Safety and Efficacy of Medical Abortion with Mifepristone and Misoprostol in Pregnancy with Gestational Age of 63-90 Days

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Abstract

Background: The study was conducted to assess the safety and efficacy of medical abortion with mifepristone and misoprostol in gestational age of 63 – 90 days.
Methods: This is a prospective observational study. The pregnant women opting for medical termination of pregnancy were recruited after informed consent and preliminary investigation. On day one, Tablet mifepristone (200mg) given orally followed by 36-48 hours later 800mcg misoprostol administered vaginally or sublingually. If the product of conception was not expelled within four hours of misoprostol dose then repeat doses of misoprostol (400 mcg) were given at 4 hour intervals (maximum of 4 doses).
Results: The study showed, 96% of women had complete abortion. Most of the women aborted by two doses of misoprostol (48%, 95% CI 34.15-61.85%). 44% of women had aborted within 4-8 hours (95% CI 30.24-57.7%).
Conclusion: The results of this study suggests that the medical abortion regimen, using mifepristone and misoprostol in the late first trimester (63 – 90 days) can meet the need for an effective alternative to surgical technique for inducing abortion in developing countries as well.
Keywords:Mifepristone/Misoprostol /Medical abortion /Late first trimester/ Safety/Efficacy

1. Introduction

Unsafe abortion is a major public health problem .[1]Over the past two decades, there is a growing consensus that unsafe abortion is an important cause of maternal death that should be prevented through promotion of sexuality education, family planning, and safe abortion services to the full extent of the law, and post-abortion care in all cases .[2-5]World Health assembly in 2004 included unsafe abortion as a part of 'Millennium Development Goal' on improving maternal health and other international development goals and targets.[6]

It is estimated that in 2008, 21.6 million unsafe abortions took place worldwide in all developing countries resulting in 47000 maternal death and millions of mother suffered from injury and long term disability .[7-8] Globally abortion related deaths account for 13 percent of all pregnancy related death.[9]

According to consortium on national consensus for medical abortion in India, 11 million abortions take place annually and around 20,000 women die due to abortion related complication .[10] Therefore, illegal abortion performed by unskilled provider in an unauthorized setting remains a constant challenge in India.

Since the legalization of abortion in India, surgical method of termination of pregnancy has been the accepted method for inducing abortion. Surgical methods of vacuum aspiration require human and financial resources to organize surgical services with appropriate equipment and its maintenance. In addition, this method may result in complication like injury to adjacent viscera, hemorrhage and shock.[11]

The term 'Medical abortion' (MA) is defined as "use of drug or combination of drugs to terminate pregnancy".[12] Therefore, with the current scenario in India, medical abortion provides a great potential of safety & easy accessibility.

In 2000, Food and Drug Administration (FDA) approved medical abortion up to 63 days gestation with mifepristone & misoprostol regime.[13]In 2002, the drug Controller of India approved drugs for terminating early pregnancy in India.[14]

According to World Health Organization (WHO) , dose regimen from 9–12 weeks (63–84 days) gestation is 200 mg mifepristone administered orally, followed by 36 to 48 hours later 800 μg vaginal misoprostol, administered in a health-care facility. A maximum of four further doses of misoprostol 400 μg may be administered at 3-hourly intervals, vaginally or sublingually.[15-16]

International Federation of Gynecology and Obstetrics in 2011 (FIGO) has recommended medical method of abortion for late first trimester (9-12 weeks gestation) with 200 mg mifepristone followed by 36–48 hours later by 800 μg of misoprostol vaginally, maximum of 4 further doses of 400 μg of misoprostol vaginally or sublingually at three hour intervals until abortion. The rate of complete abortion is 95 percent .[17,18]

Lokeland et al.in 2010 have shown a success rate of 91.7 % by using mifepristone and misoprostol from 63-90 days of gestation. In their study this method was highly acceptable (91%).[19]

There is a paucity of studies regarding safety, efficacy of medical abortion in late first trimester from India. Therefore, we planned this study to evaluate efficacy, safety of medical abortion from 63 – 90 days of gestation in our setup by using 200 mg of mifepristone orally followed by 800 mcg of misoprostol vaginally / sublingually, 48 hours later. If the product of conception is not expelled within four hours of misoprostol dose then additional four doses of misoprostol (400 mcg) were used at 4 hourly intervals.

2. Meterials and methods

2.1 Study Design

This study was conducted at Department of obstetrics and gynaecology, ESI-PGIMSR & ESIC Medical College and Hospital, Joka, Kolkata from May 2013 to April 2014 (one year) a prospective observational study. A total of 50 pregnant women were selected according to inclusion criteria. Inclusion criteria were , Pregnant women with 63 to 90 days of viable gestation confirmed by USG and Singleton, viable intrauterine pregnancy with no scar on uterus.

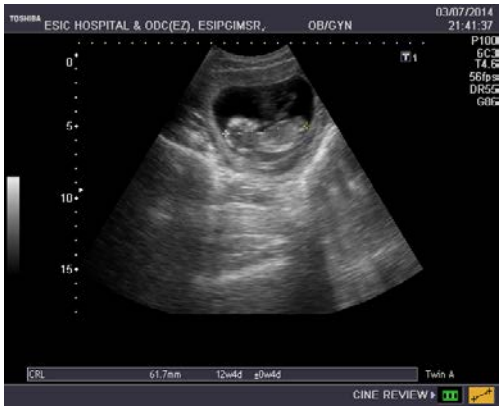

Fig 1: Crown- Rump Length (CRL) measurement (Trans Abdominal Scan)

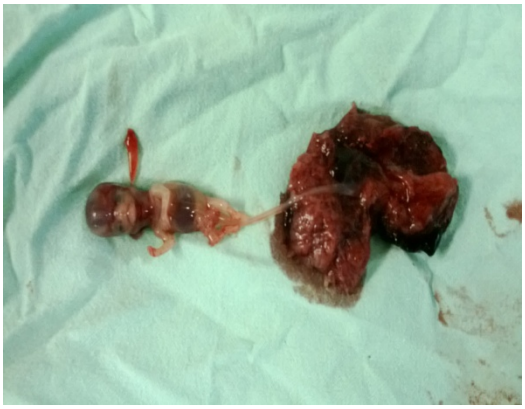

Fig 2: Product of conception after expulsion

The exclusion criteria were patient with pregnancy more than 90 day of gestation , non viable pregnancy, multiple gestation , any suspected ectopic pregnancy, previous scar on uterus, anemia with Hemoglobin <8 gm%, history of allergy to mifepristone, misoprostol or other prostaglandin, any medical disorder like women with known heart disease ,chronic adrenal failure, hemorrhagic disorders or concurrent anticoagulant therapy, severe renal, liver or respiratory diseases, glaucoma , uncontrolled hypertension with BP>160/100mmHg , Broncheal asthma etc.Patients, fulfilling the criteria were admitted in the labour ward of the hospital. Complete history was taken and physical examination was performed. Preliminary basic investigations like urine pregnancy test, Hemoglobin, ABO grouping & Rh typing, Ultrasonography for dating in early trimester was done on first visit(Fig1). After hospitalization, tablet mifepristone (200mg) was given orally after written informed consent under direct supervision of medical person .Tablet Misoprostol (800 mcg) was given in posterior fornix of vagina or sublingually (as per patient's choice)after 36-48 hours of mifepristone dose.

If the product of conception is not expelled within four hours of misoprostol dose then repeat doses of misoprostol (400 mcg) were given at 4 hourly intervals (maximum of 4 doses).

The induction to abortion interval was calculated in hours from administration of first dose of misoprostol to passing the product of conception and was recorded on the pre-structure proforma.

The parameters were studied pain, vaginal bleeding, and expulsion of pregnancy products was recorded on a pre-written proforma , the completeness of abortion was confirmed by visual inspection by nursing staff or Doctor. USG was performed in case of severe bleeding, ongoing pregnancy, and infection & missed abortion, routine record of induction to abortion interval, after 10th day USG was performed for all subjects.

On third visit (day-10), Assessment of completeness of abortion was done by history, pelvic examination and ultrasonography.Complications like bleeding & pain was assessed by detailed history.

2.2 Study technique

All the abortion seekers were explained about both medical and surgical methods of abortion including their advantages and disadvantages & they can choose either of them.

Informed written consent was taken.

Reasons for choosing / refusing medical abortion after counseling were taken.

Before they proceed for abortion detailed information was taken regarding the current practice of contraception. They were also counseled regarding future contraception.

Once they accept abortion, irrespective of the procedure carried out, each of them was followed up until 15 days after abortion.

3. Results and analysis

During the study period , a total number of 50 pregnant women , who requested for abortion and fulfilled the inclusion and exclusion criteria, were selected for medical termination of pregnancy.

Demographic profile distribution of subjects (n=50) shows majority of women came from urban population (54%) and only 22% women were from rural population.Fig1 (b) shows most of the women's were Class X passed (38%) and belonged to middle socio-economic status (82%).Majority of the study population are Class X passed (38%), only one (2%) women was graduate and 5 women (10%) were illiterate. Table 1 shows Most of the women in our study was para-2 (58%). 6% of women were para-4 and 16 % (8, n=50) of women were para-1. Median value of the parity was two.

Table-1: Distribution of subjects according to Parity (n=50)

Parity	Number	Percentage
1	8	16
2	29	58
3	10	20
4	3	6

Table 2 shows Majority of the women were in age group of 31-35 yrs (50%). Mean age for the study group was 29.9 ±4.13yrs. The youngest woman in study group was 20 yrs old and eldest was 37 yrs old.

Table -2 : Distribution of subjects according to Age (n=50)

Age group in year	Number	Percentage	Mean Age (SD)
<25	8	16	
26-30	16	32	29.9± 4.13
31-35	25	50	
36-40	1	2	

Majority of the women in the study group had gestational age between 70 – 76 days (46%). The minimum gestational age was 64 days and maximum gestational age was 86 days. The mean gestational age was 78.18± 5.07 days.

Table- 3: Distribution of subjects according to Gestational age (n=50)

Gestational age	Number	Percentage
63-69 days	11	22
70-76 days	23	46
77- 83 days	13	26
84 – 90 days	3	6

Most of the women in study group had Crown- rump length between 33-40 mm (46%). The mean crown rump length in this study was 36.5± 6.8 mm. The minimum CRL was 25.2 mm and the maximum was 54.8 mm in the study group.

Table- 4: Distribution of subjects according to Crown-rump length (n=50)

CRL (mm)	Number	Percentage
25-32	16	32
33-40	23	46
41-48	8	16
49-56	3	6

The median number of misoprostol applications required was two, equal to 1200 micrograms of misoprostol. A total of 16 women (32%, 95% CI 19.08-44.92%) aborted after only one dose of misoprostol while 24 (48%, 95% CI 34.15-61.85%) had aborted after two doses of misoprostol.6% of women required four doses of misoprostol(95% CI 0.58-12.58%).

Table-5: Distribution of subjects according to dose of misoprostol required (n=50)

No. of misoprostol Doses(mcg)	Study group (n=50)	Percentage	95% Confidence Interval (CI)
1 (800 mcg)	16	32	19.08-44.92%
2 (1200 mcg)	24	48	34.15-61.85%
3 (1600 mcg)	7	14	4.38-23.62%
4 (2000 mcg)	3	6	0.58-12.58%

The induction – to –abortion interval was defined as the time interval in hours from administration of misoprostol to passing the products of conception. The median induction –to – abortion time was 6.5 hours. A total of 16 women (32%, 95% CI 19.08-44.92%) had aborted within 4 hours and 22 women (44%, 95% CI 30.24-57.7%) had aborted between 4-8 hours. The minimum duration for expulsion of product of conception was 2.2 hrs.

Table 6: Association between gestational age and Induction to Abortion Interval (n=50)

Characteristics		Induction to abortion Interval (hours)				P value by (Fisher's exact test)
		(0-4)	(4-8)	(8-12)	(12-16)	
Gestational days	63-69	5	3	2	1	
	70-76	9	10	3	1	0.425
	77-83	2	8	2	1	
	84-90	0	1	1	1	

In the current study, most of the women (44%) aborted between 4-8 hours. When gestational age compared with Induction to Abortion Interval, the statistical analysis showed no significant association between the induction to abortion interval and gestational age (P= 0.425).

Table-7: Distribution of subjects according to Induction abortion interval (n=50)

Induction-to- abortion interval (h)	Number	Percentage	95% Confidence Interval (CI)
0- 4 hrs	16	32	19.08-44.92%
4-8 hrs	22	44	30.24-57.76%
8-12 hrs	8	16	5.84-26.16%
12-16 hrs	4	8	0.48-15.52%

In the study group, 4 women (8%, 95% CI 0.48-15.5%) experienced cramping in the abdomen and none of the study women had gastrointestinal symptoms.8% of women had prolonged bleeding. After USG, two women had incomplete abortion and were managed by surgical evacuation. Other two on USG had no product of conception found and managed conservatively.

Overall complete abortion rate was 96 % in the study group. A total of two women required surgical evacuation because of incomplete abortion. Therefore failure rate was 4 %.

Table-8: Outcomes of medical abortion with mifepristone – misoprostol regimen (n=50)

Study outcome	Number	Percentage
Complete abortion rate	48	96
Incomplete abortion (surgical evacuation required)	2	4

Total two women (4 %) required surgical evacuation because of incomplete abortion. They had gestational age between 70- 77 days (10-11 weeks gestation). Both of them were second parity.

Table – 9: Details of women who required surgical evacuation (n=50)

Patient	Parity	Gestational age (day)	No.of days from Misoprostol administration to Surgical treatment	No.of misoprostol administrations	Indication for surgical aspiration
1.	2	77	33	2	Prolong bleeding , Ultrasound showed retained product of conception.
2.	2	74	22	1	Prolong bleeding, Ultrasound showed retained product of conception.

4. Discussion

Mean age of the participants was 29.9 ± 4.13 years and most of them were from urban area (54%). The median parity was two. Mean hemoglobin of the participants was 11.16 ± 1.3 gm%. Complete abortion was 96 % and the only adverse effect was prolonged bleeding reported by four women (8%).92% of women were satisfied with their abortion experience and 64% of the women showed willingness to use the method again if required.

Medical abortion by using mifepristone and misoprostol has become the treatment method of choice for late first trimester abortion as per Norwegian national guidelines.[20]

International Federation of Gynecology and Obstetrics recommends medical method of abortion for late first trimester (64-84 days) with 200 mg mifepristone followed by 36–48 hours later by 800 µg of misoprostol vaginally. Maximum of four further doses of 400 µg of misoprostol vaginally or sublingually to be administered at 3- hour intervals until abortion. Beyond 84 days (12 weeks) of gestation up to 22 -24 weeks, the dose regime is similar, except the maximum number of doses of misoprostol is five.[17]

Combination of mifepristone and misoprostol for medical abortion is included in the WHO model list of essential medicines.[21,22] The doses prescribed for late first trimester abortion (64-84 days) and beyond 84 days are similar to FIGO guideline.[23,24]

Lokeland et al used 200 mg of mifepristone orally followed by 800 mcg of misoprostol vaginally 48 hours later from 63 – 90 days of gestation. 400 mcg of misoprostol was repeated every 3 hours orally, to a maximum of five doses if needed.[25]

In the present study, we used 200 mg of mifepristone orally followed by 800 mcg of misoprostol vaginally, 48 hours later. Further 400 mcg of misoprostol was repeated every 4 hourly, up to maximum of four doses if abortion not completed.

Complete abortion rate in the present study was 96% which is similar as reported earlier.[17,18,,26,27] Ashok et al. in 2004 evaluated efficacy and acceptability of medical abortion for pregnancy between 13-21 weeks and reported complete abortion rate is 97.1 % of the women.[27] Similar success rate of medical abortion is also reported by Goh and Thong in 2006 between 12-20 weeks of gestation.[28]

Lokeland et al reported overall complete abortion rate of 91.7% with no complication between 63-90 days of gestation which is less than the present study.[25]This difference could be due to the less number of subjects in our study. It can also be explained by different route of administration of subsequent doses of misoprostol. In the present study, subsequent doses of misoprostol were given vaginally whereas in the previous study subsequent doses of misoprostol were given orally.[25] In addition, in their study 58 % of women were nulliparous[42] whereas none of the women were nulliparous in the current study. This finding is supported by the study conducted by Goh et al. in 2006 who reported that nulliparous women took significantly longer time (7.6 hours) to abort as compared to multiparous women (6.0 hours).[28]

In the present study, the median number of misoprostol applications required was two (1200mcg) which is similar to the previously reported study.[25]Mean number of misoprostol doses required for complete abortion was two(1200mcg) as reported by Hamoda et al in 2005.[18]

Induction- to-abortion interval (from the first dose of misoprostol till completion of abortion) in our study was 6.5 hours (median value) which is higher than reported median induction-to –abortion interval of 4.5 hours in the previous study.[25] This could be due to proportionately large number of cases beyond 69 days in the present study. In the study conducted by Lokeland et al, 53 % of women had gestational age between 63-69 days and 47 % were beyond 70 days whereas in our study, only 22 % of women had gestational age between 63-69 days and 78 % had beyond 70 days. Ashok et al in 1998 reported median induction to abortion interval of 4.15 hours up to 63 days of gestation[29] which is lower than median induction to abortion interval in the previously reported studies conducted at late gestation.[27-29] This supports that the induction to abortion interval may be longer at higher gestation. However, less number of participants in the current study could be an additional reason for this difference because when induction to abortion interval was compared between different gestational groups within the present study, no significant association was found between the two (P=0.425).

Prolonged vaginal bleeding (> 14 days) and cramping abdominal pain were the only adverse effects reported by the women in the present study. Ultrasound was performed in all the women complaining of prolonged vaginal bleeding and it was found that two of them had incomplete abortion which was managed by suction evacuation. Cramping pain abdomen was noted in four women (8%) and was mild in intensity. None of the women required analgesia. However, in the previous study 54.2% of women had moderate pain and nearly 40 % had severe pain abdomen and analgesia was given to all the women.[25] Hamoda H et al in 2004 reported 72 % of women required analgesia for pain relief in medical abortion ≤ 22 weeks of pregnancy with mifepristone and misoprostol regimen.[18]

Completion of abortion by observing the expelled product of conception by a medical personal was found to be a successful method in the present study as no ongoing pregnancy was observed in any of the participants. This finding is in concordance with the early first trimester abortion studies[30, 31] and also with late first trimester study.[25]

Fiala C et al. reported that home use of misoprostol up to 49 days of gestation was highly acceptable (96%). In their study, women had chosen this method because home administration of misoprostol was more natural, allowed presence of partner and ensured privacy[30]

Kallner H, et al. in 2010 showed that home administration of vaginal misoprostol was safe and highly acceptable in 92.3 % of women at gestational age of 50-63 days.[31]

Agarwal M et al. in 2010 from India evaluated efficacy and acceptability of medical abortion by single visit treatment regimen for termination of pregnancy up to 59 days. They found that it was acceptable in 96.2 % of women[32] which is slightly higher than study reported by Fiala et al.

However, the present study was conducted at gestational age from 63-90 days for which safety and acceptability of home administration is yet to be evaluated by larger studies and especially in our country.

5. Conclusion

Medical abortion in the early first trimester is safe & efficacious in India. However, this method of inducing abortion can also be an effective alternative to surgical method in late first trimester. Prior to implementing medical abortion for late first trimester on a wider scale in India, its safety and acceptability by the women who have undergone this procedure is required.

The results of this study suggest that the medical abortion regimen, using mifepristone and misoprostol in the late first trimester (63 – 90 days) can meet the need for an effective alternative to surgical technique for inducing abortion in developing countries as well.

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