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Research Article

# ASSESSMENT OF PHARMACIST MEDIATED EDUCATION ON HEALTH-RELATED QUALITY OF LIFE IN TYPE 2 DIABETES MELLITUS PATIENTS IN RURAL SOUTH INDIAN POPULATION

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**ABSTRACT**

**Objective:** The objective of this study was to assess the influence of pharmacist mediated education on health-related quality of life (QOL) in rural patients with Type 2 diabetes mellitus.

**Methods:** This is a prospective, randomized interventional study approved by the institutional ethics committee. Eligible Type 2 diabetic patients with written informed consent were enrolled and randomized into control and test group. Diabetic health profile-18 (DHP-18) questionnaire was administered to all patients at baseline and three subsequent follow-ups. Patients in the test group received structured education at every follow-up, whereas the control group patients received education only at the final follow-up. Statistical Package for the Social Sciences software was used to evaluate the data.

**Results:** Among the 72 patients enrolled, 35 were randomized into control group and 37 into test group. Majority of the study patients were males (65.2%) with an age range of 30–72 years and were from agriculture profession (34.72%) with school-level education (59.7%). The mean body mass index of the study patients was 25.01. At baseline, the mean HbA1 values of patients were 6.48±1.39% in the control group and 6.23±1.16% in the test group. During the last follow-up, a significant ($p<0.05$) improvement was observed in the DHP-18 scores in test group patients compared to control group patients which were supported by statistically significant ($p<0.05$) improvement in capillary blood glucose values.

**Conclusion:** Pharmacist mediated structured education has shown a positive impact on health-related QOL in test group patients toward their disease management.

**Keywords:** Diabetes, Therapeutic outcome, Health-related quality of life.

## INTRODUCTION

Diabetes mellitus (DM) is a metabolic disorder characterized by hyperglycemia. Increasing at an alarming pace, particularly in developing countries [1], and it is estimated that globally about 382 million people are suffering from diabetes [2]. The World Health Organization (WHO) has estimated that by 2030, diabetes will be the 7th leading cause for death [3]. The global expenditure due to diabetes is estimated to be 548 billion US dollars, and in India, it is estimated to be 6 billion US dollars and the overall mortality rate is about 55% [2].

Inadequate management of diabetes leads to several health problems with increased risk of complications. This is mainly associated with patient's poor knowledge about the disease and its management. Medication non-adherence is another multifaceted problem, especially with chronic diseases which play an important role in determining the therapeutic outcomes. Studies have confirmed the positive influence of pharmacist mediated education on knowledge, attitude, and practices about disease and therapy which has shown a positive impact on health-related quality of life (HRQOL) [4].

Diabetic patients often develop complications due to inadequate glycemic control mainly because of poor practices regarding the disease and management [5]. Patient education is the most effective way to improvise patient responsibility toward disease management and minimize the diabetes complications and improve the outcomes. Diabetic patients wishing to lead a normal life should understand about their illness and the strategies to put the disease under control [6]. This corroborates the importance of awareness among diabetics in DM management.

The available research evidences emphasize the importance of pharmacist mediated patient education in improving the patient awareness and thereby improving medication adherence and good glycemic control along with reduced diabetes-related complications [7].

QOL is measured as physical and social functioning and perceived physical and mental well-being. Studies of clinical and educational interventions suggested that improving patient's health status and perceived ability to control their disease results in improved QOL [8].

In a study conducted by Ramanath and Santhosh has applied the WHO-Bref QOL to assess the influence of pharmacist mediated patient education on health-related QOL. At the end of the study, a significant increase in QOL, KAP, and medication adherence scores ($p<0.05$) was observed in patients suffering from diabetes. A significant change in glycemic control was also seen [9].

In another study conducted by Kaskurthy *et al*. has applied SF-36 questionnaire to assess the pharmacist mediated education on health-related QOL. At the end of the study, there was a statistically significant improvement in the QOL scores in patients from baseline to final follow-up ($p<0.05$). Clinical pharmacist mediated counseling to Type 2 diabetes patients significantly improved the QOL of the patients. The data suggest that hospital-based pharmacist's counseling can play an important role in the multidisciplinary health-care team [10].

## METHODS

This is a prospective interventional study conducted in medicine outpatient department of Adichunchanagiri Hospital and Research Centre, Mandya, Karnataka, India, over a period of 6 months. Type 2 DM

patients of both genders meeting the inclusion criteria were enrolled in the study using block randomization technique to avoid selection bias. Type 2 DM patients with disease duration of <3 years were included in the study.

Pediatric, gestational diabetes, and psychiatric patients were excluded from the study.

This study was approved by the institutional human ethics committee and issued a letter to conduct the study.

Before initiating the study, the knowledge level of the surrounding community helps in selecting the appropriate population and the level of awareness to be provided can be known.

A suitably designed data collection form was developed, details such as patient demographics, educational status, social habits, socioeconomic status, medical history and medication history, family history, allergies, body mass index (BMI), diet, marital status, smoking, and alcohol status were obtained.

Diabetic health profile-18 (DHP-18) questionnaire was administered at baseline to assess the health-related QOL about the disease and its management [11,12]. The questionnaire covers three aspects of health-related QOL - psychological distress (6 items), barriers to activity (7 items), and disinhibited eating (5 items). There are a total of 18 questions. This questionnaire was filled by the patient or patient's attender at face-to-face interview with the investigator.

Glycosylated hemoglobin (HbA1C) was performed at baseline to assess the diabetic status of the enrolled patients. All the enrolled patients were followed for 3 months from baseline with an interval of 30 days between the follow-ups. At every follow-up visit, blood pressure and capillary blood glucose (CBG) were recorded (fasting blood sugar [FBS] and postprandial blood sugar [PPBS]). Test group patients received the pharmacist mediated structured education regarding the disease, medication, diet, and lifestyle modification at baseline and further follow-ups, and patient information leaflet (PIL) was provided. Control group patients received detailed education only at the final follow-up visit.

**Statistical analysis**

Results were analyzed using Statistical Package for the Social Sciences for Windows Version 20. The significance of the change in CBG at each follow-up visit compared to the first follow-up was assessed using independent t-test. The significance of the change in DHP-18 QOL scores from baseline to final follow-up was also assessed using paired t-test. $p<0.05$ is considered as statistically significant.

## RESULTS

A total of 72 eligible Type 2 DM patients meeting the inclusion criteria were enrolled in the study. These patients were randomized into control and test group, 37 patients were from the test group and 35 patients were from the control group. 65.27% were male and 34.72% were female. The minimum age of the patients was 30 years and maximum age of the enrolled patients was 72 years. The mean (±SD) age of test group patients was 51.29±10.82 years and that of the control group patients was 58.05±12.75 years. The majority of the enrolled patients were literate (79.16%), with most of the patients had completed primary school education (59.7%), who were farmers, daily wage laborers, and small business by profession since they belonged to the rural population.

The demographic details of the patients completed all the follow-ups are presented in Table 1.

The mean BMI of male patients was 24.76% and BMI of female patients was 25.27%. Majority of the patients (62.5%) had an average annual income of 50,000–100,000 and rest of the patients were homemakers. Smoking status of patients in control group was 11% and test group was 24%. Alcoholic status of patients in control group was 39% and test group was 45%.

**Table 1: Demographic characteristics**

| Parameter | Control (n=35) | Test (n=37) | p value |
|---|---|---|---|
| | n (%) | n (%) | |
| Gender | | | |
| Male | 18 (25) | 29 (40.27) | 0.937 |
| Female | 17 (23.6) | 8 (11.1) | |
| Age | | | |
| 30–40 | 4 (5.5) | 8 (11.1) | 0.813 |
| 41–50 | 8 (11.1) | 10 (13.8) | |
| 51–60 | 9 (12.5) | 10 (13.8) | |
| 61 and above | 14 (19.4) | 9 (12.5) | |
| Educational qualification | | | |
| Illiterate | 11 (15.2) | 4 (5.5) | 0.866 |
| Primary school | 11 (15.2) | 9 (12.5) | |
| Secondary school | 9 (12.5) | 13 (18.05) | |
| PUC | 3 (4.1) | 4 (5.5) | |
| Graduate | 0 (0) | 6 (8.3) | |
| Postgraduate | 1 (1.3) | 1 (1.3) | |
| Profession | | | |
| Agriculture | 14 (19.4) | 11 (15.2) | 0.900 |
| Business | 4 (5.5) | 12 (9.72) | |
| Employment | 2 (2.7) | 7 (9.72) | |
| Housewife | 15 (20.8) | 7 (9.72) | |
| Smoking status | | | |
| Yes | 2 (2.7) | 7 (9.72) | 0.844 |
| No | 33 (45.8) | 30 (41.6) | |
| Alcoholic status | | | |
| Yes | 7 (9.72) | 13 (18.05) | 0.874 |
| No | 28 (38.8) | 24 (33.3) | |

At the baseline, HbA1C test was conducted to know the diabetic status of the enrolled patients. The mean HbA1C value was 6.48±1.39% in the control group patients and 6.23±1.16% in the test group patients.

At first follow-up and subsequent follow-ups, CBG was monitored to assess the influence of educational intervention on health-related QOL and glycemic control. In the control group at the first follow-up, the mean FBS was 133 mg/dl and mean PPBS was 180 mg/dl. In the final follow-up, the mean FBS was 132 mg/dl and the mean PPBS was 175 mg/dl. These values suggest that the glycemic control did not change in the control group patients. Whereas, the mean FBS during the first follow-up in test group patients was 123 mg/dl and mean PPBS was 175 mg/dl. In the final follow-up, the mean FBS was 105mg/dl and the mean PPBS was 133 mg/dl (Figs. 1 and 2).

As per the WHO definition, health is defined as physical, mental, and social well-being. Majority of the chronic diseases with uncontrolled symptoms are uncontrolled may affect the patients' health-related QOL.

In our study to assess the health-related QOL, DHP-18 scale in diabetes patients was applied on both control and test group from baseline to final follow-up. Test of significance (t-value) was calculated for both the groups comparing the baseline and final follow-up. Findings of DHP-18 in control group patients from baseline to final follow-up were non-significantly improved ($p=0.939$), whereas in test group the scores were significantly improved ($p<0.05$).

DHP-18 measures the impact of the diabetes disease on individuals' social and emotional well-being.

The scores of the DHP-18 are presented in Fig. 3.

## DISCUSSION

Diabetes is a chronic disease and important public health problem nationally and internationally and the global prevalence of diabetes is on the rise. Inadequate management of diabetes leads to several health problems with increased risk of complications. This is mainly associated with patient's poor knowledge about the disease and its

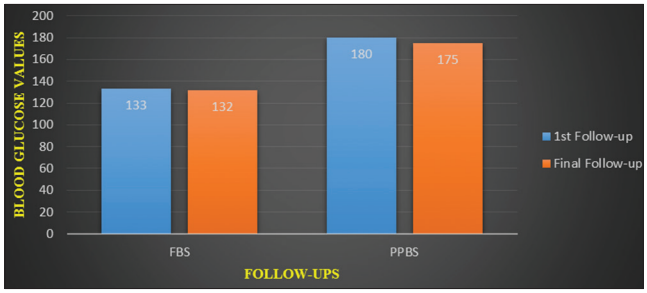


**Fig. 1: Mean fasting blood sugar and mean postprandial blood sugar in control group**

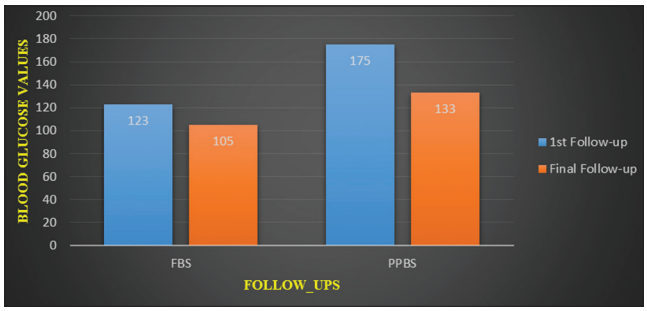


**Fig. 2: Mean fasting blood sugar and mean postprandial blood sugar values in test group**

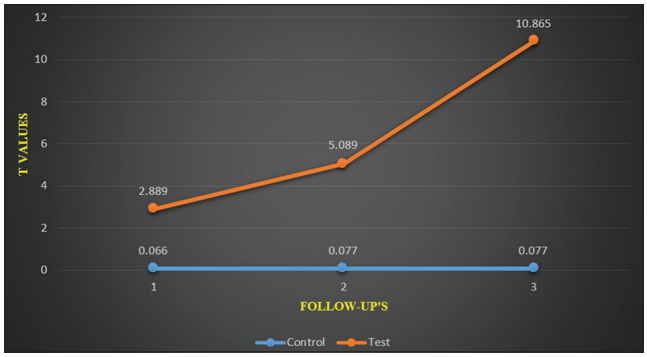


**Fig. 3: Diabetic health profile-18 (DHP-18) health-related quality of life scores. 1DHP-18 Copyright© DHP Research and Consultancy 2000. All rights reserved. Isis Innovation Limited is exclusively licensed to grant permissions to use the DHP. DHP-18 English (US)**

management. Pharmacists by virtue of their professional status act as a liaison between the clinicians and patients not only by dispensing the prescribed medications but also by assisting the patients in the safe use of prescribed medicines and thereby enhancing their medication adherence behavior and thereby improving the health-related QOL.

A total of 72 patients were included in the study. Males (65.2%) outnumbered females (34.72%) and a maximum number of patients (n=23, 31.9%) were in the age group of 61 and above, which is similar to the study conducted by Ramanath and Santhosh.

Literacy rate in our study was (79.16%) (n=57, patients) which eased structured patient counseling with the usage of PIL, as they could recall the information by reading PIL at home, which was similar to the study conducted by Malathy *et al*., Adepu *et al*., and Ramanath and Santhosh [5,9,13-15].

A strict adherence to medication will improve the desired clinical outcomes such as glycemic control in diabetes patients. This, in turn, will improve the health-related QOL in diabetes patients. A healthy individual demonstrates productivity and satisfaction in the life.

Patient education has been the primary intervention associated with assisting individuals with lifestyle change in DM. The major components of DM self-management (medication, diet, exercise, and self-monitoring blood glucose) require challenging lifestyle changes for even the most disciplined people. The underlying assumption is that education influences behavior, which subsequently influences glycemic control. Education about DM has gradually changed from imparting knowledge about the cause and treatment of DM to an interactive approach in DM self-management. The approach has changed from passive learning to active participation in self-care and decision-making. The focus of the patient DM education approach has changed from compliance to adherence, self-efficacy, and empowerment. The power of the patient educator shifted from the educator to the patient. The main results of the present study are increase in knowledge, behavioral changes, and improvement in FBS, PPBS, adherence behavior, and HRQOL. The patient's knowledge about the disease and its management is important. In our study, the interventional group had shown statistically significant increase in knowledge. One of the reasons why people do not manage their diabetes fully may be lack of knowledge. Several studies have concluded that lack of knowledge of self-care skills and wrong information or misunderstanding of the therapeutic plan was major aspects of involuntary non-compliance. However, knowledge should not be overestimated because people may know what to do but not able to implement it into practice. The success of DM management largely depends on patient compliance with the prescribed management plan. They must change several behaviors all at once: Diet, medications, and lifestyle modifications. The study confirms that using interactive approach in education is effective in the management of DM and improves metabolic control and health-related QOL. In our study, we have applied DHP-18 questionnaire that measures the impact of diabetes on every day social and emotional functioning. In our study, at the final follow-up, the DHP-18 score was significantly improved ($p<0.05$) from baseline to final follow-up in the test group patients compared to control group patients (DHP-18 scores, 0.077). Many research studies also confirmed similar findings. A study conducted by Aghamolaei *et al*. [16], in Iran, has observed a statistically significant improvement in the HRQOL scores in patients with educational intervention compared to the control group patients. In another study conducted by Vadstrup *et al*. [17] has shown an improved score in various domains of SF36 in Type 2 diabetes patients when one-to- one counseling was provided compared to group counseling. Other Indian-based studies [9,13-15] also shown similar improvements in patients received educational intervention by pharmacists compared to the control group patients corroborating the influence of educational intervention on health-related QOL.

## CONCLUSION

Diabetes is a chronic disorder that affects the social and emotional well-being of the patients if the glycemic control is not adequately maintained. A structured education empowers the patients to take responsibility in adhering to their prescribed medications and thereby achieving the desired clinical outcomes. Our study concludes that structured education by a pharmacist can significantly improve health-related QOL of Type 2 DM patients, and it also supports the educational interventional role of the pharmacist.

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**CONFLICTS OF INTEREST**

Sai Pawan AR, Steny Sam, Cuckoo Omanakuttan, Ramanath KV, and Yashaswini Yegurla hereby declare that they have no conflicts of interest.

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