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MEDICAL TREATMENT OF EARLY MISSED MISCARRIAGE AND ANEMBRYONIC PREGNANCIES: A PROSPECTIVE STUDY OF OUTPATIENT MANAGEMENT USING MISOPROSTOL ALONE

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Abstract

Medical treatment using misoprostol has been recommended as an alternative to surgical evacuation for missed miscarriage in the first trimester in order to avoid anesthesia, surgical operation and hospitalization. Our aim is to assess the efficacy and safety of vaginal misoprostol in out-patient management of early miscarriages.

This prospective study included patients with missed miscarriage of ≤10 weeks gestation. The protocol used 800 microgram of misoprostol on day 1 at clinic, followed by another dose of 800 microgram of misoprostol on day 2 if miscarriage was not complete.

The included 150 patients, had missed miscarriage or anembryonic pregnancies. The success rate defined has complete miscarriage without need for surgical evacuation and without short-term complications. Complete expulsion occurred within 2 days in 90.7% of cases. There were 14 patients needed surgical evacuations and admission to hospital (5 for method failure, 2 for incomplete miscarriage and 7 according to women decision). No one required blood transfusion.

In conclusion, it is possible to use misoprostol as an out-patient treatment, since it gives satisfactory efficacy and is sufficiently safe.

Introduction

Clinically recognized spontaneous miscarriages occur in about 10-15% of all pregnancies[1]. Until recently, the majority of cases less than 12 weeks of gestation were treated by dilatation and currettage[2]. However this approach has disadvantage, including the need for admission to hospital, anesthesia errors[3], and it is associated with major morbidity in up to 1% of women and minor morbidity in 10%[4], like uterine perforation, hemorrhage, infection, intra uterine adhesions, cervical trauma and impaired future fertility[5].

Many of the complications of surgical approach can be avoided by medical treatment and this is especially important in developing countries where surgical evacuation is unsafe[4].

The first agent used for medical treatment was mifepristone, initially approved in France in 1988[6]. Research in the past two decades has identified several highly effective regimens for early medical abortion with a success rate of 95-98%, consisting of 200 mg of mifepristone followed by 400 or 800 mcg of misoprostol[7].

Misoprostol introduced in our market after 2003, it is a synthetic prostaglandin oestrone analogue, has been shown to be effective for cervical ripening prior to dilation and curettage in first trimester pregnancy terminations[8]. In many studies, repeated doses of misoprostol were used for medical abortion in the first trimester. Recently they use misoprostol sublingually as buccal mucosa is very vascular[4]. Vaginal administration of misoprostol minimizes gastrointestinal side effects and is more effective locally in the uterus. A strictly supervised

procedure and several visits to the clinic are barriers to acceptability of this method. However lately, self-administration of the drug with telephone evaluation of symptoms and less frequent hospital visits has improved its acceptability[3].

The aim of this study is to assess the efficacy and the safety of vaginal misoprostol alone in first trimester medical abortion up to 10 weeks of gestation at clinic and follow up by phone.

Material and method

A total of 150 women presenting with missed miscarriage or anembryonic pregnancy up to 10 weeks of gestation were recruited to the study at private clinic in Basrah. The agreement was obtained from every patient after explanation the method of medical regimen and outcome of it.

The including criteria for this prospective study were as follows:

1. ≤10 weeks gestation (missed or anembryonic pregnancy), confirmed by transvaginal ultrasound.
2. Age between 18-38 years.
3. Hemoglobin level >10.5 g/dL.
4. Dependant person present with her.
5. House no more than 30 minutes travelling from hospital.
6. No contraindication to misoprostol.
7. No medical problem like cardiac diseases diabetic mellitus, hypertension and blood diseases.

Three clinic visits were scheduled.

At first visit (day 1) the women received a vaginal administration of 800 mcg of misoprostol by digital insertion deeply in the pouch of Douglas. Prescriptions of paracetamol 1g and mefenamic acid (ponstan) 500 mg three times per day as analgesia, with prophylactic antibiotic in form of Azthromycin 1g single dose were given to all patients. Furthermore, they were advised to contact Basrah General Hospital on the presence of heavy bleeding, severe abdominal pain and fever, otherwise follow up by phone.

At the second visit (day 2), patients returned for a transvaginal ultrasound examination. During this period, the women were monitored for expulsion of the conceptions by phone. If intrauterine pregnancy was still present or miscarriage was incomplete, an additional 800 mcg of misoprostol was administered vaginally.

At third visit (2 weeks later), transvaginal ultrasound examination was done, along with hemoglobin estimations. The women were asked to keep a symptoms log of abdominal pain, vaginal bleeding, nausea, vomiting, diarrhea and fever. Patient satisfaction was evaluated and whether they would choose this method again or recommend it to someone else. The primary outcome was complete miscarriage after the 1st dose of misoprostol and secondary outcome was complete miscarriage after the 2nd dose.

Results

The age group of women was between 18-38 years. The estimated gestational age was between 5 to 10 weeks from the last menstrual period, confirmed by transvaginal ultrasound. The proportion of women at 6 to 8 weeks was (66%) and those at 8 to 10 weeks were (26%) while those at ≤6 weeks of gestation compromised 17.3%. Of the 150 women, 46% had one child while 13.3% had two or more children. Primigravida women compromised 22.7% of the total study population, 30% of the women had surgical termination previously. On transvaginal examination, 60.7% of women had missed miscarriage and 39.3% had un embryonic (Table I).

Table I: Women characteristic (N0. = 150)

Age (years)	Number	Percentage
18-22	21	14%
22-26	37	24.7%
26- 30	40	26.6%
30-34	33	22%
34-38	19	12%
Parity		
0	34	22.7%
1	69	46%
≥ 2	47	31.3%
Previous surgical termination		
1	27	18%
> 1	18	12%
Gestational age		
≤ 6	26	17%
6-7	68	45.3%
7-8	31	20.7%
8-9	13	8.7%
9-10	12	8%
Trans vaginal ultrasound finding		
Missed miscarriage	91	60.7%
An embryonic pregnancy	59	39.3%

The therapeutic medical regimen was successful in 136 out of 150 women (90.7%). A total of 82 women (54.7%) had aborted after the 1st dose of misoprostol, while 54 women (36%) aborted after the 2nd dose. Failure rate and subsequent surgical termination was (9.3%) (only 14 women). Five of the women due to method failure, 7 women did not wish to continue medical treatment after the 1st dose of misoprostol and only 2 women required emergency curettage for incomplete miscarriage as they had heavy bleeding (Table II).

Table II: Incidence of side effects

Side effects	Number	Percentage
Abdominal pain	150	100%
Bleeding	148	98.6%
Blood transfusion	0	0
Nausea / vomiting	20	13%
Diarrhea	5	3%
Fever	0	0
Headache	4	2.6%

The expected consequences of this regimen included vaginal bleeding and abdominal pain as a component of abortion process. Oral analgesia in form of paracetamol (1g) and mefenamic acid (500 mg), achieved adequate pain control.

The duration of bleeding was well accepted in all women, only 2 patients required emergency curettage for heavy bleeding, no one need blood transfusion.

Minor side effects occurred in (18.6%) of women and were tolerable, and decreased gradually after the 1st day of treatment (Table III). No further intervention was required in any of the women who successfully managed. Post treatment

infection was not observed. Satisfaction regarding the used method of misoprostol treatment in outpatient appeared to be high among those women who were successfully managed.

Table III: Success rate

Outcome	Number	Percentage
Success rate	136	90.7%
* primary	82	54.7%
* secondary	54	36%
Failure rate	14	9.3%
* method failure	5	3.3%
* women decision	7	4.7%
* incomplete miscarriage	2	1.3%
Need for emergency curettage	2	1.3%

Discussion

The results of this study demonstrated that the use of two doses of vaginal misoprostol alone is effective, acceptable and safe method of medical treatment for miscarriage at clinic up to 10 weeks of gestation, with a successful rate of 90.7%.

In this study, women given the options to choose about this method. Only two visits were required for treatment and follow up by phone evaluation of symptoms, which is acceptable in terms of safety.

In the USA, home administration of misoprostol has become the most widely used method for medical termination of pregnancy, and has been shown to be safe and effective[9]. Now is fully implemented in clinical practice in most countries in Europe. They were concluded that most women would welcome the choice of having the termination at home or in a clinic[10]. Also this method was used in developing countries[3].

The success rate of medical miscarriage using this regimen was 90.7%. It is comparable with other studies[2,11-13]. Although 14 of women (9.3%) had surgical termination, this may be due to that 4.7% did not continue treatment after the 1st dose of misoprostol and all of these women had dilated cervix at the time of surgery. Only 2 women had emergency curettage due to heavy bleeding, none of these women was in need of blood transfusion[14-16].

It is found from this study that percentage of women who had previous surgical termination was 30% and all of these women preferred this regimen because it is more private, non invasive and avoid hospitalization.

The absence of infection could be attributed to the absence of invasive intra uterine procedure and the use of prophylactic Azthromycin.

Other side effects like neasea, vomiting and headache are dose and route dependent[17]. Ninety percent of women preferred this method and they would undergo the same procedure if needed again, and will recommend it for others.

Conclusion

Medical termination of pregnancy is a promising alternative to surgical curettage and outpatient treatment with only two visits and follow up by phone evaluations of symptoms, which is acceptable in term of safety (1.3% needing emergency curettage and none of women need blood transfusion). However, outpatient management should only be performed after explaining the treatment and its risk to the patient.

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