



Severe hypoglycemia and ketoacidosis over one year in Italian pediatric population with type 1 diabetes mellitus: A multicenter retrospective observational study

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Abstract *Background and aims:* Evaluation of incidence and correlates of severe hypoglycemia (SH) and diabetes ketoacidosis (DKA) in children and adolescents with T1DM.

Methods and results: Retrospective study conducted in 29 diabetes centers from November 2011 to April 2012. The incidence of SH and DKA episodes and their correlates were assessed through a questionnaire administered to parents of patients aged 0–18 years. Incidence rates and incident rate ratios (IRRs) were estimated through multivariate Poisson regression analysis and multilevel analysis. Overall, 2025 patients were included (age 12.4 ± 3.8 years; 53% males; diabetes duration 5.6 ± 3.5 years; HbA1c $7.9 \pm 1.1\%$). The incidence of SH and DKA were of 7.7 and 2.4 events/100 py, respectively. The risk of SH was higher in females (IRR = 1.44; 95%CI 1.04–1.99), in patients using rapid acting analogues as compared to regular insulin (IRR = 1.48; 95%CI 0.97–2.26) and lower for patients using long acting analogues as compared to NPH insulin (IRR = 0.40; 95%CI 0.19–0.85). No correlations were found between SH and HbA1c levels. The risk of DKA was higher in patients using rapid acting analogues (IRR = 4.25; 95%CI 1.01–17.86) and increased with insulin units needed (IRR = 7.66; 95%CI 2.83–20.74) and HbA1c levels (IRR = 1.63; 95%CI 1.36–1.95). Mother's age was inversely associated with the risk of both SH (IRR = 0.95; 95%CI 0.92–0.98) and DKA (IRR = 0.94; 95%CI 0.88–0.99). When accounting for center effect, the risk of SH associated with the use of rapid acting insulin analogues was attenuated (IRR = 1.48; 95%CI 0.97–2.26); 33% and 16% of the residual variance in SH and DKA risk was explained by center effect.

Conclusion: The risk of SH and DKA is mainly associated with treatment modalities and strongly depends on the practice of specialist centers.

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Introduction

Many children and adolescents with type 1 diabetes (T1DM) do not achieve optimal metabolic control, representing a common problem at the national and international level [1–3].

One of the most important barriers to the achievement of the metabolic target in young patients is represented, on the part of the patients and their families, by the fear of hypoglycemia [4]. Fear for acute effects of hypoglycemia, in particular of severe hypoglycemia (SH) episodes, are often perceived as more important than long-term consequences. The behaviors adopted to avoid hypoglycemia can lead to poor control of the disease, increasing the risk of micro- and macrovascular complications that are associated with prolonged states of poor metabolic control [5,6].

Diabetic Ketoacidosis (DKA) is another acute diabetes complication that in severe cases can lead to coma and death [7]. Therefore, having more knowledge and tools on which to build the prevention of these complications is a primary goal of the treatment of T1DM.

Italian data on these two diabetic acute complications are very poor. Despite these problems are strongly felt by both families and health care professionals, is still not clear what the incidence and the characteristics of the major episodes of hypoglycemia and DKA are in children and adolescents with T1DM under routine clinical practice conditions.

Moreover, it is plausible to imagine that therapeutic approaches, educational resources and structural and organizational characteristics of diabetes centers can vary and have a different impact on the ability to manage these complications.

Aim of the study was to evaluate the incidence of SH and DKA over a year in a large population of children and adolescents with T1DM cared by Italian pediatric diabetes Centers, and to identify the main risk factors associated with the characteristics of children and their parents.

Methods

This multicenter retrospective observational study was conducted in 29 Italian pediatric diabetes Centers throughout the Country from November 2011 to April 2012 and was approved by the Ethic Committee of reference of each Center. Each Center was asked to collect information on all eligible patients consecutively seen over a period of four months. Patients aged between 0 and 18 years, regardless of the regimen used, and followed by the Center for at least one year, were involved. An informed consent was signed by the parents before inclusion in the study. Information about the episodes of SH or DKA occurred in the previous 12 months was collected. Severe hypoglycemia was defined as any episode leading to hospitalization or requiring the administration of glucagon because the patient was unconscious or had seizures [8].

DKA was defined as a metabolic derangement characterised by the triad of hyperglycaemia, acidosis and ketosis

that occurred in the presence of very low levels of effective insulin action, leading to hospitalization [9].

Furthermore, information about any other hospitalizations and their causes during the same period was recorded. The first hospitalization or acute episode that led to the diagnosis of diabetes was excluded from the survey.

Information on the following clinical and socio-demographic patient characteristics was collected: age, sex, class attended, puberty stage, weight, height, duration of diabetes, insulin scheme and doses, average weekly number of blood glucose tests, last HbA1c value, presence of other chronic conditions, participation in educational group activities and regular practice of sport activities.

Information on the characteristics of the family included parents' age, education, employment status, marital status, number of children, number of family members, presence of other people with diabetes in the family, distance of the living house from the pediatric center.

All information was collected through a computerized questionnaire administered to the parent by a doctor or nurse during a routine visit.

Statistical analysis

In descriptive analyses, continuous variables are summarized as mean and standard deviation (normal distribution) or median and interquartile range (non normal distribution and ordinal variables). Categorical variables are expressed as percentages. Incidence rates are expressed as number of events/100 patients/year (py). The risk of SH and DKA events was estimated through Poisson regression analysis; the following covariates were tested: patient gender, age, diabetes duration, insulin type and dose, last HbA1c value, parent's age, employment status, and school education level. Results are expressed as incident rate ratios (IRRs) with their 95% confidence intervals (95% CIs). To evaluate the possible effect of the pediatric centre in determining an increased rate of SH or DKA, and to estimate the proportion of residual variance due to between center variation, multilevel Poisson regression analysis was utilized, taking into account the same set of covariates used in regression analysis plus clustering. A p -value <0.05 was considered statistically significant. All statistical analyses were performed using SAS version 9.1 (SAS Institute Inc.).

Results

Overall, 2025 consecutive patients followed by 29 pediatric diabetes Centers were included. Patients' characteristics according to the presence of acute diabetes complications (SH and DKA) are shown in Table 1.

Severe hypoglycemia

Overall 102 (5.0%) patients experienced one or more SH episodes during 12 months. Individuals reporting SH were younger, more frequently treated with NPH insulin, and

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