

ORIGINAL RESEARCH

Inadvertent use of medical abortion pills: A cause of concern

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ABSTRACT

Background: Medical Methods of Abortion are gaining popularity and fast becoming the preferred mode of termination of early pregnancy. Although slated to be safe in various studies, they are not without ill effects in taken indiscriminately. A recent trend has been to procure these drugs over-the-counter and consume them unsupervised. **Objectives:** To study the demographic trends of the patients coming with adverse effects of medical abortion pills and to ascertain any common factors which help provide an insight into any social trends influencing the use of the same. **Methods:** This study was an observational study conducted in a semi urban district of Western Uttar Pradesh. A total of 144 women coming with side effects of home ingestion of medical abortion pills were studied over a period of 5 months. **Results:** The most common presenting complaint was persistent bleeding per vaginum which was seen in 77%. A few patients came in hemorrhagic shock and needed blood transfusions (2.1%). 4.9% of women came with ectopic pregnancy. 133 women (92.36%) procured these drugs over-the-counter without taking advice from any registered medical practitioner. The dosage schedule was also improper. The educational status and area of residence (urban or rural) did not seem to be significantly affecting the choices made by these women as in both these groups p value >0.05. **Conclusion:** Medical abortion pills, though proven to be safe and convenient, can prove harmful when taken unsupervised. Easy availability of medical abortion drugs over-the-counter is a problem that needs to be acknowledged and addressed by the policy makers. Social trends also need to be studied regarding to the choices made by women for unwanted pregnancies.

Key words: medical abortion pills, over-the-counter

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INTRODUCTION

Motherhood has long been, and is still considered, the greatest joy in a woman's life. On the other hand, an unwanted pregnancy can be a source of great unhappiness and ill health at the same time posing an economic burden on the family. Frequent unwanted pregnancies, take a toll on a woman's health- both mentally as well as physically. The abortion scenario in our country is still bleak. Unsafe abortions account for 8% of all maternal deaths in our country¹. Medical Termination of Pregnancy (MTP) was made legal in 1971 vide the MTP Act. It laid down provisions as to who, where, how and when of termination of pregnancy². While the previous act allowed termination up to 20 weeks of pregnancy, the latest amendment of the MTP Act have now allowed termination of pregnancy up to 24 weeks.³ However, there are certain impediments to access to safe abortion practices. According to the Act, MTP can only be performed by a Registered Medical Practitioner (RMP) with adequate training. The centers offering MTP services have also been

specified in the Act. Many a times, dearth of trained providers, equipment and registered centers may limit access to legal abortion centers. This leads to the woman tuning to the untrained sector for abortions with consequent complications⁴.

WHO has now recommended the use of Manual Vacuum Aspiration and Medical Methods of Abortion (MMA) as safe methods of pregnancy termination⁵. The MTP Act was also amended in 2002 to include MMA. According to the amendment, MMA could be prescribed up to 63 days (9 weeks) of gestation⁶. Only trained RMP are allowed to prescribe these drugs in legally approved facilities. RMP in unapproved facilities may also prescribe MMA drugs, but they should have adequate referral linkages with approved facilities and proper referral services in case of any untoward complications. Proper documentation of all MMA cases is also mandatory⁶

A combi pack of Mifepristone 200 mg and 4 tablets of Misoprostol 200ug each, has been approved by the Central Drugs Standard Control Organization,

Directorate General of Health Services for termination of pregnancy up to 9 weeks in December 2008⁷. It was hoped that the advent of MMA would bridge the service delivery gap and help in decreasing the incidence of unsafe abortions. However, that does not appear to be the case. It is estimated that about 16 million abortions take place in India annually: out of these, almost 75% take place in unauthorized centers. Most of these abortions are medical. Despite the fact that abortion cases and complications are vastly under reported, a recent study by Singh et al reported a whopping 67% of abortions as unsafe⁸. At our center also, we have observed a sharp increase in the number of cases presenting to the outpatient department (OPD) and emergency with varying complications post medical abortion; most of these drugs self-administered in improper doses. Considering the high contribution of unsafe abortions to maternal mortality in India and an even higher percentage of maternal morbidity, this is a matter to be considered by our policy makers.

MATERIAL AND METHODS

This study was a cross sectional study conducted on women coming to the hospital after having taken MMA and was done over a period of 5 months. During this. A total of 144 women were studied

INCLUSION CRITERIA

All women coming to the hospital either in the OPD or in the emergency with complications arising due to ingestion of MMA were included in the study.

EXCLUSION CRITERIA

Those women who were prescribed MMA from our center were excluded from the study.

Women with history of having taken medical abortion pills more than 2 months back were excluded from the study.

Women with complaints unrelated to intake of medical abortion pills were excluded from the study.

Women unwilling to share demographic details were also excluded from the study.

Demographic details of all these women were studied after obtaining consent from these patients. Data was collected regarding age of the patients, literacy level, residential area, method of drug intake, source of obtaining the medical abortion pills, period of gestation, presenting complaints and any other associated high-risk factors. Ultrasound was done on all these patients and adequate treatment was administered.

OBSERVATIONS

The present the present study was done on 144 women who presented to the Obstetrics and Gynecology Department, Government Medical College, Badaun, with complaints after ingestion of medical abortion pills.

The following data were obtained from the present study.

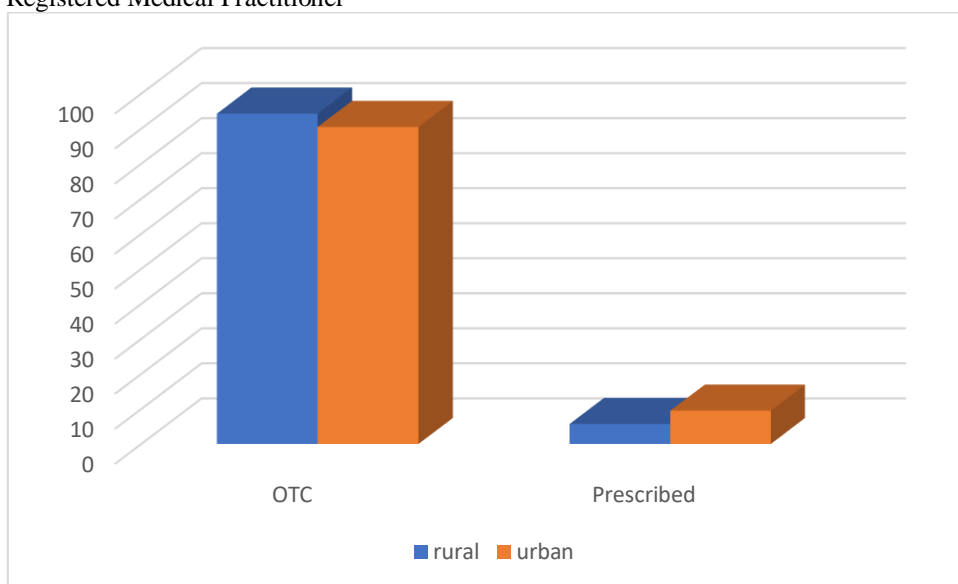
The demographic profile shows that majority 90 (62.50%) women belong to age group of 20-30 years followed by 51 (35.42%) women had age group 31-40 years. Very few 3 (2.08%) women were more than 40 years of age.

Majority of the women 66(45.83%) were Gravida 3 followed by 53(36.11%) Gravida 4 and above, while 24(16.67%) of patients were with gravida 2. Only one patient was a Primigravida.

	OTC	Prescribed	Total	P- Value
Residence				0.398
Rural	66 (94.3%)	4 (5.7%)	70 (100%)	
Urban	67 (90.5%)	7 (9.5%)	74 (100%)	
Educational Status				0.704
Illiterate	25 (96.2%)	1 (3.8%)	26 (100.0%)	
Literate	50 (90.9%)	5 (9.1%)	55 (100.0%)	
Graduate	58 (92.1%)	5 (7.9%)	63 (100.0%)	
Complaints				0.769
Persistent BPV	102 (91.9%)	9 (8.1%)	111 (100.0%)	
BPV with pain	19 (90.5%)	2 (9.5%)	(100.0%)	
Shock & Amenorrhoea	3 (100.0%)	0	(100.0%)	
Scanty Bleeding after MTP	9 (100.0%)	0	(100.0%)	
Diagnosis				0.687
Incomplete Abortion	115 (92.0%)	10 (8.0)	125 (100.0%)	
Pregnancy Continued	8 (100.0%)	0	8 (100.0%)	
Ectopic Pregnancy	4 (80.0%)	1 (20.0%)	5 (100.0%)	
Caesarean Ectopic	2 (100.0%)	0	2 (100.0%)	
Women Conceived in next Pregnancy	4 (100.0%)	0	4 (100.0%)	

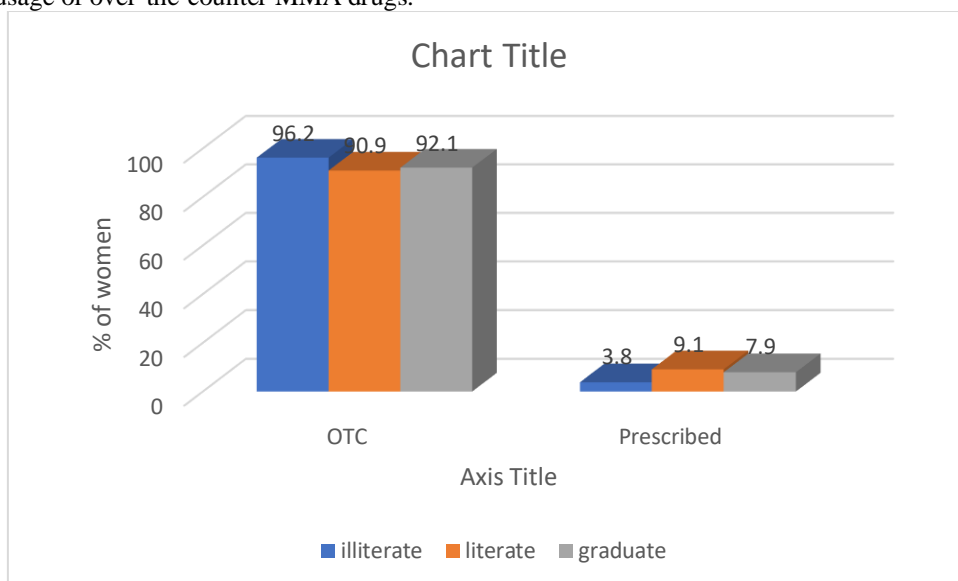
The area of residence of the women or was somewhat equal with 74 women belonging to the rural area whereas 70 women were residing in the urban area.

133 out of 144 women bought the drug over- the counter (OTC) and only 11 patients were prescribed MMA drugs by a Registered Medical Practitioner



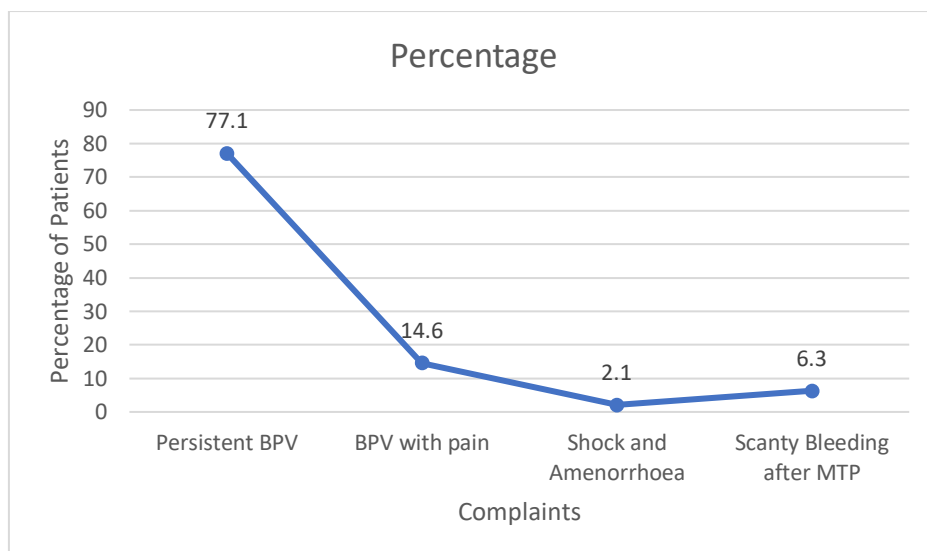
66 out of 133 women who brought the MTP kits over the counter belong to Rural area and 67 belonged to urban area. The p- value for this data is 0.398 which is insignificant.

26 out of 144 women were illiterate, 55 out of 144 literate and 63 women were graduates or postgraduates. The p-value calculated was 0.704(not significant) showing that educational status had no impact on the awareness about the usage of over-the-counter MMA drugs.



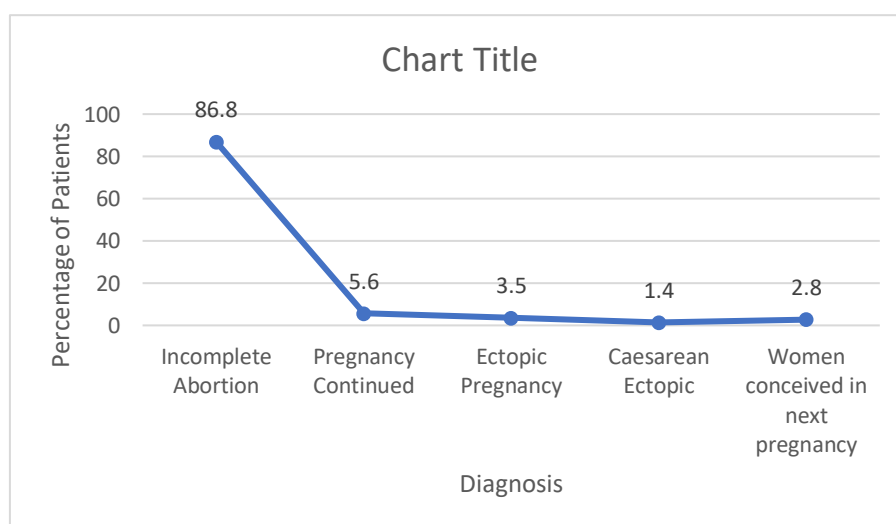
Among 144 women, 77.1% presented with persistent bleeding per vaginam, 14.6 % with abdominalpain, 2.1 % women came in shock and 6.3 % with scanty bleeding or persistent amenorrhoea.

COMPLAINTS					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Persistent BPV	111	77.1	77.1	77.1
	BPV with pain	21	14.6	14.6	91.7
	Shock	3	2.1	2.1	93.8
	Scanty Bleeding or amenorrhoea after MMA	9	6.3	6.3	100.0
	Total	144	100.0	100.0	



Diagnosis of Incomplete abortion was made in 86.8%, followed by pregnancy continued in 5.6 %, followed by ectopic in 3.5% and cesarean ectopic in 1.4%. 2.8% of these were diagnosed as women who conceived in the next menstrual cycle

DIAGNOSIS					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Incomplete Abortion	125	86.8	86.8	86.8
	Pregnancy Continued	8	5.6	5.6	92.4
	Ectopic Pregnancy	5	3.5	3.5	95.8
	Caesarean Ectopic	2	1.4	1.4	97.2
	Women conceived in next pregnancy	4	2.8	2.8	100.0
Total		144	100.0	100.0	



DISCUSSION

Mifepristone is a drug that was developed in 1980, first used in France as early as 1987. It is a progesterone receptor antagonist and works by blocking the effect of progesterone. By virtue of this action, it produces changes in the cervix leading to cervical dilatation and also causes uterine contraction. When combined with misoprostol (PGE₂), it has been found to be an effective method of abortion.

As mentioned earlier, InIndia, about 3/4th of abortions take place at home, unsupervised, outside of any qualified medical guidance or care through medical abortion pills. With proper care and counselling, MMA is an extremely successful and convenient method of abortion. There have been numerous studies establishing the fact that rate of complete termination with medical abortion pills is not affected by home administration⁹¹⁰. The Ministry of Health and Family Welfare has spelt out stringent norms and

guidelines for prescription, documentation and follow up while prescribing these drugs these so as to increase the safety profile⁷.

Sadly, these drugs are freely available over the counter and are taken unsupervised by women. And whereas it is mandatory to report prescription and follow up of MMA drugs, there is no norm for reporting these women who have procured these drugs over the counter and report to the hospital with complications. So, the magnitude of this problem remains unrecognized.

In our study also, 92.36% obtained these drugs over the counter with unsupervised intake. The dosage schedule was also improper in these women.

Most women (77.1%) came to the hospital with persistent bleeding. This is a well-known complication of these drugs. Henderson et al in a study reported a problem of excessive bleeding per vaginum with these drugs but a low incidence of blood transfusions¹¹. 3 patients (2.1%) in our study, came in shock and to be given blood transfusions. All these patients had taken these drugs OTC. We also observed women taking these drugs beyond the permissible gestation obviously leading to failure of abortion or excessive bleeding per vaginum. A history of previous caesarean was also not a deterrent for them. The side effects in our study were similar to those found by Kumar et al in their study although on a more severe magnitude¹². 4 patients conceived in the very next cycle as evidenced by a positive pregnancy test and an ultrasound revealing a fresh pregnancy.

A point of interest in our study was revealed in the demographic profile, which revealed that more than half the women were graduates and postgraduates. Comparison of the groups of educated and uneducated women, and of urban and rural groups showed a p value of 0.704 and 0.398 respectively which is not significant. A similar study by Singh et al in 2015⁸, had attributed a high concentration of health care facilities in the urban areas as one of the reasons for poor abortion services in the rural areas. However, in our study we have found no significant difference in the urban and the rural groups. Women in both the urban and the rural population have chosen to opt for over-the-counter medication rather than approach a registered health care facility. Clearly, lack of access to health care facility does not seem to be an important deciding factor. On closer questioning of these women, it was revealed that in all these cases these pills were procured by their spouses over-the-counter without consulting any Registered Medical Practitioner or a qualified gynecologist. Also, the dosage schedule and timing of ingestion of MMA drugs in most women was not as recommended, understandably leading to resultant complications. This reluctance in seeking medical help even amongst the educated group of women is a matter of concern and the author feels that there is a

big lacuna in understanding the social perspective of these women and is an area that calls for further qualitative studies.

CONCLUSION

In conclusion, MMA, although known to be safe and convenient, can also prove dangerous if taken unsupervised. However, despite this knowledge, a vast population of women still continue to do so. More stringent measures for restricting free availability of these drugs need to be taken. Perhaps, we need to accept the reality of easy over-the-counter availability of medical abortion pills and devise ways to make them safer. Maybe, illustrations on the pill packets regarding proper dosage schedule, display of contraindications and warning messages may help. Also, in depth studies need to be undertaken regarding the practices and choices made by women with regards to contraception and unwanted pregnancy termination.

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