortion status if needed. Ultrasound was used to determine eligibility for medical abortion in 12% of cases (n=12). For none of the women ultrasound was needed to confirm abortion status at a follow-up visit. All women were provided with the telephone number of the clinic and/or the mobile number of the clinician and information on referral facilities. Women were instructed to telephone the clinic if they had any questions about symptoms or adverse effects, or if they had any other concerns. Women were advised to return to the clinic if their bleeding was very heavy or persistent, or if they required surgical intervention at any time. At each clinic visit, clinical and acceptability data were collected from women using standardized questionnaires. Data were analyzed using SPSS version 12.0.

Results

0ne hundred women who sought pregnancy termination at BPKIHS between February 2007 and January 2008 participated in the study. Most of the women in the study belonged to the age group between 25 - 35 years with a median age of 27 years and had completed 10 years of schooling .For 11 women this was their first pregnancy while 64 women reported the present abortion to be their first termination. The majority of the eligible women presented at d" 6 weeks of pregnancy. Period of gestation was based on menstrual history alone in 68 women. For twenty women menstrual history and clinical examination was used while ultrasonography was used only in twelve women. (Table 1).

Table 1
Participant characteristics (n= 100)

Case characteristics	No. (range/%)
Median age (years)	27 (18-46)
Median years in school	10(0-25)
Primigravida	11(11)
Prior elective abortion	36(36)
Median gestational age (days)	44(30-56)
Gestational age in weeks	
d" 6 weeks	47(47)
6-7	31(31)
7-8	22(22)

At enrollment women were asked reasons for opting medical method of termination of their pregnancy. Of the most frequently cited category of reasons, offered by 64% of women, was, the regimen is easier, simpler and more comfortable. More than 50% said, they chose medical abortion because of fear of surgery and manipulation while 31% women said it is more private and confidential.

As a pilot study the first ten participants recruited at the study were not given the option of choosing the site for misoprostol administration and were called at the clinic on day 3 of study for oral misoprostol

administration. Out of remaining ninety women, 87 women i.e. 96.66% selected home administration of misoprostol while only 3 women (3.33%) selected clinic administration. So, there were 13 women in clinic user group and 87 women in home user group.

When asked about the reasons for their choice, most of the women in home user group reported that it was more compatible with their duties at work or at home (58.62%) and it is easy (52.87%) and were more comfortable at home (41.37%).(Table-2)

Table-2: Selection of site of misoprostol administration (%) [a]

Reasons	Home user (n=87)	Clinic user[b](n=3)
Convenient for work /home duties	58.62 (51)	0 (0)
Easier	52.87 (46)	33.33(1)
comfortable at home	41.37 (36)	0 (0)
Confidential	24.13 (21)	0 (0)
Less travel	16.09 (14)	0 (0)
Stay nearby so can come when needed	12.64 (11)	0 (0)
Safer, fear of complication	3.44 (3)	66.66(2)
No response	4.59 (4)	0 (0)

[a] Women gave one or more than one reason
[b] The first 10 women were not given option of choosing the location of misoprostol administration

All of the 13 women in the in-clinic misoprostol administration group followed up on time on the day of appointment. Out of them two women believed that their abortion is complete as they had heavy bleeding and observed expulsion of products of conception. One of them also said she no longer feels pregnant. On clinical assessment indeed one was found to have complete abortion and it was uncertain in another. Ultrasound was used in two out of 13 women. (Table-3)

Table-3: In clinic misoprostol administration (n=13)

Categories	No (%)	
Followed up on time	13 (100)	
Women belief about abortion	Complete	2(15.38)
	Reason: Expulsion observed	2
	Reason: No longer feels pregnant	1
	Reason: Heavy bleeding	2
Clinical assessment among above two women	Complete	1
	uncertain	1
Ultrasound used	yes	2

Out of 100 women, 17 women did not return as scheduled for their follow up visit. Diligent efforts were made to trace them by calling. Upon calling five women could be followed up. The remaining 12 women were finally lost to follow-up. All the women lost to follow up were in home user group. So, total of 88 women are included in final data analysis.

Of the 88 women, two women in home user group had medically indicated surgical intervention after taking mifepristone but before they took misoprostol. They were discharged from clinic after surgical intervention and were not followed up till day15 of study but were included in final analysis. Out of 88 women, excluding the five women who were contacted over phone and two women discharged earlier, 81 women were expected to follow up on study day 15. Twenty-one did not comply with the protocol and followed up late. Total of 86 women had taken tablet misoprostol and among them 83 (96.51%) had taken it on time. Out of three women who didn't take misoprostol on time, two forgot to take and took it the next day and one had

misunderstood the instructions and took it one day earlier. Eventually all these three had successful abortion.

Upon follow-up visit 78(90.69%) women had complete abortion, while 8(9.30%) had incomplete/ uncertain status of their pregnancy. Ultrasound was used for assessment in 6 women. One of them with incomplete abortion requested for surgical evacuation which was offered to her at study clinic. Remaining seven women agreed for extended follow-up visit which was scheduled after one week. All women returned on time on date of extended follow-up visit. Out of seven women three had complete abortion while 4 had incomplete abortion. Ultrasound was used for assessment in 3 women. All these four women were provided surgical evacuation. Women with complete abortion either on scheduled follow-up visit or on extended follow-up visit or after surgical intervention were discharged from study. One woman in home user group after being discharged on scheduled follow up visit with successful abortion returned after 11 days with incomplete abortion. Surgical intervention was provided to her. So finally 92% women who followed up had successful medical abortion while seven (8%) women had failure i.e. they required surgical method for completion of abortion process. (Table 4)

Table-4: Final Medical abortion outcome (%)

	N=88
Success rate	92(81)
Failure rate	8(7)

Precisely 91.36% ranked the experience as very or moderately satisfactory. Patient for whom the method failed were less likely to rank the medical abortion regimen as very or moderately satisfactory, although 12.5% gave these ratings. Women for whom the method failed were more inclined than successful user to classify the experience as unsatisfactory (25% vs 1.25%). Two third of women rated medical abortion as more satisfactory than their previous surgical abortion. Women also reported they would choose the method again (if needed) in future or recommend it to friends. In both respects mifepristone-misoprostol use won nearly universal approval: 88.63% would select the method again, & 92.04% would recommend it to a friend or relative.

When asked about the best and worst features of the regimen 75% cited at least two best features and 44% cited at least two worst features. The most commonly cited positive attributes were no surgery and/or hospitalization (55.68%); easy, simple and faster (37.5%); private and more confidential (35.22%); natural like menses (23.86%); and fewer risk or complication (18.18%). The most commonly cited worst features were bleeding or fear of heavy bleeding (43.18%) & uncertainty of the procedure (35.22%).

The final feasibility questions pertained to the possible use of the regimen's two drugs by women in their homes. Most of the home as well as clinic user prefer to take the drugs at home accounting to total of 95.45%. Among clinic user 84.61% of women would like to take the drugs at home in future if needed. Even among women having unsuccessful medical abortion (n=8), 75% would like to take the drugs at home for future use.

Serious side effects were rare. None of the participants required blood transfusions. The most prevalent side effects were similar to those experienced with spontaneous abortion: cramping and bleeding. However, although these effects were included as side effects, they may be symptoms of a medical abortion; indeed, if they do not occur, the woman is unlikely to have a successful medical abortion. The average duration of all bleeding was about 10 days. Women reported to have heavy bleeding for mean duration of 3.37 days, ranging from 1day to 11days. Other side effects were feeling of excessive weakness, headache and dizziness. Most of these side effects were self limited and were manageable at home.

Discussions

A simplified medical abortion using a regimen of 200mg mifepristone + 400ìg oral misoprostol is a highly effective, safe and acceptable method of pregnancy termination. Nearly all women (92%) with known outcomes had successful medical abortions. Women also reported high level of satisfaction with the method.

The abortion success rate of 92 % observed in the study is comparable with international experience with this regimen for pregnancy of 56 days or less since the last menstrual period, which demonstrates success rates from 92%–96%[6]. This 2-visit medical abortion

protocol allowing home use of misoprostol offers substantial cost savings and increased convenience, both for clinic systems and women, an important factor in low-resource settings like Nepal.

Although the study did not assess provision of medical abortion in clinics without surgical back-up services, the findings suggest that future programs should explore this option. Existing referral mechanisms for the management of spontaneous abortion and pregnancy complications may be appropriate for the provision of routine back-up services for medical abortion.

Since the study is done at BPKIHS with good infrastructure compared with other urban centers or rural areas of Nepal, the findings may not be generalizable to regions where transportation services and referral networks are less developed. Further study should be done to examine the introduction of the method in rural Nepal and employ mid-level and paramedical personnel, often the only available trained healthcare providers in remote and primary healthcare facilities. A simplified medical abortion protocol, together with easy-to-use training and patient materials, and well-designed community outreach and mobilization strategies, may help improve access to abortion services for those most in need.

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