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## Original Article

## Prevalence of lipid abnormalities and cholesterol target value attainment in Egyptian patients presenting with an acute coronary syndrome

Mohamed Sobhy<sup>a,\*</sup>, Adel El Etriby<sup>b</sup>, Amany El Nashar<sup>c</sup>, Sameh Wajih<sup>d</sup>, Martin Horack<sup>e</sup>, Philippe Brudi<sup>f</sup>, Dominik Lautsch<sup>f</sup>, Baishali Ambegaonkar<sup>f</sup>, Ami Vyas<sup>g,1</sup>, Anselm K. Gitt<sup>e,h</sup><sup>a</sup> Faculty of Medicine, Alexandria University, Egypt<sup>b</sup> International Cardioscan Center, Cairo, Egypt<sup>c</sup> Merck Sharp & Dohme-Egypt, Cairo, Egypt<sup>d</sup> Merck Sharp & Dohme, Medical Affairs EEMEA, United Arab Emirates<sup>e</sup> Stiftung Institut für Herzinfarktforschung, Ludwigshafen, Germany<sup>f</sup> Merck & Co., Inc., Kenilworth, NJ, USA<sup>g</sup> Rutgers University, School of Public Health, Department of Epidemiology, Piscataway, NJ, USA<sup>h</sup> Klinikum der Stadt Ludwigshafen, Medizinische Klinik B, Ludwigshafen, Germany

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## ABSTRACT

**Background:** Effective management of hyperlipidemia is of utmost importance for prevention of recurring cardiovascular events after an acute coronary syndrome (ACS). Indeed, guidelines recommend a low-density lipoprotein cholesterol (LDL-C) level of <70 mg/dL for such patients. The Dyslipidemia International Study II (DYSIS II) – Egypt was initiated in order to quantify the prevalence and extent of hyperlipidemia in patients presenting with an ACS in Egypt.

**Methods:** In this prospective, observational study, we documented patients presenting with an ACS at either of two participating centers in Egypt between November 2013 and September 2014. Individuals were included if they were over 18 years of age, had a full lipid profile available (recorded within 24 h of admission), and had either been taking lipid-lowering therapy (LLT) for ≥3 months at time of enrollment or had not taken LLT. Data regarding lipid levels and LLT were recorded on admission to hospital and at follow-up 4 months later.

**Results:** Of the 199 patients hospitalized for an ACS that were enrolled, 147 were on LLT at admission. Mean LDL-C at admission was 127.1 mg/dL, and was not significantly different between users and non-users of LLT. Only 4.0% of patients had an LDL-C level of <70 mg/dL, with the median distance to this target being 61.0 mg/dL. For the patients with LDL-C information available at both admission and follow-up, LDL-C target attainment rose from 2.8% to 5.6%. Most of the LLT-treated patients received statin monotherapy (98.6% at admission and 97.3% at follow-up), with the mean daily statin dose (normalized to atorvastatin) increasing from admission (30 mg/day) to follow-up (42 mg/day).

**Conclusions:** DYSIS II revealed alarming LDL-C goal attainment, with none of the patients with follow-up information available reaching the target of LDL-C <70 mg/dL, either at hospital admission or 4 months after their ACS event. Improvements in guideline adherence are urgently needed for reducing the burden of cardiovascular disease in Egypt. Strategies include the effective use of statins at high doses, or combination with other agents recommended by guidelines.

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\* Corresponding author at: Faculty of Medicine, Alexandria University, Alexandria, Egypt.

E-mail addresses: [sobhy53@yahoo.com](mailto:sobhy53@yahoo.com) (M. Sobhy), [etriby1@yahoo.com](mailto:etriby1@yahoo.com) (A. El Etriby), [amany\\_nashar@merck.com](mailto:amany_nashar@merck.com) (A. El Nashar), [sameh\\_wajih@merck.com](mailto:sameh_wajih@merck.com) (S. Wajih), [horack@ihf.de](mailto:horack@ihf.de) (M. Horack), [philippe\\_brudi@merck.com](mailto:philippe_brudi@merck.com) (P. Brudi), [dominik.lautsch@merck.com](mailto:dominik.lautsch@merck.com) (D. Lautsch), [baishali\\_ambegaonkar@merck.com](mailto:baishali_ambegaonkar@merck.com) (B. Ambegaonkar), [avyas@uri.edu](mailto:avyas@uri.edu) (A. Vyas), [gitt@stiftung-ihf.de](mailto:gitt@stiftung-ihf.de) (A.K. Gitt).

<sup>1</sup> Present address: University of Rhode Island, College of Pharmacy, Department of Pharmacy Practice, Kingston, RI, USA.

## 1. Introduction

Patients suffering from an acute coronary syndrome (ACS) are considered to be at very high risk of experiencing further cardiovascular events.<sup>1</sup> Effective management of associated risk factors such as dyslipidemia, hypertension, and diabetes mellitus is essential for limiting adverse outcomes in these patients. This is of particular importance in Egypt, where the number of deaths due to

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cardiovascular disease is significantly higher than those for other countries in the region.<sup>2</sup>

Hyperlipidemia is highly prevalent in patients with an ACS, with previous studies reporting high low-density lipoprotein cholesterol (LDL-C) levels on admission to hospital.<sup>3,4</sup> In the Get With The Guidelines (GWTG) study, Javed et al. reported that only 20.3% of patients were found to have a value of <70 mg/dL,<sup>5</sup> in line with the TARGET study, in which a mere 16.2% of ACS patients presented with LDL-C at this level, with over 50% having a value of >130 mg/dL.<sup>6</sup> Initiation of intensive statin therapy is advised for all patients experiencing an ACS,<sup>1</sup> with patients having been shown to benefit from such treatment even if they have an LDL-C level  $\leq$ 80 mg/dL.<sup>7</sup> However, studies show wide variability in statin use between treating physicians.<sup>8,9</sup>

DYSIS II was designed to obtain details on the management of cholesterol in patients suffering an ACS. This was a multinational, observational study that employed standardized methodology to enable evaluation of the prevalence of lipid abnormalities in patients from countries throughout the world. Here, we present the results collected in Egypt, providing an overview of the extent of hyperlipidemia in ACS patients, and how LLT is used in a real-world setting.

## 2. Methods

### 2.1. Study design and patients

Patients were enrolled at two centers within Egypt from November 2013 to September 2014. Individuals were included if they were over 18 years of age, hospitalized for an ACS (ST-segment elevation myocardial infarction [STEMI]/left bundle branch block myocardial infarction [LBBB MI], non-ST-segment elevation myocardial infarction [NSTEMI], or unstable angina [UA]) at the time of enrollment and had a full lipid profile available (recorded within 24 h of admission). Patients were excluded if they died during the hospital stay or if they were participating in a clinical trial at the same time as the study. If a patient was receiving LLT, the duration of treatment had to be  $\geq$ 3 months prior to admission. Data were collected on admission to hospital for ACS, and at 4 months ( $\pm$ 15 days) post-admission.

All included patients provided written informed consent. The study received ethical approval from the relevant committees at each participating center as per local regulations, and was performed in accordance with the Declaration of Helsinki.

### 2.2. Documentation

Data were recorded on a standardized case report form (CRF) and later entered into a central web-based database maintained at the Institut für Herzinfarktforschung, Ludwigshafen, Germany. At the time of admission to hospital, patient demographics, cardiovascular history, comorbidities, lipid profile and current medications were recorded. Demographic and clinical variables collected at admission included age, gender, race/ethnicity, body mass index (BMI), hypertension, type 2 diabetes mellitus, sedentary lifestyle, smoking status, documentation of coronary heart disease (CHD), previous myocardial infarction (MI), chronic renal failure (CRF), chronic kidney disease (CKD), stroke, peripheral vascular disease (PVD), and family history of CHD. Obesity was defined as BMI  $>30$  kg/m<sup>2</sup>. Diabetes was defined as current treatment for diabetes, a previous diagnosis of diabetes, or a fasting plasma glucose level of  $\geq$ 126 mg/dL. Likewise, hypertension was defined as current treatment, a previous diagnosis, or having blood pressure  $>140/90$  mmHg. A sedentary lifestyle was defined as  $<20$ – $30$  minutes of walking on  $<3$ – $4$  days per week. Stroke could be ischemic or

hemorrhagic. Use of selected classes of cardiovascular medications (e.g., beta-blockers, calcium channel blockers, diuretics, ACE inhibitors, antiplatelet agents) and laboratory values of HbA1c and blood glucose at admission were also recorded.

Patients were divided into subgroups based on treatment status at admission: LLT users and LLT non-users. Use of LLTs at the time of the lipid test was determined at admission and by patient report at follow-up. The following classes of LLT were assessed: statin monotherapy, non-statin monotherapy, statin plus ezetimibe, and statin plus other non-statin therapy ('other' non-statins included nicotinic acid, fibrates, omega-3 fatty acids, and other less common agents). The statins assessed were atorvastatin, fluvastatin, lovastatin, pravastatin, pitavastatin, rosuvastatin, and simvastatin. Atorvastatin dose equivalents were based on clinical trial data on the LDL-C-lowering efficacy of various statins.<sup>10</sup>

A full lipid profile was recorded within 24 h of admission. The lipid profile included measurements of serum levels of total cholesterol (TC), LDL-C, high-density lipoprotein cholesterol (HDL-C), non-HDL-C, and triglycerides. Pre-admission cardiovascular risk status (very high, high, moderate, or low) was determined for all patients, and goal attainment according to this classification was based on the lipid values determined at admission. Targets for LDL-C for very high-risk, high-risk, moderate-risk, and low-risk patients were defined according to the 2011 joint European Society of Cardiology (ESC) and European Atherosclerosis Society (EAS) guidelines as  $<70$  mg/dL,  $<100$  mg/dL,  $<115$  mg/dL, and  $<130$  mg/dL, respectively.<sup>1</sup> Of note, very high- and high-risk patient groups have clearly set target values based on comorbidity, whereas for moderate and low risk, additional risk factors or markers such as obesity or high C-reactive protein (CRP) are taken into account. At 4 months ( $\pm$ 15 days) post-admission, any lipid profiles available from the follow-up period were collected, and the medications that the subjects were receiving at this time were documented. The median distance to the LDL-C target was calculated for patients who had not attained the LDL-C target on the date of the lipid profile. Any occurrence of cardiovascular-related adverse events (rehospitalization, MI, stroke, percutaneous coronary intervention [PCI], and coronary artery bypass grafting [CABG]) during the follow-up period was recorded. These outcomes were not mutually exclusive.

### 2.3. Statistics

The study followed patients on LLT at admission through to the follow-up time point. Unless otherwise stated, throughout the text, the terms 'treated' and 'on LLT' refer to the treatment status at admission. Data are presented as means with standard deviations (SD), medians with interquartile ranges (IQR), or absolute values with percentages. Statistical significance was determined using the chi-squared test or the Mann-Whitney-Wilcoxon test. LDL-C target attainment was assessed first by risk classification and then, in the subgroup of patients with LDL-C data at both admission and follow-up. Data were analyzed using SAS version 9.3 (Cary, NC, USA) and a *p*-value  $< 0.05$  was considered statistically significant.

## 3. Results

### 3.1. Patients

A total of 199 patients fulfilled the eligibility criteria. Their mean (SD) age was 58.0 years ( $\pm$ 11.5) and 77.4% were male (Table 1). A high proportion of patients were classed as being obese (59.3%), and cardiovascular risk factors and comorbidities were common. In particular, 69.8% reported a sedentary lifestyle, 47.7% had hypertension, and 46.2% had type 2 diabetes mellitus.

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