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The management of severe hypoglycemia by the emergency system: The HYPOTHESIS study



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KEYWORDS

Hypoglycemia; Diabetes; Hypoglycemic agents; Emergency services **Abstract** *Background and aims:* Severe hypoglycemia is not rare in diabetes and markedly impacts on health resource use. We aimed to describe the characteristics of patients attending emergency departments (EDs) following a severe episode of hypoglycemia, the factors associated with the management of events and the final outcome.

Methods and results: We carried out a retrospective analysis of cases attending 46 Italian EDs for hypoglycemia from January 2011 to June 2012. A total of 3753 records were retrieved from the databases of the participating centers, part of a network repeatedly involved in collaborative studies; 3516 episodes occurred in subjects with diabetes (median age, 76 years; range, 1 –102). Comorbidities were recorded in 2320 (65.9%) diabetes cases; association with trauma or road accidents in 287 (8.2%) and 47 (1.3%), respectively. Patients were treated with insulin (49.8%), oral agents (31.4%), or combination treatment (15.1%). The event required assistance by the out-of-hospital Emergency services in 1821 cases (51.8%). Following the ED visit, admission to hospital departments was deemed necessary in 1161 cases (33.1%). Diabetes treatment (oral agents: OR, 1.63; 95% confidence interval (CI), 1.37-1.94), increasing age (OR, 1.39; 95% CI, 1.31-1.48) and the number of comorbidities (OR, 1.51; 95% CI, 1.38-1.66) were the main drivers of admission. The in-hospital death rate was 10%, associated with the number of comorbidities (OR, 1.28; 95%CI, 1.01-1.63).

Conclusion: Severe hypoglycemia requiring referral to EDs is associated with a significant workup of the Emergency services and a remarkable in-hospital death rate in frail individuals with diabetes.

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Introduction

Hypoglycemia represents a major issue in both type 1 (T1DM) and type 2 diabetes mellitus (T2DM) [1]. Severe episodes, defined by the need of external help, may be life-

threatening [2], whereas mild iatrogenic events severely impact quality of life [3]. The resulting fear of hypoglycemia limits treatment and metabolic control, favoring complications.

Hypoglycemia occurs at a rate around 1.0 per patientyear in T1DM, and reportedly less frequent in insulintreated T2DM. This myth has however been challenged, and a recent study showed that the event rates of severe hypoglycemia requiring emergency assistance are similar in T1DM and insulin-treated T2DM with poor metabolic

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control and longstanding and complicated disease [4]. The importance of hypoglycemia in diabetes was highlighted by recent trials of intensive metabolic control in T2DM, where the negative results were partly related to the adverse effects of hypoglycemia [5,6]. The recent availability of new classes of glucose-lowering drugs, less prone to produce hypoglycemia further drew the attention of the scientific community on the topic [7].

The economic cost of hypoglycemia is remarkable and goes beyond the personal burden. The use of health resources (ambulance call, on-site treatment, hospital admission [8]) is probably much higher than estimated by administrative data [9], and particularly relevant in T2DM [10], often characterized by long-term disease and complex comorbid profiles.

Very few data exist on the emergency management of hypoglycemia and its related outcomes [10,11]. A recent combined analysis of different US databases estimated a total of nearly 100,000 emergency department (ED) visit per year, with high rates of hospital admission and poor outcomes in insulin-treated diabetes [12]. We collected data on demographic and clinical characteristics of subjects attending the EDs of Italian general hospitals following a hypoglycemic event requiring emergency treatment. The study was intended to determine the associated factors, the out-of-hospital and in-hospital management, and the final outcome of severe hypoglycemia.

Methods

Data collection

In 2012, the Study and Research Center of Italian Society of Emergency Medicine (SIMEU) launched a study on all cases attending the EDs for a hypoglycemic event between January 2011 and June 2012 (HYPOTHESIS Study: HYPOglycemia Treatment in the Hospital Emergency System — Italian Study). According to a predefined case report form, 46 EDs covering an area of approximately 12 million inhabitants (scattered throughout Italy, in both rural and metropolitan areas), collected data on all cases with an acceptance diagnosis of hypoglycemia. The terms "hypoglycemia" or "hypoglycemic event" were used to search the ED databases.

The case report form included data on age, gender, previous diagnosis of diabetes or solid tumors, current alcohol abuse and malnutrition. Association with trauma or road accidents, glucose-lowering drug use and blood glucose values at the time of the event, as well as procedures to treat hypoglycemia (initial medication at home, intervention of the out-of-hospital Emergency service), were extracted from history, as recorded by the ED medical personnel.

Comorbidities were recorded according to a predefined form. Cardiovascular morbidity included both arrhythmias (atrial fibrillation, bundle blocks) and any diagnosis of coronary artery disease; chronic kidney disease included any diagnosis of moderate to severe chronic renal failure; liver disease was limited to cirrhosis or hepatocellular carcinoma. ED treatment was available in all cases; disposition (referral to general practitioners [GPs] or Diabetes Units; short-term (<24 h) intensive observation; admission to hospital wards) and post-admission outcomes were available for 40 centers (Fig. 1).

The ethical committee of Bologna University approved the study (175/2012/O/OssN, September 11, 2012).

Data analysis

The population was described as number of cases and percentages (categorical variables) or as means with standard deviation (SD) (continuous variables). We then tabulated data on disposition according to drug use and differences between groups were analyzed by χ^2 . Treatment modalities were studied according to the age of patients, using χ^2 to evaluate differences. An analysis of factors associated with disposition following the ED visit and treatment was carried out by logistic regression analysis as crude odds ratios (ORs) and corresponding 95% confidence interval (CI). We repeated the analysis considering in-hospital death as dependent variable. Independent variables were age, sex, blood glucose at the event time, occurrence of trauma or road accidents, previous treatment with either insulin or oral agents and the presence of comorbidities. For each dependent variable, we fitted a multivariate model including age, gender, and the number of comorbidities as covariates. As a sensitivity analysis, we recomputed the regression analyses in subjects with a pre-hospital recorded blood glucose <3.9 mmol/L, fulfilling the definition of hypoglycemia as defined by the American Diabetes Association (ADA) [1]. p values <0.05 were considered statistically significant. Analyses were performed using StatView 5.0™ (SAS Institute Inc, Cary, NC, USA).

Results

Hypoglycemic events

Overall, we identified 3753 hypoglycemic events. Cases without diabetes (n = 237, 6.3%) included a high number of patients with cancer (18.5%; 3.1% with hepatocellular carcinoma), poor nutritional status (22.3%), alcohol abuse (13.1%), hypothyroidism (8.4%), anorexia nervosa (4.1%), liver failure (9.3%). This subpopulation without diabetes is no longer considered in the present report. Information on cases with diabetes are shown in Table 1. A total of 3516 (93.7%) events occurred in subjects with diabetes (repeated events in the same individual, 4.1%). Cases with diabetes had a median age of 76 years (range, <1-102) and 50.5% were males. The duration of disease varied from less than one month to 60 years (median, 100 months). Association with trauma was present in 287 cases (8.1%); with road accidents in 47 (1.3%). Blood glucose at the time of event (mean, $2.33 \pm \text{SD}$ 1.22 mmol/L) was recorded in 2314 cases. A value <3.9 mmol/L was confirmed in 2122 cases (91.7%); in 1244 (53.7%) it was <2.2 mmol/L.

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