ECRONICON OPEN ACCESS

EC GYNAECOLOGY
Research Article

Effectiveness of Oral Mifepristone and Misoprostol Per Vagina for Medical Abortion

S Jayanthi[1] and Manjubala Dash[2]*

[1]*Dean, Mother Theresa PG and Research Institute of Health Sciences, Puducherry, India*

[2]*Professor and Head, Department of Ob and Gy Nursing, MTPG and RIHS, Puducherry, India*

***Corresponding Author:** Manjubala Dash, Professor and Head, Department of Ob and Gy Nursing, MTPG and RIHS, Puducherry, India.

Received: May 03, 2021; **Published:** May 25, 2021

Abstract

Objective: To examine the effectiveness of Mifepristone and Misoprostol for Medical abortion and its acceptability and feasibility among the participants.

Methodology: Study was conducted in a selected clinic of Puducherry. In total, 2539 women who were eligible for legal pregnancy termination with a gestational age of up to 60 days since last menstrual period were enrolled in the clinic between May 2008 and July 2020. Participants received 200 mg of oral mifepristone in the clinic under the supervision of the researcher and then 800 µg of misoprostol administered vaginally after 24 hours (1 days later) in the clinic itself. Participants were instructed to come for follow-up visit after 10days to clinic for an assessment of abortion status. All the participants underwent Ultrasonography to determine outcome on their follow-up visit. Prospective data were collected to determine the women's experience, abortion outcome and the feasibility, acceptability for providing the method. The data were gathered by the help of checklist.

Result: Total 2154 (84.84%) participants were under 49 days of gestation out of which only 2 (0.09%) had incomplete abortion who had undergone Dilatation and Evacuation procedure. Around 77 (3%) of the mother had expressed side effects of the drugs like nausea, vomiting and 1270 (50%) of the participants had mild level of abdominal pain on the second day of the treatment.

Conclusion: Researchers concluded that Mifepristone and Vaginal misoprostol are very good combination of drugs to be used for the success of medical abortion. It is 100% (99.9%) successful and safe below 49 days of gestation.

Implications: Vaginal Misoprostol is more efficacious and quick in action since it targets directly. The side effects of oral misoprostol like nausea, vomiting, diarrhoea and gastritis is not there. By this method unnecessary hospital stay and the cost involved was avoided. They can resume work on the second day of treatment as well as from the fourth day of treatment.

Keywords: *Accessibility; Feasibility; Abortion with Medication; Women; Early Gestation Abortion*

Introduction

Medical methods emerged as an alternative to surgical abortion with the discovery of prostaglandins in the early 1970s [1-4]. The 2012 World Health Organization (WHO) safe abortion guideline had varying regimens for induced abortion at < 12 weeks. The primary regimens include two drugs: mifepristone and misoprostol. Because mifepristone potentiates the abortifacient action of misoprostol, the combination is highly effective, resulting in complete abortion in more than 95% of women through 63 days of gestation and 93% between 64 and 70 days [5-8].

Their use has evolved in the last two decades and various drugs have been used for first trimester medical abortion. Several studies have explored utilization of mifepristone, methotrexate and various prostaglandins with different doses, routes and intervals of administration [9-11]. A Cochrane review compared different medical methods for first trimester abortion in 2011 and since that time, there has been growing evidence assessing the effectiveness and safety of medical methods using two specific regimens: the combination regimen (mifepristone and misoprostol) and misoprostol alone [12]. A systematic review conducted by Ferid A Abubeker., *et al*. [13] 2020 with inclusion of thirty-three studies composed of 22,275 participants reported that Combined regimens using mifepristone and misoprostol had lower rates of on-going pregnancy, higher rates of successful abortion and satisfaction compared to misoprostol only regimens. In combined regimens, misoprostol 800 µg was more effective than 400 µg. There was no significant difference in dosing intervals between mifepristone and misoprostol and routes of misoprostol administration in combination or misoprostol alone regimens. The rate of serious adverse events was generally low. Further they suggested that studies evaluating both the different combination and misoprostol alone regimens are needed to strengthen existing evidence as well as assess patient perspectives.

Objective of the Study

The objectives of this present study are to evaluate the effectiveness, safety and acceptability of medical abortion containing mifepristone and misoprostol at ≤ 60 days of gestational age.

Methodology

The perspective study was conducted by the researcher from May 2008 to July 2020. Ultrasound examination is a part of confirming the pregnancy in early week and to rule out ectopic pregnancy, all the participants had trans-vaginal scan. After confirming the pregnancy the choice of surgical evacuation or medical treatment was explained to each participants and the medical method of abortion decided in accordance with the women's choices. Total 2539 participants were included in the study those who were eligible for medical abortion and asked for medical abortion method willingly. The standard eligible criteria's by WHO for medical abortion are followed to select the participants. Written consent was obtained from the participants and they were explained the purpose of the study also assurance given for the confidentiality of the information. All the samples were selected by Purposive sampling technique for the purpose of the study. ethical clearance was obtained from the Institutional ethical committee.

After getting the written consent from each participants tablet Mifepristone 200 mg was given to the mother orally under the supervision of the Researcher. Then on next day that is after 24 hours Misoprostol 800 µg was inserted vaginally by the Researcher. Women were instructed to report to clinic if they don't get bleeding within 24hrs for the repeat dose of Misoprostol.

All the participants were instructed for follow-up visit on 10^{th} day to review the outcome. During the follow-up visit all the participants underwent Ultrasonography to determine outcome. The data was collected with the help a checklist. It has two sections. Section A deals with the demographic and obstetric variables like age of the women, gravida or para, gestation days, history of previous medical abortion, history of previous LSCS etc and section B deals with outcome of the medical abortion that is - days of complete expulsion, any complications/side effects, days of bleeding, types of bleeding and chances of failure of medical abortion/require D and E, etc.

The tool used for this study was divided into 2 sections. section A deals with demographic and obstetrical variables and section B deals with checklist to assess the condition of the participants and success rate of medical abortion. The tool was sent to experts in the field to get the validity and reliability of the tool was checked with Interrater reliability. The r value was 0.7 and shows reliable to proceed for the study. Section A data's were collected on the day of visit to the clinic and Section B information's were asked individual participants during their follow-up visit to clinic and filled. Each participants were asked about when they noticed to start bleeding, expulsion of conceptual product, no. of days bleeding etc. For the complications and side effects of the drugs participants were asked to report for complications like heavy bleeding, abdominal pain and side effects like Nausea, Vomiting and gastritis etc. To assess bleeding one sanitary napkin was

shown to the participants and asked for the no of pad soaked per day, how many times they changed the pad per day and to assess the pain level the facial pain scale was used by the researcher. The faces were shown to the mother and asked to mark the types of face to find out the severity of pain they had. The facial pain scale has total score of 10. It was classified as mild pain (0 - 3 score), moderate pain (4 - 6 score) and severe pain (7 - 10 score). All the participants were prescribed Drug. Aceclofenac and Dicyclomine 1 tab TDS and instruction was given to use this drug SOS, when they will have abdominal pain. The whole procedure was done as outpatient measure, so women no need to stay in the hospital. All the collected data panned to analyse with descriptive and inferential statistics.

Result

The result highlights that in relation to the age group of the participants most of the participants 1142 (44.98%) were in the age group of 20 - 39 years, 1109 (43.7%) participants were under gravida two, Majority of the participants 2145 (84.84%) were under 49days of gestation period i.e. below 7 weeks of gestation (Table 1).

Variables	No	%
Age (yrs)		
<19	819	32.26
20-39	1142	44.98
40-44	577	22.73
45 and above	1	0.03
Gravida/Para		
Primi	107	4.22
G2	1109	43.7
G3	826	32.53
G4	353	14
G5	114	4.5
G6 and above	26	1.024
Gestation days		
Below 49days	2154	84.84
50-60days	384	15.12
Above 60days	1	0.03

Table 1: *Distribution of age, gravida and gestation days of participants (N = 2539).*

With regard to previous history of (H/O) Medical abortion the result shows that 472 (18.59%) participants had previous one time medical abortion, 93 (3.66%) participants had previous two times medical abortion. Participants those had medical abortion reported previous LSCS. 419 (16.5%) and 92 (3.62%) participants had one previous LSCS and two previous LSCS respectively (Table 2).

Previous H/O Medical Abortion		
One time	472	18.59
Two times	93	3.66
Three times	16	0.63
Four times	2	0.08
Five times	1	0.03
Previous H/O LSCS		
1	419	16.5
2	92	3.62
3	3	0.11
4	1	0.03

Table 2: *Distribution of Participants (Previous H/O Medical Abortion and LSCS) (n-2539).*

In relation to onset of bleeding, expulsion of product it showed that all most all (100%) women had bleeding within 5 hrs of vaginal misoprostol and majority (90%) had complete expulsion of conceptual product within 24 hrs of vaginal misoprostol application.

Regarding bleeding none of the participants had severe bleeding but very few i.e. only 3 (0.11%) participants got fear due to bleeding and asked for admission in the clinic for their safety. The bleeding was not heavy as there was no clinical sign of heavy bleeding on assessment and they did not require any intervention except close observation. Bleeding lasted for 5 to 8 days among 90% women (Moderate bleeding up to 4 to 5 days and mild bleeding till the 8th day).

With regards to complication and side effects of the drugs the report presents that around 77 (3%) of the women had expressed side effects of the drugs like nausea, vomiting on the second day of treatment which could also have been due to the vomiting of pregnancy per se.

1270 (50%) of the participants had mild level of stomach pain and do not required medication, whereas 762 (30%) and 507 (20%) of the participants reported moderate and severe level stomach pain respectively and they took the medicine (Figure 1).

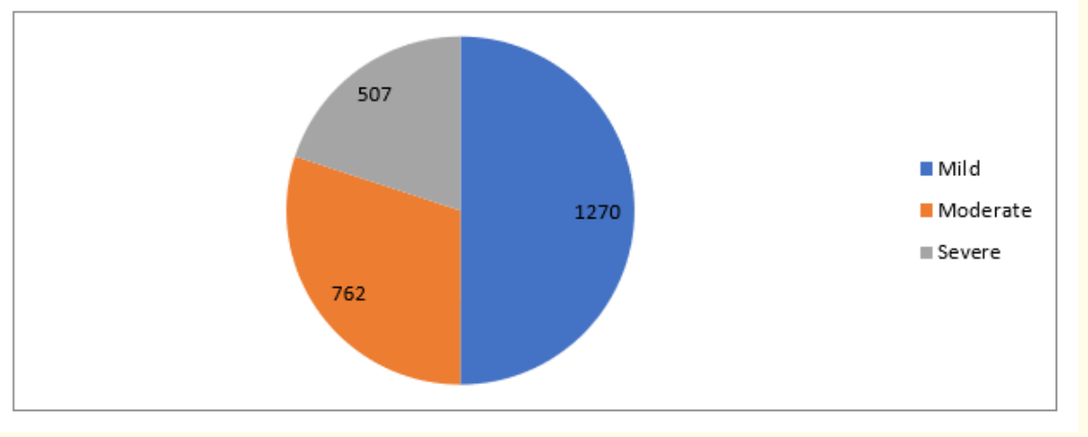

Figure 1: *Distribution of Level of pain among the participants.*

Success rate of Medical Abortion presents that almost all the participants had complete abortion without any complications those who were under 49 days of gestation or below 7 weeks of gestation. Total 2154 (84.84%) participants were under 49days of gestation out of which 119 (5.5%) had reported to clinic for 2nd dose of Vaginal Misoprostol (800 µg) and out of these 119 women 117 (98.31%) had complete expulsion after 2nd dose but only 2 (0.09%) had incomplete abortion who had undergone D and E procedure for expulsion of product. Participants from 50 - 60 days of gestation were 384 (15.12%) and out of them 27 (7%) had reported to clinic for the 2nd dose of Misoprostol (800 µg) and among these 27 mothers 24 (88.88%) had complete expulsion after 2nd dose but only 3 (0.78%) had incomplete abortion who had undergone D and E procedure. Further out of total 2539 participants only one woman was above 60 days and she had incomplete abortion and required D and E procedure (Table 3 and figure 2).

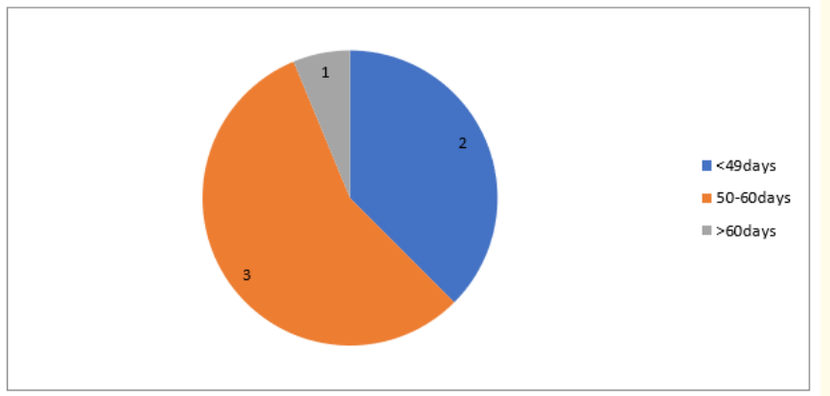

Figure 2: *Distribution of failure of medical abortion as per days of gestation.*

No. of Participants	No. of Days	Success in 1st dose of Mifepristone and Misoprostol	Need for 2nd dose of Misoprostol	Need for D and E (After failure from 2nd dose.)	Success Rate
2154	49	2035 (94.47%)	119 (5.5%)	2 (0.09%)	2152 (99.9%)
384	50 - 60	357 (92.96)	27 (7%)	3 (0.78%)	381 (99.2%)
1	> 60	-	1 (100%)	1 (100%)	--

Table 3: *Distribution of rate of success of medical abortion among women (N = 2539).*

Further to add success to vaginal misoprostol the result of 51 (2%) women highlighted that they had given 200 mg of mifepristone orally and after 24 hours 200 µg of misoprostol 2 tab BD (total 800 µg) given orally. These entire mothers did not get bleeding. Afterwards when Misoprostol (800 µg) inserted vaginally and they all reported bleeding within 5hrs and had complete expulsion within 24 hours.

From this above result it was very clear that the days of gestation and misoprostol administration per vagina that matter for the success of Medical abortion. Further it was also observed that though the participants had previous history of medical abortion and previous history of LSCS but that did not show any statistical significant association with the success of abortion process.

Almost all (100%) participants were satisfied or very satisfied with the abortion method and it was acceptable or very acceptable to all participants. Almost all participants preferred a medical abortion than surgical procedure in future (95%).

Discussion

The present study result on medical abortion with two combine drugs like Mifepristone and misoprostol highlights that most of the participants were under the age group of below 40 years, under G2 and G3 and under 49days of gestation week (Table 1).

The present study highlighted that there is 99.73% of success rate when the women is under 49days of gestation proved high success rate with combined medication use for medical abortion. The result supported by Ingrida Platais., *et al*. 2016 conducted a prospective study on home use of mifepristone and misoprostol for medical abortion among 290 women reported that the overall success rate was 99.0% (95% confidence interval 97.0%-99.7%). No serious adverse events occurred. They concluded that medical abortion with mifepristone and misoprostol is safe and effective up to 70days of pregnancy.

The result congruent with Justin J Chu., *et al*. 2020 [14] conducted a RCT, Double blinded study on Mifepristone and Misoprostol Vs Misoprostol alone for the management of missed miscarriage among 2595 women shown the result that treatment with mifepristone and misoprostol was more effective for missed medical abortion compare to misoprostol alone. They suggested that mifepristone to be administered to women as pre-treatment before misoprostol for successful management and in order to reduce surgical abortion.

Further the present study result consistent with the study conducted by Yiu-TaiLi James Ching-HungHsieh., *et al*. 2011 [15] on "Simultaneous use of mifepristone and misoprostol for early pregnancy termination" reported that The complete abortion rate was 92.6%. Concurrent administration of oral mifepristone 200 mg and vaginal misoprostol 600 µg is an efficacious regimen for medical abortion of pregnancies up to 49 days of gestation. The mean induction to abortion interval was about 5.8 hours. The mean bleeding duration was about 12.6 days. The women indicated that the side effects were tolerable and 90% of them said that their experience was satisfactory.

The result also supported by Nguyen Thi Nhu Ngoc., *et al*. 1999 [16] conducted a study on "Safety, Efficacy and Acceptability of Mifepristone-Misoprostol Medical Abortion in Vietnam" among 393 women reported that there was 96% success rate in medical abortion. They concluded that it is safe and effective for management of medical abortion.

Conclusion

Mifepristone and vaginal Misoprostol is an effective method for medical abortion. It showed 99.9% almost towards 100% success rate within 49days of delayed period. Further it is an acceptable and feasible option for women. The method worked well for all participants which could greatly expand current method options and improve the quality of reproductive health care in Puducherry and other rural settings of India where access to hospital for abortion services is limited. It is a safe and convenient method than surgical abortion as the whole procedure was carried out as out patient measure which avoids hospital stay and reduces the cost of the treatment too. So, it was recommended that awareness need to be created among women that early onset of medical abortion leads to high success rate so that they can seek early treatment measures.

Bibliography

1. Elizabeth G Raymond., *et al*. "Efficacy of Misoprostol Alone for First-Trimester Medical Abortion: A Systematic Review". *Obstetrics and Gynecology* 133.1 (2019): 137-147.
2. Moore AM., *et al*. "Provision of medical methods of abortion in facilities in India in 2015: A six state comparison". *Glob Public Health* 14.12 (2019): 1757-1769.
3. Singh S., *et al*. "Abortion service provision in South Asia: A comparative study of four countries". *Contraception* 102.3 (2020): 210-219.
4. Kulczycki A., *et al*. "Abortion and fertility regulation". *Lancet* 347.9016 (1996): 1663-1668.
5. Raymond EG., *et al*. "First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review". *Contraception* 87 (2013): 26-37.
6. Chen MJ and Creinin MD. "Mifepristone With Buccal Misoprostol for Medical Abortion: A Systematic Review". *Obstetrics and Gynecology* 126 (2015): 12-21.
7. Abbas D., *et al*. "Outpatient medical abortion is safe and effective through 70 days gestation". *Contraception* 92 (2015): 197-199.
8. Friday Okonofua., *et al*. "Acceptability and feasibility of medical abortion with mifepristone and misoprostol in Nigeria". *International Journal of Gynaecology and Obstetrics* 125.1 (2014): 49-52.
9. Tsereteli T., *et al*. "Acceptability and feasibility of 400 µg buccal misoprostol after 200 mg mifepristone for early medical abortion in Georgia (2016).
10. The European Journal of Contraception and Reproductive Health Care: the Official Journal ofthe European Society of Contraception 21.5 (2020): 367-371.
11. Chanda Karki., *et al*. "Acceptability and feasibility of medical abortion in Nepal". *International Journal of Gynecology and Obstetrics* 106.1 (2009): 39-42.
12. Anupama Goel., *et al*. "Simultaneous administration of mifepristone and misoprostol for early termination of pregnancy: a randomized controlled trial". *Archives of Gynecology and Obstetrics* 283.6 (2011): 1409-1413.
13. Ferid A Abubeker., *et al*. "Medical termination for pregnancy in early first trimester (≤ 63 days) using combination of mifepristone and misoprostol or misoprostol alone: a systematic review". *BMC Women's Health* 20 (2020): 142.
14. Ingrida Platais., *et al*. "Prospective study of home use of mifepristone and misoprostol for medical abortion up to 10weeks of pregnancy in Kazakhstan". *International Journal of Gynaecology and Obstetrics: the Official Organ of the International Federation of Gynaecology and Obstetrics* 134.3 (2016).

15. Yiu-TaiLia James Ching-HungHsieh., *et al*. "Simultaneous use of mifepristone and misoprostol for early pregnancy termination". *Gynecology* 50.1 (2011): 11-14.

16. Nguyen Thi Nhu Ngoc., *et al*. "Safety, Efficacy and Acceptability of Mifepristone-Misoprostol Medical Abortion in Vietnam". *International Family Planning Perspectives* 25.1 (1999): 10-14.

Volume 10 Issue 6 June 2021