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ASSESSMENT OF AWARNESS ABOUT HYPOGLYCEMIA IN DIABETIC PATIENTS IN SOUTH INDIA – HYPO D STUDY

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INTRODUCTION

Hypoglycemia or low blood sugar means a blood glucose reading lower than 70 milligrams per deciliter (mg/dL). Hypoglycemia is common among people with Type 1 and Type 2 Diabetes Mellitus patients who are receiving pharmacological therapies like insulin or oral hypoglycemic agents (OHAs). In a study conducted globally it was shown that at least 4 in 5 people with Type 1 Diabetes Mellitus and half the Type 2 Diabetes Mellitus patients have reported an experience of hypoglycemia at least once.^[1,2]

Hypoglycemia is one of the major barriers for achieving glycemic control. A study conducted in Tamil Nadu estimated that the prevalence of Hypoglycemia among T2DM patients was 57.44%. Frequent episodes of hypoglycemia have been associated with increased incidence of cardiovascular problems therefore the American Diabetes Association has recommended that strict glycemic control targets should be forgone while treating chronic Diabetic patients with comorbidities.^[3]

Hypoglycemia can lead to neurogenic symptoms like tremors, palpitations, anxiety, sweating, hunger, paraesthesia and neuroglycopenic symptoms like dizziness, weakness, drowsiness, delirium and confusion. As the plasma glucose level maintains a decreasing trend seizure or coma can occur. These can affect the cerebrovascular system, the cardiovascular system and cause neurocognitive impairment. Diabetic patients should be able to recognize the symptoms of hypoglycemia and know the immediate treatment for it thereby preventing the need for hospitalization. Individuals who

lack knowledge to recognize these as symptoms of hypoglycemia can be prone to get delayed treatment which will have detrimental effects like brain injury or loss of consciousness because blood glucose is essential for brain activity. In a study conducted in South India, about 34% of participants had a poor understanding of hypoglycemia.^[4,5,6]

This dictates the need to assess how aware diabetic patients are regarding hypoglycemia which this study aims to do.

MATERIALS AND METHODS

Study design

This cross-sectional study was conducted in a tertiary care hospital in south india from January to May of 2024. The data for this study was collected using the Clarke's and Gold questionnaire.

Sample size

The sample size for this study was calculated using the Cochrane formula. The estimated sample size was 271. We used simple random sampling technique by selecting diabetic patients who came to the tertiary care hospital for treatment or follow up. Individuals with Type 2 Diabetes Mellitus who are on pharmacotherapeutic management for the same with either OHAs or Insulin were included in the study. Patients diagnosed with Type 1 Diabetes Mellitus, Gestational Diabetes and Individuals who refused to participate in the study were excluded.

Data collection methods

Data for this study was collected using previously validated questionnaires. Informed consent was obtained, and confidentiality of information was assured to the patient. The data was collected individually from patients. The questionnaire contained three sections. The first section had demographic data that included Age, Gender, Body Mass Index (BMI) and other socio-economic data. The second section was the Clarke's Questionnaire which includes 8 questions. These 8 questions assess the patients experience during hypoglycemic episodes. Each question's response was valued as "aware" (Value A) or "Reduced Awareness" (Value R). The third section is the gold questionnaire which has only one question, "Do you know when your hypoglycemic episodes are commencing?". The individual answers in a 7-point likert scale with 1 being always aware and 7 being never aware. In both these questionnaires a score \geq 4 suggests Impaired awareness ; a score \leq 2 suggests normal hypoglycemia awareness; and a score of 3 represents undetermined / Borderline awareness status.

Data analysis

Data analysis was performed using the SPSS Software and MS Excel. Baseline descriptive analysis was expressed as mean \pm SD along with frequency and percentage distribution of the variable. Pearson's correlation, independent sample t-test and one-way ANOVA were used to evaluate associations between qualitative and quantitative variables. A p-value of 0.05 or less was statistically significant.

Ethical considerations

Ethical approval was obtained from the Gleneagles Health City Ethics Committee in Chennai. Informed consent was obtained and confidentiality was maintained.

RESULT

Participant Characteristics

A total of 373 diabetic patients participated in the study. Predominant population was female (55%). The mean age of our population was 61.7 ± 11.6 with 43.9% of them having at least a bachelor's degree. 36.2% of our cohort were found to be overweight and 71.6% of them were not working which included housewives and retired individuals. 60.9% of the patients had a family history of Diabetes. 40.2% of our population have been on therapeutic management for DM for more than 10 years and 48% of them were on dual drug therapy for its management. The socio-demographic characteristics of the participants are elucidated in Table 1.

Participant Characteristic		Frequency	Percentage
GENDER	Male	168	45%
	Female	205	55%
EDUCATIONAL QUALIFICATION	Primary school	12	3.2%
	Secondary school	82	22%
	Higher secondary school	102	27.3%
	Diploma	13	3.5%
	Bachelor's Degree	110	29.5%
	Master's Degree	54	14.5%
	Housewife	152	40.8%
OCCUPATION	Retired	112	30.0%
	Working	106	28.4%
	Not working	3	0.8%
FAMILY HISTORY OF T2DM	Yes	227	60.9%
FAMILY HISTORY OF 12DM	No	146	39.1%
	Mono Therapy	33	8.8%
TYPE OF THERAPY	Dual Therapy	179	48.0%
	Triple Therapy	121	32.4%
	Quadruple Therapy	12	3.2%
DURATION ON DM	Less than 1 year	23	6.2%
	1 to 5 years	95	25.5%
	6 to 10 years	105	28.2%
	More than 10 years	150	40.2%

Table 1: Socio-demographic characteristics of the participants.

Hypoglycemia Awareness

According to our findings, the participant's average hypoglycemic awareness score using the Gold Questionnaire was 4.4 ± 2.4 . The percentage of participants who were found to be aware of hypoglycemia was 72.1% in Clarke's questionnaire and 31.4% in Gold Questionnaire. According to our study, the prevalence of Impaired Awareness of Hypoglycemia (IAH) among type 2 diabetic patients was found to be 10.2% through the Clarke questionnaire and 60.1% through the gold questionnaire. The distribution of patients across the three categories of awareness in both the Clarke and Gold Questionnaire is shown in Figure 1. When the scores from both the questionnaires were compared, they showed strong correlation with each other (r = 0.139, P value < 0.01). When the patients who were classified as aware in both the questionnaires were evaluated, it revealed that only 26.1% of the T2DM in our study were found to be aware about hypoglycemia. Figurative representation of this is shown in Figure 2.

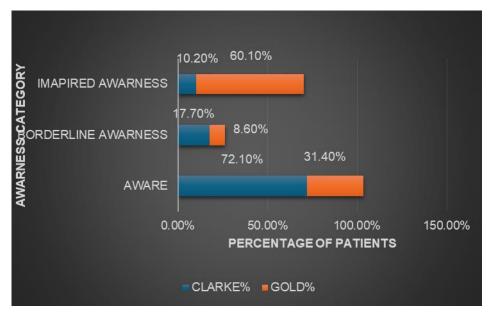


Figure 1: Stacked bar graph showing the distribution of participants according to their Hypoglycemia Awareness status identified by using the Gold and Clarke Questionnaires.

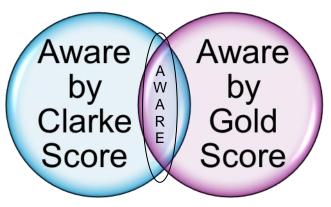


Figure 2: Shows the population classified as aware by both clarke and gold questionnaire.

Our research revealed that many of the patients (34.9%) experienced symptoms of hypoglycemia when their blood sugar was low and almost everyone (95.2%) who participated did not lose their symptoms of hypoglycemia. 39.6% of participants revealed to have experienced moderate hypoglycemic symptoms like confusion, disorientation and lethargy in the last six months once or more than once while 15% of them have experienced severe hypoglycemic episodes at least once in the past year.

When the incidence of hypoglycemia was evaluated 70.2% of the individuals have had readings less than 70 mg/dL in the past month with symptoms in which 5.6% of them have had this experience almost every week. 90.1% of the study population revealed that they have never had readings less than 70 mg/dL without the warning signs of a hypoglycemia episode. Table 2 shows the frequency distribution of participants based on their answers in both the questionnaires.

VARIABLE		FREQUENCY	PERCENTAGE
1. Do you feel hypoglycemia	I always have symptoms	127	34%
symptoms when your blood	I sometimes have symptoms	128	34.3%
glucose is low?	I no longer have symptoms	118	31.6%
2. Have you lost symptoms that	Yes	19	5.1%
used to occur when your blood glucose is low?	No	354	94.9%
3. In the past six months how often have you had moderate hypoglycemia episodes like confusion, disorientation or lethargy	Never	223	59.8%
	Once or twice	142	38.1%
	Every other month	4	1.1%
	More than once a month	4	1.1%
4. In the past year how often have you had severe hypoglycemic episodes? (Episodes where you were unconscious)	Never	316	84.7%
	1 time	49	13.1%
	2 times	7	1.9%
	3 times	1	0.3%
	Never	111	29.8%
5. How often in the last month have you had readings less than 70 mg/Dl with symptoms?	1 to 3 times	233	62.5%
	1 time/week	21	5.6%
	2 to 3 times/week	7	1.9%
	4 to 5 times/week	1	0.3%
6. How often in the last month have you had readings less than 70 mg/Dl without any symptoms?	Never	338	90.6%
	1 to 3 times	31	8.3%
	1 time/week	3	0.8%
	2 to 3 times/week	1	0.3%
7. How low does your blood sugar need to go before you feel symptoms?	60 - 69 mg/dl	360	96.5%
	50 - 59 mg/dl	11	2.9%
	40 - 49 mg/dl	2	0.5%
8. To what extent can you tell by your symptoms that your blood sugar is low?	Always	83	22.3%
	Often	36	9.7%
	Sometimes	56	15%
	Rarely	32	8.6%
	Never	166	44.5%
	Aware	117	31.4%
GOLD SCORE	Borderline Awareness	32	8.6%
	Impaired Awareness	224	60.1%

Table 2: Frequency distribution of participants based on their answers in both the Clarke and Gold questionnaire.

Factors associated with Hypoglycemia Awareness

When the level of awareness was compared using the gold questionnaire between various groups, our study observed significant mean difference by one-way ANOVA (F (3,369) = 12.784 P = 0.000) when duration of diabetes mellitus was compared. A Games-Howell post-hoc test revealed that the awareness score of patients with a longer duration of diabetes was significantly lower (mean = 3.62 ± 2.51) than other patients who have been diagnosed with T2DM for less than a year (Mean = 6 ± 1.7), 1 to 5 years (Mean = 5.09 ± 2.19) and 6 to 10 years (4.81 ± 2.34). The decrease in gold score with an increase in duration of T2DM is seen in Figure 2.

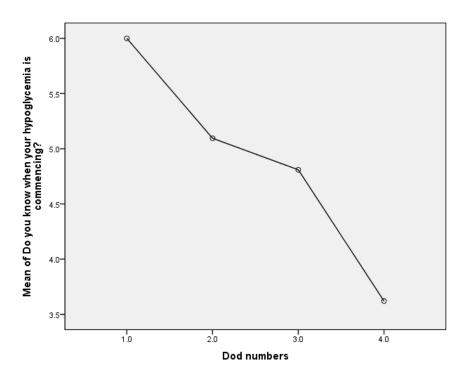


Figure 2: Means plot showing the difference in awareness scores in different duration of diabetes (DOD).

Furthermore, statistically significant differences between the mean scores were found when Family history of T2DM was compared (t (371) = -2.759, P value = 0.006). The mean score of patients with a family history of T2DM was less than (mean = 4.19 ± 2.45) the score of patients without the same (mean = 4.91 ± 2.39). It was also found that patients who were not on insulin therapy had a higher significant mean score (mean = 4.96 ± 2.26) than those who were taking insulin (mean = 3.463 ± 2.53) when independent t-test was performed (t (371) = -5.76, P value = 0.000).

Statistically significant mean difference was determined using one-way ANOVA when the educational qualification of the patients was compared (F (5,367) = 4.390, P value = 0.001). The mean score of patients with a master's degree was less than (mean = 3.519 ± 2.48) the score of patients with a Diploma (mean = 5.53 ± 1.66), Higher secondary education (mean = 4.83 ± 2.31) and secondary education (mean = 5.08 ± 2.34).

From our results we did not find any significant correlation between the level of awareness and age, gender, BMI, and occupation.

DISCUSSION

The study aimed to assess the awareness about hypoglycemia among type 2 diabetes mellitus patients. Generally, more importance is given in educating type 1 diabetic patients regarding hypoglycemia and its symptoms. While it is well-known that hypoglycemia is a risk involved in the pharmacotherapeutic management of T2DM, education about effects of hypoglycemia is more focused on T1DM patients. A study conducted in Tamil Nadu revealed that 57.43% of their T2DM patients had hypoglycemic episodes.^[7] and a hypoglycemia prevalence and awareness study conducted in Brazil revealed that 61.8% of T2DM patients had at least one episode of hypoglycemia and 34.6% of them had impaired awareness about hypoglycemia.^[8] This emphasizes the importance of educating all diabetic patients about hypoglycemia and not solely focusing on T1DM patients.

Currently it is recommended to employ both Gold and Clarke questionnaires either in combinations or separately to identify the population who are aware of hypoglycemia.^[9] Our results revealed that while 72.1% of people were determined to be aware about hypoglycemia by the Clarke questionnaire, only 31.4% of people were classified as aware by the Gold questionnaire which contrasts with the results found by Stefenon P, et.al.^[10] This difference can be attributed to the bifactorial structure of the Clarke questionnaire explained in a study by Ang LC, et.al, explaining the two factors of the Clarke questionnaire to be "awareness of hypoglycemia" and "experience of hypoglycemia." ^[11]

Further analysis revealed significant associations between awareness about hypoglycemia and various clinical and demographic factors. Our results found that duration of diabetes mellitus, family history of diabetes mellitus and educational qualification had a significant effect on hypoglycemia awareness among patients. Patients with longer duration of diabetes were found to be more likely to be aware about hypoglycemia than those who were recently diagnosed with the same. Similarly, patients who have a family history of T2DM also seemed to be more aware about hypoglycemia and its symptoms. This could be attributed to them having firsthand experiences in taking care of their family members when they experienced a hypoglycemic episode. A study by Jorgensen RN, et.al, concluded that the family of diabetic patients can recall more severe episodes of hypoglycemia and that they can usually recognize the impending hypoglycemia before the patient becomes aware of the problem.^[12] Additionally, patients with higher educational qualifications showed greater awareness about hypoglycemia than others. It was also observed that patients who were on adjunct insulin therapy were more aware about hypoglycemia than patients who weren't on insulin therapy. It was found that education about hypoglycemia was given along with insulin education which improved their level of awareness.

Statistical analysis between the two scores revealed a strong correlation between them suggesting overlapping aspects of hypoglycemia awareness in both the tools. The Clarke score is influenced by past experiences of hypoglycemic events which doesn't necessarily translate to awareness about hypoglycemia. A study by Hatle H et.al, stated the Clarke questionnaire was superior at identifying patients at risk of clinically significant hypoglycemia and Gold questionnaire was superior in identifying patients who were at a risk of asymptomatic hypoglycemia like nocturnal hypoglycemia.^[13] Our study results aligned with the study by Rubin NT, et.al, where the participants were more likely classified as aware by the Clarke questionnaire than the Gold score. They inferred that using a combination of both the questionnaires can provide a more accurate awareness status.^[14] We wanted to ascertain the actual prevalence of hypoglycemia awareness among our study population by combining both scores. When both scores of our study were considered together it revealed that only 26.2% of our population were aware of hypoglycemia. This highlights the significant gap in knowledge and awareness among T2DM patients regarding hypoglycemia awareness. A study by Moghissi E, et.al, reported that hypoglycemia is an important risk factor for mortality and morbidity in type 2 diabetes patients and hypoglycemic events in T2DM patients are often underreported and underrecognized.^[15] Greater awareness about hypoglycemia is necessary among diabetic patients in our community with special attention to newly diagnosed diabetics and patients who have no prior familial history. Healthcare professionals play a pivotal role in educating patients on recognizing, managing and preventing hypoglycemia.

Our study had certain limitations like recall bias especially for questions in the Clarke questionnaire that requires the patients to recall events over a 6-month period, misinterpretation of the question and inaccurate reporting of

hypoglycemic episodes. Further research should focus on developing tailored interventions to improve hypoglycemia awareness among T2DM patients which can ultimately improve their overall diabetes management and quality of life.

CONCLUSION

In conclusion our study revealed a lack of hypoglycemia awareness among T2DM patients. These findings stress the need for a more comprehensive patient education which includes all types of diabetic patients ensuring that they are equipped with proper knowledge and skills to recognize and manage hypoglycemic events. Interventional programs aimed at raising awareness about hypoglycemia should be conducted in healthcare facilities. By doing so we can reduce the risk of severe hypoglycemic episodes and the prevalence of IAH thereby improving the quality of life for diabetic patients.

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