Research Article

Impact of Clinical Pharmacist Interventions and Tele-Monitoring on Clinical Outcomes of Type-2 Diabetes Mellitus Patients

Swetha Reddy Ramidi[1], Manasa Vancha[1], Vamshi Guggila[1], Syeda Nishat Fathima[2], Satyanarayana Reddy K[3], Rama Manda[2] , Vasudeva Murthy Sindgi[2,*]

[1]Department of Pharmacy Practice, Jayamukhi College of Pharmacy, Narsampet, Warangal (Rural), Telangana, INDIA.
[2]Department of Pharmacology, Jayamukhi College of Pharmacy, Narsampet , Warangal (Rural), Telangana, INDIA.
[3]Dr. Satyam's Clinic, Warangal (Urban), Telangana, INDIA.

ABSTRACT

Background: Since the occurrence of diabetes is increasing, contact between doctor and patient, decreasing, hence as the effective counselling which projects a need for the clinical pharmacist. **Aim:** To evaluate the outcome among Type 2 diabetes mellitus (T2DM) patients after interventions and tele-monitoring by clinical pharmacist. **Patients and Methods:** This is a prospective study conducted with a sample size of 140 T2DM patients. The intervention program included patient education and counselling. Patients after assessment of blood glucose parameters, giving information on diabetes and medication adherence and patients received counselling from clinical pharmacist are included in the study. Follow-up was done periodically through phone calls for assessment of health. Blood glucose parameters such as postprandial blood glucose levels (PLBS), Fasting Blood Glucose (FBG), Glycosylated Haemoglobin (HbA_{1c}) and familiarity about knowledge on diabetes, medication adherence were reassessed after 3-month intervention. **Results:** There was a significant improvement in FBG, HbA_{1c}, PLBS, diabetes knowledge, medication adherence among patients after intervention by the clinical pharmacist **Conclusion:** Standard counselling and regular follow-up by the clinical pharmacists will improve the glycaemic control among diabetes patients and the role played by clinical pharmacists in educating patients about diabetes management is noticeable.

Key words: Glycosylated haemoglobin, Morisky Green Levine Scale, Tele-monitoring, Post prandial blood sugar, Type 2 diabetes mellitus.

INTRODUCTION

Diabetes mellitus is given prime concern globally due to the increase in morbidity and premature mortalities.[1] AS IDF Atlas 2017 estimates the incidence of diabetes for the years 2017 and 2045, it has been observed that 425 million people worldwide of age between 20-79 years suffer from diabetes and the figure is anticipated to grow 451 million if the age group of the people is between 18-99 years. It has also been estimated that 693 million people of age 18 to 99 years or 629 million people between 20 to 79 years will suffer from diabetes by 2045.[2]

The WHO defined diabetes mellitus as a lifelong disease caused by deficiency in insulin production, which is inherited or acquired or by the inefficiency of the produced insulin and this deficiency contributes to increased blood glucose concentrations, which damage many systems in the body, especially the blood vessels and nerves.[3] By comparison, T2DM is more common in humans due to the altered lifestyle that is part of urbanization in developing nations. Many clinical studies have confirmed that type 2 diabetes can be delayed or prevented in high-risk populations and good glycaemic control and other interventions can slow down its complications.

Diabetes management is a joint effort of patients, pharmacists and other health care professionals. The involvement of the

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Address for correspondence:
Dr.Vasudeva Murthy Sindgi,
Department of Pharmacology,
Jayamukhi College of Pharmacy,
Affiliated to Kakatiya University
Narsampet, Warangal (Rural), 506 332, Telangana, INDIA.
Phone no: +91-8143635527
Email Id: sgvmurthy@gmail.com

www.ijopp.org

clinical pharmacist leads to better health management in patients. Pharmacists are progressively selected as part of the health maintenance system.[4] The diabetes management by a pharmacist has shown to increase the outcomes of patients in various medical settings worldwide.[5] The involvement of the clinical pharmacist improves drug compliance and other factors related to the treatment of diabetes.[6] The present work is meant to evaluate the effects of interventions and tele-monitoring provided by the clinical pharmacists on the outcomes of type 2 diabetes mellitus patients.

Aim

To asses the outcome of the patients education and counselling by the pharmacists periodically and reassessing again the familiarity about awareness on diabetes and medication adherence.

Objectives

To determine the outcome among Type 2 diabetes mellitus (T2DM) patients after interventions and tele-monitoring by clinical pharmacist.

METHODOLOGY

Study procedure

This was a prospective study done with a sample size of 140 patients in a secondary diabetes care clinic in Warangal over a period of five months from April to August after the approval of the Institutional Review Board (IRB/JCP/PharmD/2018/1003). The baseline characteristics of patients were recorded using the data collection form. The blood glucose parameters of the subjects are recorded from their medical records at the outset and also after intervention. Patient's knowledge of diabetes and their medication adherence was assessed using modified diabetes knowledge assessment questionnaire and Morisky Green Levine Scale respectively before and after intervention. After assessing patients' diabetes knowledge they were educated on basic aspects of T2DM, diabetes related complications, regarding oral antidiabetics and insulin, signs and symptoms of hypoglycemia and sick day management, proper self- monitoring of blood glucose and healthy lifestyle.

In this study periodic follow up of patients was performed through phone calls. Tele monitoring was done on 30th and 50th day after initial counselling at the clinic. During each session, the clinical pharmacist discussed with each patient about their medication adherence, self-monitoring of glycemic control, diet and exercise and reminded them of their next visit as scheduled. Patients were allowed to open up their enquiries regarding diet, medication, physical activity. To improve medication adherence among patients reminder messages was sent to them.

Study population

Inclusion criteria

- Type II diabetes patients of both genders
- Type II diabetes patients with or without hypertension
- Age ≥ 25 years
- Type II diabetes patients who are willing to visit the hospital on a regular basis.

Exclusion criteria

- Type 1 diabetes mellitus patients
- Patients with pre-existing endocrine diseases
- Type II diabetes patients with comorbidities
- Type II diabetes patients who are unable to communicate verbally
- Patients with psychiatric illness

Study materials

1. Modified diabetes knowledge assessment questionnaire: Adapted for South Asian countries to assess the patient knowledge and understanding of diabetes and its management for the study.
2. Counselling aids: patient information leaflets, prescription aids and other support materials used to educate the patients.
3. Data collection form: This form is used to collect information regarding patient's socio demographic details, lab investigations, meal plan, exercise, treatment plan etc.
4. Morisky Green Levine scale: Used to assess medication adherence in the patients.

Clinical pharmacist interventions

This includes providing individualised patient counselling using visual aids on various aspects related to diabetes mellitus such as regarding diabetes and its complications, signs, symptoms of hyperglycaemia, hypoglycaemia and its management, diabetic ketoacidosis, about oral hypoglycaemic agents and their possible side effects and insulin administration techniques, information on

importance of HbA_{1c} test and target range of all blood glucose parameters was provided, individualised diet plans were suggested to the patients, importance of physical activity, regular blood glucose monitoring and annual dental, ophthalmic examination was explained. Pamphlets with foot care and summer tips for diabetes patients were given.

Statistical analysis

Data analyzed using SPSS version 25.0 (SPSS Inc., Chicago, USA) descriptive statistics were calculated (the mean and Standard Deviation (SD) and 95% Confidence Interval (CI) for quantitative variables and percentages for qualitative variables). For the assessing between pre intervention and post intervention outcomes used paired *t*-test and A level of significance of 5% ($p<0.05$) was used in a conventional way to reject the null hypothesis. Multiple regression analysis was done to find out the factors affects HbA_{1c}.

RESULTS

Initially a total of 160 patients were evaluated by applying inclusion and exclusion criteria finally 140 members were recruited. Among them, 125 members successfully completed this study, remaining 15 were withdrawn during the study without our consent due to multiple reasons like financial issues, individual interest, busy lifestyle and due to lack of knowledge. The demographic details of the subjects were presented in Table 1.

Table 1: Demographic details of the participants.

Variables	*n* (%)
Age	
Below 30	6 (4.28)
Above 30	134 (95.71)
Gender	
Males	79(56.42)
Females	61(43.57)
Locality	
Rural	61 (43.57)
Urban	79 (56.42)
Annual Income	
>1 lakh	80 (57.14)
<1 lakh	60 (42.85)
Level of Education	
Illiterate	56 (40)
Educated	84 (60)
Occupation	
Employed	95 (67.86)
Unemployed	45 (32.14)
Duration of Diabetes	
<1 year	15 (10.71)
1-5 years	47 (33.57)
6-10 years	44 (31.42)
11-20 years	31(22.14)
21-30 years	3 (2.14)
Hypertension	73 (52.1)
Alcohol consumption	40 (28.57)
Smoking	7 (5)
Tobacco chewing	3 (2.14)

Assessment of outcome in study population

As shown in Table 2, all blood glucose parameters (HbA_{1c}, FBS, PLBS) reduced significantly after intervention ($p<0.0001$). It was observed that the mean HbA_{1c} was decreased to 7.3% after 3 months of intervention. The number of patients with target FBS (below 115 mg/dL) and PLBS (below 160 mg/dL) were raised after clinical pharmacist interventions.

Medication adherence

Medication adherence was evaluated at the beginning of the study. Multiple reasons were noted for non-adherence to the provided treatment regimen such as busy schedule of the individuals, forgetfulness and financial problems. It was noted that medication adherence significantly improved after 3 months of intervention. The percentage of patients with poor adherence decreased from baseline 9.6% to 7.2% by the end of the study. While the subjects with high adherence increased from 5.6% to 36% after intervention by the clinical pharmacists.

Response to dosing card

The primary step for improving patient medication adherence involves accurately assessing whether or not patients have followed the treatment recommended to them. In this study, patients were provided with a customized check card where patients updated their regular medicine intake and positive result observed in most of the patients (20.8%), which further led to better clinical outcomes. Few patients returned incompletely filled in form (16.8%). All the patients in spite of returning incompletely filled in form had acceptable adherence to medication regimen.

Response to diabetes knowledge assessment questionnaire

Awareness regarding the disease plays a significant role in preventing, managing and controlling any chronic illness. In this study, patient knowledge of diabetes mellitus

Table 2: Comparison of blood glucose parameters before and after intervention.

Variables	Pre intervention		Confidence Interval	Post intervention		Confidence Interval	*P* value
	n	Mean ±SD	n	Mean ±SD			
HbA_{1c} (%)							
Good Control	20	6.66±0.30	6.52- 6.80	40	6.40±0.39	6.28-6.49	<0.0001
Fair control (7.1-8)	45	7.50±0.28	7.42-7.59	45	7.40±0.27	7.31-7.45	<0.0001
Unsatisfactory Control (8.1-10)	34	8.69±0.55	8.51-8.90	29	8.82±0.54	8.56-9.017	<0.0001
Poor control (>10)	21	11.48±1.80	10.5-12.08	6	11.31±1.07	9.62-12.05	<0.0463
FBS							
Below- 115	30	102.26±11.53	98.06-106.4	56	98.78±10.79	95.91-101.3	<0.0001
Above-115	95	165±51.09	153.8-174.6	69	142±23.33	136.1-148.0	<0.0001
PLBS							
Below-160	18	145.55±7.36	141.9-149.2	58	140.93±15.97	135.4-143.8	<0.0001
Above-160	107	254.04±68.9	239.6-265.5	67	197.97±33.4	189.1-204.5	<0.0001

was assessed using Modified Diabetes Knowledge Questionnaire (MDKQ) during pre and post intervention (Table 3). The study ascertained the majority of the patients unaware of sick day management, importance of HbA_{1c} and its target range, the necessity of self-monitoring of blood glucose. After intervention, it was interesting to note that the majority of respondents had good knowledge regarding diabetes irrespective of their educational status, all the values are statistically significant.

Out comes on tele-monitoring

To get better clinical outcomes during treatment period, patients were counselled using their contact number. Tele-monitoring executed on 30th and 50th day after initial counselling. Positive response was obtained from most of the participants and follow up was done on their respective dietary plan and for their physical activities. This study noticed that patients who had a sedentary lifestyle earlier started engaging in physical activities and very few quit smoking and alcohol consumption. All the reciprocated individuals ensued prescribed diet plan throughout the study. Comprehensively there were only few enquiries from the patients with reference to the drugs (4.28%), disease (7%), diet (7.1%) and physical activity (5.7%). Information was provided to most of the patients on their disease and diet, physical activity related complaints while few are suggested to visit the hospital only to the patients requiring a change in dose frequency, hypoglycaemic episode, experienced ADR. Reminder messages and contacted over phone to the patients from time to time to improve their medication adherence.

Factors effecting HbA_{1c}

Strict glycemic control is necessary in diabetes patients to prevent the development of complications. This can be accomplished by determining factors that affect glycemic control. In this study multiple regression analysis was used examine the variables which may affect post HbA_{1c}. It was observed that scores of adherence after 3 months of intervention was a major influencing factor and found to be statistically significant. Every single degree gain in score of medication adherence after intervention by clinical pharmacist resulted in a base reduction of HbA_{1c} by 1%. However, it was found that the other factors such as age, gender, educational status, duration of diabetes have not significantly influenced HbA_{1c} (Table 4) and the various other risk factors observed in patient population shown in Figure 1.

DISCUSSION

High blood sugar levels are the main risk factor to develop diabetic complications. Since it's not feasible for a patient to be under doctor supervision all the day and diabetes is a lifelong progressive disorder and it requires a good knowledge of patient about various aspects of effective blood glucose control.

The emphasis of this work is to infer the dignity of a clinical pharmacist involvement in diabetes management. Some of the interventions used during this study to analyze the effect of those interventions on patient outcomes with respect to diabetes. Patient's diabetic knowledge assessment, medication adherence and blood glucose parameters (HbA_{1c}, FBS and PLBS) were

Table 3: Patient response to modified DKQ before and after intervention.

S.nos	Contents of modified DKQ	Pre Intervention	Post intervention	*P*-value
		Mean ±SD	Mean ±SD	
1	Diabetes is a condition	0.95±0.21	1±0	0.0247
2	Which of the following statements about diabetic diet are true	0.18±0.38	1±0	<0.0001
3	Why is doing regular exercise or being physically active good for health	0.21±0.20	0.89±0.13	<0.0001
4	Do you know how often should people with diabetes exercise or be physically active	0.53±0.50	1±0	<0.0001
5	What are the habits which help a person with diabetes to prevent complications	0.27±0.27	0.88±0.14	<0.0001
6	What is the ideal fasting blood glucose levels a person with diabetes should aim for	0.52±0.50	1±0	<0.0001
7	Why are people with diabetes advised to test their own blood glucose	0.03±0.009	0.80±0.24	<0.0001
8	What is HbA_{1c}	0.08±0.15	0.76±0.21	<0.0001
9	What is HbA_{1c} which a person with diabetes should aim for	0.08±0.27	1±0	<0.0001
10	What should a person with diabetes do if she/he become ill	0.16±0.07	0.83±0.22	<0.0001
11	Well managed diabetes decreases the risk of	0.36±0.31	0.94±0.10	<0.0001
12	Person with diabetes need a medical check-up for their eyes, nerves and kidney function atleast once a year	0.93±0.24	1±0	0.0247
13	What are the foot problems that can devlop in a person with diabetes	0.09±0.14	0.78±0.17	<0.0001
14	Which of the following statements about diabetes medication are true	0.19±0.39	0.98±0.12	<0.0001
15	If a person with diabetes has a hypoglycemia reaction, what should be done	0.94±0.15	0.98±0.07	0.0195
16	A person with type 1 diabetes feeling unwell and unable to eat, what should be done	0.01±0.10	0.55±0.23	<0.0001
17	What are the precautions a person with diabetes should take before travelling	0.16±0.12	0.76±0.18	<0.0001
18	What a person with diabetes should do if he/she experiences side effects	0.11±0.14	0.77±0.24	<0.0001

Table 4: Multiple regression analysis on factors effecting HbA_{1c}.

Variables	Coefficient	*P* value
Age	-0.002044	0.7056
Education	0.09467	0.4018
Gender	0.1211	0.3887
Duration of diabetes	0.002281	0.8044
Occupation	-0.109	0.1836
Scores of adherence after the intervention	-0.2136	0.0334
Scores of adherence before intervention	-0.01261	0.9505

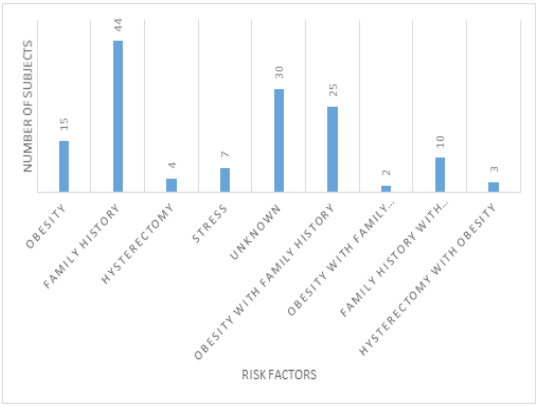

Figure 1: Risk factors observed in study population.

documented at the beginning before clinical pharmacist intervention. Later on a period of 90 days (3 months), patient's diabetic knowledge, medication adherence and blood glucose parameters were reassessed to fulfil the aim of the study. It was found that the levels of HbA_{1c}, FBS, PLBS, diabetes knowledge and medication adherence significantly improved in the subjects after intervention by clinical pharmacist and identical results were observed in preceding research work.[7,8]

Medication adherence can be improved amongst diabetes patients by the participation of clinical

pharmacist.[9] Similarly in our study there was a significant improvement in patient's medication adherence due to clinical pharmacist interventions i.e. by educating patients on the importance of proper medication adherence, understanding their reasons for non-adherence and providing a customized dosing check card which acts as a reminder. This dosing card also developed consciousness among patients towards medication adherence, which assisted the health care provider to understand patient's medical adherence. Patient's knowledge of diabetes has been usually poor among developed and developing countries.[10-12] In this study it was observed that major portion of the participants had an average knowledge of diabetes.

It was apparent that there was no association between the diabetes knowledge of the patient and their glycemic control.[13] In this present study, it was discovered that there is no relationship between HbA_{1c} levels and their diabetes knowledge. Present study revealed majority of patients who were uneducated had a significantly lower DKQ score. Overall observations states that the majority of patients were not able to respond to a few questions which include quires regarding the importance of HbA_{1c}, the necessity of self-monitoring of blood sugar, sick day management, all this is due to lack of awareness among patients about diabetes. However, after clinical pharmacist intervention, there is a significant improvement recorded in patient's knowledge about diabetes by the end of the study. As mentioned earlier, tele-monitoring is the unique feature in this study. A study found that pharmacist-provided interventions facilitated by tele-monitoring resulted in significant improvements in diabetes control among patients.[14] Similar observations recorded in the present study where follow-up post counselling performed through telephone calls. Patients were very responsive, the majority of patients found it useful and voluntarily sought advice, asked few queries about drug usage, safeguarding and to store the drugs in the time of travelling, potential side effects with anti-diabetic drugs, missing dose, hypoglycaemic episode and infections. Enquiries regarding to diet includes what is the ideal diabetes diet. Indirectly tele-monitoring is a significant contributor to effective blood glucose management.

CONCLUSION

Though overall knowledge about diabetes among the patients was acceptable, through this study it was noted that there are few areas where improvement in knowledge is however required among patients. This study provided evidence on the importance of clinical pharmacists in diabetes management team. There was a noteworthy improvement in glycemic control and mental health functioning by clinical pharmacist led tele-monitoring program. Tele-monitoring was well accepted by patients. Tele- monitoring would be an excellent approach by clinical pharmacist in providing better health care management for many other disease conditions. We conclude that the results of this study are positive and indicate a dire need of clinical pharmacist participation in diabetes management.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

T2DM: Type 2 diabetes mellitus; **PLBS:** Post prandial blood sugar; **FBG:** Fasting blood glucose; **HbA_{1c}:** Glycosylated haemoglobin; **IDF:** Indian Diabetes Federation; **WHO:** World Health Organisation; **ADR:** Adverse drug reactions; **DKQ:** Diabetes knowledge assessment questionnaire.

SUMMARY

This prospective study is all about effective education of diabetes patients by the clinical pharmacists by the way of tele- monitoring and using counselling aids. The interventions and follow up and counselling of the patients resulted in improved levels of PLBS, FBG and HbA_{1c} with betterment of medication adherence observed.

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