

ORIGINAL RESEARCH CONTRIBUTION

Emergency Ultrasound-assisted Examination of Skin and Soft Tissue Infections in the Pediatric Emergency Department

Jennifer R. Marin, MD, MSc, Anthony J. Dean, MD, Warren B. Bilker, PhD, Nova L. Panebianco, MD, MPH, Naomi J. Brown, MD, and Elizabeth R. Alpern, MD, MSCE

Abstract

Objectives: The objective was to evaluate the test characteristics of clinical examination (CE) with the addition of bedside emergency ultrasound (CE+EUS) compared to CE alone in determining skin and soft tissue infections (SSTIs) that require drainage in pediatric patients.

Methods: This was a prospective study of CE+EUS as a diagnostic test for the evaluation of patients 2 months to 19 years of age evaluated for SSTIs in a pediatric emergency department (ED). Two physicians clinically and independently evaluated each lesion, and the reliability of the CE for diagnosing lesions requiring drainage was calculated. Trained pediatric emergency physicians performed US following their CEs. The authors determined and compared the test characteristics for evaluating a SSTI requiring drainage for CE alone and for CE+EUS for those lesions in which the two physicians agreed and were certain regarding their CE diagnosis (clinically evident). The performance of CE+EUS was evaluated in those lesions in which the two physicians either disagreed or were uncertain of their diagnosis (not clinically evident). The reference standard for determining if a lesion required drainage was defined as pus expressed at the time of the ED visit or within 2 days by follow-up assessment.

Results: A total of 387 lesions underwent CE+EUS and were analyzed. CE agreement between physicians was fair ($\kappa = 0.38$). For the 228 lesions for which physicians agreed and were certain of their diagnoses, sensitivity was 94.7% for CE and 93.1% for CE+EUS (difference = -1.7% ; 95% confidence interval [CI] = -3.4% to 0%). The specificity of CE was 84.2% compared to 81.4% for CE+EUS (difference = -2.8% ; 95% CI = -9.7% to 4.1%). For lesions not clinically evident based on CE, the sensitivity of CE was 43.7%, compared with 77.6% for CE+EUS (difference = 33.9% ; 95% CI = 1.2% to 66.6%). The specificity of CE for this group was 42.0%, compared with 61.3% for CE+EUS (difference = 19.3% ; 95% CI = -13.8% to 52.4%).

Conclusions: For clinically evident lesions, the addition of ultrasound (US) did not significantly improve the already highly accurate CE for diagnosing lesions requiring drainage in this study population. However, there were many lesions that were not clinically evident, and in these cases, US may improve the accuracy of the CE.

ACADEMIC EMERGENCY MEDICINE 2013; 20:545–553 © 2013 by the Society for Academic Emergency Medicine

From the Division of Emergency Medicine, Children's Hospital of Pittsburgh, Department of Pediatrics, University of Pittsburgh School of Medicine (JRM), Pittsburgh, PA; the Department of Emergency Medicine, University of Pennsylvania Perelman School of Medicine (AJD, NLP), Philadelphia, PA; the Department of Biostatistics and Epidemiology, Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania Perelman School of Medicine (WBB), Philadelphia, PA; the Department of Pediatrics, Division of Emergency Medicine, A.I. duPont Hospital for Children (NJB), Wilmington, DE; and the Division of Emergency Medicine, The Children's Hospital of Philadelphia, Department of Pediatrics, University of Pennsylvania Perelman School of Medicine (ERA), Philadelphia, PA.

Received April 13, 2012; revision received July 17, 2012; accepted January 30, 2013.

Presented at the Pediatric Academic Societies annual meeting, Denver, CO, May 2011.

Funding was provided by the National Institutes of Health, National Institute of Allergy and Infectious Diseases (F32AI080063), and by the Nicholas Crognale Chair for Emergency Medicine, The Children's Hospital of Philadelphia, Philadelphia, PA.

Dr. Marin received support in the form of loaned ultrasound equipment for the duration of the study from SonoSite, Inc. The authors have no potential conflicts of interest to disclose.

Registered at clinicaltrials.gov: NCT00595881.

Supervising Editor: Chris Moore, MD.

Address for correspondence and reprints: Jennifer Marin, MD, MSc; e-mail: jennifer.marin@chp.edu.

Skin and soft tissue infections (SSTIs) encompass a spectrum of disease from cellulitis to frank abscess. Treatment of most abscesses requires incision and drainage¹⁻⁸ or needle aspiration,⁵ while cellulitis is treated with systemic antibiotics and supportive care. It may be difficult to distinguish between these two entities, as both have similar clinical features.⁹ In some cases the physical examination alone may provide insufficient information as to the extent of the infection.⁸ Therefore, as the presence or absence of purulent material may be difficult to determine, children may undergo unnecessary drainage procedures, possibly with exposure to procedural sedation. Conversely, if a fluid collection is missed on examination, the patient may experience worsening of the disease process and require further treatment and interventions, including additional emergency department (ED) visits.

The ability to differentiate a cellulitis from an abscess by ultrasound (US) has been well described in the radiology literature.¹⁰⁻¹⁴ However, many institutions do not have the resources to support soft tissue US performed by technologists and interpreted by radiologists during "off-hours."^{15,16} US performed at the patient's bedside by the clinician offers the opportunity of immediate integration of sonographic and clinical information. Studies involving bedside emergency ultrasound (EUS) suggest that soft tissue US is a useful adjunct to the clinical examination (CE) in adults and may alter clinical management.^{17,18}

The role of EUS in the ED evaluation of SSTIs in the pediatric population has not been fully evaluated. Extrapolating data from the adult to the pediatric population is problematic, as young children may be less cooperative for the US examination than adults, making an examination difficult to accurately perform and interpret. The primary aim of this study was to compare the test characteristics of CE alone, consisting of history and physical examination, to those of CE with the addition of EUS (CE+EUS) for determining SSTIs requiring drainage in pediatric patients. We hypothesized that test characteristics for CE+EUS would be better than those of CE alone.

METHODS

Study Design

We conducted a prospective evaluation of CE+EUS as a diagnostic test for the evaluation of SSTIs in pediatric ED patients. The study adhered to the Standards for Reporting of Diagnostic Accuracy (STARD) criteria for research.¹⁹ Parents or guardians provided written consent, and patients capable of understanding the consent process provided assent. The institutional review board at our institution approved the study.

Study Setting and Population

Patients were enrolled on a convenience basis from July 2008 through April 2010 in a tertiary care, university-affiliated, urban pediatric ED, with approximately 90,000 visits annually. During the study period, trained research associates screened all ED visits between 7 a.m. and 12 a.m., 7 days per week using the ED electronic patient tracking system.

Patients were eligible for enrollment if they were 2 months to 19 years of age and the attending physician responsible for the management of the patient ("treating physician") considered the diagnosis of an isolated SSTI requiring treatment with systemic antibiotic therapy. It was standard practice at our institution to treat SSTIs with systemic antibiotics, regardless of whether a drainage procedure was performed. We included lesions with a history of drainage prior to the ED visit, since a history of drainage did not preclude the possibility of a recurrent or persistent collection requiring drainage at the ED visit. We excluded patients without an English-speaking parent or guardian available, previously enrolled patients, patients who had imaging (such as US or computed tomography) of the lesion prior to arrival to our ED, patients in custody of law enforcement, and immunocompromised patients. We also excluded lesions involving the face, genital, or perirectal region; postoperative wound infections; paronychia; and infections surrounding indwelling catheters or tubes, because we determined, a priori, that either a subspecialty consultant would likely make management decisions for these lesions or the infection would represent a process other than a simple SSTI.

Study Protocol

EUS Use. A total of eight pediatric emergency medicine (PEM) attending and fellow physicians ("study physicians") were trained to perform soft tissue US. The principal investigator served as one of the study physicians and completed prior US training in accordance with the recommendations of the American College of Emergency Physicians.²⁰ Seven other physicians with limited or no prior experience in EUS completed a 6-hour training program that included lectures and hands-on scanning practice.²¹ Following the course, these physicians were supervised at the bedside by experienced sonologists (senior emergency medicine residents and the principal investigator) and had to perform a minimum of five proctored exams, 80% of which had to be correctly interpreted and deemed technically adequate prior to enrolling patients in the study. This training curriculum was previously reported and demonstrated that novice PEM physicians were able to develop technical proficiency in soft tissue EUS and interpret images with excellent agreement with an expert.²¹ In addition, the expert sonologist, who was blinded to the CE by the study and treating physicians and to the outcome of the lesion, reviewed 75% of the US scans performed throughout the study and provided feedback to the study physicians for quality assurance.

A standardized data collection sheet was used to obtain US information and study physicians recorded digital video clips and still images in a systematic fashion. Study physicians were instructed to scan the area of interest and record video clips in two orthogonal planes and note signs of cellulitis (cobblestoning, thickened and/or hyperechoic dermis) and signs of an abscess (hypoechoic, heterogeneously echogenic, irregularly shaped lesion with posterior acoustic enhancement). If a fluid collection was identified, it was measured in three orthogonal axes and still images

were recorded. It was at the study physician's discretion whether to image the contralateral side for comparison, to use compression to evaluate for mobility of pus, or to use color flow Doppler. Figure 1 demonstrates the spectrum of lesions identified by US.

Ultrasound examinations were performed using a SonoSite MicroMaxx (SonoSite, Inc., Bothell, WA) machine using a 6- to 13- or 5- to 10-MHz linear array transducer, or in rare cases of deep buttock abscesses, a 2- to 5-MHz curved array transducer. The digitally recorded clips (in .avi format) and images (in .bmp format) were transferred from the US machine onto a compact flash disc and then to a computer hard drive for image review.

Enrollment. Two groups of patients were enrolled. The primary group (CE+EUS group) was composed of those patients who presented when a study physician (who could not also be the treating physician for that patient) was available to perform CE+EUS. Patients who presented when no study physician was available to perform EUS (no-EUS group) were enrolled as a second group to evaluate for selection bias. In the no-EUS group, no EUS was performed and we obtained only demographic and lesion information and final outcome. A physician member of the treating team, using a tape measure, measured the length of erythema, induration, and fluctuance in two dimensions at the bedside for all patients. Up to three separate lesions could be assessed per enrolled patient. In such cases, each lesion was analyzed as a separate data point. If a patient had more than three lesions, the treating physician decided which three should be evaluated.

For the EUS group, treating attending physicians performed CE and recorded "yes," "no," or "uncertain" regarding the presence of a lesion requiring drainage. Similarly, study physicians, blinded to the treating physician CE, performed their CEs and recorded their diagnoses. Following each CE, the study physician performed EUS and recorded an opinion ("yes," "no," or "uncertain") as to whether their combined CE+EUS revealed a lesion requiring drainage. To minimize test-review bias,²² all treating and study physician CEs and EUS exams were performed prior to diagnostic or treatment procedures by the treating team.

For the very reason that the diagnostic accuracy of EUS in the evaluation of SSTIs in children is unknown, we had clinical equipoise as to its performance and therefore conducted the study as a nonintervention study, without using the information from CE+EUS in the clinical management of patients. As such, the treating attending physician made all clinical decisions blinded to the results of EUS. Patients and families were also blinded to the study physician interpretation of CE+EUS. Treating physicians were able to order any tests they thought clinically indicated to manage and treat patients (including US examinations from the department of radiology); however, the clinical impression was recorded prior to obtaining such ancillary studies. At the time of this study, EUS was not authorized for use in clinical decision-making within our institution's ED, and its use was strictly limited to this study; therefore, physicians were unable to use US outside the confines of the study protocol.

Data Collection. We collected data for each patient on a study form completed by the research associate, the treating physician caring for the patient, and the study physician performing EUS and entered the data into an electronic database (Access, 2007, Microsoft Corp., Redmond, WA). After completion of data entry, we verified all data by comparing database entry with all original data collection forms.

Outcomes

Using information from previous studies, we developed an a priori composite reference standard using the findings from the drainage procedure (if performed) or information obtained from follow-up.^{23,24} Therefore, the outcome of a lesion requiring drainage was defined in one of two ways: 1) drainage procedure in the ED (incision and drainage, needle aspiration, or manual pressure), revealing pus; or 2) follow-up^{17,23} (if no ED drainage procedure was performed), indicating progression within 2 calendar days to spontaneous drainage or pus expressed from a drainage procedure.

We recognized that there would be multiple methods in which to obtain follow-up information. We, therefore, established a hierarchy, such that in cases with more than one follow-up method available, the method of

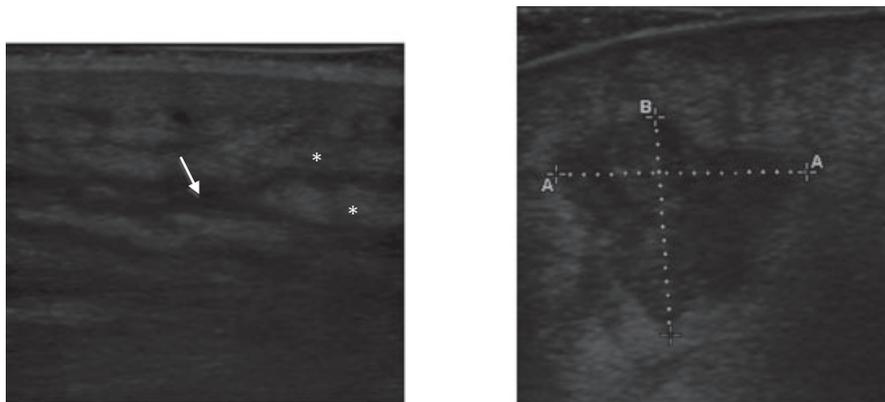


Figure 1. Ultrasound images demonstrating fat lobules (*) with interlobular fluid (arrow) consistent with cellulitis (left) and irregular-shaped hypoechoic fluid collection (measured) with posterior acoustic enhancement consistent with an abscess (right.)

highest priority (in descending order: medical record review, phone follow-up, primary care physician follow-up questionnaire) was used. Medical record review was placed before other methods of follow-up as it would best capture objective evaluation of lesions by a medical provider. If we were unable to obtain any follow-up information on a lesion, that lesion was excluded from the analysis. Two study investigators completed medical record review and three trained research assistants and the principal investigator performed phone follow-up, all of whom were blinded to study physician assessments (CE and EUS results).

Data Analysis

We described subject and lesion characteristics using standard summary statistics. To evaluate for selection bias, we compared demographics and outcomes between patients and lesions in the EUS and no-EUS groups. For patients in the EUS group, we estimated sensitivity, specificity, positive and negative predictive values, and the associated 95% confidence intervals (CIs) for CE alone and for CE+EUS. Prior studies showed a lack of agreement between physicians in their clinical evaluations of SSTIs.^{25,26} Therefore, we further divided the CE+EUS group such that we analyzed clinically evident lesions separately from those which were not clinically evident, based on CE. Clinically evident lesions were defined as those for which both the treating and study physicians agreed and were each certain in their diagnoses for whether the lesion required drainage. Lesions that were not clinically evident were those for which the treating and study physicians either disagreed with each other or were “uncertain” in their diagnoses. We determined inter-rater reliability between physicians using percentage agreement and Cohen’s kappa statistic.²⁷

We used a model-based approach,²⁸ at the level of the lesion, extended to a multilevel mixed-effects logistic regression model,²⁹ to adjust for the hierarchical nature of the data. We used the bootstrap method with 1,000 replications³⁰ to obtain valid CIs and to compare the test characteristics of the two diagnostic tests. The bootstrap approach both took into account the nonindependence of these paired measurements and adjusted for clustering of data at the level of the lesion and also the study physician.

Assuming a baseline sensitivity of physician CE similar to that published in a study of adult patients with SSTIs (86%),¹⁷ a type 1 error rate of 0.05, and an intraclass correlation coefficient of 0.5 for the relationship of lesions within patients, we estimated that a sample size of 393 lesions would provide 80% power to detect at least a 9% difference in the sensitivity of CE+EUS compared to CE alone. We performed all statistical analysis using Stata 10.0 software (StataCorp, College Station, TX).

RESULTS

During the study period, 3,743 children presented with SSTIs (Figure 2). Of these, 1,511 were present when neither research associates nor study physicians were available. Of the remaining 2,232, a total of 63 refused

to participate in the study and 1,414 patients did not meet inclusion criteria. A total of 420 lesions were enrolled in the EUS group, and 453 lesions were enrolled in the no-EUS group. We obtained outcome data on 98% of lesions in both the EUS and the no-EUS groups. Those lesions that did not have follow-up information were excluded from the analysis of test characteristics. An additional 23 lesions in the EUS group were not included in the analysis because either the treating or study physician CE data was not available, resulting in 387 lesions in 348 patients to be analyzed in the EUS group and 442 lesions in 370 patients in the no-EUS group.

Patients enrolled in the EUS group had a median age of 7 years (IQR = 2.8–14.1 years) and the majority (65%) were African American (Table 1). Most lesions were located on the leg or buttock, and the prevalence of an abscess requiring drainage, as defined by our reference standard, was 62%. In assessing for selection bias for patients enrolled when a study physician was available, patient demographics between the EUS and no-EUS groups were similar, with the exception of a higher proportion of females in the EUS group. Lesions in the EUS group had a larger median area of induration, as measured on CE, when compared with lesions in the no-EUS group, but were otherwise similar.

Table 2 shows study physician CE and CE+EUS impressions and lesion outcomes for all 387 lesions in the EUS group. Overall, the addition of a positive EUS result to an already positive CE did not result in a significant improvement in the proportion of correctly diagnosed lesions with pus (83.2% vs. 87.6%; difference = 4.5%, 95% CI = -2.9% to 11.7%). Similarly, the addition of a negative EUS result to an already negative CE did not result in a significant improvement in the proportion of lesions correctly diagnosed as not requiring drainage (difference = 9.1%, 95% CI = -2.4% to 19.7%).

The agreement between the CE assessments of the study physicians and the treating physicians was 62.8% ($\kappa = 0.38$, 95% CI = 0.30 to 0.46, indicating only “fair” agreement).³¹ Table 3 compares the test characteristics for the study physician CE and CE+EUS for the clinically evident lesions and shows no improvement with the addition of EUS for those lesions. For the remaining 159 lesions (41.1%) that were not clinically evident, CE+EUS was positive in 83, negative in 55, and uncertain in 21 lesions. In the 138 lesions when CE+EUS was either positive or negative, CE+EUS had a sensitivity of 77.6% (95% CI = 58.2% to 89.7%) and a specificity of 61.3% (95% CI = 45.6% to 71.2%), for an overall accuracy of 70.3% (95% CI = 61.9% to 77.8%).

We examined further the 159 lesions that were considered not clinically evident. The median age of the patients in this group was 4.7 years (IQR = 1.6 to 12.0 years), compared to 9.3 years (IQR = 1.9 to 15.2 years) in the clinically evident group ($p = 0.003$). Fifty (31.5%) lesions were located on the leg, and 44 (27.7%) were located on the buttock, which was similar to the location distribution in the clinically evident group ($p = 0.14$). Seventy-three (45.9%) were noted to have pus prior to the ED visit, which was similar to that in the clinically evident group ($p = 0.27$). Eighty-seven lesions (54.7%) were abscesses requiring drainage per

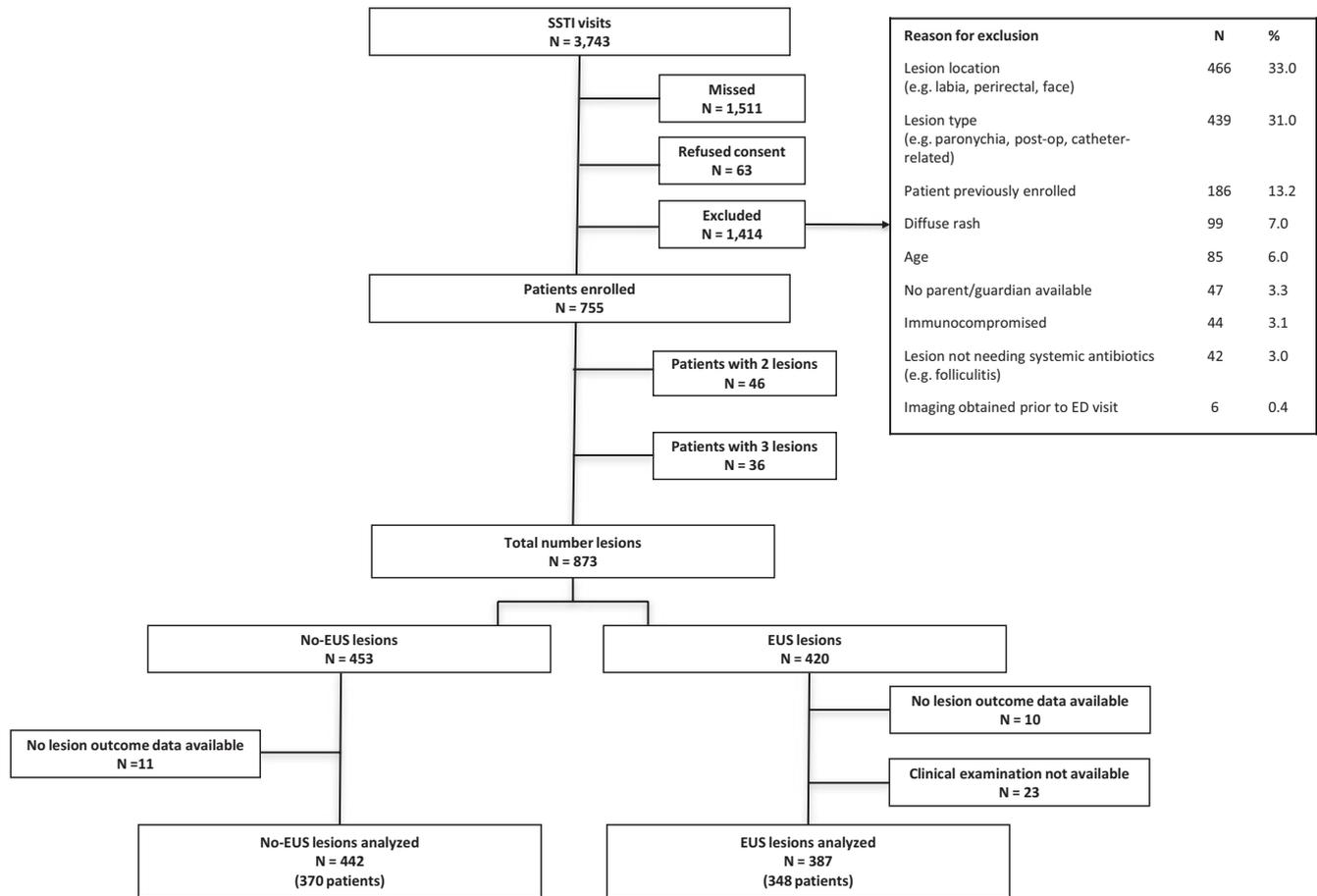


Figure 2. Flow diagram of patient/lesion enrollment. EUS = emergency ultrasound; SSTI = skin or soft tissue infection

the outcome criteria, compared to 66.7% requiring drainage in the clinically evident group ($p = 0.02$).

The median abscess volume as measured on EUS for those lesions without either expression of pus by ED drainage or by follow-up criteria was 0.24 cm^3 (IQR = 0.06 to 0.64 cm^3), compared to a median volume of 0.51 cm^3 (IQR = 0.16 to 1.39 cm^3) for lesions that did yield pus ($p < 0.001$).

Seventy-two lesions in the EUS group also underwent US evaluation in the department of radiology as requested by the treating physician. For 10 of these lesions, the study physicians rated their CE+EUS examination as uncertain. Evaluating the remaining 62 lesions, study physician CE+EUS had a higher sensitivity (80%, 95% CI = 58.6% to 92.3%) for detecting a lesion requiring drainage than radiology US (45.7%, 95% CI = 34.3% to 60.5%; difference = 34.2%, 95% CI = 16.7% to 54.5%). The difference in specificity between the two groups was not significant.

A total of 303 US exams were reviewed by the expert sonologist for the presence of abscesses. The agreement between the study physician and expert as expressed by the kappa statistic was 0.69 (95% CI = 0.64 to 0.70), indicating "substantial" agreement.³¹

DISCUSSION

Our study of pediatric patients demonstrates that for clinically evident lesions, CE was highly accurate for

diagnosing SSTIs requiring drainage and the addition of EUS did not improve the accuracy. In cases that were not clinically evident, we found that CE+EUS was reasonably sensitive, and more sensitive than CE, although specificity was only moderate and not statistically improved from CE alone. Our findings differ from those of prior studies. One study of 135 adult patients with SSTIs¹⁷ found that EUS had a sensitivity of 98% and a specificity of 88%. Nearly half (25 of 51) of the patients who did not receive drainage (presumed cellulitis by EUS) were lost to follow-up and were excluded from the analysis. If any of these lesions ultimately expressed pus, the sensitivity of EUS would have been significantly lower. There have been two small studies of pediatric patients with SSTIs,^{32,33} in which CE+EUS sensitivity was 90% to 98% compared with CE sensitivity of 75% to 79%, and CE+EUS specificity was 69% to 83% compared with CE specificity of 67% to 80%. These studies suffered from small sample sizes,^{32,33} as well as a lack of patient follow-up.³³ None of the aforementioned studies involved formal statistical comparisons to assess for true differences between the CE and CE+EUS. For those studies that included follow-up, there was a lengthy follow-up period, which may not reflect the disease pathology occurring at the time of the ED visit when CE+EUS was performed. We restricted our follow-up period to 2 days to minimize the misclassification of lesions. Perhaps the most important

Table 1
Comparison of Patient Demographics and Lesion Characteristics for All Enrolled Patients by Group

Characteristics	EUS Group	No-EUS Group	p-value
Patient	<i>n</i> = 348	<i>n</i> = 370	
Age (yr), median (IQR)	7.0 (1.8–14.1)	5.8 (2.1–12.8)	0.60
Race/ethnicity			
African American, non-Hispanic	225 (65)	248 (67)	0.64
White, non-Hispanic	91 (26)	96 (26)	
Hispanic	14 (4)	9 (2)	
Female	201 (58)	182 (49)	0.02
SSTI exposure history*	144 (41)	145 (39)	0.5
Lesion	<i>n</i> = 387	<i>n</i> = 442	
Location			
Leg	122 (32)	150 (34)	0.96
Buttock	96 (25)	105 (24)	
Arm	26 (7)	34 (8)	
Abdomen	24 (6)	33 (7)	
Pus noted prior to ED visit	193 (50)	220 (50)	0.88
Area (cm ²), median (IQR)			
Erythema	9 (1–30)	6 (1–20)	0.14
Induration	6 (1–16)	4 (1–12)	0.001
Fluctuance	0 (0–2)	0 (0–1)	0.52
Lesions not drained in ED	156 (40)	174 (39)	0.78
Lesion outcome determined by medical record review	78 (50)	89 (51)	
Lesion outcome determined by phone follow-up	78 (50)	85 (49)	
Lesion outcome determined by PCP questionnaire	0 (0)	0 (0)	
Prevalence of abscess requiring drainage (per reference standard of either ED drainage or follow-up)	239 (62)	266 (60)	0.64

Data are reported as *n* (%) unless otherwise noted.
PCP = primary care physician; SSTI = skin and soft tissue infection.
*Exposure history defined as personal or close contact with history of SSTI within past year.

methodologic difference is that in these prior studies, physicians were allowed to incorporate EUS into lesion management decisions. This practice may lead to a bias in favor of the CE+EUS test characteristics. SSTIs represent a spectrum of disease, and this spectrum is well visualized by US. Consequently, there may be differences of opinion as to which lesions would be amenable to drainage versus conservative therapy. Therefore, although a lesion produced an amount of purulent drainage when incision and drainage was employed due to EUS information, the lesion may have also responded to systemic antibiotics alone if no drainage was performed. Conversely, if the conclusion after EUS was that a lesion did not require

drainage, it is possible that if the lesion was drained in the ED, pus would have been obtained.

Our study was able to capture the inherent physician uncertainty that exists when diagnosing SSTIs. In addition, it is important to note that there was only “fair” agreement between physicians in their diagnostic clinical impressions, which is similar to findings by other investigators.²⁵ As a result, physicians should take into account the limitations of CE in diagnosing SSTIs. As expected, our study did demonstrate a larger sonographic abscess volume in the group of lesions requiring drainage; however, further investigation is needed into sonographic measurements that define the need for a drainage procedure.

Although our study only enrolled patients when a study physician was available, based on our analysis of the EUS and no-EUS groups, no clinically relevant selection bias was present. Our follow-up rate was high, with only 2% of lesions without outcome data; therefore, verification bias²² was unlikely to affect our results. Finally, study physicians’ US scans were reviewed throughout the study to ensure adequate performance of EUS. Analysis of the reliability of those images indicated that study physicians were proficient in their interpretation of images.

The sensitivity and negative predictive value of CE+EUS were significantly higher than those of radiology-performed US. This may indicate an advantage of sonologists to directly integrate the CE in their interpretation of imaging modalities that outweighs the experience and knowledge of imaging specialists. This information may be useful to practitioners who, due to uncertainty of a clinical diagnosis of a lesion requiring drainage, are considering a radiology-performed US.

LIMITATIONS

The limitations of this study should be noted. Our reference standard was designed to identify lesions requiring drainage by incorporating ED management and a narrow follow-up period, since it would be unethical to require ED drainage of all lesions, particularly those deemed to not require drainage by the treating team. It is possible that this standard led to misclassification in several ways. First, lesions correctly identified as not requiring drainage at the time of EUS might have progressed to abscess formation within the 2-day follow-up period, leading to misclassification as a false-negative due to the natural progression of disease; in fact, the lesion would not have benefitted from drainage at the time of the EUS. Also, there is the case where EUS was interpreted as a lesion not requiring drainage because the lesion was sonographically small, but the lesion was drained and any amount of pus was obtained. This may have represented a false-negative misclassification of a lesion that might have been adequately treated by antibiotics alone. Currently, there is no consensus as to how small a collection of pus does not require drainage and how much pus drained from a lesion constitutes evidence of a collection that should have been drained. Finally, some abscesses identified by EUS may have been inadequately drained (i.e., no pus with drainage), resulting in the misclassification of

Table 2
Study Physician CE and CE+EUS Impressions and Outcome (Lesion Requiring Drainage) for All Lesions in the EUS Group

Physician Impression	CE Positive (<i>n</i> = 196), 50.5%	CE Negative (<i>n</i> = 106), 27.3%	CE Uncertain (<i>n</i> = 85), 22.0%
ED drainage procedure	161 (82.1%)	19 (17.9%)	51 (60.0%)
Lesions requiring drainage*	163 (83.2%)	24 (22.6%)	52 (61.8%)
CE+EUS positive	<i>n</i> = 170	<i>n</i> = 11	<i>n</i> = 49
Lesions requiring drainage*	149 (87.6%)	6 (54.6%)	38 (77.6%)
CE+US negative	<i>n</i> = 14	<i>n</i> = 81	<i>n</i> = 27
Lesions requiring drainage*	5 (35.7%)	11 (13.6%)	11 (40.7%)
CE+US uncertain	<i>n</i> = 12	<i>n</i> = 14	<i>n</i> = 9
Lesions requiring drainage*	9 (75.0%)	7 (50.0%)	3 (33.3%)

N = 387.

CE = clinical examination; CE+EUS = clinical exam with bedside emergency ultrasound.

*Outcome of lesion requiring drainage defined as pus obtained during ED drainage procedure or on follow-up.

Table 3
Test Characteristics of Study Physician CE Alone and CE+EUS of Those Lesions That Were Clinically Evident and Not Clinically Evident

Physician Impression	Number	Lesions Requiring Drainage per Outcome	Sensitivity, % (95% CI)	Specificity, % (95% CI)	PPV (95% CI)	NPV (95% CI)
Clinically evident (<i>n</i> = 228)						
Study/treating physician CE+	156	144	94.7 (90.2 to 97.9)	84.2 (74.7 to 91.7)	92.3 (87.3 to 96.3)	88.9 (80.2 to 95.3)
Study/treating physician CE-	72	8				
Study physician CE+EUS+	147	134	93.1 (88.4 to 96.6)	81.4 (70.9 to 90.0)	91.2 (85.8 to 95.4)	85.1 (76.1 to 92.5)
Study physician CE+EUS-	67	10				
Study physician CE+EUS uncertain	14	8				
Difference			-1.7 (-3.4 to 0)	-2.8 (-9.7 to 3.2)	-1.2 (-3.8 to 1.7)	-3.8 (-7.2 to 0.2)
Not clinically evident (<i>n</i> = 159)						
Study physician CE+	40	19	43.7 (0.0 to 85.3)	42.0 (0.0 to 79.5)	42.9 (0.0 to 66.7)	45.6 (0.0 to 71.4)
Study physician CE-	34	16				
Study physician CE uncertain	85	52				
Study physician CE+EUS+	83	59	77.6 (58.2 to 89.7)	61.3 (45.6 to 71.2)	71.1 (62.5 to 79.5)	69.1 (56.5 to 79.1)
Study physician CE+EUS-	55	17				
Study physician CE+EUS uncertain	21	11				
Difference			33.9 (1.2 to 66.6)	19.3 (-13.8 to 52.4)	28.2 (8.8 to 47.6)	23.2 (0.6 to 45.8)

CE = clinical examination; CE+EUS = clinical examination plus bedside emergency ultrasound; PPV = positive predictive value; NPV = negative predictive value.

EUS as a “false-positive.” All of these scenarios would have biased our study results toward the null hypothesis of no difference between the test characteristics of CE+EUS and CE. These issues will only be resolved when sonographic findings and their relationship with the spectrum of interventions (conservative management vs. drainage) are more extensively studied. This will allow us to better define the “cutoffs” for invasive procedures by developing characteristics of lesions that do and do not benefit from drainage based on clinical outcomes.

Lesion management was determined by the treating physician and therefore was likely biased in favor of clinical impression. However, if treating physicians were able to incorporate EUS results, lesion management may have been different and the study physician

CE and CE+EUS test characteristics may have been higher. However, as stated in the Methods, we determined blinding of EUS results to be the most methodologically rigorous means of evaluating our hypotheses, given the current state of scientific knowledge on this topic and the resultant clinical equipoise regarding the diagnostic accuracy of EUS.

Despite blinding the study physicians to the treatment team management plan, there may have been test review bias if subtle clues revealed the management plan to the study physician prior to performing EUS (e.g., an intravenous catheter in place suggesting sedation or topical anesthesia over the lesion suggesting drainage procedure to be done). This bias would also minimize any difference in test characteristics between CE and CE+EUS.

Finally, our study may not be generalizable to non-PEM trained physicians, those without significant exposure to SSTIs, or those with more prior experience using EUS. The prevalence of an abscess requiring drainage per our reference standard was 62%; therefore, our predictive values are only applicable to those institutions with similar prevalences.

CONCLUSIONS

We demonstrated that in our pediatric study population, the addition of emergency ultrasound to the clinical examination for the diagnosis of skin and soft tissue infections does not improve on the test characteristics of the clinical examination alone for clinically evident lesions. Many lesions are not clinically evident, and in these cases emergency ultrasound may be useful as a diagnostic adjunct. Further trials are needed that incorporate emergency ultrasound into patient care and evaluate whether the addition of emergency ultrasound improves clinical outcomes in pediatric patients with skin and soft tissue infections.

The authors thank the study physicians (Elizabeth Alpern, Monika Goyal, Toni Gross, Rakesh Mistry, Sage Myers, Kyle Nelson, and Mark Zonfrillo) who donated their time and skills to enroll patients; Stephen Yakscoe and Matthew Albert for their dedication to the study as research coordinators; and the patients and families who volunteered to participate in this study. We are also grateful to SonoSite, Inc., for the use of their ultrasound machine for the duration of the study and to the decision editor of *Academic Emergency Medicine* for his insightful suggestions.

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