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Study of Efficacy and Success Rate of Single Dose Oral Mifepristone and Vaginal Misoprostol vs Vaginal Misoprostol alone for Second Trimester Termination of Pregnancy

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1. Introduction

Abortion is defined as 'termination of pregnancy (TOP) by any means before the fetus is viable'. Medical abortion is becoming popular nowadays as a method of termination of pregnancy in the second trimester because it is effective and technically less demanding when compared to surgical methods. Second trimester or mid trimester is a period ranging from 13 to 28 weeks of gestation, which again is subdivided into an early period between 13 to 20 weeks and a late period between 20 to 28 weeks.[1]

Abortion in India is legal only up to twenty weeks of pregnancy under specific conditions and situations which are broadly defined as The Indian abortion law which falls under the Medical Termination of Pregnancy (MTP) Act, which was enacted by the Indian Parliament in the year 1971 with the intention of reducing the incidence of illegal abortion and consequent maternal mortality and morbidity[2]. The MTP Act came into effect from 1 April 1972 and was amended in the years 1975 and 2002. Medical methods of abortion have been proved to be safe and effective. Mifepristone combined with Misoprostol is already an established regime for second trimester termination of pregnancy up to 63 days in India. The use of both these drugs i.e., Mifepristone followed by Misoprostol is likely to improve the efficacy of Misoprostol in the second trimester termination of pregnancy.

2. Aims and Objectives

To study the efficacy and the success rate of single dose oral Mifepristone plus vaginal Misoprostol versus vaginal Misoprostol alone for second trimester termination of pregnancy.

3. Materials and Methods

Study Design: A prospective randomized control study
Study Site: Department of Obstetrics and Gynaecology, OPD, DHIRAJ HOSPITAL, PIPARIYA, VADODARA
Size: 144 random cases attending the Obstetrics/ Gynaecology OPD of Dhiraj hospital from August 2018 to January 2019. Healthy women, fitting in the given below criteria requesting for termination of pregnancy between 12 to 20 weeks were selected.

Selection Criteria

a) Inclusion Criteria

- Women between gestational age > 12 weeks and < 20 weeks of gestation.
- Women with or without a congenital anomaly of the fetus.

b) Exclusion Criteria

- Women with previously scarred uterus
- Women presenting with bleeding disorders, inherited Porphyria.
- Women with anemia (Hb < 10g/dl)
- Women with uterine or vaginal infection.
- Any known allergy to the study medication.
- Women with congenital malformations of the uterus.
- Women with cardiac or bronchial asthma.
- Women with multiple pregnancy and missed abortion.

Group A (study group) - received 200mg of oral Tablet Mifepristone followed 48 hours later by **400ug** of vaginal misoprostol which was repeated every 4 hourly by **200ug** of vaginal misoprostol up to a maximum of 4 doses and any dose more than this was considered as an additional dose.

4. Results

Table 1(a): Induction abortion interval after administration of misoprostol

Induction Abortion Interval(In Hours)	Study Group N=72	Control Group N=72
1-5 Hrs	29 (40.3%)	01 (1.4%)
5-10 Hrs	42(58.3%)	33(45.8%)
10-15 Hrs	01(1.4%)	34(47.2%)
15 ad Above	0(0%)	04(5.6%)
Total	72(100%)	72(100%)

Group B(Control group) - received 400ug of vaginal misoprostol directly and the dose was repeated every 4 hourly by 200ug of vaginal misoprostol up to a maximum of 4 doses and any dose more than this was considered as an additional dose.

The side effects such as nausea, vomiting, fever were recorded. The blood pressure, pulse and frequency of uterine contractions and amount of blood loss were monitored. After abortion, the products of conception were examined to see whether the abortion was complete. Rh antibody was given

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to Rh negative mothers.The induction abortion interval was defined as the time of administration of first dose of misoprostol to the time when the fetus was aborted. The number of doses of misoprostol required was calculated and recorded.

Table 1 (b)

Induction Abortion Interval (I-A-I)	Group	N	Mean	SD	P Value
	Study	72	6.2	2.1	<0.01
	Control	72	10.8	2.5	

Table 1 (c)

Induction Abortion Interval In Hours	Study Group (N=72)		Control Group (N-72HRS)	
	PRIMI	MULTI	PRIMI	MULTI
1-5 HRS	7	22	NIL	1
5-10 HRS	7	35	9	24
10-15 HRS	NIL	1	14	20
>15 HRS	NIL	NIL	NIL	4
TOTAL	72		72	

Table 2: Distribution of study subjects according to dosage of misoprostol needed for complete abortion

Dose of Misoprostol	Cumulative Dose of Misoprostol	Study Group (N=72)	Control Group (N=72)	pvalue
First (400 ug)	400ug	12 (16.60%)	00 (0%)	<0.00001
Second(200ug)	600 ug	48 (66.66%)	09 (12.5%)	
Third (200ug)	800 ug	11 (15.27%)	42 (58.33%)	
Fourth (200ug)	1000 ug	01 (1.38%)	21 (29.16%)	
Total		72 (100%)	72 (100%)	

Table 3: Distribution of study subjects according to the completeness of abortion and requirement of any additional procedure

Completeness of Abortion	*Study Group*	*Control Group*	*Total*
Complete	71(98.6%)	61(84.7%)	132(91.7%)
Incomplete	01(1.4%)	11(15.3%)	12(8.3%)
Total	72(100%)	72(100%)	144(100%)
	P VALUE	<0.01	

Table 4: Distribution of study subjects depending on the amount of blood loss and requirement of a blood transfusion

Blood Loss	Study Group	Control Group	Total
<500CC	72(100%)	71(98.6%)	143(99%)
>500CC	0(0%)	01(1.4%)	01(0.7%)
TOTAL	72(100%)	72(100%)	144(100%)

5. Discussion & Conclusion

The study compared the difference between the Induction abortion interval, dose of misoprostol required, completeness of abortion & requirement of any additional procedure and the amount of blood loss in second trimester abortions.

There was no significant difference in the prevalence of gastrointestinal side effects between the two groups.

1) **Induction Abortion Interval**
Pre- induction with Mifepristone significantly reduces the induction abortion interval in second trimester abortions which is 3-10 hrs in study group and 4-15 hrs 30mins in the control group.

2) **Dose of Misoprostol**
In our study the amount of misoprostol required in patients pre induced with mifepristone was significantly lower i.e. 600ug as compared to patients who aborted with misoprostol alone (1600ug).

3) **Completeness of procedure and requirement of any additional procedure**
Higher rates of complete abortion were seen in the study group (98.6%) as compared to control group(84.7%) and also the requirement of check curettage was less in the study group. Hence, the associated complications like bleeding, perforation, intestinal injury, sepsis & post operative morbidity were also less.

4) **Pain**
With mifepristone and misoprostol combination pain suffered is less as compared to the use of misoprostol alone as mifepristone causes cervical ripening & makes the cervix soft by sensitizing it to prostaglandins (i.e. misoprostol)

5) **Amount of blood loss and requirement of a blood transfusion**
In our study only one patient from the control group had a significant amount of blood loss which was calculated clinically to be more than 500 cc.

6. Conclusion

- Pre-induction with Mifepristone in the second trimester termination of pregnancy is highly successful and has a very good outcome with a lesser Induction abortion interval considering all the aspects mentioned before. This will not only help in reducing the morbidity related to larger doses of misoprostol required in second trimester but also in better patient compliance and relatively shorter hospital stay a nd being cost effective too.
- Hence, this method should be routinely carried out in all Tertiary care Centers for second trimester termination of pregnancy which is a safe procedure, simple and easy to perform in our setup

Shock index of all patients was calculated and it was found that patients with shock index > 0.9 were given blood transfusion.
The same patient had an incomplete abortion requiring check curettage & so this patient needed blood transfusion and a longer duration of stay in the hospital.

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