ANOMI-Study Intent Letter

Artificial Intelligence Based Timing, Infarct Size and Outcomes in Acute Coronary Occlusion Myocardial Infarction

2024

AI-BASED ECG OMI DETECTION IMPROVEMENT AND ITS IMPLICATIONS ON REPERFUSION TIMING AND INFARCT SIZE

Official Study Title

Artificial Intelligence Based Timing, Infarct Size and Outcomes in Acute Coronary Occlusion Myocardial Infarction

NCT Number

NCT06910436

Document Date

Bolzano, March 2024

Document Type

Study Intent Letter / Protocol Synopsis

Principal Investigator

Assoc. Prof. Dr. Dr. Matthias Unterhuber

Department of Cardiology
Regional Hospital of Bolzano
Bolzano, Italy

AUTONOME PROVINZ BOZEN – SÜDTIROL | PROVINCIA AUTONOMA DI BOLZANO – ALTO ADIGE
PROVINZIA AUTONOMA DE BULSAN – SUDTIROL

Südtiroler Sanitätsbetrieb | Azienda Sanitaria dell'Alto Adige
Azienda Sanitera de Sudtirol

GESUNDHEITSBEZIRK BOZEN
Krankenhausbereich

COMPRENSORIO SANITARIO DI BOLZANO
Area Ospedaliera

ANOMI-Study Intent Letter

*A*rtificial Intelligence Based Timing, Infarct Size a*N*d *O*utcomes in Acute Coronary Occlusion *M*yocardial *I*nfarction

2024

AI-based ECG OMI detection improvement and its implications on reperfusion timing and infarct size

Principal investigator
Assoc. Prof. Dr. Dr. Matthias Unterhuber

Indice

1 Introduction

The 12-lead electrocardiogram (ECG) is the most widely used initial diagnostic tool to guide the management of patients with suspected acute coronary syndrome (ACS). At present, ACS is divided into ST-segment elevation myocardial infarction (STEMI) and non-ST-segment elevation acute coronary syndrome (NSTE-ACS), with different treatment protocols. However, some patients with NSTE-ACS have an acute coronary occlusion (OMI) and may benefit from immediate reperfusion by percutaneous coronary intervention (PCI), but are often treated late. ECG signs suggestive of OMI have been described, but their visual interpretation by experts is variable and suboptimal. Recent studies have shown that artificial intelligence (AI) models for ECG analysis can outperform clinicians in the detection of OMI, suggesting the potential use of AI to improve triage and timely access to PCI.

2 The ANOMI study

This prospective observational study aims to assess the ability of an AI model to identify OMI in patients with suspected ACS without ST-segment elevation and to analyze the impact of the time elapsed between patient presentation and percutaneous revascularization on infarct size, as measured by peak troponin levels, echocardiography, and / or cardiac magnetic resonance imaging.

The study will be conducted at the Department of Cardiology of the Regional Hospital of Bolzano and will enroll adult patients (>18 years) with an initial diagnosis of NSTE-ACS. Patients with STEMI, ventricular arrhythmias, poor-quality ECGs, or inadequate digitization will be excluded. The ECGs of included patients will be analyzed (without the addition of sensitive data, using only the electrical waveforms) and classified by AI as OMI or non-OMI. This result will be compared with the coronary angiography

findings. Clinical practice will not be altered; only the potential difference between the two classifications will be observed. The collected data will allow evaluation of:

- The feasibility of AI-ECG interpretation in patients with suspected ACS without ST-segment elevation
- The accuracy of AI in the diagnosis of OMI compared with conventional criteria (ROC-AUC)
- The correlation between infarct size and the time elapsed between presentation and percutaneous revascularization, in order to assess the potential benefit of a change in clinical practice for patients with OMI identified by the algorithm.

3 Primary outcomes

Cardiovascular Mortality at 12 months

Determination of whether there is a difference in myocardial infarct size (ventricular function on follow-up echocardiography and/or cardiac magnetic resonance imaging) according to AI categorization (OMI or non-OMI)

4 Secondary outcomes

Sensitivity and specificity of the PMCardio AI-ECG app for the diagnosis of OMI compared with expert clinical decision-making.

- Pre-intervention peak troponin values in patients with OMI undergoing PCI according to OMI / non-OMI categorization
- Left ventricular ejection fraction (LV-EF) according to categorization
- Major adverse cardiovascular events (MACE)

5 Sample size and statistical analysis

For the infarct size analysis, peak troponin levels will be considered as a proxy for myocardial damage as a function of time to percutaneous revascularization, with a minimum of 176 patients required to ensure adequate statistical power (80% with $\alpha = 0.05$) to detect a statistically significant difference in peak troponin of 500 ± 200 ng/ml. A statistically significant difference in infarct size will also be assessed in terms of left ventricular ejection fraction on echocardiography or late gadolinium enhancement on cardiac magnetic resonance imaging. A difference of 10% (effect size) with a standard deviation of 10% can be detected with 80% statistical power and an alpha of 0.05 if the study sample includes n=15 individuals per arm; therefore, 30 patients will be sufficient to detect statistically significant differences in ventricular infarct size. Thus, once the above-mentioned 176 patients have been reached, a statistically significant difference with adequate power in terms of infarct size will also be ensured.

6 Study collaborators

- Unterhuber Matthias
- Donazzan Luca
- Rainer Oberhollenzer

The ANOMI study will provide crucial data to better understand the role of AI in the early diagnosis of OMI and its potential impact on the clinical management of patients with ACS. Furthermore, it is certified that no sensitive data other than the ECG tracing alone will be analyzed by the artificial intelligence system; therefore, no exchange of sensitive data with third parties will take place.

The duration of the main study ends once the above-mentioned sample size has been reached and after at least one year of follow-up.

Thanking you for your kind attention,
best regards
Bolzano, March 2024
Assoc. Prof. Dr. Dr. Matthias Unterhuber