



A prospective study of oral misoprostol following mifepristone for second trimester abortion: A tertiary hospital based prospective study in central India

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Abstract

Objective: This prospective study was done to evaluate the potency, satisfactoriness and after effects of oral misoprostol for second trimester abortion.

Material and methods: This tertiary hospital based prospective study was intended on 110 women presenting to the Department of Obstetrics and Gynecology, Zanana Hospital, S.M.S. Medical college, Jaipur for second trimester abortion from 12-20 weeks during 2012-13. The women enrolled received 200 mg mifepristone, than oral misoprostol 400 microgram 3 hourly for 5 doses after 48 hours. The results were expressed in terms of induction abortion interval, dosage, success rate, satisfactoriness and after effects.

Results: The mean gestational age in studied women was 17.34 ± 2.181 weeks. The mean gravidity in studied population was 2.13 ± 0.791 . The mean induction-abortion interval was 6.44 ± 1.79 hours. The mean induction-abortion interval was shorter in multigravida i.e. 6.51 ± 1.962 hours as compare to primigravida i.e. 6.63 ± 1.457 hours. The mean induction-abortion interval was shorter with period of gestation 12-16 weeks i.e. 6.67 ± 1.966 hours as compare with gestational age 17-20 weeks with induction-abortion interval of 6.84 ± 1.529 hours ($p=0.4$, NS). The mean dose of misoprostol required was 1003.6 ± 274.9 μ g. Dose of oral misoprostol was lesser in multigravida i.e. 900.0 ± 309.1 μ g as compare to primigravida i.e. 1009.5 ± 277.6 μ g ($p=0.9$, NS). The mean dose of misoprostol required for gestational age 12-16 weeks was 1006.0 ± 312.7 μ g and 1000.0 ± 246.8 μ g for gestational age 17-20 weeks ($p=0.9$, NS). The success rate was 100% and evacuation was needed in 3.64% cases. The mean haemoglobin was 10.16 ± 1.248 g/dl and 9.815 ± 1.138 g/dl before and after abortion. The acceptability was 100.0%. The side effect observed was pain abdomen (34.5%), nausea/vomiting (34.5%), Headache (17.3%), diarrhoea (17.3%) and fever (0.90%).

Conclusion: From present study we conclude that oral misoprostol following mifepristone is highly competent and effectual method of second trimester abortion.

Keywords: Oral misoprostol, second trimester abortion

Introduction

Abortion is defined as annihilation of pregnancy either by medical or surgical methods prior to 20 weeks. The Government of India data of 2003 had documented 11% abortion rate for mid-trimester abortion^[1]. Unsafe abortion remain a neglected health care problem in developing countries. In India MTP act was came into force from 2nd April 1972 and amended in 2003 to further strengthen the act^[2]. As a result of proper enforcement of MTP act, the services for abortions became easily assessable to remote areas. This act allows termination of pregnancy upto 20 weeks for a broad range of indications by an approved medical practitioner. The methods for abortion can be either medical or surgical. Medical abortion is a non-invasive and non-surgical method of termination of pregnancy using a drug or combination of drugs. Medical second trimester abortion using Mifepristone and misoprostol is becoming more acceptable as it is technically less demanding as compare to surgical method^[3]. Combination of mifepristone and misoprostol is recommended by WHO as the most secure and efficacious method of second trimester abortion

^[3].

Material and Methods

This tertiary hospital based prospective study was conducted on 110 women attending to the Department of Obstetrics and Gynecology, Zenana Hospital, S.M.S. Medical college, Jaipur for second trimester termination of pregnancy from 12-20 weeks during 2012-13. The sample size was calculated at 80% study power and alpha error of 0.05 assuming standard deviation for duration of induction to abortion interval of 5 hours and minimum difference to be detected of 2 hours. Thus sample size comes 100 which was enhanced to 110 assuming 10% drop out rates. After clearance from ethical committee and satisfying the inclusion criteria women were given medical abortion with mifepristone and oral misoprostol after written and informed consent.

Women received mifepristone 200 mg followed by oral misoprostol 400 μ g 3 hourly for 5 doses. Induction abortion

interval was defined as time interval between first dose of misoprostol and expulsion of fetus. Abortion was successful if products expelled within 24 hours without need of any other medication.

The data was analysed using Microsoft excel, SPSS 20 and primer. Mean, standard deviation and proportion were used to summarize study variable. Paired T test was used to compare data. 95% confidence interval

difference of mean was used. A p-value of < 0.05 was considered significant statistically.

Results

Table 1: Representing distribution of cases according to gestational age and gravidity

Characteristics	No. of women (n= 110)	%	P value
Gestational Age group (in weeks)			
12-16	45	40.91	NS
17-20	65	59.09	
Gravidity			
G1	28	25.45	NS
≥G2	82	74.55	

Table 2: Distribution of cases according to mean induction – abortion interval

Mean Induction- abortion interval (in hours)	No. of women (n=110)	Percentage
≤ 4	11	10.00
5-8	87	79.10
9-12	11	10.00
13-16	1	0.90
17-20	0	0.00
20-24	0	0.00
Total	110	100.00

CHI SQUARE- 90.147 d.f.=3

The mean Induction- abortion interval was 6.44 ± 1.79 hours.

Table 3: Shows the distribution of cases according to mean induction abortion interval for women with gestational age 12-16 weeks and for gestational age 17-20 weeks.

Gestational age (in weeks)	No. of women (n=110)	Induction-abortion interval (in hours)
12-16	46	6.67 ± 1.966
17-20	64	6.84 ± 1.529
		P=0.4, NS

Table 4: Shows distribution of cases according to mean Induction-abortion interval and gravidity

Gravidity	Number of women (n=110)	Induction- abortion interval in Hours
G1	28	6.63±1.457
≥G2	82	6.51± 1.962

Table 5: Distribution of cases according to dose of Misoprostol required.

Dose of misoprostol (in µg)	Number of women (n=110)	Percentage
1	4	3.64
2	53	48.18
3	47	42.73
4	5	4.54
5	1	0.91
TOTAL	110	100

CHI SQUARE=73.2 d.f.=4

Table 6: Distribution of cases according to mean dose of misoprostol, gravidity and gestational age

Variables	No of women (n=110)	Mean dose of misoprostol (µg)
Gravidity		
G1	28	1009.5 ± 277.6
≥G2	82	900 ± 309.1
		P=0.9, NS
Gestational age (in weeks)		
12-16	46	1006.0 ± 312.7
17-20	64	1000.0 ± 246.8
		P=0.9, NS

Table 7: Distribution of cases according to success rate, need for evacuation, acceptability and side –effects and mean Haemoglobin

Variables	No. of women (n=110)	Percentage (%)
Successful rate		
Successful abortion	110	100
Failure	0	0
Need for evacuation		
Required	4	3.64
Not required	106	96.36
Acceptability		
Fairly acceptable	100	100.00
Difficult to tolerate	0	0.00
Side-effects		
		P value
Pain	38	34.50 NS
Nausea/vomiting	38	34.50 NS
Headache	19	17.30 NS
Diarrhoea	19	17.30 NS
Fever	1	0.90 NS
Mean Haemoglobin level	Before abortion	After abortion P value
	10.16±1.248	9. 815± 1.138 NS

Discussion

The mean gestational- age in our study was 17.34 ± 2.181 weeks. The results were similar to the study done by Tang Os *et al.* [4] where mean gestational age was 15.2 ± 1.4 weeks. The results were consonant to the study done by Gomez O, *et al.* [5] They reported mean gestational age of 18.0 weeks. Our results were comparable to study done by Suk Wai Ngai *et al.* [6] where mean gestational age was 16.2± 1.9 weeks. In the study done by Tripti Nagaria *et al.* [7] mean gestational age was 16.04 ± 2.57 weeks.

The mean gravidity in our study was 2.13 ± 0.791 . In a similar study done by Tripti Nagaria *et al.*^[7] the mean gravidity in similar population was 3.62 ± 1.35 years.

The Induction- abortion interval in our study was 6.44 ± 1.79 hours. In our study 10% women aborted in ≤ 4 hours, 89% women got aborted in ≤ 12 hours, and 100% women got aborted in 24 hours. The results were similar to study done by Tang Os *et al.*^[5] they reported mean induction abortion interval of 7.5 hours, 15% women got aborted in ≤ 4 hours, 63% women got aborted in 12 hours and 85% got aborted in 48 hours. The results were consonant with the study done by Ngai *et al.*^[6] where mean induction- abortion interval was 10.4 hours. In a similar study done by Devendra Kushwaha *et al.*^[8] who found the mean induction- abortion interval was 9.44 ± 5.61 hours.

The mean induction- abortion interval for gestational age 12-16 weeks and 17-20 weeks was 6.67 ± 1.966 hours and 6.84 ± 1.529 hours respectively in our study. The results were consonant with the study done by Gomez O *et al.*^[5] where reported mean induction- abortion interval for gestational age 12-16 weeks and 17-20 weeks were 8.2 hours and 7.8 hours respectively.

In our study the mean induction abortion interval for primigravida was 6.63 ± 1.457 hours and for multigravida was 6.51 ± 1.962 hours. The results were congruent with the study done by Tang Os *et al.*^[4] who found the mean induction abortion interval in primigravida was 8.3 hours and in multigravida was 7.5 hours. The results were similar to study done by Manninen HJ *et al.*^[9] they reported induction abortion interval ≤ 8 hours.

In our study mean dose of misoprostol required was 1003.6 ± 274.9 μg . The mean dose of misoprostol in primigravida was 1009.5 ± 277.6 μg and in multigravida was 900 ± 309.1 μg . The results of our study were similar to Ngai *et al.*^[6] who reported mean dose of misoprostol was $1200\mu\text{g}$ and dose misoprostol required in primigravida and multigravida were $1729 \pm 1084\mu\text{g}$ and $1745 \pm 1200\mu\text{g}$ respectively.

In our study 95.55% women got aborted with 3 doses of misoprostol and 5.45% women required upto 5 doses. The result of our study were consonant with study done by Devendra Kushwaha *et al.*^[8], where 90% women got aborted with 3 doses of misoprostol and 10% women required 4 doses.

In our study success rate was 100%. The result were similar to Tang Os *et al.*^[4], who reported 85% success rate in their study. In another consonant study by Devendra Kushwaha *et al.*^[8], 84% success rate was reported. 100% success rate was also reported by Tripti Nagaria *et al.*^[7]

4 women in our study required evacuation i.e. 3.64%. The result were comparable to study done by Tang Os *et al.*^[4], where 11.7% i.e 7 women required surgical evacuation.

The mean Haemoglobin level before and after abortion in our study were 10.16 ± 1.248 gm% and 9.815 ± 1.138 gm% respectively. The results were comparable to study done by Tang Os *et al.*^[5], where mean Haemoglobin before and after abortion was 11.3gm% and 10.8 gm%. In a similar study done by Devendra Kushwaha *et al.*^[8] 46% women in oral misoprostol group has blood loss < 1 gm%.

The acceptability in our study was 100%. In a similar study done by Devendra Kushwaha *et al.*^[8] acceptability of oral misoprostol was 72%. Suk Wai Ngai *et al.*^[6] reported 82% acceptability of oral misoprostol.

The most common side effect in our study was pain (34.5%) and

nausea/vomiting (34.5%). Headache (17.3%), diarrhoea (17.3%), and fever (0.90) are other side effects noted. The results were comparable to study done by Tang Os *et al.*^[4], they reported nausea (43.3%) and fatigue (46.7%) as most common side effects. Other reported side –effects in their study was headache (23.3%), diarrhoea (21.7%), pain (28.3%) and fever (0%). The result were similar to study done by Suk Wai Ngai *et al.*^[6], the side effect reported in their study was nausea (21.4%), vomiting (11.4%), lower abdominal pain (15.7%), diarrhoea (1.4%) and headache (8.6%). The results were congruent with the study done by Devendra Kushwaha *et al.*^[8], they reported nausea (34%), vomiting (22%), diarrhoea (48%), and fever (20%).

Conclusion

Thus we conclude that mifepristone followed by oral misoprostol is highly potent and effectual method for second trimester abortion.

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