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Original Article

Impact of pharmaceutical care on quality of life in patients with type 2 diabetes mellitus

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Abstract

BACKGROUND: Diabetes mellitus has become an international healthcare crisis that requires new approaches to prevent and treat it. The objective of this study was to evaluate the impact of pharmaceutical care on quality of life (QOL) in patients with type 2 diabetes mellitus.

METHODS: A prospective study on impact of pharmaceutical care on QOL in patients with type 2 diabetes mellitus was conducted in a private tertiary care teaching hospital in South India for a period of 8 months. Study was done on 120 eligible patients with type 2 diabetes mellitus enrolled randomly in the intervention group (with pharmaceutical care teachings) or the control (without drug related educations). The intervention group patients received pharmaceutical care through diabetes education, medication counseling, instructions on lifestyle that needed modifications (necessary for better drug function) and dietary regulations regarding their prescribed drugs, whereas the control group patients were deprived of any pharmaceutical care till the end of the study. The "Audit of Diabetes Dependent Quality of Life" standard questionnaire was used to assess the relevant parameters (including: Fasting Blood Glucose, HbA1c, Body Mass Index) and to evaluate the impact of the pharmaceutical care on the subjects. Data were analyzed using t-student test.

RESULTS: The intervention group showed an improvement in the quality of life score from -2.156 ± 0.12 at the baseline to -1.41 ± 0.13 at the final interview ($p < 0.01$). The average HbA1c values decreased from 8.44 ± 0.29% to 6.73 ± 0.21% ($p < 0.01$). There was a significant decrease in the fasting blood glucose from 195.57 ± 10.10 mg/dl to 107.25 ± 3.70 mg/dl between the baseline and the final interview in the intervention group ($p < 0.01$). The findings in the diabetes treatment satisfaction score also changed in a similar pattern.

CONCLUSIONS: The pharmaceutical care program was effective in improving the clinical outcome and the patients' QOL with type 2 diabetes mellitus.

KEYWORDS: Quality of Life, Pharmaceutical Care, Clinical Pharmacy, Diabetes Mellitus, South India.

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Diabetes is one of the world's leading chronic diseases with serious social and economical impact. In 2007, diabetes caused 3.5 million deaths globally.[1] The International Diabetes Federation estimates that 246 million adults worldwide have Diabetes mellitus. The incidence of diabetes is escalating to epidemic proportions and by 2025, the figure is expected to reach 380 million. Diabetes accounts for around 6% of total global mortality, with 50% of diabetes- associated deaths being attributed to cardiovascular disease.[2]

The diabetes pandemic is rapidly spreading and mostly affects developing countries like India. According to the International Diabetes Federation (IDF) Diabetes Atlas (2006) which

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was released at 19th World Diabetes Congress, there were an estimated 40.9 million people with diabetes in India and this number is predicted to rise to almost 70 million by 2025.[3] The countries with the largest number of diabetic people will be India, China and USA by 2030.[4]

Diabetes mellitus has become an international healthcare crisis that requires new approaches to prevent and treat it. In many parts of the developing world, low birth weight and maternal malnutrition during pregnancy may be a major factor underlying the insulin resistance syndrome and thus in an increased risk of diabetes in the later life.[5]

Diabetes is a disease that desperately needs more pharmacist involvement. Pharmacists who are specialized in this growing chronic condition can make a significant, positive impact on the patient, the health care system and themselves.[6] Pharmaceutical care and the expanded role of pharmacist are associated with many positive diabetes-related outcomes, including improved clinical measures, improved patient and provider satisfaction, and improved cost management.[7]

Health-care professionals are becoming increasingly aware of the need to assess and monitor the quality of life (QOL) as an important outcome of diabetes care. The QOL is an important outcome on its own right and, because it may influence in the patient's self-care activities, may consequently impact their diabetes control.[8] Pharmaceutical care is the direct, responsible provision of medication-related care with the purpose of achieving definite outcomes that improve a patient's quality of life. It is also the determination of the drug needs for a given individual and the provision of not only the required drug, also the necessary services (before, during or after treatment) to ensure the optimally safe and effective drug therapy.[9]

Many pharmaceutical care programs have been established in various countries to enhance clinical outcomes and the health-related quality of life (HRQOL). These programs were implemented by pharmacists, with the cooperation of the physicians and other health care professionals. However, such programs are not very common in the Indian scenario. The community pharmacist is a professional with knowledge of medicines and health care and is easily accessible to patients throughout the day. The pharmacist can, therefore, in collaboration with physicians and other health care professionals, contribute to the improvement of diabetic patients' quality of life by informing and educating patients, answering their questions and, at the same time, monitoring the treatment they receive and carrying out their own assessments of the patients' health.[10]

Therefore, this research aimed to evaluate the role of pharmaceutical care on the quality of life in patients with type 2 diabetes mellitus in our medical setting (a Private Tertiary Care Hospital) in South India.

Methods

This prospective, control versus intervention group clinical trial was conducted in the general medicine department of a 550 bedded multi specialty tertiary care teaching hospital, located at Coimbatore, in the south of India from May 2009 through December 2009 (8 months). The main endpoint outcome of this study was improvement in the Quality of Life in patients with Type 2 Diabetes mellitus and in their clinical parameters such as Fasting Blood Sugar, glycosylated hemoglobin, and BMI. The target population for this study were Indian diabetic (Type 2) patients in Tamil Nadu province and all adult (Age>18 years) men and women with type 2 diabetes mellitus as the main reason for the hospital visit, with or without other diseases, who gave informed consent and had sufficient English literacy (at least high school educated) to answer the questionnaire. Pregnant women, mentally incompetent patients and critically ill patients were excluded from the study. Eligible patients were included in the study using the convenient sampling method and on the basis of their medical visits.

Permission to carry out the study was obtained from the hospital authorities and concerned Physicians after submitting the study

protocol. Patients were enrolled according to the inclusion and exclusion criteria of the study. Patients were briefed on the study through the Patient Information Form and there after the written informed consent were obtained.

A total of 165 patients were interviewed during the study period. Out of which 120 participants met the inclusion criteria and were enrolled in the study. At their first visit, the patients were randomly allocated to the intervention group or to the control group using random number table. Randomization was stratified by age, sex and duration of diabetes (60 patients in each group). All data concerning general medical history and specific diabetes history were collected by using customized Data entry forms for I.P and O.P separately which were specially developed for the study.

Bradley's questionnaire was used, the Audit of Diabetes Dependent Quality of Life (ADDQOL),[11] which is designed to measure an individual's perception of the impact of diabetes on their quality of life, was called. The questionnaire was content and cultural validated and tested for reliability for the new language (Cronbach's alpha = 0.79) by using standard methods which will be described elsewhere.[12-14] Prior written permission was obtained from the developer of the questionnaire (Dr. Claire Bradley). All patients were asked to answer the prevalidated QOL questionnaire and the treatment satisfaction questionnaire.

The design of the questionnaire included 18 life domain specific items and 2 overview items to be scored between -9 to +9 which diabetes are affected by. The questionnaire took approximately 15 minutes to complete.

Diabetes Treatment Satisfaction Questionnaire (DTSQ)[15] was used, to measure the patients' satisfaction with diabetes treatment. It is consisted of six item scales assessing treatment satisfaction and two items assessing perceived frequency of hyperglycemia and hypoglycemia. The DTSQ items are scored on a scale from 6 to 0. Individual satisfaction with the treatment items (items 1, 4, 5, 6, 7 and 8) were considered separately. The higher the score, the greater the satisfaction gained with each aspect of the treatment. Item 2 and item 3 were, perceived frequency of hyperglycemia and hypoglycemia, respectively. Here the lower score indicated the blood glucose level closer to the ideal. The higher score indicated a problem. The questionnaire took approximately 10 minutes to complete and the whole process of validation and testing the reliability of the questionnaire were completed for its usage in a new language as well.[16]

Controlling the blood glucose was assessed using fasting blood glucose measurements recorded during the baseline, second and the final interview with the patients. Glycosylated hemoglobin (HbA1c), a measure of the average control of blood glucose, over the three previous months was also assessed. Both parameters were analyzed using an ordinary calibrated biochemical auto analyzer located in the hospital laboratory of. With regards to HbA_{1c}, individuals were categorized according to the targets from the Clinical Practice Guidelines for Diabetes Management in Canada.[17] Similarly, the patients'blood pressure and weight were recorded in every visit which had an interval of 3 months. The weight was monitored to determine the body mass index(BMI).An ideal body mass index of 18.5-24.9 kg/m^2 and a systolic blood pressure of less than or equal to 130 mmHg was recommended.

Patients in the intervention group received the pharmaceutical care which included medication counseling, instructions on dietary regulation, exercise and other lifestyle modifications, while the control group patients did not receive any pharmaceutical care till the end of the study.

The pharmaceutical care provided by the pharmacist was documented in the forms designed for the purpose. The patient information leaflet, diabetic diet chart (prepared in English and Tamil in discussion with the chief dietician of the study hospital) and Diabetic Diary were also provided to the intervention group in order to provide better counseling.

Pharmacist followed the patient's progress with follow up visits and phone calls and the

patient's progress was recorded. Attempts were also made to have all the participants repeat the completion of the ADDQOL questionnaire during the final interview. The interventions made in this study are described in detail in the result section in order to enable utilization of the experience by others.

The paired t-student test was used for intra-group analysis (baseline and final scores) and the t-student test was also used for inter-group analysis using the SPSS 14.0 for Windows software. $P < 0.05$ was considered as the statistically significant level.

Results

The age range of the participants in both groups was between 32 to 85 years old. Male/female ratio in both groups was equal to one. The methodology of random allocation was stratified by patients' gender. The control group had an average age of 57.98 ± 2.62 years old and the intervention group had an average age of 53.65 ± 2.38 ($p > 0.05$). All the participants were type 2 diabetics taking an average of two oral drugs for treatment. In addition to the medications for diabetes treatment, these patients were taking an average of two other drugs for co-morbidities that mainly included hypertension and hyperlipidemia.

The baseline characteristics of the participants including sex and the length of time elapsed from the diagnosis of disease between the two groups were not statistically different ($p > 0.05$). The average fasting blood glucose for the control group was 186 ± 9.10 mg/dl and that for the intervention group was 195.57 ± 10.10 mg/dl (Table 1). Statistical tests revealed that the values were not significantly different ($p > 0.05$). In the final interview it was found that the control group subjects showed fasting blood glucose levels of 149.57 ± 4.22 mg/dl which was not significantly different from the basal values ($p > 0.05$). But, in the intervention group the levels were 107.25 ± 3.70 mg/dl and that was significantly different from the basal values ($p < 0.01$).

The average HbA1c values for the control group was 9.03 ± 0.46% and that for the intervention group was 8.44 ± 0.29% (Table 1). Statistical tests revealed that the values were not significantly different ($p > 0.05$). In the final interview it was found that the control group subjects showed fasting blood glucose levels of 8.31 ± 0.16% which was not significantly different from the basal values ($p > 0.05$). But, in the intervention group the levels were 6.73 ± 0.21 mg/dl and that was significantly different from the basal values ($p < 0.01$).

All the patients completed the ADDQOL questionnaire at their first visit with the pharmacist, prior to any counseling and also were interviewed after three months during the last

Table 1. Comparison of the baseline and final parameters of the study groups

Parameters	Control Group		Intervention Group	
	Baseline interview	Final interview	Baseline interview	Final interview
Quality of Life score	-1.899 ± 0.05	-1.974 ± 0.05^{NS}	-2.156 ± 0.12^{NS}	-1.41 ± 0.13§
Fasting Blood Glucose Level (mg/dl)	186.00 ± 9.10	149.57 ± 4.22^{NS}	195.57 ± 10.10^{NS}	107.25 ± 3.70§
HbA1c (%)	9.03 ± 0.46	8.31 ± 0.16^{NS}	8.44 ± 0.29^{NS}	6.73 ± 0.21§
Diabetes Treatment Satisfaction Score	26.97 ± 0.33	26.15 ± 0.34^{NS}	26.73 ± 0.34^{NS}	30.58 ± 2.48§
Body Mass Index (kg/m^2)	24.66 ± 0.49	24.75 ± 0.47^{NS}	25.01 ± 0.41^{NS}	23.16 ± 0.35**

Values are expressed as Mean ± SEM (n = 60 for each group).
^{NS} denotes difference is not statistically significant ($p > 0.05$) when compared with basal control values.
§ denotes difference is statistically significant ($p < 0.01$) when compared with basal control values.
** denotes difference is statistically significant ($p < 0.05$) when compared with basal control values.

visit. The average baseline score was -1.899 ± 0.05 for the control group and -1.974 ± 0.05 for the intervention group (Table 1). The groups were not significantly different ($p > 0.05$). In the final interview it was found that the control group subjects showed scores of -2.156 ± 0.12 which was not significantly different from the basal values ($p > 0.05$). But, in the intervention group the levels were -1.41 ± 0.13 and that was significantly different from the basal values ($p < 0.01$).

The average diabetes treatment satisfaction score for the control group was 26.97 ± 0.33 and that for the intervention group was 26.73 ± 0.34 (Table 1). Statistical tests revealed that the values were not significantly different ($p > 0.05$). In the final interview it was found that the control group subjects showed a diabetes treatment satisfaction score of 26.15 ± 0.34 which was not significantly different from the basal values ($p > 0.05$). But, in the intervention group the levels were 30.58 ± 2.48 and were significantly different from the basal values ($p < 0.01$).

The body mass index was found to be 24.66 ± 0.49 kg/m^2 and 25.01 ± 0.41 kg/m^2 in the control and intervention groups, respectively, during the first interview ($p > 0.05$; not significant). In the final interview the index was found to be 24.75 ± 0.47 in the control group ($p > 0.05$ when compared with basal values) and 23.16 ± 0.35 in the intervention group ($p < 0.05$ when compared with basal control values).

Discussion

The study evaluated the impact of the pharmaceutical care on the QOL in the type 2 diabetic patients. The results of the study demonstrated that the intervention group which was provided with the pharmaceutical care reported overall excellent diabetes related quality of life. Patients were satisfied with their treatment, felt little affected due to their disease, and rarely worried about the negative consequences their diabetes. Furthermore, several clinical parameters correlated well with the quality of life. Patients who were more satisfied with their current treatment tend to have better glycemic and blood pressure control. Most studies addressed humanistic outcomes in the form of HRQOL. These patients have consistently reported lower scores when assessed compared to both healthy patients and those with other chronic diseases. Several studies have acknowledged the importance of pharmacist providing counseling for diabetes patients.[18-21]

The present study showed an improvement in diabetes- specific health related quality of life using ADDQOL and the DTSQ's questionnaire which was contented and culturally validated for use in Indian population. In this study, the patients with diabetes mellitus who were managed by a clinical pharmacist had significantly lower blood glucose and HbA1c levels compared to the baseline. Significant changes in the quality of life and diabetes treatment satisfaction score of the diabetes patients can be obtained by providing long term pharmacists managed diabetic care services. Improvement in the intervention group was especially noted with decrease in concern of future, worries, and living condition domain of the patients. This study was consistent with similar interventions of pharmacists in other populations.[22,23] The patients compliance is considered as a limitation factor in this study and further studies with controlled measurements are recommended to make sure the patients' compliance to drugs during the study is controlled.[24]

Conclusion

The results demonstrated the positive impact of clinical pharmacist in achieving a primary therapeutic goal in the diabetic patients for overall diabetes control. The improved quality of life scores clearly indicated the benefits of pharmacist-provided counseling and the importance of consultations with a pharmacist in a hospital setting. The Pharmaceutical Care provided by the clinical pharmacist to the type 2 diabetic patients was effective in reducing the blood glucose levels and in improving their overall quality of life.

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Conflict of Interests

Authors have no conflict of interests.

Authors' Contributions

SS was the head of this research team, developed and wrote the protocol, and was responsible for the data analysis and interpretation of results. LEC was responsible for data gathering and data analysis. RR was responsible for scientific consultation and technical/clinical issues of this clinical trial. AG helped in data analysis. TKR had valuable suggestions for guideline preparations and helped in clinical coordination. AMS contributed in manuscript preparation and reviewed the data analysis and interpretation of results. All authors have read and approved the contents of the manuscript.

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