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COMPARATIVE STUDY OF VAGINAL MISOPROSTOL ALONE AND MIFEPRISTONE WITH MISOPROSTOL IN SECOND TRIMESTER MEDICAL TERMINATION OF PREGNANCY.

Obstetrics & Gynaecology

Dr. Rohidas P. Chavan Professor And Head, Department Of OBGY. Government Medical College, Akola December 2022 Associate Professor And Head, Department of OBGY, Shri Vasantrao Naik Government Medical College, Yavatmal.

Dr. Seema Balasaheb Wede Junior Resident 3rd Year Department Of OBGY Shri Vasantrao Naik Government Medicalcollege, Yavatmal

ABSTRACT

Background: Various medical methods for second-trimester medical termination of pregnancy (MTP) exist. The present study was undertaken to compare the efficacy of Mifepristone and Misoprostol combination and Misoprostol alone for second trimester termination of pregnancy. BTotal 50 participants were enrolled in the study and divided into 2 groups of 25 each. Group I was Vaginal Misoprostol and group II with Mifepristone +Vaginal Misoprostol. Induction Abortion Interval (IAI), complete abortion and success rate, side effects, complications and total number of misoprostol doses required were noted. **Results:** In group I, mean IAI was 723.2±223.8 and in group II it was 297.9±154.7, ($p<0.05$). The mean dose of Misoprostol in group I was 1756±171.4 microgram and in group II it was 1163± 241.8 microgram, ($p<0.05$). In group I, 21 and in group II 24 complete abortions, while only 4 in group I and 1 patient in group II with retained placenta, ($P<0.05$). In group I and group II the mean blood loss was 114±12.77 ml and 65.3±16.2 ml respectively, ($p<0.05$). In group I, 7 cases and in group II 18 cases have side effects respectively, ($p>0.05$). In group I, 4 cases had complications and in group II, only 1 case had complication $p>0.05$. Group I had good efficacy in 21 cases and group II had good efficacy in 24 cases, ($p>0.05$). **Conclusion:** The combination of mifepristone and misoprostol is now an established and highly effective method for second trimester abortion. Therefore, whenever possible, the combined regimen should be used. Where mifepristone is not available or affordable, misoprostol alone has also been shown to be effective, although a higher total dose is needed, and efficacy is lower than for the combined regimen.

KEYWORDS

Mifepristone; Misoprostol; Second trimester; Induction Abortion Interval; Efficacy

INTRODUCTION

Abortion is defined as the termination of pregnancy before the period of viability. Mid-trimester abortions (13-20weeks) constitutes about 10-15% of all induced abortions and it is also responsible for two-thirds of major abortion related complications. Nowadays due to widespread use of antenatal screening techniques in detecting pregnancies complicated by serious cardiovascular & skeletal malformations, there is gradual increase in second trimester termination of pregnancies [1]. With the global trend of raised cesarean section rate, obstetricians are faced with the challenge of termination of pregnancy in women with a scarred uterus. This becomes more and more challenging as the number of previous cesareans increases and there is no consensus on the safest method of therapeutic abortion in such patients [2].

Annually 46 million cases of induced abortion take place, out of which 26 million abortions are legalized. However, 6.7 million MTPs take place; out of which 40% pregnancies are unplanned and 25% are unwanted [1]. In spite of the law, there are abortions which are done by a less qualified person and unhygienic conditions There are various methods available for second trimester MTP.

Termination in second trimester could be surgical or medical. Medical methods used are Mifepristone and Misoprostol, Extra-ovular instillation of drugs like ethacridine lactate, hypertonic saline and prostaglandins and Intracervical or Extraovular instillation of cerviprime gel (PGE2). Mechanical methods used is Foley bulb induction alone or along with misoprostol. Surgical methods are Dilatation and Evacuation, and Aspirotomy [3].

However, over the last few decades, there have been continuing efforts to evaluate the various methods of termination in terms of effectiveness, its complications, acceptability of the methods and the ease of performance [4, 5]. Misoprostol is a synthetic prostaglandin E1 analogue. It was first used in obstetrics to induce abortion in 1985. Now it is widely used for induction of labour, termination of pregnancy and management of postpartum hemorrhage but still its use in obstetrics is not approved by FDA [6].

Moreover, the use of Misoprostol in termination of pregnancy is associated with safe abortion, reduces chances of long-term disability or death due to chronic health consequences of unsafe abortion, also reduced cost of the abortion specially for the societies with low-income countries. Hence the present prospective study was conducted to compare the efficacy of Mifepristone and Misoprostol combination and Misoprostol alone for second trimester termination of pregnancy.

MATERIALS AND METHODS

After obtaining Institutional Ethical Committee approval and written informed consent from all the patients, this Hospital based prospective observational study was performed in the Tertiary care center in central India. A total of 50 pregnant women between 14–20 weeks of gestation came for second trimester medical termination of pregnancy indicated as per MTP Act, with single live fetus, closed cervical OS, also with no vaginal bleeding and who were admitted in-the department of Obstetrics and Gynecology were included in the study. Patients with 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 and patients not willing to participate in the study were excluded.

Investigations including blood sugar and HB% were done. Outcome and progress of the patients were observed who were given Mifepristone and misoprostol or Misoprostol only. Various parameters have been studied were Induction - Abortion Interval, complete abortion rate, success rate, side effect profile (Vomiting, Diarrhea, Fever, Headache, Rigor, Hemorrhage, Infection), total number of misoprostol doses required, need for additional procedures like curettage, misoprostol or oxytocin, requirement of transfusion, and cost in both groups.

Outcomes Were-
Complete Abortion:
When both placenta and fetus expelled in 48 hours.

Incomplete Abortion:
When either placenta or fetus retained and

Failed:
Neither fetus nor placenta expelled.

Statistical Analysis
Data was entered into Microsoft excel data sheet and analyzed using SPSS 22 version software. Categorical data was represented in the form of Frequencies and proportions. Chi square test, Fisher Exact tests was used as test of significance for qualitative data continuous data was represented as mean and standard deviation. Unpaired t test

was used as test of significance to identify the mean difference between two quantitative variables for comparison. P value of 0.05 was considered as statistically significant after assuming all the rules of statistical tests.

OBSERVATIONS AND RESULTS

A total of 50 participants were enrolled in the study and randomly divided into 2 groups of 25 each. Group I have Vaginal Misoprostol and group II with Mifepristone + Vaginal Misoprostol. Both the groups were comparable and found no significant difference with respect to age distribution, gestational age and gravida with p value of >0.05 as shown in table 1.

Table 1: Age distribution, Gestational age, and Gravida of patients

Parameters		Group I	Group II	P value
Age in Year	20-25	14	13	>0.05
	25-30	10	10	
	>30	1	2	
Gestational age in Weeks	14 to 17	18	20	>0.05
	17to 20	7	5	
Gravida	Primi	10	8	>0.05
	Multi	15	17	

In group I, mean IAI was 723.2±223.8 min and in group II it was 297.9±154.7 min, this was statistically significant (p<0.05) as depicted in figure 1.

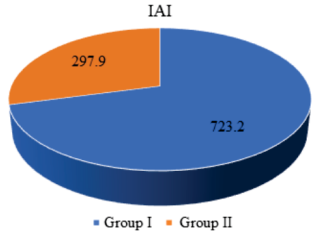

Figure 1: Mean induction abortion interval (IAI)

The mean dose of Misoprostol in group I was 1756±171.4 microgram and in group II it was 1163± 241.8 microgram, (p<0.05). In group I and group II the mean blood loss was 114±12.77 ml and 65.3±16.2 ml respectively, (p<0.05).

The Induction Abortion Interval (IAI) was noted in both the groups taking into consideration the gravida status and gestational age in weeks, both these parameters were highly significant with IAI, (p value=0.001), (Table 2).

Table 2: Association of IAI with gravida and gestational age in week

IAI in min		Group I	Group II	P value
Gravida	Primi	769.6±248.8	490.5±99.4	<0.001
	Multi	692.3±208.6	207±65.8	<0.001
Gestational age	14 to 17	711.1±214.6	290±155.4	<0.001
	17 to 20	754.2±261.4	326.6±166.1	<0.001

In group I, 21 and in group II 24 complete abortions, while only 4 in group I and 1 patient in group II with retained placenta, (P<0.05) as depicted in figure 2.

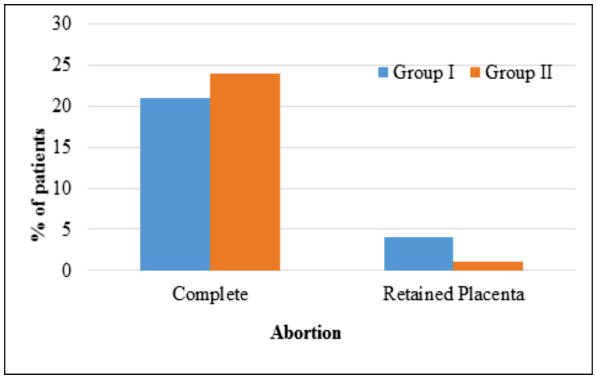

Figure 2: Success Abortion Rate

Group I had good efficacy in 21 cases and group II had good efficacy in 24 cases, (p>0.05) as shown in figure 3.

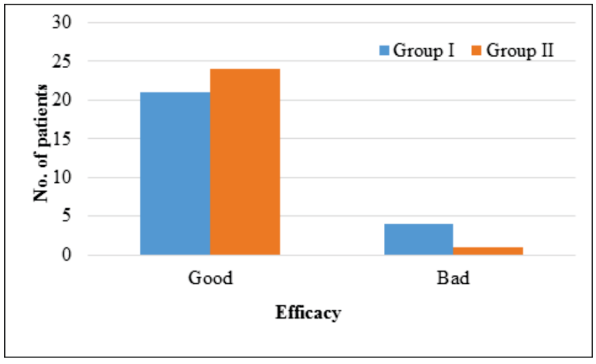

Figure 3: Efficacy of Misoprostol alone (Group I) and Mifepristone and Misoprostol combination (Group II)

In group I and group II the mean blood loss was 114±12.77 ml and 65.3±16.2 ml respectively, (p<0.05). In group I, 7 cases and in group II 18 cases have side effects respectively, (p>0.05). In group I, 4 cases had complications and in group II, only 1 case had complication p>0.05.

DISCUSSION

The various methods used for second trimester termination of pregnancy are undergoing critical appraisal worldwide. 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 in spite of its high cost.

In the present study, the mean age for group I was 23.9±3 and for group II it was 25.1±3.4 years. Both the groups were comparable and found no significant difference with respect to age, gestational age and gravida which is comparable with the study done by Akkenapally PL [7] and Mukhopadhyay P et al [8].

In group I, mean IAI was 723.2±223.8 min and in group II it was 297.9±154.7 min, which was significantly lower with a p value of <0.05. However, in group I, the IAI for Primi was 769.6 mins, while for multi gravida, it was 692.3 mins. For gestational age 14 to 17 weeks, it was 711.1 mins and for 17 to 20 weeks, it was 754.2 mins. In group II, the IAI for Primi was 490.5 mins, while for multi gravida, it was 207 mins. For gestational age 14 to 17 weeks, it was 290 mins and for 17 to 20 weeks, it was 326.6 min. These findings are correlated with the previous studies [8-11]. It is known that induction of labour is easily accomplished in multiparous compared with primiparous [7, 8], women, in present study also the induction abortion interval is shortened in multiparous compared to primiparous woman in mife + miso group.

Mifepristone enhances the action of misoprostol there by reducing the induction to abortion interval and dose of misoprostol. In the current study, the mean dose of misoprostol required in group-II (1163± 241.8 mcg) was significantly lower (p value < 0.05), as compared to group-I (1756±171.4 mcg) like in other similar studies [7, 8].

We also observed that in group-II the mean blood loss (65.3±16.2 ml) was less than in group I (114±12.77 ml), (p<0.05) probably due to shorter IAI. These results are in accordance with the study conducted by Akkenapally PL [7] and Mukhopadhyay P et al [8].

However, in group I, 21 patients and in group II 24 had complete abortions, while only 4 in group I and 1 patient in group II with retained placenta, this was statistically significant (P<0.05). Similar findings are reported in previous studies [12, 13].

In the present study, there were no major side effects like uterine rupture, infection, sepsis, hypersensitivity reactions or maternal deaths in either group. In group I, 7 cases and in group II 18 cases have side effects respectively which was statistically insignificant, (p>0.05). Also, in group I, 4 cases had complications and in group II, only 1 case had complication p>0.05. There was no post procedural genital

infections or cervical tears which was comparable to other studies. Dickinson et al conducted a prospective randomized concluded that intravaginal misoprostol performs as effectively as gemeprost in achieving delivery in the second trimester without an increase in adverse effects and displaying a significant cost advantage [12]. In a study by Akoury et al, vaginal misoprostol group were most satisfied with the procedure and had fewer side effects than the other two groups [14]. Study by Patel et al showed that fewer side effects and complications and also reduces the dose of misoprostol [15]. Study by Mukhopadhyay P et al showed that ninety percent of group B and 80.7% of group A had no complications [8].

In current study, group I had good efficacy in 21 (84%) cases and group II had good efficacy in 24 (96%) cases, but this was not statistically significant, (p>0.05). Similarly, Akkenapally PL et al reported success rate in group I (only misoprostol) was 89% and II (mifepristone + misoprostol) was 96% [7]. Women with missed miscarriage should be offered mifepristone pretreatment before misoprostol to increase the chance of successful miscarriage management, while reducing the need for miscarriage surgery. Study by Mukhopadhyay P et al [8] showed that success rate was higher in group B (mifepristone + misoprostol) 100% and 96.7% in group A (only misoprostol) also showed that pretreatment mifepristone followed by misoprostol was found to be a very effective regimen for 2nd trimester abortion with lesser complications and higher efficacy. Patil SB et al reported mifepristone followed by misoprostol (Group A) is found to be more effective, has a shorter IAI and fewer side effects for second trimester abortion compared to Misoprostol alone (Group B). There was also difference in success rate in both the groups but statistically not significant. The success rate was 96.7% in Group A, 90% in Group B [16].

Thus, Mifepristone followed by misoprostol has been found to be a more effective regimen for second trimester abortion because of the shorter IAI, lesser failure rate and fewer side effects and complications as compared to the single drug misoprostol only protocol.

CONCLUSION

Medical second trimester termination of pregnancy, pre-treatment with oral mifepristone 200mg prior to vaginal misoprostol provides a non-invasive effective regimen with significantly reduced induction to expulsion interval, lesser side effects and good patient compliance.

The combination of mifepristone and misoprostol is now an established and highly effective method for second trimester abortion. Where mifepristone is not available or affordable, misoprostol alone has also been shown to be effective, although a higher total dose is needed, and efficacy is lower than for the combined regimen. Therefore, whenever possible, the combined regimen should be used. Efforts should be made to reduce unnecessary surgical evacuation of the uterus after expulsion of the fetus.

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