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Abstract

Background: Over-the-counter (OTC) sale of medical abortion (MA) inducing drugs is a common practice. Exploring its impact on women's health and the barriers to avail free MA services at hospital by these women is essential to improve upon policy decision. **Methods:** A prospective observational study included 112 women following ingestion of MA drugs from nonformal providers. Demography, clinical details, and reasons for not availing free abortion services at hospital were recorded. **Results:** Among 112 women, mean age was 28.63 (SD 4.7) years. Seventy one (63.39%) women were from rural region; 70.54% were educated below high school; 44 (39.28%) had prior induced abortion; 62.5% had never used any contraception. Majority (101; 90%) took two drugs (Mifepristone and Misoprostol), 28 (25%) used correct dosage. Drugs were consumed beyond 9 weeks of gestation by 25 (22.4%) women. Abnormal vaginal bleeding was commonest 105 (93.75%) presentation. Haemorrhagic shock was noted in 21 (18.75%) women, while 21 (18.7%) women required blood transfusion. "Easy and quick availability of these drugs OTC" was the commonest statement for not attending hospital. **Conclusion:** Easy and quick availability of OTC drugs, distance to hospital were major barriers. Incorrect dosage and lack of gestational age calculation were two most common errors in the risk assessment protocol. Expanding provider base, by training midlevel providers, can overcome these and unmask the full potential of MA to make abortion safer.

Keywords: Maternal morbidity, medical abortion, mifepristone, misoprostol, safe abortion

Introduction

Unsafe abortion, a significant social and economic burden, contributes to short and long-term maternal morbidity and mortality.^[1] As per World Health Organization (WHO) systematic analysis, abortion accounts for 8% of maternal deaths.^[2] In 2010, nearly four decades following legalization of abortions, 9% of maternal deaths were attributed to pregnancy with abortive outcomes in India.^[3]

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Medical abortion (MA) drugs, a major milestone in reproductive health, are shown to be safe and effective in early pregnancy.^[4] MA drugs were approved in India 2002.^[5] Initial reports have shown reduced abortion related complications, as women switched from more damaging methods to using this medication.^[6] However, subsequently, there has been a rising trend towards unsupervised self-medication of these drugs because of over the counter sale (OTC) by pharmacist and other nonformal providers in India.^[7] As per pharmaceutical sources sale of misoprostol tablet increased from 7 million in 2007 to 100 million in 2011 and 20 million mifepristone tablets were sold in 2011.^[7] Consequently increasing number of women with varied severity of complications subsequent to consumption of MA drugs from nonformal providers were reported attending different tertiary care hospitals.^[8,9] The WHO defines unsafe abortion as "a procedure for terminating unintended pregnancy

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carried out either by a person lacking necessary skills or in an environment that does not conform to minimal medical standard".^[10] Therefore, all these unsupervised self-medication contributes to unsafe abortion. Such cases remain highly under reported and are not reflected in health indices of the nation in spite of being a serious health hazard. Earlier studies from India have focused on the magnitude unsupervised usage of these abortion inducing drugs and its related maternal morbidity and mortality.^[8,9] These studies are retrospective and did not address the reasons for not availing free hospital-based abortion services by women. This present study was planned to explore impact of over the counter sale of abortion inducing drugs on maternal morbidity and mortality, socio-demographic profile of these women seeking medical abortion through nonformal providers, and the reasons for not availing free abortion services at hospital by these health insured women.

Material and Methods

This prospective observational study was conducted after approval from institutional ethics committee, from January 2014 to December 2016 in the department of Obstetrics and Gynecology at ESI-PGIMSR and ESIC Medical College (ESIC -MC), Kolkata, which is a tertiary care institution to provide health services to its population on cashless basis. The women, taking MA inducing drugs from nonformal providers and reporting to the outpatient and casualty of department of obstetrics and gynecology, were included in the study after written informed consent. Detailed history including demography, drug providers' information, obstetric history, gestational age at the time of drug ingestion, any pre-abortion counselling, contraceptive behaviour along with clinical examination and requisite investigations details were recorded in a case record form. Treatment was provided to these women as required by their clinical condition. These women were followed during treatment period and six weeks postabortion. The barriers/reasons for not opting for hospital based free abortion services were explored by prestructured open-ended questionnaire. Data were analysed by using Microsoft Excel 2007 software.

Results

One hundred and twelve women were enrolled for the study after informed consent. These women attended the outdoor patient department (OPD) and casualty of department of obstetrics and gynaecology of ESI-PGIMSR and ESIC-MC after ingestion of medication for inducing abortion from nonformal providers between January 2014 and December 2016. Mean age of participants was 28.63 years (SD 4.74) and minimum age recorded was 18 years. Nearly two third (71; 63.39%) women resided in rural areas [Table 1].

Nearly a half of these women, 55 (49%) had at least one living child while 11 (9.82%) women had three or more children. Almost one third 36 (32.1%) of these women had prior one induced abortion and remaining, nearly two third 68 (60.7%),

current abortion was first induced abortion. Majority 70 (62.5%) had never used any of the modern method of contraception. Among 42 (37.5%) women, contraceptive ever users, combined contraceptive pill had been the commonest 25 (59.52%) and the most preferred method followed by barrier method.

Different dosages and drug combinations were used by these abortion seekers. Majority of these women 97 (86.6%) received these drugs over the counter without any prescription while 15 (13.39%) women sought the local medical practitioner for the prescription. Combination of two drugs, mifepristone and misoprostol, was used by 101 (90%) women. However, correct dosage of the combination drug regimen, was used only by 28 (25%) women. Period of gestation at the time of ingestion of drug was up to 7 weeks in 45 (40.17%) women between 7 to 9 weeks in 42 (37.5%) and beyond 9 weeks in 25 (22.32%) women.

The commonest presenting symptom was abnormal vaginal bleeding, reported by 105 (93.75%) women while 21 (18.75%) women reported with features of haemorrhagic shock. Blood transfusion was required in 21 (18.75%) women. Severe anaemia

Table 1: Demographic characteristics of participants						
(n=112)						
Variables	No.	%				
Age of women (years)						
≤20	02	01.78				
21-30	78	69.64				
31-40	31	27.67				
≥40	01	00.89				
Place of residence						
Urban	41	36.60				
Rural	71	63.39				
Religion						
Hindu	89	79.46				
Muslim	23	20.54				
Others	0	0				
Educational level of women						
illiterate	12	10.71				
<high school<="" td=""><td>79</td><td>70.54</td></high>	79	70.54				
≥High school	21	18.75				
Educational level of husband						
Illiterate	10	08.93				
<high school<="" td=""><td>54</td><td>48.21</td></high>	54	48.21				
≥High school	48	42.86				
Employment of women						
Homemaker	94	83.93				
Working	18	16.07				
Monthly income of family (Rupees)						
≤5000	37	33.04				
>5000 -10,000	70	62.50				
>10,000	05	04.38				
Number of times pregnant						
G1	02	01.79				
G2	35	31.25				
G3	47	41.96				
≥G4	28	25.00				

requiring blood transfusion was found in 5 (4.4%) women. One of these women developed severe blood transfusion reaction leading to acute kidney injury, which responded to conservative management.

Six women (5.36%) presented with ectopic pregnancy and underwent emergency laparotomy and salpingectomy. Histopathology revealed tubal ectopic gestation in all cases. Most women 95 (84.82%) required dilatation and evacuation for retained products of conception while 2 women expelled spontaneously after reporting to hospital. Six women (5.3%) were managed conservatively as ultrasonography showed complete abortion. Histopathology was available for 97 (86.6%) cases. Of these, products of conception were reported in 83 (85.5%) and clot in 14 (14.4%) cases. Two women reported at 19 and 20 weeks of gestation with ongoing pregnancy and abortion was induced after hospitalization on their request. One woman reported at 22 weeks of gestation, she continued her pregnancy and delivered a preterm live born baby.

While exploring the reason, for not availing free abortion services at the hospital, the most common statement recorded was, "easy and quick availability of these drugs over the counter from nearby sources". Ten women (8.92%), residing in rural areas, stated travelling distance and lack of accompanying person as a barrier to attend the hospital [Table 2].

Discussion

In the current study, majority 71 (63.4%) of the women were from rural areas and nearly one fourth (22.3%) of these women consumed MA drugs beyond 9 weeks of gestation. In addition, none of these women in present study had base line investigation, like haemoglobin estimation and blood grouping, prior to drug ingestion. Surgical evacuation of uterus was the commonest (84.8%) surgical intervention needed by these women in the present study. Consumption of these drugs beyond 9 weeks is not permitted in Medical termination of pregnancy act, India, and prescription is mandatory for sale of these drugs.^[11,12]

Table 2: St	atements	of reaso	on for n	ot availing	the medical
abortion	n comicos	from in	0.01110000.00	a hasnital (n = 112

abortion services from insurance nospital (n=112)					
Reasons	No.	%			
Easy availability of medical abortion services nearby home	48	42.86			
Wanted to ensure complete privacy by not attending hospital	16	14.29			
Not aware about availability of medical abortion services in	10	08.93			
hospital					
Lack of time/unable to get time from her daily activity	10	8.9			
Distance from hospital and transport problem	07	06.25			
Heard from neighbour that drugs work well	06	05.36			
Fear of hospitalization as she presumed pregnancy	04	03.57			
termination always need hospital admission					
Fear of unknown	04	03.57			
No one available to accompany her to hospital	03	02.68			
Unable to provide any specific reason	02	01.78			
Unable to make decision and husband takes decision	02	01.78			

Similar findings were noted from state of Uttar Pradesh, India, where more than half of these women took abortion pill beyond nine weeks of gestation.^[13] Surgical evacuation had been the commonest reported intervention in the prior studies from India.^[8,14] These findings indicate a serious health issue as induced abortion by medications beyond the prescribed gestational age lead to higher complications^[15] and thus directly increasing maternal morbidity and mortality.

A study from Chhattisgarh, a state of India, revealed that 57% of the women consuming these drugs from nonformal providers were from rural areas.^[16] This could be due to lack of medical abortion services in primary health centres. A study from 33 districts of Rajasthan revealed that there were 0.85 certified abortion facilities per 100,000 population in rural blocks as compared to 3.65 in urban blocks.^[17]

Commonest life-threatening complication noted in the current study was haemorrhagic shock in 21 women (18.75%) followed by ectopic pregnancy in 6 (5.4%) women. Blood transfusion was required in 21 (18.75%) cases. Similar to this, need of blood transfusion has been variously reported as 16.2% to 22.2% while ectopic pregnancy is reported as 5.4% to 11.6% in the prior reports from India.^[8,13] No maternal death happened in our study which is similar with most of the reported studies.^[9,13,14] However, a study from western part of India, revealed one maternal death due to sepsis following curettage for prolonged bleeding subsequent to consuming these drugs.^[8] Although maternal death had been a rare event in all the reported studies, but this does not provide true measure of the safe abortion services. Maternal morbidity matrix developed by Maternal Morbidity Working Group (MMWG) WHO, is a tool to measure the maternal morbidity beyond near miss and can serve as a better measure for assessing quality of health care.^[18] Using this matrix, all the reported complications related to abortion inducing medication in the current study are direct cause of maternal morbidity.^[18]

Kay reported 11 million annual sales of mefipristone and misoprostol combination kits in India while 70000 abortions were reported from formal centers.^[19] This data implies a reasonable possibility of prescription of these drugs by nonformal sources and thus many abortions remain unreported formally. The number of admissions in the health care facilities with some complication following consumption of such drugs from nonformal sources is simply tip of the iceberg of this unseen huge problem. In a systematic review from low- and middle-income countries it was found that pharmacy workers and drug sellers had poor knowledge of effective regimens of medical abortion inducing drugs.^[20] Thus, such a large number of over the counter sale of abortion kits by the chemist is a menace to safe abortion services in India. In addition, the discrepancy between the sold number of abortion drug kits and annual abortions in India, uncovers the huge need of trained providers of these drugs. It is estimated that 15.6 million abortions occurred in India in 2015.^[21] Of these only 3.4 million abortions (22%) were obtained in health facilities and the remaining 11.5 million (73%) abortions were medication abortions done outside of health facilities.^[21] This further highlights the gaps in the availability of safe medical abortion services in India.

In Bangladesh, a low-resource country, nonphysician health workers are permitted to perform menstrual regulation over four decades.^[22] More recently plenty of evidence is emerging regarding safety and efficacy of medical abortion by mid-level workers.^[23] WHO guideline in 2015 provides a recommendation on role of trained nonphysician healthcare provider for providing safe abortion, postabortion care, and contraception at primary care level.^[24] Therefore, keeping this recommendation in perspective, provision of training, and involvement of nonphysician healthcare personnel should be made permissible in the current MTP act of India in order to achieve uniform and wider availability of safe abortions in remote areas of the country and unmask the hidden great potential of medical methods.

Women seeking access to pharmacies and OTC sale of medical abortion drugs is a common challenge for delivering the safe abortion services to women in different countries.^[25,26] Recently the evidence is evolving regarding training of pharmacy staff to facilitate provision of complete and correct information to the client.^[25,26] Weaver *et al.*^[25] in their study from Mexico reported the need for target education of pharmacy staff and women about safe and effective use of medical abortion drugs. Tamang *et al.*^[26] from Nepal showed that training of pharmacy workers had helped them in dispensing MA drugs safely and effectively and this positive impact of training has continued till several years.

In present study 97 (86.6%) women received medication from non-medical untrained persons and hence contributed to unsafe abortions according to WHO guideline.^[10] More recently in 2021 Yokoe et al.,^[27] in their study from India reported that 67% of abortions in India across the states were classified as unsafe and women living in rural settings had 26% higher odd of unsafe abortion compared with women living in urban settings. Similar to this the current study also revealed that majority (63.4%) of these women were from rural areas. While exploring the reasons for approaching nonformal providers, "easy and nearby availability of these drugs" was the commonest statement recoded from these women. In addition, 8.9% of the women reported lack of knowledge about its availability in hospital and 8.9% women expressed their apprehension about more time required in hospital [Table 2]. This lack of knowledge could be partly due to failure to provide adequate information by the formal providers by offering a choice between medical versus surgical abortion. Iyanger et al.^[28] highlighted that abortion seeking women desiring to take pills are often unsure where to go for the service they opt, as many facilities do not offer choice of medical abortion. Therefore, increasing efforts are required for dissemination of information in mass through media, group discussions by voluntary healthcare workers, in addition to health professionals especially primary care physicians, who are the first contact doctors. Long travel distance, transport problem, and lack of availability of family members to accompany had been reported by 8.93% of the women. Similarly, Francis and Doran had reported that travel and waiting for the appointment had been main impediment for women to access timely abortion in rural areas of New South Wales, Australia.^[29] Nearly half of statements (49%) expressed by the participants, addressed about easy accessibility of abortion inducing drugs at nearby place and long travel distance to hospital, further highlight the need regarding expansion of provider base in India.

These findings reveal that in spite of great potential of medical method of inducing abortion, its introduction in developing country like India, could not effectively curtail the number of unsafe abortions. More recently Rath et al.[30] in 2021, from Oddissa, reported similar spectrum of complications subsequent to unsupervised use of medical abortion drugs. Hence, this study observation remains relevant even in the current scenario. Easy and quick availability of these drugs OTC along with sparse availability of formal providers especially in rural areas are major barriers to the access of safe medical abortion in India under current scenario. This study can help in revisiting the policy decisions regarding expanding the provider base by training mid-level nonphysician health workers. These findings are further relevant and supported by data from rural health statistics from Government of India, Ministry of Health and Family Welfare, Statistics Division, which shows huge shortfall of obstetrician and gynaecologist at rural health centres.^[31] Thus, authors suggest that the policies to be revisited to amend the Indian MTP law, and to appropriately train midlevel health-care providers to provide safe, low-technology medical abortion services for abortion seeking women in India.

In addition, the current study also revealed that more than half (62.5%) women had never used any modern method of contraception, and nearly one third (32.1%) of these women had one prior abortion. Similarly a prior report, in 2010, from rural part of northern India revealed that nearly half (53.2%) of the participants had never used any modern method of contraception and one third of those women had at least one prior induced abortion.^[32] This reveals that in India, over a decade, there had been no change in the contraceptive behavior of the young women and women practice induced abortion for spacing birth and avoiding unwanted pregnancy. Therefore, a more focused approach with special attention to antenatal women in the antenatal clinics and indoor post-partum women may increase the contraceptive use by the eligible couples and reduce the unintended pregnancies.

Limitations of the study

There may be case selection bias as the current study has included only single centre for recruiting women reporting with some kind of complication after consumption of these MA drugs from nonformal providers and failed to include others with no complication.

Conclusion

- Easy access of medical abortion drugs from nearby sources, long distance to hospital, and lack of proper information had been the common barriers for not availing safe abortion services at hospital.
- Majority of the abortion seeking women were from rural regions and hence, strengthening the abortion care services and information, education, and communication regarding safe use of medical abortion drugs at Primary Health Centre (PHC) level can play a key role in making the use of these drugs safer.
- Expanding provider-base by training mid-level health workers can overcome these issues by reaching these women who are far from the hospital-based care and will unmask the full potential of medical abortion.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity.

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Conflicts of interest

There are no conflicts of interest.

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