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Impact of hypoglycaemia on patient-reported outcomes from a global, 24-country study of 27,585 people with type 1 and insulin-treated type 2 diabetes

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ABSTRACT

Aims: Data on the impact of hypoglycaemia on patients' daily lives and diabetes self-management, particularly in developing countries, are lacking. The aim of this study was to assess fear of, and responses to, hypoglycaemia experienced by patients globally.

Materials and methods: This non-interventional, multicentre, 4-week prospective study using self-assessment questionnaires and patient diaries consisted of 27,585 patients,

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≥18 years, with type 1 diabetes (n = 8022) or type 2 diabetes (n = 19,563) treated with insulin for >12 months, at 2004 sites in 24 countries worldwide.

Results: Increased blood glucose monitoring (69.7%) and seeking medical assistance (62.0%) were the most common responses in the 4 weeks following hypoglycaemic events for patients with type 1 diabetes and type 2 diabetes, respectively. Approximately 44% of patients with type 1 diabetes or type 2 diabetes increased calorie intake in response to a hypoglycaemic episode. Following hypoglycaemia, 3.9% (type 1 diabetes) and 6.2% (type 2 diabetes) of patients took leave from work or study. Regional differences in fear of, and responses to, hypoglycaemia were evident – in particular, a lower level of hypoglycaemic fear and utilisation of healthcare resources in Northern Europe and Canada.

Conclusions: Hypoglycaemia has a major impact on patients and their behaviour. These global data for the first time reveal regional variations in response to hypoglycaemia and highlight the importance of patient education and management strategies.

1. Introduction

Tight glycaemic control achieved through intensive insulin regimens has been shown to reduce the risk of long-term complications of diabetes and is often the goal of treatment for both type 1 and type 2 diabetes [1–4]. However, insulin therapy, and particularly intensive insulin therapy, is associated with an increased risk of hypoglycaemia [1–3]. Hypoglycaemia, in addition to morbidity and mortality, is associated with a reduction in health-related quality of life, increased fear and anxiety, reduced productivity and increased healthcare costs through increased utilisation of healthcare resources and blood glucose monitoring [5–8]. As a result, patients may take compensatory actions in order to avoid hypoglycaemia, such as reducing their insulin dose, reducing exercise levels or increasing their calorie intake [9,10], which can lead to poor glycaemic control.

Currently, the majority of data on the prevalence of hypoglycaemia and its consequences come from industrialised Western countries [1,7,9–13], with multinational studies focusing on economies with advanced healthcare systems. Estimates of the frequency of hypoglycaemia are 3.5–7.2 events/month (42–91 events per patient-year [PPY]) for type 1 diabetes [6,8,10,14] and 0.8–4.0 events/month (20.3–44.4 events PPY) for type 2 diabetes [6,8,10,14–17], and rates of hypoglycaemia increase with duration of disease and duration of insulin treatment [18]. Increasing frequency of non-severe hypoglycaemic events has been reported to lead to an increased risk of severe hypoglycaemic events [19,20]. Severe hypoglycaemia, defined by the American Diabetes Association (ADA) as requiring third-party assistance [21], accounts for significant medical expenditure due to hospitalisation [22–24] and a lower health-related quality of life [9], as well as increased mortality risks [11,12]. It is not surprising that patients respond to hypoglycaemia by taking compensatory actions to avoid future occurrences [7].

Until now, the impact of hypoglycaemia on patient behaviour has not been ascertained on a truly global level due to a requirement for systematic data capture, involving a large number of patients from different countries. Comparing potential country-specific differences based on current data remains difficult due to differences between individual study designs.

In this study, we report on patient fear of, and responses to, hypoglycaemia from the Hypoglycaemia Assessment Tool (HAT) study – a global, 4-week prospective study of hypoglycaemia in clinical practice.

2. Research design and methods

2.1. Study design

This study was a non-interventional, multicentre, 4-week prospective-cohort survey of hypoglycaemic events conducted across 2004 sites in 24 countries (Argentina, Austria, Bulgaria, Canada, Croatia, Czech Republic, Denmark, Finland, Germany, Hungary, India, Israel, Lebanon, Malaysia, Mexico, The Netherlands, Poland, Romania, Russia, Saudi Arabia, Serbia, Slovakia, Slovenia, and Sweden). The study was conducted from 2012 to 2013 in a staggered fashion (start times varied by country). The study protocol and assessments were conducted in accordance with the Declaration of Helsinki (2004) and the International Conference on Harmonization Guidelines for Good Clinical Practice (1996), and approved by country-specific regulatory agencies.

2.2. Study population

Consecutive eligible patients were enrolled during a routine scheduled clinical consultation with their healthcare provider. Eligible patients were ≥18 years of age at the time of enrolment, with type 1 diabetes or type 2 diabetes treated with insulin for >12 months. Exclusion criteria included non-ambulatory patients, illiterate patients or patients otherwise unable to complete a written survey.

2.3. Study objectives

The primary endpoint was the proportion of patients experiencing at least one hypoglycaemic event during the 4-week observational period (detailed methodology and results in Khunti et al. [25]). This manuscript reports on patient knowl-