International Journal of Current Advanced Research
ISSN: O: 2319-6475, ISSN: P: 2319 – 6505, Impact Factor: SJIF: 5.995
Available Online at www.journalijcar.org
Volume 6; Issue 9; September 2017; Page No. 5775-5778
DOI: http://dx.doi.org/10.24327/ijcar.2017.5778.0798

Research Article

A COMPARATIVE STUDY ON THE EFFECTIVENESS, SAFETY AND ACCEPTABILITY OF MEDICAL ABORTION AT HOME BETWEEN GESTATIONAL AGE UP TO 49 DAYS AND FROM 50 TO 63 DAYS

Nalini Sharma[1]., Das Rituparna[2] and Barooah Rituparna[3]

[1]Department of Obstetrics and Gynaecology North eastern Indira Gandhi Regional Institute of Health and Medical Sciences Shillong.Meghalaya
[2]Department of Obstetrics and Gynecology. North Eastern Indira Gandhi Regi onal Institute of Health and Medical Sciences
[3]Department of Physiology North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences Shillong.Meghalaya

A R T I C L E I N F O

Article History:

Received 19th June, 2017
Received in revised form 3rd July, 2017 Accepted 18th August, 2017
Published online 28th September, 2017

Key words:

First trimester, Abortion, Mifepristone, Misoprostol, Efficacy

A B S T R A C T

Background: Medical abortion is the method to terminate the pregnancy by using mifepristone and misoprostol tablets by giving them at 48 hours interval. As per WHO medical abortion is a safe and effective method upto 9 weeks (63 days) of gestation.In home setting mifepristone isusually given in clinic and misoprostol self-administered by woman at home.We hypothesized that both mifepristone and misoprostol can be given in home based setting.

Objectives: To compare the effectiveness and safety of mifepristone and misoprostol upto 49 days of gestation with gestational age of 50-63 days in complete home based setting.

Method: nThis prospective, comparative study was done on 210 women who opted for first trimester abortion upto 63 days of gestation. They were divided into two groups: Group 1 with gestational age of ≤ 49 days and Group 2 with gestational age of 50-63 days. After confirmation of gestational age by transvaginal ultrasonography oral mifepristone (200mg) was followed after 48 hours by sublingual misoprstol (800µg), both self-administered by the women at home. They returned for follow-up after 14 days to confirm the completeness of abortion. Primary aim was to evaluate the efficacy of medical regimen in the form of percentage of complete abortion. And secondary aim was to compare the safety profile and acceptability in both the groups.

Result: In this study, conducted in complete home based setting, it was found that overall in both the groups the success rate in the form of complete abortion was high (95.7%) and both the groups were comparable with 97% complete abortion in group 1 and 93.8% in group 2, p value being 0.4522.Side effects profiles in both the groups were also low and comparable.

Conclusion: Our study shows the efficacy and safety of mifepristone and misoprostol upto 63 days of gestation in home setting for medical abortion. It also shows a high acceptability rate amongst women. Women should be offered this option to allow more flexibility and privacy in their abortions.

INTRODUCTION

Availability of safe abortion services is an important means for the reduction of maternal mortality and morbidity as unsafe abortion is responsible for 13% of maternal mortality.(1) Medical abortion is the method to terminate the pregnancy by using mifepristone and misoprostol tablets by giving them at 48 hours interval. As per WHO medical abortion is a safe and effective method upto 9 weeks (63 days) of gestation.(2) In home setting usually mifepristone is given in clinic and misoprostol self-administered by woman at home. In the home setting, there is privacy, lesser number of hospital visits and hence less work load in the hospital thus simplifying the medical abortion regimenand increasing the acceptance rate.In various countries like USA, France and Sweden majority of the women opted for home based medical abortion when options were given between home based and clinical setting.(3) There were no study from India which mentioned about abortion service in complete home based setting in which mifepristone and misoprostol were both taken at home. We hypothesized that both mifepristone and misoprostol can be given in home based setting, safely and effectively for first trimester medical abortion upto 63 days of gestation.

The goal of present study was to compare the efficacy and safety of mifepristone and misoprostol regimen upto 49 days of gestational age with gestational age of 50-63 days in complete home based setting in north eastern population in

Corresponding author:* **Nalini Sharma
Department of Obstetrics and Gynaecology North eastern Indira Gandhi Regional Institute of Health and Medical Sciences Shillong. Meghalaya

India. Various parameters ofcomparison were the percentage of complete abortion, duration of bleeding per vaginum, acceptability and side effect profile between the two groups.

MATERIAL AND METHOD

This prospective, comparative study was done in a tertiary level institute of north eastern India from September 2015to April 2017. The efficacy, safety and acceptability of medical abortion upto 49 days of gestation was compared with gestational age of 50-63 days in complete home based settings. Mifepristone and misoprostol were administered 48 hours apart in both the groups. Primary outcome was to determine the efficacy of medical regimen in the form of percentage of complete abortion.Secondary outcome were to compare safety profile and acceptability in both the groups. Clearance was taken from institutional ethical committee. Women who visited for first trimester abortion in gynecology department and requested medical abortion during this time period, eligible as per MTP act and who fulfilledthe study criteria were invited to enroll in study. Inclusion criterion was single live intrauterine pregnancy upto 63 days of gestation.Gestational age was determined by menstrual history and clinical examination and confirmed by ultrasonography. Woman who provided informed consent and agreed complete follow up, having access to telephone facility and easy access to health facility were included. Our exclusion criteria were pregnancy >63 days of gestation, women<18 years of age, having haemorrhagic disease, on anticoagulant therapy, allergic to mifepristone and misoprostol, contraindication to mifepristone like patient on chronic systemic corticosteroid administration or adrenal disease, contraindication to misoprostol like glaucoma,mitral stenosis, poorly controlled seizure disorder, smokers and breast feeding women. A total of 210 women participated in the study. We divided them into two groups according to gestational age at presentation, group 1 included those ≤49 days of gestation and group 2 included those between 50 to 63 days of gestation.

Women were explained about doses and schedule of mifepristone and misoprostol. They were asked to take a single tablet of 200mg of mifepristone orally during morning hours followed after 48 hours by tablet misopros to l800 microgram sublingually at home.Women were instructed to report to hospital in case of heavy bleeding or severe pain abdomen. They were given prescriptions of tablet paracetamol and tramodol. They were instructed to return to hospital after 14 days when history, examination and transvaginal ultrasonography performed to determine if complete abortion had occured.Women were inquired about duration of bleeding per vaginum, pain, nausea, vomiting, diarrhea or any other side effect. Successful termination was considered when there were no retained products of conception on ultrasound.For acceptability women were asked whether they would opt for the same method if need for abortion arises again.

Statistical analysis

For demographic and obstetric variables descriptive statistics was used to calculate the mean ± SD. To compare the means of parameters of both the groups independent student t test was performed. A 95%limit and 5% level of significance were adopted . P <0.05 was considered significant.

RESULT

A total of 213women were initially enrolled in the study.Three women didn't complete the regimen and hence 210 women remained in the study. The demographic and obstetric variables were similar in both the groups except gestational age (Table 1) as per study protocol.Completed family and birth spacing were the most common indications of termination of pregnancy. (Table-2)

Table 1 Clinical profile of women in both the groups

Variable	Group 1 (N= 130)	Group 2 (N= 80)	P value
Mean age (years)	28.03 ±4.916	28.5 ±4.503	0.4890
Mean Parity	1.45 ± 1.005	1.49 ± 0.856	0.8036
Mean gestational age in days	40.66 ± 4.778	54.16 ±6.575	<0.0001
Unmarried	7 (5.38%)	5 (6.25%)	0.7930
H/O previous LSCS	26 (20%)	17 (21.25%)	0.9666
Primigravida	14 (10.76%)	9 (11.25%)	0.9137
H/O Previous induced abortion	39 (30%)	26 (32.5%)	0.8205

Table 2 Indications of MTP

Indications of MTP	Number of patients (percentage)
Completed family	62 (29.5%)
Birth spacing	48 (22.8%)
Contraceptive failure	42 (20%)
Financial reasons	30 (14.3%)
Social reasons	28 (13.3%)

Overall rate of complete abortion upto 63 days of gestation was 95.7% indicating very high efficacy of medical abortion in complete home based setting. In group 1 it was 97% and in group 2 it was 93.7% and the difference was not statistically significant (pvalue0.4522). Out of 9 women of incomplete abortion suction evacuation was required in 5 women, rest were managed by stat dose of 400 microgram of sublingual misoprostol. Three women from group 1 and two from group 2 required suction evacuation.

Side effects are presented in table 3.

Table 3 Outcome in both the groups

Variables	Group 1(N= 130)	Group 2 (N= 80)	P value
Complete Abortion	126(97%)	75(93.8%)	0.4522
Incomplete abortion	4(3.1%)	5(6.3%)	0.4522
Continuation of pregnancy	0 (0%)	0 (0%)	
Need for subsequent surgical evacuation	3 (2.3%)	2 (2.5%)	0.6276
Duration of Bleeding per vaginal(>7 days)	10(7.7%)	24(30%)	<0.0001
Acceptability	117(90%)	73 (91.3%)	0.9540

Table 4 Side effects profile in both the groups

Variables	Group 1 (N= 130)	Group 2 (N= 80)	P value
Excessive Pain	29 (22.3%)	20 (25%)	0.7795
Nausea/vomiting/Diarrhoea	25(19.2%)	15 (18.8%)	0.9313
Headache	1(0.8%)	0 (0%)	0.4317
Fever	0 (0%)	0 (0%)	
Endometritis	1(0.8%)	0 (0%)	0.4317

There were no cases of excessive bleeding per vaginum that required emergency evacuation or blood transfusion in either group. There were no significant differences in side effects experienced between the two groups except that more women in group 2 than in group 1 had bleeding per vaginum for more than 7 days (p value <0.05). One woman had bleeding for > 3 weeks but there was no retained product of conception on transvaginal ultrasonography. Acceptability was high in

both the groups, 90% in group 1 and 91% in group 2, and statistically comparable. (pvalue >0.05). Out of 210, 3 women did not turn up for followup. With these women telephonic discussion was done regarding cessation of bleeding, efficacy, side effects or any other complication. Histories via telephone were consistent with complete abortion without any complication.

DISCUSSION

This prospective, comparative study compared the efficacy and safety of medical abortion by mifepristone and misoprostolbetween gestational age upto 49 days and from 50-63 days in complete home based setting and found that overall rate of complete abortion upto 63 days of gestation was 95.7% indicating very high efficacy of the regimen. Also in group 1 it was 97% and in group 2 it was 93.8% and the difference was not statistically significant (p value 0.4522). In various clinical trial reports the rate of complete abortion ranged from 91% to 98% for pregnancies upto 9 weeks when misoprostol is administered at home. (4,5)

Various observational studies also demonstrated the effectiveness of home based medical abortion in the range of 87% to 98% in different dose combinations.(6,7,8,9)

One study which used similar drug dosage and route had shown same efficacy. (10). Here we want to highlight the high efficacy in our present study in complete home based setting. In one of the study the rate of complete abortion was 85.5% in home based setting but they used lower doses (200 and 400 microgram of misoprostol) (11) Other studies where misoprostol was used in higher doses (600 and 800 microgram) abortion rate was comparable to our study.(7, 10,12,). Our findings are consistent with other studies regarding efficacy of same regimen in home setting (4, 5, 8,13)

Side effects were mild and comparable in both the groups. Pain and nausea were the most common side effect in both the groups.There were no serious side effects and comparable to other studies. (8,11,12). One woman had bleeding for > 3 weeks but there were no retained product of conception on tranvaginal ultrasonography and she responded to antibiotic. Routine antibiotic prophylaxis was not given to the participants. In one study which compared misoprostol in home and hospital setting pain, fever and vomiting were more in home setting.(14)

Acceptability of medical abortion with the present regimen in home setting was very good in both the groups (90% and 91%). Flexibility was more when both the drugs are administered in home setting and it increases the acceptability rate. This is comparable to other observational studies where acceptability rate was in the range of 86% to 98%, (6,7,8,9)

In our study women took both the drugs in home setting and showed good efficacy and safety profile upto 63 days of gestation. With this study it can be recommended that it is equally efficacious and safe to administer both the drugs in home setting upto 63 days of gestation. It will not only reduce the number of hospital visits (only two visits) but also give woman more control over the abortion timings. It will increase accessibility and acceptability of medical abortion and will be helpful in decreasing maternal mortality related to unsafe abortion.

There were certain limitations of the present study. One is that sample size is small and it is a single center study. Multicenter study with large sample size may be justified to confirm the finding of the present study.

CONCLUSION

Our study shows the efficacy and safety of mifepristone and misoprostol upto 63 days of gestation in home setting for medical abortion. It also shows a high acceptability rate amongst women. Women should be offered this option to allow more flexibility and privacy in their abortions.

References

1. World health organization(WHO): Unsafe abortion global and regional estimates of the incidence of unsafe abortion and associated mortality in 2008. 6th edition.
2. World health Organization (2012). Safe abortion care: the public health and human rights rationale. Safe Abortion: Technical and Policy Guidance for Health Systems second edition.
3. BererM. Medical abortion a fact sheet.Reprod Health Matters.2005; 13:2020-4
4. Creinin MD, Fox MC, Teal S, Chen A, Schaff EA, Meyn LA, MOD Study Trial Group. A randomized comparison of misoprostol 6 to 8 hours versus 24 hours after mifepristone for abortion. *Obstet Gynecol* 2004; 103: 851-9
5. Creinin MD, Schreiber CA, Bednarek P, Lintu H, Wagner M-S, Meyn LA, Medical Abortion at the Same Time (MAST) Study Trial Group. Mifepristone and misoprostol administered simultaneously versus 24 hours apart for abortion: a randomized controlled trial. *Obstet G.ynecol* 2007; 109: 885-94
6. Clark WH, Gold M, Grossman D, Winikoff B. Can mifepristone medical abortion be simplified? A review of the evidence and questions for future research. *Contraception* 2007; 75: 245-50
7. Hamoda H, Ashok PW, Flett GMM, Templeton A. Home self-administration of misoprostol for medical abortion up to 56 days' gestation. *J FamPlannReprod Health Care* 2005; 31: 189-92
8. Chuni N, Chandrashekhar TS. Early pregnancy termination with a simplified mifepristone: Medical abortion outpatient regimen. *Kathmandu Univ Med J* 2009; 7: 209-12
9. Guengnant JP, Bangou J, EulB, Ellertson C Mifepristone- Misoprostol MedicalAbortion: home administration of misoprostol in Guadeloupe. Contraception.1999;60:167-72.
10. Winikoff B,DzubaIG,CreininMD, CrowedenWA, GoldbergAA, Gonazales J *et al.* Two distinct oral routes of misoprostol in mifepristone medical abortion;a randomized controlled trial. *Obstetrics and gynecology.*2008112:1303-10
11. Bracken H, Family Planning Association of India (FPAI)/Gynuity Health Projects Research Group for Simplifying Medical Abortion in India. Home administration of misoprostol for early medical abortion in India. *Int J Gynaecol Obstet* 2010; 108: 228-32

12. Dagousset I, Fourrier E, Aubény E, TaurelleR.Use of misoprostol for medical abortion:a trial of acceptability for home use . *Gynecol Obstet Fertil* 2004; 32: 28-33
13. Hamoda H, Ashok PW, Flett GMM, Templeton A. Home self-administration of misoprostol for medical abortion up to 56 days' gestation. *J FamPlannReprod Health Care* 2005; 31: 189-92
14. Bracken H, Gliozheni O, Kati K, Manoku N, Moisiu R, Shannon C, et al., Medical Abortion Research Group, et al. Mifepristone medical abortion in Albania: results from a pilot clinical research study. *Eur J ContraceptReprod Health Care* 2006; 11: 38-46

How to cite this article:

Nalini Sharma *et al* (2017) 'A Comparative Study on The Effectiveness, Safety and Acceptability of Medical Abortion At Home Between Gestational Age Up to 49 Days and From 50 to 63 Days ', *International Journal of Current Advanced Research*, 06(09), pp. 5775-5778. DOI: http://dx.doi.org/10.24327/ijcar.2017.5778.0798

****