



openheart Severe aortic stenosis detection using seismocardiography

Jouni Pykäri ¹, Ismail Elnaggar ², Matti Kaisti,² Antti Airola,² Tero Koivisto,² Tuija Vasankari,^{1,3} Mikko Savontaus¹

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ABSTRACT

Background Patients with severe aortic stenosis (AS) are at high risk of mortality, regardless of symptom status. Despite this, aortic valve replacement rates remain low for patients with severe AS due to challenges in identifying clinically significant AS in time. This has prompted the need to develop and investigate novel diagnostic modalities. The objective of this study was to develop and validate novel, non-invasive diagnostic algorithm leveraging seismocardiography (SCG) data to detect severe AS.

Method A device capable of collecting a single-lead ECG and a three-dimensional SCG signal using a microelectromechanical-based accelerometer was used to collect sensor data. Phase 1 data were collected for training and validation of an algorithm for AS detection. Phase 2 data were collected as a blinded independent test set with age-matched and sex-matched patients as controls.

Results In phase 1 of the study, 115 subjects (n=56 AS patients and n=59 controls; mean age 73.8±10.4 years) were collected for training and validation of an algorithm for AS detection. Once model development was complete, the frozen model was then evaluated in a fully independent, single blinded phase 2 cohort of 99 subjects (n=50 AS patients and n=49 controls; mean age 76.8±6.4 years) for final analysis. The algorithm accurately classified 89 out of 99 patients, with four true AS cases misclassified as controls and six true control cases misclassified as AS. The sensitivity, specificity and area under the curve of the model were 92% (95% CI 84.5% to 99.5%), 87.8% (95% CI 78.6% to 96.9%), and 96% (95% CI 91.9% to 99.9%), respectively.

Conclusions This SCG-based algorithm to detect severe AS demonstrated high sensitivity and specificity when tested in a blinded, age-matched and sex-matched cohort. These findings suggest that this technology may hold potential as a low-cost diagnostic tool for the detection of AS.

INTRODUCTION

Aortic stenosis (AS) is the most common valvular heart disease leading to intervention in western countries.¹ Prevalence of severe aortic valve stenosis is 3%–4% in 70–75 year olds and it increases with age.^{2,3} Treatment for severe symptomatic AS is valve replacement either by surgical aortic valve

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Seismocardiography (SCG) has shown promise for aortic stenosis (AS) detection, but prior studies were limited by small, heterogeneous cohorts and unmatched controls.

WHAT THIS STUDY ADDS

⇒ This is the first study to evaluate an SCG-based algorithm in an independent, blinded cohort of age-matched and sex-matched participants, demonstrating high sensitivity and specificity.
⇒ These findings suggest that this technology may hold potential as a low-cost screening tool for the detection of severe AS.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ These results support further research into integrating SCG-based methods into portable, point-of-care screening devices to enable earlier AS detection in primary care.
⇒ Larger studies are warranted to validate performance across diverse populations.

replacement (AVR) or transcatheter AVR (TAVR) and these treatments have demonstrated excellent results in alleviating symptoms and reducing mortality.^{4,5} However, the prognosis in patients with symptomatic severe AS is poor if left untreated.⁶

Initial diagnosis of AS can be challenging because symptoms typically present later in the natural progression of the disease. Before the onset of symptoms, a cardiac murmur is typically the only clinical finding in AS patients. However, the sensitivity and specificity of detecting valvular heart diseases with a stethoscope are modest.^{7,8} Echocardiography is the gold standard diagnostic modality for AS.⁹ However, the availability of echocardiography limits its use, for example, in primary health-care or in low-income countries. Due to the projected increase in valvular heart disease and cardiovascular disease in general,¹⁰ non-invasive diagnostic approaches that can be used outside of cardiology clinical settings, such as in general practitioner outpatient



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¹Turku University Central Hospital, Turku, Finland

²Department of Computing, University of Turku, Turku, Finland

³University of Turku, Turku, Finland

Correspondence to

Dr Jouni Pykäri; jouni.pykari@gmail.com

clinics, have garnered growing interest. Recent studies have investigated the usefulness of seismocardiography (SCG) and gyrocardiography (GCG) based techniques to attempt to diagnose and monitor different types of heart diseases, for example, valvular heart diseases, heart failure, atrial fibrillation (AF) and myocardial infarction, either with one sensing modality or in combination.^{11–14}

SCG is measured by attaching an accelerometer sensor to the skin of the chest on the sternum. SCG signals are currently understood to measure the vibrations at the sternum produced by the mechanical processes of the heart during a cardiac cycle, such as the cardiac muscle contraction, valve movement, blood flow turbulences and momentum changes within the heart.¹⁵

The published results from previous studies on detecting AS with SCG have been promising. However, the generalisability of these results is limited by small sample sizes, heterogeneity between AS and control groups and incomplete characterisation of patient demographics and cardiovascular risk factors.^{11 16–19} Additionally, studies employing artificial intelligence (AI)-based methods, such as digital stethoscopes or ECG analysis, have encountered similar methodological limitations.^{20–23}

In the present study, we have analysed for the first time the ability of an SCG-based algorithm to detect severe AS using age-matched and sex-matched controls. The aim of the study is to validate the accuracy of SCG-based measurements as a non-invasive and low-cost diagnostic tool for clinically significant AS.

METHODS

Study protocol and data description

Subject recruitment and study phases

This study is a single-site study with all patients enrolled from the Heart Center, Turku University Hospital. The protocol received approval from the Medical Ethics Committee of the Wellbeing Services of the County of Southwest Finland (reference number: 70/1801/2019), and the medical device clinical investigation was approved by the Finnish Medicines Agency (Fimea). All interventions adhered to relevant legislation, the Declaration of Helsinki and good clinical practice. Written informed consent was obtained from all participants. Data analysis was conducted at the Department of Computing, University of Turku, Finland.

Data collection was divided into two phases (figure 1): phase 1 (6 October 2020–28 March 2022) for model development and validation of the AS detection algorithm, after which development was frozen. Phase 2 (12 February 2022–14 April 2023) created a prospective blinded test cohort for independent evaluation. SCG algorithm developers were blinded to patient diagnoses and demographics.

Patient and public involvement

Patients were not formally involved in designing this study. Recruitment occurred via clinical referral with

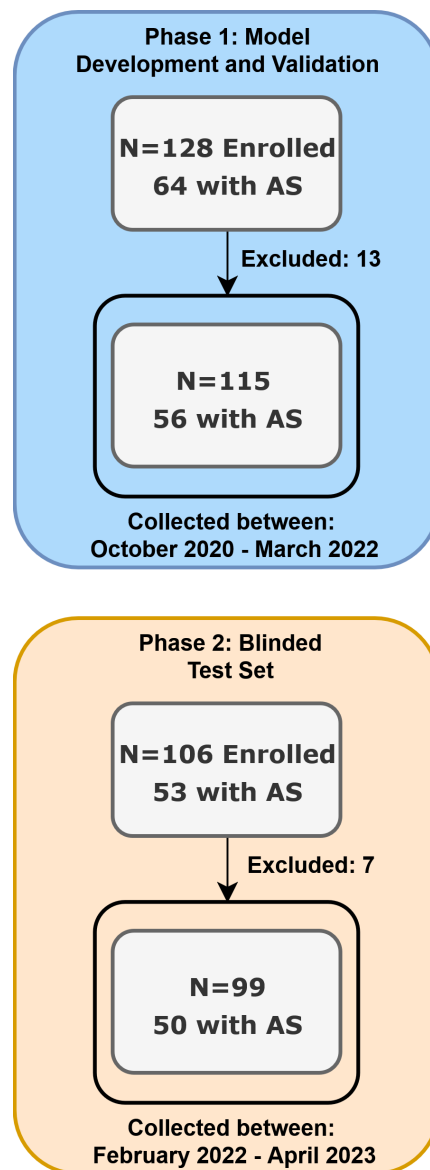


Figure 1 Flow chart outlining data collection of phase 1 and phase 2. AS, aortic stenosis.

informed written consent. Sensor placement and measurement duration were explained, allowing for comfort feedback. No formal burden assessment was conducted.

Inclusion and exclusion criteria

In both study phases, AS patients were recruited consecutively from those referred for TAVR due to symptomatic severe AS. Control subjects were recruited from the cardiac ward at Turku University Hospital.

Exclusion criteria for AS patients included severe mitral valve disease, severe aortic regurgitation or heart failure with reduced ejection fraction (HFrEF $\leq 30\%$). Control subjects were excluded if they had any degree of severe mitral valve disease, severe aortic regurgitation or HFrEF $\leq 30\%$.

Phase 1: model development cohort

Initially, 128 subjects were enrolled in phase 1. 13 subjects were excluded due to data collection issues such as poor

sensor positioning or significant patient movement. The target number of patients was 50 in each group to ensure sufficient data for algorithm development. The final dataset comprised 115 subjects, of whom 56 had severe AS and 59 were controls with a history of cardiac diseases excluding AS, moderate-to-severe mitral valve disease, severe aortic regurgitation or heart failure.

Phase 2: independent test cohort

In phase 2, 106 subjects were enrolled. The control group subjects were specifically selected to match the AS patients in age (± 5 years) and sex. Seven subjects were subsequently excluded due to poor signal quality, resulting in a final analysis set of 99 patients (50 with severe AS and 49 controls).

Measurement protocols

Before measurement recording, demographic data, relevant medical history and blood pressure were collected. Severe AS diagnosis was confirmed using two-dimensional and Doppler transthoracic echocardiography based on standardised criteria for severe AS, including assessment of aortic valve area (AVA), left ventricle ejection fraction (EF), left ventricular outflow tract diameter and mean pressure gradient.²⁴ Controls underwent bedside qualitative echocardiography prior to data collection to ensure absence of exclusion criteria. Quantitative echocardiographic parameters measured in the AS group were not available for the control group.

SCG and ECG were recorded with participants supine on a bed inclined 15–30° in a quiet room. Participants were instructed to remain still and breathe normally. The sensor was positioned on the upper sternum (figure 2). Average measurement duration was approximately 9 min in phase 1 and 5 min in phase 2.

Signal acquisition

A custom Holter data logger was used to capture time-series signals. Three-axis SCG signals were measured with a micro-electro-mechanical system accelerometer (ADXL355, Analog Devices). The ADXL355

accelerometer sensor integrates a micromachined mechanical sensing structure and readout electronics on a single chip. When the chest wall moves, the sensor captures this motion, which the on-board electronics convert into digital signals proportional to linear acceleration. The three sensing axes are oriented approximately along the cranio-caudal (X-axis), medio-lateral (Y-axis), and antero-posterior (Z-axis) directions of the sternum, so that chest vibrations are captured in three dimensions and sampled simultaneously as synchronised SCG time series signals from which features are then extracted to be fed into the model proposed in this study. The three-axis GCG signal was measured using a 3D digital gyroscope (LSM6DS3, STMicroelectronics). Single-lead ECG signal was measured using a single biopotential channel (MAX30003, Maxim Integrated). The single-lead ECG signal in this study was only used for cardiac cycle gating to accurately segment the SCG signals into individual cardiac cycles. Only the single-lead ECG and the three-axis SCG (ADXL355, Analog Devices) signals were considered in this study. The GCG signals captured by the LSM6DS3 sensor were discarded due to having a lower initial sampling frequency. The ECG and SCG signals were recorded simultaneously and resampled to have a sampling frequency of 400 Hz. The data logger was attached to the skin in the upper sternum using double-sided tape without hair removal. Additional information on the sensing device used in this study can be found in our previous report.¹⁴ SCG filtering was done using the SciPy Python package (V.1.10.1).²⁵

Model development

Online supplemental figure S4 illustrates the pipeline from signal acquisition to feature extraction and model development. A detailed description of the signal acquisition and filtering parameters, dynamic time warping (DTW) methodology, continuous wavelet transform (CWT) implementation specifics, model hyperparameter settings and feature selection criteria for the classifiers are provided in the online supplemental material.

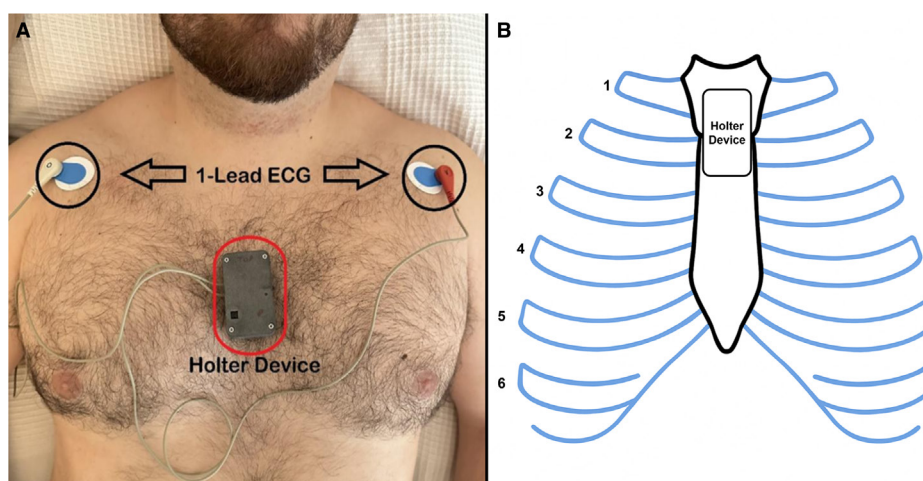


Figure 2 (A) Photo depicting the device used in this study, and (B) the target device placement.

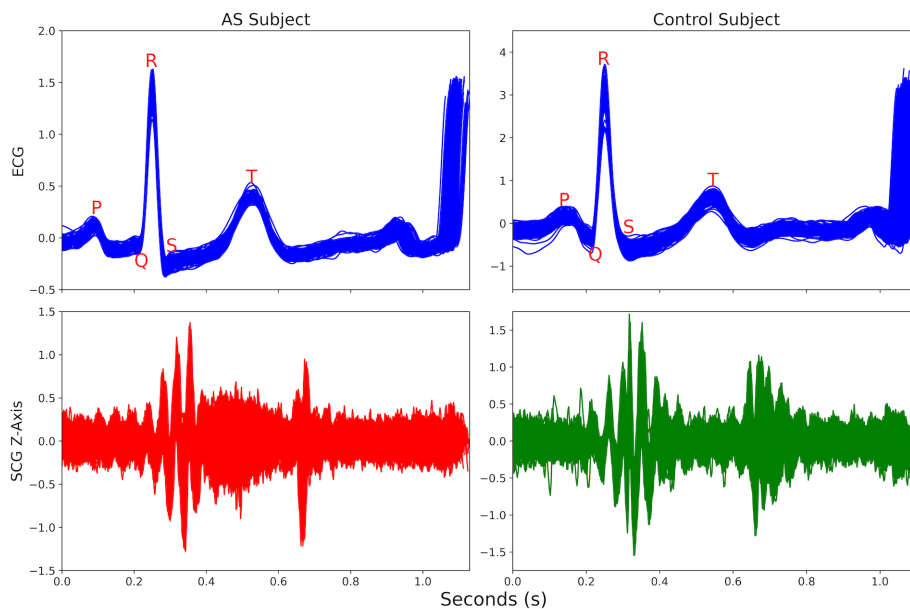


Figure 3 Example of accepted cardiac cycles plotted in an overlaid fashion for one AS subject in red and one control subject in green. Cardiac cycles are extended in time in order to properly label ECG fiducial points in red text. AS, aortic stenosis; SCG, seismocardiography.

Signal processing and artefact removal

Following signal acquisition, both ECG and SCG signals underwent filtering to remove baseline noise and artefacts. ECG R-peaks were identified using an R-peak detection algorithm from the NeuroKit2 Python package (V.0.2.3).²⁶ Identified R-peaks were used to segment SCG signals into individual cardiac cycles.

Each cardiac cycle was then evaluated using a DTW distance measure to identify and exclude significantly distorted or noisy cardiac cycles. This artefact removal process ensured only noise-free cardiac cycles were used. Typical examples of accepted cardiac cycles from AS and control patients are depicted in [figure 3](#) in an overlaid fashion.

Identification of key cardiac events

For each subject, the cardiac cycles that passed DTW-based quality criteria were averaged, generating an ensemble-averaged SCG signal. This ensemble average facilitated automated detection of two cardiac events: the aortic valve opening (AO) and aortic valve closure (AC). Identification of AO and AC allowed for approximation of eight cardiac event time windows used for feature extraction from the accepted cardiac cycles when using the detected R-peaks as reference points.

Feature extraction using CWT

Following identification of the cardiac event time windows, a CWT was applied to each accepted cardiac cycle, creating a time-frequency representation. Three features were calculated from each CWT coefficient row (online supplemental figure S2): max value, mean value and total energy. These three features were extracted across 200 scales representing frequencies from 1 Hz to 200 Hz for the X, Y and Z axis of acceleration across eight

predefined time windows, resulting in 14400 candidate features per cardiac cycle.

Classification model and ensemble strategy

An ensemble of three gradient boosting classifiers (models A, B and C) was trained on phase 1 data (115 subjects). Model A used all 14400 features directly, while models B and C applied two-step feature selection based on selecting features with non-zero feature importance. Model B used a gradient boosting classifier to select 493 features, and model C used adaptive boosting with decision trees to select 141 features. Both models B and C then trained a separate gradient boosting classifier on their feature subsets. Final predictions were produced by hard majority voting across the three models. Hyperparameters were tuned on an internal validation set of 20 subjects from the phase 1 training set (settings in online supplemental material). Performance on the phase 2 blinded test set was evaluated by sensitivity, specificity, the receiver operating characteristic curve (ROC), and the area under the curve (AUC).

Analysis and interpretation of misclassifications

To systematically interpret model misclassifications and evaluate the algorithm's performance, retrospective analysis was applied to all incorrectly classified subjects. Additionally, subgroup analyses were performed to determine if particular clinical characteristics influenced the classification performance of the algorithm. Clinical data and echocardiographic parameters from misclassified patients were reviewed in detail to identify potential explanations for incorrect predictions.

Statistical analysis

The demographic data and clinical variables were analysed using the JMP Pro analytics software (V.16.2.0,

Table 1 Demographics of phase 1 training data

Demographics and clinical parameters	All patients (n=115)	AS (n=56)	Control (n=59)	P value
Age	73.8±10.4	79.2±5.9	68.4±10.8	<0.001
Sex, male	70 (60.3)	26 (46.4)	44 (74.6)	0.002
BMI, kg/m ²	27.2±3.9	27.1±3.9	27.3±3.9	0.73
DM	28 (24.1)	16 (28.6)	12 (20.3)	0.39
Hypertension	78 (67.2)	44 (78.6)	33 (55.9)	0.01
CAD	51 (44)	27 (48.2)	23 (39.0)	0.32
AF	4 (3.4)	4 (7.1)	0	0.037
Prior MI	9 (7.8)	6 (10.7)	3 (5.1)	0.26
EF, %	60.9±7.7	61.8±7.9	60.6±5.9	0.37
AVA, cm ²		0.7±0.2	N/A	
Peak gradient, mm Hg		78.1±22.5	N/A	
Mean gradient, mm Hg		47.3±13.9	N/A	

Values in table are presented as the number with/without the percentage in parentheses or the mean±SD.
 AF, atrial fibrillation; AS, aortic stenosis; AVA, aortic valve area; BMI, body mass index; CAD, coronary artery disease; DM, type I or II diabetes mellitus; EF, ejection fraction; MI, myocardial infarction.

SAS Institute, Cary, North Carolina, USA). Visual assessment was used for continuous variables to determine the normality of the variables. Continuous variables were assessed for normality and reported as mean±SD or median (IQR) if not normally distributed, then compared by Student's t-test or Wilcoxon rank-sum test. Categorical variables were compared by χ^2 or Fisher's exact test. Variance homogeneity was evaluated with Levene's test. CIs were calculated from standard errors and Z-scores.

RESULTS

Patient demographics

Phase 1 model development and validation phase

SCG recordings from 115 subjects (56 AS, 59 controls; mean age 73.8±10.4 years) were included in the model training and internal validation phase (phase 1). AS patients were significantly older and had higher prevalence of hypertension and AF compared with controls. The majority of AS patients had normal EF (two patients had EF ≤40%) and none had other severe valvular heart diseases. Control patients exhibited normal EF and lacked moderate or severe valvular diseases, as well as other acute cardiac conditions such as heart failure and acute coronary syndrome. Demographic details for phase 1 patients are presented in [table 1](#).

Phase 2: blinded test phase

SCG recordings from 99 patients (50 AS, 49 controls; mean age 76.8±6.4 years) were included in the blinded test phase (phase 2). Age, sex, body mass index (BMI) and cardiovascular risk factors (heart failure, AF, coronary artery disease, prior percutaneous coronary intervention (PCI)/coronary artery bypass graft (CABG)) were comparable between groups, except prior myocardial infarction was more frequent in controls (8.2% vs 0%;

p=0.04). AS patients were more symptomatic (p<0.001), while EF did not differ (61.6% vs 60.5%; p=0.38). Three patients in the AS group had moderate aortic regurgitation. Three patients (two in the AS group and one in the control group) had moderate mitral regurgitation. Additionally, three patients (one in the AS group and two in the control group) had moderate tricuspid regurgitation. Demographic details for phase 2 patients are presented in [table 2](#).

AS detection

In the blinded test cohort (phase 2), the algorithm correctly classified 89 of 99 patients. Four patients with severe AS were misclassified as controls (false negatives), and six control patients were incorrectly classified as having AS (false positives). The algorithm demonstrated high overall diagnostic accuracy, with a sensitivity of 92.0% (95% CI 84.5% to 99.5%), specificity of 87.8% (95% CI 78.6% to 96.9%) and AUC of 96% (95% CI 91.9% to 99.9%).

In subjects with AF or a history of AF (n=36), the model achieved a sensitivity of 87.5% (95% CI 71.3% to 100.0%), specificity of 90.0% (95% CI 76.9% to 100.0%) and AUC of 98.1% (95% CI 93.7% to 100.0%). Among patients with documented CAD (n=27), the model achieved a sensitivity of 93.3% (95% CI 80.7% to 100.0%), specificity of 91.7% (95% CI 76.0% to 100.0%) and AUC of 98.8% (95% CI 94.5% to 100.0%).

After evaluation of cases with misclassification, two out of four patients with AS misclassified as control cases had low-flow, low gradient (LF-LG) severe AS (AVA <1.0 cm², mean gradient <40 mm Hg), but normal EF (>50%) and one patient had a BMI of 51 kg/m². For control patients misclassified as AS, no specific clinical or echocardiographic details could explain the misclassification.

Table 2 Demographics of phase 2 test data

Demographics and clinical parameters	All (n=99)	AS (n=50)	Control (n=49)	P value
Age	76.8±6.4	76.9±5.7	76.7±7.2	0.91
Sex, male	63 (64)	31 (62)	32 (65)	0.38
BMI, kg/m ²	28±5.7	29±6.1	27±5.0	0.052
DM	15 (15.2)	11 (22)	4 (8.2)	0.055
Hypertension	75 (75.8)	40 (80)	35 (71.4)	0.32
History of heart failure	8 (8.1)	6 (12)	2 (4.1)	0.15
AF	36 (36.4)	16 (32)	20 (41)	0.36
CAD	27 (27.3)	15 (30)	12 (24.5)	0.54
Prior MI	4 (4)	0 (0)	4 (8.2)	0.04
Prior PCI	5 (5.1)	2 (4)	3 (6.1)	0.63
Prior CABG	7 (7.1)	5 (10)	2 (4.1)	0.25
NYHA				
I	29 (29.3)	1 (2)	28 (57.1)	
II	45 (45.5)	29 (58)	16 (32.7)	
III	22 (22.2)	18 (36)	4 (8.2)	
IV	0 (0)	0 (0)	0 (0)	<0.001
ECG				
Bundle branch block (LBBB or RBBB)	11	7 (14)	4 (8.2)	0.36
Ventricular pacing	1	0	1	0.31
Echocardiography				
EF, %	61.0±6.5	61.6±6.4	60.5±6.6	0.38
Peak gradient, mm Hg		79.9±19.6	N/A	
Mean gradient, mm Hg		48.4±12.4	N/A	
AVA, cm ²		0.8±0.13	N/A	

Values in table are presented as the number with/without the percentage in parentheses or the mean±SD.

AF, atrial fibrillation; AS, aortic stenosis; AVA, aortic valve area; BMI, body mass index; CABG, coronary artery bypass graft; CAD, coronary artery disease; DM, type I or II diabetes mellitus; EF, ejection fraction; LBBB, left bundle branch block; MI, myocardial infarction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; RBBB, right bundle branch block.

DISCUSSION

This study evaluated the feasibility of using single-lead ECG with three-axis SCG signal measurements as a non-invasive low-cost diagnostic tool for detecting severe AS. The algorithm achieved high sensitivity, specificity and AUC: 92% (95% CI 84.5% to 99.5%), 87.8% (95% CI 78.6% to 96.9%) and 96% (95% CI 91.9% to 99.9%), respectively, in a blinded test cohort.

This study design incorporated two distinctly different datasets. Phase 2 data differed significantly from those of phase 1, particularly in demographic and cardiovascular profiles. Phase 2 controls were significantly older (76.7±7.2 vs 68.4±10.8 years in phase 1) and closely matched AS patients in cardiovascular comorbidities and risk factors such as history of AF, CAD, prior PCI or CABG. This demographic divergence provided a more challenging evaluation of the algorithm and reduced the likelihood that high predictive performance resulted from features specific to younger, healthier training controls.

Previous SCG-based AS detection studies used only single heterogeneous datasets.^{11 16–19}

Although phase 2 controls matched AS patients in age and risk factors, AS patients were more symptomatic due to disease nature and referral for TAVR (table 2). Four true AS patients were misclassified as controls in our study; two of these presented with LF-LG AS, which could explain the misclassification. This specific patient population poses a unique clinical challenge even when using echocardiography and cardiac CT.²⁷ One of the misclassified patients had a BMI of 51 kg/m² suggesting that severe obesity may potentially suppress the SCG signal. Subgroup analysis of patients with AF or CAD history yielded results comparable to the overall cohort.

This study aimed to address gaps and limitations present in previous studies using SCG or GCG signals to detect severe AS.^{11 16–19} Those studies had small dataset sizes, included control subjects who were significantly younger and lacked documented cardiovascular disease history and did not disclose patient demographics and

risk factors, thus failing to account for confounding variables. Such factors restrict evaluation of diagnostic accuracy and limit generalisability.

Other novel non-SCG modalities for AS detection have been explored in recent years. Digital stethoscope-based methods have provided promising sensitivity and specificity.^{21 23} However, these studies encounter similar limitations as those aforementioned. A deep learning algorithm using ECG demonstrated sensitivity and specificity (78% and 74%, respectively), with an excellent negative predictive value of 98.9%, while the positive predictive value was poor (10.5%), suggesting that this method may not be suitable for AS screening.²² AI-based AS screening using single-lead ECG showed better diagnostic performance (AUC 84.5%), but profound demographic differences between AS and non-AS groups indicated potential confounding bias.²⁰ Although handheld and AI-assisted mobile ultrasound technology has advanced, it still requires training and expertise, limiting its use for AS screening.²⁸

An advantage of SCG-based detection is its integration potential into standard smartphone technologies (all modern smartphones include accelerometer sensors), facilitating ease of use and broad implementation. Similar to a 12-lead ECG measurement, the SCG measurements in this study were conducted by a nurse and did not require physician involvement. Until recently, screening for asymptomatic AS patients has received little attention, as AVR, the standard treatment for AS, is not usually performed until the patient becomes symptomatic. However, symptoms can be subjective, especially in elderly sedentary patients, and treatment benefit has been demonstrated in asymptomatic patients with severe AS.^{29 30} In addition, patients with AS have high mortality risk across all levels of untreated AS severity, and AVR rates remain low for patients with severe AS.^{26 31} Thus, there is significant evidence to warrant research for AS screening.

Potential clinical applications for this SCG-based technology include: (1) detecting appropriate patients for echocardiography referral in asymptomatic subjects presenting with a systolic murmur and (2) population-wide screening to detect AS. However, further research is warranted to validate these findings and evaluate the device's resolution across all levels of AS severity. As the prevalence of moderate or severe AS is approximately 4%, the number of false positives is likely to be significant despite the high specificity of the technology, and the SCG analysis needs to be integrated into a comprehensive clinical evaluation.

Study limitations

This study focused exclusively on symptomatic severe AS patients referred for TAVR. Mild and moderate AS cases were not included, and the algorithm's ability to detect earlier stages or distinguish severity was not assessed. Symptomatic referrals may also exhibit haemodynamic features that differ from those of asymptomatic

individuals with similar anatomy. In addition, patients with other severe valvular diseases were excluded from this study, which limits the generalisability of the findings. More data are also needed for specific patient populations in which SCG signals may be interfered with, such as patients with cardiac implantable electronic devices, severe chronic lung disease or chest deformities.

This study relied on SCG recordings performed by two trained cardiac nurses. Although the system is simple and operator-independent, correct sternum placement still requires basic training. In our study, 10% of phase I and 7% of phase II patient datasets were excluded due to poor signal quality, highlighting the importance of the proper device positioning. In real-world settings, measurements performed by healthcare personnel with varying experience could introduce variability that affects algorithm performance.

The controls in phase 2 were screened by bedside echocardiography to exclude significant valvular and structural heart diseases, but complete echocardiograms were not available for all controls. Future studies with full imaging protocols and diverse populations are needed to validate and generalise these findings.

CONCLUSION

In this study, we introduce a low-cost SCG-based algorithm for the detection of AS. This algorithm demonstrated high sensitivity and specificity when tested in a blinded age-matched and sex-matched cohort. These findings are encouraging and suggest that this technology may hold potential as a diagnostic tool for the detection of AS.

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Competing interests TK is a shareholder of Precordior Oy. All other authors have no competing interests to declare.

Patient consent for publication Not applicable.

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Data availability statement Data are available upon reasonable request. All data relevant to the study are included in the article or uploaded as supplementary information.

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ORCID iDs

Jouni Pykärä <https://orcid.org/0000-0002-6563-5758>

Ismail Elnaggar <https://orcid.org/0000-0002-2230-983X>

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