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Original article

Atrial fibrillation, intra-ventricular thrombus, and other anticoagulant indications relationship with adverse outcomes in acute anterior myocardial infarction patients

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ABSTRACT

Background: The aim of this study was to assess the predictive value of atrial fibrillation (AF), left ventricular thrombus (LVT), and other oral anticoagulant (OAC) indications on 1-year major adverse cardio-cerebrovascular events (MACCE) and bleeding in acute anterior ST-elevated myocardial infarction (STEMI) patients treated by primary percutaneous coronary intervention (PPCI).
Methods: Our study population included 969 anterior STEMI patients referred for PPCI from the prospective multicenter CIRCUS trial. Patients with a formal indication of OAC within the first year were compared to those without indication.
Results: A total of 161 (16.6%) patients were eligible for OAC after anterior STEMI mainly for AF (51.5%) and LVT (39.7%). This group had a higher morbidity profile despite similar reperfusion settings – 67% of them were treated with OAC. At 1 year, OAC indication was associated with a significant increase in MACCE rate [OR 3.37 95% CI (2.36;4.82) $p < 0.001$] as well as bleeding [OR = 1.96 95% CI (1.09;3.50) $p = 0.02$]. After adjustment for principal confounders, OAC indication remained strongly associated with MACCE [HR 3.40 (1.26;9.14) $p = 0.016$].
Conclusions: In a prospective cohort of anterior STEMI, AF, LVT, and other OAC indications were present upon discharge in 1 patient out of 6 and only two thirds were treated with OAC. OAC indication was independently associated with an increased risk of MACCE and bleeding at one year.
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Introduction

In the setting of an acute myocardial infarction (AMI), oral anticoagulant therapy (OAC) is indicated for stroke prevention in combination with dual antiplatelet therapy (DAPT) in case of increased risk of thrombo-embolic events such as atrial fibrillation or left ventricular thrombus (LVT). Each component of triple therapy improves cardiovascular prognosis [1,2]. International

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societies recommend triple therapy combining OAC and DAPT (aspirin and clopidogrel) in this clinical setting [3]. European Society of Cardiology guidelines on non-ST-segment elevation acute coronary syndromes patients with atrial fibrillation recommend triple therapy with either vitamin K antagonists (VKA) or non VKA oral anticoagulant therapy (NOAC) for 1–6 months [3]. Triple therapy should be prescribed for the shortest time as possible and adapted to the absolute individual embolic and hemorrhagic risk.

Bleeding is the major adverse event caused by OAC and antiplatelet therapy combination [4]. This risk is proportional to the number of drugs used and to the exposure duration. Registries have shown a three-fold bleeding risk under triple therapy compared to DAPT in patients with acute coronary syndromes [1,5]. Moreover, myocardial infarction mortality is significantly increased in case of in-hospital major bleeding [6]. In the WOEST open randomized trial, dual therapy combining one antiplatelet agent with VKA offered the best safety profile with fewer cardiovascular outcomes in stable coronary artery disease (CAD) patients undergoing percutaneous coronary intervention (PCI) [7].

There are limited prospective data on OAC indications and use combined with DAPT in the clinical setting of AMI. In studies performed prior to the reperfusion era, patients requiring chronic OAC had an increased risk of adverse cardiovascular outcomes in comparison to patients free from OAC indication [8,9]. In more recent studies increased adverse outcomes were observed but data on ST-elevation myocardial infarction (STEMI) patients with OAC indications and use are conflicting [10–17]. In these studies, patients with OAC indications are less likely to undergo primary PCI and more likely to experience in-hospital complications [18]. Therefore it is not clear whether the increased risk observed in AMI patients with OAC indications is related to increased severity in myocardial infarction characteristics, comorbidities, or differences in therapeutic management including anticoagulation strategy.

Our main objective was to investigate the incidence and characteristics of patients with OAC indications within the first year following an acute anterior STEMI and their relationship with major adverse cardio-cerebro-vascular events (MACCE) and bleeding in a modern setting.

Methods

Our study is based on a post hoc analysis of the CIRCUS trial database.

CIRCUS was a prospective international multicenter randomized double-blinded placebo-controlled study that assessed the effect of a single cyclosporine bolus in the setting of anterior STEMI. In brief, 969 patients referred for primary PCI (PPCI) within the first 12 h from a chest pain and anterior STEMI on electrocardiogram (ECG) were randomly assigned in a ratio of 1:1 to cyclosporine or placebo between 2011 and 2014. All patients underwent PCI and were treated according to the updated STEMI European guidelines [3].

Complete study protocol and primary results from this study have previously been published [19,20]. All subjects gave their informed consent before inclusion in the study. The trial was registered in www.clinicaltrials.gov: (NCT01502774).

Study groups

We defined different subgroups of patients from the CIRCUS population to perform our study. Individual data on adverse events and medication prescription were retrospectively analyzed from the CIRCUS database.

Patients presenting an indication for OAC therapy within the first year of follow-up were categorized in the OAC indication group and were compared to patients without any OAC indication.

OAC eligibility was defined as the presence of a formal oral anticoagulant indication at inclusion, during the acute phase or post-discharge:

- atrial arrhythmia (atrial fibrillation) with CHADS-VASC score ≥ 2
- left ventricular thrombus
- any other indication (history of pulmonary embolism, heart valve prothesis, any other venous or arterial thrombo-embolism)

Combination of OAC and antiplatelet drugs was recorded for each patient from the study database. Stroke risk was estimated using the CHA2DS2vasc score [21] for all patients with atrial fibrillation. In the same way, a simplified HASBLED Score was calculated to estimate the hemorrhagic risk for all patients with OAC indication on the basis of the following risk factors: age > 65 years, history of arterial hypertension, stroke, and or renal failure and use of drug at risk of bleeding.

Patients with an OAC indication receiving an OAC combined to a single or dual antiplatelet therapy at discharge were further classified as OAC users and compared to OAC non-users comprising patients without any OAC despite formal OAC indication.

Clinical outcomes

All patients from the CIRCUS study were prospectively followed-up during one-year with clinical visits at one year and telephone calls by trained research coordinators at 1, 3, and 6 months. All adverse events were reported and all clinical events were adjudicated by an Endpoint Validation Committee whose members were unaware of study group assignment.

The principal clinical outcome for our study was a composite of MACCE at one year. They included all causes of death, heart failure worsening during index event and re-hospitalization for heart failure, recurrent myocardial infarction, and stroke. All bleeding events defined as major if requiring blood transfusion or invasive hemostasis (superior to a type 3 bleeding according to the Bleeding Academic Research Consortium (BARC) classification [22]) were also reported.

Statistical analysis

All analyses for this study were performed post hoc. The first set of analyses was performed comparing patients with OAC indications during the first year to patients without OAC indication. The second set of analyses was performed within the OAC indicaiton patient group between patients under anticoagulation therapy and patients without anticoagulants. Categorical variables were compared using the chi-square or Fisher's exact tests and expressed as percentage. Continuous variables were compared using the Student T test if parametric or the Wilcoxon rank sum test if non parametric and presented as means $\pm$ standard deviation or medians and interquartile range.

Primary endpoint analysis was performed using time-to-event data (censored date was the last follow-up visit at 12 months), and are displayed using the Kaplan–Meier method and compared between study groups with the log-rank test.

Univariable logistic regression analysis was performed to assess the relationship between OAC therapy indication and the occurrence of each component of primary end point (MACCE and hemorrhage). Then, this association was analyzed in a multivariate Cox model after adjustment for other important clinical confounders: age, Killip class at admission, creatine phosphokinase peak level, coronary multivessel disease status,

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