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Original Research Article

Efficacy of combination of oral mifepristone and vaginal misoprostol in termination of pregnancy up to 63 days of gestation

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ABSTRACT

Background: Unsafe and illegal abortions are one of the major problems in women health in India. Despite legal approval for medical termination of pregnancy in 1971, unsafe abortion still remains the third leading cause of maternal deaths in the country, contributes eight percent of such deaths annually. The objective of this study was to study efficacy of Mifepristone 200 mg orally followed 36-48 hours later by Misoprostol 800 microgms per vaginally in women undergoing medical termination of early pregnancy (up to 63 days of gestational age).
Methods: The present study included 60 pregnant women requesting termination of pregnancy in the first trimester. Women who fulfilled the inclusion criteria were included in the study. Women without medical or surgical contraindications to Mifepristone and Misoprostol were included. Patients with previous caesarean sections were also included.
Results: In our study 60 women were included, majority were in age group 20-29 years of age and majority of cases were primipara or multipara. The success rate in terms of complete abortion was 97%, 2% needed surgical evacuation and 1% lost to follow up. Side effects were nausea, vomiting, diarrhoea, abdominal cramps, pyrexia etc. The method proved to be safe, effective, cheap, non-invasive and has minimal or no complications.
Conclusions: Medical termination of pregnancy with oral mifepristone and vaginal misoprostol is an effective method for first trimester abortion. The prerequisite for the method is patient counselling, patient participation and willingness for regular follow up and to report any complication. Hence this method comes out to be a safe alternative to surgical method which is invasive and costly.

Keywords: Caesarean sections, Mifepristone, Misoprostol

INTRODUCTION

Millions of unwanted and unplanned pregnancies occur all over the world owing to lack of awareness of family planning measures. These unintended pregnancies increase the population burden if continued till term or landed up to illegal and unsafe abortions. Despite wider availability of contraceptive methods, the incidence of induced abortions is increasing. According to a recent survey, 13% of 1.5 crore women who opt for abortion to terminate their pregnancy lose their life every year.[1] These are mainly due to illegal abortions. During 2010-2014, an estimated 56 million induced abortion occurred every year worldwide. Out of them 25 million (45%) are unsafe.[2] Almost there is one unsafe abortion for every ten pregnancies or one abortion every seven life births.[3] In India, 15.6 million abortions occurred in 2015, out of them 11.5 million (73%) were done outside the health facilities.[4] So there is a need of safe, inexpensive and easy abortion method.

Medical abortion provides a better alternative to surgical evacuation especially in a low resource country like India. Various regimes are being used for termination of pregnancy. Our study was undertaken to determine the efficacy and side effects of oral mifepristone 200 mg and misoprostol 800 mcg vaginally after 48 hours.

METHODS

60 cases were studied prospectively with pregnancy up to 63 days of gestation opting for voluntary medical termination of pregnancy during six months duration (January 2019 to June 2019). Ethical clearance and pre consent procedure (under MTP act 1972) were done. Vital baseline parameters like pulse, BP and temperature were recorded. Systemic examination with per abdominal, per speculum and per vaginal examination were done. All the concerned patients underwent basic investigations including hemogram, blood grouping and typing, urine routine examination, blood sugar level (R), Austria antigen, VDRL and HIV. Ultrasonography was done before to determine exact gestation age and to confirm intrauterine location of pregnancy. Scanning was done later to assure complete abortion. Further patients were informed regarding dose of the drug, the side effects, the number of visits required and the need for surgical evacuation in case of failure.

Inclusion criteria

- Patients with singleton live gestation till 63 days (9 weeks) seeking abortion services for valid indication under the MTP Act
- Patients willing to give written consent and regular follow up visits
- Patients willing for surgical intervention in case of failure of medical method.

Exclusion criteria

- Patients with multiple pregnancies
- Patients with intrauterine device in situ
- Patients with haemoglobin <8.5 gm/dl
- Patients with history of major medical illnesses or allergic issues
- Patients not willing to give consent.

All the included patients were given 200 mg of mifepristone. After 48 hours, patients were called back and 800mcg of misoprostol (four tablets of 200 mcgs each) was administered per vaginum and were observed for 6 hours. Patients were again called after 15 days. Clinical evaluation, history regarding side effects, per vaginal examination and transvaginal ultrasonography was done to ensure complete abortion.

Outcome were assessed as complete abortion (complete expulsion of products of conception with no need for surgical evacuation) and incomplete abortion (persistent gestational sac, excessive or prolonged uterine bleeding requiring surgical intervention). Women who did not respond to medical treatment within 24 hours of misoprostol administration, were offered surgical methods for termination of pregnancy.

Statistical analysis

Statistical analysis was done for differences in onset of bleeding after misoprostol administration and side effects among primigravida and multigravida.

RESULTS

A total of 60 patients were studied. Maternal characteristics are shown in Table 1. Majority of patients were seen in age between 26 and 30 years. Only 10% patients were primigravida as only married women were included in the present study. Majority of patients did not have prior abortion. There were 7 cases of previous one LSCS and 3 cases of previous two LSCS. Maximum numbers of cases were in gestational age between 36-50 days. The average induction abortion time in the study was 5.26 hours. About 70% patients aborted within 8 hours and all the patients aborted within 24 hours (Table 2).

Table 1: Maternal characteristics.

Maternal characteristics	Number of patients	Percentage
Age distribution		
18-20	2	3
21-25	17	28
26-30	20	33
31-35	16	26
>36	5	10
Parity		
Primi	7	11
Para	20	33
Para	26	45
Para	7	11
Previous abortions		
1	8	13
2	2	3
3	1	1.6
Previous LSCS		
Previous 1 LSCS	7	11
Previous 2 LSCS	3	5
Gestation age (by USG)		
20-35days	17	28
36-50days	25	42
51-60days	14	24
66-80days	4	6

There was a statistically significant difference in the onset of bleeding among primigravida (6.12±0.42hours) and multigravida (5.05±0.55hours) ($p < 0.0001$). However, there was no statistically significant difference

found in onset of bleeding between previous LSCS and previous normal delivered patients.

Table 2: Induction abortion interval.

Induction abortion interval	No. of cases	Percentage
Within 5 hours	30	50
Within 8 hours	45	75
Within 24 hours	60	100

In present study, 56 (94%) patients had complete abortion.4 patients (6%) had incomplete abortion. In 2 of the above repeat 200 misoprostol vaginally resulted in complete abortion within 7 days, remaining 2 needed surgical evacuation because of heavy bleeding (Table 3).

Table 3: Completeness of procedure.

Abortion	No. of cases	Percentage
Complete abortion	56	94
Incomplete abortion	4	6

Majority of the patients, 42 (71%) experienced abdominal cramps, nausea in 12 (20%), vomiting in 10 (16%), diarrhoea in 5 (8%) and excessive bleeding in 2 (3%), (Table 4). Majority of patients presented with more than one side effects and within 3 days of misoprostol administration. There was statistically significant association between age $\leq$ 30 years and there were side effects like abdominal cramps ($p < 0.01$), nausea ($p < 0.05$) and diarrhoea ($p < 0.05$).

Table 4: Side effects related to drugs used.

Side effects	No. of cases	Percentage
Abdominal cramps	42	71
Nausea	12	20
Vomiting	10	16
Diarrhoea	5	8
Excessive bleeding	2	3

DISCUSSION

Unsafe abortion is a major cause of mortality among women in India accounting for approximately 15% of maternal deaths. Currently in India, mifepristone has been approved for use in medical termination of intrauterine pregnancy up to 63 days. Various regimes of combined mifepristone and misoprostol have been studied in different studies with efficacy up to 63 days of gestation. Comparative trials have shown that a reduction in the oral dose of mifepristone from 600 to 200 mg does not affect the efficacy in termination of early pregnancy.

In the present study, 200 mg of mifepristone and 800 mcg of misoprostol were used in women with gestation age up to 80 days. Complete abortion occurred in 94% of cases. Our results are consistent with similar studies in past.

Ashok et al, studied the result of 200 mg oral mifepristone with 500 mcg of vaginal misoprostol till gestation age < 49 days and < 63 days in 928 patients.[5] The success rate was 98.5% (< 49 days) and 96.5% (< 63 days).

Kumar S et al, found complete abortion by medical abortion in 95.6% of patients.[6] Similarly, Grossman D et al, found complete abortion rate by medical abortion in 93.8% of cases.[7]

Silvestre L et al, and Nicholas CW Hill, studied different prostaglandin composition with mifepristone and found similar efficacy of different regimes.[8,9]

Elaine et al, used 200 mcg of mifepristone and 500 mcg of misoprostol, found a success rate of 94.5% in 253 patients of gestational age, 63-85 days.[10]

Although no relevant literature references available for association between age of the patient and the incidence of side effects, in the current study, there was a statistically significant association between age $\leq$ 30 years and side effects like abdominal cramps ($p < 0.001$), nausea ($p < 0.05$) and diarrhoea ($p < 0.05$). Further time of onset of bleeding after misoprostol administration was statistically significant in both primigravida and multigravida. [primigravida (6.12±0.42hour) and multigravida (5.05±0.55hour) ($p < 0.0001$).] However, there was no statistically significant difference found in onset of bleeding between previous LSCS and previous normal delivered patients.

CONCLUSION

Medical abortion with 200 mg and 800 mcg vaginal misoprostol has proved to be a safe, reliable and non-invasive method. Surgical measures have inherent association of anaesthetic complications, genital tract infection and increased cost. In developing countries like India with limited operation theatre setup and cost restraints, medical abortion may prove a boon to combat the ongoing problem of unsafe abortion. This may boost up the reproductive health of women.

However, medical abortion requires active participation of health professionals and patients in terms of proper counselling, consent proceedings and regular follow-up.

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