

Research Article

Study of Home use of Oral Misoprostol in Medical Abortion

Bhakti Kalyankar^{*1}, Vijay Kalyankar¹, Kanan Yelikar² and Archana Kshirsagar³

¹Associate Professor, Dept. of Obstetrics and Gynaecology (OBGY), Govt. Medical College, Aurangabad, Maharashtra, India

²Professor and Head, Dept. of Obstetrics and Gynaecology (OBGY) Govt. Medical College, Aurangabad, Maharashtra, India

³Resident, Dept. of Obstetrics and Gynaecology (OBGY), Govt. Medical College, Aurangabad, Maharashtra, India

***Correspondence Info:**

Dr. Bhakti Kalyankar, M.D, (OBGY)
Associate Professor,
Dept. of Obstetrics and Gynaecology (OBGY),
Govt. Medical College, Aurangabad- 431001, Maharashtra, India
E-mail: bhaktikalyankar@gmail.com

Abstract

Objective: To evaluate the simplification of medical abortion by home administration of Misoprostol by assessing feasibility, efficacy and women's acceptability of home self-administration of Misoprostol.

Methods: This was a prospective study of 80 patients done from Oct 2011 to Sept 2013. Women with amenorrhoea of less than or equal to 63 days received 200 mg Mifepristone orally at hospital. 48 hrs later, women took oral 400 µg Misoprostol at home. All women returned on day 14 of tab. Mifepristone for abortion confirmation.

Results: Efficacy of regimen was 100% in gestational age up to 49 days and 95.45 % in gestational age of 50-63 days. The overall success rate was 97.5%. 96.25% women were ready to choose same method in future if required.

Conclusion: Medical abortion was simplified by home use of oral Misoprostol as it required less hospital visits and less supervision by trained persons. Acceptability of home self-administration of Misoprostol was high. Hence home administration of oral Misoprostol is safe and feasible for introduction into medical abortion services in India.

Keywords: Medical abortion, Mifepristone, Home-use, Misoprostol

1. Introduction

Medical abortion consists of using drugs to terminate a pregnancy. It is an important alternative to surgical methods. One of the most widely used and first approved abortifacient is Misoprostol. The WHO recommends initial dose of mifepristone followed by Misoprostol 36-48 hours later. In home medical abortion, a health care provider administers mifepristone at the clinic and the pregnant woman later takes misoprostol at home. The home based medical abortion intends to simplify the abortion regime, give privacy at home giving woman greater control with family members' support. In April 2002, the Drug Controller of India approved mifepristone + misoprostol combination. Clinical trials from Canada, Turkey and the USA report rates of complete abortion from 91%-98% for pregnancies up to 9 weeks when misoprostol is administered at home.¹ In India, medical abortion is primarily available in urban settings. A regime of reduced dose of mifepristone and the option of home-administration of misoprostol may increase the feasibility to provide non-invasive abortion in rural areas through the Public Healthcare System; thereby greatly increasing access to safe abortion in India.² We thus assessed the feasibility and acceptability of such a simplified abortion regime.

Objective of the Study:-

To evaluate the simplification of medical abortion by home administration of misoprostol by assessing –

1. Feasibility of complete and successful medical abortion at home without hospital admission.
2. Efficacy.
3. Women's acceptability of home self administration of misoprostol.

2. Material and Methods

This was a prospective study of 80 patients seeking for MTP with amenorrhoea less than or equal to 63 days gestation fitting in the inclusion criteria done from Oct 2011 to Sept 2013.

2.1 Inclusion Criteria

1. All women requesting and fit for medical abortion.
2. Gestational age less or equal to 63 days by LMP, clinical assessment or USG Pelvis.
3. Agrees for follow-up visit, provides address and/or telephone no. for purpose of follow-up. Consent to study participation.
4. Leaving within 4km of hospital and can access hospital even at midnight odd hours.

2.2 Exclusion Criteria

1. Gestational age more than 63 days.
2. Unable to provide contact information.
3. Willing for surgical method of abortion.
4. Women with pelvic pathology, ex: - Fibroid, Polyp, Endometriosis etc.
5. Ectopic or Molar pregnancy.
6. Anomalies of uterus.
7. Threatened or spontaneous abortion.
8. Medical or psycho-social problems in mother.

2.3 Patient counseling

1. Decision of abortion taken by patient was voluntary and unforced.
2. Both medical and surgical options of MTP given. Risk and benefits of both methods explained. Potential teratogenicity of tablet mifepristone and misoprostol was explained, emphasizing that once administered, the abortion should be completed either medically or surgically.
3. Risk of incomplete abortion and bleeding necessitating surgical evacuation was explained.
4. Confidentiality was assured to patients.
5. We advised them to come for follow-up on day 14 of tab. Mifepristone and also discussed future contraception.

No control group was analyzed. We did not want to compare home use of misoprostol with the standard regime of hospital use.

2.4 Protocol

- 1) Informed consent was signed by patient with a relative witness who later accompanied and observed the patient
- 2) Detail history and complete examination (including gynecology) was done.
- 3) Investigations—Hb%, Blood group and Rh typing, Urine, USG, others if required.
- 4) Tab. Mifeprestone 200 mg made to swallow in our presence in clinic in morning. Patient observed for 30 min for any drug reactions/effects.
- 5) Women were asked to take Tab. Misoprostol 400 microgram orally 48 hrs after Tab. Mifepristone at home in presence of husband/relative/friend.
- 6) Women were counseled to expect pain in abdomen, bleeding per vaginum after taking misoprostol.
- 7) Symptomatic treatment with tab. Paracetamol 500mg, Tab. Pantaprozole and Domperidone, Tab. Tranexamic acid 500mg thrice a day for two days if bleeding persisted more than normal menstrual bleeding.
- 8) All Rhesus negative women received Anti-D Immunoglobulin 150 microgram within 72 hours after ingestion of Tab. Mifepristone.
- 9) All patients received Tab. Amoxycillin 500 mg four times a day for 5 days from day 1.
- 10) Follow –up visit on day 14 of tab. Mifepristone.
- 11) Women were told to call investigator telephonically and come to emergency room of hospital at any time if they had excessive bleeding (soakage of 2 or more large pads per hour for 2 or more consecutive hours) or any other symptoms.
- 12) Women completed standardized Questionnaires prior to beginning of treatment, at follow up and all unscheduled visits or call. It covered demographic characteristics and main reasons for their choice of home use of Misoprostol and satisfaction with treatment.

2.5 Failure of Procedure

- 1) Not achieved complete abortion on day 14 after taking Tab. mifepristone.
- 2) Needed surgical evacuation for incomplete abortion, Missed abortion, heavy bleeding after the consumption of Tab. Misoprostol.
- 3) Ongoing live pregnancy on USG pelvis on Day 14 after Tab. Mifepristone.

3. Observations

Table No 1: Gravida

Gravida	Number	Percentage
G1	6	7.50
G2	23	28.75
G3	30	37.50
G4 and more	21	26.25

Most of the patients were Gravida 3 followed by Gravida 2.

Table no 2: Gestational age in weeks

Gestational age in weeks (days)	No. of Patients	Percentage
5-6 (35-42)	11	13.75%
6.1-7 (43-49)	25	31.25%
7.1-8 (50-56)	24	30.00%
8.1-8(57-63)	20	25.00%

Most of the patients for MTP were at 6.1-7 weeks and Mean Gestational age was 49 days.

Table 3: Mode of previous delivery

Mode of previous delivery	Number	Percentage
Normal delivery	62	83.78%
Caesarean delivery	12	16.22%

Here n=74 because 6 were Primigravidae

Table 4: Duration of bleeding

Duration in days	No. of Cases	Percentage
<5 days	20	25.00 %
5-7 days	38	47.50 %
7.1 -10 days	21 (spotting)	26.25 %
>10 days	01	01.25 %

Most (43.75%) women had bleeding for 5-7 days after ingestion of Tab. Mifepristone.

Table 5: Efficacy of regime in various gestational ages

Gestational age	Success rate	Failure rate
Up to 49 days (n=36)	100%	0%
50-63 days (n=44)	95.45%	4.55%

Regime is highly Effective (100%) in early Gestational age

Table 6: Reason for satisfaction with home use of misoprostol administration

Reasons	No. of Cases	Percentage
Less visits	35	43.75%
Continue household responsibility	20	25%
Convenience	38	47.50%
Feels better at home	42	52.50%
Privacy	25	31.25%

Convenience, homely environment & less visits satisfied home use of Misoprostol.

Table 7: Choose medical abortion in future if required

Choose medical abortion in future if required	No. of cases	Percentage
YES	77	96.25%
NO	03	03.75%

Table 8: Satisfaction with regimen

Satisfaction with regimen	No. of cases	Percentage
Satisfactory	78	97.50%
Unsatisfactory	2	2.50%

97.50% were satisfied with the regimen and equally were successful.

Table 9: Efficacy

Efficacy	No. of cases	Percentage
Success	78	97.50%
Failure	02	2.50%

4. Discussion

Primigravidae seeking for medical abortion in study of Mundle *et al*² were 3.3% and in Our study they were 7.5%. So it can be said that medical abortion with tab. mifepristone and tab. Misoprostol is safe, effective and acceptable even in Primigravidae at home. The number of Primigravidae for this procedure has increased from (2007) 3.3% to 7.5% (2013).

The Mean Gestational age (in days) of women coming for medical abortion in study of Chuni *et al*³ was 50.6 days, in study of Hazri *et al*⁴ was 44.2 days, in study of Mundle *et al*² was 42.8 days and in Our study it was 49 days. So, all these Studies are comparable.

Abortion failure was because of ongoing pregnancy and incomplete abortion for which we did surgical intervention to complete their abortion. In study of Chuni *et al*³, 1.8% cases had ongoing pregnancy and 7.7% cases had incomplete abortion. In study of Hazri *et al*⁴, 1.7% cases had ongoing pregnancy and 1.2% cases had incomplete abortion. In study of Mundle *et al*², 0.7% cases had ongoing pregnancy and 0.7% cases had incomplete abortion. In study of Sheila *et al*⁵, 1.5% cases had ongoing pregnancy and 0.4% cases had incomplete abortion. In our study, 0.7% cases had ongoing pregnancy and 0.7% cases had incomplete abortion. The overall success rate was good and very few required intervention in all Studies.

We compared reasons for selecting home use of oral misoprostol administration by the patients with different studies. In study of Hazri *et al*⁴, the reasons were Less visits (27.4%), Continue household responsibility (20.7%), Convenience (28.6%), Feels better at home (21.6%) and Privacy (34.4%). In study of Mundle *et al*² the reasons were Less visits (65.3%), Continue household responsibility (20%), Convenience (3.8%), Feels better at home (3.8%) and Privacy (3.8%). In our study, the reasons were fewer visits (43.75%), Continue household responsibility (25%), Convenience (47.5%), Feels better at home (52.5%) and Privacy (31.25%). In all, females preferred to continue house hold responsibilities, take mental support from family member and maintain privacy.

In study of Mundle *et al*² 97.9% women; in study of Hazri *et al*⁴ 96.5% women and in Our study 96.25% women were ready to choose medical abortion in future. The method was acceptable in future as they were satisfied.

Success rate of the regimen in different studies were 86% in study of Chuni *et al*³; 96.7% in study of Hazri *et al*⁴; 98.6% in study of Mundle *et al*²; 97.4% in study of Sheila *et al*⁵; 89.2%, in study of Ngo *et al*¹; 89% in study of Bracken Hillary⁷; 95.4% in study of Guengant *et al*⁸ and 97.5% in Our study, which are comparable to other studies.

5. Conclusion

Medical abortion was simplified by home use of oral misoprostol as it required less hospital visits & less supervision by trained person. Women felt better at home as they could fulfill domestic responsibilities and had accompanied family member persons.

Efficacy of regimen used in our study was excellent as success rate was 97.5%. The regimen was more effective for early gestational age (up to 49 days). Minor side effects were treated by only symptomatic treatment without hospitalization. Being non-invasive, without anesthesia and economical, women were more comfortable and accepted the regimen.

This method can be used in an outpatient clinic provided referral is possible in emergency at other centers. Morbidity and mortality due to illegal abortions can be markedly reduced. Hence, home administration of oral misoprostol is safe and feasible for introduction into medical abortion services in India.

The study included only 80 cases. Hence, more studies could be recommended with more number of subjects for further consideration.

References

1. Ngo T D, Park M H, Shakur H, Free C. Comparative effectiveness, safety and acceptability of Medical Abortion at Home and in a Clinic: A Systematic review. *Bulletin of the World Health Organization* 2011; 89: 360-70.
2. Mundle S, Kalyanwala S, Elul B, Ughade S. Simplifying Medical Abortion: Home Administration of Misoprostol. *J Obstet Gynecol India* 2008; 58 (5): 410-16.
3. Chuni N, Chandrashekar TS. Early pregnancy termination with a simplified Mifepristone: Medical Abortion outpatient regimen. Kathmandu Univ. *Med J* 2009; 7: 209-12.
4. Hajri S, Blum J, Gueddana N, Saadi H, Maazoun L, Che'lli H, *et al*. Expanding medical abortion in Tunisia: Women's experiences from a multisite expansion study. *Contraception* 2004; 70: 487-91.
5. Raghavan S, Comendant R, Digol I, Ungureanu S, Dondiuc I, Turcanu S, Winikoff B. Two pill regimens of Misoprostol after Mifepristone medical abortion through 63 days gestational age: Randomized control trial of sublingual and oral Misoprostol. *Contraception* 2009; 79: 513-9.
6. Hamoda H, Ashok P W, Flett GM, Templeton A. Home self administration of Misoprostol for Medical Abortion up to 56 days Gestation. *J Fam Plann Reprod Health care* 2005; 31: 189-92.
7. Bracken H, Family Planning Association of India/ Gynuity Health Project Research Group for Simplifying Medical Abortion in India. Home administration of Misoprostol for early Medical abortion in India. *Int J of Gynecol Obstet*; 2010; 108: 228-32.
8. Guengant J P, Bangou J, Elul B, Ellertson C. Mefipristone-Misoprostol medical abortion: Home administration of Misoprostol in Guadeloupe. *Contraception* 1999; 60: 167-72.