Original Article

Study Comparing Between Surgical Evacuation and Medical Management with Vaginal Misoprostol for Early Pregnancy Loss

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Abstract:

Background: *Early pregnancy loss is one of the most common clinical problems that is encountered in daily gynaecological practice. The aim of this study is to assess the effectiveness and acceptability of using vaginal misoprostol for management of first trimester spontaneous incomplete abortion as an alternative to direct vaginal surgical evacuation in our setting.*

Methods: *This prospective randomized study was carried out in the Department of Obstetrics and Gynaecology in Shaheed Ziaur Rahman Medical College Hospital, Bogra. from January 2008 to December 2008. This study performed on 400 patients with first trimester incomplete abortion between 8 and 12 weeks requesting medical management. They were divided into two groups according to patients' choice; group (I) received 800 microgram misprostol vaginally by digital insertion into the posterior fornix while group (II) underwent surgical vaginal evacuation directly under general anesthesia.*

Results: *Although vaginal surgical evacuation was successful in solving the problem in 100% of cases, misoprostol was successful in 70% after 1st dose and remained incomplete 30% after administration of 2nd dose. The overall satisfaction was slightly higher in the surgical group. No serious side effects or complications were reported in the misoprostol group. The incidence of excessive post-abortive bleeding was more in the misoprostol group than in the surgical evacuation group (p = 0.049).*

Conclusion: *Although vaginal surgical evacuation is more effective than misoprostol in solving the problem still medical treatment is effective and acceptable especially when surgical management is not available or risky or patients refuse to do surgical management.*

Keywords: *Early pregnancy loss, misprostol, surgical evacuation.*

Introduction

Early pregnancy loss is one of the most common clinical problems that is encountered in daily gynaecological practice. It has been estimated that over 10-20% pregnancies end up in spontaneous abortion and 80% of all these occur before 12 weeks and known as early pregnancy loss[1]. Approximately one in four women will have an early pregnancy loss during her lifetime[2]. The most common clinical types of early pregnancy loss include blighted ovum, incomplete abortion, inevitable abortion, missed abortion and complete abortion, septic abortion.

For more than 50 years the standard management of early pregnancy loss has been surgical evacuation (i.e. evacuation and curettage, electric vacuum aspiration, manual vacuum aspiration of the uterus). However dilatation and suction evacuation of the uterus under anaesthesia has certain morbidity, such as the risk of anaesthesia, uterine perforation, intrauterine adhesions, cervical trauma, and infections leading to infertility, pelvic pain and increased chance of ectopic pregnancy[3].Recent evidences show that using misoprostol as an alternative to surgery is highly acceptable and reduces the cost of services[4]. Medical evacuation by using misoprostol is a simple, non invasive method and may be preferred by women[5]. Studies showed that vaginal application of misoprostol increases the success rate and reduces the side effects[6-8].

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It is used (and approved in other countries) to induce labour as an abortificient[9]. There are also other medical measures to manage early pregnancy loss such as misoprostol with methotrexate or mifepristone[10].The lowest effective dose of misoprostol for each condition for which it is used in not yet clear and the dose differs in different categories of pregnancy loss[11,12].

We have selected misoprostol in our study as it is cheap, stable at room temperature, easy to transport, does not require refrigeration and readily available in most areas of the country. It interacts with prostaglandin receptors, causes the cervix to soften and uterus to contract resulting in the expulsion of the uterine content[13].

In our country many women go for and suffer from the complication of induced abortion. They are very vulnerable to short and long term morbidities. These morbidities are in the form of haemorrhage, infection and physical damage to reproductive organ[14]. It has been estimated that 13% of all maternal death worldwide are due to unsafe abortion[15]. If misoprostol is found to be safe and effective, a large number of patients will be benefitted and will escape from surgical intervention and complication.

So, the main aim of this study is to evaluate the efficacy, safety and acceptability of the treatment and also to compare its effectiveness with surgical evacuation as a management of early pregnancy loss.

Materials and Methods

This prospective randomized study was carried out in the Department of Obstetrics and Gynaecology in SZMCH, Bogra from January 2008 to December 2008.

A total 400 cases of abortion including missed, incomplete, blighted over fulfilling the selection criteria were selected during the study period. Patients suffering from Incomplete abortion of > 12 weeks gestation, Incomplete abortion with excessive P/V bleeding, H/O medical disorders like cardiac, respiratory, renal, hepatic or adrenal disease, H/O thromboembolism, hypertension, coagulopathy. Anaemic patient Hb% <8 gm%, allergy to prostaglandin or NASID and induced abortion were excluded from the study. Ethical approval of the study was from the Ethical committee of Shaheed Ziaur Rahman Medical College Hospital, Bogra. Informed written consent was obtained from each of the participants after explaining the objective of the study. A total of 400 women with first trimester pregnancy loss were randomly selected. They were divided into two groups according to patients' choice; group (I) received 800 microgram misoprostol vaginally by digital insertion into the posterior fornix while group (II) underwent surgical vaginal evacuation directly under general anesthesia.

Gestational age was determined from the 1st day of last menstruation according to menstrual history and transabdominal ultrasonography. A base line blood sample was obtained for Hb% blood sugar, blood for ABO grouping and Rh typing.

On admission in hospital women who are selected for medical treatment, interval between administration of misoprostol and expulsion of product of conception was recorded. If expulsion of product of conception occur after giving 1st dose then trans abdominal ultrasonography was done to see the completeness of expulsion of product of conception and they discharged form the hospital. If expulsion does not occur within 24 hrs of giving 1st does of misoprotol then 2nd of misoprostol was given in the same manner. Then they discharged from the hospital. Similarly women who are selected for surgical treatment dilatation, evacuation and curettage were done in those patients in operation theatre under anaesthesia by a medical officer and discharged from the hospital on the next day if the haemodynamic condition of the patient was stable.

Every women were advised for follow up on 15th day and were asked to complete a data collection sheet about duration and intensity of bleeding, intensity of pain and other side effects of the medical treatment e.g. fever, diarrhea, headache etc. and ultimately to the acceptability of treatment. Misoprostol treatment was considered failed if there was persistent abnormal vaginal bleeding and signs of retained product of conception by sonography. Similarly curettage was considered failed where 2nd intervention is needed because of abnormal per vaginal bleeding and persistence of signs of retained product of conception.

Data were expressed mean (±SD) and number (percent) as appropriate. Statistical tools t-test, chi-square were performed statistical difference between groups as applicable. Statistical calculations were performed using Statistical Package for Social Sciences (SPSS) - version 16. P value <0.05 was taken as level of significance.

Result and observations:

Table 1: Demographic Characteristics of the woman

	Groups Medical Treatment	Surgical Treatment
Age in year		
≤20	60 (30.0%)	54 (27.0%)
21-25	51 (25.5%)	45 (22.5)
25-30	54 (27.0%)	48 (24.0%)
30-35	20 (10.0%)	38 (19.0%)
>35	15 (7.5%)	15 (7.5%)
(Mean ± SD)	26.02 ± 6.18	26.59 ± 6.15
Parity		
0	50 (25.0%)	54 (27.0%)
1	65 (32.5%)	46 (23.0%)
2	52 (26.0%)	63 (31.5%)
>2	33 (16.5%)	37 (18.5%)
Mean gestational age		
≤6 weeks	21 (10.5)	31 (15.5)
7-8 weeks	54 (27.0)	41 (20.5)
9-12 weeks	125 (62.5)	128 (64.0)
(Mean ± SD)	9.55 ± 2.06	9.93 ± 2.51

Maximum respondents (30%) and (27%) were at or below 20 years of age between receiving medical and surgical treatment. Women reviving medical treatment highest percentage (32.5%) were para-1 and in women receiving surgical treatment highest percentage (31.5%) were para 2. Maximum respondents (62.5%) and (64%) of both groups receiving medical and surgical treatment had gestational age between 9-12 weeks.

Table 2: Requirement of blood transfusion & Duration of hospital stay (Day)

	Groups		
Blood transfusion	**Medical Treatment**	**Surgical Treatment**	**p value**
Nil	104 (52.0%)	0 (0)	
1 unit	56 (28.0%)	58 (29.0%)	0.001
2 unit	25 (12.5%)	89 (44.5%)	
>2 unit	15 (7.5%)	53 (26.5%)	
Duration (of Hospital Stay):			
1-2 days	94 (47.0%)	57 (28.5%)	
3 days	67 (33.5%)	60 (30.0%)	0.001
>3 days	39 (19.5%)	83 (41.5%)	

Table-2 shows that majority of respondents (52%) in medical treatment were not needed any blood transfusion and (7.5%) were needed transfusion >2 unit. In surgical treatment majority of the respondents (44.5%) were needed transfusion of 2 units. The differentiation was statistically significant between two groups (P<.05) Maximum respondents (47%) of medical treatment were discharged from hospital in 1-2 days. But (41.5%) respondents of surgical treatment were needed hospital stay for > 3 days. The differentiation was statistically significant (p<0.05)

Table 3: Side effects of medical and surgical treatment reported by the patients

	Groups			
Side effects	Medical Treatment	Surgical Treatment	χ^2	p value
Per vaginal bleeding	58 (29.0%)	41 (20.5%)	3.879	0.049
Lower abdominal pain	51 (25.5%)	14 (7.0%)	25.148	0.001
Fever	10 (5.0%)	3 (1.5%)	3.896	0.048
Vomiting	7 (3.5%)	0 (.0%)		0.015
Diarrhoea	6 (3.0%)	0 (.0)		0.030

Table 3 shows that in respondents of medical treatment (29%) developed pervaginal bleeding, (25.5%) had lower abdominal pain, (3.5%) had vomiting and (3%) had diarrhea. But in respondents getting surgical treatment maximum (20.5%) developed pervaginal bleeding (7%) had lower abdominal pain and (5%) had fever. The differentiation was statistically significant (P<0.05).

Table 4: Frequency of complete/Incomplete expulsion following insertion of misoprostol

	Frequency	**Percent**
Complete evacuation after 1st dose	140	70.0
Incomplete evacuation after 1st dose	60	30.0
Complete evacuation after 2nd dose	30	15.0
Incomplete evacuation after 2nd dose	30	15.0
Need surgical evacuation	**30**	**15.0**

Table 4 shows that complete evacuation after 1st dose 140 (70%) and remained incomplete 60 (30%) after administration of 2nd dose

Discussion

Medical management of early pregnancy loss is becoming increasingly popular. Our study indicates that treatment of early pregnancy loss with 800microgram of misoprostol vaginally, with the dose repeated after 24 hours when necessary is efficacious. The success rate by day 15 was 85%. The risks of hemorrhage and pelvic infection were very low and the side effects were tolerable and minimum. Misoprostol treatment was acceptable to most women.

The efficacy of misoprostol treatment for early pregnancy loss has varied greatly (ranging from 13 to 100 percent) in previous retrospective and prospective studies[16]. This variation may be due to small sample sizes, the type of pregnancy loss, the dose of misoprostol and the criteria used to define success.

The study of Herabutya and Presertwawat (1997) showed that 200microgram vaginal misoprostol caused a significant increase in the passage of tissue mass (83.3%) when compared with a placebo(17.1%) [17].

In our study, we have used 800 microgram misoprostol only per vagina. In about 70% of women expulsion of uterine content has occurred after 1st dose. And about 60% of women have empty uterine cavity after 12 hours and after 24 hours.

In a study of Zhang et al(2005) showed treatment of early pregnancy loss by 800microgram of misoprostol vaginally with the dose repeated after 48 hours. The success rate by day 30 was 84% [18]. Zalanyi[19] treated 25 women with missed abortion at less than 13 week gestation using 200 microgram of intravaginal misoprostol at every 4 hours for a total 4 doses. He reported 88% success rate after the third dose and no further success after the fourth. Absence of echogenic structures more than 15 mm in antero posterior diameter in trans vaginal ultrasound was used as a criterion for success. Creinin et al[20]showed 88% success rate in treating early missed abortion with vaginal misoprostol (800 microgram), in two doses 24 hours apart. They considered the absence of an intrauterine gestational sac as a criterion for complete evacuation.

Rokeya Begum et al[21] showed 94% success rate in treating missed abortion at or below 14 weeks gestation with intra

vaginal misoprostol, 400 microgram 6 hourly with maximum 3 doses. Complete expulsion and cervical dilatation with protrusion of product of conception at cervical os were used as the criteria for success.

Here we have used 800 microgram of intravaginal misoprostol in two doses 24 hours apart at or below 12 weeks and the success rate by day 15 was 85%.Criterion used for success was same as Rokeya Begum et al.

D. Ayers - de - campos et al[22] treat 74 women with missed abortion at or below 13 weeks gestation by giving 600 microgram of intra vaginal misoprostol and the dose was repeated after 4 hours if necessary. He reported 56.8% complete expulsion. The criterion used for complete expulsion was same as Zalanyi[19].

The advantage of the regimen of the present study is, it requires fewer vaginally applications of drug. It avoids considerable number of operations and when complete expulsion does not occur it usually provides adequate cervical dilatation making surgical evacuation easy and less complicated; duration of hospital stay is also shortened. In the current study, the comparison of the short term side effects did not show any significant difference between the study and the control groups.

In this study, 47% of women receiving misoprostol is discharged from hospital after 1 day and 19.5% require hospitalizing for more than 3 days.

High success rates as well as low side effects of this approach seems to lead to a high satisfaction rate with this treatment. Medical treatment is accepted by 80% of responder, in comparison surgical treatment by 60%.No significant side effects were observed in the various studies described above [19-21]. 6% of women developed intense bleeding and only required blood transfusion.

In this study 20% of women getting misoprostol develop per vaginal bleeding and requires transfusion for more than two units.

Misoprostol treatment was acceptable to most women. It is a cheap substance and easy to store. This allows a significant reduction in the cost of management by avoiding anaesthetic and theater cost. We found that women with incomplete or inevitable spontaneous abortion were more likely to have complete expulsion after one dose of misoprostol than those women with embryonic or foetal death or women with an anembryonic gestation. However by using a second dose a similarly high success rate is required.

Although the success rate was slightly lower than the 100% success rate of the surgical control group, patient satisfaction was significantly higher in groups using misoprostol. It did not reveal whether 800microgram of misoprotol represents the lowest effective dose for all subtypes of early pregnancy loss. Another observation in our study was that there were additional benefits of using misoprostol treatment. The patients who needed surgical evacuation had soft and dilated cervix at the time of evacuation, which reduced the risk of perforation and cervical injury. Our trial involved a 15 days follow up period. A small number required surgical evacuation even after 2 weeks. In some patients retained product was often seen on internal os which was removed in many cases with sponge holding forceps.

The safety of misoprostol suggests that it can possibly be used as an out patient treatment without admission to the hospital, which will reduce the costs further; However, larger studies will need to confirm its safety for this purpose.

Conclusion

This randomized control study demonstrated the efficacy and safety of the administration of 800microgram of misoprostol intra vaginally for the management of missed, incomplete and an embryonic abortion.

Recommendation:

Larger studies are needed to conclude that whether the treatment can be considered as an outpatient basis.

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