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Hypoglycaemia Fear among Diabetics

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ABSTRACT

Background: This study aimed to evaluate whether fear of hypoglycaemia (FOH) ispresent in diabetic patients receiving oral hypoglycemic agents or insulin and factorsthat can influence it.

Methods: This study is a cross sectional survey of diabetic patients attendingendocrine clinics in Jordan University Hospital, King Abdullah University Hospital and Royal Medical Services, from June 2013 till may 2014.

Results: Out of 326 approached 268 patients participated. The mean age ofparticipants was (49.81±14.09), and 141 (52.6%) were females. FOH was present in allpatients and with all antidiabetic medications. Among antidiabetic agents, patientstaking insulin were found to have the highest score of overall FOH ($p<0.001$). Level offear correlated with type of diabetes ($p<0.01$), and being female ($p<0.01$). Patientsworking in medical field behavioral fear scores were higher compared with patientsworking in non-medically related field ($p<0.01$). In addition, as the duration of diabetesincreases the overall FOH increases ($p<0.01$). It had been found that as the FOHincreases the quality of life decreases ($p<0.001$).

Conclusion: Type of diabetes, age and type of antidiabetic agent affect FOH. Diabetes
Mellitus duration and gender affect the behavioral scale of hypoglycaemia fear survey.
FOH has been found to affect quality of life.

Keywords: Diabetes, Jordan, hypoglycaemia, fear.

1. INTRODUCTION

Diabetes mellitus (DM) is a chronic condition caused by an absolute lack of insulin or relative lack of insulin as a result of impaired insulin secretion and action. Its hallmark is symptomatic glucose intolerance resulting in hyperglycemia and alterations in lipid and protein metabolism. In the long term, these metabolic abnormalities contribute to the development of macro and micro-complications such as cardiovascular disease (CVD), retinopathy, nephropathy, and neuropathy[(1)]. According to the International Diabetes Federation (IDF) 382 million people have diabetes in 2013 and by 2035 this will rise to 592 million worldwide. The number of people with type2 diabetes is increasing in every country, 80% of people with diabetes live in low- and middle-income countries and the greatest number of people with diabetes are between 40 and 59 years of age (IDF, 2013). In Jordan, the prevalence of diabetes in adult's ≥25 years of age is 17.1%, while an additional 7.8% of Jordanians have impaired glucose tolerance with no significant differences between women and men[(2)].

The overall goal of diabetes management is to achieve and maintain controlled blood glucose and reduce the risk

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of long-term complications. Recent Studies have shown that intensive glycemic control can limits, delays or even prevents the chronic complications of diabetes. However; this way of management associated with an increased risk of hypoglycaemia[3]. Hypoglycaemia is common in diabetic patient; studies have shown that hypoglycaemic events occur in 24% to 60% of diabetic patients[4].

Hypoglycaemia is defined as abnormally low plasma glucose concentration which may expose the patients to potential harm[5].There are no defined or single threshold value for the symptoms of hypoglycaemia, however; patients must be alerted to the risk of hypoglycaemia when plasma glucose is ≤ 70 mg/dl or ≤3.9mmol/L[5]. The symptoms of hypoglycaemia are classified as neuroglycopenic or neurogenic (autonomic) which are further classified as adrenergic or cholinergic. Neuroglycopenic symptoms are caused by the direct low glucose level in the brain, and neurogenic symptoms are caused by perception of physiologic changes triggered by hypoglycaemia[6-8].

Hypoglycaemia is considered as a true medical emergency which requires immediate recognition and treatment to prevent organ and brain damage. The symptoms of hypoglycaemia depend on the duration and the severity of hypoglycaemia and vary from autonomic activation, behavioural changes, altered cognitive function, to seizures or coma[3]. It can occur suddenly and it's characterized by unpleasant physical and psychological symptoms such as shaking, sweating, drowsiness, nausea, poor motor coordination, mental confusion, negative mood, and unconsciousness[9] [3]. Repeated hypoglycaemic episodes lead to compromise physiologic and behavioural defences against future falling glucose concentration, causing a cycle of recurrent hypoglycaemia[10]. Untreated hypoglycaemia can cause a significant economic and personal burden, so the identification and prevention of hypoglycaemia can reduce diabetes burden by prevention of hypoglycaemia complications[11].

The frequency of hypoglycaemic events in diabetic patients treated with oral antidiabetic (OAD) or incretin-based therapies are lower than patients treated with insulin, however; the incidence increases when incretin based therapies, especially glucagon like peptide-1 receptor agonists, are combined with sulphonylureas[12, 13].

Given the potential life threatening nature of severe hypoglycaemia, it would not be surprising that many of diabetic patients have a significant fear of developing hypoglycaemia. This fear may have significant clinical implications for diabetes management. Patients with FOH may engage in 'over-compensatory behaviours' to avoid the aversive symptoms of past hypoglycaemic episodes, this may include taking less medication or overeating to avoid hypoglycaemia. The latter may result in poor metabolic control and increase the risk of serious health consequences associated with diabetes[14].

The aim of this research was to evaluate level of FOH in diabetic patients receiving oral hypoglycaemic agents or insulin, and to investigate the factors that can influence FOH including.

Methodology

This study is cross sectional based survey targeting diabetic patients attending endocrine clinics at Jordan University Hospital (JUH), King Abdullah University Hospital (KAUH) and Royal Medical Services (RMS). Ethical approval was obtained from all participating institutions. Participants' verbal consent was obtained before any information was collected from them. Inclusion criteria: patients aged 18 years or older with DM who sought care at the outpatient clinics who have been diagnosed with DM for at least one year. The sample size of this study was calculated based on the average number of patients daily visiting endocrinology clinic in JUH, KAUH and RMS are 1000/month, sample size at a 95% confidence interval will be 370.

A structured interview based questionnaire was used. It included:

1) Patient information (demographics, diabetes assessment, other chronic conditions and current medication)
2) Hypoglycaemia fear survey: (HFS[15]. It consists of two subscales with a total of 27 items measuring

behavioral and affective aspects of FOH. The behavior subscale (avoidance subscale) consisted of 10 items that measure an individual's behavior in his or her effort to avoid hypoglycaemia or the effects of hypoglycaemia. The second subscale (Worry), measuring the emotional/affective aspect of FOH, which consists of 17 items describing a person's concerns of hypoglycaemia and its consequences. The items are rated on a five-point Likert scale ranging from Never (1) to Always (5). Total FOH score was calculated by adding both subscale scores. The instrument has been translated to Arabic language and validated (face and content validation) by the authors and a physician.

Data was analyzed using the Statistical Package for Social Sciences (SPSS) software version 20 including descriptive statistics, independent-Sample T-test, one way ANOVA, and Pearson correlation. Because of multiple comparisons, bonferroni correction was applied and all *p* values < 0.01 was considered statistically significant.

Results

Out of 326 patients invited to be enrolled in the study only 268 were actually included. Fifty four were excluded due to incomplete information or refusal to participatedue to lack of time or interest(Figure 1).

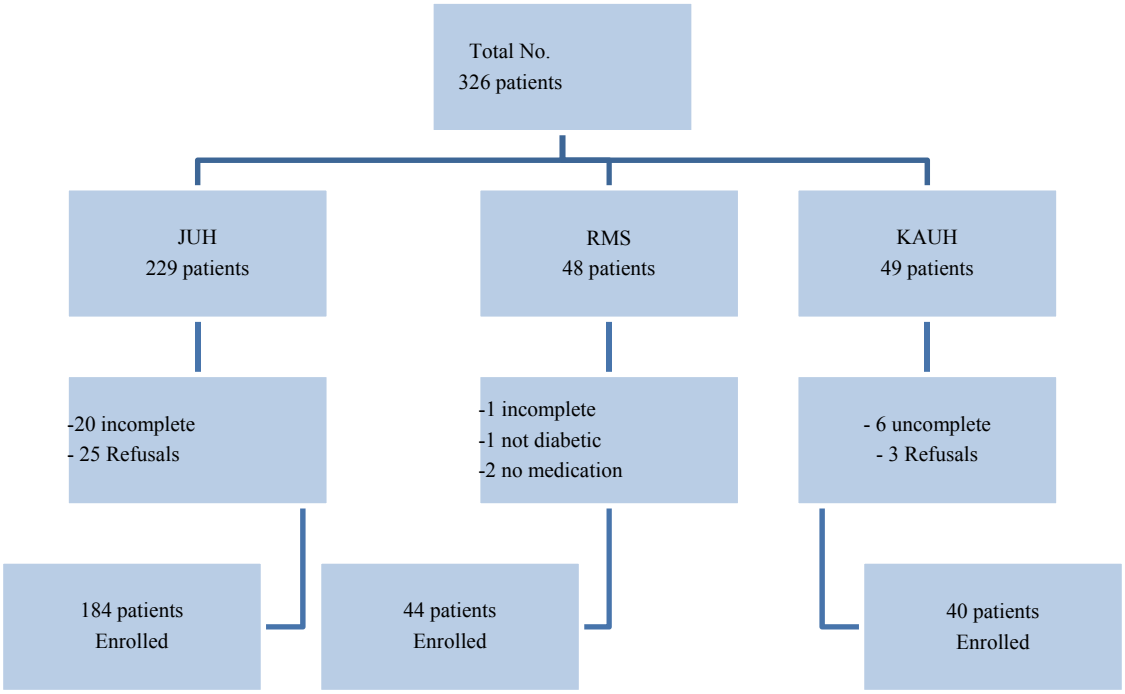

Figure 1: Patients recruitment flow chart

The average age of participants was 49.8, and 52.6% were females. Only 7.8% of the patients' population were working in a medically related field (Table1).

Table 1. Basic information of patients

Demographics (N= 268)		**Total**
Age (Mean ±SD) from 18-84		49.81±14.09
Gender [N (%)]	**Male**	127 (47.2%)
	Female	141 (52.6%)
Type of DM	**T1DM**	46(17%)
	T2DM	222(83%)
BMI (Mean ±SD)		29.8±6.125
DM duration (Mean ±SD)		10.6±7.3
HbA1c (Mean ±SD)		8±2
Fasting Blood Glucose		172±84
Marital status (divorced=0)	Single	42 (15.6%)
	Married	209 (77.7%)
	Widowed	17 (6.33%)
Education level [N (%)]	Elementary	34 (12.6%)
	Secondary	98 (36.4%)
	College	100 (37.2%)
	Post graduate	28 (10.4%)
	Not educated	8 (3%)
Field of employment [N (%)]	**Medical**	21 (7.8%)
	Non-medical	246(91.5%)
Employment Status [N (%)]	**Employed**	101 (37.5%)
	Retired	44 (16.4%)
	Unemployed	123 (45.7%)

T1DM: type 1 diabetes mellitus, T2DM: type 2 diabetes mellitus, DM: Diabetes mellitus, BMI: body mass index, HbA1c: Glycated haemoglobin.

The most commonly used diabetic management drug was metformin. The most commonly reported drug for co morbidities was a statin. Details are shown in Table 2.

Table 2. The most frequently used medications as reported by patients (total number of patients 268)

	Total number 268
Medications used by patients	Frequency (%)
Metformin	203 (75.5%)
Sulfonylurea	91 (33.8%)
DPP-4 Inhibitors	22 (8.2%)
Insulin	179 (66.5%)
Angiotensin Converting Enzyme Inhibiters	65 (24.2%)
Angiotensin Renin Blockers	50 (18.6%)
Beta Blockers	47 (17.5%)
Calcium Channel Blockers	27 (10%)
Statins	140 (52%)
Aspirin	123 (45.7%)

In general, patients' level of worry was low, except for the fact that they were worried that hypoglycaemia would cause decrease or loss of consciousness. They were also worried that the loss of consciousness would lead to other health problems. The most frequently reported fear component was carrying pieces of sugar, the administration of food, in addition to reducing drug dose due to fear of hypoglycaemia. Patients' FOH; behaviour and worry results were detailed in Table 3.

Table 4 shows quality of life assessment in which; generally patients are satisfied with their situation, particularly they are mostly satisfied with their knowledge about their diabetes and current treatment, while they are not surely satisfied about time spent on exercise. Also, the least to worry about is "missing work "compared to "sometimes feel physically ill and passing away".

Field of employment was found to affect the behaviour part of FOH; patients working in the medical field behavioural score were higher than patients who are not. As the duration of diabetes increases the FOH behavioural and overall scores increase. Patients with higher HbA1c and fasting blood glucose level also scored higher in regard to FOH. As FOH increases the quality of life decreases, younger patients had higher FOH score than elderly. Details are shown in Table 5. As expected, patients with type 1 DM and those taking insulin had the highest FOH scores. Those taking DPP-4 inhibitor had the lowest score, details showed in Table 6.

Table 3. Hypoglycaemic fear survey behaviour and worry scores of 268 patients.

Behaviour:	**Score*** (Mean ±SD)
Eat large snacks at bedtime	2.71 ±1.238
Avoid being alone when my sugar is likely to low	2.75 ±1.584
To be on safe side: urine test: spill a little sugar. Blood glucose: run a little high	1.65 ±1.159
Keep my sugar higher when I will be alone for a while	2.28 ±1.52
Eat something as soon as I feel the first sign of low blood sugar	4.41 ±1.068
Reduce my medication (insulin/pills) when I think my sugar is too low	3.25 ±1.594
Keep my blood sugar higher when I plan to be in a long meeting or at a party	2.92 ±1.594
Carry fast-acting sugar with me	3.35 ±1.641
Avoid a lot of exercise when I think my sugar is low	2.93 ±1.711
Check my sugar often when I plan to be in a long meeting or go out to a party	2.62 ±1.535
Worry:	**Score*** (Mean ±SD)
Not recognizing / realizing I am having a reaction	2.88 ±1.556
Not having food, fruit, or juice with me	2.47 ±1.485
Feeling dizzy or passing out in public	3.19 ±1.548
Having a reaction while asleep	2.81 ±1.6
Embarrassing myself or my friend / family in a social situation	2.13 ±1.542
Having a reaction while alone	2.7 ±1.577
Appearing stupid or drunk	2.28 ±1.534
Losing control	2.86 ±1.585
No one being around to help me during a reaction	2.71 ±1.536
Having a reaction while driving	2.51 ±1.614
Making a mistake or having an accident at work	2.21 ±1.429

Getting a bad evaluation at work because of something happens my sugar is low	1.25 ±1.32
Having seizures or convulsions	2.51±1.53
Difficulty thinking clearly when responsible for others (children, elderly, etc.)	2.36 ±1.49
Developing long-term complications from frequent low blood sugar	3.17 ±1.56
Feeling lightheaded or faint	3.14 ±1.52
Having an insulin reaction	2.37 ±1.54

***: Score as follows: 1=Never, 2=Rarely, 3=Sometimes, 4=Often, 5=Very Often**

Table 4. Quality of life assessment for 268 patients

How satisfied*:	**Mean ±SD**
How satisfied are you with your current diabetes treatment	1.96 ±1.191
How satisfied are you with amount of time it takes to manage your diabetes?	2.09 ±1.255
How satisfied are you with the time you spend to know your blood glucose	2.37 ±1.33
How satisfied are you with the time you spend exercising	3.05 ±1.352
How satisfied are you with your sex life	2.39 ±1.283
How satisfied are you with the burden your diabetes is placing on your family	2.79 ±1.431
How satisfied are you with time spent getting check-up's for your diabetes	2.25 ±1.345
How satisfied are you with your knowledge about your diabetes	1.87 ±0.93
How often:**	
How often do you eat thing you shouldn't instead of telling that you have DM	2.29 ±1.258
How often do you worry about whether you miss work	1.67 ±1.03
How often do you have a bad night's sleep because of diabetes	2.01 ±1.191
How often do you feel diabetes limits your career	2.07 ±1.257
How often do you have pain because of the treatment for your diabetes	2.29 ±1.291
How often do you feel physically ill	2.84 ±1.232
How often do you worry about whether you will pass out	2.55 ±1.345

Satisfaction rated as :1=very satisfied, 2=moderately satisfied, 3=neither, 4=moderately dissatisfied, 5=very dissatisfied.
How often rated as :**1=Never, 2=Rarely, 3=Sometimes, 4=Often, 5=Very Often**

Table 5. Factors influencing Fear of Hypoglycaemia

	Mean ±SD	**Behavior**	**Worry**	**Sum of all**
DM type	T1DM	32 ±6.398	53.11 ±15.14	85.11 ±18.104
	T2DM	28.12 ±7.57	42.32 ±16.276	70.43 ±21.18
	P-Value	0.001	0.000046	0.000017
Gender	Male	27.39 ±7.387	42.5 ±16.034	69.89 ±20.561
	Female	30.04 ±7.431	45.67 ±16.953	75.71 ±21.805
	P-Value	0.004	0.119	0.026
Educational Level	One-way ANOVA P-Value	0.557	0.218	0.429
Employment status	One-way ANOVA P-Value	0.071	0.35	0.371
Field of employment	One-way ANOVA P-Value	0.008	0.54	0.729

Duration of DM	Pearson P-Value	0.007	0.09	0.024
HbA1c	Pearson P-Value	0.046	0.055	0.028
Fasting	Pearson P-Value	0.007	0.09	0.024
Quality of Life	Pearson P-Value	0.000028	0.000001	0.000001
Age	P-Value	0.015	0.001	0.001

Table 6. Medications and Fear of Hypoglycaemia

	No. of Patients	**FOH**	**Mean ±SD**	**P value (1) with DPP-4 inhibitors**	**P value (2) with insulin**
Metformin	203	Behavior	28.04±7.6866	0.0245	0.0057
		Worry	42.45±16.404	0.1933	0.0085
		All	70.49 ±21.51	0.0702	0.0024
Sulfonylurea	91	Behavior	27.64 ±7.635	0.0549	0.0076
		Worry	42.25 ±15.64	0.1995	0.0254
		All	68.89 ±20.72	0.1412	0.0021
Insulin	179	Behavior	30.14 ±6.993	0.0002	
		Worry	46.86 ±16.07	0.0112	
		All	77 ±19.995	0.0008	
* DPP-4 inhibitors	22	Behavior	24.18 ±7.294		0.0002
		Worry	37.73±13.024		0.0112
		All	61.91 ±15.43		0.0008

* DPP-4 inhibitors: Dipeptidyl peptidase-4 Inhibitors

Discussion

This study found that as the FOH increases, the quality of life decreases, this correlate with results of Lundkvist study in 2005[16]. In general; FOH has a negative impact on quality of life, diabetes management and metabolic control, subsequent health outcomes and increased fear and anxiety[14, 15]. Like other diabetic patients globally, Jordanian patients have fear of hypoglycaemia with all of their antidiabetic drugs. As the diabetes self-management decreases, hypoglycaemia and the development of long-term complications associated with low glycemic control increases. Recurrent hypoglycaemic events are associated with increased health care costs and resources required to treat hypoglycaemic events, as well as personal financial costs and loss of productivity at school or work. Also fear and worry about future hypoglycaemia events interfere with patient's quality of life[17]. Health related quality-of-life (HRQoL) is affected by FOH in diabetic patients. It has been shown that patient with hypoglycaemia symptoms report more fear and worry of hypoglycaemia and more influenced by their diabetes compared with patients without hypoglycaemia symptoms[16].

The most common causes for hypoglycaemia in diabetic patients are insufficient food (43% in type 1 diabetes mellitus (T1DM) and 47% in type 2 diabetes mellitus (T2DM;[18]. In this study patients reported that the often administered food, and reduction of antidiabetic medication dose when they feel the first sign of low blood sugar. The practice of patients is understandable, since the aggressiveness of therapy to achieve glycemic control is considered as most important risk factor for hypoglycaemia[19]. Other risk factors such that can cause hypoglycaemia include: antecedent hypoglycaemia,[13] alcohol, increased glucose utilization (e.g., exercise), female sex, sleep and decreased glucose and production

(e.g., liver disease)[20]. Duration of diabetes, age and progressive insulin deficiency are also found to be associated with high risk of hypoglycaemia in patients with T2DM, which appear to be increased in patients who have received insulin for more than 10 years[11]. In this study females reported higher FOH scores than men. The duration of diabetes was also correlated with higher FOH score that is considered as important risk factor for severe hypoglycaemia. In this study; older patients FOH scores were lower than younger patients. This might be due to lack of awareness as over the time, symptoms of hypoglycaemia become less intense or even diminish altogether, resulting in hypoglycaemia unawareness in a significant proportion of diabetic patients,[21]. The latter is dangerous, as studies shows that hypoglycaemia unawareness leads to increased risk of sever hypoglycaemia by 6-fold in T1DM and 9-fold in T2DM[22, 23].

Patients use insulin for diabetes management had the highest FOH score. It is reported that approximately 90% of diabetic patient who receive insulin have experienced hypoglycaemic events[10]. In T1DM individuals, they experience two events of symptomatic hypoglycaemia per week and one event of severe hypoglycaemia per year[10]. The incidence of hypoglycaemia events in T2DM is one third of T1DM[10, 24]. Studies showed that the incidence of sever hypoglycaemic event per patient-year in insulin treated T2DM was 0.35 compared to an incidence of 1.15 per patient-year in T1DM[24]. Most of the hypoglycaemic events seen in T2DM because of the prevalence of disease is 20 times greater than that of T1DM and most of these patients will need insulin therapy[10]. The prevalence of an event varies according to the type of therapy. It ranges from 61.5% with the combination of sulfonylurea, metformin, insulin, to 30.5% with insulin alone; and 6% with metformin alone[25]. A hypoglycaemia event also reduces productivity and increases healthcare costs. The cost of hypoglycaemia event varies depend on the severity of the episode, and ranges from minimal (€63) for a mild episode, to very high (€3917) for a severe episode requiring hospitalization[26].

In diabetic individuals, FOH increases the psychological distress associated with diabetes. This has a behavioural impact on diabetes management and metabolic control. Which is represented by taking a counteractive action to prevent hypoglycaemia by keeping high blood glucose or over treats the early signs of hypoglycaemia[15]. Some diabetic patients see hypoglycaemia events are more tangible than the possibility of future health problems. FOH has also been connected to state and trait anxiety. Studies have shown that in patients with both type 1 and type 2 diabetes there was a correlation between higher scores on the worry scale of the hypoglycaemia fear survey (HFS) and higher levels of trait anxiety and general fearfulness[27]. This may lead to a diminished ability to differentiate between anxiety and hypoglycaemia that could delay or prevent the patient from responding appropriately to hypoglycaemia, and thus, a more severe hypoglycaemic episode may occur[26].

The unpleasant symptoms associated with hypoglycaemic event and its negative consequences may lead to anxiety or FOH in patients with diabetes. This may increase risk for keeping blood glucose levels high to avoid episodes by the diabetic patient when fear is high, thereby contributing to poorer metabolic control and subsequent health outcomes, FOH is considered as a major barrier for optimal blood glucose control and this may outweigh concerns about long-term consequences of the effects of hyperglycaemia[14]. In agreement with previous studies, this study showed high FOH score in patients on sulfonylurea or insulin because of the high incidence of hypoglycaemia with these agents[28, 29]. These result are also related to the finding in study by[15] that FOH have a behavioural impact on diabetes management and metabolic control. This impact is represented by taking a counteractive action to prevent hypoglycaemia by keeping high blood glucose or over treating the early signs of hypoglycaemia.

Conclusions

FOH exists among patients taking hypoglycemic agents. FOH has been found to affect quality of life

negatively. So further research is needed to specify this FOH more among agents used to treat diabetes in order to increase awareness and educate patients not to feel fear with agents without hypoglycaemia risk, taking into consideration not only antidiabetic agent, but also type of diabetes, age, diabetes duration and gender.

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الخوف من هبوط مستوى السكر عند مرضى السكري

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ملخص

هدفت هذه الدراسة إلى معرفة وجود الخوف من هبوط السكر عند مرضى السكري الذين يتناولون الأدوية الفموية الخافضة للسكر أو الأنسولين والعوامل المؤثرة على ذلك.

أجريت الدراسة على المرضى المراجعين لعيادة السكري في كل من مستشفى الجامعة الأردنية، مستشفى الملك المؤسس، والخدمات الطبية الملكية في الفترة ما بين حزيران 2013 أيار 2014. وقد شارك في هذه الدراسة 268 مريضاً من أصل 326 بمعدل عمر 49.81 منهم 52.6% إناث. وقد بينت الدراسة وجود الخوف من هبوط السكر مع كل الأدوية التي تعالج السكري. سجل الأنسولين أعلى درجة خوف من ضمن هذه الأدوية ($p<0.001$) وأن مستوى الخوف مرتبط بنوع السكري ($p<0.01$)، وكون المريض أنثى ($p<0.001$). كما تبين أن سلوك الخوف من هبوط السكري للمرضى العاملين في المجال الصحي أعلى من المرضى غير العاملين في هذا القطاع ($p<0.01$). بالإضافة إلى أنه كلما زادت مدة مرض السكري، زاد الخوف من هبوط السكر ($p<0.01$)، كما أن زيادة الخوف من هبوط السكر تقلل من نوعية الحياة عند مرضى السكري ($p<0.001$).

استنتجت الدراسة أن نوع ومدة مرض السكري عند المريض، عمر وجنس المريض، ونوع دواء السكري الذي يتناوله يؤثر على الخوف من هبوط السكر الذي بدوره يؤثر على نوعية حياة المريض (Quality of life).

الكلمات الدالة: هبوط السكر، الأدوية الفموية، الأنسولين، مرضى السكري، الأردن.

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