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Assessment of Various Risk Factors of Severe Hypoglycaemia: A Retrospective Study

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Abstract

Background: The incidence of severe hyperglycaemia (SH) depends on the place where diabetes therapy is delivered. Patients who are treated in hospitals for acute diabetes complications have higher incidences of SH compared with those in diabetes clinics. Hence; under the light of above mentioned data, we planned the present study to assess various potential risk factors of SH in patients who received diabetes therapy.

Materials & Methods: The present study included assessment of various potential risk factors of SH in patients who received diabetes therapy. In the present study, we included patients with known diabetes. Recording of all the event of SH in patients during the past one year was done. Measurement of glycosylated haemoglobin A1c (GHb) was done using high-performance liquid chromatography. The incidence of SH was calculated. All the data were recorded on excel sheet and were analysed by SPSS software.

Results: A total of 550 subjects were included in the present study, out of which, 50 were type I diabetic and 500 were type II diabetic. Insulin was required in 100 percent of the subjects of type I diabetes whereas, it was required in 31 percent of the subjects of type II diabetes. Mean GHb in type I and Type II diabetic subjects was 7.3 and 6.8 percent respectively. Significant results were obtained while comparing the insulin requirement and GHb (%) in all the subjects.

Conclusion: Intensive treatment regimens including early initiation of insulin treatment are important to prevent late complications in type 2 diabetes. As the incidence of SH is low, it might be an inappropriate parameter for evaluation of quality of outcome of diabetic therapy.

Key words: Diabetes, Hyperglycaemia, Incidence.

INTRODUCTION

The prevalence of diabetes worldwide was estimated to be 2.8% in 2000 and is projected to be 4.4% in the year 2030, with the total number of people with diabetes expected to rise from 171 million in 2000 to 366 million in 2030. Reasons for an increased prevalence of diabetes among patients with schizophrenia remain speculative.[1-4] However, in a previous study, the authors reported that in a survey of several large databases containing medical information on patients with schizophrenia, the patients with diabetes were more likely to be older, non-white, and to have hypertension – findings consistent with those in the general population.[5] The incidence of SH depends on the place where diabetes therapy is delivered. Patients who are treated in hospitals for acute diabetes complications have higher incidences of SH compared with those in diabetes clinics.[6-8] Hence; under the light of above mentioned data, we planned the present study to assess various potential risk factors of SH in patients who received diabetes therapy.

MATERIALS & METHODS

The present study was conducted in the department of General Medicine of Major S D Medical College, Farrukhabad, Uttar Pradesh (India) and included assessment of various potential risk factors of SH in patients who received diabetes therapy. Ethical approval was taken from institutional ethical committee and consent was obtained after explaining in detail the entire research protocol to the patients. In the present study, we included patients with known diabetes. Recording of all the event of SH in patients during the past one year was carried out.

SH was defined as hypoglycemia with coma or the need for intravenous glucose or intramuscular glucagon injection. Recording of the data on SH was done using patient interviews, medical records and discharge cards from medical institute and hospitals. Recording of the complete demographic details of all the subjects was done. Measurement of glycosylated haemoglobin A1c (GHb) was done using high-performance liquid chromatography. The incidence of SH was calculated as the proportion of patients with at least one SH during the last year, in subgroups with and without insulin therapy. The event rate of SH was calculated as the proportion of all SH in the last year in defined subgroups. All the data were recorded on excel sheet and were analysed by SPSS software. Chi- square test and student t test were used for assessment of level of significance. P-value of less than 0.05 was taken as significant.

RESULTS

Demographic and biochemical details of the subjects of the present study are shown in Table 1 and Graph 1. A total of 550 subjects were included in the present study, out of which, 50 were type I diabetic and 500 were type II diabetic. Duration of diabetes in Type I and Type II diabetic subjects were 18.5 and 7 years respectively. Insulin was required in 100 percent of the subjects of type I diabetes whereas, it was required in 31 percent of the subjects of type II diabetes. Mean BMI of type I and Type II diabetic subjects was 29.5 and 31.2 Kg/m^2 respectively. Mean GHB in type I and Type II diabetic subjects was 7.3 and 6.8 percent respectively. Significant results were obtained while comparing the insulin requirement and GHb (%) in all the subjects (p-value < 0.05) (table 2).

DISCUSSION

In the present study, we observed that severe hypoglycemia was an infrequent side effect of antidiabetic pharmacological therapy. Nyenwe EA et al[9] explored the pathogenetic rationale for the treatment of type 2 diabetes. The diagnostic criteria including the role of hemoglobin A1c in the diagnosis of diabetes are discussed. Due attention was given to the different therapeutic maneuvers and their utility in the management of the diabetic patient.

The controversial subject of optimum glycemic control in hospitalized and ambulatory patients was discussed in detail and the study gave special attention to the initiation of insulin therapy in patients with type 2 diabetes, with explanation of the pathophysiologic basis for insulin therapy in the ambulatory diabetic patient.

In the present study, significant results were obtained while comparing the insulin requirement and GHb (%) in all the subjects. Insulin was required in 100 percent of the subjects of type I diabetes whereas, it was required in 31 percent of the subjects of type II diabetes.

Samann A et al[10] investigated the incidence and risk factors of severe hypoglycemia (SH) in primary care. SH was defined as hypoglycemia

with coma, or the need of glucose or glucagon injection. They analyzed an unselected sample of participants with type 1 (n = 373) and type 2 diabetes (n = 4481) who participated in an insurance plan from the health care insurer Deutsche BKK.

The incidence of SH in type 1 diabetes was found to be 1.3% (CI: 0.4%, 3.1%) per year; type 2 diabetes with insulin therapy: 0.9% (CI: 0.5%, 1.7%); without insulin therapy: 0.3% (CI: 0.1%, 0.6%). The event rate was 0.02 SH per patient/year in type 1 diabetes and 0.01 in type 2 diabetes, respectively.

Low BMI, GHb, insulin therapy and female gender were associated with an increased risk of SH. In primary care, patients with diabetes can achieve good glycemic control with very rare events of SH. Due to low incidence, SH would have been an inappropriate parameter to evaluate the outcome quality of diabetes therapy in primary care.

Cavazzoni P et al[11] assessed the short-term risk of treatment-emergent diabetes (TED) among patients with schizophrenia during clinical trials of antipsychotic medications. From a non-diabetic cohort of patients with schizophrenia (n=5013), the relationship between baseline non-fasting glucose measurement, presence at baseline of risk factors for diabetes, weight gain and therapy assignment on the risk of treatment-emergent diabetes were assessed. At the baseline assessment, about a third of patients identified with TED during treatment had non-fasting glucose levels over 7.8 mmol/l and two-thirds had multiple diabetes risk factors. Both baseline non-fasting glucose level and the presence of multiple pre-existing diabetes risk factors appeared to have a major impact on the risk of developing diabetes. Overall, risk factors for diabetes in patients with schizophrenia overlap those in the general population. The results also suggest that many patients identified with TED might have had pre-existing glycaemic abnormalities or a high baseline burden of diabetes risk factors.

Akram K et al[12] studied the assumed risk of severe hypoglycemia (SH) which is a major barrier to initiation of insulin treatment and also evaluated the frequency of SH as reported in the literature. The incidence of SH in the retrospective studies varied from 15 to 73 episodes per 100 patient-year with a proportion of the patients having one or more episodes between 1.4 to 15%. In the prospective studies, both incidence rate and proportion of the patients having one or more episodes of SH were lower than in the retrospective studies. Impaired hypoglycemia awareness, high age, long duration of diabetes and insulin therapy increased the risk, while no association was found with HbA1c and insulin dose.

Yurgin N et al[13] examined patterns of antidiabetic treatment among individuals with type 2 diabetes in Germany and investigated potential differences in attainment of glycemic control associated with the use of specific antidiabetic regimens. Potential associations between age, sex, and diabetic complications and the use of specific antidiabetic medications were examined.

Also examined were potential associations between attainment of the HbA(1c) target for glycemic control (56.5%), particular patient characteristics, and the use of specific antidiabetic medications. There were significant differences between patients attaining the HbA(1c) target and receipt of specific antidiabetic medications ($P < 0.001$).

Patients treated with insulin monotherapy or oral plus insulin combination therapy were least likely to reach the HbA(1c) target (26.4% and 22.9%, respectively, attained glycemic control; both, $P < 0.001$). Only 179 (31.9%) of 562 patients treated

with oral combination therapy achieved the HbA(1c) target ($P < 0.001$). Over half of these German patients with type 2 diabetes failed to attain the HbA(1c) target for glycemic control. Patients who were prescribed insulin monotherapy or combination therapy were least likely to achieve the target.

CONCLUSION

Intensive treatment regimens including early initiation of insulin treatment are important to prevent late complications in type 2 diabetes. Hence, we conclude that as the incidence of SH is low; it might be an inappropriate parameter for evaluation of quality of outcome of diabetic therapy. However; we advocate future studies for better exploration of this field of medicine.

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Table 1: Demographic and biochemical details of the subjects of the present study

Parameter	Type 1 diabetic	Type II diabetic
Subjects	50	500
Duration of diabetes (years)	18.5	7
Requirement of insulin (%)	100	31
BMI (Kg/m^2)	29.5	31.2
GHB (%)	7.3	6.8

Graph 1: Demographic and biochemical details of the subjects of the present study

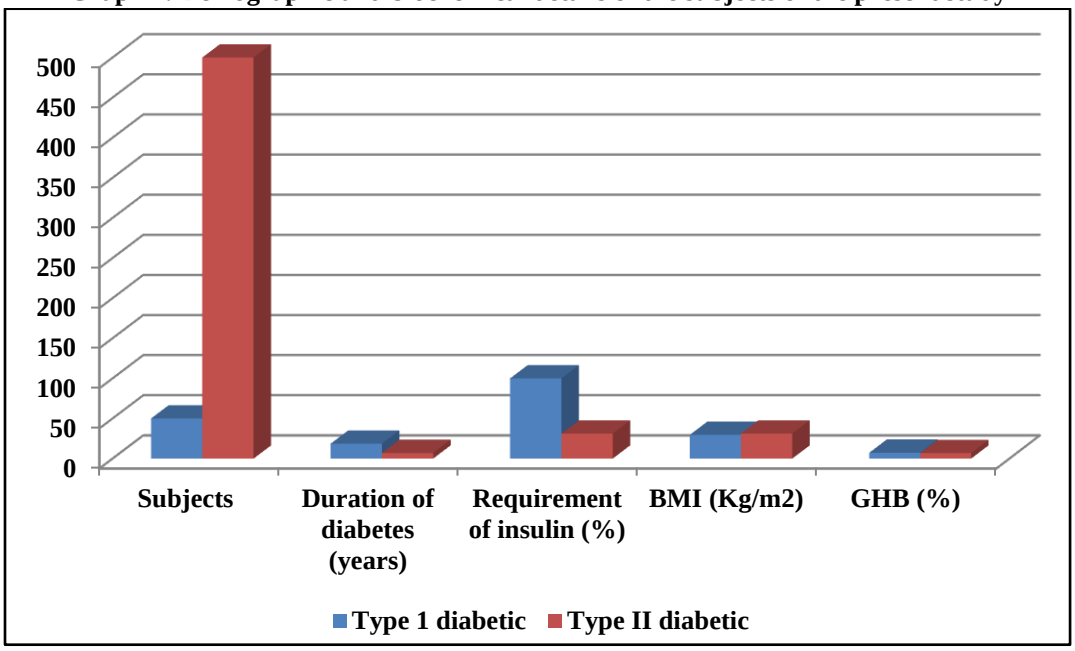

Table 2: Comparison of biochemical parameters

Parameter		95% CI	P- value
Insulin requirement	Yes	3.52	0.02
	No	1.00	
GHB (%)		0.63	0.03