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Original Research

The Canadian Hypoglycemia Assessment Tool Program: Insights Into Rates and Implications of Hypoglycemia From an Observational Study

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ABSTRACT

Objective: The true prevalence of hypoglycemia in insulin-treated patients with diabetes and its impact on patients, employers and healthcare providers is poorly appreciated owing to a paucity of real-world data. The global Hypoglycemia Assessment Tool (HAT) study addressed this issue, and here we report data from the Canadian cohort of patients.

Methods: This noninterventional, 6-month retrospective and 4-week prospective study enrolled patients aged ≥ 18 years receiving insulin treatment for >12 months from community endocrinology practices. Data were collected using self-assessment questionnaires and patient diaries. The primary endpoint was the proportion of patients experiencing ≥ 1 hypoglycemic event during the 4-week prospective observational period.

Results: Four hundred ninety-eight patients with type 1 diabetes ($n=183$) and type 2 diabetes ($n=315$) were enrolled. The prevalence of hypoglycemia was similar in the retrospective (type 1 diabetes, 92.3%; type 2 diabetes, 63.5%) and prospective (type 1 diabetes, 95.2%; type 2 diabetes, 64.2%) periods. Prospective rates of any, nocturnal and severe hypoglycemia per patient-year (95% confidence interval) were 69.3 (66.4; 72.2), 14.2 (12.9; 15.6) and 1.8 [1.4; 2.4]. Higher rates were reported retrospectively, reaching significance for nocturnal hypoglycemia per patient-year (30.0 [28.1; 32.0] vs. 14.2 [12.9; 15.6]; $p<0.001$). Hypoglycemia led to increased healthcare utilization and absenteeism and was associated with potentially harmful self-care behaviours (e.g., reduced or skipped insulin doses) and increased blood glucose self-monitoring.

Conclusions: Prevalence and incidence of hypoglycemia were high among insulin-treated patients with diabetes in Canada, and some patients took harmful or costly actions when they experienced hypoglycemia. Identifying the insulin-treated patients who are at greatest risk may help to reduce the incidence of hypoglycemia.

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R É S U M É

Objectif : La prévalence réelle de l'hypoglycémie chez les patients diabétiques sous insuline et ses répercussions sur les patients, les employeurs et les fournisseurs de soins de santé sont mal caractérisées en raison d'un manque de données factuelles. L'étude HAT (*Hypoglycemia Assessment Tool*) a permis d'aborder cette question à l'échelle mondiale, et nous présentons ici les données issues de la cohorte de patients canadiens.

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Méthodologie : Cette étude non interventionnelle, rétrospective durant 6 mois et prospective durant 4 semaines, a été menée chez des patients de 18 ans ou plus sous insuline depuis plus de 12 mois qui étaient traités par des endocrinologues communautaires. Les données ont été recueillies au moyen de questionnaires d'auto-évaluation et de journaux remplis par les patients. Le paramètre d'évaluation principal était la proportion de patients chez qui survenait au moins 1 épisode hypoglycémique pendant la période d'observation prospective de 4 semaines.

Résultats : Au total, 498 patients atteints de diabète de type 1 (n=183) ou de type 2 (n=315) ont été admis à l'étude. La prévalence de l'hypoglycémie a été semblable au cours des périodes rétrospective (diabète de type 1 : 92,3 %; diabète de type 2 : 63,5 %) et prospective (diabète de type 1 : 95,2 %; diabète de type 2 : 64,2 %). Les taux prospectifs d'hypoglycémie tous types confondus, nocturne ou grave par année-patient (intervalle de confiance à 95 %) ont atteint 69,3 (66,4–72,2), 14,2 (12,9–15,6) et 1,8 (1,4–2,4). Les taux signalés rétrospectivement étaient plus élevés, et ils se sont révélés significatifs dans le cas de l'hypoglycémie nocturne par année-patient (30,0 [28,1–32,0] vs 14,2 [12,9–15,6]; $p < 0,001$). L'hypoglycémie a entraîné une augmentation de l'utilisation des ressources de soins de santé et de l'absentéisme, en plus d'être associée à des comportements potentiellement dangereux en matière d'autosoins (p. ex. réduction ou omission de doses d'insuline) et à une autosurveillance glycémique accrue.

Conclusions : La prévalence et l'incidence de l'hypoglycémie étaient élevées chez les patients diabétiques sous insuline au Canada, et certains patients ont pris des mesures dangereuses ou coûteuses en présence d'hypoglycémie. Le repérage des patients sous insuline exposés à un risque plus élevé peut aider à réduire l'incidence de l'hypoglycémie.

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Introduction

Insulin therapy is essential in the management of type 1 diabetes and is often required in type 2 diabetes to restore glycemic control and reduce the risks of comorbidities and mortality accompanying high blood glucose (BG). Hypoglycemia is common when insulin treatment is intensified and is a consideration when insulin strategies and glycemic targets are selected (1). Hypoglycemia is a major concern for patients living with diabetes (2), who may take actions to reduce the incidence of hypoglycemia (3), which has been associated with fear, anxiety and depression (4,5), reduced health-related quality of life, reduced productivity and increased health-care costs (6–8).

Although the implications of hypoglycemia are understood, the scale of the problem remains unknown as there are few studies reporting rates of hypoglycemia in insulin-treated patients managed according to real-world clinical practice. Much of our hypoglycemia incidence data has emerged from clinical trials that enroll patients who are more motivated and health literate, exclude patients with comorbidities and history of frequent or severe hypoglycemia, randomize patients to compare different treatments or treatment algorithms, and titrate doses to achieve common treatment targets rather than individualized glycemic targets. One recent review in which real-world and clinical trial settings were compared revealed higher rates of hypoglycemia in real-world reports (9).

The global Hypoglycemia Assessment Tool (HAT) study was designed to collect information from 27,585 insulin-treated patients with type 1 or type 2 diabetes in real-world clinical practice in 24 countries and showed higher than expected rates of hypoglycemia with significant geographic variation (10). The aims of this analysis were to determine the real-world incidence and impact of hypoglycemia and to investigate predictors of hypoglycemia in Canadian patients with insulin-treated type 1 and type 2 diabetes.

Methods

Study design

The current analysis evaluates data from a Canadian cohort of insulin-treated patients enrolled in the global HAT study – a

noninterventional, multicentre, retrospective and prospective survey of hypoglycemia in patients with type 1 and type 2 diabetes. The HAT study design and patient population have been described previously (10).

Study population

Patients were enrolled through consecutive sampling during routinely scheduled consultations with their healthcare providers (HCPs). Eligible patients were ≥ 18 years of age and had insulin-treated type 1 or type 2 diabetes for > 12 months. Patients excluded were those who were nonambulatory or illiterate. Patients were not paid for their participation.

Assessments

The study comprised a 2-part self-assessment questionnaire (SAQ). Part 1 was a cross-sectional, retrospective assessment completed at baseline, recording demographic and treatment information, knowledge and perceptions of hypoglycemia, as well as history of nonsevere hypoglycemia and severe hypoglycemia over the previous 4 weeks and 6 months, respectively. Part 2 evaluated the occurrence of severe and nonsevere hypoglycemia over the 4 weeks after baseline. Patients were provided with a diary to record hypoglycemia during the 4-week prospective period. If hypoglycemic events were reported at a higher rate in the patient diary versus the SAQ, diary values were used to calculate hypoglycemia prevalence to compensate for potential recall bias. Data are presented from the full analysis set (Part 1) and completers' analysis set (Parts 1 and 2).

Study objectives

The primary objective was to evaluate the proportion of patients experiencing ≥ 1 hypoglycemic event during the 4-week prospective period. Secondary objectives included incidence of hypoglycemia (any, nocturnal, severe and nonsevere), relationship between glycated hemoglobin (A1C) and hypoglycemia (including proportion of patients with A1C $< 7.0\%$ [53 mmol/mol], 7.0% to 9.0% and $> 9.0\%$ [75 mmol/mol] in the 4 weeks after baseline). Response to hypoglycemia in the 4 weeks after baseline was measured by investigating the proportion of patients consulting their doctor/nurse, reducing exercise, reducing insulin dose, skipping insulin dose or

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