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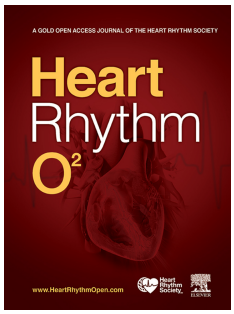

Ventricular tachycardia risk prediction with an abbreviated duration mobile cardiac telemetry

Economou Lundeberg, MD, Alexandra Måneheim, MD, Anders Persson, MD, Marek Dziubinski, PhD, Arun Sridhar, MD, MPH, Jeffrey S. Healey, MD, MSc, FHRS, Magdalena Slusarczyk, MSc, Gunnar Engström, MD, PhD, Linda Johnson, MD, PhD

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Short title: Predicting ventricular tachycardia with ambulatory ECG.

Authors:

First name: Johan Family name: Economou Lundeberg[a,b], MD

Alexandra Måneheim[a,b], MD

Anders Persson[a,b], MD

Marek Dziubinski[c], PhD

Arun Sridhar[d], MD, MPH

Jeffrey S Healey[f], MD, MSc, FHRS

Magdalena Slusarczyk[c] , MSc

Gunnar Engström [b], MD, PhD

Linda Johnson [b,f], MD, PhD

Affiliations

a Department of Clinical Physiology, Skåne University Hospital

Postal address: Skåne University Hospital, VO BoF 221 85 Lund

b Department of Clinical Sciences, Malmö. Lund University, Sweden

Postal address: Carl-Bertil Laurells gata 9 214 28 Malmö, Sweden

c MEDICALgorithmics, Warsaw

Postal address: Aleje Jerozolimskie 8, 02-001 Warsaw, Poland

d University of Washington Medical Center, Seattle, WA, United States of America

Postal address: 1959 NE Pacific Street, Seattle WA, 98195

f Population Health Research Institute, McMaster University, Canada

Postal address: 237 Barton St East, L8L 2X2, Hamilton, ON, Canada

Disclosures

MD is a MEDICALgorithmics equity holder. LJ receives consulting fees from MEDICALgorithmics. MS is a MEDICALgorithmics employee. JEL, AM, AP, AS, JSH, GE none declared.

Address for correspondence

Johan Economou Lundeberg MD, PhD-candidate

postal address: Carl-Bertil Laurells gata 9

214 28 Malmö, Sweden

email: johan.economou_lundeberg@med.lu.se

Co-author email:

Alexandra Måneheim alexandra.maneheim@med.lu.se

Anders Persson anders_p.persson@med.lu.se

Marek Dziubinski marek.dziubinski@gmail.com

Arun Sridhar dr.arunraghav@gmail.com

Jeff S Healey jeff.Healey@phri.ca

Magdalena Slusarczyk m.slusarczyk@medicalgorithmics.com

Gunnar Engström gunnar.engstrom@med.lu.se

Linda Johnson linda.johnson@med.lu.se

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Data will be shared upon reasonable request.

Abstract

Background: Ventricular tachycardia (VT) occurs intermittently, unpredictably, and has potentially lethal consequences.

Objective: Our aim was to derive a risk prediction model for VT episodes ≥10 beats detected on 30-day mobile cardiac telemetry (MCT) based on the first 24 hours of the recording.

Methods: We included patients who were monitored for 2-30 days in the USA using full-disclosure MCT, without any VT episode ≥10 beats on the first full recording day. An elastic net prediction model was derived for the outcome of VT≥10 beats on monitoring day 2-30. Potential predictors included age, sex, and ECG data from the first 24h: heart rate, premature atrial and ventricular complexes occurring as singlets, couplets, triplets, and runs, and the fastest rate for each event. The population was randomly split into training (70%) and testing (30%) samples.

Results: In a population of 19,781 patients (mean age 65.3±17.1, 43.5% men), with a median recording time of 18.6±9.6 days, 1,510 patients had at least one VT≥10 beats. The prediction model had good discrimination in the testing sample, area under the ROC curve 0.7584, 95%CI 0.7340-0.7829. A model excluding age and sex had an equally good discrimination (ROC 0.7579, 95%CI 0.7332-0.7825). In the top quintile of the score more than one in five patients had a VT≥10 beats, while the bottom quintile had a 98.2% negative predictive value.

Conclusion: Our model can predict risk of VT≥10 beats in the near-term using variables derived from 24h ECG, and could be used to triage patients to extended monitoring.

Keywords: Ventricular tachycardia, ambulatory ECG, prediction, cardiac arrythmia, mobile cardiac telemetry, epidemiology

Background

Ventricular tachycardia (VT) occurs intermittently, unpredictably and can be found in both people with severe cardiovascular disease as well as apparently healthy individuals[1]. Non-sustained VT (NSVT) episodes, defined as those lasting <30 seconds, have been associated with poor prognosis and sudden cardiac death in several different patient cohorts [2-4]. NSVT episodes are associated with a doubled risk of sudden cardiac death after myocardial infarction, [5] and it has been argued that patients with NSVT after an acute coronary syndrome should receive a more thorough evaluation[6]. The presence of NSVT is also integral for evaluation of symptoms, as well as treatment response after initiation of antiarrhythmic drugs, or post VT ablation. NSVT episodes are additionally a component of the recently published hypertrophic cardiomyopathy risk prediction model suggested by European Society of Cardiology, as well as the Montreal Arrhythmogenic Right Ventricular Cardiomyopathy risk prediction rule [7, 8].

Finally, subjects with incidentally detected NSVT episodes have a doubled risk of mortality and cardiovascular events in a population without known structural heart disease [9]. Early detection could potentially lead to improved risk factor control to prevent adverse outcomes.

Mobile cardiac telemetry (MCT) recordings are indicated as part of the diagnostic work up for a diverse range of symptoms, including chest palpitations, syncope and near syncope[10]. The optimal monitoring duration for these indications remains unknown; while short recording durations imply a risk of under-detection of significant arrhythmias, [11] longer recordings are associated with increased cost and patient discomfort as well as incidental detection of arrythmias without clinical relevance[12, 13].

Currently, data collected during short MCT recordings is not used to inform the need for extended or repeated monitoring, but a computer-derived risk score could be used by physicians to triage patients to shorter or longer monitoring durations depending on the clinical situation.

Methods

We included all patients who were monitored in the USA using the PocketECG device (MEDICALgorithmics, Warsaw, Poland) for 2-30 full days (n=19,947) in 2020. We excluded 158 patients with a VT event ≥10 beats on the index day, defined as the first full day of recording, as well as 8 patients aged >100 years, resulting in a final study population of 19,781 patients monitored for a clinical indication. All arrhythmias were algorithmically detected and manually verified by trained ECG technicians. The Swedish Ethical Review Authority has waived the need for ethics approval for studies using this database since all analyses are performed on retrospective and fully anonymized data. The study conforms to the Declaration of Helsinki.

Potential predictors were derived from the ECG collected during the index day and included measures of heart rate during sinus rhythm (minimum and maximum heart rates measured as 1-minute averages and mean heart rate overall), as well as the prevalence and pattern of occurrence of premature atrial and ventricular complexes (PACs and PVCs). PACs and PVCs were included as the total number of each beat type as well as their occurrence as singlets, couplets, and triplets. Supraventricular tachycardia (SVT) and VT were defined as 4 or more consecutive PACs or PVCs, respectively, with a frequency ≥ 100 beats per minute (bpm). Accelerated idioventricular rhythm (AIVR) was defined as an episode of 4 or more broad QRS-complexes without detectable P-waves and a frequency <100 bpm. Bradycardia was defined as sinus rate <50 bpm with a minimum duration of 1 min. We also included the fastest rate of each arrhythmic event class, derived from the shortest pair-interval rate, for all arrhythmias lasting ≥2 beats. To avoid the introduction of missing data to the model for variables describing heart rate during arrhythmia, the fastest heart rate

was set to 0 for those without any occurrences of the arrhythmia in question. Mean, max and minimum heart rate was calculated based on sinus beats only, excluding the time spent in any arrhythmia, and measured over 1-minute durations in beats per minute. The outcome was defined as a VT event with a duration ≥10 beats (VT≥10 beats), occurring any day after the index day (registration day 2-30).

Statistical methods

All statistics were performed using Stata17.0 (StataCorp College Station, TX). The study population was randomly split into training (70%) and testing (30%) datasets, and a prediction model for VT≥10 beats was derived using elastic net, with selection of the best model by 10-fold cross-validation. We assessed several potential prediction models. In a “full model” we specified 28 potential predictors, including age, sex, and ECG data from the first 24h: heart rate (minimum, maximum and mean), lowest rate during bradycardia, the number of premature atrial and ventricular complexes, occurring as singles, couplets, and triplets, the fastest rate during each of these arrhythmias, and maximal heart rate as well as duration of SVT, VT and AIVR episodes. We also derived a second “ECG-only” model without age and sex. These models were compared to an age and sex only model, as well as a fourth model which included only the total PVC count on the index day.

ß-coefficients for the main model and the ECG-only model were used to calculate individual predicted risks of VT≥10 beats, and the resulting predicted risk scores were included as a single predictor in a logistic regression model in the testing sample. Model discrimination was assessed using receiver operating characteristic (ROC) -curves and area under the ROC curve with 95% confidence intervals (CIs). Model calibration was assessed with the Hosmer-Lemeshow test using ten equal sized bins.

The results were plotted visually with estimation of calibration-in-the-large, slope, and expected/observed ratio using the Stata plugin pmcalplotevents, downloaded from Boston College Statistical Software Components (SSC). In order to estimate the occurrence of sustained VT episodes we identified the longest VT for each patient and estimated sustained VT as any VT with a duration ≥60 beats, which we consider to be a conservative estimate.

Results

The mean age was 65.3 ± 17.1 (43.5% male), with a range of 17-100 years. The mean monitoring duration was 18.6 ± 9.6 days. 27%, 27% and 46% had a recording time of between 1-10, 11-20 and 21-30 days respectively. VT≥10 beats occurred in 1510 patients (7.6%), after a median recording time of 10 days (IQR 4-19). In patients with VT events ≥10 beats the median duration of the longest VT was 13 beats (IQR 10-258). 93 patients had at least one VT episode ≥ 25 beats. Twenty patients had at least one sustained VT. VT≥10 beats were more common among males compared to females (10.3 % vs 5.6%). Population statistics are reported in more detail in **Table 1.**

Prediction model discrimination, calibration, and goodness of fit

Of 28 potential predictors, 14 variables were selected in the “full model” and 16 variables in the “ECG-only” model. The selected variables for both models are available in the appendix (Table A.1), along with the corresponding ß-coefficients and the formula used for calculation of predicted risk.

Both the full model and ECG-only model had good discrimination in the testing sample: area under the ROC curve 0.7584 (95%CI 0.7340-0.7829), and **area** under

the ROC curve 0.7579 (95%CI 0.7332-0.7825), respectively (**Figure 1A and Figure 1B**). Observed events by predicted risk quintiles in the testing data set are reported for both the main and ECG-only model in **Table 2**. For both models, the observed risk was within the range of predicted risk in all quintiles except the 3rd (where risk was somewhat lower). In the top quintile for predicted risk, sex was more evenly distributed for the ECG-only model compared to the full model (male sex 56.4% vs 69.7%). In the bottom quintile the negative predictive value for the full model was 98.0% and for the ECG-only model 98.2%. All sustained VT events were detected in the top quintile of predicted risk both models.

The output of the model is a predicted risk that assumes continuous values between 0-100%, and we consider this to be the most useful way to consider the data. However, we also calculated the maximally predictive point, based on the Youden method. With this method the optimal cut-off for the main model was at a sensitivity of 70% and a specificity of 70% in the testing sample. For the ECG-only model the optimal cut-off yielded a sensitivity of 67% and a specificity of 74%.

A model based only on age and sex, or only total PVC count, had substantially worse discrimination: ROC statistic 0.6461 (95%CI 0.6208-0.6715), and ROC statistic 0.7089 (95%CI 0.6855-0.7324) respectively (**Figures 1C and 1D**).

There was no sign of over- or underfitting of the data, neither for the full model nor the ECG-only model (Slope=1.070 and intercept -0.068 for the full model and Slope=1.089, intercept -0.066 for the ECG-only model). Calibration plots for all four models are available in the appendix (Figures A.1).

Subsequently, we examined patients with a minimum of 14 days of ambulatory ECG to assess the model's performance. In the testing sample, the main model demonstrated an area under the ROC curve of 0.7487 (95% CI 0.7216-0.7759) with acceptable discrimination (Slope=1.082 and Intercept=0.214).

Discussion

Using only data easily derived from 24 hours of MCT, we derived a risk prediction model for NSVT episodes ≥10 beats on MCT monitoring in the next 29 days. In the top quintile of the predicted risk score roughly 1 in 5 patients had an episode of VT≥10 beats during the subsequent monitoring. In the bottom quintile the negative predictive value was 98% for both models.

This model could be useful both to identify low- and high-risk patients. In instances of abbreviated duration, the risk score can assist in determining if a renewal of the MCT is necessary. For high-risk patients extended or renewed monitoring might be indicated depending on the clinical situation. The prediction algorithm could also be useful as an integrated automatic tool to alert physicians to high VT risk when patients are monitored with shorter MCT recordings for other indications. In patients in whom an incidental finding of NSVT would be clinically relevant the monitoring duration could then be extended. In areas with limited resources and device availability, prediction models such as these can be used to identify which patients are more likely to benefit from prolonged monitoring.

MCT has been commercially available since 1963 for detection and quantification of arrythmias such as VT[14]. The clinical relevance and interpretation of VTs found on MCT are under scientific discussion. In specific patient groups, such as patients with hypertrophic cardiomyopathy, left ventricle dysfunction and after hospitalization due to acute coronary syndrome, VT has been linked to cardiac mortality [2-4, 15]. Conflicting results have nevertheless been found where non-symptomatic VT detected by pacemaker interrogation have not been found to be independently associated with

mortality[16]. However, in the 2019 EHRA/HRA/HRS consensus document for the management of asymptomatic arrhythmias, it is recommended that all patients with asymptomatic NSVT should undergo an evaluation to detect underlying heart disease[17]. Consistent with these guidelines a recently published study from the population-based Copenhagen Holter study showed that incidentally detected non-sustained VT was associated with a doubled risk of mortality and cardiovascular events[9]. We therefore believe that this MCT-based VT risk score could have clinical utility.

In recent years, there has been an increasing research interest in the clinical significance of relatively low levels of PVCs, since they have been shown to predict future risk of heart failure and mortality[18, 19]. PVCs, and in extension VTs, are however a heterogeneous group of arrythmias with varying underlying mechanisms and one could therefore argue that it is not enough to classify PVCs and VTs on quantity alone[20, 21]. Other characteristics such as QRS-duration, mono- or multiform complexes, morphology and coupling interval to previous normal beat have been suggested as novel predictors of cardiovascular disease[22-24]. To create a simple and parsimonious model, these variables have not been included in the present risk score, but it is possible that such detailed ECG-derived data could be implemented in future models, and that this could prove valuable not only for prediction of VT but also of incident cardiac events and mortality.

Risk assessment based on a MCT examination result is often not straightforward for physicians in different clinical settings. Predictive analytics for specific arrhythmias or diseases incorporated in an MCT report could help physicians make more informed

decisions about whether to pursue extended monitoring or other interventions. However, a computer-derived risk score should always be used as a tool to aid clinical decision-making, rather than as a substitute for physician judgment. Ultimately, the decision to pursue extended monitoring should always be made on a case-by-case basis.

Limitations

This study has some limitations which should be kept in mind when interpreting the results. Considering the lack of sufficient scientific evidence of what defines a clinically relevant VT the chosen cutoff at ≥10 beats was based on clinical expertise as well as the 2020 AHA/ACC guidelines for management of hypertrophic cardiomyopathy[25].

Since the data for this study was shared by the device manufacturer, no clinical data was available, beyond age and sex, and this has limited our ability to test the derived model in specific patient subgroups that would be of relevance, for example patients with and without coronary artery disease or heart failure. We have also been unable to assess whether the score predicts sustained VT episodes or clinical outcomes, including death from cardiovascular causes. However, by using a large, unselected patient material from the USA, we believe our model is based on a population that is generalizable to diverse patient cohorts. Future studies assessing the performance and clinical utility of the score in defined patient populations would be of value.

Conclusion

A risk score based on variables from 24 hours of MCT can predict a high risk of VT≥10 beats within 30 days and can be used to triage patients according to their

need for extended monitoring. In the top quintile of the risk score, a VT event with a duration of ≥10 beats was detected in 1 in 5 patients.

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Table 1. Study population characteristics

Age, mean (SD)	65.3 (17.1)
Male sex, percent	43.5
Mean heart rate, mean (SD)	73.5 (12.0)
Maximum heart rate, mean (SD)	113.7 (22.1)
Minimum heart rate, mean (SD)	56.3 (9.8)
Total beats, mean (SD)	95 333 (21641)
Total PACs, median (IQR)	70 (12-659)
Single PACs, median (IQR)	37 (7-229)
PAC couplets, median (IQR)	1 (0-5)
PAC triplets, median (IQR)	0 (0-2)
SVTs ≥4 beats, median (IQR)	0 (0-2)
AIVR beats, median (IQR)	0 (0-0)
Total PVC count, median (IQR)	22 (2-261)
Single PVC count, median (IQR)	21 (2-254)
PVC couplets, median (IQR)	0 (0-1)
PVC triplets, median (IQR)	0 (0-0)
VT runs≥4 beats, median (IQR)	0 (0-0)

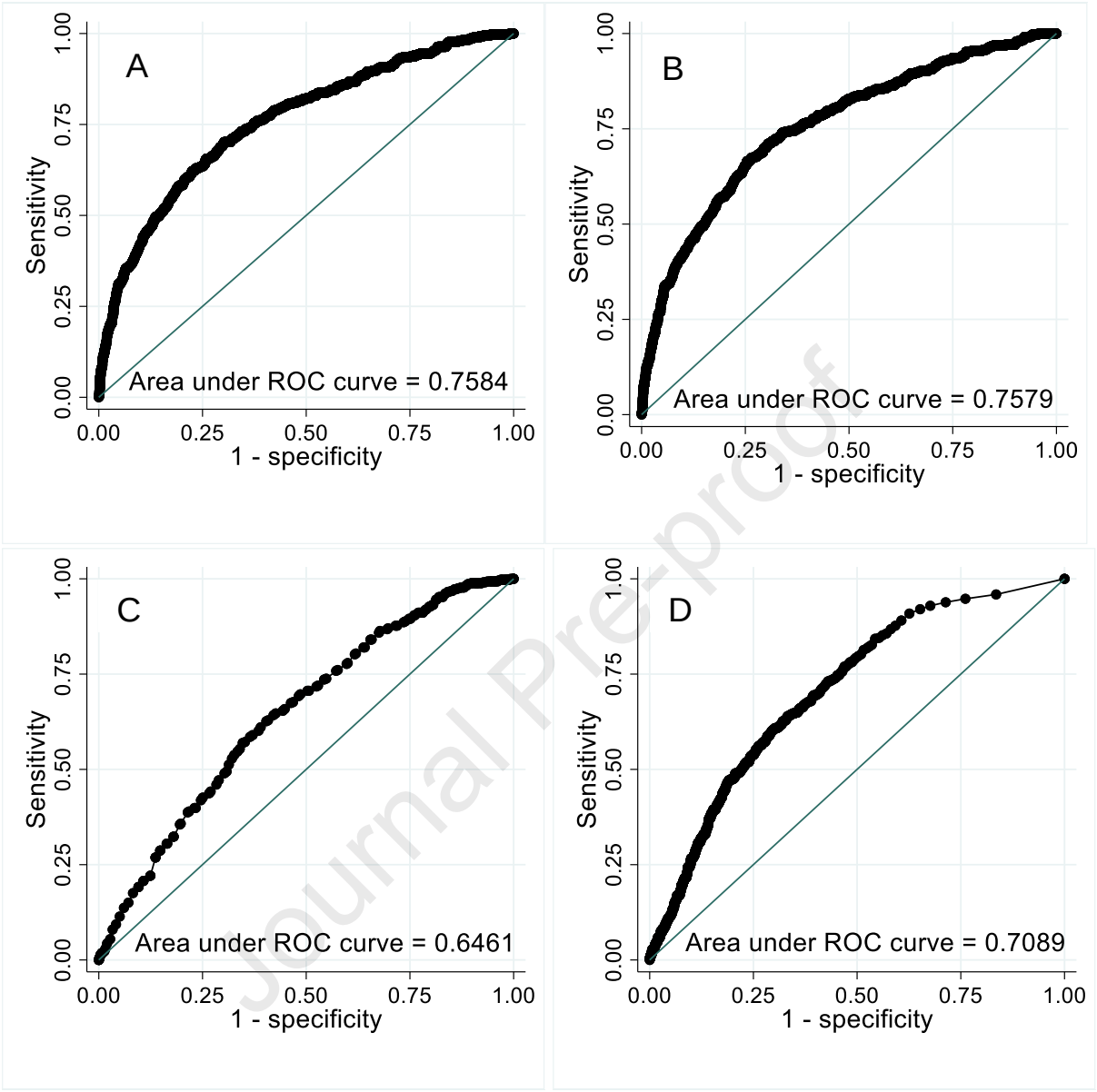
AVIR = accelerated idioventricular rhythm, IQR= inter quartile range, PAC= premature atrial complex, PVC= premature ventricular complex, SD= Standard deviation, SVT= supraventricular tachycardia, VT= ventricular tachycardia.

Table 2. Observed and predicted ventricular tachycardia events ≥10 beats by quintiles of predicted risked in the testing dataset (n=5934).

Main model	**Q1 (n=1186)**	**Q2 (n=1187)**	**Q3 (n=1187)**	**Q4 (n=1187)**	**Q5 (n=1187)**
Predicted risk, %	1.5-3.3	3.3-4.6	4.6-6.1	6.1-10.1	>10.1
At least one VT≥10 beats, n (%)	24 (2.0%)	40 (3.4%)	46 (3.9%)	90 (7.6%)	239 (20.1%)
Mean age, years (SD)	41.3 (14.9)	64.3 (13.3)	71.0 (9.6)	74.2 (10.6)	75.3 (8.9)
Male sex, %	241 (20.3%)	331 (27.9%)	497 (41.9%)	694 (58.5%)	827 (69.7%)
NPV	98.0%	96.6%	96.1%	92.4%	79.9%
ECG only model	**Q1 (n=1186)**	**Q2 (n=1187)**	**Q3 (n=1187)**	**Q4 (n=1187)**	**Q5 (n=1187)**
Predicted risk, %	1.8-3.5	3.5-4.5	4.5-6.0	6.0-10.0	>10.0
At least one VT≥10 beats, n (%)	21 (1.8%)	43 (3.6%)	46 (3.9%)	93 (7.8%)	236 (19.9%)
Mean age, years (SD)	45.1 (17.5)	64.1 (15.0)	70.5 (11.8)	72.2 (11.9)	74.3 (9.6)
Male sex, %	457 (38.5%)	506 (42.6%)	450 (37.9%)	508 (42.8%)	669 (56.4%)
NPV	98.2%	96.5%	95.8%	92.7%	80.2%

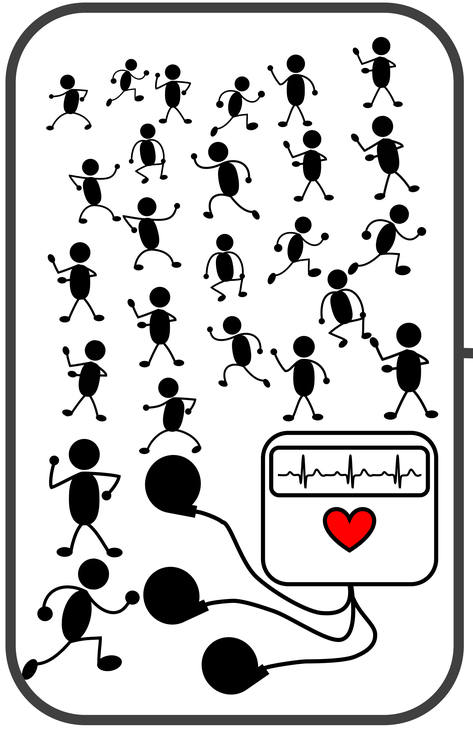
SD = Standard deviation, VT= ventricular tachycardia, NPV = negative predictive value

Figure 1 ROC curves for ventricular tachycardia≥10 beats occurrence by predicted risk in the testing sample.

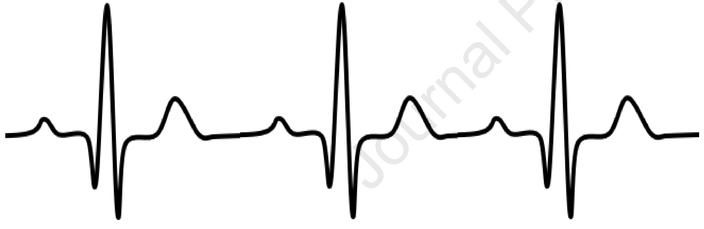


A = Main model, B = ECG-only model, C = Age and sex model, D = Premature ventricular complex model

Ventricular tachycardia risk prediction with mobile cardiac telemetry

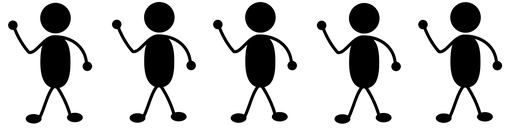


MCT risk score for VT≥10 beats



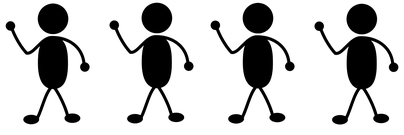
Based on simple 24hECG data

1/5 Low risk



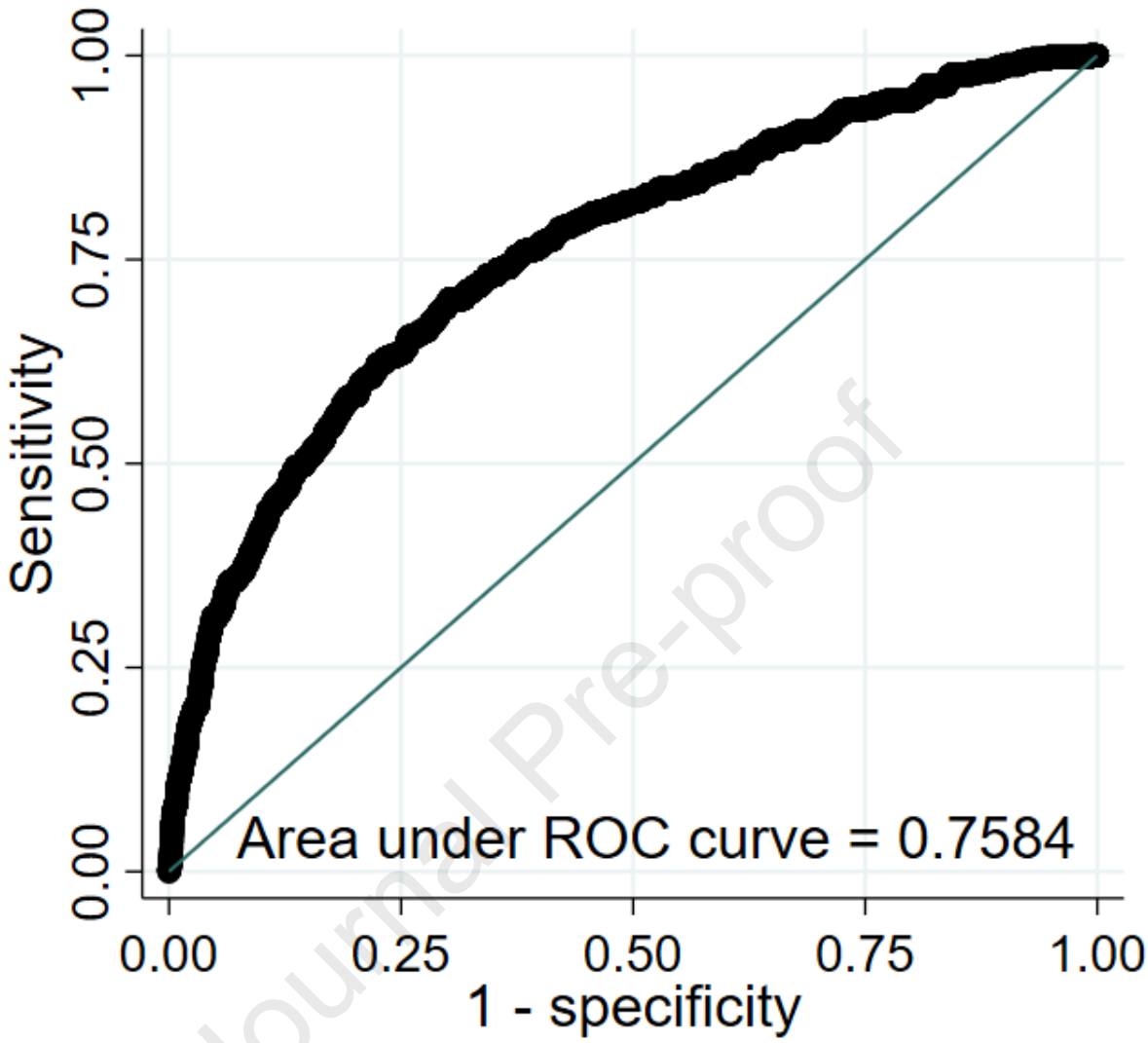
Negative predictive value 98%

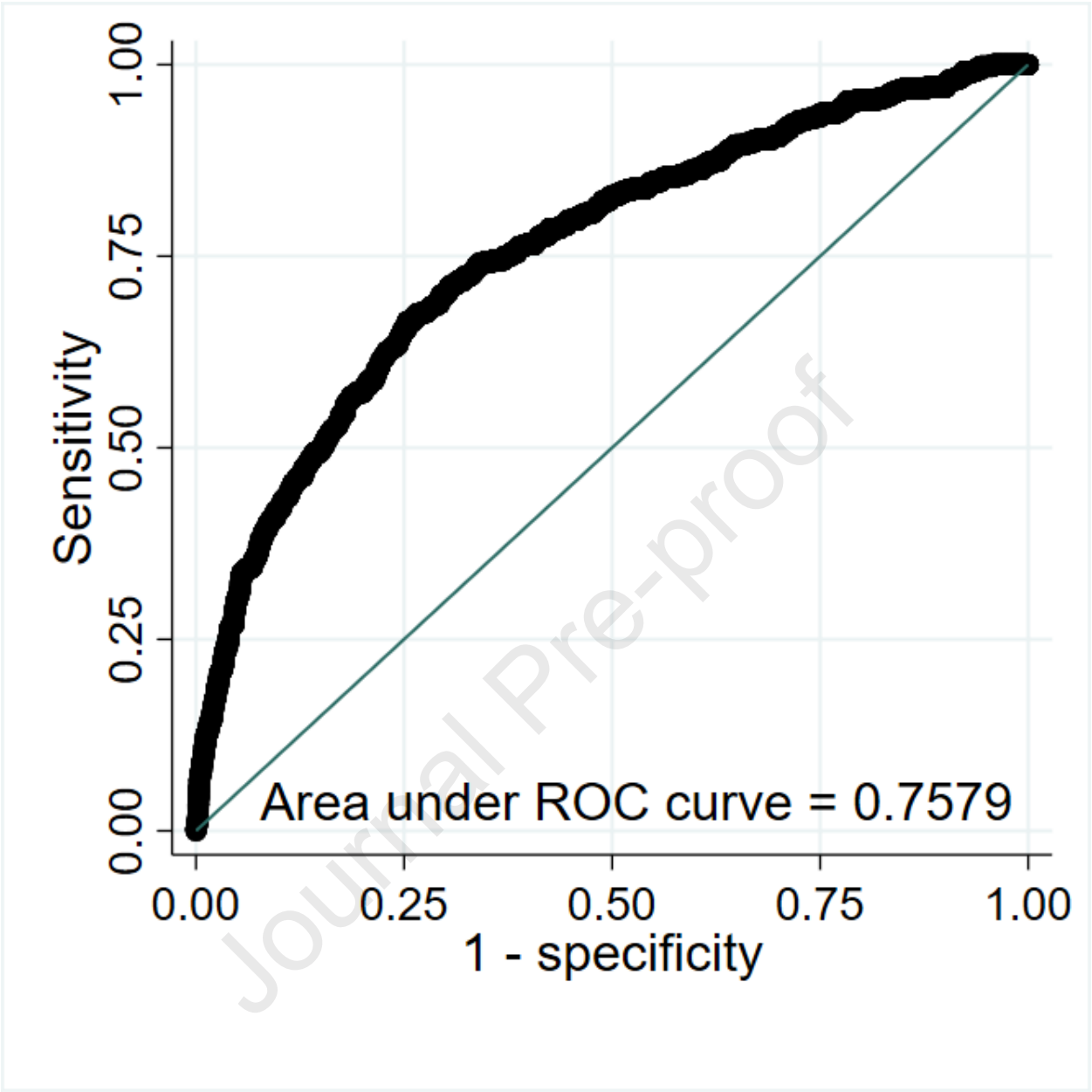
1/5 High risk

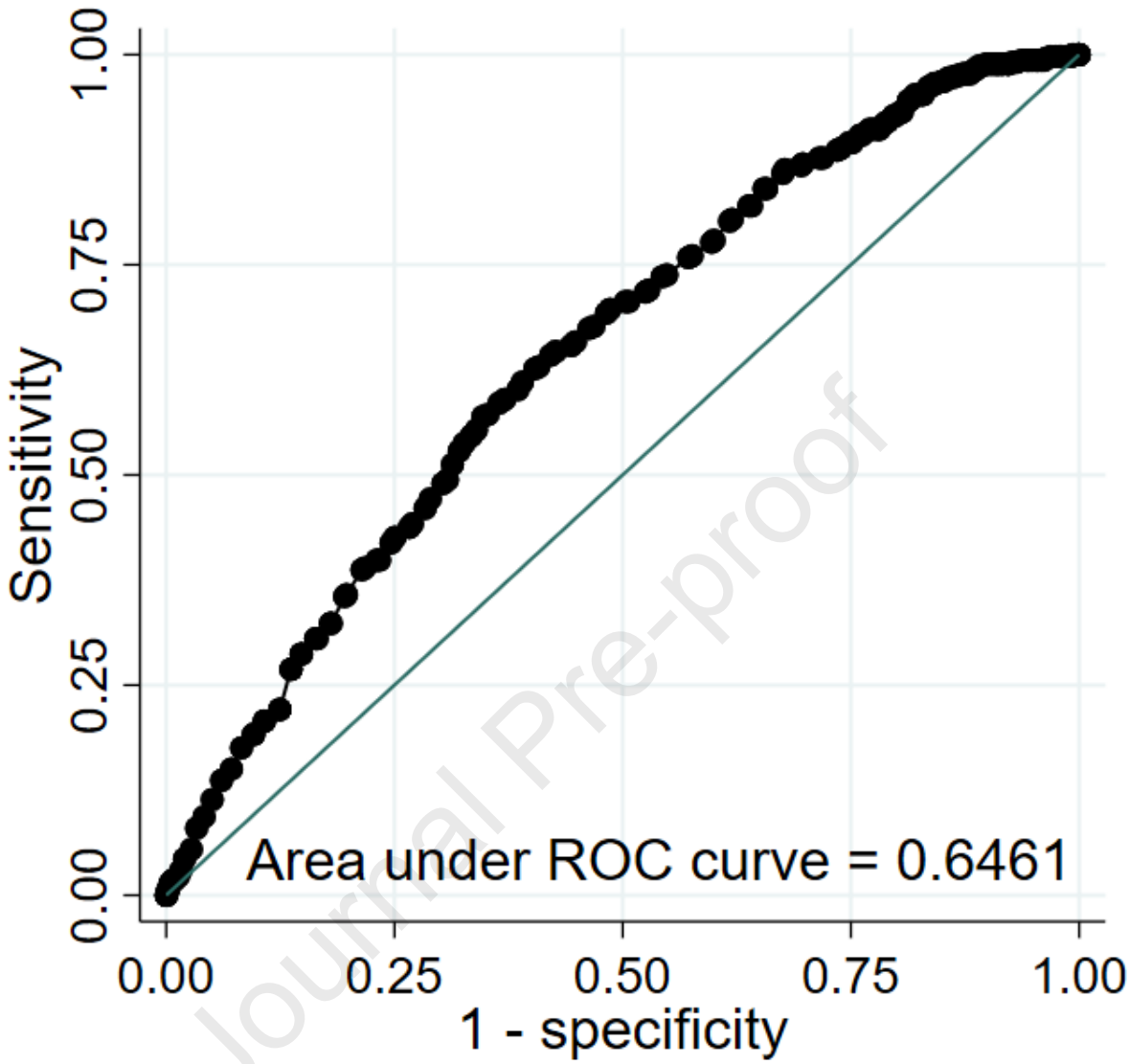


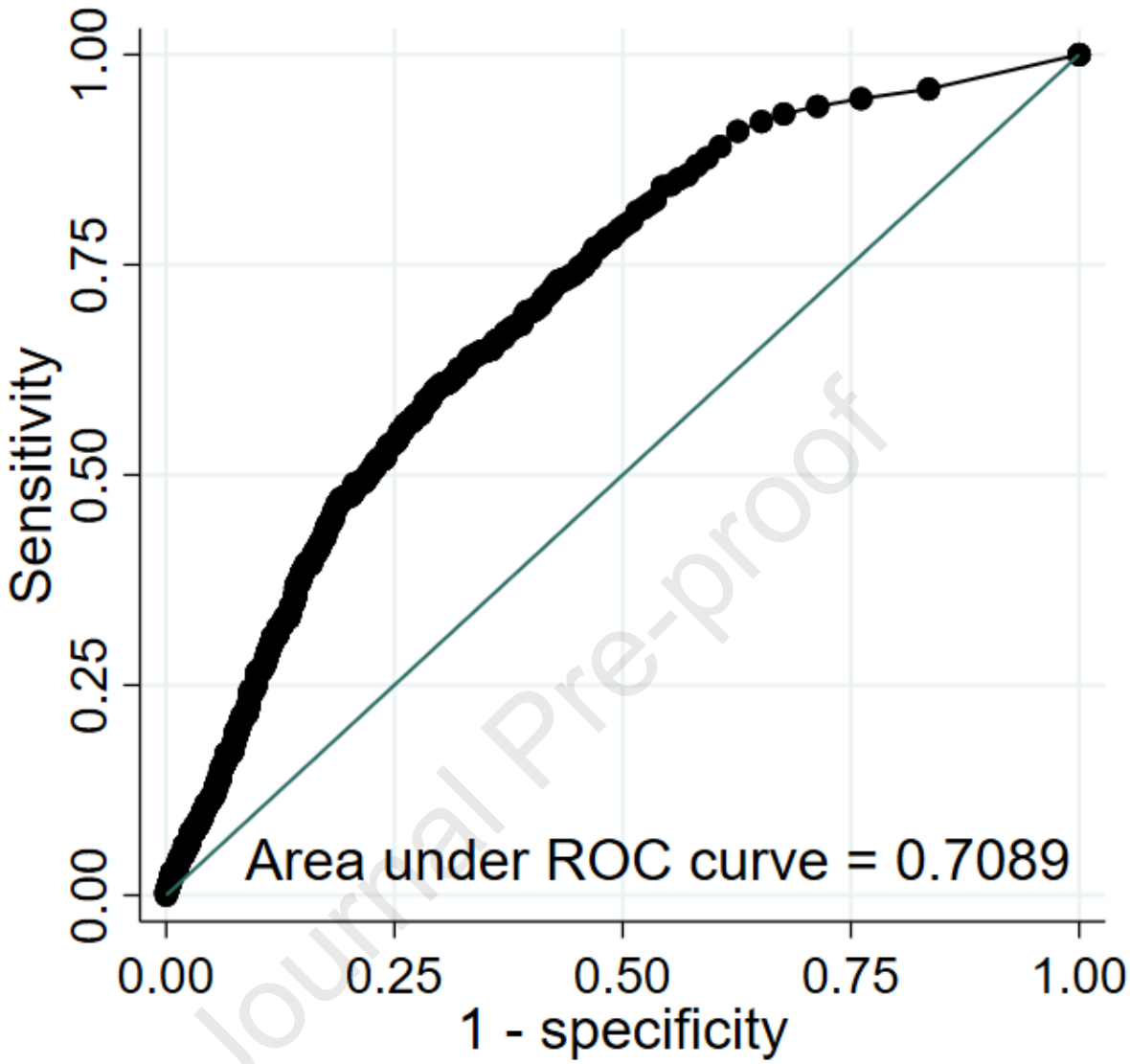
1 in 5 will have a VT ≥10 beats

MCT = mobile cardiac telemetry, VT = Ventricular tachycardia









Main model

FACTOR	VALUE
Age, per year	
Sex (Female=1, Male=2)	
Maximum heart rate, per bpm	
Lowest rate during bradycardia, per bpm	
Fastest rate during PAC couplet, per bpm	
Fastest rate during SVT≥4 beats, per bpm	
Fastest rate during AIVR, per bpm	
Total PVC count, per 1000 beats	
Total number of PVC couplets, per 100 couplets	
Fastest rate during PVC couplet, per bpm	
Number of PVC triplets, per 10 triplets	
Fastest rate during PVC triplet, per bpm	
VT runs≥4 beats	
Longest duration of VT run, per beat	

Predicted risk*	0.01178515

*Input the value 0 if an event has not occurred.

ECG-only model

FACTOR	VALUE
Maximum heart rate, per bpm	
Lowest rate during bradycardia, per bpm	
Total number of beats, per 10'000 beats	
Total PAC count, per 1000 beats	
Fastest rate during PAC couplet, per bpm	
Number of PAC triplets, per 100 triplets	
Fastest rate during SVT≥4 beats, per bpm	
Fastest rate during AIVR, per bpm	
Longest duration of AIVR, per beat	
Total PVC count, per 1000 beats	
Total number of PVC couplets, per 100 couplets	
Fastest rate during PVC couplet, per bpm	
Number of PVC triplets, per 10 triplets	
Fastest rate during PVC triplet, per bpm	
VT runs≥4 beats	
Longest duration of VT run, per beat	

Predicted risk*	0.07304076

*Input the value 0 if an event has not occurred.

KEY FINDINGS

- A risk score based on variables from 24 hours of ambulatory ECG can predict a high risk of VT≥10 beats within 30 days and can be included in the ambulatory ECG report.
- In the top quintile of the risk score, a VT event with a duration of ≥10 beats was detected in 1 in 5 patients.
- In 20% of ambulatory ECG recordings VT events ≥10 beats can be ruled out with a negative predictive value of 98%