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Simplified medical abortion screening: a demonstration project☆,☆☆,★

Elizabeth G. Raymond[a,*], Yi-Ling Tan[a], Rodica Comendant[b], Irina Sagaidac[b], Stelian Hodorogea[b], Melissa Grant[c], Patricio Sanhueza[d], Emigdio Van Pratt[d], Ginger Gillespie[e], Christy Boraas[f], Mark A. Weaver[g], Ingrida Platais[a], Manuel Bousieguez[a], Beverly Winikoff[a]

[a]*Gynuity Health Projects, New York, NY 10010, USA*
[b]*Reproductive Health Training Center, Moldova*
[c]*Carafem, Chevy Chase, MD*
[d]*Secretariat of Health, Mexico City*
[e]*Institute for Family Health, New York*
[f]*Planned Parenthood Minnesota, North Dakota, South Dakota, Minneapolis, MN*
[g]*University of North Carolina at Chapel Hill, NC*

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Abstract

Objectives: The objectives were to evaluate the safety and acceptability of outpatient medical abortion in selected women without a pretreatment ultrasound or pelvic examination.

Study design: We conducted a prospective case-series study to estimate the incidence of serious adverse events (death, life-threatening event, hospitalization, transfusion or any other medical problem that we judged to be significant), surgical completion of the abortion and satisfaction in women provided with medical abortion without a pretreatment ultrasound or pelvic examination. We enrolled 406 women requesting medical abortion in Moldova, Mexico and the United States. To be eligible, a woman must have been certain that her last menstrual period started within the prior 56 days, have had regular menses before the pregnancy, not have used hormonal contraceptives in the prior 2 months (in the United States and Mexico) or 3 months (in Moldova), have no risk factors for or symptoms of ectopic pregnancy, and not have had an ultrasound or pelvic exam in this pregnancy. One site also excluded women with uterine enlargement on abdominal palpation. Each participant received mifepristone (200 mg orally) and misoprostol (400 mcg sublingually in Moldova; 800 mcg buccally at all other sites) and was followed until complete abortion, defined as requiring no further treatment.

Results: Of the 365 (90%) participants who provided sufficient follow-up information for analysis, 347 (95%) had complete abortion without additional treatment, 5 (1%) had surgical aspiration, and 10 (3%) had extra misoprostol. Three participants (1%) had serious adverse events; these included two hospital admissions for heavy bleeding managed with aspiration and one diagnosis of persistent gestational sac 19 days after enrollment. Most (317, 90%) participants were pleased with omitting the pretreatment ultrasound and pelvic exam.

Conclusions: In this study, medical abortion without screening ultrasound or pelvic exam resulted in no serious adverse events that were likely to have been prevented by those tests and was highly acceptable.

Implications: Screening for medical abortion without exam or ultrasound shows promise as a means for increasing access to this service. More research is needed to develop screening criteria that are more inclusive and simpler for clinical use.

Keywords: Medical abortion; Last menstrual period; Ectopic pregnancy; Ultrasound

☆ Clinical Trial Registration: Clinicaltrials.gov NCT02381223.

☆☆ The findings and conclusions in this article are those of the authors and do not necessarily represent the views of Planned Parenthood Federation of America, Inc.

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* Corresponding author. Tel.: +1 212 448 1230 (Office).
E-mail address: eraymond@gynuity.org (E.G. Raymond).

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1. Introduction

Medical abortion providers commonly use either ultrasound or pelvic examination to assess gestational age (GA) and to exclude ectopic pregnancy before providing the abortifacient drugs. These examinations may require substantial resources and time, they are uncomfortable, and they must be performed by personnel with specialized skills and equipment. Evaluating medical abortion eligibility without these tests could facilitate access by decreasing cost and expanding the range of personnel and venues that could offer them.

Recent analyses of data from abortion patients have concluded that gestational age can be estimated with reasonable accuracy from menstrual dates [1,2]. The largest and most recent of these analyses included 4257 women presenting for medical abortion at 10 clinics in the United States [3]. Of the 3660 who said that their last menstrual periods had started within the prior 56 days, only a small proportion, 0.9%, were found by ultrasound to have GAs of >70 days, the current accepted limit for outpatient medical abortion. Definitively excluding ectopic pregnancy without ultrasound is more problematic as many women with that condition have no risk factors or symptoms. However, some data suggest that ectopic pregnancy is rare in women presenting for medical abortion [3], and many current guidelines explicitly allow provision of abortion drugs to asymptomatic, low-risk women with pregnancies of unknown location [4–6].

We planned this study to evaluate the safety and acceptability of outpatient medical abortion in carefully selected women without pretreatment pelvic ultrasound or exam. Our primary objectives were to estimate the incidence of serious adverse events, surgical completion of the abortion and satisfaction with the abortion process.

2. Materials and methods

We conducted this case-series study at one clinic in Moldova, one in Mexico, and one in each of three states in the United States: Maryland, Minnesota and New York. The Bioethics Committee of the Public Health Care Institution Municipal Clinical Hospital No. 1, Chesapeake Institutional Review Board, the Institutional Review Board of the Institute for Family Health and the Comisión de Ética en Investigación de la Secretaría de Salud del Districto Federal approved the protocol.

We enrolled women presenting for medical abortion if they consented to participate; had not had a prior ultrasound, pelvic exam, abdominal exam, or quantitative serum or urine human chorionic gonadotropin (hCG) test during the pregnancy; and met specified clinical criteria (Table 1). At the Maryland site, a clinician performed an abdominal exam after enrollment and discontinued participants with evidence of advanced gestation. The participant and the site clinician (physician, nurse practitioner or nurse–midwife) agreed on a plan for confirmation of abortion completeness based on ultrasound, pelvic exam, serial quantitative serum hCG testing and/or serial semiquantitative urine hCG testing with a multilevel pregnancy test (MLPT). The US Food and Drug Administration had not at the time approved the MLPT (dBest; AmeriTek, Seattle, WA, USA), but research had shown that a decline in urine hCG concentration identified by this test reliably indicates abortion of viable pregnancy in women undergoing medical abortion at ≤63 days of gestation [7]. If the follow-up plan included serum hCG testing or the MLPT, site staff obtained the relevant specimen and had it tested. The participant then ingested mifepristone 200 mg in the clinic and was given misoprostol (400 mcg sublingually in Moldova; 800 mcg buccally or vaginally at other sites) to take at home within the subsequent 72 h. One week later, site staff evaluated each participant for abortion completeness using the planned assessment strategy or another appropriate approach and provided additional treatment if needed. If a participant failed to keep her follow-up appointment, the site staff attempted to contact her multiple times using as many modalities as had been authorized by her and permitted by the site's privacy policies, including a final attempt if needed at least 4 weeks after the initial visit. We requested records from other facilities if appropriate. Follow-up continued until the abortion was complete, which we defined as having occurred when the clinician determined that no further treatment was needed. Each participant received

Table 1
Clinical screening criteria for medical abortion without pretreatment ultrasound or pelvic exam

To be eligible for enrollment, a patient must have all of the following characteristics:

- She is pregnant according to a highly sensitive urine pregnancy test performed on the day of enrollment.
- During this pregnancy, she has not had a positive pregnancy test more than 4 or 6 (depending on site) weeks ago.
- She is certain that her LMP was ≤56 days prior to enrollment.
- She had an IUD or implant removed within the past 8 weeks and was not known to be pregnant at removal *OR* during the 2 months (in the United States and Mexico) or 3 months (in Moldova) before her LMP, she had normal monthly menses without intermenstrual bleeding, and she was not using a hormonal contraceptive during that time.
- She has none of the following risk factors for ectopic pregnancy:
  - Previous ectopic pregnancy
  - Intrauterine device in place at the time of conception
  - Vaginal bleeding or spotting since her LMP
  - Unilateral pelvic pain
  - Previous treatment for pelvic inflammatory disease.
- She has no indication for a pelvic exam or ultrasound today unrelated to the abortion itself.
- She is fully eligible for medical abortion with mifepristone followed by misoprostol according to the site's normal criteria (except for criteria related to pelvic exam or ultrasound).