

Are Over-the-Counter Abortion Pills Safe? A Study on Abortion Pill Self-Medication Outcomes

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Abstract: ***Background:** Consumption of medical abortion pills without supervision is becoming a health risk for the general public. However, since abortion pills are available over the counter, the practice of self-administering these medications is widespread across the nation. Because of this widespread usage, we intended to conduct this study to assess the clinical presentation and outcome of patients suffering from this condition. **Aim:** The purpose of this study was to investigate the effects of pregnant women self-administering abortion medications and reporting to a tertiary care center. **Method:** A prospective observational study was conducted on 40 patients who presented to the Postpartum OPD, Department of Obstetrics and Gynaecology, S.S. Hospital BHU, after self-administering medical abortion pills. **Results:** The most common presenting symptom was excessive vaginal bleeding. Self-administration of abortion medications typically results in partial abortions. Fifteen percent of the patients showed signs of shock, and thirty percent of the patients had severe anemia. Other complications related to self-administered abortion drugs included sepsis, severe bleeding, failed abortion, and ectopic pregnancy. **Conclusion:** Most pregnant women taking MTP pills experience substantial side effects, such as bleeding, missed or incomplete abortions, and ectopic pregnancies. This study demonstrates the urgent need for laws and restrictions on over-the-counter medications available for medical termination of pregnancy. It is also necessary to increase women's awareness of the side effects of using MTP pills without prior counsel.*

Keywords: Medical abortion pills, Self-administration, complications, Unsafe abortion, over-the-counter medications

1. Introduction

Willful termination of a pregnancy before the period of viability is known as abortion. With a few exceptions, it is typically the result of an unintended pregnancy (1). Unwanted pregnancies are a widespread issue worldwide. The World Health Organization estimates that every year, 19 million women worldwide have unsafe abortions. Of these cases, 18.5 million happen in underdeveloped countries (2). The actual number of abortions is significantly higher than what is reported because a significant proportion of them are not reported.

The WHO recommends mifepristone in combination with misoprostol or misoprostol alone as a safe and effective method of pregnancy termination (3). Medication abortion is a reasonably easy, secure, affordable, and prosperous way to terminate a pregnancy. However, there are still obstacles to clinic-based abortion services. These include constrictive legal environments, a shortage of qualified or willing clinicians, the expense of clinical services, personal accounts of abuse at medical facilities, and other practical and social issues. As a result, the majority of medication-assisted abortions worldwide take place outside of medical facilities (4).

Medical abortion is permitted in India up to nine weeks of pregnancy as per the guidelines prepared by the World Health Organization in partnership with the Ministry of Health and Family Welfare, the Government of India, and the Indian Council of Medical Research(5). Despite the fact that there have been advancements in science that have made it possible to provide safe abortions at the primary care level, unsafe abortions continue to occur, which leads to a significant number of complications (4).

Because medical abortion avoids problems like infection, uterine perforation, cervical trauma, and cervical incompetence, it is a safer method of abortion than surgical

abortion. However, it is only a blessing if taken as directed by a doctor and in accordance with conventional protocol. Due to ease over-the-counter availability despite legal restrictions, widespread overuse by non-allopathic doctors, dais, and quacks, as well as women's ignorance, it is becoming a public health issue in India(2). Due to simple and illegal access, many women self-administer these medicines despite explicit guidelines. Some rely on this birth spacing procedure without understanding its risks, which can range from severe hemorrhage to death (6).

Medical abortion has a very high success rate of 93–98% if it is used wisely, which means that it is performed after carrying out an accurate assessment of the patient's condition and the gestational age of the patient (7). Research indicates that women who self-administer abortion drugs are more likely to experience significant consequences such as anemia, sepsis, failure, and incomplete abortion compared to those under medical supervision (8). It is recommended by the Federation of Obstetrics and Gynaecological Societies of India (FOGSI) that the distribution of these pharmaceuticals be closely monitored and that the medical profession and the pharmaceutical sector should exercise due care in the promotion and utilization of drugs that are used for medical abortion. The MTP Act of India only allows registered medical practitioners to prescribe abortion pills, neither non-allopathic doctors nor pharmacists. WHO recommends having a backup healthcare facility in case of failed abortions (9). Despite this, the general public has the impression that medical abortions are a very safe alternative, mainly when performed by professionals who lack the necessary training. This impression has led to the distribution of abortion drugs over the counter, which may result in a rise in the number of unsupervised terminations and potentially fatal complications (10).

2. Method

This prospective study was conducted on 40 patients who visited the Postpartum unit and emergency of the Obstetrics and Gynaecology Department S.S Hospital, IMS, BHU, with unsupervised use of medical abortion pills. This study aims to examine demographics, clinical aspects, problems, therapeutic options, maternal mortality, and morbidity resulting from self-consumption of MTP pills.

By self-administration, we refer to pregnant women who used abortion pills without medical consultation from a registered medical practitioner. All of the following information was gathered.

Age, marital status, parity, educational status, last menstrual period, time of pregnancy as perceived by the women, confirmation of pregnancy, presenting complaint of the patient, any known medical or surgical complications, haemoglobin level at the time of admission, whether the patient was in shock, evidence of sepsis such as fever and tenderness on the pelvic examination. After a thorough examination and ultrasound, the patient's condition was assessed, and a treatment plan was developed.

3. Results

Between January 2018 and December 2018, our institution reported 98 abortions in total, including both spontaneous and induced ones. Of those, 40 women reported using abortion pills for self-medication without first visiting a doctor. 90% (36) of the participants in our study were married, and 10% (4) were unmarried. A maximum number of patients (47.5%) belong to the middle age group, i.e., 30-39 years. 75% of parous women self-administered abortion pills, while 25% were primigravida.

Table 1: Demographic Analysis

Demographic profile		
Variable	Frequency	%
Age Group		
<20	4	10
20-30	12	30
30-40	19	47.5
>40	5	12.5
Marital Status		
Unmarried	4	10
Married	36	90
Gravida		
Primigravida	10	25
Multi-parous	30	75

The majority (52.5%) of patients reported excessive vaginal bleeding and the passage of a fleshy lump. Irregular bleeding was present in 20% (8) of patients. In 25% (10) of patients, bleeding was accompanied with abdominal pain. In 15% (6) of the cases, signs of haemorrhagic shock were present, and resuscitation was needed. One patient had surgery in the form of a D&C elsewhere, but she still had irregular bleeding, and she presented to us in shock. She was diagnosed with a ruptured ectopic pregnancy for which an urgent laparotomy was done.

Table 2: Presenting complains analysis

Presenting Complain		
Chief presenting complains	Frequency	%
Excessive bleeding per vaginum	21	52.5
Bleeding on & off	8	20
Bleeding with abdominal pain	10	25
Products of conception not expelled	2	5
Fever	2	5
Non-specific symptoms	2	5
Shock	6	15

Anaemia of different grades was the most common medical condition that went along with it in 80% (32) of patients; 30% (12) of them had severe anaemia that needed blood transfusions.

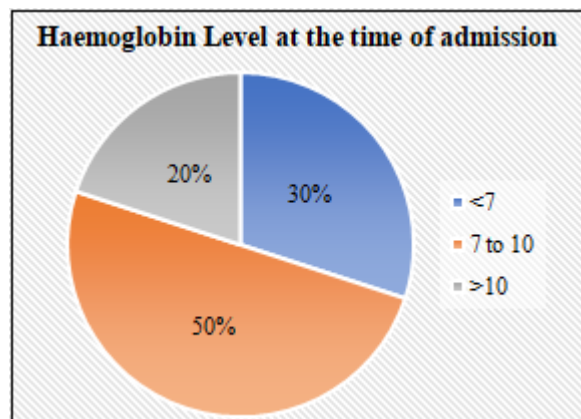


Figure 1: Anaemic level analysis

Participants reported pregnancies ranging from 5 weeks to 16 weeks at baseline. The fact that 25% of patients used abortion pills beyond nine weeks of pregnancy is significant, given medical abortion is only allowed up to 63 days of gestation.

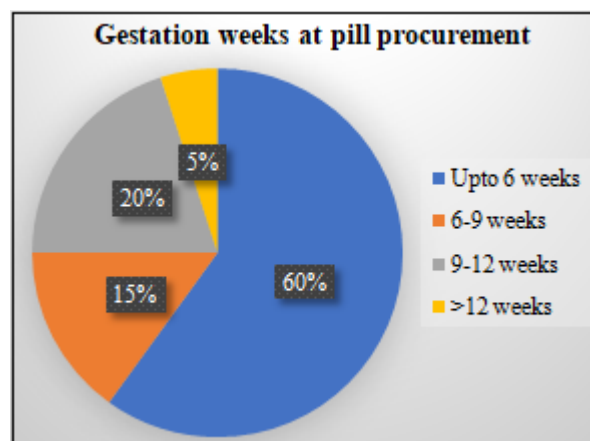


Figure 2: Gestation weeks descriptives

The majority of patients (70%) took the pill without undergoing ultrasound to establish gestational age or locate the pregnancy. The results of our investigation after the use of abortion pills are shown below:

Table 3: Diagnosis table

Diagnosis at admission		
Diagnosis	Frequency	%
Complete Abortion	2	5
Incomplete abortion	23	57.5
Failed abortion	4	10
Incomplete abortion with Sepsis/shock	12	30
Ectopic Pregnancy	1	2.5

Table 4: Management/ Procedures undertaken

Management executed in the patients.					
S.no	Outcome	Number	%	Management	
1	Incomplete abortion	23	57.5	Surgical (S&E)	18
				Medical	15
2	Complete abortion with anemia	2	5	Blood transfusion was given to 1 patient	
3	Sepsis	12	30	Antibiotics with Suction evacuation	
4	Ectopic	1	2.5	Laparotomy with blood transfusion	
5	Failed abortion	4	10	Suction evacuation	

Although post-abortive contraceptive counselling was offered to all, only 26 (65.5%) accepted it.

4. Discussion

The Indian MTP Act of 1971, which made abortion legal, was created to cut down on the number of mothers who die due to unsafe abortions. Still, 8% of deaths of mothers in India are linked to unsafe abortions(7). Despite the availability of safe and effective contraception, women in rural and tribal communities remain unaware, resulting in unmet needs (11).

We discovered that almost 40.8% of the patients who came to our hospital for an abortion had a history of self-administering abortion pills. This was despite clear guidelines that said these pills should only be taken under medical supervision and can only be prescribed by someone authorized under the MTP Act. A similar finding was present in a study by Nivedita et al. (7).

In the study, 10% were less than 20 years, 30% were between the ages of 21 and 30, 47.5% were between the ages of 31 and 40, and 12.5% were above 40 years. The women's ages ranged from 19 to 44. Nonetheless, 52% of women in research by Giri et al. were in the 20–29 age range, while 44% were in the 30-39 age range (5), the same as in our study. In another study conducted by Sreya et al., the maximum number of patients were in the age group 21 to 25 years (12).

25% of the women in our study were primi-gravidas, and 75% were multigravidas. K. Nivedita et al.(7) also found comparable results. Similarly, Giri et al.(13) found that 79% of women were multigravida and 21% were primigravida, which is consistent with our findings.

In our study, 90 % of females procuring these drugs were married. A similar finding was present in another survey conducted by Bibechan et al. (6). Unmarried women accounted for 10% of the study population. This was similar to a study by K. Nivedita et al., where 12.5% of participants were unmarried (7).

Over 12 months, 40 individuals experienced complications from self-administered abortion drugs. The most common presenting complaints were about excessive bleeding per vaginum (52.5%) and bleeding along with stomach pain (25%). Other signs, such as not being able to pass the products of conception and bleeding irregularly in the vagina, were seen in 25% of patients. This finding is similar to what Nivedita et al. (6) and Giri et al. (13)found.

In our study, 75% of women were multiparous, which was similar to a study by Mishra et al. (14), who found that 78% of women who self-administered abortion pills were multiparous. This demonstrates that women rely on medical abortion and consider it a better technique for spacing the birth than taking contraception and preventing undesired pregnancy in the first place.

In this study, 24(80%) of the patients had taken abortion pills while they were as early in their pregnancy as the sixth week, whereas 6 (15%) and 8 (20%) of the patients had taken the pills between 6- 9 and 9-12 weeks of their pregnancy, respectively.

The number of women who took abortion pills after 12 weeks of pregnancy was two (5%). There is a high risk of complications with medical abortions in the second trimester, with a higher chance of surgical removal and infection (15). In our study, one woman who tried to have an abortion in the second trimester had a failed abortion, whereas one had an incomplete abortion with sepsis.

In our nation, anemia affects about 87% of expectant mothers, and anemia-related maternal fatalities are thought to account for 22,000 annual maternal deaths (16). It could be lethal for women with severe anemia to self-medicate with abortion pills. Our study discovered that 50% of patients had moderate anemia at the time of presentation, and 30% of women had severe anemia.37.5% of the study group in a related study on the effects of self-medication with abortion pills had severe anemia, and 30% had moderate anemia (13).

Our study found that 57.5% of patients had incomplete abortions, 5% had a live pregnancy, 30% had septic incomplete abortions, and 2.5% had ectopic pregnancy.

Similar to our study, Nivedita et al. found that 62.5% of abortions were incomplete, requiring surgical evacuation (7). Bennett et al. found that medical abortion with the right mifepristone and misoprostol regimen resulted in a 96.5% success rate, 1.2% incomplete abortion, and 1.45% failed abortion (17). The high percentage of failed and incomplete abortions in this study may have resulted from the pharmacist's use of a medical abortion regimen that was neither optimal nor advised by the government or WHO. Less than 1% of women in a systematic evaluation comprising 46,421 cases experienced infection following a medical abortion performed under optimal conditions (18).

5. Conclusion

Abortion pills should not be sold over the counter, and public access should be limited to MTP-approved institutions. Strict legislation is necessary to monitor and control sales. To stop this dangerous practice of using abortion pills for self-medication, it will be helpful to educate the public about the need for medical counselling and supervision during an abortion, the dangers of self-medication, emergency contraception, and practical ways to meet unmet needs for contraception.

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