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Factors Related to Successful Misoprostol Treatment for Early Pregnancy Failure

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Abstract

OBJECTIVE—To identify potential predictors for treatment success in medical management with misoprostol for early pregnancy failure.

METHODS—We conducted a planned secondary analysis of data from a multicenter trial that compared medical and surgical management of early pregnancy failure. Medical management consisted of misoprostol 800 µg vaginally on study day 1, with a repeat dose if indicated on day 3. Women returned on days 3 and 15, and a telephone interview was conducted on day 30. Failure was defined as suction aspiration for any reason within 30 days. Demographic, historical, and outcome variables were included in univariable analyses of success. Multivariable analyses were conducted using clinical site, gestational age, and variables for which the univariable analysis resulted in a $P < .1$ to determine predictors of overall treatment success and first-dose success.

RESULTS—Of the 491 women who received misoprostol, 485 met the criteria for this secondary analysis. Lower abdominal pain or vaginal bleeding within the last 24 hours, Rh-negative blood type, and nulliparity were predictive of overall success. However, only vaginal bleeding within the last 24 hours and parity of 0 or 1 were predictive of first-dose success. Overall success exceeds 92% in women who have localized abdominal pain within the last 24 hours, Rh-negative blood type, or the combination of vaginal bleeding in the past 24 hours and nulliparity.

CONCLUSION—Misoprostol treatment for early pregnancy failure is highly successful in select women, primarily those with active bleeding and nulliparity. Clinicians and patients should be aware of these differences when considering misoprostol treatment.

Abnormal early pregnancy is a common experience for women. Approximately 1 in 4 women will experience a miscarriage during her lifetime.¹ Between 15% and 20% of clinically recognized pregnancies are diagnosed as abnormal in the first or early second trimester.² For more than 50 years, the standard management of early pregnancy failure has been a dilation

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and curettage (D&C). Typically, the procedure is performed in an operating room, which significantly increases cost. In recent years, the medical community began to question whether immediate evacuation by surgical intervention is truly necessary for most cases of early pregnancy failure.^{3–5}

Misoprostol, a prostaglandin E₁ analogue, has garnered attention over the past few decades, both in regimens for medical abortion and by itself for early pregnancy failure.⁶ Overall, comparison of trials using misoprostol for early pregnancy failure is difficult because the studies included various patient populations and dosing regimens (for example, repeat dosing every 3–4 hours or every 24 hours), different routes of administration (oral or vaginal), varying definitions of success (the time allowed until dilation and curettage was performed),⁷ and a misunderstanding of how to use ultrasonography to define both inclusion and success.^{8–10} Additionally, most of the large studies involve inpatient admission for medical management, a scenario that would be unlikely in the United States.^{11,12}

To address these weaknesses, we conducted a multicenter randomized trial including 491 women treated with misoprostol 800 µg vaginally and 161 women who had a vacuum aspiration procedure for early pregnancy failure.¹³ Misoprostol treatment success was 71% (95% confidence interval [CI] 67–75%) after one dose and 84% (95% CI 81–87%) overall. Although this overall success was statistically equivalent to the 97% (95% CI 94–100%) for vacuum aspiration, the rates are clinically quite different. There may be easily identifiable subgroups for whom misoprostol treatment will be more or less effective and, ideally, some women for whom the success rates may more closely approximate those of vacuum aspiration. This report details the findings of a planned substudy of this multicenter trial to evaluate factors related to success with misoprostol treatment.

MATERIALS AND METHODS

This multicenter study was performed at Columbia University, the University of Miami, the University of Pennsylvania, and the University of Pittsburgh. This trial was designed to compare the efficacy and safety of misoprostol and vacuum aspiration for the treatment of early pregnancy failure. The study design included the prospective collection of data to allow a planned analysis of the predictors of successful treatment with misoprostol. The study was approved by the institutional review boards of the respective institutions, Clinical Trials and Surveys Corporation, and the National Institute of Child Health and Human Development.

The study protocol, population demographics, and treatment outcomes have been previously described.¹³ Women who had an anembryonic gestation or embryonic/fetal demise were eligible for inclusion if they had an ultrasound examination demonstrating an embryonic pole or crown-rump length between 5 and 40 mm without cardiac activity¹⁴, an anembryonic gestational sac with a mean diameter between 16 and 45 mm¹⁵, growth of gestational sac less than 2 mm over 5 days or less than 3 mm over 7 days,¹⁶ or an increase in human chorionic gonadotropin by less than 15% over 2 days with a yolk sac visualized by ultrasound examination. Women who had incomplete or inevitable abortions were also included.

Incomplete spontaneous abortion was defined as passage of some products of conception with the residual anterior-posterior endometrial lining greater than 30 mm by transvaginal ultrasonography and uterine size less than 13 weeks. This cutoff was based on evidence from prior studies of women treated with misoprostol for medical abortion¹⁷ or early pregnancy failure.⁹ *Inevitable abortion* was defined as an intrauterine gestational sac less than 45 mm or embryonic pole less than 40 mm and an open internal cervical os to digital examination with active vaginal bleeding. Women were excluded from the primary study if they were anemic (hemoglobin level below 9.5 mg/dL), were hemodynamically unstable, had a history of a clotting disorder or were using anticoagulants, were allergic to prostaglandins or nonsteroidal

anti-inflammatory drugs, or had previously undergone surgical or medical abortion, either self-induced or by other physicians during the current pregnancy. All subjects provided written informed consent.

Women who enrolled were randomized in a 3:1 ratio to medical treatment or vacuum aspiration. Randomization was stratified by study sites and type of pregnancy failure (anembryonic gestation or fetal demise versus incomplete and inevitable spontaneous abortion) using randomly permuted blocks. The day of randomization was considered study day 1. Women randomized to medical treatment had four 200 µg tablets (800 µg) of misoprostol (Cytotec, Searle Pharmaceuticals, Chicago, IL) inserted into the posterior fornix through a speculum. Rh-immune globulin was administered if the subject was Rh-negative and had not already received Rh-immune globulin. The subjects returned on day 3 (range: days 2–5) for a follow-up evaluation including transvaginal ultrasonography. If the ultrasound examination demonstrated a gestational sac or the endometrial lining was greater than 30 mm, a second dose of 800 µg of vaginal misoprostol was administered. On day 8 (range: days 6–10), if the expulsion of products of conception was still not completed, vacuum aspiration was offered. The subjects returned for a follow-up visit on day 15. A telephone interview was conducted on day 30 (range: days 25–35) to determine whether any subject underwent additional treatment. Women with symptoms potentially related to the study treatment were followed until they were resolved.

For this secondary analysis, only women who received misoprostol and were not lost to follow-up were included. Misoprostol success was defined as complete abortion without the need for a vacuum aspiration within 30 days of treatment. Univariable analysis was performed using χ^2 analyses or 2-sample median tests as appropriate to evaluate all demographic, medical history, and outcome variables for prediction of misoprostol success. Variables with $P \leq .1$ were considered for inclusion in the multivariable analysis. Two additional variables, clinical site and best estimate of gestational age, were forced into the multivariable analysis due to clinical relevance.

Logistic regression analyses were performed for both overall misoprostol success and first-dose success of misoprostol treatment. Success by day 30, defined as no surgical intervention by day 30, was the modeled event. A step-wise selection procedure was used, with entry significance 0.25 and stay significance of 0.1. After completing the predictor model, gestational age and clinical site were then inserted into the model. Additionally, pregnancy type was maintained in the first-dose success model to be comparable with the overall success model. All statistical analyses were performed with SAS 8.2 (SAS Institute, Cary, NC).

RESULTS

A total of 652 women were enrolled in the primary study between March 2002 and March 2004, of whom 491 were randomized to receive misoprostol, and 485 met the criteria for this secondary analysis. The 485 subjects included 177 (36.5%), 279 (57.5%), and 29 (6.0%) women with a diagnosis of anembryonic gestation, embryonic/fetal demise, and incomplete/inevitable abortion, respectively. Univariable predictors of treatment success are presented in Table 1. Multivariable analysis revealed that the presence of localized lower abdominal pain within the past 24 hours, vaginal bleeding within the last 24 hours, Rh-negative blood type, and nulliparity were predictive of a high probability of overall success (Table 2). However, only vaginal bleeding within the last 24 hours and parity of 0 or 1 were predictive of first-dose success (Table 3). Clinical sites, subtypes of early pregnancy failure, and gestational age at treatment did not affect treatment success. The outcomes in the multivariable model, when not including the forced-in variables (gestational age and clinical site), resulted in no significant changes from those in the full model.

Using these predictors, comparative rates were tabulated for women presenting with a combination of 2 or more of these symptoms or characteristics for overall success and single (first)-dose success. All of the tabulations for overall success resulted in efficacy rates of 92% or greater, but all except for two resulted in small numbers in the subgroups ($n = 44$ or less). The specifics from the two combinations of characteristics with significant numbers for overall success and the predictors of single-dose success are presented in Table 4.

DISCUSSION

Misoprostol treatment of women with early pregnancy failure provides an opportunity for women who desire active management to have a timed expulsion and avoid a vacuum aspiration procedure. This trial included 485 women, which allows unique opportunities for analyses unlike prior, smaller studies. We have demonstrated that successful treatment is significantly more likely in women who are nulliparous or have localized lower abdominal pain within the past 24 hours, vaginal bleeding within the last 24 hours, or Rh-negative blood type. These predictors of successful treatment demonstrate a relative gradient of efficacy. Specifically, the overall efficacy gradient of approximately 95–85–80% is evident for women who have pain and bleeding in the prior 24 hours, all subjects, and those with neither pain nor bleeding in the past 24 hours. A similar gradient is present for first-dose efficacy of approximately 80–70–60% for women who are nulliparous and have bleeding in the prior 24 hours, all subjects, and those who are not nulliparous and have not had bleeding in the past 24 hours.

The finding that Rh-negative blood type is highly associated with overall treatment success is surprising and not previously reported. One may hypothesize that Rh-mismatch could be an underlying reason for early pregnancy failure and create a situation in which misoprostol is more effective. Additionally, this finding may imply that women who are Rh-negative may have an underlying cause of early pregnancy failure that is different from Rh-positive women. However, because of the lack of an easily plausible explanation, we would recommend awaiting further trials before assuming this association is definitely true. Conversely, the findings of associations of recent bleeding and cramping with overall misoprostol success are expected. Low parity as a predictor suggests that the receptivity of the uterus to the effects of misoprostol changes with growth or stretching of the myometrium with past pregnancies.

We used vaginal misoprostol in our study based on what we have learned from medical abortion studies. When used in regimens for medical abortion after either mifepristone¹⁸ or methotrexate¹⁹ treatment, vaginal misoprostol results in a higher rate of complete abortion than oral misoprostol, as well as a more rapid rate of pregnancy expulsion. A small, nonrandomized trial suggests the same is true when using misoprostol for early pregnancy failure.²⁰

One of the primary problems with many published trials of medical treatment of early pregnancy failure is the definition of success. Some studies had used an endometrial thickness of 15 mm when assessed by transvaginal sonography as cutoff for “success.”^{21–27} However, mounting evidence from literature on medical abortion (Fox MC, Creinin MD, Meyn LA, Murthy AS, Harwood B. Ultrasound appearance of the endometrium after medical abortion [abstract]. *Contraception* 2004;70:261)¹⁷ and early pregnancy failure^{8–10} indicate that such a cutoff is too stringent. Interestingly, medical abortion studies, which commonly quote success rates exceeding 95%,²⁸ do not use endometrial thickness to define success. In medical abortion studies, women who have sonographic disappearance of the gestational sac are highly likely not to need any further intervention, which accounts for the high success rate. Our current study confirms that almost all women with an endometrial thickness less than 30 mm after misoprostol treatment for early pregnancy failure also complete expulsion spontaneously and uneventfully.¹³ As such, women who failed treatment in this study truly required clinical

intervention. Therefore, the predictors of success we present in this analysis realistically reflect clinical outcomes. Unfortunately, even in this study, when aspirations were only performed when clinically indicated (in other words, aspiration was not performed solely because the endometrial thickness exceeded 15 mm), misoprostol is still only 70–80% successful after one dose.¹³ Importantly, we have been able to define the most ideal candidates for medical treatment with misoprostol alone.

Health care providers should discuss the options for treatment of early pregnancy failure with a keen sense of what the patient strongly desires. It is highly likely that the first-dose success rate may be most important for women, especially when the option is a vacuum aspiration that could be performed in a relatively short period of time. Women who have vaginal bleeding within the last 24 hours and a parity of less than 2 are the women most likely to be treated successfully with a single dose of misoprostol. Interestingly, Rh-negative women and those who have had lower abdominal pain in the last 24 hours are more than 90% likely, based on those individual factors, to have overall success, but each of these factors is not important in increasing the likelihood of success with a single dose of misoprostol.

Because women generally prefer some treatment to no treatment,^{5,29} the success rate of vaginal misoprostol for early pregnancy failure appears to be an advance in medical treatment. However, this rate is significantly lower than the success rates for combination treatment with mifepristone and misoprostol for medical abortion. Multiple large trials have demonstrated more than 95% complete abortion rates using mifepristone 200 mg followed 6–24 hours later by misoprostol 800 µg vaginally through 63 days of gestation.^{30,31} As clinicians and researchers, we must ask why women with an undesired normal pregnancy can receive a treatment regimen that is more effective than that tested for women with a desired abnormal early pregnancy. The information presented in this analysis will allow us to better tailor misoprostol treatment for early pregnancy failure.

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APPENDIX

The National Institute of Child Health and Human Development Management of Early Pregnancy Failure Trial (principal investigators are indicated by asterisks)

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Table 1
Univariable Predictors of Vaginal Misoprostol Treatment Success With P Value $< .1$ *

Univariable Predictor	n	Success (%) (n = 410)	Failure (%) (n = 75)	P
Localized abdominal pain within last 24 h				
Yes	116	92.2	7.8	
No	369	82.1	17.9	.008
Number of people younger than 18 years old in household				
0	178	90.5	9.6	
1	160	83.8	16.3	
≥ 2	147	78.2	21.8	.009
Vaginal bleeding within last 24 h				
Yes	312	87.5	12.5	
No	173	79.2	20.8	.018
Rh type				
Negative	53	94.3	5.7	
Positive	432	83.3	16.7	.042
Pregnancy type				
Fetal demise	279	87.5	12.5	
Anembryonic gestation	177	79.1	20.9	
Incomplete/inevitable abortion	29	89.7	10.3	.048
Parity				
0	199	88.4	11.6	
1	155	84.5	15.5	
≥ 2	131	78.6	21.4	.059
Fever/chills during the past week				
Yes	70	77.1	22.9	
No	415	85.8	14.2	.074
Cervical os				
Open	38	94.7	5.3	
Close	444	83.6	16.4	.099
Pool of blood present in vagina				
Yes	85	90.6	9.4	
No	399	83.2	16.8	.099

* Demographic variables with $P > .1$ included age, race, education, best estimate of gestational age, number of previous pregnancies, planned versus unplanned pregnancy, time since first diagnosis of pregnancy, time since being told pregnancy was abnormal, human chorionic gonadotropin level, hemoglobin, number of previous pregnancies, number of previous miscarriages, height, weight, marital status, living with partner, number of adults living in the household, religion, daily physical activity, health insurance, employment status, weekly working hours, cigarettes per day, alcoholic drinks per day, regularity of periods, age at first menstrual period, menstrual length, and use of ovulation-stimulating drugs. (This list does not include all of the variables tested.)

Table 2

Multivariable Predictors of Overall Misoprostol Success

Multivariable Predictor	n	Odds Ratio	95% Confidence Interval	P
Localized lower abdominal pain within 24 h				
No	365	Referent		
Yes	115	3.05	1.37–6.76	.006
Vaginal bleeding within 24 h				
No	172	Referent		
Yes	308	1.77	1.03–3.05	.038
Rh type				
Positive	428	Referent		
Negative	52	5.64	1.30–24.6	.021
Pregnancy type				
Incomplete/inevitable abortion	29	Referent		
Fetal demise	275	1.66	0.43–6.31	.461
Anembryonic gestation	176	0.85	0.22–3.25	.808
Parity				
0	196	2.25	1.18–4.26	.013
1	154	1.70	0.89–3.26	.110
≥ 2	130	Referent		
Fever/chills in the last week				
No	410	Referent		
Yes	70	0.55	0.28–1.08	.082
Gestational age (best estimate, wk)				
≤ 6	118	Referent		
7–8	241	1.37	0.73–2.57	.321
≥ 9	121	1.69	0.75–3.81	.203
Study site				
University of Pittsburgh	110	Referent		
Columbia University	98	1.22	0.54–2.74	.632
University of Miami	165	1.29	0.63–2.61	.488
University of Pennsylvania	107	1.43	0.66–3.11	.367

Table 3

Multivariable Predictors of Single-Dose Misoprostol Success

Multivariable Predictor	n	Odds Ratio	95% Confidence Interval	P
Vaginal bleeding within 24 h				
No	173	Referent		
Yes	312	1.84	1.21–2.81	.005
Pregnancy type				
Incomplete/inevitable abortion	29	Referent		
Fetal demise	279	0.99	0.37–2.63	.982
Anembryonic gestation	177	0.72	0.27–1.95	.519
Parity				
0	199	2.01	1.22–3.32	.006
1	155	1.79	1.06–3.02	.030
≥ 2	131	Referent		
Gestational age (best estimate, wk)				
≤ 6	122	Referent		
7–8	241	1.33	0.82–2.18	.250
≥ 9	122	1.80	0.97–3.34	.064
Study site				
University of Pittsburgh	110	Referent		
Columbia University	98	1.20	0.63–2.29	.578
University of Miami	166	1.05	0.61–1.82	.854
University of Pennsylvania	111	1.31	0.72–2.40	.375

Success Rates Based on a Combination of Symptoms and Demographic Characteristics That Are Correlated With a High Likelihood of Misoprostol Success

Table 4

	Factors Present			Neither Factor Present		
	n	%	95% Confidence Interval	n	%	95% Confidence Interval
Overall success						
Pain and bleeding in the past 24 h	86	95.4	88.5–98.7	144	77.8	70.1–84.3
Nulliparous and bleeding in the past 24 h	120	92.5	86.2–96.5	94	76.6	66.7–84.7
Success with single dose of misoprostol						
Nulliparous and bleeding in the past 24 h	120	79.2	70.8–86.0	94	58.5	47.9–68.6
Primiparous and bleeding in the past 24 h	105	77.1	67.9–84.8	124	60.5	51.3–69.1