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A Comparative Study of Mifepristone and Misoprostol Versus Misoprostol in Second Trimester Termination of Pregnancy

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ABSTRACT

Objective : To assess and compare the efficacy and safety of Mifepristone and Misoprostol versus Misoprostol in second trimester termination of pregnancy.

Methods : This comparative study was conducted in the Department of Obstetrics and Gynaecology, S.M.S. Medical College, Jaipur for Mid – trimester termination of pregnancy. Women admitted for MTP were randomly allocated into two groups of 50 cases each. Group A women received 200 mg oral Mifepristone followed vaginal Misoprostol 400µg three hourly for a maximum of 5 doses 24 hrs later. Group B women received vaginally Misoprostol 400µg three hourly for a maximum of 5 doses. The results were analyzed in both groups.

Results : The mean Induction – abortion interval of Group-A was 7.080± 2.19 hrs and Group-B was 13.420 ± 3.79 hrs. The mean dose of Misoprostol in Group-A was 888.0 ± 381.53 µg and in Group-B was 1536 ± 355.57 µg. Success rate was 100% in both regimens. Among the side effects fever was significantly more common in Group-A as compare to Group-B probably due to increase dose of Misoprostol.

Conclusion : From our study we conclude that, Among the two methods, Mifepristone followed by Misoprostol was more effective with a shorter induction-abortion interval and fewer side effects. However, Misoprostol is also effective in case where Mifepristone is not available or affordable.

KEYWORDS Second trimester abortion, Mifepristone, Misoprostol

INTRODUCTION

Abortion is defined as termination of pregnancy prior to 20 weeks of gestation or fetus weighing <500 gm.[1]

In India, MTP Act, 1971 allows termination of pregnancy upto 20 weeks of gestation under specified conditions. However, the opinion of two registered medical practitioners (RMP's) is required to terminate a second trimester pregnancy.[2]

Midtrimester termination of pregnancy has to be done when the woman delays in seeking advice, due to ignorance, psychological factors, socio-cultural problem, late identification of medical disorders and fetal abnormalities.

Thus it is essential that second trimester abortion services are available and accessible as a critical component of reproductive care. Provision of safe second trimester abortion ensure, women to make decision about their reproductive health need.[2]

Midtrimester abortion can be carried out by either surgical or by medical methods. Medical abortion is becoming more popular nowadays, as a method of termination of pregnancy in the second trimester, as it is effective and technically less demanding when compared to surgical methods.[3]

The advantage of medical abortion include, no anaesthesia, no surgery, no surgical trauma leading to life threatening problems like uterine perforation and bowel injuries.

Mifepristone plays primary role in second trimester abortion is to prepare the cervix, to sensitize the uterus to prostaglandins and thus making administration of Misoprostol more effective. Misoprostol serves to dilate the cervix and induce uterine contraction.[4]

WHO recommend the combined use of Mifepristone and Misoprostol as the safest and most effective method of second trimester pregnancy termination.[3]

METHODS

This hospital based comparative study was conducted on 100 women attending in the Department of Obstetrics & Gynaecology, Zenana Hospital, SMS Medical College, Jaipur for mid-trimester termination of pregnancy between 13-20 weeks of gestational age. After taking informed consent and proper counselling detailed history was taken and thorough general, abdominal and pelvic examination was done. After satisfying inclusion criteria, women were recruited for our study and allocated in respective groups.

Group A : Women received 200 mg oral Mifepristone followed by vaginally Misoprostol 400 μg every 3 hourly for a maximum of 5 doses 24 hrs later.

Group B : Women received vaginally Misoprostol 400 μg every 3 hourly for a maximum of 5 doses.

The course of Misoprostol was repeated if the woman fails to abort within 24 hrs of Misoprostol. The women were closely monitored for the onset of contraction, bleeding, cervical dilatation and side-effects each time before insertion of Misoprostol.

The induction-abortion interval was defined as the interval between the time of administration of the first dose of Misoprostol to the time when the fetus aborted.

Successful abortion was defined as abortion occurring within 24 hrs without the need for further prostaglandins or oxytocin. In case of failure another method was used. The data were analyzed in both groups.

RESULTS

In our study mean induction-abortion interval of Group-A was 7.080 ± 2.19 hrs and of Group-B was 13.420 ± 3.79 hrs. Induction-abortion interval of Group-A was significantly shorter than Group-B (P< 0.001) (Table-1).

The mean dose of Misoprostol in Group-A was 888.0 ± 381.53 μg and in Group-B 1536 ± 355.57 μg. Less doses were required among Group-A as compared to Group-B (p < 0.001).

In Group-A, 22% women got aborted with single dose of Misoprostol and 46% required 2 doses of Misoprostol and 22% required 3 doses of Misoprostol, 8% required 4 doses and only 2% required 5 doses of Misoprostol, whereas in Group-B 36% women required 3 doses of Misoprostol, 32% required 4 doses of Misoprostol and 28% required 5 doses of Misoprostol and only 4% required 2 doses of Misoprostol. There was no woman in Group-B who required single dose of Misoprostol for abortion (Table-2).

Most common side effect in Group-A and Group-B was fever (28% and 50% respectively) followed by nausea/vomiting (26% and 40% respectively), pain (26% and 34% respectively), diarrhoea (18% and 32% respectively) and headache (20% and 18% respectively). In above mentioned variables p-value > 0.05 and the difference was statistically not significant except fever where the p-value = 0.04 which was statistically significant (Table-3).

DISCUSSION

The combination of Mifepristone and Misoprostol is now an established and highly effective and safe method for medical method second trimester abortion.

Various studies conducted so far reached to the final conclusion that addition of Mifepristone for second trimester termination significantly reduces the induction-abortion interval with fewer side effects and requiring less dose of Misoprostol.

Future studies should focus on improving pain management, the treatment of women with failed medical abortion after 24 hrs and the safety of medical abortion regimens in women with a previous caesarean section or uterine scar.

Our study offers a reliable, safe and cost effective option by combining Mifepristone before Misoprostol to decrease the induction-abortion interval.

CONCLUSION

Second trimester termination of pregnancy using combination of Mifepristone and Misoprostol is a safe, non-invasive, highly cost-effective method with a high success rate and short induction-abortion interval. Pretreatment with Mifepristone adds to the effectiveness of the Misoprostol as an abortifacient.

WHO recommend the combined use of Mifepristone and Misoprostol as the safest and most effective method of second trimester pregnancy termination.

In our study we conclude that among the two methods, Mifepristone followed by Misoprostol was more effective with a shorter induction-abortion interval and fewer side effects. Misoprostol is also effective in case where Mifepristone is not available or affordable.

TABLES

Table – 1
Distribution of Cases According to Mean Induction-Abortion Interval

Induction-Abortion Interval (in hrs)	Group-A		Group-B	
	No.	%	No.	%
□4	5	10.00	0	0.00
5 - 8	33	66.00	3	6.00
9 - 12	10	20.00	19	38.00
13 - 16	2	4.00	14	28.00
17 - 20	0	0.00	13	26.00
21 - 24	0	0.00	1	2.00
Total	50	100.00	50	100.00

$\chi^2 = 55.793$ d.f. = 6
$p < 0.001$ Sig

Mean ± SD (Group-A) = 7.080 ± 2.19 hrs

Mean ± SD (Group-B) = 13.420 ± 3.79 hrs

Table – 2
Distribution of Cases According to Mean Dose of Misoprostol

Dose of Misoprostol Required (in μg)	Group-A		Group-B	
	No.	%	No.	%
400	11	22.00	0	0.00
800	23	46.00	2	4.00
1200	11	22.00	18	36.00
1600	4	8.00	16	32.00
2000	1	2.00	14	28.00
Total	50	100.00	50	100.00

$\chi^2 = 48.796$ d.f. = 4
$p = 0.000$ HS

Mean ± SD (Group-A) = 888.0 ± 38.153 μg

Mean ± SD (Group-B) = 1536 ± 355.57 μg

Table – 3
Distribution of Cases According to Side Effects

Side Effects	Group-A		Group-B		P-value, LS
	No.	%	No.	%	
Pain	13	26.00	17	34.00	0.51, NS
Nausea / Vomiting	13	26.00	20	40.00	0.202, NS
Headache	10	20.00	9	18.00	1.0, NS
Diarrhoea	9	18.00	16	32.00	0.16, NS
Fever	14	28.00	25	50.00	0.04, Sig

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