Characteristics of Women With Fetal Loss in Symptomatic First Trimester Pregnancies With Documented Fetal Cardiac Activity

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Study objective: The purpose of this study is to determine fetal outcomes of women diagnosed with live intrauterine pregnancy after emergency department (ED) presentation for abdominopelvic pain or vaginal bleeding during the first trimester.

Methods: A retrospective medical record review of prospectively recorded data of consecutive ED charts from December 2005 to June 2006 was performed to identify patients diagnosed with live intrauterine pregnancy. Demographic data, obstetric/gynecologic history, and presenting symptoms were obtained. Outcomes were determined by computerized medical records. Fetal loss was diagnosed by decreasing β-Human chorionic gonadotropin or pathology specimen. Live birth was diagnosed by viable fetus at 20-week-gestation ultrasonography or delivery.

Results: A total of 837 patients were evaluated during the first trimester. Three hundred forty patients (41%) met inclusion criteria, with a diagnosis of live intrauterine pregnancy. Outcome data were obtained for 303 (89%) of these patients. Fetal loss occurred in 28 (9.2%) pregnancies (95% confidence interval [CI] 5.9% to 12.5%). Fetal loss incidence was 13.8% (95% CI 9.9% to 17.7%) in patients presenting with vaginal bleeding compared with 2.5% (95% CI 0.007% to 4.3%) in patients without bleeding (P<0.002). Twenty five of 28 (89%) patients with resulting fetal loss presented with vaginal bleeding. Vaginal bleeding was the most important predictor of fetal loss; risk ratio 5.6 (95% CI 1.7 to 18.2).

Conclusion: Fetal loss before 20 weeks occurs in 9.2% of patients with live intrauterine pregnancy diagnosed by ultrasonography. Vaginal bleeding carries a higher fetal loss rate of 13.8%. These data will assist the emergency physician in counseling women experiencing symptomatic first trimester pregnancy. [Ann Emerg Med. 2008;52:143-147.]

INTRODUCTION

Background

Concern about the possibility of spontaneous miscarriage is one of the most common reasons women seek evaluation in the emergency department (ED) during their first trimester. According to the obstetrics and gynecology literature, it is estimated that 20% to 25% of all clinically recognized pregnancies result in spontaneous miscarriage.1,2 Once a viable fetus is diagnosed by ultrasonography, however, the rate of spontaneous miscarriage subsequently decreases to 3% to 6%.3,4 The incidence of spontaneous miscarriage after documentation of fetal cardiac activity by ED ultrasonography is not currently known. We therefore sought to determine fetal outcomes of women diagnosed with live intrauterine pregnancy after ED presentation for abdominopelvic pain or vaginal bleeding during the first trimester.

Importance

Symptomatic first trimester pregnancies are a common presentation to the ED. Many EDs are now equipped with ultrasonographic capability. With this increased use of ultrasonographic technology by ultrasonography-credentialed emergency physicians, more women are being sonographically evaluated in the ED5 to document an intrauterine pregnancy. In a low-risk patient (ie, without assisted reproductive techniques...
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Editor’s Capsule Summary

What is already known on this topic
Although many women who have vaginal bleeding during early pregnancy miscarriage, the rates are not well reported for patients presenting to the emergency department (ED).

What question this study addressed
In 303 consecutive women in the ED with a first trimester intrauterine pregnancy with cardiac movement on ultrasonography, how is the risk of miscarriage affected by the presence of vaginal bleeding, abdominal pain, or both?

What this study adds to our knowledge
The overall incidence of miscarrying before 20 weeks’ gestation was 9.2%. Women with vaginal bleeding had a 5-fold higher risk than those who did not.

How this might change clinical practice
This study helps physicians provide women with realistic information about the likelihood that they will have a successful pregnancy.

Goals of This Investigation
We sought to determine longitudinal fetal outcomes in women who presented to the ED with pain, vaginal bleeding, or both during their first trimester who had a viable intrauterine pregnancy documented by ED ultrasonography. Our aim was to determine whether the prognostic outcomes of fetal loss after documentation of a live intrauterine pregnancy by ultrasonography were similar to that reported in the obstetrics literature and to further assist the emergency physician in counseling women with symptomatic first trimester pregnancies. In addition, we sought to determine the risk of spontaneous abortion among 3 separate presenting symptoms (pain only, vaginal bleeding only, pain and vaginal bleeding together).

MATERIALS AND METHODS

Study Design
A retrospective medical record review of prospectively gathered data was performed from December 6, 2005 through June 15, 2006. Naval Medical Center Portsmouth uses a computer-based charting system termed Composite Health Care System (CHCS). A query was performed of CHCS, for the study period, generating a list of all patients treated in the ED. The query lists patients by chief complaint and final discharge diagnosis. Each patient encounter was evaluated for the presence of 1 or more of the following: pregnant, abdominal pain, vaginal bleeding, intrauterine pregnancy, threatened abortion, spontaneous abortion, complete abortion, incomplete abortion, missed abortion, and embryonic demise. The emergency treatment record was then reviewed for inclusion into the study. The emergency treatment record used in the ED is a unique documentation template for women who present with symptomatic first trimester pregnancy (≤12 weeks’ estimated gestational age by last menstrual period). This template was created to standardize all patient encounters. Data collected included patient demographics, presenting symptoms, ultrasonographic data, and outcome of the pregnancy. All CHCS queries and subsequent data collection were performed by the primary investigator using a data collection sheet created for the study. This study was approved by the hospital’s institutional review board.

Setting
Naval Medical Center Portsmouth is a tertiary care-level hospital with an annual ED census of 75,000. The ED employs resident and staff physicians credentialed in transvaginal and transabdominal ultrasonography, with a monthly census of approximately 150 symptomatic first trimester pregnancies (annual incidence approximately 2%).

Selection of Participants
Criteria for inclusion were positive pregnancy test result; first trimester (≤12 weeks’ estimated gestational age by last menstrual period); chief complaint of at least 1 of the following: vaginal bleeding, abdominal pain, pelvic pain, or back pain; and documentation of fetal cardiac activity by ultrasonographic evaluation.

Fetal cardiac activity was determined either by documentation of fetal cardiac activity on the emergency treatment record by the emergency physician or by review of CHCS for results of a formal ultrasonography performed in the radiology department. All ED staff physicians are credentialed in the performance of transvaginal and transabdominal ultrasonography for the determination of an intrauterine pregnancy. The Naval Medical Center Portsmouth ED uses a Sonosite Titan portable ultrasonographic system (SonoSite, Inc., Bothell, WA) with a 3-MHz transabdominal probe and 7-MHz transvaginal probe. All ED residents are required to perform 25 supervised (by the ED attending physician) transvaginal ultrasonographic evaluations and 25 supervised transabdominal ultrasonographic evaluations before they are allowed to scan patients independently. All scans performed independently by residents are presented to the ED attending physician before patient discharge for evaluation of adequacy and completeness. One hundred percent of the ultrasonographic...
evaluations performed in the ED are then catalogued and reevaluated by an independent reviewer as part of quality assurance. If an ultrasonographic evaluation performed in the ED is indeterminate (ie, empty uterus or an empty gestational sac without the presence of a yolk sac), then serum β-Human chorionic gonadotropin (β-HCG) levels are obtained. If the serum β-HCG level is above the discriminatory zone of 1,000 IU/L to 1,500 IU/L (staff dependent), a formal ultrasonograph is obtained by the radiology department. The use of discriminatory zones for serum β-HCG levels to correlate with the expected appearance of an intrauterine pregnancy is well documented. A formal ultrasonograph can be obtained for any reason by an emergency physician if there is a concern for ectopic pregnancy regardless of ED ultrasonographic findings or laboratory data. Naval Medical Center Portsmouth has 24-hour capability to perform pelvic ultrasonographic evaluations. All ultrasonographic evaluations 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.

Methods of Measurement

CHCS tracks all laboratory values obtained from a patient, in addition to providing information about 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% after their evaluation in the ED or if the pathology report from tissue collected either in the emergency or gynecology department confirmed products of conception. A formal second trimester ultrasonograph (performed in the radiology department) was used as an endpoint for successful pregnancy outcome. If the ultrasonograph demonstrated an estimated gestational age greater than or equal to 20 weeks, no further investigation was undertaken. If the ultrasonograph demonstrated an estimated gestational age less than 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 treated on or after her 20-week date by completed obstetrics/gynecology orders (ie, glucose tolerance testing, repeated ultrasonographic 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 ultrasonographic results confirming a 20-week or greater estimated gestational age. Patients presenting more than once during the study period were included as a separate patient encounter only if their chief complaint changed.

Data Collection and Processing

The emergency treatment record for symptomatic first trimester pregnancy was specially designed to facilitate documentation of the medical encounter. Demographic data, obstetric/gynecologic history, presenting symptoms, physical examination results, laboratory analysis, and results of ED ultrasonography were prospectively recorded. Results from consecutive patients with symptomatic first trimester pregnancies evaluated in the ED from December 6, 2005, to June 15, 2006, were entered onto 2 data collection sheets. One sheet was used for patient identification (name and social security number), and the second sheet was used for primary data collection. The data collection sheets were created to facilitate subsequent result analyses. All data collection was performed by the principal investigator.

Primary Data Analysis

SPSS version 15 software (SPSS, Inc., Chicago, IL) was used for statistical analysis. Binary logistic regression analysis was used to predict patient outcome (miscarriage versus ≥20 weeks’ estimated gestational age) with respect to chief complaint (vaginal bleeding with or without a pain complaint versus pain only). Interrater reliability of patient complaints and outcomes produced a κ score of 1.0 when 10% of all included emergency treatment records were reviewed by an independent physician. Patients were divided into 3 treatment arms: patients presenting with pain and vaginal bleeding, patients presenting with pain only, and patients presenting with vaginal bleeding only. An omnibus $\chi^2$ test was computed to test for differences among groups in proportions of patients who miscarried. To isolate effects of vaginal bleeding, patients with vaginal bleeding and pain were compared with patients with pain only. Effects of pain were assessed by comparing patients with vaginal bleeding and pain with patients with vaginal bleeding only. These pairwise comparisons of groups yielded Yates’ corrected $\chi^2$ with 1 df. An $\alpha$ level of 0.05 was adopted for all tests.

RESULTS

A total of 837 patients presented during the study period with a first trimester symptomatic pregnancy. Four hundred seventy-six women were excluded for the following reasons: empty uterus (199), yolk sac with no fetal pole (94), empty gestational sac (81), no ultrasonographic evaluation performed (62), intrauterine fetal demise (31), ectopic pregnancy (6), and molar pregnancy (3). Of the remaining 361 patient encounters, 3 women were excluded because of documentation of a confirmed elective abortion. There were 20 women who presented twice during their first trimester. Of the 20 patients with return presentations, only 2 were included in the study as separate data points; the other 18 were excluded. These 2 women had a change in their presenting symptoms between ED visits and were coded as separate encounters. The final study population, therefore, consisted of 340 patient encounters, which were reviewed. The mean maternal age was 25.4 years, and the median age was 24 years (range 18 to 42). Thirty-seven patients were lost to follow-up. Demographic data are shown in Table 1.

Frequencies produced by the cross-tabulation of group and outcome are presented in Table 2, along with percentages of each group that reached 20 weeks. Twenty-eight patients (9%)
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In patients presenting with pain, the odds of fetal loss were 6.77 times greater for patients with bleeding than without bleeding (95% confidence interval [CI] 1.9 to 23.6; Yates’ corrected $\chi^2(1)=9.36; P=.01$). Among patients who presented with vaginal bleeding, the risk of fetal loss was no greater for patients with pain than without pain (risk ratio [RR] = 1.1; 95% CI 0.5 to 2.3). Vaginal bleeding was the greatest predictor of fetal loss, regardless of pain; RR = 5.6 (95% CI 1.7 to 18.2), summarized in Table 3.

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 emergency treatment record 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 $k$ statistic.8 Despite our efforts, however, there is the possibility that patients were inadvertently excluded because of misdiagnosis or miscoded information. We attempted to overcome this limitation by reviewing all emergency treatment records of women with complaints of either “vaginal bleeding” or “abdominal pain” to determine whether these patients were also pregnant. Our study population was derived from a single institution whose patients are composed of 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 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 loss to follow-up. By having the primary investigator also serve as the data collector, bias may have been introduced; however, because there were only 2 variables for chief complaint and only 2 possible patient outcomes, this potential bias was most likely minimal. In addition, using a 20-week ultrasonographic result as a surrogate for successful pregnancy outcome is somewhat problematic. The risk of pregnancy loss after 20 weeks’ estimated gestational age, although small, is a possibility. However, obstetrics literature frequently uses the 20-week ultrasonographic result as an endpoint for viability and successful pregnancy outcome. Last, because the accuracy of the second trimester ultrasonographic result lends itself to a standard deviation of ±7 days, there is a potential that our 20-week ultrasonographic endpoint in fact represented a fetus at 19 weeks.

DISCUSSION

Symptomatic first trimester pregnancies are a common presentation to the ED. The emergency physician is expected to exclude ectopic pregnancy. However, the expectation of the patient is reassurance about viability of her pregnancy. Standard approach is medical history-taking, documentation of ectopic risk factors, physical examination, laboratory analysis, and transabdominal or transvaginal ultrasonography.

In terms of longitudinal fetal outcomes, symptomatic first trimester pregnancies have been studied primarily in the obstetrics population. Casher et al3 performed a study to examine fetal loss rates after chorionic villous sampling. To accurately predict the risk of fetal loss after sampling, a reference loss rate of pregnant women with viable intrauterine pregnancy between 8 and 12 weeks was obtained prospectively and determined to be 2%. Unlike our study population, women with estimated gestational age less than 8 weeks were not included, perhaps accounting for their decreased miscarriage rate. As did we, Siddiqi et al10 demonstrated rates of spontaneous abortion as 5.2% in women with no vaginal bleeding and 16.4% in women with vaginal bleeding after confirmed live intrauterine pregnancy. Tongsong et al3 demonstrated an overall spontaneous abortion rate of 5% in pregnant women with vaginal bleeding but demonstrable fetal cardiac activity. Both study populations were similar to ours in that women with less than 8 weeks’ estimated gestational age were included.

Our decision to follow women until they reached their 20-week estimated gestational age is based on previous obstetrics literature that accepts this date as a surrogate for live delivery. Our results demonstrating the significance of vaginal bleeding with regard to predicting spontaneous abortion rates are also in agreement with the previously reported obstetrics literature.
Gracia et al\textsuperscript{11} showed an odds ratio of 7.35 for spontaneous abortion associated with vaginal bleeding. Johns and Jauniaux\textsuperscript{12} observed a relative risk of abortion of 2.91 for vaginal bleeding compared with that of controls. Hill et al\textsuperscript{13} conducted a review of 347 patients presenting for their obstetric care and found a statistically significant increase in miscarriage rates in women who had a documented live intrauterine pregnancy and experienced vaginal bleeding versus no vaginal bleeding (12.7\% versus 4.2\%; \( P < .006 \)). We did not attempt to quantify the amount of bleeding either through medical history or physical examination for this study. Both of these determinations would be highly variable. The visual calculation of the amount of blood observed on speculum examination would be extremely physician dependent even if a nonnumeric scale (ie, mild, moderate, and severe) were used. However, an increased amount of vaginal bleeding compared with scant amounts has also been shown to increase miscarriage rates.\textsuperscript{14}

In conclusion, our analysis of ultrasonographically confirmed live intrauterine pregnancies complicated by first trimester bleeding or pain demonstrated an overall fetal loss rate of 9.2\%. If the patient had vaginal bleeding, the fetal loss rate increased to 13.8\%. We hope our results will provide the emergency physician useful information for bedside counseling.

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