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A PROSPECTIVE COMPARATIVE STUDY OF VAGINAL VERSUS ORAL MISOPROSTOL ONLY REGIMEN FOR EARLY SECOND TRIMESTER PREGNANCY TERMINATION

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Conflicts of Interest: Nil

ABSTRACT:

Background: Medical methods for second trimester abortion are being favoured now a day over surgical methods .Out of various medical methods available misoprostol only regime is a cheap, safe and readily available method which can be used in various doses and by various routes. Comparison between vaginal and oral route of misoprostol forms the basis of this study.

Methods: This was a prospective comparative study of misoprostol for second trimester abortion between 12-20 weeks, comparing vaginal and oral routes.120 patients were randomly allotted to two groups 60 received vaginal misoprotol 400 µgms 4 hourly upto maximum of 4 doses and 60 patients received oral misoprostol with water in same dose and duration. In both groups, oxytocin infusion was started if abortion did not occur. Efficacy, induction abortion interval and need of surgical evacuation were analysed.

Results: Both groups were well matched in terms of age, parity .Mean gestational age and indication for MTP. The mean induction-abortion interval was 10.71± 2.21 hours for vaginal group and it was 14.73± 01.73 hours with oral route. The complete abortion rate was almost 75% for vaginal group but only being 55% for oral route. The failure rate was 25% with oral route compared 15% with vaginal group.

Conclusions: Though both vaginal and oral misoprostol are safe, vaginal route appears to be more efficacious for second trimester MTP.

Keywords: abortion interval, misoprostol, second – trimester MTP.

Introduction

Abortion is defined as termination of pregnancy before the period of viability, which occurs at 20 weeks of gestation and the foetus weighing 500 g. MTP was legalized in India in 1971 to reduce the number of unsafe abortions[(1)]. Estimate indicate that 46 million pregnancies are voluntarily terminated each year[(2)].

Mid-trimester abortion constitutes 10–15% of all induced abortions but is responsible for two-thirds of all major complications. There is a gradual increase in second trimester abortions because of the widescale introduction of prenatal screening programs detecting women whose pregnancies are complicated by serious fetal abnormalities. In addition to this, teratogenic effects of drugs used in early pregnancy, late diagnosis of associated diseases that may be a threat to the wellbeing of woman or infant, PPROM and contraceptive failure.

There are various methods being used for second trimester abortion as dilation and evacuation (D&E), systemic medications, intra-amniotic or extra-amniotic abortifacients and hysterotomy[3]. The traditional use of D&E in the second trimester

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basically is safe and effective but its safety depends on the surgeon's skill and experience, and it may cause psychologically trauma. Thus, less traumatic and non-invasive methods for termination of pregnancy seem to be the better choices. So medical approaches are also being used such as intra-amniotic prostaglandin (PG) F2- α instillation, PGE2 vaginal suppositories, PGE2 and high-dose oxytocin.[4]

During the last decade, medical methods for mid-trimester-induced abortions have become safe and more accessible, effective and feasible alternatives to surgery. In first- and second-trimester abortion, combined treatment with misoprostol and mifepristone is more effective than treatment with misoprostol alone, and are considered the gold standard for medical abortion[5]. However, misoprostol-alone regimens may be the treatment of choice in settings in which mifepristone is not available or is too costly. Misoprostol is being more widely used because it is inexpensive and stable at room temperature, does not need refrigeration and is associated with few side effects. A comparison between vaginal and oral routes forms the basis of the study.

Methods

This study included women in 12-20 weeks gestation period scheduled to have pregnancy termination as per MTP Act guidelines presenting to outwoman department.

Study Design -

Prospective comparative study.

Place of Study -

SMS Hospital & Medical College, Jaipur

Duration of Study

April 2017 to September 2018.

Inclusion Criteria

- Pregnant women with 12-20 weeks gestation as calculated from LMP, clinical examination & confirmed by ultrasound.
- Giving consent.

Exclusion Criteria

C/I to misoprostol

- Uncontrolled asthma
- Irritable bowel syndrome
- Previous caesarean section
- Previous uterine scar
- Intrauterine death.

METHOD

After applying inclusion and exclusion criteria for each patient, all participants were provided with written informed consent before enrolment.

The selected women were admitted, detailed history, physical examination done and routine investigations were performed. Indication for MTP was taken and consent for MTP was taken in standard MTP form. Study consent was taken separately.

Women were divided into 2 groups of 60 each by Chit method: -

- **Group-A -** Vaginal
- **Group-B -** Oral

In both groups we kept the same dose of misoprostol.

400 micrograms at 4 hours interval upto maximum of 4 doses in each group. 1 dose comprised 2 tablets of 200 micrograms each.

- In Group-A premoistened Misoprostol was placed in posterior fornix of vagina after taking aseptic precautions.
- In Group-B, Misoprostol was given orally with water.

Vital parameters were noted every 4 hourly. After abortion, products of conception were examined and if incomplete, evacuation of the uterus was performed.

Subjective assessment of the women's comfort with the different routes of administration in the two groups was also made. The women were discharged 24 hours after the abortion if there were no complications and called for a follow-up visit after 1–3 weeks. Women who did not abort within 24 hours of starting the induction were labeled as failure and given alternative methods. The methods used were repeat schedule of misoprostol by the same or different route or high dose of oxytocin. These cases were considered as a failure.

Primary outcome measure was the success rate at 24 h. Success rate was defined as abortion (complete/partial) occurring without the need for further prostaglandin analogs or syntocinon.

Complete abortion was defined as the expulsion of both fetus and placenta without operative intervention.

Secondary outcome measures were failure rate induction to abortion interval need of oxytocin augmentation need of currettage.

Failure was defined as cases with incomplete dilatation or no dilatation.

Induction–abortion interval was defined as the time interval from the administration of first dose of misoprostol up to the time when the fetus aborted. Comparison between groups was done with multiple qualitative and quantitative tests-chi square test, pearson's chi-square test and fischer's exact test.

Results

Table 1: Age distribution of study groups

Age group (years)	Group A		Group B	
	N	%	N	%
<20	00	0	01	1.7
20 – 24	20	33.3	24	40
25 – 29	37	61.7	30	50
≥30	03	5	05	8.3
Total	60	100	60	100
Mean ± SD	25.50 ± 2.86		24.91 ± 3.14	

Table 2: Distribution of study subjects according to their gravidity

Gravidity	Group A		Group B	
	N	%	N	%
Primigravida	09	15	11	18.3
2	19	31.7	23	38.3
3	21	35	16	26.7
>/=4	11	18.3	10	16.7
Total	60	100	60	100

Table 3: Distribution of study subjects according to history of previous abortion

History of Previous abortion	Group A		Group B	
	N	%	N	%
Present	21	35	21	35

Table 4: Comparison of mean gestational age at weeks

Group	Gestation period in weeks (mean ± SD)
A	15.46 ± 2.18
B	15.15 ± 2.51

Table 5: Comparison of mean induction to abortion time

Group	Mean ± SD (Hours)	Range (Hours)	p value (ANOVA)
Group A	10.71± 2.21	09.21-12.21	**P<.001(S)**
Group B	14.73 ± 01.73	14.21 - 15.25	

Table 6: Comparison of abortion/success rate*

Abortion	**Group A**		**Group B**	
	N	**%**	**N**	**%**
Successful	51	85	45	75
Unsuccessful/ failure rate	09	15	15	25
Total	**60**	**100**	**60**	**100**

*Considering complete and incomplete abortion as successful

p = 0.08 (NS)

Table 7: Comparison of Complete abortion rate

Complete Abortion	Group A		Group B	
	N	%	N	%
Yes	45	75	33	55
No	15	25	27	45
Total	60	100	60	100

Chi- p = 0.035 (S)

A total of 120 patients (6o in each group) were studied. Maternal characteristics are shown. Mean age of both study groups was 24.86±2.90 years with most of the study subjects belonging to 25 – 29 years (51.7%) and 20 -24 years (41.7%) age group. Both groups were found to be similar in their age composition.

There was no statistical difference in any of these parameters (age, parity, previous abortions and mean gestational age) between both these groups.

The mean induction-abortion interval was 10.71± 2.21 hours in vaginal group and 14.73 ± 01.73 hours in oral group; the difference was statistically significant

(p< .001)with vaginal group taking lesser time. Success rate at 24 hours was 85% for vaginal group and 75% for oral group; the difference being statistically insignificant

(p .08).Complete abortion rate was 75% and 55% in vaginal and oral route respectively (p .035);with incomplete abortion rate of 10% and 20% respectively which is again statistically significant .Failure rate at 24 hours was 20% ; 15% for vaginal group and 25% for oral group; the difference being statistically insignificant

(p .08) . Side effects were almost similar in two groups except for fever which was more with vaginal group 23.3% compared to 6.3% with oral route.

Discussion

Unsafe abortions including less safe and least safe abortions are a major cause of maternal mortality worldwide. The earlier rationale of mifepristone use before misoprostol is now a days is changing with misoprostol only regimen for second trimester abortion which has shown to be have a good success rate by various studies. Also availability in various schedules and by various doses, easy availability and stability at room temperature, low cost makes it an attaractive option especially in low resource countries.

Most of the study subjects belonging to 25 – 29 years (51.7%) and 20 -24 years (41.7%) age group. Both groups were found to be similar in their age composition. The women of reproductive age group have maximum fertility and sex drive, so these women are prone for pregnancy. Maximum number of women were gravida 2 followed by gravid 3. Only 15 % and 18.3% patients were primigravida in vaginal and oral group respectively. Majority of patients did not have a prior abortion. Mean gestational age

was 15.46±2.18 years in vaginal group and 15.15± 2.51 years in oral group.

Nautiyal D et al[6] in 2014 compared efficacy of 3 groups of misoprostol sublingual,vaginal and oral route with 400 micrograms at 4 hourly intervals for maximum 4 doses and showed similar results with mean Induction–abortion interval in the sublingual (9.8 ± 3.6 h) and vaginal (10.6±2.9 h) groups was significantly shorter than in the oral group 14.3±3.3, (p <0.001).

Ganguly RP et al [7] in 2009 compared sublingual, oral and vaginal routes of misoprostol administration (400 mcg of misoprostol 6 hourly, maximum up to four dosages) respectively for 9-16 weeks gestation termination. Rate of complete abortion was higher in sublingual group in comparison to oral (p = 0.0338) and vaginal route (p = 0.5627) which is similar to our study. Induction-abortion interval was also least with the sublingual route, p <or = 0.0001 (versus oral) and 0.0011 (versus vaginal).Failure rate was highest with the oral route and least with the sublingual route as in our study .

Tahir S et al[8] in 2015 conducted a study to compare the clinical efficacy, side effect and acceptability of oral versus vaginal misoprostol for second trimester termination of pregnancy. Dosage regimen was similar in both groups that were 400µg 6 hours apart till expulsion of fetus or maximum of up to 4 doses. The mean induction-expulsion interval in the group A and B was 22.87±7.74 and 19.15±8. 24 hours respectively p-value (0.016) which was statistically significant as seen with present study. The longer induction abortion interval in this study might be due to longer interval between 2 doses. 38% in group A and 58% in group B had complete expulsion with 1to 4 doses of misoprostol and remaining 62% in group A and 42% in group B either needed syntocinon to augment process of expulsion after four doses of misoprostol, post expulsion evacuation for retained product of conceptions or alternate method of termination of pregnancy after 24 hours period of rest after last dose of Misoprostol. There was no reported case of nausea, diarrhea, headache, dizziness, shivering, and hyperstimulation in both the groups. They concluded that efficacy of vaginal misoprostol was better than oral misoprostol for second trimester termination of pregnancy as we found in our study.

Abortion rate in the oral group was almost similar to the vaginal group. This result is similar to studies by Karsidaq et al. [9] and Tanha et al [10]. Mahjabeen et al [11]) in 2009 compared misoprostol orally vs Vaginally as 200 microg 4 hours apart till maximum of upto 5 doses. The mean induction-expulsion interval in the group 1 and 2 was 11.8+/-8.3 and 12.8+/-8.5 hours respectively, which was not different statistically. The process of expulsion was complete in 53.3% of subjects in both groups by misoprostol only, while 36.6% required surgical evacuation in oral group versus 33.3% in vaginal group. The rate of failed induction in groups 1 and 2 was 10% and 13.3% respectively. There was no reported case of nausea, diarrhoea, headache, dizziness, shivering, pyrexia and hyper stimulation in both the groups. However, a case of vomiting (3.3%) was observed in the vaginal group.

Oral group had a longer induction–abortion interval of 14.71 h. The difference in efficacy and induction–abortion interval between both the routes of misoprostol may be explained by variable pharmacokinetics vaginal, and oral routes. The failure rate and need for surgical intervention were similar in both groups. Fever occurred more in vaginal group and lesser in the oral group. The incidences of other side effects like nausea, vomiting, chills, and significant vaginal bleeding were similar. Oral route has shown to be more acceptable compared to vaginal route of administration. But the efficacy of oral administration is less.

A recent 2017 publication by FIGO on their updated recommendation for misoprostol use alone recommends a dose of 400µg misoprostol(sublingual, buccal or vaginal)every 3 hourly till expulsion(no maximum dose suggested),for terminations between 13-26 weeks.Our study and findings are keeping with these guidelines. To conclude,400µg misoprostol 4 hourly by both vaginal and oral routes are safe for second trimester MTP .Vaginal route appears to be more efficacious with an over all induction

–abortion interval of 10.71 hours, lesser need of oxytocin and lesser need of surgical intervention.

Ehical approval: all procedures followed were in accordance of ethical standards of institutional ethics committeeand with Helsinki declaration 1975,as revised in 2008

Informed consent:informed consent was obtained from all patients being included in the study.

Conclusion

Though both vaginal and oral routes of misoprostol can be used for early second trimester abortion,vaginal route because of its shorter induction-abortion interval and higher complete abortion rate is more efficacious and better than oral route.

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