

Is It Safe to Provide Abortion Pills over the Counter? A Study on Outcome Following Self-Medication with Abortion Pills

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ABSTRACT

Background: Medical abortion is a safe method of termination of pregnancy when performed as per guidelines with a success rate of 92-97 %. But self-administration of abortion pills is rampant throughout the country due to over the counter availability of these drugs and complications are not uncommon due to this practice. The society perceives unsupervised medical abortion as a very safe method of termination and women use this as a method of spacing.

Aim of the Study: The aim of this study was to study the implications of self-administration of abortion pills by pregnant women.

Materials and Methods: Retrospective observational study done in Sri Manakula Vinayagar Medical College & Hospital between the period of July 2013 to June 2014. Case sheets were analysed to obtain data regarding self-administration of abortion pills and complications secondary to its administration. The following data were collected. Age, marital status, parity, duration of pregnancy as perceived by the women, confirmation of pregnancy, duration between pill intake and visit to hospital, whether any intervention done elsewhere, any known medical or surgical complications, Hb level on admission, whether patient was in shock, USG findings, evidence of sepsis, blood transfusion, treatment given and

duration of hospital stay. Descriptive analysis of the collected data was done.

Results: Among the 128 cases of abortion in the study period, 40 (31.25%) patients had self-administered abortion pills. Among these 40 patients 27.5% had consumed abortion pills after the approved time period of 63 days of which 17.5% had consumed pills after 12 weeks of gestation. The most common presentation was excessive bleeding (77.5%) Severe anaemia was found in 12.5% of the patients and 5% of patients presented with shock. The outcome was as follows : 62.5% of the patients were found to have incomplete abortion, 22.5% had failed abortion and 7.5% of patients had incomplete abortion with sepsis. Surgical evacuation was performed in 67.5% of the patients whereas 12.5% of the patients required surgical evacuation with blood transfusion. Medical methods were used in 15% of the patients whereas 2.5% required transfusion along with medical methods.

Conclusion: Unsupervised medical abortion can lead to increased maternal morbidity and mortality. To curtail this harmful practice, strict legislations are required to monitor and also to restrict the sales of abortion pills over the counter and access to abortion pills for the public should be only through centers approved for MTP. Large scale prospective studies are required to assess the actual magnitude of this problem.

Keywords: Complications, Medical abortion, Self-administration, Unsafe abortion

INTRODUCTION

The number of induced abortions in India in approved centers is estimated to be 6,20,472 and the maternal mortality due to unsafe abortions is 8% as reported in the Family Welfare Statistics 2011 [1]. The actual number of induced abortions is greatly underestimated as a high percentage of them go unreported and also because there is a rampant and irresponsible practice of self-administration of abortion pills throughout the country.

Medical abortion with mifepristone and misoprostol is a very safe option for termination of pregnancy when consumed under medical supervision with a success rate of 92-97% [2]. Clear guidelines have been formulated by organizations like WHO and in India by FOGSI regarding the use of abortion pills. WHO guidelines indicates the necessity of pre abortion care for women requesting abortion to confirm pregnancy, to estimate the correct gestational age and to locate the site of pregnancy as either intra or extra uterine. It also emphasizes the need to obtain a detailed medical history to rule out contraindications for medical abortion such as bleeding disorders, uncontrolled seizure disorder, chronic adrenal failure etc and the importance of bimanual examination to assess the size of the uterus and a basic laboratory workup [3]. Both FOGSI & WHO consider that ultrasound is not mandatory but where it is available can be used to exclude an extra uterine pregnancy and to diagnose nonviable pregnancies.

Medical abortion is restricted for use in the early first trimester (up to 63 days) the dose being 200 mg of Mifepristone (oral) followed by 400 mcg of Misoprostol after 48 h vaginally or orally for < 49 d. Between 49-63 d, Mifepristone 200 mg orally and M isoprostol 800 mcg vaginally or orally after 48 h is recommended [2]. The patient has to be educated with details of the procedure like correct administration of the drug, the expected duration of bleeding, complications like excessive bleeding and pain, the possibility of failure and the need for surgical evacuation if necessary. A follow up visit on day 14 to ensure completion of the process and to discuss contraception is recommended. In addition to the contraindications mentioned above, FOGSI also discourages medical abortion in patients with Hb < 8 g and if they lack access to 24 h emergency services. It also recommends anti-D injection to Rh negative mothers following medical abortion but routine use of antibiotics is not recommended [2].

The MTP act of India permits that abortion pills be prescribed by only registered medical practitioners and not by non allopathic doctors or by pharmacists. WHO recommends that the person or facility prescribing abortion pills should have a backup health care facility in case of failed or incomplete abortion [3].

In spite of such clear guidelines and recommendations, self-administration of these drugs by pregnant women without any medical consultation or supervision has become highly prevalent

due to availability of these drugs over the counter without any prescription. Many women depend on medical abortion and consider it as a method of spacing between pregnancies [4]. Due to unrestricted availability of these drugs the society considers this to be an extremely safe option of termination of pregnancy. Life threatening complications like excessive hemorrhage, sepsis and deaths due to undiagnosed ectopic pregnancies are not uncommon in women administering these drugs by themselves.

This retrospective observational study was carried out in Sri Manakula Vinayagar Medical College and Hospital to study the implications of self-administration of abortion pills by pregnant women to induce abortion.

MATERIALS AND METHODS

This study was a retrospective observational study carried out in Sri Manakula Vinayagar Medical College & Hospital after due permission from the hospital authorities. All case records with the diagnosis of abortion whether spontaneous or induced were analysed between the period of July 2013 – June 2014 from medical records department and data was collected from case sheets in which pregnant women had given a history of induced abortion following self-administration of abortion pills and its complications. By self-administration we mean that these pregnant women had no medical consultation with a registered medical practitioner and has taken abortion pills which was purchased from the pharmacy without any prescription either by self or by some close relative. The following data was collected. Age, marital status, parity, duration of pregnancy as perceived by the women, confirmation of pregnancy, duration between pill intake and visit to hospital, whether any intervention done elsewhere, any known medical or surgical complications, Hb level on admission, whether patient was in shock, USG findings of incomplete abortion, complete or failed abortion, evidence of sepsis like fever and tenderness on pelvic examination, blood transfusion, treatment given and duration of hospital stay. Management was based on whether patient was bleeding profusely, when surgical evacuation was performed whereas when bleeding was less and the amount of retained products as assessed by ultrasound was minimal medical methods were used.

RESULTS

The total number of abortions in our institution including spontaneous and induced abortions between the period of July 2013 – June 2014 was 128 of which 40 women had given a history of self-medication with abortion pills obtained without prior medical consultation. In our study we found that 85% were married, 12.5% were unmarried and one woman was a widow. The youngest patient was 15-year-old and all 4 (10%) patients between the age group of 15-19 were unmarried. 92.5% of the women belonged to rural population whereas 4.5% were from urban areas. The percentage of parous women who had self administered abortion pills was 75% and 25% were primigravida.

The gestational age at the time of consumption of abortion pills is shown in [Table/Fig-1].

S. No.	Gestational Age	no	%
1	Early pregnancy to 7 wk	10	25%
2	7 wk to 9 wk	19	47.5%
3	9 wk to 12 wk	4	10%
4	> 12 wk	7	17.5%

[Table/Fig-1]: Timing of Consumption of Abortion Pills

The finding that 27.5 % of patients had consumed abortion pills after 9 wk of pregnancy is significant, as medical abortion is permitted only upto 63 d of gestation. The maximum period of gestation of self-administration was done was at 20 wk of pregnancy and this patient presented with shock following expulsion of the fetus and

came with retained placenta and underwent subsequent surgical evacuation.

Pregnancy was confirmed by 39 women with urine pregnancy test and 1 woman had undergone USG along with UPT. The interval between pill intake and hospital visit is shown in [Table/Fig-2].

S. No.	No. of Days Since Consumption of Pill to Hospital Visit	no (40)	%
1	1-5	19	47.5
2	6-10	11	27.5
3	11-15	5	12.5
4	16-20	1	2.5
5	21-25	0	0
6	26-30	2	5
7	>1month	2	5

[Table/Fig-2]: Interval between Pill Intake and Visit to Hospital

The complaints with which women came after self-administration of abortion pills is shown in [Table/Fig-3].

S. No	Complaints	no	%
1	Excessive bleeding per vagina	31	77.5
2	Irregular bleeding per vagina	1	2.5
3	Bleeding with abdominal pain	2	5
4	Abdominal pain	3	7.5
5	Fever with pain and irregular bleeding	1	2.5
6	Not expelled products	2	5

[Table/Fig-3]: Complaints at Presentation to Hospital

One patient had an intervention in the form of D and C elsewhere but still presented with irregular bleeding and diagnosed to have incomplete abortion. Among the 40 patients at least 42.5% of them had some associated medical or surgical disorders the details of which were obtained from the past history and from investigations [Table/Fig-4].

S. No.	Associated Medical or Surgical Disorders	no.
1	Severe anaemia (Hb < 7 grams)	5
2	Rh negative	2
3	Seizure disorder	2
4	Cardiac disease	2
5	Bronchial asthma	1
6	HIV positive	1
7	Post caesarean pregnancy	4

[Table/Fig-4]: Associated Medical or Surgical Disorders

Features of hemorrhagic shock and resuscitative measures were required in 5% of the patients. The hemoglobin level on admission is shown in [Table/Fig-5].

S. No	Hemoglobin Level	no.	%
1	< -7grams	5	12.5
2	7 - 10 grams	15	37.5
3	> 10 grams	20	50

[Table/Fig-5]: Hemoglobin Level on Admission

The outcome following consumption of abortion pills in our study is shown in [Table/Fig-6].

S. No	Outcome	no.	%
1	Incomplete abortion	25	62.5%
2	Complete abortion	1	2.5
3	Failed abortion	9	22.5
4	Incomplete abortion with sepsis	3	7.5
5	Incomplete abortion with shock	2	5

[Table/Fig-6]: Outcome Following Self-administration

Among 15% of the patients who required blood transfusion 2 patients required 3 units of whole blood, 2 required 2 units of whole blood and 2 patients were given 1 unit of packed cells. Incomplete abortion with features of associated sepsis confined to uterus was found in 7.5% of the patients. The management of complications in these patients who had self-administered abortion pills is shown in [Table/Fig-7].

S. No	Management	no.	%
1	Medical methods only (misoprostol repeated)	6	15
2	No Intervention	1	2.5
3	Medical method and blood transfusion	1	2.5
4	Surgical evacuation only	27	67.5
5	Surgical evacuation with blood transfusion	5	12.5

[Table/Fig-7]: Management of complications

Patients who presented with profuse bleeding were managed by immediate surgical evacuation whereas when bleeding was minimal and with the USG showing minimal products of conception vaginal misoprostol was used to complete the procedure.

The average duration of hospital stay is shown in [Table/Fig-8].

S. No.	No. of days (hospital stay)	no.
1	1-5	30
2	6 -10	9
3	>10	1

[Table/Fig-8]: Duration of Hospital Stay

DISCUSSION

The MTP act of India, legalizing abortions was passed with the aim of reducing the number of maternal deaths due to unsafe abortions. But still 8% of maternal deaths are attributed to unsafe abortions in India. Any procedure which is performed outside the bounds of law tends to be unsafe and 5 million unsafe abortions are performed per year in India.

We found that almost 31.25% of patients of the total number of abortions in our hospital during the study period had come with history of self-administration with abortion pills in spite of clear guidelines that these pills have to be taken only under medical supervision and can be prescribed only by a person authorized under the MTP act. This is due to easy availability of these pills over the counter even in rural areas.

In our study, 9 primigravid women of which 5 were unmarried had self-administered abortion pills. Even though studies have indicated that there were no long term complications like increased risk of spontaneous abortions, ectopic pregnancies, low birth weight babies or preterm babies following medical abortion [5], when undertaken under unsafe conditions without medical supervision there is a risk of long term sequelae like infertility secondary to PID.

The number of patients who had consumed abortion pills after 12 wk of gestation was 7 (17.5%). Studies indicate that the complication of II trimester medical abortions is high with an increased risk of surgical evacuation and infection [6]. In our study we found that among seven patients, who attempted second trimester abortion, three failed to abort, three had incomplete abortion and one patient had incomplete abortion with sepsis.

The duration of bleeding following medical abortions ranged between 1-54 d with a median of 7 d and increased gestational age was associated with longer bleeding time [7]. Due to lack of pre abortion counseling in these women, they did not know what to expect following self-administration of the abortion pills. Many women (47.5%) reported as early as 1-5 d to the hospital whereas some did not visit the hospital even after 15 d of prolonged bleeding and other complications.

The prevalence of anaemia in pregnant women in our country is almost 87% and estimated maternal deaths due anaemia is 22,000 / year [8]. Self-medication of abortion pills in women with severe anaemia could be fatal. In our study we found that 12.5% of women were severely anemic and 14.5% of patients had moderate anaemia at the time of presentation. Two patients had presented with hemorrhagic shock requiring more than 2 units of blood transfusion. A similar study on consequences of self-medication of abortion pills found that 13.5% of their study group had severe anaemia and 56.7% had moderate anaemia and two patients had presented in shock [9].

The chance of scar rupture in post caesarean pregnancy following first trimester medical abortion is nonexistent but the risk of rupture is 0.28% in II trimester abortions [10]. We had 4 (10%) patients with postcaesarean pregnancy in our study who had consumed abortion pills even without confirmation of gestational age with the existent risk of scar rupture which could have been fatal.

The overall frequency of infection after medical abortion is <1% compared to surgical methods when done under prescribed settings [11]. But serious infections like fatal *Clostridium sordellii* infections have been reported following medical abortions [12]. However, the complication of sepsis tends to be higher in women undergoing unsafe abortions. Studies comparing intake of abortion pills with medical supervision and self-administration showed that serious complications like anaemia, sepsis, failure and incomplete abortion is higher in women who self-administered the drug [13]. In our study 7.5% of patients had come with features of incomplete abortion and sepsis and responded to surgical evacuation and antibiotics.

Studies comparing medical and surgical methods have shown that hemorrhage and incomplete abortion and rate of surgical evacuation was more after medical abortion [14]. In our study 62.5% of patients had presented with incomplete abortion, 5% with incomplete abortion in shock, 7.5% with incomplete abortion with sepsis and 22.5% with failed abortions. Thirty two (80%) patients required surgical evacuation in our study. Similar study on consequences of self-administration showed that 70.2% had incomplete abortion and 10.8% had failed abortion [9]. This study also reported ruptured ectopic pregnancy and also one maternal death following self-administration of abortion pills [9]. Another study reported 41.54% of incomplete abortion, 6.54% of septicemia and 1.15% of failed abortion [4].

The chance of failed abortion is 1 % following medical abortion and the possibility of teratogenesis due to misoprostol in the form of skull defects and limb abnormalities are documented and hence the process should be completed by surgical evacuation and continuation of pregnancy is not an alternative [15].

Moreover we had coexistent medical disorders like cardiac disease, epilepsy and bronchial asthma in 5 patients which would make the whole process further unsafe and highly risky. Two patients were found to have Rhesus negative group and these women were not even aware of their blood group or the necessity for anti-D administration.

With the above list of complexities involved in medical abortion, we find that our society perceives medical abortion as a very safe option for terminating pregnancy. The reasons for this attitude are lack of education, lack of awareness regarding legal status of abortion, lack of awareness of the complications involved in medical abortion, the necessity to maintain secrecy, the cost involved and mainly because the drugs are available to them without any restriction. Second trimester medical abortions done in this manner could be also sex selective in our scenario.

LIMITATION OF THE STUDY

The sample size of this retrospective study done in a medical college hospital is small but the magnitude of this problem, that is,

self-medication of abortion drugs and its implications is indeed high and large scale studies involving governmental organizations are warranted to assess the actual situation.

CONCLUSION

Strict legislations are required to monitor and also to restrict the sales of abortion pills over the counter and access to abortion pills for the public should be only through centers approved for MTP. Educating the society regarding the need for medical counseling and supervision during an abortion, the risks of self-medication, creating awareness regarding emergency contraception and effective strategies to fulfill the unmet needs of contraception will be useful to curtail this harmful practice of self-medication with abortion pills.

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