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Original Contributions

FETAL OUTCOMES IN FIRST TRIMESTER PREGNANCIES WITH AN INDETERMINATE ULTRASOUND

Michael L. Juliano, LCDR/MC/USN, and Bettina M. Sauter, LCDR/MC/USN

Department of Emergency Medicine, Naval Medical Center Portsmouth, Portsmouth, Virginia
Reprint Address: Michael L. Juliano, LCDR/MC/USN, Department of Emergency Medicine, Naval Medical Center Portsmouth, 620 John Paul Jones Circle, Portsmouth, VA 23708

☐ **Abstract—Background: Pregnant women commonly present to the Emergency Department (ED) for evaluation during their first trimester. These women have many concerns, one of which is the viability of their pregnancy and the probability of miscarriage. Study Objectives: We sought to determine fetal outcomes of women with an indeterminate ultrasound who present to the ED during the first trimester of pregnancy. Methods: A retrospective analysis of consecutive ED patient encounters from December 2005 to September 2006 was performed to identify patients who were pregnant and who had an indeterminate transvaginal ultrasound performed by an emergency physician or through the Radiology Department during their ED visit. Demographic data, obstetric/gynecologic history, and presenting symptoms were recorded onto a standardized patient chart template designed to be used for any first trimester pregnancy. Outcomes (spontaneous abortion, ectopic pregnancy, and 20-week gestation) were determined via computerized medical records. Results: During the study timeframe, a total of 1164 patients were evaluated in the ED during the first trimester of their pregnancy; 359 patients (30.8%) met inclusion criteria and had a diagnosis of indeterminate ultrasound. Outcome data were obtained for 293 patients. Carrying the pregnancy to ≥20 weeks occurred in 70 patients (23.9%). Spontaneous abortion occurred in 193 women (65.9%), and 30 women (10.2%) were treated for an ectopic pregnancy. Total fetal loss incidence was 89.2% in patients presenting with any vaginal bleeding, compared to 34.7% in patients with pain only. Conclusion: Indeterminate ultrasounds in the setting of first trimester symptomatic pregnancy are indicative of poor fetal outcomes. Vaginal bleeding increased the risk of fetal loss. These data will assist emergency physicians in counseling women in the ED who are found to have an indeterminate ultrasound. Published by Elsevier Inc.**

☐ **Keywords—ultrasound; pregnancy; indeterminate; fetal outcome; vaginal bleeding; abdominal pain**

INTRODUCTION

According to reproductive literature, it is estimated that as many as 20–25% of all clinically recognized pregnancies result in a spontaneous miscarriage (1,2). First trimester symptomatic pregnancies commonly present to an emergency department (ED) for evaluation. Although the primary emergency physician focus will be exclusion of an ectopic pregnancy, there is a need to be able to discuss with the patient other potential fetal outcomes (normal intrauterine pregnancy and spontaneous abortion). Ultrasounds performed in the ED can

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diagnose an intrauterine pregnancy or other abnormality (ectopic pregnancy), but can also be indeterminate (empty uterus or empty gestational sac). Rates of indeterminate ultrasound vary, but are approximately 20% for first trimester symptomatic pregnancies, experiencing vaginal bleeding or pain, evaluated in the ED (3,4). The majority of indeterminate ultrasound literature attempts to identify risks or likelihood of ectopic pregnancy (5). We sought to determine all fetal outcomes of women diagnosed with indeterminate ultrasound with respect to chief complaint (abdominopelvic pain or vaginal bleeding) after ED presentation during the first trimester. We hope to provide the emergency physician and patient with accurate information concerning the possible outcomes of that patient's pregnancy to further assist the emergency physician in counseling women who present to the ED with symptomatic first trimester pregnancies. In addition, we sought to determine the likelihood of specific fetal outcomes with respect to the chief complaints of vaginal bleeding and abdominopelvic pain.

MATERIALS AND METHODS

Research data derived from an approved Naval Medical Center, Portsmouth, VA IRB protocol.

A retrospective medical record review of data was performed on all first trimester symptomatic pregnancies that presented to the ED from December 2005 through September 2006. Our hospital is a tertiary care-level military hospital with an annual ED census of 76,000. Active duty military, retirees, and dependents (primarily spouses and children) are seen at this facility. All of these patients have health insurance and access to a primary physician. All pregnancies <20 weeks estimated gestational age (EGA) are evaluated in the ED, regardless of chief complaint. The ED has a monthly census of approximately 150 symptomatic first trimester pregnancies (2% annual incidence) and employs emergency medicine residents and staff physicians credentialed in transvaginal ultrasounds. All residents are required to perform 25 staff-supervised transvaginal ultrasounds before being credentialed and allowed to scan patients independently. At least five of these examinations are required to be abnormal (e.g., not an intrauterine pregnancy). All scans performed independently by residents are presented to the ED attending for evaluation of adequacy and completeness. One hundred percent of the ultrasounds performed in the ED are reviewed by an independent staff emergency physician as part of quality assurance. All women enrolled in this study had a transvaginal ultrasound performed. A computer-based charting system termed Composite Health Care System (CHCS) is utilized for patient care. A query was performed of CHCS, for the study timeframe, generating a list of all patients seen in the ED. The query lists patients by chief complaint and final discharge diagnosis. Each patient encounter was evaluated for the presence of one or more of the following: pregnancy (ectopic, intrauterine, incidental), abdominal pain, pelvic pain, vaginal bleeding, abortion (threatened, spontaneous, complete, incomplete, missed), and embryonic demise. Pregnant women evaluated in the ED for non-pregnancy-related issues (e.g., cold symptoms) were not enrolled. The Emergency Treatment Record (ETR) was then reviewed for inclusion into the study. The ETR utilized in the ED is a unique documentation template for women who present with symptomatic first trimester pregnancy, ≤12 weeks EGA by last menstrual period. This template was created to standardize all patient encounters. Data collected included: patient demographics, presenting symptoms, ultrasound data, and outcome of the pregnancy. All CHCS queries and subsequent data collection was performed by the primary investigator using a data collection sheet created for the study after Institutional Review Board approval.

Criteria for inclusion were: 1) positive pregnancy test; 2) first trimester (≤12 weeks EGA via last menstrual period; 3) chief complaint of at least one of the following: vaginal bleeding (of any amount), abdominal pain, or pelvic pain; and 4) indeterminate transvaginal ultrasound performed by either emergency physicians or in the radiology suite by ultrasound technicians and read by a radiologist (staff daylight hours and residents after-hours). Patients were excluded for multiple ED visits during the same pregnancy.

Indeterminate ultrasound was determined either by documentation of an empty gestational sac or empty uterus on the ETR via the emergency physician, or by review of CHCS if a patient was sent to the Radiology Department for a formal transvaginal ultrasound. Our ED uses a SonoSite TITAN portable ultrasound system (SonoSite Inc., Bothell, WA) with a 3-MHz transabdominal probe and 7-MHz transvaginal probe.

All women enrolled in the study received an ultrasound evaluation in the ED by an emergency physician. Serum β-human chorionic gonadotropin (hCG) levels are obtained for all patients with indeterminate ultrasounds. The use of discriminatory zones for serum β-hCG levels to correlate with the expected appearance of an intrauterine pregnancy is well documented. If the serum β-hCG is below the discriminatory zone of 1000 mIU/mL–1500 mIU/mL (staff dependent), the patient was discharged home with a 48-h Obstetrics appointment. Obstetricians did not evaluate these patients in the ED before discharge. No formal radiology ultrasound evaluation was performed in these patients unless requested by the ED staff physician. A formal ultrasound can be obtained for any reason

by an emergency physician if there is a higher concern for ectopic pregnancy, regardless of ED ultrasound findings or laboratory data. If the serum β-hCG is above the discriminatory zone of 1000 mIU/mL–1500 mIU/mL (staff dependent), a formal ultrasound is obtained via the Radiology Department. Results of the Radiology Department ultrasound were used for data collection in this study when the patient received an ultrasound in both the ED and the Radiology Department. Our hospital has 24-h capability to perform pelvic ultrasounds. All ultrasounds performed in the Radiology Department are read immediately by a radiology resident (after hours) with a preliminary report called to the ordering emergency physician. Dictated reports are viewable the next day in CHCS. CHCS tracks all laboratory values obtained from a patient in addition to providing information regarding which clinic/department ordered the test. Patients entered into the study were considered to have miscarried if their quantitative serum β-hCG decreased by at least 50% within 7 days after their evaluation in the ED, or if the pathology report from tissue collected either in the ED or Gynecology Department confirmed products of conception. A formal second trimester ultrasound (performed in the Radiology Department as part of routine anatomical evaluation of the fetus) was used as an endpoint for successful pregnancy outcome. If the ultrasound demonstrated an EGA ≥20 weeks, no further investigation was undertaken. If the ultrasound demonstrated an EGA <20 weeks, then the patient's future 20-week date was calculated and CHCS was queried again. Determination was made that the patient had been seen on or after their 20-week date via completed Obstetrics/Gynecology orders (i.e., glucose tolerance testing, repeat ultrasound evaluation, medication orders, or documentation of a live birth).

Patients were considered lost to follow-up if there were no further entries into CHCS after their initial visit to the ED, or no ultrasound results confirming a 20+ week EGA. Patients presenting more than once during the study timeframe were included as a separate patient encounter only if their chief complaint changed.

For data analysis, patients were divided into two treatment arms: patients presenting with a chief complaint of vaginal bleeding, and patients presenting with pain only. Patients who experienced fetal loss were further divided into two groups: those who experienced a spontaneous miscarriage and those who experienced ectopic pregnancies. Odds ratios were calculated to compare the odds of fetal loss between treatment arms and to determine whether a chief complaint was predictive of fetal loss. Pairwise comparisons of groups yielded a Yates' corrected chi-square with one degree of freedom. An alpha level of 0.05 was adopted for tests. Kappa values were determined among the investigators.

Table 1. Demographic Data

Demographic	n (%)
Race	
White	139 (47%)
Black	90 (31%)
Hispanic	16 (6%)
Asian	13 (4%)
Unknown	29 (10%)
Other	6 (2%)
Age, years	
<20	33 (11%)
20–24	117 (40%)
25–29	78 (27%)
30–34	34 (12%)
≥35	31 (10%)

RESULTS

During the study timeframe, a total of 1164 presented with first trimester symptomatic pregnancy, of which 359 women met inclusion criteria. Forty-four patients (12.3%) were lost to follow-up and 22 patient encounters were excluded as the second or third presentation with no change in chief complaint after the initial patient encounter had already been enrolled in the study. This resulted in a final total of 293 patient encounters included for statistical analysis. Patient demographic data are presented in Table 1.

Seventy women (23.9%, 95% confidence interval [CI] 19.0–28.8%) carried their pregnancy to at least a 20-week gestation; 193 women (65.9%, 95% CI 60.4–71.3%) experienced a spontaneous abortion; and 30 women (10.2%, 95% CI 6.8–13.7%) were treated for an ectopic pregnancy. Vaginal bleeding (with or without pain) occurred in the majority of spontaneous abortions, 178 (92%, 95% CI 88.2–95.8%), and in the majority of ectopic pregnancies, 21 (70%, 95% CI 53.6–86.4%). Results are summarized in Table 2.

By presenting chief complaint, 224 women presented with vaginal bleeding, which resulted in 178 patients with a spontaneous abortion (79.5%, 95% CI 74.2–84.8%), 21 ectopic pregnancies (9.4%, 95% CI 5.6–13.2%), and 25 women reached a 20-week gestation (11.1%, 95% CI 7.0–15.3%). The results for the 69 women who presented with pain only were as follows: spontaneous abortion

Table 2. Outcome of Pregnancy

Outcome	n	%	95% Confidence Interval
20-week gestation	70	23.9%	19.0–28.8%
SAB	193	65.9%	60.4–71.3%
Ectopic	30	10.2%	6.8–13.7%
Total	293		

SAB = spontaneous abortion.

Table 3. Outcome of Pregnancy by Chief Complaint

Outcome (n = 293)	Vaginal Bleeding (n = 224) n (%, 95% CI)	Pain (n = 69) n (%, 95% CI)
20-weeks	25 (11.1%, 7.0–15.3%)	45 (65.2%, 54.0–76.5%)
SAB	178 (79.5%, 74.2–84.8%)	15 (21.7%, 12.0–31.5%)
Ectopic	21 (9.4%, 5.6–13.2%	9 (13.1%, CI 5.1–21.0%)

CI = confidence interval; SAB = spontaneous abortion.
Odds ratio of fetal loss with vaginal bleeding (n = 199) vs. pain (n = 24): 14.9 (95% CI 7.8–28.5).

occurred in 15 (21.7%, 95% CI 12.0–31.5%), ectopic pregnancy in 9 (13.1%, 95% CI 5.1–21.0%), and 45 reached a 20-week gestation (65.2%, 95% CI 54.0–76.5%). Results are summarized in Table 3.

In patients presenting with a chief complaint of vaginal bleeding, the total fetal loss (ectopic pregnancy and spontaneous abortion) was 89.2% (95% CI 85.2–93.3%), compared to a total fetal loss incidence of 34.7% (95% CI 23.7–45.9%) in patients with pain only. For patients presenting with any vaginal bleeding, total fetal loss was 14 times higher than a chief complaint of abdominopelvic pain with no bleeding (odds ratio 14.9, 95% CI 7.8–28.5, Yate's corrected $\chi^2 = 78.2$, $p < 0.0001$). Results are summarized in Table 4.

Thirty women had an ectopic pregnancy with a range of initial quantitative β-hCG in the ED between 72 and 27,825 mIU/mL (median value of 1839 mIU/mL). The breakdown of ectopic pregnancies with respect to chief complaint was 9 women (16.4%, 95% CI 13.6–46.4%) had pain only, and 21 women (70%, 95% CI 53.6–86.4%) had vaginal bleeding (with or without pain). The odds ratio of a woman with an indeterminate ultrasound having an ectopic pregnancy with a chief complaint of vaginal bleeding vs. pain was 0.69 (95% CI 0.3–1.6).

A kappa value of 0.839 was achieved when 10% of the patient encounters were reviewed by the associate investigator, who was not involved with the primary data collection.

DISCUSSION

Many women present to the ED with a symptomatic first trimester pregnancy. Although the primary focus of the patient may be the viability of the pregnancy, the initial concern for the emergency physician is to determine if a life-threatening diagnosis, specifically ectopic pregnancy, exists. All components of history, physical examination, laboratory results, and sonographic data are assessed together to aid the clinician in decision-making. However, ultrasonography has advanced to the forefront in the ED as the primary means to evaluate a first trimester symptomatic pregnancy. Although the importance of an ultrasound evaluation for these patients has been established, there are times when the ultrasound (performed either in the ED or the radiology suite) is deemed indeterminate (6,7). Although the risk of an ectopic pregnancy still exists, the majority of women with an indeterminate ultrasound do not have an ectopic pregnancy. Multiple studies by Dart et al. in women with an indeterminate ultrasound in the ED showed retrospective ectopic rates of 14% (32 patients out of 228 enrolled) and 10.7% (33 patients out of 307 enrolled) (8,9). A prospective study following 628 women demonstrated fetal outcomes of normal intrauterine pregnancy at 16.9%, spontaneous abortion at 75.8%, and ectopic at 7.3% (after exclusion of 7 women with an elective abortion) (10). These numbers mirror those of our study; however, the lost-to-follow-up rate for the prospective study was 18.6%. The rates for our study were similar, with 23.9% normal intrauterine pregnancy, 65.9% fetal demise, and 10.2% ectopic pregnancy. Tayal et al. performed a study evaluating the outcome of patients with initial indeterminate ED ultrasounds and found embryonic demise and ectopic pregnancy rates to be 53% and 14%, respectively (11). None of these studies look at the difference in presenting complaint with regard to fetal outcome; they grouped all women into one group with indeterminate ultrasounds regardless of presenting complaint. Our analysis of symptomatic first trimester pregnancy presenting with vaginal bleeding or pain with an indeterminate ultrasound result revealed a fetal loss rate of 76.1%, confirming again

Table 4. Total Fetal Loss by Chief Complaint

Chief Complaint	Fetal Loss (n = 223) n (%, 95% CI)	20-Week Gestation (n = 70) n (%, 95% CI)
Vaginal bleeding	199 (89.2%, 85.2–92.3%)	25 (35.7%, 24.5–46.9%)
Pain	24 (34.7%, CI 23.7–45.9%)	45 (64.3%, 53.1–75.5%)

CI = confidence interval.
Odds ratio of fetal loss with vaginal bleeding vs. pain: 14.9 (95% CI 7.8–28.5).

the poor outcomes found in previous studies. Vaginal bleeding was more predictive of fetal loss, with a rate of 89.2% of all women presenting with vaginal bleeding suffering a loss (odds ratio 14.9, 95% CI 7.8–28.5, Yate's corrected $\chi^2 = 78.2$, $p < 0.0001$).

No presenting chief complaint or β-hCG value was predictive for ectopic pregnancy. This result is in concordance with multiple previous studies performed concerning ectopic pregnancies. Of note, in this study, nine women were discharged home with a 48-h Obstetrics Clinic appointment and were ultimately deemed to have an ectopic pregnancy. None of these women returned early to the ED, and the highest β-hCG value in this group was 1523 mIU/mL.

Limitations

Limitations to our study include the expected errors associated with retrospective chart review. Recommended strategies used to minimize such errors were: creation of a new standardized ETR facilitating future data extraction, recording data directly onto a computerized data spreadsheet, limiting the number of variables extracted for each patient, and recruiting a physician not involved with the study to review results and obtain a kappa statistic. Despite our efforts, however, there is the possibility that patients were inadvertently excluded due to misdiagnosis or miscoded information. We attempted to overcome this limitation by reviewing all ETRs of women with complaints of either "vaginal bleeding" or "abdominal pain" to determine if these patients were also pregnant. Our study population was derived from a single institution whose patients comprise women either in the military or dependents of military members (spouses or children). All active duty military members and dependents have access to emergency care without financial concern. Patients often seek emergency care at very early stages of their disease processes and therefore, may not represent the typical population presenting to a civilian ED with complaints of a symptomatic first trimester pregnancy. The transient nature of military families greatly contributed to our rate of lost to follow-up. By having the primary investigator also serve as the data collector, bias may have been introduced; however, because there were only two variables for chief complaint and only two possible patient outcomes, this potential bias was most likely minimal. The diagnosis of a spontaneous abortion is also limited by using declining β-hCG levels such that if there is no passage of products of conception, there could be a concern that this is actually an ectopic pregnancy that spontaneously resolved, making our outcome data incorrect. In addition, using a 20-week ultrasound as a surrogate for successful pregnancy outcome is somewhat problematic. The risk of pregnancy loss after 20 weeks EGA, although small, is a possibility. However, obstetrics literature frequently uses the 20-week ultrasound as an endpoint due to the decreased risk of spontaneous abortion once this point is reached. Lastly, because the accuracy of the second trimester ultrasound lends itself to a standard deviation of ± 7 days, there is a potential that our 20-week ultrasound endpoint in fact represented a fetus at 19 weeks or less.

CONCLUSION

In conclusion, our study agrees with previously published literature that an indeterminate ultrasound in the setting of an ED presentation for a first trimester symptomatic pregnancy portends a poor fetal prognosis. However, our study adds some increased prognostic value that vaginal bleeding increases the chances of fetal loss when compared to abdominopelvic pain only. The goal of this study was patient-oriented to determine fetal outcomes of first trimester symptomatic pregnancies with indeterminate ultrasounds with regard to presenting chief complaint. Our hope is that this information will assist the emergency physician during bedside counseling of patients with symptomatic first trimester pregnancy.

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ARTICLE SUMMARY

1. Why is this topic important?

This topic is important because it provides the treating physician with prognostic information, which will assist when counseling patients in first trimester pregnancies about possible fetal outcomes.

2. What does this study attempt to show?

This study attempts to give accurate percentages when trying to predict fetal outcomes in first trimester symptomatic pregnancies with indeterminate ultrasounds.

3. What are the key findings?

The key findings of this study are that fetal outcomes are poor in first trimester symptomatic pregnancies with indeterminate ultrasounds. The risk of fetal loss is increased with a presenting symptom of vaginal bleeding.

4. How is patient care impacted?

Patient care is impacted by giving the treating physician better prognostic information when counseling this population of women in the emergency department.