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ABUSE OF MTP- PILL WITHOUT PROPER PRESCRIPTION: "AN ANALYTICAL STUDY"

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ABSTRACT

The MTP act of India emphasizes that abortion pills should be prescribed by only registered medical practitioners. Inspite of recommendations and clear guidelines, due to availability of these drugs over the counter self-administration of these drugs by pregnant women has become highly prevalent. Thus this study is an attempt to collect data regarding the rampant purchase of medical abortifacients over the counter without any medical supervision along with their effects on maternal health. The study was conducted in Department of Obstetrics and Gynaecology, Government Medical College and Rajindra Hospital Patiala from January 2010 to December 2012. 131 pregnant females who reported to family planning outdoor with history of intake of mifepristone/misoprostol for purpose of abortion were enrolled. Gestational age at which drugs were taken was between 5 - 14 weeks. Per vaginal examination was done in none of the women and urine for pregnancy test was done in 76.3% of the women before intake of pill. Majority of the women 53.4% took the pill from chemist. Only 1.5% of the women took the pill on prescription of gynaecologists. Pregnancy was continued in 44.3% of the women. 38.3% had incomplete abortion. Abortion was complete only in 12.2% of the women. Only 15.26% took the drugs according to proper dosage schedule. The drugs for termination of pregnancy should be available only on prescription of qualified medical practitioner so that misuse is avoided. More focus should be on use of contraception practices for avoiding pregnancy rather than undergoing abortion.

KEYWORDS: Medical methods of abortion, mifepristone, misoprostol.

INTRODUCTION

More than half of the unintended pregnancies (nearly 46 million) are terminated every year worldwide. Unsafe abortion is associated with higher maternal morbidity and mortality. The mortality is more common in the countries where the abortion is not legalized.[1]

Government figures estimate that 6, 20,472 abortions are being performed in approved centers in India according to family welfare statistics 2011.[2] Presently in India, out of 15 million abortions which are taking place annually, 10 million are performed by quacks or untrained abortion providers. Risk of death is 0.4/lac for legal and 500/lac for illegal abortions.

WHO defines unsafe abortion as a procedure of terminating an unwanted pregnancy by person lacking the necessary skills and in an environment lacking minimal medical standards.[3]

Medical abortion as defined by WHO is the "usage of pharmacological drugs to terminate pregnancy".[3] The Indian Parliament passed the MTP act in 1971. The goal of MTP act was to regulate and ensure access to safe abortion.[4] After 2003's amendment, medical methods of abortion (MMA) using mifepristone and misoprostol have been approved as a legal method of termination of early pregnancy.[5] It also specifies to whom, by whom and where pregnancy is to be terminated MMA with mifepristone and misoprostol is a very safe option for termination of pregnancy with a success rate of 92-97%.[1] Mifepristone is a derivative of norethindrone and has antiprogestin action. It binds to progesterone receptors at endometrium and decidua, thus leads to necrosis of placenta and its detachment. It softens cervix and causes uterine contractions. Mifepristone also sensitizes uterus to the effect of prostaglandin, which is given 1-2 days later to cause abortion. Misoprostol is a synthetic methyl analogue of Prostaglandin E1, it binds to myometrial cells causing strong myometrial contractions, cervical softening and dilatation. This leads to expulsion of the products of conception.[6]

WHO guidelines emphasize the necessity of pre-abortion care to confirm the pregnancy, the site of pregnancy and to estimate the correct gestational age. It also indicates

the necessity to obtain a detailed medical history to rule out contraindications for medical abortion such as bleeding disorders, chronic adrenal failure, uncontrolled seizure disorder etc and the importance of bimanual examination to assess the size of the uterus and basic laboratory investigations. WHO has documented clear guidelines for medical method abortion upto 7 weeks with tablet mifepristone 200mg followed by single dose of oral or sublingual tablet misoprostol 400ug after 24-48 hours. Upto 9 weeks mifepristone 200mg stat and after 24-48 hours single oral or sublingual dose of tablet misoprostol 800ug[3].

According to both FOGSI & WHO ultrasound is not mandatory but where it is available can be used to exclude an extra uterine pregnancy and to diagnose nonviable pregnancies.[1,3]

The MTP act of India emphasizes that abortion pills should be 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 following medical abortion.[3]

Inspite of recommendations and clear guidelines, due to availability of these drugs over the counter self-administration of these drugs by pregnant women without any medical consultation or supervision has become highly prevalent. Many women consider medical abortion as a method of spacing between pregnancies. Life threatening complications like excessive hemorrhage, sepsis, DIC and high maternal mortality due to undiagnosed ectopic pregnancies are not uncommon in pregnant women taking these drugs by themselves without medical consultations. Lack of awareness about the MTP act and existing guidelines, concerns about privacy and affordability etc. lead women to procure medical abortion drugs over the counter.

Thus this study is an attempt to collect data regarding the rampant purchase of medical abortifacients over the counter without any medical supervision along with their effects on maternal health.

AIMS AND OBJECTIVES

To conduct an analytical study regarding abuse of mifepristone/misoprostol i.e. MTP-Pill (as commonly referred by patients) for abortion without a proper prescription, its consequences and management.

MATERIALS AND METHODS

The study was conducted in Department of Obstetrics and Gynaecology, Government Medical College and Rajindra Hospital Patiala from January 2010 to December 2012. Pregnant females who reported to family planning OPD with history of intake of mifepristone/misoprostol for purpose of abortion were enrolled Total 131 women were included in this study with history of intake of abortion pill. Following point were noted:

- Age of the women
- Belong to urban or rural area
- At what gestational age the pill was taken
- Who prescribed the pill
- Any examination/test done before intake
- With what complains patient reported to hospital
- Any follow up done
- Pregnancy outcome
- How these patients were managed in our institute

OBSERVATIONS

131 cases reported with H/O intake of pills for abortion. All the subjects were multigravidas Table I showing the age wise distribution of the women. Majority of the women were in age group 26-30 years. Mean age was 29.36 years.

Table II shows the demographic profile of the women.48.09% of the women was from rural area while 51.91% of the women were from urban area thus the use was almost equally prevalent.

Gestational age at which drugs were taken was between 5 - 14 weeks. The minimum reported was 1 month and 3 days and maximum as 3 months and 8 days.

Majority of the subjects presented to us with bleeding P/V. Some reported when symptoms persisted and area health workers brought them to the OPD. Others reported when no bleeding occurred and repeat UPT (urine for pregnancy test) or USG (Ultrasonography) depicted continuation of pregnancy.

Table III shows the examination and investigations undertaken by the women before intake of the abortion pill. Per vaginal examination was done in none of the women. UPT was done in 76.33% of the women and ultrasound pelvic organ was done in only 3.82% of the women.

Majority of the women 53.43% took the pill from chemist. In 33.59% of the women the pill was prescribed by RMP (village doctors/quacks). 6.11% of the women took the medicine by self without any supervision. In 3.82% of the women pill was given by ANM (Auxiliary Nurse Midwife). Only 1.53% of the women took the pill on prescription of gynaecologists.(Table IV).

As depicted in Table V, pregnancy was continued in 44.27% of the women. 38.17% had incomplete abortion. Abortion was complete only in 12.21% of the women. 2.29% of the women had missed abortion. Serious complications like ectopic pregnancy and septic abortion were seen in about 1.53% each.

Table VI shows the procedure done in our tertiary hospital after they presented to us in family planning OPD. Dilatation & curettage was done in 38.18% of the

women. 31.30% underwent MTP & bilateral laprosterilization. Pregnancy continued in 12.21% of the women because of advanced gestation or patient refused termination. Surgical evacuation along with IUCD insertion was done in 2.29% of the women. Laparotomy due to ruptured ectopic was done in 3.05% of the women. Only one woman was managed medically. 11.45% of the women didn't require any intervention.

Only 20 subjects i.e. 15.26% took the drugs according to proper dosage schedule. Other various schedules used were

- One tablet only
- One tablet on Day 1, 2 on Day 2 and 2 on Day 3
- One tablet stat then one daily for 2 days
- One tablet stat and then one BD for 2 days
- One tablet stat and then 2 after 12 hours and another 2 after 12 hours
- One tablet stat and then one tablet 4 hourly - 3 – 4 doses

No counselling was done in any of the subjects. None were aware of any side effects. In general there was lack of awareness regarding regular contraception among subjects and they were not counselled regarding contraception after MMA. None knew about the necessity of follow-up. Bleeding was taken as normal periods have occurred.

In Table VII, we have compared the results of our study with the figures given in guidelines[6]. The complete abortion rate was 12.21% where as its reported to be 95-99% with MMA. 38.16% required vacuum aspiration because of incomplete abortion where as its estimated to be 1-2%. Also need for blood transfusion arises only in 0.1-0.2% whereas in our study it was 5.34%.

Table I: Age wise distribution

Age (in years)	No of subjects	%age
21-25	24	18.32
26-30	68	51.91
31-35	29	22.14
36-40	9	6.87
> 40	1	0.76
Total	131	100
Mean age	29.36 years	

Table II: Demographic profile

Area	No of subjects	%age
Rural	63	48.09
Urban	68	51.91
Total	131	100

Table III: Tests done before drug intake were as follows

Examination/Test	No of patients	%age
P/V Exam	None	None
UPT	100	76.33
USG	5	3.82

(Rest took the drug when days were over).

Table IV: Took the tablets on whose advise

Provider	No of subjects	%age
Gynaecologist	2	1.53
Village doctors/quacks (not qualified doctors)	44	33.59
Chemist	70	53.43
ANM	5	3.82
Dai	1	0.76
Self	8	6.11
Advised by neighbour	1	0.76
Total	131	100

Table V: Pregnancy outcome

Pregnancy Outcome	No of subjects	%age
Pregnancy continued	58	44.27
Incomplete abortion	50	38.17
Complete abortion	16	12.21
Missed abortion	3	2.29
Ectopic pregnancy	2	1.53
Septic abortion	2	1.53

Table VI: Procedure done (at our institution)

Procedure done	No of subjects	%age
MTP with B/L laprosterilization	41	31.30
D & C	50	38.18
Pregnancy continued	16	12.21
B/L Laprosterlization	1	0.76
MTP and CuT	3	2.29
Laparotomy	4	3.05
Medical Management	1	0.76
No Procedure	15	11.45
Total	131	100

Table VII: Results of our study

Condition	Effectiveness	In our study
Complete abortion	95-99%	12.21%
Heavy bleeding requiring vacuum aspiration	1-2%	5.34%
Incomplete abortion requiring vacuum aspiration	1-2%	38.16%
Heavy bleeding requiring blood transfusion	0.1-0.2%	5.34%

DISCUSSION

This drug is easily available over the counter and women who are not much educated take these pills without any supervision. These women are not aware of the complications, risk and failure of the pills. They do not have the knowledge about when to take and the correct dose and when to report to doctor. In our study 48.09% women were from rural area and 51.91% were from urban area. The MTP act was passed with the aim of legalizing the abortion and decreasing the number of maternal deaths due to unsafe abortions. But still 8% of maternal deaths are attributed to unsafe abortions in India and 10 million risk their lives by approaching quacks or untrained abortion providers. In our study all the patients were multigravida where as other authors have reported upto 33.33% to be primis.[7] The pills were taken from chemists directly in 53.43% in our study mostly by husbands when days were overdue as quoted by other studies as Bajwa SK et al[8] (29.61%), Agarwal M[7] (76.66%) in spite of clear guidelines that these pills can be prescribed only by a person authorized under the MTP act and to be taken only under medical supervision. In our study the pills were prescribed by Village doctors(not qualified doctors) or quacks in 33.59% of cases. Most of the females reported to OPD with complaint of bleeding per vaginum as seen in studies by other authors.[8,9,10] The incomplete abortion rate was much higher in our study (36.16%) as compared to that given in WHO-CCR research (1-2%).[6] Similar to our study various other authors have also reported very high rate 56.66% by Agarwal M[7], 41.54% by Bajwa SK[8] and 62.5% by Nivedita K.[9]

The infection rate after medical abortion is <1% compared to surgical methods when done under MTP guidelines.[6] However, sepsis found to be higher in women undergoing unsafe abortions. Studies comparing intake of abortion pills with medical supervision and self-administration found women who self-administered the drug have higher complication rate like anaemia, sepsis, failure and incomplete abortion. In our study only two women had features of incomplete abortion and sepsis and responded to surgical evacuation under cover of antibiotics.

Studies comparing medical and surgical methods have shown that incomplete abortion, rate of surgical evacuation and heavy bleeding were more after medical abortion.[11] Thus the need for supervision.

In 1% of the pregnancy following medical abortion there are chances of failed abortion. That means pregnancy continues but the incidence in present study was 12.21%. Misoprostol is teratogenic and causes skull defects and limb abnormalities in the fetus. Hence the process should be completed by surgical evacuation and continuation of pregnancy is not an alternative We could not offer them termination because by the time they reported to us pregnancy was in advanced stage. The reasons for so many complications that we could assess were no proper examination, no supervision and most importantly no

proper intake of medicines. Varied self made regimes were used by patients.

The reasons for increased use of abortion pills without supervision are lack of education and awareness regarding legal status of abortion, lack of awareness of the complications involved in medical abortion, the need to maintain privacy, the cost involved and mainly the easy availability of the drugs.

CONCLUSION

Abortion can be offered at an early stage of pregnancy and with more privacy by MMA. Counseling and ruling out contraindications is mandatory before initiating MMA procedure. All the MTP rules apply to MMA as well. All the documentation required for surgical abortions is also required for MMA (including Forms C, I, II, III). The drug protocol should be strictly followed for success of MMA. Potential side effects during the MMA process and the warning signs and symptoms should be discussed with the woman before initiating the procedure. Once initiated, the process of abortion has to be completed by surgical methods as vacuum aspiration in case of failure of the procedure because of slight risk of teratogenic effect of the drugs. We should assist MoHFW in developing and updating standards, guidelines and protocols for implementing abortion services. There should be policies to educate chemists/ pharmacists on the legal issues around abortions since a study conducted by PSI on chemists revealed that 70% of MMA drugs are dispensed through chemists without prescriptions. As patients had easy access to these drugs for termination of pregnancy, they should not be available over the counter but only on prescription of qualified medical practitioner so that misuse is avoided. More focus should be on use of contraception practices for avoiding pregnancy rather than thinking undergoing abortion.

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