Ultrasound Availability in the Evaluation of Ectopic Pregnancy in the ED: Comparison of Quality and Cost-Effectiveness With Different Approaches

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The liberal use of ultrasonography has been advocated in patients with first trimester cramping or bleeding to avoid misdiagnosis of ectopic pregnancy in the emergency department (ED). The cost-effectiveness of different approaches to ultrasound availability has not been previously reported. In this study, we investigated measures of quality and cost-effectiveness in detecting ectopic pregnancy in the ED over a 6-year period, divided into three approximately equal epochs with three distinct approaches to ultrasound availability. The study retrospectively identified 120 cases of ectopic pregnancy seen in the ED over 6 years. There was significant improvement in the percentage of patients with ectopic pregnancy who were documented to have absence of intrauterine pregnancy (IUP) at the first visit from 76% during Epoch 1, when there was limited availability of ultrasound through medical imaging (MI Sono), to 88% in Epoch 2, when MI Sono was readily available, to 96% in Epoch 3, when both MI Sono and ultrasound by emergency physicians (ED Sono) were readily available ($P = .02$). The estimated number of MI Sonos ordered by emergency physicians in patients at risk for ectopic pregnancy increased from 5.2 per ectopic pregnancy in Epoch 1 to 11.8 per ectopic pregnancy in Epoch 2, and declined to 5.5 per ectopic pregnancy in Epoch 3, when 19.9 ED Sonos per ectopic pregnancy were also done. The cost of ED Sono in Epoch 3 was more than offset by savings from avoiding calling in ultrasound technicians after regular medical imaging department hours. The specificity of ED Sono in ruling in an IUP was 100% (95% CI 98.3 to 100%), but analysis of secondary quality indicators reflecting times from first ED visit to treatment in Epoch 3 raised the possibility that an adnexal mass or signs of tubal rupture may have been missed on some ED Sonos. We conclude that increased availability of ultrasonography leads to improved quality in the detection of ectopic pregnancy in the ED, but at the expense of a disproportionate increase in the number of ultrasound studies done per ectopic pregnancy detected. Our study suggests that the most cost-effective strategy is for emergency physicians to screen all patients with first trimester cramping and bleeding with ED Sonos, and to obtain MI Sonos at the time of the initial ED visit in all cases in which the ED Sono is indeterminate or shows no IUP. (Am J Emerg Med 2000;18:408-417. Copyright © 2000 by W.B. Saunders Company)

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The diagnosis of ectopic pregnancy may be readily apparent in a patient who presents to the emergency department (ED) with amenorrhea, vaginal bleeding, acute abdominal pain, and signs of peritoneal irritation. In many cases, though, the diagnosis is less obvious. It is often difficult on clinical grounds alone to distinguish between patients with threatened miscarriage and ectopic pregnancy, particularly if the ectopic pregnancy has not yet ruptured. Two independent retrospective studies published in the emergency medicine literature in 1990 showed that the diagnosis of ectopic pregnancy was missed almost half the time at the first ED visit.[1,2] A recent prospective study has confirmed that in most cases it is not possible using history and physical examination alone to confirm or exclude the diagnosis of ectopic pregnancy with a high degree of certainty.[3]

If the diagnosis of ectopic pregnancy is missed or delayed, significant patient morbidity, or even death may result. The most recent data from the Centers for Disease Control and Prevention indicate that while ectopic pregnancy accounts for approximately 2% of reported pregnancies, it is responsible for 9% of pregnancy-related deaths.[4] Diagnosing an ectopic gestation before rupture prevents the potential morbidity and mortality of intraabdominal hemorrhage. If the ectopic pregnancy is diagnosed early enough, chemotherapy may be used rather than surgery.[5] When surgery is required, diagnosis before tubal rupture may allow the use of laparoscopy and preservation of tubal patency.

Over the past decade, technological advances in pelvic ultrasound, including high resolution endovaginal sonography, along with the development of sensitive quantitative assays for serum beta-HCG, have led to significant improvement in physicians' ability to diagnose ectopic pregnancy at an early stage.[6,7,8] To avoid missing the diagnosis of ectopic pregnancy in the ED, ultrasound screening has been advocated for all patients who present with first trimester cramping or bleeding.[3,6] The cost-effectiveness of this approach has not been studied, however, and in many EDs, immediate ultrasound is not routinely available.[9]

Recently, there has been growing interest among emergency physicians in performing ultrasounds themselves. Several studies have shown that after relatively brief training periods, emergency physicians can reliably determine the presence or absence of an IUP using bedside ultrasound.[10,11,12,13,14] It seems reasonable to expect that ultrasound by emergency physicians (ED Sono) might offer a

cost-effective alternative to ultrasound by medical imaging departments (MI Sono) for screening patients with first trimester cramping and bleeding. The relative costs of ED Sono and MI Sono have not been studied, however, and concerns have been raised that widespread use of ultrasound by relatively inexperienced emergency physicians could lead to misdiagnosis and treatment errors.[15,16,17]

At our own medical facility, ultrasound availability in the ED was relatively limited until 1994 when emergency physicians proposed developing a program for training and credentialing in ED Sono. The Medical Imaging Department opposed this proposal, but made ultrasound studies more readily available to the ED. In 1996, the ED succeeded in passing an ED Sono protocol through the hospital's Privileges and Credentials Committee, and emergency physicians began performing ED Sono for a variety of indications, including the evaluation of patients at risk for ectopic pregnancy. As part of the ED Sono project, a study was begun to compare quality and cost-effectiveness in the ED in the evaluation of suspected ectopic pregnancy with different approaches to ultrasound availability. In this report, we present the results of this study.

METHODS

The setting for this study and the ED Sono training and credentialing protocol have previously been described in detail.[18] Briefly, the study was done in the ED of a staff model HMO with an annual census of approximately 30,000 patients. The study period consisted of the 6 years from June 1, 1992 through May 31, 1998. During this period, the ED staff was composed of 10 or 11 emergency physicians, all of whom were either board-certified or residency-trained in emergency medicine. Two physicians left the staff and one joined during the study period.

The 6-year study period was divided into three approximately 2-year epochs, corresponding to three different strategies for ultrasound availability in the ED. Epoch 1 included June 1992 through July 1994, during which ultrasound examinations were available through medical imaging, but ultrasound technicians were not present at the hospital after regular medical imaging department hours. Ultrasound technicians were usually available on call on nights and weekends, but emergency physicians were discouraged from ordering ultrasounds without first consulting with an obstetrics and gynecology specialist. Epoch 2 included August 1994 through May 1996, during which ultrasound technicians were present in the hospital from 8 AM to 10 PM on weekdays and available on call at all other times. During Epoch 2, emergency physicians could order MI Sonos at their own discretion. Epoch 3 included the period June 1996 through May 1998, during which an ultrasound machine was available in the ED and all emergency physicians had the capability of performing ED Sonos, although MI Sonos were still available as in Epoch 2. Ten of the 11 emergency physicians on the staff obtained ultrasound training by attending a 3-day class in general ED sonography offered by Advanced Health Education of Houston, Texas. The class included 12 hours of didactic teaching and 12 hours of practice on live models. One emergency physician obtained training by doing a 1-month ultrasound elective during his residency.

MI Sonos were done in the ultrasound suite of the medical imaging department, which is immediately adjacent to the ED, by full-time ultrasound technicians using an Acuson XP-128 ultrasound machine (Acuson Corp., Mountain View, CA). The ultrasound machine used for ED Sonos during the first 6 months of Epoch 3 was a General Electric RT3200 equipped with 3.5 MHz curved and 5.0 MHz endovaginal transducers (General Electric Corporation, Milwaukee, WI) and a Sony UP-870MD black and white page printer (Sony Corporation of America, New York, NY). In January of 1997, the ED replaced the RT3200 ultrasound machine with a GE Logiq400, equipped with similar transducers, but with improved image resolution and the added capability of color Doppler. Emergency physicians prospectively recorded the "rule out" indication for each ED Sono, and whether the study was positive, negative, or indeterminate for the condition or pathology being sought. In the case of patients with first trimester cramping and bleeding, the rule out indication was intrauterine pregnancy (IUP). The accuracy of all ED Sonos done to rule out IUP was confirmed by comparing ED Sono interpretations with surgical pathology, with repeat MI Sonos, or with clinical follow-up. Accuracy was judged solely on whether the physician correctly identified the presence or absence of an IUP. Clinical follow-up was done by reviewing either the patient's paper medical record or computerized summaries of the medical record. Computerized summaries included data not only on visits to our own facility, but also on visits to all other related health plan facilities in the northern half of the state. No attempt was made to contact patients by telephone when medical records were not available. The accuracy of MI Sonos with regard to the correct identification of the presence or absence of an IUP was also reviewed in cases of confirmed ectopic pregnancy.

Computerized searches were done to identify all patients treated for ectopic pregnancy at our facility during the 6-year study period. Patients who were hospitalized or who had surgery for ectopic pregnancy were retrospectively identified by computerized search of International Classification of Diseases (ICD)-9 discharge and procedure codes (633.0, 633.1, 633.2, 633.8, and 633.9). Patients who were treated as outpatients with methotrexate were identified by computerized search of laboratory records for cases in which a patient had both a quantitative beta-HCG and an SGOT or SGPT drawn on the same day. (The protocol used by our obstetrics and gynecology department for methotrexate treatment of ectopic pregnancy requires that these labs be drawn as a baseline.)

Quality indicators were defined before the beginning of data analysis. The percentage of patients documented to have absence of an IUP at the first ED visit was set as the primary quality indicator in the study. This was felt to be the outcome measure which would be most directly affected by ultrasound availability and most reflective of quality of care in the ED. The percentage of patients treated for ectopic pregnancy at the first ED visit, the number of days from the first ED visit to treatment, and the percentage of patients returning with ruptured ectopic pregnancy after an earlier ED visit were set as secondary quality indicators. It was felt that these outcome measures would reflect quality of care in the ED, but might also be affected other factors which were outside of the control of the ED.

Data were extracted from the patient's paper medical record by medical records analysts using preprinted data abstraction forms with explicit review criteria. Any visit with a complaint of pelvic or abdominal discomfort or vaginal bleeding during the patient's pregnancy was considered to be an ectopic pregnancy-related visit. For patients treated surgically, the diagnosis of ectopic pregnancy was considered to be confirmed if either the surgeon's operative note or the pathology report described an ectopic gestation. Confirmation of ectopic pregnancy in patients treated with methotrexate required that the patient have either an MI Sono or an ED Sono showing no IUP with a corresponding beta-HCG greater than 6000 mIU/mL for transabdominal examinations or greater than 1,000 mIU/mL for endovaginal exams; and at least two beta-HCG values at least 2 days apart showing an abnormal rate of rise (less than doubling every 2 days). The patient was considered to have hemoperitoneum if greater than 50 mL of free intraabdominal

blood was described in the surgeon's operative note. Hemoperitoneum was considered to be the equivalent of tubal rupture.

Data on the number of pelvic MI Sonos ordered by emergency physicians were obtained by computerized search of the health plan's laboratory utilization database which includes the type and number of ultrasound studies ordered by each physician in the facility. This database does not include the indication for the ultrasound study. In a previous study of ultrasound at our facility, 74% of pelvic ultrasounds were done to rule out IUP.[18] In the present study, the actual number of pelvic MI Sonos ordered by emergency physicians was reduced by a factor of 0.74 to obtain an estimate of the number of studies done to rule out IUP. The cost of calling in an ultrasound technician after regular medical imaging department hours and the charges for nonhealth plan members for ultrasound studies were obtained from the manager of the medical imaging department. The cost of leasing and maintaining the ED ultrasound machine and the cost of physician training was obtained from the hospital administrator.

Statistical analysis of the data was done using the statistical packages included with EpiInfo version 6 (Centers for Disease Control, Atlanta, GA), Microsoft Excel 97 (Microsoft Corporation, Redmond, WA), and SAS version 6.11 (SAS Institute, Cary, NC). The Kruskall-Wallace test was used to determine the significance of differences in numeric data that were not normally distributed. Ages were compared using ANOVA. Nominal variables were compared using Chi squared or the two-tailed Fisher's exact test when cell sizes were small. For comparisons of data across the three epochs, a P-value of $\leq .05$ was considered statistically significant. For comparisons between any two epochs, a P-value of $\leq .0167$ (.05/3) was considered significant, in accordance with the Bonferroni correction. Power calculations were done using the StatCalc function in EpiInfo, using the model of an unmatched cohort study. The mean number of days from first ED visit to treatment was calculated both as a raw value and as an adjusted value, subtracting 2 days for all methotrexate-treated cases, to take into account the fact that cases treated successfully with methotrexate required at least a two day interval between beta-HCG values to meet inclusion criteria for the study.

RESULTS

Patient Characteristics

One hundred ninety-one cases were identified as being treated for ectopic pregnancy at our facility during the 6-year study period. Eight patients were diagnosed with ectopic pregnancy on two separate occasions, and these separate episodes were treated as distinct cases. In 15 cases treated with methotrexate and in one treated surgically, data in the patient's medical record did not meet study criteria for confirming the diagnosis of ectopic pregnancy. Of the remaining 175 cases, 120 were seen in the ED at some time before or including the point at which the diagnosis of ectopic pregnancy was made, and 55 were seen in obstetrics and gynecology clinic only. There were no deaths in this series. Only two patients required transfusions (one in Epoch 1 and one in Epoch 2). Patient characteristics for the 120 cases of confirmed ectopic pregnancy seen in the ED are summarized in Table 1.

Quality Indicators

The results of the primary and secondary quality indicators are shown in Table 2. There was a statistically significant difference across the three epochs in the primary quality indicator, the percentage of patients documented to have absence of IUP at the first ED visit, with the highest rate in Epoch 3 and the lowest rate in Epoch 1. Only 2 out of 50 patients in Epoch 3 did not have absence of an IUP documented at the first ED visit. In one of these cases, only an ED Sono was done which was indeterminate. In the other case, both ED and MI Sonos were indeterminate. There were no statistically significant differences across the three epochs in the secondary quality indicators, though there was a

TABLE 1. Characteristics of Patients With Confirmed Ectopic Pregnancy Who Were Seen in the ED

Characteristics	Epoch 1	Epoch 2	Epoch 3	Combined	*P* Value
Number of cases seen in ED	38	32	50	120	
Number of ectopic cases/year	17.5	17.5	25.0	20.1	
% of all ectopic pregnancy cases at facility	75%	67%	67%	69%	.55
Mean age	28.7	29.2	28.5	28.6	.88
Number (%) who had ultrasound at first ED visit	26 (68%)[a]	27 (84%)	49 (98%)[a]	102 (85%)	<.001
MI sono only	26	27	12 (26%)		
ED sono only	0	0	20 (30%)		
Both	0	0	17 (42%)		
Number (%) who had beta-HCG determination at first visit	17 (45%)[b]	16 (50%)[c]	44 (88%)[b,c]	77 (64%)	<.001
Mean beta-HCG (mIU/mL)	2721	5136	4508	4213	.89
Median beta-HCG	1200	1815	2024	1727	
Range	165-9400	107-48,425	121-36,700	107-48,425	
Number (%) found to have tubal rupture at first visit	14 (37%)[d]	21 (66%)[d]	28 (56%)	63 (53%)	.045
Method of treatment					.19
Successful methotrexate	7 (18%)	3 (9%)	10 (20%)	20 (17%)	
Surgery for failed mtx	3 (8%)	0	4 (8%)	7 (6%)	
Laparotomy	10 (26%)	12 (38%)	21 (42%)	43 (36%)	
Laparoscopy	18 (47%)	17 (53%)	15 (30%)	50 (42%)	

[a,b,c] $P < .001$ for pairwise comparisons of values with corresponding superscripts.

[d] $P = .016$.

For all other pairwise comparisons in the table, $P > .0167$.

TABLE 2. Quality Indicators for Patients With Confirmed Ectopic Pregnancy Who Were Seen in ED

Quality Indicator	Epoch 1 n = 38	Epoch 2 n = 32	Epoch 3 n = 50	Combined n = 120	*P* Value
Primary quality indicator					
Number (%) of patients documented to have absence of IUP at first visit	29 (76%)*	28 (88%)	48 (96%)*	106 (88%)	.02
Secondary quality indicators					
1. Number (%) of patients treated for ectopic pregnancy at first visit	22 (58%)	24 (75%)	33 (66%)	80 (66%)	.34
2. Mean number of days from first visit to treatment (range)	3.1 (0-21)	1.4 (0-20)	2.4 (0-21)	2.4 (0-21)	.18
3. Mean number of days from first visit to Rx adjusted for methotrexate cases (range)	2.7 (0-19)	1.3 (0-20)	2.0 (0-21)	2.1 (0-21)	.15
4. Number (%) of patients returning with tubal rupture after earlier visit	5 (13.2%)	3 (9.4%)	6 (12%)	14 (12%)	.94

*$P = .008$ for pairwise comparison. For all other pairwise comparisons in the table, $P > .0167$.

trend toward best outcomes in Epoch 2 and worst outcomes in Epoch 1 for all four indicators.

In the 55 patients with confirmed ectopic pregnancy who were seen only in obstetrics and gynecology clinic, there were no significant differences across the three epochs in any of the quality indicators. Comparing patients seen only in obstetrics and gynecology clinic with patients seen in the ED, significantly more ED patients had the absence of an IUP documented at the first visit in Epoch 2 (88% versus 56%, $P = .027$) and in Epoch 3 (96% versus 65%, $P < .001$), but the difference in favor of ED patients in Epoch 1 (76% versus 54%, $P = .16$) did not reach statistical significance.

Accuracy of Ultrasound Interpretation

In the 175 cases of confirmed ectopic pregnancy seen either in obstetrics and gynecology clinic or the ED during all three epochs, a total of 174 ultrasounds were done by medical imaging in 156 patients and 36 ultrasounds were done by emergency physicians in 36 patients. Two MI Sonos (1.1%, 95% confidence interval [CI] 0.1 to 4.1%) were falsely positive for an IUP in patients proved surgically to have only ectopic pregnancy. There were no false positive ED Sonos. Six MI Sonos (3.4%, 95% CI 1.3 to 7.4%) and three ED Sonos (8.3%, 95% CI 1.8 to 22.5%) were indeterminate. Most indeterminate studies were cases in which no IUP was seen but a corresponding beta-HCG was below 1000 mIU/mL, or cases in which there was a small fluid collection within the uterus but it could not be determined with certainty whether the fluid was within a gestational sac. A live ectopic pregnancy was noted in 21 MI Sonos (12.1%, 95% CI 7.6 to 17.9%) and in three ED Sonos (8.3%, 95% CI 1.8 to 22.5%). The mean interval from first ectopic pregnancy-related ED visit to detection of a live ectopic pregnancy on MI Sono was 3.2 days, with a range of zero to 20 days. All three live ectopic pregnancies detected on ED Sono were noted at the first ED visit. Overall, in patients proved to have an ectopic pregnancy, the absence of an IUP was correctly documented by MI Sono in 95.4% of cases (95% CI 91.1 to 98.0%) and by ED Sono in 91.7% of cases (95% CI 77.5 to 98.2%).

During Epoch 3, emergency physicians performed a total of 996 ultrasounds in patients with first trimester cramping and bleeding who had not had previously documented IUP's. Seventy-five scans (7.5%, 95% CI 6.0 to 9.4%) were indeterminate. The results of follow-up to determine the accuracy of the remaining 921 nonindeterminate scans are shown in Table 3. Definitive follow-up was available in 85.5% of cases. Excluding indeterminate cases and cases in which follow-up was unavailable or could not confirm the accuracy of the ED Sono, the sensitivity of ED Sono for detecting IUP was 98.4% (95% CI 96.9 to 99.2%) and the specificity was 100% (95% CI 98.3 to 100%). Excluding indeterminate scans, the accuracy of ED Sono for detecting IUP was 98.9% (95% CI 97.8 to 99.4%). Including indeterminate scans, the accuracy of ED Sono was 90.3% (95% CI 88.0 to 92.1%).

Cost-Effectiveness

In the 921 nonindeterminate ED Sonos which were done in Epoch 3 in patients with first trimester cramping and bleeding who had not been previously documented to have an IUP, 669 (67.2%) showed an IUP to be present and 252 (25.3%) were interpreted as showing an IUP to be absent. In 125 (13.6%) of these nonindeterminate scans, repeat MI Sonos were ordered by the emergency physician. Of the remaining 796 nonindeterminate ED Sonos which were not repeated in medical imaging, 311 (39.1%) were done during hours when there was an ultrasound technician scheduled to be in the hospital, and 485 scans (60.9%) were done at other times. Assuming that all nonindeterminate ED Sonos which were not repeated in medical imaging avoided an MI Sono being done, the availability of ED Sono in Epoch 3 saved 15.9 MI Sonos and 9.7 ultrasound technician call-ins per ectopic pregnancy diagnosed.

TABLE 3. Results of Follow-Up to Confirm Accuracy of ED Sono

Confirmation Status	Positive Scans (IUP present)	Negative Scans (IUP absent)	Totals
Confirmed by MI sono	78	37	115
Confirmed by surgery or pathology	26	10	36
Confirmed by clinical follow-up	136	104	240
Confirmed by combination of above	325	62	387
Unconfirmed despite follow-up	50	17	67
Lost to follow-up	53	11	64
Disparity in ED and MI sono*	1	2	3
Error in ED sono	0	9	9
Totals	669	252	921

*Cases in which ED and MI Sono interpretations disagreed, but in which followup could not confirm the accuracy of either study. These cases were not considered errors in ED Sono.

The marginal salary cost of calling in an ultrasound technician at our facility during Epoch 3 was $135 per call-in. Figures and assumptions used to estimate the marginal costs of an ED Sono to rule out IUP are shown in Table 4. For the intermediate and lowest estimates of the cost of an ED Sono, it was assumed that ED Sonos to rule out IUP constituted 25% of all ED Sonos done. This assumption was based on the results of a previous study of ED Sono at our facility.[18] The net differences between the expense of ED Sonos and savings from avoiding call-ins of ultrasound technicians are shown in Figure 1. The magnitude of the differences varied depending on whether the high, low, or intermediate estimate of the cost of an ED Sono was used for the calculations, but there were net cost savings with all three estimates.

The medical imaging department charged nonhealth plan members $270 for a limited pelvic ultrasound, $360 for a complete pelvic ultrasound, and $410 for a complete pelvic ultrasound including endovaginal examination. The actual cost of these studies was not known. There was no charge at our facility for an ED Sono. The estimated numbers of MI Sonos ordered by emergency physicians to rule out IUP and the actual numbers of ED Sonos done by emergency physicians are shown by epoch in Figure 2. The projected charges for MI Sonos by epoch, assuming that all patients were charged at the nonmember rate, are shown in Figure 3.

DISCUSSION

This study shows that as ultrasound became more readily available to the ED, the percentage of patients with ectopic pregnancy who had an ultrasound done at their first ED visit increased significantly. Correspondingly, the percentage of patients documented to have absence of an IUP at the first ED visit, which was the primary quality indicator in this study, also showed significant improvement. The trend in improvement in the primary quality indicator between Epoch 2 and Epoch 3 suggests that even when MI Sono was readily available through on-call ultrasound technicians in Epoch 2, there may have been impediments to obtaining ultrasound studies at the first ED visit in some patients at risk for ectopic pregnancy.

As with any study using historical controls, there is the possibility that the improvement in the primary quality indicator in this study may have been attributable to some factor other than the main intervention being studied, which was ultrasound availability. It seems unlikely that a change in ED personnel was responsible for the improvement in the primary quality indicator as the same emergency physicians were on the ED staff during most of the 6 years of the study period. There was no similar improvement in the primary quality indicator in patients with ectopic pregnancy who were not seen in the ED, making it unlikely that a different approach by the obstetrics and gynecology consultants was responsible for the improvement seen in the ED over the three epochs. The percentage of patients who had a quantita-

TABLE 4. Estimated Marginal Cost of ED Sono to Rule Out IUP

Cost Item	Lowest Estimate	Intermediate Estimate	Highest Estimate
Lease of ultrasound machine	$1,647	$3,676	$14,704
Maintenance agreement	$ 0	$2,250	$ 9,000
Physician training	$ 0	$ 825	$ 3,300
Total annual costs	$1,647	$6,751	$27,004
Cost per ED Sono to r/o IUP	$ 3	$ 14	$ 54

Note. The highest estimate assumes that the GE Logiq 400 ultrasound machine was leased for all of Epoch 3, that GE's most comprehensive maintenance agreement was purchased, and that the complete costs of physician training were paid for over 2 years. The intermediate estimate incorporates the same assumptions as the highest estimate, but costs are multiplied by 0.25, assuming that 25% of ED Sonos are done to rule out IUP, and that ED Sonos done for other indications have equal worth. The lowest estimate assumes that the less expensive GE RT3200 ultrasound machine could have been used for the entire study, that no maintenance was required over the first 2 years, that physicians bore their own cost of training, and that 25% of ED Sonos were done to rule out IUP.

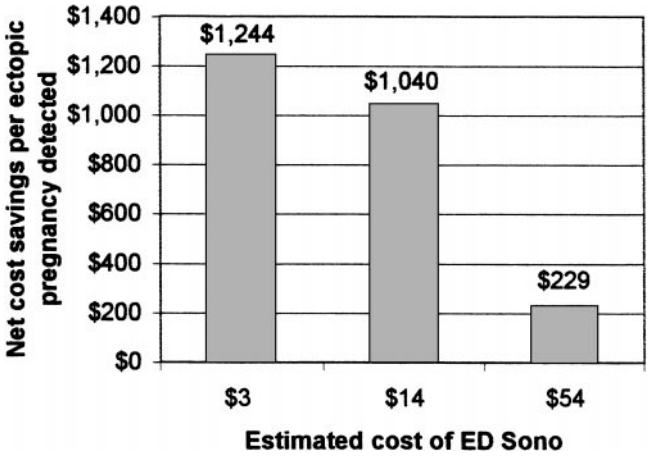

FIGURE 1. Projected net cost savings per ectopic pregnancy detected in Epoch 3 comparing additional cost of ED Sonos with cost savings from avoiding calling in ultrasound technicians after regular medical imaging department hours. Projected savings are shown for the low, intermediate, and high estimates of the cost of an ED Sono.

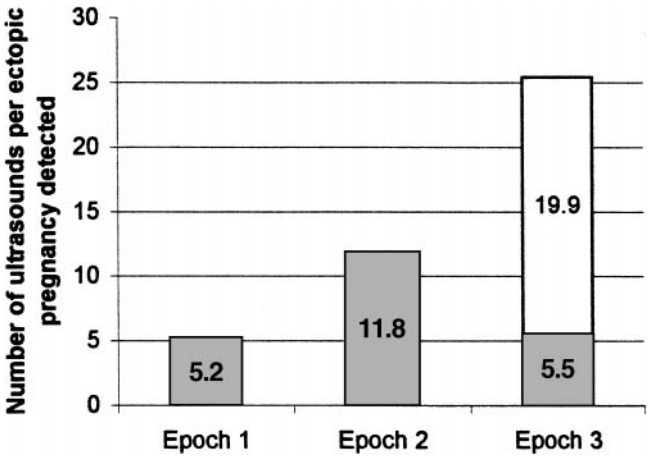

FIGURE 2. Numbers of ultrasound studies done per ectopic pregnancy detected by epoch. Numbers of MI Sonos are estimates based on total numbers of pelvic MI Sonos ordered by emergency physicians multiplied by 0.74, the estimated fraction ordered to rule out IUP (see "Methods"). □ ED Sonos, ▨ MI Sonos.

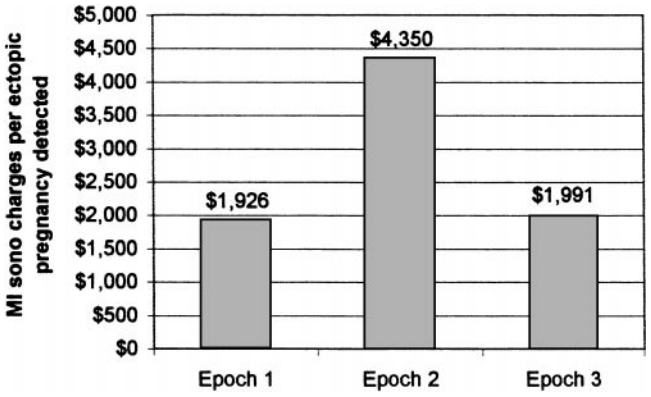

FIGURE 3. Projected MI Sono charges per ectopic pregnancy detected by epoch.

tive beta-HCG determination at their initial ED visit, as shown in Table 1, was significantly greater in Epoch 3 than in Epochs 1 or 2. It has been shown that a single beta-HCG measurement is not useful in ruling in or out ectopic pregnancy, however, unless it is correlated with the results of an ultrasound study.[19] The increased frequency of beta-HCG determinations at the first ED visit in Epoch 3 in this study coincided with the increased frequency of ultrasound examinations and probably was the result, rather than the cause, of ultrasounds being done more often.

Documenting the absence of an IUP in patients with first trimester cramping and bleeding identifies patients at highest risk for ectopic pregnancy, but is not equivalent to documenting the presence of an ectopic pregnancy. In this study, the date of first specific treatment for ectopic pregnancy was considered to be the date at which the diagnosis was definitively established. The time from the patient's first ED visit to treatment was considered to be a secondary indicator of quality in the ED because to some extent, the decision of when to treat was beyond the control of the emergency physicians. As would be expected on the basis of the trend toward improvement in the primary quality indicator going from Epoch 1 to Epoch 2, there was a corresponding trend between these epochs toward improvement in the number of patients treated at the first visit and in the mean number of days from the patient's first visit to treatment, as shown in Table 2. It was somewhat surprising to find, though, that as the percentage of patients documented to have absence of an IUP at the first ED visit increased further from Epoch 2 to Epoch 3, the percentage of patients treated at the first visit decreased and the number of days from the first visit to treatment increased.

There are a number of possible explanations for the discordance between the primary and secondary quality indicators in Epochs 2 and 3. One possibility is that the adverse trend in the secondary quality indicators was caused by chance. The actual differences in the secondary quality indicators were small and were not statistically significant. Although the present study is one of the larger reports in the literature on the subject of the use of ultrasound in the ED to screen for ectopic pregnancy, it still had relatively low power to determine statistically significant differences in quality indicators between Epochs 2 and 3. For example, if it is assumed that the actual percentage of cases treated at the first visit during Epoch 2 was the observed value of 75%, the power of the study to detect an absolute 10% difference in favor of Epoch 3 with 95% confidence was only 14%. To have 80% power to detect such a difference, the study would have required a combined total of 558 cases in Epochs 2 and 3.

Assuming that the observed differences in times to treatment between Epochs 2 and 3 were real, it is possible that the higher percentage of ectopic pregnancy cases treated with methotrexate during Epoch 3 (28%) as compared with Epoch 2 (9%) led to the apparent delay in treatment in Epoch 3. Successful treatment with methotrexate requires early diagnosis, before tubal rupture has occurred and before fetal cardiac activity has appeared or the ectopic gestation has reached a critical size.[20,21] To avoid including cases in the study in which spontaneous miscarriage or embryonic resorption (''blighted ovum'') were misdiagnosed and treated as ectopic pregnancy, the study design required that for cases treated nonsurgically to meet inclusion criteria, there had to be at least a 2-day interval with an abnormal rise in beta-HCG between the first ED visit and the time the patient was treated with methotrexate. Adjusting for this delay by subtracting 2 days from time to treatment for methotrexate cases in the data analysis still resulted in slightly longer times to treatment in Epoch 3 (2.0 days) than in Epoch 2 (1.3 days), as shown in Table 2. There were probably longer intervals than 2 days, though, between the initial visit and treatment with methotrexate in clinically stable patients with low, slowly rising beta-HCGs, and these cases could have contributed to the longer times to treatment in Epoch 3.

A live ectopic pregnancy was identified more often by MI Sono than by ED Sono in our study (12% versus 8%), but the differences in the rate of detection were not statistically significant. The rate of detection of a live ectopic pregnancy in a previous study in which 62% of scans were done by obstetrics and gynecology residents and the remainder done by medical imaging was 3%.[1] In a study of screening ultrasounds by medical imaging for all ED patients at risk for ectopic pregnancy with a beta-HCG greater than 1500 mIU/mL, a live ectopic pregnancy was detected in 18% of cases.[22] In another study of patients referred to a medical imaging department with suspicion of ectopic pregnancy, the rate of detection of a live ectopic pregnancy was 32%,[7] although the mean beta-HCG value in these patients was 30,031 mIU/mL, much higher than the mean value of 4,214 mIU/mL in the present study. The rate of detection of a live ectopic pregnancy by ED Sono has not been previously reported. In the present study, most of the cases of live ectopic pregnancy detected on MI Sono were not found at the first ED visit. The average number of days from first ED visit to treatment was longer in cases in which a live ectopic pregnancy was detected on MI Sono (3.2 days) than the average time to treatment in all cases combined (2.4 days). The differences in times to treatment between Epoch 2 and Epoch 3 cannot be attributed, therefore, to a higher rate of detection of a live ectopic pregnancy by MI Sono as compared with ED Sono. On the other hand, we did not collect data on the rates of detection of adnexal masses or ectopic gestations without detectable cardiac activity. Such data are difficult to obtain accurately in a retrospective study because qualifiers such as ''probable'' or ''possible'' are often used in ultrasound reports describing suspected ectopic

gestations. We cannot rule out the possibility that there was a higher rate of detection of adnexal masses or ectopic gestations without cardiac activity in Epoch 2 versus Epoch 3 which could have led to shorter times to treatment in Epoch 2. Similarly, we cannot rule out the possibility that obstetrics and gynecology consultants may have had more confidence in reports of an adnexal mass on MI Sono than on ED Sono, leading them to act more promptly on the results of an MI Sono.

The percentage of patients diagnosed with tubal rupture at the first ED visit, as shown by epoch in Table 1, was inversely related to the mean number of days to treatment, as shown in Table 2. This relationship is not surprising, as one would expect that all patients who are diagnosed with tubal rupture at the first visit would be treated at that visit. The difference in the percentage of patients found to have tubal rupture at the first visit between Epoch 1 (37%) and Epoch 2 (66%) was statistically significant, and unlikely, therefore, to have occurred entirely by chance. The difference in the rate of tubal rupture at the first visit between Epoch 2 (66%) and Epoch 3 (56%) was not statistically significant, but still may have contributed to longer times to treatment in Epoch 3. The differences in the rates of tubal rupture at the first visit among the three epochs raises the possibility that signs of tubal rupture may have been missed in some cases in Epochs 1 and 3. The rate of tubal rupture at the first visit in Epoch 1 was similar to the reported rate of 37% in an older study in which ultrasound availability in the ED was limited.[2] The rate of tubal rupture at the first visit in both Epochs 2 and 3 was higher than the reported 51% rate of finding either an adnexal mass or signs of tubal rupture in a more recent study of ED Sono in patients at risk for ectopic pregnancy.[14] If signs of tubal rupture were missed at an initial visit in the present study, it would be expected that the patient would be found to have tubal rupture on a return visit. Indeed, as shown in Tables 1 and 2, there was an inverse correlation across the three epochs between the rates of tubal rupture at the first visit and the rate of patients returning with tubal rupture. The differences in the rates of return with tubal rupture were small, though (13.2% in Epoch 1, 9.4% in Epoch 2, and 12% in Epoch 3), compared with the differences in the rates of detection of tubal rupture at the first visit, suggesting that if failure to detect tubal rupture at the first visit was a factor in longer times to treatment in Epochs 1 and 3, it was a relatively minor one.

Returning with tubal rupture implies an inappropriate delay in treatment. The rate of patients returning with tubal rupture in our study was higher in all three epochs than in the previously published report of ED Sono by Mateer *et al,* in which the incidence was one in 40, or 2.5%.[14] The higher rate of patients returning with tubal rupture in Epochs 1 and 2 could be attributed to failure to obtain ultrasounds at the first visit in some cases, but in Epoch 3, either an MI Sono or an ED Sono was done at the first visit in every case except for one patient who was taken directly to surgery.

The rate of patients returning with tubal rupture can be influenced by a number of factors other than the quality of care at the initial ED visit, including the availability of obstetrics and gynecology consultation and follow-up and the level of patient compliance with follow-up instructions. These factors are difficult to compare between studies. There are several identifiable differences between our study and the one by Mateer *et al,* however, which may account for the higher percentage of patients returning with tubal rupture in Epoch 3 of the present study. Mateer *et al* used a volume of blood in the operative report of >100 mL as defining tubal rupture, whereas we used a volume of >50 mL, which is the usual upper limit of normal blood loss for laparoscopy or laporotomy described by obstetrics and gynecology consultants at our facility. Immediate obstetrics and gynecology consultation was required by protocol in the Mateer study in all patients with no IUP and a beta-HCG level greater than 2,000 mIU/mL, whereas the decision of whether or not to obtain obstetrics and gynecology consultation at the time of the ED visit was left to the discretion of the emergency physician in our study. Only one of the six patients who returned with tubal rupture in Epoch 3 of our study, though, had an initial beta-HCG greater than 2000 mIU/mL. To some extent, the more favorable results achieved by Mateer *et al* might be attributable to the fact that their study was done on a convenience sample of patients who presented to the ED during hours when selected emergency physicians trained in ED Sono were on duty. The physicians trained in ED Sono may have had more interest or expertise in the evaluation of ectopic pregnancy than the rest of their ED colleagues, and might be expected to have better results than a department in which all emergency physicians are performing ED Sono.

Another potentially important difference in the study by Mateer *et al* which might explain the lower rate of patients returning with tubal rupture in their study is that in their approach to ED Sono, they stressed the importance not only of looking for the presence or absence of an IUP, but also for an adnexal mass or free fluid. Previous studies on ED Sono have emphasized a ''limited, goal-directed'' approach,[11,23] and this was the approach taken in the present study, with the goal in patients at risk for ectopic pregnancy being to rule in or out an IUP. The rationale for the ''limited, goal directed'' approach toward ED Sono is that keeping the study simple lessens the likelihood of emergency physicians making errors in interpretation. Our study raises the possibility that in the case of patients at risk for ectopic pregnancy, limiting the ED Sono to determining only the presence or absence of an IUP and not looking for an adnexal mass or signs of tubal rupture could possibly lead to delays in treatment.

The rate of treatment at the first ED visit in Epoch 1 in our study (58%) is similar to reported rates of diagnosis of ectopic pregnancy at the first ED visit of 55% to 57% in the older ED literature in studies in which ultrasound availability through medical imaging was limited.[1,2] The rates of treatment at the first ED visit in Epoch 2 (75%) and Epoch 3 (66%) in our study are comparable with a rate of detection of ectopic pregnancy at the first ED visit of 72% in the more recent ED study by Mateer *et al* advocating screening ED Sonos on all patients at risk for ectopic pregnancy.[14] In a study by Barnhart *et al* using ultrasound screening by medical imaging in all patients with first trimester cramping or bleeding who had beta-HCG values above 1500 mIU/mL, the rate of diagnosis at the initial ED presentation was only 49%.[24] These authors noted that 36% of patients eventually diagnosed with ectopic pregnancy in their study had an initial beta-HCG below 1500 mIU/mL.

The concept of a ''discriminatory zone'' for beta-HCG

values, below which ultrasound is of little value, was advanced in the earlier medical imaging literature on screening ultrasounds in patients at risk for ectopic pregnancy. The ''discriminatory zone'' is the value of beta-HCG at which one would first expect to reliably be able to visualize an IUP. For transabdominal ultrasonography, a ''discriminatory'' beta-HCG value of 6,000 to 6,500 mIU/mL has been proposed,[25] and for endovaginal ultrasound, beta-HCG values of 1,000 to 2,000 mIU/mL have been used.[6,22,24,26] More recently, Dart *et al* have shown that endovaginal ultrasound may be diagnostic in up to one-third of patients with ectopic pregnancy who present with beta-HCG values below 1,000 mIU/mL.[27] In the present study, no ''discriminatory'' beta-HCG level was used to determine whether or not an ultrasound should be done. The high rates of treatment at the first ED visit in Epochs 2 and 3 of the present study, as compared with the results of Barnhart *et al,* lend support to the argument that to maximize early diagnosis and treatment, an ultrasound should be done at the first ED visit in all patients at risk for ectopic pregnancy regardless of the beta-HCG level.

Our results with regard to the accuracy of ED Sono for ruling in or out an IUP confirm the results of prior studies showing that emergency physicians can perform ultrasound for this indication with a high degree of accuracy.[10,11,12,13,14] The most serious error in ultrasound interpretation that can be made from the point of view of the physical well being of the mother is to mistake an ectopic pregnancy for an IUP. This can occur when an ultrasonographer mistakes a fluid collection within the endometrial cavity (pseudosac) for a gestational sac,[28] or when a true gestational sac outside the uterus is mistakenly believed to be within the uterus.[29] Such errors can result in a fatal outcome, as was reported in a recent medical-legal case.[30] In the present study, none of 996 ED Sonos (including 36 ED Sonos in patients eventually proved to have an ectopic pregnancy) was falsely positive for an IUP, whereas two of 174 MI Sonos (1.1%) were falsely positive for IUP in patients with ectopic pregnancy. In a previously published series of 1,427 MI Sonos done in patients with first trimester cramping and bleeding, including 103 patients with ectopic pregnancy, there was one false positive study for IUP in a patient proved subsequently to have an ectopic pregnancy.[22] To date, no false-positive ED Sonos for IUP in patients with ectopic pregnancy have been reported in the medical literature, but the absence of such cases could reflect reporting bias rather than the rarity of their occurrence.

Ruling in an IUP does not completely exclude the possibility of an ectopic pregnancy. Estimates of the incidence of simultaneous intrauterine and extrauterine gestations (heterotopic pregnancy) vary from one in 30,000[31] to one in 2,600.[32] For practical purposes, though, the specificity of ultrasound in ruling in an IUP is equivalent to the specificity in ruling out ectopic pregnancy. In the present study, the specificity of ED Sono in ruling in IUP was 100%. On the other hand, as discussed earlier, our study raises the possibility that in some cases in which no IUP was found on ED Sono, signs of an adnexal mass or tubal rupture may have been missed. The question of whether emergency physicians can detect an adnexal mass or signs of tubal rupture as accurately as sonographers in medical imaging requires further study.

No previous study has addressed the relative cost-effectiveness of MI Sono versus ED Sono in the evaluation of patients at risk for ectopic pregnancy. The actual cost of an MI Sono is difficult to determine. A detailed analysis of medical imaging costs in intermediate referral hospitals in Finland in 1996 estimated that the cost of a generic ultrasound study, taking into account physician and nonphysician personnel costs, capital equipment, and administrative and physical plant overhead, was 296 Finnish marks, or approximately 54 US dollars per study.[33] It was not practical to determine the actual cost of an MI Sono at our facility, but the marginal cost of calling in an ultrasound technician after regular medical imaging department hours was known to be $135 per call-in. The different cost elements of the ED Sono program were directly identifiable, but even so, estimates of the marginal cost of an ED Sono varied by more than 10-fold from the high to low estimates, as shown in Table 4, depending on which assumptions were made regarding the type of machine used, the need for maintenance during the first 2 years, whether the facility or individual physicians bore the cost of physician training, and whether ED Sonos were of value only to rule out IUP or for other indications as well. Comparing the additional cost of ED Sonos done to rule out IUP with the cost savings from avoiding calling in ultrasound technicians, ED Sono led to a net savings as shown in Figure 1 using any of the estimates for the cost of an ED Sono, assuming that each definitive ED Sono which was done after regular medical imaging department hours avoided a call-in.

We did not include in our calculations of the marginal cost of an ED Sono the cost of the physician's time in performing the study. The amount of time the emergency physician spends or saves in performing ED Sono is difficult to quantitate. In an opinion survey of emergency physicians at our facility after one year of experience with ED Sono,[34] physicians were equally divided between those who felt ED Sono had a positive impact versus those who felt it had a negative impact on their own efficiency. Based on this survey and on previous studies showing decreased lengths of stay in the ED for patients who have ED Sono,[13,35,36] we assumed for the purpose of the present study that the amount of extra time the emergency physician spends in actually doing the ED Sono is approximately offset by time the physician saves in obtaining a more rapid diagnosis and disposition.

The incremental expenses in ultrasound studies for each additional patient documented to have absence of an IUP at the first ED visit can be estimated from the data in the present study, comparing the three different strategies for ultrasound availability. The difference in projected MI Sono charges per ectopic pregnancy diagnosed between Epoch 1 and Epoch 2, as shown in Figure 3, was $2,424. Dividing this figure by the difference between the two epochs in the primary quality indicator (12%, or 0.12) indicates that the improvement in quality in Epoch 2 came at the expense of $20,200 in ultrasound charges per additional case documented to have absence of an IUP at the first ED visit. As a result of the availability of ED Sono in Epoch 3 and the fact that there was no charge for an ED Sono, ultrasound charges

in Epoch 3 went back down to approximately the same as in Epoch 1, despite a further 8% improvement in the primary quality indicator between Epochs 2 and 3. The total ultrasound charges would have been the same in Epochs 2 and 3 if the charge for an ED Sono had been $118 per study. On the other hand, if ED Sono had not been available in Epoch 3 and all 796 definitive ED Sonos which were not repeated in Medical Imaging had been done and charged as MI Sonos instead, the improvement in the primary quality indicator from Epoch 2 to Epoch 3 would have come at the expense of $42,550 in ultrasound charges per additional patient documented to have absence of an IUP at the first ED visit.

At an expense in the range of $20,000 to $40,000 for each additional case documented to have absence of an IUP at the first ED visit, it might be argued that screening most or all patients at risk for ectopic pregnancy with ultrasound at the first ED visit is not cost-effective, and that obtaining ultrasounds only on patients with high clinical suspicion of ectopic pregnancy is the best strategy after all. If the Finnish estimate of $54 per study for the cost of an MI Sono is used instead of MI Sono charges, however, the liberal use of ultrasound screening appears somewhat more reasonable. The improvement in the primary quality indicator between Epochs 1 and 2 would have come at the cost of $2,970 per additional patient documented to have absence of IUP at the first ED visit. The improvement between Epoch 2 and Epoch 3, assuming that ED Sono was not available, would have come at the cost of $6,500 per additional case. To the extent that ED Sono is less expensive than MI Sono and reduces the number of MI Sonos ordered, substituting ED Sono for MI Sono further enhances the cost-effectiveness of universal ultrasound screening of patients at risk for ectopic pregnancy. For example, if the Finnish estimate of $54 for the cost of an MI Sono and the intermediate estimate of $14 for the cost of an ED Sono are used in the present study, the cost of the 20% improvement in the primary quality indicator from Epoch 1 to Epoch 3 was $1,474 per additional case documented to have absence of an IUP at the first ED visit.

As noted in ''Methods,'' the estimates for the number of MI Sonos ordered by ED physicians in patients at risk for ectopic pregnancy were obtained by multiplying the total number of pelvic ultrasounds ordered, which was known, by a factor of 0.74. This adjustment was necessary because the database from which the information on MI Sono use was obtained includes the type of study but not the rule out indication. The factor of 0.74 was derived from a previous study of patient satisfaction with ED Sono at our facility during the transition period between Epochs 1 and 2, in which it was found that 74% of all pelvic ultrasounds were done for the purpose of ruling out IUP.[18] The extent to which the actual percentage of pelvic ultrasounds done to rule out IUP varied from this estimate across the 6 years of the present study is unknown. Variations from this estimate could have led to overestimation of the savings in Epoch 3 as a result of the availability of ED Sono to rule out IUP, but the amount of any such overestimate would represent savings as a result of the availability of ED Sono to rule out other pelvic pathology.

In conclusion, our study shows that over a 6 year period, during which there was a transition from limited ultrasound availability to universal ultrasound screening of patients at risk for ectopic pregnancy, the percentage of patients documented to have absence of an IUP at the first ED visit increased significantly, but at the expense of a disproportionate increase in the total number of ultrasound studies done. ED Sono, which became available during the last two years of the study, was highly accurate in determining the presence or absence or an IUP and appeared to be a cost-effective alternative to MI Sono for screening patients at risk for ectopic pregnancy. Our study raises the possibility, though, that an adnexal mass or signs of tubal rupture may have been missed on some ED Sonos, leading to delays in treatment in some cases. Our study suggests that given the present level of sonographic expertise of emergency physicians at our facility, the best strategy from the combined viewpoint of quality and cost-effectiveness is for emergency physicians to screen all patients at risk for ectopic pregnancy with ED Sonos at the initial ED visit, and to obtain MI Sonos in all cases in which the ED Sono is indeterminate or shows no IUP.

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