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How and when human chorionic gonadotropin curves in women with an ectopic pregnancy mimic other outcomes: differences by race and ethnicity

Katherine E. Dillon, B.A.^a, Vasileios D. Sioulas, M.D., Ph.D.^b, Mary D. Sammel, Sc.D.^c, Karine Chung, M.D., M.S.C.E.^d, Peter Takacs, M.D., Ph.D.^e, Alka Shaunik, M.D.^a, and Kurt T. Barnhart, M.D., M.S.C.E.^{a,c}

^aDepartment of Obstetrics and Gynecology, University of Pennsylvania, Philadelphia, Pennsylvania

^bThird Department of Obstetrics and Gynecology, University of Athens, Attikon Hospital, Chaidari, Athens, Greece

^cDepartment of Biostatistics and Epidemiology, University of Pennsylvania School of Medicine, Philadelphia, Pennsylvania

^dDepartment of Obstetrics and Gynecology, University of Southern California, Los Angeles, California

^eDepartment of Obstetrics and Gynecology, University of Miami School of Medicine, Miami, Florida

Abstract

Objective—To investigate the hCG profiles in a diverse patient group with ectopic pregnancy (EP) and to understand when they may mimic the curves of an intrauterine pregnancy (IUP) or spontaneous abortion (SAB).

Design—Retrospective cohort study.

Setting—Three university hospitals.

Patient(s)—One hundred seventy-nine women with symptomatic pregnancy of unknown location.

Intervention(s)—None.

Main Outcome Measure(s)—Slope of log hCG; days and visits to final diagnosis.

Result(s)—Of women with an EP, 60% initially exhibited an increase in hCG values, with a median slope of 32% increase in 2 days; 40% of subjects initially had an hCG decrease, with the median slope calculated as a 15% decline in 2 days. In total, the hCG curves in 27% of women diagnosed with EP resembled that of a growing IUP or SAB. Of the EP hCG curves, 16% demonstrated a change in the direction of the slope of the curve. This was more common in African Americans and less evident in Hispanics. Furthermore, it was associated with more clinical visits and days until final diagnosis.

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Reprint requests: Kurt T. Barnhart, M.D., M.S.C.E., Reproductive Research Unit, Department of Obstetrics and Gynecology, University of Pennsylvania Medical Center, 3701 Market Street, Suite 810, Philadelphia, PA 19104 (kbarnhart@obgyn.upenn.edu).

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Conclusion(s)—The rate of change in serial hCG values can be used to distinguish EP from an IUP or SAB in only 73% of cases. The number of women who had a change in direction of serial hCG values was associated with race and ethnicity.

Keywords

hCG curves; ectopic pregnancy; pregnancy of unknown location; time to diagnosis; race

Ectopic pregnancy (EP) has been reported to range from 0.64%–2.62% of all pregnancies in the United States (1, 2) and accounts for 0.5 maternal deaths per 100,000 live births (3). Clinical history, serum quantitative hCG measurement, and transvaginal sonography (TVS) are the basic tools for the evaluation of symptomatic early pregnancies (4, 5); however, definitive diagnosis may be challenging in some cases (4, 6). Twenty-five to 50% of women with EP initially receive the diagnosis of pregnancy of unknown location (7–9), a term used when no evidence of either an EP or intrauterine pregnancy (IUP) on TVS is recognized (10). The work-up includes serial serum hCG tests, TVS, and, occasionally, dilation and curettage (4, 11). This algorithm can be time-consuming and costly for the health care system, as well as burdensome for the patient (12).

During the past decade, the hCG curves for a viable IUP and a miscarriage have been refined by our group (13, 14). In contrast, there is no single pattern of hCG able to characterize EPs (15). Studies in the past have recruited a predominance of African American women, which may have undermined the generalizability of those results (15). Indeed, numerous studies reveal that racial and ethnic factors are associated with differences in EP clinical and epidemiologic characteristics (3, 16, 17).

Defining the hCG curves for EPs in a more representative population sample may add valuable information concerning the prediction of outcomes in symptomatic pregnancy of unknown location. We aim to examine the hCG profiles in a diverse set of patients finally diagnosed with EP, with emphasis on the possible ethnic, racial, and geographic disparities.

Materials and Methods

This study was conducted at three sites: the University of Pennsylvania, the University of Miami, and the University of Southern California as part of the Predictors of Ectopic Pregnancy Study. Institutional Review Board approval was obtained at each site. Data were collected during a 2-year period using a centralized computerized database of women who presented in the first trimester of pregnancy with pelvic pain and/or vaginal bleeding.

The patients included in this study presented between August 2007 and June 2009. All patients presented with a pregnancy of unknown location (10) and thus did not have signs of an intrauterine or extrauterine gestation on TVS at presentation. The included subset had at least two hCG values (at least 1 day apart but no more than 7 days apart), and a documented date of eventual definitive diagnosis of EP. Patients were excluded if they were diagnosed at initial presentation or did not have an eventual definite diagnosis. Diagnosis of EP was confirmed by pathology specimens in the fallopian tube or an increase in hCG values after endometrial curettage failed to reveal products of conception. The analysis was restricted to hCG values before, and including, the date of diagnosis. Post-treatment or post-intervention values were not included. In addition, analysis was restricted to singleton pregnancies and heterotopic pregnancies were excluded.

As this was a pragmatic study using standard clinical care, serum hCG concentration measures were performed at the clinical laboratory of each participating center. All clinical laboratories were College American Pathologists certified. College American Pathologists

certification standards require coefficients of variation (CV) for hCG laboratories to be 8% or less (but does not require reporting of each laboratory on a yearly basis).

Clinical characteristics of women at each of the three study sites were compared using analysis of variance (ANOVA) or χ^2 test as appropriate. Days to clinical diagnosis were the number of days from presentation to diagnosis. If necessary, charts were reviewed to adjudicate diagnosis and date. Serial hCG values were analyzed after natural log transformation of the values to alleviate skew and reduce the influence of large values. Semiparametric and parametric random effect models and graphic methods were used to determine the overall shape of the hCG curve for all EPs as a group.

We then focused analysis on the first two hCG measurements. The change in hCG levels between the first two measurements was characterized by the slope, which was estimated by the difference in the log hCG levels divided by the observed time between measurements. A start time of “0” was assigned to the first hCG. Slopes were stratified by percentile, and subjects were split into two groups: those with an initial positive slope (initially increasing hCG values) and those with a negative slope (initially decreasing hCG values). Clinical characteristics of the women in these two groups were compared using the Student's *t*-test or the χ^2 test as appropriate. For those subjects with three or more hCG values, a subanalysis was performed based on the presence or absence of an inflection point (change in the direction of the slope) anywhere in the individual hCG trend. Clinical characteristics between these two subgroups (those with an inflection point and those without) were compared using the χ^2 test or Fisher's exact test as appropriate.

Finally, the percentiles of slopes for women with EPs were compared with the percentiles of the slopes for women with potentially viable IUPs or completed miscarriages. The projected frequency that the hCG increase (or decrease) for women with EP would be within the range expected for a viable IUP (13) or a completed abortion (14) was calculated. These calculations were also performed for the slope of the first two points of the curve after an inflection point, if present. The presence of an inflection point was identified wherever there was a change in the direction of the slope at any point along the hCG curve.

Results

There were 179 EPs included in this study. The mean age of the population was 30.0 years with an average gravity and parity of 2.8 and 0.87, respectively. A total of 47% of the women were African American, 41% were white, and 12% were “other.” Thirty-six percent of the population was of Hispanic ethnicity. Descriptive characteristics of the total population, including length of time to make a diagnosis, hCG at presentation, and gestational age at presentation are presented in Table 1. The distribution of gestational age did not vary by site.

During evaluation of the curves generated from the hCG values we observed that no model could adequately describe the pattern of serial hCG values from women with EP. Figure 1 shows examples of individual hCG profiles. Because diagnosis of women at risk for EP compares two values of hCG, we then focused on the assessment of the slope of the curves based on the first two hCG values.

Sixty percent of our population had a slope of the hCG curve that was rising, whereas 39% were initially decreasing. Clinical characteristics for these groups are shown in Table 2. Those with an initially increasing slope had lower hCGs at presentation and required more clinical visits and a longer time before a definitive diagnosis was reached. The median slope of an increasing EP was 0.139 (or a 32% increase in 2 days, range 1%–270%), whereas the median slope for those with decreasing hCG was –0.078 (or a 15% decrease in 2 days, range

–0.1% to –68%). The distributions of slopes for these two groups were found to have no difference by race and ethnicity, nor did they vary by gestational age at presentation. Table 3 shows the percentile distributions of slopes for the increasing and decreasing samples in comparison to the reference points for normally increasing IUP and normally decreasing spontaneous abortion (SAB) (13, 14).

Descriptive characteristics examined by race and ethnicity showed that both African American and white patients had similar characteristics at presentation. African American patients initially presented with symptomatic pregnancies at a median of 6 weeks gestation and a median hCG of 579, whereas non-African American patients presented at a median of 5.9 weeks gestation and a median hCG of 573. However, African American patients took significantly more days to achieve a diagnosis, with a median of three visits during 5 days whereas non-African American patients only required a median of two visits during 4 days ($P=.3$, $P=.02$, respectively).

Both Hispanic and non-Hispanic patients presented at a median gestational age of 5.9 weeks. The hCGs at presentation were also similar with a median hCG at presentation for Hispanic patients of 579 compared with 534 for non-Hispanic patients. However, Hispanic patients required less time and fewer clinic visits to make a final diagnosis (median of two visits and 3 days) than non-Hispanic patients who required a median of three visits and 5.5 days ($P<.05$ for each).

Of the total sample population, 49% of the patients had three or more hCG values. Of these, 29% had a change in direction of the slope of their hCG curve, or an inflection point. The descriptive characteristics of those who had an inflection point compared to those who did not are also presented in Table 2. Those with an inflection point required more clinical visits and more total days until a diagnosis was made than those who did not have an inflection point ($P<.001$ and $P=.027$, respectively). In addition, those with an inflection point were more likely to have a rupture of their EP than those without an inflection point (18.5% vs. 9.1%), but this was not statistically significant ($P=.2$). The increased number of days required to make the diagnosis for those with an inflection point cannot be attributed to disparate rates of surgical interventions in each group, as the rate of surgery was 14% in the inflection group and 18% in the group without an inflection ($P=.69$).

The presence of an inflection point was associated with race. African American patients were more likely to have an inflection point in their hCG curve than other patients (35% vs. 22%, $P=.045$), whereas Hispanic patients were less likely to have an inflection point in their curves than non-Hispanic patients (8% vs. 37%, $P<.001$). African American women with inflection points took significantly longer and required more visits for diagnosis than African American women without an inflection point ($P=.02$ and $P=.002$, respectively). These differences remained when clinical site was controlled for.

Discussion

Ectopic pregnancy is a cause of significant morbidity and mortality. Although many EPs are diagnosed with ultrasound, up to 50% are diagnosed by following serial hCG values. In line with a previous report (15), this study confirms that there is no single hCG pattern to predict EP and many may mimic that of an IUP or SAB. Validating these results in a diverse set of patients, as presented in this report, is important as prediction models may lose test characteristics when applied externally, or may need to be amended to maintain accuracy (18). Importantly, the use of a more representative population highlights the value of our conclusions, as EP epidemiologic indices vary among different races and ethnicities (3, 16, 17).

Our analysis primarily focused on the first two hCG values, as this reflects common clinical practice. We found that the median slope for EP patients with increasing hCG values was a 32% increase in 2 days, which is slower than the 124% median increase for a viable IUP (13). In addition, the median slope for those with falling hCG levels was a 15% decline in 2 days, which is less than the mean 70%–75% decrease for complete SAB (14). However, extensive overlap exists. Our results confirm that the pattern of hCG increase or decrease in EP may also be consistent with that of a viable IUP or SAB (15), and that this mimic occurred in 27% of the total EP cases. Stratified by initial increase or decrease of the slope, 30% of women who had initially increasing hCG curves met the criteria of growing IUP (13) and 23% of those with an initially decreasing slope were consistent with the established cutoffs for spontaneous miscarriage (14). There was no difference in these distributions based on race or ethnicity.

In contrast to hCG curves describing a viable IUP or SAB, 16% of the EP curves in our population experienced a change in the direction of the slope of the hCG curve, or an inflection point. These findings indicate that an inflection point is highly predictive of EP. Although a change in direction of serial hCG values is classically associated with an EP, perhaps counterintuitively, in practice the presence of inflection point(s) in hCG curves made the diagnosis more challenging. In these patients, an increase in median days to diagnosis and EP rupture was revealed, although the latter did not reach statistical significance.

We are not able to determine the cause of this delay in diagnosis. An inflection point may provide the practitioner reason to recompare the observed hCG curve to the standard curve, thus delaying action, or it may be some innate characteristic of the EP itself. Interestingly, women with inflection point(s) presented with lower median hCG values. This may be partly responsible for delayed EP diagnosis, given that hCG levels are correlated with TVS accuracy in visualizing EP (7). Although we recognize that the total number of inflection events is relatively small, this is one of the largest studies of EPs and the evaluation of inflection points is an important novel investigation.

Importantly, the overlap demonstrated between EP curves and IUP or SAB curves was evident when we evaluated two consecutive hCG measurements, at presentation and after an inflection point of the relevant curves. This may imply that EP misclassification as a viable IUP or SAB could occur at any time during evaluation, independent of which consecutive hCG values we choose to compare. When evaluating a pregnancy of unknown location, practitioners must not be reassured by hCG curves that fit the pattern of IUP or SAB after an inflection point.

Stratifying our results by race and ethnicity may aid in better understanding the EP clinical and epidemiologic phenomena. National trends may not accurately represent EP-related statistics in certain geographic areas, especially where rapidly growing and culturally diverse populations live (17). In this context, converging evidence points out that African Americans have higher EP incidence and mortality ratio (3, 16, 17). Data on Hispanics are sparse. According to a study in California, Hispanics have the lowest EP rate among all racial and ethnic groups; however, the percentage of ruptured EPs in Hispanics is similar to that of African Americans (17).

It has traditionally been thought that socioeconomic parameters such as limited access to health care and lower educational attainment may account for racial and ethnic disparities in EP mortality or severe complication rate (3, 16, 17). Less health insurance coverage, failure of women to recognize early pregnancy signs and symptoms, or lack of EP awareness may impede early prenatal care (3, 16, 17). It should be stressed that in our study, African

Americans and Hispanics did not exhibit any significant difference in hCG values at presentation or gestational age at diagnosis, compared with the remaining population.

In light of our findings, the explanation of the higher EP mortality ratio in African Americans is intriguing. As we demonstrated, a unique hCG pattern in African Americans with EP marked by increased inflection point rate may exist, contributing to delayed diagnosis and, thus, enhancing EP rupture risk. There is very little available literature demonstrating differences in hCG curves by race, whether at one point in time or changes over time. Two groups have reported that hCG values may be higher among African Americans in the first trimester than white patients (19, 20), and this is an area for future research. The substantiation of our observation by larger studies is mandatory before definite conclusions are drawn.

In summary, these data confirm that no one unique pattern in hCG curves can be derived from EPs. Although the rate of change can often be used to distinguish an EP from an IUP or an SAB, EP may mimic both diagnoses in at least 27% of cases. The presence of inflection points is highly predictive of an EP but was associated with a delay in diagnosis with a greater percentage of rupture. The sole use of hCG surveillance to recognize or to rule out an EP raises major concerns about its safety and efficacy and should be avoided. Particular diligence is needed in patients with inflection points in their curves, especially the African American population.

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Figure 1.
Example of hCG profiles in ectopic pregnancies.

Table 1
Descriptive characteristics of patients diagnosed with ectopic pregnancy stratified by site.

	No. of visits Mean, median (SD) [range]	Days to diagnosis Mean, median (SD) [range]	β hCG at presentation (mIU/mL)		β hCG at diagnosis (mIU/mL)		Gestational age at presentation (wk)		Gestational age at diagnosis (wk)	
			Mean, median (SD) [range]	Mean, median (SD) [range]	Mean, median (SD) [range]	Mean, median (SD) [range]	Mean, median (SD) [range]	Mean, median (SD) [range]	Mean, median (SD) [range]	Mean, median (SD) [range]
Total (n = 179)	3.1, 3.0 (1.5) [2–11]	7.1, 4.0 (7.1) [1–41]	1,122, 539 (1,514) [24–8,261]	1,122, 539 (1,514) [24–8,261]	1,565, 775 (1,804) [0–8,501]	1,565, 775 (1,804) [0–8,501]	5.9, 5.9 (2.4) [0.7–14.8]	5.9, 5.9 (2.4) [0.7–14.8]	6.9, 6.9 (2.6) [1.4–18.4]	6.9, 6.9 (2.6) [1.4–18.4]
Miami (n = 86)	2.6, 2.0 (0.9) [2–6]	5.4, 3.0 (6.6) [1–41]	1,336, 692 (1,526) [74–6,656]	1,336, 692 (1,526) [74–6,656]	1,545, 962 (1,618) [78–7,439]	1,545, 962 (1,618) [78–7,439]	6.3, 6.1 (2.1) [1.1–12.6]	6.3, 6.1 (2.1) [1.1–12.6]	7.1, 7.0 (2.3) [1.6–15.4]	7.1, 7.0 (2.3) [1.6–15.4]
UPenn (n = 67)	3.9, 3.5 (1.8) [2–11]	9.8, 8.0 (7.8) [1–39]	770, 383 (1,463) [24–8,261]	770, 383 (1,463) [24–8,261]	1,518, 672 (1,939) [0–7,832]	1,518, 672 (1,939) [0–7,832]	5.5, 5.4 (2.5) [1.4–14.9]	5.5, 5.4 (2.5) [1.4–14.9]	7.0, 6.7 (2.9) [2.1–18.4]	7.0, 6.7 (2.9) [2.1–18.4]
USC (n = 26)	2.7, 2.0 (1.2) [2–7]	5.9, 4.0 (5.1) [2–24]	1,294, 558 (1,524) [29–4,519]	1,294, 558 (1,524) [29–4,519]	1,746, 520 (2,107) [88–8,501]	1,746, 520 (2,107) [88–8,501]	5.4, 5.4 (2.7) [0.7–10.9]	5.4, 5.4 (2.7) [0.7–10.9]	6.3, 5.8 (2.9) [1.4–14.3]	6.3, 5.8 (2.9) [1.4–14.3]
Pvalue	<.05	.05	.93	.93	.14	.14	.29	.29	.12	.12

Table 2
Descriptive characteristics of patients diagnosed with ectopic pregnancy stratified by human chorionic gonadotropin (hCG) pattern.

	No. of visits Mean, median (SD) [range]	Days to diagnosis Mean, median (SD) [range]	β hCG at presentation (mIU/mL)		β hCG at diagnosis (mIU/mL)		Gestational age at presentation (wk)		Gestational age at diagnosis (wk)	
			Mean, median (SD) [range]	Mean, median (SD) [range]	Mean, median (SD) [range]	Mean, median (SD) [range]	Mean, median (SD) [range]	Mean, median (SD) [range]	Mean, median (SD) [range]	Mean, median (SD) [range]
Initially rising ^a (60%)	3.3, 3.0 (1.6) [2–11]	7.9, 6.0 (6.4) [1–39]	913, 445 (1,270) [25–5,868]	1,897, 1,261 (1,947) [0–8,501]	5.6, 5.6 (2.4) [0.7–12.9]	6.8, 6.8 (2.4) [1.4–18.4]				
Initially decreasing ^a (39%)	2.6, 2.0 (1.0) [2–6]	6.0, 3.0 (8.2) [1–41]	1,468, 709 (1,810) [35–8,261]	1,090, 527 (1,467) [54–7,832]	6.4, 6.1 (2.9) [1.4–14.9]	7.2, 7.1 (2.9) [1.7–17.0]				
<i>P</i> value	.01	.05	.03	.02	.4	.2				
Inflection point ^b (29%)	5.0, 5.0 (1.9) [3–11]	14.3, 12.0 (10.3) [3–41]	657, 261 (1,329) [30–5,485]	739, 336 (986) [0–4,362]	5.6, 5.3 (2.8) [1.6–14.9]	7.8, 6.9 (3.3) [3.1–18.4]				
No inflection point ^b (71%)	3.6, 3.0 (1.0) [3–7]	9.1, 7.0 (5.9) [3–36]	630, 425 (840) [24–5,453]	1,697, 962 (1,910) [17–8,501]	5.8, 5.8 (2.3) [0.7–12.6]	7.1, 6.9 (2.6) [1.4–15.4]				
<i>P</i> value	<.001	.03	.55	.007	.76	.36				

^aTotal population, n = 179.

^bOnly those with >2 hCG values, n = 96.

Change in serial human chorionic gonadotropin (hCG) for women with ectopic pregnancy, percentiles, stratified by initial pattern.

Table 3

Comparison values									
Women with initial increase in hCG (n = 107)					Increase for intrauterine pregnancy (13)				
Percentile	25	50	75	90	95	99	1st percentile	Median	
Slope ^a	0.070	0.139	0.239	0.363	0.432	0.640	53%	124%	
Two-day change ± (%)	15	32	61	107	137	300			
Women with initial decrease in hCG (n = 69)					Decrease for spontaneous abortion (14)				
Percentile	75	50	25	10	5	1	95th percentile	Mean	
Slope ^a	-0.029	-0.078	-0.150	-0.305	-0.356	-0.562	-28%	-72%	
Two-day change ± (%)	-6	-15	-26	-46	-51	-68			

Note: Three patients with no change in hCG are not included in this table. ± Two-day change represents the relative 2-day decrease or increase in hCG (mIU/mL). Computed as exp (slope × 2).
^aSlope represents the change in log hCG expected for the first two visits, including presentation for care.