DEM Journal Club

# Article Appraisal

**Article:** 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 by Linden et al. 2017 in Annals of Emergency Medicine

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## Background and Study Objective(s):

It is unknown whether pelvic examinations enhance the management of first trimester vaginal bleeding or lower abdominal pain, although some prospective observational studies have shown that findings on pelvic examination rarely change diagnoses or influence management in the emergency department (ED) evaluation of first trimester vaginal bleeding. There has been no randomized controlled trial (RCT) to date to determine whether pelvic exams are necessary.

This RCT examined the utility of the pelvic exam in pregnant patients under 16 weeks gestational age presenting to the ED with a chief complaint of vaginal bleeding and/or abdominal pain when intrauterine pregnancy (IUP) had been confirmed by ultrasound. Specifically, it examined the pelvic exam's impact on patient morbidity, satisfaction and length of stay (LOS) in the ED.

## Study Design:

This was a prospective, open-label, randomized equivalence trial. The original intent was to enrol 720 participants from two centres over a two-year period in order to detect a 15% change in morbidity outcomes. Unfortunately, only 202 patients were enrolled over a 4.5 year period, with one of the study centres being dropped due to limited enrolment.

A convenience sample was enrolled mostly from a large urban academic ED in Boston of patients who presented with either vaginal bleeding or lower abdominal pain and who were less than 16 weeks pregnant with IUP confirmed on ultrasound (ordered at triage). These patients were randomized to either the intervention group (no pelvic exam) or the control group (pelvic exam). The research assistants were blinded to the randomization arms; however, participants, providers and chart reviewers understandably were not.

The inclusion criteria were patients who were 18 years of age and older and had confirmed IUP by both ultrasound and positive B-human chorionic gonadotropin level. Exclusion criteria were extensive, most of which included high

risk features such as in vitro fertilization, heavy vaginal bleeding, hemodynamic instability, suspected vaginal trauma or IUD in place. Notably, clinical suspicion of ED provider for an alternative syndrome requiring a pelvic examination also exempted patients from the study. This resulted in a total of 875 excluded patients, leaving just 221 participants to be evenly randomized to each arm, which was done by block randomization. Important to generalizability, randomization occurred AFTER ultrasound confirmed IUP but before the pelvic exam had a chance to occur (in fact, patients who had already received a pelvic exam were excluded from the study).

The primary outcome was a composite morbidity endpoint at 30 days. This included need for further treatment or intervention, unscheduled return visits to the ED or clinic, need for hospital admission, emergency procedure, transfusion, infection or subsequent identification of other source of symptoms. Analysis was conducted on an intention to treat basis. Secondary outcomes included length of ED stay and patient satisfaction. For secondary outcomes participants completed a survey before discharge rating patient discomfort, embarrassment, satisfaction, as well as perception of LOS and thoroughness of care received. ED throughput time was examined based off of the EMR, which measured several throughput variables including triage to bed, bed to disposition, disposition to actual discharge as well as entire LOS.

## Results:

Of the 1280 patients who were eligble, 875 had to be excluded because 421 did not speak English. Just 221 were randomized. After accounting for patients lost to follow-up, only 102 patients were analysed in the intervention group and 100 patients were analyzed in the control group. Everyone was accounted for and patients were analysed in the groups to which they were randomized.

Researchers performed a 2 one-sided test procedure, and chose their margin of equivalence to extend from -8% to 8%. No statistically significant differences in the pelvic examination versus no pelvic examination groups were found, either in the 30-day return visit outcome or any of the morbidity outcomes. The composite morbidity outcome had confidence intervals that were too wide to impart statistical significance, as the 90% confidence interval was -11.3 to 7.1. So, the upper bound lay wthin the a priori margin of equivalence, but the lower bound did not. This is likely an issue of power, and if there were more prticipants then perhaps the confidence interval would be tighter and might have fallen within the margin of equivalence. Unfortunately, equivalence for the primary outcome could not be determined.

The difference in ED length of stay was also not significant, with a difference of 30 minutes having been chosen as clinically important. However, the average ED LOS decreased by 19 minutes. Participant satisfaction, as evaluated by survey, reported that patients not receiving a pelvic examination were half as likely to report feeling uncomfortable, with no other statistically significant differences found for other satisfaction variables.

## Validity of Results:

The study question was arguably not well conceived, as it included patients with either vaginal bleeding and/or abdominal pain. The differential diagnosis and concerns for these may be different and can require a different investigational approach.

Obviously this study ended up being very underpowered and the authors were unable to state equivalence. It was unfortunate that many patients were excluded due to language barriers, which could have been avoided by having a translator. Most subjects were black or hispanic with lower socioeconomic statuses, which have a known correlation to poorer health outcomes and could be considered a higher risk population. However, pros included that the participants were well randomized and the groups well matched.

## Generalizability of Results:

Due to the extensive exclusion criteria, the population studied was a low risk group of women in whom IUP had already been confirmed by radiology (as opposed to point of care ultrasound). Furthermore, patients who had

already received a pelvic exam were excluded. This is opposite to the approach we use in Canadian EDs where we would first take a history and perform a physical exam prior to ordering formal ultrasound. The demographics of participants are also not comparable to those seen by many Canadian EDs, although this may vary based on where your ED is located.

## The Bottom Line:

Although this is the largest RCT to date on this subject, this study does little to impact current practice. The primary question - that of equivalence in not performing the pelvic examination - could not be answered due to the small number of participants.

There are some interesting take-aways, though. The study demonstrated increased patient satisfaction in the intervention group (those who did not receive a pelvic exam). Furthermore, a large number of patients refused to participate in the study because they did not want the possibility of receiving a pelvic exam. Of the 184 who declined to participate 74 of those did not want a pelvic exam, whereas only four people declined because they wanted a pelvic exam. However, this was surely tainted by the fact that ultrasounds were ordered at triage and patients already knew whether they had miscarried before the possibility of a pelvic exam was offered. This group of patients tends to be more concerned about whether the pregnancy is viable, and not what the actual cause of bleeding is (our job!).

Of note, there were two subjects with alternate causes of bleeding found on pelvic exam, but the study tells us nothing about these patients. For most of us, this is the entire reason why we do the pelvic exam, and it would have been nice to know what was missed by foregoing the pelvic exam. This highlights another issue in that the composite morbidity outcome was made up of factors that should not necessarily be given equal weight. For example, finding an alternate cause of bleeding should be weighted far more heavily than unscheduled return visits, as these patients are a population that is likely to return to the ED regardless because they tend to (understandably) worry. However, the composite score was used in order to reduce the sample size needed due to individual outcomes being so rare.

Overall, this study did attempt to address an important issue regarding the utility of pelvic examinations in pregnant women; however, due to the aforementioned limitations, this article does not provide any practice-changing guidance. We think a pelvic exam should still be offered, and an informed consent process should take place as to whether the exam should be undertaken. We do not have enough evidence to say that the physical exam should not be part of the work-up for the chief complaints of abdominal pain or vaginal bleeding in women with confirmed IUP in their first trimester.