## **RESEARCH ARTICLE**

## **Diabetes Management**

Attitudes and barriers to insulin therapy: Is there a difference between developed countries and developing countries?



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#### ABSTRACT

Introduction: Trinidad is a small island middle income country with a high prevalence of type 2 Diabetes. As much as 60% of patients are likely to need insulin therapy in the future. The first step in preparing a patient to convert to insulin therapy is to determine barriers to insulin therapy. The aim of this study is determine barriers to initiating insulin therapy in a primary care setting in Trinidad, to inform appropriate intervention towards effective conversion. Methods: A structured pretested questionnaire was designed to collect demographic data, which included age, gender and highest level of education attained as well as knowledge and beliefs about insulin therapy among patients on oral hypoglycaemic agents only. In addition we compared these findings with a group of patients on insulin. Results: Knowledge of insulin was high (98%) yet the majority of patients (64.2%) were unaware they may require insulin in the future. Key barriers to initiating insulin treatment were, fear of needles, pain and apprehension about injecting oneself were prominent among respondents (85, 53.5%). The largest barrier to insulin therapy (54.1%) was anxiety about mastering the skill of giving oneself an injection, the general hassle of taking injections, concern about preparing the correct dose of insulin, and apprehension about the proper technique of needle injection. Conclusion: This research the first of its kind to be undertaken in this setting identified the most important common beliefs of insulin-naïve patients who may need to initiate insulin therapy in the future. In addition it provides evidence to guide diabetes educators and other health care professionals to use in educating patients.

#### Introduction

Type 2 Diabetes Mellitus (T2DM) is a chronic, progressive illness characterized by insulin resistance and progressive  $\beta$ -cell dysfunction. In 2000, the World Health Organization reported that there were 60 000 persons living with diabetes in Trinidad and Tobago (TTO) which was projected to increase to 125, 000 in 2030 [1]. In 2015 the International Diabetes Federation (IDF) reported that there were 140 300 cases of diabetes, a prevalence of 14.5% [2]. The republic of TTO is a small island middle-income country with a comparatively high prevalence of T2DM compared to the rest of the world and the region. In 2013 TTO based on the estimated prevalence of T2DM was ranked 37<sup>th</sup> in the world and tenth in the western hemisphere by the IDF [3]. Despite tight glycaemic control with oral hypoglycaemic agents as much as to 60% of patients will require insulin within 6 to 10 years of initial diagnosis—and even sooner if they have had long-standing undetected T2DM [4,5]. In addition early initiation of insulin therapy may also improve health outcomes [6-10]. As far back as 1995 Edelman and Henry, in a review of clinical studies suggested a treatment algorithm that provides early insulinization to preserve

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### **KEYWORDS**

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 $\beta$ -cell function and quickly achieve and maintain normoglycaemia and more recently by Weng et al. and Alvarsson et al. [11-13]. Further evidence indicates that short-term use of intensive insulin therapy at initial presentation or diagnosis of T2DM allows either more preservation or partial reversal of  $\beta$ -cell function in these patients; this allows them to have a normal glycemic profile and to continue with normal glycaemia without diabetes medications for multiple years [14]. More importantly the availability of basal insulin, analog insulin, insulin pens and smaller needles has all contributed to better acceptance of insulin therapy.

Notwithstanding, both patients and clinicians are often reluctant to begin or intensify insulin treatment, a phenomenon referred to as Psychological Insulin Resistance (PIR) [12-16]. In the insulin-naïve patient, PIR may arise in several ways such as perceived difficulties in administrating self-injecting insulin, the ability to accurately measure doses and coordinate administration with meals [12]. Other barriers to insulin initiation include: (a) Misconceptions regarding insulin risk, (b) Beliefs that needing insulin reflects a personal failure, (c) Concerns that insulin is ineffective (efficacy), (d) Insulin injections are painful, (e) Anxiety about longterm complications and side effects of therapy, (f) Loss of independence, and (g) Cost [12,17-19]. All of which may also provide obstacles to appropriate treatment intensification, optimal blood glucose control, and long-term diabetes management. Thus identifying these barriers is crucially important at the initiation of insulin treatment in order to attain compliance in the first instance and better health outcomes in the long run.

The aim of this study is determine barriers to initiating insulin therapy in a primary care setting in Trinidad, to inform appropriate intervention towards effective conversion to insulin therapy.

#### Methods

A prospective observational study design was used. In TTO there is a two-tier system of health care a private health care system that operates on a fee for service model and a public health care system under the Ministry of Health in which all services are free. This service is delivered through 4 Regional Health Authorities (RHA). We randomly selected one RHA (North-Central RHA) from which we randomly selected 10 Primary Care Facilities (PCF). We considered each PCF a cluster from which we selected participants who satisfied the criteria for entry into the study. We stipulated the following entry criteria: 1) Patients with a physician diagnosis of T2D, 2) Patients currently taking oral hypoglycemic drugs, or 3) Were already receiving insulin therapy. Patients with type 1 diabetes, lactating mothers and patients with gestational diabetes were excluded from the study.

A structured pretested questionnaire was designed both to collect demographic data which included age, gender and highest level of education attained as well as knowledge and beliefs about insulin therapy. Among the items includes in the questionnaire were the duration of diabetes and current therapy. Patients on oral medication were assessed on the awareness of insulin. Specifically patients were asked if they ever heard of insulin, how they heard about it, if they knew that insulin was used to treat diabetes and if they were aware that they might have to use insulin in the future. Their knowledge of the benefits to be derived from insulin therapy was also elicited. Patients already on insulin were asked about their concerns before and after initiating insulin therapy. The data collected were stored using Microsoft Excel and analyzed using SPSS version 16.0. The Ethics Committee of the University of the West Indies approved the protocol for the study. After a detailed explanation of the study, informed verbal consent was obtained from each participant.

#### Results

A total of 201 patients who met the entry criteria were recruited into the study. There were 74 (36.8%) males and 127 (63.2%) females. The majority of patients (78.1%) were in the age group 46-75 years. Approximately two-thirds (119, 59%) of the patients had a primary level education and one-third (56, 28%) a secondary level education. Hence all participants were literate and no one refused to participate. The majority of patients (61%) were diagnosed with diabetes for 1-10 years while the remainder of patients had the disease for >10 years. Currently 159 (79.1%) patients were using oral hypoglycemic agents only while 42 (20.9%) were already on insulin therapy. Of those patients using oral hypoglycaemic agents, 156 (98.1%) had heard of insulin of Knowledge of insulin was obtained predominantly from other patients (102, 64.1%) all of whom were already on insulin therapy. Significantly (p<0.05) less

patients received information from a health care provider (doctors=44, 27.7%, nurse=6, 3.8%), and only participant 1 (0.6%) was informed about insulin from a pharmacist. Only 3 (1.9%) patients interviewed had never heard of insulin. Among insulin naïve patients 57 (35.8%) were aware that they might have to use insulin in the future while 102 (64.2%) were not aware.

In regard to patient-reported key barriers to initiating insulin treatment, fear of needles, pain and apprehension about injecting were prominent among respondents (85, 53.5%) (TABLE 1). The burden of use was measured by asking concerns about difficulties in scheduling/ arranging to inject insulin during the course of their day and around meals. This was the largest barrier reported (86, 54.1%).

Only a small percentage (8%) of respondents felt that having to travel with insulin was a perceived difficulty, while 49 (31%) patients felt that there were no benefits of taking insulin, and only 82 (52%) felt that insulin use would result in better control of their diabetes.

A logistic regression analysis was conducted in which each barrier was considered an outcome variable with a binary outcome "Yes" or "No" and predictor variables were age, gender, level of education, duration of disease and source of information. Results for all p-values are shown in **TABLE 2**, with significant p-values highlighted. There were only barriers found to significant hence the adjusted odds ratio with the 95% confidence intervals is reported in the text. First women were more likely than men to be concerned with injection of insulin being painful (OR 2.07, 95% CI 1.36-3.14).

Second, the belief that insulin does not control diabetes effectively was dependent on level of education and was more common (OR 1.56, 95% CI 1.1-2.2) among patients with only a primary level education. Third the belief that the need for insulin meant failure to control diabetes effectively was influenced both by the age (more common in the older age groups, OR 2.1, 95% CI 1.4-3.2) of the participant as well as who the participant received information about insulin, (physician vs. non-physician (OR 1.7, 95% CI 0.98-2.9).

Data on Insulin-treated Patients (ITP) i.e., who were previously on oral hypoglycaemic agents and now on insulin therapy were collected and compared to insulin-naïve patients (INP). Of the 42 ITP, 30 (71.4%) patients were on insulin therapy for less than 5 years, 8 (19%) between 6-10 years and 4 (9.5%)  $\geq$ 11 years. The fear of pain among INP was 53.5% compared to ITP 28.6% representing a significant decline of 24.9%, (p<0.05, 95% CI for the difference between two independent proportions 8-38) (**TABLE 3**).

Weight gain in the INP was one of the least important barriers (23.3%) however this grew to 26.2% in the I-group, while 4.8% indicated that the issue of weight gain was not resolved.

Table 1. Patient-reported key barriers to initiating insulin treatment.							
Barrier	Yes (n, %)	No (n, %)	Don't know (n, %)	Total (n, %)			
Pain	85 (53.5)	57 (35.8)	17 (10.7)	159 (100)			
Burden to use	86 (54.1)	60 (38)	13 (6.9)	159 (100)			
Weight gain	37 (23.3)	69 (43.4)	53 (33.3)	159 (100)			
Efficacy	26 (16.4)	76 (47.8)	57 (35.8)	159 (100)			
Dangerous	38 (23.9)	48 (30.2)	73 (45.9)	159 (100)			
Hypoglycaemia	47 (29.6)	47 (29.6)	65 (40.8)	159 (100)			
Failure	72 (45.3)	43 (27)	44 (27.7)	159 (100)			

# Table 2. P-values for each barrier reported *vs*. age, gender, level of education, duration of disease and source of information.

Barrier	Age	Gender	Level of education	Duration of disease	Source of Information
Insulin injections are painful	0.280	0.03	0.057	0.769	0.481
Insulin is a burden to use	0.795	0.162	0.218	0.068	0.967
Insulin causes weight gain	0.342	0.261	0.205	0.537	0.114
Insulin does not control diabetes effectively	0.702	0.108	0.046	0.385	0.102
Insulin is more dangerous to use than tablets	0.112	0.583	0.389	0.135	0.477
Insulin causes hypoglycaemia	0.834	0.717	0.254	0.986	0.170
Need for insulin means that I have failed to control diabetes	0.038	0.960	0.806	0.466	0.007

Table 3. Concerns of patients started on insulin therapy.							
Concern	Unresolved	Resolved	New concern	Never a concern			
Pain	12 (28.6)	21.4	7.1	42.9			
Burden	16.8	19	7.1	57.1			
Weight gain	4.8	0	26.2	69			
Efficacy	14.3	0	14.3	71.4			
Danger	7.1	7.1	2.5	83.3			
Hypoglycaemia	2.5	7.1	21.4	69			
Failure	23.8	11.9	2.4	61.9			

Notwithstanding we found that 17 (40.5%) patients on insulin therapy gained weight since beginning insulin therapy, 70% of these patients gained between 1-5 kg. Overall most patients (38, 90.5%) on insulin therapy reported they would recommend insulin therapy to other patients with diabetes.

#### **Discussion and Conclusion**

The study showed the belief that insulin injections are painful is high (53.5%) among insulin-naïve patients. Higher proportions (51-71%) have been reported among Asian countries [20,21] and lower proportions in developed countries. In the UKPDS 27% of patients allocated to insulin therapy refused [22] and in other western countries a similar 28-39% were reluctant to start insulin [13,14,23]. In the United States (US) approximately 50% of patients were fearful of injecting themselves [24,25-27]. We also showed that women had a greater fear than men (OR 2.07, 95% CI 1.36-3.14). However 21.4% of patients who began using insulin reported that this fear had resolved. Notwithstanding, 28.6% maintained that this fear was unresolved and 7.1% indicated that it was a new concern. These findings emphasize that the fear of injections is higher in the developing world compared to developing countries hence it is an important but neglected aspect of diabetes care. The implications of this finding are: 1) The need for greater physician awareness, 2) Specific training in this aspect of care or as a component in the transitioning to insulin therapy directed at injection-related concerns and distorted beliefs and misconceptions as well as providing practical and emotional support through effective communication and patientcentered approach.

In 45.3% of our patients the need for insulin therapy was reported as a personal failure to manage their diabetes appropriately. Several explanations may be offered which may include the culture and the health care systems, especially in developing countries where resources are limited, clinics are overwhelmed and diabetes educators are nonexistent [20]. In addition this sense of failure may also be attributed to a personal sense of failure to control their disease [28-30] by not properly caring for themselves [31,32], or being able to self-manage their disease with diet, exercise, or oral medications alone [33]. This sense of personal failure may leave the patient with feelings of dejection, incompetence and guilt [34], as well as a 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 difference to their overall health [35-38]. Insulin may also be perceived as a threat or punishment, resulting in anger or betrayal, because patients may feel unfairly punished for poor self-care [29,39].

The largest barrier to insulin therapy (54.1%) was anxiety about mastering the skill of giving oneself an injection, the general hassle of taking injections, concern about preparing the correct dose of insulin, and apprehension about the proper technique of needle injection. Similar findings were reported by Morris et al. [29], Hunt et al. [40] and Korytkowski [41]. Other findings of the study included a high level of knowledge of insulin (98%), mostly obtained from fellow patients, yet the majority (64.2%) of patients were unaware that they may require insulin in the future. The least important issues were efficacy, weight gain, and hypoglycaemia.

This research, the first of its kind to be undertaken in this setting, identified the most important common beliefs of insulin-naïve patients who may need to initiate insulin therapy in the future. In addition it provides evidence to inform educational tools for diabetes educators and other health care professionals to use in educating patients. When a decision is made to initiate insulin therapy the physician may encounter resistance from the patient because of their beliefs, myths or misconceptions. Hence at this time any barriers to initiating insulin therapy have to be confronted. An intervention that directly responds to the most common issues raised at this juncture has the potential to facilitate the process, and improve compliance for better outcomes for the patient.

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