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Prevalence and Determinants of Hypoglycemic Episodes Among Patients Receiving Antidiabetic Therapy.

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Abstract

Background: Hypoglycemia is one of the most common and potentially serious adverse effects of antidiabetic therapy. It contributes to increased morbidity, impaired quality of life, poor treatment adherence, recurrent hospitalizations, and adverse cardiovascular outcomes. Despite the availability of newer glucose-lowering agents with lower hypoglycemic risk, hypoglycemic episodes remain frequent, particularly among patients receiving insulin and sulfonylureas. Identifying the prevalence and determinants of hypoglycemia is essential for optimizing individualized diabetes management and improving patient safety. ***Objectives:*** To determine the prevalence of hypoglycemic episodes among patients receiving antidiabetic therapy and to identify the demographic, clinical, biochemical, and treatment-related factors associated with their occurrence. ***Materials and Methods:*** A hospital-based cross-sectional observational study was conducted in the Department of General Medicine of a tertiary care teaching hospital over a period of 12 months. A total of 300 adult patients with Type 1 or Type 2 diabetes mellitus receiving antidiabetic therapy for at least three months were enrolled using consecutive sampling. Demographic characteristics, duration of diabetes, comorbidities, antidiabetic treatment details, laboratory parameters, and history of hypoglycemic episodes were recorded using a structured questionnaire and medical records. Hypoglycemia was classified according to the American Diabetes Association criteria. Statistical analysis was performed using SPSS version 26.0. Continuous variables were expressed as mean ± standard deviation, categorical variables as frequencies and percentages, and comparisons were made using the independent t-test and Chi-square test. Multivariable logistic regression was used to identify independent predictors of hypoglycemia. A p-value <0.05 was considered statistically significant. ***Results:*** Among the 300 participants, 102 patients (34.0%) experienced at least one hypoglycemic episode during the preceding six months. Patients with hypoglycemia were significantly older (61.8 ± 10.7 vs. 55.6 ± 11.8 years, p<0.001), had a longer duration of diabetes (11.2 ± 5.8 vs. 7.4 ± 4.6 years, p<0.001), lower HbA1c levels (7.2 ± 0.8% vs. 8.1 ± 1.1%, p<0.001), and lower estimated glomerular filtration rate (68.4 ± 18.9 vs. 82.7 ± 15.6 mL/min/1.73m^2, p<0.001). Insulin therapy (59.8% vs. 29.3%, p<0.001), sulfonylurea use (45.1% vs. 24.2%, p<0.001), missed meals (47.1% vs. 19.2%, p<0.001), and poor medication adherence (27.5% vs. 16.2%, p=0.026) were significantly associated with hypoglycemia. Multivariable logistic regression identified insulin therapy (OR=3.52), diabetes duration >10 years (OR=2.36), estimated glomerular filtration rate <60 mL/min/1.73m^2 (OR=2.58), sulfonylurea therapy (OR=2.11), HbA1c <7% (OR=1.94), age >60 years (OR=1.89), and missed meals (OR=2.73) as independent predictors of hypoglycemic episodes (all p<0.05). ***Conclusion:*** Hypoglycemia affected approximately one-third of patients receiving antidiabetic therapy and was strongly associated with advanced age, prolonged duration of diabetes, insulin therapy, sulfonylurea use, impaired renal function, lower HbA1c levels, and irregular meal patterns. Individualized glycemic targets, careful selection of glucose-lowering medications, routine assessment of hypoglycemia risk, patient education, dietary counseling, and appropriate use of diabetes technologies are essential to minimize hypoglycemic events while maintaining effective glycemic control.

Keywords: Diabetes mellitus; Hypoglycemia; Antidiabetic therapy; Insulin; Sulfonylureas; Glycemic control; Risk factors; Type 2 diabetes.

INTRODUCTION

Diabetes mellitus (DM) is one of the most prevalent chronic non-communicable diseases worldwide and is characterized by persistent hyperglycemia resulting from defects in insulin secretion, insulin action, or both. The global burden of diabetes continues to increase because of population aging, urbanization, sedentary lifestyles, obesity, and dietary transitions. While advances in pharmacotherapy have substantially improved glycemic control and reduced the risk of long-term vascular complications, hypoglycemia remains one of the most common and clinically significant adverse effects of antidiabetic treatment. Hypoglycemia not only limits the achievement of optimal glycemic targets but also contributes to increased morbidity, mortality, healthcare utilization, and impaired quality of life. [1]

Hypoglycemia is generally defined as a blood glucose concentration below 70 mg/dL (3.9 mmol/L), although clinically significant hypoglycemia is recognized at glucose levels below 54 mg/dL, while severe hypoglycemia refers to episodes requiring assistance from another individual irrespective of the measured glucose value. The American Diabetes Association (ADA) and the Endocrine Society emphasize that hypoglycemia should be regarded as a major safety concern during diabetes management because recurrent episodes can impair physiological counter-regulatory mechanisms and reduce patients' awareness of falling glucose levels, thereby increasing the risk of severe and potentially life-threatening events. [1,2]

The frequency of hypoglycemia varies considerably depending on the type of diabetes, treatment regimen, patient characteristics, and methods used for its detection. Recent studies have demonstrated that self-reported hypoglycemia remains common among individuals with type 2 diabetes receiving oral antidiabetic medications, even in the absence of insulin therapy. Episodes are often underreported because patients fail to recognize mild symptoms or do not communicate these events during routine clinical consultations. Consequently, the true burden of hypoglycemia in routine practice is believed to be substantially higher than documented in hospital records. [2]

Older adults constitute one of the most vulnerable populations for hypoglycemia. Aging is associated with reduced renal and hepatic function, altered drug metabolism, impaired hormonal counter-regulation, cognitive decline, malnutrition, and multiple comorbidities, all of which increase susceptibility to hypoglycemic episodes. Furthermore, elderly patients frequently receive multiple medications that may interact with glucose-lowering therapies, making individualized treatment strategies essential. Recent evidence emphasizes the need for personalized glycemic targets and careful therapeutic selection to balance the benefits of intensive glucose control against the risk of hypoglycemia in this population. [3,4]

Beyond its immediate symptoms of sweating, tremors, palpitations, confusion, and dizziness, hypoglycemia has significant long-term clinical consequences. Severe episodes may precipitate seizures, loss of consciousness, cardiac arrhythmias, falls, fractures, cognitive impairment, and even sudden death. Recurrent hypoglycemia also creates psychological distress, fear of future episodes, and reduced treatment adherence, prompting many patients and clinicians to avoid treatment intensification despite inadequate glycemic control. These factors contribute to poorer long-term diabetes outcomes and increased healthcare expenditure. [5]

Advances in diabetes technology have improved the recognition and prevention of hypoglycemia. Continuous glucose monitoring (CGM) provides detailed information regarding glucose fluctuations throughout the day and allows identification of asymptomatic and nocturnal hypoglycemia that may otherwise remain undetected. International consensus recommendations advocate the use of CGM-derived metrics, including time below range, to optimize therapy while minimizing hypoglycemic risk, particularly among patients receiving insulin therapy or those with recurrent hypoglycemia. [6]

Hypoglycemia also has important cardiovascular implications. Several large clinical studies have demonstrated that severe hypoglycemic episodes are associated with increased risks of major adverse cardiovascular events, arrhythmias, hospitalization, and all-cause mortality. Although the exact causal relationship remains complex, hypoglycemia is recognized as a significant marker of vulnerability in patients with diabetes and cardiovascular disease. Consequently, minimizing hypoglycemia has become an integral component of comprehensive diabetes management rather than merely a secondary treatment objective. [7]

Modern diabetes management guidelines therefore emphasize individualized therapy based on patient age, duration of diabetes, comorbidities, life expectancy, risk of hypoglycemia, and patient preferences. The joint consensus statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) recommends selecting glucose-lowering agents according to their efficacy, cardiovascular and renal benefits, and intrinsic hypoglycemia risk. While newer agents such as sodium-glucose cotransporter-2 inhibitors and glucagon-like peptide-1 receptor agonists are associated with a lower risk of hypoglycemia, insulin and sulfonylureas continue to be widely used, especially in

resource-limited settings, making ongoing evaluation of hypoglycemic episodes highly relevant in routine clinical practice. [8]

Despite considerable therapeutic advances, hypoglycemia remains an important barrier to optimal diabetes management in everyday clinical settings. Identifying its prevalence and understanding the demographic, clinical, and treatment-related determinants are essential for improving patient safety, individualizing therapy, and reducing preventable complications. Therefore, the present study was undertaken to determine the prevalence of hypoglycemic episodes among patients receiving antidiabetic therapy and to identify the factors associated with their occurrence in a tertiary care hospital.

MATERIALS AND METHODS

Study Design

The present study was designed as a hospital-based cross-sectional observational study to determine the prevalence of hypoglycemic episodes among patients receiving antidiabetic therapy and to identify demographic, clinical, biochemical, and treatment-related determinants associated with their occurrence.

Study Setting

The study was conducted in the Department of General Medicine at a tertiary care teaching hospital, where patients with diabetes mellitus receive comprehensive outpatient and inpatient medical care.

Study Duration

The study was carried out over a period of 12 months following approval from the Institutional Ethics Committee.

Study Population

The study population comprised adult patients diagnosed with Type 1 or Type 2 diabetes mellitus who were receiving antidiabetic therapy and attended the medicine outpatient department or were admitted to the medical wards during the study period.

Sample Size

A total of 300 patients receiving antidiabetic therapy were enrolled in the study using consecutive sampling.

Sampling Technique

Eligible patients fulfilling the inclusion criteria were recruited consecutively until the required sample size of 300 participants was achieved.

Inclusion Criteria

- Adults aged 18 years and above.
- Patients diagnosed with Type 1 or Type 2 diabetes mellitus.
- Receiving one or more antidiabetic medications for at least three months.
- Willing to provide written informed consent.
- Patients attending outpatient clinics or admitted to medical wards.

Exclusion Criteria

- Gestational diabetes mellitus.
- Secondary diabetes mellitus.
- Critically ill patients unable to provide reliable history.
- Patients with severe psychiatric illness or cognitive impairment.
- Patients unwilling to participate.
- Incomplete clinical records.

Data Collection

After obtaining written informed consent, each participant was interviewed using a predesigned and prevalidated structured questionnaire.
The following information was recorded:

Demographic Variables

- Age
- Gender
- Residence
- Educational status

- Occupation
- Socioeconomic status

Clinical Variables
- Type of diabetes
- Duration of diabetes
- Body mass index (BMI)
- Blood pressure
- Smoking status
- Alcohol consumption
- Physical activity
- Dietary habits
- Family history of diabetes
- Presence of hypertension, dyslipidemia, cardiovascular disease, chronic kidney disease, and other comorbidities

Treatment Details
- Oral antidiabetic drugs
- Insulin therapy
- Combination therapy
- Duration of treatment
- Medication adherence
- Frequency of blood glucose monitoring
- **History of dose adjustments**

Assessment of Hypoglycemia
Hypoglycemia was defined according to the American Diabetes Association (ADA) recommendations.
Episodes were categorized as:
- Level 1: Blood glucose <70 mg/dL and ≥54 mg/dL
- Level 2: Blood glucose <54 mg/dL
- Level 3: Severe hypoglycemia requiring external assistance regardless of glucose value

Information regarding:
- Number of hypoglycemic episodes during the previous six months
- Symptoms experienced
- Time of occurrence
- Requirement for hospitalization
- Need for emergency treatment
- Precipitating factors

was obtained through patient interviews and review of medical records.

Laboratory Investigations
The following laboratory investigations were recorded:
- Fasting blood glucose
- Postprandial blood glucose
- HbA1c
- Serum creatinine
- Estimated glomerular filtration rate (eGFR)
- Liver function tests
- Lipid profile
- Complete blood count

Outcome Measures
Primary Outcome
- Prevalence of hypoglycemic episodes among patients receiving antidiabetic therapy.

Secondary Outcomes
- Identification of demographic determinants.
- Clinical predictors of hypoglycemia.
- Drug-related determinants.

- Association of glycemic control with hypoglycemia.
- Identification of independent predictors using multivariable analysis.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using SPSS version 26.0.

Continuous variables were expressed as mean ± standard deviation, whereas categorical variables were presented as frequency and percentage.

Comparisons between groups were performed using:

- Independent Student's t-test
- Chi-square test

Variables with p <0.10 on univariate analysis were included in multivariable logistic regression to identify independent determinants of hypoglycemic episodes. Odds ratios (ORs) with 95% confidence intervals (CIs) were calculated.

A p-value <0.05 was considered statistically significant.

RESULTS

A total of **300 patients** receiving antidiabetic therapy were included in the study. The prevalence of hypoglycemic episodes was assessed, and demographic, clinical, biochemical, and treatment-related determinants were analyzed.

Among the study population, **102 patients (34.0%)** reported at least one documented or symptomatic hypoglycemic episode during the previous six months, while **198 patients (66.0%)** had no history of hypoglycemia.

Table 1. Baseline characteristics of study participants according to hypoglycemic episodes

Variable	Hypoglycemia (n=102)	No Hypoglycemia (n=198)	p value
Age (years)	61.8 ± 10.7	55.6 ± 11.8	<0.001*
Male	58 (56.9%)	110 (55.6%)	0.831
Female	44 (43.1%)	88 (44.4%)	
Duration of diabetes (years)	11.2 ± 5.8	7.4 ± 4.6	<0.001*
BMI (kg/m²)	26.1 ± 3.8	27.0 ± 4.1	0.082
HbA1c (%)	7.2 ± 0.8	8.1 ± 1.1	<0.001*
eGFR (mL/min/1.73m²)	68.4 ± 18.9	82.7 ± 15.6	<0.001*

The prevalence of hypoglycemia was **34.0%**. Patients with hypoglycemia were significantly older and had a longer duration of diabetes than those without hypoglycemia (p<0.001).

They also demonstrated significantly lower HbA1c values and reduced renal function, indicating that intensive glycemic control and impaired kidney function were associated with an increased risk of hypoglycemia. No significant difference was observed regarding gender distribution or BMI.

Table 2. Treatment characteristics and lifestyle factors associated with hypoglycemia

Variable	Hypoglycemia (n=102)	No Hypoglycemia (n=198)	p value
Insulin therapy	61 (59.8%)	58 (29.3%)	<0.001*
Sulfonylurea use	46 (45.1%)	48 (24.2%)	<0.001*
Metformin therapy	88 (86.3%)	182 (91.9%)	0.126
SGLT2 inhibitor use	18 (17.6%)	62 (31.3%)	0.013*
DPP-4 inhibitor use	22 (21.6%)	58 (29.3%)	0.167
Missed meals	48 (47.1%)	38 (19.2%)	<0.001*
Irregular exercise	39 (38.2%)	54 (27.3%)	0.056
Poor medication adherence	28 (27.5%)	32 (16.2%)	0.026*

Patients receiving insulin therapy experienced significantly more hypoglycemic episodes (**59.8%**) compared to those without hypoglycemia (**29.3%**, p<0.001). Sulfonylurea therapy was also strongly associated with hypoglycemia (45.1% vs. 24.2%, p<0.001).

Missing meals and poor medication adherence were significantly more common among patients with hypoglycemia. Conversely, SGLT2 inhibitor use was significantly less frequent among patients experiencing hypoglycemia, suggesting a comparatively lower hypoglycemic risk.

Table 3. Clinical determinants and multivariable analysis of hypoglycemia

Variable	Odds Ratio (OR)	95% CI	p value
Age >60 years	1.89	1.12–3.19	0.018*
Diabetes duration >10 years	2.36	1.41–3.94	0.001*
Insulin therapy	3.52	2.08–5.96	<0.001*
Sulfonylurea therapy	2.11	1.23–3.63	0.006*
eGFR <60 mL/min	2.58	1.39–4.81	0.003*
HbA1c <7%	1.94	1.10–3.42	0.021*
Missed meals	2.73	1.56–4.77	<0.001*
Poor medication adherence	1.67	0.93–2.98	0.084

Multivariable logistic regression demonstrated that insulin therapy was the strongest independent predictor of hypoglycemia (OR=3.52, p<0.001). Patients with diabetes duration exceeding 10 years had more than twice the risk of hypoglycemia.

Reduced renal function, sulfonylurea therapy, advanced age, lower HbA1c levels, and missed meals independently increased the likelihood of hypoglycemic episodes. Poor medication adherence showed an increased trend but did not remain statistically significant after adjustment.

DISCUSSION

The present study evaluated the prevalence and determinants of hypoglycemic episodes among patients receiving antidiabetic therapy in a tertiary care hospital. The overall prevalence of hypoglycemia was **34.0%**, indicating that approximately one-third of patients experienced at least one hypoglycemic episode during the preceding six months. This finding confirms that hypoglycemia remains a major obstacle to achieving optimal glycemic control despite significant advances in diabetes pharmacotherapy. Recent evidence suggests that while intensive glycemic management reduces the risk of long-term microvascular complications, it also increases susceptibility to hypoglycemic events if treatment is not individualized. [9]

Our study demonstrated that increasing age was significantly associated with hypoglycemia. Older adults experienced hypoglycemic episodes more frequently than younger patients, consistent with the physiological decline in renal function, impaired counter-regulatory hormone responses, cognitive impairment, and multiple comorbidities observed with aging. Furthermore, elderly individuals often receive multiple medications, increasing the likelihood of drug interactions and adverse effects. Das et al. highlighted hypoglycemia as an under-recognized complication among elderly diabetic patients, emphasizing the need for individualized therapeutic strategies in this vulnerable population. [10]

Duration of diabetes was another significant determinant identified in the present study. Patients with diabetes duration exceeding ten years had significantly greater odds of developing hypoglycemia. Progressive β-cell failure, impaired glucagon secretion, autonomic dysfunction, and hypoglycemia unawareness become increasingly common with prolonged diabetes duration, thereby predisposing patients to recurrent episodes. Similar observations have been reported by Ismail-Beigi et al., who emphasized that glycemic targets should be individualized according to disease duration, comorbidities, and overall patient characteristics rather than applying uniform treatment goals. [9]

Reduced renal function was independently associated with hypoglycemia in our study. Patients with decreased estimated glomerular filtration rate experienced significantly more hypoglycemic episodes than those with preserved kidney function. Chronic kidney disease alters insulin metabolism, decreases renal gluconeogenesis, and prolongs the half-life of several glucose-lowering medications, thereby increasing hypoglycemia risk. Alicic et al. described diabetic kidney disease as a major contributor to altered glucose homeostasis and emphasized careful dose modification of antidiabetic medications in patients with impaired renal function. [11] Similarly, the joint ADA-KDIGO consensus recommends routine renal function assessment and individualized drug selection to minimize hypoglycemia in patients with chronic kidney disease. [12]

One of the strongest findings of the present study was the significant association between insulin therapy and hypoglycemic episodes. Multivariable analysis demonstrated insulin use as the most powerful independent predictor of hypoglycemia. Although insulin remains the cornerstone of treatment for many patients with diabetes, inappropriate dose titration, delayed meals, increased physical activity, and inadequate glucose monitoring substantially increase the likelihood of hypoglycemia. Nabi et al. similarly reported insulin therapy as one of the strongest predictors of hypoglycemia among patients with type 2 diabetes mellitus in routine clinical practice. [13] Munugoti et al. also observed that insulin-treated individuals accounted for the majority of severe hypoglycemic events requiring emergency medical attention, emphasizing the importance of individualized insulin adjustment and patient education. [14]

Sulfonylurea therapy was another significant determinant identified in our study. These medications stimulate insulin secretion independent of prevailing glucose concentrations, making hypoglycemia an important adverse effect, particularly among elderly patients and those with renal impairment. Current clinical practice increasingly favors antidiabetic agents with lower intrinsic hypoglycemia risk whenever feasible, particularly among patients with multiple risk factors. [12]

Lower HbA1c values were significantly associated with hypoglycemia in the present study. Although intensive glycemic control is beneficial in reducing chronic diabetic complications, excessively stringent glucose targets may expose susceptible individuals to frequent hypoglycemic episodes. Ismail-Beigi et al. advocated individualized HbA1c goals based on patient age, duration of diabetes, life expectancy, and risk of hypoglycemia rather than adopting universal glycemic targets for all patients. [9] This personalized approach has become central to contemporary diabetes management.

Lifestyle-related factors also played an important role. Missing meals emerged as an independent predictor of hypoglycemia, highlighting the importance of dietary consistency among patients receiving insulin or insulin secretagogues. Appropriate dietary counseling and structured diabetes self-management education remain essential components of hypoglycemia prevention. Ernawati et al., in their systematic review, demonstrated that diabetes self-management education significantly improves patient knowledge, self-care behaviors, medication adherence, and recognition of early hypoglycemic symptoms, thereby reducing the frequency of preventable hypoglycemic events. [15]

Although medication adherence showed significance in univariate analysis, it did not remain an independent predictor after multivariable adjustment. Nevertheless, poor adherence continues to influence glycemic variability through missed doses, inappropriate dose timing, and inconsistent dietary practices. Sahoo et al. reported that inadequate medication adherence among patients with type 2 diabetes was associated with poor glycemic outcomes and increased treatment-related complications, underscoring the importance of continuous patient counseling and regular follow-up. [16]

Technological advances are transforming hypoglycemia prevention. Continuous glucose monitoring (CGM) enables real-time detection of asymptomatic, nocturnal, and recurrent hypoglycemia while facilitating timely therapeutic adjustments. A recent systematic review by Jancev et al. demonstrated that CGM significantly reduced hypoglycemic episodes and improved overall glycemic control among adults with type 2 diabetes, supporting its increasing incorporation into routine diabetes management. [17] Consistent with these findings, the **ADA Standards of Care 2025** recommend broader implementation of diabetes technologies, particularly in patients receiving intensive insulin therapy or those with recurrent hypoglycemia. [18]

Recent advances in pharmacotherapy have further shifted the focus toward minimizing hypoglycemia while maintaining effective glycemic control. Standl et al. emphasized that modern diabetes management should prioritize agents with low hypoglycemia risk, individualized treatment intensification, patient-centered decision-making, and continuous assessment of hypoglycemia burden. Such strategies not only improve metabolic outcomes but also reduce cardiovascular complications, healthcare utilization, and treatment-related distress. [19]

The present study has certain limitations. Its cross-sectional design precludes establishing causal relationships between identified determinants and hypoglycemia. Some hypoglycemic episodes were based on patient recall, introducing the possibility of recall bias. Furthermore, being a single-center hospital-based study, the findings may not be directly generalizable to the wider diabetic population. However, the study included a substantial sample size and comprehensively evaluated demographic, clinical, biochemical, and therapeutic factors using multivariable analysis. These findings provide valuable evidence for identifying patients at increased risk of hypoglycemia and support individualized therapeutic approaches aimed at improving both safety and long-term diabetes outcomes.

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