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Self-assessment of medical abortion outcome using symptoms and home pregnancy testing☆

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Abstract

Objectives: We aimed to evaluate compliance with a strategy to enable medical abortion patients to assess treatment outcome on their own and decide whether to seek clinical follow-up.

Study design: We enrolled women undergoing medical abortion with mifepristone and misoprostol at three clinics in the United States. Each participant was instructed to perform a multilevel pregnancy test (MLPT) 7 days after mifepristone ingestion and to contact the clinic immediately if the test indicated a possible ongoing pregnancy or if specified symptoms occurred. A telephone call was scheduled 14 days after mifepristone ingestion to evaluate participants who had not contacted the clinic earlier.

Results: Of the 343 enrolled participants, 90 (26%) did not provide sufficient follow-up information for analysis of compliance with instructions. Of the 253 (74%) who did, 218 (86%) implemented the self-assessment strategy as instructed, 20 (7.9%) failed to report a non-reassuring MLPT result, 4 (1.6%) failed to promptly report symptoms that the study clinician subsequently judged to require evaluation, and 11 (4.3%) did not perform the MLPT. We ascertained abortion outcomes for 239 (70%) of the enrolled women, of whom three were diagnosed with ongoing pregnancies. One other participant was hospitalized for bleeding. All four women had implemented the strategy correctly. Of the 219 enrolled participants (64%) who provided opinions, 170 (78%) indicated that most could use the MLPT to decide whether they are "OK" after an abortion. We did not ascertain opinions from 124 enrolled participants (36%).

Conclusions: At least two thirds of enrolled participants correctly implemented a strategy using symptom evaluation and a MLPT to assess their own medical abortion outcomes. No ongoing pregnancies occurred in women documented not to have implemented the strategy as intended. Perceived feasibility of the self-assessment approach was high.

Implications Statement

The common practice of scheduling a clinical contact after every medical abortion may not be necessary to ensure safety; enabling patients to determine for themselves whether or not a contact is needed can be a reasonable approach.

Keywords: Medical abortion; Ongoing pregnancy; Self-assessment; Pregnancy test

1. Introduction

Medical abortion is an increasingly popular method for early pregnancy termination. Although current regimens using mifepristone and misoprostol are highly effective and very safe [1,2], abortion providers commonly require that every patient should have a post-treatment clinical test, usually ultrasound or serum human chorionic gonadotropin (hCG) assay, and a consultation with the provider to ensure that any ongoing pregnancies or complications are identified and managed promptly. Complying with this requirement can be inconvenient and costly for both women and the health care system.

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We planned the current study to evaluate an alternative strategy designed to enable medical abortion patients to assess treatment success on their own and decide for themselves whether or not to seek clinical follow-up. This strategy relied on symptom assessment and a semiquantitative multilevel dipstick pregnancy test (MLPT) designed to estimate the approximate hCG concentration in urine. A recent meta-analysis of data from seven studies included 3499 women who had MLPT results. These studies showed that a decline in concentration as indicated by this test a week after taking mifepristone is highly accurate for excluding ongoing pregnancy after treatment within the first 63 days of pregnancy [3]. The MLPT is inexpensive relative to a clinical interaction and can be performed by women at home. The goal of our study was to examine women's compliance with this self-assessment strategy.

2. Materials and methods

We conducted the study at three clinics in the United States: Carafem Health Center (Chevy Chase, MD), Presidential Women's Center (West Palm Beach, FL), and Philadelphia Women's Center (Philadelphia, PA). The site investigator or delegated staff with appropriate clinical credentials and licensure in the site's jurisdiction and who were trained in study procedures by Gynuity Health Projects made all clinical decisions at the sites. The Allendale Investigational Review Board (Old Lyme, CT) approved the protocol.

Site staff recruited women aged 18–56 years with confirmed intrauterine pregnancies at ≤63 days of gestation by ultrasound presenting for medical abortion with mifepristone and misoprostol. Each woman who was interested read an informed consent form that explained the self-assessment strategy. The form noted that the MLPT to be used (dBest; AmeriTek, Seattle, WA, USA) was not at the time approved by the US Food and Drug Administration but that research had shown it to be highly accurate for identifying abortion failure. After the woman signed the form, staff collected baseline data and performed an MLPT on a sample of her urine and showed her how to perform and interpret the MLPT herself. Staff gave her an MLPT to perform at home in 7 days and counseled her to contact the clinic immediately if the hCG level did not decline, if she had specified symptoms (scant or excessive bleeding, continued feeling of pregnancy) or if she did not think she passed the pregnancy. Staff also gave her a standardized study instruction sheet on which the initial MLPT reading was recorded for her reference. The participant then took mifepristone 200 mg in the clinic. Staff provided misoprostol and other routine care according to the clinic's standard medical abortion protocol. Before the participant left the clinic, staff scheduled a follow-up phone call for 14 days after the enrollment visit.

Site staff called the participant at the appointed time if she had not called in on her own earlier. If the post-treatment MLPT results reported by the participant indicated a decline in hCG concentration and if she had no symptoms of clinical concern, staff considered her abortion to be complete and discharged her from the study. Otherwise, the staff arranged further evaluation to ensure abortion completeness. This evaluation could occur either at an in-person visit or remotely by asking participants to perform a second urine pregnancy test at home. If a participant missed her follow-up appointment, the site staff attempted to contact her at least twice using two or more modalities (phone, email, text, mail, etc.). The final attempt occurred at least 2 weeks after the scheduled appointment. We attempted to obtain medical records if participants had abortion-related care at outside facilities.

The primary study outcome was the proportion of enrolled participants who successfully implemented the self-assessment strategy: that is, either (a) the post-treatment MLPT indicated that the hCG concentration declined and the participant had no other indication for further evaluation in the judgment of the clinician, or (b) the participant had at least one substantive post-treatment contact with a clinician regarding her abortion before the scheduled follow-up call. Substantive contacts included in-person visits or telephone calls at which the clinician evaluated the participant's clinical condition and recommended or provided additional evaluation or treatment if needed. The primary analysis of this outcome included all women who had an initial hCG result, took home a MLPT, and provided sufficient data to allow evaluation of the primary outcome, such as MLPT results if done, reports of other problems, and/or records of substantive contacts with the clinician. We assessed differences in this outcome by baseline characteristics using Fisher's exact tests, each conducted at the 5% significance level. We report abortion outcomes (ongoing pregnancy or not) and serious adverse events (deaths, life-threatening events, hospitalizations, transfusions, or any other medical problems that we judged to be significant) as secondary study outcomes.

We initially planned to enroll 236 women to allow us to estimate the proportion of subjects who failed to execute the strategy with a two-sided 95% confidence interval half-width of no more than ±7%, allowing for up to 15% loss to follow-up. During the study, additional funding became available, which we used to expand the sample size in order to achieve greater precision around this estimate and to assess the effect of study compensation. The first 247 participants enrolled were told at enrollment that they would receive $25 after completing follow-up; the last 96 participants, all of whom were enrolled at the Maryland site, were offered no compensation.

3. Results

Between September 2015 and October 2016, we enrolled 343 demographically diverse participants (Table 1), of whom 90 (26%) did not provide sufficient follow-up information for inclusion in the primary analyses (Fig. 1).