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Review Article

Challenges and Threats of Over the Counter Dispensing of Medical Termination of Pregnancy Pills: A Review

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Abstract:

Introduction of menstrual regulation with medication (MRM) is a revolutionary advancement towards reducing unsafe abortion and related complications. A systematic literature search was conducted using Google scholar, Pubmed and science direct. Search terms included MTP, unsafe abortion, Misoprostol, self medication, over the counter, menstrual regulation, pharmacy worker, complication. Studies were limited to the English language. MRM is safe and effective if carried out under medical supervision. Unsupervised over the counter use is associated with many complications like excess bleeding, incomplete abortion, ruptured ectopic, rupture uterus. Although there are well defined guidelines for dispensing MRM pills often those are not followed. Over the counter availability of the drug and self-medication deprive women of accurate information, correct dosage and necessary referral. Proper training of pharmacy dwellers on MRM dosage, eligibility, complications, and referral criteria is necessary. At the same time restriction of over the counter dispensing of MRM is current demand of time.

Key words: *Medical abortion, MRM, over the counter, pharmacy worker, self-administration*

Introduction:

Over the decades there have been innovation and availability of newer version of contraceptives with formulations of lower dose, increasing efficacy and less chance of complication. There has been reported increase in use of contraception globally yet there are over 41.6 million abortion occur annually[1]. Almost 55% of them are unsafe abortion and about 95% of them occur in developing countries[2]. It is estimated that unsafe abortion results in death of about 47000 women annually and there are additional five million women with disabilities resulting from its complications[3].

World Health Organization has defined medical abortion as "usage of pharmacological drugs to terminate pregnancy"[4]. Availability of these pills in communities has revolutionized access to safer abortion and reduced morbidity and mortality from unsafe abortion in many situation[5]. A medical abortion is said to be successful when the correct medication dosage has been followed and the expulsion of the products of conception has been completed, without the need of any surgical intervention [6]. According to World Health Organization (WHO) unsafe abortion is that which is not provided through approved facilities and or person[7]. There is extensive and growing evidence that MRM is a safe and effective method for menstrual regulation if administered correctly according to the national guidelines and according to clinical standards[8, 9]. Over the counter use of MRM drugs often lack compliance to guideline and may result in considerable complications.

Abortion is not legal in Bangladesh. However, menstrual regulation is legal up to a maximum of 10 weeks after a woman's last menstrual period since 1974 [10]. Although menstrual regulation has been permitted in Bangladesh for over 30 years, there are still barriers to women's access to menstrual regulation services that lead women instead to unsafe abortion. Majority of women are unware of available services, feel ashamed or embarrassed to access it or fear disapproval from husband, family, religious

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leaders or community members[11]. Limited provision by health facilities, providers' unsanctioned rejection of women seeking services and unauthorized charging for services, judgmental attitudes on the part of providers, stigma and shame surrounding the procedure been documented as barriers to menstrual regulation [12]. The cost of travel and fees associated with menstrual regulation procedures, along with inequality in charging fees, also is a challenge particularly for poorer women[13]. Introduction of MRM has posed a new hope to prevent unsafe abortion. It is recommended that early first trimester medical abortion regime is 98.3% effective if used safely, adequately and with proper supervision [9].

Introduction of MRM in Bangladesh

The introduction of MRM was a milestone in expanding menstrual regulation access for women who find accessing MR through manual vacuum aspiration (MVA) in public and private facilities hard. There are also different advocacy efforts around the safety and efficacy of MRM through pharmaceutical promotion and IEC materials[8].

The Bangladesh National Service Delivery Guideline on Menstrual Regulation with Medication states that, before performing an MRM service, women seeking MRM should be informed of the methods available; pain management options; and what will happen before, during and after the drug intake [14]. The guideline also stipulates that written consent should be obtained from the client before starting the procedure. The DGFP formal circular states that within 6-9 weeks of women's last menstrual period, 200 milligrams of mifepristone and 800 micrograms (4 tablets of 200 mcg) of misoprostol can be prescribed by service providers who have received training on MRM.[14]. The recommended procedure is that MRM clients take the first drug, mifepristone, orally at the health care facility and are asked to stay at the facility for a maximum of 30 minutes for monitoring potential side effects. Then she can take the second drug, misoprostol, at the health facility or at home, 24 hours after taking the first drug sublingually[13].

In India abortion is legalized through Medical Termination of Pregnancy (MTP) Act since 1971.[15] In the 2003 Amendment, Medical Method of Abortion (MMA) was approved. The guidelines states for termination of pregnancy up to seven weeks of gestation, Mifepristone (200 mg) orally followed 48 hours by oral or vaginal Misoprostol (400 mg.) can be prescribed by a registered medical practitioner (RMP) either from a Government approved MTP centers or an outdoor clinic provided there is an established link with a Government approved MTP center [2]. However, evidence shows that the current practice is far deviant from the recommendations and misuse of MRM is now becoming a public health problem[2].

Why people use over the counter drug

Women in low- and middle-income countries (LMICs) often turn to pharmacies as their main source of health care services due to convenience, geographic accessibility and relative anonymity. Pharmacies also attract people seeking care for stigmatized health needs including sexually transmitted infection (STI), family planning and abortion[8]. When a patient, her husband, a family, or a friend buys an abortion pill over the counter without medical supervision or prescription, it is referred to as "self-medication". Study revealed about 67% patient procured pills by husband, 4% by allopath, and 29% by self [16]. Pallavi et al found that only 29% of participants herself brought the medicines from chemists, 36.7% of patients husbands brought medicines and in 34.3% patients' other relatives brought medicines [17].

In existing social structure women are less confident with low decision power for their wellbeing and rely on husband for the abortion pill[18]. As most of the time drugs are dispended without a prescription or support from a trained health care professional It is quite natural that this can lead to inaccurate advice and incorrect dispensing[8] . The pharmacy worker often poorly trained may be may not provide adequate counseling nor adequate options for follow up care[12]. The husband may not be able to ventilate the information properly to the women who are using the drugs even if counselling is done

Over the last few years in Bangladesh, concerns have been raised about the potential for increased risk and a side effect when women self-administer MRM drugs or receive the drugs from pharmacist's or drug sellers. It is reported that fewer than 50% of the pharmacists offered misoprostol or other medicines for menstrual regulation to customers, only 7% provided the correct regimen and 75% did not provide any information about complications.[11]

Gaps in over the counter use

There is a dearth of evidence assessing the safety and effectiveness of self-administered MRM when

purchased without prescription from pharmacies. Such data are difficult to obtain. Recruiting and following up women who self-administer drugs are challenging because pharmacies and women may be unwilling to report its use, hindrance of the identification of women who purchase and self-administer these medications, chance of missing the women who have complete, uncomplicated abortions without the need for follow-up care or those who manage adverse events outside of the formal health system.

There is little regulation of pharmacies in Bangladesh, and many medications are sold over the counter without prescription [19]. Misuse of MRM by non-allopath doctors, dais and quacks, easy availability of medicine without medical prescription and ignorance on part of women is now becoming a public health problem[16, 20]. In many cases drug dealers are too busy and not get enough time or they lack space for privacy to counsel the purchaser. Huda et al has found that 54% provided the recommended dosage of mifepristone–misoprostol combination; 42% provided information on its effectiveness; 12% recommended at least one follow-up visit; 11% counseled on possible complications; and only 5% offered post-MR contraceptives to the clients[8].

Evidence shows that with availability of medical termination pills women view this as a better way to space out their pregnancies than taking regular contraception and preventing undesired pregnancies in the first place[17]. Sing found 48% women were contraceptive non user and that they have ample access to unregulated sources that provide MRM[16]. In a study (46%) patients had previous history of one or more MTP and that 91.37% had no history of any contraceptive usage[2]. These findings points to the high unmet need for contraception and is alarming for ensuring reproductive health of women.

Study found that pharmacy workers did not adequately screen clients for eligibility especially gestational age determination and drugs are dispensed for gestation beyond 9 weeks. .There is also lack of contraceptive advice or post abortion service in over the counter use of MRM and this remains a continuing threat of unwanted or unplanned pregnancy for the women. Provision of adequate information about warning signs and complications before selling the medications is necessary [5]. Women's ability to distinguish side effects from complications or to self-assess completion without adequate information may also hinder care-seeking after self-administration[8].

Safety and reported complications for OTC use of MTP

There is higher likelihood of complications when MRM pills are consumed over the counter- such as failure, incomplete abortion, excessive bleeding per vagina, shock, missed ectopic pregnancy, septic abortion, uterine rupture, etc. This not only jeopardizes the women's health, it also puts a burden on the healthcare services. However, reported complications are from women who consulted any hospital for complications after the drug use. A significant number of women may take treatment from private practitioners or again from the pharmacy or recover with longtime morbidity. So there is a chance of underreporting.

In a study from India among women who had consumed MRM pills over the counter (69%) presented with anaemia, (65.50%) with incomplete abortion, (22.41%) showed features of shock, (12.07%) had signs of septic abortion and (5.17%) were eventually diagnosed to have ruptured ectopic pregnancy[2]. About 1.72%) presented with uterine rupture, (13.79%) had problems like fever, jaundice and convulsions[2]. In a more recent study morbidity in the form of severe anaemia in 16.8%, shock 5.6%, needed blood transfusion, higher antibiotics, ICU admission in 6.4% was reported[18]. The proportion of incomplete abortion was reported 75%[16], 62.5% [21], 70.2% [22] 62.5%, and 78.8% [18] respectively in different studies. In the studies by Rajal V[23], Thacker et al[22] and Nivedita K[21] et al , the rate of surgical evacuation for women taking OTC abortion pills was 75.6% , 67.5%, of 60.34% respectively.

There was reported 14.4% and 15.5% drug failure rate that is patients came with single life intrauterine fetus (SLIUF)[2, 18]. It is postulated that the failure rate of any medical abortion on ongoing pregnancy should be less than 1% when taken before 7 weeks and by correct regimen[18].(Neha, 2023). The reported high rate of failure may indicate any discrepancy either in dose or gestational age from recommendation during drug administration.

Studies show higher rate of sepsis after self-administration of abortion pills. This may happen because of not maintaining proper hygiene by patient while taking the medicine per vaginally, few were not changing pads frequently and many were bleeding per vagina for longer duration. The proportion of septic

abortion was reported as 7.4%[21],14. 4%24, and 6.4%[18] in different studies respectively. Common infection after any medical abortion is seen is Clostridium dorselli infection.

Concerns about the use of MRM over the counter

Unregulated and nonprescription usage of the MRM pills is a serious concern. Self-prescription or over-the-counter usage of MMA pills can have grave and life threatening consequences for the woman. Proper assessment about the eligibility of a woman for termination, including determination of gestational age, exclusion of medical disorder, counselling on proper dose, post-abortion follow-up is important. Equally important is the eligibility of the MRM provider.

Estimation of gestational age and its location is important. The guideline permits use at 7 weeks and up to 9 weeks. However, different study found that 27.5% women had consumed abortion pills after 9 weeks of pregnancy [17,21]. Another study found that 12% women took pill at correct gestation age and 26% took up to 9weeks and 72% took pill after 9 weeks. Most women were unaware of importance of gestation age and possible complication before taking pills. To obtain a medical history to rule out contraindications for medical abortion such as bleeding disorders, uncontrolled seizure disorder, chronic adrenal failure, etc. is not possible in over the counter use. There is also chance of missing ectopic pregnancy and patient may end up with catastrophe of ectopic rupture. There should be counselling and advice regarding post abortion follow up, contraception and care seeking for complication.

Way forward

Majority of women in different study showed positive experiences with medication for menstrual regulation and had successful outcomes, regardless of whether they obtained their medication from medicine sellers/ pharmacies, doctors or clinics. In one study from Bangladesh it was found in their study that over 90% of women taking medication for menstrual regulation are satisfied with the method[19].

Women are strongly influenced by their providers when deciding which method to use. There is a need to educate not only women of reproductive age, but also communities as a whole, about medication for menstrual regulation, with a particular emphasis on branding the medication and the cost [11].

It is necessary to ensure before dispensing over the counter MRM that patient is able to understand the instructions and is ready for minimum three follow-up visits, ready for a surgical procedure if failure or excessive bleeding occurs, there is family support and easy access to appropriate healthcare facility is available[2]. It should reach to public only through approved medical termination of pregnancy (MTP) centers after prescription. Society need to be educated for risk of self-intake of abortion pills and their dangerous consequences. Medical termination of pregnancy should be done under strict vigilance. Pharmacy workers need to be trained on legal time limits, on providing accurate information about dosage, complications of disbursed medicines and on proper referral linkage.

Information regarding the contraceptive choices and its advantages should be properly dispersed among the general population to decrease the unmet needs of contraception. Maternal as well as adolescents health clinics can be utilized in a proper manner to promote the information regarding the safe sex practices and advantages of various methods of contraceptive choices as well as emergency contraception in modern practices. The media can be utilized to create awareness specifi-cally targeting the reproductive population regarding the risks, side effects, complications involved with the self-use of MTP pills. It is to be made clear that MRM is not a regular contraceptive method. A referral linkage strategy between pharmacy workers and public hospitals should be in place to facilitate continuity of care [8]. Existing law can be enacted in an effective way with proper monitoring.

Conclusion:

MRM is a strong measure to help women to exercise reproductive rights and protect maternal health if administered according to recommended guidelines. Injudicious use of over the counter drug is a great threat to women's health. The drug should be available only via health care facilities under the supervision of trained personnel. Malpractice regarding rampant use of MRM should be nipped in bud.

References:

1. Abortion Worldwide: A Decade of Uneven Progress, Guttmacher Institute, October 2009, p.17.
2. Anupriya Maharshi, Shubhangi Mande, Swati Shiradkar& Lakshmi Rachakonda: Over-The-

Counter Misuse of Medical Abortion Pills- an Analysis of The Complications and Comparison: International Journal of Current Medical and Applied sciences; 2019, 24(2), 16-22.

3. WHO. Preventing Unsafe Abortion. World Health Organization Factsheet. 26 June 2019. https://www.who.int/news-room/fact-sheets/detail/preventing-unsafe-abortion

4. Bearak J, Popinchalk A, Ganatra B, et al. unintended pregnancy and abortion by income, region, and the legal status of abortion: Estimates from a comprehensive model for 1990–2019. Lancet Glob Health 2020;8(9):e1152–e1161. DOI: 10.1016/S2214-109X2030315-6

5. Katharine Footmana,, Rachel Scott, Fahmida Taleb, Sally Dijkermand, Sadid Nuremowla, Kate Reisse, Kathryn ChurchFeasibility of assessing the safety and effectiveness of menstrual regulation medications purchased from pharmacies in Bangladesh: a prospective cohort study Contraception 97 (2018) 152–159http://dx.doi.org/10.1016/j.contraception.2017.08.002

6. ACOG. American College of Obstetricians and Gynecologists. Medical management of first-trimester abortion. Practice Bulletin number 143, March 2014.https://www.acog.org/Clinical-Guidance-andPublications/Practice-Bulletins/Committee-on-Practice-Bulletins-Gynecology/Medical-Management-ofFirst-Trimester-Abortion

7. Bhalla S, Goyal LD, Bhalla S, Kaur B. Self-administered medical abortion pills: evaluation of the clinical outcome and complications among women presenting with unsupervised pill intake to a tertiary care hospital in Malwa region of Punjab, India. Int J Reprod Contraception Obstet Gynaecol. 2018;7(4):1537- 42.

8. Huda FA, Mahood HR, Alam A, Ahmmed F, Karim F, Sarker BK, Haque NA and Ahmed A. Provision of menstrual regulation with medication among pharmacies in three municipal districts of Bangladesh: a situation analysis. Contraception, 2018,97(2):144-151. https://www.sciencedirect.com/science/article/pii/S0010782417305231

9. Thakur A, Dabar D, Mangal A, Daral S, Yadav V, Raut DK. Perceptions and Practices of Married Women Regarding Medical Abortion in an Urbanized Village of South Delhi, India. Int J Med Public Heal. 2020; 10(1):18-23.

10. Singh, S., A. Hossain, I. Maddow-Zimet, H. U. Bhuiyan, M. Vlassoff, and R. Hussain. 2012. "The Incidence of Menstrual Regulation Procedures and Abortion in Bangladesh, 2010." International Perspectives on Sexual and Reproductive Health 38 (3): 122–132

11. Marlow HM, Biswas K, Menzel J. Women's experiences with medication for menstrual regulation in Bangladesh. Culture, Health and Sexuality, 2016, 18(3):349-360. http://europepmc.org/articles/PMC4732455

12. Hossain A, Maddow-Zinet I, Ingerick M, Bhuiyan HU, Vlassoff M and Singh S. Access to and quality of menstrual regulation and post abortion care in Bangladesh: evidence from a survey of health facilities, 2014. Guttmacher Institute, March 2017. https://www.guttmacher.org/report/menstrual-regulationpostabortion-care-bangladesh +

13. Johnston H. B., Schurmann A., Oliveras E., Akhter H. H. A Review of Bangladesh's Menstrual Regulation Program and Its Impact. In: Blas E., Sommerfeld J., Kurup A. S., editors. *Social Determinants Approaches to Public Health: From Concept to Practice*. Geneva: WHO; 2011. pp. 9–24. [Google Scholar

14. DGFP - Government of the People's Republic of Bangladesh. Directorate General of Family Planning (DGFP): MCH Services Unit. Memorandum No.: DGFP/MCH-RH/pro-sha (admin) 23/05/108. 03 February 2015.

15. Medical Termination of Pregnancy Act (Act 34 of 1971) Published in the Gazette of India, Part 2, Section 1; pages: 237-240.

16. Singh S, Rangappa SS. Self-administered medical abortion pills: evaluation of the clinical outcome and complications among women presenting with unsupervised pill intake to a tertiary care hospital: a cross-sectional study. Int J Reprod Contracept Obstet Gynecol 2021;10:3424-8

17. Singh P, Dhurwey N, Patel J. Demography, clinical profile and outcomes of self prescribed abortion pills among women, experience from a tertiary care teaching hospital in central India.

Int J Reprod Contracept Obstet Gynecol 2023;12:2949-53

18. Thakur N, Verma RS, Nagaria T. Self administration of Abortion Pills and its Maternal Outcome in Tertiary Care Center. J South Asian Feder Obst Gynae 2023;15(2):142–146.
19. Alam, A., H. Bracken, H. Bart Johnston, S. Raghavan, N. Islam, B. Winikoff, and L. Reichenbach. 2013. "Acceptability and Feasibility of Mifepristone-misoprostol for Menstrual Regulation in Bangladesh." International Perspectives on Sexual and Reproductive Health 39 (2): 79–87
20. Kahabuka C, Pembe A, Meglioli A. Provision of harm-reduction services to limit unsafe abortion in Tanzania. Int J Gynaecol Obstet 2017; 136(2):210–214
21. Nivedita K, Fatima Shanthini. Is It Safe to Provide Abortion Pills over the Counter? A Study on Outcome Following Self Medication with Abortion Pills. Journal of Clinical and Diagnostic Research; 2015:9(1): QC01-QC04
22. Thaker RV, Deliwala KJ, Shah PT. Self Medication of Abortion Pill: Women's Health in Jeopardy. NHL Journal of Medical Sciences. 2014;3(1). Corpus ID: 78349653.
23. Rajal V Thacker, Kruti J Deliwala, et al. Self Medication of Abortion Pills: Women's Health in JeopardyNHL Journal of Medical Sciences; Jan 2014:3(1), 14-19.
24. Jethani M, Yadav K, Muchhoria S, Sharma S. Monika. Self Medicated Abortion – Care or Crime JMSCR. 2015;3 (09):7507–7512. DOI: http://dx.doi.org/10.18535/jmscr/v3i9.33.