Comparison of Quality and Cost-Effectiveness in the Evaluation of Symptomatic Cholelithiasis With Different Approaches to Ultrasound Availability in the ED

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Ultrasound is the imaging study of choice for the detection of gallstones, but ultrasound through medical imaging departments (MI Sono) is not readily available on an immediate basis in many emergency departments (EDs). Several studies have shown that emergency physicians can perform ultrasound themselves (ED Sono) to rule out gallstones with acceptable accuracy after relatively brief training periods, but there have been no studies to date specifically addressing the effect of ED Sono of the gallbladder on quality and cost-effectiveness in the ED. In this study, we investigated measures of quality and cost-effectiveness in evaluating patients with suspected symptomatic cholelithiasis during three different years with distinctly different approaches to ultrasound availability. The study retrospectively identified a total of 418 patients who were admitted for cholecystectomy or for a complication of cholelithiasis within 6 months of an ED visit for possible biliary colic. The percentage of patients who had gallstones documented at the first ED visit improved from 28% in 1993, when there was limited availability of ultrasound through the Medical Imaging Department (MI Sono), to 56% in 1995, when both MI Sono and ED Sono were readily available (P < .001). There were also significant differences over the 3 years in the mean number of days from the first ED visit to documentation of gallstones (19.7 in 1993, 10.7 in 1995, 7.4 in 1997, P < .001); the mean number of return visits for possible biliary colic before documentation of gallstones (1.67 in 1993, 1.24 in 1995, and 1.25 in 1997, P < .001); and the incidence of complications of cholelithiasis in the interval between the first ED visit for possible biliary colic and the date of documentation of cholelithiasis (6.8% in 1993, 5.9% in 1995, 1.5% in 1997, P = .049). The number of MI Sono ordered by emergency physicians per case of symptomatic cholelithiasis identified increased from 1.7 in 1993 to 2.5 in 1995 and dropped back to 1.7 in 1997, when 4.2 ED Sonos per study case were also done. The cost of ED Sonos was more than offset by savings in avoiding calling in ultrasound technicians after regular Medical Imaging Department hours. The indeterminate rate for ED Sono was 18%. Excluding indeterminates, the sensitivity of ED Sono for detection of gallstones was 88.6% (95% CI 83.1-92.6%), the specificity 98.2% (95% CI 96.0-99.3%), and the accuracy 94.8% (95% CI 92.5-96.5%). We conclude that greater availability of MI Sono in the ED was associated with improved quality in the evaluation of patients with suspected symptomatic cholelithiasis but also with increased ultrasound costs. The availability of ED Sono in addition to readily available MI Sono was associated with further improved quality and decreased costs. The indeterminate rate for ED Sono was relatively high, but excluding indeterminates, the accuracy of ED Sono was comparable with published reports of MI Sono. (Am J Emerg Med 2001;19:260-269. Copyright © 2001 by W.B. Saunders Company)

Cholelithiasis is relatively common in the adult population in the United States. The 10 year prevalence of cholelithiasis in adults ages 30 to 62 in the Framingham study was 8.2%. In Hispanic women, the prevalence of cholelithiasis has been reported to be as high as 40%. It has been estimated that from 2.5% to 12% of emergency department (ED) visits for abdominal pain are related to cholelithiasis, although the frequency with which biliary colic is either missed or overdiagnosed in the ED has not been systematically studied. Biliary colic is usually self-limited, but it is frequently recurrent and may cause severe patient discomfort. The annual incidence of serious complications in patients with initially asymptomatic or minimally symptomatic cholelithiasis is estimated to be 1% to 3%. The presence or absence of gallstones is difficult to predict on the basis of the patient’s clinical signs and symptoms, particularly in the elderly. Multiple studies have shown that symptoms such as fatty food intolerance, postprandial epigastric pain, radiation of pain to the back, and even right upper quadrant pain have poor predictive value for determining the presence or absence of cholelithiasis. Laboratory tests, including white blood count and liver function tests, are normal in most patients with uncomplicated biliary colic and in about a third of patients with acute cholecystitis.

Over the past 2 decades, ultrasonography has been the imaging study of choice for determining the presence or absence of cholelithiasis. In many EDs, however, ultrasound studies through medical imaging departments (MI Sonos) are not routinely available on an immediate basis. Recently, there has been growing interest among emergency
physicians in performing ultrasound studies themselves (ED Sonos). Several relatively small studies have suggested that emergency physicians can perform ED Sonos of the gallbladder with reasonably high accuracy after relatively brief training periods. Concerns have been raised, though, both by emergency physicians and by the Medical Imaging community, that emergency physicians may be more likely to make errors in ultrasound interpretation than sonographers in Medical Imaging, and that such errors could lead to adverse patient outcomes. The effect of ED Sono on quality and cost-effectiveness in patients with suspected biliary tract pain has not been systematically studied.

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 agreed to make ultrasound examinations 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 with suspected symptomatic cholelithiasis. 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 biliary tract pain with different approaches to ultrasound availability. In this report, we present the results of this study.

MATERIALS AND METHODS

The setting for this study and the ED Sono training and credentialing protocol have been previously described in detail. 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 three 1-year epochs: 1993, 1995, and 1997. During these years, 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.

During 1993, 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 at night and on weekends, but emergency physicians were discouraged from ordering ultrasounds of the gallbladder without first obtaining surgical consultation. During 1995, ultrasound technicians were present in the hospital from 8 AM to 10 PM on weekdays and available on call at all other times. In 1995, emergency physicians could order MI Sonos at their own discretion. During 1997, an ultrasound machine was available in the ED and all emergency physicians were trained to perform ED Sonos, though MI Sonos were still available as in 1995.

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 was a General Electric Logiq 400 equipped with a 3.5 MHz curved transducer (General Electric Corporation, Milwaukee, WI) and a Sony UP-870MD black and white page printer (Sony Corporation of America, New York, NY). Emergency physicians prospectively recorded the “rule out” indication for each ED Sono, and whether the study was positive, negative, or indeterminate for the presence of gallstones. Under an agreement with the Surgery and Medical Imaging departments, emergency physicians ordered confirmatory outpatient MI Sonos on all patients referred for elective surgical consultation after a positive ED Sono for gallstones.

An initial list of patients potentially eligible for the study was generated by a computerized search for all patients who had a cholecystectomy or who were admitted to the facility with a possible complication of biliary tract disease, including cholecystitis, cholangitis, or pancreatitis, within 6 months of an ED visit in 1993, 1995, or 1997. Medical records of patients identified by this computerized search were then reviewed by research assistants using explicit review criteria and preprinted data abstraction forms. Cases were included in the study if the patient had an ED visit for possible biliary colic within 6 months of a cholecystectomy or an admission for a possible complication of cholelithiasis; and if gallstones were documented on a pathology report or on an imaging study. For the purpose of the study, possible biliary colic was defined as any upper or right-sided abdominal pain for which no cause other than biliary tract disease or pancreatitis was specifically documented. Cases of acalculous cholecystitis and pancreatitis without cholelithiasis or cholecdocholithiasis were excluded. Cases were also excluded if the patient had previously documented cholelithiasis before the first ED visit for possible biliary colic. Cases with false-positive imaging studies for cholelithiasis were included.

The presence of gallstones was considered to be confirmed if gallstones were described as being present in the pathologist’s report; if the surgeon described opening the gallbladder and finding stones in the operative report; or in cases in which the patient did not have surgery, if 2 independent imaging studies (including at least 1 study done in the Medical Imaging Department) documented the presence of gallstones. Pancreatitis, gram negative bacteremia, or cholangitis were considered to be present if the hospital admission history and physical or discharge summary included these diagnoses. Acute cholecystitis was considered to be present only if this diagnosis was documented in the pathology report.

Primary and secondary quality indicators were defined before the beginning of data analysis. The percentage of patients documented to have cholelithiasis at the first ED visit was designated as the primary quality indicator in the study. Secondary quality indicators included the number of days from the first ED visit for possible biliary colic to documentation of the presence of cholelithiasis; the number of unscheduled return visits for possible biliary colic in the intervim between the first ED visit and documentation of the presence of cholelithiasis; and the incidence of complications of cholelithiasis in the intervim between the first ED visit and documentation of the presence of gallstones. The number of return visits in the 6 months after cholecystectomy for abdominal pain that was not directly attributable to a complication of the surgery or a retained common bile duct stone was also included as a secondary quality indicator to serve as a potential measure of the number of inappropriate cholecystectomies.

The accuracy of all ED Sonos done in 1997 to rule out gallstones was assessed by comparing ED Sono interpretations with surgical pathology, with repeat MI Sonos or other imaging studies, or with clinical follow-up. Accuracy of ultrasound interpretation was judged solely on whether the presence or absence of gallstones was correctly identified. 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 a region with a radius of approximately 150 miles. The presence of gallstones could not be confirmed by clinical follow-up alone. The absence of gallstones was considered to be confirmed by clinical follow-up if the patient was followed in the health plan for at least 2 years after an ED Sono and had no imaging studies or surgery showing cholelithiasis over that time period.
Data on the number of abdominal 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. 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 were obtained from the hospital administrator. It was estimated that 32% of all ED Sonos were done for the purpose of ruling out gallstones based on a previous study of ED Sono at our facility.24

Statistical analysis of the data was done using the statistical packages included with EpInfo 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-square or the 2-tailed Fisher exact test when cell sizes were small. For comparisons of data across the three epochs, a P value less than .05 was considered statistically significant. For comparisons between any 2 epochs, a P value less than .0167 (.05/3) was considered significant, in accordance with the Bonferroni correction.

RESULTS

Patient Characteristics

Initial computerized review identified 550 potential cases for inclusion in the study over the 3 epochs of the study period. After chart review, 418 cases (76%) met criteria for inclusion in the final analysis of quality indicators. The number of cases excluded in each epoch and the reasons for excluding them are shown in Table 1. There was no significant difference across the 3 epochs in the number of cases excluded or in the reasons for exclusion. Most cases which were excluded on the basis that the patient had no documented gallbladder disease were cases of alcoholic or idiopathic pancreatitis. Most cases excluded on the basis that the patient had no ED visits with possible biliary colic were cases in which patients were seen in the ED for a condition other than abdominal pain within 6 months of a cholecystectomy.

The characteristics of the 418 patients included in the final data analysis are shown by epoch in Table 2. The percentage of patients included in the study relative to the total number of patients seen in the ED increased significantly in each subsequent epoch. The percentage of patients having an ultrasound done at the first ED visit also increased significantly in each subsequent epoch. There were no significant differences across the three epochs in the age or sex of patients or in the percentages of patients presenting with a complication of cholelithiasis at their first ED visit.

Quality Indicators and Other Outcome Measures

Primary and secondary quality indicators are shown in Table 3. In one case in 1995 and in two cases in 1997, preoperative sonograms were reported to show gallstones, but no gallstones were documented at surgery. These cases were included in the denominator but not in the numerator in calculations of the primary quality indicator, the percentage of patients correctly documented to have gallstones at the first ED visit. These cases were excluded from calculations of secondary quality indicators.

There was significant improvement in each subsequent epoch in the primary quality indicator, the percentage of patients documented to have gallstones at the first ED visit. There was also significant improvement in each subsequent epoch in mean number of days from the first ED visit for possible biliary colic to the date of documentation of gallstones. The mean number of unscheduled visits for possible biliary colic before documentation of gallstones was significantly lower in 1995 and 1997 than in 1993. The incidence of complications of cholelithiasis occurring between the first ED visit and the date of documentation of gallstones was statistically different across the 3 epochs, with a trend toward the highest rate of complications in 1993 and the lowest rate in 1997, though the difference between any 2 epochs was not statistically significant at the level of P < .016. There was no statistically significant difference across the 3 epochs in the rate of return visits for nonbiliary abdominal pain in the 6 months after cholecystectomy.

Accuracy of ED Sono Interpretation

During 1997, emergency physicians performed a total of 802 ED Sonos to rule out gallstones. In 36 cases, ED Sonos confirmed the results of a prior ED Sono on the same patient. In 12 cases, ED Sonos confirmed the results of a prior MI Sono. Of the remaining 754 ED Sonos that were not repeat studies, 185 (24.5%) were interpreted as showing gallstones to be present, 429 (56.9%) were interpreted as showing gallstones to be absent, and 140 (18.6%) were indeterminate. The results of follow-up to confirm the accuracy in the 614 nondeterminate ED Sonos that were not preceded by prior imaging studies are shown in Table 4. ED Sonos confirmed by more than one method are listed only once in Table 4, under the most stringent method, with

<table>
<thead>
<tr>
<th>TABLE 1. Basis for Excluding Cases Identified by Initial Computerized Search From the Final Data Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>Total potential cases identified</td>
</tr>
<tr>
<td>Number (%) of cases meeting inclusion criteria</td>
</tr>
<tr>
<td>Number (%) of cases excluded and basis for exclusion</td>
</tr>
<tr>
<td>Acalculous cholecystitis</td>
</tr>
<tr>
<td>Gallstones previously documented</td>
</tr>
<tr>
<td>No gallbladder disease</td>
</tr>
<tr>
<td>No ED visits for possible biliary colic</td>
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</table>
TABLE 2. Characteristics of Patients Included in Study

<table>
<thead>
<tr>
<th></th>
<th>1993</th>
<th>1995</th>
<th>1997</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ED Census</td>
<td>31,044</td>
<td>31,912</td>
<td>32,456</td>
<td></td>
</tr>
<tr>
<td>Number of study cases</td>
<td>88</td>
<td>135</td>
<td>195</td>
<td></td>
</tr>
<tr>
<td>% of total ED cases</td>
<td>.28%†‡</td>
<td>.42%†§</td>
<td>.60%‡§</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td>.98</td>
</tr>
<tr>
<td>Mean</td>
<td>47.7</td>
<td>47.5</td>
<td>47.9</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>45.5</td>
<td>46</td>
<td>47</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>16-86</td>
<td>14-87</td>
<td>16-90</td>
<td></td>
</tr>
<tr>
<td>% Female</td>
<td>69%</td>
<td>71%</td>
<td>76%</td>
<td></td>
</tr>
<tr>
<td>Number (% patients having ultrasound at first visit)</td>
<td>26‡ (30%)</td>
<td>81‡ (60%)</td>
<td>165‡ (85%)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>MI Sono only</td>
<td>26</td>
<td>81</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>ED Sono only</td>
<td>0</td>
<td>0</td>
<td>111</td>
<td></td>
</tr>
<tr>
<td>Both</td>
<td>0</td>
<td>0</td>
<td>47</td>
<td></td>
</tr>
<tr>
<td>Number (% of patients with complication(s) at first visit)</td>
<td>22 (25%)</td>
<td>41 (30%)</td>
<td>40 (21%)</td>
<td>.12</td>
</tr>
<tr>
<td>Acute cholecystitis</td>
<td>13</td>
<td>23</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>Pancreatitis</td>
<td>9</td>
<td>17</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Cholangitis or bacteremia</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Perforation or gangrene</td>
<td>3</td>
<td>8</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

* Some patients had more than one complication.

P values for pairwise comparisons of data in same row with same superscripts are as follows: † P = .003; ‡ P < .001; § P = .002; ¶ P < .001; || P = .005. For all other pairwise comparisons in same row, P ≥ .016.

surgical pathology being considered most stringent and clinical follow-up least stringent. For the purpose of further calculations, all cases in which ED Sono results were disparate either with surgical pathology or with repeat medical imaging studies, if surgical pathology was not available, were considered to be errors in ED Sono interpretations. Excluding indeterminate scans, scans confirming prior imaging studies, and scans in which follow-up was unavailable or could not confirm the accuracy of the ED Sono, the sensitivity of ED Sono for detecting the presence or absence

TABLE 3. Primary and Secondary Quality Indicators

<table>
<thead>
<tr>
<th>Primary quality indicator</th>
<th>1993 (n = 88)</th>
<th>1995 (n = 135)</th>
<th>1997 (n = 195)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number (% of patients correctly documented to have gallstones at first ED visit)</td>
<td>25 (28%)‡§</td>
<td>76 (56%)‡#</td>
<td>137 (70%)§#</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Secondary quality indicators

1. Number of days from first ED visit to documentation of gallstones
   - Mean 19.7‡§ | 10.7‡¶ | 7.4§||<.001
   - Median 2 | 0 | 0
   - Range 0-179 | 0-164 | 0-152

2. Number of unscheduled visits for possible biliary colic from first ED visit to documentation of gallstones
   - Mean 1.67‡§ | 1.24‡ | 1.25§<.001
   - Median 1 | 1 | 1
   - Range 1-6 | 1-5 | 1-5

3. Incidence of complications between first visit and documentation of gallstones
   - Acute cholecystitis 2 | 5 | 3
   - Pancreatitis 4 | 2 | 0
   - Cholangitis or bacteremia 2 | 2 | 0
   - Perforation or gangrene of gallbladder 1 | 1 | 0
   - Death 0 | 0 | 0

4. Number of visits for ongoing abdominal pain in 6 months following cholecystectomy†
   - Mean 0.21 | 0.16 | 0.25
   - Median 0 | 0 | 0
   - Range 0-3 | 0-3 | 0-3

* Some patients had more than one complication.
† Abdominal pain not directly attributable to biliary tract disease or a complication of surgery.
‡ P < .001; § P < .001; ¶ P = .011; || P = .008. For all other pairwise comparisons in same row, P ≥ .016.
of gallstones was 88.6% (95% CI 83.1-92.8%), the specificity 98.2% (95% CI 96.0-99.3%), and the accuracy 94.8% (95% CI 92.5-96.5%).

Cost-Effectiveness

Including both MI Sonos of the gallbladder done at the time of the ED visit and studies done subsequently on an outpatient basis, emergency physicians ordered a total of 146 MI Sonos in 1993, 331 MI Sonos in 1995, and 320 MI Sonos in 1997. The combined numbers of MI and ED Sonos done per case of symptomatic cholelithiasis identified as being eligible for the study are shown by year in Fig 1. The charge for an MI Sono of the gallbladder at our facility, which also includes ultrasound of the kidneys and pancreas, was $370 for patients who were not health plan members. There was no charge for an ED Sono. Assuming that all patients were charged at the non-member rate, the total ultrasound charges per case of symptomatic cholelithiasis identified as meeting study eligibility criteria was $629 in 1993, $925 in 1995, and $629 in 1997.

Out of the 614 ED Sonos done in 1997 which were not indeterminate and which were not preceded by prior imaging studies of the gallbladder, repeat MI Sonos were obtained at the time of the ED visit in 83 cases (13.5%) and at a later date in 191 cases (31.1%). In 340 cases (55.4%), no repeat MI Sono was obtained. Of the 531 cases in which neither no repeat MI Sono was obtained or an MI Sono was obtained at a later date, 344 ED Sonos (64.8%) were done at times when ultrasound technicians were not scheduled to be in the hospital.

The actual cost of an MI Sono of the gallbladder at our facility in 1997 was not known. The marginal salary cost of calling in an ultrasound after regular hours was $135 per call-in. Figures and assumptions used to estimate the marginal cost of an ED Sono to rule out gallstones are shown in Table 5. For the intermediate and lowest estimates of the cost of an ED Sono, it was assumed that ED Sonos to rule out gallstones constituted 32% of all ED Sonos done (see Methods).

Assuming that an ultrasound technician call-in was saved by each of the 344 definitive ED Sonos done at times when ultrasound technicians were not scheduled to be in the hospital, the net differences between the expense of ED Sonos and the savings which resulted from avoiding ultrasound technicians call-ins are shown in Fig 2. The magnitude of the differences varied depending on whether the high, low, or intermediate assumptions for the cost of an ED Sono were used for the calculations, but there were projected net cost savings as a result of the availability of ED Sono with all 3 estimates.

DISCUSSION

This study shows that as the availability of ultrasound in our ED increased, there was a significant increase in the percentage of ED patients presenting with possible biliary colic who had an ultrasound examination done at their first ED visit. Correspondingly, there was significant improvement in the primary quality indicator in the study, the percentage of patients documented to have gallstones by an imaging study at their first ED visit. The improvement in quality from 1993, when availability of MI Sono was limited, to 1995, when MI Sono was readily available through
the first ED visit for possible biliary colic to the date of confirmation of cholelithiasis sooner rather than documentation of gallstones, assumes that it is better to cause of the patient's symptoms. Lead the physician to search beyond the biliary tract for the inal pain in the ED, and the absence of gallstones should more likely. Similarly, although absence of gallstones does the patient may coincidentally have one of these other conditions, which may mimic biliary colic, the results of an ultrasound examination are not going to change patient management. In fact, however, multiple studies have shown that it is not possible in the majority of patients to make the diagnosis of symptomatic cholelithiasis with any degree of certainty based on the history, physical examination, and standard laboratory tests, without a confirmatory imaging study.9,10,12,13 The treatment for biliary colic and for complications of cholelithiasis are different than the treatment for gastritis, peptic ulcer disease, myocardial ischemia, and other conditions which may mimic biliary tract pain. Although the documentation of the presence of gallstones does not rule out the possibility that the patient may coincidentally have one of these other conditions, it certainly makes symptomatic cholelithiasis more likely. Similarly, although absence of gallstones does not rule out acalculous cholecystitis25 or "biliary dyskinesia,"26 these conditions are probably rare causes of abdominal pain in the ED, and the absence of gallstones should lead the physician to search beyond the biliary tract for the cause of the patient's symptoms.

Secondary quality indicator 1, the number of days from the first ED visit for possible biliary colic to the date of documentation of gallstones, assumes that it is better to confirm the presence of cholelithiasis sooner rather than later. This assumption is supported by the results of secondary quality indicators 2 and 3 which showed that shorter times to documentation of gallstones were associated with fewer return visits for possible biliary colic and fewer complications. These outcome measures were designated as secondary quality indicators because in addition to reflecting accuracy in identifying symptomatic cholelithiasis in the ED, they could also have been influenced by factors such as waiting times for outpatient ultrasounds and outpatient surgery consultation.

The only quality measure that did not show improvement across subsequent epochs was secondary indicator 4, the number of visits for nonbiliary abdominal pain in the 6 months after surgery. There was no statistically significant difference in this quality indicator across the 3 epochs, but there was a trend toward a slightly higher number of return visits in 1997. The occurrence of ongoing pain after cholecystectomy is well documented and much discussed in the surgical literature.27 Although the cause of "postcholecystectomy syndrome" is not entirely clear, in some cases it is probably due to the fact that the patient's abdominal symptoms were not related to the patient's gallstones in the first place. The trend toward the highest number of return visits for postcholecystectomy pain in the third epoch of the present study, during which ultrasound was performed most often at the first ED visit, serves as a caution that more frequent use of ultrasound in the ED could lead to more frequent inappropriate cholecystectomies if patients' clinical presentations are not weighed carefully along with the ultrasound results.28

The decision to use 6 months as the maximum interval between the index ED visit and subsequent cholecystectomy or admission for complications of cholelithiasis as one of the eligibility criteria in the present study was based on several considerations. This same interval was used as the cutoff for defining delayed treatment for symptomatic cholelithiasis in a previous study.29 It has been estimated based on radioactive dating of gallstones in patients with exposure to nuclear explosions that it takes about 2 years from the beginning of gallstone formation for stones to become symptomatic.30 Another study of patients in family practice offices found an average latency period of about 3 1/2 years between the incidental detection of gallstones in patients being worked up for other conditions and the onset of symptoms attributable to biliary tract disease, although the range of latency was 4 months to 8 years.31 Other studies have suggested even longer intervals between incidental detection of gallstones and onset of symptoms.32 We felt that using a window of 6 months in the present study would be practical in performing the study and would make it likely that if gallstones were present at surgery, they would have been detectable on ultrasound at an ED visit 6 months earlier. If we had used a longer study period window, more cases in which the diagnosis was not made at the first ED probably would have been picked up, and the apparent delay between the first ED visit and the detection of gallstones probably would have appeared longer. Because we used the same study period window for all 3 epochs, however, it is unlikely that the length of the window led to any bias in comparing quality measures with the 3 different approaches to ultrasound availability.
Another potential limitation of this study is uncertainty in determining whether visits for abdominal pain in patients with known cholelithiasis were attributable to their gallstones or to some other coincidental, undiagnosed pathology. Some of the visits classified as "possible biliary colic" in the present study were probably not, in fact, related to the patient’s gallstones, while some visits for chest pain, nausea and vomiting, or other nonspecific gastrointestinal complaints, which were not included in the study, may have been because of symptomatic cholelithiasis. This uncertainty as to whether or not a patient’s symptoms are caused by gallstones is a limitation in any study of precision in diagnosing biliary tract pain. Although there was probably some misclassification in the present study of visits for nonbiliary pain as possible biliary colic, and vice versa, because the same criteria were used for all 3 epochs, it is unlikely that any misclassification biased the comparisons across the 3 epochs.

The increase in the percentages of all ED patients who met study inclusion criteria from 1993 to 1997, as shown in Table 2, could be because of an increase in the prevalence of symptomatic cholelithiasis in the study population, more frequent misdiagnosis of biliary colic during ED visits in the earlier epochs, a trend for surgeons to perform cholecystectomies more often in the later epochs, or a combination of these factors. An increase in the prevalence of symptomatic cholelithiasis in the study population seems unlikely. It cannot be determined from the available data whether more frequent misdiagnosis of symptomatic cholelithiasis in the ED in the earlier epochs or a more liberal approach to surgery in the later epochs was most important in the observed trend toward a higher cholecystectomy rate over time, but both factors probably contributed. With the increasing use of laparoscopic cholecystectomy over the past decade and its lower morbidity as compared with open cholecystectomy, there has been an increase in the cholecystectomy rate in the United States. The question of whether or not prompt cholecystectomy constitutes better treatment than expectant management in patients with symptomatic cholelithiasis has not been conclusively answered and remains a point of controversy in the medical literature.

For several reasons, it was not practical to compare the accuracy of ED Sono with the accuracy of MI Sono of the gallbladder at our own facility. Most cases of positive MI Sonos for gallstones were picked up by the computer search for patients admitted for cholecystectomy or a complication of cholelithiasis. It was not practical, though, to identify all cases in which MI Sonos of the gallbladder were done and did not show gallstones. Also, because MI Sono results were used as the "gold standard" for the accuracy of ED Sono in cases in which surgical pathology was not available, any comparison of the relative accuracy of ED Sono and MI Sono at our facility would have been biased in favor of MI Sono. Finally, in 1997, most MI Sonos ordered by emergency physicians were done after gallstones had already been identified on ED Sonos, and the results of the ED Sonos were available to the sonographers in Medical Imaging.

There have been several, relatively small previous studies reporting that emergency physicians can perform ED Sono for the detection of cholelithiasis with acceptable accuracy after brief training periods. In the 2 studies which report the most complete data, the sensitivity of ED Sono was 86% to 95% and specificity 87% to 97%, using MI Sono as the gold standard. It is of interest that there is also a report in the surgical literature of ultrasound of the gallbladder by surgeons in a convenience sample of 77 cases with a reported sensitivity of 100% and specificity of 95%, using MI Sono as the gold standard.

In a previous study of the accuracy of MI Sono in detecting cholelithiasis in 993 patients, the indeterminate rate was reported to be 1.3%, the sensitivity 98%, the specificity 93.5%, and the accuracy (excluding indeterminate scans) 96%. The investigators do not state, however, what standard was used to confirm the accuracy of sonograms interpreted as showing no gallstones. In a meta-analysis of 3 studies on MI Sono with a total of 552 patients, the indeterminate rate for MI Sono was 1%, the sensitivity 97% (95% CI 95-99%) and the specificity 95% (95% CI 88-100%).

The sensitivity of a test reflects the rate of falsely negative studies. Most studies of the accuracy of MI Sono in detecting cholelithiasis use surgical pathology as the gold standard for the presence of gallstones. In such studies, the problem of verification bias could make the false negative rate of MI Sonos appear lower than it actually is, as patients with falsely negative studies are less likely to go to surgery. Verification bias would be less likely to affect the falsely negative rate of ED Sonos in the present study as patients who did not have a confirmatory imaging study or surgery were followed for a full 2 years, longer than in any of the above cited studies, before a negative study for gallstones was considered to be confirmed. Correcting for verification bias in the meta-analysis cited earlier, the investigators calculated the adjusted sensitivity of MI Sono for the detection of cholelithiasis to be 84% (95% CI 76%-92%).

In the 802 patients in the present study who had ED Sono to rule out gallstones in 1997, the indeterminate rate (18%) was considerably higher than in previous studies of MI Sono. Excluding indeterminate studies and studies for which confirmation was not available, though, the sensitivity of ED Sono for detecting cholelithiasis in the present study (88.6%) is comparable with the sensitivity adjusted for verification bias (84%) in the meta-analysis of MI Sono cited earlier. Likewise, the specificity (98.2%) and overall accuracy (94.8%) of ED Sono in the present study are comparable to the previously cited reports on MI Sono.

Besides lack of operator experience or expertise, a number of other factors could contribute to a higher indeterminate rate for ED Sono. These factors include the condition of the patient at the time of the study, the environment in which the study is performed, and the equipment used to perform the study. Patients in the ED are often nonfasting. Acute biliary colic is probably caused, in most cases, by stones becoming lodged in the neck of the gallbladder, the cystic duct, or the common bile duct, where they are more difficult to visualize sonographically than while they are lying in the body of the gallbladder. The lighting conditions in the ED and the time available for the study are usually suboptimal, as compared with a scheduled appointment in the ultrasound suite of the Medical Imaging Department. Finally, the resolution of portable ultrasound machines used in the ED is usually not as good as the resolution of larger,
more expensive machines used in most Medical Imaging Departments. It is of interest that in one small study assessing the accuracy of sonography performed for a variety of indications in the ED, the accuracy rates for ED physicians and for trained sonographers were not significantly different when both used the same machine in the ED setting.43 We believe that an indeterminate rate in the range of 18% is acceptable for ED Sono to rule out cholelithiasis, and that it is preferable to consider scans indeterminate than to risk calling them falsely positive or negative.

In this study, we did not specifically address the accuracy of either ED or MI Sonos in assessing features of gallbladder disease other than the presence or absence of stones. Factors such as thickening of the gallbladder wall, dilatation of the common bile duct (CBD), the presence of stones greater than 20 millimeters in diameter, and contraction of the gallbladder have been shown to predict the need for conversion from laparoscopic to open cholecystectomy.45 Also, dilatation of the CBD on ultrasound has been shown to be a reliable predictor of the presence of common bile duct stones and of the need for endoscopic retrograde cholangiopancreatography (ERCP) either before or after laparoscopic cholecystectomy.46-49 To date, only one small study has addressed the correlation between ED Sono and MI Sono in determining the presence or absence of sonographic signs of cholecystitis.20 This study found only a moderate correlation (κ = .46). We are not aware of any studies looking at the correlation between ED Sono and MI Sono in measuring CBD diameter.

When we began our study, the emphasis in the ED literature was for emergency physicians to perform “limited, goal-directed” ED Sonos,17,50 with the limited goal in patients with suspected biliary colic being to rule out gallstones. The rationale for this approach was that keeping the study limited and goal-directed would reduce the likelihood of errors by relatively inexperienced physicians. On the other hand, failure to identify sonographic signs of cholecystitis or CBD obstruction could potentially have an adverse effect on patient management. If signs of cholecystitis or CBD obstruction had been missed on ED Sono in the present study, one might expect a trend toward an increased frequency of patients returning with complications of cholelithiasis in 1997. In fact, however, the trend was toward fewer complications during the ED Sono epoch. Nevertheless, we have modified our approach to ED Sono of the right upper quadrant as we have gained experience, and we now expect our emergency physicians to document not only the presence or absence of gallstones, but also to look for sonographic signs of cholecystitis and CBD dilatation.

To our knowledge, no previous study has directly addressed the relative cost-effectiveness of limited versus liberal MI Sono availability or of MI Sono versus ED Sono in suspected symptomatic cholelithiasis. As shown in Fig 1, the number of MI Sonos done per case identified as eligible for the study increased from 1.7 in 1993, when the availability of MI Sono was limited, to 2.5 in 1995, when MI Sono was readily available. The number of MI Sonos per case went back down to 1.7 in 1997, when 4.2 ED Sonos were also done per study case. Since there was no charge for an ED Sono, the projected ultrasound charges per case identified, assuming that all patients were charged at the same non-member rate ($370), showed a similar rise and fall. From these data, it can be calculated that the total ultrasound charges per case identified in 1997 would have been the same as in 1995 if the charge for an ED Sono had been $70.

If it is assumed that there is no cost to missing the diagnosis of symptomatic cholelithiasis in the ED, then the strategy of limited availability of MI Sono in 1993 would be the most cost-effective. Clearly, however, there are costs to missed or delayed diagnoses, though the exact amount of these costs is difficult to estimate. The medical costs include return visits and treatment for the complications of cholelithiasis. If cholecystectomy is performed before acute cholecystitis develops, there is a greater chance that the procedure can be done laparoscopically rather than open,51-53 with shorter hospitalizations and lower hospital costs. Other costs of missed or delayed diagnosis include patient pain and suffering, missed days of work, and potential medical-legal liability. If it is assumed that the lower rate of return visits for possible biliary colic in 1995 compared with 1993 was a result of the more frequent use of ultrasound at the first visit in 1995, then the additional charges for more frequent MI Sonos in 1995 would have equaled the reduction in charges for return visits if the charge for a return visit had been $698. Considering that there are other costs of delayed or missed diagnoses beyond the charges for return visits, it seems likely that liberal use of MI Sono is more cost-effective than limited availability of MI Sono in the evaluation of patients in the ED with suspected symptomatic cholelithiasis.

To the extent that ED Sono is less expensive than MI Sono, the substitution of ED Sono for MI Sono should further enhance the cost-effectiveness of liberal ultrasound use. 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 U.S. dollars per study.54 In a 1999 U.S. study of the relative cost-effectiveness of computed tomography versus ultrasound for suspected appendicitis, it was estimated that the cost of an abdominopelvic ultrasound in a medical imaging department was $270.55 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 components of an ED Sono were directly identifiable, but even so, estimates of the marginal cost of an ED Sono varied from $6 to $38 per study, depending on which assumptions were made regarding the need for ultrasound machine maintenance, whether the facility or the individual physician bore the cost of training, and whether ED Sonos were done only to rule out cholelithiasis or for other indications as well.

Assuming that the only costs of an MI Sonos were the costs of calling in technicians after regular hours and that each nondeterminate ED Sono done after regular hours saved a call-in, the availability of ED Sono led to a net savings in 1997 of approximately $16,000 to $42,000 in ultrasound costs, as shown in Fig 2, depending on which
estimates were used for the cost of an ED Sono. It could be argued that not all after hours ED Sonos saved a call-in, and that in some cases, an MI Sono could have reasonably been done during regular hours the next weekday. Dividing ED Sono costs by call-in costs gives the “break even” point at which the added cost of ED Sonos would have exactly equaled the cost savings from avoiding calling in ultrasound technicians. Using the intermediate estimate ($12) for the cost of an ED Sono, ED Sono costs would have exactly equaled savings in call-ins if it were assumed that 21% of after hours ED Sonos saved a call-in. Using the high ($38) or low ($6) estimates for the cost of an ED Sono, the “break-even” points would have occurred when 65% or 10% of ED Sonos, respectively, precluded call-ins.

In calculating the cost of an ED Sono, we did not include the time the emergency physician spends in actually performing the study. In previous studies addressing the time it takes to perform an ultrasound of the gallbladder, the reported times have ranged from 5 minutes for radiologists14 to 7 minutes for emergency physicians18 to 12 minutes for surgeons.42 In an opinion survey at our facility after 1 year of experience with ED Sono, emergency physicians were equally divided between those who felt ED Sono increased their efficiency and those who felt it reduced it.56 It has previously been shown that the length of stay in the ED for patients with abdominal pain is approximately an hour less for patients who have ED Sono as compared with patients who have MI Sono.57 In the present study, for the purpose of comparing the cost-effectiveness of ED Sono versus MI Sono, we assumed that the cost of the emergency physician’s time in performing the study was approximately offset by the time saved in getting a more timely diagnosis and disposition.

In conclusion, our study shows that as MI Sono became more readily available in our ED from 1993 to 1995, there was approximately a 50% increase in MI Sono utilization by emergency physicians accompanied by significant improvement in measures of quality reflecting the time to diagnosis in the evaluation of patients with symptomatic cholecystitis. The addition of ED Sono in 1997 was associated with further improvements in quality and a reduction in MI Sono utilization to 1993 levels. The cost of the ED Sono program was more than offset by savings in avoiding call-ins of ultrasound technicians after regular Medical Imaging Department hours. The indeterminate rate for ED Sonos was relatively high, but excluding indeterminates, the sensitivity, specificity, and accuracy were comparable to published reports for MI Sono. Our study suggests that the best approach for identifying patients with symptomatic cholecystitis in the ED is to screen all patients with possible biliary colic with ED Sono, and to have MI Sono readily available for cases in which ED Sono is indeterminate.

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