Accuracy of Pocket-sized Ultrasound Devices to Evaluate Inferior Vena Cava Diameter and Variability in Critically Ill Patients

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Abstract

Purpose: By using inferior vena cava (IVC) measurements, clinicians can detect fluid status and responsiveness and find out the etiology of hypotension, acute heart failure, and sepsis easier. Pocket-sized ultrasound devices (PSUD) may take this advantage a few steps further by their lower costs, user-friendly interface, and easily applicable structure.

In this study, we aimed to determine the diagnostic value of a PSUD compared with a standard ultrasound device (SD) for the measurement of IVC diameter (IVCD) and its respiratory variability.

Materials and methods: We measured the inspiratory, expiratory diameters of IVC, and calculated the inferior vena cava collapsibility index (IVCCI). We investigated 42 intensive care unit (ICU) patients.

Results: There was no difference in inspiratory (PSUD: 1.34 ± 0.67 cm; SD: 1.35 ± 0.68 cm) and expiratory (PSUD: 1.98 ± 0.53 cm; SD: 2.01 ± 0.49 cm) IVCD among measurements with PSUD and SD ($p > 0.05$). There was also no difference between IVCCI's measured with PSUD (39 ± 20%) and SD (39 ± 20%) ($p > 0.05$). The Bland–Altman analysis revealed that the width of 95% limits of agreement were similar for both devices. There was a good inter-device agreement among PSUD and SD for measurements of IVCD, and there was no difference between IVCCI's measured using both ultrasound devices.

Conclusion: We support that the idea of a PSUD is as reliable as a SD for IVC measurements.

Keywords: Inferior vena cava, Inferior vena cava diameter, Pocket-sized ultrasound device, Standard ultrasound device.

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Highlights

In this study, we evaluated the diagnostic efficacy of a pocket-sized ultrasound device (PSUD) compared with a standard ultrasound device (SD) for measuring inferior vena cava diameter (IVCD) and its respiratory variability in 42 ICU patients.

Results demonstrated no significant differences in IVCD and collapsibility index between PSUD and SD measurements.

Our findings support the reliability of PSUDs for IVC assessments, offering a relatively cost-effective and user-friendly alternative.

Introduction

In intensive care unit (ICU) practice, point of care ultrasonography (POCUS) has an essential role in hemodynamic evaluation and fluid therapy management. Inferior vena cava collapsibility index (IVCCI) can help determine fluid responsiveness in shock patients.[1–3] Additionally, examining IVC with ultrasound can also guide etiology in hypotension, congestive heart failure, sepsis, respiratory failure, some primary lung pathologies, possible pulmonary thromboembolism (PTE), trauma, and burns according to recent guidelines.[1,4,5] European Society of Cardiology recommended using IVCCI as evidence of volume overload in patients with acute heart failure (AHF) in patients admitted to the emergency department (ED) with dyspnea. Inferior vena cava collapsibility index values lower than 50% have 83% sensitivity and 81% specificity for diagnosing AHF. This guideline mentioned dilatated IVC as a complementary finding for PTE.[1] Pocket-sized ultrasound devices (PSUDs) may provide an accurate diagnosis for shock patients by evaluating the cardiovascular system rapidly and reliably for steering therapeutical approach. Thus, availability of PSUDs may significantly improve the diagnostic approach and management of shock.[6,7]

For this reason, a practical, reliable, fast, and affordable ultrasound device may be more convenient. Previous studies reported that PSUDs can be used for POCUS in cardiology, EDs, and ICUs effectively and reliably.[8,9] New generation PSUDs can display images as good as SD, and they are mostly as compact to carry in a pocket. In our recent study, we found a PSUD can visualize and measure diaphragm as good and reliable as a SD in our ICU patients.[10] Especially in ICU patients, there is no available data about if a PSUD is sufficient for IVC ultrasound up to now. Motivated by the pressing

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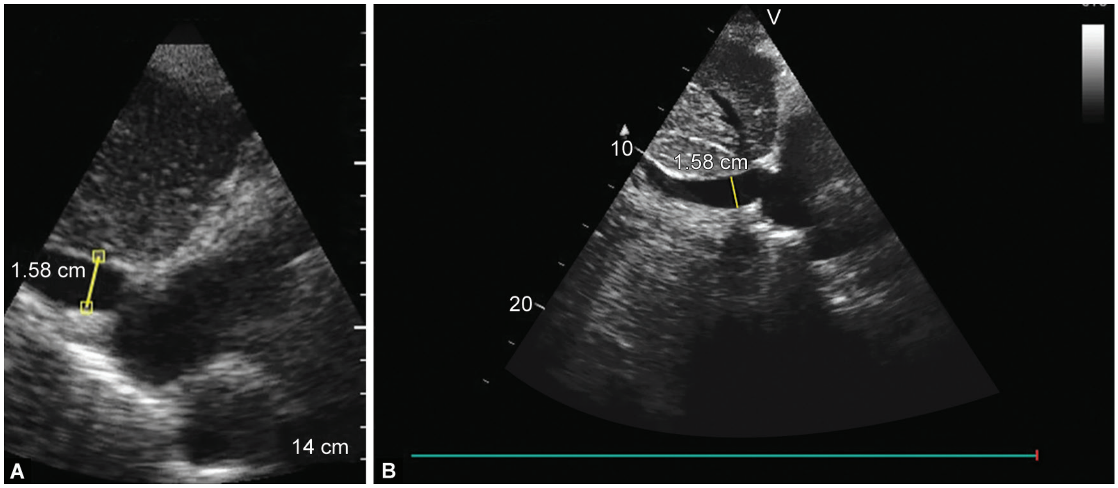

Figs 1A and B: Ultrasonographic measurements. (A) Inferior vena cava diameter, Pocket-sized device; (B) Inferior vena cava diameter, Standard device

need for a practical, relatively cost-effective ultrasound device in ICUs, our study aimed to validate the technical plausibility of PSUDs, known for their rapid and reliable cardiovascular evaluation in outpatient clinics and hospital wards. We specifically address the burning question surrounding the technical sufficiency for measurement reliability of PSUDs for IVC ultrasound in comparison with the SD in ICU patients. We aimed to offer a compelling perspective, demonstrating the potential of PSUDs as a viable and efficient solution, comparing them with SDs in our tertiary adult pulmonary ICU.

Materials and Methods

We prospectively recruited 42 adults in our tertiary medical ICU of a university hospital over 5 months between January 1 and May 31, 2017. We designed the study to have an 80% power to detect a 20% difference in percentage collapse of the IVC between measurements of two devices. Alpha was set at 0.05. The selected cut-off, expected differences and standard deviation was obtained from the study comparing the effect of sampling location on IVC percentage collapse during respiration by Wallace et al. Minimum required sample size was 22 subjects according to our calculation, we used NCSS PASS to calculate the minimum required sample size.[11,12] All spontaneously breathing patients and mechanically ventilated patients who could spontaneously breathe without any mechanical ventilatory support for at least 30 minutes without any respiratory symptoms or change in vital signs admitted to our ICU were included in the study, consequently. The study protocol was approved by our institution's ethics committee and conducted conveniently with its guidelines (28.12.2015/166). Written informed consent was obtained from the patient or his/her next of kin. In the same session, ultrasonographic examinations were carried out using the ultrasound machines according to a standardized protocol by two intensivists experienced in IVC ultrasonography. The operators were blinded to the results of previous IVC measurements. Patients were examined in a randomized order with V-Scan with dual probe device by GE Systems as PSUD and Vivid-q (GE) as a SD with all range of standard modalities and measurements. Inferior vena cava diameters (IVCDs) were measured with phased array probes in both respiratory phases (3.5 MHz in Vivid q and 1.7–3.8 MHz in V-Scan) by using B-mode in both devices (Fig. 1). The examiners had experience in using both ultrasound devices and applying measurements of IVCD. All images were saved as cine-loop records, and measurements were performed on these records according to recent guideline recommendations with both intensivists independently from each other.[13] The IVC has been assessed at a depth of 6–15 cm via a subcostal window using phase array US probes for both devices. The IVCD was measured 2 cm caudal to the hepatic vein-IVC junction. We made recordings involving the image of maximum and minimum diameters of IVC during respiratory phases. We made serial ultrasonographic cine-loop recordings with the SD and PSUD in a randomized order with both intensivists independently from each other in all patients. Then, measurements of both SD and PSUD recordings were done on different days from each other by both intensivists blinded to the results of previous IVC measurements. Then, IVCCI was calculated with the following formula: ([IVCmax – IVCmin]/IVCmax) × 100.[14] Mechanically ventilated patients who were enrolled in our study were the ones in their weaning process or could tolerate being disconnected from the mechanical ventilator for several hours a day. Thus, all of these patients could spontaneously breathe without any mechanical ventilatory support for at least 30 minutes or an hour without any respiratory symptoms or change in vital signs. In our study, we measured respiratory variability of IVCD after disconnecting from the ventilator in mechanically ventilated patients before any spontaneous breathing trial was performed on the day their measurements were done. None of the mechanically ventilated patients had any respiratory changes or alterations in vital signs after disconnecting from the ventilator. We measured respiratory variability of IVCD after disconnecting from the ventilator in mechanically ventilated patients for calculating IVCCI. To be sure that if the measurements were performed during inspiration or expiration, we included in the diaphragm to the images and decided phases of breathing (Fig. 1).

For both devices, evaluations were carried out at the bedside, and both examiners performed examinations with both devices. At least three images were recorded in each patient using both devices during each examination, and results were documented to a standardized report form. Ultrasonographic images captured during the examination were stored digitally on both devices. Time spent on both examination processes and evaluation of measurements were calculated using a stopwatch for each device. The time required for the preparation of the device, setting it up for screening IVCDs, making the measurements, evaluating the results, and noting down by an assistant were identified. We also

Table 1: Baseline characteristics of critically ill adults

N	*40*
Gender: F/M *n* (%)	20 (50%)/20 (50%)
Age (years)	66 ± 17
BMI (kg/m^2)	27 ± 6
IMV *n* (%)	20 (50%)
NIMV *n* (%)	10 (25%)
Spontaneous *n* (%)	10 (25%)
Diagnosis *n* (%)	
Pulmonary system	38 (90%)
COPD attack	21 (50%)
Hearth failure	21 (50%)
Sepsis	16 (38%)
Renal system	8 (19%)
Neurological	8 (19%)
Gastrointestinal system	7 (17%)
Malignancy	6 (14%)
Outcome *n* (%)	
Discharge from hospital	24 (57%)
Exitus	10 (24%)
Discharge from ICU	8 (19%)

BMI, body mass index; COPD, chronic obstructive pulmonary disease; F/M, female/male; ICU, intensive care unit; IMV, invasive mechanical ventilation; N, number; NIMV, noninvasive mechanical ventilation

Table 2: Comparison of diagnostic ability and estimated time for IVCD and IVCCI measurements

Measurements (n = 40)	*Standard device*	*PSUD*	*p-value*	*ICC**
IVCD minimum (cm ± SD)	1.35 ± 0.68	1.34 ± 0.67	0.63	0.94
IVCD maximum (cm ± SD)	2.01 ± 0.49	1.98 ± 0.53	0.34	0.85
IVC collapsibility (% ± SD)	39 ± 20	39 ± 20	0.93	0.82
Application time (*n* = 11)				
(Time ± SD)	10.53 ± 3.43	9.62 ± 3.21	0.18	0.81

*Interobserver correlation coefficient >0.8; CM, centimeters; ICC, interclass correlation coefficient; IVC, vena cava inferior; IVCD, vena cava inferior diameter; PS, pocket-size; SD, standard deviation

noted down the time needed to measure IVCD with respiratory variations for both devices. For both SD and PSUD, we started time measurements in "off" mode before all examinations. To assess IVCD measurements' reproducibility, we performed 10 assessments on our 10 patients, and images were analyzed separately by two ultrasonographers to assess interobserver reliability. Continuous variables were presented as medians and interquartile range (IQR) and categorical variables as counts and percentages. The number of necessary patients was 22 according to power analyses for significance level of $p < 0.05$. Comparison and analysis of quantitative data for estimated time and measurements were made with *t*-test for two independent samples. All of the *p*-values were two-sided and based on a significance level of <0.05. Bland–Altman analyses were used to calculate mean differences and 95% limits of agreement for each pairwise comparison. Intraclass correlation coefficient (ICC) was used to determine the intrarater reliability for repeated measurements by both operators, and ICC greater than 0.7 was accepted to indicate a good correlation. The evaluation was carried out with IBM SPSS version 21.0 (IBM SPSS Statistics, IBM Corporation, Armonk, NY, USA).

Results

Forty-two patients were enrolled in this study, and no postoperative patients were included. By using both SD and PSUD, we could visualize IVC in 40 (95%) of the patients. In one of these patients, IVC could not be visualized. He had multiple abdominal surgical interventions in his medical history. The other patient had severe kyphoscoliosis with severe subcutaneous edema. Table 1 presents baseline demographic and diagnostic characteristics of 40 patients who were included in data analysis. The age of the patients was 66 ± 17 years, 20 (50%) of them were male, and 20 (50%) were female. 20 (50%) patients were followed under mechanical ventilation therapy, and 10 (25%) of them were receiving noninvasive ventilation. 10 (25%) patients were receiving no mechanical ventilation support. As also seen in Table 2, there was no statistically significant difference in inspiratory (PSUD: 1.34 ± 0.67 cm; SD: 1.35 ± 0.68 cm) and expiratory (PSUD: 1.98 ± 0.53 cm; SD: 2.01 ± 0.49 cm) IVCD among PSUD and SD ($p > 0.05$). There was also no significant difference between IVC respiratory variability rates with PSUD (39 ± 20%) and SD (39 ± 20%) ($p > 0.05$). When we evaluate the mechanically ventilated and not mechanically ventilated patients separately, we found no statistically significant difference between IVC respiratory variability rates between SD and PSUD in both groups of patients ($p > 0.05$). The Bland–Altman analysis revealed that the width of 95% limits of agreement were similar for both devices, and there was no proportional bias in IVCD measurements (Fig. 2). There was a very good inter-device agreement among the PSUD and SD for IVCD measurements in both respiratory phases. There was no significant difference in IVC respiratory variability between two devices. Mean time for overall examination with both devices were similar (PSUD: 9.6 ± 3.2 minutes, SD: 10.5 ± 3.4 minutes, $p = 0.13$). ICCs were higher than 0.80 in interobserver reliability analysis for all measurements applied with both of the ultrasound devices.

Discussion

Our study showed that IVCD can be visualized using PSUD in most of the ICU patients. For both visualization and measurements, success ratio of PSUD was same as SD. The overall time spent on the procedure was approximately equal in both devices. There was a very good agreement between the measurements of the devices, and there was no bias in the measurements of both IVCD measurements.

When POCUS is performed with PSUDs by experts, it may result in rapid and cost-effective improvement at diagnostic accuracy.[15,16] In a study of Andersen GN et al., in which a total of 199 emergency room patients were examined. Median time spent was 5.7 minutes for the cardiac examination and 4.7 minutes for the abdominal examination and in 25% of the patients, an additional important diagnosis was made.[17] When considered the importance of time to make a diagnose and immediately initiate therapeutic approach in a critically ill patient, these results are remarkably promising for the use of PSUD in ICUs. In our study, the mean time needed to evaluate IVC with PSUD was 9.62 minutes. The time we spent to evaluate a major vascular structure may be considered acceptable as a result of technical challenges encountered in an ICU patient. Even though there is no significant difference in the measurement times between two devices in our study, with a PSUD, we can reach more patients and operate more easily due to its compact and user-friendly structure, which is substantial in complex ICU environments.

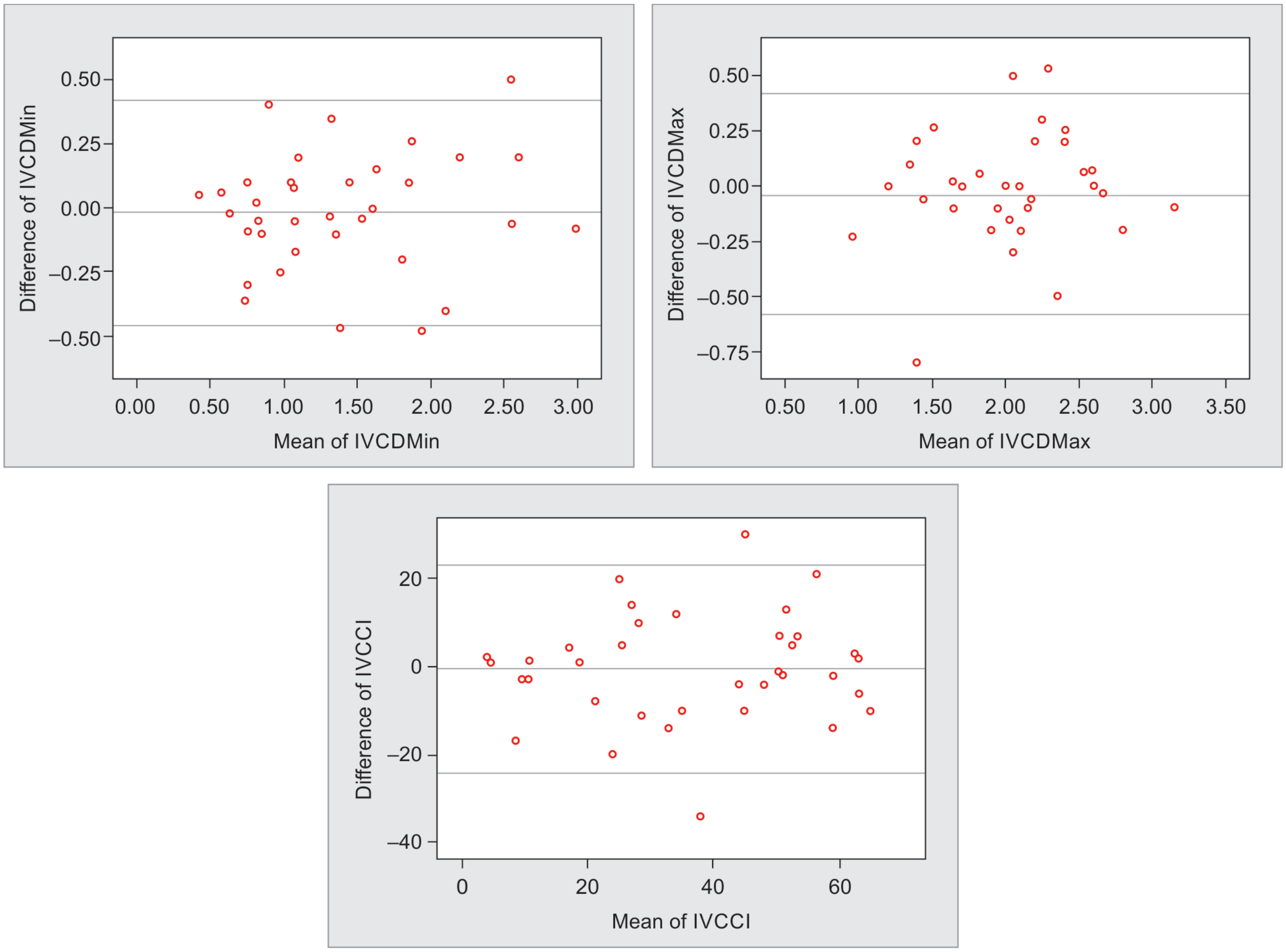

Fig. 2: Blant–Altman graphics of minimum IVC diameters, maximum IVC diameters and IVC collapsibility indexes

Many studies are targeting ICU and cardiology patient population, which aims IVCD measurements and detecting respirophasic variability. However, there is no study that evaluates the diagnostic accuracy of PSUDs comparing with SDs in ICU patients. According to recent data, adequacy of a PSUD to evaluate abdominal structures is unclear. In their study, Esposito et al. found that the PSUD may be a reliable tool for screening abdominal aorta diameter, which may be associated with coronary artery disease and which is also a deep intra-abdominal vascular structure likewise IVC.[7] In addressing the challenge of detecting clinically relevant differences in a small structure like the IVC, our study employs standardized protocols, experienced operators, and rigorous measurement techniques with both the PSUD and the SD we used. In addition to methodological aspects, the clinical relevance of measurement differences in a small vascular structure between two devices may be questioned. Previous data suggest a 20% variance in the percentage collapse of the IVC between different measurement locations, which has been considered both clinically and statistically significant. This aligns with previously published discriminatory breakpoints near this threshold by various authors.[11,18,19] Our study results reveal that the differences between the calculated IVC collapse indices measured by the two devices are considerably lower than the mentioned acceptable variation. Therefore, we assert that our study provides both clinically and technically meaningful results.

Current PSUDs are known to be capable of reliable echocardiographic evaluation, and this result may be an important issue, especially in critically ill population, in which cardiac dysfunction is frequent.[20] On the other hand, according to a study of Stock et al. in which they enrolled 28 internal medicine inpatients, they found that organ size measurements may be substantially smaller with PSUD. They added that this might be an important limitation for reliability. On the contrary, we did not encounter such a limitation even though we evaluated an intra-abdominal structure either. This result may be related to factors related to operators or technical details regarding the devices used in that study.[21]

In our study, we could not visualize IVC in two patients. The IVC could not be visualized by both using PSUD and SD in these patients. One of these patients had severe kyphoscoliosis causing an alteration in abdominal visceral organ positions. The other patient had multiple previous abdominal surgical interventions related to advanced hepatobiliary carcinoma in his medical history. There was no patient in which IVCD could not be visualized with PSUD and could be with SD. To successfully visualize an intra-abdominal structure using ultrasonography, fasting for 8 hours before the examination is recommended. In ICU patients, ultrasonographic evaluation is occasionally needed under emergent conditions. Most of these patients are continuously fed in an enteral route, making things more difficult for the clinicians. Despite these limitations, we had a high success rate for both visualization and measurements of IVCD. On the other hand, PSUD proved its potential as an essential modality for the collection of heart, lung, and vein imaging information among patients with severe critically ill COVID-19 during the pandemic.[22]

In ICUs, IVCD and its variability are mostly used for detecting fluid status and responsiveness and planning fluid resuscitation. However, it can also guide diagnosing heart failure, other hypervolemic conditions, some specific lung pathologies, PTE, and some types of shock, which are frequent and mortal diseases for the ICU's patient population.[8,9] Additionally, PSUDs have important above-mentioned advantages on several counts. Moreover, current PSUDs have a simpler interface and more minimalist design depending on their size, and this feature makes them easier to learn and apply. Besides, some PSUDs are also compatible with mobile phones by using an application, and only a probe can be enough to make an ultrasonographic evaluation, which is expected to make things even more easier for daily ICU routine. During guiding fluid management via IVCD measurements, evaluation of lungs and B lines may give additional information to intensivists about fluid overload or heart failure, which are frequent and vital problems.[23] Limitations about using PSUDs are mostly based on their more compact and simpler interface and smaller structure. Lack of M-Mode and restricted probe types in some models depending on different types of brands and models may restrict clinician's diagnostic capability. Our PSUD also did not have an M-Mode, but recent guidelines recommend using B-Mode rather than M-Mode because it is more reliable for evaluating IVCD and IVCCI. Depending on the change of place in IVC under the cursor with respiration may make M-Mode less reliable. Thus, we think the lack of M-Mode in our PSUD was not a technical disadvantage for our study.[8,11] Our device had a dual probe but did not have a convex probe, so we used a sector probe to evaluate IVCD for standardization in two devices. In our study, we found that the mean time for the overall examination with both devices were similar. PSUDs are compact and have a simpler interface; however, making measurements on a smaller screen with smaller and fewer buttons assigned with multiple functions is expected to make time spent for measurements to be longer than SDs. We conclude that the time needed from decision to application of ultrasonographic evaluation is quite shorter in a PSUD, but the time needed to be spent for measurements may be longer than SD depending on its technical usage details. This may explain why mean time for overall examination with both devices was similar even though PSUD is easier to set up.

We should remember depending on brand, release date, technical properties, including hardware and software, both PSUDs and SDs have a wide product scale. Limitation of our study is number of our patients and compared IVCD measurements to be done in only B-Mode with both devices. Even though there are studies that support the idea IVC ultrasonography is a reliable method when necessary technical and patient-related conditions are provided, current status of IVC ultrasonography in current anesthesia and ICU practice is questionable.[24,25] Recent data regarding previous studies have found significant heterogeneity in IVC ultrasonography methods both in ICU and in perioperative patients.[24,25] On the other hand, our study can be evaluated as a technical study, which aims to compare technical capability of two different devices for IVCD measurements rather than a clinical study that aims to decide fluid status or responsiveness in medical ICU patients. More randomized controlled studies should be done for understanding the place of PSUDs in daily ICU routine for different clinical conditions in which ultrasonography is capable of evaluating.

Conclusion

Depending on our results, we suggest that a PSUD may be used as reliable and useful as a SD for IVCD and IVCCI in ICU patients.

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