Diagnostic influence of cardiovascular screening by pocket-size ultrasound in a cardiac unit

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Aims
We aimed to study the diagnostic influence of adding a routine cardiovascular ultrasound screening of the cardiac anatomy and function, the pericardium, the pleura and the abdominal great vessels by the new pocket-size ultrasound device (pUS) with grey scale and colour Doppler imaging.

Methods and results
In 119 randomly selected patients admitted to a cardiac unit at a non-university hospital, routinely adding a cardiovascular ultrasonography of only 4.4 min with a pocket-size device corrected the primary diagnosis in 16% of patients. In addition, 29% had the primary diagnosis verified and in 10% an additional important diagnosis was made. Higher age predicted any diagnostic influence of pUS screening with an increase of 61% (P = 0.003) per 10 years of higher age. Overall, the pUS screening had a sensitivity and specificity with respect to detecting at least moderate pathology of 97 and 93%. Positive and negative predictive values were 93 and 87%, respectively. In the sub-group of subjects with a change in the primary diagnosis following pUS there was no false-negative or false-positive findings.

Conclusion
Screening by pUS assessed vascular and cardiac anatomy and function accurately and enabled correction of the diagnosis in 16% of patients admitted to a cardiac unit. In 55% of the participants, the cardiovascular ultrasound screening had important diagnostic influence. We suggest that it would be appropriate to implement strategies and systems for routinely adding an ultrasound cardiovascular examination to patients in cardiac units.

Keywords
Echocardiography • Vscan • Hand-held • Scanner • Workflow • Device

Introduction
Diagnosis and treatment are the key elements in every inpatient’s stay. Unfortunately, a correct diagnosis is not always made in time with a possible non-favourable outcome, time delay and patient’s suffering as the result. Former studies have shown that adding an echocardiographic or cardiovascular ultrasound examination to the usual care diagnostics improve the accuracy of the diagnosis.2–5 The last decade’s miniaturization of ultrasound devices capable of offering high-quality recordings has made possible a logistic basis for applying ultrasound examinations in a more routine way. The pocket-size ultrasound devices (pUS) of the last years have the potential to dramatically rearrange physical examinations and diagnosis.6,7 The pUS has been shown to be both accurate and feasible as a tool for cardiac imaging when used by experienced operators.8–10 However, it is not known how the pUS could be used as a tool in a cardiac unit influence diagnosis. In addition, it is uncertain how reliable the pUS examinations are when they are performed at the bedside under non-optimal conditions. We therefore aimed to study the diagnostic influence of routinely adding a bedside pUS cardiovascular screening with examination of the heart, the pericardium, the pleura and the abdominal great vessels. Furthermore, we wanted to study the reliability of the bedside pUS examination, and at last, study predictors of diagnostic influence of the pUS cardiovascular screening.

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Committee decided the grading of the diagnostic usefulness.

or (iv) not useful, depending on the descriptions of diagnosis, findings
primary diagnosis, (ii) verification of the primary diagnosis, (iii) added
tee individually graded the diagnostic usefulness as: (i) change in the
bedside pUS screening. From the patients’ journal files, the Commit-
University Hospital) cardiologists experienced in echocardiography
Committee, consisting of two internal and one external (Trondheim
study. As the second-call duty at this hospital is served by three cardi-
ologists experienced in echocardiography and abdominal ultrasound
28 mm. The device offers two-dimensional grey scale and colour
image. The length of recordings of other structures is prede-
width with a range of 1.7–3.8 MHz is automatically adjusted. An algor-
ithm enables automatic storage and looping of a cardiac cycle without
ECG signal.12 The length of recordings of other structures is prede-
fining and limited to 2 s. Patient identification was performed by
voice recording and the automatically assessed examination number.

Diagnostic usefulness of screening with pocket-size ultrasound
Prior to the pUS examination, the primary diagnosis was recorded in
the patient’s journal files. Secondly, the results of the bedside pUS
screening and the cardiologist own opinion of the diagnostic usefulness
of the pUS screening were reported according to European Association
of Echocardiography (EAE) recommendations.11 Thirdly, the Study
Committee, consisting of two internal and one external (Trondheim
University Hospital) cardiologists experienced in echocardiography
and abdominal ultrasonography, graded the diagnostic usefulness of
the bedside pUS screening. From the patients’ journal files, the Commit-
tee individually graded the diagnostic usefulness as: (i) change in the
primary diagnosis, (ii) verification of the primary diagnosis, (iii) added
diagnosis important for further treatment or follow-up of the patient
or (iv) not useful, depending on the descriptions of diagnosis, findings
and therapeutic influence. In case of doubt, the clear majority in the
Committee decided the grading of the diagnostic usefulness.

Cardiovascular screening
The cardiovascular screening was performed with a pUS, Vscan (GE
Vingmed Ultrasound, Horten, Norway). The device weighs 390 g,
including the phased-arrayed probe, which is sized 135 × 73 ×
28 mm. The device offers two-dimensional grey scale and colour
Doppler imaging, with a movable colour Doppler sector. The band-
width with a range of 1.7–3.8 MHz is automatically adjusted. An algo-
rithm enables automatic storage and looping of a cardiac cycle without
ECG signal.12

The most severe valvular pathology was used in the analyses. Percar-
dial effusion was classified as (i) not present or (ii) present. The size of
the left atrium was measured on grey-scale parasternal long-axis
measurement images by the device’s caliper mode. An attempt was
made in case of doubt by visual assessment. The inferior
vena cava diameter was measured end expiratory within 2 cm from
the right atrium orifice and respiratory variation was assessed to esti-
mate the right atrium filling pressure.13 All measurements of size were
done on the pUS. With patients in the supine position the pleura was
assessed by grey-scale imaging from left and right lateral views, and the
amount of pleural effusion was classified as (i) no pleural effusion, (ii)
insignificant or moderate pleural effusion or (iii) significant pleural effu-
sion.14 All recordings were saved on the pUS and the time used for the
screening was calculated as the time from start to end of the
examination.

Validation of pUS screening
A high-end echocardiographic examination was performed by a Vivid 7
(GE Vingmed Ultrasound) scanner. One of the four experienced car-
diologists other than the one who performed the pUS screening per-
formed the examination. They were blinded to the result of the pUS
examination. The same cardiovascular structures as described above
were measured and classified according to the guidelines of the
EAE.15–19 Ejection fraction was measured by Simpson’s rule from
apical four-chamber and two-chamber views, dimensions were
measured by motion mode from parasternal recordings.18 Valvular
pathology was graded according to the recommendations from the
EAE.15–17 In addition, imaging techniques as computer tomography,
magnetic resonance imaging or ultrasound were used by usual care
at the Department of Radiology. For the analyses in the patients
who underwent both echocardiographic and radiologic examinations,
the radiologists grading of pleural effusion and size of the abdominal
aorta was preferred compared with the echocardiography. At last all
examinations were graded as described for pUS.

Statistics
As the different echocardiographic and anthropometric measures
partly deviated from normal distribution, the basic characteristics are
presented as mean ± standard deviation (SD) and range. Comparison
of continuous variables between groups was done by the non-
parametric Mann–Whitney U test of independent samples, and propor-
tions between groups were analysed by the χ² test or
Fisher’s exact test. The Spearman’s rho (r) is used for comparison of the
grading of pathology between the pUS and the high-end echocar-
diographic or radiologic examinations. Data are presented as r [95%
confidence interval (CI)] where the 95% CI is analysed by determining
the bootstrap distribution randomly re-sampling the study population
10,000 times. For comparison of continuous variables between the pUS and the high-end examinations Pearson’s rho (r) was used, respectively. In order to assess predictors of influence of the pUS screening, logistic regression analyses were used. Diagnostic influence, graded as diagnostic usefulness or no diagnostic usefulness, was used as the dependent variable, and the age and known increased risk of cardiovascular disease were used as explanation variables. As there was a linear relationship between the diagnostic usefulness and increasing age, age was entered into the analyses as a continuous variable. Increased risk was classified as present if the patients had any known cardiovascular disease, hypertension or diabetes. Sample size of around 100 participants was estimated by expecting a change in the main diagnosis of at least 8–10% points, in addition to a more pronounced proportion in which the diagnose was verified or another important diagnose was added. However, from these estimates we expected only around 50–70% power to detect significant predictors of diagnostic usefulness of pUS screening with respect to change in the main diagnosis, and some underpowered analyses with respect to detecting predictors of any diagnostic usefulness as well (SamplePower, SPSS, Inc., Chicago, IL, USA). All the statistical analyses were performed using SPSS for Windows (version 18.0, SPSS, Inc.).

**Results**

**Study population**

Table 1 shows basic characteristics of the 119 study participants (45 women and 74 men). Mean ± SD (range) age was 67 ± 15 (25–85) years among women and 66 ± 14 (20–89) years among men, with no significant difference (P = 0.31). The distribution of age departed from the normal distribution and was positively skewed (Figure 1), P < 0.001. Each of the pUS measurements was obtained in at least 78% of the participants, and complete visualization of the abdominal aorta and the inferior vena cava diameter had lowest feasibility. Except for these latter measurements, all structures were assessed to satisfaction in at least 98% of the participants. A total of 65% had previous known atrial fibrillation, hypertension, diabetes or any kind of known cardiovascular disease and these participants were classified as at increased cardiovascular risk. The time used for the bedside pUS screening was 4.4 ± 1.7 (2.0–13) min.

**Diagnostic usefulness of screening with pocket-size ultrasound**

The diagnostic usefulness of bedside cardiovascular ultrasound screening with the pocket-size Vscan is shown in Table 2 and Figures 2 and 3. In 19 (16%) participants the primary diagnosis was changed following pUS. In a total of 65 (55%) patients there was diagnostic usefulness, classified as either change in primary diagnosis, verification of primary diagnosis or adding a diagnosis important for treatment or follow-up of the patient. In Table 3 basic characteristics, the primary diagnosis, the findings and the correct diagnosis after pUS screening are listed for the 19 patients, with a change in the primary diagnosis following the pUS screening.

![Figure 1 Age distribution of the 119 participants. Distribution deviated significantly from normal distribution (P < 0.001).](https://example.com/figure1.png)

**Table 1** Basic characteristics of 119 study participants

| Table 1 | \hline
| Mean ± SD (range) |  
| Age (years) | 66.5 ± 14.2 (20–89) |
| Women [n (%)] | 45 (38) |
| Height (cm) | 172 ± 9 (146–189) |
| Weight (kg) | 80 ± 15 (45–122) |
| Body mass index (kg/m²) | 27.4 ± 4.9 (17–44) |
| Systolic blood pressure (mmHg) | 146 ± 31 (58–250) |
| Diastolic blood pressure (mmHg) | 80 ± 20 (32–161) |
| Heart rate (bpm) | 81 ± 24 (29–150) |
| Atrial fibrillation [n (%)] | 19 (16) |
| Known hypertension [n (%)] | 44 (37) |
| Known diabetes [n (%)] | 19 (16) |
| Known myocardial infarction [n (%)] | 34 (29) |
| Known angina [n (%)] | 26 (22) |
| Known heart failure [n (%)] | 10 (8) |
| Known peripheral vessel disease [n (%)] | 9 (8) |
| Known stroke [n (%)] | 8 (7) |
| Increased cardiovascular risk [n (%)] | 77 (65) |
| Known cancer [n (%)] | 4 (3) |

**Table 2** Diagnostic influence of bedside cardiovascular screening by pocket-size ultrasound in 119 study participants

| Diagnostic influence | Number (%) |
|----------------------|------------|
| Change in primary diagnosis | 19 (16%) |
| Verification of primary diagnosis | 34 (29) |
| Additional diagnosis made | 12 (10) |
| No diagnostic usefulness | 54 (45) |
Figure 4 show the electrocardiogram and an echocardiographic image of one of the patients who had the diagnosis changed.

Age and known increased risk of cardiovascular disease of the study participants differed significantly between those with any diagnostic influence of the pUS screening and those without. Mean age was almost 10 years higher in those where pUS screening influenced the diagnosis ($P = 0.001$) with mean $+ SD$ (range) 70.9 $+ 11.7$ (38–89) compared to 61.2 $+ 15.2$ (20–85). The proportion of participants with increased cardiovascular risk, assessed as previous known atrial fibrillation, hypertension, diabetes, angina, myocardial infarction, heart failure, peripheral vessel disease or stroke, was 75% in those with any diagnostic usefulness of pUS screening compared to 52% in the other group ($P = 0.007$). Figure 2 shows the probability and 95% CI of diagnostic usefulness of pUS screening according to pre stratified age groups ($< 40$, 40–59.9, 60–79.9 and $> 80$ years). Figure 3 illustrates diagnostic influence of the pUS screening according to the two age groups of participants between 40 and 80 years. In logistic regression analyses 10 years higher age was found to increase the probability of any diagnostic influence of pUS screening with 61% ($P = 0.003$) adjusted for increased cardiovascular risk as present or absent (Table 4), but the corresponding 33% ($P = 0.2$) increased probability of change in primary diagnosis was not significant. Correspondingly, increased cardiovascular risk, assessed as present or absent, did not show significant increased probability of changed primary diagnosis or any diagnostic use when adjusted for age ($P \geq 0.14$). However, as shown in Table 4 there was a clear trend towards increased probability of diagnostic usefulness of cardiovascular bedside screening with pUS in those with higher cardiovascular risk. The other basic characteristics did not predict diagnostic usefulness of the cardiovascular screening with pUS.

Validation of pUS screening

Validation of pUS screening was tested in a sample of 90 (76%) of the population. The correlation coefficient was $1.0$ for the grading of pericardial effusion and detection of abdominal aortic aneurysm, 0.94 (CI: 0.88–0.99) and 0.92 (CI: 0.83–0.99) for the grading of global and regional LV functions, respectively, 0.84 (CI: 0.60–1.0) for the grading of RV size and function, 0.89 (CI: 0.81–0.95) for the grading of valvular function, 0.67 (CI: 0.54–0.79) for the assessment of end-expiratory size of the inferior vena cava and 0.66 (CI: 0.51–0.78) for left atrium. All correlations were very highly significant (all $P < 0.001$). The inferior vena cava and the complete abdominal aorta were available for comparison in 81 (90%) and 59 (66%), respectively. All other structures were feasible in at least 97% of the participants.

In analyses of the 90 subjects that had been re-examined with at least one of the high-end reference methods, the sensitivity and specificity of the pUS examination with respect to detecting moderate or severe pathology of LV global and regional functions, RV function, valvular function and dilatation of the left atrium, detection of pericardial or pleural effusion as well as abdominal aortic aneurysms was 97 and 93%. The corresponding positive and negative predictive values were 93 and 87%, respectively. In the 19 subjects with change in the primary diagnosis following pUS there was no misclassification at all.

Discussion

In 119 randomly selected patients admitted to a cardiac unit at a non-university hospital routinely adding a cardiovascular ultrasonography of only 4.4 min with a pocket-size device corrected the primary diagnosis in 16% of patients. In addition, 29% had the primary diagnosis verified and in 10% an additional important diagnosis was made. Thus, in only 45% of the participants the cardiovascular ultrasound screening had no diagnostic influence.
Cardiovascular screening by pUS

Study population
Median age was 69 years, and as shown in Figure 1 the distribution of age was positively skewed. The basic characteristics are in line with those published in former studies and thus, it might reflect the everyday clinical setting at cardiac departments.

Diagnostic usefulness of pUS screening
The diagnostic influence of routinely adding a pocket-size cardiovascular ultrasound examination performed by experts is remarkable, but still in line with previous publications on screening of patient groups by larger mobile ultrasound devices. The cost-benefit of a screening programme depends on the accuracy of the method used and the prevalence of pathology in the population. This study, as well as others, shows the high prevalence of underlying disease among inpatients with suspected cardiac or internal medical diseases. Furthermore, it underlines how difficult it is to make a correct diagnosis based on medical history, clinical examination, laboratory tests and routine imaging alone. Even though many of the incorrect diagnosis would have been corrected during the patient’s stay, usual care practice would have lead to a significant time delay as well as a probable misdiagnosing. The accuracy of pUS screening presented is in line with recent publications performed under more optimized conditions compared with examinations performed bedside. We therefore suggest that screening with cardiovascular ultrasound in addition to usual care examinations should be recommended in patients admitted to a cardiac unit to optimize diagnostic accuracy and inpatient workflow.

Table 3 Characteristics and findings of the 19 participants with a change in primary diagnosis after cardiovascular screening with pocket-size ultrasound

| Characteristics | Primary diagnosis | Main findings at bedside screening with pocket-size cardiovascular ultrasound | Changed diagnosis |
|------------------|-------------------|--------------------------------------------------------------------------------|-------------------|
| M, 75 years, HT, MI, op. CABG | Dyspnea | AAA 56 mm, PE, PIE | PE, AAA |
| W, 82 years, HT, AP, op. AVR | Dyspnea | PIE | PIE, severe amount |
| M, 78 years, asthma | Chest pain | Aortic valve stenosis/insufficiency | Aortic stenosis |
| W, 83 years, HT, COPD | Dyspnea LAI | PIE, moderate valvular insufficiencies, LV dysfunction | Heart failure |
| M, 75 years, AFIB, AP, PerVes, COPD | Heart failure | Normal LV and RV function | COPD |
| W, 60 years, HT | Chest pain | LVH | Hypertensive heart disease |
| W, 64 years, HT | Chest pain | Dissection of thoracic and abdominal aorta | Aortic dissection |
| W, 59 years, HT, DM | NSTEMI | Dilated and dysfunctional LV, multi-valvular pathology | NSTEMI |
| M, 70 years, AFIB | AFIB | Anterior wall dysfunction | NSTEMI |
| W, 58 years, HT | Chest pain | Anteroscpetal wall dysfunction | NSTEMI |
| W, 80 years, HT, DM, PerVes | Pneumonia | Dilated and dysfunctional LV | Heart failure |
| W, 67 years, AFIB, HT, DM | AFIB | Severe LA dilatation, dilated IVC, PIE | Heart failure |
| M, 62 years, MI, AP | Dyspnea | Global and regional LV dysfunction, severe MR | Heart failure (MR) |
| W, 81 years, HT, PerVes, stroke | Chest pain | LVH, moderate MI, severe dilated IVC | Hypervolemia (HF) |
| W, 81 years, HT, op. | Pneumonia | RV dilatation and dysfunction, dilated IVC | Ac. cor pulmonale (PuE) |
| M, 53 years, asthma | NSTEMI | Severe LV dilatation and dysfunction | DCM |
| W, 56 years, asthma | PuE | Inferior wall dysfunction | NSTEMI |
| M, 87 years, MI, AP, HF | Heart failure | Severe AS, PIE, near normal LV function | Severe AS |
| W, 81 years, MI | Dizziness | AAI 100 mm | AAA |

AAA, abdominal aortic aneurysm; AFIB, atrial fibrillation; AP, angina; AS, aortic stenosis; AVR, aortic valve replacement; DCM, dilated cardiomyopathy; DM, diabetes mellitus; HF, heart failure; HT, hypertension; IVC, inferior vena cava; LA, left atrium; LAI, lower airway infection; LV, left ventricular; LVH, left ventricular hypertrophy; MI, myocardial infarction; MR, mitral regurgitation; NSTEMI, non-ST-elevation myocardial infarction; op., recent surgery; PE, pericardial effusion; PIE, pleural effusion; PuE, pulmonary embolism; COPD, chronic obstructive pulmonary disease; PerVes, peripheral vessel disease.

*Excessive salt intake.
and negative predictive values in this study indicate that screening programmes of similar populations may be cost beneficial.

Validation
There was a very high accuracy of pUS screening compared with high-end echocardiography or radiologic examinations for assessment of aortic aneurysms, pericardial effusion, LV global and regional size and function, RV size and function and valvular function. Assessment of size of the left atrium and end-expiratory diameter of the vena cava was fair and in line with a recent publication. With respect to these two structures, there are some methodological aspects that might have influenced the results. As the use of ECG cables is unpractical on pUS devices, the exact timing in the cardiac cycle may be non-optimal on the pUS device as it depends on visual assessment. However, the high accuracy with respect to detecting abdominal aortic aneurysms as well as a almost perfect correlation for aortic dimension with \( r = 0.99 \) (95% CI: 0.98–1.0) in those where aortic dimension was measured with pUS indicates that the non-optimal accuracy of measuring size of the left atrium and inferior vena cava is influenced by timing of the measurement in the cardiac or respiratory cycle. In addition, the time delay from the pUS screening to the high-end echocardiography was mean (SD) 16 h, which may have influenced the repeatability of the inferior vena cava measurements, due to physiological reasons and treatment during the time period.

Conclusion
In this study we found that a quick cardiovascular ultrasound screening by pUS assessed vascular and cardiac structures’ size and function accurately and enabled correction of the diagnosis in 16% of patients admitted to a cardiac unit. In addition, several patients had their diagnosis verified or an additional diagnosis important for treatment or follow-up made. We suggest that implementing strategies and systems for routinely adding an ultrasound cardiovascular examination to patients in cardiologic units are appropriate.

Limitations
The main limitation of this study is that the bedside cardiovascular pUS screening was performed by consultant cardiologists experienced in echocardiography as well as in abdominal ultrasonography. How these findings correspond to non-expert use of pUS have to be proved. Secondly, we studied patients admitted to a non-university hospital without a catheterization laboratory. Patients with ST elevation in pre-hospital electrocardiograms or cardiogenic shock were directed to the regional university hospital with catheterization laboratory facilities and were not included in the acute phase of the disease. Thus, the study results may not be generalized to such patient populations. However, the complete cardiovascular pUS of 4 min makes it possible to do a fast cardiovascular ultrasound screening also in such patients without significant time delay, and the evolving attention to the so-called stress cardiomyopathies are examples of a potential benefit of following the same strategies also in this patient group. The possible usefulness in such a population needs to be proved. The intention was to validate all examinations, but due to internal logistics 29 (24%) of the pUS was not validated by high-end examinations.

Table 4 Predictors of any diagnostic influence of bedside cardiovascular ultrasound screening

| Predictor                                      | OR  | 95% CI    | P-value |
|------------------------------------------------|-----|-----------|---------|
| Age per 10 years \(^{a}\)                    | 1.72| (1.27–2.32)| <0.001  |
| Any increased cardiovascular risk \(^{b}\)    | 2.84| (1.31–6.18)| 0.008   |
| Age per 10 years \(^{b}\)                    | 1.61| (1.17–2.21)| 0.003   |
| Any increased cardiovascular risk \(^{b}\)    | 1.89| (0.81–4.39)| 0.14    |

Any usefulness is changed primary diagnosis, verified diagnosis or additional diagnosis. CI, confidence interval; OR, odds ratio.

\(^{a}\)Not adjusted for cardiovascular risk.

\(^{b}\)Adjusted for cardiovascular risk.

\(^{c}\)Adjusted for age.
Out of these patients the numbers with changed diagnosis, verified diagnosis, added important diagnosis and no diagnostic usefulness of pUS was 1, 2, 2 and 24, respectively. For those of diagnostic importance, these findings were verified on the same recording, but these examinations were excluded from the validation analyses. No data are available from those who did not consent to participate. There was only around 50–70% power to detect significant predictors of diagnostic usefulness of pUS screening with respect to change in main diagnosis, and some underpowered analyses with respect to detecting predictors of any diagnostic usefulness as well.

Supplementary data

Supplementary data are available at European Journal of Echocardiography online.

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Conflict of interest: none declared.

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