

# Attainment of Goal and Normalized Lipid Levels With Lipid-Modifying Therapy in Malaysia

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## ABSTRACT

**Background:** Although LDL-C is the primary lipid target for coronary heart disease (CHD) risk reduction, HDL-C and triglycerides (TG) have also emerged as CHD risk factors.

**Objective:** The objective of this study was to evaluate goal/normal lipid level attainment after lipid-modifying therapy (LMT) in an ethnically diverse sample of patients in Malaysia.

**Methods:** Retrospective, longitudinal data were collected from the medical records of patients aged  $\geq 35$  years in whom LMT was initiated between January 2004 and December 2006. Eligible patients had records of full lipid panels 12 months before and after the start of therapy. LDL-C goals and normal levels of HDL-C and TG were defined as per the Clinical Practice Guidelines on Management of Dyslipidemia (4th edition), Malaysia. A subgroup of patients at high risk for CHD events (established CHD, diabetes but no CHD, or a 10-year history of Framingham risk score  $\geq 20\%$ ) was also studied.

**Results:** Among 607 eligible patients (mean age, 57.1 years; 40% male), 89% had elevated LDL-C, 37% had low HDL-C, 56% had elevated TG, and 62% had  $\geq 2$  abnormal lipid levels before LMT. Despite therapy (87% statins only), 60% had elevated LDL-C, 37% had low HDL-C, 40% had elevated TG, and 44% continued to have  $\geq 2$  abnormal lipid levels.

**Conclusions:** In this longitudinal study of Malaysian patients treated with lipid-modifying therapy, primarily using statins, attainment of LDL-C goal is suboptimal. Furthermore, a large proportion of patients do not achieve normal levels of HDL-C and TG. Therefore, patients may benefit from a more comprehensive approach to lipid management that treats all 3 lipid risk factors, as suggested in clinical guidelines. (*Clin*

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**Key words:** coronary heart disease, high-density lipoprotein cholesterol, lipid-modifying therapy, low-density lipoprotein cholesterol, Malaysia, triglycerides.

## INTRODUCTION

Clinical guidelines have consistently identified elevated LDL-C as the primary lipid target and HMG-CoA reductase inhibitors (statins) as the principal lipid-modifying therapy (LMT) for the treatment of patients at high risk for coronary heart disease (CHD).<sup>1,2</sup> Nonetheless, high-risk patients treated with statins may remain at substantial risk for CHD events.<sup>3</sup> To help address this residual risk, both low HDL-C and elevated triglycerides (TG) have emerged as lipid risk factors for the reduction of CHD events.<sup>1</sup> Low HDL-C has been reported as an independent risk factor for CHD.<sup>4,5</sup> Elevated TG, although correlated with low HDL-C, has also been associated with increased cardiovascular risk in population-based studies.<sup>6,7</sup> Randomized clinical trials have further demonstrated a reduction in CHD risk with other LMTs, such as niacin and fibrates, which have beneficial effects on multiple lipid abnormalities.<sup>8,9</sup> As a result, current guidelines recommend combination therapy with statins and other LMTs in high-risk patients with multiple lipid abnormalities, characterized as mixed dyslipidemia.<sup>1,2</sup>

Although clinical guidelines stress the importance of recognizing and treating elevated TG and low HDL-C

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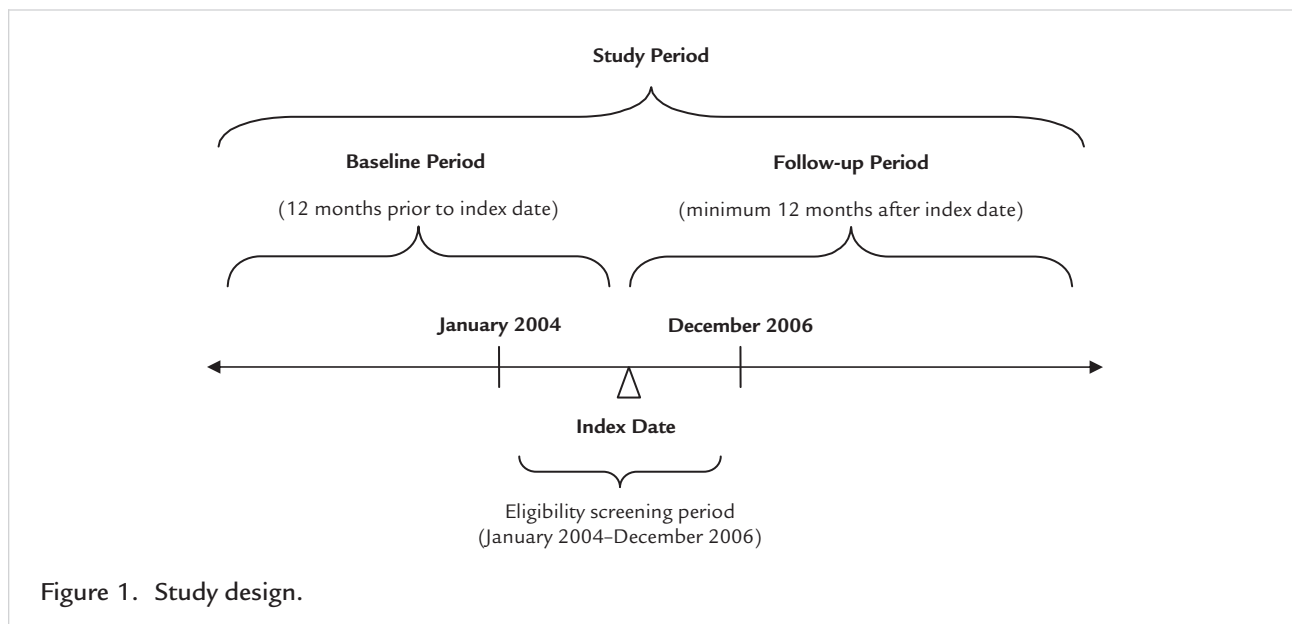


Figure 1. Study design.

in addition to elevated LDL-C, studies have reported that not all patients achieve normal lipid levels in clinical practice. A longitudinal study using data from a US health maintenance organization reported that LMT use significantly improved LDL-C goal attainment; however, nearly 50% of patients did not achieve normal HDL-C, and 24% of patients continued to have multiple lipid abnormalities.<sup>10</sup> Studies conducted in Europe have reported that the prevalence of multiple lipid abnormalities in patients primarily treated with statins is 30% to 40%.<sup>11,12</sup>

In contrast, few studies have investigated the attainment of multiple normal lipid levels in Asian patients treated with LMTs. A study conducted in Hong Kong reported that 48% of patients treated primarily with LMTs continued to have  $\geq 1$  lipid abnormality, and 16% had multiple lipid abnormalities.<sup>13</sup> In Malaysia, little is known about the prevalence of lipid abnormalities in clinical practice, particularly in high-risk patients with preexisting CHD or established CHD risk equivalents, such as diabetes and the metabolic syndrome, which are highly prevalent in Malaysia<sup>14,15</sup> Therefore, the objective of this study was to evaluate attainment of normal HDL-C and TG in addition to LDL-C goals in a multiethnic sample of Malay, Chinese, and Indian patients treated with LMTs in Malaysia. In addition, the study sought to characterize the predictors of normal lipid-level attainment after LMT initiation in clinical practice.

## PATIENTS AND METHODS

### Study Sample

This longitudinal, retrospective observational study was conducted at 9 primary care practices in Malaysia. Each participating institute's committee on human research approved the study protocol. The committees determined the study design involved minimal risk to study participants; thus the requirement for informed consent was waived.

Data were collected from administrative claims and medical records. Data collection consisted of 3 stages (Figure 1). Eligible patients received an initial prescription for an LMT—consisting of statins, ezetimibe, fibrates, niacin, bile acid sequestrants, long-chain  $\omega$ -3 fatty acids (LCFAs), or cholesterol absorption inhibitors—during the index period, defined as January 2004 through December 2006. To assess the presence of lipid disorders before (baseline) and up to 12 months after LMT initiation, complete baseline and follow-up lipid profiles were collected from 12 months before to at least 12 months after the index date.

All patients initially selected at the index date were screened based on several inclusion/exclusion criteria. Only patients aged  $\geq 35$  years at the index date were included. Patients were required to have complete lipid-panel data available, including LDL-C, HDL-C, total cholesterol (TC), and TG, from 12 months before to  $\geq 12$  months after the index date. To ensure adherence to LMT, patients were required to have had prescrip-

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