Reason for refusal of insulin therapy among type 2 diabetes mellitus patients in primary care clinic in Bangalore

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ABSTRACT

Background: Early initiation of insulin therapy and thereby the better control of blood sugar levels has shown reduction in complications. Although insulin therapy has been demonstrated to be efficacious, its initiation is often delayed due to multiple factors including the refusal of insulin therapy by the patients. This study aims to explore the reasons for the refusal of insulin therapy in a resource-constrained primary care setting in an urban slum in India. **Materials and Methods:** We included 148 patients who required insulin therapy but refused. A semi-structured questionnaire was administered by a primary care physician. Chi-square test was done to test the association between demographic factors and the reasons for refusal. P < 0.05 was considered as significant. **Results:** The mean age of the patients was 49.53 (SD+/-9.8) years. Majority (40.5%) of the patients had diabetes for 6-10 years, and most of them were living with their families (89.9%) and 77% of them were dependent on their family for their financial and physical needs. Financial constraint was the most common reason for reason (74.3%) followed by afraid of pain (68.9%) and fear of dependency (57.4). Gender, occupation, and duration of diabetes and witnessing insulin administration were significantly associated with stigma related to insulin therapy. **Conclusion:** Financial constraint is one of the key factors as patients have to buy insulin out of pocket and are not covered by insurance. Government initiatives to reduce and monitor the cost of the insulin would be of great benefit to the patients in this setting.

Keywords: Diabetes, insulin refusal, primary care

Introduction

Diabetes is fast becoming the epidemic of the 21st century. Both the United Kingdom Prospective Diabetes Study (UKPDS) and the Diabetes Control and Complications Trial (DCCT) have shown that aggressive glycemic control can prevent diabetic complications. ^[1] The value of this approach has been shown from evidence gained in landmark clinical and epidemiological studies where the reduced incidence of micro and macrovascular complications was apparent

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with intensive glycemic control and has further been confirmed in a published meta-analysis of observational studies. ^[2-6] Early initiation of insulin therapy and thereby better control of blood sugar levels has shown reduction in complications. ^[1] Although insulin therapy has been demonstrated to be efficacious, its initiation is often delayed due to multiple factors.

A study conducted in the USA showed that 33% of type 2 diabetic patients were unwilling to use insulin therapy, while another study conducted among Bangladeshi patients found that 42.5% of patients with type 2 diabetes were unwilling to start insulin therapy initially, with 20.3% were refusing insulin use even after repeated counseling.^[7,8] In an another study among Singaporean patients with type 2 diabetes mellitus, 7 of

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every 10 patients (70.6%) expressed unwillingness to use insulin therapy. A study conducted in a rural community of Malaysia, where the prevalence of insulin therapy refusal was found to be much higher compared to that in urban settings. With the increasing prevalence of diabetes mellitus in India, one of the main challenges managing diabetic patients who have suboptimal control will be insulin therapy refusal.

In our primary care clinic, we manage a fair number of patients with diabetes, of which nearly half refuse to take insulin for their diabetes management. We have insufficient published studies in India on reasons for refusal to take insulin among patients from resource-constrained settings. So, this study aims to identify what could be the possible factors which hinder a patient's acceptance of insulin therapy. In majority of these studies, the common reasons for insulin refusal were the patient's perceptions that requirement for insulin was an indicator of disease severity, needle anxiety, premature death from insulin injection, fear of hypoglycemia, weight gain, loss of independence, and reliance on others to give insulin.

Materials and Methods

This study used a cross-sectional study design and was conducted by the Department of Family Medicine and Community Health, Bangalore Baptist Hospital in Deverajeevanahalli slum in Bangalore. This slum is served by our Urban Health Center located in the heart of the slum. This center provides primary medical care at an affordable cost with a laboratory, pharmacy, ophthalmology, and dental services. It also caters to a large number of patients with chronic diseases such as diabetes and hypertension.

Patients with poor glycemic control (HbA1C > 9%) in spite of being on maximum doses of biguanides and sulphonylureas were included for the study, and those with cognitive decline which was assessed using abbreviated mental test score were excluded. To calculate the sample size, the most common cause for the refusal of insulin therapy as found in an Iranian study fear of pain (43.7%) was used. Using the formula 4pq/d2 and an absolute precision of 8%, the sample size calculated as 148.[11] Consecutive patients who fulfilled the inclusion criteria were included in the study. A questionnaire was administered by the principal investigator. The study tool contained socio-demographic characters and questions related to reasons for refusal. The data were coded and entered into Microsoft Excel, and the statistical software Statistical Package for Social Sciences (SPSS for Windows, Version 16.0. Chicago, SPSS Inc.) was used for the analysis. Descriptive and inferential statistical analysis was carried out. Perceived barriers and causes for the refusal of insulin were calculated in percentages. Univariate analysis was carried out to assess the association between contributing factors and refusal of insulin therapy. A P < 0.05 was considered statistically significant. Voluntary participation was ensured, and patients were assured of nondiscrimination in case if they did not wish to take part in the study. The study was approved by the Institutional Review Board of Bangalore Baptist Hospital.

Results

A total of 148 patients who fulfilled the inclusion criteria were interviewed. The study population had more number of women (68.9%) than men (31.1%). The mean age of the patients was 49.53 (SD+/-9.8) years ranging from 34 to 74 years [Table 1]. Majority of them were from 41 to 50 years age group. Almost two-third (59.5%) of them belonged to Muslim community. Most of the study groups were homemakers (34.4%). The median monthly income was Rs. 4000 with a range of 0 to Rs. 25,000. Majority (40.5%) of the patients had diabetes for 6-10 years, and most of them were living with their families (89.9%) and 77% of them were dependent on their family for their financial and physical needs. More than two thirds of them were on two oral hypoglycaemic agents (62.2%), and rest (37.8%) were on more than two drugs. More than three fourths (75.7%) also had other co-morbid illnesses such as hypertension.

Financial constraint was the most common reason for the refusal of insulin therapy in our study population as 74.3% felt insulin was very expensive [Table 2]. More than two-third (68.9%) of them were afraid of pain. More than half of them (57.4%) had a fear of becoming dependent on insulin. A large proportion (42.6%) of them refused because of social stigma.

Nearly half (45.9%) of the study population had witnessed someone injecting insulin. Similarly, more than half (51.4%) of them responded that they won't be able to convince someone to give insulin. Participants who were women (82.4%), homemakers (81%), earned income less than Rs. 5000 (82.8%) were more afraid of pain compared to men (39.1%), non-home

Table 1: Socio demographic characters							
Characters	Variables	Frequency	Percentage				
Sex	Male	46	31.1				
	Female	102	68.9				
Age	30-40	35	23.6				
	41-50	62	41.9				
	51-60	28	18.9				
	>60	23	15.5				
Religion	Hindu	36	24.3				
	Christian	24	16.2				
	Muslim	88	59.5				
Occupation	Unskilled	15	10.1				
	Semi skilled	33	22.2				
	Small business	23	15.5				
	Home maker	51	34.4				
	Pensioner	26	17.5				
Income	0-5000	114	77				
	5001-10000	33	22.3				
	>10000	1	0.7				
Years of DM	5	36	24.3				
	6-10	60	40.5				
	11-15	25	16.9				
	16-20	22	14.9				
	>20	5	3.4				
Living with family	Yes	133	89.9				
	No	15	10.1				

makers (60%) and those earned more than Rs. 5000 (45.5%) and this difference was statistically significant (P < 0.05). Similarly, those who were more than 40 years (81.4%) of

age perceived insulin was more expensive than younger age group (46.7%) (P < 0.05). There were no factors associated with the perception of dependence on insulin [Table 3].

Table 2: Perceived barriers for Insulin therapy									
Barriers	Yes		No						
	Frequency	9/0	Frequency	0/0					
Afraid of pain	102	68.9	46	31.1					
Worried about Hypoglycemia	47	31.8	101	68.2					
Think they will gain weight	30	20.3	118	79.7					
Think they become dependent	85	57.4	63	42.6					
Fear of social stigma	63	42.6	85	57.4					
Think insulin with interfere with their work and diet	79	53.4	69	46.6					
Think insulin is expensive	110	74.3	38	25.7					
Think starting insulin is the last stage of disease process	57	38.5	91	61.5					
Feel they are responsible for uncontrolled sugar	53	35.8	95	64.2					

Table 3: Factors associated with perception on dependency on insulin																
Factors	Variables	Afraid				Dependency				Expensive						
		Yes		No		P	Yes		No		P	Yes		No		P
		n	0/0	n	0/0		n	0/0	n	%		n	0/0	n	%	
Age	<40	20	66.7	10	33.3	0.76	14	46.7	16	53.3	0.18	14	46.7	16	53.3	0.00*
	>40	82	69.5	36	30.5		71	60.2	47	39.8		96	81.4	22	18.6	
Gender	Male	18	39.1	28	60.9	0.00*	24	52.2	22	47.8	0.38	32	69.6	14	30.4	0.37
	Female	84	82.4	18	17.6		61	59.8	41	40.2		78	76.5	24	23.5	
Occupation	Home makers	51	81.0	12	19.0	0.00*	41	65.1	22	34.9	0.10	48	76.2	15	23.8	0.65
	Others	51	60.0	34	40.0		44	51.8	41	48.2		62	72.9	23	27.1	
Income	< 5000	77	82.8	16	17.2	0.00*	51	54.8	42	45.2	0.40	72	77.4	21	22.6	0.26
	>5000	25	45.5	30	54.5		34	61.8	21	38.2		38	69.1	17	30.9	
Years with DM	<10 years	52	67.5	25	32.5	0.70	44	57.1	33	42.9		53	68.8	24	31.2	
	=>10 years	50	70.4	21	29.6		41	57.7	30	42.3	0.94	57	80.3	14	19.7	0.11
Living with family	Yes	90	67.7	43	32.3	0.32	77	57.9	56	42.1	0.73	99	74.4	34	25.6	0.92
	No	12	80	3	20		8	53.3	7	46.7		11	73.3	4	26.7	

*Significant P

Factors	Variables		Perception	Chi- square	\boldsymbol{P}		
		Y	es	N	No	value	
		n	0/0	n	0/0		
Gender	Male	6	13	40	87	23.7	0.00*
	Female	57	55.9	45	44.1		
Age	<= 40 years	17	56.7	13	43.3	3.05	0.80
	>40 years	46	39.0	72	61.0		
Occupation	Home makers	40	63.5	23	36.5	19.6	0.00*
	Others	23	27.1	62	72.9		
Years with DM	<10 years	42	54.5	35	45.5	9.4	0.02*
	>=10 years	21	29.6	50	70.4		
Income (INR)	< 5000	42	45.2	51	54.8	0.68	0.40
	=>5000	21	38.2	34	61.8		
Living with family	Yes	54	40.6	79	59.4	2.0	0.15
	No	9	60	6	40		
Witnessed insulin administration	Yes	37	54.4	31	45.6	7.21	0.007*
	No	26	32.5	54	67.5		
Confident in self administration	Yes	31	56.4	24	43.6	6.81	0.009*
	No	32	34.4	61	65.6		
Ability to convince someone to administer insulin	Yes	42	58.3	30	41.7	14.2	0.000*
	No	21	27.6	55	72.4		

*Significant P

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Women (55.9% vs 13%), homemakers (63.5% vs 27.1%), those who had the disease for more than 10 years (54.5% vs 29.6%), those who witnessed insulin administration by their friends and family members (54.4% vs 32.5%), felt they will more stigmatized if they start on insulin as compared to their counterparts (P < 0.05) [Table 4].

Discussion

This study was conducted in an urban slum setting where the majority of the patients were from low socioeconomic strata. We had identified patients who would need insulin based on their clinical and biochemical parameters as per the guidelines.

In the study like Wong S, *et al.*, Singapore and Wei Leong Tan, Malaysia the main reason for the patient's refused for insulin was fear of pain and thus did not want to use it daily. [9,10] Another common cause for not accepting insulin was it might affect their day-to-day work and thus not able to fulfill their responsibilities, half of our study population also felt the same.

It was noted in our study that over two-third of the patients refused insulin due to financial constraints. This can be explained as patients have to buy their own insulin unlike in other studies where it was funded by government sector. This plays an important role in their decision making to buy and take insulin on a regular basis.

In a study done in East London among Bangladeshi patients, over half of them felt that their disease is in final stage if insulin is added to their medication list. [8] This is similar to our study, as nearly 40% of the study population felt that insulin should be taken only if they were in the last stage of disease, and at this point in time, their condition was not that serious as to warrant insulin injections. Similar observation was noted in a prospective study conducted in Korea, where nearly one-third of the patients felt that their disease is in last stage if insulin is suggested by their physicians. [11]

In DAWN study (Diabetes Attitudes, Wishes, and Needs study), there was detailed discussion among the patients and providers. [6] Patients felt that the progression of disease is because of their poor control of sugars and there was an element of self-blame. In our study, around 35% of the study population felt that they were responsible for their illness, henceforth take in lot of self-blame which in turn affected their future sugar control and appropriate decision making.

In a study conducted at Iran among type-2 diabetes patients, multiple factors were identified such as financial implications, fear of injection, literacy of the population. [12] In our study also, similar factors were the hindrance for starting insulin therapy.

In Wong S, et al. study, one of the key reasons along with the pain after injection is fear of hypoglycaemia which was also noted in

Wei Leong Tan study, but in our study population, more than 70% of the group were not worried about hypoglycaemia. [9,10] This could be explained in two ways, first, as majority had witnessed someone using insulin, their fear for pain could have been reduced and, second, they might be ignorant about the signs of hypoglycaemia and either do not recognize it or not be able to inform the healthcare providers.

Nearly half of our study population was not confident about injecting themselves though they had witnessed someone injecting insulin. This finding is similar to Khan S study, where more than 40% of the study group was not confident administering on their own. [8] This could be due to multiple reasons like fear of dependency and inability to read the correct unit and name of the drug.

In our study, majority of the patients who needed insulin were above 40 years of age and are homemakers. They were financially dependent on their spouses and, henceforth, were not the decision-makers in their household. One of the key reasons for refusing insulin was due to financial constraints.

As a community, patients are very apprehensive about starting insulin, one of the important factors identified in our study along with financial constraints is their knowledge about insulin. It is a common belief that a patient's feel that insulin is used only in the last stage of disease and their death is imminent in the near future. Also, there is plenty of social stigma in using insulin, especially among women. This particular finding mirrors similar findings in the study conducted among Bangladeshi population in East London.^[8]

Limitation

Delay in starting insulin is not only from a patient's perspective, it can also be from providers' end. One of the limitations of our study is that we have not looked into the providers' side. Once we outline the reasons for refusal from both sides, we would be able to make a structured format to enhance the insulin utilization and, henceforth, reduce complications in our primary care clinics.

Conclusion

Insulin is a key for effective blood sugar control in patients with type 2 diabetes. We have standard guidelines both locally and internationally on when to start insulin in type 2 diabetes mellitus. There have been various reasons for the refusal of insulin from a patient's perspective. In our study, financial constraint is one of the key factors as patients buy insulin out of pocket and are not covered by insurance. During the study, we also noted patients' knowledge on insulin was inadequate as they felt their disease is in the end-stage if they start using 0insulin along with various other myths about insulin.

To improve the glycemic level and avoid complications secondary to high sugar level, educating our patients about the advantages of insulin and quashing the myths associated with insulin are important. Healthcare professionals, doctors, nurse educators play an important role in educating patients and thereby reduce the complications of diabetes.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Declaration of patient consent

All Informed consent was obtained from all individual participants included in the study.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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