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Normal Prehospital Electrocardiography is Linked to Long-term Survival in Patients Presenting to the Emergency Department with Symptoms of Acute Coronary Syndrome

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Abstract

Aims/Methods—We studied 735 patients who activated “911” for chest pain and/or anginal equivalent symptoms and received 12-lead ECG monitoring with specialized ischemia monitoring software in the ambulance. Prehospital electrocardiograms (PH ECG) were analyzed to determine the proportion of patients who present with completely normal PH ECG findings (absence of ischemia/infarction, arrhythmia, or any other abnormality) and to compare outcomes amongst patients with and without any PH ECG abnormality.

Results—Of 735 patients (mean age 70.5, 52.4% male), 68 (9.3%) patients had completely normal PH ECG findings. They experienced significantly less adverse hospital outcomes (12% vs 37%), length of stay (1.19 vs 3.86 days), and long-term mortality (9% vs 28%) than those with any PH ECG abnormality ($p < .05$).

Conclusion—Normal PH ECG findings are associated with better short and long-term outcomes in ambulance patients with ischemic symptoms. These findings may enhance early triage and risk stratification in emergency cardiac care.

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Keywords

Acute coronary syndrome; emergency medical services; prehospital electrocardiography; ST-segment monitoring

Introduction

Acute coronary syndrome (ACS) is a life-threatening complication of coronary heart disease (CHD) and remains a top cause of death in the United States [1]. Each year, nearly 6 million patients present to the emergency department (ED) with chest pain and 620,000 are diagnosed with acute myocardial infarction (AMI) [2, 3]. An estimated 10-59% of patients with chest pain activate the emergency medical system (EMS) for transport to the hospital. Prehospital triage and identification of patients with ACS is critical since each minute of delay from symptom onset to intervention for AMI increases mortality [4, 5]. Conducting a prehospital electrocardiogram (PH ECG) is becoming the standard of care for patients activating EMS and the American Heart Association (AHA) designated PH ECG a Class I recommendation (supported by strong evidence) in its 2010 Cardiac Life Support guidelines [6]. Abnormal PH ECG signs of ischemia (ST elevation, ST depression, T-wave inversion) drive early treatment decisions for patients with myocardial infarction such as the decision to bypass what may be the closest hospital for a further one that offers definitive cardiac treatment [7]. Moreover, PH ECG signs of ischemia are independent predictors of adverse hospital outcomes, a final diagnosis of ACS, and direct admission to acute coronary care units [8-10]. PH ECG can also uncover significant arrhythmias that may be indicative of underlying cardiac disease [11].

However, the value of completely normal ECG results (absent of ischemia, arrhythmia, or other abnormalities) in the prehospital setting for patients with chest pain and/or anginal equivalent symptoms is unknown. Therefore, the primary aims of this study were 1) to determine the proportion of patients transported for ischemic complaints with completely normal PH ECG findings, and 2) to describe the incidence of adverse hospital outcomes, length of hospital stay, and long-term mortality in this population.

Material and Methods

Study Design

Data for this retrospective analysis were obtained from the ST SMART (Synthesized Twelve-lead ST Monitoring and Real-time Tele-electrocardiography) Trial, a prospective randomized clinical trial in Santa Cruz County, California from 2003-2009 [12]. The primary aims of the ST SMART Trial were to compare patients with and without PH ECG ST-segment monitoring in paramedic scene time, hospital time to treatment, and survival over the period of the study. The primary outcome measure for the present analysis was to compare two groups (those with completely normal PH ECG and those without normal PH ECG) on the differences in the proportion of adverse hospital outcomes and long-term mortality, and the difference in mean length of hospital stay.

The Institutional Review Boards at the University of California, San Francisco, and the two hospitals in the County approved the study with a waiver of consent in the field to avoid delays in patients reaching the hospital. Community assent was obtained by a front-page report in the county's newspaper (*Santa Cruz Sentinel*, 2003) and by information posted on hospitals' and EMS agencies' websites [12]. Once study participants were comfortable and hemodynamically stable at the hospital, research nurses obtained written consent.

Study Setting and Population

Enrollment for the study occurred 7 days a week, 24 hours a day in the prehospital setting. All paramedics in Santa Cruz County were trained to include the following: any persons 30 years of age and older who activated "911" with complaints of non-traumatic chest pain and/or anginal equivalent symptoms (i.e. new onset shortness of breath not due to asthma or syncope not due to drug overdose or intoxication). Exclusion criteria were participants who were unwilling or unable to consent [12].

Study Protocol

All 26 paramedic-staffed emergency vehicles responding to 911 calls in the county were equipped with specially designed portable monitor-defibrillator devices (Lifepak12, Physio-Control, Redmond, Washington)[12]. The study device software was designed to enable: 1) synthesis of a 12-lead ECG from five electrodes, 2) measurement of ST amplitudes (J+60 milliseconds) every 30 seconds in all 12 leads, and 3) automatic storage and transmission of an ECG to the destination ED if there was a change in ST amplitude of 0.2 mV in 1 lead or 0.1 mV in 2 contiguous leads lasting 2.5 minutes [12]. The study device used a bandwidth of 0.05 to 150 Hz, which is the filtering recommended for diagnostic standard 12-lead ECGs.

A previous validation study was conducted to compare the synthesized 5-lead ECG and standard 12-lead ECG for major diagnoses of interest in the prehospital setting (i.e. myocardial ischemia/infarction, bundle branch block, arrhythmia) [13]. A high percentage of agreement was determined between the synthesized 5-lead PH ECG and standard 12-lead ECG for diagnoses of ACS, thus corroborating use of the 5-lead method for prehospital use in this study [13].

The portable monitor-defibrillator study device collected 20 seconds of electrocardiographic data and then selected the 10 seconds with the best signal-to-noise ratio to develop a noise-free median beat from which all 12-lead ST-segment measurements were obtained. If the initial 20-second sample was noisy, the device automatically analyzed the subsequent 20 seconds of data [12]. The ST SMART monitoring device had ischemia monitoring software designed for exercise stress testing that had powerful noise reduction technology to ensure high quality ECGs.

All county paramedics (n=83) were taught to apply the 5 electrodes and manually transmit an initial PH ECG for patients with ACS symptoms [12]. The initial manual ECG transmission activated the ongoing ST-segment monitoring software. Any subsequent ST-event PH ECGs were automatically transmitted without paramedic decision-making. To

optimize PH ECG transmissions, the device automatically attempted to redial up to 3 times if the EMS vehicle was in a location where mobile telephone communication was unavailable.

PH ECG data were stored in the device and analyzed offline (CodeStat Suite version 8.0, Physio-Control, Redmond, Washington). The investigator (JZH) manually analyzed all PH ECGs. Normal PH ECG was defined by the absence of all of the following: ST-T wave changes, arrhythmias, bundle branch block, first degree block, second degree block, third degree block, paced rhythm, left ventricular hypertrophy (LVH), long QT interval, or abnormal axis deviation. All ECG abnormalities are presented in detail in Table 1. The universal criteria for the diagnosis of ACS as defined by the European Society of Cardiology and American College of Cardiology Committee were applied to determine changes of ischemia/infarction [14]. The revised criteria were developed to improve the sensitivity and specificity of the ECG by recognizing gender, age, and lead differences. These include: 1) ST segment elevation at the J-point with cut-off points 0.2 mV in men > 40 years; >0.25mV in men < 40 years; and 0.15 mV in women in leads V₂ and V₃ or 0.1mV in other leads; 2) horizontal or down-sloping ST segment depression 0.05 mV; or 3) T-wave inversion of 0.1 mV in leads with prominent R waves or R/S ratio >1 [14]. All ECG criteria for ischemia/infarction were required be present in two contiguous leads. An expert (CES) conducted random audits of ECG analysis to establish inter-rater reliability.

Three research nurses were trained for data abstraction exclusively for the ST SMART Trial. They reviewed medical record notes, ICD-9 codes, and conducted follow-up telephone calls to obtain information about the occurrence of adverse hospital outcomes and long-term mortality. Follow-up data were collected at 30 day, 1, 2, 3, and 4-year time periods after hospital discharge. The Social Security Death Index (SSDI) was used for follow-up when research nurses were unable to acquire information by the prior strategies described. A project director conducted random study chart audits to ensure reliable and accurate data collection. The American College of Cardiology (ACC) key data elements for measuring clinical management and outcomes of patients with ACS were used to define hospital complication variables (Table 2) and patient characteristics (demographics, cardiac history, coronary risk factors) [15].

Data analysis

All statistical tests were conducted in SPSS statistical software (Version 22, Somers, NY) at the 0.05 significance level. Descriptive statistics were used to report baseline characteristics and clinical information. The list of possible ECG abnormalities in Table 1 were collapsed and denoted by normal ECG (yes/no). The nine individual hospital complication variables were combined into one dichotomous endpoint, adverse hospital outcome (yes/no). A time-to-death variable (days) was created for survival analyses. χ^2 testing was used to compare categorical variables. Logistic regression modeling was used to assess the relationship between the adverse hospital outcome endpoint and the presence or absence of a normal ECG, while controlling for the effects of the following risk factors: age, gender, history of myocardial infarction (yes/no), history of coronary artery disease (CAD) (yes/no), diabetes (yes/no), hypertension (yes/no), history of smoking (yes/no), history of dyslipidemia (yes/

no), and family history of CAD (yes/no). Log rank testing was used to assess the relationship of time-to-death and the presence or absence of a normal ECG. Cox proportional hazards modeling were conducted to analyze the same relationship, while controlling for the effects of the previously specified risk factors. Power analysis based on Fisher's 2 x 2 exact test showed that a sample size of 794 patients would provide at least 80% power, at the 0.05 significance level, to detect a small effect size of $h=0.23$.

Observations with missing values were omitted for each test.

Results

PH ECGs selected for analysis

All PH ECGs that were acquired and stored in the prehospital ECG device in the ST SMART Trial were analyzed. A total of 794 subjects with PH ECGs were enrolled in the ST SMART trial. Of these, 59 patients were excluded because they had been enrolled in the study previously, resulting in a final cohort of 735 unique patients for the present analysis (Figure 1).

Subject characteristics

The mean age of subjects was 70.5 years (SD 14.5) and 52.4% were male. Ethnicity included 91.6% white, 9.5% Latino, 0.7% black, and 3.0% mixed/unknown.

Baseline sample characteristics including coronary risk factors and cardiac history are summarized in Table 3.

Of 735 patients with ACS symptoms, 68 (9.3%) had completely normal PH ECG findings. There were 667 (90.7%) patients with any one of these abnormalities on PH ECG. Notably, 9 (4.3%) patients with a hospital discharge diagnosis of ACS (ST-elevation myocardial infarction, non ST-elevation myocardial infarction, MI of unknown origin, or definite/probable unstable angina) had completely normal PH ECG findings.

There were significant differences in clinical outcomes between those with and without completely normal PH ECG findings. Overall, 12% (95% CI: 4.2%-19.8%) of patients with completely normal PH ECG findings had adverse hospital outcomes compared with 37% (95% CI: 33.3%-40.7%) of the group with any ECG abnormality in the prehospital setting ($p<0.05$). Specifically, patients with normal PH ECG had significantly less onset of new heart failure (0% vs. 17.5%; $p<0.001$) or atrial dysrhythmias requiring intervention (4.4% vs. 14.7%; $p<0.05$) during hospitalization than those with any PH ECG abnormality. Length of hospital stay was significantly shorter for patients with completely normal PH ECG (mean = 1.19 days; SD = 1 day) than for those without normal PH ECG (mean = 3.86 days; SD = 15 days; Mann-Whitney test, $p<.001$). At the median 2 year follow-up, significantly fewer patients with completely normal PH ECG died relative to those with any PH ECG abnormality (9% vs. 28%; $p<0.05$)(Table 4).

Having a completely normal PH ECG decreased the odds of having an adverse event during hospitalization. Specifically, controlling for the effects of the other risk factors in the model, the odds of patients with a completely normal PH ECG having an adverse hospital outcome

were estimated to be 68% smaller than those for patients with any PH ECG abnormality [odds ratio = 0.32, $p=.004$, 95% CI: (0.15, 0.69)]. Age, gender, history of coronary artery disease, history of hypertension, and history of smoking were also significant predictors of any adverse hospital outcome (Table 5). The full model including normal PH ECG (yes/no) and the other risk factors as predictors was statistically significant ($p<.001$), and explained 13% (Nagelkerke R Square) of the variance in the presence/absence of adverse hospital outcome. The quality of model calibration was assessed using the Hosmer-Lemeshow test statistic, which was equal to 10.539 ($p=0.229$). This non-significant test statistic ($p=0.229$) indicates the model was well calibrated. Discrimination quality was assessed using the c-statistic, which was estimated to equal 0.71, indicating a fair level of discrimination accuracy.

The time to death for patients with completely normal PH ECG (mean = 1369.19 days; SD = 38.26 days) was higher than that for patients with any PH ECG abnormality (mean = 1219.56 days; SD = 25.67 days). Ignoring the effects of the other risk factors, the hazard of death at a particular time significantly differed between patients with normal or abnormal PH ECGs ($p=.005$). Controlling for these effects, the hazard of death at a particular time was estimated to be 44.4% smaller for patients with a normal PH ECG than for patients without normal ECG, although this difference is not statistically significant [hazard ratio = 0.556, $p=.165$, 95% CI: (0.24, 1.28)].

Discussion

To our knowledge, our study is the first to report on the value of completely normal PH ECG findings acquired with ST-segment monitoring in the prehospital setting. Our data showed that 9.3% of patients activating “911” for symptoms of ACS had completely normal PH ECG findings in the ambulance, and that these patients had significantly lower incidence of adverse hospital outcomes, shorter length of stay, and less long-term mortality. The presence of a completely normal PH ECG was an independent predictor for less adverse outcomes during hospitalization, and patients with normal PH ECG had longer time to death than those without normal PH ECG findings.

Prior studies have focused on the initial, “snap-shot” 10-second ECG acquired in the hospital setting and short-term outcomes. Brush and colleagues [16] evaluated the prognostic value of the initial hospital ECG conducted in the ED for patients admitted with chest pain. An ECG was considered normal if the following were absent: ST-segment elevation, ST-segment depression, T-wave inversion, pathologic Q-waves, LVH, left bundle branch block, or ventricular pacing. Patients with normal ECG findings experienced significantly less hospital complications (i.e. life-threatening arrhythmia), emergent interventions (electrical cardioversion), and no hospital death as compared to those with abnormalities. Notably, 15% of the normal ECG group was diagnosed with ACS but still experienced significantly less adverse hospital complications when controlling for final diagnosis [16]. While our findings are in general agreement with those by Brush et al [16], we applied more comprehensive criteria beyond ischemic changes alone for determination of normal ECG and considered long-term mortality.

Chase et al [17] examined patients with either normal *or* non-specific ECG findings and with/without active chest pain/anginal equivalent symptoms during initial ECG acquisition. Normal ECG criteria were limited to no electrocardiographic evidence of ischemia (ST-T wave changes) and 80% of patients with ACS symptoms had a normal/nonspecific ECG. Of the whole group with normal/nonspecific ECG and with or without active symptoms, 2.8% was diagnosed with AMI, 11% with ACS, and 5% experienced a 30-day follow-up event [17]. There were no significant differences in outcomes between patients with and without active ischemic symptoms with normal/nonspecific ECG. Similar to the prior work by Brush et al [16], this study was limited to a snap-shot ECG acquired over 10 seconds in the ED nor was long-term mortality examined. Investigators emphasized that normal/nonspecific ECG findings do not exclude the possibility for short-term adverse hospital events.

More recently, Turnispeed and colleagues [18] examined the correlation of completely normal initial ECG findings in the ED with a final diagnosis of ACS. Like the prior study [17], patients with and without active chest pain symptoms during ECG acquisition were compared. Criteria for normal ECG were extended beyond ischemic changes to include sinus rhythm and normal variants of the following: QRS interval, ST-segment, T-wave morphology, normal QRS axis, and the absence of pathologic Q-waves or LVH. Of the 17% with a final diagnosis of ACS, no differences were noted in the frequency of patients with and without chest pain symptoms. These findings support those of prior work by Chase and colleagues [17] in that the presence or absence of symptoms did not influence the likelihood of an ACS diagnosis in the setting of normal ECG findings.

Lastly, Welch et al. [19] conducted a large study using registry data to compare in-hospital mortality among AMI patients with and without a normal or nonspecific initial ECG. The primary outcomes were in-hospital death and/or the composite of in-hospital death/adverse outcomes (ventricular tachycardia/fibrillation, new onset pulmonary edema, cardiogenic shock, or hypotension requiring intervention). Investigators found that 4.4% of patients with AMI diagnosis had a normal ECG, but the specific criteria applied to determine normal ECG were not described which is a limitation of the study. Patients with either a normal or non-specific ECG with AMI diagnoses had significantly lower in-hospital mortality and composite death/adverse hospital events rates [19]. However, patients with initially normal ECG findings who had ECG abnormalities on subsequent tracings experienced significantly greater death and composite death/adverse events in the hospital [19]. These findings underscore the importance of continuous ECG monitoring for capturing transient myocardial ischemia. This study was similar to ours in its examination of serial ECG tracings, as opposed to a single ECG tracing that could miss dynamic changes of myocardial ischemia.

Our study has several limitations that need to be considered. First, PH ECGs were recorded using a five-electrode reduced lead configuration that was specially developed and validated for the parent study. However, different methods of ECG acquisition can still result in different ST or T-wave morphology so differences should be considered in the setting of myocardial ischemia or hypoxia. Second, the sample population was predominantly white, so the generalizability of findings to more ethnically and racially diverse groups beyond this community may be limited. The time-to-onset of symptoms was not part of this study but may provide more robust conclusions about patients with completely normal ECG findings.

Finally, there were failed ECG transmissions despite ongoing technical support, troubleshooting, and EMS provider education of the ECG equipment. Failures were random and occurred more often in mountainous regions of the county but may threaten the generalizability of this study.

Conclusion

There is value to completely normal PH ECG findings acquired by ST-segment monitoring in the ambulance. Patients with completely normal PH ECG findings have significantly less adverse hospital outcomes, shorter length of stay, and less long-term mortality and longer time-to-death than patients with any ECG abnormality. Moreover, normal PH ECG findings are prognostic for fewer adverse hospital events. While clinical decisions should not be made on the basis of ECG alone, integration of PH ECG findings into ambulances provides clinicians a greater opportunity for early triage, risk stratification, and clinical decision-making in the spectrum of patients with ACS complaints.

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Highlights

- Pre-hospital electrocardiography (PH ECG) acquisition is becoming standard of care for patients who activate '911' with symptoms of acute coronary syndrome (ACS).
- We examine differences in short-term and long-term outcomes in patients with and without completely normal PH ECG findings in the pre-hospital setting. The absence of ST-T wave changes, arrhythmia, and any other ECG abnormalities constitute a completely normal PH ECG.
- Patients with completely normal PH ECG findings have significantly less adverse hospital outcomes, length of stay, and long-term mortality than patients with any PH ECG abnormality.
- Normal PH ECG findings offer additional opportunity for early triage, risk stratification, and clinical decision-making in patients with ischemic symptoms.

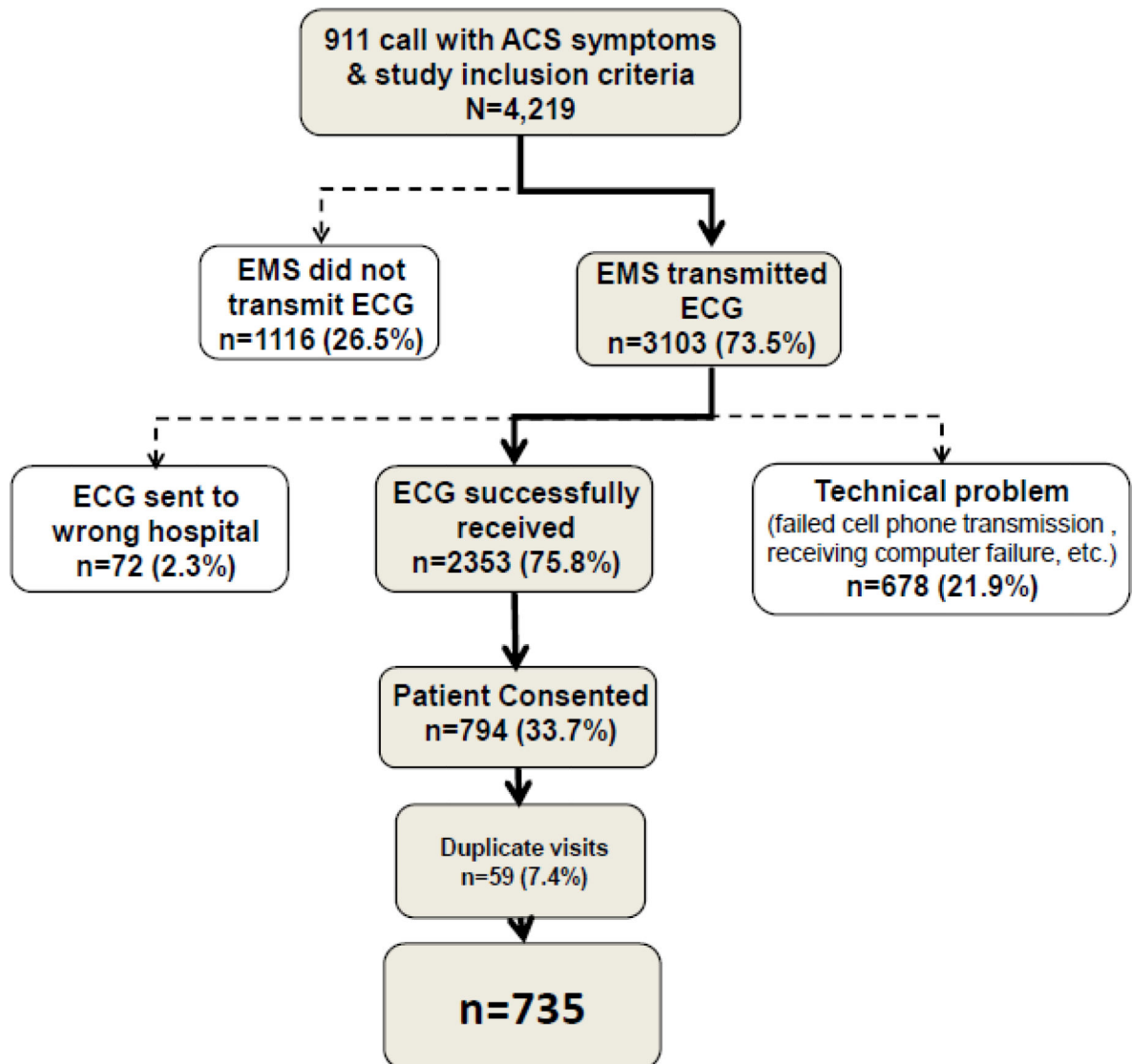


Figure 1. Patient enrollment summary (including total number of patients screened for the ST SMART trial, the number of patients excluded due to PH ECG technical problems, the number of patients who consented, and those excluded due to duplicate enrollments).

Table 1

A normal PH ECG required absence of all ECG abnormalities below.

1. Atrial fibrillation/flutter
2. AV paced
3. Multifocal atrial tachycardia
4. Junctional rhythm
5. 1st degree heart block
6. 2nd degree heart block
7. 3rd degree heart block
8. SVT of unknown origin
9. Sustained VT
10. Non-sustained VT
11. Frequent PVCs
12. Ventricular bigeminy
13. Frequent PACs
14. LBBB
15. RBBB
16. LVH
17. Abnormal QT interval
18. Abnormal QRS axis
19. Other abnormalities

AV = atrioventricular

SVT=supraventricular tachycardia

VT=ventricular tachycardia

PVC=premature ventricular contraction

PAC=premature atrial contraction

LBBB=left bundle branch block

RBBB=right bundle branch block

Table 2

Adverse hospital outcomes

1. Death
2. AMI distinct from the admission event
3. Recurrent rest angina with ECG changes
4. Recurrent rest angina without ECG changes
5. Heart failure that developed after hospital admission
6. Cardiogenic shock
7. Atrial dysrhythmia requiring intervention
8. Ventricular dysrhythmia requiring intervention
9. High-degree atrio-ventricular block (third degree block or second-degree block with bradycardia requiring pacing)

AMI = acute myocardial infarction

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Table 3

Baseline sample characteristics (n=735)

Age	70.5 (\pm 14.5)
Male Gender	385 (52.4%)
Race	
White	673(91.6%)
American Indian/Alaskan Native	18 (2.4%)
Asian	17 (2.3%)
Black	5 (0.7%)
Unknown	22 (3.0%)
Hispanic Ethnicity	70(9.5%)
Past Medical History	
Hypertension	471(64.1%)
Dyslipidemia	287(39.1%)
Smoker (current, former, or recent)	250 (34.0%)
History of CAD	241(32.8%)
Diabetes	162(22.0%)
History of MI	144(19.6%)
Angina pectoris	224(30.6%)
PCI	131(17.8%)
CABG	97(13.2%)
Family History of CAD	115(15.7%)

CAD = coronary artery disease

MI = myocardial infarction

PCI=percutaneous coronary intervention

CABG=coronary artery bypass

Table 4

Frequencies of clinical outcomes comparing patients with and without completely normal PH ECG (n=735)

Clinical outcomes value	Normal PH ECG (n=68) n (%)	Abnormal PH ECG (n=667) n (%)	P
Adverse hospital outcomes	8(11.8)	244(36.6)	<.001
In-hospital death	0(0)	8(1.2)	1.000
MI	0(0)	11(1.7)	0.54
Angina with ECG changes	0(0)	7(1.1)	1.000
Angina without ECG changes	3(4.4)	33(5.9)	0.80
New heart failure	0(0)	116(17.5)	<.001
Shock	0(0)	16(2.4)	0.39
Atrial dysrhythmia *	3(4.4)	98(14.7)	0.02
Ventricular dysrhythmia *	1(1.5)	48(7.2)	0.08
AV block	1(1.5)	25(3.8)	0.62
Length of hospital stay (days)	1.19(SD+1)	3.86(+15)	<.001
Death (median 2-year follow-up)	6(9.0)	145(28.0)	<.001

* requiring urgent intervention; SD = standard deviation

Table 5

Multiple logistic regression analyses on predictors of any adverse hospital outcome (n=734)

Predictor variables	Odds ratio (95% CI)	P-value
<i>Dependent variable: adverse hospital outcomes</i>		
Normal ECG	0.32(0.15-0.69)	0.00
Gender	0.70(0.502-0.974)	0.03
Age	1.02(1.007-1.033)	0.00
History of MI	0.75(0.48-1.17)	0.20
History of CAD	1.91(1.29-2.82)	0.00
Diabetes	1.31 (0.90-1.92)	0.17
Hypertension	1.62(1.12-2.34)	0.01
History of Smoking	1.54(1.10-2.17)	0.01
History of Dyslipidemia	1.00(0.70-1.40)	0.96
Family History of CAD	0.90(0.57-1.42)	0.65

Omnibus Tests of Model Coefficients $\chi^2 (10) = 72.68, p < .001$

CI = confidence interval

ECG=electrocardiogram

MI=myocardial infarction

CAD=coronary artery disease