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Severe hypoglycaemia during treatment with sulphonylureas in patients with type 2 diabetes in the Capital Region of Denmark

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ABSTRACT

Aims: Sulphonylureas (SU) are currently recommended as a well-established second line treatment in guidelines for type 2 diabetes (T2DM). In the Capital Region of Denmark 16,865 patients were given SU as part of their treatment of T2DM in 2010–2011. To what extent SU are associated with hospitalizations due to severe hypoglycaemic episodes, defined as episodes with a need for external assistance, was investigated. The prevalence and characteristics of these patients and potential risk factors were studied.

Methods: ICD-10 diagnosis codes were used to identify patients hospitalized due to hypoglycaemia and T2DM for a period of 2 years (2010–2011). Inclusion criteria were T2DM, hospitalization due to hypoglycaemia and treatment with SU as monotherapy or in combination with other glucose-lowering drugs except insulin treatment.

Results: We identified 161 patients fulfilling the inclusion criteria. Their mean age was 76 (53–97) years and 54% were males. Sixty percent of the patients had diabetic complications, including 19% with diabetic nephropathy. The major reason for severe hypoglycaemia was an unchanged dose of SU despite of a significant decline in food intake (45%). In 22% of the patients more than one reason was listed, most commonly a concomitant infection associated with decreased food intake and unchanged dose of SU.

Conclusion: The incidence of hospital admission-requiring severe hypoglycaemia in patients treated with SU was 0.48 episodes per 100 patient-years of SU-treated patients. It was mainly older patients with diminished food intake, excessive alcohol use or other medications, concomitant infection, and with diabetic complications.

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1. Introduction

Sulphonylureas (SU) stimulate endogenous insulin secretion and are widely used to manage type 2 diabetes (T2DM) as impaired insulin secretion plays an important role in the pathophysiology of hyperglycaemia [1]. SU represent a well-established second line treatment in current guidelines for T2DM [2] and they are efficacious both as monotherapy and in combination with most other glucose-lowering agents. Similar to metformin, SU are widely available at significantly lower cost than newer classes of oral antidiabetic agents [1].

Risk of hypoglycaemia during treatment with SU is well-known [2] and represents a barrier toward the achievement of tight glycaemic control needed to prevent or delay diabetic complications. Severe hypoglycaemia represents a major clinical problem for the individual patient in terms of quality of life, risk of falls, coma and hospitalization [1,3]. For the health care system treatment of severe hypoglycaemia is associated with significant costs [1,3]. Previous studies have reported severe hypoglycaemia with varying frequency and duration with different kinds of SU [3–5]. It is less known to what extent SU are associated with hospitalizations due to severe hypoglycaemic episodes. In an Italian prospective study of people with T2DM and aged 80 years or more, severe hypoglycaemia was reported in 25% of the patients admitted to hospital [6].

The aim of the present study was to investigate the prevalence of SU-induced severe hypoglycaemia requiring hospitalization of patients with T2DM in the Capital Region of Denmark and to identify risk factors for these episodes.

2. Materials and methods

From the Danish National Patient Register for a 2-year period, from January 1, 2010, to December 31, 2011, all patients admitted to the hospital with the ICD-10 diagnostic codes for T2DM (E11.0, E11.1, E11.2, E11.3, E11.4, E11.5, E11.6, E11.7, E11.8, and E11.9) or hypoglycaemia (E15.9, E16.0, E16.1, E16.1B, E16.2, E11.0B, E12.0B, and E14.0D) were identified. All eight hospitals with emergency departments in the Capital Region of Denmark were included. In all cases fulfilling at least one of the ICD-10 codes, the medical records were examined and patients were included if they met the following inclusion criteria: T2DM according to WHO criteria, hospitalization due to severe hypoglycaemia, and treatment with SU as monotherapy or in combination with other glucose-lowering drugs (excluding insulin treatment). We defined a severe hypoglycaemic event as an episode requiring external help for recovery even though plasma glucose was not available during the event but according to the definition, neurological recovery following the return of plasma glucose to normal is considered sufficient evidence that the event was induced by a low plasma glucose concentration [7]. When plasma glucose was available hypoglycaemia was defined as a plasma glucose level below 4.0 mmol/l [7].

In 2010–2011, 78,567 persons were living in the Capital Region of Denmark registered with a diagnosis of diabetes according to the National Diabetes Registry. It was estimated

that 90% of these patients had T2DM. Of these were 16,865 (approximately 24%) prescribed SU according to the MED-STAT.DK register at the Danish National Board of Health.

Figures are number (%) or mean \pm 1 SD (range) as appropriate. The estimated incidence of hypoglycaemia among patients treated with SU was calculated by using the background information obtained from MEDSTAT.DK register and the Danish Health and Medicines Authority's National Diabetes Registry.

3. Results

A total of 161 of 3156 (5%) patients admitted to hospital with T2DM and/or hypoglycaemia fulfilled the inclusion criteria. Their characteristics appear from Table 1. Twenty (12%) patients had been hospitalized due to hypoglycaemia before the present visit to the emergency department; 16 (9%) once and 4 (3%) 2–5 times.

Patients aged 70 years or more had the highest frequency of emergency department visits due to hypoglycaemia (Fig. 1); of these 66 (41%) were aged 80 years or more. No patients aged less than 54 years were admitted to the emergency department for hypoglycaemia.

Hypoglycaemia was documented by plasma glucose measurements (<4.0 mmol/l) in the medical record at all visits to the emergency department. In most cases hypoglycaemia occurred at home. The overall mean of the plasma glucose level was 2.0 ± 0.6 mmol/l. In 147 cases (91%) the plasma glucose level was 2.8 mmol/l or less (0.7–2.8). Fourteen patients (9%) had a plasma glucose level between 2.9 and 3.9 mmol/l. HbA1c were measured in 86 (53%) of the patients. The average HbA1c level was $6.2 \pm 0.8\%$ (44 ± 9 mmol/mol). Fifty-five patients (64%) had an HbA1c level equal to or below the upper normal limit of 6.4% (46 mmol/mol). Severe neurologic symptoms such as loss of consciousness or hypoglycaemia-associated altered mental status were

Table 1 – Characteristics of patients with sulphonylurea-treated type 2 diabetes admitted to emergency departments in the Capital Region of Denmark in 2010–2011 with severe hypoglycaemia. Figures are number (%) or mean \pm 1 SD (range).

Number (% males)	161 (54)
Age (years)	76 \pm 12 (53–97)
Presence of any late diabetic complication	97 (60)
Diabetic retinopathy	12 (7)
Diabetic nephropathy	30 (19)
Peripheral diabetic neuropathy	21 (13)
Heart disease	74 (46)
Stroke (including transient cerebral ischemia)	41 (25)
Increased alcohol intake*	25 (15)
Present smokers	38 (24)
Hypertension	102 (63)
Hypercholesterolaemia	100 (61)
Obstructive pulmonary disease (COPD)	24 (15)
Dementia	24 (15)

* Above 21 units per week for men and 14 units per week for women according to recommendations from the Danish Health and Medicines Authority.

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