Research Article

Impact of Patient Education on Diabetic Distress & Clinical Outcomes in Type II Diabetes Mellitus Patients

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ABSTRACT

Diabetes Mellitus is an insidious disease having wide impact on lifestyle & stress levels of the patient. Enormous physical limitations, mental stress and social fear on coping up with the disease add to the irony of the situation. Many live with diabetes undiagnosed and become accidentally aware of the same when they go for some other disease diagnosis. The bug does not stop here. Stress Complicates the control of the disease and also leads to various co-morbidities. With 9-10% of global population already affected, 552 million cases are projected by 2030. In India it's expected to reach 101.2 million cases by 2030. Approximately 25% of Diabetics suffer one or more multiple depression symptoms. Distress leads to depression and it's associated with increased HbA1C levels, co-morbidities, mortality & poor diet and exercise adherence. Stress affects adherence to medication, diet, exercise routine and use of insulin. Pharmacists have been effective as was substantiated by various studies in providing pharmaceutical care that leads to better clinical outcomes & control of stress. The southern part of India more so consumes rice and with the recent job profiles the physical inactivity and job related stress and increased obesity has all led to decrease in the age limits where DM is diagnosed. This study was aimed at understanding the relationship between disease and stress and whether patient education by a pharmacist could bring down the complimentary effects of disease on stress and stress on disease both leading to various co morbidities which may again complicate the disease management further. This study was completed with 122 patients, who received patient education by a pharmacist resulted in favourable outcomes with Decreased HbA1c, Blood pressure and PPBS apart from significant impact on the distress reduction by decreasing the emotional, physician related distress, regimen related distress, interpersonal distress thereby reducing the scores of overall distress measured by the DDS. This was measured in a total of 3 visits in 6 months period. A self administered questionnaire and the DDS scale were used to assess the changes in the clinical parameters and the DDS scale. Drop-outs and patients not interested in HbA1c testing for economical reasons cannot be ignored while interpreting the results of the study, as this was a major limitation.

Keywords: Diabetes Distress, Pharmaceutical care, Pharmacist education, DDS.

INTRODUCTION

As per WHO, **Diabetes Mellitus (DM)** is a group of metabolic disorders characterized by hyperglycemia and abnormalities in carbohydrate, fat, and protein metabolism. Diabetes may result from defects in insulin secretion, insulin sensitivity, or both. Chronic micro vascular, macro vascular and neuropathic complications become a part of the disease when early detection and treatment is not initiated.

Diabetes Mellitus – Global Overview[1]

One person out of a dozen in the globe is diabetic. Every alternate person with diabetes does not know that he/she is suffering from the disease at all.

With 9-10 of global population[2] already affected, 552 Million[3] cases are projected by 2030. In India it's expected to reach 101.2 million cases by 2030[4]. Approximately 25% of Diabetics suffer one or more multiple depression symptoms[5].

Current state of Diabetes Mellitus in India[6]

The National Urban Survey conducted across metro cities of India recorded diabetes statistics as follows: 11.7 per cent in Kolkata (Eastern India), 6.1 per cent in Kashmir Valley (Northern India), 11.6 per cent in New Delhi (Northern India), and 9.3 per cent in West India (Mumbai) compared with (13.5 per cent in Chennai (South India), 16.6 per cent in Hyderabad (south India), and 12.4 per cent Bangalore (South India).

Need for such intervention[6]

Diabetes is worryingly now seem to be associated with a wide range of complications that too at a relatively younger age within the country.

In India, there is steady migration of people from rural to urban areas, for jobs, the economic boom, and subsequent changes in life-style; all affects the level of diabetes and its progression. Yet the numbers of studies involving various medical and paramedical professionals have not increased proportionately.

Given the current condition that this has become a very visible tragedy in the healthcare sector in India, it's time for various paramedical staff also to pull in to fill the gap that's there because of the increased patients and no proportionate increase in the doctor numbers to treat the people who are affected at both regional and national levels.

A pharmacist is well placed as a bridge between the patient and the doctor and he can ensure that the various reasons for the complications like the not sticking to the timely advise, of the doctor, medication non adherence & lack of exercise and diet control are kept under control and progression of the disease to the next level of co-morbidities can be avoided.

Also the pharmacist can ensure by regular education programs, that their patients follow:

- Self monitoring of various parameters like the BP and the Blood glucose
- Weight management by exercise and diet control
- Understanding the disease
- Understanding its complications whereby the patient is able to cope up to living with diabetes and can live with reduced levels of stress.

Diabetes-Stress-Co-Morbidities

Approximately 25% diabetics suffer – 1/a multiple depression symptom[7]. Distress & its progression leading to depression – Associated with increased HbA_{1c} levels[8], Micro & Macro-vascular complications[9], Mortality[9,10], Poor diet/Exercise adherence[11], Increased impairment of functions[12] & poor Self management of diabetes[13-15].

Marigo[16], and Weil & Sussman[17] studied specific stress kinds leading to acetonuria/gycosuria in diabetic children.

Poor diabetic control leads to emotional liability by Sanders[18], Vandenberg[19], Gaydanus & Hoffman[20], and Chere & Jackson[21] also shows that Stress affects adherence to medication, influence diet habits, exercise routines & use of insulin etc.

Pharmacist's Patient Education in Diabetes Management

Three studies[22-24] showed that pharmacist-based clinics have a positive impact on CV risk factors, like BP, hyper-lipidaemia and blood glucose control in patients with type II diabetes and also a positive impact on the risk of their cardiovascular disease.

Pharmacist-led clinics had been established in primary and secondary care sites in NHS Lothian since 2003.

These led to decrease in patients' blood pressure and improved lipid profiles.

Rajaei-Dehkordi investigated the impact of community pharmacists in identifying, understanding and catering to the needs of patients with DM, in collaboration with other healthcare professionals[25].

Wermeille through their study, demonstrated the electiveness of the community pharmacist as a member of a multi-disciplinary team providing care for DM Type 2 patients[26].

Fornos from Spain evaluated the results of a pharmacotherapy follow-up program conducted in 14 pharmacies and involving 112 patients[27].

Asheville project[28] was a PC program where community pharmacists provided services like the patient education, Patient training, clinical assessment, monitoring lab reports, follow-up, and referrals. The project followed up patients for a period of 5 years and found that patients showed improvement in glycaemic control over this period.

There have been a large number of clinical trials evaluating pharmacists interventions in diabetes mellitus (DM). Pharmacist management of patients with diabetes significantly reduces HbA1C and allows more patients to meet ADA treatment goals; a clinical pharmacist-run diabetes clinic can provide numerous clinical benefits to patient.

But Indian data (more so south Indian data) on the DDS or on the pharmacist led patient education programs and their impact on DDS & clinical outcomes combined were not widely documented and this study aimed at that.

AIM AND OBJECTIVES

Aim of the study

To understand the impact of patient education program on DDS & Clinical outcomes in Type II Diabetes Mellitus patients.

Objectives

1. Understand the kind of stress the patient is experiencing

2. Clinical outcomes in patients receiving patient education program by a pharmacist over 6 months time

3. Improvement in self monitoring practice habits in patients because of the pharmacist

METHODOLOGY

Study Design

A 6 month prospective open label study in Diabetes Mellitus out patients who visited the diabetic clinic in a tertiary care hospital.

Study Criteria:

Inclusion Criteria

- Type 2 DM patients.
- Both male and female
- The patient must have been on drug treatment for upward of 6 months
- Diabetes Mellitus patients who have been on drug treatment with OHA with/without insulin were added.

Exclusion Criteria

- Inpatients
- Patients on dietary modification and/or exercise alone.
- Patients with BMI <18.

Data Collection

Randomly sampled out patients with type 2 DM those visited the consultant outpatient clinic, over a period of a month were interviewed using a pre tested, structured data collection form to collect the demographic profile and present illness/complaints of patients along with the laboratory parameters of the patients in a total of 3 visits including the baseline.

DDS scale was administered in all visits apart from the questionnaire which had details of the patient.

Informed consent was taken prior to data collection.

The study was duly approved by the IEC before initiation.

Statistical Tools

Data was fed into the MS Office excel sheet and the percentages for various parameters were calculated and the inference arrived at.

RESULTS AND DISCUSSION

Age

122 patients successfully participated in the study of which the maximum (40%) were from the 51-60 years of age, followed by (28%) from the 61-70 years of age. The mean age of the study population was 57 years.

Sex

Men constituted 70% and the remaining 30% were women.

Education

Higher no of people (36%) have completed only the primary school education followed by the secondary school (30%) and only 22% had a degree or a post graduate degree.

Occupation

Of the 122 study population, 30% were engaged in some sort of business, followed by 23% of daily wages population, followed by the unemployed or retired (18%) then followed by 15% of private employees.

Duration of Diabetes

In 83% of the study population, Diabetes was diagnosed at-least before 5 years and in 16% the disease was diagnosed between 2-5 years. In a single patient the disease was diagnosed less than 2 years.

Table 1: Diabetes History in Years

Duration of illness	No. of patients (N=122)	Percentage (%)
Less than 2 yrs	1	1%
2-5 yrs	20	16%
5 yrs	101	83%

Social History

53% of the study population did not seem to consume Tobacco, Alcohol or was not smoking. 20% study population smoked, 16% consumed alcohol & 11% chewed tobacco.

Table 2: Social History of Patients

Habits	No. of Patients (N=122)	Percentage (%)
Smoking	25	20%
Alcohol	20	16%
Tobacco chewing	13	11%
None of the above	64	53%

Clinical Outcomes

While studying the results, the availability of the data and the dropouts should not be ignored. The lipid profile parameters were available with 43 patients to start with at baseline and were available with only 27 patients during the 2nd visit.

The FBS (Fasting blood Sugar) and the PPBS (Post Prandial Blood Sugar) was available in all 122 patients as those who visit the doctor for check up are made to take the blood sugar levels both times on the day of the visit.

On the contrary HbA1C was available in 45 patients during baseline and was available in only 16 patients in 2nd visit.

The results are expressed as a percentage here for a better understanding. There were significant changes in the number of patients getting into normal range in HDL & HbA1C values.

Though there were positive changes in all parameters, the change in these two parameters were quite significant.

Diabetes Distress

Diabetes Distress Scale (DDS) was used for assessing the distress throughout the study.

The DDS contains a 2 point scale and a 17 point scale. The 17 point scale was used in the study. The scale grouped questions on various types of distresses like emotional, regimen related and physician related distress etc. Separately and there was an overall score combining all such groups to one.

Any score below 3 was considered normal and above that was considered as a distress condition requiring clinical attention.

Table 3: Laboratory Parameters/Clinical Outcomes

Laboratory parameters analysis		Baseline		Visit 2	
		No. of patients	Percentage	No. of patients	Percentage
		(N=43)	(%)	(N=27)	(%)
LDL	Normal	17	39.5	14	51.9
	Abnormal	26	60.5	13	48.1
HDL	Normal	6	14.0	9	33.3
	Abnormal	37	86.0	18	66.7
VLDL	Normal	14	32.6	12	44.4
	Abnormal	29	67.4	15	55.6
TGL	Normal	16	37.2	11	40.7
	Abnormal	27	62.8	16	59.3
TOTAL CHOLESTEROL	Normal	15	34.9	12	44.4
	Abnormal	28	65.1	15	55.6
Laboratory parameters analysis		Baseline		Visit 2	
		No. of patients	Percentage	No. of patients	Percentage
		(N=122)	(%)	(N=122)	(%)
FBS	Normal	83	68.0	98	80.3
	Abnormal	39	32.0	24	19.7
PPBS	Normal	76	62.3	96	78.7
	Abnormal	46	37.7	26	21.3
HBA1C	Limits	No. of patients (N=46)	Percentage (%)	No. of patients (N=16)	Percentage (%)
	Normal	3	6.7	9	56.3
	Abnormal	42	93.3	7	43.8

Lipid profile was available in only 43 patients in baseline and was available with 27 patients only in Visit 2.

DDS Overall Score

There was a seemingly good improvement in the normal scores from Baseline (38%) to visit 2 (81%).

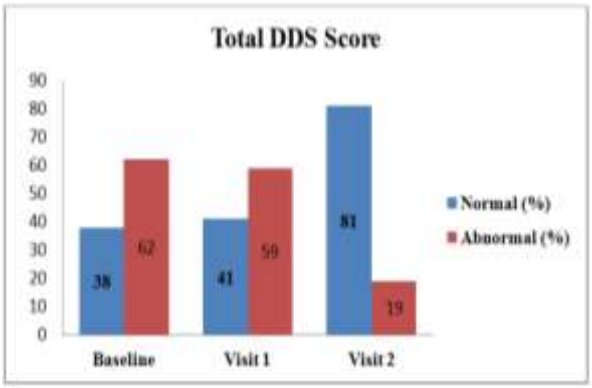

Figure 1: Total DDS Score

Emotional Burden Scores

At baseline there were 30% of patients with normal emotional burden scores which went up to 88% over 2 visits after baseline.

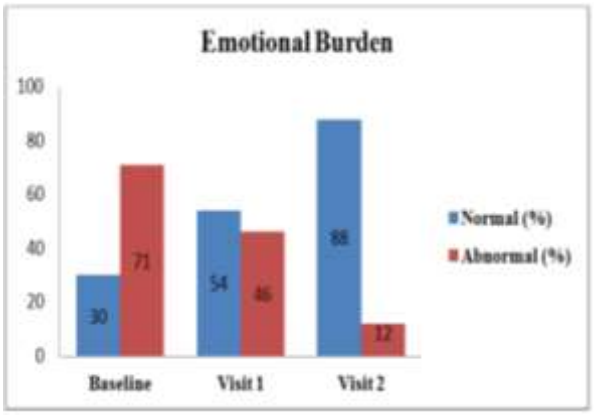

Figure 2: Emotional Burden Score

Physician Related Distress Scores

Even at baseline 71% patients were in the normal range which improved to 98% in Visit 2.

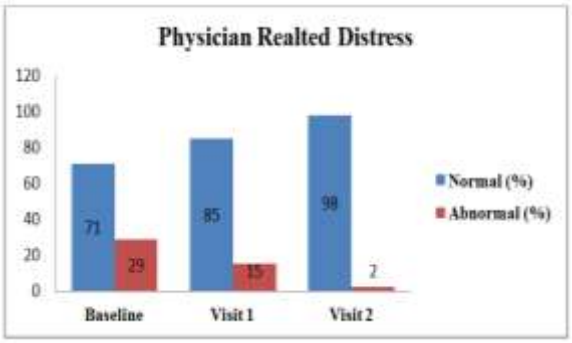

Figure 3: Physician Related Distress Score

Regimen Related Distress Scores

The change was improvement from a mere 47% in normal scores to 92% in visit 2.

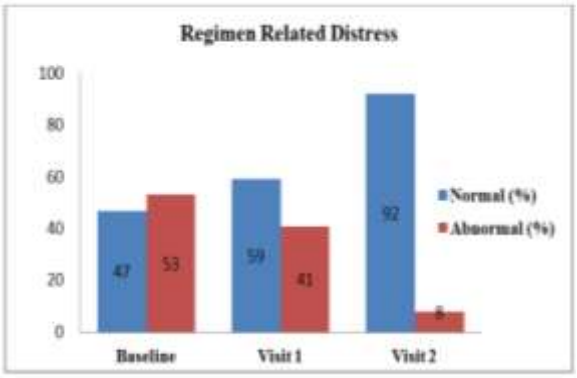

Figure 4: Regimen Related Distress Score

Interpersonal Distress Scores

There was an improvement from 42% normal scores to 85% normal scores in the interpersonal distress group of questions.

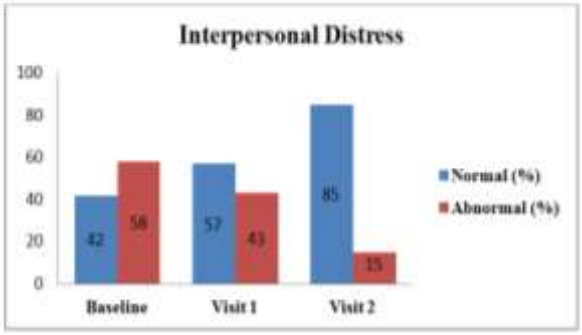

Figure 5: Interpersonal Distress Score

CONCLUSION

Patient education by Pharmacist has positive impact on the clinical outcomes and in reducing the distress related to Diabetes Mellitus in Type II Diabetes mellitus outpatients. This can help control the vicious cycle of Diabetes leading to complications leading to stress again complicating the management of Diabetes.

Controlled trials are warranted to assess further.

Limitations of the Study

- ❖ Visit irregularities of patients
- ❖ Drop out in between the study
- ❖ Concurrent testing of HbA1C and lipid profile in all patients was limited for economical reasons.

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