

Identifying and Addressing the Barriers of Insulin Use in Type II Diabetes Patients

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Abstract

Background: Diabetes mellitus type 2 is characterized by a gradual decrease in insulin sensitivity in the peripheral tissues and liver (insulin resistance), followed by a gradual decline in beta cell function and insulin secretion. However, patients with poor glycemic control require the use of Insulin therapy to achieve the target of American Diabetes Association in recommending HbA1c to be less than 7% \geq 8% with or without optimal doses of anti-diabetic drugs.

Objective of the study: This study aimed to evaluate and address the barriers of the use of insulin in type 2 diabetes mellitus patients, where their glycaemic control is poor i.e. HbA1c is \geq 8%, despite being administered optimal doses of anti-diabetic drugs.

Research design and Methods: This study utilized a cross sectional quantitative study, with a sample population of 200 patients with type 2 diabetes mellitus; patients who were already undergoing treatment with one or more oral agents and were also recently prescribed insulin to control their metabolic status, showed poor glycaemic control (HbA1c \geq 8%). Data were obtained through patients' interview using a validated questionnaire. The study was conducted in the diabetes mellitus clinic, of Al-Farwaniyah Primary Health Care Center in Kuwait.

Results: Patients with type 2 diabetes who failed to adhere to the prescribed insulin therapy reported misconceptions regarding the fear of hypoglycaemia in 49% of the total sample, pain from injection in 68%, and self-blame about the need for insulin i.e. sense of failure in 61% of total sample of the study. Other factors that were addressed included sensation in regard to severity of the disease, fear of weight gain and, other negative self-perceptions and attitudinal barriers were studied.

Conclusion: Reducing the negative influence of psychological insulin resistance (PIR) on treatment outcomes should be a clinical priority. Approaching and understanding the multifaceted and complex nature of PIR and discussing the etiology of every patient's PIR is the first important step. The incorporation of well - validated clinical measures for assessing these barriers, as well as further research should be conducted on the impact of intervention in overcoming such barriers. Clinicians should prescribe simple insulin regimen to decrease their patient's fear of insulin dependency and, the use of modern insulin analogs and insulin pen services, may greatly reduce PIR by mitigating the fear of life style changes and side effects, as well as social stigma associated with using insulin in a vial and syringe.

Keywords: Psychological Insulin Resistance; Barriers; Insulin Refusal; Type 2 Diabetes; Psychology; PIR

Introduction

The management of Type 2 diabetes mellitus using oral hypoglycemic drugs may fail to achieve the ideal metabolic control, in which case, a large percentage of patients will require exogenous insulin therapy to achieve good glycaemic control. There is a progressive impairment of insulin secretion by B cells, where these cells undergo dysfunction with time, as demonstrated in a Prospective Diabetes study in the UK. More than 50% of newly diagnosed cases of type 2 diabetes mellitus undergo insulin Therapy within 6 years of the onset of the disease [1]. When medical interventions such as the initial life style modifications, and oral anti-diabetic drugs are not sufficient to achieve a good glycaemic control in patients with type 2 diabetes mellitus, subsequent insulin initiation is recommended to achieve hemoglobin A1c targets [2,3]. Despite the demonstrated efficacy of insulin therapy in achieving and maintaining the glycaemic control in patients with type 2 diabetes mellitus, there are factors associated with reluctance from both doctors and patients to initiate insulin therapy at the right time, due to poor glycaemic control and the presence of micro vascular and macro vascular complications of diabetes mellitus [4].

A study conducted in the U.S.A., showed that 33% of patients with type 2 diabetes are unwilling to initiate insulin therapy [5]. Factors causing insulin refusal in those patients were related to the misconception of patients that Insulin initiation demonstrates the severity of the disease; feeling of failure and guilt; fear of needle injections, fear of premature death from insulin injection, fear of hypoglycemia, fear of weight gain, loss of independence and reliance on others to give insulin [6].

Diabetes mellitus type 2 in an escalating epidemic nowadays in the world [7]. There is new irrefutable evidence that strict control of type 2 diabetes mellitus delays the onset of complications of the disease [8] and causes improvement in the overall quality of life of the patients [9].

According to last figures released by the International Diabetes Federation (IDF) a rising trend of prevalence of diabetes mellitus, for 20 Arab countries for which the data is available, nearly 20.5 million people are living with diabetes mellitus and 13.7 million are in the pre-diabetes, having impaired Glucose Tolerance (IGT) [10].

The highest prevalence of diabetes mellitus was found in Kuwait (21.1%), Lebanon 20.2%, Qatar 20.2%, Saudi Arabia 20.0%, Bahrain 19.9% and UAE 19.2%, So that it is reported Gulf region has now faced by epidemic of diabetes mellitus. In developed countries most people with diabetes mellitus are above the age of retirement, while in the Arab region nearly 73.4% diabetics are under the age of 60 years of age and in the peak of their productive years, which makes the burden in terms of disability due to diabetes greater [11,12]. Also diabetes complications are increasing where the prevalence of diabetic retinopathy in patients who had type 2 diabetes mellitus is 31% among patients who have diabetes for 10 years in Saudi Arabia. Also, the prevalence of neuropathy is 82% in data obtained from the Western part of Saudi Arabia [13].

Aim of the Study

The primary aim of this study is to determine the factors associated with the barriers of the use of insulin in type II diabetes mellitus patients.

Patients and Methods

Participants

This study utilized a cross sectional descriptive research methodology, which covered the period from May 2017 to August 2017. 200 type 2 diabetes mellitus patients agreed to participate in the study. Authors sought patients' informed consent prior to inclusion in the study; inclusion criteria were:

- 1) Patients diagnosed with type2 diabetes and currently undergoing treatment with oral hypoglycemic drugs,
- 2) Never used insulin before in their therapeutic management plan,
- 3) Speak Arabic or English,
- 4) Have no visual defects or impaired manual movement skills that would interfere with proper insulin injection.

The study was conducted in the out-patient diabetes clinic at the Al-Farwaniah primary health care center in Kuwait. A self-administrated questionnaire was used to collect patients' bio-data including age of the patents, gender, nationally, duration of diabetes education, and presentation of poor glycemic control, in which HbA1c \geq 8.0% (normal range 4 - 6%) on maximum drug therapy (metformin plus sulfonylurea), in whom insulin therapy was deemed necessary by the treating physicians. Exclusion criteria included patients diagnosed with type 1 diabetes mellitus, with severe psychiatric illness or dementia; patients diagnosed with type II diabetes mellitus but currently on insulin treatment.

The patients were asked series of questions including questions about their knowledge of insulin and its benefits; their willingness to initiate insulin therapy if is prescribed for them, which was rated using a Likert scale, ranging from willing to not willing. This questionnaire was aimed at measuring patients' negative and positive attitudes towards insulin usage; the attitudinal items were identified from four recent studies and validated by a number of consultants of diabetes mellitus in the ministry of health in Kuwait. Pilot study was conducted among 18 patients with type 2 diabetes mellitus to assess the reliability and validity of the 18 attitudinal items.

No selection or recall bias in this study.

Statistical analysis

Data was collected and entered SPSS (Statistical Package for Social Sciences) version 18 and the data were analyzed. Mean and standard deviation were estimated, for continuous variables and proportions for categorical variables. Chi-Square test the test of association was used to compare the proportion between those accepted and those rejected insulin therapy.

Results

This study included 200 patients with diabetes mellitus, all are adults above 18 years of age from total 256 patients asked to participate in this study, so the responding rate was 78.1%. the age of majority of patients in this sample was between 40 - 60 years of age with mean 55 ± 7.6 years, males were more than females, and the majority of included patients have diabetes mellitus for more than 10 years and the majority of the sample 83 % has uncontrolled diabetes mellitus.

The study showed that 45 % of the sample were accepting insulin therapy, on the other hand 55% of the 200 patients were refusing insulin therapy, and the study showed that very willing patients 20% of the willing group, moderately willing were 70 % and slightly willing = 10%.

We studied associated factors affecting acceptance and refusal of insulin therapy in the sample of the study, the most expressed factor fear from frequent injections was recorded among 68% of patients and then, was self-blame due to failure in controlling the metabolic state in and this was recorded in 61% of the total sample of the study ,and fear from starting insulin ,the will be used over the life of the patients was reported among 49% of the total patients, then followed by a factor that patients have no time for injecting themselves esp. in the work place and the patients have to make adaptation in their meals regimen ,exercise and diet was recorded in 87 patients with diabetes 43.5% of the total sample.

Insulin use denoting the severity of the disease was reported among 34% of total 200 diabetic patients, but positive attitudes like insulin prevents the complications of disease were showed in 41.5% of diabetic patients and other factors are recorded in table 2.

Characteristics	Willingness		Total 200	X ²	P value
	Willing No = 90	Not willing No =110			
Age					
Less than 40y	10 (11.1%)	15 (13.6%)	25 (12.5%)	0.771	0.382
41 - 60	51 (56.7%)	60 (54.5%)	111 (55.5%)		
More than 60	29 (32.2%)	35 (31.58%)	64 (32.0%)		
Gender					
Male	56 (62.2%)	47 (42.5%)	103 (51.5%)	7.532	< 0.001
Female	34 (37.8%)	63 (57.3%)	97 (48.5%)		
Working status					
Working	51 (56.7%)	60 (54.5)	111 (55.5%)	3.849	0.854
Not working	39 (43.3%)	50 (45.5)	89 (44.5%)		
Education					
Illiterate	21 (23.3%)	26 (23.6%)	47 (23.5%)	0.069	0.320
Primary school	40 (44.4%)	48 (43.6)	88 (44%)		
Secondary school	21 (23.3%)	27 (24.5%)	48 (24%)		
University	8 (8.9%)	9 (8.2%)	17 (8.5%)		
Duration of diabetes					
< 5 Year	10 (11.1%)	12 (10.9%)	22 (11%)	0.003	0.767
5 - 10 years	21 (23.3%)	26 (23.6%)	47 (23.5%)		
> 10 Years	59 (65.6)	72 (65.5%)	131 (65.5)		
Diabetes status					
Controlled	15 (16.7%)	19 (17.3%)	34 (17%)	0.013	0.033
Un-controlled	75 (83.3)	91 (82.7%)	166 (83%)		

Table 1: Patients `characteristics and willingness to receive insulin therapy.

*P < 0.05 = significant

Barrier/attitude	Willingness to take insulin				Total 200		X ²	P Value	
	Willing		Not willing		n	%			
	N = 90	%	N = 110	%					
1	Self-blame due to insulin use	45	50	77	70	122	61	8.32	0.007
2	Injecting is embarrassing	42	46.7	71	64.5	103	51.5	5.24	< 0.001
3	Injecting insulin is painful	54	60	82	74.5	136	68	4.81	< 0.001
4	Fear of hypoglycemia	31	34.4	67	60.9	98	49	13.87	< 0.001
5	Fear of social stigma	28	31.1	57	51.8	85	42.5	8.69	< 0.001
6	Life style adaptation	31	34.4	56	50.9	87	43.5	8.69	< 0.001
7	Continuous use of insulin	33	36.7	65	59.1	98	49.0	10.14	< 0.001
8	Fear of weight gain	40	44.4	35	31.8	75	37.5	3.37	0.212
9	Don't have enough time	27	30	65	59.1	92	46.0	16.86	< 0.001
10	I feel like a drug addict	22	24.4	46	41.8	68	34.0	6.66	< 0.001
11	Low self-efficacy	31	34.4	39	34.5	70	35.0	0.021	0.062
12	Severity of diabetes mellitus	30	33.3	38	34.5	68	34.0	0.032	0.321
13	People with insulin feel better	46	51.1	35	31.8	81	40.5	7.65	< 0.001
14	Regular blood-sugar checks are exhausting	22	24.4	27	24.5	49	24.5	0.0002	0.215
15	Insulin can prevent health problems and complications	55	61.1	28	24.5	83	41.5	25.92	< 0.001
16	Insulin works better than tablets	38	42.2	29	26.4	67	33.5	5.59	< 0.001
17	Taking insulin would mean more dependent on my doctor	10	11.1	16	14.5	26	13.0	0.516	< 0.001

Table 2: Attitudinal beliefs in willing and non-willing patients to use insulin therapy.

Discussion

This study revealed that 55% of patients with type 2 diabetes mellitus refused to use insulin therapy as a treatment as there was failure of oral anti-diabetic drugs to reach the target glycaemic level, which is 7%. Female patients who are not willing to use insulin are more than females willing to initiate insulin in non-will group (57.3% vs 42.5%), at the same time, 65% of the sample have had diabetes mellitus for more than 10 years. The study revealed that about 71% of patients in the non-willing group were more afraid of problematic hypoglycaemia than the willing group (34.4%), with a statistical significance between willing and willing groups ($P < 0.001$).

Hypoglycaemic symptoms result from physiological changes that occur to protect the brain when blood glucose falls below 3.8/L, the attacks of hypoglycaemia are unpleasant for the patients with diabetes mellitus, so that instead of NPH insulin, we can use insulin glargine or long acting insulin.

There will always be some risk of hypoglycaemia associated with diabetes management; however, this risk must be balanced with the greater risk of late diabetic complications and their impact on morbidity and mortality. Of interest in the DAWN study, despite an increased frequency of hypoglycaemic attacks, there was no major difference observed in fear of hypoglycemic events in type 2 diabetes patients treated with insulin [14]. Patients feel better when their blood glucose levels are under control [15]. Data obtained from UKPDS showed that there were no adverse effects of hypoglycemia on the well-being and quality of life of type 2 diabetes patients [16]. The selection and use of appropriate low dose of insulin may reduce the effects of rapid normalization of glycaemia and reduce the risk of hypoglycaemia during dose titration [17]. Risk of hypoglycaemia can be managed by effective patient education regarding symptoms, treatment and peak times for insulin or oral anti-diabetic drugs action. Patients should also be encouraged to do glucose monitoring in their homes and subsequent adjustment of their hypoglycemic regimen.

Sense of personal failure or self-blame on the need for insulin treatment may be the result of feeling that insulin is required because they have "failed" in other therapies or failed to control their disease by properly caring themselves according to the study of Brunton 2006 [18] and Ho., *et al.* 2006 [19], or being able to self-manage their disease with diet, exercise, or oral medications alone This sense of failure was recorded in 61% of the total sample of 200 DM patients with more self-blame attitude in the non-willing group than the non-willing group, with significant statistical difference between willing and non-willing groups ($P < 0.01$). This sense of failure may leave the patient with feelings of guilt [20], and the belief that they will be unable to control the disease in the future, regardless of treatment, and that insulin will not be effective and will not make a positive impact on their overall health [21-24]. Insulin may also be perceived as a threat or punishment, resulting to anger or feeling of betrayal, because patients may feel unfairly punished for poor self-care [25,26].

Concerns about weight gain

Weight gain is a concern for some patients With diabetes mellitus, in this study, only 31 patients with diabetes (37.5% of total sample), have had a concern about weight gain; this result coincide with Bryden., *et al.* [27], have reported that one-third of women of all ages with type 1 diabetes, with approximately half of the respondents reporting an omitting insulin, the women were doing that for weight -management purposes [28] however; insulin omission for weight control among women who skipped their insulin therapy, resulted to poor glycemic control, more DM-related hospitalizations, greater distress, more fear of hypoglycemia, and higher rates of retinopathy and neuropathy [29]. Also, increased weight in type 2 diabetes is associated with increased insulin resistance; therefore, weight gain may even compromise the efficacy of treatment [30], which could further re-enforce the belief that Insulin is not good for one's health, thus strengthening psychological insulin resistance; but increased body weight may be attributed to other factors such as sedentary life, or high fat diets that are observed in obese population without diabetes. Up to 90% of patients with type 2 diabetes are already overweight and further weight gain is probably Inevitable in type 2 diabetes when enthusiasm for diet or exercise programs reduces.

Concern about daily and painful insulin injections

The burden of self-injection plays a significant role in patients' failure to adhere to an insulin therapy regimen. This concern was reported in the majority of the study sample in 136 patients with diabetes mellitus type 2; (68%) in the willing group 60% of 90 people with diabetes and 74.5% in the not-willing group, with significant statistical association between the 2 groups ($P < 0.05$). This coincides with Zambanin, *et al.* 1999 [31], who reported that 115 patients with type 1 and 2 diabetes treated with insulin therapy showed that about 70% of patients are bothered if they had to inject themselves more than twice a day, and 45% of the study participants avoided injections of their prescribed insulin therapy due to anxiety or needle phobia. The relationship between injection anxiety and glycemic control can have important therapeutic implications. In a study conducted by Berlin, *et al.* [32] poor glycaemia control in patients with diabetes mellitus was associated with higher levels of anxiety, depression and phobic symptoms. The study of Lustman, *et al.* [33] demonstrated that co-morbid psychiatric illness was associated with high levels of glycosylated haemoglobin HbA1c compared to diabetic patients with no psychiatric illness symptoms (10.8% vs 9.6%) respectively, ($p = 0.02$). Other study in a survey found that ~20% of patients with diabetes mellitus intentionally skip insulin injections and the fear of self-injection is the major driver of this behavior [34].

Life style adaptations and restrictions

Patients with DM have concerned that insulin adds to the burden and stress, they already experience from managing diabetes on daily basis [27] and do not feel confident that they can handle the day to day demands of insulin therapy, which could become a source of inconvenience and result to loss of personal freedom.

In this study, 87 patients with diabetes mellitus, (43.5% of total sample), reported that insulin therapy will severely restrict their lives, thus become too inconvenient, time consuming and complex to manage, this result coincides with Hunt, *et al.* [35] and Bogatean, *et al.* [36] and Peragallo -Dittko [37].

Fear of Social Stigma

Patients with diabetes may develop fear of social stigma in relation self-injection of insulin in public places, as they feel they may be seen by others as intravenous drug addicts or patients with severe illness [38] such as diabetes, and that may result to feeling of social rejection and embarrassment [21,37] Patients with DM may select suboptimal locations to inject themselves when they are outside their homes, such as in public toilets, which may cause and force some patients to delay injections and avoid social activities [38,39]. The fear of social stigma on injection of insulin in public places may have a great impact on the compliance to treatment, as the net result maybe omission of insulin injection, or injecting themselves too early [40].

Limitations of the Study

In this study, healthcare provider factors affecting the acceptance to insulin use in type 2 diabetes were not studied, these health care professional factors include fear of patients' anger and compliance, fear of losing or alienating patient, inadequate time to teach patients all information about insulin therapy, concerns of physicians about hypoglycaemia and weight gain may occur to patients, the relative small sample of the study may be another limitation, and the study was in one diabetes clinic, not like DAWN study that conducted in multicenter all over the world in Asia, Australia, Europe and North America. also, we did not use multivariate analysis in statistical analysis of this study.

Conclusions

There are many barriers to implementing insulin therapy in type 2 diabetes patients, therefore, to reduce the psychological insulin resistance (PIR) on treatment outcomes should be a clinical priority. Appreciating and understanding the multifaceted and complex nature of PIR and discussing the causes of this PIR, the first important step is the incorporation of well, validated clinical measures in assessing

this problem, as well as further research on the impact of such measures in reducing PIR, are very crucial. Based on this information, physicians can help patients to overcome PIR, by working to establish self-efficiency and to increase patients' sense of control over their lives. Clinicians should emphasize the simplicity of the treatment in order to decrease the patients' fear of dependency on insulin and its consequent disruption of their way of life. Tailoring insulin treatment modalities, such as the use of modern insulin analogs, and insulin pen devices may, greatly reduce PIR by mitigating the fear of life style changes and side effects as well as the social stigma associated with using insulin in a vial and syringe. Use of new nasal insulin is another promising item in overcoming such barriers.

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