International Journal of Reproduction, Contraception, Obstetrics and Gynecology
Abbas ABM et al. Int J Reprod Contracept Obstet Gynecol. 2016 May;5(5):1360-1363
www.ijrcog.org

pISSN 2320-1770 | eISSN 2320-1789

DOI: http://dx.doi.org/10.18203/2320-1770.ijrcog20161288

Research Article

The use of single dose of oral misoprostol (600µg) at home in management of first trimester miscarriages in El-Mukala, Yemen

Abo Bakr A. Metwaly[1], Ahmed M. Abbas[1]*, Maher Al-Sakkaf[2]

[1]Department of Obstetrics and Gynaecology, Assiut University, Egypt
[2]Department of Obstetrics and Gynaecology, Hadhramout University, Yemen

Received: 21 February 2016
Revised: 22 February 2016
Accepted: 18 March 2016

***Correspondence:**
Dr. Ahmed M. Abbas,
E-mail: bmr90@hotmail.com

ABSTRACT

Background: In the management of first trimester miscarriage, the use of oral misoprostol is beneficial for patients as it offers a more discrete and less invasive route for those women who find vaginal administration unacceptable. In spite of high incidence of side-effects from use of oral misoprostol women still found oral route satisfactory.
Methods: This study was a prospective cohort study done at El-Mukala maternal and child hospital and Hadhramout maternal and child university hospital in the period between 1st October 2014 and 30th September 2015. All pregnant women (less than 14 weeks) who were diagnosed as an embryonic pregnancy or missed miscarriage were included in the study. Every patient received single dose of oral misoprostol 600 µg in half full stomach at home. The primary outcome measure was complete miscarriage rate.
Results: One-hundred women were included in the study. The mean age of study participants was 26.25±4.08 years, the mean BMI was 27.35±3.6 while the mean parity was 2.6±1.5.Ten cases needed emergency surgical evacuation within the period of first 48 hours. Complete miscarriage had occurred in 75 cases, 65 of them in the first 48 hours. Fifteen cases presented by incomplete miscarriage after waiting for one week. They needed surgical evacuation at the end of 7 days due to still considerable intrauterine contents.
Conclusions: In our closed community in El-Mukala, Yemen, the use of oral misoprostol in single dose of 600 µg at home as a method for termination of first-trimester miscarriage was effective (75%, success rate), tolerable regarding side effects, has the advantage of high confidentiality and privacy resulting in good satisfaction.

Keywords: Oral misoprostol, First trimester miscarriage, Missed miscarriage

INTRODUCTION

First-trimester miscarriage is defined as a pregnancy that ends spontaneously before the fetus is viable.[1] Nearly 8-20% of clinically recognized pregnancies fewer than 20 gestational weeks end in miscarriage, with 80% occurring in the first 12 gestational weeks.[2] Three options are available for managing first-trimester miscarriage in a patient; expectant management, surgical evacuation or medical management.

While surgical evacuation is a fast and effective procedure when performed by a well-trained physician, it is nevertheless a blind and invasive procedure that carries a risk of injury, bleeding and infection, in addition to possible complications from the anesthesia. Medical termination requires less extensive maneuver than surgical evauation.[3,4]

Prostaglandins offer the advantage of promoting both cervical ripening and myometrial contractility. Misoprostol is a synthetic analog of prostaglandin E1,

which was initially licensed for the prevention and treatment of peptic ulcers. It has been used to induce miscarriage through its various routes of administration.[5] Misoprostol has advantages over other prostaglandins and other drugs in the set of pregnancy termination: less cost, widely available in many countries, stable at room temperature and has multiple routes of administration (oral, vaginal, rectal or sublingual).[6]

However the ideal dosage and route of misoprostol still remains to be determined, with more than thirty different dosage regimens described in the literature for its use in obstetrics.[7]

In spite of higher peak serum level of sublingual route than oral and vaginal route due to very rapid absorption, the oral route was characterized by its steady high serum level and longer duration than sublingual route and its higher efficacy than vaginal route as vaginal route may associated with less absorption due to associated vaginal bleeding.[8,9]

Oral route is preferable due to avoiding repeated vaginal examination needed for the vaginal route of misoprostol which may be inconvenient and more invasive. Taking the drug at home decreases the long hospital stay. This will agree with the culture of Yemen society which are enclosed environment regarding females, as there is agreement of most people in the society (male and females) that there is no need for genital examination even if it is necessary and if any method or procedure will avoid genital examination it will be preferable, even if the service will be provided by a female doctor, and receiving the drug orally at home give the patient the sensation of comfortability and confidentiality.

So the objective of our study is to determine the efficacy, safety, tolerability, side effects and acceptance of single dose (600µg) of oral misoprostol at home to the women in El-Mukala city the capital of one of the biggest governorate of south Yemen (Hadhramout).

METHODS

This study was prospective cohort study done at El-Mukala maternal and child hospital and Hadhramout maternal and child university hospital in the period between 1st October 2014 and 30th September 2015.The study protocol was approved by our institutional ethical committee of Hadhramout faculty of medicine. The participants were recruited from the antenatal care outpatient Clinic of the aforementioned hospitals

All pregnant women (less than 14 weeks) who were diagnosed as an embryonic pregnancy or embryonic death (missed miscarriage) by transvaginal ultrasound (TVUS) were included in the study. An embryonic pregnancy was defined as an intrauterine gestational sac measuring 20 mm in diameter with no embryonic pole or yolk sac. Embryonic death was defined as an intrauterine pregnancy with a fetal CRL more than 6 mm without cardiac activity and in different gestational age.

We excluded patients with scarred uterus, inevitable or incomplete miscarriage, known allergy to misoprostol, asthmatic women and those who refused to participate in the study. An assessment of basic data was done involving age, parity, BMI and gestational age before the start of the study.

After recruitment, the patients were given a detailed explanation about the study protocol and signed an informed consent if they agreed to participate in the study. Every patient received single dose of oral misoprostol 600 µg (3 tablets of 200 µg misotac, sigma, one shot) in half full stomach (after a meal by half an hour) at home.

After receiving the drug, patients were requested to come immediately to the emergency department of both hospitals if any considerable bleeding or intolerable pain has occurred at any time even before the pass of first 48 hours, and report the passing of any tissue vaginally. Any patient received analgesic drugs were recorded with the dose of used analgesics.

Forty-eight hours after misoprostol administration, a physical examination and TVUS were performed to evaluate whether or not complete expulsion had occurred. If a woman had complete expulsion, this was defined as success. Patients who still had an incomplete miscarriage after 48 hours but without symptoms, this was defined as failure and that patient choose either to have surgical evacuation immediately or to come after 7 days for reassessment by TVUS to detect occurrence of complete miscarriage or not.

But during this period, strict advice was given again to the patient to come immediately to the emergency department of the hospitals if any disturbing symptoms like considerable bleeding or pain has occurred and broad spectrum antibiotic in the form of doxycycline 100 mg capsule twice daily plus metronidazole tablet 500 mg 3 times daily for 7 days. Those women who still did not have complete miscarriage by the 7th day, surgical evacuation was done for them.

The primary outcome measure was complete miscarriage rate which was defined clinically by complete expulsion of the uterine contents confirmed by TVUS showing completely empty uterus. Secondary outcomes were side-effects of misoprostol and the need for analgesics for management of pain in first 48 hours from the start of the therapy. Patient satisfaction was assessed and defined by woman acceptance of the method regarding efficacy, tolerability of side effect and agreement to use it in the future or recommend it to a friend.

All data were analyzed using SPSS software Chicago, IL, USA, version 21. Qualitative data were expressed as

frequency and percentage. Quantitative data were presented in terms of mean and standard deviation.

RESULTS

One hundred twenty-two women were approached to participate in this study. Twenty-two women were excluded due to the presence of different exclusion criteria or their refusal to participate in the study. The remaining 100 women received misoprostol dosage at home as proposed in the protocol. The mean age of study participants was 26.25±4.08 years, the mean BMI was 27.35±3.6 while the mean parity was 2.6±1.5. The mean gestational age for all cases diagnosed as missed miscarriage and presented for termination of pregnancy was 10.85±2.4 weeks.

(Table 1) shows the outcome of study participants. Ten cases needed emergency surgical evacuations within the period of first 48 hours (presented to the emergency department before the end of the first 48 hours by severe vaginal bleeding). Complete miscarriage had occurred in 75 cases, 65 of them in the first 48 hours. Fifteen cases presented by incomplete miscarriage after waiting for one week. They needed surgical evacuation at the end of 7 days due to still considerable intrauterine contents.

Table 1: The outcome of study participants.

Outcomes	N	%
Complete miscarriage rate within the first 48 hours (primary outcome)	65	65%
Cases need surgical evacuation within the first 48 hours due to considerable bleeding or pain	10	10%
Cases of complete miscarriage within 7 days without surgical evacuation (success at the end of 7 days)	10	10%
Cases need surgical evacuation at the end of 7 days due to incomplete miscarriage	15	15%
Total	**100**	**100%**

Table 2: Patients' satisfaction after the end of the procedure.

Items of satisfaction	n (%)
Efficacy	65 (65%)
Tolerability towards side effects	60 (60%)
Patient recommends using this route in the future	80 (80%)
Patient recommends this route to friend	82 (82%)
Sensation of privacy and confidentiality	100 (100%)

The most common side effect that reported by the cases were gastrointestinal tract symptoms in the form of nausea (20%), diarrhea (20%) and vomiting (5%). There were two types of pain recorded, first was a tolerable pain without the need of analgesics and has occurred in 40 cases, the other was intolerable pain which required analgesics has occurred in 5 cases and all of them responded to a single dose of intramuscular ketolac according to pain attacks.

In spite of considerable side effects, single dose of 600 µg misoprostol was found to have good satisfaction rate and a higher percentage of recommendation in the future for the same patient or her friend. All of the women were satisfied regarding privacy and confidentiality as all of them received oral drug simply at home without affection upon the expected incidence of side effects or emergency surgical evacuation.

DISCUSSION

In the current study, we investigated the use of oral misoprostol as single a dose of 600 µg at home as a method for termination of first-trimester miscarriage and it was proved that it is effective, with tolerable side effects and resulted in high rates of patients' satisfaction.

The success rate in our study was 75% (65% after 48 hours increasing to 75% after one week).The patients who needed surgical evacuation were 25 women (40%) were emergency within the first 48 hours due to considerable vaginal bleeding and 60% of evacuation after 7 days due to incomplete miscarriage. This agree with the study done by Benchamanon and Phupong, in which the overall rate of complete termination with misoprostol was 61.38% within the first 48 hours of receiving a single dose of oral misoprostol 600 µg while 38.62% of cases required further surgical evacuation in the same period.[10]

Our results were lower than Tang et al. who reported a success rate 87.5% and this difference may be related to using of different route of misoprostol (sublingual route) and also due to repeated dose 600 µg every 3 hours of this route instead of a single dose that was in our study.[11] Also, Bhadra and Deb reported a success rate 97.9% in the first 72 hours and this may be due to using of single dose of oral misoprostol in management of incomplete miscarriage not missed miscarriage of our study.[12]

Regarding side effects, the most common side effect was related to gastrointestinal tract, in the form of nausea (20%), diarrhea (20%) and vomiting (5%). Also, tolerable pain that not need analgesics was occurred in 40 % of cases and intolerable pain which required analgesics had occurred only in 5 cases. This agrees with Benchamanon and Phupong study in which the incidence of side effects was pain 85.5%, diarrhea 61.55%, nausea 41.85%, fever 10.9%, rigors 5.5% and vomiting 5.5%.[10] From previous studies it was found that the route of administration affects the side effects rate more than the dosage.[13]

Regarding satisfaction, in our study, we found that women had a good satisfaction rate and a higher percentage of the recommendation in the future for

themselves or her friends. This agrees with the study of Benchamanon and Phupong, who found total percentage of satisfaction, was 71%.[10]

CONCLUSIONS

It was found in our closed community in Hadhrmout governorate in Yemen, that the use of oral misoprostol as a single dose of 600 µg at home as a method for termination of first-trimester miscarriage was effective, tolerable regarding side effects and had advantage of high women privacy resulting in good satisfaction.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Ambusaidi Q, Zutshi A. Experience at effectiveness of misoprostol for induction of first-trimester miscarriages. Sultan Qaboos Univ Med J. 2015;15(4):534-53.
2. Robledo C, Zhang J, Troendle J, Barnhart K, Creinin MD, Westhoff C, et al. Clinical indictors for success of misoprostol treatment after early pregnancy failure. Int J Gynaecol Obstet. 2007;99:46-51.
3. Niinimäki M, Suhonen S, Mentula M, Hemminki E, Heikinheimo O, Gissler M. Comparison of rates of adverse events in adolescent and adult women undergoing medical abortion: Population register based study. BMJ. 2011;342:2111.
4. World health organization. Safe abortion: technical and policy guidance for health systems. 2nd ed. Geneva WHO; 2011.
5. Vimala N, Dadhwal V, Mittal S. Sub lingual misoprostol for second-trimester abortion. Int J Gynecol Obstet. 2004;84(1):89-90.
6. Borgatta L, Kapp N. Society of family planning. clinical guidelines. Labor induction abortion in the second trimester. Contraception. 2011;84:4-18.
7. Wildschut H, Both MI, Medema S, Thomee E, Wildhagen MF, Kapp N. Medical methods for mid-trimester termination of pregnancy (Review). The Cochrane Library. 2011;(1):CD005216.
8. Tang OS, Danielsson KG. Misoprostol: pharmacokinetic profiles, effects on the uterus and side-effects. Int J Gynecol Obstet. 2007;99(2):160-1.
9. Ngai SW, Tang OS, Chan YM. Vaginal misoprostol alone for medical abortion up to 9 weeks of gestation: efficacy and acceptability. Human Reprod. 2000;15:1159-62.
10. Benchamanon, Phupong V. Effectiveness of a single dose of oral misoprostol 600 µg for treatment in early pregnancy failure. J Obstet Gynaecol. 2014;34:726-9.
11. 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. Human Reprod. 2003;18:176-81.
12. Bhadra B, Deb T. Role of oral misoprostol for treatment of incomplete abortion. J Indian Med Assoc. 2013;111(10):689-91.
13. Faúndes A, Fiala C, Tang OS, Velasco A. Misoprostol for the termination of pregnancy up to 12 completed weeks of pregnancy. Int J Gynaecol Obstet. 2007;99:172-7.

Cite this article as: Abbas ABM, Abbas AM, Sakkaf MA. The use of single dose of oral misoprostol (600µg) at home in management of first trimester miscarriages in El-Mukala, Yemen. Int J Reprod Contracept Obstet Gynecol 2016;5:1360-3.