

Original Article

Determining the clinical significance of computer interpreted electrocardiography conclusions

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Abstract: Background: Computerized electrocardiogram (EKG) interpretation technology was developed in the mid-20th century, but its use continues to be controversial. This study aims to determine clinical factors which indicate greater odds of clinical significance of an abnormal computerized EKG interpretation. Methods: The inclusion criteria for this retrospective study were patients who underwent outpatient echocardiography for the indication of an abnormal EKG and had an EKG abnormality diagnosed by the computerized EKG system. Qualifying patients had the results of their computerized EKG, echocardiogram, and charted patient characteristics collected. Computerized diagnoses and patient characteristics were assessed to determine if they were associated with increasing or decreasing the odds of an echocardiographic abnormality via logistic regression. Chi-square and t-test analyses were used for categorical and continuous variables, respectively. Odds ratios are presented as odds ratio [95% confidence interval]. A *P*-value of ≤ 0.05 was considered statistically significant. Results: A total of 515 patients were included in this study. The population was 59% women with an average age of 57 ± 16 years, and a mean BMI of 30.1 ± 7.3 kg/m². Patients with echocardiographic abnormalities tended to have more cardiac risk factors than patients without abnormalities. In our final odds ratio model consisting of both patient characteristics and EKG diagnoses, age, coronary disease (CAD), and diabetes mellitus (DM) increased the odds of an echocardiographic abnormality (1.04 [1.02-1.06], 2.68 [1.41-5.09], and 1.75 [1.01-3.04], respectively). That model noted low QRS voltage decreased the odds of an abnormal echocardiogram (0.31 [0.10-0.91]). Conclusion: Our findings suggest that in patients with an abnormal computerized EKG reading, the specific factors of older age, CAD, and DM are associated with higher odds of abnormalities on follow-up echocardiography. These results, plus practitioner overreading, can be used to determine more appropriate management when faced with an abnormal computerized EKG diagnosis.

Keywords: Electrocardiography, echocardiography, computerized electrocardiographic interpretation, clinical management

Introduction

According to the U.S. National Center for Health Statistics, over 41 million electrocardiograms (EKGs) were performed in the ambulatory setting in 2016 (see: https://www.cdc.gov/nchs/data/ahcd/namcs_summary/2016_namcs_web_tables.pdf). Even though EKGs are a very common procedure, many medical trainees and physicians still struggle with EKG interpretation [1-3]. It can take approximately one minute to properly review an EKG, even for a skilled interpreter [4, 5]. Therefore, the development of computerized EKG reading systems

has been considered an important objective for the medical community. Attempts to develop computerized EKG interpretation systems date back to the mid-20th century [6]. While the accuracy of these systems has improved, there are still concerns regarding the accuracy of these computerized EKG reading algorithms [7]. Studies have indicated that these algorithms perform suboptimally in patients with arrhythmias, especially atrial fibrillation, and in patients with pacemakers [7]. Several studies have demonstrated both high false positive and high false negative rates in the diagnosis of ST-elevation myocardial infarctions (STEMI) wi-

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th computerized EKG algorithms [7]. Additionally, different computerized systems can produce varying QT interval measurements [7].

However, these systems have also been shown to decrease EKG reading time, have good accuracy in detecting normal rhythms, and can help physicians notice possibly critical information helping to direct proper patient care [7, 8]. Computerized systems receive recordings from the twelve leads simultaneously, providing the physician with even more information, such as a more detailed analysis of beat-to-beat variability [8]. When the algorithm makes the correct diagnosis, these systems can improve interpreter accuracy. If incorrect, they have also been shown to increase the rate of error by interpreters, which could subject patients to inappropriate interventions [9-12].

While there is considerable literature regarding the accuracy of these machines, this does not seem to answer another key question that practitioners may ask: when should these computerized outputs be given greater consideration? There is a paucity of data regarding in what clinical contexts should the reading of these computerized EKG systems be given greater consideration. Therefore, this study was developed to determine what clinical factors may be of use for a practitioner when deciding the management of a patient with an abnormal computerized EKG reading, specifically, what clinical and diagnostic factors may warrant further evaluation via echocardiography.

Materials and methods

Study design

This retrospective study was approved by the Nassau Health Care Corporation's institutional review board (IRB # 18-183). Inclusion criteria were that the patient: 1) had a transthoracic echocardiogram performed in the outpatient setting, 2) the indication for the transthoracic echocardiogram was for an abnormal EKG, and 3) the EKG had an abnormal diagnosis via the computerized EKG system. It is important to note that the practitioners' EKG diagnosis was not assessed in this investigation. All EKGs were obtained using the Nihon Kohden Cardiofax V Electrocardiograph ECG-1550A (Shinjuku, Japan) and EKG analysis was performed using the machine's interpretation software

ECAPS 12C (see: <https://access-med.com/medical/uploads/2016/05/ECG-1550-Brochure.pdf>). EKG abnormalities diagnosed by the computerized system were grouped as the following for analysis: arrhythmia (all types), hypertrophy, bundle branch blocks (all types), abnormal PR interval, abnormal QT interval, low QRS voltage, ST segment abnormalities, T-wave abnormalities, and Q-wave abnormalities. Baseline characteristics were collected from the patient chart and included: age, body mass index (BMI), gender, and histories of coronary artery disease (CAD), renal disease, hyperlipidemia, hypertension, smoking history, diabetes mellitus (DM), and the use of insulin. An abnormal echocardiogram was defined as the presence of any of the following: an abnormal ejection fraction, wall motion abnormalities, and valvular abnormalities.

Statistical methods

For analysis, the patients were separated into two groups: normal echocardiogram and abnormal echocardiogram. Analysis of patient characteristics and EKG diagnoses between the normal and abnormal echocardiogram patients were performed using chi square analysis and t-tests for categorical and continuous variables, respectively. Odds ratios were performed using logistic regression with Fisher's scoring for optimization. Odds ratio models were created to assess how certain factors impacted the odds of a patient having an abnormal echocardiogram. To answer this question, three models were created: one model of only the patient characteristics, one model of only the computerized EKG diagnoses, and a final model consisting of both.

A *P*-value ≤ 0.05 was considered statistically significant. Data are presented as either frequency (percentage) or mean \pm standard deviation. Odds ratios are presented as ratio [95% confidence interval]. Statistical analyses were completed using SAS University Edition 3.8 (SAS Institute Inc., Cary, North Carolina).

Results

A total of 515 patients who met the criteria for inclusion were identified. Our population comprised of 306 women (59%) with an average age of 57 ± 16 years and an average BMI of 30.1 ± 7.3 kg/m². The demographic data for

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Table 1. Overall patient characteristics (515 total patients)

Variable	N (%) or Mean \pm SD
Age (years)	57 \pm 16
BMI (kg/m ²)	30.1 \pm 7.3
Female gender	306 (59%)
CAD	63 (12%)
HTN	356 (69%)
Renal disease	44 (9%)
Hyperlipidemia	248 (48%)
DM	151 (29%)
Using insulin	38 (7%)
Current or former smoker	103 (21%)

Abbreviations: BMI, body mass index; CAD, coronary artery disease; DM, diabetes mellitus; HTN, hypertension; N, number of patients; SD, standard deviation.

the overall population can be seen in **Table 1**. Patients that had an abnormal echocardiogram tended to be older and have more cardiac risk factors, such as coronary artery disease and diabetes mellitus, than patients who had a normal follow-up echocardiogram (**Table 2**).

A total of 879 EKG abnormalities were diagnosed by the computer, for an average of 1.7 abnormalities per patient. The most common EKG abnormality was arrhythmia (254, 29%). Other EKG abnormalities are noted in **Table 3**. In total, 259 patients (50%) had only one EKG abnormality diagnosed, 166 patients (32%) had two EKG abnormalities diagnosed, and 90 patients (18%) had three or more EKG abnormalities diagnosed. Having two abnormalities diagnosed versus one abnormality did not significantly affect the odds of an echocardiographic abnormality (1.35 [0.87-2.10]). Having three or more abnormalities significantly increased the odds of an echocardiographic abnormality as compared to having one abnormality (1.83 [1.09-3.08]).

The odds-ratio model consisting of only patient characteristics found age and CAD increased the odds of echocardiographic abnormality (1.04 [1.02-1.06] and 2.50 [1.35-4.57], respectively). The odds ratio model consisting of only EKG diagnoses found bundle branch blocks, hypertrophy, and Q-wave abnormalities increased the odds of echocardiographic abnormality (1.80 [1.13-2.86], 1.84 [1.04-3.25], and 1.86 [1.41-3.02], respectively). The final model (**Table 4**) comprised of both patient character-

istics and EKG diagnoses found age, CAD, and DM increased odds of an echocardiographic abnormality (1.04 [1.02-1.06], 2.68 [1.41-5.09], and 1.75 [1.01-3.04], respectively) while low QRS voltage decreased the odds of an echocardiographic abnormality (0.31 [0.10-0.91]). No specific EKG abnormality increased the odds of an echocardiographic abnormality in this final model.

Discussion

A basic introduction to computerized EKG systems

While there may be variability among computerized EKG interpretation algorithms, there are general principles for how these systems operate. Once the recorded data are filtered for low and high frequency noise and amplified, measurements of amplitudes and durations may be made. This may be done either by analyzing the data from an individual lead or globally (in which the machine scans temporally to find the earliest start and latest end of a waveform complex and is the preferred methodology as per guidelines) [13]. Measurements may be affected by several sources of error and certain algorithms may generate minor, but possibly significant, differences in measurements, such as the QT interval [13-15]. In the algorithm used by our hospital's machine, which is manufactured by Nihon Koden, the QT interval is measured globally. This could lead to longer QT interval measurements as compared to other machines using different sampling methods [16].

In continuation, representative waveforms can be formed from the lead data, after which the data can be compressed for transmission and storage. Computerized EKG interpretation systems then analyze these data using diagnostic algorithms. Algorithms may be heuristic (experience-based), or statistical (probability-based); the latter is the preferred algorithmic type according to the most recent guidelines [13].

Comparison to the available literature

Few investigations assess the clinical implications of computerized EKG diagnosis systems. In general, studies of these computerized systems aim to compare the accuracy of the ma-

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Table 2. Baseline characteristics and EKG abnormalities for patients with echocardiographic abnormalities versus those without abnormalities

Variable	No echo abnormality (N=375)	Echo abnormality (N=140)	P-value
<i>Patient Characteristics</i>			
Age (years)	54 ± 16	65 ± 15	0.29
BMI (kg/m ²)	30.1 ± 7.3	29.9 ± 7.3	0.94
Female gender	232 (62%)	74 (53%)	0.07
CAD	28 (7%)	35 (25%)	<0.0001*
HTN	236 (63%)	120 (86%)	<0.0001*
Renal Disease	19 (5%)	25 (18%)	<0.0001*
Hyperlipidemia	161 (43%)	87 (62%)	0.0001*
DM	90 (24%)	61 (44%)	<0.0001*
Using insulin	21 (6%)	17 (12%)	0.02*
Ever smoker	71 (20%)	32 (23%)	0.54
<i>EKG abnormalities</i>			
Arrhythmia	187 (50%)	67 (48%)	0.69
T-wave abnormal	125 (33%)	39 (28%)	0.24
BBB	74 (20%)	44 (31%)	0.01*
Q-wave abnormal	64 (17%)	40 (29%)	0.01*
ST seg. abnormal	53 (14%)	17 (12%)	0.66
Hypertrophy	40 (11%)	25 (18%)	0.04*
PR int. abnormal	35 (9%)	20 (14%)	0.11
Low QRS voltage	35 (9%)	5 (4%)	0.04*
QT int. abnormal	9 (2%)	0 (0%)	0.12

*denotes significance at P ≤ 0.05. Abbreviations: BBB, bundle branch block; BMI, body mass index; CAD, coronary artery disease; DM, diabetes mellitus; HTN, hypertension; int., interval; seg., segment.

Table 3. Abnormal EKG findings (879 findings total)

Finding	N (%)
Arrhythmia	254 (29%)
T-wave abnormalities	164 (19%)
Bundle branch block	118 (13%)
Q-wave abnormalities	104 (12%)
ST abnormalities	70 (7%)
Hypertrophy	65 (7%)
PR interval abnormalities	55 (6%)
Low QRS voltage	40 (5%)
QT abnormalities	9 (1%)

chine to an overreading physician. Studies have noted that these computerized EKG systems work quite well in the diagnosis of sinus rhythms. However, these systems have poorer accuracy in diagnosing cardiac rhythm abnormalities. Shah and Rubin observed computerized EKG interpretation had an overall accuracy rate of 88% and diagnosed sinus rhythm with a sensitivity of 95% and a specificity of 66.3%. They noted a greater specificity in diagnosing

non-sinus rhythms (sensitivity of 72% and specificity of 93%) [17]. Fatemi *et al.* determined that their EKG system diagnosed rhythm disorders with a sensitivity and specificity of 67.6% and 75.7%; conductive disorders at 70% and 96.6%, respectively; and structural conditions at 92.8% and 83.3%, respectively [18]. Lindow *et al.* found that nine percent of computer diagnoses of atrial fibrillation were inaccurate [12]. A meta-analysis by Taggar *et al.* found that computerized EKG programs diagnosed atrial fibrillation with a sensitivity and specificity of 89% and 99%, respectively [19]. In a 1986 study, Timmis *et al.* analyzed patients previously diagnosed with LVH via echocardiogram and compared this to a computerized EKG output. They noted an accuracy of 63%, sensitivity of 32% and a specificity of 89% [20]. Other investigations have noted that computerized EKG systems diagnose left ventricular hypertrophy with a greater rate of specificity than sensitivity [21, 22].

For the relatively few amount of trials focused on the clinical implications of these EKG sys-

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Table 4. Final odds ratio model consisting of both patient characteristics and EKG diagnoses affecting the odds of an echocardiographic abnormality

Variable	Odds Ratio [95% confidence interval]
Age	1.04 [1.02-1.06]*
Gender	0.79 [0.49-1.28]
BMI	1.00 [0.97-1.04]
CAD	2.68 [1.41-5.09]*
HTN	1.38 [0.71-2.66]
Renal disease	1.40 [0.66-2.94]
Hyperlipidemia	0.73 [0.43-1.24]
DM	1.75 [1.01-3.04]*
Use of insulin	0.42 [0.44-2.49]
Smoking history	0.80 [0.46-1.39]
Arrhythmia	0.91 [0.57-1.43]
T-wave abnormal	0.80 [0.47-1.35]
BBB	1.61 [0.95-2.72]
Q-wave abnormal	1.49 [0.86-2.56]
ST seg. abnormal	1.07 [0.55-2.09]
Hypertrophy	1.83 [0.95-3.50]
PR int. abnormal	1.12 [0.57-2.21]
Low QRS voltage	0.31 [0.10-0.91]*
QT int. abnormal	<0.001 [<0.001->999.99]

*denotes statistical significance. Abbreviations: BMI - body mass index, CAD - coronary artery disease, DM - diabetes mellitus, HTN - hypertension, BBB - bundle branch block, int. - interval, seg. - segment.

tems, they generally assess the rate of treatment or testing as a result of an inaccurate computerized EKG diagnosis. Furthermore, most of these investigations are limited to patients with atrial fibrillation and atrial flutter. In a 2004 study, Bogun *et al.*'s analysis of approximately 2300 EKGs in 1085 patients uncovered that 35% of patients had an inaccurate diagnosis of atrial fibrillation by their computerized system [23]. Almost a quarter of these patients were then subjected to inappropriate treatments [23]. A more recent study by Hwan Bae *et al.* found that 9.3% of over one thousand EKGs were misdiagnosed by their machine system as atrial fibrillation and about 15% of these patients were subjected to inappropriate interventions such as anticoagulation and rate/rhythm control [11]. In 2019, Lindow *et al.* discovered a computer misdiagnosis rate of 9.0% for atrial fibrillation and atrial flutter in a group of about 1000 EKGs [12]. They also found that

about 10% of these misdiagnosed patients were subject to inappropriate anticoagulation [12]. Massel *et al.* noted that solely relying on a computer diagnosis would have led to a statistically significant underuse of thrombolytics in STEMI patients [24].

There is an abundance of literature regarding potential pitfalls and clinical issues regarding computerized EKG interpretation. However, these widely available systems do not have clear evidence suggesting under which clinical circumstances an abnormality diagnosed by these computerized systems should raise concern to the ordering practitioner. The goal of this investigation was to answer this very question: what clinical and diagnostic factors could be used by practitioners to assist in their management of an abnormal computerized EKG reading. Particularly, in cases where the computer diagnosis is of clinical importance, this investigation provides practical information that may be used to guide appropriate patient management. The results of our final odds ratio model noted that the patient factors of advanced age, coronary artery disease, and diabetes mellitus increased the odds of an echocardiographic abnormality on follow-up. The former two factors are not a particularly surprising result; for example, advanced age is associated with valvular abnormalities and advanced CAD could present with wall motion abnormalities [25, 26]. While DM is a critical risk factor for CAD and could explain an association with increased odds of an echocardiographic abnormality, it is also an independent risk factor for other echocardiographic abnormalities such as left ventricular diastolic dysfunction and left ventricular hypertrophy [27].

Interestingly, the only factors our final combined odds-ratio model found to increase the risk of an echocardiographic abnormality were clinical variables. While our model composed of only EKG diagnoses noted bundle branch blocks, hypertrophy, and Q-wave abnormalities were associated with increased odds of an echocardiographic abnormality, this trend did not continue in the final model. Instead, the only EKG abnormality of significance was low QRS voltage which decreased the odds of an echocardiographic abnormality. While low QRS voltage is associated with certain cardiac abnormalities such as amyloidosis, it is a rather

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nonspecific finding. Non-cardiac causes of low QRS voltage include chronic obstructive pulmonary disease and obesity - the latter being quite prevalent in both arms of this study [28].

Study limitations

There are several limitations to this investigation. Firstly, we assessed the clinical implications of an abnormal EKG as compared to an echocardiogram. Other follow-up tests, such as 24-hour Holter monitoring or electrophysiologic studies, should also be assessed. Secondly, these results may also be influenced by the practice of defensive medicine. This study was conducted within the State of New York, which has one of the highest malpractice payouts per capita in the United States (see: <https://www.diederichhealthcare.com/the-standard/2020-medical-malpractice-payout-analysis/>). While the ordering practitioner may have had sufficient knowledge that the listed EKG abnormality may have no clinical significance, medicolegal concerns may have influenced the provider's decision to continue with further, and possibly unnecessary, testing. Finally, this was a retrospective investigation and these results should be confirmed via prospective analyses.

Conclusion

This investigation finds that an abnormal computerized EKG reading in the setting of advanced age, coronary artery disease, or diabetes mellitus is more likely to be associated with an echocardiographic abnormality on follow-up. While computerized EKG systems may provide an additional tool for the practitioner, experts agree that it is still a supplement to the interpretation by the practitioner. However, when faced with a challenging EKG or discrepancy between computer versus human interpretation, a practitioner can use these results in helping guide the next step in management. Specifically, this investigation demonstrates in patients with an abnormality diagnosed by a computerized EKG system, advanced age, history of CAD, and DM significantly increased the odds of having an abnormal echocardiogram in follow-up. In these patients, it is possible that further work-up is warranted in the setting of an abnormal computerized EKG reading.

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Disclosure of conflict of interest

None.

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