



Contents available at [ScienceDirect](#)

Diabetes Research
and Clinical Practice

journal homepage: www.elsevier.com/locate/diabres



International
Diabetes
Federation



Impact of nonadherence on complication risks and healthcare costs in patients newly-diagnosed with diabetes

Haruhisa Fukuda*, Miki Mizobe

Department of Health Care Administration and Management, Graduate School of Medical Sciences, Kyushu University, 3-1-1 Maidashi Higashi-ku, Fukuoka 812-8582, Japan

ARTICLE INFO

Article history:

Received 17 May 2016

Received in revised form

25 October 2016

Accepted 10 November 2016

Available online 19 November 2016

Keywords:

Nonadherence

Diabetes

Complication risks

Healthcare costs

ABSTRACT

Aims: To investigate the association between nonadherence to diabetes treatment and the occurrence of diabetes complications.

Methods: Our study retrospectively identified adherence and nonadherence to diabetes treatment in patients during the first year of observation after new diagnoses of type 2 diabetes enrolled in commercial database from 52 health insurers in Japan. Participants were insurance enrollees with type 2 diabetes who received healthcare between 2005 and 2013, and who could be tracked for more than 12 months from the initiation of diabetes treatment. We compared the occurrence of diabetes-related complications (retinopathy, nephropathy, neuropathy, ischemic heart disease, cerebrovascular disease, and chronic arterial occlusion) and all-cause healthcare expenditure during the second to eighth years. **Results:** We identified 1784 nonadherent patients and 9547 adherent patients. Cox proportional hazard models showed that the occurrence of microvascular complications was significantly higher in the nonadherent group: the hazard ratios (95% confidence intervals) for retinopathy, nephropathy, and neuropathy were 2.04 (1.57–2.66), 1.91 (1.35–2.72), and 1.83 (1.02–3.27), respectively. However, no significant differences were observed between the adherent and nonadherent groups for the macrovascular complications (ischemic heart disease, cerebrovascular disease, and chronic arterial occlusion). In addition, the nonadherent group had a significantly higher cumulative healthcare expenditure than the adherent group during the second-to-fifth-year period ($p = 0.029$) and the second-to-sixth-year period ($p = 0.009$) after treatment initiation.

Conclusions: Nonadherence in the first year of diabetes may increase the incidence of complications and result in higher expenditures for patients and payers.

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1. Introduction

Diabetes is a major chronic disease that affects people throughout the world. The global estimate of diabetes preva-

lence in 2011 was 366 million people, and this figure is projected to rise to 552 million people by 2030 [1]. The treatment of diabetes imposes a massive economic burden on patients and healthcare systems, with a global health

* Corresponding author. Fax: +81 92 642 6961.

E-mail address: h_fukuda@hcam.med.kyushu-u.ac.jp (H. Fukuda).

<http://dx.doi.org/10.1016/j.diabres.2016.11.007>

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expenditure of at least 548 billion US dollars directed toward diabetes-related care [2]. In the US, the economic costs associated with treating diabetic persons account for one-fifth of all healthcare costs [3]. Furthermore, people with type 2 diabetes are at higher risk of developing microvascular (e.g., retinopathy, neuropathy, and nephropathy) and macrovascular complications (e.g., ischemic heart disease, cerebrovascular disease, and chronic arterial occlusion), which are serious problems that can heighten the risk of premature mortality [4,5].

Despite the heavy clinical and economic impact of diabetes, there is widespread patient nonadherence to diabetes treatment regimens. A systematic review has reported that the mean adherence to oral hypoglycemic agent therapy ranged from 36% to 93% [6]. Nonadherence to therapy is a crucial element that can influence the outcomes of diabetes patients. Previous studies have reported that nonadherence to diabetes treatment is associated with increased hospitalization rates [7–10], higher medical expenses [8,10–12], and increased mortality rates [10,13]. This issue of nonadherence to diabetes treatment has also been documented in Japan, where an estimated 9.7% of patients who had previously been treated for diabetes were no longer receiving active treatment [14], and the treatment discontinuation rate has been estimated to be 82.5 cases per 1000 person-years [15].

Although several studies have previously documented the relationship between nonadherence to diabetes drug therapy and HbA1c levels [16], there is, to the best of our knowledge, only 1 published report that addressed the association between nonadherence to drug therapy and the occurrence of diabetes complications [17]. Furthermore, few studies have investigated the association between nonadherence and the occurrence of long-term outcome events. The number of patients with newly diagnosed diabetes continues to rise in Japan and other countries, and failure to adhere to treatment regimens in these patients can incite the progression of diabetes into a more severe state. With a focus on newly diagnosed diabetes patients, this study investigates the association between nonadherence to diabetes treatment and the occurrence of diabetes complications. In addition, we also compare healthcare expenditures between adherent and nonadherent patients.

2. Material and methods

2.1. Data source

This study used the Japan Medical Data Center (JMDC) Claims Data Base, which is a commercial database of health insurance claims data (JMDC Co. Ltd., Tokyo, Japan). The data encompassed insurance claims for 3,139,731 persons from 52 health insurers that provide coverage for employed workers and their dependents throughout Japan. Data were obtained from between January 2005 to June 2013, and included basic insurance enrollee information such as patient visits to authorized insurance healthcare institutions (e.g., hospitals, clinics, and pharmacies), sex, age, dependents, and classification of the healthcare institutions where care was received. In addition to this basic information, the data-

base also included detailed information on all recorded diagnoses and health services provided (including prescribed or administered drugs). The authorized insurance healthcare institutions generate monthly claims data for enrollees who receive healthcare, and these data are submitted to the JMDC. Therefore, examination of the JMDC claims data allows analysts to identify the treatment practices provided to each patient, including the specific date and healthcare institution where the patient received care. Analysts are also able to identify the diagnoses that necessitated specific treatments.

Here, the study sample comprised cases who had at least one recorded diagnosis of type 2 diabetes during the study period. Type 2 diabetes was identified according to the corresponding International Classification of Diseases, 10th revision (ICD-10) codes of E10 to E14.

2.2. Study design

To evaluate the effect of nonadherence to diabetes treatment on the occurrence of complications, we tracked the treatment of patients from the month of their initial diagnosis of type 2 diabetes (Fig. 1). The index month was identified for each patient as the first month during the study period that they were diagnosed with type 2 diabetes. In order to ensure that the patient had not developed type 2 diabetes prior to the start of data collection, we only analyzed cases with a minimum of 6 months of data before the index month. The 12-month period beginning from the index month was designated the “nonadherence observation period”. We defined nonadherent patients as those who did not receive any antidiabetic treatment at an authorized insurance healthcare institution for a consecutive period of 6 months or more during the nonadherence observation period. Adherent patients were identified as those with periods of non-treatment (if any) that were shorter than 6 months. We defined the occurrence of diabetes complications as new diagnoses of target conditions (described below) during the period beginning from the month after the nonadherence observation period had ended (i.e., 13 months after the index month); this period was designated the “complication observation period”.

Patients were excluded from analysis if they fulfilled any of the following criteria: diagnosis of type 1 diabetes, aged 18 years or less during the index month, death during the follow-up period, lack of claims data for 6 months before the index month, a nonadherence observation period of less than 12 months, occurrence of a complication or hospitalization during the nonadherence observation period, and nonadherence (6 months or more of non-treatment) during the complication observation period. The subject selection process is presented in Fig. 2.

2.3. Outcome measures

The primary outcome measure of this analysis was the occurrence of diabetes complications. The target complications included in this analysis were diabetic retinopathy (ICD codes: E113, E143 or H360), diabetic nephropathy (E112 or E142), diabetic neuropathy (E114, E115, E124, E125, E134, E135, E144, E145, G590, G632, G730, G990, M142, M146, I702,

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