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Research Article

Efficacy of Vaginal Misoprostol in Termination of Early Pregnancy Failure

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Abstract: Nearly 20% of all confirmed pregnancies end in spontaneous abortion. Misoprostol's use in early pregnancy failure is varied and dose and route are not well established. The aim was to study the efficacy of vaginal misoprostol in causing expulsion of products of conception in early pregnancy failure. Women with an ultrasound diagnosis of early pregnancy failure, less than 12 weeks gestation were included in the study. Tablet Misoprostol 800 mcg was given six hourly vaginally for 3 doses. All observations were noted and analyzed. Mean gestational age was 7.905 $\pm$ 1.2 weeks. Mean Induction abortion interval was 18.125$\pm$1.1 hours. Women with less than six weeks gestational age had least mean induction-abortion interval 15.75$\pm$2.82 hours. Mean dose required was 2044mcg. Efficacy of protocol was 88.89% in achieving complete abortion. The regime had 88.89% efficacy, acceptability (90%) and few side effects. Thus by using a lower dose and appropriate interval between two doses (six hours), the side effects were lessened with high efficacy.
Keywords: Missed Abortion, Misoprostol, Efficacy, Early Pregnancy Failure.

INTRODUCTION

Vacuum aspiration for uterine evacuation in cases of early pregnancy failure is associated with morbidity and mortality. However, the high expense of the PGE2 OR PGF2a vaginally and its instability in room temperature were barriers to their use in developing countries. Misoprostol-a synthetic prostaglandin E_1 analogue, is cheap, stable at room temperature and effective in inducing uterine contractions [1]. However, the regimes for it's use in early pregnancy failure are varied.

Clinical trials had shown vaginal misoprostol to be superior to oral misoprostol [2]. Misoprostol given vaginally took longer to start working, had a lower peak (peak concentration after 60 min), but a more sustained effect. Thus, smaller doses were needed when misoprostol was used vaginally [3].

Aim

The aim of this study was to study the efficacy and the side effects of 800 mcg of vaginal misoprostol six hourly for three doses in causing complete expulsion of products of conception in early pregnancy failure.

METHODOLOGY

This was an observational hospital based prospective study conducted from April 2012 to May 2013. Women with an ultrasound diagnosis of early pregnancy failure, singleton pregnancy, less than 12 weeks gestation, who had not experienced uterine cramping, no active bleeding (os closed on per vaginal examination) and were in a normal frame of mind to give consent and willing for a surgical evacuation in case of failure with medication or active bleeding, were included in the study.

The USG criteria used for diagnosis of early pregnancy failure (missed abortion) were-embryo greater than 7 mm with no embryonic cardiac activity or irregular gestational sac with mean sac diameter greater than 16 mm or a gestational sac more than 15 mm with no visible fetal pole.

Sample size was calculated at 80% study power and alpha error of 0.05 assuming standard deviation for duration of induction to abortion interval of 5 hours and minimum difference to be detected of 2 hours. Thus sample size came to be 50 patients which was enhanced 60 assuming 10% dropout rates.

After counseling and informed written consent, the women were given vaginal tablet Misoprostol 800 mcg every 6 hourly for 3 doses.The dose was decreased to lessen the side effects. Evaluation was done 6 hours after 3rd dose of misoprostol, i.e.at 24 hours. If the uterus was was not felt empty on per vaginal examination or ultrasonography shows products of

conception, then dilatation and evacuation was done and was considered a true drug failure.

RESULTS

The mean age of women in the study was 24.57, ± 4.1 years. 70.37% women came with complaints of bleeding per vaginum. 33 % women had come for routine checkup and USG had shown missed abortion. 81.48% of the women had fetal pole absent or irregular gestational sac in the ultrasonographic findings.

Mean gestational age was 7.905± 1.2 weeks. 51.85% women had an induction abortion interval of 12 to 18 hours. 31.48% aborted in 18 to 24 hrs. Only 5.56% aborted in 6 to 12 hours. Mean Induction abortion interval was 18.125±1.1 hours. Duration of induction to abortion interval of more than 24 hours was seen in 11.11% and was considered true drug failure and these women were surgically evacuated. Efficacy of protocol was 88.89% in achieving complete abortion Table 1.

Mean induction abortion interval was studied in different gestational ages. Women with less than six weeks gestational age had least mean induction-abortion interval 15.75±2.82 hours, while those with gestational age six to eight weeks had highest mean induction-abortion interval time of 18.84±2.37hrs (Table 2).

Table 1: Induction-Abortion Interval

Induction-Abortion Interval (in hrs)	No.	%	Efficacy
6 – 12	3	5.56	88.89% (Complete Abortion)
12 – 18	28	51.85	
18 – 24	17	31.48	
More than 24 hrs	6	11.11	11.11% (True Drug Failure)
Total	56	100.00	

Table 2: Gestational Age and Mean Induction-Abortion Interval Time

Gestational Age (in wks)	No.	Mean Induction-Abortion Interval ±SD (in hours)
Less than 6	4	15.75±2.82
06 to 08	33	18.84±2.37
08 to 10	11	18.18±3.94
10 to 12	6	16.67±3.26
Total	**54**	18.24±2.96

Majority of women with missed abortion required three doses. Women who required one dose were 3.70%. Mean dose required was 2044mcg (Table 3).

Abdominal pain was reported by almost all cases but analgesia was required only by 27.78%. Other adverse effects requiring treatment were diarrhea (more than 4 episodes) in 7.41%, fever/chills, vomiting and mild allergy in 3.70%, headache and dizziness in 1.85%. Most of women did not find these adverse effects difficult to tolerate (Table 4).

Table 3: Number of doses required

Doses	No.	%
1	2	3.70
2	19	35.19
3	33	61.11
Total	54	100.00

Table 4.Various Side Effects

Side Effects	No.	%
Cramping Abdominal Pain	15	27.78
Vomiting	2	3.70
Diarrhoea (more than 4 episodes)	4	7.41
Fever / Chills	2	3.70
Headache	1	1.85
Dizziness	1	1.85
Allergic Reaction	2	3.70

50% women were found to be highly satisfied, 15.45% women were not satisfied because of either failure of treatment or side effect of Misoprostol. The overall acceptability of medical management was good. Most women said they would choose the medical method if they were allowed to choose again and would recommend the method to others.

Four women were dropped from the study due to excessive bleeding per vaginum and were taken for surgical evacuation. One woman got severe urticaria and Misoprostol was stopped and was taken surgical evacuation. One women did not take second dose of vaginal misoprostol timely so was dropped from study.

On follow-up visit, most of cases had no complaints. Few women came with bleeding per vaginum, 3.7% which was mild in amount and no treatment was required. No women required evacuation on follow-up visit.

DISCUSSION

Mean Induction abortion interval was 18.125±1.1 hours.By using 800 mcg, three doses given six hourly we could reduce the side effects and increase the efficacy to 88.89% with high satisfaction level.

Kovavisarch E *et al*. [4] used intravaginal misoprostol 400mcg, single dose with success rate 63%, while Demetroulis *et al*. [5] used single dose of 800mcg misoprostol vaginally with 82.5% success. Francisco Barcelo *et al*. [6] compared 800 mcg and 600 mcg of intravaginal misoprostol 24 hourly for two doses and reported success rate 90.6% and 87.8% while Chen BA *et al*. [7] used misoprostol 800 µg vaginally and repeated if expulsion was not confirmed 2 days after treatment. Expulsion rates after a single misoprostol dose 69% and overall success at 30 days was 82%. Both of them had but had a very long induction abortion interval. Wood Sl *et al*. [8] used two 800 mcg doses of misoprostol vaginally with 80% success Ayres-de-Campos D *et al*. [9] used Misoprostol 600 mcg vaginally and repeated 4 hourly and noticed complete evacuation in 56.8% with higher side effects due to short interval between doses. 13.5% nausea, 5.4% vomiting, 6.8% diarrhea, and 5.4% transient hyperthermia.

CONCLUSION

The advantage of evacuation by Misoprostol is that it includes no surgery and hence no anaesthesia. Vaginal Misoprostol route has ease of administration, no disadvantage of taste. Thus, it may be advocated to be used in outpatient setting in the treatment of early pregnancy failure even at the primary care level .However, the dose schedule should be adhered to and according to the route these should be altered.

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