ALTERNATIVE TO SURGICAL EVACUATION OF UTERUS: MISOPROSTOL FOR POST-ABORTION CARE

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ABSTRACT

Objective *To compares the effectiveness of single 600 micrograms (µg) dose of sublingual misoprostol with manual vacuum aspiration (MVA) for treatment of incomplete and missed abortions.*

Study design *Quasi- Experimental study*

Place & Duration of study *Post-abortion care room, Jinnah Postgraduate medical centre (JPMC) Karachi, from September 2008 to December 2008.*

Patients and Methods *Hundred consenting women with incomplete and missed abortions were randomized to either a single dose of 600 micrograms of sublingual misoprostol or MVA for treatment of their condition. Main outcome measure was complete abortion following initial treatment. Secondary outcome measures were satisfaction rate and acceptability of the method.*

Results *Regardless of treatment assigned, nearly all participants had a complete uterine evacuation (Misoprostol =92 % MVA= 100% p = 0.12). A slightly more satisfaction rate was observed in the misoprostol group (p=0.001) as 86% participants expressed desire to choose misoprostol again while the number was 76% in MVA group.*

Conclusions *Sublingual misoprostol is as safe and as effective as manual vacuum aspiration for post-abortion care.*

Key words *Incomplete abortion, Missed abortion, Misoprostol*

INTRODUCTION:

First trimester abortion is responsible for the maximum number of pregnancy loss.[1] South-Asia (Bangladesh, Nepal, India, Pakistan and Sri-lanka) is home to 28% of World's population and almost one third (30%) of world's maternal deaths takes place in this region.[2] The World Health Organization has estimated that 13% of all the maternal deaths in South-Asia are related to abortion procedures.[3] In Pakistan, approximately 890,000 women present with missed abortion or incomplete abortion annually and estimate annual abortion rate is 29 per 1000 women aged 15-49 years.[4]

Post-abortion care (PAC) for missed and incomplete abortion can be done surgically, medically with misoprostol or expectantly by awaiting spontaneous expulsion.[5-7] Surgical evacuation is an effective method with more than 95% success rate.[8] Traditional methods for surgical evacuation of uterus are associated with major morbidity in up to 1% of women and minor morbidity in 10%.[9] Surgical aspiration with manual vacuum aspirator is a safe and effective technology and when used correctly empty the uterus almost completely.[8]

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In large studies of medical abortion and vacuum aspiration, the frequency of failure does not seem to differ.[10,11,12] Expectant management was accepted by only 40% of women due to uncertainty in predicting the success(20- 80%).[13]

Misoprostol is a safe option for first trimester PAC.[14] It has become an important drug in obstetrics and gynecological practice because of its uterotonic and cervical priming action. A pharmacokinetic study compared oral, vaginal, sub-lingual and rectal routes of administration of misoprostol.[15] Sublingual route avoids first pass effect through the liver, has the shortest time to peak concentration that is 30 minutes as compared to 75 minutes in the vaginal route and greatest bioavailability when compared to other routes. This is because of high vascularity of buccal mucosa. It also avoids painful vaginal administration, more convenient to take and offers more privacy for the women.

Nineteen different studies have shown efficacy of misoprostol with success rates ranging from 13-100% but most showing efficacy with misoprostol regimen at around 90%.[16-25] In the Weeks trial, a single dose of 600 micrograms of oral misoprostol performed slightly better than MVA (96.3% versus 95.5%) when used to treat 317 women with incomplete miscarriage at a large teaching hospital in Kampala, Uganda.[26] Rate of satisfaction were similarly high for both the groups. To complement PAC program, the present study was designed to assess the role of sublingual misoprostol as an alternative to MVA for post-abortion care.

PATIENTS AND METHODS:

From September to December 2008,100 women were recruited for the study in ward-9, JPMC, Karachi.The eligibility for incomplete abortion was defined as; uterine size equivalent to a gestation of less than 12 weeks LMP, open cervical os, past or present history of vaginal bleeding during pregnancy and if available an ultrasound evidence of retained products of conception or fetal demise.Similarly,missed abortions were eligible on clinical assessment of uterine size in relation to period of gestation and an ultrasound evidence of the same. Additional inclusion criteria were no signs of profuse bleeding, severe infection and no known contraindication to misoprostol and good general health. Previous scarred uteri were not included in the study. Women were asked if their current abortion was spontaneous or induced. Given the clandestine nature of induced abortion in this region, it is likely that some women may not have provided full account of events leading to incomplete abortions.

In women with signs of infection, fever commonly associated with unsafe induced abortions were prescribed additional medications as antibiotics (capsule vibramycin 100 milligrams for 5 days to treat or as a prophylaxis against late infections and tablet ibuprofen 200 milligrams for pain relief).

All eligible women were counseled and given detailed information about the protocol by the hospital staff. Consenting women were randomized to either Group I, a single dose of 600 micrograms of sublingual misoprostol or Group 2, MVA (the present standard of care in the department). After informed consent, women received misoprostol sublingually in the presence of clinician/duty nurse. Women allocated to MVA (Ipas, Chapel Hill, NC, USA) were given surgical evacuation by the trained clinician. All participants, regardless of the treatment assigned, were given paracetamol 200 milligrams for pain and counseled about adverse effects. Those receiving misoprostol were admitted in the ward for 48 hours to deal with any heavy episode of bleeding that might occur. Later, they were discharged and scheduled to return to the hospital for follow-up care after 10 days. Women were also informed that they could return to the hospital or contact the study providers at anytime if they had additional concerns.

At the day 10 follow-up visit, each woman's status was assessed by clinical examination including a detailed history, a bimanual examination and an ultrasound scan. Women with retained products in the uterus on examination on study day 10 could wait an additional week for the products to evacuate on their own. If they agreed, a second follow-up appointment was scheduled on study day 20. Women who did not wish to wait until day 10 underwent surgical evacuation using MVA. Where the treatment was completed, women were interviewed to assess the acceptability of the method assigned.

The primary outcome measure was complete uterine evacuation without recourse to surgical evacuation for any reason. Other outcome measures were adverse effects, pain and acceptability. As the study sought to assess women's satisfaction and acceptability of the method, each participant was asked that if given the choice she would select the method again.

Data entry and analysis were conducted using the Statistical Package for the Social Sciences, version 13 (SPSS Inc; Chicago, IL, USA). Frequency and percentages were computed for variables like age groups, parity and history of previous abortion success rate, satisfaction and acceptability of the patient. A Chi-square test was used for comparison of outcome measures between study groups and values 0.05 were considered statistically significant.

RESULTS:

A total of 100 patients were included in the study. Fifty patients were treated with manual vacuum aspiration and other fifty with sublingual misoprostol for post-abortion care. The mean age of patients was 27.4± 5.16 years (range 41-16 years). Age difference was not statistically significant between groups (p=0.55) as shown in table 1.

Majority of the women were multiparous in both the groups followed by grand multiparity (parity >4). Parity greater than 7 was significantly higher in misoprostol group than MVA (p=0.016). Previous miscarriage was not significant between the groups while previous induced abortions were significantly higher in those patients who were treated with manual vacuum aspiration than those treated with misoprostol (p=0.0001).

The rate of successful abortions was 92% (46 out of 50 women) in patients with misoprostol and 100% with manual vacuum aspiration. The success rate for MVA was slightly higher than misoprostol, however statistically significant difference was not observed between the groups (Fisher exact test; p=0.12).

The data showed that women in both the groups were satisfied with their treatment. Misoprostol users were significantly more likely to report that they were "very satisfied" with the method. When asked about future selection for the two methods, reports from both the user groups was positive. 86% users replied misoprostol to choose again in future if needed while 76% replied in favor of MVA as shown in table-2.

Table: I: Characteristics of Study Patients

Characteristics of the patients	Misoprostol Groups n=50	MVA Groups n=50	P-value
Age (Years)			
16- 20 years	13 (26%)	18 (36%)	0.55
21-30 years	29 (58%)	25 (50%)	
31-41 years	08 (16%)	07 (14%)	
Parity			
1-4	25 (50%)	30 (60%)	0.016*
5-7	15 (30%)	19 (38%)	
>7	10 (20%)	01 (2%)	
History			
Previous Miscarriage	13(26%)	19(38%)	0.18
Previous induced abortion	17(34%)	35(70%)	0.0001*

Table: II: Satisfaction and Acceptability of Patients

Variable	Misoprostol Groups n=50	MVA Groups n=50	P-value
Overall Satisfaction			
Very Satisfied	33 (66%)	17(34%)	0.001*
Satisfied	17 (34%)	30 (60%)	
Unsatisfied	00 (0%)	03 (6%)	
Acceptability (Would choose the method again)			
Yes	43 (86%)	38 (76%)	0.18
No	04 (8%)	03 (6%)	
Not sure	03(6%)	09(18%)	

DISCUSSION:

Spontaneous and missed abortions occur in approximately 15% of clinically recognized pregnancies.[27] The results of this study have demonstrated that the use of single 600 micrograms sublingual dose of misoprostol is an effective and acceptable method of post-abortion care up to 12 weeks gestation. The complete abortion rate of this regimen was 92% as compared to MVA (100%). However, there was no significant difference between the two groups.

A misoprostol alone regimen will be considered effective if the complete abortion rate reaches 90%. Different misoprostol alone regimens have been reported in the literature for medical abortion in the first trimester.[28-31] These studies are difficult to compare as different regimens of misoprostol were used and the waiting time to diagnose complete abortion was also different. The high efficacy rate with single 600 micrograms of sublingual misoprostol is similar to that shown by Ngoc et al in Vietnam and slightly higher than other reports using the same regimen.[16] This is likely due to strict inclusion criteria, which excluded women with closed cervical os for incomplete abortion, the limited use of ultrasound as a determining factor of success and a longer duration of time from enrolment to assessment of abortion completion.

The regimen using repeated doses of misoprostol alone that can be finished within one day have the advantage of requiring less hospital visits and ultrasound examination. Only two studies used regimen that can be finished within one day.[29,31] It appears that increasing the dose and shortening the dosing interval of vaginal misoprostol does not improve the complete abortion rate. By changing the route of administration to sub-

lingual, a complete abortion rate of almost 92% was achieved in this study with no serious complication reported in any case. However, more studies are required to confirm the safety of sub-lingual misoprostol.

Women allocated to misoprostol group praised the method's simplicity and were also satisfied with the result, although there was no significant statistical difference in women's satisfaction rate and acceptability of their assigned treatment. The study also involved all eligible women regardless of whether they reported their current abortion to be induced or spontaneous. Some providers may believe that the misoprostol may work differently in these two subsets of women; however there is no scientific evidence to support this presumption.[14]

Abortion related complications continue to cause maternal death throughout South-Asia, including Pakistan. It is crucial that every available option be used in an effort to reduce mortality and morbidity. Developing countries require high quality data on abortion related mortality and morbidity to monitor the success of interventions aimed at improving and saving women's lives. This study supports for inclusion of misoprostol in PAC programs by demonstrating as being safe, effective and acceptable non-surgical alternative to MVA.

CONCLUSIONS:
Misoprostol for post-abortion care would decrease the burden on tertiary health care facilities because of its low cost. It has an additional benefit of being highly acceptable to women as it is less invasive. It would also limit the burden on busy gynecologists as well as reducing the need for surgical equipments, sterilization and anesthesia.

REFERENCES:

1. Khaskheli M. Evaluation of early loss in Pakistan. Pak J Med Research 2002; Vol:41 No(2).
2. World Health Organization, United Nations Children's Funds, United Nations Population Funds, Maternal mortality in 1995.Geneva: World Health organization: 2001
3. State of World's Population. Newyork.NY: United Nations Population Fund 2000
4. Sattar ZA, Singh S, Faryal F. Estimating the incidence of abortion in Pakistan. Stud Fam Plann 2007;38:11-22.
5. Zhang J, Gilles GM , Barnhart K, Creinin MD, West Hoff C, Freidrick MM. A Comparison of medical management with misoprostol and surgical management for early pregnancy failure. N Engl J Med 2005; 353:761.
6. Jurkovic D, Ross JA, Nicholaides KH. Expectant management of missed miscarriage. Br J Obstet Gynaecol 1998;105: 670.
7. Child TJ, Thomas J, Rees M, Mac Kenzie I.Z. Morbidity of first trimester aspiration termination and the seniority of the surgeon. Hum Reprod 2001;16,875-8.
8. Joint Study Of Royal College Of General Practitioners and the Royal College of Obstetricians and Gynecologists. Inducction abortion operations and their early sequele. J R Coll Gen Pract.1985;35:175-80.
9. Balogh S. Is curettage needed for uncomplicated incomplete spontaneous abortions? Am J Obstet Gynecol 1988; 179:1279.
10. Freedman MA, Jillson DA, Coffin RR, Novick LF. Comparison of complication rates in first trimester abortions performed by physicians assistants and physicians. Am J Public Health 1986; 76:550-4.
11. Henshaw RC, Naji SA, Russell T, Templeton AA. A comparison of medical abortion (mifepristone and gemeprost) with surgical vacuum aspiration: efficacy and early medical sequele. Hum Reprod 1994;9:2167-72.
12. Ulmann A, Silvestre L, Chemana L, Rezvani Y, Renault M, Aguillaume C J et al. Medical termination of early pregnancy with mifepristone (RU 486) followed by prostaglandin analogue. Acta Obstet Gynaecol Scand 1992;71:278-83.
13. Shamim S, Fahima T, Salahuddin R, Irfani I, Usmani I. New trends in medical management of missed miscarriages. Ann Abbasi Shaheed Hospital. 2004; 9: 481-5.
14. Tango OS, Schweer H, Seyberth HW, Lee SWH, HO PC. Pharmacokinetics of different routes of administration of misoprostol. Hum Reprod 2002;17: 332-6.
15. Women of the World: Laws and Policies affecting their Reproductive Lives:Francophone Africa. New York, NY; The Centre for reproductive law and policy, 1999.

Africa. New York, NY; The Centre for reproductive law and policy, 1999.

16. Dao B, Blum J, Theiba B, Rhagavan S, Oveder A, Lankoaride J, Winikoff B. Is misoprostol safe, effective and acceptable alternative to manual vacuum aspiration for post-abortion care? Results from a randomized trial Burkina Faso, West Africa. Br J Obstet Gynaecol 2007;114:1368-75.

17. World Health Organization. Safe abortion: Technical and policy guideline for health system. Geneva, Switzerland : WHO, 2003.

18. Nagai SW, Chan YM, Tango OS, Ho PC. Vaginal misoprostol as medical treatment for first trimester spontaneous miscarriage. Hum Reprod 2001; 16:1493-6.

19. Blanchard K, Taneepanichskul S, Kiriwat O, Sirimai K, Svirirojana N, Mavimbela N et al. Two regimens of misoprostol for treatment of incomplete abortion . Obstet Gynaecol 2004;103: 860-5.

20. Ngoc NTN, Blum J, Durocher J, Quan TT, Winikoff B. Medical management of incomplete abortion using 600 versus 1200 mcg of misoprostol. Contraception 2005;72:438-42.

21. Chung TK, Cheung LP, Leung TY, Haines CJ, Chang AM. Misoprostol in the management of spontaneous abortion. Br J Obstet Gynaecol 1995; 102:832-5.

22. Demetroulis C, Saridogan E, Kunde D, Naftalin AA. A prospective randomized controlled trial comparing medical and surgical treatment for early pregnancy failure. Hum Reprod 2001;16:365-9.

23. Henshaw RC, Copper K, EL Refaey H, Smith NC, Templeton AA. Medical management of miscarriage: Non-surgical uterine evacuation of incomplete and inevitable abortion. Br Med J 1993;306:895-5.

24. Muffley PE, Stitely ML, Gherman RB. Early intrauterine pregnancy failure: A Randomized trial of medical versus surgical treatment. Am J Obstet Gynaecol 2002;187:321-6.

25. Pandian Z, Ashok P, Templeton A. The treatment of incomplete miscarriage with oral misoprostol. Br J Obstet Gynecol 2001;108:213-4.

26. Weeks A, Alia G, Blum J, Winikoff B, Ekwaru P, Durocher J et al. A randomized trial of oral misoprostol versus manual vacuum aspiration for the treatment of incomplete abortion in Kampala Uganda. Obstet Gynaecol 2005;106:540-7.

27. Trinder J, Beocklehurst P,Porter R, Read M, Vyas S, Smith L. Management of miscarriage: expectant, medical or surgical? Results of randomized controlled trial (miscarriage treatment (MIST) trial). Br Med J 2006;332:1235-40.

28. Bugalho A, Faundes A, Jamisse L, Usfa M, Maria E, Bique C. Evaluation of the effectiveness of vaginal misoprostol to induce first trimester abortion. Contraception 1996;53:244-6.

29. Koopersmith TB, Mishell DR. The use of misoprostol for termination of early pregnancy. Contraception 1996;53: 237-42.

30. Carbonell J, Velazco A, Fernandez C. The use of misoprostol for termination of early pregnancy. Contraception 1007;55:165-8.

31. Tang OS, Wong KS, Tang LCH, Ho PC. Pilot study on the use of repeated doses of misoprostol in termination of pregnancy at less than 9 weeks of gestation. Adv Contraception 1999;15:211-6.