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Challenges Arising from Self-Administered Misoprostol for Unintended Pregnancies Amidst Covid-19 Lockdown

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ABSTRACT

Background: The COVID-19 pandemic placed unprecedented strain on healthcare globally, which exacerbated factors leading to unplanned pregnancies. This study aimed to assess the complications of self-administration of misoprostol for miscarriage during the COVID-19 lockdown.

Methods: This was a retrospective cohort study conducted at the Department of Obstetrics and Gynecology, Abbasi Shaheed Hospital, Karachi, from 1st March to 30th September 2020. Case records were compiled and analyzed. All women who reported after self-administration of misoprostol were included. The primary outcome measure was complications; anemia, blood transfusion, heavy bleeding, shock, sepsis, ruptured ectopic pregnancy, and ruptured uterus. A bivariable analysis was done to see the effect of gestational age at intake of misoprostol on the complications encountered, the chi-square test or Fischer's exact test was also applied.

Results: In this study, a total of 54 cases were studied. The most common complication was anemia (63%) followed by incomplete abortion (61.1%). Heavy bleeding ($p<0.001$), blood transfusion ($p=0.020$), and incomplete abortion were significantly ($p<0.001$) more common in women who used misoprostol at gestational ages greater than 6 weeks.

Conclusion: Our results suggested that health complications were found in women who self-medicated misoprostol for induced abortions after gestational ages greater than 6 weeks during the COVID-19 lockdown.

Keywords: Abortion, Misoprostol, Over-the-Counter Drug, Self-medication.

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INTRODUCTION

Unsafe abortions are very common in Pakistan and lead to many deaths. Women who opt for such abortions counter many complications. These are often recognized late and women reach hospitals in critical condition. Commonly encountered complications are severe hemorrhage, trauma to the genital tract, uterine perforation, and severe sepsis. Most of these complications are avoidable and can be treated successfully, however poor accessibility to health care and delays in seeking care are often the reasons for these catastrophic outcomes[1].

Heavy bleeding may ensue from the genital tract in some cases and can jeopardize maternal health. Women are vulnerable in pregnancy due to physiological changes and bleeding may increase the chance of needing blood transfusion and treatment for correction of anemia which may not be readily available and accessible. In certain cases, heavy bleeding can lead to hysterectomy, and sepsis due to unsafe abortion which can lead to multi-organ failure. Surgical termination of pregnancy is therefore a procedure that needs training and is often not acceptable to women. Medical terminations however have an edge over their surgical counterparts because they are perceived to be safer. The medications needed for medical termination are available over the counter and can be dispensed with minimal instructions [2]. During the COVID-19 lockdown in Pakistan, the inequalities in sexual and reproductive health were further exposed and women were unable to access reproductive healthcare facilities and seek clinic-based abortion care[3,4].

The majority of women in the West terminate unwanted pregnancies medically[5]. It is considered safe and more acceptable; routine follow-up is not recommended provided the user understands the implications[6]. In Western countries, misoprostol is a regulated prescription drug and not available over the counter[7]. In Pakistan it is available over the counter therefore a medical prescription is therefore not needed. Women use this medication to terminate pregnancy and do not get checked to assess the feasibility of this drug for them[8]. This harmful practice leads to the medication being used without proper counseling for warning signs and at gestational ages not suitable for misoprostol use[9]. Being a tertiary care center, we came across many cases of self-administration of misoprostol during lockdown, leading to many complications. The objective of this study was to consider the problems of self-administration of misoprostol for miscarriage during the COVID-19 lockdown.

METHODS

This was an observational study conducted at Abbasi Shaheed Hospital from 1st March to 30th Sep 2020. This study was undertaken to study the complications of self-consumption of misoprostol tablets during the lockdown period. Women who reported that they had consumed misoprostol tablets for termination of pregnancy without consulting a medical professional were included. Those who took the medication after consulting a medical professional were excluded. Also excluded were women with complications after misoprostol intake when prescribed by a medical professional and those who had undergone any surgical intervention after misoprostol consumption in any other health facility.

All participants gave written and informed consent on admission. On admission, detailed general, systemic, and obstetric examinations and routine investigations were done in all women. A proforma was used to collect the following data. A brief history regarding previous pregnancies, gestational age at which misoprostol tablets were taken, and reason for self-medication. Heavy bleeding (as defined by the women on presentation), anemia (hemoglobin less than 11gram/deciliter, as documented in the blood report done on admission), incomplete abortion (defined as products of conception visible in the uterine cavity, on the ultrasound done at the time of admission), missed abortion, (fetus visible but no fetal cardiac activity seen, on the ultrasound done at the time of admission). The need for blood transfusion, ruptured uterus, and ruptured ectopic pregnancy (on clinical examination later confirmed on surgery) was also documented.

Data were analyzed using SPSS version 23. Mean and standard deviations were calculated for the quantitative variables like maternal age and gestational age at administration. Frequencies and percentages were calculated for the qualitative variables like anemia, blood transfusion, heavy bleeding, shock, sepsis, ruptured ectopic pregnancy, and ruptured uterus (yes/no). A bivariable analysis was done to see the effect of gestational age at intake of misoprostol on the complications encountered, chi square test or Fischer's exact test was applied taking a p-value of ≤ 0.05 as statistically significant.

RESULTS

A total of 54 cases were studied. The mean age of the women was 31+/- 5 years. The mean gestational age at taking misoprostol was 7 +/- 2 weeks. The most common reason for taking misoprostol was to avoid surgery. (Table 1) The most common complication was anemia followed by incomplete abortion. There was one case of a ruptured uterus, the patient had previous 4 cesarean sections. One woman with a ruptured ectopic presented in a state of shock.

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Table 1: Characteristics of the study population

Variables	Mean± Standard Deviation (n=54) n %
Age in years	31±5
Gestational Age in weeks	7±2
Heavy bleeding	28(51.9%)
Anemia	34(63.0%)
Incomplete Abortion	33(61.1%)
Missed Abortion	17(31.5%)
Sepsis	8(14.8%)
Shock	13(24.1%)
Blood Transfusion	22(40.7%)
Ruptured Uterus	1(1.9%)
Ruptured Ectopic pregnancy	1(1.9%)

When stratified according to gestational age the complications were more common at gestational age greater than 6 weeks. (Table 2) Heavy bleeding (p<0.001), blood transfusion (p=0.020), and incomplete abortion (p<0.001) were significantly more common in women who used misoprostol at gestational ages greater than 6 weeks.

Table 2: Stratification according to gestational age at self-administration of misoprostol

Variables		Gestational Age category n %		
		≤6 weeks	7-11 weeks	p-value
Age category	≤ 30	6(24.0%)	18(62.1%)	0.005*
	! 30	19(76.0%)	11(37.9%)	
Bleeding	Heavy bleeding	6(24.0%)	22(75.9%)	" 0.001*
	No bleeding	19(76.0%)	7(24.1%)	
Anemia	Anemic (>8)	17(68.0%)	17(58.6%)	0.477
	Healthy (<8)	8(32.0%)	12(41.4%)	
Abortion	Incomplete	8(32.0%)	25(86.2%)	" 0.001*
	No Abortion	17(68.0%)	4(13.8%)	
Missed Abortion	yes	14(56.0%)	3(10.3%)	" 0.001*
	no	11(44.0%)	26(89.7%)	
Infection	Sepsis	4(16.0%)	4(13.8%)	0.820
	No infection	21(84.0%)	25(86.2%)	
Shock	yes	5(20.0%)	8(27.6%)	0.516
	no	20(80.0%)	21(72.4%)	
Blood Transfusion	yes	6(24.0%)	16(55.2%)	0.020*
	no	19(76.0%)	13(44.8%)	
Uterus status	Ruptured Uterus	0(0.0%)	1(3.4%)	0.349
	Normal	25(100.0%)	28(96.6%)	
Ruptured Ectopic pregnancy	yes	1(4.0%)	0(0.0%)	0.277
	no	24(96.0%)	29(100.0%)	

**The Chi-square or Fischer's exact test statistic is significant at the .05 level*

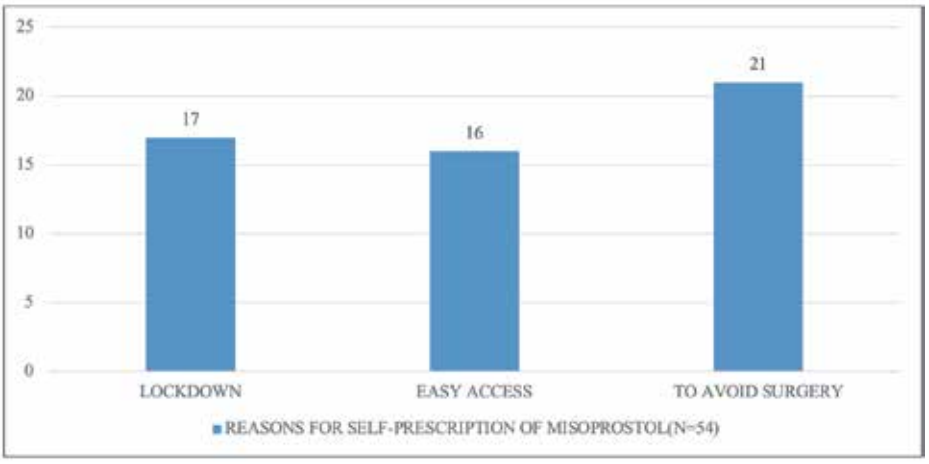

Figure 1: Presents the collective reasons for the self-medication of Misoprostol during the COVID-19 lockdown.

DISCUSSION

Misoprostol is famous as a single agent for medical abortion but is less successful than the combination of misoprostol and mifepristone[10-11]. The current standard and the Food and Drug Administration-approved regimen for medical abortion is 200 mg of mifepristone followed in 24–48 hours by 800 mcg misoprostol[12]. In our study, women came in with incomplete abortions and missed abortions but did not get a complete abortion. The effectiveness of misoprostol for termination is around 95%. These women may or may not have taken the complete dosage of the drug. Compliance with the protocol for drug administration is of utmost importance to achieve desirable results.

Heavy bleeding is much more likely in women who take misoprostol around 12 weeks and is less likely in women in earlier gestations. In our study, the heavy bleeding and the need for blood transfusion were significantly less likely in women who ingested misoprostol at earlier gestations. This is in agreement with previous studies on the topic [13-15]. In our study, 48 out of 54 women just used misoprostol without any scan. This can be extremely dangerous in cases where the patient has an ectopic pregnancy and she takes misoprostol to abort it. In our study, 1 out of 54 women had this complication and she came in with ruptured ectopic. This is in contrast to the study from South America where no major adverse event was noted[16].

Moreover, Misoprostol is contraindicated in women with previous cesarean sections and has been shown to cause uterine rupture in women. In our study a woman also presented with uterine rupture, she had previous 4 cesarean sections and did not want this pregnancy. She ingested a heavy dose and came in with torrential bleeding. These complications are not commonly encountered in Western countries because the access to medical care is significantly different, women are literate and abortion is not seen as a taboo topic[17]. Women who receive in-person follow up with a counselor are more likely to report a complete miscarriage. An ultrasound before administration of misoprostol can be helpful. It is not recommended that an ultrasound is done before giving misoprostol but women are always counseled to seek help if they develop complications and a pregnancy test needs to be repeated to ensure the pregnancy has been successfully terminated[18].

WHO's task-sharing guidelines recommend involving women in the management of combined mifepristone and misoprostol abortion regimens[19]. However, no such recommendations exist for misoprostol-only abortions. Our women mostly used a misoprostol-only regimen. Findings from a study suggest that perceptions of needing care are related to information or lack thereof, they received from drug sellers about potential complications and care-seeking needs[20]. Around 50% of women who reported that they needed some care had been warned by the drug dispensers that some complications could occur. In light of these findings, we conclude that misoprostol should be available only as a prescription drug. The policymakers should ensure that women are only given misoprostol when needed and after proper counseling and a follow-up is put in place for them to ensure continuity of care as it was proven to be of significance [21, 22, 23].

Our study is the first to assess the complications of self-administration of misoprostol for unwanted pregnancies during COVID-19 where health facilities are a stigmatized issue in Pakistan. The main limitation is its single-center design so the findings cannot be generalized to the whole population due to single-centered study and also not to higher socioeconomic groups of the city who may have a better understanding of the complications and are more

likely to seek help before the situation deteriorates.

CONCLUSION

Misoprostol after gestational ages greater than 6 weeks was found associated with complications. There should be some restrictions on the over-the-counter availability of drugs used for medical termination of pregnancy. These should be administered only by healthcare providers in regions where women are unaware of complications and are less likely to access healthcare facilities for seeking care due to stigma.

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CONFLICT OF INTEREST

The authors declared no conflict of interest.

ETHICS APPROVAL

The study used data records of the patients who came after taking misoprostol to terminate unwanted pregnancies. The study used retrospective data. Instead of formal ethics committee approval, the principles of the Helsinki Declaration were followed. Data was coded and confidentiality was ensured. The Head of the department granted permission for the study.

AUTHORS CONTRIBUTIONS

ZM, RI, and FA collected, analyzed, and interpreted the patient data and wrote the manuscript. SH, MM, and JM contributed to writing the manuscript.

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