

# Hypoglycaemia assessment tool (HAT) study: subanalysis of the Lebanese cohort

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## Abstract

**Background:** Diabetic hypoglycaemia affects medication adherence, patients' productivity and quality of life. It is also associated with an increased risk of cardiovascular complications.

**Aims:** To examine the impact of hypoglycaemia in insulin-treated patients in the Lebanese cohort of the Hypoglycaemia Assessment Tool (HAT) study.

**Methods:** The HAT study was an observational study covering a 6-month retrospective and a 4-week prospective period in 24 countries including Lebanon. Data were collected using self-assessment questionnaires and patient diaries from 1158 invited Lebanese patients, aged  $\geq 18$  years, with type 1 or type 2 diabetes mellitus (T1DM/T2DM) treated with insulin for  $> 12$  months. The primary endpoint was the proportion of patients experiencing  $\geq 1$  hypoglycaemic event during the 4-week follow-up period.

**Results:** After 4 weeks of follow-up, 177/225 [78.7%; 95% confidence interval (CI): 72.7–83.8] of patients with T1DM and 291/630 (46.2%; 95% CI: 42.2–50.2) patients with T2D experienced at least 1 hypoglycaemic event. Rates of nocturnal and severe hypoglycaemia were 10.7 (95% CI: 9.1–12.3) and 13.2 (95% CI: 11.5–14.9) events/patient-year for T1DM, and 3.3 (95% CI: 2.8–3.8) and 4.2 events/patient-year (95% CI: 3.6–4.8) for T2DM, respectively. Fear of hypoglycaemia was significantly associated with nocturnal and severe hypoglycaemia in both diabetes types ( $P < 0.001$ ).

**Conclusion:** The results suggest that the less-advanced healthcare systems in Lebanon are implicated in lower levels of patient knowledge about hypoglycaemia and related preventive measures. Treatment strategies and glycaemia goals should be individualized according to patient preference, medical benefits, and risk of hypoglycaemia.

Keywords: diabetes, hypoglycaemia, insulin, nocturnal hypoglycaemia, severe hypoglycaemia.

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## Introduction

Diabetes is a worldwide health problem associated with serious morbidity, mortality, and considerable economic burdens (1). The prevalence of type 2 diabetes mellitus (T2DM) in Lebanon was reported to be high (8.5%) between 2008 and 2009 (2), including many Lebanese patients who were not adequately controlled or followed up according to the International Diabetes Management Practices Study (3). As reported in that study, 22.6% of the Lebanese patients were treated with insulin; most commonly basal insulin alone followed by premix insulin alone.

Insulin is the cornerstone of therapy for patients with type 1 diabetes mellitus (T1DM) and it is among the major therapeutic classes recommended for treating type 2 DM (T2DM). However, different studies have shown an association between insulin therapy and increased risk of hypoglycaemia (4,5), in which 25–30% of insulin-treated patients with diabetes had 1 or more severe hypoglycaemic episodes every year (6). The Diabetes Complications and Controls Trial found that intensive therapy in patients

with T1DM caused a 3-fold increase in the number of hypoglycaemic events, compared with those treated less aggressively (7). Hypoglycaemia is a common adverse effect of insulin (8), and is a hindrance to achieving treatment goals in T1DM and T2DM (4, 9). This has driven the American Diabetes Association (ADA) Standards of Medical Care in Diabetes – 2017 to recommend a less-stringent, glycated haemoglobin (HbA1c) goal of  $< 8\%$  in patients with a history of severe hypoglycaemia (10).

Hypoglycaemia affects medication adherence, patients' productivity (11), and quality of life at the mental, physical and social functioning levels (12). It also places a heavy burden on healthcare systems (12). Pai-Feng Hsu et al. showed that clinically severe or mild hypoglycaemia is associated with an increased risk of cardiovascular events, all-cause hospitalization, and all-cause mortality (13). Various studies have reported that hypoglycaemia is associated with higher risks of cardiovascular complications (14–16).

Data available from clinical trials are not enough to address the problem of hypoglycaemia. Also, lack of real-

world data on hypoglycaemia in Lebanon necessitates the conduct of a large-scale study to assess the problem of hypoglycaemia in terms of rates, risk factors, and at-risk patients, and utilizing these data in clinical practice. The aim of the Hypoglycaemia Assessment Tool (HAT) study was to examine the impact of hypoglycaemia in an insulin-using global patient population (which includes the Lebanese cohort) in an epidemiological observational study covering a 6-month retrospective and 4-week prospective time periods.

## Methods

### Study design and ethical considerations

This study was a noninterventional, multicentre, 4-week 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, Netherlands, Poland, Romania, Russian Federation, Saudi Arabia, Serbia, Slovakia, Slovenia, and Sweden) from 2012 to 2013 in a staggered fashion (start time varied by country). The same protocol was followed across all participating countries. The study used self-assessment questionnaires (SAQs) and patient diaries where all study materials were translated into local languages and collected data were translated into English for analysis. The study protocol and assessments were conducted in accordance with the Declaration of Helsinki (2004) and the International Conference on Harmonisation Guidelines for Good Clinical Practice (1996), and approved by country-specific regulatory agencies and ethics committees. Informed consent was obtained from all individual participants included in the study.

### Study population

Inclusion criteria consisted of patients with T1DM or T2DM, aged  $\geq 18$  years, being treated with insulin for  $> 12$  months, and who had given informed consent to participate in the study. Nonambulatory patients, illiterate patients and patients unable to complete a written survey were excluded. Eligible patients were enrolled consecutively during a routinely scheduled clinical consultation with their healthcare provider.

### Ethical approval and consent to participate

The study protocol and assessments were conducted in accordance with the Declaration of Helsinki (2004) and the International Conference on Harmonisation Guidelines for Good Clinical Practice (1996), and approved by country-specific regulatory agencies and ethics committees. Informed consent was obtained from all individual participants included in the study.

### Study endpoints

The primary endpoint was to determine the proportion of patients experiencing at least 1 hypoglycaemic event during the 4-week follow-up period. Secondary endpoints included: hypoglycaemia rates, HbA1c level at baseline,

relationship between HbA1c and hypoglycaemia, including proportion of patients with HbA1c  $< 7.0\%$  (53 mmol/l) and  $> 9.0\%$  (75 mmol/l) with or without hypoglycaemia, and relationship between hypoglycaemia and factors such as age, fear of hypoglycaemia, disease duration and duration of insulin use.

### Assessments

This study was based on a 2-part SAQ. Part 1 was introduced upon patient entry and it recorded baseline demographics, treatment information, as well as history of severe hypoglycaemia over the last 6 months and non-severe hypoglycaemia over the previous 4 weeks. Part 2 was completed 4 weeks after baseline visit and recorded the occurrence of both severe and nonsevere hypoglycaemia during these 4 weeks. In order to improve patients' recall, they were provided with a diary, which was also used to record hypoglycaemic events. If a patient recorded more hypoglycaemic events using the patient diary than the SAQ Part 2, the patient diary value was used to calculate prevalence of hypoglycaemia in the 4 weeks after baseline.

### Hypoglycaemia classification

Nonsevere hypoglycaemia was defined as an event managed by patients alone; severe hypoglycaemia was defined based on the ADA definition, as any hypoglycaemic event requiring assistance of another person to administer carbohydrate, glucagon or other resuscitative actions (17); and nocturnal hypoglycaemia was defined as any event occurring between midnight and 06:00 hours. These 3 categories of hypoglycaemia were included in the SAQ and the patient diary. Combined measures of hypoglycaemia refer to the sum of all individual hypoglycaemic events, and were calculated based on data collected from the patient diary and questionnaire.

### Sample size and statistical analyses

To calculate the percentage of patients experiencing a hypoglycaemic event with a 95% confidence interval (CI) precision, a sample size of approximately 12 000 patients was selected. Taking into consideration a 37% response rate in SAQ Part 2, the total number of patients was estimated to be around 32 000. In Lebanon, 1158 patients were invited to participate in the study based on convenience sampling, accounting thus for 3.6% of the overall study cohort.

For the primary endpoint, the percentage of patients experiencing any hypoglycaemia during the 4-week follow-up period was calculated along with its 95% CI. For the secondary endpoints of severe or nocturnal hypoglycaemic events, the number and proportion of patients having an event, number of events, follow-up time (patient-years), estimated hypoglycaemia rate with corresponding 95% CI, and number of patients missing were reported for the 4 weeks after baseline.

Univariate negative binomial regression models were used to examine the relationship between hypoglycaemia and the following factors: age; sex; HbA1c in Mmol/mol

and percentage; duration of diabetes in years; duration of insulin therapy in years; type of insulin therapy; frequency of blood glucose testing in average number of checks per day; knowledge of hypoglycaemia (i.e., knowing what hypoglycaemia is before reading the definition in the SAQ introduction); fear of hypoglycaemia; study period (prospective/retrospective); and diabetes type. These models were based on the complete analysis set (patients who completed SAQ Part 2) and were stratified by country, specifying a log-transformed exposure time offset term and adjusted for all variables in the model. The statistical significance was two-sided and set at  $P < 0.05$ .

All other variables are presented descriptively only, with the mean and 95% CI being presented. No imputation of missing data was performed.

## Results

### Population characteristics

Out of 1158 patients invited to participate in the study, 905 (78.2%) (250 with T1DM and 655 with T2DM) were recruited and completed SAQ Part 1. Out of those recruited, 851 patients (94%) (222 with T1DM and 629 with T2DM) completed SAQ Part 2 and 837 patients (92.5%) (224 with T1DM and 613 with T2DM) completed the patient diary. All patients were followed up by endocrinologists.

Both types of diabetes were almost equally distributed among the sexes (male/female: 54.2/45.8% with T1DM vs 48/52% with T2DM). Patients with T2DM were older ( $60.5 \pm 11.0$  years) than those with T1DM ( $35.2 \pm 15.9$  years) and had a longer disease duration ( $14.6 \pm 8.0$  years vs  $12.8 \pm 8.8$  years, respectively). As expected, T1DM patients were using insulin for a longer period than T2DM patients were ( $11.8 \pm 8.7$  years vs  $5 \pm 4.1$  years). Mean HbA1c levels and percentage were almost similar in T1DM and T2DM patients [ $63.8 \pm 17.6$  Mmol/mol (8%) vs  $68.4 \pm 17.2$  mmol/mol (8.4%), respectively]. Most patients checked blood sugar levels [T1DM, 97.6% ( $n = 241$ ); T2DM, 90.5% ( $n = 588$ )] and reported experiencing at least 1 hypoglycaemic event [T1DM, 91% ( $n = 223$ ); T2DM, 80.3% ( $n = 521$ )].

### Reporting of hypoglycaemia

After 4 weeks of follow-up, among 225 T1DM patients, 177 experienced at least 1 hypoglycaemic event (78.7%; 95% CI: 72.7–83.8%); 70 experienced severe hypoglycaemia (31.1%; 95% CI: 25.1–37.6%); 167 experienced nonsevere hypoglycaemia (74.2%, 95% CI: 68.0–79.8%); and 90 experienced nocturnal hypoglycaemia (41.5%; 95% CI: 34.8–48.3%). Among 630 T2DM patients, 291 experienced at least 1 hypoglycaemic event (46.2%; 95% CI: 42.2–50.2%); 92 experienced severe hypoglycaemia (14.6%, 95% CI: 11.9–17.6%); 269 experienced nonsevere hypoglycaemia (42.8%, 95% CI: 38.9–46.7%); and 101 experienced nocturnal hypoglycaemia (16.3%; 95% CI: 13.5–19.5%). The estimated annual incidence rate of hypoglycaemic events requiring hospital admission at 4 weeks after baseline was 5.5% (95% CI: 2.9–9.4%) for patients with T1DM and 2.4% (95% CI: 1.3–3.9%) for patients with T2DM.

The estimated annual rate of any hypoglycaemic event was 73.7 (95% CI: 69.6–77.8) and 18.1 (95% CI: 16.9–19.3) events/patient-years for patients with T1DM and T2DM, respectively. For nonsevere hypoglycaemia, the estimated annual rate was 60.5 (95% CI: 56.9–64.3) and 13.9 (95% CI: 12.8–15.0) events/patient-years for patients with T1DM and T2DM, respectively. For nocturnal hypoglycaemia, the estimated annual rate was 10.7 (95% CI: 9.1–12.3) and 3.3 events/patient-years (95% CI: 2.8–3.8) for patients with T1DM and T2DM, respectively. For severe hypoglycaemia, the estimated annual rate was 13.2 (95% CI: 11.5–14.9) and 4.2 events/patient-years (95% CI: 3.6–4.8) for patients with T1DM and T2DM, respectively. The estimated annual incidence rate of hypoglycaemic events requiring hospital admission at 4 weeks after baseline was 0.8 (95% CI: 0.4–1.3) for patients with T1DM and 0.3 (95% CI: 0.2–0.5) for patients with T2DM.

### Factor associated with hypoglycaemia

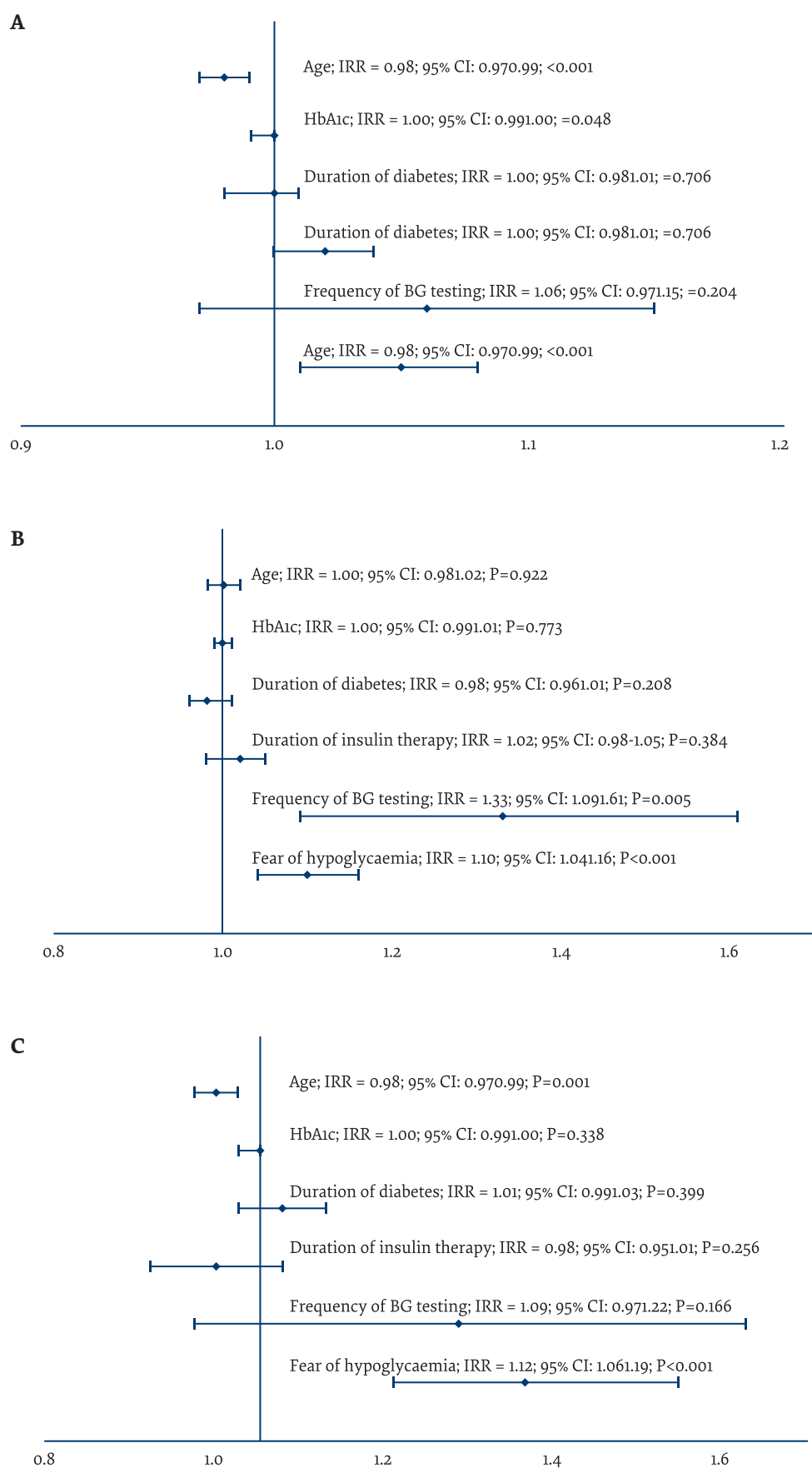
The relationship between any, nocturnal or severe hypoglycaemia and age, HbA1c, duration of diabetes, duration of insulin use, and fear of hypoglycaemia (as indicated on a 10-point scale) was studied using fully adjusted negative binomial modelling. Older age of patients with either type of DM was significantly associated with a reduced risk of any hypoglycaemia ( $P < 0.001$ ) and nocturnal hypoglycaemia ( $P = 0.001$ ) (Figure 1). As fear of hypoglycaemia increased, the risk of any hypoglycaemia ( $P = 0.014$ ) and nocturnal hypoglycaemia ( $P < 0.001$ ) increased significantly. Similarly, fear of hypoglycaemia was significantly associated with severe hypoglycaemia in both T1DM and T2DM patients ( $P < 0.001$ ). Among 52 T1DM patients and 75 T2DM patients with HbA1c  $< 7\%$  at baseline, 44 (84.6%) and 35 (46.7%) had any hypoglycaemia in the 4 weeks after baseline, respectively. The association between different baseline levels of HbA1c and proportion of patients with any hypoglycaemia is shown in Figure 2.

## Discussion

The aim of our study was to determine the percentage of insulin-treated patients with T1DM or T2DM experiencing at least 1 hypoglycaemic event during a 4-week observational period, and to study the relationship between hypoglycaemia and other factors. Among T1DM patients, the prevalence of any, severe and nocturnal hypoglycaemia was 78%, 31% and 41%, respectively. In the Diabetes Complications and Controls Trial, the annual prevalence of severe hypoglycaemia was 36% (18,19). In our study, the reported prevalence of severe hypoglycaemia among T1DM patients was within the range of 30–40% reported in other studies (20–23).

Among T1DM patients, the estimated annual rates were 73.7, 13.2 and 10.7 events/patient-year for any, severe and nocturnal hypoglycaemia, respectively. The estimated annual rate of severe hypoglycaemia was considerably greater than in other studies (0.7–1.59 episodes/patient-year) (24,25). Two studies done in the United Kingdom of Great Britain and Northern Ireland (UK) reported a severe hypoglycaemia rate of 1.15–3.2

**Figure 1** Fully adjusted negative binomial modelling of the associations between patient characteristics and incidence rate ratios for (A) any, (B) severe or (C) nocturnal hypoglycaemia ( $n = 680$ ).



BG = blood glucose; CI = confidence interval; HbA1c = glycated haemoglobin; IRR = incidence rate ratio.



events/patient-year (23,26). A recent study involving 7 European countries (25) reported a rate of nocturnal hypoglycaemia among T1DM patients almost double (20 events/patient-year) that reported in our study.

Among T2DM patients, the prevalence of any, severe and nocturnal hypoglycaemia was 46%, 14.6% and 16.3%, respectively. The estimated annual rates were 18.1, 4.2 and 3.3 events/patient-year for any, severe and nocturnal hypoglycaemia, respectively. A recent meta-analysis of population-based studies reported that the prevalence of severe hypoglycaemia was 21% among insulin-using patients (27). The UK Hypoglycaemia Study reported mild hypoglycaemia rates of 10.2 events/patient-year and severe hypoglycaemia rates of 0.7 events/patient-year in patients with T2DM using insulin for > 5 years (23). Systematic reviews considering hypoglycaemia prevalence in randomized controlled trials involving patients with T2DM (28–31) reported that severe hypoglycaemia prevalence was <1%, which is substantially lower than our findings. In the Veterans Affairs Diabetes Trial involving T2DM patients, rates of any symptomatic hypoglycaemic episode were 383–1333 per 100 patient-years, whereas rates of severe hypoglycaemia were 3–9 per 100 patient-years (5). However, these differences should be carefully interpreted taking into consideration the aspects of randomized controlled trials as they do not often reflect real-life situations. The estimated annual rate of nocturnal hypoglycaemia in T2DM patients falls within the range (0.2–13.4 events/patient-year) reported in a study by Elliott et al. (32).

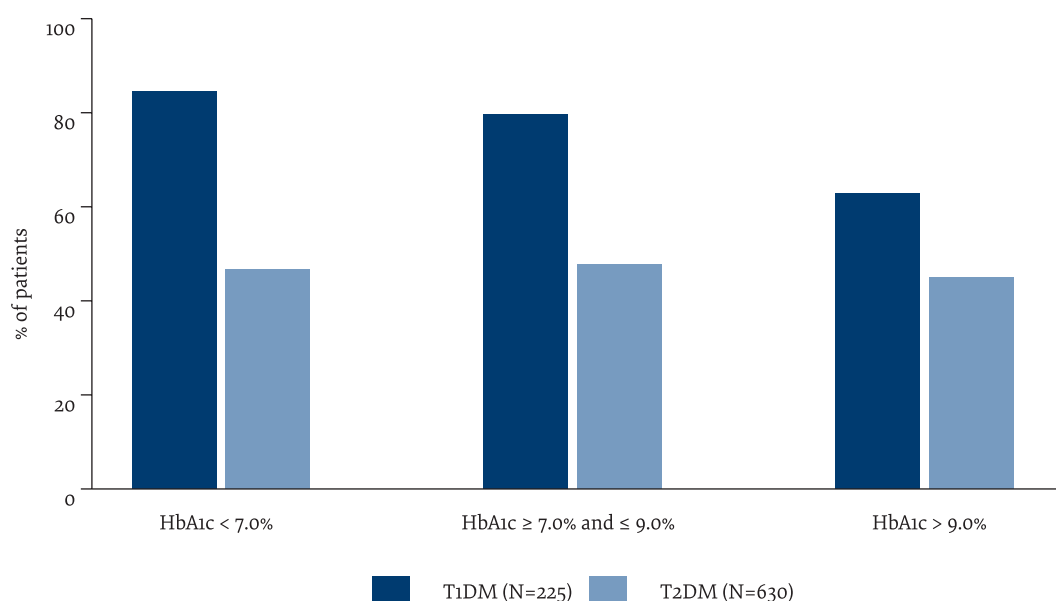
The rate of hypoglycaemia was expected to be higher in T1DM than in T2DM. This can be explained in the context of different treatment strategies for both types

of diabetes and different pathophysiology. In parallel, the counter-regulatory physiological defences against hypoglycaemia (decreases in insulin and increases in glucagon) are impaired in patients with diabetes with beta-cell failure. This failure is absolute in T1DM and more gradual in T2DM.

The higher rates of hypoglycaemia in both types of diabetes reported by our study can be explained differently. First, endocrinologists in Lebanon have low awareness on hypoglycaemia. Indeed, these specialists do not educate their patients about the risk of hypoglycaemia with insulin use, leading to lower levels of patients' knowledge about hypoglycaemia and related preventive measures. These observations reflect a less-advanced Lebanese healthcare system. Second, poor medical follow-up can result in higher rates of hypoglycaemia. A study done by Costanian et al. on the prevalence, correlates and management of T2DM in Lebanon found that adherence to management and self-care measures was suboptimal, resulting in high complication rates (2). Additionally, although the rate of glucose self-monitoring in the study was high (97.6% in T1DM and 90.5% in T2DM), the level of self-care was not adequate. Indeed, the patients were not aware of the risk of hypoglycaemia but were aware of hyperglycaemia, and frequent self-care is done to monitor hyperglycaemia rather than hypoglycaemia.

Although the results of the present study were lower or comparable to other findings, the impact of nocturnal hypoglycaemia should not be underestimated. Episodes of nocturnal hypoglycaemia may have been under-reported and undetected as patients may be unaware of such an event (32), because symptoms are

**Figure 2 Percentage of patients reporting hypoglycaemia during the prospective period stratified by baseline glycated haemoglobin level for patients with T1DM and T2DM.**



HbA1c = glycated haemoglobin; T1DM = type 1 diabetes mellitus; T2DM = type 2 diabetes mellitus.

absent during sleeping and glucose monitoring is rarely done at night (33). In T1DM patients, around 50% of all severe hypoglycaemic events occur during sleeping (18, 34). Additionally, nocturnal hypoglycaemia affects patient's well-being and sleep duration and quality (35). Furthermore, sudden nocturnal death, also known as death-in-the-bed syndrome, is associated with nocturnal hypoglycaemia and contributes to 5–6% of all deaths among young patients with T1DM (36, 37).

The rate of severe hypoglycaemia among patients with both types of DM was significantly high. Different studies have demonstrated that impaired awareness of hypoglycaemia is associated with higher rate of severe hypoglycaemia in T1DM (25) and T2DM (38). A recent large observational study reported an increased risk of mortality in the 12 months after a severe hypoglycaemic event (39). Moreover, neuroimaging has demonstrated transient cerebral deficits associated with neurological signs in patients who experience episodes of severe hypoglycaemia (40, 41). The Edinburgh Type 2 Diabetes study concluded that severe hypoglycaemia is associated with both poor initial cognitive ability and accelerated cognitive decline (42).

It has been shown that older patients are more vulnerable than younger patients to hypoglycaemia (43–45). This may be due to different comorbidity, polypharmacy, cognitive impairment, impairment in counter-regulatory hormone responses, and malnutrition (43, 46). In contrast to these previous studies, we found that older patients experienced lower rates of any and nocturnal hypoglycaemia. However, this may not reflect the reality as rates of hypoglycaemia are mainly under-reported in older patients. This is because such patients may be unfamiliar with the signs and symptoms of hypoglycaemia; loss of warning symptoms of hypoglycaemia (in older patients the threshold of autonomic symptoms of hypoglycaemia occurs at a lower blood glucose level); and cognitive impairment. In parallel, fear of hypoglycaemia was significantly associated with higher rates of any, severe and nocturnal hypoglycaemia. This is in line with the findings of a literature review that showed that patients' fear of future episodes causes

them to suffer from anxiety and panic attacks that further increase the number of hypoglycaemic episodes (47). However, fear of hypoglycaemia may eventually lead to suboptimum insulin therapy and poor glycaemic control (47).

To our knowledge, this is the first observational study that addresses the impact of hypoglycaemia among Lebanese patients with DM. Our study involved both types of DM, allowing the comparison between these subgroups. In contrast to clinical trials and physicians' case reports, observational studies allow collection of a wide variety of related data that more or less reflect real-world practice. Thus, more accurate estimations are made. The simplicity of the questionnaires may have contributed to the high completion rate.

Several limitations to our study should be considered. First, data collected through questionnaires and self-reporting are usually subjected to recall bias. Although patient diaries were used in addition to the questionnaire to minimize recall bias, this step introduced some sort of overestimation of hypoglycaemia rates. Second, the short prospective duration may not reflect the fluctuations in hypoglycaemia rates throughout a whole year. Third, willingness to participate and local literacy rates were likely to have affected patients' participation. Furthermore, the observational nature of the study does not allow us to draw a causal relationship between hypoglycaemia and most of the included variables.

## Conclusion

Further studies and analyses are required including a larger sample size for a longer prospective duration to detect the long-term impacts and associated complications of hypoglycaemia. Treatment strategies and glycaemia goals should be individualized according to patient preference, medical benefits, and risk of hypoglycaemia. Multidisciplinary integration among all healthcare providers is essential in educating patients about the definition of hypoglycaemia, associated substantial risks, treatment and preventive measures.

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**Competing interest:** None declared.

## Étude de l'outil d'évaluation de l'hypoglycémie : sous-analyse de la cohorte libanaise

### Résumé

**Contexte :** L'hypoglycémie chez les patients diabétiques affecte leur observance thérapeutique, leur productivité et leur qualité de vie. Elle est également associée à un risque accru de complications cardio-vasculaires.

**Objectifs :** Examiner l'impact de l'hypoglycémie chez les patients traités par insuline dans la cohorte libanaise faisant partie de l'étude de l'outil d'évaluation de l'hypoglycémie.

**Méthodes :** L'étude de l'outil d'évaluation de l'hypoglycémie était une étude d'observation couvrant une période rétrospective de six mois et une période prospective de quatre semaines dans 24 pays, y compris le Liban. Les données ont été recueillies à l'aide de questionnaires d'auto-évaluation et des journaux de bord de 1158 patients libanais, âgés de 18 ans et plus, atteints de diabète sucré de type 1 ou 2 traités par insuline depuis plus de 12 mois, qui avaient été invités à participer à l'étude. Le principal critère d'évaluation était la proportion de patients ayant connu un épisode d'hypoglycémie ou plus pendant la période de suivi de quatre semaines.

**Résultats :** Après quatre semaines de suivi, 177 des 225 patients atteints de diabète sucré de type 1 [78,7 % ; intervalle de confiance (IC) à 95 % : 72,7-83,8] et 291 des 630 patients atteints de diabète sucré de type 2 (46,2 % ; IC à 95 % : 42,2-50,2) ont connu au moins un épisode d'hypoglycémie. Les taux d'hypoglycémie nocturne et sévère étaient respectivement de 10,7 (IC à 95 % : 9,1-12,3) et 13,2 (IC à 95 % : 11,5-14,9) épisodes/patient-année pour le diabète sucré de type 1, et de 3,3 (IC à 95 % : 2,8-3,8) et 4,2 épisodes/patient-année (IC à 95 % : 3,6-4,8) pour le diabète sucré de type 2. La peur de l'hypoglycémie était associée de manière significative à une hypoglycémie nocturne et sévère dans les deux types de diabète ( $p < 0,001$ ).

**Conclusion :** Les résultats indiquent que les systèmes de soins de santé moins avancés au Liban contribuent à la faible connaissance des patients en matière d'hypoglycémie ainsi que les mesures préventives qui y sont liées. Les stratégies de traitement et les objectifs en matière de glycémie doivent être individualisés en fonction des préférences du patient, des avantages médicaux et du risque d'hypoglycémie.

### دراسة معنية بأداة تقييم نقص سكر الدم: تحليل فرعي لمجموعة أترابية من سكان لبنان

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#### الخلاصة

**الخلفية:** يؤثر نقص السكر في الدم بسبب داء السكري على مدى الامتثال للعلاج، وإنتاجية المريض، وجودة الحياة. كما يقترن أيضاً بزيادة مخاطر مضاعفات أمراض القلب والأوعية الدموية.

**الأهداف:** هدفت الدراسة إلى دراسة أثر نقص السكر في الدم في مجموعة أترابية من المرضى في لبنان من الذين يُعالجون بالأنسولين، وشملتهم الدراسة المعنية بأداة تقييم نقص السكر في الدم.

**طرق البحث:** شملت الدراسة المعنية بأداة تقييم نقص السكر في الدم دراسة رُصدية استرجاعية غطت فترة 6 أشهر، وأخرى استباقية غطت فترة 4 أسابيع في 24 بلداً، منها لبنان. وقد جُمعت البيانات باستخدام استبيانات التقييم الذاتي ويوميات المرضى من 1158 مريضاً لبنانياً تتراوح أعمارهم بين 18 عاماً وأكثر، من المصابين بالنمط 1 أو 2 من داء السكري الذين ظلوا يُعالجون بالأنسولين لمدة تزيد عن 12 شهراً. وكانت نقطة النهاية المبدئية هي نسبة المرضى الذين يحدث لهم نقص السكر في الدم مرةً واحدةً أو أكثر خلال فترة المتابعة التي تبلغ 4 أسابيع.

**النتائج:** تبين من المتابعة التي استمرت 4 أسابيع أن: 177 / 225 [78.7 %؛ بفواصل ثقة 95 %: 72.7-83.8] من المرضى المصابين بالنمط 1 من داء السكري، و 291 / 630 (46.2 %؛ بفواصل ثقة 95 %: 42.2-50.2) من المرضى المصابين بالنمط 2 من داء السكري حدث لهم نقص السكر في الدم مرة واحدة على الأقل. وقد بلغت معدلات النقص الليلي الحاد لسكر الدم 10.7 (بفواصل ثقة 95 %: 9.1-12.3) و 13.2 (بفواصل ثقة 95 %: 11.5-14.9) من الأحداث / المرضى - السنة بالنسبة للنمط 1 من داء السكري، و 3.3 (بفواصل ثقة 95 %: 2.8-3.8) و 4.2 من الأحداث / المرضى - السنة (بفواصل ثقة 95 %: 3.6-4.8) بالنسبة للنمط 2 من داء السكري، على التوالي. وقد ارتبط نقص السكر في الدم ارتباطاً وثيقاً بحدوث نقص ليلي حاد لسكر الدم في كلا النمطين من داء السكري ( $P < 0.001$ ).

**الاستنتاجات:** تشير النتائج إلى ارتباط نُظم الرعاية الصحية الأقل تقدماً في لبنان بالمستويات الأدنى من معرفة المريض بنقص السكر في الدم والتدابير الوقائية ذات الصلة. ويجب أن تُعد استراتيجيات العلاج والمعدلات المستهدفة لمستوى السكر في الدم حسب احتياجات كل فرد وفقاً لتفضيل المريض، والمنافع الطبية، ومخاطر نقص السكر في الدم.

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