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ORIGINAL RESEARCH ARTICLE

THE EFFICACY AND ACCEPTABILITY OF MEDICAL ABORTION OF LESS THAN 63 DAYS GESTATION IN CHITWAN

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ABSTRACT

According to the WHO more than 19 million unsafe abortions occur worldwide each year. Unfortunately, safe methods, though they exist, are just not available to the vast majority of Nepalese women. Thus this study was done to determine the effectiveness, side effects, and acceptability of oral mifepristone (200 mg) followed by vaginal misoprostol (800 mcg) after 24 hours for medical termination of pregnancy up to 63 days. This is a prospective pilot study done in department of obstetrics and gynaecology at Chitwan Medical College from 1st Jan 2011 to 15th April 2011. Women with pregnancies up to 63 days of gestation were enrolled. They were given a 200-mg oral dose of mifepristone to be followed 24 hours later by administration of 800 mcg of vaginal misoprostol and instructed to return 14 days later for ultrasound. The main outcome measure was complete abortion without surgical intervention and secondary outcome measures were induction-to abortion interval, adverse effects, and women's acceptability. A total of 30 women were enrolled in this study. Twenty six (86.7%) women had successful termination of pregnancy without requirement of surgical evacuation. Average total vaginal bleeding lasts was 7 days (3-30 days).More than 80% agreed that the overall procedure was acceptable. This pilot study suggests that mifepristone 200 mg, followed by misoprostol 800 micro gm vaginally 24 hours, is safe, effective for medical abortion in women up to 63 days' gestation and acceptable to our context also.

Key Words: *medical abortion, mifepristone, misoprostol*

INTRODUCTION

While pregnant women have sought abortifacients for thousands of years, they had no success at finding one that both worked and did not jeopardize their lives in the process. Each year forty-six million pregnancies are terminated worldwide. Out of which twenty million are terminated illegally with more than 78,000 deaths.

Surgical abortion up to 63 days by vacuum aspiration or dilatation and curettage has been the method of choice since the 1960s. The discovery of mifepristone, with both anti-glucocorticoid and anti-progesterone properties, has had a profound effect on women's lives. Medical abortion became an alternative method of first trimester pregnancy termination with the availability of prostaglandins in the early 1970s and anti-progesterones in the 1980s. Studies show that medical abortion is effective as a first-line treatment in settings that previously had not provided abortion services.[1] Evidence from India demonstrates that even in settings where surgical services are not available, providers can offer the medical abortion safely and effectively using existing referral mechanisms for the management of spontaneous abortion and without introducing a radical reconfiguration of services Although the idea of using medication to induce abortion has been around for centuries, evidence based regimens for use in first trimester of pregnancy only became reality in the last 25 years.

Mifepristone (commonly referred to as RU486) was developed in France in the 1970s and 1980s by researchers investigating glucocoticoids receptors. In 1988, France became the first country (outside China) to license Mifepristone for use in combination with a prostaglandin analog for early abortion. Since that time the method has slowly spread around the globe and millions of women have used the method worldwide. The 200mg dose of mifepristone has become standard in most services in United States and United Kingdom such as the Planned Parenthood Federation of America and the Royal College of Obstetrics and Gynecology.

Misoprostol can be administered orally, vaginally, or sublingually. Vaginal administration of misoprostol appears to increase the rate of complete abortion and may lessen side effects.[2,3] EL-Refacy first reported on the use of vaginally administered misoprostol in combination.[4]

ABORTION IN CONTEXT OF NEPAL

Nepal government amended the Nepal criminal code (Muluki Ain) for liberalizing abortion law in the month of Chaitra

2058 (march 2002) & Royal Assent was given on 10th Ashoj (27th September 2002).[5]

It was largely in response to the country's alarming high maternal mortality and morbidity rate. The law reformed and permits:

1. Abortion upon request for pregnancies up to 12 weeks to any women
2. In case of rape or incest for pregnancies up to 18 weeks
3. Any time where pregnancy poses risk to women's life, physical or mental health or if there is risk of fetal impairments
4. Sex selective abortion is illegal

Though there is vast amount of data showing the efficacy and safety of this simplified regimen worldwide, not many studies have been published in our context.[6-8] Moreover there is low level of awareness about mifepristone and misoprostol among most of the health care provider's esp. paramedics and general population. In last one year, we attended lots of patients with incomplete abortion after medical abortion in our hospital CMCTH and most of them took medicine from local medical shop without proper guidance.

Thus this study was conducted to evaluate the efficacy, acceptability and side effects of oral mifepristone followed by vaginal misoprostol (800 mcg) 24 hours for medical abortion.

MATERIALS AND METHODS

This prospective pilot study was undertaken among women requesting legal termination of pregnancy at a gestation up to 63 days in obstetrics and gynecology departments of Chitwan Medical College Teaching Hospital from 1st Jan to 15th April 2011. Women requesting medical abortion were provided with information about the study, screened for eligibility and enrolled in the study if they were healthy, older than the age of legal consent, with duration of 63 days or less, agreed to surgical termination of pregnancy if the treatment fail.

Women with any indication of serious past or present illness were excluded as well as those allergic to mifepristone or misoprostol and those with a history or evidence of disorders representing a contraindication to the use of mifepristone, (Such as chronic adrenal failure, severe asthma uncontrolled by corticosteroid therapy and inherited porphyrias). Further, we did not include women with a medical condition or disease that required special treatment, care or precaution such as corticosteroid or anticoagulant therapy, in conjunction with abortion and women who were breastfeeding. Estimated Gestational Age was based on the last menstrual period, however, if clinical examination did not correlate or women had doubt about last menstrual period, the ultrasound estimation was used.

The women ingested mifepristone 200 mg in front of a hospital staff, if all of the entry criteria were met and asked her to come after 24 hours. Next day at 24 hours interval 800 mcg of misoprostol was kept vaginally and asked to rest for 1 hour and send home to come after 14 days for follow up. All participants were given instructions to come to hospital if vaginal bleeding exceeded two soaked sanitary towels in one hour for two consecutive hours. A history of events since the prior visit was obtained. A vaginal ultrasound scan was performed during follow up.

All women received an ibuprofen + paracetamol (900 mg) at time of insertion of misoprostol and to use the same drug if necessary later also. They were questioned about side effects that occurred during the interval between mifepristone and misoprostol and after the misoprostol. When questioned about severity of bleeding, the women were instructed that "bleeding" was defined as flow equal to or heavier than menses, and "spotting" was flow lighter than menses. If the gestational sac with or without embryonic cardiac activity were present, a surgical termination of pregnancy was performed. If only small retained poc seen, the women returned in four weeks (day 30) at which time her history was taken and another ultrasound scan performed. If the ultrasound scan on day 30 showed retained poc or still she had bleeding, the woman was offered a surgical termination of pregnancy. All women were permitted at any time to request a surgical procedure rather than continuing to wait for expulsion. The main outcome measure was: Complete abortion without surgical intervention and secondary outcome measures were: induction-to abortion interval, adverse effects, women's acceptability.

STATISTICAL ANALYSIS

The data were analyzed with Epi-Info and SPSS software. Quantitative variables were summarized in terms of descriptive statistics. Categorical variables were summarized by frequencies and percentage.

RESULTS

A total of 30 women were enrolled in this study. The characteristic of the women are presented in Table 1. The mean age was 27 yrs and the mean length of current pregnancy was 6 weeks.

Table 1: Characteristics of Obstetric History (n=30).

	n (%)
Age(years)	27(20-40)
Gravidity	
1	4(13.3%)
2	9(30%)
3	8(26.5%)
>4	9(30%)
Median(range)	3(1-6)
Parity	
0	4(13.3%)
1	10(33.3%)
2	13(43.3%)
3	2(6.7%)
5	1(3.3%)
Median(range)	2(0-5)
Married	30(100%)
POG(weeks)	6(4-8)

Forty percent of women in this study are from middle class family with literacy only up to secondary level of school ,one was illiterate and eight(26.7%) are graduate and moreover

76.7% of them are house wife. Sixteen (53.3%) of women gave history of family completed but not used any measures of contraception to reason for termination of pregnancy. Other reason given is shown in Table 2.

Table 2: Reason for termination of pregnancy

Reason	Frequency(n=30)	95%CI
Family completed	16(53.3%)	34.3%-71.7%
Spacing	8(26.7%)	12.3%-45.9%
Studies	4(13.3%)	3.8%-30.7%
Financial	2(6.7%)	0.8%-22.1%

Effectiveness rates appear in Table 3. A complete medical abortion was confirmed mostly by USG and some by history and clinical examination. Twenty six (86.7%) women had successful termination of pregnancy without requirement of surgical evacuation. Two women had blighted ovum that undergone surgical evacuation on 14 days follow up. Two women who had prolong bleeding for 1 month with USG findings of retained poc were also gone for surgical evacuation but one of them had molar pregnancy in HPE.

Table 3: Outcome of medical termination of pregnancy

	n (%)
Complete abortion	26(86.7%)
Required follow up scan after 14 days	
One scan	20(66.6%)
Two scan	2(6.7%)
Failed termination	
Blighted	2
Retained poc	1
Molar pregnancy	1
Overall failed termination	4(13.3%)

Information on cramping and bleeding after dose of misoprostol is presented in table 4. Only one patient gave history of vaginal bleeding prior insertion of misoprostol and that is around 12 hours after taking oral mefipristone. On an average total vaginal bleeding lasts was 7 days (3-30 days). Two women had bleeding lasted for one month. Suction evacuation was done on day 30 which showed molar pregnancy in one of them.

Table 4: Bleeding and cramping after misoprostol

	n (range)
Median(range)	
Onset of bleeding(hr)	2(1-6)
Onset of cramping(hr)	2(1-6)
Total days of bleeding(day)	7(3-30)
Total days of cramping(day)	2(1-10)

Most of women had heavy bleeding for 3-4 days only and none of them required blood transfusion. Two women who gave history of only spotting had blighted ovum seen in USG during 14 days follow up. Similarly most of women perceived pain only for 2-3 days which is relieved with NSAIDS. They neither came to hospital with severe abdominal pain nor required narcotics for pain relief.

Only minor side effects were seen that was also transient, mild, self resolving and none of them require medication. Six women had nausea, vomiting in three, dizziness in two and headache and sweating in one.

Table 5: women's acceptability to medical abortion (n=26)

	n (%)
Over all acceptable treatment	22(84.6%)
Bleeding time acceptable	20(76.9%)
Abdominal pain acceptable	22(84.6%)
Adverse effects acceptable	22(84.6%)
Choose similar treatment in future	22(84.6%)
Recommend similar treatment for friends/relatives	22(84.6%)

The results of the acceptability questionnaire are shown in table 5. More than 80% agreed that the overall procedure was acceptable and choose and recommend similar treatment to friends and relatives in future. Dissatisfied women were those who had failure of treatment and need surgical evacuation. Patients for whom the method failed was less likely to rank the medical abortion regimen thus analysis was done only to successful candidate (26 women).

DISCUSSION

This is only pilot study which shows the efficacy of 86.7% with 200 mg orally followed by 800mcg misoprostol vaginally after 24hours. Though large number no of randomized trial have been done in UK, USA, France regarding dose, route and day of administration of misoprostol and mefipristone showing efficacy of 90%, not much studies were published in our context.[7-11] Lower rate of successful medical abortion seen in our study may be due to less sample size and also we did not use 2nd dose of misoprostol for retained gestational sac which was done in other study.

Average duration of bleeding seen in our study is 7 days. This rate is consistent with the study reported by Mitchell D et al.[11] We have found molar pregnancy in HPE done for surgical evacuation in one women bleeding for more than 30 days. Thus we recommend sending for HPE to all women who bleeds more than 30 days. In the French study of Peyron et al, nausea, vomiting and diarrhea being reported by 43%, 17% and 14% of the women, respectively. In contrast, our study shows, these side effects in 20%, 10%, and 0% respectively.[12]

In the American trial reported by spitz et al, 29% of women received narcotic analgesics but none of women in our study needed. This also shows that pain threshold of Nepalese women is much higher than American's.[13]

More than 50% of women in our study had more than 2 children and completed their family. This shows that use of long term temporary contraception and permanent sterilization is less here.

The other advantage of medical abortion is rare chances of having endometritis and Prophylactic antibiotics are not warranted. Similarly we did not use antibiotics either and

none of them needed also.

The standard reasons to monitor patients in the office after misoprostol have been to identify any medical complications and to provide emotional support to the patient throughout the process. Complications are rare during these initial 4 hours & do not appear to warrant requiring women to spend time under medical supervision. Most patients prefer the privacy of their homes. Home use of misoprostol also has the advantage of reducing the costs of treatment by decreasing the number of office visits. Since 40% of women seeking medical abortion here had not even gone to high school and more over this is only pilot study we prefer to use misoprostol in hospital rather than home. The limitation of this study is fewer samples size and not used of additional dose of misoprostol in case of retained gestationa sac, but this is only pilot study which gives us base to do large randomized trial.

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