Impact of serial cardiopulmonary point-of-care ultrasound exams in patients with acute dyspnoea: a randomised, controlled trial

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ABSTRACT

Background  Serial-point-of-care ultrasound (PoCUS) can potentially improve acute patient care through treatment adjusted to the dynamic ultrasound findings. The objective was to investigate if treatment guided by monitoring patients with acute dyspnoea with serial cardiopulmonary PoCUS and usual care could reduce the severity of dyspnoea compared with usual care alone.

Methods  This was a randomised, controlled, blinded-outcome trial conducted in three EDs in Denmark between 9 October 2019 and 26 May 2021. Patients aged ≥18 years admitted with a primary complaint of dyspnoea were allocated 1:1 with block randomisation to usual care, which included a single cardiopulmonary PoCUS within 1 hour of arrival (control group) or usual care (including a PoCUS within 1 hour of arrival) plus two additional PoCUS performed at 2 hours interval from the initial PoCUS (serial ultrasound group). The primary outcome was a reduction of dyspnoea measured on a verbal dyspnoea scale (VDS) from 0 to 10 recorded at inclusion and after 2, 4 and 5 hours.

Results  There were 206 patients recruited, 102 in the serial ultrasound group and 104 in the control group, all of whom had complete follow-up. The mean difference in VDS between patients in the serial ultrasound and the control group was −1.09 (95% CI −1.51 to −0.66) and −1.66 (95% CI −2.09 to −1.23) after 4 and 5 hours, respectively. The effect was more pronounced in patients with a presumptive diagnosis of acute heart failure (AHF). A larger proportion of patients received diuretics in the serial ultrasound group.

Conclusion  Therapy guided by serial cardiopulmonary PoCUS may, together with usual care, facilitate greater improvement in the severity of dyspnoea, especially in patients with AHF compared with usual care with a single PoCUS in the ED. Serial PoCUS should therefore be considered for routine use to aid the physician in stabilising the patient faster.

Trial registration number  NCT04091334.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Cardiopulmonary point-of-care ultrasound (PoCUS) can be used to diagnose patients with acute dyspnoea.
⇒ It is not known if treatment guided by serial cardiopulmonary PoCUS can result in a faster improvement in patient-reported dyspnoea.

WHAT THIS STUDY ADDS

⇒ In this randomised study, patients with dyspnoea managed with serial PoCUS, together with usual care, had a greater reduction in self-reported severity of dyspnoea within 5 hours from arrival at an ED compared with those receiving a single ultrasound.
⇒ The difference was more pronounced in those patients with acute heart failure.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Monitoring patients with dyspnoea presenting to the ED with serial PoCUS should be considered to facilitate faster relief of symptoms.

INTRODUCTION

Background  Patients with acute dyspnoea constitute a large proportion of adult patients admitted to an ED.1 Dyspnoea can be caused by different conditions, for example, acute heart failure (AHF), chronic obstructive lung disease exacerbation and pneumonia.2 The subjective feeling of dyspnoea causes a range of unpleasant sensations, for example, anxiety, air hunger and chest discomfort, and is an essential patient-reported outcome.3 Furthermore, patients admitted with dyspnoea have high mortality compared with patients with other complaints.4

Point-of-care ultrasound (PoCUS) has been used to diagnose the underlying aetiologies of dyspnoea in ED patients for several years. The utilisation of PoCUS of the heart, lungs and the legs’ deep veins has improved the diagnostic accuracy in patients with dyspnoea from about 60% to 90% when done within 4 hours from arrival.5 However, subsequent monitoring is often done with just a combination of the trajectories of symptoms, vital signs and medical tests. The benefit of adding serial PoCUS to reassessment has the potential to improve the diagnostic accuracy and monitoring of the severity of certain conditions because of the dynamic nature of some ultrasound parameters. In particular, B-lines, which can be seen in the loss of peripheral lung aeration, for example, in cardiogenic and non-cardiogenic pulmonary oedema, and pneumonia,
can resolve with treatment, especially in patients with heart failure. However, in our systematic review leading to this trial, no studies reported an effect of treatment guided by serial PoCUS on the severity of dyspnoea.

The objective of this randomised, controlled trial was to investigate if therapy guided by monitoring adult ED patients with a primary complaint of dyspnoea using serial cardiopulmonary PoCUS in addition to usual care could reduce the severity of dyspnoea compared with treatment guided by usual care alone including a single POCUS exam.

METHODS

Study design and setting

We conducted a randomised, controlled and blinded-outcome trial in three EDs in Denmark between 9 October 2019 and 26 May 2021 (figure 1). The EDs provide 24-hour care and receive all acute medical and surgical patients referred from a general practitioner or as direct emergency admissions. In Denmark, healthcare is tax-funded and thereby provides equal access.

The study was prospectively registered at ClinicalTrials.gov (NCT04091334) and adhered to the Consolidated Standards of Reporting Trials guideline. The published protocol is provided in online supplemental appendix S1 and protocol alterations in online supplemental appendix S2.

Selection of patients

Patients were recruited over 24 hours all days when an investigator was present in the ED during clinical duty. During the trial period of 595 days, patients were screened on 426 of the days (72%) and included over 159 days. Patients were eligible for inclusion if they: (1) arrived at the ED with a primary complaint of dyspnoea (confirmed by asking the patient on arrival); (2) were 18 years or older; (3) could provide informed consent and (4) the first evaluation of the patient including the first PoCUS exam could be done within 1 hour from arrival. No requirements regarding vital signs.

Exclusion criteria included: (1) trauma patients; (2) patients invasively ventilated within the first hour after arrival and (3) if an investigator was not present in the ED.

Randomisation and blinding

Patients in both groups were enrolled within 1 hour from arrival at the ED and received the same initial standard evaluation, including a PoCUS (figure 1). Patients were allocated on 1:1 ratio into the intervention or control group. Patients were randomised with Research Electronic Data Capture. Block randomisation was employed to ensure balance and reduce bias when assigning participants to different treatment groups. The allocation sequence was concealed from the investigators. Randomisation was conducted after informed consent but before the patient’s first examination. The investigators (MDA, SWG, HOP and GT) performed the screening, enrolment, all the examinations and treatment adjustments regardless of the study group. The investigators were all certified by the same PoCUS standards and had similar working experience with PoCUS (about 5 years).

Intervention

In both groups, the initial assessment consisted of routine physical examination, medical history, measurement of vital signs, blood samples, ABG, CXR and PoCUS (figure 1). In the subsequent assessments of the patients 2, 4 and 5 hours from inclusion, usual care consisted of a clinical evaluation of the patients, including vital signs and VDS.

In the serial ultrasound group, usual care was supplemented by a lung ultrasound (LUS) and a focused cardiac ultrasound (FoCUS). LUS and FoCUS were performed according to international standards, and a protocol developed for this trial (online supplemental appendix S3). LUS was performed with an 8-zone scanning protocol with the patient in a semi-supine position. The investigators looked for B-lines, pleural effusions, consolidations and the absence of lung sliding. In the FoCUS, the investigators assessed the right ventricle for dilatation, the function of the left ventricle, presence of pericardial effusion and calculating the inferior vena cava-collapsibility index (IVC-CI).

The ultrasound was performed with a Venue (General Electric, Boston, Massachusetts, USA) or Sonosite X-Porte (FUJIFILM Sonosite, Bothell, Washington, USA) with a curvilinear probe (2–5 MHz and 1.4–5.7 MHz on the Sonosite and Venue, respectively) and a phased array probe (1–5 MHz and 1.1–4.7 MHz on the Sonosite and Venue, respectively). The investigators were instructed to adjust the treatment according to clinical parameters as per routine care as well as the serial ultrasound findings, for example, to give more diuretics if the clinical presentation and/or number of B-lines were the same or increased during the subsequent scans and a diagnosis of AHF was suspected (online supplemental appendix S1).
Assessment
The patients’ degree of dyspnoea was measured on enrolment, and then at 2, 4 and 5 hours after arrival. Dyspnoea was measured on a verbal dyspnoea scale (VDS) from 0 to 10, with 0 indicating no dyspnoea and 10 the worst dyspnoea imaginable. VDS is previously validated in the ED setting. Assessments of dyspnoea were made by healthcare professionals serving as outcome assessors who were blinded to the allocation and any interventions and approached the patient independently of the investigator.

The final hospital diagnosis was made by two independent physicians (CF and IRS) who audited the patients’ records but were blinded to the allocation and the results of the additional ultrasound examinations done in the serial ultrasound group. Furthermore, these physicians were not involved in the enrolment process at any point. Disagreements were resolved by a third reviewer (SP). The audit was performed according to predefined diagnostic criteria (online supplemental appendix S4).

The intra-rater and inter-rater reliability of the PoCUS findings, including B-lines and IVC-CI, were estimated in a subsample of 25 randomly selected scans by an independent reviewer (HØP). Furthermore, the overall quality of the clips was graded from 1 to 5, where 5 was best.

Outcomes
The primary outcome was decreased dyspnoea on VDS evaluated at four different time points (figure 1). The secondary outcomes were: (1) length of hospital stay (LOS); (2) the proportion of readmissions within 0–7 and 8–30 days from discharge date; (3) in-hospital mortality; (4) 0–7 days and 8–30 days mortality from admission date; (5) proportion of patients with a final ED diagnosis in agreement with the audit diagnosis; (6) IVC-CI correlated to vital signs and VDS; (7) B-line count correlated to vital signs and VDS; (8) the dynamic changes in IVC-CI between the PoCUS; (9) the dynamic changes in B-line count between the PoCUS; (10) medications and fluids administered in the groups; (11) proportions of differential diagnoses during the ED stay; (12) intra-rater and inter-rater reliability of the PoCUS findings and (13) image quality of the PoCUS.

Analysis
The sample size was based on a minimally clinically important difference of 1 point on VDS. The patients in the serial ultrasound group were expected to have a 2-point change in VDS compared with a 1-point change in the control group at the final evaluation of the patient in the ED. With a power of 80%, type I error of 5% and 10% dropouts, the sample size was calculated to be 206 patients.

The primary outcome was analysed using a mixed-effect model with a change from baseline VDS as the dependent variable. Factors assumed to have the same effect across many patients were baseline score in VDS compared with a 1-point change in the control group at the final evaluation of the patient in the ED. With a power of 80%, type I error of 5% and 10% dropouts, the sample size was calculated to be 206 patients.
of the patients with AHF was conducted because dynamic B-lines are mainly seen in this patient category. The proportion of different treatments provided in the two groups was examined to explain a possible effect of the serial ultrasound intervention.

For the secondary outcomes, the continuous variable (LOS) was compared with the Mood's median test and the categorical variables with the \( \chi^2 \) test and supplemented with a two-sided significance level of 5% and a risk difference with 95% CI. A heatmap was used to visualise the correlations between B-lines, IVC-CI, VDS and vital signs. Box plots were employed to illustrate the variations in B-lines. Image quality was calculated as median. Inter-rater reliability between the presumptive diagnoses made by the investigator and the blinded audit was calculated with Cohen's kappa. Cohen's kappa was also used to calculate the intra-rater and inter-rater reliability of the ultrasound clips. Image quality was calculated as median.

Missing data were present in 6 out of 410 measurements of the IVC-CI and were only excluded in the analysis of the changes in IVC-CI during the ED stay.

All statistical analyses were performed with Stata V.17.0 (StatCorp, Texas, USA).

**Patient and public involvement**

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.
RESULTS

Characteristics of study subjects

Eligibility was assessed in 436 acute patients (figure 2). Of those, 206 (47%) patients were included and randomly assigned to the serial ultrasound group with 102 patients and the control group with 104 patients. The most common cause for patients not being included following assessment for study eligibility was absence of dyspnoea as the primary complaint during the screening of the patients. Most patients were enrolled and managed by two investigators in one ED (table 1).

The patients had a median age of 76 years, many were previous smokers and had chronic obstructive pulmonary disease or arterial hypertension as the most common comorbidities (table 1, online supplemental table S1). More patients in the serial ultrasound group had chronic heart failure. Besides dyspnoea, cough was the most common complaint. The patients had overall vital signs within normal levels.

One-third of patients had bilateral oedema of the legs. On the PoCUS, one-third had consolidations or pleural effusions. Nearly 80% had B-lines at arrival, and half had reduced ejection fraction. The proportion of pathological ultrasound findings was higher in the serial ultrasound group.

Main results

Patients in both groups experienced a decline in the severity of VDS (figure 3). At 4 and 5 hours from inclusion (measuring the effect of the first and the second extra PoCUS, respectively), the mean difference in VDS between the patients in the serial ultrasound and the control group was −1.09 (95% CI −1.51 to −0.66) and −1.66 (95% CI −2.09 to −1.23). In the planned subgroup analysis of the primary outcome in patients with a presumptive diagnosis of AHF, the difference in VDS at 4 and 5 hours were −1.52 (95% CI −2.52 to −0.52) and −1.97 (95% CI −2.70 to −1.23) (figure 4, online supplemental figure S1). A larger proportion of patients received diuretics, inhaled beta2-adrenergic agonists and oxygen in the serial ultrasound group (online supplemental table S2). However, the difference was only significant for diuretics, where patients in the serial group received a dose 6–8 times greater at 2 and 4 hours from inclusion compared with the control group.

No statistically significant differences were observed between the two groups regarding LOS, readmissions within 0–7 and 8–30 days, in-hospital mortality and 0–7 and 8–30 days mortality (table 2). The proportion of the final ED diagnoses in agreement with the audit diagnoses was higher in the serial ultrasound group (64% vs 59%), but the difference was not statistically significant. The final ED diagnoses of AHF were similar in the two groups (table 1) and with the audit diagnosis (online supplemental table S3). The overall agreement between the raters of the final audit diagnoses was 96% (kappa=0.69).

In the serial ultrasound group, the number of B-lines was nearly identical between the initial LUS and the second LUS but decreased at the final LUS exam (online supplemental figure S2A). In a subgroup of patients with a presumptive diagnosis of AHF, a similar pattern was found but with a higher median number of B-lines (online supplemental figure S2B). IVC-CI did not change between the scans (online supplemental figure S3) and there was no correlation between B-lines or IVC-CI and vital signs or VDS (online supplemental figures S4 and S5). The intra-rater and inter-rater reliability of the assessed ultrasound clips had an agreement of 96% (kappa=0.91) and 94% (kappa=0.87), respectively. Overall median image quality was 4.

DISCUSSION

This randomised trial assessed whether treatment guided by serial cardiological PoCUS in acute adult patients admitted with a primary complaint of dyspnoea could shorten the time to improvement in symptoms. We found that patients who underwent repeated PoCUS examinations had greater improvement in patient-reported dyspnoea than patients who had only a single PoCUS on arrival during their ED visit, with a larger statistically significant difference in those with AHF. The effect of serial PoCUS is likely due to the significantly greater use of diuretics in the serial ultrasound group.

The effect of treatment guided by serial ultrasounds was a reduction in VDS by 1.23 after 4 hours from inclusion and a further reduction by 0.68 after 5 hours. A carry-over effect might explain the smaller improvement between hours 4 and 5 besides the patient being more stabilised in the later phase. The overall effect was primarily driven by the effect of PoCUS in patients with AHF, which might be due to the underlying cause of the B-lines found in these patients, contrary to B-lines found in other conditions, for example, pneumonia. The effect can partly be explained by the increasing amount of diuretics administered in the serial ultrasound group.

Figure 3 Change in the primary outcome (VDS) between the two groups at the different time points. Data are mean (95% CI). *Inclusion: same standard diagnostics in both groups, including LUS and FoCUS. †2 hours: standard care in both groups. In the serial ultrasound group, an extra LUS and FoCUS. ‡4 hours: standard care in both groups. In the serial ultrasound group, an extra LUS and FoCUS. §5 hours: same standard care in both groups. No ultrasound examinations. FoCUS, focused cardiac ultrasound; LUS, lung ultrasound; VDS, verbal dyspnoea scale.
We found no difference in LOS, readmissions or short-term mortality between groups receiving a single or serial POCUS exam. Previous studies conducted in a similar setting using only a single PoCUS exam have yielded the same results. To further elucidate the potential impact of PoCUS performed within the first hours in the ED on patient prognosis, larger-scale studies are needed. However, it is noteworthy that if the final PoCUS exam is conducted prior to discharge in patients with AHF, it influences mortality and readmission rates.

The diagnostic accuracy of PoCUS was not significantly higher in the serial PoCUS group, presumably because an initial PoCUS was done in both groups. Still, the number of differential diagnoses was lower in the serial PoCUS group indicating that PoCUS might help the clinician to refine and narrow the diagnostic possibilities. However, we observed a lower overall agreement rate of 64% in our study compared with higher agreement rates of 79%–88% reported in comparable studies. This discrepancy could be attributed to differences in the audit process. In our study, we used the final ED diagnosis made by the treating investigator, whereas the other studies relied on the final diagnosis recorded in the medical journal.

Two smaller studies limited to patients with AHF have found a correlation between B-lines and RR or VDS. Although this intuitively makes sense, we found no correlation between

Figure 4  Change in the primary outcome (VDS) in patients with (A) and without a presumptive diagnosis of AHF (B). *Inclusion: same standard diagnostics in both groups, including LUS and FoCUS. †2 hours: standard care in both groups. In the serial ultrasound group, an extra LUS and FoCUS. ‡4 hours: standard care in both groups. In the serial ultrasound group, an extra LUS and FoCUS. §5 hours: same standard care in both groups. No ultrasound examinations. AHF, acute heart failure; FoCUS, focused cardiac ultrasound; LUS, lung ultrasound; VDS, verbal dyspnoea scale.
that the patients were mentally capable of assessing their dyspnoea bias. But, with the chosen primary outcome, it was a prerequisite important, the outcome assessors were blinded. Fifth, patients judgement and subsequent treatment by the same investigator The patients in the control group were also exposed to clinical information bias, and all patients had a PoCUS done despite allocation. out before the first evaluation of the patients to avoid selec-

The number of B-lines or IVC-CI and vital signs or VDS, so the patients' vital signs and clinical status do not necessarily mirror the dynamic parameters on the PoCUS or in VDS. This means that the clinician cannot solely rely on the vital signs to determine whom to re-scan.

ED physicians could incorporate serial PoCUS when handling patients with dyspnoea, especially patients suspected of fluid accumulations in the lungs. These patients could be identified upfront with PoCUS as part of a standard clinical evaluation. However, as the minimally clinically important difference for VDS is 1, which was achieved at the 2-hour evaluation, our trial suggests that only one extra PoCUS could be sufficient. Because only B-lines and not IVC change in the first couple of hours in the ED, the second PoCUS might be limited to a LUS. Although serial PoCUS is more time-consuming, the patients are, on the other hand, stabilised faster, thereby potentially resulting in early disposition.

**Limitations**

First, most patients were recruited only in one ED and by two investigators when they were present, which could influence external validity. However, baseline characteristics were similar to other comparable studies. Second, despite baseline characteristic imbalances with a higher proportion of patients with a history of heart failure in the serial ultrasound group, this should not influence the primary outcome because treatment decisions were based on the presumptive diagnoses, and the final ED diagnosis of AHF was similar in both groups. Third, we did not implement a precise algorithm for changes in the ultrasound parameters (B-line count and IVC-CI) that should trigger a specific treatment as it would have been too complex and does not reflect the reality and the setting where the emergency physician works. Fourth, the investigator and patients were not blinded to the intervention; hence an ultrasound assessment placebo effect might have influenced the primary outcome in the serial PoCUS group because of the intervention itself and the more time spent on the patient. Still, randomisation was carried out before the first evaluation of the patients to avoid selection bias, and all patients had a PoCUS done despite allocation. The patients in the control group were also exposed to clinical judgement and subsequent treatment by the same investigator at matching time points as in the serial ultrasound group. Most importantly, the outcome assessors were blinded. Fifth, patients unable to consent were excluded which could introduce selection bias. But, with the chosen primary outcome, it was a prerequisite that the patients were mentally capable of assessing their dyspnoea on VDS, and another study from Denmark has shown that the most acute patients constituted only approximately 6% of all patients with dyspnoea.

**CONCLUSION**

Our study establishes that serial cardiopulmonary PoCUS serves as an effective treatment guide for patients with dyspnoea, offering valuable support alongside standard care to alleviate the discomfort linked to dyspnoea. Notably, the observed impact is predominantly found in patients with AHF. These findings endorse the use of serial cardiopulmonary PoCUS as a beneficial tool in managing dyspnoea, with particular attention to patients with AHF.

**Table 2** Secondary outcomes in serial ultrasound and the control group

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Serial ultrasound group (n=102)</th>
<th>Control group (n=104)</th>
<th>Risk difference (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of hospital stay, days</td>
<td>4 (1–7)</td>
<td>3 (0–6)</td>
<td>3.9 (−9.8 to 17.5)</td>
<td>0.58</td>
</tr>
<tr>
<td>Readmissions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–7 days</td>
<td>15 (14.7)</td>
<td>10 (9.6)</td>
<td>5.1 (−3.8 to 14.0)</td>
<td>0.26</td>
</tr>
<tr>
<td>8–30 days</td>
<td>15 (14.7)</td>
<td>7 (6.7)</td>
<td>8.0 (−0.4 to 16.4)</td>
<td>0.06</td>
</tr>
<tr>
<td>In-hospital mortality</td>
<td>4 (3.9)</td>
<td>4 (3.8)</td>
<td>0.1 (−5.2 to 5.4)</td>
<td>0.98</td>
</tr>
<tr>
<td>Mortality</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–7 days</td>
<td>2 (2.0)</td>
<td>3 (2.9)</td>
<td>−0.9 (−5.1 to 3.3)</td>
<td>0.67</td>
</tr>
<tr>
<td>8–30 days</td>
<td>2 (2.0)</td>
<td>2 (1.9)</td>
<td>0.0 (−3.7 to 3.8)</td>
<td>0.98</td>
</tr>
<tr>
<td>No. of correct final ED diagnoses</td>
<td>64 (62.7)</td>
<td>59 (56.7)</td>
<td>6.0 (−7.4 to 19.4)</td>
<td>0.38</td>
</tr>
</tbody>
</table>

Data are n (%) or median (IQR).

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**Contributors**

Idea and study design: MDA. CBL, PHG and ATL. Database creation: MDA and AKH. Generation of allocation sequence: AKH. Recruitment and data collection: MDA, SWG, HDP and GT. Audit of diagnoses: CF, IRS and SP. Intravariability and intervariability analysis of ultrasound clips: MDA and HDP. Writing of draft: MDA. Statistical analysis: MDA with guidance from SM. Data access and verification: MDA, ATL, PHG and CBL. Interpretation of data, review, editing, approval of the final manuscript and the decision for submission: all authors. MDA is the guarantor of the study.

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Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval The study was approved by the Regional Committee on Health Research Ethics for Region Zealand, Denmark (SJ-744). The trial was approved for data storage by Region Zealand, Denmark (REG-056-2019). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. De-identified participant data may be made available on request to the corresponding author if data sharing is in accordance with applicable legislation on the processing of personal data (GDPR and the Danish Data Protection Act). Data will be provided through a secured mailing address. Data can be requested after publication and until 31 December 2022, on which data will be deleted or transferred to Danish National Archives according to Danish legislation. Data can only be reused after acceptance from MDA, ATL, PHG and CBL.

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