Clinical and Economic Burden in Patients with Diagnosis of Peripheral Arterial Disease in a Claims Database in Japan

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ABSTRACT

Purpose: The effect of peripheral arterial disease (PAD) among young and middle-aged adults can be significant, but no previous study has examined the prognosis and the associated health care cost of the disease in this population. We evaluated the clinical and economic burden of PAD in patients from a large claims database to clarify the effect of the disease on a relatively young working Japanese population.

Methods: Patients aged ≥45 and ≤64 years with first PAD diagnosis between 2005 and 2011 comprised the PAD cohort (n = 362); an age- and sex-matched non-PAD comparison cohort (n = 362) was also identified. Rates of cardiovascular events/interventions, health care utilization, and costs were compared.

Findings: The mean (SD) age of the cohort was 52.8 (5.6) years and 40.8% were women. Baseline Charlson comorbidity index was significantly higher in the PAD cohort than in the non-PAD cohort (1.90 [2.19] vs 1.16 [1.99]; $P < 0.001$). The PAD cohort had significantly higher first-year event rates than did the non-PAD cohort for myocardial infarction (2.2% vs 0.2%; $P = 0.019$) and ischemic stroke (4.1% vs 0.5%; $P = 0.001$). Health care utilization was significantly greater for the PAD cohort for all parameters assessed (number of hospitalization, inpatient days, and outpatient visits) in the first year (all, $P < 0.001$). Total annual costs for health care were significantly higher in the PAD cohort than in the non-PAD cohort in the first year ($P < 0.001$). Among patients with diabetes, patients with PAD (n = 98) had significantly greater first-year event rates (myocardial infarction, ischemic stroke, coronary artery bypass surgery, peripheral arterial revascularization, percutaneous coronary intervention, and limb amputation; all, $P < 0.001$), significantly greater number of clinic visits ($P = 0.023$), and total cost burden than did patients without PAD (n = 63).

Implications: Even in a relatively young working Japanese population, PAD is associated with substantial clinical and economic burden. (*Clin Ther*. 2014;36:1223–1230) © 2014 Elsevier HS Journals, Inc. All rights reserved.

Key words: clinical burden, economic burden, health care utilization, Japan, peripheral arterial disease.

INTRODUCTION

Peripheral arterial disease (PAD) is a manifestation of systemic atherosclerosis and is associated with increased risk of such adverse cardiovascular outcomes as myocardial infarction (MI) and ischemic stroke (IS).[1,2] Analyses from the REduction of Atherothrombosis for Continued Health (REACH) Registry have consistently reported high morbidity and mortality rates and high costs associated with patients with PAD in populations from various countries, including the United States, Canada, France, and Germany.[3–6] Although the clinical and economic burden of PAD has been well characterized in these western populations, reports in Japanese patients are limited.

The prevalence of PAD differs by ethnicity, and the prevalence in Asians has been reported to be lower than in other ethnic groups.[7] The overall prevalence of PAD in Japan has been estimated to range from 1.7% to 2.7% in the population ≥40 years, 0.4% to 1.0% in the younger population ≥40 and <60 years, and from 3.4% to 4.3% in the older population ≥60 years,

which is lower than in other countries.[8–11] However, with the changes in lifestyle, people with cardiovascular risk factors, including hypertension, dyslipidemia, diabetes, and obesity, have been increasing in Japan,[9,11,12] and the prevalence of PAD is expected to rise.

A recent study found that the prevalence of PAD has increased by 23.5% globally between 2000 and 2010, and the socioeconomic effect of the disease has been highlighted.[13] The prevalence of PAD increases with age, and previous studies have found high clinical and economic burden on the elderly associated with the disease.[4–6,14–18] Meanwhile, the effect of PAD among young and middle-aged adults can be significant, because these patients need long-term medical care, and the disease can lead to the loss of productivity. However, no previous study has examined the prognosis and the associated health care cost of PAD in a relatively young working population.

The primary objective of the present study is to evaluate the clinical and economic burden related to PAD on the basis of the large insurance claims database, to clarify the effect of the disease on a relatively young working Japanese population. Subanalyses of patients with diabetes were also conducted, because diabetes is the most important risk factor for PAD.[1]

METHODS
Data Source

Japan Medical Data Center (JMDC) partners with and collects/maintains claims data from contracted corporate health insurance societies and included approximately 1 million persons in 2010 (expanded from 300,000 persons in 2005). The claims data are obtained after removing all personally identifiable information to ensure confidentiality. Most members are employees of large employers and their family members. Thus, this database represents a relatively younger and homogenous population compared with the general population of Japan. The JMDC database has a unique system that automatically converts and updates various disease names and classifications previously entered at different health care institutions to standardized forms; this improves the reproducibility of the data and enables time-series analysis.[19]

Sample Selection

In the present study, the JMDC database was used to identify all patients who had a diagnosis of PAD for the first time and were ≥45 and ≤64 years of age between January 2006 and November 2011,

considering a date of diagnosis as an index date with at least 1 year without a diagnosis of PAD before the index date; these patients were designated as the PAD cohort. We considered 1 year to be a reasonable time frame to ascertain whether a patient had an existing PAD diagnosis because most patients would have at least 1 follow-up outpatient visit during the 6-month period after PAD diagnosis in a typical clinical practice setting in Japan. A non-PAD comparison cohort was identified from the JMDC database during this same interval from 5000 randomly selected patients who did not meet the criteria for PAD from the database. Patients without PAD (comparison cohort) were matched 1:1 to patients with PAD (case cohort) on the basis of age and sex. In addition, we anchored on the index date of each patient in the case cohort to identify an arbitrary index date for each patient in the comparison cohort to further match the 2 cohorts according to the index date. We then compared medical utilization and costs for the 2 cohorts during the subsequent 12-month period after the index date.

Patients were identified as being newly diagnosed with PAD if they had PAD diagnosis once during hospitalization or twice on outpatient basis (claims associated with the following *International Classification of Diseases, 10th Revision* (ICD-10) codes[20]: I70.2, atherosclerosis of native arteries of the extremities; I70.9, other and unspecified atherosclerosis; I74.3, embolism and thrombosis of arteries of the lower extremities; or I74.9, embolism and thrombosis of unspecified artery) during the designated time interval. The date of the first diagnosis that met the study criteria for PAD was designated as the index date. Baseline was defined as the 12-month period before the index date.

Analysis Variables

The clinical and economic burden of PAD in the first year after the diagnosis of PAD was assessed. Parameters evaluated included the number of hospital admissions, comorbidities after PAD diagnosis, rate of cardiovascular events (MI and IS), rate of cardiovascular procedure (coronary artery bypass graft, peripheral arterial revascularization, percutaneous coronary intervention, and limb amputation), and health care costs (inpatient, outpatient, medication, total, procedure, and material costs) and were compared between the 2 cohorts. Cardiovascular events were identified