The Impact of Thoracic Ultrasound on Clinical Management of Critically Ill Patients (UltraMan): An International Prospective Observational Study*

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OBJECTIVES: To investigate the impact of thoracic ultrasound (TUS) examinations on clinical management in adult ICU patients.

DESIGN: A prospective international observational study.

SETTING: Four centers in The Netherlands and Italy.

PATIENTS: Adult ICU patients (> 18 yr) that received a clinically indicated lung ultrasound examination.

INTERVENTIONS: None.

MEASUREMENTS AND MAIN RESULTS: Clinicians performing TUS completed a pre- and post-examination case report form. Patient characteristics, TUS, and resulting clinical effects were recorded. First, change of management, defined as a TUS-induced change in clinical impression leading to a change in treatment plan, was reported. Second, execution of intended management changes within 8 hours was verified. Third, change in fluid balance after 8 hours was calculated. A total of 725 TUS performed by 111 operators across 534 patients (mean age 63 ± 15.0, 70% male) were included. Almost half of TUS caused a change in clinical impression, which resulted in change of management in 39% of cases. The remainder of TUS confirmed the clinical impression, while a minority (4%) did not contribute. Eighty-nine percent of management changes indicated by TUS were executed within 8 hours. TUS examinations that led to a change in fluid management also led to distinct and appropriate changes in patient's fluid balance.

CONCLUSIONS: In this international observational study in adult ICU patients, use of TUS had a major impact on clinical management. These results provide grounds for future randomized controlled trials to determine if TUS-induced changes in decision-making also lead to improved health outcomes.

KEY WORDS: clinical decision-making; fluid management; lung; patient management; thorax; ultrasound

Point-of-care thoracic ultrasound (TUS) has become a frequent component of the critical care clinician's armamentarium. The rapid, repeatable, and noninvasive assessment of heart, vena cava, diaphragm, and lungs by ultrasound provides reliable information on circulatory, respiratory, and volume status. Its ability to diagnose, monitor, and guide interventions exceed the capabilities of the stethoscope and may parallel that of costly and invasive modalities (1–3). Its clinical integration may reduce time to diagnosis and treatment, and reduce uptake of costly and invasive modalities (4, 5).

TUS also has limitations. There is interoperator variability and risk of interpretative error. Particularly in a complex and dynamic ICU setting, TUS-induced changes in clinicians' perception may not always be translated into

*See also p. 415.

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KEY POINTS

Question: What is the impact of thoracic ultrasound examinations on clinical management in adult ICU patients?

Findings: This international prospective observational study on the use of point-of-care thoracic ultrasound on the ICU included 725 examinations by 111 operators across four centers. Thoracic ultrasound caused a management change in 39%, ranging from noninvasive to lifesaving. Eighty-nine percent were executed within 8 hours. Most executed noninvasive changes were related to fluid management and led to distinct and appropriate fluid balances.

Meaning: Thoracic ultrasound has substantial, and realizable, impact on clinical management in the ICU that extends beyond confirming existing clinical suspicions, providing ground for future randomized controlled trials.

definitive clinical management, nor lead to beneficial patient outcomes. Thus, true clinical utility of a diagnostic tool extends beyond diagnostic accuracy and depends on its degree of influence on decision-making, and the subsequent impact on quantifiable health outcomes (6, 7).

Previous research found that TUS on the ICU changes clinicians' perception of diagnosis and patient management in 44% and 42% of examinations, respectively (8). Unfortunately, most previous studies were monocentric (9), heterogeneous in design (8), and recruited small number of patients (10, 11). Further evidence that TUS produces meaningful effects on patient management and quantifiable clinical ICU outcomes is needed (12).

This study's aim is to investigate impact of TUS on ICU clinical patient management by: 1) Assessing frequency of change in management after TUS; 2) Verifying execution of intended changes; and 3) Specifically, quantifying changes in patient's fluid balance indicated by TUS.

MATERIALS AND METHODS

Study Design and Setting

This is an international prospective observational study performed on the ICU of two academic and two large nonuniversity hospitals: Amsterdam University Medical Center, Leiden University Medical Center, Noordwest Ziekenhuis Alkmaar, in The Netherlands and Regional General Hospital F. Miulli in Italy. The study period was from January 21, 2020, to February 1, 2022. Ultrasound examinations are part of conventional clinical practice in these centers and are regularly performed by physicians, provided that a clinical indication exists. The institutional review board approved this study and waived the necessity for informed consent (Medische Ethische Toetsingscommissie Vrije Universiteit medical center (VUmc), 2020.011, January 21, 2020, "Point-of-care ultrasound in the ICU"). Participating centers in The Netherlands applied local ethical practice regulations in accordance with prior approval of the VUmc institutional review board, while the Italian center acquired approval from the respective institutional review board (Comitato Etico Indipendente Azienda Ospedaliero-Universitaria, 7130, December 21, 2021, "Ecografia point of care in terapia intensive"). Procedures were followed in accordance with Helsinki Declaration of 1975. The protocol for this study was registered November 2020 (Netherlands Trial Registry trial NL9047).

Subjects

The ultrasound operators collected TUS examinations that were performed during the study period. All TUS examinations of adult (> 18 yr) patients admitted to the ICU were eligible for inclusion. Patients could be included multiple times provided that the indications for TUS were distinct. Patients dying within 8 hours of TUS were excluded as they could not be followed-up appropriately.

Measurement and Examination

TUS consisted of cardiac, lung, diaphragm, and inferior vena cava ultrasound, when respectively indicated. Depending on the clinical indication for TUS, the examination could be focused on either respiratory, circulatory, or volume status, or a combination of components. The operator completed a standardized case report form (CRF) rather than describing the examination itself (**Supplemental Digital Content 1**, http://links.lww.com/CCM/H266). The following details were completed before TUS: 1) details on operator and training level; 2) reason for

TUS; 3) current diagnosis and treatment plan. After TUS, the remaining points were completed: 4) TUS findings; 5) clinical contribution of TUS; 6) potential changes in diagnosis and management. TUS semiotics and finding definitions were in accordance with current international recommendations (13–15). CRF data was transcribed to an electronic data capture system.

Variables and Outcomes

Baseline characteristics and demographics, including admission disposition, reason, number of actual diagnoses, and medical history, were collected. Variables relating to severity of disease, including arterial blood gas variables, ratio between $Pa{O_2}$ and $F{IO_2}$, Sequential Organ Failure Assessment, and mechanical ventilation variables, when applicable, were collected closest to TUS. Cumulative fluid balance was collected at the time of TUS and 8 hours after. The calculated difference across 8 hours was the fluid balance change. The study flow and outcomes are summarized in **Figure 1**.

The primary outcome was change of management and was defined as a TUS-induced change in the clinician's treatment plan. Change of management was only considered valid when the operator indicated on the CRF that TUS had contributed to a change of clinical impression. The construct of "clinical impression" was introduced in the CRF hierarchy to increase the robustness of the primary outcome by reducing biases such as self-fulfilling prophecy. It was defined as the diagnosis and treatment plan as constructed by the operator and registered before TUS. Compatible TUS findings confirmed clinical impression, while new or other findings changed clinical impression. Uninterpretable findings made no contribution to clinical impression (e.g., when the examination was technically insufficient for decision-making). A change in treatment plan may also occur after TUS confirmed the clinician's suspicion, but these changes are not exclusively attributable to TUS itself and are more likely to have also occurred in its absence. Similarly, a change of diagnosis was only considered valid when there was a change in clinical impression.

For the assessment of actual management change realization: an investigator verified the execution of CRF-recorded changes of management within 8 hours after TUS. To avoid biasing results, only direct changes in treatment plan were verified and not their downstream impact. For example: if the change was to start furosemide, the investigator verified the actual start of furosemide administration and not whether this leads to a downstream negative fluid balance.

Last, fluid balance change reflects quantifiable TUS contribution amidst ongoing, complex, and perhaps sometimes conflicting, ICU objectives. By reassessing fluid balance after 8 hours, subjects served as their own (by calculating delta fluid balance) and each other's controls (by calculating differences between groups based on TUS-guided management change).

Statistical Analysis

Data processing and statistical analyses were performed using Python (v3.8, Jupyter Notebook) language for computing with a statistical suite of libraries. Baseline and outcome variables were presented as means ± SDs, medians and interquartile range, or numbers and percentages (%) when appropriate. Proportions or percentages for outcomes were reported with 95% CI. For results on unique patients, data from the first examination was used for aggregation.

Estimation of the required sample size was conducted in G*Power based on an exact proportion of 0.42 for management change, the primary outcome,

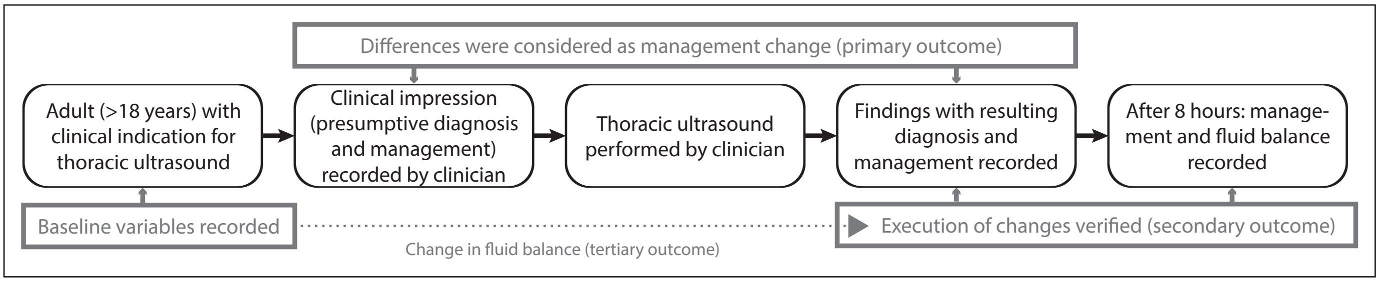

Figure 1. Study flow diagram with outcomes. *Rectangles* with rounded corners reflect the study inclusion flow, *rectangles with straight edges* correspond to the outcomes.

based on previous literature (8). Considering an effect size of 0.08, an alpha of 0.05, and a power of 0.95, a sample size of 504 patients was required. Collection continued until all participating centers had a sample size of at least 50 examinations.

RESULTS

A total of 725 TUS examinations across 534 patients were included during the study period. Four examinations were excluded due to death within 8 hours (0.5%). **Table 1** shows the characteristics of patients at the examination. The median percentage of missing values per variable was 0% (2.7%).

Table 2 shows the characteristics of TUS examinations. The TUS examinations were conducted by a total of 111 distinct operators. Operator training level ranged from supervised and inexperienced to highly experienced (> 10 yr) and internationally certified.

The most frequent TUS findings were atelectasis (32.1%), pleural effusion (30.5%), and pulmonary edema (14.8%) (full table in **Supplemental Digital Content 2**, http://links.lww.com/CCM/H266).

Out of the 725 examinations: 1) 28 (3.8%; 95% CI, 2.6–5.5%) had no clinical contribution, 2) 352 (48.6%; 95% CI, 48.6–52.3%) confirmed clinical impression of the operator, and 3) 345 (47.6%; 95% CI, 43.9–51.3%) changed the clinical impression of the operator. TUS changed or added a diagnosis in 156 (21.5%; 95% CI, 18.6–24.7%) examinations and changed intended management in a total of 279 (38.5%; 95% CI, 34.9–42.1%) of examinations. **Figure 2** shows the specific diagnostic and management changes induced by TUS.

Within 8 hours after TUS, a total of 247 (88.5%) of all management changes were executed. More than half of all executed management changes had a component related to fluid management (55.1%). **Figure 3** specifically shows the impact TUS-indicated fluid management on fluid balance in the follow-up period. The difference between groups was significant ($p < 0.001$). Dunn post hoc test for multiple comparisons showed that the difference between all respective groups was significant ($p < 0.05$). The median change in fluid balance across the total population was +200 (–250 to 735), while the median change in fluid balance across patients without fluid management changes ("unguided" in **Fig. 3**) was +186 (–252 to 680).

TABLE 1.
Characteristics of Included Patients at Time of First Thoracic Ultrasound Examination

Baseline Variables	Unique Patients (534)
Age, yr	62.5 ± 15.0
Gender (male)	372 (69.7%)
Body mass index	25.6 ± 7.8
Invasively ventilated	357 (66.9%)
PaO_2/FIO_2, mm Hg	199.5 ± 107.8
Sequential Organ Failure Assessment	8.7 (3.6)
Baseline fluid balance	1,212 (–266 to 4,794)
Medical history	
None	54 (10.1%)
Cardiovascular	326 (61.0%)
Diabetes mellitus	139 (19.2%)
Pulmonary	133 (24.9%)
Reason for admission	
Elective surgery	54 (10.1%)
Emergency surgery	42 (7.9%)
Trauma surgery	65 (12.2%)
Medical	356 (66.7%)
Other	17 (3.2%)
COVID-19	105 (19.7%)
Length of stay (d)	7.2 (12.9)

Variables were presented as means ± SDs, medians and interquartile range, or *n* (%) depending on distribution.

TABLE 2.
Characteristics of Thoracic Ultrasound Examinations

Examination Variables	TUS Examinations (725)
Reason for TUS	
Diagnostics	525 (72.4%)
Monitoring	200 (27.6%)
Main TUS domain	
Respiratory	399 (55%)
Cardiac	135 (18.6%)
Volume status	166 (22.9%)
Other	24 (3.3%)

TUS = thoracic ultrasound.
Variables were presented as *n* (%). Monitoring pertains to the (sequential) observation of certain patient condition over a period of time within the framework of a known formal diagnosis.

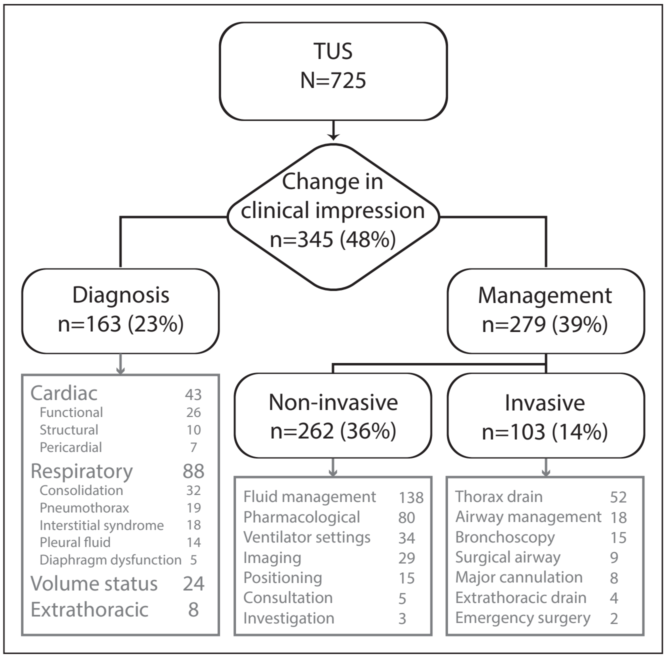

Figure 2. Diagnostic and management changes induced by thoracic ultrasound (TUS). *Rectangles* with rounded edges show percentage of patients compared with total population, while *rectangles with straight edges* show absolute numbers. Multiple changes in diagnosis or management (noninvasive and/or invasive) could occur in one patient. *N* indicates total sample population, while *n* indicates subpopulations accompanied by percentage of *N*. Airway management included intubation and extubation. Major cannulation included pulmonary artery catheter, extracorporeal membrane oxygenation, coronary angiography, and central venous cannulation. Ventilation settings included change of ventilator settings, start of high-flow nasal cannula, and noninvasive ventilation. Positioning included prone positioning and physiotherapy.

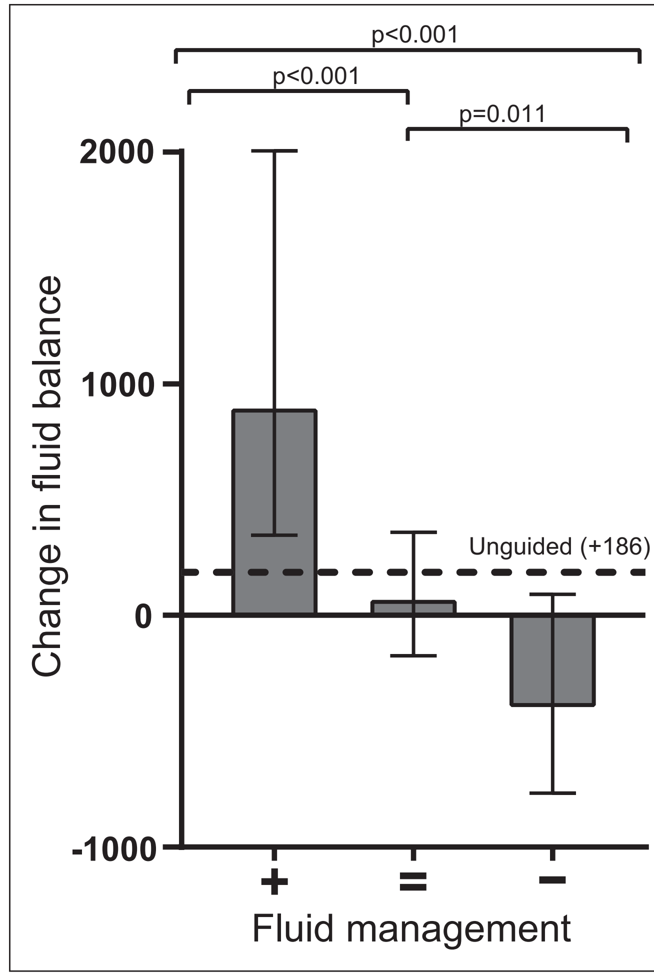

Figure 3. Thoracic ultrasound-indicated fluid management (positive +, neutral =, negative −) and resulting fluid balance change after 8 hr. Unguided fluid balance group contains both patients without any changes of management as well as patients with management changes but unrelated to fluid management (e.g., positive end-expiratory pressure titration or bronchoscopy). Fluid balance is median with interquartile range. Elaborate overview figure is shown in **Supplemental Digital Content 3** (http://links.lww.com/CCM/H266). *p* values calculated using post hoc Dunn test for multiple comparisons.

DISCUSSION

The main findings of this international observational study on the effects of TUS on clinical management of adult ICU patients are: 1) Around half of TUS led to a change in clinical impression, which resulted in a management change in 39% of examinations. The majority of management changes were noninvasive; 2) Eighty-nine percent of changes in management indicated by TUS were executed within 8 hours; and 3) TUS examinations that indicated a change in fluid management subsequently also led to a concordant change in patients' fluid balance.

The true clinical utility of a diagnostic tool can be appraised in a hierarchical model of efficacy: test attributes (development and validation of diagnostic accuracy), clinical decision-making (diagnostic and therapeutic efficacy), and health outcomes (patient-centered and societal) (7). The addition of point-of-care TUS to the standard diagnostic pathways almost universally increases percentage of correct diagnoses, sensitivity, and specificity. However, relevance of diagnostic accuracy to clinical decision-making may be limited. When selecting a test, a clinician must consider the potential downstream health impact of erroneous or indeterminate findings, clinical context, and disease prevalence (12, 16). This is particularly relevant in the complex and dynamic ICU environmental where patients may have multiple diagnoses with conflicting treatment goals, but ultrasound may be well-suited for this purpose (17).

Some previous ultrasound studies circumvent limitations of diagnostic accuracy by directly reporting changes in clinical decision-making. While most were small and heterogeneous in design, two larger and more robust ICU studies have been performed (8). One single-center single-operator study with 253 lung ultrasound examinations reported management changes in 47% of cases (9). Another study reported all 1,073 ultrasound examinations, of any type, across 142 ICUs on a single day in Europe and found that 69% had therapeutic implications (18). However, both included cases where ultrasound only acted as a confirmation of existing operational suspicions. Furthermore, none report feasibility of outlined management changes or its downstream effect on quantifiable patient-centered outcomes. The current study, across four international ICUs and 111 operators, corroborates the existing evidence and adds further evidence to bridge the gap between TUS-induced changes in clinical decision-making and verifiable patient-centered changes.

Despite more stringent conditions for management changes in the current study, the total proportion found in this study is consistent with a previous systematic review (95% CI, 34.9–42.1% compared with 42%, respectively) (8). In addition, TUS also frequently confirmed clinical impression. This is a very valuable result, as confirmation eliminates diagnostic uncertainty and may prevent both delay of medical care and uptake of more costly, or harmful, investigations. Only a small number of TUS (4%) did not contribute to clinical impression. Above all, the current study demonstrates that TUS is more than a tool for rapid confirmation of an existing clinical suspicion; it is a true diagnostic modality capable of changing clinician's behavior altogether with consequences ranging from noninvasive to lifesaving (e.g., emergency thoracotomy).

Importantly, 89% of intended clinician behavior was translated to verified changes in patient management within 8 hours. This is very high yield compared with traditional routine diagnostic modalities such as chest radiograph (19). Furthermore, instances of unexecuted management do not automatically equate to senseless investigations. Many factors may contribute to lack of feasibility: patient factors (e.g., acute change in therapeutic priorities), departmental factors (e.g., logistic or personnel issues), or TUS factors (e.g., erroneous interpretation). These factors, and their relative contributions, should be investigated in future studies.

Several characteristics of the TUS examinations are noteworthy. First, the majority of TUS indications were related to diagnostics (72.4%), which may drive frequent changes of management. Frequent diagnostic utilization can be explained by an underlying concept intrinsic to bedside ultrasound. Clinicians may use TUS more frequently at critical or uncertain moments due to its immediate (and widespread) availability, ease of bedside use, and patient safety. Second, there were more changes of management than changes of diagnosis. A change of diagnosis (almost) always causes a change of management, while changes of management can occur within the framework of one correct formal diagnosis. For example, monitoring a patient can result in the intensification of fluid extraction without changing the formal diagnosis. Last, most TUS examinations concerned the respiratory domain and most findings were pulmonary. This may be due to the high prevalence of pulmonary pathology on the ICU (e.g., patients in ventilated in supine position may readily develop posterolateral pulmonary atelectasis) as well as the relative feasibility and ease of lung ultrasound. Furthermore, cardiac ultrasound requires a high level of expertise along with availability of cardiac windows during suboptimal ICU positioning, decreasing its feasibility. Lung ultrasound, by comparison, requires few examinations to obtain basic proficiency, does not rely on specific thoracic windows, and may readily detect fluid overload as a surrogate for cardiac function (20, 21).

Interestingly, more than half of all examinations with executed management changes include at least a component related to fluid management. Normalization of interstitial fluid and circulating volume is a critical, and a highly quantifiable, therapeutic target for ICU patients. Both negative and positive fluid balance may be associated with increased morbidity and mortality (22). A recent systematic review showed that TUS may facilitate further optimization of volume status (21, 23). This current study's result emphasizes the important role of TUS in this matter and demonstrates that TUS-guided fluid management induces appropriate and feasible changes in fluid balance that distinctly reflect clinicians' intent and may not have been produced as readily by the standard diagnostic pathway alone. Across the total population, there was a +200 mL offset from neutral per 8 hours, which is comparable to previous findings (24). Last, median fluid balance was closer to neutral when guided by TUS than unguided.

This study provides comprehensive insight into the feasibility of TUS-induced changes of management and demonstrates that TUS-indicated volume changes lead to definite changes in patients' fluid balance. However, it fails to definitively capture whether these changes would have occurred in the absence of TUS and whether these would trickle down to impact patient outcomes. Conventional clinical parameters may have produced similar management decisions, albeit at a later time and likely with a more costly or invasive tool. Whether the addition of TUS leads to therapeutic strategies that convey a definite (survival) benefit should be addressed by a randomized controlled trial. Previously, diagnostic tools thought to be excellent have not produced the desired patient outcomes in randomized controlled trials and even inflicted patient harm (25). Even so, few imaging modalities have demonstrated an improvement in mortality, and this outcome may not independently serve as the definitive litmus test for the utility of TUS (12).

This study has several limitations. It relied on clinician-reporting of management changes, which is susceptible to several forms of biases. Selection bias may be two-fold: 1) form bias, clinicians were inclined to select an answer provided on the CRF. This bias was reduced by the iterated expert consensus on CRF design. 2) completion bias, clinicians might only complete the CRF when the results were beneficial. This bias was reduced by enlisting independent research students that ensured form completion during daily ward visits. Last, confirmation bias; when completing the CRF post-TUS, pre-TUS impressions may be retroactively influenced by findings. This was reduced as the form needed to be completed in two stages: before and after examination. Importantly, the results, even if susceptible to bias, are convincingly large to be of clinical importance and justify further investigation through randomized controlled trials. Last, four patients who died within 8 hours were excluded (0.5% of total cases). Although this only occurred in a minority of cases, these data may have provided insight into the TUS decisions that affect outcome or end-of-life care.

This study also has several strong points. It is the largest study on this subject to date, its sample size exceeds the cumulative sample size of all previous studies on this subject (8). The study has high external validity, owed to its multicenter and international design with more than 100 operators with varying levels of expertise. Furthermore, its strict registration on CRFs and electronic data capture systems decreases subjectivity and allows for more robust conclusions.

CONCLUSIONS

TUS induces substantial changes in clinical decision-making in almost half of examinations performed on the ICU. The large majority of resulting changes in management (both invasive and noninvasive) are executed within 8 hours. Furthermore, TUS-induced fluid management produces quantifiable and distinct fluid balances, aligned with the clinician's intended change. Future investigations are needed to establish whether TUS can bridge the gap from impact on clinical decision-making to improved health outcomes. The current results provide grounds for clinical trials on the role of TUS (and lung ultrasound) in fluid management on the ICU.

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