**Objectives:** To evaluate "the premise that direct examination of the pregnancy through bedside ultrasonography (US) is a reliable alternative to pelvic examination in patients with early pregnancy-related complaints." (p. 213)

**Methods:** This prospective, observational study was conducted in the emergency department of Our Lady of Lourdes Medical Center in Camden, NJ. Pregnant patient with an estimated gestational age (EGA) of 16 weeks or less were eligible for enrollment. Only patients with evidence of an intrauterine pregnancy (IUP) on transabdominal or transvaginal ultrasound were enrolled. Positive evidence of an IUP included a fetus with fetal heart activity or identification of an intrauterine gestational sac with a fetal pole or yolk sac.

All patients underwent pelvic examination (including both speculum and bimanual examination) with testing for *Chlamydia trachomatis* and *Neisseria gonorrhoea*, followed by pelvic ultrasound performed by clinicians with more than 2 years experience in bedside pelvic ultrasound. An initial transabdominal ultrasound was performed, followed by transvaginal ultrasound if an IUP was not identified. Findings on pelvic examination were then compared to findings on ultrasound to determine if the pelvic examination would have changed management or ED disposition for the patient.

A total of 50 patients were enrolled over a 13-month period. Half of patients had only a transabdominal ultrasound performed. The mean EGA was 8.6 weeks and the mean quantitative HCG was 7247 IU.

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**Guide**

<table>
<thead>
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<th>I. Are the results valid?</th>
<th>Comments</th>
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<td>A. Was the sample of patients representative? In other words, how were subjects selected and did they pass through some sort of “filtering” system which could bias your results based on a non-representative sample. Also, were objective criteria used to diagnose the patients with the disorder?</td>
<td>Likely no. While not explicitly mentions, it seems highly likely that this was a <em>convenience sample</em> of patients enrolled only when study physicians were on shift. Additionally, only patients whose EGA was 16 weeks or less were included, and only patients with an IUP identified on ultrasound were included. These results would not apply to patients with a pregnancy of undetermined location or those in whom ectopic pregnancy was still a consideration.</td>
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### B. Were the patients sufficiently homogeneous with respect to prognostic risk?

*In other words, did all patients share a similar risk from during the study period or was one group expected to begin with a higher morbidity or mortality risk?*

Yes. While patients at higher EGA would have an IUP more easily identified on ultrasound, and hence may be less likely to have a missed ectopic (or molar) pregnancy, all patients enrolled would be at some risk of these complications. All patients would share a similar risk of miscarriage (threatened, inevitable, incomplete, or complete).

### C. Was follow-up sufficiently complete?

*In other words, were the investigators able to follow-up on subjects as planned or were a significant number lost to follow-up?*

Patients were not followed beyond the ED stay to determine whether any additional adverse pregnancy-related events occurred. Therefore, follow-up was complete for all fifty patients.

### D. Were objective and unbiased outcome criteria used?

Investigators should clearly specify and define their target outcomes before the study and whenever possible they should base their criteria on objective measures.

No. The authors make no mention of how they determined whether the pelvic examination findings influenced management or disposition decisions. This was quite likely a subjective, unblinded interpretation made by the study investigators. Furthermore, the outcomes themselves are not detailed in the article; there is no mention of how many patients were admitted or discharged, how many were diagnosed with an ectopic pregnancy and how they were treated, how many were diagnosed with a miscarriage and what their treatment dispositions were.

### II. What are the results?

#### A. How likely are the outcomes over time?

*For the defined follow-up period, how likely were subjects to have the outcome of interest.***

- The disposition based on the pelvic examination was not different than the disposition dictated by the ultrasound in any of the cases (0%, 95% CI 0 to 7%*).
- There was one case of *Chlamydia trachomatis* based on cervical testing, which in theory would change acute management (2%, 95% CI 0.4 to 10%*). *Calculated using http://www.vassarstats.net/prop1.html*

#### B. How precise are the estimates of likelihood?

*In other words, what are the confidence intervals for the given outcome likelihoods?*

See above. This was a very small study and the resulting 95% confidence intervals were quite wide.

### III. How can I apply the results to patient care?

#### A. Were the study patients and their management similar to those in my practice?

Yes. This study only enrolled pregnant patients with an EGA of 16 week or less with an IUP identified on ultrasound. Looking at this specific subset of patients, those enrolled
in the study should be similar to patients seen in my practice (external validity).

| B. Was the follow-up sufficiently long? | No. As noted, the authors only looked at ED disposition and management, and did not look at outcomes beyond the ED stay. It is unclear how many patients eventually had a miscarriage or how many required a procedure (i.e. manual vacuum aspiration or dilation and curettage) and whether findings on pelvic examination may have affected the decision to perform these procedures. |
| C. Can I use the results in the management of patients in my practice? | No. This study provided insufficient information to draw any firm conclusions. The authors provide no information regarding patients' presenting complaints (vaginal bleeding, abdominal pain, etc.), final diagnoses, or need for subsequent intervention. We are also given little information regarding methodology, including who determined whether the pelvic examination had an effect on disposition or management decisions. |

**Limitations:**

1. The authors failed to follow reporting guidelines as outlines in the **STROBE statement** and hence provide insufficient methodological or demographic information:

   a. Nowhere is it stated when the study was performed.

   b. It is not specified whether this was a **convenience** vs. **consecutive sample**

   c. The authors make no mention of how they determined whether the pelvic examination findings influenced management or disposition decisions.

   d. There is no demographic information regarding the patients enrolled in the study, including chief complaint (vaginal bleeding, abdominal pain, etc.)

   e. The authors do not provide information regarding final diagnoses (pregnancy, threatened abortion, inevitable abortion, etc.), follow-up, or need for further procedural intervention.

   f. The authors do not provide **95% confidence intervals** or other measures of precision.
2. This was a small study that enrolled a very specific patient population (EGA 16 weeks or less with an IUP identified on ultrasound) and any conclusions would pertain only to this limited patient population.

**Bottom Line:**

This small, observational study concluded that the pelvic examination did not alter disposition decisions for pregnant patients (EGA 16 weeks or less) with an IUP identified on ultrasound. There was one case of a sexually transmitted infection identified, which would alter acute management. Unfortunately, the authors failed to report several key factors that make interpretation application of these results nearly impossible.