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Original Research Article

A prospective study of efficacy and safety of mifepristone and vaginal misoprostol in termination of pregnancy up to 63 days of gestation

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ABSTRACT

Background: Illegal abortion is still one of the important causes of maternal mortality in India accounting for approximately 13%. Medical Management of abortion is a non-surgical termination which does not require special facilities like operation theatre, hospital stay and thereby reduces complications associated with the same.
Methods: It is a prospective study done in a Tertiary care Government Hospital over a span from Jan 2015 to April 2016. After patient selection as per inclusion criteria and written informed consent after evaluating patients were enrolled in the study. In first visit Tab. mifepristone 200 mg. orally was given and advised to take Tab. misoprostol 800 mcg. Vaginally after 48 hours at home. They were counselled for side effects and asked to report in case of excess bleeding, pain, fever or no bleed for 24 hours of misoprostol. After 7 days follow up was done to ensure completion of abortion. Any additional drugs required were noted. Contraceptive advice is also given during these visits.
Results: In our study 60 cases were taken. Majority of women are between 20-29 years of age which is peak reproductive age. 61.1% women are of second parity. The success rate of medical methods is 96.6%, two cases out of 60 underwent surgical evacuation and one was lost to follow up. Most common adverse effect noted is abdominal cramps. No patient required hospitalization. Additional Misoprostol was required in 4 cases. This method is highly acceptable 95% cases as it is non invasive and preferred to adopt the same in future if needed.
Conclusions: Patient participation, motivation, compliance, regular follow up visits, ability to record and report complications are the pillars on which the success of medical methods depends. Hence overall, it came out to be safe and effective method.

Keywords: First trimester medical methods for termination of pregnancy, Up to 63 days of gestation

INTRODUCTION

Unwanted pregnancy is a proxy indicator for the unmet needs for contraception.[1] In India; women try a variety of remedies to deal with unwanted pregnancy including tablets, decoctions and visits to unsafe providers. Worldwide nearly 40 million abortions take place annually, of which approximately 10-22 million are illegal abortions.[2,3]

In India, unsafe abortion practices are an important cause of maternal mortality and morbidity. 13% of the pregnancy related deaths are attributed to unsafe abortions.[1] The study is conducted with a purpose of ensuring safe women seeking the same with medical method i.e. drugs.

Medical Management of abortion is a non surgical termination which does not require special facilities like operation theatre, hospital stay and there by reduced complications associated with the same. Hence it is a safer method of choice for women in a developing country like India where medical facilities are at times costly and limited.

Aims and objectives

1. To study efficacy of medical management of termination of pregnancy up to 63 days of gestation.
2. To study the side effects of the drugs used for medical termination of pregnancy.
3. To study the needs for add on methods in form of medical or surgical methods for first trimester termination of pregnancy.
4. To study acceptability of medical management of termination of pregnancy.

METHODS

This is a prospective study on 60 pregnant women with pregnancy up to 63 days of gestation opting for voluntary medical termination of pregnancy in Tertiary care Government hospital setting from Jan 2015 to April 2016. All underwent basic investigations in form of haemoglobin, blood group ABO/Rh typing, urine (routine and microscopy). Due Ethical Committee clearance is obtained before onset of study. Drug used are Tab. Mifepristone 200mg. and Tab. Misoprostol 200 mcg. 4 tab. (800 mcg) vaginally.

Inclusion criteria

1. Female seeking first trimester MTP with gestational age ≤ 63 days (9 weeks).
2. Opting and giving consent for the study.
3. Age: 18-40 years old.
4. Marital Status: married or unmarried.

Exclusion criteria

1. Patient not giving consent for medical method of termination of pregnancy.
2. Patients with previous scarred uterus like previous one or more cesarean section, past history of myomectomy or past history of hysterectomy.
3. Patients having absolute contraindications for prostaglandins, history of bronchial asthma, glaucoma, hypersensitivity to drugs, epilepsy.

Method of collecting data

An established protocol was followed which includes:

First visit (day 1)

- A detailed history taken and patient selection as per inclusion criteria.
- Initial pelvic examination
- Trans-vaginal sonography to confirm intra uterine pregnancy and exact gestational age.
- Basic investigation done. Anti D given to all Rh negative women.
- A written and informed consent taken in Form C.
- Patient explained about administration of Tab. Mifepristone 200mg. per oral.
- Follow up card is given and explained about what she needs to record.
- Counseling about pain and bleeding after first drug.
- She should report immediately to hospital in case of excess bleeding, fever, acute pain abdomen for which contact number is provided.

Second visit optional (day 3)

Almost all women opted for home administration of Tab. Misoprostol, hence 4 tab. i.e. 800 mcg was kept vaginally after 48 hours at the same time as the first drug. She should report if no bleeding for 24 hours after misoprostol intake.

Third visit

Patient is asked to come for follow up after 7 days of Misoprostol intake. Clinical evaluation, history regards side effects noted. Pelvic examination and TVS done to ensure complete abortion. Candidates are counselled for contraception and cafeteria approach is given.

Outcome measured in terms of Complete and Incomplete Abortion. Failure is defined as the presence of gestational sac following drug administration.

RESULTS

Majority of cases 76.7% are in the age group of 20-29 years which is the peak reproductive age group.

Table 1: Demographic profile of cases.

Age in years	No. of cases N=60	Percentage
<20	2	3.3
20-29	46	76.7
≥30	12	20

Table 2: Area wise distribution of cases.

Area	No. of cases N=60	Percentage
Rural	14	23.3
Urban	46	76.7

In our study 76.7 % cases belong to urban area due to awareness of public and location of the hospital.

Table 3: Parity wise distribution.

Parity	No. of cases N=60	Percentage
Primi	6	10
Second	37	61.7
Third	10	16.7
Fourth	6	10
>4	1	1.6

Majority of women 61.7% are of second parity this is when female do not want future conception due to various reasons.

Table 4: Indications of MTP.

Indications	No. of cases N=60	Percentage
Failure of contraceptive	4	6.7
Socio economic class	38	63.3
Unplanned Pregnancy	18	30

In our study 63.3% of women wanted MTP due to lower or middle socio economic reasons.

Table 5: Period of gestation in the study.

Gestation	No. of cases N=60	Percentage
Up to 6 weeks	22	36.7
6-7 weeks	33	55
7-9 weeks	5	8.3

As shown above 55% cases had 6-7 weeks of gestation period at time of MTP.

Table 6: Side effects of drugs.

Side effects	No. of cases N=60	Percentage
Abdominal cramps	37	61.6
Nausea	10	16.6
Vomiting	6	10
Excess bleeding	5	8.3
Diarrhoea	00	00

As per above data side effects like abdominal cramps, nausea, vomiting, excess bleeding are well tolerated and did not require hospitalization. Hence, it is safe and popular method of MTP among women.

Table 7: Efficacy of drug as per outcome.

Efficacy	No. of cases N=60	Percentage
Complete abortion	57	96.6
Incomplete abortion	1	1.7
Failure	1	1.7
Lost to follow up	1	1.7

As shown in the table our study had 96.6% success rate which is comparable with other studies. One women had incomplete abortion, one failure with continuation of pregnancy, both of which underwent surgical evacuation.

As shown above very few patients required additional drugs to treat minor side effects like fever, vomiting, bleeding. Thus it is a safe method of termination of pregnancy.

Table 8: Need for add on drug.

Drug	No. of cases N=60	Percentage
Tab Misoprostol	4	6.6
Tab Rantac	6	10
Tab Dicyclomine	2	3.3
Tab Ibuprofen/ Paracetamol	2	3.3

The average induction-abortion interval is 3-6 hours as found in 69% cases.

Table 9: Induction-abortion interval.

Interval	No. of cases N=60	Percentage
Up to 2 hours	10	17.2
3-6 hours	40	69
6-10 hours	8	13.4

Table 10: Contraceptive method adopted after abortion.

Contraceptive method	No. of cases N=60	Percentage
Condoms	39	65
OCP	2	3.3
IUCD	15	25
Tubal ligation	2	3.3
Vasectomy	1	1.6

In our study post abortion IUCD kept in 15 women, 2 underwent laparoscopic sterilization and vasectomy opted by one case. Proper counselling in this regards is having a high impact amongst the population.

DISCUSSION

During this study out of 60 cases 57 had complete abortion. Hence the success rate is 96.6%. The finding matched with other studies as follows: Kumar S et al (95.65%), Grossman D et al (93.8%), Das V, Jain S et al (96.67%), Jain JK et al (95.8%), Crenin MD (95.8%), Whikoff B et al also studied safety, efficacy and acceptability of Medical abortion and found complete abortion rate of 91.4%.(5).[2,5-9]

Hence irrespective of various regimens followed, medical abortion is a successful, safe, efficacious and clinically acceptable method for termination of first trimester pregnancy. Hence it can be concluded that medical method of termination of pregnancy with Mifepristone 200 mg. and vaginal Misoprostol 800 mcg. Is a safe and effective method of abortion.

CONCLUSION

Our study with 96.6% success rate established that it can be used safely up to 63 days of gestation termination. Careful patient selection, evaluation and counselling are highly needed to attain this success rate safely. Secondly, the success rate depends on patient participation, motivation, compliance and eagerness to follow up. Hence it is mostly preferred by urban, educated population in upper and middle socio economic start. Common side effects are well tolerated hence the method has very high acceptability with 95% opting to adopt the same method in future if needed.

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