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Comparative Study of Mifepristone Plus Vaginal Misoprostol Versus Vaginal Misoprostol Alone for Second Trimester Abortion

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ABSTRACT

This study compares the efficacy of mifepristone – vaginal misoprostol combination with vaginal misoprostol alone as a method of second trimester abortion using a prospective comparitive study design. . Misoprostol, although being used routinely for second trimester MTP has the disadvantages of long induction-abortion interval, more chances of incomplete abortion and high failure rate. Recently, Mifepristone and Misoprostol combination has been found to be very effective in the termination of second trimester pregnancy with short induction-abortion interval and high success rate inspite of its high cost.

KEYWORDS II trimester Abortion, Mifeprestone , Misoprostol

INTRODUCTION

The various methods used for second trimester termination of pregnancy are undergoing critical appraisal worldwide. The present study done at Institute of Obstetrics and Gynaecology, Egmore, was a randomized comparative study of 100 patients with gestational age between 14-20wks admitted for unwanted pregnancy or anomalous fetus.

MATERIALS AND METHODS

This study compares the efficacy of mifepristone – vaginal misoprostol combination with vaginal misoprostol alone as a method of second trimester abortion conducted at Institute of obstetrics and Gynaecology, Chennai, during October 2009 – October 2010.

Study design: Prospective randomized comparative study.

Sample Size: 100 (Randam allocation to either group),

50 – mifepristone + vaginal misoprostol group,

50 – vaginal misoprostol group

Inclusion Criteria:
14 – 20 weeks gestation, Woman full filling the MTP indicators as per the MTP act ,Single live fetus, Present with closed cervical os, No vaginal bleeding and Patients consenting to this procedure only.

Exclusion Criteria :
History of previous uterine surgery (but not a contraindication), Known allergy / Contraindications to mifepristone (or misoprostol / prostaglandin), Multiple fetus, Intra uterine fetal demise, Presentation in active labour, Low lying placenta.

METHODOLOGY:
Mifepristone – misoprostol group:

Dosage schedule:
Day I: 200mg mifepristone was given orally and after 36 hrs misoprotol 800mcg administered vaginally .3 hrs Later Misoprostol 400 mcg vaginally every 3 hrs Until delivery (or total of 4 doses). If undelivered 3 hrs after 4th dose repeat mifepristone 200mg and resume induction next day or consider surgical abortion

Misoprostol group:
800mcg misoprostol moistoned with saline inserted in posterior vaginal fornix , 3hrs later misoprostol 400mcg vaginally every 3hrs until delivery or total of 4 doses. Additional measures were adopted in patients with incomplete abortion like instrumental evacuation, oxytocin infusion. In patients who failed to expel at the end of 48hrs further management was determined by the unit policy. Check USG done next day after expulsion to exclude retained products. If determined products present further management done .

OUTCOME
COMPLETE: When both placenta and fetus were expelled in 48 hours.

INCOMPLETE: When either placenta or fetus was retained.

FAILED: Neither fetus nor placenta was expelled.

PARAMETERS STUDIED:
1. Induction - Abortion Interval ,Complete abortion rate, Success rate ,
2.Side Effect ProfileVomiting , Diarrhoea, Fever, Headache, Rigor, Hemorrhage,Infection
3. Total Number of Misoprostol Doses Required
4. Need For Additional Procedures Like Curettage , Misoprostol or Oxytocin
5. Requirement Of Transfusion
6. Cost in both groups

Data was analyzed using SPSS software using ANOVA, Independent sample test and Chi-Square test and significant p-value being less than 0.05.

OBSERVATIONS
PARAMETERS STUDIED
INDUCTION-ABORTION INTERVAL
Mean Induction-Abortion (I-A) interval in mife+miso group was 8.2 hrs and in miso group was 12.8 hrs. The difference between them was found to be statistically significant (p value 0.000). I-A Interval is shortened in Multigravida Compared to Primigravida in both groups. In Mife+miso group it is statistically significant (P Value 0.01)

TABLE 1: DOSES REQUIRED

	Method group	N	Mean	Std. Deviation	Std. Error mean
Total dosage	Mife+miso	50	1376.0000	512.12243	72.42505
	Miso only	50	1992.0000	438.84821	62.06251

TABLE 2:Repeat Dose of Misoprostol Required for Abortion

Mode	Number of doses				
	0	1	2	3	4
Mife+Miso	15	14	8	10	3
Miso	0	7	9	12	22

The Repeat dose required in mife+miso group was lesser while that in the miso group was comparatively more.

TABLE 3: OUTCOME IN BOTH GROUPS

	Mife+Miso Group		Miso Group		p - Value
	N	%	N	%	
Complete	45	90	36	72	0.53 (NS)
Incomplete	5	10	12	24	
Failure	0	0	2	4	

The percentage of complete abortion in Mife + Miso group was 90% while that in Miso group was 72%.The difference between the two group was not statistically significant. The percentage of incomplete abortion was 10% in Mife + Miso group and 24% in Miso group which was not statistically significant. There is no failure in Mife + Miso group and 4% in miso group which was not significant statistically.

TABLE 4: SUCCESS RATES IN BOTH GROUPS

Hours	Mife+miso group	Miso group
0-<12 hours	38	18
12-24 hours	12	30
25-36 hours	-	-
37-48 hours	-	-
Failure		2

ADDITIONAL INTERVENTIONS

Overall 10% in mife + miso group and 28% patients in miso group required some form of interventions for completion of the abortion process. The commonest intervention in both group was instrumental evacuation. Additional procedures like CUT insertion and tubectomy done in multigravida. There was no incidence of postprocedural infections or sepsis in either group.

ANALYSIS OF SYMPTOMS

There was no statistically significant side effects between two groups. Side effects were treated symptomatically and no major complications were found in both groups.

COST INCURRED IN BOTH GROUPS

In this study, the minimum cost per dose of Mife + Miso group was Rs.427 while that of misoprostol group was Rs.117. The average cost in this study in Mife + Miso group was

Rs.483.16 and Rs.194.22 in miso group.

DISCUSSION

Patient Characteristics

Age: In this study, the mean age of patients in mifepristone + misoprostol group was 24.9 years with a range of 16-35 years and the mean age of patients in misoprostol group was 25.1years with a range of 18-36 years. There was no association between advancing maternal age and induction abortion rates or complete abortion rates in our study. This was comparable to the study of KAPP, NATHALIE MD, MPH45 the mean age of mifepristone + misoprostol was 25.7 years and that in misotropol was 25.5years. In the study of JAN E DICKINSON the mean age of mifepristone + misoprostol was 32 years and that of misoprostol was 32 years.

Gravida: In the present study at least one prior delivery accounted for 24% in the mifepristone + misoprostol group and 34% in the misoprostol group. In the study of JAN E DICKINSON mifepristone + misoprostol group was 57.8% and misorpostol group was 60.3%.

Gestational age: In the present study, the mean gestational age in mifepristone + misoprostol group was 18.08 weeks while that in misoprostol group was 18.44 weeks. In the study of JAN E DICKINSON46 the mean gestational age was 19.1 weeks in mifepristone + misoprostol group and 19.6 weeks in misoprostol group.

Indication: In this study, the most common indication for pregnancy termination was unwanted pregnancy and it accounts for 66% in both groups and it is comparable with other studies.

Parameters Studied :

Induction abortion: In the present study the mean induction abortion interval was 8.2 hrs for mifepristone + misoprostol group and 12.8hrs for misoprostol group which was statistically significant (<0.000) In the study of JAN E DICKINSON46 the mean induction abortion interval was 8.6hrs for mifepristone + misoprostol group and 15.5hrs for misoprostol group.

OUTCOME:

The success rate at less than 12 hrs was 76% with in mifepristone + misoprostol group and 36% with in misoprostol group which is greater than most of the observations in other studies probably because of the high dose and shorter dosing interval. But the final success rate at

24hrs and 48 hrs in the present study was 100% with mifepristone + misoprostol group and 96% in misoprostol group which is comparable to other studies.

CONCLUSION

Comparing Mifepristone and Vaginal misoprostol combination with vaginal misoprostol alone for second trimester pregnancy termination, it was observed that Mifepristone with vaginal misoprostol combination group is associated with shorter induction abortion interval and 100% success rate. The complete abortion rate , success rate and side effects were comparable in both group. Vaginal misoprostol alone group also dosen't have the 36 hours anxiety/unease from the time of mifepristone administration. Vaginal misoprostol alone group is cost effective.

Hence vaginal misoprostol alone group can also be considered as an effective alternative for Mifepristone and vaginal misoprostol combination group.

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