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Analytical Assay of Self Administration of MTP Kit (Mifepristone and Misoprostol)

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Abstract
Background
The Indian MTP Act legalises the use of combination of mifepristone and prostaglandins like misoprostol, as a non surgical method for termination of pregnancy uptill 7 weeks of gestation. The beneficiaries are however ignorant about inherent limitations of the combination and the need for supervised use of MTP kit to achieve the objective of safeguarding maternal health.
Objectives
To evaluate the ignored aspects of MTP kit intake during self administration: Baseline investigations, period of gestation at time of taking MTP Kit, obstetrical history (including uterus being scarred or unscarred), dosage of drugs.
Methodology
This is a retrospective analysis of history and clinical management of patient reporting to Gynae. unit-ll, Bebe Nanki Mother and Child Care Center, Amritsar between February 2019 to February 2020 for 12 months.
After applying inclusion and exclusion criteria, 35 women with history of self administration of MTP kit who reported with different clinical symptoms that needed further management were included in the study with the aim to compare the circumstantial evidence from their history with the accepted guidelines for MTP kit intake: Baseline investigations, period of gestation at time of taking MTP Kit, obstetrical history (including uterus being scarred or unscarred), dosage of drugs.
Observations And Results
This study brings forth the fact that none of the women had got any baseline investigation (except urine for pregnancy test) done. Only 14(40%) women had taken the MTP Kit at gestational age ≤ 7 weeks and 21(60%) women took MTP Kit beyond 7 weeks of gestation. The study did not record any caution being exercised by 11 (31.42%) women with a scarred uterus.
32 (91.4%) cases in this study required surgical intervention as these included 28 (80 %) cases of incomplete abortion; 02 (5.71 %) cases of septic abortion, 2 (5.71 %) cases of ectopic pregnancy. 3(8.57%) women required no surgical intervention as the process of abortion was complete which was supported by ultrasound findings. These 3 women had presented with the complaint of persistent bleeding P/V with anaemia. Out of 35 women included in the study, 15 (42.85%) required blood transfusion. There was no maternal death in the study group.
Conclusion
This study highlights the fact that the need of the hour is to discourage the unsupervised intake of MTP kit to achieve the end result of aborting the pregnancy while safeguarding maternal health.
Keywords: *Over the counter, MTP kit, Incomplete abortion, Scarred uterus, Blood transfusions*

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I. Introduction

Abortion is the wilful termination of the pregnancy before the period of viability. Excluding few instances, in most of the cases it is an outcome of unwanted pregnancy [1]. In India, abortion facility is available legally under MTP act, 1971. Despite this, women who want to terminate a pregnancy often ignore the legal status of abortions and have unsafe abortions. The WHO defines unsafe abortion as a procedure for terminating an unwanted pregnancy either by persons lacking the necessary skills or in an environment lacking minimal medical standards or both [2]. The World Health Organization (WHO) recommendations on medical abortion are restricted to early first trimester (up to 63 days since the first day of the last menstrual period) [3].

Antiprogesterone drugs such as mifepristone (RU 486) and prostaglandins like misoprostol have been approved by the United States Food and Drug Administration (USFDA) for medical abortion [4]. As per Medical Termination of Pregnancy (MTP) Act of India, this method can only be administered by gynaecologists and registered medical practitioners (RMP) recognized for performing MTPs up to 49 days since the first day of LMP [5,6]. The medical abortion carries a very high success rate of 93–98 % if they are used judiciously, that is, after properly assessing the gestational age as well as the health of the patient [7,8]. Federation of Obstetrics and Gynaecological Societies of India (FOGSI) recommends close monitoring of distribution of these drugs and that the medical profession and pharmaceutical industry should exercise due diligence in the promotion and usage of drugs that are used for medical abortion [9]. Despite this, it has been perceived by the society that medical abortions are extremely safe option even in the hands of untrained personnel, leading to over-the-counter dispensing and possible increase in unsupervised terminations and life-threatening complications [10]. Being a tertiary care center, we come across many cases of self-medication with MTP Kit who present with a varied clinical symptomatology that requires further medical or surgical intervention to safeguard maternal health.

II. Methodology

This is a retrospective analysis of history and clinical management of patient reporting to Gynae unit-ll, Bebe Nanki Mother and Child Care Center, Amritsar between February 2019 to February 2020 for 12 months. After applying inclusion and exclusion criteria, 35 women with history of self administration of MTP kit who reported with different clinical symptoms were included in the study with the aim to compare the circumstantial evidence from their history with the accepted guidelines for MTP kit intake: Baseline investigations, obstetrical history (including uterus being scarred or unscarred), period of gestation, dosage of drugs.

- **Inclusion Criteria**

➢ All the women with history of self administration of MTP Kit without any medical consultation.

- **Exclusion Criteria**

➢ Women who had consumed MTP Kit after consulting a registered medical practitioner and reporting to us with complications.

➢ Women who had undergone any surgical intervention after MTP Kit consumption in other health care centers before reporting to our hospital. .

History regarding previous pregnancies, gestational age at which MTP kit was taken, Baseline investigations, dosage, presenting complaints was noted. On admission, detailed general, systemic, obstetric examination and routine investigations were done in all the women. Presence of retained products, incomplete abortion and ectopic pregnancy were documented upon ultrasound examination and clinical evaluation. Management methods adopted were noted and a note was made of transfusion of blood and blood products.

III. Results

A total of 35 cases were studied: The following data were obtained from the present study.

1. BASELINE INVESTIGATIONS

All the 35 women included in the study claimed of having got urine for pregnancy test done after missing the menstrual cycle and before taking MTP kit but did not furnish any other information related to any other investigation (Hb, ABORh, Urine C/E) having been got done prior to taking MTP kit.

2. AGE DISTRIBUTION OF WOMEN

The age distribution of present study group is shown in Table 1. 19(54.29%) women are within 30 years of age and 16 (45.71%) are ≥ 30 years of age.

S.N	Age of Pt.	No. Of Patients	%age
1	< 20yrs	01	2.85
2	20-25 yrs	07	20
3	25-30 yrs	11	31.42
4	30-35yrs	11	31.42
5	35-40yrs	05	14.28
	Total	35	100

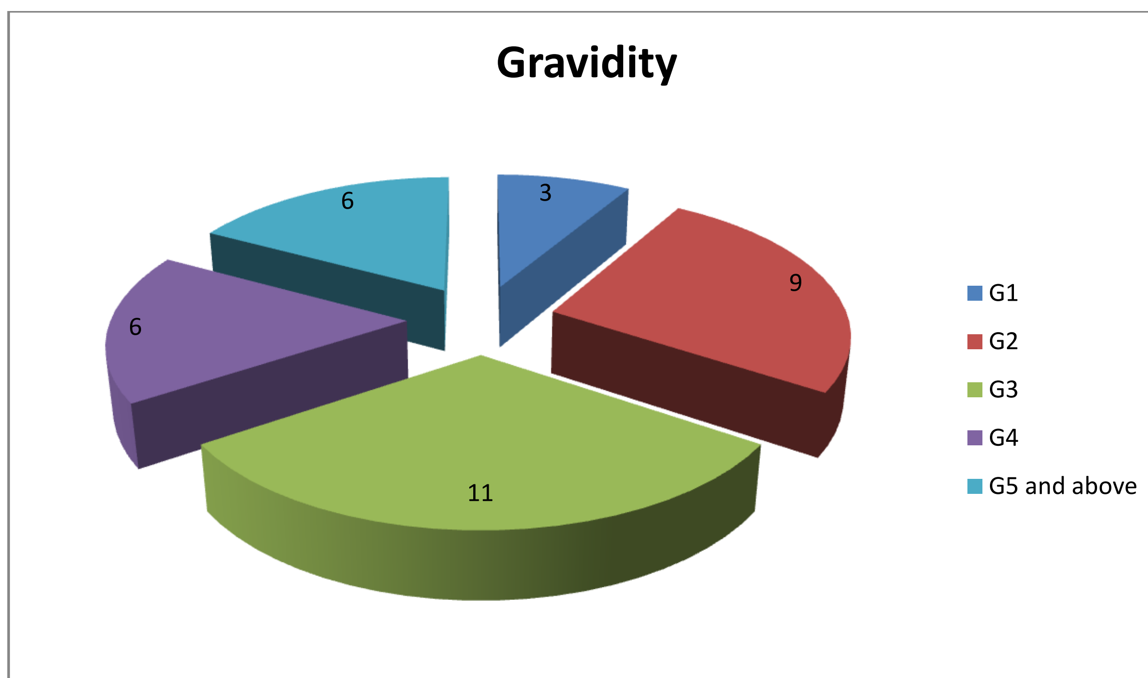
3. **AGE OF GESTATION**

S.No	Age of gestation.	No. Of Patients	%age
1	5.1- 7 weeks	14	40
2	7.1-9 weeks	10	28.57
3	9.1-11 weeks	03	8.57
4	11.1-13 weeks	03	8.57
5	13.1-15 weeks	03	8.57

6	15.1-17 weeks	00	00
7	17.1-19 weeks	02	5.71

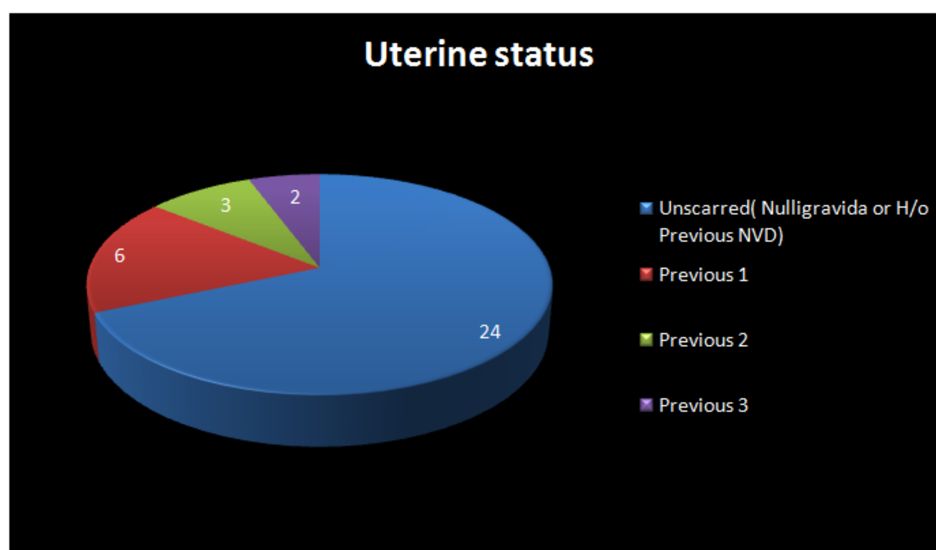
14 (40%) women took MTP kit at gestational age < 7 weeks and 21(60%) took kit beyond 7 week.

4. OBSTETRICAL STATUS



There were 3 (8.57 %) primigravidas, 9 (25.7 %) second gravidas, 11 (31.4 %) third gravidas, 6 (17.14 %) women with obstetric score of gravida 4, 6(17.14%)women with obstetric score of gravid 5 and above in this study group.Amongst the primigravidas,2 were unmarried.

5. UTERINE STATUS



11 (31.42%) of the women included in the study gave the history of having undergone LSCS. Out of these 11 women, 6 women furnished history of being previous one LSCS, 3 women had undergone previous two LSCS and two women presented with history of being previous three LSCS.

6. CLINICAL PRESENTATION AT TIME OF ADMISSION

S.No	Clinical Features at time of admission	No of women	%age
1	Clinical or USG features of incomplete abortion or excessive or persistent bleeding PV or pain abdomen	31	88.57
2	Ectopic pregnancy(USG diagnosed)	02	5.71
3	Septic abortions	02	5.71
	Total	35	100

Excessive or persistent bleeding per vagina and pain abdomen were the most common clinical features for which 31patients (88.57%) had sought the medical help. 2 (5.71%) cases presented at the hospital along with the USG showing the diagnosis of ectopic pregnancy- 1 tubal and 1 scar pregnancy. 2(5.71%) cases presented with features of sepsis and with USG documented retained products.

7. CLINICAL MANAGEMENT

S.No	Procedure done	No. Of women	%age
1	Evacuation of uterine cavity	30	85.71
2	Laprotomy	01	2.86
3	Hysterotomy	01	2.86
4	Conservative management	03	8.57
	Total	35	100

30 women (85.71%) underwent evacuation of the uterine cavity. Amongst these 30 women, 28 (80%) women were subjected to suction evacuation and 2 women(5.7%) required oxytocics to enhance the process of expulsion .In both these cases requiring oxytocics, the gestation had moved past 15 weeks of gestation. Suction evacuation was also carried out in the woman who had presented at the hospital, as a case of previous three LSCS with USG (done at the referral hospital) diagnosed scar pregnancy, with all the preparedness for laprotomy in case of any unforeseen complication. A repeat USG of this patient done at the hospital at the time of admission, before any intervention, had revealed pregnancy products away from the scar site. Laprotomy was undertaken in the woman who was diagnosed with tubal pregnancy. Salpingectomy was done in this case. Hysterotomy had to be resorted to in one case diagnosed as previous two LSCS with low lying placenta. Conservative management was done in 3 women (8.57%) who had presented history of prolonged bleeding P/V following MTP Kit intake and USG showed no RPOC.Each of these woman was transfused at least 3 or more units of blood.Out of 35 women included in the study, 15 (42.85%) required blood transfusion.

IV. Discussion

All women in this study had presented at our hospital with history of self administration of MTP kit which was easily procured over the counter at local pharmaceutical shops by self or by a relative without getting any clinical evaluation from an approved health care facility. Drug administration was not supervised, and there was no adherence to the recommended schedule in most of the cases. Few women even denied the procurement of the drug initially. The safety of women taking MTP Kit requires clinical evaluation of the health status of the women by a certified abortion provider to rule out any contraindication to the drug administration and their thorough counselling for the procedure beforehand so that they seek medical assistance at a prior ear marked health care facility in case some complication develops and be prepared for at least 3 follow-up visits to the health care facility.

Besides urine for pregnancy test, no other baseline investigations were got done prior to MTP kit intake by the women included in the study. The minimal recommended baseline investigations are urine for pregnancy test (UPT), Hb, urine complete examination and ABoRH(6). Hb less than 8 gm% is contraindication for medical method of abortion. The Govt. of India guidelines advocates the administration of injection Anti-D 50mcg to an Rh–ve pregnant female on day 1 along with intake of Tab.Mifipristone(6). USG though not mandatory, is an optional modality which can be advocated in women with suspicion of ectopic pregnancy or where gestational age cannot be ascertained.

As per the guidelines ,in India, medical termination of pregnancy should be offered to women seeking termination of pregnancy up to 7 weeks.(5,6). 14 (40%) women took MTP kit at gestational age < 7 weeks and 21(60%) took kit beyond 7 week. Similar results are also reported by Sarojini. T.R et al.(11)

In this study, 5.71% women were unmarried and 65.71 % women were gravida 3 or more; both data indicate that MTP kit was likely to have been consumed to get rid of unwanted pregnancy. It needs to be highlighted that MTP kit cannot replace contraception as a safe method of avoiding unwanted pregnancy.

The guidelines for MTP kit intake requires extra caution to be exercised in women with history of previous LSCS, hysterotomy or myomectomy (6). 11 (31.42%) of the women included in the study gave the

history of having undergone LSCS. Unsupervised self administration of MTP kit goes against the advice of using this drug with caution even under supervision while administering it to a pregnant female with scarred uterus.

From amongst the varied clinical presentation with which the patients had arrived at the hospital, 31 cases (88.57%) had sought medical consultation for complaints of excessive or persistent bleeding per vagina or pain abdomen. Similar results(89.1%) are also reported by Thacker et al(5).When the procedeure fails or when some unprecedented symptoms crop up,it is essential to seek medical consultation at the earliest as on ultrasound examination, only 3 patients (8.57 %) had complete abortion; rest 32 (91.43%) had incomplete abortion, septic abortion or ectopic gestation. Similar results are observed by Sarojini. T.R et al. (11)

Clinical management analysis points towards the fact that surgical intervention was required in cases where the MTP Kit failed to accomplish the process of abortion. Hence, the need for supervised administration of MTP Kit should not be ignored.

Out of the 35 women included in the study,15(42.85%) required blood transfusion. The need for blood transfusion would only arise either when the woman was already anaemic at the time of MTP Kit intake,which in itself is a contraindication for its intake ,or if she ignores excessive or persistent bleeding p/v before seeking help.Both the scenarios would only be dealt effectively at a health care facility. Hence, the need for counselling of the patient prior to MTP Kit intake. The need for blood transfusion which is a double edged weapon can be curtailed by helping a woman pick a method of abortion as per her clinical status and by reinforcing the fundamental principle of seeking assistance at the earliest at an earmarked health facility,in case some untoward complication sets in.

V. Conclusion

This study throws light on the need to curb the indiscriminate use of MTP Kit by drawing attention towards the fact that whereas on one hand MTP Kit provides a nonsurgical method of abortion yet it has it's inherent limitations which requires the process to be supervised by a certified abortion provider to achieve the end result while safeguarding maternal health. The MTP Act guidelines need to be implemented and followed in totality by both the service providers and the beneficiaries

. With the advent of Comprehensive Abortion Care Services in the various healthcare facility across the country, the message to be circulated in the society amongst the women is to avail the services of a certified abortion provider for taking MTP Kit rather than putting one's life in jeopardy. In the event of suspicion of ectopic pregnancy on clinical examination, ultrasound examination is recommended prior to MTP Kit intake. The study also brings to the surface the unmet need of contraception in the society which needs to be fulfilled as MTP Kit cannot match the safety of contraception to avoid unwanted pregnancy.

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