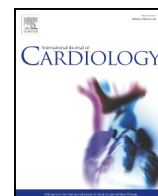




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Effectiveness of a combination of ezetimibe and statins in patients with acute coronary syndrome and multiple comorbidities: A 6-year population-based cohort study

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ABSTRACT

Background: The clinical benefits of a combination of statins and ezetimibe in patients with acute coronary syndrome (ACS) were observed in a clinical trial. However, little is known regarding the effectiveness of using statins with or without ezetimibe in patients with ACS and multiple comorbidities in real-world clinical practice.

Methods: This is a nationwide population-based cohort study using Taiwan National Health Insurance Research Database. A total of 212,110 patients with ACS who had been discharged after their first ACS events between 2006 and 2010 were enrolled. A propensity score matching approach was used to create matched cohorts for adjusting potential confounders. Cox proportional hazards regressions were performed to estimate the risk of re-hospitalization for ACS and revascularization.

Results: Patients in the statins-plus-ezetimibe group had a significantly lower risk of re-hospitalization for ACS (adjusted hazard ratio [HR] = 0.64, 95% confidence interval [CI]: 0.60–0.69) and revascularization (HR = 0.69, 95% CI: 0.63–0.76) than those in the statins-alone group. In the statins-plus-ezetimibe group, female patients had a lower risk of re-hospitalization for ACS than male patients did, and patients without diabetes mellitus had a lower risk of re-hospitalization for ACS than did patients with diabetes mellitus.

Conclusions: Patients with ACS and multiple comorbidities receiving a combination therapy of statins and ezetimibe had a lower risk of re-hospitalization for ACS and revascularization than those receiving statins alone. Significant interaction effects were observed between combination with ezetimibe, sex, and diabetes mellitus.

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1. Introduction

Low levels of low-density lipoprotein cholesterol (LDL-C) were correlated with a low risk of coronary heart disease (CHD) [1,2]. According to the US National Cholesterol Education Program Adult Treatment Panel III Guideline, the optimal LDL-C target for patients with acute coronary syndrome (ACS) is <70 mg/dL. The guideline also emphasizes the clinical benefits of lipid-lowering therapy in individuals with CHD risk factors or CHD [3]. However, the effectiveness of statins alone is often

suboptimal. Pearson et al. showed that less than one-third of patients with CHD receiving statin monotherapy achieved the target LDL level [4], leading to the investigation of a statin-based combination therapy. Several retrospective cohort studies have shown that a combination of ezetimibe and statins reduce LDL-C levels more effectively than statins alone can and may enable a larger proportion of patients at a high risk of CHD to reach the target LDL-C level [5–11].

In a population-based cohort study, Lin et al. showed that in addition to considerably reducing the LDL-C level, patients with ACS receiving statins combined with ezetimibe had a significantly lower risk of re-hospitalization for ACS and revascularization than those receiving statins alone [12]. However, the outcomes of combination therapy in patients with ACS and multiple comorbidities still need further investigation. The clinical benefits of a combination therapy involving ezetimibe

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and statins were also observed in the clinical trial IMPROVE-IT [13]. The clinical trial showed a reduction in cardiovascular (CV) events in the combination therapy group; the safety profile did not significantly differ from that of the statin-alone group [13].

Approximately one-third of the patients with ACS also have at least one active, noncardiac condition; therefore, the effect of comorbidities on the management of ACS has become a crucial issue in actual practice [14]. Lichtman et al. showed that patients with ACS and comorbidities such as pneumonia, severe gastrointestinal bleeding, anemia, stroke, or sepsis have a poor prognosis [15]. In addition to acute comorbidities, patients with ACS and chronic conditions have also been reported to show increased mortality [16]. The effectiveness of ezetimibe combined with statins in these patients has not been extensively studied. The SHARP trial evaluated the co-administration of ezetimibe and statins in patients

with chronic kidney disease. The combination therapy reduced the risk of major atherosclerotic events by 17% [17]. The outcomes of combination therapy in the presence of other comorbidities still need further investigation. Thus, this retrospective cohort study using data from the National Health Insurance Research Database (NHIRD) in Taiwan was designed to assess the clinical outcomes of using statins with or without ezetimibe in patients with ACS and multiple comorbidities.

2. Methods

2.1. Data resource

We conducted a retrospective cohort study of patients who were hospitalized for ACS from January 1, 2006 to December 31, 2010. For this nationwide population-based cohort study, we used patient data obtained from the Taiwan NHIRD from 2005 to 2011 under the

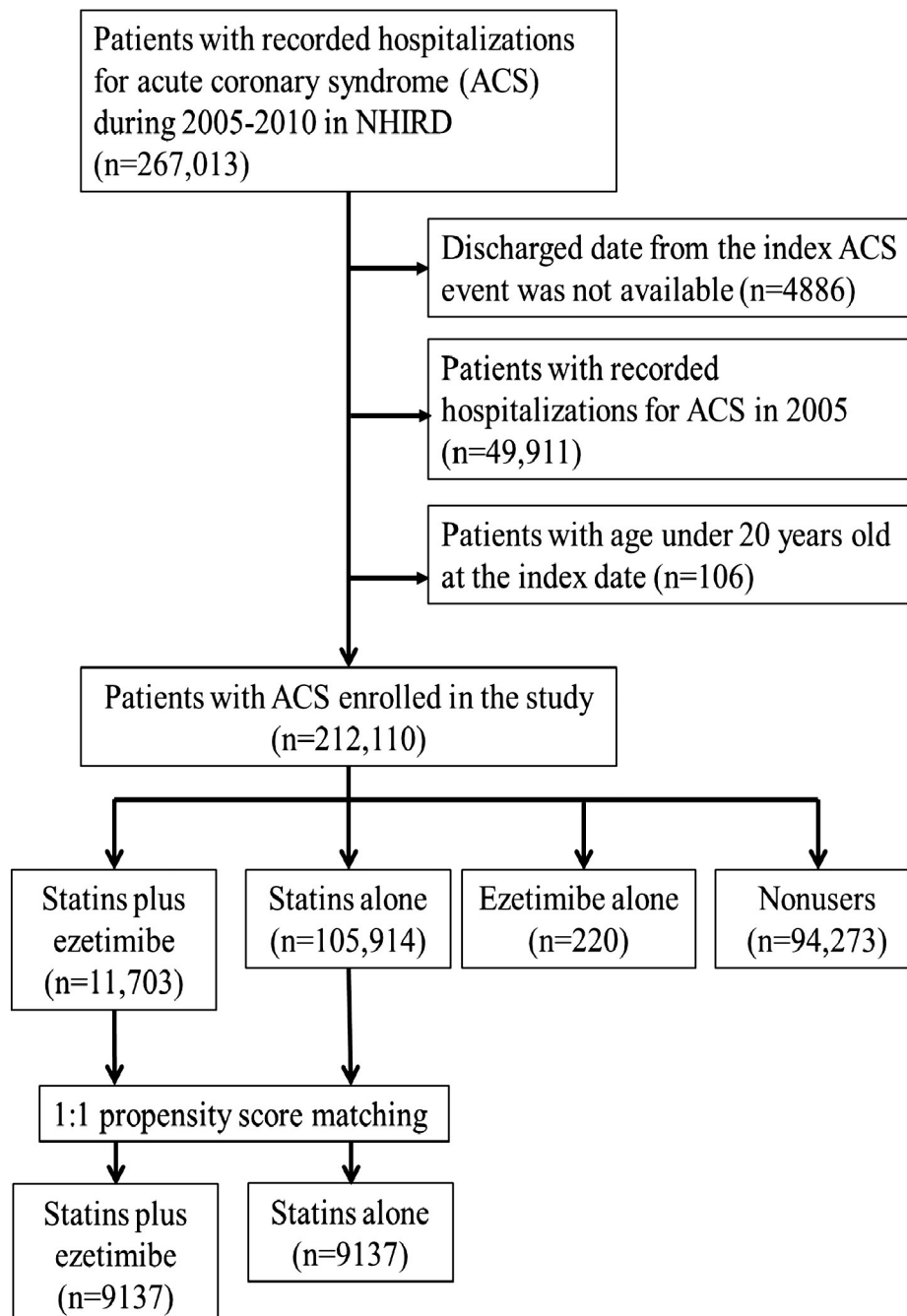


Fig. 1. Patient enrollment flowchart for the study cohort.

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