e-ISSN: 0975-1556, p-ISSN:2820-2643
Available online on www.ijpcr.com
International Journal of Pharmaceutical and Clinical Research 2024; 16(5); 1466-1469

Original Research Article

Investigation into the Outcomes of using Sublingual Misoprostol for Terminating Early Pregnancy

Poonam Singh[1], Shikha Verma[2], Usha Kumari[3]

[1]Senior Resident, Department of Obs & Gynae, NMCH, Patna
[2]Senior Resident, Department of Obs & Gynae, NMCH, Patna
[3]Professor & HOD, Department of Obs & Gynae, NMCH, Patna

Received: 27-02-2024 / Revised: 26-03-2024 / Accepted: 28-04-2024
Corresponding Author: Dr. Shikha Verma
Conflict of interest: Nil

Abstract:

Background and Objectives: Medical methods emerged as an alternative to surgical abortion with the discovery of prostaglandins in the early1930. Nearly 20% of all confirmed pregnancies end in spontaneous abortion*. Misoprostol's use in early pregnancy for termination of Pregnancy its success.

And failure is varied the dose and route are not well established. Studies evaluating different regimens, including combination mifepristone and misoprostol and alone regimens, show varying results related to safety, efficacy and other outcome. To study the efficacy of sublingual misoprostol in causing expulsion of products of conception in early pregnancy failure.

Material and Methods: Women with an ultrasound diagnosis of early pregnancy failure, less than 12 weeks gestation were included in the study. Tablet Misoprostol 600 mcg was given six hourly sublingually for 3 doses. All observations were noted and analyzed. This study was carried out NMCH Patna. Study duration One year.

Conclusion: The regime had 92.85% efficacy, acceptability (90%) and few side effects. Systemic review we find that medical methods of abortion utilizing combination mifepristone and misoprostol or misoprostol alone are effective, safe and acceptable.

Keywords: Medical Abortion, Misoprostol, systemic review.

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 E1 analogue, ischeap, stable at room temperature and effective in inducing uterine contractions [1] However, the regimes for its use in early pregnancy failure are varied. Individual studies evaluating medical management of abortion at <63days have not demonstrated superiority of one of these regimen , not only have studies compared combination mifepriston and misoprostol (combination mifepriston misoprostol) with misoprostol alone, Clinical trials had shownvaginal misoprostol to be superior to oral misoprostol [2]. Misoprostol given vaginally took longer to start working, had a lower peak (peak concentration after 60mins), but a more sustained effect. Thus, smaller doseswere needed when misoprostol was used vaginally. Pharmacokinetics now show that sublingual misoprostol has the shortest onset of action, the highest peak concentration and greatest bioavailability among the routes of administration [3].

Material and Methods

This was an observational hospital based prospective study. 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, 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. Pregnant women with more than 12 weeks amenorrhea, not compliant to treatment were excluded from 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 greaterthan 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 were enhanced 55 assuming 10% dropout rates. After counselling and informed written consent, the women were given sublingualtablet Misoprostol 600 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 not felt empty on per vaginal examination or ultrasonography shows products ofconception, then dilatation and evacuation was done and was considered a true drug failure.

Results

The mean age of women in the study was 23.79+5.1 years. 70% women came with complaints of bleeding per vagina. 30% women had come for routine checkup and USG had shown missed abortion. 79.78% of the women had fetal pole absent or irregular gestational sac in the ultrasonographic findings. The other finding was a blighted ovum seen in 20.22%. Mean gestational age was 7.946+1.2 weeks. 48% women had an induction abortion interval of 12 to 18 hours. 39.28% aborted in 18 to 24 hrs. Only 5.36% aborted in 6 to 12 hours. Mean Induction abortion interval was 18.241+1.2 hours. Duration of induction to abortion interval of more than 24 hours was seen in 7.15% and was considered true drug failure and these women were surgically evacuated. Efficacy of protocol was 92.85% in achieving completeabortion (Table 1).

Table 1: Induction Abortion Interval

Induction-Abortion Interval (in hrs)	No.	%	Efficacy
6-12	3	5.36	92.85% (complete abortion)
12-18	27	48.21	
18-24	22	39.28	
>24	4	7.15	7.15%% (complete abortion)
Total	56	100	

Mean induction abortion interval was studied in different gestational ages. Women with less than six weeks gestational age had highest mean induction-abortion interval 22 +2hrs, while those with gestational age six to eight weeks had least mean induction-abortion interval timeof 17.38+2.86 hrs. (Table 2)

Table 2: Gestational age and Mean induction-abortion interval time

Gestational Age (in wks)	No.	Mean Induction-Abortion Interval+SD (in hours)
<6	3	22+2 06
6-8	34	17.38+2.86
8-10	14	18.42+3.45
10-12	5	20+2.55
Total	56	18.123+.14

Majority of women with missed abortion required three doses. Women who required one dose were 5.35%.Mean dose required was 1560mcg(Table 3)1.79%%.Most of women did not find these adverse effects difficult to tolerate.

Table 3: Various Side Effects

Side Effects	No.	%
Vomiting	3	5.36
Fever / Chills	4	7.14
Diarrhoea	6	10.71
Headache	1	1.79
Dizziness	1	1.79
Allergic Reaction	1	1.79
Abdominal Pain	16	28.57

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. Three 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 for surgical evacuation. two woman did not take second dose ofsublingual Misoprostol timely so was dropped from thestudy On follow-up visit, most of cases had no complaints Few women came with bleeding per vaginum, 3.43% which was mild in amount and no treatment was required no. women.

Discussion

Mean induction abortion interval was 18.241+1.2 hours.Efficacy of protocol was 92.85% in achieving complete abortion. Ayres-de-Campos D et al [4] used Misoprostol 600 mcg vaginally and repeated 4 hourly. Complete medical evacuation occurred in 56.8% with higher side effects due to short interval between doses.13.5% nausea vomiting, 6.8% diarrhea and 5.4% transient hyperthermia. Ngoc NT et al [5] (2004) used 800mcg vaginal Misoprostol only single dose and mean induction abortion interval was high-21hrs. Barcelo F et al [6] had a success of 87.8% with 600 mcg sublingual misoprostol every 24 h for two days buthad a very long induction evacuation interval. Kushwah S. et al [7] in their study also reported complete abortion rate.

Table 4: Number of Doses Required

Doses	No.	%
1	3	5.35
2	18	32.14
3	35	62.51
Total	56	100

Abdominal pain was reported by almost all cases but analgesia was required only by28.57 %. Other adverse effects requiring treatment were fever/chills(7.14%) and vomiting in 5.36%, diarrhea (more than 4 episodes) in 10.71%, headache, dizziness and mild allergy in to be 92% in 600mcg misoprostol sublingual group and the side effect were hot flashes 24%, diarrhea and nausea 2% in10% with sublingual misoprostol and 92% women were satisfied with their study. [8] Tang OS, Lau WN et al[8] used 600 mcg of misoprostol three hourly up to three dosessublingually with success rates of 87.5%.their interval was shorter and they noticed a higher incidence of diarrhea (70%) and fatigue was experienced. [9,10]

Conclusion

The advantage of evacuation by Misoprostol is that it includes no surgery and hence no anaesthesia. Misoprostol tablet has advantage of low cost, long shelf life, lack of need for refrigeration and its easy availability. Thus, it may be advocated to be used in outpatient setting in thetreatment of early pregnancy failure even at the primarycare level.

References

1. Philip NM, Winikoff B, Moore K, Blumenthal P. A consensus regimen for early abortion with misprostol. Int J Gynaecol Obstet 20 04; 87: 281-3.
2. Ngai SW, Chand YM, Tang O, Ho PC. Vaginalmisoprostol as medical treatment for first trimester spontaneous miscarriage. Hum Reprod 2001; 7: 1493-6.
3. Jurkovic D, Ross JA, Nicolaides KH: Expectant management of missed miscarriage. British Journal of Obstetrics and Gynaecology 1998; 105:670-71
4. Aryes-de-Campos D, Teixeria-da-Silva J et al. Vaginal misoprostol in the management for first trimester missed abortions. Int J. Gynaecol Obstet. 2000; 74: 53-57.
5. Ngoc NTN, Blum J, Westheimer E, Quan TTV, Winikoff B. Medical treatment of missed abortion using misoprostol. Int J Gynecol Obstet 2004; 87:138-42.
6. Barcelo F, Catalina De Paco Jose J. LO, Pez-Espi´N,Silva Y, Abad L, Parrilla JJ The management of missed miscarriage in an outpatient setting: 800 versus 600 mcg of vaginal misoprostol. Australian and New Zealand Journal of Obstetrics and Gynaecology 2012; 52: 39–43.
7. Kushwah DS, Kushwah B, Salman M T, Verma V KAcceptability and safety profile of oral and sublingual misoprostol for uterine evacuationfollowing early fetal demise Indian J Pharmacol. 2011 May-Jun; 43(3): 306–310.
8. Tang OS, Lau WN, Ng EH, Lee SW, Ho PC. A prospective randomized study to compare the use of repeated doses of vaginal with sublingual misoprostol in the management of first trimester silent miscarriages. Hum Reprod; 2003; 18 (1): 176- 81.

9. Blum j, Raghavan S, Dabash R, Ngoc N, Chelli H, Haji S, Conkling k, winikoff B. comparison of misoprostol only and combined mifepriston-misoprostol regimen for home based early medical abortion in Tunisia and Vietnam .int jGynaecol obstel. 2012;118;166-71.

10. Ngoc NT, Blum J, Raghavan S, Nga NT, Dabash R, Diop A, Winikoff B. Comparing two early medical abortion regimens: mifepristone+misoprostol vs. misoprostol alone. Contraception. 2011;83(5):410–7