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Are patients on basal insulin attaining glycemic targets? Characteristics and goal achievement of patients with type 2 diabetes mellitus treated with basal insulin and physician-perceived barriers to achieving glycemic targets

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ABSTRACT

Aims: To investigate treatment patterns and achievement of glycemic targets in patients with type 2 diabetes mellitus treated with basal insulin in a real-world setting, and to determine physicians' beliefs and practices regarding these patients.
Methods: This study had two components; a retrospective analysis using a US claims database of patient and treatment data, and a survey of physicians' beliefs and practices.
Results: A total of 39,074 patients treated with basal insulin were included in this analysis. The proportion of patients achieving HbA1c < 7.0% (53 mmol/mol) was similar in ongoing basal insulin users at baseline (26%) and at 3 months follow-up (27%). The number of new initiators achieving HbA1c < 7.0% (53 mmol/mol) increased from baseline (11%) to 3 months (27%). In the physician survey component, the majority of physicians indicated they would continue to increase basal insulin dose as long as was needed to reach HbA1c/-fasting blood glucose goals (85% of physicians treating 'not on-goal' patients, 78% of physicians treating 'on-goal' patients). Physician-perceived barriers to insulin intensification included patient's lifestyle, non-adherence, and concerns about out-of-pocket costs.
Conclusions: A large proportion of patients on insulin-based therapy fail to reach glycemic goals. More education of clinicians may improve insulin intensification rates and increase the proportion of patients reaching glycemic targets.

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1. Introduction

It is estimated that approximately 29.1 million people in the US have diabetes, of whom approximately 8.1 million are undiagnosed [1]. The majority (90–95%) of adults diagnosed have type 2 diabetes mellitus (T2DM) [1]. Diabetes is associated with significant morbidity and mortality, as well as considerable health care costs; the estimated total cost (direct plus indirect costs) associated with diabetes in the US in 2012 was $245 billion [1]. The American Diabetes Association (ADA) Standards of Medical Care in Diabetes recommends glycemic targets of glycated hemoglobin (HbA1c) < 7.0% (53 mmol/mol) and fasting blood glucose (FBG) of 80–130 mg/dL for most adults with T2DM [2]. Studies have shown that low or high mean HbA1c values (<6.5% [48 mmol/mol] or >9.0% [75 mmol/mol]) are associated with increased mortality and cardiac events [3,4]. Given the progressive nature of T2DM, many patients will eventually require intensification of initial oral antidiabetes drug (OAD) treatment with the addition of a second-line OAD, insulin, or non-insulin injectable, with some of these patients requiring further treatment intensification to maintain glycemic targets as recommended by the ADA Standards of Medical Care in Diabetes [2], the ADA/European Association for the Study of Diabetes (EASD) guidelines [5], and the American Association of Clinical Endocrinologists (AACE)/American College of Endocrinology (ACE) comprehensive diabetes management algorithm [6].

Despite the availability of clinical guidelines and the wide variety of antidiabetes drugs that have reached the market, it is estimated that only about half of the patients with T2DM in the US achieve the HbA1c target of <7.0% (53 mmol/mol) [7]. A systematic review of 218 randomized clinical trials (RCTs) found that only 39% of 21,615 patients with T2DM treated with basal insulin achieved HbA1c < 7.0% (53 mmol/mol) [8]. A primary care database analysis of 4062 patients with T2DM found that after one year of basal insulin therapy, only 7% reached the glycemic target of HbA1c ⩽ 6.5% (48 mmol/mol) [9]. In a study of data from 11 RCTs and one electronic medical record (EMR) database, about 50% of patients in RCTs achieved HbA1c < 7.0% (53 mmol/mol), compared to about 27% of patients in the EMR database [10]. A retrospective study involving a European EMR database found that after two years of basal insulin therapy 17–34% of patients reached HbA1c < 7.0% (53 mmol/mol) [11]. In addition, insulin intensification appears to be underused by both primary care physicians (PCPs) and specialists despite the progression of patient's T2DM [12]. The factors underlying the non-attainment of these goals from a physician perspective are unclear, and an insight into these factors may assist in the understanding of the observed trends in glycemic control.

This study consisted of two components: the first was a retrospective study using a large US integrated-claims database to (a) estimate the proportion of patients with T2DM treated with basal insulin (alone or in combination with other injectables) achieving HbA1c and FBG targets in a real-world setting, and (b) investigate the treatment patterns of those patients who do not achieve these targets; the second component was an internet-based survey conducted among physicians to (a) better understand patient management from a physician's perspective, (b) ascertain the physicians' opinions as to why patients do not achieve glycemic targets despite basal insulin use, and (c) ascertain the characteristics and beliefs of the physicians of patients who do achieve glycemic targets.

2. Methods

2.1. Study

The study consisted of two components: a retrospective analysis of administrative claims data from the HealthCore Integrated Research Database℠ (HIRD; HealthCore Inc., Wilmington, DE, USA), and a cross-sectional survey of physicians who used basal insulin to treat patients with T2DM and who had claims in the HIRD. The HIRD includes medical and pharmacy claims data and enrollment information for approximately 38 million patients associated with a large US private payer, and diagnostic laboratory testing results for over 11 million patients.

2.2. Retrospective database analysis

2.2.1. Study design and patients

Inclusion criteria for this analysis were: adult patient aged ⩾18 years; ⩾1 inpatient/emergency department (ED) medical claim or ⩾2 outpatient visits and a diagnosis of T2DM (ICD-9-CM diagnosis codes: 250.x0 or 250.x2) [13]; ⩾2 pharmacy claims for basal insulin therapy (insulin glargine 100 units/mL, insulin detemir, or NPH insulin) from July 2006 through September 2012; and continuous medical coverage (including both commercial and Medicare Advantage plans) 6 months before index date (baseline period) and 12 months after the index date (observation period).

The index date was defined as the date of the first filled prescription for basal insulin during the period July 2006 through September 2012. Patients were grouped into two cohorts: new initiators, defined as patients without any claims for basal insulin or any other injectable antidiabetes therapy during the baseline period, and ongoing users, defined as patients with ⩾1 claim for basal insulin during the baseline period (patients with claims for other injectable antidiabetes therapies in addition to basal insulin were also included). Baseline characteristics were assessed over the baseline period and included demographic data, comorbidities, and medication utilization.

Data assessed during the baseline period and at months 3, 6, and 12 of the 12-month observation period following the index date included treatment patterns (use of basal insulin [insulin glargine 100 units/mL, insulin detemir, or NPH insulin], short-acting [regular] insulin, rapid-acting [insulin aspart, insulin lispro, insulin glulisine], pre-mix insulin, OADs, and non-insulin injectables) and HbA1c and FBG goal attainment (in those patients with available laboratory results). The 3-, 6- and 12-month timeframes were defined