

# Self administration versus supervised use of Medical Abortion pills: Impact on women's health

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## Abstract

**Background:** In India, despite of the fact that abortion facility is available legally under MTP act 1971, women seeking termination of pregnancy often ignore the legal status of abortions and have unsafe abortions. Medical abortion in the first trimester is safe, efficient and approved method of MTP, but should always be taken under the supervision of a registered medical practitioner. The unsupervised use of drug should be stopped as this can endanger life.

**Objective:** To assess the effects of self-administered use of over the counter pill and compare it with the supervised use of mifepristone-misoprostol for medical termination of pregnancy in a tertiary care hospital; and to study its impact on women's health.

**Methodology:** The study was conducted in the Department of Obstetrics & Gynaecology at a tertiary care hospital of North India over one year period. 322 patients fulfilling the inclusion and exclusion criteria were taken up for the study. Data was compared and analysed in patients with history of self consumption of medical abortion pills versus supervised pills intake.

**Result:** Majority of the patients were young, belonged to the urban area and were Hindu by religion ( $p < 0.0001$ ). Only 66.3% patients in the unsupervised group followed the correct regimen as compared to the supervised group where all the patients followed the correct regimen. The complication rate was 73.1% in unsupervised group as compared to 42.6% in supervised group ( $p < 0.0001$ ). There was significant statistical difference between both groups in respect to success and failure rate with  $p < 0.0001$ .

**Conclusion:** This study shows urgent need for legislation and restriction of drugs used for medical termination of pregnancy. Drugs should be made available via health care facilities under supervision to reduce maternal mortality and morbidity due to indiscriminate use of these pills.

**Keywords:** Medical abortion, unsupervised, supervised, mifepristone-misoprostol, women's health.

## INTRODUCTION

The MTP act legalized termination of pregnancy in India since 1971. World Health Organization recommends Medical method of abortion (MMA) or medication abortion (MA) as a safe method of termination of pregnancy over traditional dilatation and curettage<sup>2</sup>. The combination of drugs Mifepristone and Misoprostol for medical method of abortion is a safe, efficient, affordable, acceptable, and approved method of MTP up to 9 weeks (63 days) of gestation<sup>1</sup>.

As per WHO guidelines, it is necessary for a women requesting for medical abortion to consult a gynecologist for confirmation of pregnancy, estimation of correct gestational age, exact location of pregnancy and to rule out any contraindications. Thorough clinical evaluation of the patient and basic laboratory investigations should be done<sup>3</sup>.

In spite of all the guidelines, medical abortion pills (MAP) are widely being sold without medical prescription by chemist over the counter. Lack of awareness about the MTP Act, concerns about privacy and affordability lead women to procure these abortion pills over the counter. Self-medication of these drugs in India is on the rise especially in the rural areas where access to medical services is poor. Such unsupervised terminations can lead to hazardous effect on health of women, resulting in life threatening complications<sup>4</sup>.

Each year an estimated 42 million pregnancies end in induced abortion, out of which 20 million are performed under unsafe condition. Unsafe abortion is responsible for 13% of maternal deaths worldwide<sup>5</sup>.

Hence, the aim of our study is to assess the effects of self-administered use of over the counter pill and compare it with the supervised use of mifepristone-misoprostol for medical termination of pregnancy in a tertiary care hospital; and to study its impact on women's health with respect to the complications, consequences and management of the patient.

## METHODOLOGY

This case control study was conducted in the department of Obstetrics and Gynecology at a tertiary care hospital of North India over one year period from January 2021 to December 2021. The sample size was 322 subjects with 160 women as cases who visited gynaecology emergency or out-patient department with history of self-consumption of mifepristone-misoprostol for the purpose of abortion, purchased over the counter by self or by family member, without medical guidance and supervision; and 162 women as control who visited gynaecology out-patient department and showed willingness for medical method of abortion.

Approval was obtained from the Ethics committee and consent was taken from each patient.

Women of reproductive age group (18-40 years), having singleton intrauterine pregnancy of not more than 9 weeks (63 days from LMP) and having no other medical illnesses were included in the study. Any women refusing consent or having allergy to mifepristone or misoprostol, history of coagulation disorder, on anticoagulants or corticosteroid therapy, previous caesarean section, any previous surgery on uterus or cervix, multiple pregnancy, suspected ectopic pregnancy, chronic renal failure, inherited porphyrias or who consumed MTP pill under the guidance of registered medical practitioner and came to us with complications were excluded.

A detailed history, thorough examination and baseline investigations were done in all patients. Ultrasound was performed for dating a pregnancy with irregular cycles, lactation amenorrhea, clinical discrepancy or uncertainty in examination and to exclude an ectopic gestation before a medical termination of pregnancy.

Women in supervised group were given mifepristone 200 mg orally on day 1. On day 3, misoprostol 400 µg was inserted vaginally, followed by two tablets of 200 µg each intravaginally, at a gap of 3 hrs. Follow-up visit to assess for completion of abortion (by clinical examination and Ultrasound pelvis) was done on day 14.

Complications in terms of incomplete abortion, anemia, fever, allergic reaction, continuation of pregnancy and sepsis were noted on admission in unsupervised group and on day 14 in the supervised group. In patients with incomplete abortion, D&E was done.

Statistical Analysis:

The data was collected and tabulated. The observations were described in terms of percentages and proportions. Data was compiled and statistically analysed using chi square test, students t test where applicable.  $P < 0.05$  was considered statistically significant.

## OBSERVATIONS AND RESULT

Total 322 patients were included in the study, after excluding 3 patients who were lost to follow up. Out of these, 160 patients were in the unsupervised group (US) and 162 patients in the supervised Group (S). There was no difference in the two groups with regards to socio-demographic profile.

Table 1- Distribution according to socio-demographic profile

Characteristics	Sub Groups	Unsupervised (US)		Supervised (S)		Total (US+S)		P value
		n (160)	(%)	n (162)	(%)	n (322)	(%)	
Age (Years)	≤30	116	72.5	114	70.3	230	71.4	0.7121
	>30	44	27.5	48	29.7	92	28.6	
Residence	Urban	112	70	111	68.5	223	69.3	0.8097
	Rural	48	30	51	31.5	99	30.7	
Religion	Hindu	132	82.5	137	84.6	269	83.2	0.6540
	Muslim	28	17.5	25	15.4	53	16.8	
Educational Status	Illiterate	42	26.3	15	9.2	57	17.7	<0.0001
	Primary	28	17.5	15	9.2	43	13.4	
	Secondary	60	37.5	57	35.4	117	36.3	
	Graduate	30	18.7	75	46.2	105	32.6	

Of the study group (n=322), majority of the patients were young, less than 30 years of age (71.4%), belonged to the urban area (69.3%) and were Hindu by religion (83.2%). These observations were highly statistically significant ( $p < 0.0001$ ). However, when compared between unsupervised and supervised groups, there was no significant difference seen ( $p = 0.7121, 0.8097$  and  $0.6540$  respectively). Mean age in unsupervised group was  $28.32 \pm 4.803$  and in supervised group was  $28.16 \pm 4.58$ . Majority of the patients in the unsupervised group were illiterate (26.3%) as compared to supervised group where majority of the patients were graduates (46.2%) ( $p < 0.0001$ ). (Table 1)

Table 2- Distribution according to obstetric profile

Characteristics	Sub Groups	Unsupervised (US)		Supervised (S)		Total (US+S)		P value
		n (160)	(%)	n (162)	(%)	n (322)	(%)	
Gravida	1	12	7.6	9	5.6	21	6.5	0.7007
	2	30	18.7	30	18.5	60	18.6	
	≥3	118	73.7	123	75.9	241	74.9	
Period of gestation	≤7 weeks	108	67.5	135	83.3	243	75.4	0.0011
	>7 weeks	52	32.5	27	16.7	79	24.6	

Out of the total study population, 74.9% of the patients were ≥3 gravida ( $p < 0.0001$ ). But no difference was seen when comparison was made in the unsupervised and supervised groups ( $p = 0.7007$ ).

More patients in the unsupervised group had period of gestation >7 weeks as compared to patients of supervised group (32.5% versus 16.7%).

The result was found to be statistically significant ( $p = 0.0011$ ).

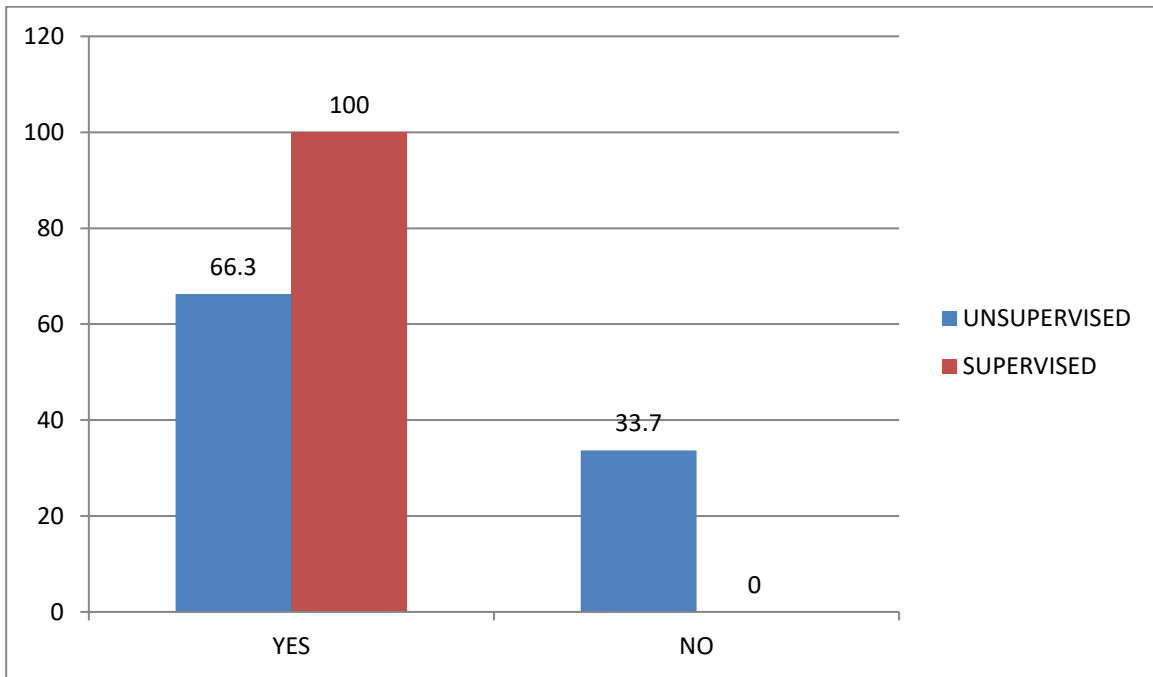


Figure 1- Correct regimen followed

In this study, it was found that only 66.3% patients in the unsupervised group followed the correct regimen as compared to the supervised group where all the patients followed the correct regimen (100%).

The result was found to be highly statistically significant ( $p < 0.0001$ ).

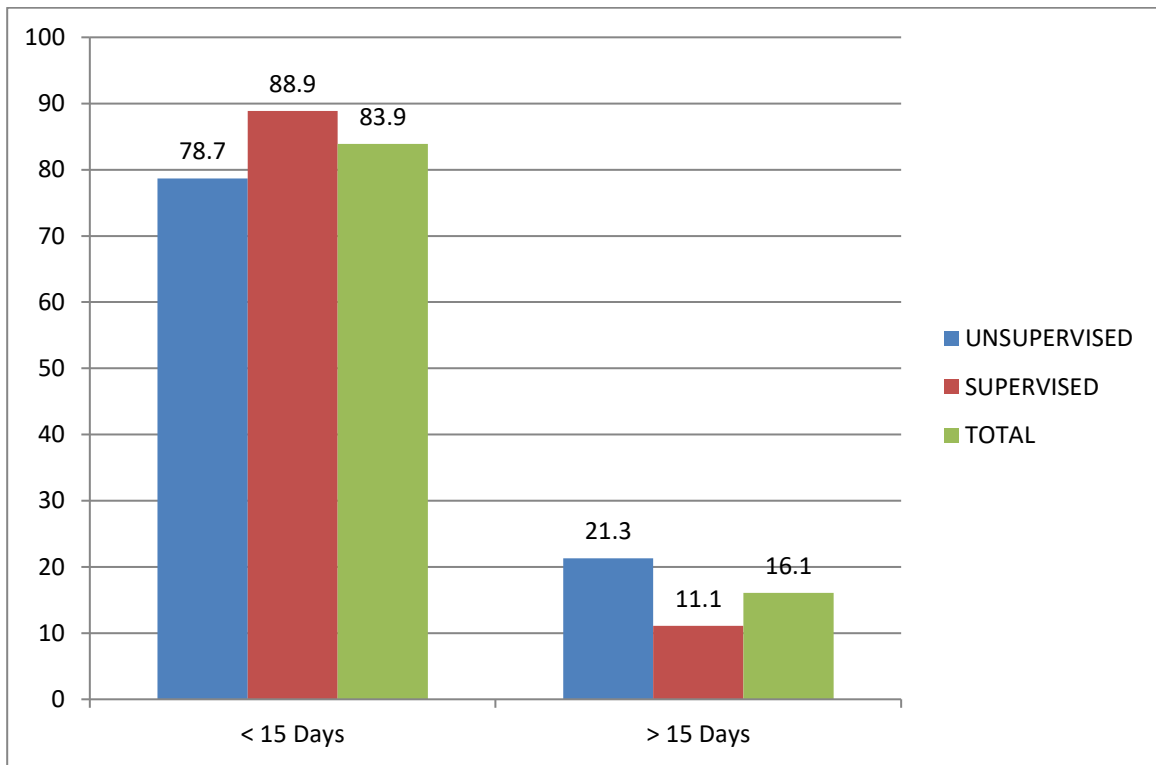


Figure 2-Duration of bleeding

Duration of bleeding in both the groups was more or less the same. 78.1% of the unsupervised group patients and 88.9% of supervised group patients had bleeding less than 15 days (83.9% of total study population). Only 16.1% of patients of the total study population had bleeding for more than 15 days. The data was statistically significant ( $p=0.0153$ ).

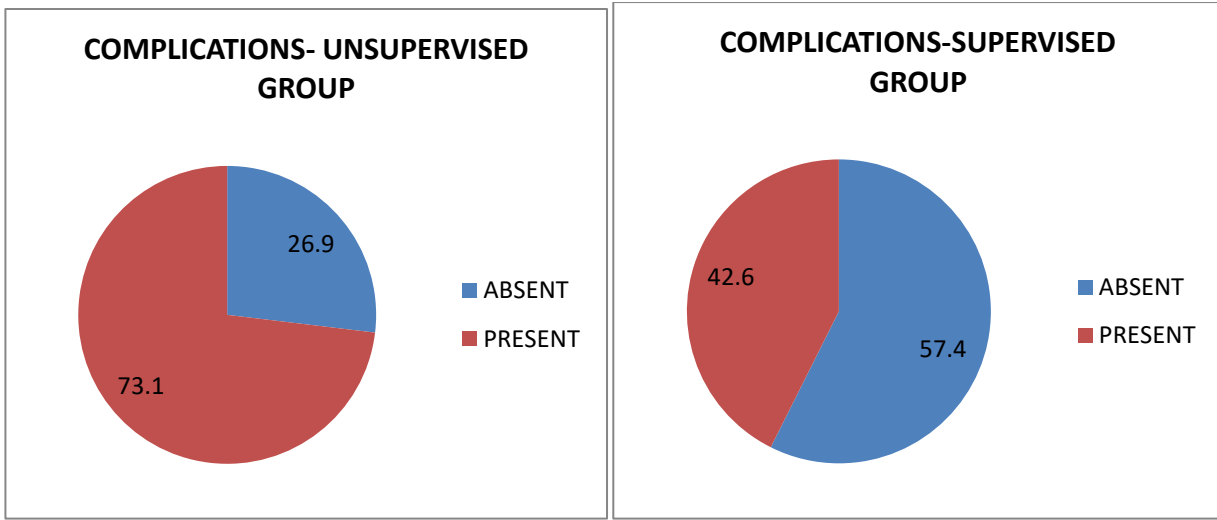


FIGURE 3- COMPLICATIONS

The complication rate was 73.1% in unsupervised group as compared to 42.6% in supervised group. The data was highly statistically significant ( $p<0.0001$ ).

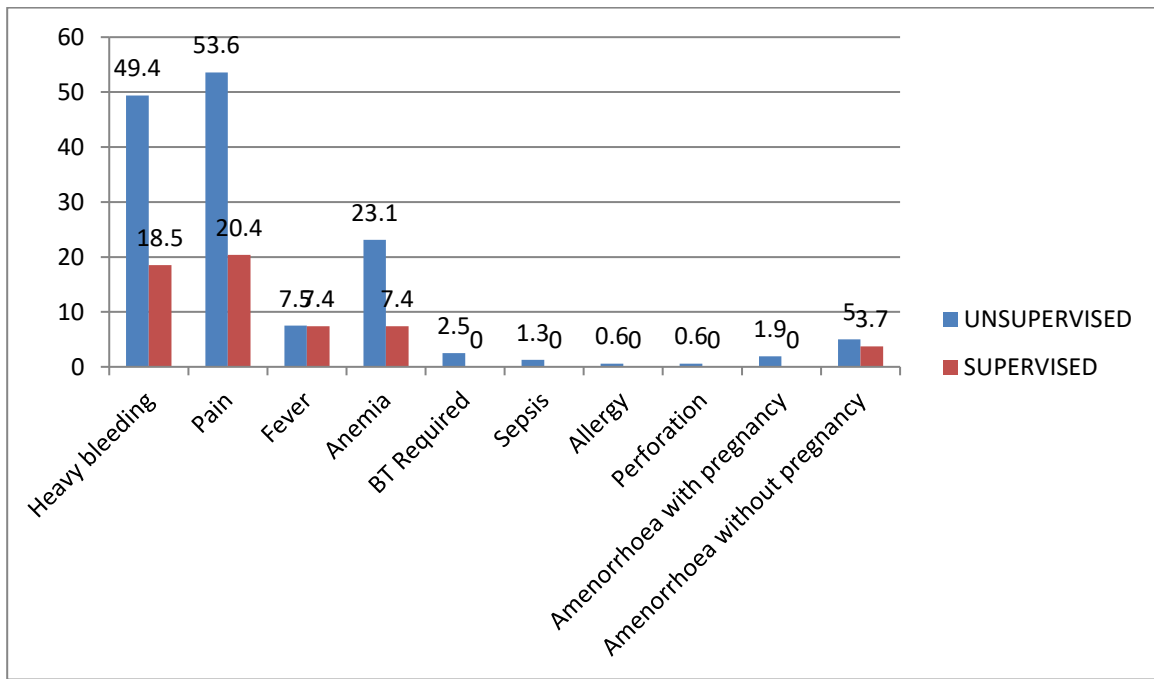


FIGURE 4-TYPES OF COMPLICATIONS

Significant difference was seen between unsupervised group and supervised group in terms of heavy bleeding, pain abdomen and anaemia (with hemoglobin  $<8$  gm%) ( $p<0.0001$ ).

Among the unsupervised group patients, 4 patients required one or more units of blood transfusion and 2 patients presented with ongoing live pregnancy on admission as confirmed on Ultrasound.

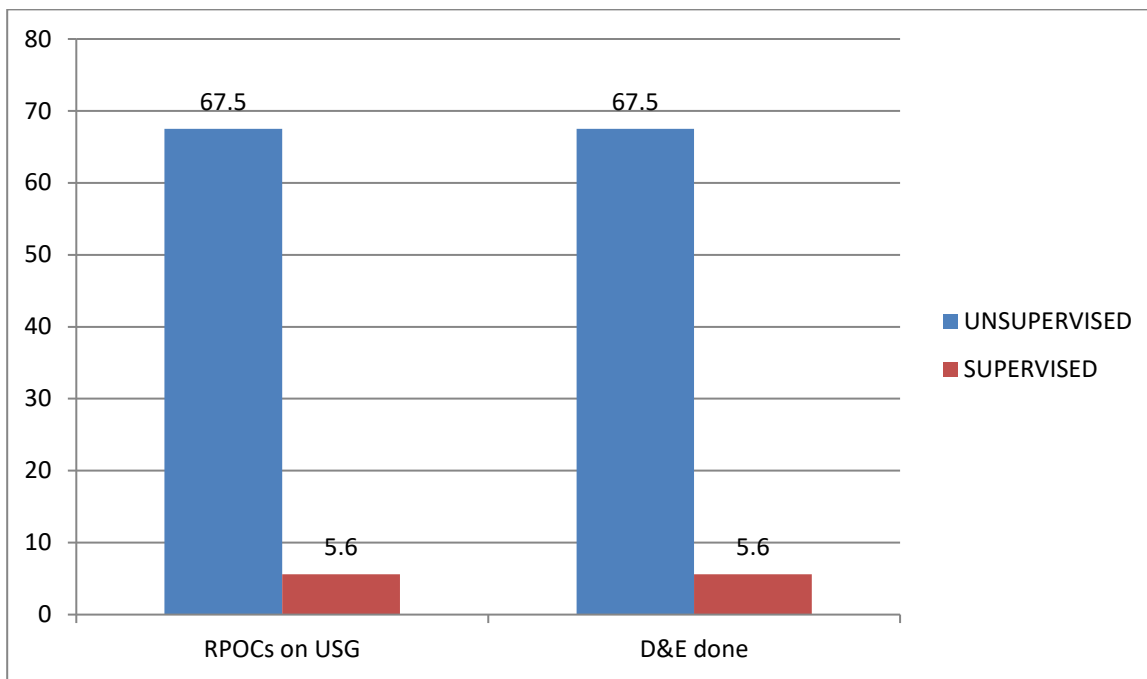


FIGURE 5-FOLLOW UP

In this study, 67.5% patients in the unsupervised group showed retained products of conception (RPOCs) in the ultrasound done on admission, signifying incomplete abortion, for which D&E was required. This was in contrast to supervised group where only 5.6% patients required D&E for retained products of conception (RPOCs) in the ultrasound done after 15 days of giving MTP pill. The result was found to be highly significant ( $p < 0.0001$ ).

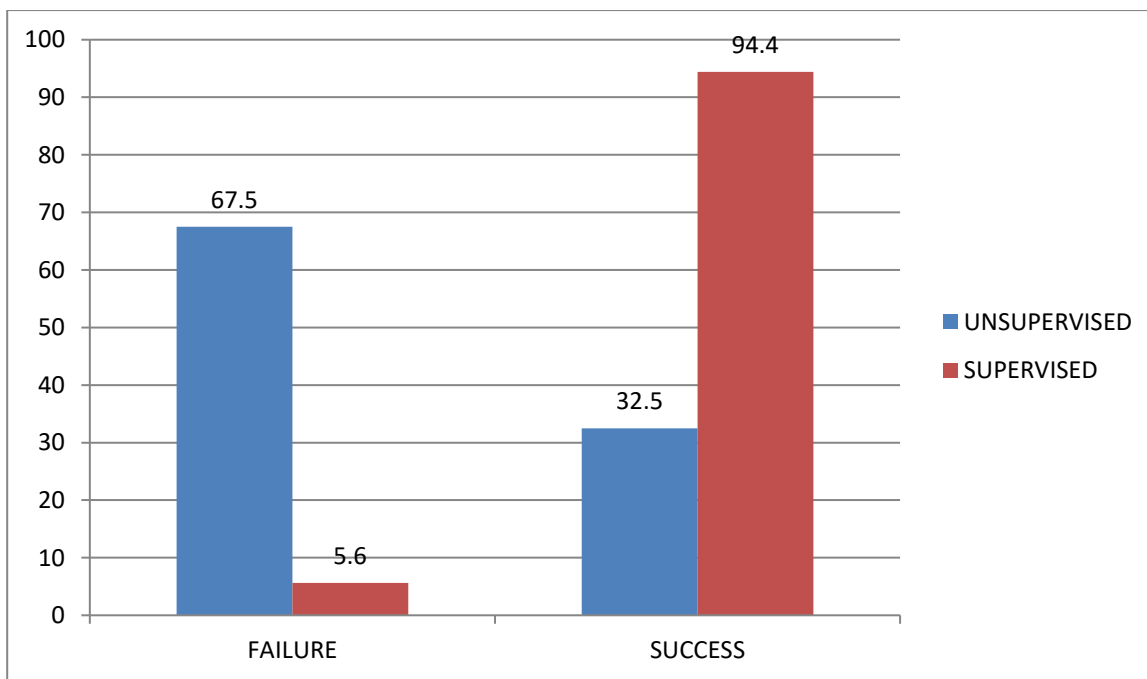


FIGURE 6-OUTCOME

In the study, outcome variables were calculated based on success and failure rates. Success rate was only 32.5% in the unsupervised group while, it was 94.4% in the supervised group. The failure rate was 67.5% in the unsupervised group whereas, only 5.6% in the supervised group. There was significant statistical difference between both groups in respect to success and failure rate with ( $p < 0.0001$ ).

## DISCUSSION

In India, despite of the availability of abortion facility legally under MTP act, 1971, women who want to terminate a pregnancy often ignore the legal status of abortions and have unsafe abortions.

Present study shows that majority of the patients were young, belonging to the urban population and were Hindu by religion. These results were consistent with other studies<sup>5-9</sup>. Increased prevalence of abortion in Hindus may be because of their greater population. Moreover, Hindus are more liberal and easily opt for family planning measures including abortions. Muslim women have both less access to and less demand for induced abortion owing to religious norms.

In present study, it was found that most of the patients in the unsupervised group were illiterate and most of the patients of supervised group were graduates. Similar results were found in the comparable studies<sup>7,9-10</sup>. This indicates that lower education status makes the women not only more vulnerable to unwanted pregnancies, but also less accessible to the knowledge about the complications associated with unsupervised MTP pill intake.

Various studies<sup>6,8,9,11</sup> including present study showed that majority of the patients seeking MTP pills were of the order of gravida three or above, revealing the fact that in spite of completed family these women got unwanted pregnancy and opted for MTP pill. There is a need to make these women aware of and to motivate them for accepting various contraceptive measures available.

An important finding in present study was that more patients in the unsupervised group had period of gestation  $>7$  weeks as compared to patients of supervised group. Similar results were seen in other studies<sup>7-10</sup>. This could be one of the contributory factors for higher failure rate in unsupervised as compared to supervised group.

Improper or inadequate intake of the dosage schedule of MTP pill was the major reason leading to the increased failure rate in unsupervised group. In present study, only 66.3% patients in the unsupervised group followed the correct regimen. The results were consistent with other studies<sup>4,8,11</sup>. Emphasis should be laid upon to these patients to avoid this in future.

The overall complication rates in unsupervised group were much more as compared to the supervised group in present study ( $p < 0.0001$ ).

Heavy bleeding and pain lower abdomen following MTP pill intake was seen more in unsupervised group. All these patients had retained products of conception on ultrasound done on admission and landed up in D&C, indicating incomplete abortion. Similar results were found in other studies<sup>6,8,11</sup>.

Present study shows that 67.5% of patients in the unsupervised group had to be taken up for D&E for incomplete abortion as compared to only 5.6% patients in the supervised group ( $p < 0.0001$ ). These results were comparable to other studies<sup>4,7,8,10</sup> reinforcing the fact that failure rate in the form of incomplete abortion is much higher when MTP pills are not taken under supervision.

## CONCLUSION

First trimester medical abortion under supervision is more effective, safe and convenient as compared to unsupervised medical abortion; yet large number of the patients use unprescribed methods for termination of pregnancy due to media publicity and over the counter availability in India without any rules to govern their sale.

This study shows urgent need for legislation and restriction of drugs used for medical termination of pregnancy. Drugs should be made available via health care facilities under supervision to reduce maternal mortality and morbidity due to indiscriminate use of these pills.

Simultaneously, there is a need for widespread dissemination of information on contraception methods in the community, as the contraceptive methods prevent unwanted pregnancies thereby reducing the need for abortions as well as the side effects and health hazards associated with termination of pregnancy.

The national health programmes should be strengthened at grass root level to ensure proper medical advice to the poor and uneducated people of the country and thus relieving them from the clutches of untrained medical personnel and quacks.

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