RESEARCH ARTICLE

Complications Necessitating Hospitalization after MTP Pill Use: A 1-year Retrospective Study at a Tertiary Care Teaching Institute in Gujarat

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Abstract

Background: Over-the-counter (OTC) medical termination of pregnancy (MTP) pill intake is on the rise across India. Clinical experience, and research, have documented several complications in such users. Adequate data from our district in this context is lacking. This study was conducted to examine the factors necessitating hospital admission in patients post-MTP pill administration and to characterize their clinical profile and sociodemographic factors.

Materials and methods: This 1 year, hospital-based retrospective study was conducted in the Department of Obstetrics and Gynecology, Pramukhswami Medical College, Karamsad, Anand, Gujarat, India.

Study population: Women hospitalized with a history of administration of MTP pills (self/health provider prescribed) between 1st January 2022 and 31st December 2022. A final sample size of 70 was obtained.

Data source: Data abstraction from hospital records.

Results: 92.85% of our study population had a self-prescribed OTC intake of MTP pills, and mainly comprised 3rd gravidas (41.42%), aged between 21 and 30 (67.14%) with pill intake at <12 weeks of gestation in 84.28%. About 87.14% presented with an incomplete abortion, complicated by severe anemia in 30% and shock in 52.85%, necessitating transfusion of blood products in 35.71%.

Conclusion: Complications and treatment related expenditure far outweigh the ease of an OTC abortifacient for many. However, given the large number of those who rely on self-intake, pilot studies assessing the feasibility of the new WHO recommendations on abortion service delivery may be one step towards safeguarding both a reproductive right and their health.

Clinical significance of our study: The establishment of OTC MTP pill intake as a preferred method of termination of pregnancy amongst our women, and the resultant adverse effects related to its use.

Keywords: Anemia, Blood transfusion, Complications, Medical abortifacients, Retrospective study, Shock.

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Introduction

The right to legalized termination of pregnancy is one of the pillars of reproductive rights for women. India, with its latest milestone amendment of the medical termination of pregnancy (MTP) law on 29th September 2022, by a ruling of the supreme court stating that all women, regardless of their marital status, have a right to safe and legal access to abortion up to 24 weeks of gestation, stands out as a highly progressive nation.

Safe abortion is a crucial part of reproductive health, and nearly every death and injury that results from an unsafe abortion is entirely preventable, has been stated by the WHO. Medical termination of pregnancy pills were approved for use in India in 2002, and the new, 2022 WHO guidelines now state self-management of medical abortion <12 weeks, as a fully recommended mode of abortion care. This guideline also incorporates new recommendations related to service delivery and telemedicine.[1]

On the other hand, clinical experience, as well as research have documented several complications, some of them necessitating hospital admissions in unsupervised/self-administered MTP pill users.[2–7] This is a major cause of concern, as selfcare necessitates access to appropriate and adequate information regarding use of MTP pills, possible complications, and when or where to avail medical/hospital-based care.

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Also, the high incidence of malnutrition in women and anemia in pregnant women in our country points towards our women being poorly equipped to deal with additional/extra blood loss, as may occur with the use of these pills.[8]

Adequate data from our region in Gujarat in this context, it became important to explore this clinical scenario as a preliminary to subsequent larger-scale studies.

The study was conducted with the objectives of examining the factors necessitating hospital admission in the patients post-MTP

pill administration and to characterize their clinical profile and associated sociodemographic factors.

Materials and Methods

This is a 1 year, hospital-based retrospective observational study that has been conducted in the Department of Obstetrics and Gynecology, Pramukh Swami Medical College, and Shree Krishna Hospital, a Tertiary Care Institute at Karamsad, Gujarat, India, with due permission from the IEC.

The study objectives were to examine the factors necessitating hospital admission in the patients post-MTP pill administration and to characterize the clinical profile and sociodemographic factors of the patients.

Our Source Population

Those attending our 800 beds, university-affiliated trust hospital and medical college in central Gujarat, India.

Sampling Methodology

Purposive sampling.

Study Population

Women admitted to SKH with a history of administration of MTP pills (self/health provider prescribed) between 1st January 2022 and 31st December 2022.

Source of Data

Data abstraction from the patient records in MRD.

Methodology

Inclusion Criteria

Patients hospitalized at varying periods after intake of the medical abortion pill were included in the study.

The data collected from their records included age and parity, gestational age at pill intake (either from documented LMP or self-assessment by the patient), the time intervening between intake of pills and hospitalization, the complaints, vitals and diagnosis on admission, laboratory investigations, management modalities including blood transfusion, duration of hospital stay and outcome. Women hospitalized following a spontaneous abortion/missed abortion/or for MTP were excluded from the study.

To address ethical issues, we ensured that absolute confidentiality of patient records was maintained.

Results

The sample size in our study was a total of 70 patients, of whom only 5 (7.14%) were prescribed the pills, the rest 65 (92.85%) were an over-the-counter (OTC) intake. Both had taken the entire set of pills twice, and 1 took an incomplete dose.

The presenting symptoms and complications which necessitated admission are outlined below. The presenting symptom was mainly varying degrees of bleeding per vaginum, ranging from severe in 28 (40%) to moderate and mild in 33 (47.14%). Bleeding per vaginum was quantified according to the patients' history of the amount/presence of clots/pads or clothes, and the examination findings.

The bleeding was associated with severe abdominal pain and syncope in 2 (2.85%), and with either fever or foul-smelling discharge in 1 patient each (1.42%). Amenorrhea with continuation of pregnancy (either live/missed) was seen in 7 (10%) and generalized fatigue with breathlessness in 2 (2.85%) (Table 1).

Table 1: Study population-symptomology necessitating admission at presentation

Presenting symptoms	*No. (%)*
Bleeding per vaginum *N* = 61/70 (87.14%)	
(A) Severe	28 (40.0)
(B) Varying intensity, moderate to mild	33 (47.14%)
Bleeding P/V with associated symptoms (in the 61/70)	
(A) Fever	1 (1.42%)
(B) Severe abdominal pain and syncope	2 (2.85%)
(C) Foul smelling discharge	1 (1.42%)
Amenorrhea	4 (5.71%) (<12 weeks)
	3 (4.28%) (>12 weeks)
Breathlessness and fatigue	2 (2.85%)

Table 2: Study population-clinical complications

Predominant complications	
Shock	
Shock index	*No. (%)*
< 0.7	15 (21.42)
0.7–< 0.9	18 (25.71)
0.9–< 1.0	10 (14.28)
1.0	11 (15.71)
1.1	10 (14.28)
1.4	6 (8.57)
Anemia	
Hb gm% (ICMR)	*No. (%)*
≥11	18 (25.71)
10–10.9	11 (15.71)
7–9.9	20 (28.57)
4–6.9	14 (20)
<4	7 (10)
Sepsis	3 (4.28)

The 3 major types of clinical complications seen in our study population were shock (considered as an index of 0.9 and above), anemia and sepsis. A total of 37 women, i.e., 52.85%, had a shock index above 0.9. All except 18 (25.71%) were anemic, sepsis was seen in 3 (4.28%) (Table 2).

The demographic profile of our patients is outlined in Table 3.

A major part – 47 (67.14%) of our study population was aged between 21 and 30, followed by 22 (31.42%) between 31 and 40. None of our patients was a teenager or aged above 40. 3rd (41.42%), and second (20%), gravidas predominated, although it is noteworthy that 17.14% were 5th gravidas and above.

The period of gestation (POG) at pill intake (as per documented LMP or the patients' self-assessment) and the interval between intake of MTP pills and hospitalization are depicted in Table 4. The majority (84.28%) ingested the medication within 12 weeks of gestation and presented to the hospital within 7 days of intake (44.28%). However, 12 (17.14%) presented between 29 and 42 days, and 9 (12.85%) after 42 days as well.

Table 3: Study population-demography ($N = 70$)

Age-group (Years)	*No. (%)*
≤ 20	1 (1.42)
21–30	(67.14)
31–40	(31.42)
>40	0
Gravida	*No. (%)*
1	5 (7.14)
2	14 (20)
3	29 (41.42)
4	10 (14.28)
≥5	12 (17.14)

Table 4: Study population-POG at intake of pills and interval between intake and hospitalization

POG at intake	*No. (%)*
<12 weeks	59 (84.29)
12–20 weeks	11 (15.71)
Interval	*No. (%)*
≤ 7 days	31 (44.28%)
8–14 days	7 (10%)
15–21 days	6 (8.57%)
22–28 days	5 (7.14%)
29–42 days	12 (17.14)
> 42 days	9 (12.85%)

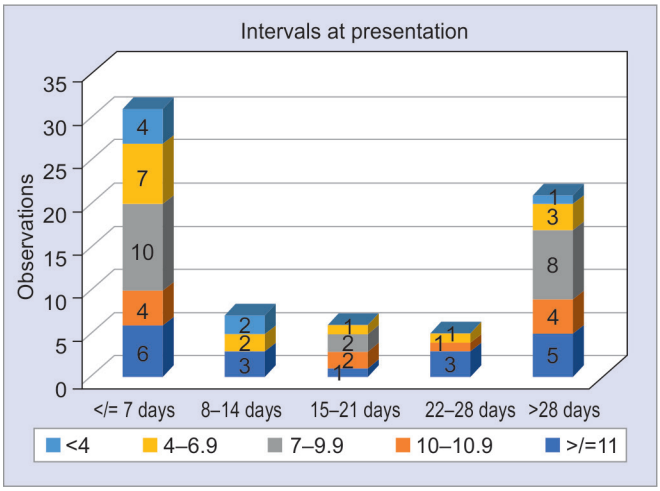

Fig. 1: Subdivision of anemia according to interval between pill intake and hospitalization

The subdivisions of anemia according to the interval between the intake of pills, and hospitalization (Fig. 1) show that most of those with severe anemia 15 out of 21 (71.42%) presented within the first 2 weeks of pill intake.

Our study subjects were categorized into 2 based upon the POG at pill intake. The first group (group A) included those ingesting the pills at POG<12 weeks/84 days. The second group (group B) had

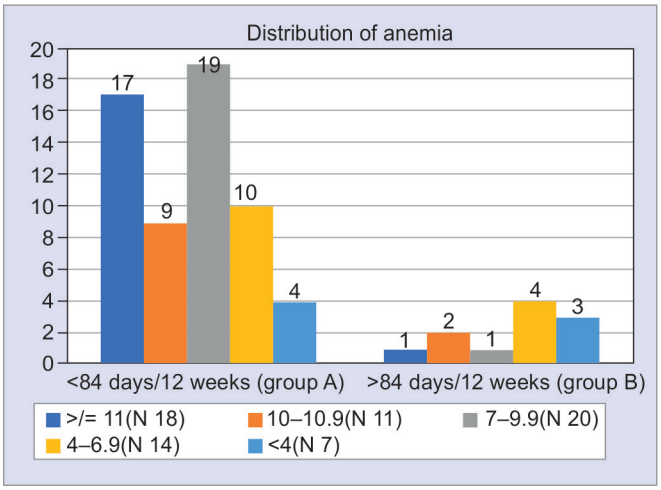

Fig. 2: Distribution of anemia between the two subgroups, dependent upon the POG at intake of MTP pills

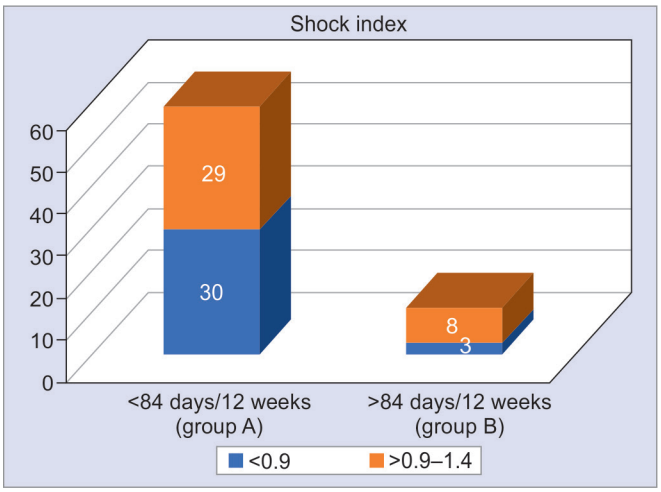

Fig. 3: Shock index between the two subgroups, dependent upon the POG at intake of MTP pills

those whose intake was between 12 and 20 gestational weeks/>84 days. The distribution of the hemoglobin status of these two groups, along with the degree of shock, is outlined in Figures 2 and 3.

The anemic subjects in group A numbered 42 (71.1%) vs group B: 10 (90.90%), with moderate and severe anemia being predominant in both 33 (55.93%) in group A and 08 (72.72%) in group B 229 (49.15%) in group A, and 08 (72.73%) in group B presented to our hospital in a state of shock.

Sepsis diagnosed in 3 of our study subjects which were seen in 2 (2.85%) group A, and 1 (1.42%) in group B.

Management

About 87.14% were diagnosed with incomplete abortions. There was an ongoing pregnancy in 7, and a complete abortion in 2. Management was according to standard guidelines, including fluids, antibiotics, blood products, and evacuation, or conservative; as and where needed. Two patients had a ruptured tubal ectopic pregnancy necessitating a laparotomy. In both the patients, the interval between pill intake and hospitalization was 2 weeks and 1 month respectively.

Table 5: Study population-outcome blood products, laparotomy and ICU care

Blood products	
PRBC units	No. (%)
1	4 (5.71)
2	15 (21.42)
3	3 (4.28)
4	3 (4.28)
FFP	2 (2.85%)
FCM/iron sucrose	6 (8.57%)
Laparotomy	2 (2.85%)
ICU care	2 (2.85%)

The clinical outcome of the study subjects is outlined below. A total of 25 (35.71%) patients needed transfusion of PRBC, of which 2 needed 4 units each of FFP as well (Table 5).

Only 2 patients (1 each in groups A and B), one with a history of convulsions (diagnosed as unrelated to pill intake), and the second with severe anemia, required ICU care, but no ventilatory support.

Duration of hospital stay the majority, 78.57% were discharged within 3 days of admission (27 were hospitalized for a day, 12 for 2 days, and 16 for 3). About 15 patients (21.42%) required a stay of ≥4 days.

All the patients recovered at the end of hospitalization. There was no mortality.

Discussion

This was the first study addressing the topic of OTC medical abortifacient pills, done at our institute. Our study results are organized in brief below.

The study population included those admitted from the trauma and emergency care, as well as from the out-patient department. The dominant factor necessitating hospitalization was varying degrees of bleeding per vaginum, ranging from severe too mild in 87.14%. Of these, 40% had severe bleeding p/v at the time of presentation to the hospital. The principal diagnosis was incomplete abortion in 87.14%, complicated in 74.28% by varying degrees of anemia, severe anemia in 30% and/or shock in 52.85%.

Patients 15 out of 21 with severe anemia (71.42%) attended the hospital within 14 days of pill intake, which might reflect the severity of the bleed and/or underlying anemia.

Range of 21–30-year-olds formed the major part (67.14%) of our study population, and 3rd (41.42%), and second (20%) gravidas predominated. The POG at pill intake was chiefly <12 weeks (84.28%). About 35.71% needed transfusions of blood products, in addition to standard treatment protocols.

All the patients recovered at the end of their hospitalization. There was no mortality.

Our dominant study population of 21–30 is similar to that of Arora et al. 69.64%, whereas 30–39 is the age-group predominant in the study by Bhalla et al. (53%).

The gravid status shows a variation in between other studies, 3rd gravidas predominate in Nalini Arora et al. (41.96%), which is similar to ours, and 2nd gravidas in Rath et al. (52%). There were 5 primigravidas (7.14%) in our study vs Gupta et al. (26.74%).

The percentage of patients ingesting the pills at <12 weeks of gestation in Nivedita et al. (82.5%), and >12 weeks in Gupta et al. (14.31%) mirrored ours.

About 69% in Bhalla et al. presented to the hospital within 15 days of pill intake. However, those hospitalized after 28 days of intake were proportionately more in our study (30%) against 5% in both Rath et al. and Nivedita et al.

As in our study bleeding per vaginum (93.75% in Nalini Arora et al.) and incomplete abortion (62.5% in Nivedita et al.) have been highlighted by others as well.

Anemia was present in 75% Sarojini et al., while severe anemia ranged from 33.56% Gupta et al. to 40.12% Rath et al.

An analysis of the degree of anemia between those ingesting the pills at gestational ages <12 weeks against those who took them between weeks 12–20 showed a *p*-value of 0.053, which is statistically significant.

Shock index as a predictor of adverse maternal outcome has been studied by Monika Chaudhary et al.[9] Shock in other studies ranges from 24% Bhalla et al. to a low of 2.9% in Sarojini et al.

In our study, a total of 37 (52.85%) subjects presented in a state of shock. The *p* value between the two groups, however, was 0.094 which is not statistically significant.

Rath et al. have documented higher rates of ruptured ectopic pregnancy (12%) and overt sepsis was seen in 4.8% Sarojini et al.

The study by Gupta et al. resulted in a 33.56% need for transfusions of blood products, similar to ours.

The period of hospitalization was 1–3 days for 78.57% of our study population, against 1–5 days for 75% in Nivedita et al. There was no mortality in the study by Nalini Arora et al. as well as in ours.

World Health Organization (WHO) has issued recommendations regarding medical management of abortion, a combination of mifepristone and misoprostol/misoprostol alone has been evaluated in systematic reviews for 1st trimester termination (<63 days of pregnancy), and institutional level comparative studies of misoprostol only and mifepristone plus misoprostol in second trimester termination of pregnancy have been carried out with good results.[10–13]

The issue of self/OTC prescribed abortion related safety has been a cause for concern however, 24.3 million (97%) of unsafe abortions worldwide between 2010 and 2014 were in developing countries. The proportion of unsafe abortions between developing countries and developed countries was 49.5% vs 12.5% and the three-tiered classification of abortion in this article states safe abortion as one provided by health care workers and with methods recommended by WHO.[14]

The new WHO Abortion Care Guideline 2022 – Recommendation 48 recommends the option of telemedicine as an alternative to in-person interactions with the health worker to deliver medical abortion services in whole or in part. The new service delivery best practice statement 49 states that "The choice of specific health workers (from among the recommended options) or management by the individual themselves, and the location of service provision (from among the recommended options) will depend on the values and preferences of the woman, girl or other pregnant person, available resources, and the national and local context. It is also important to ensure that for the individual seeking care, the range of service-delivery options taken together will provide:

- Access to scientifically accurate, understandable information at all stages;
- Access to quality-assured medicines (including those for pain management);
- Back-up referral support if desired or needed;
- Linkages to an appropriate choice of contraceptive services for those who want post-abortion contraception".

Recommendation 50 states self-management of medical abortion in whole or in part at gestational ages <12. The three component parts of the process being self-assessment of eligibility (determining pregnancy duration; ruling out contraindications) self-administration of abortion medicines outside a health-care facility and without the direct supervision of a trained health worker, and management of the abortion process and self-assessment of the success of the abortion.

Moderate quality evidence from 5 studies conducted in Australia, Canada and the USA with women and staff states that community prescribing for medical abortion and telemedicine either has, or would, improve access to abortion services, increase flexibility and facilitate a more woman-centered approach to care and it has also been stated that a telemedicine-hybrid model for medical abortion that includes no-test telemedicine and treatment without an ultrasound is effective, safe, and acceptable and improves access to care.[15,16]

Over-the-counter medical termination of pregnancy pill use does not have a legal status in INDIA at present. At the same time, it is also true that, in our country, the annual sales of MTP pills (11 million doses) far exceeds the reported no of abortions-a mere 7,00,000. Also, most women prefer medical abortion over surgical abortion, the former being far more amenable to provision in primary care settings than surgical abortion.[17]

Over-the-counter medical termination of pregnancy pill use associated complications being a fact, all previous studies have rightly focused on the morbidity related to unsupervised use of MTP pills. In our study too, the complications, at different proportions, are similar to other study results.

As per our recent National data, anemia in pregnant women aged 15–49 in the state of Gujarat stands at 55.6% urban and 66.4% rural which is more than the national statistics of 45.7 and 54.3% respectively.[18] Our trust hospital caters to patients hailing predominantly from the lower and middle socio-economic strata of society. Therefore, for our patients, not only the additional risks related to the complications, but also the expenses of the blood products, as well as the financial loss incurred to the spouse/attendants for their absence from work during the period of stay at the hospital, would far outweigh the advantages of ingesting an OTC pill.

Conclusion

Medical termination of pregnancy pill use and its related complications, in terms of maternal morbidity, is a fact, and our study results reflect this. This seeming advantage is offset by the negative impact upon both her physical and mental health, and is a further imposition upon the finances of many poor families. On the other hand, since so many women do rely on self-administration of medical abortifacients, the provision of accurate drug related information and follow-up care is imperative in such, along with an improvement in the knowledge and practices related to provision of MTP pills.[19]

A few pilot studies in the rural areas of the country under the purview of the government bodies to assess the feasibility and outcome of the new WHO recommendations, may be one such step; all of these are to ensure that the reproductive right of a woman in our country, to select her family size/how many children she wishes to have, remains upheld in absolute safety to her health.

Clinical Significance

Over-the-counter medical termination of pregnancy pill intake as a preferred method of termination for the overwhelming majority of our study population, side by side with manifold complications, suggesting that a multidimensional approach involving both grassroot health workers, and healthcare professionals, is definitely needed to ensure that such complications can be reduced to the bare minimum.

Limitations

A small sample size and data limitations. Due to the retrospective nature of the study, baseline/prepregnancy hemoglobin levels, reasons for termination of pregnancy, and the reasons for delayed visitation visit were unavailable.

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