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CLINICAL ARTICLE

Simplified medical abortion using a semi-quantitative pregnancy test for home-based follow-up

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ABSTRACT

Objective: To simplify follow-up after medical abortion by examining whether women could use a semi-quantitative pregnancy test at home to screen for ongoing pregnancy. *Methods:* Three hundred women seeking medical abortion at a tertiary hospital in Vietnam participated in the study. Participants used a semi-quantitative pregnancy test at the hospital to estimate baseline human chorionic gonadotropin (hCG) levels and administered another test at home 2 weeks later for comparison. Women interpreted the test result at home and then returned to hospital for follow-up care. At this visit, self-assessment was verified. To assess further the feasibility of the test as a follow-up tool in service delivery, 200 additional women completed a user comprehension survey. *Results:* The tests identified all 11 ongoing pregnancies among study participants (100% sensitivity; 89.7% specificity). Women reported that the test was easy to use (255/292 [87.3%]) and that provider instructions helped them to use the test (291/292 [99.7%]). *Conclusion:* Semi-quantitative pregnancy tests offer high sensitivity and negative predictive value. If user instructions can be further simplified, the tests could be used in lieu of transvaginal ultrasound and/or serum hCG at clinic-based follow-up or by women themselves for home-based follow-up.

Clinical trials.gov: NCT01150279

1. Introduction

Common practice for medical abortion includes clinic-based follow-up and clinical assessment, including transvaginal ultrasound, to determine abortion status. This follow-up visit can be costly and time consuming for both the healthcare system and the woman [1,2]. As medical abortion becomes more widely used, many women simply do not return to the clinic to receive clinician confirmation of complete abortion. Providing women with a safe, effective, and affordable at-home diagnostic tool to confirm whether a pregnancy is ongoing after administration of mifepristone and misoprostol could reduce costs and simplify the procedure by limiting the number of clinic visits and costly exams, and reducing waiting time. Ideally, during her initial clinic visit, a woman would receive misoprostol, a pregnancy test, and counseling on how to manage her abortion at home. With these tools, the majority of women could manage their abortion at home on their own. With this objective in mind, providers and researchers have explored ways to simplify medical abortion follow-up with serial human chorionic gonadotropin (hCG) testing, high- and low-sensitivity pregnancy tests, and telephone or other virtual follow-up [3–7].

Quantitative serum hCG testing to confirm abortion completion is commonly used in the USA and Europe. Previous research has documented change in hCG level after medical abortion [6,8–10]. Since 2005, Planned Parenthood Federation of America has waived the follow-up visit if it poses undue hardships owing to distances from abortion facilities or other reasons, and women manage their follow-up with serial hCG testing [11]. This method of follow-up has proven effective because ongoing pregnancies exhibit increasing hCG levels (hCG levels that do not increase in the 2 weeks after mifepristone administration indicate that no viable pregnancy is present). In general, in the event of a successful medical abortion, the hCG level decreases by at least half of its pretreatment level within a week of mifepristone administration [12]. Service delivery programs seeking to integrate serum hCG testing into medical abortion follow-up services must confirm that it is acceptable and affordable to women and compatible with the infrastructure and human resources available. In some instances, laboratory confirmation of hCG results can be delayed for hours or days, depending on the location of the laboratory and the volume of specimens processed. This delay might be incompatible with efficient service delivery.

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Serum hCG testing can also be very expensive. Furthermore, in some low-resource settings, serum hCG testing is not yet widely available.

Urine pregnancy tests offer another way to measure hCG level. Several studies have documented that urine hCG level is highly correlated with serum hCG level in confirming pregnancy status [3,4,13]. Other research has modeled various algorithms to confirm abortion success using patient symptoms and a low-sensitivity urine pregnancy test [14]. Grossman et al. [7] reviewed published studies examining alternatives to follow-up, including serial hCG testing, urine pregnancy tests, and telephone interview. The authors concluded that alternative follow-up modalities could successfully identify ongoing pregnancy and proposed that further research examine service delivery options that include both at-home urine pregnancy tests and self- or clinician assessment.

In an effort to offer something potentially less costly and less invasive than serum hCG testing or sonography but more informative than a simple low-sensitivity pregnancy test, the aim of the present study was to investigate the feasibility of Vietnamese women performing a semi-quantitative pregnancy test at home, on their own, to determine their abortion status.

2. Materials and methods

From September 14, 2009, to April 2, 2010, 300 women presenting for medical abortion with pregnancies dated up to 63 days since last menstrual period were recruited at a large tertiary facility in Ho Chi Minh City, Vietnam. Additional inclusion criteria were intrauterine pregnancy; no known contraindications to abortion with mifepristone and/or misoprostol; general good health; ability to provide informed consent; and willingness to return for follow-up.

Study clinical staff identified potential participants and offered them enrollment. After the consent and screening process was completed, study staff taught participants how to perform the urine-based semi-quantitative pregnancy test. The result of this initial test, carried out prior to mifepristone administration, located the range of each participant's hCG level before abortion. A 5-bracketed semi-quantitative immunochromatographic assay panel (dBest hCG Panel Test; Ameritek, Seattle, WA, USA) was used (Fig. 1). The test operates as both a high-sensitivity (at least 25-mIU/mL reading) and a low-sensitivity (at least 2000-mIU/mL and at least 10 000-mIU/mL reading) test, in addition to providing readings at 2 other ranges (>100 mIU/mL and >500 mIU/mL). The test offers a technical improvement compared with other pregnancy tests because it provides greater precision to help minimize the likelihood of false-negative results and, uniquely, provides information about the trend in hCG level, which can be compared with the pre-abortion level for each woman. Tests were conducted by dipping the test strip into a urine cup and stirring the strips for at least 10 seconds to saturate the test thoroughly. Training emphasized the need to stir and soak the panel to achieve saturation. The tests were then placed face-up on a flat surface and read 15 minutes later.

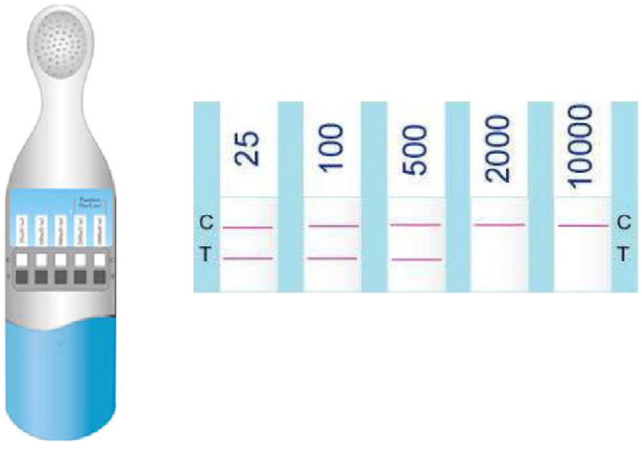

Fig. 1. The dBest (Ameritek, Seattle, WA, USA) semi-quantitative pregnancy test showing a reading of 500 mIU/mL of human chorionic gonadotropin (hCG). C denotes control line. A control line indicates that the test strip has been properly saturated with urine. A control line must appear in all 5 columns for the test to be considered valid. T denotes test line. A test line indicates a positive test result. A column with 1 line (a C line but not a T line) is indicative of a negative test reading. A column consisting of 2 lines (a C line and a T line) indicates a positive test reading for the specific level of hCG.

Each woman was provided with misoprostol for home administration, a second semi-quantitative pregnancy test, a urine sample cup, an instruction sheet, and a questionnaire to take home. Participants administered misoprostol at home 1–2 days later. Women were instructed to take the test and complete the form on the morning of their follow-up visit, which was approximately 2 weeks after mifepristone administration. Either first morning urine or random urine could be used. Emphasis was placed on the importance of saturating all 5 paper strips and waiting at least 15 minutes before reading the tests. The instruction sheet included information on how to read the test and pictorial images of each possible result, as well as a list of commonly asked questions with responses.

Regardless of the results of the pregnancy test conducted at home, each participant was scheduled for clinic-based follow-up. Participants were asked to bring their completed pregnancy tests and study questionnaires with them to this visit. Clinicians then documented the result of the at-home pregnancy tests and assessed each participant's abortion status using standard clinical means, including physical examination and/or transvaginal ultrasound. The results of this standard clinic-based examination were used to determine whether additional care was needed. Women who forgot to complete the at-home pregnancy test or for whom the at-home test showed an inconclusive result were given an additional test to perform at the clinic.

A user comprehension survey was also conducted among 200 additional women of any age from the patient waiting area to ascertain whether potential users understood how to use and interpret the test. Participants were randomly provided with a sample semi-quantitative pregnancy test that indicated 1 of the 5 possible results, the instruction sheet, and a questionnaire. Women were asked to use the instruction sheet to interpret the test results and to complete the questionnaire.

The primary outcome of the clinical study was the feasibility of using the test as part of follow-up for medical abortion. To that end, we documented whether the tests identified all ongoing pregnancies (the main outcome of interest) and whether participants were able to interpret the test correctly. Clinician assessment, via pregnancy test or ultrasound/clinical examination, determined abortion status; semi-quantitative pregnancy test results were evaluated in comparison with this assessment. The primary outcomes of the user comprehension study were the ability to both understand and interpret the test. Data entry and analysis were performed using SPSS version 15 (IBM, Armonk, NY, USA) and STATA version 11 (StataCorp, College Station, TX, USA). Sensitivity/specificity and positive/negative predictive values were calculated to assess the accuracy of the pregnancy test in identifying ongoing pregnancies. Because the main outcome of interest—identification of ongoing pregnancy—would be rare following early medical abortion with mifepristone and misoprostol, it was determined that 300 participants for the clinical study and 200 participants for the user comprehension study would be sufficient for assessing the feasibility of the test in medical abortion care. Ethics approval was provided by Hung Vuong Hospital, Ho Chi Minh City.

3. Results

On average, participants were 29 years of age and most had a secondary education or higher (Table 1). Medical abortion was successful

Table 1
Clinical participant characteristics (n = 300).[a]

Characteristic	Value
Age, y	29 ± 6 (18–44)
Education completed	
Primary school (1–5 years)	10 (3.3)
Secondary school (6–12 years)	232 (77.3)
University level or higher	58 (19.3)
Gestational age, d	42.4 ± 5.9 (30–64)
Medical abortion outcome[b]	
Complete abortion	275 (93.9)
Surgical intervention	18 (6.1)
Ongoing pregnancy	11 (3.8)
Medically indicated (persistent/heavy bleeding)	2 (0.7)
Persistent non-viable pregnancy or sac	4 (1.4)
Provider or woman's preference	1 (0.3)
Participant thought she was still pregnant (or was unsure) prior to taking at-home test[c]	54 (18.5)
Participant had complete medical abortion	41 (75.9)
Participant had surgical intervention	13 (24.1)

[a] Values are given as mean ± SD (range) or number (percentage).
[b] Data do not include 4 women who were lost to follow-up and 3 women who left the study early.
[c] Data do not include 4 women who were lost to follow-up, 3 women who left the study early, and 1 woman with successful medical abortion who did not return her home questionnaire.

for 275 of 293 (93.9%) participants. Eighteen women underwent surgical intervention owing to: ongoing pregnancy (11 [3.8%]); bleeding (2 [0.7%]); persistent non-viable pregnancy or sac (4 [1.4%]); or provider or woman's preference (1 [0.3%]). Fig. 2 shows the trial profile.

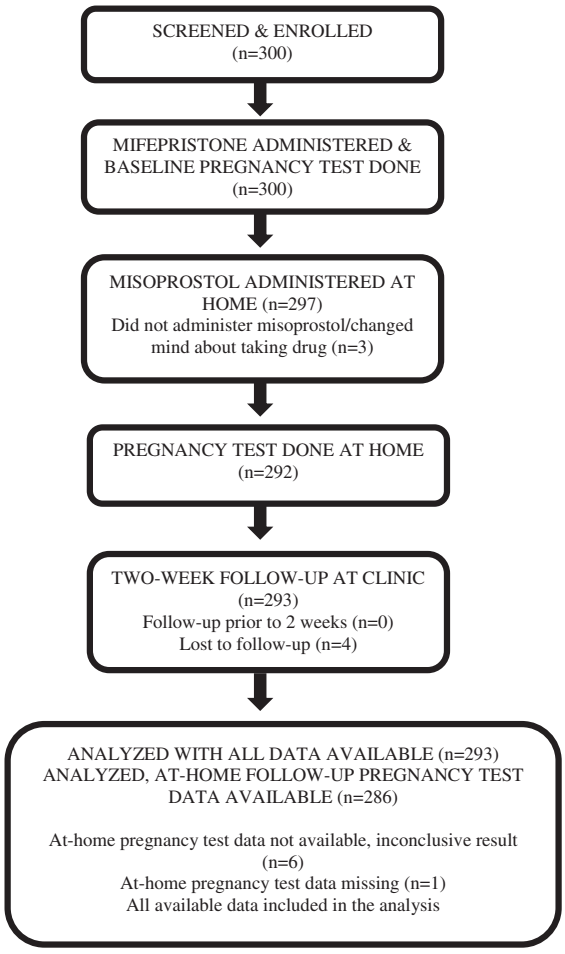

Fig. 2. Clinical trial profile.

Table 2
Sensitivity/specificity and positive/negative predictive values of SQPT to detect ongoing pregnancy versus all other outcomes based on user reading in the clinical study.[a]

	Ongoing pregnancy	All other outcomes
Test indicated steady or increasing hCG level, or test inconclusive[b]	100.0% (11/11)	10.3% (29/281)
Test indicated decreasing hCG level	0.0% (0/11)	89.7% (252/281)
Sensitivity: 100.0%		Specificity: 89.7%
Positive predictive value: 27.5%		Negative predictive value: 100.0%

Abbreviations: hCG, human chorionic gonadotropin; SQPT, semi-quantitative pregnancy test.
[a] User reading unavailable for 1 woman for whom home pregnancy test data were not available.
[b] All 6 women with inconclusive test results had successful medical abortions with no additional intervention.

On the morning of the follow-up visit, participants used the semi-quantitative pregnancy test at home and recorded their interpretation of the result. Fifty-four of 292 (18.5%) participants reported that they thought they were still pregnant prior to using the at-home test (Table 1). The test identified all 11 ongoing pregnancies, with 100% sensitivity (11/11) and 89.7% specificity (252/281) (Table 2). In addition to identifying all of the ongoing pregnancies, the test did not show a decrease in hCG level for an additional 29 women (Table 3). Of these, 24 received no intervention at follow-up and 5 underwent treatment for persistent non-viable pregnancy or sac. None of the participants whose tests showed a decrease in hCG level from baseline to follow-up was later identified as having an ongoing pregnancy. Four of 252 (1.6%) women who showed a reduction in hCG level received interventions at the follow-up visit (Table 3).

Among the 11 women for whom the test identified an ongoing pregnancy, 10 (90.9%) understood that an additional clinic visit was needed. Of the 252 women whose test indicated that clinic-based follow-up was not needed, 147 (58.3%) understood that no additional visit was necessary. Most participants (255/292 [87.3%]) reported that the test was “very easy” or “easy” to use. Nearly all participants (291/292 [99.7%]) felt that the information given by providers helped them use the test.

Results from the user comprehension survey are shown in Table 4. Participants had similar profiles to women participating in the clinical study. When given a test with a pre-configured result and shown an illustration of the 5 possible test outcomes, 195 (97.5%) women correctly matched the test they had been given with the correlating illustrated result. Education level did not impact the capacity of survey participants to interpret the test correctly. In total, 190 of 195 (97.4%) women understood the numeric value of the test. Only 7 (3.5 %) women felt that the test was difficult to use. Overall, 196 (98.0%) participants felt that they could use the test on their own in the future; this perception was not impacted by education level.

4. Discussion

The present results complement previous findings that urine hCG testing can be used as part of early medical abortion follow-up [3–5]. The use of a semi-quantitative test instead of universal clinic-based follow-up could significantly impact medical abortion service delivery because the test could be used as at-home follow-up for women living away from abortion facilities who may wish to avoid a follow-up visit if not required. For women undergoing clinic-based follow-up, the test could provide an alternative to transvaginal ultrasound (often repeated several times for each woman) as the primary means for confirming a complete medical abortion. A tool such as the semi-quantitative pregnancy test could reduce the proportion of women paying for and receiving ultrasound. It would also free-up

Table 3
Effectiveness and acceptability of SQPT in assessing medical abortion outcomes.

	No. (%)
Intervention at follow-up among women whose at-home pregnancy test showed steady or increasing hCG level, or test was inconclusive (n = 40)[a]	
No intervention	24 (60.0)
Intervention performed	16 (40.0)
Ongoing pregnancy managed surgically	11 (27.5)
Persistent non-viable pregnancy or sac managed surgically or with additional dose of misoprostol	5 (12.5)
Intervention at follow-up among women whose at-home pregnancy test showed decreasing hCG level (n = 252) [a]	
No intervention	248 (98.4)
Intervention performed	4 (1.6)
Ongoing pregnancy managed surgically	0 (0.0)
Persistent non-viable pregnancy or sac managed surgically or with additional dose of misoprostol	1 (0.4)
Medically indicated (persistent/heavy bleeding)	2 (0.8)
Provider or woman's preference	1 (0.4)
SQPT reading identified ongoing pregnancy	11/11 (100.0)
Participant understood that this result meant that an additional clinic visit was needed	10 (90.9)
Participant did not understand that an additional clinic visit was needed	1 (9.1)
SQPT reading indicated that clinic-based follow-up was not needed	252/281 (89.7)
Participant understood that this result meant that no additional clinic visit was needed	147 (58.3)
Participant did not understand that no additional clinic visit was needed	105 (41.7)
Participant report on ease of use of test (n = 292)	
Test was neither easy nor difficult	37 (12.7)
Test was "easy" to use	143 (49.0)
Test was "very easy" to use	112 (38.4)
Participant felt that the information given by providers helped them use the test (n = 292)	291 (99.7)

Abbreviations: hCG, human chorionic gonadotropin; SQPT, semi-quantitative pregnancy test.
[a] Includes 14 of the 18 women who underwent surgical intervention (all 11 with ongoing pregnancies and 3 with persistent non-viable pregnancy or sac); the other 4 had pregnancy tests indicating a decrease in hCG level.

provider time for other services and may reduce the number of unnecessary surgical completions for retained products of conception. Such effects may be especially beneficial in resource-poor countries, where clinics may be overcrowded and understaffed, with limited access to serum hCG testing and ultrasound.

The semi-quantitative pregnancy test, with its 5-bracketed ranges, enabled ongoing pregnancy to be ruled out earlier than in previous studies using high- or low-sensitivity pregnancy tests. For instance, Perriera et al. [5] investigated the at-home use of a high-sensitivity pregnancy test 4 weeks after mifepristone administration as part of a telephone follow-up study. Nearly three-quarters of participants were able to avoid clinic-based follow-up; however, they had to wait 4 weeks to confirm that their abortion was complete [5]. In the present study, women were able to confirm their abortion outcome 2 weeks after mifepristone administration. In another study using the same semi-quantitative pregnancy test, women in the USA obtained results using the test just 1 week after mifepristone administration [15]. The semi-quantitative pregnancy test enables women to find out their abortion status sooner, thereby shortening the duration of the procedure. Furthermore, in the rare event of a continued ongoing pregnancy after early medical abortion, diagnosis of a growing embryo 1 to 2 weeks after mifepristone administration facilitates earlier clinical action.

Table 4
Results of user comprehension survey (n = 200).[a,b]

Characteristic	Value
Age, y	31 ± 8 (18–55)
Education completed	
Primary school (1–5 years)	26 (13.0)
Secondary school (6–12 years)	130 (65.0)
University level or higher	44 (22.0)
Pregnancy test was matched with correct corresponding image	195 (97.5)
Among women with less than college degree	151/156 (96.8)
Among women with college degree or higher	44/44 (100.0)
Understood numeric value of test	190/195 (97.4)
Among women with less than college degree	147/151 (97.4)
Among women with college degree or higher	43/44 (97.7)
Instruction sheet helped with interpreting pregnancy test results	198/199 (99.5)
Test was easy to use	
Very easy/easy	100 (50.0)
Neither easy nor difficult	93 (46.5)
Difficult/very difficult	7 (3.5)
Woman believed she could use test on her own in the future to determine pregnancy status	196 (98.0)
Among women with less than college degree	153/156 (98.1)
Among women with college degree or higher	43/44 (97.7)

[a] Values are given as mean ± SD (range) or number (percentage).
[b] Participants in the user comprehension survey were not the same women as in the clinical study.

The potential feasibility of using this test in resource-poor settings is underscored by the fact that nearly all of the participants in both the clinical study and the user comprehension survey reported that the test was easy to use. It should be noted, however, that most of the participants in the present study had completed at least secondary-school education. Despite the nearly unanimous responses that the test was easy to use, when asked to interpret their own test results, nearly half of the women with a decrease in hCG level were not sure whether they needed clinic-based follow-up. Interestingly, an increase or no change in hCG level seemed to be more easily understandable for participants: nearly all (90.9%) of those with ongoing pregnancy correctly interpreted their results. Future simplifications of the instructions sheet should help to improve user comprehension in this regard. Upon discussion with the study investigators, we hypothesize that the design of the study protocol—stipulating that all women must return for follow-up—may have confused women when asked to respond to the question of whether they felt they "needed" to return for follow-up.

The present study was limited by its small sample size and geographic specificity to a single hospital in 1 country, with results that may not be generalizable to other settings. The small sample size meant that potential differences in the cohort could not be examined; instead, the feasibility of this potential service delivery innovation was examined and information was collected from which larger prospective studies could be conducted.

Future research should document how post-abortion contraception can be integrated into medical abortion services with at-home follow-up protocols. More operational research to document "virtual" reporting of at-home follow-up using cellular phones and/or the Internet could also reveal the benefits of this type of service delivery in a range of settings.

Allowing women the option to use semi-quantitative pregnancy tests as at-home tools in lieu of clinic-based follow-up with ultrasound has potential for significant cost-savings for both the healthcare system and women. Yet, for this to be realized, the test must be widely available and at a low cost. Currently, only 1 manufacturer produces the semi-quantitative pregnancy test, meaning that wide availability is inhibited. Future efforts should seek to increase access to this promising technology.

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Conflict of interest

The authors have no conflicts of interest.

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