TO EVALUATE OUTCOME AND COMPLICATIONS BETWEEN SUPERVISED AND UNSUPERVISED MEDICAL ABORTION PILL INTAKE

ABSTRACT

Introduction

Due to the easy access of medical abortion pill over the counter without medical consultation and despite guidelines and medical termination of pregnancy act, there is an increase in incidence of unsafe abortion, often leading to serious health complications.

Objective

To evaluate outcome and complications, socio-demographic factors that lead women to self administration of medical abortion pills and to assess awareness regarding use of medical abortion pills between supervised and unsupervised intake of medical abortion pills.

Methods

This prospective observational study was conducted between from June 2022 - June 2024, where a total of 600 patients were enrolled in the study. Patients were divided into two groups in which one group had supervised intake of MTP pills and other group had unsupervised intake of MTP pills. Their socio-demographic profile, indication of intake of MTP pill, source of drug, awareness about MTP pill or any other form of contraceptions, outcome and complications were evaluated. The data were encoded and entered into MS Excel spreadsheet application. Analysis was done using Origin pro software. Statistical analysis was done to analyse between the groups using percentage and Chi square test on categorical variables. The

correlation between dependent and independent variables was evaluated using multivariate logistic regression**.**

Result

In supervised group, majority (58.53%) were aged between 21-30 years of age, whereas in unsupervised group majority(61.33%) were aged between 31-40 years of age. It was observed that in both groups majority of patients belonged to middle economic status. It had been observed that majority(90.66%) of pregnancy in unsupervised group was diagnosed by UPT and with history of MTP pill intake between 9-12 weeks gestation(43.34%) leading to more complications, while in supervised intake, pregnancy was diagnosed by USG(99.66%)and termination of pregnancy was done before 9 weeks of gestation(72.67%) with minimal complications. Anaemia is the most common associated co-morbidity were severe anaemia was noted in 25% patients in unsupervised group compared to 15% in supervised group. In unsupervised group, 42.67% patients required suction and evacuation with blood transfusion with only 14% in supervised group.

Conclusion

It was observed that the magnitude of complications was more seen in unsupervised intake of MTP pill like need for blood transfusion, laparotomy, hysterectomy and maternal mortality. There is an urgent need of restricting the free availability of over the counter MTP pill and to educate and increase awareness about the complications of unsupervised MTP pill intake.

Keywords: MTP pill; unsupervised intake; awareness; outcome; complications

INTRODUCTION

Unsafe abortion remains a critical global reproductive health issue, presenting significant risks and often leading to severe, life-threatening complications. In India, an estimated 6.4 million abortions occur annually, with 56% classified as unsafe. These unsafe abortions contribute significantly to maternal mortality, accounting for 8-20% of all maternal deaths. (1)

In India, the All India Institute of Medical Sciences (AIIMS), in collaboration with the Ministry of Health and Family Welfare, has developed guidelines for the use of medical abortion pills. These guidelines recommend a combination pack of 1 tablet of Mifepristone (200 mg) and 4 tablets of Misoprostol (200 mcg each) for terminating pregnancies up to 63 days of gestation. According to the Medical Termination of Pregnancy (MTP) Act, only registered medical practitioners are authorized to prescribe these pills. (2)

The MTP Act of 2021, effective from March 25, 2021, extends the permissible gestational age for abortion to 24 weeks, up from the previous limit of 20 weeks. Under the revised act, the opinion of one registered medical practitioner is required for abortions up to 20 weeks, while two practitioners' opinions are needed for abortions between 20-24 weeks. This contrasts with the previous requirement of one practitioner's opinion for terminations up to 12 weeks and two practitioners' opinions for terminations between 12-20 weeks. (3)

WHO guidelines necessitate women requesting medical abortion to confirm pregnancy, estimate gestational age and locate site of pregnancy, rule out contraindications and it also recommends that the person or facility providing Medical abortion should have back up facility in case of failed or incomplete abortion.[4]Unwanted pregnancies are a significant global challenge, leading to an

estimated 42 million induced abortions annually, with about 20 million of these being unsafe[5].

This study aims to evaluate the outcomes and complications of self-administered medical abortion pills, comparing supervised and unsupervised settings in tertiary care facilities. Health education should emphasize the importance of medical counselling and supervision during abortions and the risks of self-medication. Strict enforcement of restrictions on over-the-counter abortion pills is necessary, along with increased awareness of contraception to reduce unwanted pregnancies.

MATERIALS AND METHODS

This Prospective observational study was conducted in Upper India Sugar Exchange Maternity Hospital, GSVM Medical College, Kanpur, UP in the Department of Obstetrics and Gynaecology spanning two years from June 2022 to June 2024 on 600 patients .This methodology was selected to evaluate outcome and complications between supervised and unsupervised patients following MTP pill intake. All patients visiting OPDs and IPDs with history of administration of medical abortion pills with and without prescription were taken into study. By self administration we mean that these pregnant women did not have any medical consultation with a registered medical practitioner and took abortion pills which were purchased from the pharmacy without any prescription either by self or by some close relative. Woman with any history of surgical intervention or procedure after MTP pills intake were excluded from study. The data were encoded and entered into MS Excel spreadsheet application. Analysis was done using Origin pro software. Statistical analysis was done to analyse between the groups using percentage and Chi square test on

categorical variables. The correlation between dependent and independent variables was evaluated using multivariate logistic regression**.**

Result:

Table 1 presents the overall comparison of each variable between supervised and unsupervised intake of medical abortion pill along with their contributory percentages. In supervised group, majority (58.53%) were aged between 21-30 years of age, whereas in unsupervised group majority(61.33%) were aged between 31-40 years of age. It was observed that in both groups majority of patients belonged to middle economic status. It had been observed that majority(90.66%) of pregnancy in unsupervised group was diagnosed by UPT and with history of MTP pill intake between 9-12 weeks gestation(43.34%), while in supervised intake, pregnancy was diagnosed by USG(99.66%)and termination of pregnancy was done before 9 weeks of gestation(72.67%).

Severe anaemia was noted in 25% patients in unsupervised group compared to 15% in supervised group. In unsupervised group, 42.67% patients required suction and evacuation with blood transfusion with only 14% in supervised group. Complications such as shock (2.34%), sepsis (4.35%) and mortality (1.62%) had been reported in this study compared to none in supervised group.

Table 2 presents the crude and adjusted ratio for study variables about intake of medical abortion pill between supervised and unsupervised intake. The crude odds ratio of complication after intake were higher in parity more than 3(COR:1.79,CI:1.14-2.71). However, multivariate logistic regression revealed that a parity of more than 2(AOR:1.49,CI:1.21-1.71) were more likely of landing into complications. The crude odds ratio of complication after intake were higher in period of gestation of 9-12 weeks (COR:1.35,CI:1.10-1.58),when adjusted it was it was

observed that both period of gestation of >9weeks and 9-12 weeks revealed are equally likely for causing complications.(COR:1.14,CI 0.85-1.51).

Table1: Overall study variables were shown and distribution percentage was plotted for each variables. Comparison between the supervised and un-supervised was shown in the present table along with their contributory percentages.

Characteristics		**Supervised (N)**	**%**	**Un supervised (N)**	**%**	**Chi square**	**P value**
Age(years)	<20	38	12.8	32	10.67	7.7724	.050957
	21-30	175	58.53	78	26		
	31-40	85	28.43	184	61.33		
	>40	1	0.3	6	1.3		
Religion	Hindu	258	86.29	254	86.29	399.1824	< .00001
	Muslim	41	13.71	45	13.71		
Education	Literate	276	92.31	288	96.33	4.4906	.034081
	Illiterate	23	7.69	11	3.67		
Residence	Rural	18	6.02	14	4.68	0.5283	.467336
	Urban	281	93.98	285	95.32		
Marital Status	Married	17	5.68	16	5.35	0.0321	.857868
	Unmarried	282	94.32	283	94.65		
Economic Status	Upper	15	5.06	36	12.04	9.4535	.008855
	Middle	245	81.90	227	75.92		
	Low	39	13.04	36	12.04		
Medical History	Yes	285	95.32	298	99.66	11.5565	.000675
	No	14	4.68	1	0.34		
Parity	G1	50	16.72	32	10.70	138.5755	< 0.00001
	G2	239	79.94	138	46.16		
	G3	1	0.34	100	33.44		
	>4	9	3.00	29	9.70		
POG (weeks)	<9	218	72.67	85	28.33	1.5601	.458389

	9-12	67	22.33	130	43.34		
	>12	15	5	85	28.33		
Ascertainment of pregnancy(USG/UPT)	USG	298	99.66	28	9.34	89.1209	< .00001
	UPT	1	0.34	272	90.66		
No. of Pills	Complete	151	50.51	147	49.16	0.107	.743557
	In-complete	148	49.49	152	50.84		
No. of times pills were taken	Once	276	92.31	276	92.31	0	1
	Twice	23	7.69	23	7.69		
	Thrice	0	0	0	0		
Source of the Pills	Self	288	96.32	179	59.87	123.0527	< 0.00001
	Pharmacist	2	0.66	98	32.78		
	Others	9	3.02	22	7.35		
How were pills packed	Blister pack	299	100	299	100		
	Loose pack	0	0	0	0		
Route of administration	sublingual	0	0	0	0	50.7076	< .00001
	Oral	67	22.4	9	3.02		
	Vaginal	232	77.6	290	96.98		
Indication of intake	unintended pregnancy	170	56.86	222	74.24		
	Life risk/ medical reason	19	6.36	0	0		
	Unmarried pregnancy	0	0	6	2		
	failure of contraception	110	36.78	71	23.74		
	Congenital anomalies	0	0	0	0		
	Others	0	0	0	0		
Interval between intake and	< 24h	41	13.71	29	9.7	2.3299	.126912
	>24h	258	86.29	270	90.3		

visit							
Chief complaint	Heavy menstrual bleeding Passage of fleshy mass	276	92.3	181	60.54		
	Irregular vaginal bleeding	15	5.02	53	17.73		
	Pain abdomen	4	1.34	24	8.03		
	Continued pregnancy	4	1.34	11	3.67		
	Pain abdomen with four smelling discharge per vaginum	0	0	30	10.03		
Outcome	Incomplete abortion	261	87.29	277	92.64		
	Complete abortion	32	10.7	9	3.01		
	Rupture ectopic	0	0	0	0		
	Missed abortion	6	2	1	0.34		
	Sepsis	0	0	9	3.01		
	Uterine perforation	0	0	1	0.34		
	Others	0	0	2	0.68		
Duration of stay	<3 days	295	98.66	274	91.63	15.9819	.000064
	>3 days	4	1.33	25	8.36		

Complications	Mild to moderate anemia	255	85.28	184	61.56		
	Severe anemia	44	14.71	74	24.76		
	Sepsis	0	0	13	4.35		
	Scar pregnancy	0	0	03	1.03		
	Mortality	0	0	5	1.62		
	Shock	0	0	7	2.34		
	Continuation of Pregnancy	0	0	13	4.34		
Management	Medical management	39	13.05	20	6.67		
	Suction & evacuation	218	72.90	114	38.13		
	S & E with blood transfusion	42	14.05	101	33.78		
	Laparotomy with blood transfusion	0	0	0	0		
	Hysterectomy with blood transfusion	0	0	2	0.67		
	Iron sucrose	0	0	55	18.39		
	Shock	0	0	7	2.36		
Awareness of MTP pills	Yes	269	89.96	250	83.61	5.2652	.021756
	No	30	10.03	49	16.38		
Awareness about other contraceptive methods	No	167	55.85	226	75.5	25.838	< .00001
	Yes	132	44.14	73	24.4		

Table 2: Crude and adjusted odds ratio abortion for study variables of both groups.

Characteristics		COR(95%Cl)	AOR(95%Cl)
Age	<20*		
	21-30	0.91(0.68,1.22)	0.91(0.68,1.22)
	31-40	0.87(0.71,1.10)	0.87(0.68,1.09)
	>40	0.77(0.59,0.96)	0.71(0.55,0.91)
Religion	Hindu*		
	Muslim	0.54(0.34,0.81)	0.51(0.32,0.74)
Education	Literate*		
	Illiterate	0.71*(0.62,1.12)	0.71(0.65,1.09)
Resident	Rural*		
	Urban	0.68(0.52,0.98)	0.65(0.51,0.87)
Marital Status	Married*		
	Unmarried	0.87(0.61,1.11)	0.88(0.60,1.11)
Economic Status	Upper*		
	Middle	0.91*(0.64,1.11)	0.89(0.61,1.02)
	Low	0.85(0.71,1.14)	0.81(0.68,1.10)
Medical History	Yes*		
	No	0.88(0.69,1.01)	0.85(0.61,1.01)
Parity	G1*		
	G2	1.66***(1.41,1.92)	1.49(1.21,1.71)
	G3	1.79***(1.14,2.71)	1.41(0.93,2.34)
	>4*		
POG (weeks)	<9	1.33***(1.13,1.69)	1.14(0.86,1.59)
	9-12	1.35***(1.10,1.58)	1.14(0.85,1.51)
	>12	0.81(0.67,1.02)	0.85(0.66,1.07)
Ascertainment of pregnancy(USG/UPT)	USG*		
	UPT	0.87(0.48,1.05)	0.88(0.51,1.06)
No. of Pills	Complete*		
	In-complete	0.78(0.61,0.92)	0.81(0.62,1.02)
No. of times pills were taken	Once*		
	Twice	0.66(0.51,0.89)	0.60(0.41,0.81)
	Thrice	0.96(0.72,1.15)	1.00(0.71,1.31)
Source of the Pills	Self*		
	Pharmacist	0.98(0.75,1.12)	0.87(0.64,1.14)
	Others	0.74(0.51,0.89)	0.74(0.55,1.10)
How were pills packed	Blister pack*		
	Loose pack	1.00(0.75,1.21)	0.99(0.75,1.14)
Route of administration	Sublingual*		
	Oral	0.87(0.74,1.10)	0.84(0.70,1.01)
	Vaginal	1.12(0.96,1.31)	1.04(0.85,1.30)
Indication of intake	unintended pregnancy*		
	Life risk/	0.99(0.54,0.86)	1.00(0.77,1.34)

	medical reason		
	Unmarried pregnancy	0.85(0.68,1.12)	0.81(0.75,1.10)
	failure of contraception	0.84(0.70,1.09)	0.81(0.81,1.12)
	Congenial from alone	1.22***(0.91,1.61)	1.18(0.91,1.41)
	Others	0.81(0.68,1.01)	0.85(0.72,1.15)
Interval between intake and visit	< 24h*		
	>24h	0.92(0.65,1.12)	0.95(0.72,1.23)
Chief complaint	Heavy menstrual* bleeding		
	Passage of fleshy mass		
	Irregular vaginal bleeding	0.92(0.67,1.15)	0.93(0.69,1.17)
	Pain abdomen	0.82(0.68,0.99)	0.90(0.70,1.15)
	Continued pregnancy	1.08(0.87,1.31)	1.10(0.86,1.21)
	Pain abdomen with four smelling discharge per vaginum	0.98(0.77,1.19)	0.90(0.064,1.21)
Outcome	Incomplete abortion*		
	Complete abortion	1.37(1.12,1.68)	1.17(0.89,1.61)
	Rupture ectopic	1.31(1.11,1.45)	1.28(1.14,1.52)
	Missed abortion	1.22(1.24,1.46)	1.19(1.18,1.13)
	Sepsis	1.05(1.15,1.31)	1.13(1.14,1.38)
	Uterine perforation	1.12(1.14,1.32)	1.19(1.15,1.24)
	Others	1.32(1.14,1.41)	1.37(1.19,1.45)
Awareness of MTP pills	Yes*		
	No	0.98(0.62,1.10)	0.95(0.65,1.17)
Awareness about other methods	No*		
	Yes	0.83(0.69,0.99)	0.85(0.70.1.03)
Duration of stay	<3 days*		
	>3 days	0.68(0.52,0.90)	0.60(0.44,0.81)

Complications	Mild to moderate anemia*	0.85(0.78,1.06)	0.86(0.79,1.09)
	Severe anemia	0.52(0.48,0.74)	0.55(0.49,0.76)
	Sepsis	0.84(0.52,1.14)	0.87(0.55,1.12)
	Scar pregnancy	0.75(0.62,1.12)	0.77(0.68,1.05)
	Mortality	0.81(0.61,1.08)	0.81(0.65,1.01)
	Shock	0.77(0.58,0.98)	0.75(0.61,0.99)
	Continuation of Pregnancy	0.81(0.58,1.05)	0.78(0.61,1.06)
MANAGEMENT	Medical management*		
	Suction & evacuation	1.12(0.85,1.15)	1.12(0.89,1.22)
	S & E with blood transfusion	0.89(0.65,1.10)	0.85(0.61,1.17)
	Laparotomy with blood transfusion	0.92(0.81,1.12)	0.92(0.87,1.17)
	Hysterectomy c blood transfusion	0.81(0.67,1.08)	0.65(0.61,0.94)
	Iron sucrose	0.71(0.62,0.95)	0.74(0.65,0.99)
	Shock	0.66(0.57,0.81)	0.65(0.59,0.94)
Awareness of MTP pills	Yes*		
	No	0.98(0.62,1.10)	0.95(0.65,1.17)
			0.85(0.70.1.03)

Note: *Reference category; *p<0.05; ***p <0.001

Table: Crude and adjusted odds ratio for study variables of both groups.

In table the multivariate logistic regression was performed to estimate the COR and AOR of the study variables. The results shown that among the study variables, education, socioeconomic status, period of gestation and parity along with indication of intake were among the major predictors of the study.

DISCUSSION

According to WHO guidelines, medical termination of pregnancy can be safely performed up to 9 weeks of gestation by a registered medical practitioner. However, self-administration of medical abortion pills by unqualified individuals and lack of awareness regarding the potential complications of unsupervised MTP pill intake can result in severe complications such as sepsis, uterine perforation, cervical trauma, and ectopic pregnancy, posing significant risks to maternal health globally.

This study assessed the outcomes and complications associated with supervised versus unsupervised use of medical abortion pills. In the supervised group, 58.34% of patients were aged 21-30 years, similar to findings by Giri et al(4). and Reema Kumari et al(10)., while in the unsupervised group, 61.33% were aged 31-40 years, consistent with studies by Bhalla S et al(9). Most patients belonged to the middle socio-economic strata, highlighting issues such as early marriage, unplanned pregnancies, career priorities, and the easy availability of MTP pills.

In the supervised group, all pregnancies were confirmed via ultrasound to rule out ectopic pregnancies before proceeding with termination. Conversely, 90% of patients in the unsupervised group used MTP pills based on urine pregnancy tests, a higher rate than reported by Reema Kumari et al(10). The majority of patients in both groups were from the Hindu community. In the supervised group, 72.67% of patients terminated within the recommended gestational period, compared to only 28.33% in the unsupervised group, which had higher termination rates at 9-12 weeks and post-12 weeks gestation.

The unsupervised group had a higher prevalence of patients who were gravida 2, followed by gravida 3 and 1, similar to findings by Reema Kumari et al(10). and Singh A et al(5). In the supervised group, most patients were gravida 2. The primary reason for termination in both groups was unintended pregnancy. However, studies

by Reema Kumari et al.[10] and Bhalla S et al.[9] indicated that privacy concerns and contraception failure were also significant factors.

Excessive vaginal bleeding, a sign of incomplete abortion, was the main complaint in 92.66% of unsupervised cases, aligning with findings by Rath S et al(1)., Reema Kumari et al(10)., and Bhalla S et al(9). This study revealed that 59.67% of patients in the unsupervised group obtained the drugs without a prescription, underscoring the widespread misuse of MTP pills despite existing sale restrictions.

While awareness of MTP pills was high in both groups, knowledge of alternative contraceptive methods was limited. This highlights the need for enhanced education on contraception and the supervised use of MTP pills to prevent complications. Enforcing prescription requirements for MTP pills and implementing comprehensive sex education programs are essential.

In the supervised group, patients were informed about potential complications and the risk of ectopic pregnancy, allowing for timely medical intervention and minimizing complications. Only 14% of supervised patients required surgical intervention, compared to 73.67% in the unsupervised group. Blood transfusions were necessary for 42% of unsupervised patients, and two required life-saving hysterectomies. Complications such as shock (2.34%), sepsis (4.35%) and mortality (1.62%) had been reported in this study compared to none in supervised group. Similar studies were shown in the study conducted by Thakur et al(11) and Sarojini et al(13)

Additionally, 7 patients in unsupervised group needed laparotomy due to complications like scar ectopic pregnancy and uterine perforation.

The study underscores the urgent need for increased awareness and strict regulations regarding the use of MTP pills to reduce maternal morbidity and mortality associated with unsupervised medical abortions.

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CONCLUSION

The current study indicates that complications are significantly higher in the unsupervised group compared to the supervised group, including increased need for blood transfusions, laparotomy, hysterectomy, and even maternal mortality. To address this issue, it is crucial to educate and raise awareness among women at the community level about family planning and the contraceptive options available at hospital centres. Emphasizing the importance of taking MTP pills under medical supervision is essential. Additionally, strict actions and surveillance should be implemented to control the easy availability of over-the-counter pills. Addressing these issues urgently is necessary to reduce the risk of women experiencing severe complications or losing their lives due to unsupervised MTP pill intake.

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