

# Adoptability and Accuracy of Point-of-Care Ultrasound in Screening for Valvular Heart Disease in the Primary Care setting

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## Abstract

Background: Despite continued efforts, the majority of patients with valvular heart disease (VHD) remain undiagnosed and untreated. This study aimed to assess the adoptability and accuracy of point-of-care handheld echocardiographic assessments (POCE) in the primary care setting. Methods: Eleven previously untrained primary care providers were trained to use the Vscan Extend (GE, WI) POCE to assess VHD, left ventricular function (LVEF), and major extra-cardiac findings. Their assessments were compared to those of 3 blinded expert readers. A total of 180 assessments were evaluated using Kappa statistics ( $\kappa$ ) together with their estimated standard error, p-value, and 95% CI bounds. Results: Identical or nearly identical agreement between previously untrained primary providers and expert readers was evident for the diagnosis of tricuspid regurgitation, mitral regurgitation, pericardial effusion, volume status. These agreements were strongest in apical long axis ( $\kappa=1$ ,  $p<0.001$ ) and parasternal long and short axis views ( $\kappa\geq 0.82$ ,  $p<0.001$ ), though agreement remained robust in apical 4-chamber views ( $\kappa\geq 0.76$ ). The agreements in LVEF assessment were identical in the apical long axis view ( $\kappa=1$ ,  $p<0.001$ ) and robust in the remaining 3 views ( $\kappa\geq 0.66$ ,  $p<0.001$ ). The assessments of aortic stenosis (parasternal/long,  $\kappa=0.42$ , and parasternal/short,  $\kappa=0.47$ , both  $p<0.001$ ) were weak in their agreement. Conclusion: Compared to expert echocardiography readers, the untrained providers' use of POCE for VHD shows high user adoptability and diagnostic accuracies in the primary care setting.

## Title Page

## Original Article

Adoptability and Accuracy of Point-of-Care Ultrasound in Screening for Valvular Heart Disease in the Primary Care setting

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**Methods:** Eleven previously untrained primary care providers were trained to use the Vscan Extend (GE, WI) POCE to assess VHD, left ventricular function (LVEF), and major extra-cardiac findings. Their assessments were compared to those of 3 blinded expert readers. A total of 180 assessments were evaluated using Kappa statistics ( $\kappa$ ) together with their estimated standard error, p-value, and 95% CI bounds.

**Results:** Identical or nearly identical agreement between previously untrained primary providers and expert readers was evident for the diagnosis of tricuspid regurgitation, mitral regurgitation, pericardial effusion, volume status. These agreements were strongest in apical long axis ( $\kappa = 1$ ,  $p < 0.001$ ) and parasternal long and short axis views ( $\kappa \geq 0.82$ ,  $p < 0.001$ ), though agreement remained robust in apical 4-chamber views ( $\kappa \geq 0.76$ ). The agreements in LVEF assessment were identical in the apical long axis view ( $\kappa = 1$ ,  $p < 0.001$ ) and robust in the remaining 3 views ( $\kappa \geq 0.66$ ,  $p < 0.001$ ). The assessments of aortic stenosis (parasternal/long,  $\kappa = 0.42$ , and parasternal/short,  $\kappa = 0.47$ , both  $p < 0.001$ ) were weak in their agreement.

**Conclusion:** Compared to expert echocardiography readers, the untrained providers' use of POCE for VHD shows high user adoptability and diagnostic accuracies in the primary care setting.

### Introduction

Despite continued efforts to improve the early diagnosis of severe VHD, the majority of patients with this condition remain undiagnosed and untreated(1-3). In the United States (U.S.), the estimated prevalence of VHD is 2.5%, corresponding to a burden of 4.2 to 5.6 million adults; of these, only 75,600 to 100,800 are diagnosed(1). Due to the high prevalence among the elderly and as the U.S. shifts to an older population, the burden in undiagnosed VHD will continue to increase(1).

The burden of valve disease can be attributed to several factors, including the lack of access to health care(4), missed diagnosis in the absence of patient symptoms or subtle exam findings(4), and reliance on diagnosis via echocardiography(1). Given the burden of undiagnosed VHD and its detrimental effects, early diagnosis is paramount. Further, the utilization of a screening tool for point-of-care testing, such as a portable handheld imaging device, may be a promising resource to overcome some of these hurdles(1).

Several studies have used handheld echocardiography to evaluate LV function and VHD in the emergency room(5), and inpatient settings(6) and have been shown to be feasible. Handheld imaging tools have excellent imaging capabilities, added connectivity, and ease of use, making them great for diagnosing and managing many diseases.

There is limited data on the utility of handheld imaging tools to screen for VHD. A few studies have shown a trend towards comparable accuracy and reliability of the handheld device compared to a standard echocardiogram(7-9). The utility of handheld point-of-care cardiac imaging in risk stratifying acutely ill patients based on their LV function infected with Corona Virus-2019 (COVID 19) was also recently highlighted in an observational study from New York during the COVID 19 pandemic(10).

It is conceivable that handheld imaging tools, like the Vscan Extend (GE, Wisconsin), will enhance the cardiac physical exam in the primary care setting, allowing for an earlier diagnosis of significant VHD, left ventricular function, and appropriate specialty referral. In this study, we aimed to assess the adoptability and accuracy of echocardiographic Vscan Extend (GE, Wisconsin) assessments in the hands of previously untrained users in the primary care setting to diagnose VHD and left ventricular function.

## Methods

### Study Design

This prospective observational study was carried out between January 2018 to January 2020 at five outpatient sites within the Allina Health system and the main outpatient site within the Minneapolis Heart Institute Foundation. The study protocol was approved by the Institutional Review Board (IRB), following which 180 consecutive patients underwent echocardiographic assessment with the Vscan (GE Medical Systems, Milwaukee, Wisconsin, USA) by 11 previously untrained primary care providers.

The inclusion criteria were: (i) presence of at least one of the following symptoms during a routine visit; shortness of breath or lack of energy; or (ii) the presence of at least one of the following clinical signs: edema or a new cardiac murmur on auscultation. There were no exclusion criteria for patient enrollment.

All 11 primary care providers (including internists and advanced practice providers such as physician assistants) were provided basic instructions and self-directed learning tools on utilizing the Vscan device, and were taught basic image acquisition for the following views: Parasternal long/short axis as well as apical 3- and 4-chamber, and given. The providers were also trained in utilizing the color Doppler exam as needed. Prior to their participation in this study, the providers' experiences with handheld imaging devices varied from no to minor experience.

Aortic stenosis was assessed using the parasternal long and short axis views: a 2D assessment was performed to assess for leaflet mobility, valve opening. Color Doppler acceleration in the left ventricular outflow tract was added as necessary. Mitral and tricuspid regurgitation was assessed using the parasternal long, apical 4-, and apical 3- chamber views utilizing 2D assessment to identify leaflet coaptation and color Doppler.

Patients underwent evaluation for VHD and LV function using the Vscan, and all data were collected using a simple data collection sheet (supplement 1). The providers recorded the following findings: (i) Presence of Pericardial or Pleural Effusion, (ii) Presence of mild, moderate or severe Aortic stenosis, Mitral regurgitation, and Tricuspid regurgitation, (iii) LVEF using semi-quantitative analysis as normal (EF>55%), mildly (EF>45 <55%), moderately (EF <45 >35%) or severely (EF <35%) reduced.

Following image acquisition by the outpatient provider, the patients' echocardiographic Vscan images were read by 3 blinded expert echocardiography readers and results reported on the same collection sheets. Vscan devices for the study were provided through a research grant by GE Healthcare.

### Statistical Analysis

Vscan assessments made by the outpatient providers were compared to those made by the blinded expert echocardiography readers. Discordance between the two readers was considered when disagreement in diag-

noses of significant abnormality was found. Kappa coefficients ( $\kappa$ ) were calculated as the degree of agreement between the two p-values  $<0.05$  were considered significant.

Kappa coefficients above 0.90 were considered identical or nearly identical in their agreement, 0.80-0.90 were considered a strong level of agreement, 0.60-0.79 as moderate, and 0.40-0.59 weak.

The study was powered based on Kappa agreements of the two variables: (i) Accuracy of valve disease severity grading (none, mild, moderate/severe) (ii) Accuracy of grading of ejection fraction (none, mild, moderate/severe) and assumes the proportion of patients that fall into each of these groups will be equally distributed at one-third. Power analyses were carried out for agreement levels (alternate hypothesis) of 0.9 and 0.8 compared to baseline (null hypothesis) levels of 0.6 and 0.7 at sample sizes of 100 to 500 incremented by 50 with a two-sided alpha of 0.05. Because of the large volume of echocardiograms performed at Abbott Northwestern Hospital, the investigators believe we should use a sample size of 350, which achieves a power of 0.91 to detect a true Kappa value of 0.80 (alternate hypothesis) in a test of  $H_0$ : Kappa = 0.70.

## Results

There were 15 measures studied to determine the level of agreement between the outpatient provider and expert echocardiography readers. A total of 180 assessments, each read by both, were evaluated using Kappa statistics ( $\kappa$ ).

### Valvular heart disease:

The measurements of all levels of severity of tricuspid regurgitation in the parasternal/short ( $\kappa = 1$ ,  $p < 0.001$ ) and apical 4-chamber views were identical in their agreement ( $\kappa = 1$ ,  $p < 0.001$ ).

The measurements of all levels of severity of mitral regurgitation in the apical 3-chamber were identical in their agreement ( $\kappa = 1$ ,  $p < 0.001$ ), moderate and moderate to severe grades in the parasternal/long were strong in their agreement ( $\kappa = 0.82$ ,  $p < 0.001$ ), and mild grades were moderate in agreement in the apical 4-chamber ( $\kappa = 0.76$ ,  $p < 0.001$ ).

The measurements of aortic stenosis (all levels of severity) in parasternal/long ( $\kappa = 0.42$ ,  $p < 0.001$ ) and parasternal/short ( $\kappa = 0.47$ ,  $p < 0.001$ ) were weak in their level of agreement.

### LVEF, Volume Status, Pericardial, and Pleural Effusion:

The apical-3-chamber assessment of LVEF ( $\kappa = 1$ ,  $p < 0.001$ , all levels of severity), were identical in their agreement. The measurements of parasternal/long LVEF ( $\kappa = 0.66$ ,  $p < 0.001$ ), parasternal/short LVEF ( $\kappa = 0.76$ ,  $p < 0.001$ ), apical 4-chamber LVEF ( $\kappa = 0.72$ ,  $p < 0.001$ ) were moderate in their agreement.

For the assessment of pleural effusion ( $\kappa = 1$ ,  $p < 0.001$ , all levels of severity), pericardial effusion ( $\kappa = 1$ ,  $p < 0.001$ , all levels of severity), and the diagnosis ( $\kappa = 0.96$ ,  $p < 0.001$ ) they were identical or nearly identical in their agreement.

The assessment of volume status (utilizing the IVC), euvolemic, and overloaded ( $\kappa = 0.83$ ,  $p < 0.001$ ) were strong in their agreement.

## Discussion

This study demonstrates that handheld imaging stools like the Vscan Extend (GE, Wisconsin) are easily adopted by previously untrained users and can reliably detect VHD, assess LVEF, and extra-cardiac findings with comparable accuracy to expert echocardiography readers. Integrating history taking and clinical examination with POCE in the primary care setting is feasible and may help relieve the community's burden of undiagnosed VHD. Further, we may be able to close the current gap in diagnosing and treating severe VHD in our patient population.

Various studies have reported comparable results between handheld technology and standard echocardiograms concerning cardiac function, left ventricular systolic dysfunction (LVSD), and valve regurgitation(7-9). A recent study done by Olesen et al. used both standard and handheld echocardiography to evaluate LVSD

in persons 75 years and older and found comparable quality and reliability between handheld echocardiography and standard echocardiography(8). The comparison showed good level of agreement in diagnosing LVSD and cardiac function(8). Another study by Kitada et al.(9) compared the diagnostic accuracy of handheld and standard echocardiography to measure cardiac chamber size and function and assess valvular regurgitation(9). They found a strong level of agreement between the handheld and standard echocardiography, both performed and interpreted by experts, in assessing cardiac structure and functionality(9). The handheld echo also accurately detected all valvular stenosis cases observed in the patient cohort, making it useful in assessing significant valvular disease(9). Similarly, Williams et al, studied the use of handheld echocardiography in the primary care setting for VHD screening in the elderly population, performed by an experienced sonographer. Of the 100 patients included, 13 patients had at least moderate AS or moderate MR, and five of the 100 needed a valve replacement or follow-up at a valve clinic based on the findings of the handheld scanner(11). The handheld scanner allowed for early intervention and referrals for patients. Perez et al.(12) conducted a study assessing handheld echocardiographic devices' accuracy compared to standard echocardiography in an oncology clinic. In 101 patients, the study showed good concordance between the two in evaluating cardiac function in patients under chemotherapy(12). Similar levels of inter-reader variability in assessing LV function have been discussed in one further study, where one reader was an expert echocardiographer and the other a well-trained intensivist(13).

In our study, the detection of tricuspid or mitral regurgitation had comparable accuracy between the expert readers and previously untrained providers using the Vscan Extend (GE, Wisconsin). Further, a similar accuracy was noted when assessing pericardial, pleural effusion, and patient's volume status. The assessment of aortic stenosis (2D only) and LV function had a moderate level of agreement between the trained providers and expert readers.

In the context of the here discussed prior studies, that mostly relied on expert echocardiographers' scanning, our study demonstrates the rapid adoptability and high accuracy of handheld echocardiography by previously untrained providers in the assessment of VHD. Handheld echocardiography has promise in becoming an ideal tool for early identification of VHD in the primary care setting.

## Limitations

The study did not assess handheld echocardiography's impact on altering patient management, changes in referral patterns, or healthcare expense utilization. The Vscan Extend evaluations were semi-quantitative and thus limited by the absence of continuous and pulse wave doppler, so VHD severity assessment relied only on Color Doppler and 2D assessment; therefore, we also could not evaluate pulmonary hypertension and diastology.

## Conclusions

This study demonstrated that the untrained providers' use of the POCE in the primary care setting is feasible, showing high user adoptability and diagnostic accuracy with the potential of becoming an application for broad VHD detection.

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### Legend to Tables and Figures:

Table 1: Comparison of diagnosis between outpatient providers using Vscan Extend and expert echocardiography reader using standard transthoracic echocardiogram

Table 2: Level of agreement in the diagnosis between outpatient providers using Vscan Extend and expert echocardiography reader using standard transthoracic echocardiogram

### Legend to Supplementary Material:

Supplement 1: Data sheet used for recording Vscan Extend assessments

### Hosted file

Tables 1 and 2.pdf available at <https://authorea.com/users/394469/articles/507846-adoptability-and-accuracy-of-point-of-care-ultrasound-in-screening-for-valvular-heart-disease-in-the-primary-care-setting>