EFFICACY AND SAFETY OF VAGINAL MISOPROSTOL IN SECOND TRIMESTER ABORTION

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ABSTRACT

BACKGROUND

Termination of pregnancy has been legalised in India in 1971, mainly to prevent the complications of illegal abortions. Surgical methods of termination in second trimester are not without maternal risks and complications. A search for safer and easier methods of termination of pregnancy prompted by numerous potential complications has resulted in various medical approaches. Hence, prostaglandins were thought to be the answer. Using vaginal misoprostol was cheaper and more effective compared to other methods.

The aim of this study was to study the safety and efficacy of vaginal misoprostol in second trimester termination of pregnancy.

MATERIALS AND METHODS

This is a study involving 75 patients who attended the OBG OPD for second trimester termination between the period of 2007 and 2012 with the inclusion criteria of singleton pregnancy in both nulliparous and multiparous patients with gestational age between 14 and 24 weeks using 400 micrograms to 1200 micrograms of vaginal misoprostol.

RESULTS

The present study further documents the positive experience on the safety and efficacy of misoprostol (PG E1 analogue) in the vaginal route in inducing second trimester abortion.

CONCLUSION

Misoprostol is really a wonder drug with safety and efficacy in achieving the second trimester abortion by medical methods, cost-effective and easy to administer with minimal side effects.

KEYWORDS

Medical Abortion, Misoprostol.

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BACKGROUND

Termination of pregnancy has been legalised in India during 1971, mainly to prevent illegal abortions. Increased practice of contraceptives has reduced the number of terminations to certain extent in developed countries. But in developing countries like India large number of medical termination of pregnancies have to be performed for medical, social or for family welfare purpose. Many of the medical termination seekers both primi and multigravida seek termination during second trimester, when the surgical evacuation is risky where complications like severe haemorrhage, cervical or uterine injuries and severe infections may lead to grave immediate or late consequences. Abortion is frequently performed in unsafe and undesirable conditions. Illiteracy, ignorance combined with lack of adequate contraceptive services has led to the problem of unwanted pregnancies very commonly extending to second trimesters. With the advances in prenatal screening more and more abnormal foetuses are being detected and hence the need arises for safe methods of mid-trimester termination of pregnancy.

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Surgical methods in second trimester are not without medical risks and complications. So there is a need for alternate methods of termination of pregnancy, preferably medical methods without any risks or at least with minimal complications, easy and inexpensive. Use of prostaglandin analogue E1 could be the right choice now.

Objective

The aim of this study is to evaluate the efficacy and safety of vaginal misoprostol in second trimester abortion in both nulliparous and multigravida with anomaly baby, dead foetus due to failure of contraception or due to other medical causes.

MATERIALS AND METHODS

This is a descriptive hospital-based study design involving 75 patients attending the outpatient department for second trimester pregnancy fulfilling the inclusion criteria.

Inclusion Criteria

1. Singleton pregnancy.
2. Nulliparous and multiparous.
3. Gestational age between 14 and 28 weeks.
4. Therapeutic termination.
   a) Maternal- Severe postpartum haemorrhage. Antepartum eclampsia.
   b) Foetal- IUD, Congenital anomalies.
   c) E- Unmarried pregnancy, sterilisation failure.
   d) Contraceptive failure.

Exclusion Criteria

1. Multiple gestations.
2. Abnormal vaginal bleeding.
3. Evidence of vaginal or cervical injuries.
4. H/O previous uterine surgeries.
5. H/O asthma, heart diseases, renal and hepatic dysfunctions.

Method

Informed written consent was obtained. General physical examination to rule out systemic illnesses, local infections or any uterine adnexal pathologies and to find out gestational age. Routine blood investigations and urine analysis was done. Ultrasound examination for gestational age, number of foetuses and their viability were documented.

Two tablets of misoprostol of 200 µgm were inserted intravaginally into the posterior fornix and repeated after 6 hrs., if not aborted. After the second dose, patients were observed for 24 hrs. as inpatients in the hospital. Hourly monitoring was done for vital signs and excessive vaginal bleeding. Progression of labour was assessed at the time of repeat drug administration and also when bleeding was profuse or uterine contractions were painful. Induction abortion interval was noted. If abortion occurred within 24 hrs., the method was considered successful.

Incomplete abortions were treated by oxytocin injections initially. In case of failure to expel the placenta even with oxytocin or when the women were bleeding profusely, suction or instrument evacuation of retained products of conception was done under general anaesthesia.

Amount of post-abortion bleeding was assessed clinically. If neither placenta nor foetus expelled even after 24 hrs., the induction was judged to be a failure. A post-abortion antibiotic coverage was given for 5 days with oral ampicillin. All failures were treated with alternative methods like extra-amniotic ethacridine lactate, oxytocin infusion, cerviprime or hysterotomy as a last resort. Women requiring sterilisation underwent bilateral tubal ligation in the immediate post-operative period.

Age (yrs.)	Total No. of Cases	%
< 20	15	20
21-25	36	45
26-30	15	20
31-35	7	9.3
> 35	2	2.7
Table 1. Age Distribution		

Gestation Weeks	Total No. of Cases	%
14-18	29	38.7
19-23	21	28
24-28	25	33.3
Table 2. Period of Gestation		

Indication	Total No. of Cases	%
Low socio-economic status	20	26.7
Eclampsia	15	20
Missed abortion	19	25.3
Sterilisation failure	2	2.7
Unmarried	17	2.7
Congenital anomaly	2	2.7
Table 3. Indications for Termination of Pregnancy		

Dose	Total No. of Cases	%
Single dose (400 ugm)	36	54.5
Double dose (800 ugm)	30	45.5
Table 4. No. of Doses Required		

	Total No. of Cases	%
Dead foetus	19	25.4
Live foetus	56	74.6
Table 5. Comparison of Live and Dead Foetus		

Side Effects	Total No. of Cases	%
Fever	6	8
Vomiting	3	4
Diarrhoea	3	4
Allergic reaction	0	0
Table 6. Side Effects of Misoprostol		

Time	Total No. of Cases	%
0-6 hrs.	13	19.7
6-12 hrs.	26	39.4
12-18 hrs.	19	28.8
18-24 hrs.	8	12.1
Table 7. Induction-Abortion Interval		

Outcome	Total No. of Cases	%
Complete abortion	64	85.4
Incomplete abortion	2	2.6
Failure of expulsion	9	12
Table 8. Outcome		

RESULTS

In our study with 75 patients with vaginal misoprostol for second trimester of pregnancy, the safety and efficacy were definitely higher than other methods of induction of abortion like Emcredil or higher doses of oxytocin with very few side effects.

Total number of patients who developed side effects was 12 (16%). Most common side effect was fever with temperature > 38^{o}C (8%), vomiting (4%) and diarrhoea (4%). There was no incidence of any adverse reactions to the drug. Induction abortion interval was also superior to other methods; 26 patients expelled the foetus within 6 - 12 hrs. (39.4%) and the least was 8 patients within 18 - 24 hrs.; 12% patients were considered as failure, as they did not respond to the higher doses of misoprostol also.

DISCUSSION

It is difficult to terminate pregnancy in the second trimester with reasonable safety as in first trimester. After the invention of the prostaglandins, termination of pregnancy in second trimester is done with ease with least side effects. The word prostaglandin was coined by Von Euler (1985) believing it to be the active principle originating from prostate gland. However, later it was found to be a family of substances ubiquitously found in mammalian body. Corey et al (1969) first synthesised prostaglandins. Prostaglandins are the family of polyunsaturated 20-carbon compounds synthesised from arachidonic acid in all living cells. Prostaglandin causes pronounce decrease in amount of collagen, increasing collagenase activity and elastase activity. Reduction in ground substance proteoglycan occurs as a result of local or systemic administration of prostaglandins.

With oral administration half-life is less than 30 minutes and peak level is at 15 minutes. After vaginal administration, there is a gradual rise to a maximum level at 60 to 120 minutes, but at 240 minutes the level is still at 60% peak level. The toxic dose of misoprostol in human beings has not been determined. Cumulative daily dose of 1600 µgms has been tolerated.

In a study by KS Wong et al doses upto 4000 µgms of misoprostol have been tolerated.[1] Side effects are mainly gastrointestinal side effects and fever.

For all the gestations of 11 to 20 weeks, dilatation and evacuation is the method of choice in US according to Grimes (1977) and Peterson (1983).[2] In India we prefer both medical methods and dilatation and evacuation.

Jain JK et al reported in a study, induction abortion interval rate within 6 hrs. was 14%; 12 hrs. was 39.3% and within 24 hrs. was 15.7%.[3] He also concluded that the live foetus had high failure rate of abortion and longer time to abort than dead foetus. But in our study, the complete abortion rates of live and dead foetus were 83.9% and 89.7% respectively. Failure rate for live and dead foetus were 12.5% and 10.5% respectively. According to Chi-square test, X^2= 0.059 suggesting difference was not statistically significant.

In spite of various methods of contraception available, patients go for illegal abortions and second trimester terminations. This according to David T Baird, may be related to inadequate organisation of abortion services and lack of widespread availability of these drugs (Misoprostol) to the woman throughout the country.[4]

Srisomboon J, in his study (1977), evaluated the efficacy and side effects of vaginal misoprostol in termination of second trimester pregnancy in women who were recruited to receive 400 µgms of Misoprostol every 6 hrs.[5] The rate of complete abortion defined as passage of foetus and placenta without operative assistance was 80%. Side effects were fever (8%), nausea and vomiting (6%) and diarrhoea (2%). Thus, in his conclusion misoprostol is effective, cheap, safe and relatively convenient method for second trimester termination of pregnancy. This is comparable to our study where complete abortion rate is 85.4% and failure rate is 12%.

Pongpisuttinum S, in his study described about the complications, compared the success rate in induction abortion interval between the live and dead foetus in second trimester termination with vaginal misoprostol.[6] In his study, the rate of successful abortion within 24 hrs. in live foetus and dead foetus were 54.7% and 83.3% respectively. The success rate within 24 hrs. in live group was significantly lower than those of dead foetus group. No serious complications occurred in terms of haemorrhage, febrile morbidity, diarrhoea, nausea and vomiting. In our study, complete abortion rate for live and dead foetus was 83.9% and 89.7% respectively and failure rate was 12.5% and 10.5%. According to Chi-square test X^2= 0.059, suggesting difference was statistically not significant.

Even though oral administration is appealing for several reasons like convenient and lack of invasiveness, vaginal route seems to be more advantageous (Dickinson JE, 2014).[7]

Another study by Elami-Suzin compares the efficacy of mifepristone plus misoprostol and mifepristone plus oxytocin; also confirms vaginal misoprostol has least side effects and convenient.[8]

A study by MacIsaac revealed the absorption kinetics of misoprostol with a dose of 400 µgms compared between oral administration and vaginal treatment.[9] This study showed systemic bioavailability of vaginally administered misoprostol was three times greater than oral route.

Lesser the dosage used, side effects were less. Herabutya in his study compared the doses of 200 µgms and 400 µgms over a period of 6 hrs. and concluded that 400 µgms dose was more effective as an abortifacient with fewer side effects.[10] High doses were associated with adverse effects like fever, nausea, vomiting and diarrhoea.

Though studies done by Webster D had used 200 µgms mifeprin tablets prior to misoprostol for second trimester termination, our study obviates the need for prior use of Tab. Mifepristone in second trimester termination of pregnancy.[11]

CONCLUSION

The present study further documents the positive experience on the safety and efficacy of vaginal misoprostol tablets in inducing second trimester abortions. It is cost-effective, easy to administer and has very less side effects. The failure rate and incomplete abortion is very less. Nevertheless, as shown in this study, problem still remains in a minority of non-responding women and it is a responsibility of any clinician to be able to offer alternative methods to complete the abortion in safe manner.

Study Design

A descriptive hospital-based study design was used for this study. Purposive sampling was done for this study.

Sample Size

Sample size was determined by referring the book of WHO publication 1991 titles sample size determination in health studies, written by Lwanga SK and Lemeshow S; anticipating population proportion of second trimester pregnancies attending OG OPD using the formula-

$2SD^2(Z\alpha/2 + Z\beta/d^2)^2$

d= effect size + difference between the mean value

Statistical Analysis

Data was entered in Microsoft XL and analysis was done using Epi Info software version 3.5.4. Proportions were calculated for various variables and Chi-square test and student's test were done for statistical significance of the outcome.

P value of < 0.05 was taken as significance.

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