Abscess Incision and Drainage With or Without Ultrasonography: A Randomized Controlled Trial

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Study objective: We hypothesize that clinical failure rates will be lower in patients treated with point-of-care ultrasonography and incision and drainage compared with those who undergo incision and drainage after physical examination alone.

Methods: We performed a prospective randomized clinical trial of patients presenting with a soft tissue abscess at a large, academic emergency department. Patients presenting with an uncomplicated soft tissue abscess requiring incision and drainage were eligible for enrollment and randomized to treatment with or without point-of-care ultrasonography. The diagnosis of an abscess was by physical examination, bedside ultrasonography, or both. Patients randomized to the point-of-care ultrasonography group had an incision and drainage performed with bedside ultrasonographic imaging of the abscess. Patients randomized to the non–point-of-care ultrasonography group had an incision and drainage performed with physical examination alone. Comparison between groups was by comparing means with 95% confidence intervals. The primary outcome was failure of therapy at 10 days, defined as a repeated incision and drainage, following a per-protocol analysis. Multivariate analysis was performed to control for study variables. Our study was designed to detect a clinically important difference between groups, which we defined as a 13% difference.

Results: A total of 125 patients were enrolled, 63 randomized to the point-of-care ultrasonography group and 62 to physical examination alone. After loss to follow-up and misallocation, 54 patients in the ultrasonography group and 53 in the physical examination alone group were analyzed. The overall failure rate for all patients enrolled in the study was 10.3%. Patients who were evaluated with ultrasonography were less likely to fail therapy and have repeated incision and drainage, with a difference between groups of 13.3% (95% confidence interval 0.0% to 19.4%). Abscess locations were predominantly torso (21%), buttocks (21%), lower extremity (18%), and axilla or groin (16%). There was no difference in baseline characteristics between groups relative to abscess size, duration of symptoms before presentation, percentage with cellulitis, and treatment with antibiotics.

Conclusion: Patients with soft tissue abscesses who were undergoing incision and drainage with point-of-care ultrasonography demonstrated less clinical failure compared with those treated without point-of-care ultrasonography. [Ann Emerg Med. 2018;■:1-7.]

Please see page XX for the Editor's Capsule Summary of this article.

0196-0644/$-see front matter

https://doi.org/10.1016/j.annemergmed.2018.05.014

INTRODUCTION

Treatment of superficial soft tissue abscesses has not changed significantly during the last few decades, with incision and drainage as the standard of care. Point-of-care ultrasonography is used clinically for patients presenting with abscesses in the emergency department (ED),[1] but there is limited literature supporting its use. The few studies on point-of-care ultrasonography in patients presenting with an abscess are retrospective or do not focus on clinical outcomes.[2-5] The question of whether point-of-care ultrasonography improves clinical outcomes has not been prospectively studied, to our knowledge. We hypothesized that clinical failure rates would be lower by a clinically important margin in patients treated with point-of-care ultrasonography and incision and drainage compared with that of those who underwent incision and drainage after physical examination alone.

MATERIALS AND METHODS

Study Design and Selection of Participants

We performed a prospective randomized controlled trial of adult patients presenting to the ED with an uncomplicated soft tissue abscess. We used a parallel design with 1:1 allocation. A convenience sample of patients requiring incision and drainage was randomized to point-of-care ultrasonography, physical examination and incision and drainage, or physical examination and incision and drainage without point-of-care ultrasonography. The study

Editor's Capsule Summary

What is already known on this topic

Ultrasonography can assist with accurate diagnosis of skin abscess; it is unknown whether use of ultrasonography improves outcomes of incision and drainage.

What question this study addressed

One hundred twenty-five patients with skin abscesses ranging in size from 0.4 to 79 cm^2 were randomized to incision and drainage with or without use of bedside ultrasonography.

What this study adds to our knowledge

Rates of failure, defined as a repeated instance of incision and drainage, were 3.7% with bedside ultrasonography and 17% without it.

How this is relevant to clinical practice

Beside ultrasonography may improve success of abscess incision and drainage. Results should be confirmed because of limitations from small sample size and outcome measures.

was performed at a large academic ED with an annual census of 92,700 that covers both an urban and a suburban population. This study was approved by the UMass institutional review board.

We identified patients for inclusion in this study as adults presenting to a single large academic ED who had a suspected skin abscess requiring incision and drainage. Patients were included in the study if they were determined to have an abscess requiring incision and drainage, diagnosed by physical examination or ultrasonography. Patients were identified by clinical staff working in the ED, who alerted research staff for assessment for enrollment. Inclusion criteria were atraumatic swelling, pain, or erythema consistent with an abscess cavity. Patients were identified for enrollment by clinical staff and enrolled by research staff present in the ED. Patients clinically ill at presentation (defined as documentation of fever, hypotension, or "appearing clinically ill") were not considered for study inclusion. Patients with a soft tissue abscess after foreign body trauma or animal bite were excluded. Patients presenting with paronychia, dental abscesses, genital abscesses, or peritonsillar abscesses, or who were unwilling or unable to consent, were also excluded.

Because of the nature of the study intervention, both patients and clinicians were not blinded to the study intervention arm. Clinicians performing follow-up and determining patient outcomes were blinded to the study intervention arm and ultrasonographic data. Information on demographics (eg, age, sex), medical history (eg, diabetes, intravenous drug abuse, previous abscesses), abscess characteristics (eg, size, location, presence of purulence, duration of symptoms, erythema), and symptoms (eg, fever, tachycardia, pain) was obtained by research personnel at the initial visit, using a standardized data form. Abscess size measurement was recorded as the length and width of fluctuance from the outer edges of the fluctuant cavity. For abscesses without palpable fluctuance, the abscess size measurement was recorded according to the outer margins of induration.

Soft tissue ultrasonography imaging was standardized, including image acquisition and interpretation. Abscess images were obtained with a high-frequency linear transducer, with separate images of the abscess cavity and surrounding tissue in the long and short axis. Interpretation of the soft tissue ultrasonography was either positive or negative for an abscess cavity. The sonographic definition of an abscess cavity included either hypoechoic focus with surrounding induration or hyperechoic or isoechoic focus with posterior acoustic enhancement and surrounding induration. The incorporation of ultrasonography into the incision and drainage was not standardized but fell into 3 categories: static ultrasonographic guidance when ultrasonographic images were obtained before incision and drainage, dynamic ultrasonographic guidance when ultrasonographic images were obtained during incision and drainage, and comprehensive ultrasonographic guidance when cycles of images were obtained before and after incision and drainage attempts, with repeated incision and drainage if residual abscess cavities were visualized after incision and drainage.

Patients were approached by study personnel for written consent and evaluation for inclusion and exclusion criteria. They were randomized at enrollment to point-of-care ultrasonography, physical examination, and incision and drainage; or physical examination and incision and drainage. Randomization was performed with a computerized randomization schedule using 20-patient block randomization schemes (http://www.randomization.com). Allocation concealment was accomplished with sequentially numbered sealed envelopes.

For patients randomized to point-of-care ultrasonography, ultrasonographic images were obtained before incision and drainage. Ultrasonographic imaging was performed by clinicians (emergency medicine faculty and residents) with experience in soft tissue ultrasonography

(median 65 soft tissue ultrasonographic images; interquartile range 31 to 275). Additional ultrasonographic imaging was performed during or after the incision and drainage at the discretion of the clinician performing the drainage. Some patients randomized to physical examination alone underwent point-of-care ultrasonographic imaging before incision and drainage if the diagnosis of an abscess requiring incision and drainage was in doubt. For these patients, a separate clinician would perform the ultrasonography, and detailed information beyond confirmation of the presence or absence of an abscess was blinded to the clinician performing the incision and drainage.

For both study groups, incision and drainage was performed with local anesthetic, with a linear incision over the abscess cavity. The abscess cavity was manually explored and purulence was expressed. The placement of a wick into the abscess cavity and prescription of antibiotics was performed at the discretion of the treating clinician. Patients were asked to return in 2 to 3 days for a repeated examination, at which time the clinician (not research staff) determined the need for additional therapy. Patients were also contacted by telephone 10 days later and asked a series of scripted questions related to clinical outcome by physician research staff. Sixty-eight patients returned for in-person follow-up on days 2 to 3 after incision and drainage. All patients were telephoned for follow-up on days 7 to 14.

Outcome Measures

Primary outcome was failure of therapy, defined as having a repeated incision and drainage that produced purulence. Patients were categorized as failing or not failing initial therapy at the 10-day point after incision and drainage after in-person or telephone follow-up. Failure was defined in all cases as having a repeated incision and drainage performed. A repeated incision and drainage was performed in cases in which ultrasonography demonstrated a retained abscess pocket that was not draining, or in which the patient returned with fluctuance at the abscess site that did not produce purulence with manual expression or manual exploration of the abscess cavity. Cases in which incision and drainage produced only blood or serosanguineous fluid were not characterized as failure. Secondary outcomes included need for additional antibiotics and continued symptoms (pain and purulence) at follow-up. To ensure blinding, follow-up data were recorded on separate study sheets for both in-person and telephone follow-up. Clinical staff performed follow-up without access to the study intervention, with the exception of 2 cases in which they were unavailable and research staff performed the in-person follow-up.

Primary Data Analysis

The study was designed as a superiority trial using assumptions based on previous research. In accordance with previously published abscess studies and site-specific retrospective data, we estimated the failure rates of incision and drainage after physical examination alone to be 20% and those of incision and drainage after point-of-care ultrasonography to be 7%.[6-8] Although many recent studies of patients with soft tissue abscess incision and drainage demonstrate failure rates in the mid teens, these studies lump patients treated with and without point-of-care ultrasonography together. Power calculation was performed with a 2-sample and 2-sided equality. Assuming a 2-tailed type I error rate of 5%, a sample size of 53 in each group was needed for 80% power to detect a 13% difference between groups.

Data elements were collected on data sheets at enrollment or follow-up and uploaded into a centralized electronic database. Demographic and clinical data are presented as median with interquartile range unless noted. Categorical data are presented as percentile of the representative study group.

Our primary analysis focused on the between-group differences in clinical cure rates after incision and drainage for patients who had follow-up data and thus our primary outcome of clinical cure. In other words, our primary analysis focus excluded patients who lacked information on clinical cure as an outcome to more accurately evaluate outcomes in our intended study group. We performed an additional analysis using intention-to-treat principles.

A multivariate analysis was used to accommodate variations in patient characteristics and clinician practice patterns in regard to adjuvant therapies. Multivariate logistic regression was used to assess whether ultrasonography use was independently associated with treatment failure, controlling for patient and treatment variables. Covariates and confounding variables were chosen according to previous literature and included abscess size, clinician performing incision and drainage, history of intravenous drug abuse, ultrasonography use, and antibiotic use. Analysis was performed with SAS (version 9.4; SAS Institute, Inc., Cary, NC). We examined correlation among our variables with Pearson χ^2 test and found no association ($P>.10$ for all comparisons). This modeling of the data should be considered exploratory because of the limited number of patients who demonstrated clinical failure in the data set.

Analyses were conducted following both the intention-to-treat approach and a per-protocol approach. We used the fit measurements in JMP to assess model overfitting (version 13.1; JMP, Carey NC). There were no missing data for the patients included in the primary analysis.

RESULTS

Characteristics of Study Subjects

This study was performed and reported in conformance to the Consolidated Standards of Reporting Trials (CONSORT) guidelines for randomized trials.[9] Patients were enrolled from January 2015 through July 2017. During that period, 452 patients presented with an abscess and received incision and drainage. Figure 1 shows recruitment and participant flow for the study. Overall, 125 patients were enrolled, 63 to the point-of-care ultrasonography group and 62 to physical examination alone. A total of 15 patients randomized to physical examination alone had diagnostic ultrasonography before incision and drainage, results of which were withheld from the person performing the incision and drainage. Protocol deviations included 3 patients randomized to point-of-care ultrasonography and 2 randomized to physical examination alone. One patient randomized to point-of-care ultrasonography was sent to the operating room and underwent incision and drainage without ultrasonography. Another 2 patients randomized to point-of-care ultrasonography were treated with antibiotics only without incision and drainage. Two patients randomized to physical examination alone underwent ultrasonographically guided incision and drainage. Patient characteristics and adjuvant therapies were balanced between groups, with a few notable exceptions. Patients undergoing ultrasonographically guided treatment were more likely to have purulence on initial examination and were more likely to have it located on the torso. Patients treated after physical examination alone were more likely to have a medical history of IVDA or a previous abscess and receive packing and antibiotics. Abscess location was more likely to be in the torso or buttocks region, but there was a wide range of abscess locations (Table 1).

With a per-protocol analysis, the overall clinical failure rate after incision and drainage for both groups was 10.3% (95% confidence interval [CI] 5.7% to 17.6%). Patients with point-of-care ultrasonography were less likely to fail therapy compared with those receiving physical examination alone (3.7% versus 17.0%), with a difference between groups of 13.3% (95% CI 0.0% to 19.4%). Multivariate logistic modeling demonstrated similar findings, with the largest predictor of failure being the lack of ultrasonography (Table 2). A total of 50 physicians performed incision and drainage on patients enrolled in the study. Most physicians enrolled 1 to 2 patients, with 8

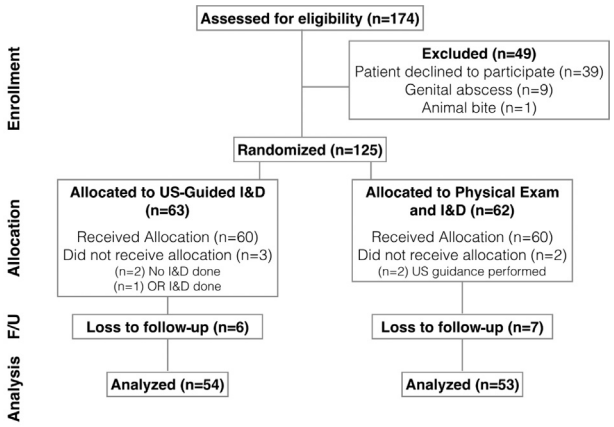


Figure 1. Study flow diagram. *I&D*, Incision and drainage; *OR*, odds ratio; *F/U*, follow-up.

Table 1. Patient characteristics.

Characteristics	POCUS, n = 54	Physical Examination, n = 53
Male sex, No. (%)	26 (48.1)	35 (66)
Age, y		
Median (IQR)	34 (24–45)	31 (26–43)
Range	18–71	18–62
Abscess size, cm^2		
Median (IQR)	7.1 (3–13)	7.1 (3–14)
Range	0.8–79	0.4–57
Abscess size >10 cm^2, No. (%)	19 (35.2)	24 (45.3)
PMHx DM, No. (%)	8 (14.8)	7 (13.2)
PMHx IVDA, No. (%)	4 (7.4)	10 (18.8)
PMHx abscess, No. (%)	28 (51.9)	33 (62.2)
Duration of symptoms, days		
Median (IQR)	4 (3–7)	4 (3–7)
Range	1–10	1–14
Cellulitis, No. (%)	24 (44.4)	24 (45.3)
Purulent drainage, No. (%)	10 (18.5)	7 (13.2)
Adjuvant treatments, No. (%)		
Packing	10 (18.5)	16 (30.2)
Antibiotics (all)	28 (51.9)	33 (62.2)
Began receiving ABX in ED	23 (42.6)	23 (43.4)
Abscess location, No. (%)		
Axilla and groin	9 (16.6)	8 (15.1)
Buttocks	11 (20.3)	12 (22.6)
Head and neck	4 (7.4)	4 (7.5)
Lower extremity	8 (14.8)	11 (20.8)
Upper extremity	6 (11.1)	11 (20.8)
Torso	16 (29.6)	7 (13.2)

POCUS, Point-of-care ultrasonography; *IQR*, interquartile range; *DM*, diabetes mellitus; *IVDA*, intravenous drug abuse; *PMHx*, past medical history; *ABX*, antibiotics.
Area calculated as an ellipse with length×width×π×1/4.

Table 2. Logistic regression analysis assessing effect of intervention on failure among 107 patients.

Predictors	OR	95% CI
Antibiotics		
No	1.00	
Yes	0.56	0.15 to ≈2.15
Hx IVDA		
No	1.00	
Yes	0.84	0.14 to ≈5.15
Size		
Small	1.00	
Large	4.16	0.97 to ≈17.80
Ultrasonography use		
No	1.00	
Yes	0.19	0.04 to ≈0.97

OR, Odds ratio.

physicians enrolling 3 or more patients. One physician enrolled 24 patients. The majority of patients were enrolled by senior residents (n=49) and faculty (n=48). Experience of the providers and numbers enrolled are included in Appendix E1 (available online at http://www.annemergmed.com). There was no clustering of failures with any provider or provider experience level. The 11 clinical failures were treated by 11 providers, divided between faculty (n=4), fellows (n=1), senior residents (n=5), and junior residents (n=1).

Patients who underwent a second incision and drainage at follow-up did so primarily for 2 reasons. The most common reason was increased or constant pain with palpable fluctuance that did not produce purulence with manual compression or mechanical exploration of the incision site. Two patients without palpable fluctuance had ultrasonography performed at follow-up that showed a retained abscess cavity. See Table 3 for reasons for clinical failure. Patients who failed therapy did so most commonly within 3 days of the initial incision and drainage at the in-person follow-up. Seven of the 11 patients with failures had incision and drainage within 3 days of initial therapy (Figure 2).

A few patients in each study arm did not receive the study allocation (Figure 1). Analysis following intention-to-treat principles did not substantively change our primary outcome results. Overall clinical failure for point-of-care ultrasonography and physical examination alone was 4.8% and 16.1%, respectively, following intention-to-treat principles, with a difference between groups of –0.01 and 11.3. Following intention-to-treat principles, we also analyzed our results for patients excluded because of lack of follow-up, using a variety of assumptions (Appendix E1, available online at http://www.annemergmed.com). Assuming no additional failures in the excluded patients or assuming a similar failure rate in the excluded patients did not change our conclusions. Similarly, assuming all excluded patients in the physical examination arm failed but those excluded in the point-of-care ultrasonography arm did not fail did not change our conclusions. Assuming 100% failure after point-of-care ultrasonography but no failure after physical examination alone in excluded patients resulted in no clinical difference in failure rates between groups (13.3% versus 15%, respectively).

At follow-up, some patients had continued symptoms, with pain as the most common (36 of 107; 33.6%), followed by continued purulence (24 of 107; 22.4%). A majority of patients were receiving antibiotics when presenting to the ED or began receiving antibiotics (57%). More patients randomized to physical examination alone received antibiotics (52% versus 62%; difference between groups 10.4%; 95% CI –10.1% to 30.0%). The majority of patients reported that their symptoms were resolved or improved (84 of 107; 78.5%). There was no clinical difference in symptoms between study groups at follow-up, with less than an 8% difference between groups for all symptoms. See Appendix E1 (available online at http://www.annemergmed.com) for more detail on secondary findings at follow-up. A total of 13 patients (10.4%) were lost to follow-up, with a similar number in each study group. Because of our inability to determine their primary outcome, they were excluded from analysis.

LIMITATIONS

This study has a number of limitations. Not all patients who presented with an abscess during the study period were enrolled, and there undoubtedly is some selection bias. We performed blinding during the follow-up, but it was impossible to blind patients to study arm allocation, and they may have informed the physician performing follow-up. In addition, because of staffing limitations during the follow-up visit, 2 patients underwent follow-up by research staff who were not blinded. It is possible that these issues with blinding influenced the results. Another limitation relates to the small number of patients in the study. Because only 11 patients in both arms failed therapy, the CIs are wide and statistical modeling is limited.

DISCUSSION

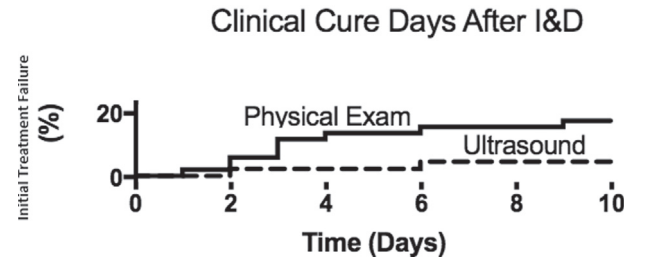
Patients with an abscess who were undergoing incision and drainage without ultrasonography were more likely to fail therapy and have repeated incision and drainage compared with those undergoing incision and drainage with point-of-care ultrasonography. Our failure rate after

Table 3. Characteristics of patients who failed initial incision and drainage.

Study Group	Reason for Failure	Failure Day (After I&D)
Physical examination	Pain and fluctuance without purulence on manual expression	2
Physical examination	Continued pain, with ultrasonography showing abscess cavity	2
Physical examination	Worsening clinically, retained purulence	2
Physical examination	Patient with worsening pain and swelling; went to outside hospital	3
Physical examination	Pain and fluctuance without purulence on manual expression	3
Physical examination	Patient with worsening pain and swelling; went to outside hospital	3
Physical examination	Pain and fluctuance without purulence on manual expression	4
Physical examination	Pain and fluctuance without purulence on manual expression	6
Physical examination	Fluctuance without purulence on manual expression	9
Ultrasonography	Pain and fluctuance without purulence on manual expression	2
Ultrasonography	Continued pain, with ultrasonography showing abscess cavity	6

incision and drainage with physical examination alone (17%) is similar to that of other published randomized controlled trials of adult abscesses (10.5% to 26%).[6,7,10,11] A large recent randomized controlled trial involving abscess incision and drainage found rates of repeated incision and drainage of 10.5%; however, it is difficult to directly compare this with our trial because it is unclear to what extent ultrasonographic guidance was used.[11] Our finding of a failure rate of 3% after ultrasonographic guidance is lower than that of published abscess trials. It is possible that our findings are related to unknown confounders, but we performed a multivariate analysis to control for the variables in this study that supports our findings. We did not standardize the ultrasonographic guidance, so it is possible that variations in technique (static guidance versus dynamic guidance versus repeated ultrasonography during incision and drainage) resulted in different outcomes.

Clinical failure after abscess incision and drainage is likely due to retained purulence from inadequate initial drainage. Clinical failures occurred more commonly in the first few days after the incision and drainage, but it is possible that these patients' abscesses may have resolved without intervention had they been left to continue to drain. Regardless, the residual purulence in patients who underwent additional drainage may reflect a more comprehensive initial drainage. We speculate that ultrasonographic guidance improves drainage through better planning for the initial incision, better execution of the procedure, or accurate assessment for residual purulence. This is supported by our finding that larger abscess cavities on physical examination were more likely to fail therapy.



Day	Physical Examination (No.)	Ultrasonography (No.)
0	53	54
2	50	53
4	46	53
6	45	52
8	45	52
10	44	52

Figure 2. Failure days after incision and drainage.

To our knowledge, our findings represent the first clinical study demonstrating improvement in outcomes when ultrasonography is integrated into the care of patients with skin abscesses. The study included a small sample size with a lower CI of 0.0, so this does not exclude the possibility of a less than clinically significant outcome. Future studies should confirm these results.

There have been few prospective randomized trials exploring variations in the treatment of skin abscesses outside of antibiotics. The 2 most recent large randomized controlled trials on antibiotics and abscess drainage demonstrated a benefit from antibiotics,[11,12] but neither study included the use of ultrasonography as a possible confounder for its results. In the current study, antibiotic use was not associated with clinical cure. It is possible that the current study is simply underpowered to observe an effect with antibiotics, but it is also possible that including ultrasonography use in the analysis of the previous studies would decrease the effect of antibiotic use on clinical cure.

Overall, incorporating ultrasonographic evaluation of soft tissue abscesses by clinicians with surgical drainage was associated with improved clinical cure rates. Patients undergoing physical examination and incision and drainage without ultrasonography were more likely to fail therapy

and have repeated incision and drainage. Point-of-care ultrasonography should be used to help guide incision and drainage of uncomplicated soft tissue abscesses in the ED.

Supervising editor: Gregory J. Moran, MD

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Author contributions: RG conceived the study, designed the trial, supervised the conduct of the trial and data collection, provided statistical advice on study design, analyzed the data, and drafted the article. All authors undertook recruitment of patients; managed the data, including quality control; and contributed substantially to article revision. RG takes responsibility for the paper as a whole.

All authors attest to meeting the four ICMJE.org authorship criteria: (1) Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND (2) Drafting the work or revising it critically for important intellectual content; AND (3) Final approval of the version to be published; AND (4) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Funding and support: By *Annals* policy, all authors are required to disclose any and all commercial, financial, and other relationships in any way related to the subject of this article as per ICMJE conflict of interest guidelines (see www.icmje.org). The authors have stated that no such relationships exist.

Publication dates: Received for publication January 25, 2018. Revisions received March 29, 2018, and May 3, 2018. Accepted for publication May 8, 2018.

Presented at the Society for Academic Emergency Medicine annual conference, May 2016, Orlando, FL.

Trial registration number: NCT02264392

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