Contraception

Contraception 93 (2016) 119–125

Original research article

Predictors of uterine evacuation following early medical abortion with mifepristone and misoprostol☆

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Received 3 June 2015; revised 11 August 2015; accepted 13 August 2015

Abstract

Objectives: We sought to determine predictors of uterine evacuation for women undergoing medical abortion using mifepristone and vaginal misoprostol through 63 days' gestation.

Study Design: We pooled data from two prospective multicenter medical abortion trials. In one study, women received mifepristone 200 mg followed either 6–8 or 23–25 h later by misoprostol 800 mcg vaginally. In the second study, women received mifepristone 200 mg followed either <15 min or 23–25 h later by misoprostol 800 mcg vaginally. We examined the absolute risk (AR) of uterine evacuation using Fisher's Exact Tests for categorical variables and Student *t* test and Wilcoxon rank-sum tests for continuous variables. We used logistic regression to calculate odds ratios (ORs) of uterine evacuation.

Results: Uterine evacuation was performed for 75 (3.5%) of 2160 women. In multivariable analysis, 5 or more prior deliveries (AR 11.9%, OR 4.6) and gestational age of 8 weeks or more (AR 4.1%, OR 2.1) were significantly associated with uterine evacuation, while age of 20 years or younger (AR 1.4%, OR 0.4) was significantly and inversely associated with uterine evacuation. Prior cesarean delivery, multiple gestations, smoking, weight, body surface area and body mass index were not predictive of uterine evacuation in univariate or multivariable analysis.

Conclusion: Uterine evacuation is an uncommon outcome in medical abortion with mifepristone and vaginal misoprostol. Five or more deliveries are the only significant predictor that identifies a group with an AR of uterine evacuation of more than 6%.

Implications: Uterine evacuation is uncommon in medical abortion with mifepristone and vaginal misoprostol. Parity of five or more is the only significant predictor of uterine evacuation exceeding 6%. Until additional research is completed, medical abortion should not be withheld from women with five or more deliveries.

Keywords: Medical abortion; Mifepristone; Misoprostol; Uterine evacuation

1. Introduction

Medical abortion with mifepristone and misoprostol is highly effective. With a regimen of mifepristone and vaginal misoprostol, approximately 3% to 5% of women will subsequently undergo uterine evacuation [1–3]. Regimens using mifepristone and buccal misoprostol have a similar (3.3%) risk of requiring uterine evacuation [4,5]. In approximately 2%–3% of women, uterine evacuations are performed after expulsion of the pregnancy due to pain or bleeding [1–3,5].

Predictors of uterine evacuation following medical abortion have been examined previously using regimens of mifepristone followed by oral misoprostol. These regimens are less effective than regimens with vaginal misoprostol and thus less relevant to current clinical practice [6–9]. Three of these studies included from 271 to 879 women, with 7% to 36% undergoing uterine evacuation [6–8]. These three studies identified increasing parity, prior cesarean delivery, obesity [body mass index (BMI)], initial human chorionic gonadotropin (hCG), older age and prior spontaneous abortion as predictors of uterine evacuation. A prior pooled

☆ Conflict of Interest: Dr. Creinin is a consultant for Danco Laboratories, LLC. The other authors do not have any conflicts of interest.

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http://dx.doi.org/10.1016/j.contraception.2015.08.010
0010-7824/

Table 1
Summary of pooled study populations from two studies including women having a medical abortion with mifepristone 200 mg and misoprostol 800 mcg vaginally.

Study group	MOD study[a]		MAST study[b]		Pooled	
Total subjects enrolled	1080		1128		2208	
Excluded[c]	22	(2.0%)	26	(2.3%)	48	(2.2%)
Included in analysis	1058	(98.0%)	1102	(97.7%)	2160	(97.8%)
Uterine evacuation performed	31	(2.9%)	44	(4.0%)	75	(3.5%)
Days from mifepristone to uterine evacuation						
6 or fewer	8	(25.8%)	6	(13.6%)	14	(18.7%)
7–13	2	(6.5%)	2	(4.5%)	4	(5.3%)
14–27	13	(41.9%)	27	(61.4%)	40	(53.3%)
28 or more	8	(25.8%)	9	(20.5%)	17	(22.7%)
Indication for uterine evacuation						
Bleeding or pain	18	(58.1%)	18	(40.9%)	36	(48.0%)
Viable pregnancy	2	(6.5%)	6	(13.6%)	8	(10.7%)
Persistent gestational sac	4	(12.9%)	13	(29.5%)	17	(22.7%)
Other	5	(16.1%)	7	(15.9%)	12	(16.0%)
Repeat dose of misoprostol[d]	17	(1.6%)	57	(5.2%)	74	(3.4%)

[a] Medical abortion in 1 day [1].
[b] Medical abortion at the same time [2].
[c] Reasons for exclusion: lack of follow-up data (n=45) and withdrawal from study prior to use of misoprostol (n=1).
[d] Subjects in both studies were offered a repeat dose of misoprostol if the pregnancy was not expelled based on transvaginal ultrasonography at the follow-up visit.

analysis of four trials who received mifepristone 600 mg with oral misoprostol, with uterine evacuation performed in 3.9% to 14.6%, reported that women younger than 23 years, at less than 50 days' gestation and with no prior abortions were more likely to have a successful medical abortion [9].

We sought to identify predictors of uterine evacuation in a sample with a risk of uterine evacuation similar to that seen in typical clinical practice today. We specifically sought predictors which would be available prior to starting the medical abortion process to help clinicians and the patients that they are counseling. Based on prior research, we hypothesized that increasing gestational age, increasing obesity, increasing parity, prior cesarean delivery and increasing age might be associated with an increased risk of uterine evacuation.

2. Materials and methods

This study is a pooled secondary analysis of data from two multicenter randomized trials of medical abortion. In the first study, 1080 women received an oral dose of mifepristone 200 mg after which they were randomly assigned to self-administer misoprostol 800 mcg vaginally within the next 6 to 8 h or in 23 to 25 h [1]. Women were enrolled at the University of Pittsburgh, Columbia University, Boston University and the University of Rochester. In the second study, 1128 women received mifepristone 200 mg after which they were randomized to self-administer misoprostol 800 mcg vaginally within the next 15 min or in 23 to 25 h [2]. Women were enrolled at the University of Pittsburgh, Oregon Health Science University, Northwestern University and the University of Southern California. Population demographics and treatment outcomes have been previously described [1,2]. Both studies were approved by the institutional review boards of participating institutions. All data were collected prospectively.

The follow-up and outcome assessment were similar for the two study protocols. In both studies, participants were scheduled to return for a follow-up visit including sonographic examination approximately 6–8 days after taking mifepristone. Women who had not expelled the gestational sac were given a repeat dose of misoprostol 800 mcg vaginally. In both protocols, subjects who missed the first follow-up visit but were seen within 11 days after receiving the mifepristone could receive a second dose of misoprostol for a persistent sac. Subjects who received a second dose of misoprostol had another follow-up visit scheduled 12–16 days after receiving mifepristone. Transvaginal ultrasonography was performed at each visit with successful expulsion defined as absence of the gestational sac. The research staff attempted to contact all subjects by telephone 5 weeks after initiating the study to review if there had been any problems during or after the medical abortion process. We only included women who used both agents (mifepristone and misoprostol) and had at least one follow-up visit during the study.

The primary outcome for this analysis was uterine evacuation, regardless of the indication. In both clinical trials, uterine evacuation was performed following pregnancy expulsion if clinically necessary because of subject request or symptoms consistent with incomplete abortion such as prolonged or heavy bleeding or cramping. In both studies, uterine evacuation was recommended for women with a persistent sac with gestational cardiac activity at the second follow-up visit. Women with a non-viable persistent gestation at the second follow-up were offered uterine evacuation or expectant management. In neither trial was the decision for uterine evacuation based on endometrial thickness as assessed