

IMPACT OF CLINICAL PHARMACIST PROVIDED PATIENT EDUCATION ON QOL OUTCOME IN TYPE II DIABETES MELLITUS IN RURAL POPULATION

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ABSTRACT

Background: Diabetes mellitus is one of the major causes of illness and disability across the world. Patient knowledge, attitude, practice of the diabetes is an important aspect and it has direct effect on quality of life.

Objective: The main objective of the study is to assess the impact of clinical pharmacist provided patient education on Quality of life outcomes.

Methodology: A prospective randomized control study was conducted in general medicine department of a tertiary care hospital. Patients were enrolled and randomized in to control and intervention group based on inclusion and exclusion criteria. A total of three follow ups were made from the baseline. At each follow up questionnaires were applied to both the groups and their blood glucose was measured. Educational materials PIL (patient information leaflet) and formal counseling was given to intervention group at each level and to the control group at final follow up.

Results and Discussion: A total of one hundred and thirteen patients were enrolled. A significant increase in QOL, KAP, adherence scores (P value < 0.05) was observed in intervention group when compared to control group. A Blood glucose level in intervention group was significantly changed, but was altering in the control group.

Conclusion: Hence this study concludes that pharmacist plays an important role in educating the patients to maintain their quality of life.

Keywords: Quality of life (QOL), Diabetes mellitus, Clinical pharmacist, Patient Education, Blood glucose

INTRODUCTION

Diabetes mellitus is a metabolic disorder characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both.¹ According to the Diabetes atlas 2006 published by the International Diabetes Federation, the number of people with diabetes in India is currently around 40.9 million is expected to rise to 69.9 million by 2025.² Diabetes and other chronic non-communicable diseases (NCDs) are significant public health challenges in the 21st century. It is estimated that 3.8 million deaths were attributable to diabetes in 2007, equivalent to 6% of all deaths globally. India has the largest population of diabetes patients when compared to any other country, diabetes deaths accounts for 9.7%.

In India the prevalence of diabetes is increasing. Diabetes once viewed as a rich man's disease but this idea is wrong. The reasons for prevalence of diabetes are changing lifestyle, sedentary occupations, and irregular food habits. There have been corresponding changes in semi-urban environments also. So this leads to increase morbidity and mortality of non communicable diseases (NCDs). Therefore prevention is the best strategy.³ Quality of life is an important health outcome in its own right, representing the ultimate goal of all health interventions. People with diabetes have a poor quality of life than people with no chronic illness. The goals of chronic care are 'not to cure but to enhance functional status, minimize distressing symptoms, prolong life' through secondary prevention and enhance quality of life.⁴ Quality of life (QOL) measurements are increasingly recognized as important in the assessment of chronic diseases and in evaluating medical outcomes.

Several studies have reported the positive impact of clinical pharmacists provided patient education intervention counseling on glycaemic control and quality of life outcomes in diabetic population^{5,6,7,8}

MATERIALS AND METHODS

A prospective educational interventional hospital based study was carried out in the medicine outpatient and inpatients department of Adichunchanagiri Hospital & Research Center. Ethical clearance was

obtained from the institutional ethical committee of the hospital. Patients consent was obtained and randomized into control and intervention group by simple randomized technique.

A patient data collection form was prepared to collect the demographic details of the enrolled patients. A total of three follow-ups were made from baseline, with an interval of one month in each follow-up. Educational materials and counseling was given to interventional group and at last follow-up to control group by the clinical pharmacist.

A WHO-Bref QOL was used to assess the patient QOL; prior permission was obtained from the WHO to use the questionnaire. Based on the patient preference the questionnaire was given in English or Kannada. The questionnaire consists of 26 items, divided in to 4 domains. The questionnaire was administered at each follow up to both the groups. . The four domain scores denote an individual's perception of quality of life in each particular domain. Domain scores are scaled in a positive direction (i.e. higher scores denote higher quality of life). The mean score of items within each domain is used to calculate the domain score. Mean scores are then multiplied by 4 in order to make domain scores comparable with the scores used in the WHOQOL-100. The obtained scores are added within each domain and thus become the raw score and then it will be converted into transform score where finally it will be compared with the WHO QOL- 100 score scale.

A validated questionnaire was used in order to assess the subject's score of Knowledge, Attitude and Practice concerning diabetes management. Both in English and Kannada languages were used based on patient understanding. Prior permission was taken from the MediMedia USA, Inc., publishers of *P&T* Journal to use the questionnaire for the study. The questionnaire was administered at baseline and final follow up to know the influence of education by pharmacist. The questionnaire contains 25 questions out of which 18 were Knowledge based questions, 4 questions were designed to assess the attitude and 3 questions to assess the actual practice of management of diabetes. The various topics covered in the questionnaire were knowledge related issues such as the diabetes symptoms.

Medication adherence behavior was assessed at each follow up for both the groups by using a 4 item scale and license agreement was

made before incorporating into the study. Scoring was given based on the scheme of "Yes" = 0 and "No" = 1. Blood glucose was done for both groups using a SD Check gluco-meter at each follow-up.

Statistical software such as SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data.

RESULTS

One hundred thirteen patients were enrolled into the study after considering the inclusion and exclusion criteria. Out of which one hundred patients completed the study (i.e., three follow-up of one-month interval each) fifty-two patients in intervention group and forty-eight patients in control group. Thirteen patients were dropped out (due to not completing the follow up), in which five patients in intervention group and eight patients in control group. Thirteen dropouts may be because of left the place, negligence, illiteracy, dependent on others, economic status, age factor and duration of diabetes. The detailed demographic details of the enrolled patients are depicted in the table 1

Medication adherence of the patients

Significant improvement was observed in all the follow ups in intervention group but variation in the control group. Comparative evaluation was made between the groups made where there was no significant ($P > 0.05$) but in the second and final follow up there was

strong significant ($P > 0.05$). Figure 1 shows the change in the scores between the groups.

Blood glucose levels

The mean fasting blood glucose levels at baseline of control group patients was 138.50mg/dl and that of intervention group was 151.13mg/dl. Post prandial blood glucose at baseline in control group was found to be 200.42mg/dl and in intervention group was 219.69mg/dl. At the last follow up a significant reduction in mean blood glucose in intervention but not in control group as shown in figure 2 and 3.

Knowledge, Attitude and Practice of the patients

A significant improvement was observed in intervention group compared to control group and their mean score are shown in table 2.

Quality of life

The quality of life of the patients in the intervention and control group was measured by using the WHO-Bref QOL questionnaire during each visit and their mean average scores are shown in table 3 for control and table 4 intervention group. The subscales correlation was analyzed between the groups as shown in figure 4 (Domain 1), figure 5 (Domain 2), figure 6 (Domain 3) and figure 7 (Domain 4). The Pearson correlation was made between the total mean QOL and mean blood glucose as shown in figure 8 (Intervention group) and figure 9 (Control group).

Table 1: Baseline demographic details of the patients

Baseline Variables	Intervention group (n=52)		Control group (n=48)		P value
	No	%	No	%	
31-40	06	11.5	08	16.7	0.618
41-50	17	32.7	12	25.0	
51-60	14	26.9	09	18.8	
61-70	12	23.1	16	33.3	
>70	03	5.8	03	6.3	
Gender					0.104
Female	17	32.7	24	50.0	
Male	35	67.3	24	50.0	
Educational qualification					0.883
No formal education	13	25.0	12	25.0	
Primary school	13	25.0	08	16.7	
High school	15	28.8	16	33.3	
PUC	07	13.5	08	16.7	
Degree	04	7.7	04	8.3	
Occupation					0.101
Business	11	21.2	11	22.9	
Employed	16	30.8	06	12.5	
Professional	02	3.8	07	14.6	
Housewife	16	30.8	19	39.6	
Others	07	13.5	05	10.4	
History of diabetics					0.943
Mother	11	21.2	12	25.0	
Father	14	26.9	12	25.0	
Brother	05	9.6	03	6.3	
Sister	02	3.8	01	2.1	
Other	00	0.0	00	0.0	
None	20	38.5	20	41.7	
Duration of diabetics					0.857
<1 year	08	15.4	05	10.4	
2.5 years	25	48.1	25	52.1	
6-30 years	17	32.7	16	33.3	
4-20 years	01	1.9	02	4.2	
>20 years	01	1.9	00	0.0	
Alcohol					0.311
No	33	63.5	35	72.9	
Yes	19	36.5	13	27.1	
Smoking					0.025*
No	33	63.5	40	83.3	
Yes	19	36.5	08	16.7	

DISCUSSION

QOL is increasingly viewed as a therapeutic outcome and is gradually gaining the same level of importance as clinical or physiological outcome parameters. QOL in this context refers to health – related problems, including the impact of disease and treatment on functioning, health beliefs and subjective well-being. A number of studies suggest that, pharmacists can play an important role in improving the health and quality of life in patients with chronic illnesses. Diabetes is one such chronic disease where patients report a lower quality of life than the general population.^{9, 10, 11, 12.}

Assessment of medication adherence

Pharmacist provided educational influence was assessed on medication adherence behavior by MMAS-4 scale. At baseline most of the patients in both control and intervention group suggest that the patients were non-adherent to their treatment. The scores of the patients at final follow up in intervention group showed significant improvement, this may be due to education influence of pharmacist on disease and medication. Similar results were observed in the study conducted by Morisky et al^{13, 14, 15.}

Assessment of Knowledge, attitude and practice

Patients' knowledge, attitude and beliefs have been shown to affect their medication taking behavior. Medication adherence is essential to achieve better therapeutic outcomes in chronic and asymptomatic diseases like diabetes mellitus. An understanding of the cause of diabetes and the changes in habits required to control blood glucose also helps to improve treatment outcomes. At baseline only a few patients in either group were aware about the signs, symptoms, complications and management of diabetes and the dietary and life style modifications essential to control blood glucose levels. At the final follow, the test group, who had received extensive education regarding their disease management, medication importance, dietary and life style modification necessary to control their disease, showed a significant improvement in KAP score. Though the patients in the control group did show a slight increase in score, this was not significant as showed in intervention group and this may be due to repeatedly follow up provoked the group to ask questions to doctors or friends etc.

Assessment of Quality of life

WHO- Bref QOL questionnaire was administered to measure the quality of life of the enrolled patients. An increase in the QOL score indicates and improvement in QOL. Although it is a generic instrument, studies have demonstrated its sensitivity in patients with diabetes^{16.} A gradual improvement in the overall quality of life scores was observed in the test group patients where as in control group patients, change in the overall scores was no significant.

The overall QOL of both the intervention and control groups were similar (P value > 0.05) at the base line. However a non significant improvement in the overall QOL was observed in the first and second follow up but a significant improvement was observed in

final follow up. In the 3 follow up there was significant improvement in the QOL (P value < 0.05) when compared with baseline whereas in control group there was no improvement in all the three-follow ups. This was due to the fact that patient education influenced in proper glycemic control, which has reduced the diabetic symptoms that improved the patients' enjoyment in day-to-day life activities

Domain 1 (Physical health)

Domain 1 consists of activities of daily living, dependence on medicinal substances and medical aids, energy and fatigue, mobility, pain and discomfort, sleep and rest, work capacity. Comparative analysis was made between the groups in the Domain 1 at baseline and first follow-up there was statistically insignificant. But in second follow up there was moderately significant (P value: 0.01<0.033≤ 0.05) and in third follow up strongly significant (P value: <0.001≤0.01) was observed. This could be attributed to the fact that an increased understanding of their disease management, improved adherence and thus resulted in improvement of their Quality of Life.

Domain 2 (Psychological)

Domain 2 consists of bodily image and appearance, negative feelings, positive feelings, self-esteem, spirituality / religion / personal beliefs, thinking, learning, memory and concentration. Comparative analysis was made between the groups in the Domain 2 at baseline and first follow-up there was no significant, but in second follow up there was moderately significant (P value: 0.01<0.047 ≤ 0.05) and in third follow up strongly significant (P value: <0.001≤0.01) was observed. The improvement seen in the intervention group patients could be due to the impact of education about their disease and life style modifications. It is probable that the pharmacist provided education helped the patients to understand their condition and about their disease state and thus improved their Quality of Life.

Domain 3 (Social relationships)

Domain 3 consists of personal relationships, social support, and sexual activity. Comparative analysis was made between the groups in the Domain 3 at baseline, first follow-up and second follow up showed statistically insignificant. But in final follow up strongly significant (P value: 0.001≤0.01) was observed. This may be due to the fact that social relationship is influenced by the patient's disease and depends on each individual's reaction.

Domain 4 (Environment)

Domain 3 consists of financial resources, freedom, physical safety and security, Health and social care: accessibility and quality, home environment, opportunities for acquiring new information and skills, participation in and opportunities for recreation / leisure activities, physical environment (pollution / noise / traffic / climate), transport. Comparative analysis showed baseline, first follow up insignificant but at second follow up moderately significant (P value: 0.01<0.085 ≤ 0.05) and in final follow up strongly significant (P value: 0.011≤0.01) was observed.

Table 2: Shows the total average mean KAP score in both the groups

KAP Score	Intervention group (n=52)	Control group (n=48)
Baseline	5.28 ±1.8	6.05±2.53
Final follow up	8.99 ±3.375	6.59±2.40

Table 3: Total QOL and subscale scores of QOL in the Control group (n=48)

QOL scores	Base line	First follow-up	Second follow- up	Third follow-up
Domain 1	42.75±5.93	40.63±6.93	40.75±7.95	40.17±7.24
Domain2	42.79±7.01	42.25±6.15	41.73±6.78	39.17±6.56
Domain 3	34.65±10.55	33.17±13.07	32.77±12.92	30.15±11.28
Domain 4	42.9±9.76	40.42±7.11	40.33±8.73	40.02±6.7
Total quality of life score	40.78±9.17	39.12±9.38	38.90±9.98	37.38±9.14

Table 4: Total QOL and subscale scores of QOL in Intervention group (n=52)

QOL scores	Base line	First follow-up	Second follow-up	Third follow-up
Domain 1	41.06±7.31	41.67±6.18	44.08±7.46	45.96±5.54
Domain 2	41.54±7.44	41.21±6.27	44.42±6.59	46.19±5.18
Domain 3	34.40±10.43	34.12±10.44	36.00±10.64	37.94±11.31
Domain 4	41.31±7.92	41.58±6.83	43.37±5.85	44.21±4.8
Total quality of life score	39.58±8.83	39.65±8.23	41.77±8.88	43.57±7.92

CONCLUSION

This study confirms that improvement in knowledge of the disease and its management, improves medication adherence, which in turn

has a positive impact on Quality of Life of diabetes patients. Hence we can conclude that there is a positive impact of clinical pharmacist provided education and counseling for improving the health outcomes like QOL, KAP in diabetes mellitus patients.

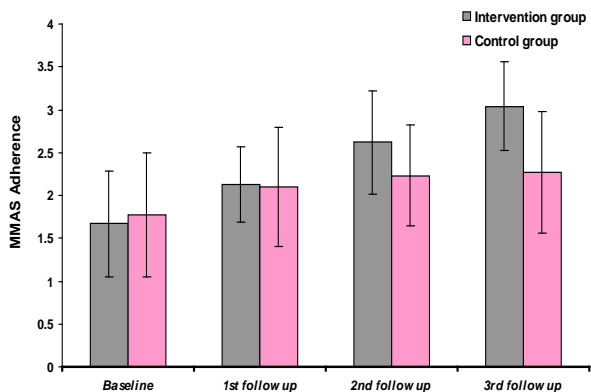


Fig. 1: Shows the medication adherence at each level in both the groups

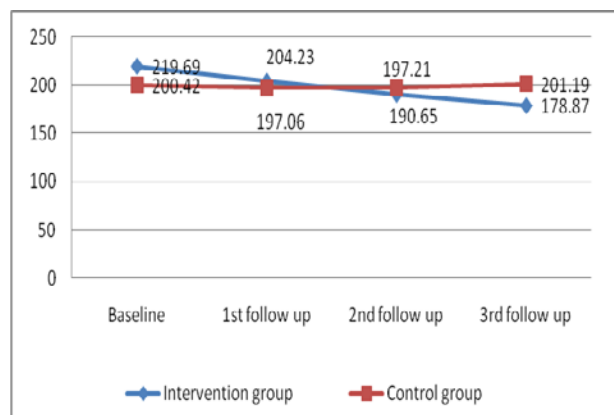


Fig. 2: Shows the FBS at each level in both the groups

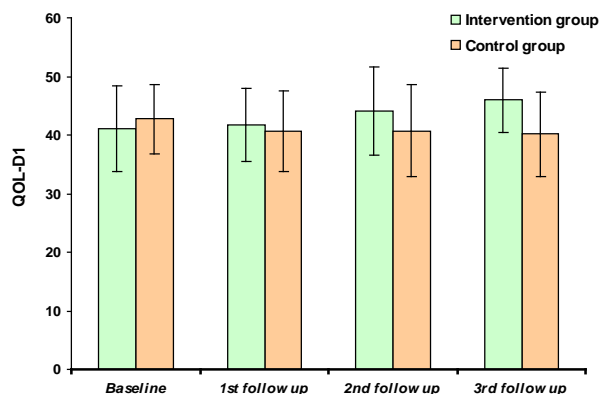


Fig. 3: Shows the PPBS at each level in both the groups

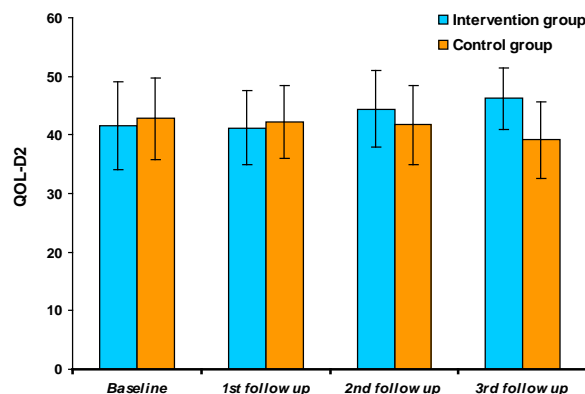


Fig. 4: Shows the Domain 1 score at each level in both the groups

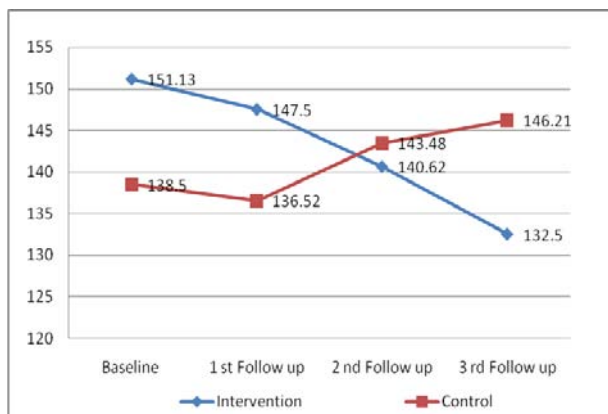


Fig. 5: Shows the Domain 2 score at each level in both the groups

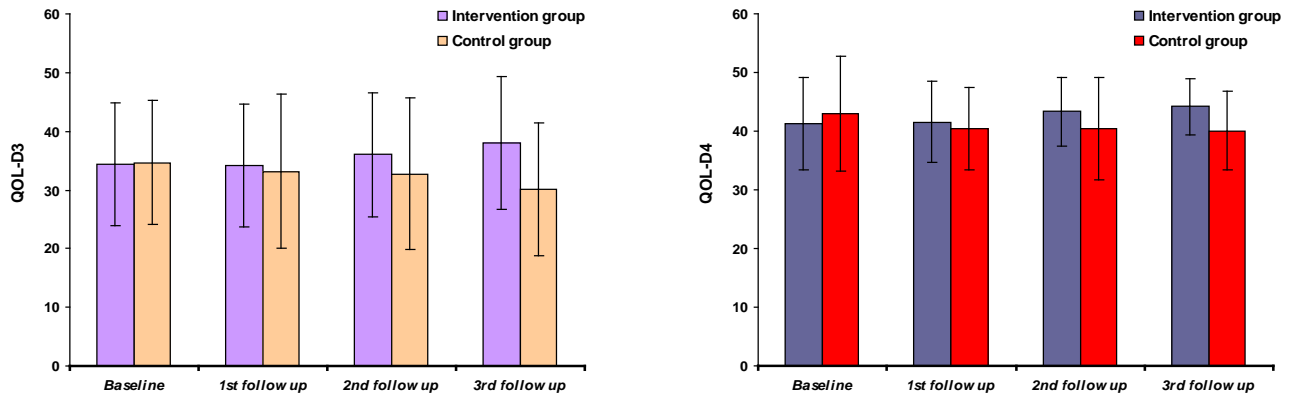


Fig. 6: Shows the Domain 3 score at each level in both the groups

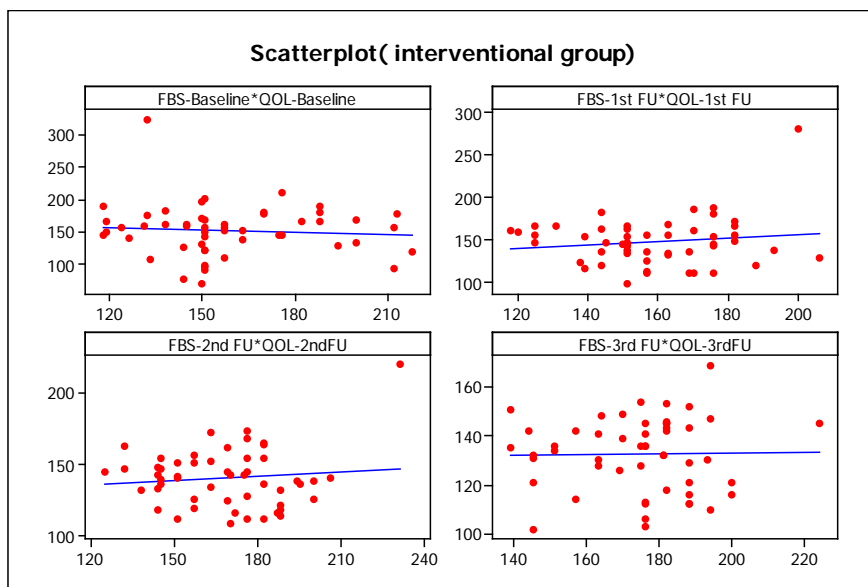


Fig. 8: Pearson correlation of Total QOL with Blood glucose in intervention group

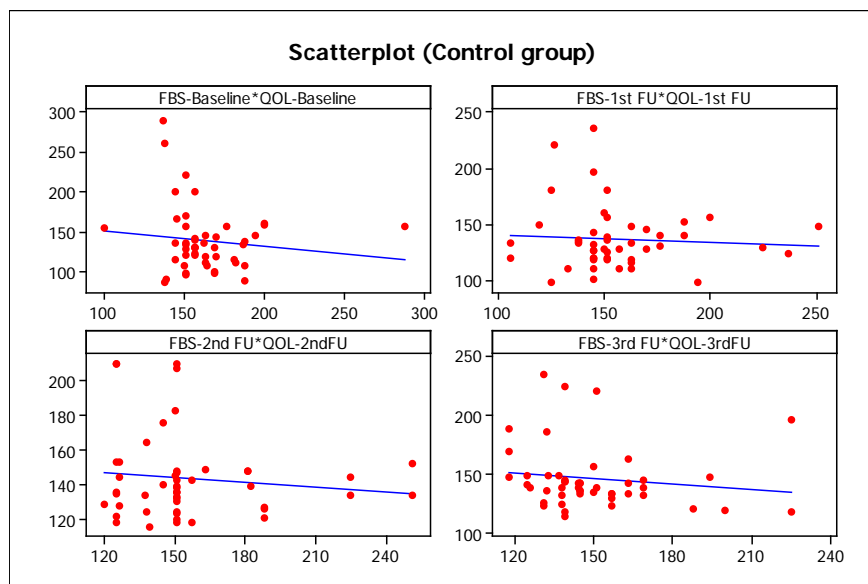


Fig. 9: Pearson correlation of QOL with Blood glucose in control group

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