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A COMPARISON OF MIFEPRISTONE AND VAGINAL MISOPROSTOL IN FIRST TRIMESTER ABORTION OVER VAGINAL MISOPROSTOL ALONE

Obstetrics & Gynaecology

Dr. Khedkar Amit* Resident, Kalpana Chawla Government Medical College, karnal, Haryana. *Corresponding Author

Dr. Kansal Richa Professor& HOD, Kalpana Chawla Government Medical College, Karnal, Haryana.

Dr. Bansal Isha Associate professor, Kalpana Chawla Government Medical College, Karnal, Haryana.

ABSTRACT

Introduction: The MTP Act may help reduce maternal mortality and morbidity by promoting safe abortion. Where it is legal, abortion is generally safe, but when it is not, issues arise frequently, and each year, 78 000 people pass away as a result of these complications. **Aims:** To determine if mifepristone and misoprostol together are effective for first-trimester abortion, To contrast the effects of this mixture with those of vaginal misoprostol alone for first trimester MTP and to compare the different MTP parameters used by the two procedures and determine which one is best for MTP in the first trimester. **Materials And Methods:** The present study was a comparative study. This Study was conducted from June 2021 to May 2022 at Department of Obstetrics and gynaecology. 200 patients were included in this study. **Result:** In our study, 16% of the women who received the combination of mifepristone and misoprostol were over 30 years old, whereas only 8% of the women receiving the combination were under 20. The change is insignificant (p = 0.001) in this case. 60% of the women in the mifepristone + misoprostol group had gestations under 45 days, while only 10% had gestations above 56 days. In contrast, 56% of the women in the misoprostol group had gestations between 45 and 56 days. The shortened interval in the mifepristone-misoprostol group is significantly shorter when the induction abortion interval between the two drugs is compared to that of misoprostol alone, as shown by the p value of 0.000. Vomiting occurred in 8% of the women using mifepristone plus misoprostol and in 2% of the women taking misoprostol, although prolonged bleeding did not occur in either group of women. **Conclusion:** Misoprostol and mifepristone are the most effective at-home management options for early MTP and are an effective outpatient treatment. The rate of complete abortion is high with this combination. Additionally, this method reduces the time between induction abortions.

KEYWORDS

Misoprostol, Mifepristone, Second trimester and Termination.

INTRODUCTION

The MTP Act may help reduce maternal mortality and morbidity by promoting safe abortion.

Where abortion is permitted, it's generally safe, but where it's prohibited, complications are common and 78 000 people pass away every year as a result of them.

Regardless of individual views on the morality of ending pregnancies, professionals have a duty to be aware of the medical realities surrounding abortion and to share those facts with their patients.

The World Health Organization considers 46 million abortions, or about half of all abortions done worldwide each year, to be "unsafe" and unlawful.

The term "unsafe abortion" refers to a "procedure for terminating an unwanted pregnancy, either by a person lacking the necessary skills or in an environment lacking the minimal medical standards, or both."

GLOBAL ABORTION SCENARIO

Of the 210 million pregnancies that occur each year around the world, 46 million (22%) result in induced abortions, of which 20 million are deemed to be dangerous.

The majority of women should have at least one abortion by the time they are 45 years old. It is unfortunate and depressing to observe that one unsafe abortion is still carried out for every seven live births, despite more relaxed abortion rules.

INDIAN ABORTION SCENARIO

With 3.1 lakh legal abortions performed each year, the abortion rate is 2.3% per 1000 pregnancies.

130 to 200 illegal abortions are performed for every 1,000 pregnancies, or an estimated 4.6 million each year.

MATERNAL MORTALITY

0.7 out of 100,000 people had legal abortions, while 500 out of 100,000 abortions were performed illegally.

The risk of mortality following complications from an improper abortion procedure is significantly higher in undeveloped countries than it is when the abortion was performed by a professional under safe conditions. Complications from unsafe abortions may have side effects like infertility, recurrent PID, TO mass, etc. Therefore, there is a pressing need for simple, safe early-induced abortion treatments. When performed by trained medical personnel utilizing the proper equipment, procedures, and standards, abortion is one of the safest medical procedures.

MATERIALS AND METHODS

The purpose of study is to compare the efficacy of mifepristone - vaginal misoprostol combination with vaginal misoprostol as a method of first trimester abortion.

Study Design: Comparative Study

Study place: Institute of Kalpana Chawla Government Medical College, karnal at Department of Obstetrics and gynaecology.

Study Population: Patients requesting MTP who attended family planning Dept. Obstetrics and gynaecology, Chennai.

Sample size: 200 (Random Allocation to either of groups)

100 - Mifepristone + Misoprostol Group 100 - Misoprostol Group

Year of Study: June 2021 to May 2022

Inclusion Criteria

1. Confirmed pregnancy up to 9 weeks
2. Single intra uterine live gestation
3. No other medical or surgical contra indication for the procedure.
4. Contraceptive failure.
5. MTP for social & eugenic causes.

Exclusion Criteria

1. Gestation age > 9 weeks
2. Women smoke > 10 cigarettes / day
3. Missed / incomplete / inevitable abortion
4. Suspected ectopic pregnancy
5. Any previous attempts at terminating the present pregnancy
6. Pregnancies with IUD in situ.

METHODOLOGY

All these women were thoroughly investigated before MTP. The work up included;

- Details of patient
- Investigations
- Examination of vital signs
- Abdominal and pelvic examination
- USG only on indication
- Counseling

RESULT

In both groups, 75% of the patients were between the ages of 20 and 30. In our study, 16% of the women who received the combination of mifepristone and misoprostol were over 30 years old, whereas only 8% of the women receiving the combination were under 20. The change is insignificant (p = 0.001) in this case.

Only 4% of women in the mifepristone + misoprostol group had an unmarried pregnancy, compared to 80% of women in both groups who were fertile. Everyone in the misoprostol group was married.

In both categories, 80% of the women have a socioeconomic grade of IV or V.

60% of the women in the mifepristone + misoprostol group had gestations under 45 days, while only 10% had gestations above 56 days. In contrast, 56% of the women in the misoprostol group had gestations between 45 and 56 days.

The shortened interval in the mifepristone-misoprostol group is significantly shorter when the induction abortion interval between the two drugs is compared to that of misoprostol alone, as shown by the p value of 0.000.

Complete abortion rates between the two groups significantly differed in favor of the combination of mifepristone and misoprostol.

Both groups demonstrated statistically significant incidence of side effects when comparing the relevance of variables in the symptoms. To corroborate the findings, nevertheless, a larger study would be needed (p = 0.001).

Vomiting occurred in 8% of the mifepristone + misoprostol group and in 2% of the misoprostol group, but not in either group did any women experience prolonged bleeding.

Table 1: Parity And Gestational Age

		Mifepristone + Misoprostol		Misoprostol	
		No. of Cases	%	No. of Cases	%
Parity	UMP	4	4	-	0
	Primi	8	8	8	8
	G_2	72	72	76	76
	G_3	16	16	16	16
Gestational Age	< 45 Days	60	60	36	36
	45 - 56 Days	30	30	56	56
	> 56 Days	10	10	8	8

Table 2: Induction Abortion Interval

Characters		Mifepristone + Misoprostol (in Hrs).	Misoprostol
Parity	UMP	5.00	-
	G1	5.00	20
	G2	4.00	18
	G3	3.30	12.40
GA	< 45	3.30 - 4.00	18
	45 - 56	4 - 4.30	18
	> 56 days	6.00	24

Table 3: Analysis Of Complete Abortion

Characters	Mifepristone + Misoprostol				Misoprostol				p value
	Incomplete Abortion		Method failure		Incomplete Abortion		Method failure		
	No. of Cases	No. of %	No. of Cases	No. of %	No. of Cases	No. of %	No. of Cases	No. of %	
Nullipara	0	0	0	0	0	0	0	0	0.000
Parous	4	8	2	4	48	96	10	20	

Table 4 : Analysis Of Symptoms And Post Abortive Complications

		Mifepristone + Misoprostol		Misoprostol	
		No. of Cases	%	No. of Cases	%
Symptoms	Symptom Free	0	0	0	0
	Abd / Ut. Cramps	60	60	32	32
	Excessive Bleeding	28	28	44	44
	Vomiting	8	8	24	24
	Dizziness	4	4	0	0
Conditions	Vomiting	8	8	2	2
	Persistent Bleeding	0	0	0	0

DISCUSSION

This study was conducted at Institute of Obstetrics and Gynaecology, June 2021 to May 2022. 200 Women were included in this study and the outcome analyzed using various parameters. The results were subjected to statistical analysis using the T-test-2 tailed one sample test and chi-square test.

In both groups, 75% of the patients were between the ages of 20 and 30. Women aged 35 years and above were not included in the original French study -**WHO-1994** [1]

In our study, 16% of women who received the combination of Mifepristone and Misoprostol were over 30 years old, while only 8% of those receiving the combination were under 20. The distinction is insignificant (p=0.001).

When parity of women seeking MTP in the first trimester was examined, it was discovered that more than 80% of patients were second-time mothers, while only 4% were single. The success rate of medical abortion is significantly influenced by parity.

Gestational age in nulliparous women has no bearing on the result of early pregnancy termination. However, when the gestational age was greater than 7 weeks, there were considerably decreased rates of complete abortion in nulliparous women.

This is a retrospective analysis of 3161 cases by **Bartley et al**[2]**.**
In the current study, 83% of the female participants from both groups were parents.

The reason behind these various observations at various gestational ages is still unknown. Parity does not have variable relevance.

Between 75 and 80 percent of the women in both groups belonged to socioeconomic classes IV and V because the majority of the women who visit our hospital are members of a marginalized group. Social and economic standing has no bearing on the result.

The most crucial factor in determining a successful outcome is gestational age.

There has been a lot of research on how long a pregnancy is and how successful MTP is. According to Kahn's meta-analysis, the rate of complete abortion is 96% when the amenorrheic period is less than 49 days, and it drops to 85% when the gestational age is greater than 57 days.

Spitz[3] also concur with other studies were it has been established that lesser the gestational age more is the success rate.

Our study compares favorably with existing studies, with a complete abortion rate of 94% when the amenorrheic phase is less than 49 days.

Induction Abortion Interval

According to **EL. Rafecy et al.**[4]**,** when misoprostol was supplied vaginally together with mifepristone, 93% of abortions took place within 4 hours, whereas 78% did so when misoprostol was taken orally.

Similar to the findings of **EL. Rafecy et al**[4]**,** the current investigation likewise demonstrates that the induction abortion interval is only 4 to 5 hours after vaginal injection of misoprostol.

When vaginal misoprostol alone was utilized for early MTP in this investigation, it was discovered that the induction abortion interval

was 23 to 24 hours in both nulliparous and parous women. Additionally, parous women experienced a higher expulsion rate than nulliparous women. Thus, the study's conclusions are comparable to those of studies by **Blanchard[5], Velazco [6], and Carboneil et al [7].**

None of the women in our study were Rh negative. Therefore, giving anti-D immunoglobulin was not necessary. Anti-D immunoglobulin 50 mcg should be given at the time of induction if the patient is Rh negative.

Therefore, compared to when misoprostol alone was given, the combined regimen has a higher rate of complete abortion with a shorter induction abortion interval.

ANALYSIS OF COMPLETE ABORTION

The mifepristone-misoprostol group in the current study had 4 occurrences of partial abortion; the technique failure rate was 2%; this suggests that additional procedures, such MVA, were utilized in these individuals. These findings were consistent with those of **El Refacy et al.**[4] who reported that the complete abortion rate for misoprostol in the first trimester MTP was 95% when administered vaginally and 87% when administered orally. This confirms that vaginal administration causes a complete abortion more frequently than oral administration. In a 1993 trial using the combination of mifepristone and misoprostol, **Peyron et al.**[8] observed 96.9% complete abortions and 0.8% incomplete abortions.

It was discovered that the complete abortion rate when misoprostol was taken alone for first trimester MTP was only 50%, with a significant rate of incomplete abortion and technique failure that made this regime unattractive.

Misoprostol has an 85% to 95% success rate when taken alone, according to a research by **Peyron et al[8].** This means that when used in conjunction with mifepristone, misoprostol is more successful than when used alone to induce a medical abortion.

All of these trials, including the current one, confirm that misoprostol alone or in combination with mifepristone causes more complete abortions in early pregnancy. Similar to this, a meta-analysis of 2000 patients shows that parous women in the misoprostol group have a higher rate of incomplete abortion.

This difference is statistically significant.

ANALYSIS OF SYMPTOMS

The symptoms were examined, and the study's findings are explained as follows:

8% of our patients experienced vomiting, compared to 15% in the **Cabeza et al.**[9] study9 from 1998. Only 28% of our patients experienced significant bleeding, despite Spitz6 reporting 100% hemorrhage in his trial. When misoprostol alone was used for MTP, there was a greater incidence of vomiting and bleeding (24 and 44%, respectively).

Although blood transfusion was a possibility in cases of significant or protracted bleeding, no such requirement emerged in our investigation. Blood loss, however, was not a frequent side effect in the WHO, 200030 research either.

Similar to the rate of pain described by **Cabaze et al.,** 60% of the women in our sample reported experiencing pain.[9] Even though many patients reported experiencing discomfort, it was not extremely severe. According to **Henshaw et al.,** pain and bleeding get worse as gestational age rises.[10]

ANALYSIS OF POST ABORTIVE COMPLICATIONS

In our study, 8% of the women in the Mifepristone + Misoprostol group experienced vomiting, compared to 2% of the women in the Misoprostol group. In either group, no patients reported chronic bleeding.

CONCLUSION

An efficient outpatient treatment for early MTP, misoprostol combined with mifepristone is best for at-home management.

With this combination, the rate of total abortion is high.

The induction abortion interval is also shorter using this procedure.

There are less additional related issues.

The cost, which is almost 20 times that of misoprostol alone, is the only confusing element.

As a result, where cost is not a factor or when an early abortion is necessary, the routine use of the mifepristone misoprostol combination for first trimester abortion is a viable alternative.

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