

DOI: <https://dx.doi.org/10.18203/2320-1770.ijrcog20263980>

Original Research Article

Complication of over-the-counter use of medical abortion pills including ectopic pregnancy: a prospective observational study from a tertiary care centre

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Received: 03 July 2026

Revised: 20 October 2026

Accepted: 21 October 2026

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ABSTRACT

Background: Over-the-counter (OTC) availability of medical abortion pills has led to widespread unsupervised self-administration, increasing clinical complications and the risk of missed ectopic pregnancy.

Methods: A prospective observational study was conducted on 50 women presenting with a history of self-administered abortion pills between October 2025 and March 2026 at a tertiary care centre in northern India. Clinical presentations, diagnostic findings, and therapeutic management were systematically analyzed using IBM SPSS Statistics software.

Results: Bleeding per vaginum was the most common presentation (84%). Major complications included incomplete abortion (68%), severe anemia requiring blood transfusion, and ruptured ectopic pregnancy (8%). All ectopic pregnancies identified were ruptured at presentation and required emergency exploratory laparotomy, with intraoperative hemoperitoneum ranging from 400 to 800 ml.

Conclusions: OTC use of abortion pills is associated with significant morbidity, including life-threatening ruptured ectopic pregnancy. Proper medical evaluation prior to abortifacient use is indispensable. Stricter enforcement of drug distribution regulations and enhanced public awareness regarding safe abortion practices are urgently needed.

Keywords: Medical abortion, OTC use, Incomplete abortion, Ectopic pregnancy, Anemia

INTRODUCTION

Medical abortion using a combination of mifepristone and misoprostol is an established, safe, and effective method for the termination of early pregnancy when administered under appropriate medical supervision.^{1,2} The World Health Organization (WHO) recommends this regimen for termination of pregnancy up to 12 weeks of gestation, provided it is preceded by clinical and sonographic evaluation to confirm intrauterine pregnancy and accurately determine gestational age.³

However, in low- and middle-income countries (LMICs) including India, mifepristone and misoprostol have become freely available over the counter (OTC) at commercial retail pharmacies without prescription, leading to widespread unsupervised self-administration.^{4,5} Studies from South Asia have consistently reported that a large proportion of women using medical abortion pills do so without prior medical consultation, ultrasound evaluation, or gestational age assessment.^{6,7} This unregulated access has transformed what is fundamentally a safe clinical intervention into a potential source of serious morbidity and preventable mortality.

Unsupervised use of medical abortion pills may lead to a wide spectrum of serious clinical complications, including incomplete abortion associated with prolonged bleeding and iron-deficiency anemia, severe hemorrhage necessitating packed red blood cell (PRBC) transfusion and missed or undiagnosed ectopic pregnancy, including scar ectopic pregnancy.⁸⁻¹⁰

Ectopic pregnancy represents the most alarming and life-threatening complication in this context. Medical abortion pills do not treat an ectopic gestation; their use may partially mask early symptoms such as mild bleeding or pelvic discomfort, thereby delay diagnosis and facilitate tubal rupture.¹¹

Rajasekar and Hall reported that use of abortifacients in women with undiagnosed ectopic pregnancies could accelerate tubal rupture and haemodynamic compromise.¹² More recent Indian studies have similarly highlighted that OTC misuse significantly delays presentation of ectopic pregnancy to tertiary facilities, often resulting in life-threatening hemoperitoneum requiring emergency surgery.^{13,14}

Despite increasing evidence of harm, OTC abortion pill use continues to rise, driven by social stigma, lack of awareness, cost constraints, and easy pharmacy access.¹⁵ This has resulted in an escalating burden on tertiary care hospitals that receive women with advanced complications preventable by simple pre-treatment ultrasound evaluation.¹⁶ There is therefore an urgent need for prospective data from Indian tertiary centres documenting the clinical spectrum and severity of these complications.

The primary objectives of the present study were to investigate the clinical complications following over-the-counter use of medical abortion pills, to determine the incidence and characteristics of ectopic pregnancy among patients presenting after OTC abortion pill intake, and to evaluate the management strategies and clinical outcomes in this patient cohort.

METHODS

Study design and setting

A prospective observational study was conducted in the Department of Obstetrics and Gynaecology, Maharani Laxmi Bai Medical College (MLBMC), Jhansi, a tertiary care teaching institution, over a six-month period from October 2025 to March 2026.

Sample size and enrollment

A total of 50 patients meeting the predefined eligibility criteria were consecutively enrolled during the study period upon presenting to the outpatient or emergency department.

Inclusion and exclusion criteria

The inclusion criteria of the study participants comprised women of reproductive age who presented with a documented history of self-administration of medical abortion pills (mifepristone, misoprostol, or combipack) obtained over the counter without a valid medical prescription, exhibiting acute symptoms such as bleeding per vaginum, lower abdominal pain, giddiness, or syncope. The exclusion criteria comprised patients who had undergone supervised medical abortion under the guidance of a qualified healthcare provider or registered medical practitioner, as well as women who had undergone prior surgical uterine evacuation at an outside facility before presenting to our tertiary care centre.

Parameters studied and clinical assessment

Detailed clinical histories, socio-demographic details, and reproductive histories were documented for all participants. The key parameters evaluated included maternal age, parity, and gestational age at the time of pill consumption. Presenting clinical symptoms, vital signs, and hemodynamic status were thoroughly assessed. All patients underwent pelvic examination and transabdominal and/or transvaginal ultrasonography to confirm the definitive diagnosis. Laboratory investigations included baseline hemoglobin concentration to determine the severity of anemia, blood grouping, and cross-matching. Detailed records were maintained regarding the medical interventions, surgical procedures (such as dilatation and curettage or exploratory laparotomy), intraoperative findings, hemoperitoneum volumes, and requirement for blood and blood product transfusions.

Statistical tool and data analysis

Data were systematically entered and curated in Microsoft Excel (Microsoft Corp., Redmond, WA, USA) and subsequently analyzed using the statistical software package IBM SPSS Statistics for Windows, Version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were summarized as mean, standard deviation, and range, whereas categorical variables were presented as absolute frequencies and percentages. Descriptive statistical tools were utilized to analyze demographic profiles, gestational age distribution, symptomatology, final diagnoses, and procedural management outcomes across the study cohort.

RESULTS

Demographic profile

A total of 50 patients were enrolled during the study period. The majority of participants (60%, n=30) were in the 20–30-year age group, while 40% (n=20) were aged above 30 years. In terms of obstetric parity, 70% (n=35) were multigravida and 30% (n=15) were primigravida (Table 1).

Gestational age at the time of pill intake

The gestational age at the time of abortifacient pill intake varied considerably across the study population. The highest proportion of patients (40%, n=20) took the medication between 7 and 9 weeks of gestation. Thirty percent (n=15) consumed the pills at less than 7 weeks of gestation, and another 30% (n=15) consumed them beyond 9 weeks of gestation (Table 2).

Clinical presentation

Bleeding per vaginum was the single most common presenting complaint, observed in 42 (84%) patients. Lower abdominal pain was reported by 30 (60%) patients, and 10 patients (20%) presented with acute giddiness or syncope, reflecting significant hemodynamic instability. A majority of patients presented late to our hospital following initial pill intake (Table 3).

Final diagnosis

The most frequent final clinical diagnosis was incomplete abortion, confirmed in 34 (68%) patients. Complete abortion was noted in 4 (8%) patients, ectopic pregnancy in 4 (8%) patients, and other diagnoses, including failed abortion with ongoing viable intrauterine pregnancy, in 8 (16%) patients (Table 4).

Table 1: Demographic profile (n=50).

Variable	Number (%)
Age 20–30 years	30 (60%)
Age >30 years	20 (40%)
Multigravida	35 (70%)
Primigravida	15 (30%)

Table 2: Gestational age at the time of pill intake (n=50).

Gestational age	Number (%)
< 7 weeks	15 (30%)
7–9 weeks	20 (40%)
> 9 weeks	15 (30%)

Table 3: Clinical presentation (n=50).

Presenting symptom	Number (%)
Bleeding per vaginum	42 (84%)
Abdominal pain	30 (60%)
Giddiness / syncope	10 (20%)

Table 4: Final diagnosis (n=50).

Final diagnosis	Number (%)
Incomplete abortion	34 (68%)
Complete abortion	4 (8%)
Ectopic pregnancy	4 (8%)

Ectopic pregnancy findings

Multiple cases of ruptured ectopic pregnancy were identified in the cohort. All four ectopic pregnancies (8%) were ruptured at the time of presentation and required emergency exploratory laparotomy. Unilateral salpingectomy was successfully performed in all four cases. Measured hemoperitoneum ranged from 400 ml to 800 ml, and all patients required intraoperative and postoperative blood transfusions. Delayed presentation contributed critically to the clinical severity and life-threatening nature of these cases.

Anemia and transfusion requirements

A substantial proportion of patients presented with moderate-to-severe anemia secondary to prolonged or heavy vaginal bleeding. Multiple patients required packed red blood cell (PRBC) transfusions during their hospital admission, both in the setting of incomplete abortion with heavy blood loss and ruptured ectopic pregnancy with hemoperitoneum.

Management strategies

Regarding clinical management, the majority of incomplete abortion cases required surgical intervention via dilatation and curettage (D&C) to clear retained products of conception. All cases of ectopic pregnancy were ruptured upon arrival and necessitated emergent exploratory laparotomy with unilateral salpingectomy. Furthermore, blood transfusions were frequently required across all diagnostic categories to correct acute hemorrhage and severe anemia.

DISCUSSION

The present study highlights the alarming trend of unsupervised medical abortion pill use driven by easy over-the-counter availability, confirming patterns previously described in Indian and international literature.^{4,6} In our cohort of 50 patients, a wide spectrum of serious complications was observed, ranging from incomplete abortion necessitating surgical evacuation to life-threatening ruptured ectopic pregnancy requiring emergency laparotomy and blood transfusion.

Incomplete abortion was the most common complication (68%), consistent with findings reported by Ngoc et al who documented incomplete abortion rates ranging from 2% to 5% under supervised medical settings, with substantially higher rates following unsupervised or improper use.⁸ The high proportion observed in our study directly reflects the perilous consequences of OTC use without proper medical guidance regarding dosage, gestational age limitations, or scheduled follow-up examinations.

A significant proportion of patients presented with moderate to severe anemia, aligning with observations from other tertiary care centres across India where

prolonged post-abortion bleeding due to incomplete evacuation is a leading cause of transfusion-dependent anemia.^{9,17} The prolonged and unmonitored bleeding experienced in the absence of clinical follow-up allowed anemia to progress to severe levels requiring packed red blood cell transfusions.

Ectopic pregnancy: a critical and alarming complication

The occurrence of ruptured ectopic pregnancy in 4 (8%) patients who self-administered OTC abortion pills without prior ultrasonographic confirmation of intrauterine gestation represents the most critical finding of this study. This observation corroborates an expanding body of evidence linking unregulated abortion pill use to delayed diagnosis and catastrophic outcomes in ectopic gestations.^{10,11,13}

Medical abortifacient pills are entirely ineffective against ectopic gestations. Pharmacologically, misoprostol induces uterine cramping and vaginal bleeding that closely mimics the expected symptoms of an early medical termination, thereby masking the cardinal signs of ectopic pregnancy such as unilateral pelvic pain and hemodynamic instability and falsely reassuring women that the abortion has proceeded successfully.^{11,12} This delay in symptom recognition and medical consultation allows the ectopic pregnancy to advance undetected to tubal rupture, as occurred in all four ectopic cases in our study series.

Sivalingam et al emphasized that any woman of reproductive age presenting with abdominal pain and a positive pregnancy test after taking abortion pills should be presumed to have an ectopic pregnancy until definitively excluded by ultrasonography.¹¹ Our findings strongly support this clinical tenet. The intraoperative hemoperitoneum volumes of 400–800 ml documented in our patients indicate that these women presented at an advanced, life-threatening stage, demonstrating the catastrophic dangers of missed ectopic pregnancy in the setting of OTC pill self-administration.

Similar findings have been documented in other Indian tertiary healthcare institutions. Mittal et al reported that a significant proportion of women presenting with ruptured ectopic pregnancy had a prior history of taking OTC abortion pills, which markedly delayed their presentation and resulted in greater intraoperative hemoperitoneum compared to women without such history.¹³ Kaur et al similarly demonstrated that easy over-the-counter access to medical abortion pills served as a major contributing factor to delayed ectopic pregnancy diagnosis and elevated surgical morbidity in North India.¹⁴

Public health and regulatory implications

Our findings carry profound public health implications. Under the Drugs and Cosmetics Act and the Medical Termination of Pregnancy (MTP) Act of India, mifepristone is classified as a Schedule H drug requiring a

valid prescription from a registered medical practitioner; however, enforcement of this mandate at retail pharmacy counters remains severely compromised.⁵ Community pharmacy surveys across India have confirmed widespread over-the-counter dispensing of mifepristone-misoprostol combination kits without medical prescriptions.¹⁵ This unrestricted over-the-counter availability directly promotes medication misuse in the absence of prior medical evaluation or ultrasound confirmation.^{4,15} Furthermore, a widespread lack of public awareness regarding the dangers of unconfirmed pregnancy locations leads to perilous delays in seeking emergency care.^{13,14} Consequently, an avoidable and substantial burden is placed on tertiary care referral hospitals, consuming critical emergency surgical and transfusion resources to rescue hemodynamically compromised patients.¹⁶

Both the World Health Organization and the Federation of Obstetric and Gynaecological Societies of India (FOGSI) have issued clinical practice guidelines mandating clinical and sonographic evaluation prior to medical termination of pregnancy to rule out ectopic gestation and accurately establish gestational age.^{3,18} Strict compliance with these clinical guidelines must be reinforced through vigorous pharmacy regulation, stringent penalization of illicit dispensing, healthcare provider education, and wide-reaching public awareness campaigns highlighting the severe risks of self-medication.

CONCLUSION

Over-the-counter use of medical abortion pills is associated with substantial maternal morbidity, including life-threatening ruptured ectopic pregnancy, severe anemia, and incomplete abortion requiring emergency surgical intervention. The omission of pre-treatment ultrasonography to confirm intrauterine gestation and rule out ectopic pregnancy is a dangerous clinical gap that precipitates preventable catastrophic emergencies. Comprehensive medical evaluation including ultrasound confirmation of an intrauterine pregnancy prior to abortifacient administration is non-negotiable. Strict regulatory enforcement to eliminate unauthorized retail dispensing of medical abortion pills, coupled with targeted public health education on safe abortion practices, is urgently required to protect women's reproductive health and prevent avoidable maternal morbidity and mortality.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Kanal P, Soni A, Agnihotri S, Gautam R. Complication of over-the-counter use of medical abortion pills including ectopic pregnancy: a prospective observational study from a tertiary care centre. *Int J Reprod Contracept Obstet Gynecol* 2026;15:4374-8.