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Factors Affecting Non-adherence and Impact of Patient Education in Poorly Controlled Type 2 Diabetes Patients on High-dose Insulin Therapy

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Abstract

Introduction: *Non-adherence among patients with type 2 diabetes (DM) is high and may be an important cause for increased morbidity and mortality. The present study was conducted to assess various factors related to non-compliance in poorly controlled type 2 DM patients and to evaluate the effects of educational interventions on glycaemic control.*

Methods: *It was a prospective, interventional study of thirty human participants aged 18 - 65 years with type 2 DM who had poor glycaemic control (defined as HbA1c ≥ 7.5%), were on high-dose of insulin defined as ≥ 1 unit/kg body weight and on concurrent medication with metformin and/or sulfonylurea. Patients having history of type 1 DM, myocardial infarction, unstable angina or Congestive Heart Failure NYHA class III or IV were excluded. Different validated questionnaire was used to assess the patient's knowledge (MDRTC-DKT questionnaire), adherence to the treatment (Morisky 8 questionnaire), dietary advice and questionnaire related to self-care (SDSCA questionnaire) and quality of life (WHO-BREF QOL). After the baseline interventions patients were followed-up at 6 weeks and 12 weeks. There were also telephonic conversations with the patients at 3 weeks and 9 weeks. Biochemical tests include HbA1c, FBS, LFT, KFT, urine exam, haemogram, lipid panel were done at baseline and week 12.*

Results: *Mean age of participants was 52.17 ± 4.15 years (male: female; 2.3:1). Mean duration of DM was 5.57 ± 1.4 years with mean HbA1c 8.91 ± 0.207 at baseline (at initiation of study). All aspects of intervention were reinforced at each contact with the patient and results revealed that there are significant changes in mean values of patient's knowledge MDRTC-DKT (9.90 ± 1.788; 20.07 ± 0.907, p = 0.0001), dietary SDSCA (2.34 ± 0.258; 5.1 ± 0.275, p = 0.0001) and exercise adherence SDSCA (1.91 ± 0.373; 3.65 ± 0.233, p = 0.0001) from baseline to week 12, respectively. There was significant rise in the score for the domains of WHO BREF-QOL, i.e., physical health (31.493 ± 4.949; 53.877 ± 2.353, p = 0.0001), psychological (35.383 ± 4.979; 52.19 ± 2.08, p = 0.0001), social relationships (34.13 ± 5.909; 50 ± 0, p = 0.0001) and environment QOL (34.443 ± 3.242; 51.653 ± 1.573, p = 0.0001) from baseline to end of study, i.e., at end of week twelve. Significantly decline in mean HbA1C value was found to 8.91 ± 0.207 and 7.857 ± 0.366 at baseline and week twelve respectively. There were also statistically significant (p < 0.05) difference in serum creatinine, haemoglobin, WBC and HDL levels from baseline. However, these values were in the normal range.*

Conclusion: *Diabetic patients who were on high-dose of insulin and having high HbA1c levels had poor knowledge of disease as well as adherence to pharmacotherapy and lifestyle changes was also low. Frequent follow-up and extensive education about disease, insistence on adherence and emphasising the importance of self-care activities led to improved glycaemic control and quality of life. Eventually such educational interventions will help in lowering the increased financial burden both on patients and healthcare delivery system.*

Key words: *DM, adherence, glycaemic control, medication nonadherence.*

Introduction

Increasing prevalence and emergence of complications of type 2 diabetes mellitus (DM) makes it a great burden on the health care system and a priority health concern[1]. Management of DM requires a multifaceted approach with a focus on dietary modification, physical exercise, and pharmacotherapy. The importance of patient education and promoting self-care has long been recognised as a key component in its management and improving patient outcomes[2]. One component of self-care is adherence to the complicated medication regimes. The World Health Organisation defined adherence as "the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a healthcare provider"[3]. Adherence is multifactorial and it is determined by patient-related, condition-related, socio-economic, health system-related, and therapy-related factors[4,5].

Despite the fact that many studies have been performed globally on adherence to antidiabetic medicines (and the majority have showed varied non-adherence from low to high) we felt it justified to undertake a study in our hospital, as each community has its own culture and lifestyle that may affect adherence in a different way. The present study

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was conducted with the objective to assess and manage various factors related to non-compliance in poorly controlled type 2 DM patients on high-dose insulin therapy in combination with metformin and/or sulfonylurea and to evaluate the effects of managing these factors with interventions on glycaemic control.

Material and methods

Patients were recruited from the Out-Patient Department of Medicine, Lok Nayak Hospital, Delhi.

Study patients

Patients aged between 18 and 65 years with type 2 DM who had poor glycaemic control (defined as HbA1c ≥ 7.5%), were on high-dose of insulin defined as ≥ 1 unit/kg body weight and on concurrent medication with metformin and/or sulfonylurea were included in the study. Subjects having history of type 1 DM, myocardial infarction, unstable angina or CHF NYHA class III or IV were excluded.

Study design and procedure

It was a prospective, interventional study in which we randomly selected and screened thirty-five patients who required high insulin dose. Thirty patients then entered the study who met the criteria. An evaluation was done to assess the factors for poor glycaemic control including events of hypoglycaemia and any other adverse event in the last 3 months. Based on the assessment, a customised intervention was designed for each patient. The questionnaires used were:

1. Michigan Diabetes Research and Training Centre Brief Diabetes Knowledge Test (MDRTC-DKT) Questionnaire[6] was used to assess the knowledge of the patient and also as a tool to educate the patients.
2. For assessing quality of life, WHO-BREF quality of life questionnaire (WHO-BREF QOL) was administered[7].
3. Patient's socio-economic status was recorded using modified Kuppuswamy's socio-economic status scale at the study onset[8].
4. Patients' adherence was assessed using Morisky 8 item medication adherence questionnaire[9].
5. For self-care activities Summary of Diabetes Self-Care Activities (SDSCA) questionnaire was used[10]. SDSCA has 11 items, which cover diet, exercise, blood sugar testing, foot care, and smoking.

Interventions

The intervention given to the patient included education about correct insulin storage, injection technique, injection site rotation, syringe used, dosing and timing, compliance with insulin and other anti-diabetic medications was emphasised. Patients were taught self-dose titration of insulin based on blood glucose levels and stressed upon right dosing and timing of other anti-diabetic medications. Advice regarding regular physical activity and diabetic diet was given to every patient enrolled in the study.

After the baseline interventions, patients were followed-up at 6 weeks and 12 weeks. There were telephonic conversations with the patients at 3 weeks and 9 weeks and this conversation lasted for about 10 minutes/conversation. All aspects of intervention were reinforced at each contact with the patient. Biochemical tests were done at baseline and week 12. Fasting blood sugar was done baseline, at week 6, and week 12. Every patient was advised to report the adverse event at any time during the study duration and also enquired at each telephonic visit or hospital visit.

Study outcomes

Primary end-point of the study was change in HbA1c from week 0 (baseline) to 12 (end of study) and change in fasting blood glucose concentration which was assessed at 0 week to 12th week. Secondary end-points included quality of life assessed using WHO-BREF QOL score, adherence to treatment with the help of Morisky's score, self-care by SDSCAA score and MDRTC-DKT questionnaire to assess patient education.

Statistical analysis: Sample size was calculated based on change in mean difference of HbA1c value (1.33 ± 0.66) in a study by Zareban *et al*[11]. Based on a power of 80% and an alpha error of 0.05, a statistically significant sample size was calculated as 14 for detecting a change of at least 0.5. For better results, we included 30 patients in the study. The data was entered into MS excel and analysed using statistical software SPSS, for quantitative data. In pre- and post-intervention paired t-test was used. For qualitative data, Mc Nemar test was used and a p value < 0.05 was considered as significant.

Results

The mean age of the patients was 52.17 ± 4.15 years (male: female; 2.3:1). Duration of DM in the patients was 5.57 ± 1.4 years (range of 3 to 8 years). Out of 30 patients, twelve were taking glimepiride along with insulin, ten were taking metformin with insulin, and eight were taking both glimepiride and metformin together with insulin. Patient responses were recorded about incorrect insulin storage, wrong injection technique, infrequent injection site rotation, syringe used more than 3 times, wrong syringe used, missed dosing, inconsistent timing and self-dose titration at baseline

and at week 12th as showed in Fig. 1.

MDRTC-DKT

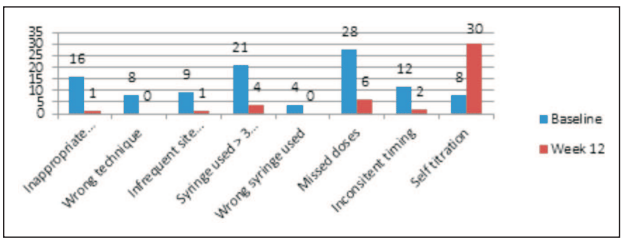

Fig. 1: *Assessment of intervention given to the patient at baseline and week twelve.*

MDRTC-DKT was poor for all patients at baseline with a mean score of 9.90 ± 1.788. When the questionnaire was administered again at week twelve following extensive patient education all thirty patients had good knowledge with a mean score of 20.07 ± 0.907 which was statistically significant (p = 0.0001) (Table I).

Table I: Questionnaires used to assess the patient's knowledge, treatment adherence, dietary and self-care.

	Baseline	Week 6	Week 12	p value
MDRTC-DKT	9.90 ± 1.788	-	20.07 ± 0.907	0.0001
MMAS-8	4.33 ± 0.994	1.6 ± 0.498	1 ± 0	0.0001
SDSCA				
Dietary adherence	2.34 ± 0.258	3.35 ± 0.259	5.1 ± 0.275	0.0001
Exercise schedule adherence	1.91 ± 0.373	2.41 ± 0.373	3.65 ± 0.233	0.0001
WHO-BREF QOL				
Physical health	31.493 ± 4.949		53.877 ± 2.353	0.0001
Psychological quality	35.383 ± 4.979		52.19 ± 2.08	0.0001
Social relationships	34.13 ± 5.909		50 ± 0	0.0001
Environment	34.443 ± 3.242		51.653 ± 1.573	0.0001

MMAS-8

The mean values of MMAS-8 at baseline, week 6 and week 12 were 4.33 ± 0.994, 1.6 ± 0.498 and, 1 ± 0 respectively (p = 0.0001) (Table I). The adherence considerably improved but no patient could attain a score of zero which is defined as high adherence.

SDSCA

The analysis revealed that the mean number of days out of last week the patients adhered to their dietary advice was 2.34 ± 0.258 at the baseline and it increased to 3.35 ± 0.259 at week six. This further rose to 5.1 ± 0.275 at week twelve (p = 0.0001). Similarly, analysis revealed that the mean number of days the patients performed exercise over last week was only 1.91 ± 0.373 at baseline. At week six and twelve the mean number of days the patients performed exercise over last week rose to 2.41 ± 0.373 and 3.65 ± 0.233 respectively (p = 0.0001).

The mean number of days over the last week patients inspected their foot was found to be zero at the baseline and the mean number of days over the last week patients inspected their foot rose to 0.5 at both week six and week twelve as per SDSCA. There were nine smokers at the baseline and they continued to remain smokers both at the week six and at week twelve. However, it was found that all nine smokers had cut down on their number of cigarettes at week twelve. There were no alcoholics in the study.

WHO-BREF QOL

WHO-BREF QOL was used to assess quality of life. There was a statistically significant rise in the score for the domains of WHO BREF-QOL, i.e., physical health (31.493 ± 4.949; 53.877 ± 2.353, p = 0.0001), psychological (35.383 ± 4.979; 52.19 ± 2.08, p = 0.0001), social relationships (34.13 ± 5.909;50 ± 0, p = 0.0001) and environment QOL (34.443 ± 3.242; 51.653 ± 1.573, p = 0.0001) from the baseline to end of study, i.e., at end of week twelve (Table II and Fig. 2).

Table II: Biochemical parameters.

Parameter (Units)	Baseline	Week 12	p value
HbA1C (%)	8.91 ± 0.207	7.857 ± 0.366	0.0001
FBS (mg/dl)	180 ± 7.895	139.7± 7.415	0.0001
Mean hypoglycaemic events/week	5.4 ± 0.77	3.57 ± 0.568	0.0001
Bilirubin (mg%)	0.913 ± 0.145	0.907 ± 0.146	0.873
Total Protein (gm/dl)	6.967 ± 0.464	7.03 ± 0.402	0.576
Albumin (gm/dl)	4.093 ± 0.402	4.227 ± 0.384	0.192
Serum creatinine (mg/dl)	0.977 ± 0.234	1.093 ± 0.206	0.046*
Urea (mg/dl)	31.73 ± 4.948	33.27 ± 5.152	0.242
Haemoglobin (gm/dl)	12.48 ± 0.389	12.687 ± 0.338	0.0318*
WBC/mm^3	7164.7 ± 1374.2	6256.33 ± 1502.2	0.0176*
Platelets (thousand/mm^3)	200.87 ± 57.204	178.33 ± 28.748	0.058
HDL (mg/dl)	39.77 ± 3.421	41.60 ± 2.872	0.028*
LDL (mg/dl)	128.9 ± 12.161	127 ± 11.697	0.539
Cholesterol (mg/dl)	204.03 ± 26.392	208.63 ± 28.31	0.517

**Considered to be statistically significant difference between the group at 95% CI (p < 0.05).*

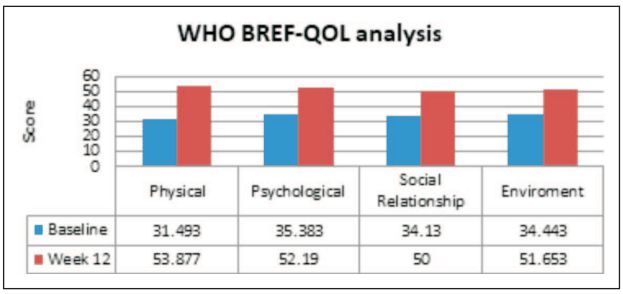

Fig. 2: *WHO-BREF QOL analysis.*

Biochemical parameters

Biochemical parameters measured at baseline and week twelve (Table II). The results revealed significant decline in mean HbA1c, FBS, and mean hypoglycaemic events per week at the baseline at week twelve respectively. There was also observed difference in serum creatinine, haemoglobin, WBC and HDL levels from baseline which was statistically significant ($p < 0.05$). However, these values were in the normal range.

Discussion

The management of DM is a challenge for both the patient as well as the healthcare provider. When glycaemic control is not optimised, diabetes imposes additional burdensome healthcare requirements, costs, and high-risk of disabling complications[12-14]. The glycaemic status in Indian diabetics is poor, leading to high complication rates and a tremendous burden on the healthcare delivery system[15].

The present study identified thirty patients who required high insulin doses. These patients were followed-up for a period of 3 months to assess the reasons for poor glycaemic control. Various factors – namely, poor dietary habits, improper insulin use and storage, poor adherence to the treatment, poor knowledge of the disease and the associated low quality of life could be attributed to the poor glycaemic control in these patients. Other studies conducted to assess factors leading to poor glycaemic control reported similar factors as our study[16,17]. These factors included increased duration of diabetes (> 7 years vs. ≤ 7 years), not following eating plan as recommended by dietitians, negative attitude towards diabetes, and barriers to adherence. These were significantly associated with increased odds of poor glycaemic control.

The MDRTC-DKT has been used in several studies to assess diabetes knowledge[6,18,19]. In the present study, the knowledge of DM and its complications was poor amongst the patients and after reinforcement on each interaction, it significantly improved. This improvement in patient's knowledge of disease was directly related to the decline in HbA1c. A community-based randomised control trial by Clifford *et al* (2005) with an intervention strategy similar to that used in the present study (i.e., individualised education on a patient-specific profile along with regular telephone follow-up) for patients with type 2 diabetes indicated that HbA1c decreased by a mean of 0.5% in the intervention group, whereas there was no change in the control group over a 12-month follow-up period[20]. Different studies also confirmed that education of patients regarding disease was reflected in their disease outcome in the form of decline in HbA1c[21-23].

The ADA position statement has specified and emphasised various aspects related to insulin administration such as storage, injection technique, injection site rotation, type of syringe, reuse of syringe, dosing and dose titration[24]. Patients in the present study lacked sufficient knowledge about these aspects of insulin injection use. Correct information about these aspects and frequent reinforcement led to better glycaemic status in these patients after three months. Nakatani *et al* (2013) reported better glycaemic control after re-education in insulin injection technique in patients with DM[25].

Research has indicated that adherence to medication in type 2 diabetes is poor and is considered as one of the main barriers to the benefit of optimal diabetes care and a major cause of unnecessary hospitalisation[26,27]. Morisky's adherence questionnaire has been used in various studies to evaluate adherence[9]. Consistent with findings from earlier research, patients who received the intervention in the present study demonstrated significantly better self-reported medication adherence compared with baseline (prior to intervention)[28]. Although there was improvement in the adherence scores from the baseline, no patient could attain a score of zero on Morisky's adherence questionnaire at week twelve which is indicative of high adherence. Patients who received the intervention in the present study had significantly better self-reported physical activity as compared to the baseline. Evidence of the beneficial effects of exercise on blood glucose control in patients with type 2 diabetes exists in the literature[29].

The reported improvement in self-monitoring of blood glucose in the patients could be attributed to the provision by the researcher for emphasising about the blood glucose values indicative of hyperglycaemia, hypoglycaemia and about how to respond appropriately to these results. These improvements in self-care activities may be due to repeated questioning of the patients using a structured questionnaire (SDSCA), which may have imparted greater responsibility and accountability on the part of the patient for their self-care activities[10]. Hence, there is a need for sustained interactions between patients and healthcare providers.

The quality of life has a direct impact on the patient's

adherence to treatment regimens. In the present study all thirty patients had a poor quality of life and raised HbA1c values at the baseline. A telephonic follow-up at week three followed by a visit at week six, revealed better adherence to medications as well as improvement in self-care activities. When the quality of life analysis was done at the end of week twelve following a telephonic review at week nine, there was significant improvement in quality of life of patients. Similar results have been obtained by many such interventions in past by Hänninen *et al*[30] (2001) and Goddijn *et al*[31] (1999). The improvement in quality of life in the present study can be attributed to improved medication adherence, healthy dietary practices, improved physical activity and more importantly as a result of all these a decline in fasting blood glucose and HbA1c. There was also significant increase in serum creatinine levels after intervention. However, serum creatinine was normal (range < 1.5 mg/dl). This could reflect in improvement in dietary (protein intake) and physical health rather than deterioration of renal function.

The present study had few limitations such as that it enrolled a limited number of patients due to time and manpower constraints and the socio-economic status of all patients in the study emerged out to be category IV (upper lower) as per the Kuppuswamy's scale and studies must be undertaken in other socio-economic group patients. Hence, there is a need to carry out a larger study, of longer duration follow-up amongst patients of varied socio-economic status. There should be studies done making the secondary end-points as primary objective for assessing their significance.

Conclusion

The study concluded that type 2 DM patients who were on high-dose of insulin together with metformin and/or sulfonylurea and high HbA1c levels had poor knowledge of disease and its complications. The adherence of patients to pharmacotherapy as well as lifestyle changes was low. The quality of life in these patients was poor in all four domains, i.e., physical, psychological, social relationships and environment. Extensive education about disease, insistence on adherence and emphasising the importance of self-care activities led to improved glycaemic control and quality of life. Frequent follow-up of the patients after every three weeks including telephonic conversations are needed for optimising both the pharmacological and non-pharmacological aspects of diabetes management such as adherence to a diet plan, regular exercise, self-monitoring of blood glucose and foot care that are vital to attain the goals of pharmacological intervention. These aspects do not incur any additional monetary cost to patients. More so, without using any additional financial resources these aspects could significantly reduce the morbidity and mortality associated with this chronic condition. Eventually such interventions will help in lowering the increased financial burden both on patients and healthcare delivery system.

Compliance with ethical standards

- **Disclosure of potential conflicts of interest:** Each author of the study declares that he/she has no conflict of interest.
- **Research involving human participants:** The study was approved by the Institutional Ethics Committee. All procedures performed in studies were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.
- **Informed consent:** A written informed consent form was obtained from all the subjects before their enrolment in this study.

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FORM IV (See Rule 8)

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