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OVER-THE-COUNTER MTP PILLS – A STUDY ON OUTCOME FOLLOWING SELF- MEDICATION WITH ABORTION PILLS

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ABSTRACT **Background:** Unwanted pregnancy is a common problem globally. It has been perceived by the society that medical abortion is 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. With this background, we planned to undertake this study to evaluate the clinical presentation and outcome of such patients. **Aim of the study:** Aim of the study was to study the implications of self administration of abortion pills by pregnant women. **Materials and Methods:** This is a Retrospective study including 55 patients presenting to outpatient and emergency department of Obstetrics and Gynaecology, Government Medical College and Hospital, Anantapur for a period of 3 months with history of unsupervised intake of medical abortion pill. **Results:** Majority (40%) of the patients were aged between 20-25 years. 74.5% were Gravida 3 or more. 43.5% had taken the pill within the prescribed gestational age limit for MMA , <9 weeks. Majority (78%) presented with incomplete abortion, of them 60% required surgical evacuation. Anaemia was the most common associated co-morbidity in 89% patients and 58.1% required blood transfusion. 7.2% presented with shock, 16.3%with sepsis, Emergency Laparotomy was required in 5.4% cases. Unintended pregnancy and failure of contraception were main reasons cited for abortion by 34.5% and 18.1% women. Over the counter easy availability was the main reason for unsupervised pill intake in 54.54% cases. **Conclusion:** This study shows urgent need for legislation and restriction of drugs used for medical termination of pregnancy. Also, increasing awareness among women regarding complications of unsupervised pill intake and regarding availability and safety of various contraceptive methods can help control this hazard.

KEYWORDS : Over the counter MTP Pills, Incomplete Abortion, Unintended pregnancy.

INTRODUCTION

Abortion is spontaneous or induced termination of pregnancy before fetal viability. The National centre for Health Statistics and WHO defines it as loss or Termination of Pregnancy with a fetus aged younger than 20 weeks or weighing <500 grams.

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.

Unwanted pregnancy is a common problem globally. According to WHO, 6 out of 10 (61%) of all unintended pregnancies, 3 out of 10 (29%) of all pregnancies end in induced abortion.

Global estimates from 2010-2014 demonstrate that 45% of all induced abortions are unsafe, of them 97% occurs in developing countries. Of all unsafe abortions, 1/3rd were performed under the least safe conditions i.e., by untrained persons using dangerous and invasive methods.

Each year 4.7-13.2% of maternal deaths can be attributed to unsafe abortions. In developing regions about 220 deaths occur per 100000 unsafe abortions. Unsafe abortions are the 3rd leading cause of maternal mortality in India and close to 8 women die from complications related to unsafe abortions each day, according to UNFPA's state of world population report 2022.

Medical abortion is safer alternative to surgical abortion as it avoids the complications like infection, uterine perforation, cervical trauma, cervical incompetence. But, it is a blessing, only if, used according to standard protocol and under proper medical guidance. In India it is becoming a public health problem due to easy over the counter availability despite legal ban, widespread misuse by non –allopath doctors, dais and quacks and ignorance on part of women. The pills are being dispensed blindly without proper medical evaluation and even without ruling out the contraindications.

Medical abortion is approved up to 9 weeks of pregnancy by WHO under the MTP Act. 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 health of the patient.

It has been perceived by the society that medical abortion is 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.

The MTP act of India permits that abortion pills are 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.

METHODOLOGY

This is a Retrospective study including 55 patients presenting to outpatient and emergency department of Obstetrics and Gynaecology, Government Medical College and Hospital, Anantapur for a period of 3 months from October,2022 to December,2022 with history of unsupervised intake of medical abortion pill.
Inclusion criteria:

a) Women who reported to our hospital after self consumption of abortion pills (purchased OTC by self/ family member without Medical guidance/ supervision).

Exclusion criteria:
a) Women who have consumed MTP pills after consulting a Registered Medical Practitioner and reporting to us with complications.
b) Women who have undergone any surgical intervention after MTP pill consumption in other health care centres before reporting to our hospital.

Detailed history was collected from the patients regarding age, parity, last menstrual period, presenting complaints, source of pill procurement, reason for abortion, time interval between pill intake and visit to hospital and reason for avoiding tertiary centre as first approach. The detailed examination and Ultrasonography was done and according to the condition of the patient, treatment was given and the outcome and complications analyzed.

RESULTS

A total of 55 cases were studied. The following data were obtained from the present study:

Table 1 - Age Distribution:

AGE	Number of cases	Percentage(%)
19 years	3	5.4
20-25 years	22	40
26-30 years	14	25.4
>30 years	16	29
Total	55	

Majority (40%) women are between 20-25 years of age.

Table 2 - Distribution of Marital status:

Marital Status	No.	Percentage(%)
Married	50	90.9
Unmarried	5	9.1
Total	55	

Five (9.1%) women in the study were unmarried.

Table 3 - Obstetric Score:

Obstetric Score	Number	Percentage(%)
G1	5	9.09
G2	9	16.3
G3	23	41.8
≥G4	18	32.7
Total	55	

About 41 (74.5%) women were Gravida 3 or more indicating that MTP tablet consumption might be to get rid of unwanted pregnancy.

Table 4 - Gestational Age Distribution

Gestational Age	Number	Percentage(%)
<7w	5	9
7-9w	19	34.5
9-12w	13	23.6
>12w	18	32.7
Total	55	

24 (43.5%) cases had consumed pills before 9 weeks of pregnancy, 13 (23.6%) had consumed between 9-12 weeks, 18(32.7%) had consumed pills with gestational age of >12 weeks.

Chart 1:

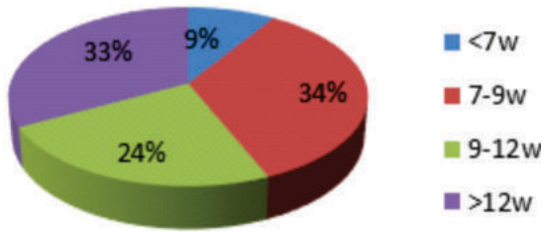

Table 5 - Time interval between consumption of pills to Hospital visit:

Interval b/n consumption of pills to Hospital visit	Number	Percentage(%)
0-7d	35	63.6
8-14d	11	20
15-21d	4	7.2
21-28d	3	5.45
>28d	2	3.6
Total	55	

Majority of the women 83.6% attended the hospital between 0-14 days of pill intake.

Table 6 - Reason cited for Abortion:

Reason for Abortion	Number	Percentage(%)
Unintended pregnancy	19	34.5
Limiting family size	26	47.2
Failure of contraception	10	18.1
Total	55	

Unintended pregnancy, Limiting family size and Failure of contraception were the main cited reasons for abortion by 34.5%, 47.2%, 18.1% women respectively.

Chart 2:

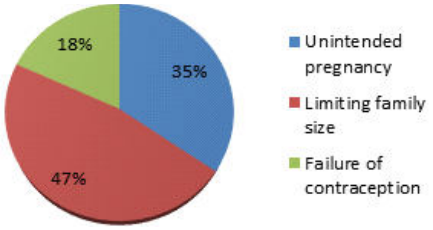

Table 7 - Reason cited for avoiding authorised medical centre as first approach:

Reason cited for avoiding authorised medical centre as first approach	Number	Percentage(%)
Easy availability of the drugs OTC	30	54.54
Unawareness of complications	13	23.6
Cost and time related factors	12	21.8
Total	55	

Easy over the counter pill availability was cited by 54.5% patients as a quicker solution to their problem.

Chart 3:

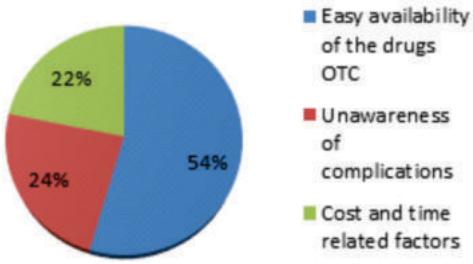

Table 8 - Source of pill procurement:

Source of Pill	Number	Percentage(%)
Non allopath dais and quacks	20	36.3
Husband/Relative	21	25.4
Self	14	38.1
Total	55	

Majority 36.3%, procured the pill from Non allopath doctors, dais or quacks.

Table 9 – Ultrasonography prior to pill intake:

Usg prior to pill intake	Number	Percentage(%)
yes	10	18.18
No	45	81.8
Total	55	

Majority (81.8%) had consumed the pill without prior usg to confirm the gestational age or localise the pregnancy.

Table 10 – Clinical features at presentation

Clinical features	Number	Percentage(%)
Excessive bleeding P/v	32	58.1
Bleeding P/v with Abdominal pain	15	27.2
Abdominal pain	2	3.6
Fever with pain and bleeding p/v	2	3.6
Not expelled products	2	3.6
Usg report of retained products	2	3.6
Total	55	

Majority (58.1%) patients presented with bleeding with per vaginum. 27.2% were presented with bleeding p/v with abdominal pain and 3.6% with fever with abdominal pain and bleeding p/v.

Chart 4:

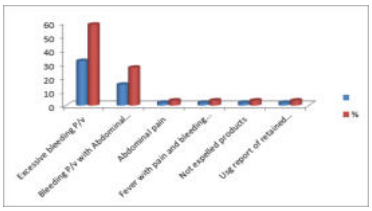

Table 11 – Haemoglobin levels:

Hemoglobin	Number	Percentage(%)
<4	7	12.72
4-6.9	22	40
7 to 10	20	36.3
>10	6	10.9
Total	55	

Majority of the patients (40%) had severe Anaemia at admission.

Table 12 – Outcome (clinical and USG) of unsupervised intake of MTP pills among study group:

Outcome	Number	Percentage(%)
Incomplete Abortion	30	54.54
Complete Abortion	3	5.4
Missed Abortion	4	7.2
Live Gestation	2	3.6
Incomplete Abortion with sepsis	9	16.3
Incomplete Abortion with shock	4	7.2
Ruptured Ectopic	1	1.81
Scar Rupture	2	3.6
Maternal Death	0	
Total :	55	

54.54% of the patients had incomplete abortion. 5.4% had Complete abortion. Incomplete abortion with sepsis in 16.3% and with shock in 7.2% cases. 1.8% had Ruptured Ectopic pregnancy and 3.6% had Scar Rupture, thus requiring immediate Laparotomy.

Chart 5

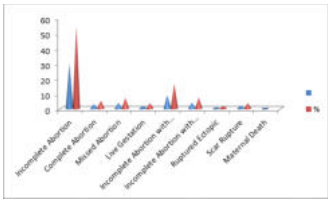

Table 13 – Associated Medical or Surgical Disorders:

Associated Medical/Surgical Disorders	Number	Percentage(%)
Severe Anaemia	29	52.72
Rh negative pregnancy	2	3.63
HIV positive	1	1.81
Cardiac Disease	0	
Bronchial Asthma	1	1.81
Seizure Disorder	0	
Post caesarean pregnancy	14	25.4
No disorder	8	14.54
Total	55	

Anaemia of varying degrees was the common associated medical co-morbidity in 52.7% patients.

Table 14 - Management

Management	Number	Percentage(%)
No intervention	0	0
Medical methods only	3	5.4
Medical methods with blood transfusion	3	5.4
Surgical evacuation only	17	30.9
Surgical evacuation with blood transfusion	27	49.1
Exploratory Laparotomy	3	5.4
Shock Management	2	3.6
Total	55	

Surgical evacuation was performed in 80% of the cases. 58.1% required blood transfusion, of these 15.62% had transfusion reactions. 5.4% required emergency exploratory Laparotomy.

Chart 6:

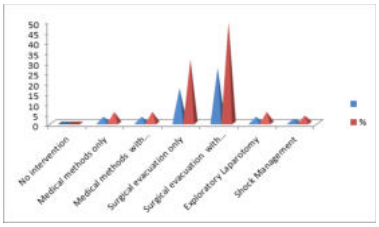

Table 15 – Transfusion Reactions

Transfusion Reactions	Number	Percentage(%)
yes	5	15.62
No	27	84.37
Total	55	

Table 16 – Duration of Hospital stay:

Duration of Hospital Stay	Number	Percentage
1-5d	41	74.5
6-10d	12	21.8
>10d	2	3.63
Total :	55	

Majority (74.5%) of them were discharged within 5 days and 3.63% cases required >10 days of hospital stay.

DISCUSSION

Unsafe abortion is an important cause of increased maternal morbidity and mortality in developing countries. The advent of medical abortion pill was intended to protect women from complicated surgical procedure of abortion. However, its widespread misuse by untrained personnel's, ignorance and unawareness of complications of unsupervised intake on part of women and easy over the counter availability of the pill despite legal ban has made this pill a public health hazard.

In this study 9.1 % women are unmarried and 74.5 % 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 (58.1 %) followed by pain abdomen. Similar results are also reported by sarojini et al (69.3%). 43.6 % had consumed pills before 9 weeks of gestation which is the recommended period for medical termination of pregnancy. 56.4 % had taken the pills beyond the recommended period of gestation. This substantiates the findings by sarojini et al. 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 5.4 % had complete abortion rest and 94.6 % had incomplete abortion, missed abortion, continuation of pregnancy or rupture ectopic.

There was 1 case of rupture ectopic; who underwent Laparotomy and partial salpingectomy. The patient 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 sarojini et al.

Serious life-threatening complications like sepsis are common in women undergoing unsafe abortions. In our study, 3.6% women presented with features of sepsis like fever, pain abdomen etc. This is similar to the study by Bhalla S et al where sepsis rate was 3%.

The most common associated medical co-morbidity was anaemia of varying degrees noted in 89% patients. The incidence of co existing anaemia was comparable to other studies by Bhalla S et al i.e. 80%.

In present study, 25.4 % patients had history of one or more prior cesarean sections which is similar to Bhalla S et al. (20%). This category is more vulnerable to life threatening complications as there is high risk of scar rupture.

36.3% of the patients procured the pill from non-allopath doctors, dais, and quacks. These results are similar to studies by Bhalla S et al (37%). Hence this depicts the true scenario , that despite legal ban on over the counter supply of this drug and strict guidelines of MTP Act, the drug is being widely misused.

Evidence shows that restricting access to abortions does not reduce the number of abortions; however it does affect whether the abortions that women and girls attain are safe and dignified. The proportions of unsafe abortions are significantly higher in countries with highly restrictive abortion laws than in countries with less restrictive laws.

Barriers to accessing safe and respectful abortion include high costs, stigma for those seeking abortions and health care workers, and the refusal of health workers to provide an abortion based on personal conscience/ religious belief. Multiple actions are needed at the legal, health system and community levels so that everyone who needs abortion can have access to it. The three cornerstones of an enabling environment for quality comprehensive abortion care are:

1) Respect for human rights, including a supportive framework of law and policy.
2) The availability and accessibility of information.
3) A supportive, universally accessible, affordable and well functioning health system.

FOGSI recommends close monitoring of distribution of these drugs and that the medical profession and pharmaceutical industries should exercise due diligence in the promotion and usage of drugs that are used for medical abortion.

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.

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.
Also, increasing awareness among women regarding complications of unsupervised pill intake and regarding availability and safety of various contraceptive methods can help control this hazard. This is also an indicator of unmet need for contraception in the community which must be addressed.

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