

Over-the-Counter Use of Medical Abortion Pills: A Prospective Cohort Study

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ABSTRACT

Introduction: Medical abortion is a safe intervention in the first trimester that requires access to accurate information and the support of a trained healthcare provider. However, women often use medical abortion pills on their own or with guidance from friends, relatives, quacks, or pharmacists due to the easy availability of these drugs over-the-counter without a medical prescription.

Aim: To study the effects of over-the-counter use of medical abortion pills on maternal health and to explore the possible reasons for it.

Materials and Methods: This prospective cohort study was conducted in the Department of Obstetrics and Gynaecology at Rajendra Institute of Medical Sciences, Ranchi, Jharkhand, India. The study duration was one year and five months, from June 2020 to October 2021. A total of 98 women who reported unsupervised consumption of medical abortion pills over a period of 17 months were included in the study. Demographic and obstetric profiles, clinical presentation, diagnosis, outcomes, and complications were analysed. Reasons for unsupervised intake were also explored. The data were analysed using the Statistical Package for Social Sciences (SPSS) version 20.0.

Results: The study included 98 women, with the majority (54.08%) belonging to the 25-31 years age group. Out of these, 49 (50%) women took the abortion pills between 7-12 weeks,

32 (32.65%) before seven weeks, and 17 (17.35%) between 13-20 weeks. Pregnancy was confirmed with a Urine Pregnancy Test (UPT) kit in 64 (65.30%) women, with Ultrasonography (USG) in 22 (22.45%) women, while 12 (12.25%) took pills based solely on missed periods. The most common clinical presentation was excessive vaginal bleeding in 70 (71.42%) cases. Incomplete abortions were observed in 77 (78.56%) women, missed abortions in 10 (11.22%) women, and septic abortions in 4 (4.08%) women. Laparotomy was needed in six women with ectopic pregnancy. Two women required hysterectomy, one due to uterine perforation after suction evacuation in a private hospital, and the other due to intractable haemorrhage. Blood transfusion was needed in 25 (25.5%) women, and Intensive Care Unit (ICU) care in 15 (15.3%) women. However, none experienced acute kidney injury, Disseminated Intravascular Coagulation (DIC), or mortality. The main reasons for over-the-counter use of abortion pills were privacy or non-disclosure of pregnancy in 48 (48.9%) cases, opposition from the husband in 31 (31.6%) cases, avoiding a hospital visit in 25 (25.51%) cases, and easy availability of the pills in 27 (27.55%) cases.

Conclusion: Unsupervised intake of pills increases the risk of complications like incomplete or missed abortion, sepsis, and ectopic pregnancy, which may require blood transfusion, ICU admission, and major surgeries like laparotomy or hysterectomy in a few cases. Therefore, there is a need for supervised intake of pills to reduce maternal morbidities.

Keywords: Complications, Maternal morbidity, Self-administration, Unsupervised

INTRODUCTION

Medical abortion is a safe method of terminating a pregnancy in the first trimester. Approximately 73 million induced abortions occur worldwide each year. Six out of ten (61%) unintended pregnancies and three out of ten (29%) pregnancies end in induced abortion [1]. According to a survey conducted in 2015 at healthcare facilities in six states in India, the abortion rate was estimated to be 47 per 1000 women. Of these, 12.7 million (81%) abortions were medication abortions, 2.2 million (14%) were surgical abortions, and 0.8 million (5%) were performed using other potentially unsafe methods. The survey also found that abortions accounted for one-third of all pregnancies, with nearly half of them being unintended [2].

The World Health Organisation (WHO) recommends medical abortion using a combination regimen of orally administered mifepristone 200 mg followed by vaginally, orally, or buccally administered misoprostol 800 mg within 63 days of gestation [3]. The US Food and Drug Administration (FDA) also approves mifepristone and misoprostol combination regimen [4]. The American College of Obstetricians and Gynaecologists (ACOG) provides evidence-based guidance on the provision of medication abortion up to 70 days of gestation [5].

When conducted using a WHO-recommended method appropriate for the duration of pregnancy and by providers with the necessary skills, medical abortion is a safe intervention [6,7]. It is more convenient, safer, and cost-effective than surgical methods. Medical abortion eliminates the need for hospitalisation and reduces the risk of surgical complications such as infection, uterine perforation, cervical trauma, cervical incompetence, and anaesthetic complications. It also ensures the privacy of women [8]. However, medical abortion requires access to accurate information and the support of trained healthcare providers [9]. Despite this, women often use medical abortion medications on their own or with guidance from friends, relatives, quacks, or pharmacists due to the availability of these drugs over-the-counter without a medical prescription. Many women use medical abortion as a method of contraception to space their pregnancies [10].

Previous studies have reported an increased risk of complications such as incomplete abortion, shock, infection, and even life-threatening conditions like ectopic pregnancy associated with unsupervised use of medical abortion pills [11-13]. However, only a few studies have explored the reasons for unsupervised intake

[10,14]. Therefore, the present study was conducted at a tertiary care teaching hospital to identify the effects of over-the-counter use of medical abortion pills on maternal morbidity and to determine the possible reasons for this practice.

MATERIALS AND METHODS

A prospective cohort study was conducted in the Department of Obstetrics and Gynaecology at Rajendra Institute of Medical Sciences, Ranchi, Jharkhand, India. The study lasted for one year and five months, from June 2020 to October 2021. The study was done after taking approval from the Institutional Ethics Committee (IEC number 228, dated 21.12.2019).

Inclusion criteria: During the study period, 98 women who reported to the hospital after unsupervised consumption of abortion pills were included in the study.

Exclusion criteria: Women who took abortion pills after consultation in the hospital or after consulting a registered medical practitioner outside the hospital and subsequently reported with complications were excluded from the study.

Study Procedure

Unsupervised pill intake refers to the purchase of pills over-the-counter by the woman herself, her husband/partner, family member, or friends without medical prescription or supervision. It also includes cases where the pills had been prescribed by untrained personnel or quacks. A detailed history was obtained from each woman, including demographic characteristics, presenting complaints, gestational period, menstrual history, previous obstetric history, and medical and surgical history. The authors also inquired about the methods used for confirming pregnancy. All patients underwent a detailed general examination, systemic examination, abdominal examination, and pelvic examination. Routine investigations were performed for all women. Ultrasound evaluation was conducted to document cases of incomplete abortion, missed abortion, uterine perforation, pelvic abscess, and ectopic pregnancy. Appropriate management was provided based on the clinical condition and diagnosis. The outcomes and complications were analysed. Reasons for unsupervised pill use were explored through interviews with the women. They were followed-up until discharge from the hospital and provided counselling on various family planning methods.

STATISTICAL ANALYSIS

A standard template was created using Microsoft Excel 2017 to enter the data collected in the present study. The data were then transferred to SPSS software version 20.0 for statistical analysis. Categorical variables were reported as numbers and percentages.

RESULTS

The majority of women (53/98) belonged to the 25-31 years age group. Out of the total participants, 5 (5.1%) were unmarried, 15 (15.3%) had a history of previous caesarean section, and 36 (36.73%) had a previous history of induced abortion [Table/Fig-1].

Variables	Number (n)	Percentage (%)
Age (in years)		
<18	2	2.04
18-24	24	24.49
25-31	53	54.08
32-38	18	18.37
39-41	1	1.02
Residence		
Urban	52	53.06
Rural	46	46.94

Education status		
Illiterate	38	38.78
Primary level	26	26.53
Matriculation	19	19.39
Above matriculation	15	15.30
Socioeconomic status*		
Upper middle class	2	2.04
Lower middle class	25	25.51
Upper lower class	44	44.89
Lower class	27	27.55
Gestational age of pill intake (in weeks)		
<7	32	32.65
7-12	49	50.00
13-20	17	17.35
Gravidity		
Primigravida	13	13.26
Gravida 2	43	43.88
Gravida 3 or more	42	42.86
Method of confirmation of pregnancy prior to pill intake		
UPT	64	65.30
USG	22	22.45
Presumptive diagnosis on basis of missed period	12	12.25

[Table/Fig-1]: Demographic and Obstetric profile (N=98).

*According to Kuppuswamy scale [14]; UPT: Urine pregnancy test; USG: Ultrasonography

The most common presenting complaint was excessive vaginal bleeding, reported by 70 (71.42%) women [Table/Fig-2]. Incomplete abortion was the most frequent diagnosis, observed in 77 (78.57%) women, with seven of them presenting in a state of shock [Table/Fig-3].

Complaints	Number (n)	Percentage (%)
Heavy vaginal bleeding	70	71.42
Irregular vaginal bleeding	8	8.16
Pain lower abdomen	5	5.10
Foul smelling vaginal discharge	4	4.08
Vaginal bleeding with shock	7	7.14
Pain abdomen with shock	4	4.08

[Table/Fig-2]: Profile of clinical presentation at the time of admission (N=98).

Clinical diagnosis	Number (n)	Percentage (%)
Incomplete abortion	70	71.42
Incomplete abortion in shock	7	7.14
Incomplete abortion with sepsis	4	4.08
Missed abortion	10	11.22
Uterine perforation	1	1.02
Ruptured ectopic pregnancy in shock	4	4.08
Chronic ectopic pregnancy	2	2.04

[Table/Fig-3]: Clinical and ultrasonography diagnosis (N=98).

Among the participants, 20 (20.4%) women could be managed medically with repeat doses of misoprostol, while 70 (71.4%) women required suction evacuation. Four cases of sepsis among the suction evacuation group received a combination of broad-spectrum intravenous antibiotics. Additionally, 17 (17.34%) women required blood transfusion. Hysterectomy was performed in two cases, one for uterine perforation and another for uncontrolled haemorrhage [Table/Fig-4].

The most common reasons cited for self-intake of abortion pills were non-disclosure of pregnancy (privacy) in 48 (48.97%) cases,

Management methods	Number (n)	Percentage (%)
Medical methods only (misoprostol repeated)	20	20.40
Suction and evacuation	49	50.00
Suction and evacuation with blood transfusion	17	17.34
Suction and evacuation with intravenous antibiotics	4	4.08
Laparotomy with blood transfusion	6	6.12
Hysterectomy with blood transfusion	2	2.04

[Table/Fig-4]: Management methods (N=98).

being forced by the husband in 31 (31.63%) cases, easy availability of the pill over-the-counter in 27 (27.55%) cases, and avoiding a hospital visit in 25 (25.51%) cases [Table/Fig-5]. On being enquired, it was found that in 63 (64.2%) cases, pharmacists did not ask for a prescription before selling the drug. Furthermore, 12 (12.24%) women initially denied having consumed the medication.

Reasons*	Number (n)	Percentage (%)
Residence remote from the hospital	8	8.16
For privacy	48	48.97
Unmarried pregnancy	5	5.10
Failure of contraceptives	14	14.28
Easy availability without doctors' prescription	27	27.55
Opposed by husband	31	31.63
To avoid a hospital visit	25	25.51

[Table/Fig-5]: Reasons for unsupervised medical abortion pills intake.

*The sum of percentages does not add to 100% because multiple reasons were reported by the same women

DISCUSSION

Medical Termination of Pregnancy (MTP) can be offered to women up to nine weeks of pregnancy, according to WHO guidelines, with the need for follow-up visits [3]. In India, the MTP Act was passed in 1971 to reduce maternal mortality and morbidity resulting from unsafe abortions [9]. However, despite national policies and guidelines on MTP, unsafe abortions due to unsupervised self-administration of MTP pills for terminating undesired pregnancies are common, leading to maternal morbidity and mortality. In the present study, the majority of women (65%) took MTP pills after confirming their pregnancy using an UPT kit. Twenty-two women had confirmed their pregnancy through both USG and UPT, while 12 women took the pills based solely on missed periods. These findings align with a study by Sarojini et al., where 70.2% of cases confirmed their pregnancy with a positive UPT and 22.1% with a pelvic ultrasound examination before taking the tablets. In 7.7% of instances, the pills were taken based on missed periods [11]. Bhalla S et al., also reported that the majority (66%) consumed the pills without an ultrasound to confirm the gestational age or localise the pregnancy [15]. Women find UPT kits more convenient for confirming pregnancy than going to a healthcare facility.

In the present study, 54.08% of women belonged to the 25-31 years age group, which is similar to the most common age group of 26-30 years reported by Dodiya D et al., [16]. This reflects an increased number of unwanted pregnancies in this age group. Five women in the study were unmarried, and 43 women were gravida 3 or more, indicating self-administration of pills to terminate unwanted pregnancies. Additionally, 42 women were gravida 2, highlighting the need for contraception for birth spacing. The proportion of gravida 3 or more has been reported as 65.4% and 89.47% in other studies by Sarojini et al., and Singh A et al., respectively, suggesting similar reasons for terminating unwanted pregnancies [11,17]. A total of 67% of women in the present study took the pills beyond the recommended gestation period. Other studies have also reported a high proportion of pill intake beyond the recommended gestation period, at 64.4%, 40%, and 27.5%, respectively [11,12,18]. Reported that the majority (71.57%) of women consumed pills within the

recommended gestation period, with only 1% taking them after 12 weeks of gestation [17]. When self-medicating, women often take abortion pills beyond the recommended gestational age, unaware of associated complications such as ectopic pregnancy, excessive bleeding, and infection [19]. In the present study, 71.42% of patients presented with excessive vaginal bleeding, suggestive of incomplete abortion. This finding is consistent with other studies where the reported rates of incomplete abortion were 75 (72.1%) out of 104, 29 (60%) out of 48, 26 (70.2%) out of 37, 43 (61.4%) out of 70, 25 (62.5%) out of 40, and 17 (56.6%) out of 30 [11-13,16-18]. The authors did not encounter any cases of complete abortion, whereas other studies have reported complete abortion rates ranging from 8.7%, 19%, and 15.7% [11,15,16]. Bajwa SK et al., reported a high rate of complete abortion in 129 out of 260 cases (49.62%) [10]. In the present study, a total of 4 cases (4.08%) presented with septic abortion, which aligns with reported sepsis rates in other studies ranging from 4.8%, 6.54%, 3% to 7.5% [11,12,15,18].

The rate of ectopic pregnancy in the present study was 6 (6.12%), out of which four cases had ruptured ectopic pregnancies and presented in a state of shock. These cases had taken pills based on missed periods without any clinical examination or ultrasound evaluation. The ectopic pregnancy rate in this study is higher than that reported by Bajwa SK et al., (1.15%) and Sarojini et al., (1.9%) [10,11]. Giri A et al., and Thaker RV et al., have reported similar rates of ectopic pregnancies, 5.4% and 6.5%, respectively [12,13]. This highlights the need for supervised intake of MTP pills to prevent this potentially life-threatening complication. Supervised administration of abortion pills involves counselling about the possibility of an ectopic pregnancy and the need for immediate follow-up if acute abdominal pain occurs. In contrast, during self-administration of pills, women who are unaware of the complications often seek medical care very late, resulting in morbidity and mortality. A total of 11 women (11.2%) in the present study presented in a state of reversible haemorrhagic shock, which is higher than the rate reported in the study by Singh A et al., (5.26%) [17]. Blood transfusion was required in 25.5% of women, which is lower than the rate reported by Giri A et al., (52%) [12]. In the present study, two cases required hysterectomy as a life-saving procedure. One had severe haemorrhage following suction evacuation, and the other case, with a history of two previous caesarean sections, presented with uterine perforation following attempted uterine evacuation at 16 weeks at a local hospital., Sarojini et al., reported two cases of uterine rupture and hysterectomy in one out of 104 cases due to unsupervised pill intake at 18 weeks in previous caesarean cases [11]. Scar site rupture is unlikely in post-caesarean cases after first-trimester medical abortion, but the rate is 0.28% in the second trimester [20]. Potdar J also mentioned that medical abortion is a safe method of terminating pregnancies up to seven weeks gestation in women with two previous caesarean sections [21].

Intensive Care Unit (ICU) care was required for 15 women (15.3%), but none experienced acute kidney injury, DIC, or mortality. Bhalla S et al., and Singh A et al., also found no maternal mortality in their studies [15,17]. However, other studies have reported maternal deaths at rates of 1.9% and 2.7% [11,13]. Multiple reasons were cited for unsupervised intake of abortion pills. The leading reasons were privacy or non-disclosure of pregnancy (48.9%) and opposition from the husband (31.6%). Women preferred non-disclosure of pregnancy due to fear of being judged by others for being multigravida or elderly gravida and with the intention to limit family size or space out pregnancies. In some cases, pregnancy was discontinued against the women's wishes due to poor socioeconomic status and lack of resources in the family. Preferring home stay over seeking hospital treatment for abortion (25.5%), easy availability of the pills without a doctor's prescription (27.5%), and failure of contraceptives (14.2%) were cited as other

reasons. Women wanted to avoid hospital visits as it would disrupt their routine duties as homemakers or daily wage workers. Similar reasons were found in a study by Bajwa SK et al., where 65.38% of females were unaware of the availability of medical abortion services in government centres, and 35% and 12.31% of women cited compulsion of sterilisation in the form of Intrauterine Contraceptive Device (IUCD) insertion and opposition by the spouses, respectively [10]. Another study by Bhalla S et al., found that patients avoided healthcare facilities because they were unaware of the dangers of unsupervised drug ingestion and due to time and economic constraints in 30% and 11% of women, respectively [15]. The lack of supervision by trained providers during the medical abortion procedure can result in severe complications affecting maternal health. Therefore, there is a need to raise awareness about the importance of supervision during medical abortion. Counselling women to use various family planning methods and emergency contraception, strengthening the government's health system at the primary level, educating peripheral health workers and pharmacists about possible complications of self-administration of pills, and implementing measures to prevent the deliberate sale of abortion pills without a prescription are some ways to address this issue.

Limitation(s)

The present study was a single-centre hospital-based study with a small sample size. Therefore, it may only reflect the magnitude of the problem as the tip of the iceberg. There may be a group of women who had no complications after unsupervised intake of medical abortion pills. Larger studies are required to assess the actual magnitude of the problem.

CONCLUSION(S)

The present study highlights the complications associated with unsupervised intake of abortion pills, including incomplete abortions, septic abortions, ectopic pregnancies, the need for blood transfusion, and ICU care. These complications are influenced by prevailing social stigmas in society. Non-disclosure of pregnancy due to fear of judgment for being multigravida or elderly gravida, a preference for home stay instead of seeking hospital visits, and various socioeconomic factors were identified as the main reasons for over-the-counter usage of abortion pills. It is important to incorporate medical abortion procedures judiciously into family welfare programme, as a tool for empowering women and allowing them to make informed and responsible decisions.

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