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"IMPACT OF COUNSELLING ON QUALITY OF LIFE OF PATIENTS WITH TYPE 2 DIABETES MELLITUS AT A TERTIARY CARE TEACHING HOSPITAL"

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ABSTRACT

To assess the relationship between Quality Of Life and Capillary Blood Glucose levels in Type 2 Diabetes Mellitus patients at a tertiary care teaching hospital. A randomized prospective controlled study was conducted for a period of 6 months in the General Medicine OPD of SSIMS & RC. Patients enrolled were randomized into test and control groups. Audit of Diabetes Dependent Quality of Life -18 Questionnaire was used to assess the quality of life of patients. Students't' test was applied. Correlation coefficient method was used. Mean Fasting Blood Sugar levels was decreased in the test group ($^{*}P<0.05$) and an improvement in mean Quality Of Life scores (*P<0.05) were observed. The correlation between the Fasting Blood Sugar and Quality Of Life scores were highly significant in the test group (*r = -0.556). It was found that all domains were affected by diabetes. Diabetes Mellitus affects the Quality Of Life of patients and proper education play a major role in improving health care outcomes like glycemic control and Quality Of Life. The study observed that, hospital pharmacists can play a key role in the management of Diabetes Mellitus and patient care.

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INTRODUCTION

The worldwide prevalence of Diabetes Mellitus (DM) has risen dramatically over the past two decades. It is a silent disease that has become more prevalent with increased age.[1]

At present, India is considered as the "Diabetic Capital of The World". There are approximately 3.5 crore diabetic patients in India, and this figure is expected to increase up to 5.2 crore by 2025. Keeping in view the alarming increase in the incidence and prevalence of DM in India, the World Health Organization (WHO) has declared India as the "Diabetic Capital of The World".[2]

According to the Diabetes Atlas 2006 published by the Internal Diabetes Federation, the number of people with Diabetes in India is currently around 40.9 million. It is expected to rise to 69.9 million by 2025 unless urgent preventive steps are taken.[3]

Diabetes Mellitus refers to a group of common metabolic disorders that share the phenotype of hyperglycemia. Depending on the etiology of DM, factors contributing to hyperglycemia include reduced insulin secretion, decreased glucose utilization, and increased glucose production.[5]

Lack of insulin affects the metabolism of carbohydrate, proteins, and fat, resulting in significant disturbances in water and electrolyte homeostasis. Death may result from acute decompensation.[4] Complications of DM are frequently divided into macrovascular and microvascular. The general etiology of both complications are the same and results from atherosclerosis of the vessels which may lead to occlusion.[6]

The American Diabetes Association recommends using the fasting glucose as the principal tool for the diagnosis of DM in non-pregnant adults.[7]

Patient counselling refers to the process of providing information, advice and assistance to help patients use their medications appropriately. The information and advice is given by the pharmacist directly to the patient or to the patient's representative, and may also include information about the patient's illness or recommended lifestyle changes. The information is usually given verbally, but may be supplemented with written material.[8]

In general, patient counselling has 3 main objectives: assessing the patient's understanding of the therapy, including proper use and adverse effects of the medication; improving patient adherence; and motivating the patient to take an active role in health management.[8]

Self-care education is an essential element in the treatment of a person with DM and its importance is acknowledged in several studies carried out in communities with different socioeconomic and cultural profiles. The intricacies of the diabetic diet, insulin injection, and home glucose level monitoring place even greater educational requirements for patients. Patient education also plays a critical role in facilitating patients' acceptance of their diagnosis and understanding behavioural changes required for active participation in treatment.[9]

The Audit of Diabetes Dependent Quality of Life Questionnaire (ADDQoL) is recommended for measuring the impact of diabetes on quality of life. The measurement of Quality Of Life (QoL) in people with diabetes has been reviewed elsewhere and several instruments claim to measure the impact of diabetes on QoL. However, the ADDQoL has important advantages over other questionnaire-based instruments, allowing patients to indicate:

- What aspects of life apply to them?
- The perceived importance of each aspect of life for their QoL.
- Whether the impact of diabetes on that aspect of life is positive or negative.

The ADDQoL consists of two overview items designed for audit purposes: generic "present QoL" and diabetes-specific "impact of diabetes on QoL". A further 18 items have been designed for clinical and research use that concern the impact of diabetes on specific aspects of life.[10]

Pharmacists are in a unique position to play vital role in patients medication adherence and quality of life improvement. The present study is designed to assess the impact of pharmacist provided patient counseling on treatment outcomes and quality of life in type-2 diabetes mellitus patients, by improving their knowledge, attitude and practice.[1]

MATERIALS AND METHODS

Materials used:

- Informed Consent Form
- Patient Data Collection Form
- Patient Information Leaflet
- Audit of Diabetes Dependent Quality of Life (ADDQoL) Questionnaire

Study design:

A randomized prospective controlled study.

Ethical issues:

The ethical clearance for the study was obtained from the Institutional Ethical Committee of Bapuji Pharmacy College, Davangere.

Methods:

The study was conducted in the General medicine OPD of a tertiary care teaching hospital for a period of six months Patients diagnosed with Type-2 DM of either sex above 30 years were included in the study. Patients with gestational diabetes, thyroid disease and with uncontrolled diabetes were excluded from the study. After the enrollment, patients were randomized into test and control groups. The data collected from the case sheet (Patients Demographic Details, Levels of Random Blood Sugar, Fasting Blood Sugar, and Post Prandial Blood Sugar) were properly documented in a previously designed data collection form. A disease-specific Audit of Diabetes-Dependent Quality of Life (ADDQOL-18) questionnaire was administered to assess the quality of life in all the study patient, at first visit and during each follow up (at sixty days interval). The patients in the test group received counseling on their disease, drugs, diet and lifestyle modification and also a patient information leaflet highlighting the disease, diet and lifestyle modifications. The patients in the controlled group received pharmacist provided counseling and patient information leaflets only at the end of the study. Student t test was applied to assess the changes in quality of life scores and capillary blood glucose readings between test and control groups. Correlation coefficient method was used to correlate between the quality of life score and capillary blood glucose reading.

RESULTS

After the scrutiny, using inclusion and exclusion criteria 150 patients were enrolled into the study and were randomized into test and control groups. Out of them, 127 patients (68 from test and 59 from the control group) completed all follow ups of the study. Among 150 patients 48.66 % were males and 51.33% were females. When categorizing age wise, majority of patients (28%) was founded in the age group of 51-60. Most of the patients had primary level education and were unemployed. Among the study population, 88.66% of the patients were nonsmokers and 56.66% were non alcoholics. Among the patients only 45 (30%) had a family history of DM and 62 (41.33%) had other complications. 44.66% patients enrolled were with above 5 years of diabetes disease history.

A gradual improvement in the overall quality of life scores was observed in the test group patients, whereas in the control group patients, changes in the overall score were non-significant. The comparison of mean scores of two over view items for both control group and test groups from baseline to final follow up is shown in the Table 1.

Table 1: Mean scores of overview questions.

ADDQoL Overview Items	Test Group		Control Group	
	1	2	1	2
Base line	-0.19	-1.44	-0.32	-1.41
1st assessment	0.59	-0.78	-0.35	-1.3
2nd assessment	0.98	0.32	-0.4	-1.22

ADDQoL: Audit of Diabetes-Dependent Quality of Life.

To study the impact of patient education on various domains of quality of life, such as health and function domain, social and economic domain, and family domains were analyzed. The changes in the scores of each domain from baseline to final follow up for control and test group patients were given in Table 2 and 3.

Table 2: Mean scores of 10 domain questions for Test group.

ADDQoL Domain Items	Base Line	1st Assessment	2nd Assessment
1	-2.53	-2.01	-1.5
2	-2.72	-2.11	-1.43
3	-1.11	-0.91	-0.56
4	-2.6	-1.98	-1.21
5	-2.47	-1.88	-1
6	-2.79	-2.01	-1.43
7	-2.48	-1.79	-1.33
8	-2.68	-2.11	-1.1
9	-3.39	-2.34	-1.76
10	-3.33	-2.57	-1.68

ADDQoL: Audit of Diabetes-Dependent Quality of Life.

Table 3: Mean scores of 10 domain questions for Control group.

ADDQoL Domain Items	Base Line	1st Assessment	2nd Assessment
1	-2.25	-2.21	-2
2	-2.2	-2	-1.9
3	-0.96	-0.98	-0.77
4	-3.63	-3.55	-3.1
5	-2.35	-2.13	-2
6	-2.19	-2	-1.98
7	-2.73	-2.54	-2.21
8	-2.28	-2.11	-1.87
9	-2.83	-2.67	-2.13
10	-2.8	-2.7	-2.21

ADDQoL: Audit of Diabetes-Dependent Quality of Life.

The mean scores of ADDQoL domain questions in the test and control group during their each follow up were compared using student's t test. The p value was found to be highly statistically significant in the test group were shown in table 4.

Table 4: Comparison of ADDQoL scores within the group.

Comparison of ADDQoL Scores		Base Line	1st Assessment	2nd Assessment	Paired t test		
		1	2	3	1 Vs 2	1 Vs 3	2 Vs 3
Test Group	Mean	-2.61	-1.97	-1.30	P<0.000	P<0.000	P<0.000
	Std. Deviation	0.62	0.44	0.35			
Control Group	Mean	-2.42	-2.37	-2.36	P<0.02	P<0.03	0.913
	Std. Deviation	.67	.67	.64			

ADDQoL: Audit of Diabetes-Dependent Quality of Life.

The mean scores of FBS in the test and control during their each follow up were compared using student's t test. The p value was found to be highly statistically significant in the test group was shown in table 5.

Table 5: Comparison of FBS values within the group.

Comparison of FBS Values		Base Line	1st Assessment	2nd Assessment	Paired t test		
		1	2	3	1 Vs 2	1 Vs 3	2 Vs 3
Test Group	Mean	173.23	154.80	136.45	P<0.000	P<0.000	P<0.000
	Std. Deviation	56.92	45.20	40.25			
Control Group	Mean	174.97	173.95	173.41	0.09	P<0.01	0.159
	Std. Deviation	38.34	38.00	38.16			

ADDQoL: Audit of Diabetes-Dependent Quality of Life
FBS: Fasting Blood Sugar

There is a correlation between a reduction in fasting blood glucose (FBG) and increase in quality of life (QOL) scores with a high degree of significance (r = -0.556) in the test group, whereas the control group has a moderate degree of significance (r = 0.282) at the end point of the study was shown in table 6 and depicted in figure 1.

Table 6: Pearson correlation of total QoL with FBS.

Pearson's Correlation		Test Group	Control Group
ADDQOL & FBS Values	Base Line	r = -0.05, NS	r = -0.03, NS
	End point	r = -0.556, *P<0.000	r = -0.282, *P<0.03

ADDQoL: Audit of Diabetes-Dependent Quality of Life
FBS: Fasting Blood Sugar

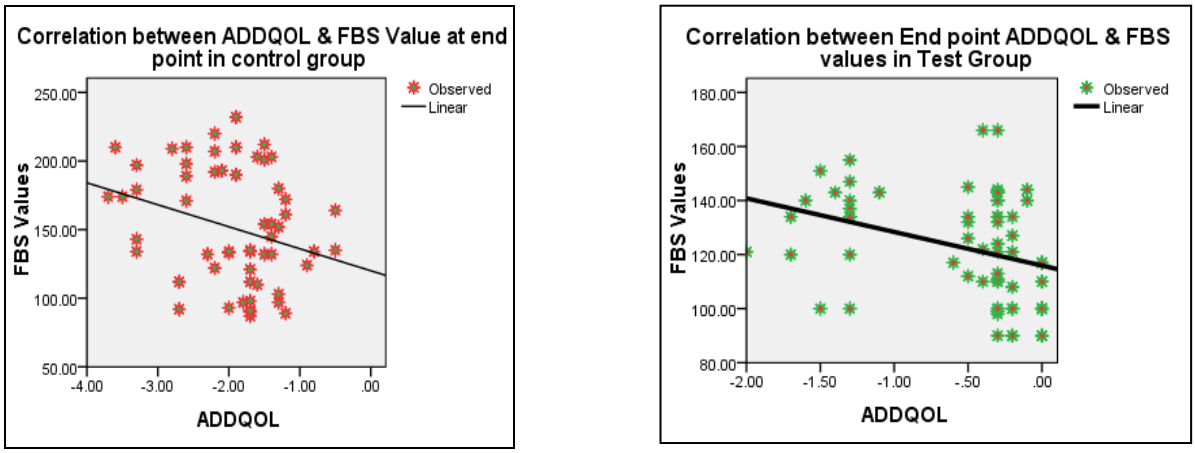

Fig. 1 Correlation between Endpoint ADDQoL scores and FBS values in Test and Control Group.

DISCUSSION

The management of DM not only requires the prescription of appropriate nutritional and pharmacological regimen by the physician but also intensive education and counselling of the patient. A total of 150 patients were enrolled into the study. Out of that 1 expired, 5 patients were hospitalized, and 17 did not respond. Remaining 127 patients (68 patients from test and 59 from the control group) completed all the follow ups.

The FBS of the patients in the test group was found to be significant ($^{*}p<0.00$) when compared from baseline to the second assessment, whereas in the control group, no significant changes were observed ($^{*}p> 0.05$). This result was supported by the reports of a study conducted by Adepu R *et al* ($^{*}p> 0.05$)[1]

A significant improvement in the overall QoL and domain score in the test group ($^{*}p<0.05$) was observed in final assessment when compared with baseline, whereas in the control group, no significant improvement was observed ($^{*}p>0.05$). This was in compliance with the studies conducted by R Adepu et al, Douglas L. Jennings et al and Ramanath KV *et al*.[1,11,12]

There was a correlation between the reduction in FBS and the increase in QoL score with a high degree of significance (r = -0.556) in the test group, whereas the control group has a moderate degree of significance (r = 0.282) at the end point of the study. This was in correlation with the study conducted by Adepu *et al*.[1]

CONCLUSION

The study concluded that the pharmacist provided counselling improved knowledge and attitude of the patients towards the disease. This study also observed the correlation between quality of life scores and FBS level. There was a reduction in FBS level and improvement in quality of life in test group with a high degree of significance (r = -0.556).

The study observed that, hospital pharmacists can play a key role in the management of DM and patient care. We conclusively state that pharmacist provided patient counselling may be a useful tool for decision making in planning and monitoring disease interventions to improve health outcomes.

This study is recommended for future Research.

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