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ORIGINAL ARTICLE

Role of Early Point of Care Ultrasound in Management of Sepsis in Emergency Department: A Randomized Clinical Trial

Asmaa Alkafafy[1], Asmaa Abdelhamid[1], Shahira Elmetainy[2], Mohammed Megahed[3], Khaled Salah Moustafa[1]

[1]Department of Emergency Medicine; [2]Department of Anesthesia and Surgical Intensive Care; [3]Department of Critical Care Medicine, Alexandria University, Alexandria, Egypt

Correspondence to *Asmaa Abdelhamid, MBBCh, MSc; Department of Emergency Medicine, Alexandria University, Alexandria, Egypt.*
E-mail: asmaamohamed697@gmail.com

Background Sepsis is a highly fatal condition. Early diagnosis and prompt management are crucial to improve outcomes. Point-of-care ultrasound (POCUS) has been used recently in different presentations in the emergency department (ED). Aim of this study was to compare the POCUS group and the clinical group regarding accuracy and time to reach a final diagnosis.

Methods Two hundred patients with suspected sepsis or septic shock were enrolled and randomized into two groups, each included 100 patients. The clinical group was managed by history taking and physical examination, and the POCUS group was managed by adding POCUS to the history taking and clinical evaluation. Diagnoses of both groups were compared to the final diagnosis. The primary outcome was to compare both groups regarding the accuracy of diagnosis, and the secondary outcome was to determine the time to reach the final diagnosis.

Results Accuracy of POCUS diagnosis in chest infection, intraabdominal sepsis, urosepsis and infective endocarditis was 90.00 (95% CI (82.38% to 95.10%)), 96.00% with 95% CI (90.07% to 98.90%), 93.00% with 95% CI (86.11% to 97.14%), and 100.00% with 95% CI (96.38% to 100.00%) respectively while for clinical group it was 96.00% with 95% CI (90.07% to 98.90%), 99.00% with 95% CI (94.55% to 99.97%), 98.00% with 95% CI (92.96% to 99.76%) and 100.00% with 95% CI (96.38% to 100.00%) respectively, time to reach a final diagnosis was longer in the clinical group (p= 0.010).

Conclusion In patients with sepsis, point-of-care ultrasound decreased time to diagnosis but was not more accurate than clinical evaluation.

Keywords Clinical group, POCUS group, Source of sepsis, Time to diagnosis.
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INTRODUCTION

Sepsis is a condition resulting from an abnormal host response to infection, which leads to inflammation, tissue destruction, and organ failure. In severe cases, sepsis can cause abnormalities at the cellular level, which may progress to septic shock, which is marked by systemic hypoperfusion and metabolic acidosis[1].

A crucial factor in the management of sepsis is the time to diagnosis and the time to start treatment[2]. POCUS is a diagnostic bedside test performed by the treating physician[3]. It has been widely accepted as a rapid diagnostic tool to evaluate patients, especially in the emergency medicine field. Incorporation of POCUS in daily practice has several advantages, especially if the sonographic findings are integrated with patient history and clinical examination[4].

Identification of the source of sepsis is important to distinguish sepsis from its mimics. Using POCUS may

aid in the assessment of patients' fluid response through stroke volume determination by velocity time integral (VTI) and respiratory variation of the inferior vena cava (IVC). Regarding volume overload, pulmonary edema can be evaluated by lung ultrasound by the appearance of B-lines[5].

MATERIALS AND METHODS

Trial settings: This prospective randomized clinical trial included two hundred patients, and was performed at Alexandria Main University Hospital, a tertiary care teaching hospital affiliated with Alexandria University, located in Alexandria, Egypt. The hospital serves as a referral center for other 4 governorates and includes departments such as e.g. Emergency, internal medicine, surgery, cardiology, pulmonology, and intensive care.

The period of recruitment started from August 2023 to July 2024. Patients were followed during their ED stay. The trial stopped when completed.

The trial was registered at clinicaltrials.gov, number: NCT 05849194, verification date: April 2023; trial results were not posted to the trial registry.

Sample size calculation:

was by the G-power software. Sample size was calculated using "two independent groups, Fisher exact test" option from "proportions" menu under "tests". Using two tails, proportion 1 (for cases) was set as 0.94, proportion 2 (for controls) was set as 0.8 according to the data obtained from the reference study. Alpha error was set at 0.05 and power at 80%, with allocation ratio of 1. Effect size= 3.92. The primary outcome was the accuracy of diagnosis. The minimum sample size required is 196 patients and was raised to 200 patients[6].

Trial design:

Parallel group, Conceptual framework: Non-inferiority, Unit of randomization: individual participant, Allocation ratio: 1:1, no changes have been made to the methods or outcomes.

Randomization type:

Randomization method was designed by a computer random number generator.

The allocation concealment mechanism was done by opaque, sealed envelopes.

Blinding: Since the intervention was the ultrasound, neither the patient nor the investigator was blinded. Data analysts were blinded to trial group assignments.

Informed consent was obtained from the patient or the patient's next of kin.

Eligibility criteria:

Inclusion criteria

Patients with any source of infection, plus two or more of the SIRS criteria[7]. (Appendix 1) and patients presented with septic shock identified by any of the following[8]:

- Persistent hypotension that needs vasopressor support to keep the mean arterial pressure (MAP) >65mmHg.

- Lactate level >2mmol/L in spite of proper fluid resuscitation.

Exclusion criteria:

Age less than 18 years, trauma victims, pregnancy, Patients with end-stage malignancy, and patients on immunosuppressive or chemotherapeutic agents.

Patients were randomized using a computer-generated method into:

POCUS group: 100 patients who underwent POCUS examination, added to basic clinical assessment.

Clinical group: 100 patients who were assessed using clinical evaluation without POCUS examination.

All the following had been done:

- The patient's history was taken from the patient or his/her relatives.

- Initial assessment by the ABCDE approach[9] (Appendix 2) and simultaneous resuscitation as needed was done by the emergency physician in charge.

- *Laboratory investigations,* including Complete blood count (CBC), Neutrophil count, and point-of-care lactate.

- The POCUS group underwent POCUS examination.

- *For the POCUS group:* POCUS assessment was done by the second author after resuscitation of the patient by the physician in charge. The operator is an emergency specialist with 8 years' experience in Emergency ultrasonography and has performed about 300 ultrasound exams before conducting this study.

Ultrasound exam was done using the curvilinear probe (2–5MHz).

Point of care ultrasound included:

- Abdominal scan to look for a collection if present.

• Diameter of the IVC and its collapsibility or distensibility index.

• Lung ultrasound to look for signs of pneumonia, like the presence of focal or multifocal coalescent B-lines, shred sign, or Sonographic consolidation (Figure 1) with dynamic air bronchogram[10].

• Cardiac systolic function, whether hyperdynamic, normal, or reduced, was documented.

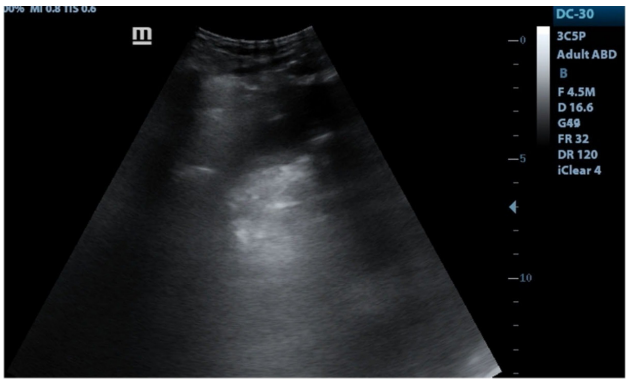

Fig 1: Lung ultrasound showing pulmonary consolidation.

Methods used to confirm patient diagn Death osis:

Laboratory methods or imaging tools (chest *X*-Ray, CT chest, or CT abdomen).

Duration of POCUS examination was documented.

Several questions were answered for each POCUS assessment:

• Has the POCUS exam provided new information?[11]

• Has the POCUS exam confirmed, altered, or added to the primary diagnosis?

• Has the POCUS exam altered management (medications given or imaging studies ordered)?

Outcomes:

• The primary outcome was to evaluate the diagnostic accuracy of the POCUS approach versus the standard clinical approach compared with the definitive diagnosis that was reached by imaging studies or laboratory tests.

• The secondary outcome was to determine the time to reach a final diagnosis in both groups.

All patients were followed during their emergency department stay and observed for any of the following (short-term outcomes):

- Intensive care unit (ICU) admission.
- Need for mechanical ventilation.
- Need for vasopressor drugs.
- Development of acute kidney injury (AKI).
- Death.

Statistical methods:

- Data were processed by the SPSS (Statistical Package for Social Science) program (Ver 25)[12].

- Shapiro–Wilk tests[13,14] of normality proved the variables are normally distributed.

- Numerical or categorical data were used as appropriate.

- Data were described by using minimum, maximum, standard deviation, mean, Standard error of the mean, 95% Confidence Interval (CI) of the mean.

- Frequency and percentage were used to describe Categorical variables.

- In order to compare between the two independent normally distributed groups the independent sample *t* test was used[15]. Welch's *t*-test was used if Levene's test for equality of variances was significant[16,17].

- To know the association between the qualitative variables. Pearsons Chi-square test was used.

- Diagnostic test evaluation was done through MedCalc Software version 14[18].

The following tests were done[19]:

Sensitivity, Specificity, Positive predictive value, Negative predictive value, and Accuracy.

RESULTS

Participant flow:

Two hundred twenty-three patients were enrolled in the study. Twenty-three patients were excluded, and 200 patients completed the study and were followed during their ED stay. Primary and secondary outcomes were evaluated (Figure 2).

Baseline data in the two groups:

The mean age (years) in POCUS Group, was mean±SD 61.13±14.10 years, while for the Clinical group it was 59.83±15.92 years.

In the POCUS Group, fifty-nine patients were males, and forty-one patients were females, while in the Clinical group, the male count was 47 patients, and the female count was 53 patients.

The mean heart rate (beats/min) in POCUS group was mean±SD 108.77±17.46 beats/min, while in the Clinical group it was 104.82±24.73 beats/min.

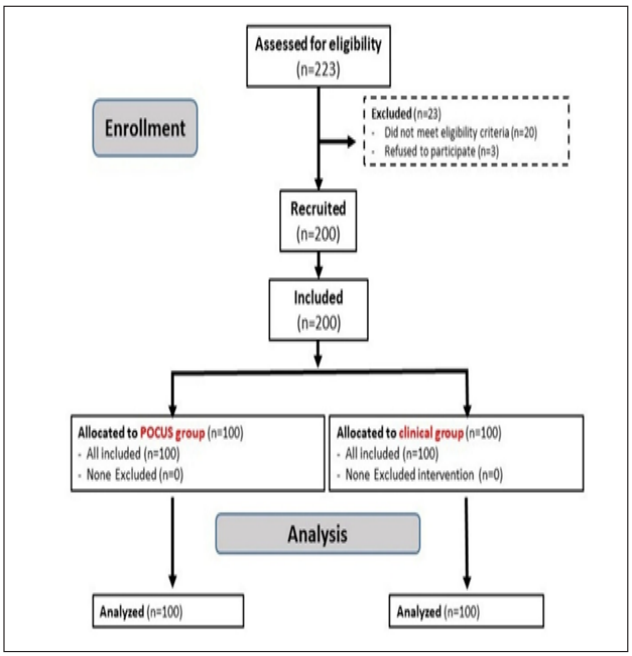

Fig. 2: Patients flow chart.

The mean systolic blood pressure in POCUS group mean±SD was 94.50±29.79mmHg while in the Clinical group It was 99.79±28.19mmHg.

The Respiratory rate was >22 cycles/min or $PaCO_2$ was <32mmHg in 84.00% of patients in the POCUS group, compared with 78.00% in the Clinical group.

In the POCUS Group, the Shock index was more than one in 63 patients, compared with 53 patients in the clinical group.

For POCUS Group The temperature (˚C) mean±SD was 37.97±0.88˚C while in the Clinical group It was 37.85±0.81˚C.

There was no statistically significant difference between groups regarding the variables mentioned above: Statistically not significant ($p \geq 0.05$) (Table 1).

POCUS effect on the primary diagnosis:

In 21 patients (21.00%) out of 100 patients in POCUS Group, the POCUS exam did not affect the primary diagnosis, and in 48 patients (48.00%) POCUS exam confirmed the primary diagnosis, in 18 patients (18.00%), it gave an additional diagnosis, and in 13 patients (13.00%), it has altered the primary diagnosis.

Accuracy of clinical diagnosis and POCUS diagnosis as compared to the final confirmed diagnosis:

Accuracy of the clinical diagnosis in chest infection, intra-abdominal sepsis, urosepsis, and infective endocarditis was 96.00%, 99.00%, 98.00% and 100.00% respectively (Table 2).

Accuracy of POCUS diagnosis in chest infection, intra-abdominal sepsis, urosepsis, and infective endocarditis was90.00%, 96.00%, 93.00% and 100.00% respectively (Table 3).

Time to reach a final diagnosis (hours):

In POCUS Group (n= 100) Time taken to reach diagnosis (hours) mean±SD was 1.93±1.36 hours, SEM of 0.14, and 95% CI of the mean of 1.66-2.19 hours. While in the Clinical group (n= 100) it was 2.46±1.54 hours, SEM of 0.15, and 95% CI of the mean of 2.15-2.77 hours.

Time to reach a final diagnosis (hours) was longer in the clinical group than in the POCUS group; there was a statistically significant difference between the groups (p= 010).

Short-term outcome in both groups:

Need for mechanical ventilation

In the POCUS Group, 40 patients needed mechanical ventilation compared to 29 patients in the Clinical group, without a statistically significant difference (p= 102).

Need for vasopressors

In the POCUS Group, 42 patients needed vasopressors, while in the Clinical group, 38 patients did. No statistically significant difference found (p= 564).

The patient died in the ED

Within the POCUS Group (n= 100), 5 patients died in ED, while in the Clinical group (n= 100), 2 patients died. No statistically significant difference (p= 284).

ICU Admission

In the POCUS Group, 73 patients were admitted to the ICU compared to 55 patients in the Clinical group with a statistically significant difference (p= 008).

Patients who developed AKI

The number of patients who developed AKI (according to KIDIGO classification) was equal in both groups (33 patients) No statistically significant difference (p= 1.000).

Table 1: Baseline data of both groups:

	Group		Test of significance *p*-value
	POCUS (*n*= 100)	**Clinical (*n*= 100)**	
Age (years)			
- Min.–Max.	20.00-92.00	21.00-92.00	
- Mean±S.D.	61.13±14.10	59.83±15.92	$t_{(df= 198)}$= 0.611
- SEM	1.41	1.59	*p*= 0.542 NS
- 95% CI of the Mean	58.33-63.93	56.67-62.99	
Sex			
- Male	59(59.00%)	47(47.00%)	$\chi^2_{(df= 1)}$= 0.202
- Female	41(41.00%)	53(53.00%)	*p*= 0.653 NS
Heart rate (beats/minute)			
- Min.–Max.	60.00-150.00	60.00-180.00	$t_{(W)(df= 178.081)}$= 1.305
- Mean±Std. Deviation	108.77±17.46	104.82±24.73	*p*(W)= 0.194 NS
- SEM	1.75	2.47	
- 95% CI of the Mean	105.31-112.23	99.91-109.73	
Systolic Blood Pressure (mmHg)			
- Min.–Max.	40.00-180.00	40.00-180.00	
- Mean±Std. Deviation	94.50±29.79	99.79±28.19	$t_{(df= 198)}$= 1.290
- SEM	2.98	2.82	*p*= 0.439 NS
95% CI of the Mean	88.59-100.41	94.20-105.38	
Respiratory rate >22 cycles/min or $PaCO_2$ <32mmHg			
- No	16(16.00%)	22(22.00%)	$\chi^2_{(df= 1)}$= 1.170
- Yes	84(84.00%)	78(78.00%)	*p*= 0.279 NS
Shock index			
- More than one	63(63.00%)	53(53.00%)	$\chi^2_{(df= 1)}$= 2.053
- Less than one	37(37.00%)	47(47.00%)	*p*= 0.152 NS
Temperature (°C)			
- Min.–Max.	36.20-41.00	35.80-40.00	
- Mean±Std. Deviation	37.97±0.88	37.85±0.81	$t_{(df= 198)}$= 0.962
- SEM	0.09	0.08	*p*= 0.337 NS
95% CI of the Mean	37.79-38.14	37.69-38.01	

n: Number of patients; Min-Max: Minimum – Maximum; S.D.: Standard Deviation; SEM: Standard Error of Mean; CI: Confidence interval; *t*: Independent *t*-test; W: Welch's *t*-test; df: degree of freedom; χ^2: Pearson Chi-Square; *: Statistically significant ($p<0.05$); NS: Statistically not significant ($p\geq0.05$).

Table 2: Predictive parameters of clinical diagnosis in different diagnoses:

Statistic	**Value with 95% CI in**			
	Chest infection	**Intra-abdominal sepsis**	**Urosepsis**	**Infective endocarditis**
Sensitivity	94.87% with 95% CI (82.68% to 99.37%)	100.00% with 95% CI (69.15% to 100.00%)	92.31% with 95% CI (74.87 % to 99.05%)	100.00% with 95% CI (2.50% to 100.00%)
Specificity	96.72% with 95% CI (88.65 to 99.60%)	98.89% with 95% CI (93.96 to 99.97%)	100.00% with 95 % CI (95.14 to 100.00%)	100.00% with 95% CI (96.34 to 100.00%)
Positive likelihood ratio	28.94 with 95% CI (7.39 to 113.30)	90.00 with 95% CI (12.82 to 632.00)		
Negative likelihood ratio	0.05 with 95% CI (0.01 to 0.20)	0.00	0.08 with 95% CI (0.02 to 0.29)	0.00
Disease prevalence (*)	39.00% with 95% CI (29.40% to 49.27%)	10.00% with 95% CI (4.90% to 17.62%)	26.00with 95% CI (17.74% to 35.73%)	1.00% with 95% CI (0.03% to 5.45%)
Positive predictive value	94.87% with 95% CI (82.53% to 98.64%)	90.91% with 95% CI (58.75% to 98.60%)	100.00% with 95% CI (85.75% to 100.00%)	100.00% with 95% CI (2.50% to 100.00%)
Negative predictive value	96.72% with 95% CI (88.43% to 99.13%)	100.00% with 95% CI (95.94% to 100.00%)	97.37% with 95% CI (90.72% to 99.29%)	100.00% with 95% CI (96.34 to 100.00%)
Accuracy	96.00% with 95% CI (90.07% to 98.90%)	99.00% with 95% CI (94.55% to 99.97%)	98.00% with 95%CI (92.96% to 99.76%)	100.00% with 95% CI (96.38% to 100.00%)

Accuracy of the clinical diagnosis in chest infection, intra-abdominal sepsis, urosepsis, and infective endocarditis was 96.00%, 99.00%, 98.00% and 00.00% espectively.

Table 3: Predictive parameters of POCUS diagnosis in different diagnoses:

Statistic	Value with 95% CI in			
	Chest infection	Intra-abdominal sepsis	Urosepsis	Infective endocarditis
Sensitivity	84.62% with 95% CI (71.92 % to 93.12 %)	77.78% with 95% CI (52.36% to 93.59%)	66.67% with 95% CI (43.03% to 85.41%)	100.00% with 95% CI (15.81% to 100.00%)
Specificity	95.83% with 95 % CI (85.75 to 99.49%)	100.00% with 95% CI (95.60 to 100.00%)	100.00% with 95% CI (95.44 to 100.00%)	100.00% with 95% CI (96.31 to 100.00%)
Positive likelihood ratio	20.31 with 95% CI (5.20 to 79.26)			
Negative likelihood ratio	0.16 with 95% CI (0.08 to 0.30)	0.22 with 95% CI (0.09 to 0.53)	0.33 with 95% CI (0.18 to 0.61)	0.00
Disease prevalence (*)	52.00% with 95% CI (41.78% to 62.10%)	18.00% with 95% CI (11.03% to 26.95%)	21.00% with 95% CI (13.49% to 30.29%)	2.00 with 95 % CI (0.24% to 7.04%)
Positive predictive value	95.65% with 95% CI (84.93% to 98.85%)	100.00% with 95% CI (76.84% to 100.00%)	100% with 95% CI (76.84% to 100.00%)	100.00% with 95% CI (15.81% to 100.00%)
Negative predictive value	85.19% with 95% CI (75.20% to 91.60%)	95.35% with 95% CI (98.62% to 97.99%)	91.86% with 95% CI (86.04% to 95.38%)	100.00% with 95% CI (96.31% to 100.00%)
Accuracy	90.00% with 95% CI (82.38% to 95.10%)	96.00% with 95% CI (90.07% to 98.90%)	93.00% with 95% CI (86.11% to 97.14%)	100.00% with 95% CI (96.38% to 100.00%)

Accuracy of POCUS diagnosis in chest infection; intra-abdominal sepsis; urosepsis; and infective endocarditis was 90.00%, 96.00%, 93.00% and 100.00% respectively.

DISCUSSION

This research demonstrated that in patients with sepsis, adding POCUS to patients' basic clinical evaluation contributed to shortening time to reach diagnosis, helped in confirmation of the suspected clinical diagnosis, identification of another source of sepsis, alteration of primary diagnosis, and modification of the management plan.

Today, in ED and ICU settings, POCUS has become an available non-invasive tool for assessment of critically ill patients. It has shortened patient length of stay in the ED and time to laboratory test and imaging studies, as proven by an uncontrolled before-and-after study[20].

Verras *et al.,*[21] run a literature review that included publications from 2010 to July 2022. Their results recommend the use of POCUS during the evaluation of patients with sepsis in the ED.

In the current study, the most prevalent source of infection was chest infection 52%, 39% of POCUS and clinical group, respectively followed by urosepsis constituted 21% and 26% in POCUS and clinical group respectively then intra-abdominal sepsis which was the confirmed diagnosis in 18 patients (18.00%) of the POCUS group and 10 patients (10.00%) in the Clinical group. This finding is consistent with Cortellaro *et al.,*[22] who found that the most common source of sepsis was pneumonia (39.5%), then urinary tract infection, and lastly intra-abdominal sepsis (23% and 19.5%, respectively).

Sensitivity and specificity for POCUS diagnosis of chest infection as compared to final diagnosis were 84.62% with 95% CI (71.92% to 93.12%), 95.83% with 95% CI (85.75 to 99.49%), respectively, in line with that, Alzahrani *et al.,*[23] conducted a systematic review for studies that compare the diagnostic accuracy of lung ultrasound versus Chest *X*-Ray or computed tomography CT. They included 20 studies. They found that lung ultrasound sensitivity was 0.85 (0.84–0.87) and specificity was 0.93 (0.92–0.95).

In the current study, biliary ultrasound discovered gallstones in 3 cases, and they were asymptomatic other 3 cases had dilated intrahepatic biliary radicals that helped to diagnose cholangitis, which is a source of sepsis that requires specific antibiotic coverage and early surgical consultation Archer *et al.*,[24] studied the accuracy of biliary POCUS by a retrospective cohort study, Analysis of the ultrasound images was compared to radiological imaging and expert review. In case of gallstones, there was almost perfect agreement with expert review (κ= 0.82, 95% confidence interval 0.72-0.93) and substantial agreement for gall bladder wall thickening (κ= 0.63, 95% confidence interval 0.42-0.83).

In this study, urinary ultrasound revealed that 10 cases had findings of cystitis, 5 cases had hydronephrotic changes, and 3 cases had pyelonephritis. Sensitivity and specificity of POCUS in case of urosepsis were 66.67% with 95% CI (43.03% to 85.41%), 100.00% with 95% CI (95.44 to 100.00%), respectively, Nixon *et al.,*[25] determined the safety, quality, and the effect of POCUS for the kidney and bladder on patient care. In case of urine retention, POCUS had a sensitivity of 100% (95% CI 88-100) and specificity of 100% (95% CI 93-100). In case of hydronephrosis, POCUS had a sensitivity of 90% (95% CI 74-96) and specificity of 96% (95% CI 89-98).

In the current study, two cases were discovered to have infective endocarditis by using POCUS, which was confirmed by echocardiography done by a cardiologist. This is consistent with Cohen *et al.,*[26] who presented a case report of a patient with a prosthetic aortic valve who was suffering from nausea and back pain and was diagnosed as a non-ST elevation myocardial infarction, then, after POCUS, vegetation was seen on the aortic valve.

In the current study, in 48 patients, POCUS exam confirmed the primary diagnosis, in 18 patients, it gave an additional diagnosis, in 13 patients, it altered the primary diagnosis, in 36 patients patients, the POCUS exam affected the medication plan, and in 21 patients, POCUS examination did not affect diagnosis, In those cases, POCUS could not detect the source of infection, while confirmatory imaging studies did. In other cases, patients were diagnosed using clinical evaluation only, like cases with diabetic foot infections and skin-subcutaneous tissue infections, such as infected bed sores and surgical wound infections. Also, patients with central nervous system (CNS) infection and septic arthritis were diagnosed by cerebrospinal fluid (CSF) analysis and joint MRI and joint aspirate analysis, respectively, and POCUS did not discover other sources of sepsis. In line with that, Haydar *et al.,*[27] assessed the POCUS effect on diagnosis. They enrolled 74 adult patients with sepsis. After point-of-care ultrasound, in 47 cases (71%), certainty increased while it decreased in 19 cases (29%). The diagnosis was changed in 12 cases (17%), and in 39 cases, treatment plans were changed (53%).

LIMITATIONS

This study was held at one center; multicenter studies are needed.

Another methodology could be used by doing an ultrasound assessment for all cases with sepsis and comparing the patient diagnosis and management plan before and after POCUS for all enrolled patients. Up till now, there is no POCUS protocol for sepsis assessment, and in this study, the treating physician was free to use other approved POCUS protocols, Rapid Ultrasound for Shock and Hypotension (RUSH) and Bedside Lung Ultrasound in Emergency (BLUE) protocols for patients in the clinical group, to guide their resuscitation.

Searching for appendicitis, diverticulitis, and dilated bowel loops as a source of sepsis was needed, but it requires experience in advanced ultrasound skills.

The investigator could have been biased by the patient's history and clinical assessment.

There was a performance bias being unable to blind patients and clinicians from the intervention.

Implementation of further studies needs advanced ultrasound skills; this may be overcome by training all emergency physicians in advanced ultrasound skills.

CONCLUSIONS

In patients with sepsis, adding POCUS to basic clinical evaluation can confirm, alter the diagnosis, reveal an additional source of sepsis, guide management, and shorten time to reach diagnosis.

CONFLICT OF INTERESTS

There are no conflicts of interest.

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