Research Article

Insulin Therapy in Type-II Diabetes Mellitus – Is it Feasible and Acceptable?

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ABSTRACT

Background: Insulin, being the mainstay of treatment for type1 and certain situations in type 2 Diabetes mellitus (DM), is still not properly utilized. Thus, this study was done to know the barriers that lead to suboptimal utilization of insulin therapy by stakeholders particularly in our group of patients who were mostly from rural background. **Methods:** An observational, cross-sectional study with sample size of 100 patients with Type 2 DM that were prescribed with insulin or were already on insulin was done. Patient were interviewed on basis of pre-structured socio-demographic, knowledge, attitude and practice questionnaire and accordingly counseled. Data was analyzed by percentages and student's *t*-test. **Results:** Around 58% patients, in whom insulin was indicated, were taking insulin therapy. Limited knowledge about the disease and insulin, in addition to wrongful attitude and practices were barriers to therapy. Less than 50% patients had proper knowledge and understanding about insulin therapy. They had misconception of "habit" forming character of insulin and of hypoglycemia. Social stigma, inconvenience, life-long therapy commitment, cost, phobias were other causes for resistance to the use of insulin. **Conclusion:** This study concludes that by understanding patient's attitude towards insulin therapy healthcare professionals can aim to modify their misconceptions. Difference can be made by educating patients through proper counseling by clinical pharmacist in harmony with other healthcare professionals. This will not only help in delivering proper patient-centered care but will also help in improving the way patient looks at diabetes and insulin, thus revolutionizing the diabetic world.

Key words: Clinical Pharmacist, Type2DM, Insulin Therapy, KAP Survey, KAP Questionnaire.

INTRODUCTION

Diabetes mellitus, characterized by chronic hyperglycemia and impaired carbohydrate, lipid and proteins metabolism was long considered a disease of minor significance to world health, but is now taking its place as one of the main threats to human health in the 21st century.[1-3] It currently affects over 366 million people worldwide and this figure is likely to double by 2030. It has emerged as a major public health problem with India ranking second having 65.1 million diabetic people.

With the introduction of insulin in 1921 by Banting and Best the dreadful picture of diabetes was about to change but due to some of the misconceptions and beliefs of the population the revolution that insulin could have bought in the treatment of diabetes just remained a dream of many.

Insulin is safe and effective; It produces a remarkable life expectancy for diabetics and can improve or correct many of the metabolic abnormalities. With a huge base of diabetic patients in India, it is anticipated that only 25% of this population is receiving treatment. Thus, it is important to know the awareness level of a disease state and its management (Here, in the light of insulin therapy) in the population so as to figure out the reasons for this level of setback to insulin therapy, which will help in providing better healthcare and reduce related morbidities.[4,5]

A good deal of work has been done in this area, but our investigation is unique in providing an insight into the economically weaker sections of the society to know whether insulin therapy is feasible and acceptable?.

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MATERIALS AND METHODS

Study design

A prospective cross-sectional study was conducted at Dhiraj General Hospital, Pipariya, Vadodara. The study was initiated after the approval of the institutional ethics committee with a sample size of 100.

Inclusion criteria

All the patients of age 18-60 years with uncontrolled Type 2 Diabetes Mellitus already on insulin therapy or those in whom insulin was indicated and were reluctant to take insulin therapy were taken for the study.

Exclusion criteria

Pregnant women and mentally incompetent patients.

Study material

Forms: Informed consent form (ICF), Patient information sheet, Patient Medication record sheet.

Questionnaires: Modified Socio-demographic Questionnaire, Modified Knowledge, Attitude and practice Questionnaire.

Methodology

- Keeping in mind the tool used by Choudhury SD *et al*.[6] and according to the results of our pilot study that we conducted in about 50 patients (25 on insulin therapy and 25 not on insulin therapy) we framed our socio-demographic questionnaire, knowledge attitude and practice questionnaire.
- Patient enrollment was started on the basis of inclusion and exclusion criteria.
- Once patient was found to be suitable for the study. Their voluntarily consent was taken by PI.
- Data was obtained and student's *t*-test was used as statistical tool for analysis.

Research and Ethical Committee Approval

Institutional research and ethical committee approved the study and issued a letter of permission to conduct the study.

RESULTS

Socio-demographic details

Table 1 shows patients of different age groups and almost equal number of male and female patients. Almost 31% patients had secondary education around 36% of the sample had less than Rs. 10, 000 as their monthly income with 83% having long standing history of diabetes (Diagnosed >1.5 year back).

As shown in Pie-chart (Figure 1), 23% of patients were not knowing as to why they have been prescribed with insulin therapy, while the rest came out with different answers.

Table 1: Socio-Demographic Data (*n*=100).

		Number (Male+ Female)	%
1. Age			
	Below 30	5(3+2)	5%
	31-40	9(8+1)	9%
	41-50	17(9+8)	17%
	51-60	38(22+16)	38%
	61-70	21(11+10)	21%
	above 70	10(6+4)	10%
2. Gender			
	Male	59	59%
	Female	41	41%
3. Education			
	Illiterate	11	11%
	Less than secondary (10^{th}) education	31	31%
	Higher secondary (12^{th}) education	38	38%
	Graduate and above	20	20%
4. Income			
	<10000	36	36%
	10000-25000	32	32%
	25000-50000	23	23%
	50000-10000	7	7%
	>100000	2	2%
5. Family history			
	Yes	53	53%
	No	39	39%
	Not sure	8	8%
6. Diagnosed			
	< 1 y	17	17%
	1. 5 - 5y	28	28%
	>5 y	55	55%
7. Insulin Therapy			
	I did not start.	42	42%
	Immediately after diagnosis.	17	17%
	Some years after diagnosis.	41	41%

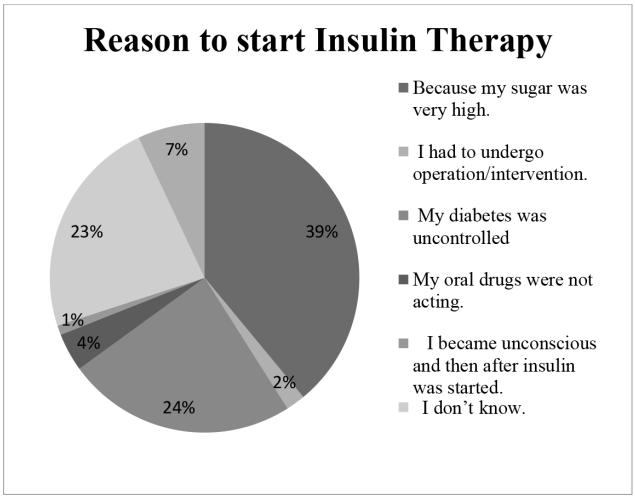

Figure 1: Reasons to Start Insulin Therapy.

As far as issue on "Initiation of insulin therapy" is concerned, 27% of the study patients did not start insulin therapy at all even after being advised and 56% sample that started a little late than were advised.

Knowledge

Table 2 and Figure 2 suggests that the knowledge of the patient regarding insulin as a therapy and diabetes as a disease is not apt. About 41% of sample population thought that there is a relation of diabetes with insulin therapy but conversely 59% were unable to comment on the same.

Regarding the knowledge of "Type and Brand" of insulin, a proportional number of people that is 84% were unaware about the type of insulin given to them. Also, 6% and 46% of the patients were aware of premix insulin and plain insulin to be adjusted with their meal pattern and plan. About 68% of the study population patient thought that insulin when started becomes a lifelong therapy. About 60% of the sample was aware of the complications related to diabetes conversely 63% of the same sample felt that such complications cannot be better dealt with insulin therapy.

Majority knew regarding site for insulin injection and about 79% of the total population gave right answers when inquired about the same. There were some bizarre answers also like it can be given on the whole body, chest and lower limb. Around 61% of the sample population was unaware of hypoglycemia and its symptoms.

Thus, regarding the assessment of knowledge (*t*-value=1.693), we saw many potential and obvious areas where work ought to be done by all the healthcare professionals in harmony to help increase knowledge of the patient regarding insulin therapy and diabetes so as to bring about a better scenario of insulin use and better health perspective to diabetic patient population.

Table 2: Knowledge Assessment.

KNOWLEDGE		
QUESTIONS	**Positive response**	**Negative response**
1. Insulin is related to diabetes?	54	46
1B. How?	41	59
2. Are you aware about types of insulin given to you?	9	49
3. Do you know about premix insulin?	4	54
4. Insulin which can be taken immediately before meal?	24	34
5. Insulin is needed for daily activity even if you are not taking food?	15	43
6. Insulin can be stopped once blood sugar levels normalize?	32	68
7. Aware of the complications of diabetes?	60	40
7B. Complications can be better dealt with insulin?	37	63
8. Do you know about insulin pen?	50	8
9. Aware of HbA1c?	18	82
10. Where will you be injecting insulin?	79	21
11. Reading the package insert supplied along with insulin?	5	53
12. What is hypoglycemia?	61	39

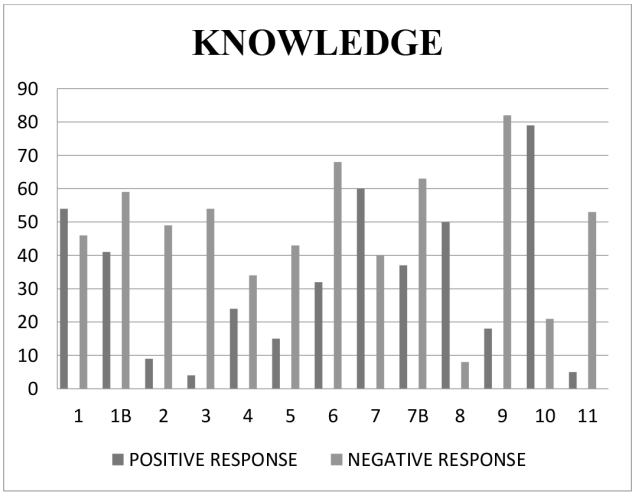

Figure 2: Knowledge Assessments.

Attitude

From the data shown, (Table 3 and Figure 3) around 13% of insulin using population thinks that it is habit forming. Also, around 80% of the sample population thinks that

insulin is not the ultimate treatment for diabetes.

This study supports previously established factors of "Psychological insulin resistance" to insulin therapy namely "Needle phobia" and "Social stigma" with 79% and 46% of the sample reporting the same respectively.

Around 63% people would like to stop taking insulin therapy if ever they were given a chance to do so; around 42% of the population samples were unwilling to start insulin therapy. About 49% of the patient population thought negative about "Insulin", like the therapy may lead to more complications. Detail probing gave us further insight as to why they were reporting like that. It was observed by them that patients who were switched to insulin therapy in chronic kidney disease patients may require hemodialysis which they misconceptualised as complication (Aãdd–Aasar: Gujarati language ever batim) of insulin therapy.

Regarding the cost of insulin therapy, 91% of patients on insulin therapy found it costly and 96% people felt it to be cumbersome.

Table 3: Attitude Assessment.

ATTITUDE		
QUESTIONS	**Positive response**	**Negative response**
1. Insulin is habit forming	50	8
2. Insulin is last resort for treatment of diabetes	20	80
3. Insulin can cause harm	65	35
4. Are you worried about pricks	21	79
5. Encouragement by family member	72	28
6. Given chance would you stop insulin	21	37
7. Insulin has any role in causation of diabetes	51	49
8. Regarding cost of insulin	5	53
9. Insulin therapy is cumbersome	2	56
10. Insulin leads to weight gain	14	44
11. Awkward while using insulin in public	12	46

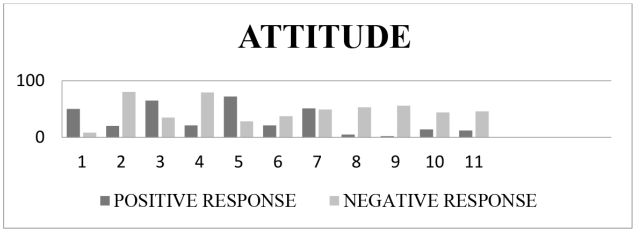

Figure 3: Attitude Assessments.

Thus, assessment of attitude (*t*-value=1. 697) delineates many factors that may play a role in changing the mindset of a patient regarding insulin therapy that needs to be looked upon.

Practice

Around 55% patient were taking insulin (Table 4 and Figure 4) either by themselves (n=32) or was injected by a family member (n=21), very less number of patient were taking with the help of a doctor (n=3) or would not take at all (n=1). Around 56% of the sample on insulin therapy told that it was difficult for them to administer insulin.

About 65% of those taking insulin therapy told that they pinch up the area to be injected with insulin. However around 31% of those on insulin therapy apply gentle pressure at the injecting site and around 25% "massage" the site of injection.

With 56% of the population reporting that it hurts injecting insulin there is almost 50% of the population knowing that if injected in a proper way it can be pain free. Adding to this a proportion of 30% of the sample population have reported that injecting insulin is making the site tough. Thus, it is worthwhile to note that how wrongful practices can make a therapy less satisfying and less rewarding.

With around 75% of the population reporting that they do use different anatomic sites when taking different types of insulin around only 25% of the population do not reuse syringes for injecting insulin. However, there was only 11% of the population that got infection at the site of injecting insulin. There were around 81% of the diabetic sample population that checked their blood glucose levels at home. Around 96% of the population rotated site of injecting insulin while 57% of the population do miss their insulin dose.

There were about 87% of the population that reported having episodes of hypoglycemia of which 32% required hospitalization for the same but still only 43% of the population kept simple carbohydrates with them always. Reports of nocturnal hypoglycemia were as high as 64%.

The results of practice throw light on many aspects of insulin administration and thus patients should be counseled accordingly regarding the dos and don'ts of the insulin therapy for better and satisfying outcomes.

DISCUSSION

Through this study we wanted to know the barriers to

Table 4: Practice Assessment.

PRACTICE				
QUESTIONS	Positive response	%	Negative response	%
1. Whom will you like insulin to be taken by?	32	55. 17	26	44. 83
2. Difficulty in administering insulin?	25	43. 10	33	56. 90
3. Pinch up area to be injected?	38	65. 52	20	34. 48
4. Do you apply gentle pressure at the injecting site?	40	68. 97	18	31. 03
5. Massaging injection site?	43	74. 14	15	25. 86
6. Does it hurt injecting site?	25	43. 10	33	56. 90
7. Injecting insulin can be pain free?	29	50. 00	29	50. 00
8. Injecting insulin making the site tough?	41	70. 69	17	29. 31
9. Check insulin before use?	45	77. 59	13	22. 41
10. Do you agitate insulin before use?	29	50. 00	29	50. 00
11. Do you choose different anatomic site while taking different insulin?	44	75. 86	14	24. 14
12. Do you reuse syringes and needles?	15	25. 86	43	74. 14
13. Ever noticed infection at injection site?	52	89. 66	6	10. 34
14. Do you check insulin blood glucose at home?	47	81. 03	11	18. 97
15. Need to consult the physician for the same?	39	67. 24	19	32. 76
16. Need to adjust the insulin do you take?	27	46. 55	31	53. 45
17. Do you rotate site?	56	96. 55	2	3. 45
18. Do you miss insulin doses?	25	43. 10	33	56. 90
19. Ever had hypoglycemic episode?	8	13. 79	50	86. 21
20. Ever been hospitalized for insulin related hypoglycemia?	40	68. 97	18	31. 03
21. Do you carry simple carbohydrates always?	25	43. 10	33	56. 90
22. Ever had nocturnal hypoglycemia?	21	36. 21	37	63. 79

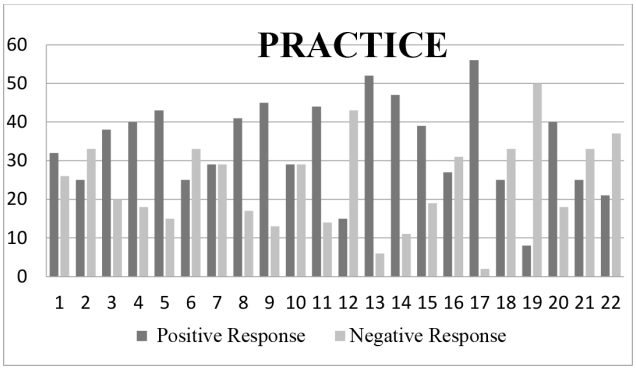

Figure 4: Practice Assessment.

insulin therapy that rural population face, perceive, retort and counteract. Study was conducted at medical college attached Dhiraj hospital which is situated at Piparia village of waghodia Taluka, of Vadodara District. It is a multi-specialty hospital having daily 600 patients medical OPD and once a week Diabetic clinic. Many diabetic patients take services from out-patient department, some of which are admitted in the wards and also come to other departments for diabetic complications. They come from the nearby as well as from interiors of Gujarat and Madhya Pradesh. Patients type and mix is different from those coming at primary, secondary as well as corporate multi-specialty hospital. They are from rural background, low to middle income group and of lower educational background. Thus, to know whether it is only their socio-demographic factors or other unidentified factors that are responsible for their reluctance towards insulin therapy, this study was done.

We conducted a pilot study in about 50 patients (25 on insulin therapy and 25 not on insulin therapy) that visited us at medical OPD, Indoor wards or Pharmacy-counseling center. In reference with the tool used by Choudhury SD *et al*.[6] and also on the basis of results of our pilot study, we framed our socio-demographic, knowledge, attitude and practice questionnaire that were used to interrogate our patients, while Maskari FA *et al*.[7] made literate patients to fill out the questionnaires themselves while illiterate participants were interviewed by trained nurses.

As in this study, the same pattern of age distribution was seen in the study done by Jasper *et al*.[8] where the participants in this study were between the age group of 51–60 years. Male population was higher than females (59% and 41%) as was the case in the studies conducted by Dinesh *et al*.[9] and Choudhury SD *et al*.[6] With only 11% illiterate population our study resonated with the study done by Dinesh *et al*.[9] where only 95% of the participants were illiterate. However, majority were up to primary and secondary education. Again, in our study we had highest

proportion of population from less than 10,000 monthly family income, while in one study conducted by Shah VN *et al*.[10] the population with annual income less than 20,000 was 39.47%.

In this study the 28% patients had diagnosis of diabetes of 1.5-5 years duration. In the study of Konduru *et al*.[11] duration of disease was >5 years in majority whereas 27% of people were having duration of disease <1 year.

Regarding the knowledge about diabetic complications like retinopathy, neuropathy, stroke, Ischemic heart disease and others are concerned, in this study, it was found that around 60% of the population was aware of the complications related to diabetes. Another fact which emerged from this study was that more than 60% of the study population felt that such complications cannot be better dealt with insulin therapy.

Moreover, they opined that Insulin may harm the body and may be cause for requirement of hemodialysis. Prevalence of Chronic Kidney Disease (CKD) in adults with type2 DM was 38.3% in a study of 2006 patients, during 2007-2012 done by WuB *et al*.[12] most studies report use of Insulin in severe CKD stages, as insulin is safer in patients having impaired renal function status. Again titration upward can be done by insulin, to achieve proper glycemic control which is associated with a reduction in the onset and progression of diabetic nephropathy.[12,13] Patients having renal dysfunction may have insulin resistance and may require a higher dose of basal insulin.[14,15] Insulin therapy thus becomes an important treatment option in patients of diabetic kidney disease. A myth which prevailed in our study patients was that, if insulin is taken, patients may have to undergo hemodialysis in future, while the fact is that it slows the progression of CKD.

During counseling session, a patient should be explained about such confusion related to diabetic complications and complication's natural progression with and without insulin therapy. The difference between FBS, PPBS, RBS and HbA1C in relation to diabetes control and complications needs a proper understanding and counseling. About 86% of insulin users had misconception regarding "Habit Forming" nature of Insulin which is also been reported by other Indian studies.[6] In our study 32% of the sample feels that insulin can be stopped once blood sugar level normalize which is much higher than what was found in the study done by Choudhury SD *et al*.[6] Knowledge of HbA1c reveals the same pattern in both the studies with least as only 18% population being aware about the same.

Some encouraging results were in relation to sphere of practices related to insulin therapy like majority knew injection technique, about pen device, about rotating site for injection, about Self-Monitoring of Blood Glucose (SMBG). Bad practices were also noted which was in form of not pinching the skin and not injecting it subcutaneously (30%), giving immediate massage and/or gentle pressure on the injection site with few others.

It happens that patient needs insulin, doctors prescribed them, but due to attitudinal differences and societal pressure, are reasons for psychological insulin resistance Brod *et al*.[16] they may not initiate insulin therapy which was present in 42% of the population which was reported by Choudhury SD *et al*. in 12.2%. Thus it is imperative to counsel the patient properly for improvements in their knowledge status regarding the disease for better adherence and good therapeutic outcomes.[17]

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CONFLICT OF INTEREST

The authors declare none.

ABBREVIATIONS

Type2DM: Type 2 Diabetes Mellitus; **KAP:** Knowledge,Attitude and Practice; **ICF:** Informed Consent Form; **PI:** Principal Investigator; **HbA1c:** Glycated Haemoglobin; **OPD:** Out Patient Department.; **CKD:** Chronic Kidney Disease; **FBS:** Fasting Blood Sugar; **PPBS:** Post Prandial Blood Sugar; **RBS:** Random Blood Sugar; **SMBG:** Self-Monitoring of Blood Glucose.

SUMMARY

Limited knowledge, wrongful attitude and practices are having an impact on how insulin is being perceived by the sample population. The reasons for this may be low interest from patient's part or improper counseling from physician due to time constraint. This study highlights the importance of proper and timely patient counseling by clinical pharmacist and other healthcare professionals to obtain better results out of the prescribed insulin therapy.

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