Is the Pelvic Examination Still Crucial in Patients Presenting to the Emergency Department With Vaginal Bleeding or Abdominal Pain When an Intrauterine Pregnancy Is Identified on Ultrasonography? A Randomized Controlled Trial

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Study objective: We determine whether omitting the pelvic examination in emergency department (ED) evaluation of vaginal bleeding or lower abdominal pain in ultrasonographically confirmed early intrauterine pregnancy is equivalent to performing the examination.

Methods: We conducted a prospective, open-label, randomized, equivalence trial in pregnant patients presenting to the ED from February 2011 to November 2015. Patients were randomized to no pelvic examination versus pelvic examination. Inclusion criteria were aged 18 years or older, English speaking, vaginal bleeding or lower abdominal pain, positive β–human chorionic gonadotropin result, and less than 16-week intrauterine pregnancy by ultrasonography. Thirty-day record review and follow-up call assessed for composite morbidity endpoints (unscheduled return, subsequent admission, emergency procedure, transfusion, infection, and alternate source of symptoms). Wilcoxon rank sum tests were used to assess patient satisfaction and throughput times.

Results: Only 202 (of a planned 720) patients were enrolled, despite extension of the study enrollment period. The composite morbidity outcome was experienced at similar rates in the intervention (no pelvic examination) and control (pelvic examination) groups (19.6% versus 22.0%; difference −2.4%; 90% confidence interval [CI] −11.8% to 7.1%). Patients in the intervention group were less likely to report feeling uncomfortable or very uncomfortable during the visit (11.2% versus 23.7%; difference −12.5; 95% CI −23.0% to −2.0%).

Conclusion: Although there was only a small difference between the percentage of patients experiencing the composite morbidity endpoint in the 2 study groups (2.4%), the resulting 90% CI was too wide to conclude equivalence. This may have been due to insufficient power. Patients assigned to the pelvic examination group reported feeling uncomfortable more frequently. [Ann Emerg Med. 2017;■:1-10.]

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INTRODUCTION

Background

First-trimester vaginal bleeding accounts for more than half a million yearly emergency department (ED) visits in the United States.[1] For pregnant patients, such visits represent significant sources of stress and anxiety.[2] For the emergency physician, each of these visits represents a possible ectopic pregnancy, with the associated morbidity and mortality.[3,4] The evaluation of first-trimester vaginal bleeding and low abdominal pain in the ED has evolved during the past half century from complete dependence on history and physical examination to incorporation of advances in laboratory testing and medical imaging.[5] Quantitative β–human chorionic gonadotropin and ultrasonographic results, in particular, have become critical components in ED evaluation of these patients in the United States.[6] Although some texts note that many providers are moving away from routine pelvic examinations in patients presenting with first trimester bleeding,[4] many authors still recommend routinely performing the pelvic exam as an important part of the evaluation.[7-9] Others note its role in evaluating the cervical os, as well as in diagnosing cervical carcinoma or vaginal lacerations.

Editor's Capsule Summary

What is already known on this topic

It is unknown whether pelvic examinations enhance the management of first-trimester vaginal bleeding or lower abdominal pain.

What question this study addressed

This randomized controlled trial compared patient morbidity, satisfaction, and length of stay among 220 patients presenting to 2 emergency departments (EDs) with lower abdominal pain or vaginal bleeding and a confirmed first-trimester intrauterine pregnancy, who were randomized to no pelvic examination (versus standard care of a pelvic examination).

What this study adds to our knowledge

Although the study did not reach target recruitment numbers, it shows similar composite morbidity endpoints and substantially higher satisfaction among patients randomized to no pelvic examination compared with those receiving one.

How this is relevant to clinical practice

This study provides the best available evidence supporting omission of pelvic examinations from ED evaluation of women with confirmed intrauterine pregnancy and first-trimester bleeding or lower abdominal pain.

Given the data supporting the use of quantitative β–human chorionic gonadotropin and ultrasonography in the evaluation of first-trimester vaginal bleeding and abdominal pain, some have begun to question whether the results of the pelvic examination contribute additional data to the ED evaluation.[5,10,11] Studies have cast doubt on the interrater reliability of bimanual examinations performed in the ED.[12] Even under ideal conditions, examination under anesthesia, the bimanual examination demonstrates poor sensitivity in detecting adnexal masses.[13] Increased training and experience do not lead to improved sensitivity.[13] Several prospective observational studies have shown that findings on pelvic examination rarely change diagnoses or influence management in the ED evaluation of first-trimester vaginal bleeding.[5,14,15] Previous studies have examined physician perceptions, rather than patient outcomes. To our knowledge, as of yet no study has prospectively followed patients to evaluate morbidity after omission of the pelvic examination. In otherwise healthy patients without concern for vaginal trauma, cervical carcinoma, or hemodynamic instability, the pelvic examination may prove to be an invasive examination with little benefit to the patient or clinician. Having the option to omit the pelvic examination in select patients may increase patient satisfaction by allowing women to safely forgo an uncomfortable examination. Omitting this examination might also decrease ED length of stay and increase throughput by decreasing the need for limited resources such as a pelvic bed, chaperone, and private room for the examination.

Importance

To our knowledge, this is the largest prospective, randomized study examining the utility of the pelvic examination in the ED evaluation of first-trimester vaginal bleeding or abdominal pain, and the first study with 30-day follow-up.

Goals of This Investigation

The goal of this study was to determine whether omitting the pelvic examination in patients who present with first-trimester vaginal bleeding or lower abdominal pain and who have signs of an intrauterine pregnancy documented on ultrasonography leads to increased morbidity. We performed a survey at one of the centers before initiation of this study to determine whether the clinical faculty would accept omitting the pelvic examination as our standard of medical care. We found that approximately half of the emergency medicine attending physicians at the primary site believed that a pelvic examination was necessary for evaluation of first-trimester vaginal bleeding or abdominal pain, whereas half did not. Therefore, we designed and conducted a prospective clinical trial that tested the effects of omitting the pelvic examination in this population.

MATERIALS AND METHODS

Study Design and Setting

This was a prospective, randomized, multicenter, equivalence trial enrolling a convenience sample of pregnant patients at less than 16 weeks' gestation, with chief complaint of vaginal bleeding or abdominal pain. The primary site for this study was a large urban academic ED in Boston, MA, with a yearly census of 130,000 patients. The secondary site was an urban academic ED in Washington, DC, with a yearly census of 75,000 patients. Patients provided written informed consent, and the protocol was approved by the institutional review boards at both hospitals.