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Trends in the use and cost of human and analogue insulins in a Colombian population, 2011–2015

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ABSTRACT

Objectives: Diabetes mellitus is a common disease among the general population and imposes considerable costs on health care systems. Insulin is used to treat type 1 diabetes mellitus and as an adjuvant to oral agents in advanced stages of type 2 diabetes mellitus. The objective was to describe the trends in use and cost of human and analogue insulins for Colombian patients.

Study design: Descriptive retrospective analysis of prescriptions of human and analogue insulins on a monthly basis for the period from July 1, 2011 to February 2, 2015.

Methods: Information was collected for the database population of two insurance companies. Frequencies and proportions were calculated; estimated economic impact was expressed as net cost and cost per thousand inhabitants per day.

Results: During the observation period, there was continuous growth in use of insulin, mainly in analogue forms (34.0% growth). At the start of the study, 10.4% of subjects were using an analogue insulin; this figure was 62.6% at the end of the study. In 2012, the average cost per 1000 inhabitants/day was US$1.7 for analogue and US$0.8 for human insulins. At the end of the observation period these costs had risen to US$9.2 for analogue (441.1% increase) and fallen to US$0.5 for human insulin (58.3% decrease).

Conclusions: There has been an increase in the unit cost and frequency of use of insulin analogues for anti-diabetic therapy in Colombian patients. Moreover, there is controversy over whether insulin analogues are a more cost-effective treatment than human insulins for the general diabetic population.

Introduction

Diabetes mellitus (DM) is a common disease among the general population and imposes considerable costs on health care systems.[1] Insulin is used to treat type 1 diabetes mellitus (DM-1) and as an adjuvant to oral agents in advanced stages of type 2 diabetes mellitus (DM-2), the most prevalent.[2,3] Since the early 1980s, it has been possible to treat DM using a molecule

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identical to human insulin which is obtained by recombinant DNA techniques; more recently structurally modified insulin analogues with specific pharmacokinetic properties have become available. These drugs have more immediate or longer-lasting effects and offer patients greater flexibility in administration.[3–5] Both insulin analogues and conventional insulin produce significant reductions in glycosylated hemoglobin (HbA1c), and there are no statistically significant differences between the molecules in terms of mortality, morbidity, or quality of life in patients with DM-2.[4,5] Although analogues appear to be associated with lower rates of overall and nocturnal hypoglycemia, they are significantly more expensive.[4,5] In patients with DM-1, there were no differences in the rates of severe hypoglycemia (human insulin: 166 cases per 1000 vs short-acting analogues 150 per 1000 patient year; odds ratio 0.89, 95% confidence interval: 0.71-1-12).[6]

Comparisons of the cost effectiveness of ultrashort-acting insulins (aspartat, lispro, and glulisine) with standard insulin have shown that the extra cost is about US$23,000 per quality-adjusted life year. Similarly, ultra-long-acting (glargine, detemir) can cost an extra US$69,471 per quality-adjusted life year for patients with DM-1 and an extra US$508,003 for those with DM-2.[4,7] The costs of treatment of diabetes mellitus have been increasing not only by the increase in the number of patients with the disease but also by the use of more aggressive and effectiveness measures to reduce glycemia and mainly to the use of insulin analogues.[8,9]

The Health System of Colombia (SGSSS) provides universal health insurance, affiliates can subscribe to the Compulsory Health Plan (POS), which entitles them to certain processes, technologies, and medicines.[10] From 2012, the drug list was expanded to include various insulin analogues, which led to debate about the relationship between costs safety, in particular the risk of hypoglycemia, and effectiveness for the new drugs.[11,12] It has been noted that the new molecules have been used indiscriminately, not just in patients at increased risk of hypoglycemia. This led to the proposal to describe the changes in prescription practice and cost with respect to human insulins and insulin analogues for patients treated in the SGSSS between 2011 and 2015.

Methods

This was a retrospective, observational study of prescribing practice with respect to human and analogue insulins. Information was collected for the database population of two insurance companies or health promoting entities (EPSs) of the payment/tax health care regime in Colombia. Monthly data on insulin prescriptions for all patients were collected from the company that provides the pharmaceutical service (Audifarma SA) for the period from July 1, 2011 to February 28, 2015.

Prescription information for all patients was extracted from an Oracle database using the application Business Objects. A Microsoft Windows 2013 Excel database including the following variable was then developed and confirmed by the researchers:

Sociodemographic variables: age, sex, and home town.

Pharmacological variables: (a) human insulin: zinc isophane insulin, zinc human insulin; (b) analogue insulins: aspartat insulin, detemir insulin, glargine insulin, glulisine insulin, and lispro insulin. Insulin usage was expressed in defined daily doses (DDDs) and the change in consumption in DDD per 1000 inhabitants per day, the index recommended by the World Health Organization for pharmacoepidemiological studies.

The protocol was classified as 'research without risk' according to Resolution No. 008430 of 1993 of the Ministry of Health of Colombia, which establishes the scientific, administrative, and technical standards for health research in accordance with the Declaration of Helsinki.

The data were analyzed with SPSS Statistics, version 22.0 for Windows (IBM, USA). Frequencies and proportions were calculated; estimated economic impact was expressed as net cost and cost per thousand inhabitants per day (CHD = [cost/30 × No. inhabitants] × 1000) in US dollars (based on a representative exchange rate between the US dollar the Colombian peso according to the official market given by Banco de la Republica the last day of each month).

Results

At the beginning of the observation period, the two EPSs had a combined total of 2,218,016 members; by February 2015, this figure had reached about 2,839,300, an increase of 21.9%. The mean age of patients with prescriptions for insulin was 59.2 ± 16.4 years (range: 1–104 years) of whom 65.4% were men; this sample was distributed across 46 different cities with populations of between 30,000 and 7.5 million, including Bogota, Medellin, Cali, Cartagena, Barranquilla, Manizales, and Pereira.

During the observation period, there was continuous growth in the use of insulin, primarily in the analogue forms. Before starting the observation (second half 2011), 9030 patients had a prescription for some form of insulin, 89.6% were prescribed some form of human insulin and 10.4% an analogue insulin. At the end of the observation period in February 2015, a total of 13,708 subjects had prescriptions for insulin (34.0% increase) of which 62.6% were for analogue insulins and 37.4% for human insulins. Fig. 1A shows the increase in prescriptions for analogue and human insulin in DDD per 1000 inhabitants/day, and Fig. 1B shows evolution discriminated per each insulin.

Before 2012, when analogue insulins were added to the POS, the two EPSs paid US$111,611 and US$53,751 per month for analogue and human insulins, respectively, although there were more prescriptions for the latter (Fig. 1A). Throughout the entire observation period, there was an upward trend in the total cost of prescriptions for analogue insulins until December 2013, when the national government introduced price regulations. In February 2015, the monthly cost stood at US$567,629 (an increase of 408.5%), mainly due to an increase in prescriptions for insulin glargine (US$370,584), whereas the monthly cost of human insulin had fallen to US$33,994 (36.7% reduction).

Before the new insulins were added to the POS (in 2012), the two EPSs were paying an average of US$1.7 per 1000 inhabitants/day for them, mainly for insulin glargine (US$1.2), whereas the cost of human insulin was US$0.8 per 1000 inhabitants/day. At the end of the observation period, February