Line Lisbeth Olesen<sup>1</sup>, Andreas Andersen<sup>1</sup> & Søren Thaulow<sup>2</sup>

# ABSTRACT

**INTRODUCTION:** Hand-held echocardiography (echo) (HE) was compared with standard echo (SE) to evaluate the quality of HE and to determine if it is safe to use HE to screen for left ventricular systolic dysfunction (LVSD) in the elderly. **METHODS:** A total of 260 high-risk persons aged 75 years and older with and without heart disease participated. SE (GE Vingmed 7/E9) and HE (GE Vscan) were performed in all 260 persons by separate, blinded and experienced echocardiographers who followed guidelines from the Danish Society of Cardiology and completed a structured data sheet. Another blinded echocardiographer revised HE (HR) and SE twice (SR). Data were analysed using STRATA and Cohen's Kappa statistic, and intra- and inter-observer variations and predictive values were calculated.

**RESULTS:** Comparison of HR and SR, and HE and SE showed modest intra- and interobserver variation and good agreement in diagnosing LVSD and other changes in cardiac function and morphology (significant valvular disease), corresponding to a low inter-method variation and a good safety; thus, HE can be used to screen for LVSD and other cardiac abnormalities. Besides, the negative predictive values were high; thus, HE can be relied upon to omit persons with normal echoes from referral to SE.

**CONCLUSION :** According to this study, HE is a valuable tool to screen for LVSD and other changes in cardiac function and morphology in a high-risk population aged 75+ years; nothing very important is missed by HE and the experienced echocardiographers; and in case of a normal HE, it is safe not to refer to SE.

**FUNDING:** Puljen til Tvaersektorielle Projekter (Research fund of cross-sectional health-projects), TrygFonden (Danish foundation TrygFonden) and Den Regionale Forskningsfond (Region Zealand Health Scientific Research Foundation).

TRIAL REGISTRATION: not relevant.

Heart failure is common in the elderly, but there are indications of under-diagnosis and under-treatment [1-3]. Consequently, there is a need for reliable methods to screen for left ventricular systolic dysfunction (LVSD) in the growing geriatric population.

The clinical diagnosis of LVSD is unreliable and cardiac dysfunction needs to be verified [4-7]. Magnetic resonance has the best diagnostic reproducibility, but it is cumbersome as opposed to classic 2D echocardiography, which is the gold standard for LVSD diagnosis in daily clinical practice [8]. In recent years, portable echocardiographs have emerged on the market. They are inexpensive and easily accessible; but only few investigations have compared them with standard echocardiographs [9-13].

The aim of the present study was to test the quality and usability of a hand-held echocardiograph compared with a standard echocardiograph for screening for LVSD in a geriatric population.

#### METHODS

This study forms part of an investigation focusing on early detection of heart failure in the elderly population. It was performed in compliance with the Declaration of Helsinki and approved by the local ethics committee and the Danish Data Protection Agency. For recruitment of patients, the study was announced locally in the Danish Association of Senior Citizens (Ældresagen), in a newspaper article, in our department of cardiology and in a heart failure clinic. The study population was representatives of a mixed and mobile geriatric population. It included a total of 260 subjects aged 75 years old or older. The subjects were recruited from the outpatient clinic and the general geriatric population with risk factors for or with known heart disease, as well as from the healthy background population. Table 1 shows the baseline characteristics of the study participants.

The 260 participants were invited to the outpatient clinic. Within one hour, each participant underwent a standard echocardiography lasting approximately 15 minutes, and a hand-held echocardiography, which lasted on average of 10 minutes. The participants stayed in the same room during the procedure and were lying on an echocardiographic stretcher in a left-sided position.

The echocardiographers performed either standard or hand-held echocardiography blinded to any subject data and to each other's results. LVSD was diagnosed from the echocardiographic images and ejection fraction (EF) < 40-50%. Unfortunately, 25 handheld echocardiograms were deleted and lost to follow-up due to a misunderstanding regarding the secure storage of the data. This left 235 cases for analysis in the present study.

# ORIGINAL ARTICLE

 Department of Cardiology, Roskilde Hospital
Department of ICT, Region Zealand, Denmark

1

Dan Med J 2015;62(7):A5100

# TABLE 1

Baseline characteristics of the study population (N = 260).

Age, yrs, median (range)	80 (75-92)
Females, n (%)	134 (51.5)
Males, n (%)	126 (48.5)
BMI, kg/m <sup>2</sup> , median (range)	25.5 (15.5-39.8)
Smoking, ex- and present, n (%)	156 (60)
Alcohol > 14 drinks a week, n (%)	31 (12)
History of, n (%)	
Acute myocardial infarction	55 (21)
Percutaneous coronary intervention	39 (15)
Coronary artery bypass graft	30 (12)
Valvular substitution	10 (4)
Systolic heart failure	72 (28)
Arrhythmias	92 (35)
Pacemaker	29 (11)
Hypertension	173 (67)
Diabetes mellitus	37 (14)
Stroke and transitional cerebral ischaemia	43 (17)
Peripheral arterial disease	23 (9)
Lung disease	67 (26)

The digitally stored recordings were reviewed by an independent and blinded echocardiographer who reviewed the 235 handheld echocardiograms once and the 260 standard echocardiograms twice (separated by an approx. three-month period to avoid bias).

As an expert on valvular diseases, the reviewing echocardiographer was asked to pay special attention to valvular changes, to select only those which were to undergo follow-up, and to disregard any insignificant changes.

All echocardiographers completed a structured data sheet. The evaluation was focused on LVSD, EF and val-

vular disease because other changes were infrequent and because of the limitations of the hand-held echocardiograph. Financial analysis was not performed.

All the echocardiographers were very experienced in standard echocardiography (expert level III), but had limited training in advance in hand-held echocardiography. Two echocardiographers performed 58% of all the standard echocardiographies and 96% of all the handheld echocardiographies.

Standard echocardiography was performed with a General Electric Vingmed Vivid 7 or E9, MJS probe 1.5-4.0 MHz and following the guidelines from the Danish Society of Cardiology.

Handheld echocardiography was performed with General Electric Vscan and probe 1.7-3.8 MHz to evaluate A) LVSD: yes, no, or cannot judge, B) EF: < 40%, 40-50%, > 50%, cannot judge, C) standard echocardiography recommended: No, Yes (No: nothing abnormal. Yes: LVSD, valvular disease, other changes in cardiac function or morphology, poor quality, technical problems, inconclusive echocardiogram or discrepancy between what was found and what was expected).

#### Statistical analysis

The statistical analysis was performed with STATA 12 (StataCorp, College Station, Texas, USA). The pairwise agreement on LVDS between methods, hand-held and standard echocardiography, and between echocardiographers was evaluated by Cohen's Kappa statistic. K-values < 0.4, 0.4-0.75, and > 0.75 were considered to represent poor, fair-to-good and excellent agreement, respectively. Kappa with and without (cannot judge) are presented in **Table 2** and **Table 3**. The hypothesis of equal proportions of LVSD was tested by McNemar's test. A p value below 0.05 was considered statistically

### TABLE 2

Positive predictive value, negative predictive value and agreement (K) regarding left ventricular systolic dysfunction – non-significant inter-method variation and intraobserver variation and significant inter-observer variation.

	Non-significant inter-method variation				Non- obsei	significant intra- ver variation	Signi	Significant inter-observer variation					
	HR <sup>®</sup> /SR2		HE/SE		SR1/5	SR2	SE/SR2		HE/HR <sup>a</sup>				
	yes	no	yes	no	yes	no	yes	no	yes	no	CJ		
Yes, n	35	9	58	21	48	9	49	20	42	26	10		
No, n	9	168	10	167	5	198	4	187	2	149	2		
CJ, n	8	6	1	3	0	0	0	0	0	2	2		
PPV		0.80	0.73		-		-		-				
NPV		0.95		0.94		-		-		-			
K-value		0.74		0.70		0.84		0.74		0.67			
p-value <sup>b</sup>		1		0.07		0.42		0.002		< 0.001			

CJ = cannot judge; HE = handheld echocardiography (on the spot); HR = handheld echocardiograms reviewed; K = kappa without CJ; LVSD = left ventricular systolic dysfunction; NPV = negative predictive value; PPV = positive predictive value; SE = standard echocardiography (on the spot); SR = standard echocardiograms reviewed (SR1 and SR2 separated by about 3 months).

a) 25 cases of HE not assessed with HR.

b) McNemar's test of equal proportions without CJ.

significant. Positive (PPV) and negative (NPV) predictive values were calculated of: 1) LVSD diagnosed by handheld echocardiography with standard echocardiography as reference, 2) LVSD diagnosed on reviewed hand-held echocardiograms with standard echocardiograms as reference, and 3) standard echocardiography recommended performing hand-held echocardiography with significant valvular disease as reference.

Trial registration: not relevant.

#### RESULTS

Concerning image quality, standard echocardiography is superior to hand-held echocardiography, illustrated in this study by the fact that every standard echocardiogram was interpreted, whereas four hand-held echocardiograms could not be judged by the performing echocardiographer and 14 hand-held echocardiograms could not be judged by the reviewing echocardiographer.

### Intra-observer variability

The same echocardiographer reviewed the standard echocardiograms twice with excellent agreement (K = 0.84) regarding presence of LVSD (Table 2) and good agreement (K = 0.70) regarding EF (Table 3) demonstrating diagnostic stability and a low intra-observer variability (p = 0.42).

#### Inter-observer variability

Table 2 shows that fair-to-well agreement between all echocardiographers regarding LVSD (K = 0.67-0.74) with no-significant inter-observer variability (p = 0.07).Never-theless, when comparing the performing echocardiographers and the reviewing echocardiographer, we observed a considerable inter-observer variability (p = 0.002 / < 0.001). Table 3 suggests that the reviewing echocardiographer had a tendency to decide on a higher EF than the performing echocardiographers and to discard LVSD when EF > 40%, often contrary to the performing echocardiographers.

Table 3 shows that regardless of the type of echocardiography (standard versus hand-held), there was considerable disagreement about the exact EF when EF was in the indecisive gray zone about 40-50%. Thus, in the grey zone, the diagnostic variation and inter-observer variability were substantial.

#### Inter-method variability

Table 2 shows good agreement on and non-significant inter-method variability of LVSD diagnosed by: 1) all performed standard and hand-held echocardiographies (K = 0.70, p = 0.07), 2) the standard and hand-held echocardiographies performed by the two echocardiographers who did most of the examinations (K = 0.74, p = 0.81)



and 3) the reviewed standard and hand-held echocardiograms (K = 0.74, p = 1).

Thus, when standard and hand-held echocardiography were compared, the inter-method variability when diagnosing LVSD was small; provided the image quality was OK.

# Handheld echocardiography and negative predictive value of left ventricular systolic dysfunction

Table 2 shows that the NPV of hand-held echocardiography in assessment of LVSD was 0.94 when standard echocardiography was used as a reference. There was disagreement on LVSD in ten cases, where hand-held echocardiography concluded EF > 40% and no LVSD; whereas standard echocardiography concluded EF < 40 % in five cases and > 40 % in five cases and LVSD in all ten cases, in three cases, rapid atrial fibrillations made it difficult to estimate EF, and five cases were in the grey zone where there is a diagnostic dilemma concerning LVSD.

# Hand-held echocardiography and negative predictive value of valvular disease

Table 4 shows that hand-held echocardiography had a NPV of 0.95 regarding the presence of significant valvular disease with significant valvular disease as a reference. Whenever hand-held echocardiography was not completely normal, standard echocardiography was recommended. In total, 20 patients out of 55 with valvular dysfunction had also LVSD. Six cases (11%) with significant valvular disease according to standard echocardiography were missed using hand-held echocardiography. One of these patients had a previously unrecognised moderate aortic stenosis and a cardiac murmur; one had a biologic aortic valve and was followed in the out-patient clinic, whereas four were without any significant valvular disorder according to a detailed follow-up using standard echocardiography. Hand-held echocardiograph (Vscan) smartphone and stethoscope.

#### TABLE 3

Agreement on ejection fraction.

	HR <sup>a</sup> /SR2			SR1/SR2			HE/SE			SE/SR2			HF/HR <sup>a</sup>			
	< 40	40-50	> 50	< 40	40-50	> 50	< 40	40-50	> 50	< 40	40-50	> 50	< 40	40-50	> 50	CJ
<i>EF, N (n)</i> <sup>ь</sup>																
< 40	31 (0)	7 (4)	0 (0)	45 (0)	10 (7)	1 (1)	52 (0)	7 (5)	5 (5)	45 (0)	14 (11)	2 (2)	35 (0)	12 (10)	6 (6)	10
40-50	8 (8)	14 (3)	10 (1)	3 (3)	26 (3)	19 (0)	7 (4)	15 (7)	39 (7)	2 (2)	20 (5)	23 (3)	3 (1)	14 (6)	36 (5)	2
> 50	0 (0)	16 (0)	134 (1)	0 (0)	10 (0)	146 (0)	1 (1)	21 (1)	108 (0)	1 (1)	12 (0)	141 (0)	0 (0)	6 (0)	106 (0)	0
CJ	8	6	1	0	0	0	1	2	2	0	0	0	0	0	2	3
K-value	0.63 0.70			.70	0.47			0.62			0.50					

CJ = cannot judge; EF = ejection fraction; HE = handheld echocardiography on the spot; HR = handheld echocardiograms reviewed; K = kappa without CJ; SE = standard echocardiography on the spot; SR = standard echocardiograms reviewed (SR1 and SR2 separated by about 3 months).

a) 25 not assessed with HR.

b) (disagreement about left ventricular systolic dysfunction).

# TABLE 4

Comparison of valvular dysfunction diagnosed by standard echocardiography (gold standard) and by handheld echocardiography (included in abnormal handheld echocardiography). Most cases of significant valvular dysfunction are recognized by handheld echocardiography. When handheld echocardiography is abnormal (heart failure, significant valvular disease etc.) standard echocardiography is recommended.

		SR (valvular dysfunction						
		yes	no					
HE (abnormal), n								
Yes		49	101					
No		6	104					
PPV		0.33						
NPV		0.9	95					

HE = handheld echocardiography on the spot; NPV = negative predictive value; PPV = positive predictive value; SR = standard echocardiograms reviewed.

## DISCUSSION

This study shows that hand-held echocardiography was comparable with standard echocardiography in terms of quality and safety in screening for LVSD in a geriatric population, when performed by expert echocardiographers. We found a small inter-method variability, but different inter-observer variability. This shows that results depend more on the operator than on the equipment, which emphasises the need for user-education and -evaluation. These findings are in accordance with previous studies [9, 11].

Table 2 and Table 3 illustrate that echocardiography is not an accurate and unfailing diagnostic method. Rather, it is open to differences in interpretation. Thus, in order to compare different echocardiographic equipment and to avoid operator-dependent bias, the intraand/or the inter-observer variability must be low [8, 9, 11]. This source of variation has gone unnoticed in a number of previous studies [6, 7, 14-16]. In our study, the reviewing echocardiographer manifested very small intra-observer variability and good concordance between hand-held and standard echocardiography for the diagnosis of LVSD. Likewise, there was non-significant inter-observer variability between the performing echocardiographers and concordance between hand-held and standard echocardiography for diagnosis of LVSD. This corresponds to a small inter-method variability and shows that the hand-held echocardiograph is a sensible alternative to the standard echocardiograph when screening for LVSD [11].

This is confirmed by the reliability of the hand-held echocardiograph which did not miss many cases with significant disease, which is reflected in the NPV > 0.90 [16]. Thus, standard echocardiography may be abstained from, when it is assessed that hand-held echocardiography is normal [6, 11, 17].

The hand-held echocardiograph, the Vscan, is the size of a smartphone, it weighs 390 g including the probe and fits into a pocket. It is used as a means to obtaining early and prompt diagnosis [17, 18], to extend the physical examination [4, 10, 13, 14, 17] and to assist some invasive procedures [12]. In addition to using it at the point-of-care and for the triage of the acutely admitted patients [13, 15, 17, 19], the present study suggests that it may be used to screen for LVSD in outpatient settings [5-7, 10, 16, 18].

It is important to keep in mind that the hand-held echocardiograph has its limitations [9, 10]. It has fewer options than the standard echocardiograph and the image quality is poorer. The hand-held echocardiograph has 2D and colour Doppler, but no M-mode and no spectral Doppler [4]. It should not be used to evaluate diseases of the valves, nor diastolic function or pulmonary pressure [6, 17, 18]. The patient has to be informed that a hand-held echocardiography does not replace a complete echocardiography [10].

Because of the limitations of the hand-held echo-

cardiograph, standard echocardiography should be performed whenever handheld echocardiography is not completely normal [7, 15, 19]. This is important especially in the elderly where heart diseases are very prevalent; and, thus, the hand-held echocardiograph should be used with particular caution in the geriatric population.

For the expert echocardiographer, it was easy to acquire and interpret images with the hand-held echocardiograph; but because unqualified users of hand-held echocardiography are more likely to make errors [14, 15] and to misdiagnose [9, 13, 17], several professional societies recommend certification for all users of the hand-held ultrasound scanners [6, 9-11, 18, 20].

#### CONCLUSION

Based on our findings, we conclude that hand-held echocardiography may be used safely by the expert to screen the elderly for LVSD and other changes in cardiac function and morphology in order to select patients for standard echocardiography. Hand-held echocardiography may increase efficiency and could prove to be both time- and cost-effective [18] as the number of relatively slow and high-cost standard echocardiographies could be reduced.

CORRESPONDENCE: Line Lisbeth Olesen, Groenagergaardsvej 5, 4070 Kirke Hyllinge, Denmark. E-mail: Ilole@regionsjaelland.dk

ACCEPTED: 22 April 2015.

CONFLICTS OF INTEREST: Disclosure forms provided by the authors are available with the full text of this article at www.danmedj.dk ACKNOWLEDGEMENTS: The authors would like to thank Hanne Elming,

Cardiologist Consultant, Department of Cardiology, Roskilde Hospital, for revision of echocardiograms and *Hans Burchardt* and *Klaus Klausen*, Cardiologist Consultants, Department of Cardiology, Roskilde Hospital, for their performance and assessment of echocardiographies.

#### LITERATURE

- Olesen LL. The Danish National Quality Project about heart failure indicates lack of reporting and treatment of the elderly. Ugeskr Læger 2015;177:338-9.
- Yancy CW, Fonarow GC, Albert NM et al. Influence of patient age and sex on delivery of guideline-recommended heart failure care in the outpatient cardiology practice setting: Findings from IMPROVE HF. Am Heart J 2009;157:754-62.e2.
- Huelsmann M, Berger R, Moertl D et al. Influence of age and in-patient care on prescription rate and long-term outcome in chronic heart failure: a data-based substudy of the EuroHeart Failure Survey. Eur J Heart fail 2005; 7:657-61.
- Mehta M, Jacobson T, Peters D et al. Handheld ultrasound versus physical examination in patients referred for transthoracic echocardiography for a suspected cardiac condition. JACC Cardiovasc Imaging 2014;7:983-90.
- Atherton JJ. Screening for left ventricular systolic dysfunction: Is imaging a solution? JACC Cardiovasc Imaging 2010;3:421-8.
- Trambaiolo P, Papetti F, Posteraro A et al. A hand-carried cardiac ultrasound device in the outpatient cardiology clinic reduces the need for standard echocardiography. Heart 2007;93:470-5.
- Vourvouri EC, Schinkel AFL, Roelandt JRTC et al. Screening for left ventricular dysfunction using a hand-carried cardiac ultrasound device. Eur J Heart Fail 2003;5:767-74.
- Wood PW, Choy JB, Nanda NC et al. Left ventricular ejection fraction and volumes: It depends on the imaging method. Echocardiography 2014; 31:87-100.
- Prinz C, Voigt JU. Diagnostic accuracy of a hand-held ultrasound scanner in routine patients referred for echocardiography. J Am Soc Echocar 2011;24:111-6.
- Sicari R, Galderisi M, Voigt JU et al. The use of pocket-size imaging devices: a position statement of the European Association of Echocardiography. Eur J Echocardiogr 2009;10:594-601.

- Prinz C, Dohrmann J, van Buuren F et al. Diagnostic performance of handheld echocardiography for the assessment of basic cardiac morphology and function: a validation study in routine cardiac patients. Echocardiography 2012;29:887-94.
- Alpert JS, Mladenovic J, Hellmann DB. Editorial. Should a hand-carried ultrasound machine become standard equipment for every internist? Am J Med 2009;122:1-3.
- Cardim N. Pocket-size devices, physical examination, and high-end echocardiography machines in perspective: Are the times a changing? J Am Soc Echocardiogr 2013;26:597-99.
- Cullen MW, Blauwet LA, Vatury OM et al. Diagnostic capability of comprehensive handheld vs transthoracic echocardiography. Mayo Clin Proc 2014;89:790-98.
- Khan HA, Wineinger NE, Uddin PQ et al. Can hospital rounds with pocket ultrasound by cardiologists reduce standard echocardiography. Am J Med 2014;127:669.el-e7.
- Lipczynska M, Szymanski P, Klisiewicz A et al. Hand-carried echocardiography in heart failure and heart failure risk population: a community based prospective study. J Am Soc Echocardiogr 2011;24:125-31.
- Cardim N, Golfin CF, Ferreira D et al. Usefulness of a new miniaturized echocardiographic system in outpatient cardiology consultations as an extension of physical examination. J Am Soc Echocardiogr 2010;24:117-24.
- Zoghbi WA. Echocardiography at the point of care: An ultra sound future. J Am Soc Echocardiogr 2011;24:132-4.
- Andrus P, Dean A. Focused cardiac ultrasound. Global Heart 2013;8:299-303.
- Choi BG, Mukherjee M, Dala P et al. Interpretation of remotely downloaded pocket-size cardiac ultrasound images on a web-enabled smartphone: Validation against workstation evaluation. J Am Soc Echocardiogr 2011;24:1325-30.