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

Judith A. Linden, MD*; Benjamin Grimmnitz, MD; Laura Hagopian, MD; Alan H. Breaud, MPH; Breanne K. Langlois, MPH; Kerrie P. Nelson, PhD; Lauren L. Hart, MD; James A. Feldman, MD, MPH; Jeremy Brown, MD; Marc Reid, BA; Elise Desormeau, MPH; Patricia M. Mitchell, RN

*Corresponding Author. E-mail: jlinden@bu.edu, Twitter: @jlinden4.

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;70:825-834.]

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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

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.

in evaluating the cervical os, as well as in diagnosing cervical carcinoma or vaginal lacerations.

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.

Selection of Participants

Trained research assistants enrolled patients on weekdays from 8 AM to 11 PM. The research assistants reviewed the ED tracking board screening for eligible participants during these hours and approached providers to discuss patient eligibility for enrollment in the study. A log was kept of patients screened, including reasons for not enrolling. Inclusion criteria were aged 18 years or older and presenting with a chief complaint of vaginal bleeding or lower abdominal pain, with a confirmed intrauterine pregnancy by combination of positive urine test results or serum β–human chorionic gonadotropin level and ultrasonography. Confirmation of intrauterine pregnancy included the presence of at least a yolk sac or fetal pole. Ultrasonography confirming intrauterine pregnancy was performed either in radiology or in the ED under the supervision of an ultrasonography-credentialed emergency medicine attending physician. At our primary center, patients are often sent from waiting room to ultrasonography. When patients are moved back into the ED before radiology is ready for ultrasonography, they are frequently triaged to the hallway. Thus, they often receive ultrasonography before pelvic examination. Randomization occurred after ultrasonographically confirmed intrauterine pregnancy and before the pelvic examination. Although occasionally this resulted in a delay in performance of the pelvic examination, randomization often occurred while patients were waiting for the availability of a curtained room and a chaperone.

We developed exclusion criteria in conjunction with colleagues in the Department of Obstetrics and Gynecology and an obstetrics-gynecology attending physician who was an institutional review board chair and agreed to serve as the data and safety monitor. Exclusion criteria were pelvic examination performed before consent and randomization, admission to the hospital, known history of cervical carcinoma, current pregnancy because of in vitro fertilization, suspicion for heterotopic pregnancy according to treating physician, reported heavy vaginal bleeding (soaking of >10 menstrual pads in 24 hours), hemodynamic instability (systolic blood pressure <90 mm Hg or pulse rate >110 beats/min), report of or suspicion for penetrating vaginal trauma, intrauterine device in place, clinical suspicion by the attending ED provider for an alternative syndrome requiring pelvic examination (such as appendicitis, pelvic inflammatory disease, or torsion), reported sexual assault, prisoner, previous enrollment in the trial, or inability to follow up by telephone. The study was approved by the institutional review board at both institutions.

Interventions

After consent, participants were randomized to 1 of 2 groups: pelvic examination omitted (intervention group) or pelvic examination performed (control group). Block randomization was computer generated in advance by a statistician, and randomization results were placed sequentially in sealed envelopes. The research assistants obtaining consent were blinded to randomization arm. After obtaining informed consent, the research assistant opened an envelope, revealing which arm of the study the participant had been randomized to. The intervention arm of the study was omission of the pelvic examination. Participants, providers, and chart reviewers were not blinded to intervention. For study purposes, all pelvic examinations included speculum examination, as well as bimanual palpation and cultures, if indicated. By ED protocol, participants' urine was tested for gonorrhea and chlamydia at the discretion of the clinician. A data and safety monitor (an obstetrics-gynecology attending physician) reviewed morbidity endpoints at predetermined intervals. Any major morbidity was to be reported to the data and safety monitor immediately.

Outcome Measures

The primary outcome was a composite morbidity endpoint at 30 days, which included need for further treatment or intervention, unscheduled return visits to the ED or clinic, need for hospital admission, emergency procedure (not including scheduled dilatation and curettage), transfusion, infection, or subsequent identification of other source of symptoms.

Some of the major rationales for the performance of a pelvic examination in this population include facilitating determination of the likelihood of progression of pregnancy loss (ie, "assess the cervix"), identifying an alternative source of bleeding (vaginal laceration, cervical polyp, or other), or narrowing a differential or making the diagnosis (retained vaginal foreign body, evidence of infection, appendicitis, or torsion). We used this theoretical framework to inform the morbidity endpoints.

We hypothesized that if the pelvic examination is informative about the risks of progression of a threatened miscarriage, it was possible that omission of this examination could lead to an increased risk of return visits and hemorrhage. We also assumed that other components of the composite endpoint such as a serious alternative diagnosis that was missed or delayed (torsion or appendicitis), infection, or other adverse outcome would be rare events and considered serious adverse events by the study monitor.

We hypothesized that although omitting the pelvic examination might speed patient throughput, it could undermine patient confidence in the thoroughness of the evaluation and result in a greater number of unscheduled return visits. This outcome was determined by 30-day chart review performed by research assistants who were trained and supervised by the resident principal investigator (L.H.). If no further visits were found since the index visit, the research assistants called the participant. Up to 5 attempts were made to contact participants by telephone, and up to 3 messages were left. After the research assistants coded for morbidity outcomes, all charts were independently reviewed by 2 emergency physicians (J.A.L. and either B.G. or L.H.). Any discrepancies were further investigated and discussed until consensus was reached in regard to proper classification and coding. Research assistants and physician chart reviewers were not blinded to intervention.

Secondary outcomes included ED throughput time and the responses to a participant experience survey. Using the electronic medical record, we measured several throughput variables, including time from triage to bed or hallway, time from bed or hallway to disposition, time from disposition to discharge, and entire ED length of stay. We considered a 30-minute difference in throughput time to be clinically important a priori. We decided that regardless of statistical significance, a threshold of 30 minutes would represent a clinically meaningful difference. Before ED discharge, participants completed a survey about satisfaction with their care during the ED visit. The survey was developed by investigators and was piloted with emergency medicine attending physician faculty. The survey rated participant discomfort, embarrassment, and satisfaction, as well as perception of length of stay and thoroughness of the care received.

Primary Data Analysis

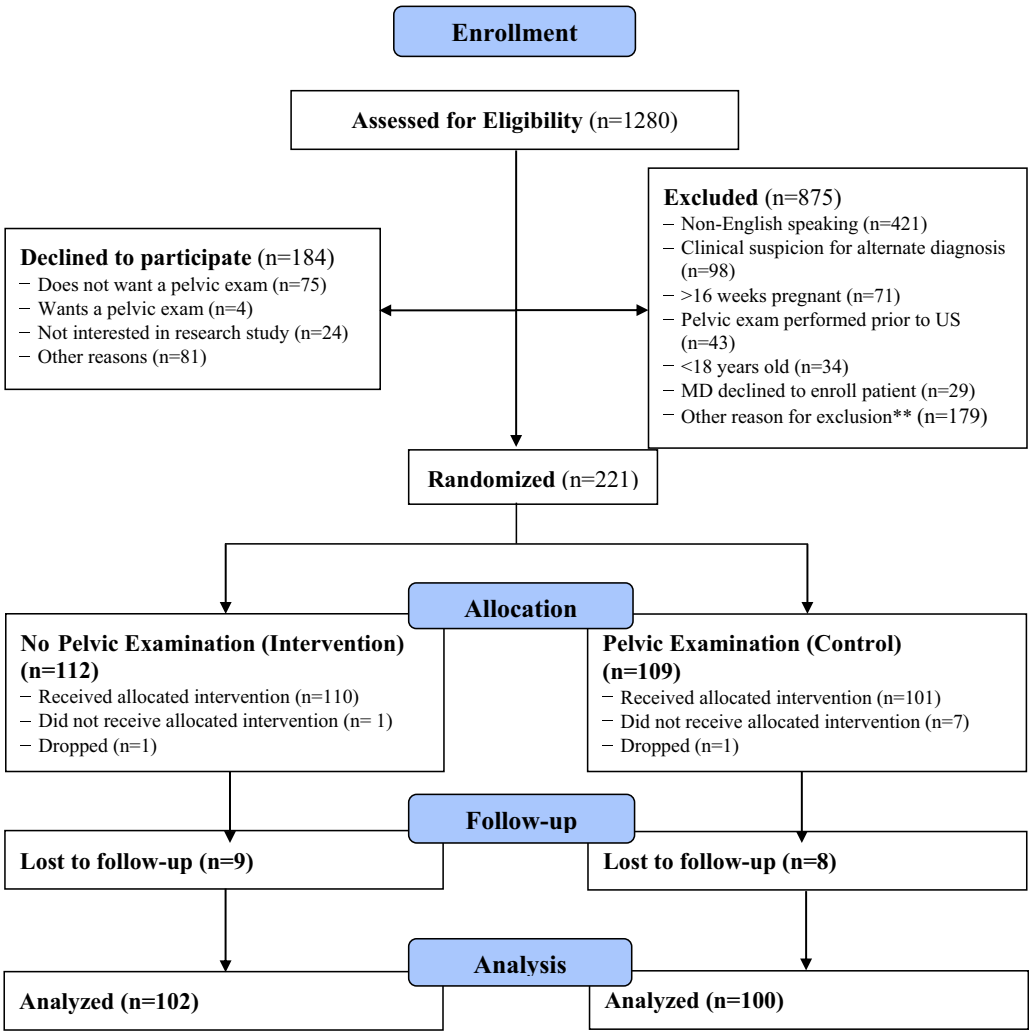
The primary analysis was an equivalence test evaluating the 30-day morbidity rate between treatment groups. The intention of the equivalence study was to demonstrate that the new treatment (not having a pelvic examination) was neither inferior nor superior to the existing standard of care (having a pelvic examination) within a reasonable margin of equivalence. We implemented the 2 one-sided test procedure.[16] This led to a 90% confidence interval (CI) because it was tantamount to performing 2 one-sided tests. Thus, using a 90% CI yielded a .05 significance level for testing equivalence. A baseline rate of adverse events was estimated at 15% according to a retrospective chart review of 440 patients receiving care as usual at our primary site before initiation of enrollment for the current study. The majority of these events were 30-day return visits. Given an expected baseline adverse event rate of 15%, our choice of margin of equivalence extended from –8% to 8% for the 2 one-sided z tests that formed the equivalence test. A sample size of 720 participants would give 83% power at the .05 level of significance. Assuming a refusal rate of 10%, it was anticipated that the sample size would be reached in 2 years. Patients who were lost to follow-up were omitted from the analysis because their primary outcomes were unknown.

Analysis was also performed on secondary outcomes related to ED throughput and patient satisfaction. ED throughput variables were compared between treatment groups with either Wilcoxon rank sum or t tests, according to distribution. Categorical patient satisfaction variables were compared with χ^2 and Fisher tests. We used SAS (version 9.3; SAS Institute, Inc, Cary, NC) for all analyses.

RESULTS

Characteristics of Study Subjects

A total of 1,280 patients were screened for eligibility; 875 patients were excluded (see Figure for reasons for exclusion). A total of 221 participants were enrolled between February 2012 and November 2015, with 2 participants omitted after enrollment (1 was admitted after enrollment and randomization, and 1 had a pelvic examination after surgery deemed this was necessary, and the treating physician withdrew the participant from the study), and 17 were lost to follow-up (Figure). Of the 17 lost to follow-up, 9 did not receive the pelvic examination (intervention group) and 8 received a pelvic examination (control group). There were 202 participants included in the final analysis, 102 who did not have the pelvic examination and 100 who did. One participant randomized not to receive pelvic examination did receive one, and 7 participants initially assigned to the pelvic group did not receive pelvic examinations. All analyses were conducted on an intention-to-treat basis. The treatment groups were similar in regard to age, pulse, systolic blood pressure, hemoglobin levels, gestational age, frequency of detection of fetal heart rate, frequency of normal intrauterine pregnancy on ultrasonography, and frequency of ED bedside ultrasonography (Table 1). The intervention group (no pelvic examination) was slightly less likely than the control group (pelvic examination) to present with a chief complaint that included both abdominal pain and vaginal bleeding (17.7% versus 23.0%, respectively) and had slightly lower mean gravity (2.6 versus 3.7, respectively). See Table 1 for further information about baseline characteristics of study participants.



** Other reasons for exclusion: IUD in place (n=20), Enrolled in study on prior visit (n=19), Hemodynamic instability (n=15), Eloped prior to enrollment (n=14), Unable to follow up (n=8), Admitted (n=8), Heavy bleeding (>10 pads per hour) (n=7), Prisoner (n=6), Inability to consent (n=3), IVF (n=3), Reported sexual assault (n=2), Known cervical carcinoma (n=1), Other (n=73)

Figure. Screening, randomization, and enrollment flow diagram.

Main Results

Table 2 presents the primary outcome of the study, composite 30-day morbidity. In the intervention group (no pelvic examination), 20 of 102 patients (19.6%) experienced the composite morbidity outcome compared with 22 of 100 (22.0%) in the control group (pelvic examination). The equivalence test yielded an estimated difference (intervention–control) between the treatment groups on the primary outcome measure of –2.4% (90% CI –11.8% to 7.1%). Because our CIs were wide and did not fall between the predefined CI of –8 to 8%, there was insufficient evidence to state equivalence between the 2 study groups. The difference in morbidity was primarily driven by unscheduled return visits to the ED: 13.7% (intervention, no pelvic examination) versus 18.0% (control, pelvic examination). Rates of subsequent unplanned procedures or testing were higher in the intervention group than the control group: 5.9% versus 2.0%. All of the procedures were unplanned dilatation and curettage. Subsequent infection rates were similar across both populations: 2.0% (no pelvic examination) versus 3.0% (pelvic examination). All of the infections documented on follow-up but not diagnosed from the ED visit were bacterial vaginosis or candida. Follow-up identified an alternate source for symptoms less frequently in the no-pelvic-examination group than the pelvic-examination group, 0.0% versus 2.0%. Similar rates of hospital admission were noted, 2.0% in both groups. No participants required

Table 1. Patient characteristics.

Characteristic	Total (n=202)	No Pelvic Examination (Intervention) (n=102)	Pelvic Examination (Control) (n=100)
Age, mean (SD), median (IQR), y	27.6 (6.1), 27.0 (9.0)	26.9 (5.7), 26.0 (9.0)	28.3 (6.4), 28.0 (10.0)
Race			
White	19 (9.5)	8 (7.8)	11 (11.0)
Black	139 (69.2)	69 (67.7)	71 (71.0)
Asian	1 (0.5)	1 (1.0)	0
Hispanic/Latino	35 (17.4)	21 (20.6)	14 (14.0)
Other	7 (3.5)	3 (2.9)	4 (4.0)
Gravity, mean (SD), median (IQR)	3.2 (4.9), 2.0 (3.0)	2.6 (1.7), 2.0 (3.0)	3.7 (6.6), 3.0 (2.0)
Pulse rate, mean (SD), beats/min	82.8 (12.7)	83.4 (13.1)	82.1 (12.3)
SBP, mean (SD), mm Hg	121.5 (18.2)	124 (16.3)	119.0 (19.6)
Hemoglobin, mean (SD), g/dL	12.3 (1.2)	12.3 (1.4)	12.3 (1.0)
Gestational age, mean (SD), median (IQR), days	59.1 (20.4), 51.0 (29.0)	58.5 (21.1), 49.0 (29.0)	59.7 (19.8), 53.0 (30.0)
Chief complaint			
Vaginal bleeding	96 (47.5)	47 (46.1)	49 (49.0)
Abdominal pain/cramping	91 (45.1)	44 (43.1)	47 (47.0)
Abdominal pain and vaginal bleeding	41 (20.3)	18 (17.7)	23 (23.0)
Abdominal pain/vaginal bleeding+other complaint	8 (4.0)	7 (6.9)	1 (1.0)
Fetal heart rate present	156 (77.2)	76 (74.5)	80 (80.0)
Ultrasonographic findings			
Abnormal yolk sac	1 (0.5)	0	1 (1.0)
Irregularly shaped gestational sac	6 (3.0)	4 (3.9)	2 (2.0)
Low-lying gestational sac	4 (2.0)	3 (2.9)	1 (1.0)
Thin trophoblastic reaction	0	0	0
Subchorionic hemorrhage	28 (13.9)	16 (15.7)	12 (12.0)
Suspected or definite fetal demise	7 (3.5)	4 (3.9)	3 (3.0)
Normal IUP	129 (63.9)	69 (67.7)	60 (60.0)
Other	70 (34.7)	34 (33.3)	36 (36.0)
Ultrasonographic type			
Beside	11 (5.5)	5 (4.9)	6 (6.0)
Radiology	191 (94.5)	97 (95.1)	94 (94.0)

SBP, Systolic blood pressure; *IUP*, intrauterine pregnancy.
Data are presented as No. (%) unless otherwise noted.

transfusion. Table 2 summarizes the disaggregated morbidity outcome measures. Participants in the no-pelvic-examination group were half as likely to report feeling uncomfortable or very uncomfortable as participants in the pelvic-examination group (11.2% versus 23.7%; difference –12.5%; 95% CI –23.0% to –2.0%). No other statistically significant differences were found for the other satisfaction variables: satisfaction, embarrassment, perceived thoroughness, and perceived length of stay (Table 3).

LIMITATIONS

This study has several limitations. First, although this is the largest prospective randomized trial to date, to our knowledge, the target sample size of 720 was not reached. This target was based on an expected enrollment time of 24 months; however, after 46 months the study was closed with 202 participants. Our nonsignificant results in the equivalence test may be attributed to this smaller-than-anticipated sample size. Loss of a second site early in the trial after enrollment of 13 participants significantly reduced the rate of enrollment. We enrolled only 2 Spanish-speaking subjects (with a Spanish-speaking research assistant available). Thus, most non-English-speaking subjects were excluded. Of screened patients, 68% were excluded from eligibility, and 46% of eligible patients declined to participate, far greater than the expected 10% rate of refusal (Figure). We hypothesized that many who declined to participate would do so because of their perception that the pelvic examination would add crucial information to their evaluation. We found, however, that most patients declined to participate because they did not want to have the pelvic examination. Our initial power calculation estimated that we would require 720 patients to detect a 15% change in morbidity outcomes. In accordance with a review of the frequency of vaginal bleeding or abdominal pain in early pregnancy in our patient population, recruitment of an additional site, and an anticipated refusal to participate of 10%, we estimated that it would take 2 years to reach our enrollment goal. We were

Table 2. Summary of morbidity endpoint outcomes.

30-Day Return Visit Outcome	Total (n=202) No. (%)	No Pelvic Examination (n=102) No. (%)	Pelvic Examination (n=100) No. (%)	95% CI (No Pelvic–Pelvic)
Returned to a hospital or clinic within 30 days for evaluation of pregnancy	123 (60.90)	61 (59.8)	62 (62.0)	−15.7 to 11.3
Morbidity outcomes				
Unscheduled ED visit	32 (15.8)	14 (13.7)	18 (18.0)	−14.3 to 5.8
Hospital admission	4 (2.0)	2 (1.9)	2 (2.0)	*
Any procedures or tests related to pregnancy (not including elective abortion)	8 (3.0)	6 (5.9)	2 (2.0)	*
Transfusion	0	0	0	*
Infection	5 (2.5)	2 (2.0)	3 (3.0)	*
Identification of other source of symptoms	2 (1.0)	0	2 (2.0)	*
Composite morbidity outcome				**90% CI equivalence test (no pelvic–pelvic)**
Primary outcome (any of the 6 morbidity outcomes)	42 (20.8)	20 (19.6)	22 (22.0)	−11.8 to 7.1

*Numbers too small to calculate CIs.

not able to reach our target study number for many important reasons. Because of resource limitations at our site, non-English-speaking subjects were ineligible (almost 50% of eligible subjects). We also found that 46% of patients eligible refused to be randomized, most because of the possibility of being included in the pelvic-examination-required arm (much higher than our estimated 10% refusal rate). This suggests strongly that there has already been a secular trend with providers omitting and patients declining a pelvic examination after an ultrasonographic examination unless there are specific clinical concerns (trauma or infection). We also believe that this observation would make a larger study impractical. A previous study also found difficulty in enrolling patients in a similar study examining whether the pelvic examination increases diagnostic accuracy in early pregnancy bleeding. They concluded their study after 2 years, short of the enrollment goal of 200, with just 135 patients included.[10]

The current study evaluated only patients with ultrasonographically confirmed intrauterine pregnancy. Patients with indeterminate ultrasonography results or clearly identified ectopic pregnancies were excluded. Our obstetrics and gynecology colleagues and our data and safety monitor believed strongly that it was unethical to include this high-risk population with possible ectopic pregnancy; thus, they were excluded. Although several studies have examined the role of the pelvic examination specifically in this population and found a dearth of evidence to support its role in ruling out ectopic pregnancy,[3,17] the results of this study cannot be extrapolated to patients with possible ectopic pregnancy. The challenges of conducting this study suggest that a

Table 3. Summary of secondary outcomes.

Secondary Outcome	Randomized Group: Intervention (No Pelvic Examination) (n=102)*	Randomized Group: Control (Pelvic Examination) (n=100)*	95% CI (No Pelvic–Pelvic)
ED LOS (SD), min	163.6 (75.3)	182.6 (63.2)	−38.8 to 0.8
Patient satisfaction during examination (very uncomfortable/uncomfortable) (%)	11 (11.2)	23 (23.7)	−23.0 to −2.0
Perceived thoroughness of care (good/excellent) (%)	95 (95.0)	95 (97.9)	−8.1 to 2.2
Rating of LOS (%)			
Longer than expected	51 (51.0)	50 (51.5)	
As expected	29 (29.0)	26 (26.8)	
Shorter than expected	20 (20.0)	21 (21.6)	
Embarrassment during physical examination (%)	11 (11.3)	16 (16.5)	−14.9 to 4.6

LOS, Length of stay.
*The n ranges from 97 to 100 in each group for each outcome measure.

prospective clinical trial that includes the subgroup of women who could have an ectopic pregnancy (positive β–human chorionic gonadotropin result and negative or indeterminate ultrasonographic result) would be challenging to complete.

Our study population was primarily urban with a lower socioeconomic status and thus may not be generalizable in other settings. Finally, it was not possible to blind the patients, providers, or research assistants to the intervention, which may have introduced confirmation bias. However, the study endpoints that were derived by structured chart review or follow-up calls were unlikely to be affected by lack of blinding.

DISCUSSION

In the era of point-of-care ED pelvic ultrasonography, easily accessible radiology-performed ultrasonography, and urine sexually transmitted disease testing, the pelvic examination adds limited information to the evaluation of the patient with nontraumatic vaginal bleeding or abdominal pain of probable gynecologic origin in early pregnancy.[5,10,14,15] Many patients prefer not to have this uncomfortable examination performed. Furthermore, in many EDs with limited private space and pelvic examination–enabled stretchers, addition of the pelvic examination has the potential to increase the length of stay.

Some textbooks and guidelines suggest performing a pelvic examination for patients who present to the ED with vaginal bleeding or abdominal pain in early pregnancy. Reasons for performing the pelvic examination include a way of the clinician's quantifying how much bleeding the patient is having, determining whether the os is open or closed, detecting lesions of the cervix or vagina that might be a cause of vaginal bleeding, detecting ovarian or pelvic mass, and detecting sexually transmitted infections.[18,19] Previous studies have shown that the clinical examination in the stable pregnant patient with vaginal bleeding is unreliable. Isoardi[5] performed a literature review addressing the role of the pelvic examination in the evaluation of bleeding during early pregnancy and concluded that the results of the pelvic examination rarely change ED management. Two randomized studies concluded that the pelvic examination rarely influenced management decisions in the initial patient assessment in patients with first-trimester bleeding.[10,15] One study was randomized but did not evaluate patient-centered endpoints, looking only at final diagnosis rather than complications.[10] The other study compared disposition of patients according to the ultrasonographic result versus the provider's preliminary expected disposition based on the pelvic examination alone.[15] In both studies, the authors pointed out that management decisions were made more on the basis of ultrasonographic and laboratory tests than the results of the pelvic examination.

To our knowledge, our study is the largest prospective randomized study that includes a 30-day follow-up period evaluating the safety of omitting the pelvic examination in patients with a documented intrauterine pregnancy on ultrasonography. A total of 17 patients were lost to follow-up (n=9 in the intervention [no pelvic examination] group and n=8 in the control [pelvic examination group]) because of no follow-up information in the chart and inability to be contacted by telephone. Sensitivity analyses demonstrated no noticeable changes to the equivalence test results for the primary outcome when the potential effect of the missing data was considered. We observed a trend toward increased morbidity in the group of patients receiving pelvic examinations (22.0% versus 19.6%; difference 2.4%), primarily driven by unscheduled return visits to the ED (18.0% versus 13.7%; difference 4.3%). The cause of this excess morbidity in the setting of pelvic examination is unknown. It is unlikely that the pelvic examination causes lasting discomfort, resulting in follow-up ED visits, nor is it likely that the pelvic examination increased the severity or duration of vaginal bleeding. The high rate of return for both groups is typical of the population of women who present with vaginal bleeding or abdominal pain in early pregnancy because they are counseled about the importance of follow-up and to return for any problem or concerns (including increased bleeding or pain, often a natural progression in miscarriage). The differences between intervention and control were likely exaggerated by lower-than-expected enrollment. This study was underpowered to detect rarer major morbidity occurrences, such as transfusion and hospitalization. As far as detecting infection, the use of urine gonorrhea and chlamydia nucleic acid amplification tests was left to the discretion of the provider but is a common practice in our ED, thus mitigating the risk of missing an undiagnosed sexually transmitted infection in patients when a pelvic examination was not performed.

To our knowledge, this is the first study to attempt to evaluate the effect of omission of the pelvic examination on ED throughput time. Although the average time from bed to disposition (length of stay) decreased by 19 minutes and trended toward lower times in the no-pelvic-examination group (163.6 versus 182.6 minutes; difference –19 minutes; 95% CI –38.8 to 0.8 minutes), it did not reach statistical significance or the predetermined threshold of 30 minutes for clinical significance.

Although omitting the pelvic examination did not significantly speed throughput, it did improve patient

comfort. Contrary to our initial expectation that women would want the pelvic examination to be reassured that they had been thoroughly evaluated, many women expressed the opposite. Participants who did not receive a pelvic examination were significantly less likely to report that their experience was uncomfortable or very uncomfortable compared with those who had the pelvic examination (11.2% versus 23.7%; difference –12.5%; 95% CI –23.0% to –2.0%). Perhaps even more telling is the fact that of 178 women who refused enrollment in the study, 74 (42%) did so because they did not want to be subjected to a pelvic examination, whereas only 4 (2%) refused enrollment because they wanted to ensure that they would receive a pelvic examination. The drastic difference in refusal rate between those preferring not to receive a pelvic examination and those women who thought it was necessary may have influenced the overall satisfaction. There could be participation bias that affected satisfaction survey responses; women who agreed to be in the study were probably largely indifferent to or wanted the pelvic examination and could differ from the large number of patients who declined to participate. It is possible that the high refusal rate biased to the null observed between group differences in patient satisfaction.

In conclusion, this study provides additional data that support the safety of omitting a pelvic examination in women with a confirmed intrauterine pregnancy on ultrasonography unless there are specific clinical concerns (such as infection or trauma). However, we were not able to definitively demonstrate that omitting the ED pelvic examination after documentation of intrauterine pregnancy on ultrasonography is equivalent to performing the pelvic examination in the evaluation of abdominal pain or vaginal bleeding in early pregnancy. We did demonstrate that there were important patient-centered benefits in omitting the pelvic examination. When the pelvic examination was omitted, patients reported improved comfort and there was a trend toward decreased ED throughput time. The preferences of patients and physicians may make future large-scale studies of this type difficult to accomplish.

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Author affiliations: From the Department of Emergency Medicine, Boston University School of Medicine and Boston Medical Center, Boston, MA (Linden, Feldman, Reid, Desormeau, Mitchell); the Boston Medical Center, Emergency Medicine Residency, Boston, MA (Grimmnitz); Lowell General Hospital, Lowell, MA (Hagopian); the Questrom School of Business (Breaud) and Department of Biostatistics (Nelson), Boston University, Boston, MA; the Department of Health and Community Medicine, Tufts University School of Medicine, Boston, MA (Langlois); the NYU Bellevue Emergency Medicine Residency, New York, NY (Hart); and National Institute of Neurological Disorders and Stroke, Bethesda, MD (Brown).

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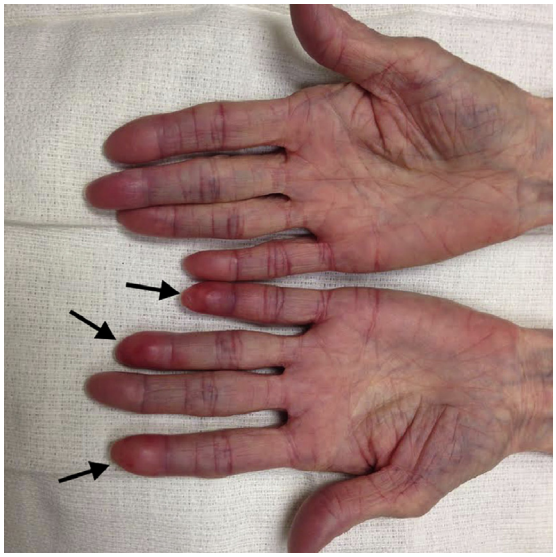

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