

Prevalence and characteristics of impaired awareness of hypoglycemia in King Fahad Medical City, Saudi Arabia

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Received: March 01, 2021; Accepted: March 17, 2021

ABSTRACT

Background: Impaired awareness of hypoglycemia (IAH) is an acquired syndrome in people with insulin-treated diabetes, with a diminished or absent ability to perceive the onset of hypoglycemia. It can result in severe hypoglycemia and possibly death. At present, no previous study was performed in Saudi Arabia region to ascertain the IAH prevalence. **Objectives:** The aim of the current study was to investigate the self-reported prevalence of moderate, severe hypoglycemia, and IAH among patient visiting KFMC Obesity Metabolic Endocrine Centre (OEMC) Type 1 and Type 2 diabetics. In addition, we assessed the possible determinants of IAH. **Materials and Methods:** This was an observational cross-sectional study conducted on diabetic patients attending outpatient clinics of the OEMC of King Fahd Medical City during a period of 12 months using Clarke questionnaire. **Results:** Findings showed a low prevalence of IAH in the region (13.8%) and that IAH patients had experienced a significantly higher rate of severe hypoglycemia compared to hypoglycemic aware patients. These findings are consistent with the hypothesis that IAH develops mostly in patients with type 1 diabetes (T1D) but also presented in type 2 diabetes (T2D). This remains to place them at risk of experiencing severe hypoglycemia. **Conclusion:** IAH and severe hypoglycemia are relatively common among T1D and T2D patients. Prospective investigations that concentrate particularly on restoring awareness of hypoglycemia are required to promote measures to manage this severe complication of insulin treatment.


KEY WORDS: Hypoglycemia; Impaired Awareness of Hypoglycemia; Severe hypoglycemia; Diabetes

INTRODUCTION

Diabetes is a significant long-term disease that people experience when the amount of glucose in their blood is elevated over a prolonged period of time. It is categorized into Type 1 diabetes (T1D), an autoimmune disorder enabling the body to produce insulin, and Type 2 diabetes (T2D), with insufficient production of insulin, or production of non-functional insulin.^[1] Despite many advances in diabetes management, hypoglycemia, defined as a blood glucose

concentration of <70 mg/dL, is the most common acute adverse event of insulin treatment.^[2] It has a negative impact on perceived quality of life and constitutes the main barrier for achieving and maintaining optimal glycemetic control in diabetes. It interferes with everyday activities, which requires help from another person to restore blood glucose levels, thus creating a risk of physical damage (such as when driving).^[3] Patients with T1D have a much increased rate of severe hypoglycemia (20–25%^[4]), albeit less cardiovascular comorbidity compared with people with T2D.^[5,6]

Impaired awareness of hypoglycemia (IAH) is an acquired syndrome in people with insulin-treated diabetes, predominantly T1D, and can be defined as a condition in which patients experience an attenuation of hypoglycemic symptoms, leading to a diminished or absent ability to perceive the onset of hypoglycemia.^[7,8] Patients with IAH experience

Access this article online	
Website: http://www.ijmsph.com	Quick Response code
DOI: 10.5455/ijmsph.2021.03022202117032021	

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neuroglycopenic symptoms as the first sign of hypoglycemia and rely on the assistance of others to manage their episodes of hypoglycemia. The risk of severe hypoglycemia is 6-fold more common in those with IAH, which, in turn, has been linked to increase in overall mortality.^[9,10]

In the absence of identification and immediate treatment for a hypoglycemic episode, the blood glucose can proceed to drop and causing severe hypoglycemia and other complexities, such as seizures, coma, emergency room admissions, and possibly death.^[11-13] For cases with IAH and recurrent severe hypoglycemia, pancreas or islet transplantation can be taken into account as possible therapy options, however, it is currently limited by graft availability, expense, and the necessity for dedicated lifelong immunosuppressant use.^[14] Therefore, real-time continuous glucose monitoring (CGM) has become a valuable tool in the management of diabetic patients by presenting immediate information regarding blood glucose levels, glycemic trends, and alerts to hypoglycemic events.^[15] Recent evidence suggests that it may lower the incidence of hypoglycemic events yet, it did not reverse IAH in some subjects.^[16,17] At present, no previous study was performed in Saudi Arabia region to ascertain the IAH prevalence. Therefore, the aim of the current study was to investigate the self-reported prevalence of moderate, severe hypoglycemia and IAH among patient visiting KFMC Obesity Metabolic Endocrine Centre (OEMC) Type1 and Type 2 diabetics. In addition, we assessed the possible determinants of IAH.

MATERIALS AND METHODS

Study Design and Participants

This was an observational cross-sectional study conducted on diabetic patients attending outpatient clinics of the OEMC of King Fahd Medical City during a period of 3 months (from May 2018 to July 2018). This study included patients aged more than 14 years, suffering from diabetes type I and II, and attending KFMC's diabetes outpatient clinics.

Ethical Considerations

The study was approved by KFMC IRB committee. Informed consent was obtained from all the enrolled participants before the commencement of the study.

Data Collection

Each participant completed with the assistance of a trained health care worker a questionnaire, which incorporates done of the commonly available instruments used to identify patients with IAH, Clarke's questionnaire.^[18] The filling of the questionnaire was during and after clinical visits and thru phone calls to the patients.

The Clarke questionnaire is comprised eight questions assessing patients' experience during hypoglycemic events. A score (0–7) is calculated based on the responses to these questions. A score of 4 and above suggests IAH, a score of 2 and under suggests normal hypoglycemia awareness, and a score of 3 represents undetermined awareness status. It consisted of two sections: The first included baseline demographic characteristics and disease management, and the other presented hypoglycemic awareness questions. Participants answered questions regarding personal experiences with hypoglycemia such as a history of mild, moderate, and severe episodes, and symptoms that are believed to be associated with low blood glucose. Hypoglycemia symptom scores were assessed using the Edinburgh Hypoglycemia scale in this questionnaire.^[19]

Statistical Analysis

Reports were collected then coded and revised, and data were introduced on statistical software IBM SPSS version 23. Frequencies and percentages were used to describe categorical variables. All statistical analyses were done using two-tailed tests and an alpha error of 0.05. $P < 0.05$ was considered to be statistically significant. Chi-squared analyses were used as appropriate to evaluate the relationships between participants' characteristics and hypoglycemia awareness (Pearson or with Fisher's exact test when conditions are not fulfilled).

RESULTS

A total of 135 diabetic patients participated in the study, 51.6% of them had Type 1 diabetes mellitus (DM), and 43.8% had Type 2 DM [Table 1]. The highest proportion of patients aged between 14 and 30 years (36.4%), followed by those aged more than 60 (24.8%), and between 45 and 60 (20.9%). More than half were female (62.9%), 40% had no history of comorbidities, and 30.1% had more than 1 comorbidity. All of the participants had diabetes for more than 1 year, of which 51.1% of them for more than 10 years. About 85% of the participants reported using insulin analogs for the management of diabetes, 50 diabetics (39.4%) had 30–60 units, and 33 (26%) had 10–30 units. Half of the participants had glycated hemoglobin (HbA1c) of 8–10 u.

Table 2 presents hypoglycemia data among participants. The majority (78.2%) always experienced symptoms when having hypoglycemia; 41.5% had moderate hypoglycemia episodes in the past 6 months and only 14.8% had severe hypoglycemia episodes in the past year. About 80% had at least one reading >70 mg/dl with symptoms in the past month. Almost half of the respondents had 60–69 mg/dl (57.9%) as a threshold of blood sugar before feeling the symptoms, and 48.9% always predicted low blood sugar by the symptoms.

Using Clarke's questionnaire, 97 (74.6%) and 18 (13.8%) participants reported normal and IAH, respectively. Among

Table 1: Participants' characteristics

Characteristics	n	Percentage
Age		
15–30	47	36.4
30–45	23	17.8
45–60	27	20.9
>60	32	24.8
Gender		
Male	46	37.1
Female	78	62.9
Comorbidities		
Nephropathy	9	6.7
Retinopathy	4	3
ESRD	2	1.5
Hypertension	9	6.7
DLP	15	11.1
More than 1 comorbidity	41	30.4
None	55	40.7
Type of DM		
T1DM	56	43.8
T2DM	66	51.6
GDM	3	2.3
MODY	3	2.3
Duration of DM		
<1 year	0	0
1–3 years	7	5.3
3–5 years	7	5.3
5–10 years	50	38.2
>10 years	67	51.1
Type of insulin		
Regular	18	14.6
Analogs	105	85.4
Insulin dose (U/d)		
<10 units	6	4.7
10–30 units	33	26
30–60 units	50	39.4
60–100 units	30	23.6
>100 units	8	6.3
HbA1c		
<6	4	3.1
6–7	14	10.8
7–8	22	16.9
8–10	61	46.9
>10	29	22.3

T2DM: Type 2 diabetes mellitus, DM: Diabetes mellitus, HbA1c: Glycated hemoglobin

Table 2: Hypoglycemia characteristics

Characteristics	n	Percentage
Symptoms when my blood sugar is low		
Always	104	78.2
Sometimes	23	17.3
No longer	6	4.5
Lost some of the symptoms that used to occur when blood sugar was low		
Yes	25	18.9
No	107	81.1
Number of moderate hypoglycemia episodes* in the past 6 months		
Never	79	58.5
Once a month	21	15.6
Once or twice	17	12.6
Every other month	5	3.7
More than once a month	13	9.6
Number of severe hypoglycemia episodes** in the past year		
Never	115	85.2
1 time	13	9.6
2 times	3	2.2
3 times	2	1.5
6 times	1	0.7
12 or more times	1	0.7
Number of readings>70 mg/dl with symptoms in the past month		
Never	27	20.0
1–3 times	55	40.7
1 time/week	19	14.1
2–3 times/week	21	15.6
4–5 times/week	11	8.1
Almost daily	2	1.5
Number of readings>70 mg/dl without any symptoms in the past month		
Never	79	58.5
1–3 times	30	22.2
1 time/week	6	4.4
2–3 times/week	12	8.9
4–5 times/week	7	5.2
Almost daily	1	0.7
Threshold of blood sugar before feeling the symptoms		
60–69 mg/dl	77	57.9
50–59 mg/dl	34	25.6
40–49 mg/dl	8	6.0
<40 mg/dl	14	10.5
Prediction of low blood sugar by the symptoms		
Never	12	8.9
Rarely	12	8.9
Sometimes	18	13.3
Often	27	20.0
Always	66	48.9

*Feel confused, disoriented, or lethargic and unable to treat yourself; **feel unconscious or had seizures and needed glucagon or intravenous glucose

the factors assessed for their relationships with the impaired awareness status [Table 3], the type of diabetes was related to impaired awareness, where T1D was significantly associated with IAH when compared to other types of diabetes. The

frequency of moderate and severe hypoglycemia episodes was significantly higher in IAH patients when compared to

Table 3: Impaired awareness status and associated factors

Characteristics	Aware, n=9 (74.6%)	IAH, n=18 (13.8%)	P-value
Age			0.365*
15–30	30 (32.6%)	9 (50%)	
30–45	15 (16.3%)	5 (27.8%)	
45–60	20 (21.7%)	2 (11.1%)	
>60	27 (29.3%)	2 (11.1%)	
Gender			0.778
Male	33 (36.7%)	5 (29.4%)	
Female	57 (63.3%)	12 (70.6%)	
Comorbidities			0.313*
Nephropathy	7 (7.2%)	1 (5.6%)	
Retinopathy	4 (4.1%)	0 (0%)	
ESRD	0 (0%)	1 (5.6%)	
Hypertension	8 (8.2%)	0 (0%)	
DLP	10 (10.3%)	2 (11.1%)	
>1 comorbidity	33 (34%)	3 (16.7%)	
None	35 (36.1%)	11 (61.1%)	
Type of DM			0.025*
T1DM ^a	34 (36.6%)	13 (61.5%)	
T2DM ^b	55 (59.1%)	4 (30.8%)	
GDM ^c	2 (2.2%)	0 (0%)	
MODY ^d	2 (2.2%)	0 (0%)	
Duration of DM			0.787*
1–3 years	5 (5.3%)	1 (5.6%)	
3–5 years	6 (6.3%)	0 (0%)	
5–10 years	38 (40%)	7 (38.9%)	
>10 years	46 (48.4%)	10 (55.6%)	
Type of insulin			0.826*
Regular	12 (13.5%)	3 (17.6%)	
Analogs	77 (86.5%)	14 (82.4%)	
Insulin dose			0.535*
<10 units	6 (6.5%)	0 (0%)	
10–30 units	25 (26.9%)	5 (29.4%)	
30–60 units	34 (36.6%)	8 (47.1%)	
60–100 units	23 (24.7%)	4 (23.5%)	
>100 units	5 (5.4%)	0 (0%)	
HbA1c			0.765*
<6	2 (2.1%)	1 (5.6%)	
6–7	11 (11.7%)	1 (5.6%)	
7–8	14 (14.9%)	5 (27.8%)	
8–10	46 (48.9%)	8 (44.4%)	
>10	21 (22.3%)	3 (16.7%)	
Moderate hypoglycemic episodes			0.002*
≤Once/month	89 (91.8%)	11 (61.1%)	
>Once/month	8 (8.2%)	7 (38.9%)	
Severe hypoglycemic episodes			<0.0001*
Yes	6 (6.2%)	9 (50%)	
No	91 (93.8%)	9 (50%)	

^aType 1 diabetes mellitus; ^bType 2 diabetes mellitus; ^cgestational diabetes mellitus; ^dmaturity-onset diabetes of the young. *Fisher's exact test. IAH: Impaired awareness of hypoglycemia. T2DM: Type 2 diabetes mellitus, HbA1c: Glycated hemoglobin

others (38.9% vs. 8.2% and 50% vs. 6.2%, respectively). IAH was more seen in younger patients (<45 years), however, the difference is not statistically significant. Participant sex, recent HbA1c levels, and insulin regimen were not related to impaired awareness/unawareness status.

DISCUSSION

In this cross-sectional observational study conducted in a large outpatient clinic population with different types of diabetes, we found that the prevalence of IAH in the OEMC was low (13.8%). We observed that younger people, females, those having diabetes for more than 10 years and using analogs insulin were more susceptible for IAH (*P*-value not significant). Interestingly, having T1D, less than 1 moderate hypoglycemic episode per month and severe hypoglycemic episodes were significantly associated with a higher prevalence of IAH.

A previous study conducted in Jordan, assessing IAH among children and adolescents with T1D reported similar prevalence rate (16%).^[20] However, the prevalence of IAH in our study was also lower than the prevalence of IAH reported in adults in a recent study; yet, it was conducted on patients with T1D with ongoing real-time CGM use who may have been recommended or met local funding criteria for real-time CGM on the basis of their awareness status.^[14] The current reduction in our findings contrasted to earlier studies may indicate advancements in diabetes management in terms of therapy and standardized education. Another possible reason for the low IAH prevalence is the poor glycemic control, where around 2/3 of participants were having uncontrolled blood glucose levels (HbA1c levels >7%). Usually, patients with IAH have lower HbA1c levels compared to aware patients because the frequency of hypoglycemia is associated with lower glycemic control.^[21] However, the difference in HbA1c level between IAH and hypoglycemia aware participants reported in the current study was not significant. These observations show that IAH is more common in T1D, in line with the literature.^[7,8] Our data on the prevalence of IAH in patients with T2D (3%) are in contrast with other studies reporting a higher rate.^[22,23] A previous nationwide cohort conducted on people with insulin-treated T2Ds reporting a prevalence of 9.7%.^[23] Furthermore, few single-center investigations reported higher IAH prevalence ranging between 31% and 94% in patients with T2D treated with insulin.^[24,25] The used methods have been examined for exaggerating the prevalence of IAH. In accordance with previous reports, increased age (non-significant) was more noted in people with IAH as compared with normal awareness.^[9,26] Nevertheless, these studies showed other determinants associated with a higher risk of developing IAH, including increased duration of diabetes and age (significant). This difference is likely due to the decreased sensitivity between different questionnaires and tools utilized

in defining IAH in small or large samples. The association between increased duration of DM and increased risk of IAH means that patients with a longer duration of DM may have experienced more frequent hypoglycemia, which can blunt glucagon and adrenergic responses to hypoglycemia and raises the patient's risk of hypoglycemia. Accordingly, subjects with recurrent hypoglycemia are expected to be at higher risk of having IAH.^[21] This was shown in the present study as IAH was significantly associated with the frequency of hypoglycemia episodes during the past 6 months. The prevalence of severe hypoglycemia in this population was low at 15 (11.1%). However, patients with IAH had experienced a higher rate of severe hypoglycemia compared to hypoglycemic aware patients. This finding was consistent with previous reports.^[1,27] Numerous studies have pointed out that IAH may be reversible. Strict avoidance of hypoglycemia over a specified period has been shown to reverse clinical symptoms of IAH, yet it is difficult to achieve it in clinical practice.^[28-31] A previous meta-analysis demonstrated that a structured education program improved IAH and had the greatest influence on these conditions.^[32] Therefore, it is necessary to provide increased education and attention or targeted hypoglycemia-focused psychoeducational interventions in the region for diabetic patients.

The current study embedded several limitations including the retrospective design resulting in the risk of underreporting data, incomplete data collection, insufficient information on the possible confounder, and missing information on data quality. It is also important to point out that the study was conducted in a single center, therefore, limiting the generalizability of its findings. The main strengths of the study are to our knowledge; this is the first study to that adds to the literature the prevalence of IAH among a large hospital clinic-based population in Saudi Arabia. The commonly used hypoglycemia awareness questionnaire was utilized. Besides, medical reports were conducted to confirm the study variables such as HbA1c, DM diagnosis, and insulin regimen.

CONCLUSION

These findings are consistent with the hypothesis that IAH develops mostly in patients with T1D but also presented in T2Ds. This remains to place them at risk of experiencing severe hypoglycemia. Prospective investigations that concentrate particularly on restoring awareness of hypoglycemia are required to promote measures to manage this severe complication of insulin treatment.

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How to cite this article: Aloriney A. Prevalence and characteristics of impaired awareness of hypoglycemia in King Fahad Medical City, Saudi Arabia. *Int J Med Sci Public Health* 2021;10(1):40-45.

Source of Support: Nil, **Conflicts of Interest:** None declared.