

Over-the-counter MTP Pills and Its Impact on Women's Health

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Abstract

Objectives To study the complications and consequences including maternal morbidity and mortality following indiscriminate self-consumption of abortion pills reporting to a tertiary care center.

Methodology This is an observational study conducted at Vanivilas hospital between January 2012 to December 2013 for 24 months. After applying inclusion and exclusion criteria, 104 women were studied with respect to period of gestation, parity, clinical features at presentation and management in the institution. An analysis of maternal morbidity and mortality was done with respect to surgical interventions, ICU admissions, need for blood transfusions and maternal deaths.

Observations and results In this study, there were 75 (72.2 %) cases of incomplete abortion, 10 (9.6 %) cases of missed abortion, 2 (1.9 %) cases of ruptured ectopic and 2

(1.9 %) cases of rupture uterus. Seventy-eight (75 %) cases received blood transfusion, 7 (6.7 %) were admitted to ICU, and 2 (1.9 %) developed acute kidney injury. There were 2 (1.9 %) maternal deaths in the study group.

Conclusion This study shows urgent need for legislation and restriction of drugs used for medical termination of pregnancy. Drugs should be made available via health care facilities under supervision to reduce maternal mortality and morbidity due to indiscriminate use of these pills.

Keywords Over the counter · MTP pills · Incomplete abortion · Rupture uterus · Blood transfusions

Introduction

Abortion is willful termination of the pregnancy before the period of viability. Excluding few instances, in most of the cases it is an outcome of unwanted pregnancy [1]. In India, abortion facility is available legally under MTP act, 1971. Despite this, women who want to terminate a pregnancy often ignore the legal status of abortions and have unsafe abortions. The WHO defines unsafe abortion as a procedure for terminating an unwanted pregnancy either by persons lacking the necessary skills or in an environment lacking minimal medical standards or both [2].

The World Health Organization (WHO) recommendations on medical abortion are restricted to early first trimester (up to 63 days since the first day of the last menstrual period) [3].

Antiprogesterone drugs such as mifepristone (RU 486) and prostaglandins like misoprostol have been approved by the United States Food and Drug Administration (USFDA) for medical abortion [4]. As per Medical Termination of Pregnancy (MTP) Act of India, this method can only be administered by gynecologists and registered medical practitioners (RMP) recognized for performing MTPs up to 49 days since the first day of LMP [5, 6]. The medical abortion carries a very high success rate of 93–98 % if they are used judiciously, that is, after properly assessing the gestational age as well as the health of the patient [7, 8]. Federation of Obstetrics and Gynecological Societies of India (FOGSI) recommends close monitoring of distribution of these drugs and that the medical profession and pharmaceutical industry should exercise due diligence in the promotion and usage of drugs that are used for medical abortion [9]. Despite this, it has been perceived by the society that medical abortions are extremely safe option even in the hands of untrained personnel, leading to over-the-counter dispensing and possible increase in unsupervised terminations and life-threatening complications [10]. Being a tertiary care center, we come across many cases of

self-medication with abortion pills leading to many complications causing maternal mortality and morbidity.

Methodology

This is an observational study conducted at Vanivilas hospital between January 2012 to December 2013 for 24 months. This study is undertaken with the objective of studying the demographic features, various clinical features, complications, various management approaches carried out, maternal mortality and morbidity as a consequence of self-consumption of MTP pills.

All 104 women who reported to our hospital after self-consumption of abortion pills (purchased over the counter by self/family member without medical guidance or supervision) are included in the study. Women who have consumed MTP pills after consulting a registered medical practitioner and reporting to us with complications and women who have undergone any surgical intervention after MTP pill consumption in other health care centers before reporting to our hospital are excluded from the study. History regarding previous pregnancies, gestational age at which MTP pills were taken, present complaints is noted. On admission, detailed general, systemic and obstetric examination and routine investigations were done in all women. Degree of pallor, rise in body temperature, sign's of shock and presence of acute abdomen noted. Presence of retained products, incomplete abortion and ruptured ectopic pregnancy are documented after ultrasound examination. Management methods of all the complications, ICU admissions, need for blood and blood product transfusions and development of complications such as DIC, acute kidney injury and maternal death are noted.

Following statistical methods were applied in the present study to evaluate the data.

1. Crosstabs procedure (contingency coefficient test)
2. Frequency distribution curve.

Results

A total of 104 cases were studied: The following data were obtained from the present study.

The age distribution of present study group is shown in Table 1. Sixty-six (63.4 %) women are within 30 years of age. Five (4.8 %) women in the study were unmarried. There were 9 (8.7 %) primis, 27 (26 %) second gravidas, 53 (51 %) third gravidas and 15 (14.3 %) women with obstetric score of gravida 4 and above in this study group. About 68 (65.4 %) women were gravida 3 or more,

Table 1 Age distribution

Age distribution (in years)	Number	Percentage
≤19	4	3.8
20–25	23	22.1
26–30	39	37.5
31–35	27	26
>36	11	10.6
Total	104	100

Table 2 Clinical features at presentation

Clinical features	Number	Percentage
Bleeding PV	72	69.3
Pain abdomen	12	11.5
Ultrasound report of retained products	10	9.6
Infection/sepsis	5	4.8
Shock	3	2.9
Ruptured ectopic	2	1.9

indicating that MTP tablet consumption might be to get rid of unwanted pregnancy.

Thirty-seven (35.6 %) cases had consumed pills before 7 weeks of pregnancy, 59 (56.7 %) had consumed between 7 and 12 weeks, and 8 (7.7 %) had consumed between 13 and 20 weeks.

Seventy-three (70.2 %) cases had confirmed their pregnancy by getting a positive urine pregnancy test and 23 (22.1 %) by a pelvic ultrasound examination before consuming the pills, whereas 8 (7.7 %) cases had neither of the tests done and had consumed the pills on the presumptive self-diagnosis of pregnancy. Fifty-three (51 %) had not followed the recommended schedule or dosage of the regimen.

Excessive bleeding per vagina (69.3 %) is the most common presenting symptom followed by pain abdomen (11.5 %). Table 2 shows the clinical features at presentation to our hospital.

All women except 2 cases were subjected to ultrasound examination after admission. Ultrasound findings are shown in Table 3. Two cases of rupture uterus were not subjected to ultrasound examination. Diagnosis is done by clinical examination followed by abdominal paracentesis.

Complications developed at or after admission are listed down in Table 4. Seventy-eight (75 %) women were anemic requiring blood and blood products transfusion. Fifty-four (52 %) had received one-unit transfusion, whereas 24 (23 %) required more than one-unit transfusion.

In cases with incomplete abortion, missed abortion and blighted ovum instrumental evacuation was done. Those with rupture ectopic underwent laparotomy and partial

Table 3 Ultrasound examination findings

Ultrasound findings	Number	Percentage
Incomplete abortion	75	72.2
Complete abortion	9	8.7
Missed abortion	10	9.6
Blighted ovum	4	3.8
Live gestation	2	1.9
Ruptured ectopic	2	1.9
Not subjected to ultrasound examination	2	1.9

Table 4 Complications

Complications	Number	Percentage
Anemia	78	75
Septic peritonitis	03	2.9
Rupture uterus	02	1.9
Rupture ectopic	02	1.9

salpingectomy. There were 7 (6.7 %) ICU admissions, 2 (1.9 %) cases of acute kidney injury and 2 (1.9 %) maternal deaths. Among two maternal deaths, one was due to hemorrhagic shock and the other one due to septicemic shock.

Discussion

All women in this study easily procured the drug over the counter at local pharmaceutical shops without prior checkup at a healthcare facility. Drug administration was not supervised, and there was no adherence to the recommended schedule in most of the cases. Few women even denied the procurement of the drug initially. As per the guidelines, medical termination of pregnancy should be offered to women seeking termination of pregnancy up to 7 weeks. These women should be of right frame of mind and must be prepared for at least 3 follow-up visits to health care facility.

In this study 4.8 % women are unmarried and 65.4 % women were gravida 3 or more; both data indicate that MTP pill consumption might be to get rid of unwanted pregnancy.

Most common presentation on admission was bleeding per vagina (69.3 %) followed by pain abdomen. Similar results are also reported by Thacker et al. [5] (89.1 %).

35.6 % had consumed pills before 7 weeks of pregnancy which is the recommended period for medical termination of pregnancy. 64.4 % had taken the pills beyond the recommended period of gestation, and 51 % had not followed the recommended schedule or dosage of the regimen. This

substantiates the findings by Thacker et al. [5] and Tran [11] that when there is a self-medication, women may take the abortion pill whatever may be the gestational age and are not aware of possibility of serious life-threatening condition like ectopic pregnancy, sepsis, hemorrhage and death.

On ultrasound examination, only 8.7 % had complete abortion rest and 91.3 % had incomplete abortion, missed abortion, continuation of pregnancy or rupture ectopic. All 9 cases with complete abortion had taken the pills within 7 weeks of gestational age and had come to us for slight bleeding per vagina.

There were 2 cases of rupture ectopic; both underwent laparotomy and partial salpingectomy. Both patients had neither undergone clinical examination nor ultrasound evaluation before consuming the pill for medical abortion. This clearly suggests the need for clinical examination. Similar results about incidence of ectopic pregnancy are found in the study conducted by Debnath et al. [12].

In this study, 75 % women were anemic requiring blood and blood products transfusion. 52 % had received one-unit transfusion, whereas 23 % required transfusion of more than one unit. In a study of 80,000 patients [13] over 18 months, only 0.01 % patients required blood transfusion when the drugs were given under medical supervision. In a study by Deshpande et al. [14], no women required a blood transfusion when drugs are given under medical supervision.

Another complication that was found in our study was septicemia. In present study, 3 women had septicemia. Out of them, 2 women responded to higher antibiotics and maternal death occurred in 1 woman.

There were 2 cases of rupture uterus: One was 18-week gestation with two prior cesarean deliveries with shock for which hysterectomy was done, and the second case was 20-week gestation with one prior cesarean for which repair was done.

ICU admissions accounted for 6.7 % of cases; among them, 4 were hemorrhagic shock and 3 had sepsis. There were 2 cases of acute kidney injury secondary to hemorrhage requiring dialysis.

Among two maternal deaths, one was G3P2L2 with 2 and half months of amenorrhea, had consumed MTP pills 14 days prior and was bleeding for 10 days, reported to us with incomplete abortion with irreversible hemorrhagic shock. The second case was a second gravida with 2 months of amenorrhea, reported to us with septicemic shock, had consumed over-the-counter pills 18 days prior to reporting, was having bleeding per vagina for 15 days and fever for 8 days. Both the women died within 12 h of admission.

Table 5 compares present study with studies of Thacker et al. [5] and Bajwa et al. [8]. All the three studies show comparable results.

Table 5 Comparison of results with similar studies

	Thaker et al. [5]	Bajwa et al. [8]	Present study
No. of patients and study period	37 women/1 year	260/2 years	104/2 years
Presenting complaint	Bleeding PV 89.1 %		Bleeding PV—69.3 %
Ultrasound findings	Incomplete abortion—70.2 %	Incomplete abortion—41.5 %	Incomplete abortion—72.2 %
Instrumental evacuation	75.6 %		90.4 %
Ectopic pregnancy	5.4 %	1.15 %	1.9 %
Shock	5.4 %		2.9 %
Sepsis	8.1 %	6.54 %	4.8 %
Death	2.7 %		1.9 %

Conclusion

This study shows urgent need for legislation and restriction of drugs used for medical termination of pregnancy. Drugs should be made available via health care facilities under supervision to reduce maternal mortality and morbidity due to indiscriminate use of these pills.

In the event of suspicion of ectopic pregnancy on clinical examination, ultrasound examination is recommended prior to drug administration.

This is also an indicator of unmet need for contraception in the community which must be addressed.

Compliance with Ethical Standards

Conflict of interest Dr. Sarojini, Dr. T.R. Ashakiran, Dr. B.T. Bhanu, and Dr. Radhika declare that we do not have any conflict of interest.

Ethical Approval All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5). Ethical committee clearance from the institution was obtained.

Informed Consent Informed consent was obtained from all patients for being included in the study.

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