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EFFICACY AND SAFETY OF MTP PILL IN FIRST TRIMESTER ABORTION AT SIMS, HAPUR, UTTAR PRADESH, INDIA

Obstetrics & Gynaecology

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ABSTRACT

Background: The most appropriate methods of abortion differ by the duration of pregnancy. First trimester medical abortion is a safe non surgical procedure in which drugs are used to induce abortion from four weeks up to seven or nine weeks of pregnancy. This study was called out to evaluate the effectiveness and safety of MTP pill in first trimester abortion under medical supervision to prevent unsafe abortion **Method:** This is a prospective study of 100 cases that were divided into two groups, Group A (50 cases) - gestational age up to 49 days and Group B (50 cases) - gestational age up to 63 days. Conducted at obstetrics and gynaecology department, SIMS, Hapur, Uttar Pradesh from December 2020 to June 2022 **Results:** In present study, successful expulsion without surgical intervention was achieved in 90% of group A and 78% in group B.Side effects were also less in group A participants as compared to group B. **Conclusions:** Medical methods of abortion are safe,effective and acceptable in first trimester of pregnancy but lesser gestation age is a good predictor for successful abortion.

KEYWORDS

Mipepristone, Misoprostol, MTP, MMA

INTRODUCTION

Abortion is defined as spontaneous or induced termination of pregnancy before fetal viability. Induced abortion implies surgical or medical termination. [1] The maternal mortality ratio for India is 130/100,000 live births (RGI-SRS: 2014-16) out of which unsafe abortion accounts for 8% of MMR. [2]

The medical termination of pregnancy (MTP) act, enacted in 1971, governs the provision of abortions in India. This act allows termination of pregnancy up to 20 weeks. [2]

The Rajya Sabha passed the MTP (Amendment) bill on 25th march 2021, resulting in comprehensive law governing abortions in India. [5] Expanding access to safe and legal abortion services on eugenic, therapeutic, humanitarian and social grounds up to 24 weeks.

First trimester medical abortion is a safe non surgical procedure in which drugs are used to induce abortion from four weeks up to seven or nine weeks of pregnancy, surgical methods are preferred from nine to fourteen weeks of pregnancy. [4] Medical abortion in India is approved up to seven weeks of amenorrhea i.e. fortynine days from the first day of last menstrual period in women with regular cycle of twenty eight days. [5]Whereas WHO recommends medical abortion up to nine weeks i.e. sixty three days since the first day of last menstrual period. [6]

MTP pill include combipack with mifepristone + misoprostol (1 tablet of mifepristone 200mg and 4 tablets of misoprostol 200mcg each) approved by Central Drug Standard Control Organization, Directorate general of Health services, India, in December 2008 for the termination of intrauterine pregnancy up to 63 days/ 9 weeks of gestation. [7]

Both the drugs are approved for medical abortions by USFDA. DCGI (Drug controller general of India) has approved the combipack of both mifepristone and misoprostol for medical method of abortion. [10]

The combination of mifepristone and misoprostol is the most effective and fastest regimen. [11] However, mifepristone is not widely available and is expensive. Misoprostol is being more widely used because it is inexpensive and stable at room temperature. It can be absorbed via oral, vaginal, sublingual, buccal, and rectal routes. [12]

The main advantage of medical abortion is that surgical and anesthetic risks are avoided and the procedure is more accessible. Medical abortion will not be a replacement but is an easy alternative to surgical method in early pregnancy. Ideally both the methods should be available to the women as the choice of procedure. Under medical supervision, it can be an easy, reachable and also reliable method for women's living in remote areas who want to terminate the pregnancy without being admitted and undergoing any surgical intervention.

MMA failure cases can be presented as :[2]

- Heavy bleeding
- Incomplete abortion
- Continuation of pregnancy

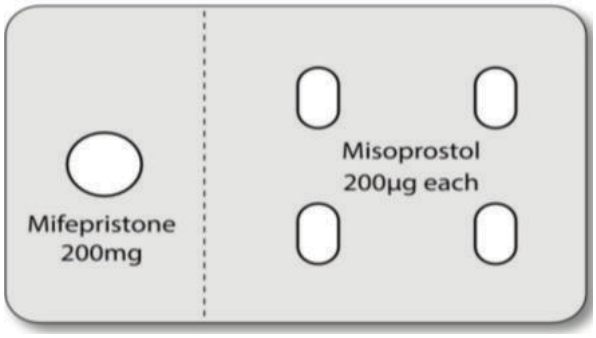

Figure 1: MMA Drugs (Mifepristone and Misoprostol)

METHODS

This was an observational study conducted at obstetrics and gynecology department, Saraswathi Institute of Medical Science (SIMS), Hapur, U.P. from November' 2020 to October' 2022.

Group A (50 cases) - gestational age up to 49 days
Group B (50 cases) - gestational age up to 63 days

Inclusion criteria: -

Women who are eligible for medical termination of pregnancy with intrauterine pregnancy of up to 63 days period of gestation, confirmed by ultrasound.

Exclusion criteria:-

- Pregnant women of more than 63 days of gestation
- Previous allergic reaction to drugs
- Anemia (hemoglobin of <8gm %)
- Pre-existing heart disease
- Undiagnosed adenexal mass
- Intrauterine device in place
- Any hemorrhagic disorder
- Chronic renal failure
- On any long term medication
- With concurrent anticoagulant therapy
- Uncontrolled seizure disorder

All the women were explained about the side effects in form of abdominal pain, persistent bleeding, incomplete abortion or need for evacuation. All women had timely access to appropriate emergency medical facilities if need arises.

Followed Medcal Abortion Protocol (wh

RESULTS

Table 1: Age Distribution

AGE	GROUP A		GROUP B		P Value
	N = 50	%	N = 50	%	
19-24 Years	8	16%	9	18%	0.87 (NS)
25-30 Years	22	44%	18	36%	
31- 35 Years	17	34%	19	38%	
>35 Years	3	6%	4	8%	

Table 1, shows majority of women seeking for medical abortion are of 25-35 years of age in both the groups followed by women between 19-24 years of age.

Table 2: Gravida

GRAVIDA	GROUP A		GROUP B		P Value
	N = 50	%	N = 50	%	
<G3	12	24%	9	18%	0.4614 (NS)
>/= G3	38	76%	41	82%	

In Table 2, majority of women are gravida 3 or more, 76% in group A and 82% in group B.

Table 3: Parity

PARITY	GROUP A		GROUP B		P Value
	N = 50	%	N = 50	%	
<PARA 2	8	16%	6	12%	0.40 (NS)
>/= PARA 2	42	84%	44	88%	

VISIT	DAY	DRUG USED	GROUP A (gestational age up to 49 days)	GROUP B (gestational age up to 63 days)
First	One	Mifepristone	200mg Oral	200mg Oral
Second	Three	Misoprostol	800mcg sublingual (4 Tablets)	800mcg sublingual (4 Tablets)
Third	Fifteen	Ultrasound	Confirm and ensure completion of abortion	Confirm and ensure completion of abortion

In table 3, 84% from group A and 88% from group B were having 2 or more children.

Table 4: Emergency Visit (Day3 To Day 14)

FOLLOW UP VISIT (DAY 3-14)		GROUP A		GROUP B		P Value
PAIN ABDOMEN	YES	8	16%	11	22%	0.611 (NS)
	NO	42	84%	39	78%	
BLEEDING	YES	2	4%	6	12%	0.268 (NS)
	NO	48	96%	44	88%	

The above table 4, on comparing showed that both the groups have Pain abdomen and bleeding as a major side effect which was slightly more with group B patients.

Table 5: Day 15 USG

DAY 15 USG	GROUP A		GROUP B		P Value
	N = 50	%	N = 50	%	
COMPLETE	45	90%	39	78%	0.0004 (S)
INCOMLETE	5	10%	11	22%	

In Table 5, the success rate of complete abortion was about 90% from group A and 78% in group B aborted when followed up on day 15th for ultrasound scan.

Table 6: Suction And Evacuation

	GROUP A		GROUP B		P Value
	N = 50	%	N = 50	%	
S & E	1	2%	6	12%	0.05 (S)

Table 6 shows amongst group A 2% patient had to undergo surgical evacuation as compared to group B in which 12% had surgical intervention as increasing gestational age lowers the success rate.

DISCUSSION

Medical abortion has been a revolution in obstetrics practice, for the ease and safety it provides to the clinician and the patient, as well as its role in preventing deaths due to unsafe abortions in developing countries like India.

Most of the patients in both the groups were from 25-35 years of age, in our study it was 78% patients from group A and 74% from group B that is within reproductive age group. Minority of patients who underwent medical abortion for the indication of early pregnancy failure belong to age group 19-24 years.

This was comparable with the study conducted by **Bharti et al.** [9] where maximum cases were between 21-30 years of age. Another study conducted by **shrestha et al.** [13] were mean age of study population was 29.38 years (SD=+/-5.91).

Looking at the parity of women seeking MTP in the first trimester it was found that more than 75% of patients were third gravida or more. 84% in group A and 88% in group B who approached for medical abortion many were Multiparous (>/= para 2).

Median gravidity and parity in present study were comparable to a **pilot study** [15] 30% clients were gravida second and 30% were gravida four and above. The median gravidity was two in **Smith et al's** [14] study. This suggests most of the couples had completed family.

Majority of women in both the study group had abdominal pain as major side effect which was managed with non narcotic analgesics. The safety profile in our study is supported by **shrestha et al.** [13] stating that 95.7% patients in the study complaint of abdominal pain as the major side effect gastrointestinal disturbance was the least that is 8.5% with overall acceptable adverse effects.

The present study had 10% of incomplete abortion in group A and 22% in group B with rate of complete abortion that is 90% in women with gestational age less than 49 days to 78% in gestational age upto 63 days. 2% amongst incomplete abortion had to undergo surgical evacuation as compared to group B in which 12% had surgical intervention.

The success rate in our study was comparable with other study by **shrestha et al** [13] where abortion rate was 87.2% only 6 patients had evidence of retained products.

The rate of surgical intervention in our study is in line with the World Health Organization goal/standard.[8]

Bharti, et al. (2020)[9] evaluated the role of combination of mifepristone and Misoprostol in first trimester of pregnancy. The study showed that 93% women had successful abortion and 7% underwent surgical evacuation.

CONCLUSION

It was concluded that medical method offers an opportunity of easy access to abortion care services especially in early pregnancy and can be provided as an outpatient basis with patient privacy being maintained. It is cost effective, easy to use with minimum drug related side effects like heavy bleeding and pain abdomen that can be managed conservatively.

Combined regimen is one of the safest and effective medical method for abortion care for termination of pregnancy of </=63 days although lesser gestational age was a key predictor for successful abortion.

Proper dose, timing, route, counseling and if taken under proper guidance of health personnel it can prevent serious post abortive complications.

Few limitations of includes:-

- minimum 3 clinical visits are required during the procedure
- Heavy prolonged bleeding may occur
- Once taken, pregnancy has to be terminated since if it continues there is a risk of fetal malformation.

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