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Impact of Community Pharmacy based Patient Education on Quality of Life in Type 2 Diabetes Mellitus

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Abstract

A prospective, open label, randomized study was conducted in a South Indian state for nine months to assess the impact of pharmacist provided patient education on knowledge, attitude and practice (KAP) and quality of life in Type 2 diabetes mellitus patients. Seventy eight patients meeting the study criteria were randomized into control and test group through envelope method. Seventy patients completed all the follow-ups of the study. Content and translation validated KAP questionnaire and Ferrans and Powers (F & P) quality of life questionnaire were administered to assess the influence of education. The validated Malayalam version of F & P questionnaire was supported by an internal consistency $\alpha = 0.96$ and a temporal stability $r = 0.89$ and construct validity $r = 0.88$.

The test group patients received pharmacist provided patient education regarding drug therapy, diet, exercise and life style modifications through the verbal and written education material (PIL) in English and Malayalam, the regional language. The control group patients received patient education at the end of the study. Johnson & Johnson one touch Glucometer® was used to measure fasting capillary blood glucose (FCBG) of all the enrolled patients.

A significant improvement was observed with respect to knowledge, practice and attitude towards disease management, QOL scores in various domains and a significant decrease in blood glucose ($P < 0.05$) was observed in test group patients.

***Key words:** patient counseling, quality of life, glycemic control, KAP*

INTRODUCTION

Diabetes mellitus (DM) is a severe medical and social problem that affects patient's general well being[1]. Despite of the advances in understanding of the disease and its management, the morbidity and mortality rate are in rise[2]. Poverty, non-compliance, lack of knowledge and poor follow ups are the factors observed in poor glycemic control[3]. Individuals with poor management of diabetes are at a greater risk of developing long term micro and macro vascular complications that lead to the damage of end organs such as kidney, heart, brain and eyes, affects the direct and indirect health care costs and over all quality of life[4].

Optimal glucose control can be achieved through strict adherence to medications, diet, and life style modifications that in turn minimizes long-term complications[5,6]. The Diabetes Control and Complication Trial (DCCT) demonstrated that good glycemic control can delay the onset and slow progression of diabetic complications and thereby help in avoiding health related expenditures[7]. Self-management is a crucial component in optimal diabetes care. Diabetes care includes knowledge in symptom recognition, diet and lifestyle modifications like routine exercise, adherence to medications, which includes dosage adjustment and timing, and detection and management of signs and symptoms of hyperglycemia and hypoglycemia.[8,9] Collaborative approach between patient and pharmacist may improve patient medication adherence behaviour and therapeutic outcomes. Role of pharmacist as diabetic educator is appreciated world wide in reducing the complications and health related expenditures and improving quality of life out comes[10]. Health related quality of life includes an individual's physical health, psychological health, social and role functions, and state of general well being. Good glycemic control can reduce the complication and thereby improve the quality of life.[11] The present study is conducted to assess the impact of pharmacist provided patient education on knowledge, attitudes, and practices regarding the management of disease and overall quality of life in type 2 diabetes mellitus.

METHODOLOGY

The present study was conducted in two Selected Community pharmacies at Pathanamthitta district of Kerala state, India, after the approval from the institutional research and ethics committee of JSS college of Pharmacy, Mysore.

Patients satisfying inclusion criteria (patients of either gender, aged more than 18 years, with type 2 diabetes and on medications) were enrolled into the study after signing the written consent form. The enrolled patients were randomized into test and control group through envelope method of randomization. Complete demographic details, past and present medical and medication history was obtained in a suitably designed patient profile form.

The test group patients received pharmacist provided education and patient information leaflet to compliment the verbal counseling. The control group patients received education at the end of the study.

To assess the Knowledge, Attitudes, and Practices (KAP) of the patients towards the disease management, a suitably designed, content and translation validated Malayalam version of KAP questionnaire was administered on all the enrolled patients at baseline and at final follow up.

To assess the influence of education on Quality of Life, diabetes disease specific translated and validated version of Ferrans and Powers quality of life questionnaire was administered on all enrolled at baseline, 1st, 2nd and final follow ups. The diabetic version of Ferrans and powers Quality of Life Index (QLI) was developed by Carol Estwing Ferrans and Marjorie J. Powers in 1984 to measure the quality of life in diabetic patients.[12] The QLI measures both satisfaction and importance of various aspects of an individual's life. The QLI comprises four domains namely health and functional, psychological or spiritual, social and economic, and family. The instrument has got a score range between 0 to 30 for all subscales and also the total score. The overall score is an addition of all subscales. Increase in the score refers to an increase in quality of life.

The fasting capillary blood glucose was measured for test and control group patients at baseline, 1st, 2nd and final follow-ups using Johnson and Johnson one touch Glucometer.

Chi square test was done to check the baseline significance between two groups. ANOVA was done to find the significance level within the test and control groups. Students t test-two tailed was used to assess the level of significance of each follow up with in the groups of both control and test. EPI info version 2001 statistical software was used to analyze the statistics. In this study, P<0.05 is considered as statistically significant.

Internal consistency reliability for QLI (total scale) was evaluated by Cronbachs á coefficient. SPSS reliability programme was used to check α co-efficient.

Test -retest was done with a month interval, which was supported, for temporal reliability for the total scale by using Pearson correlation.

Convergent validity of the QLI was assessed by using Pearson's formulation for the overall total score of QLI with the total scale of Audit of Diabetes Dependent Quality of Life (ADDQoL) questionnaire.

RESULTS

The average age of patients enrolled for the study was 54 years and with disease history of 3 to 5 years. A total of seventy-eight patients were enrolled into the study. Out of them, 70 patients (34 from Test and 36 from Control group) completed all follow ups of the study. Eight patients (10.25%) were dropped out from the study due to their personal reasons. Complete demographic details of the patients such as age, literacy details, Body Mass Index and treatment are given in table- 1

The baseline mean capillary blood glucose level of control group patients was 172.66 mg / dl and that of test group patients was 166.11mg/dl. At the last follow up, a significant reduction in capillary blood glucose (CBG)level was observed in test group patients where as in case of control group patients, an increase in the CBG was observed. Variations in capillary blood glucose levels in patients of both groups from base line to final follow up are shown in Figure.1.

The internal consistency reliability of the Malayalam version questionnaire was calculated using Cronbachs α coefficient. The total score of Malayalam version F & P QOL questionnaire has shown α coefficient 0.96. The Cronbachs α coefficient for the subscales Health & functional = 0.91, Social & economic= 0.94, Psychological/spiritual= 0.94, Family= 0.97 and supported the internal consistency of the sub-scales. The stability reliability for the total scale was provided by test-retest correlation of 0.89 with one month interval (r=0.89), 2 month interval (r=0.97), 3month interval (r=0.93). The construct validity was assessed for the Malayalam version of F&P questionnaire. This was supported by strong correlation between the overall QLI score and ADDQOL(r=0.88)

Analysis of Knowledge, Attitude and Practices.

The percentage of patients answered correctly was found to be high in the test group at the final follow up when compared with the baseline (P< 0.05) as shown in

Table no -2 and no significant improvement was observed in the awareness of control group patients (P>0.05)

Assessment of Quality of Life

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 non significant. The comparison of quality of life scores of both control group and test groups from base line to final follow up is shown in figure. 2.

Subscale Analysis of Quality of life

To study the impact of patient education on various domains of quality of life such as health and functional domain, social and economic domain, psychological or spiritual 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 figures 3, 4, 5 and 6.

Table 1. Demographic details of the study patients

Patient characteristics	Test (n=34)	Control (n=36)	Total (n=70)
Gender •			
Male	24 (70%)	19(53%)	43(61%)
Female	10(30%)	17(47%)	27(39%)
Age (mean±SD)	52.14±10.81	56± 9.98	54±10.5
Body Mass Index			
Under weight	1(3%)	3(8%)	4
Acceptable weight	17(50%)	15 (41%)	32
Over weight	15 (44%)	18 (50%)	33
Obese	1(3%)	00	01
Educational Status			
No Formal Education	0	1(2.7%)	1
Primary School	5(15%)	7(20.5%)	12
High School	24 (70.5%)	24 (66.6%)	48
University level education	5 (14.7%)	4 (11%)	9
Disease duration			
1-11 months	10 (29.4%)	3(8%)	13
12-23 months	5(15%)	5 (14%)	10
24 -59 months	10 (29.4%)	16 (44.4%)	26
> 60 months	9 (26.4%)	12 (33.3%)	21
Therapy			
Not on any drugs	4(11.76%)	2(5.55%)	6(8.57%)
Sulphonyl ureas alone	14(41.16%)	11(30.5%)	25(35.71%)
Metformin	2(5.88%)	2(5.55%)	4(11%)
Combination of sulphonyl ureas& metformin	12(35.29%)	19(52.77%)	31(44%)
Insulin +Sulphonyl urea/metformin	2(5.88%)	1(2.77%)	3(4.2%)
Thiazolidinediones	0	1(2.77%)	1(1.42%)
Drugs on hypertension	9(26.4%)	10(27.7%)	19(27.14%)

• *non significant (P value > 0.05) by chi square test*
SD = Standard Deviation

Table 2. Comparison of KAP scores at base line and at final follow up

S.No	KAP Questions	Base line		Final Follow up	
		Control % answers	Test % answers	Control % answers	Test % answers
1	Diabetes is a condition in which blood sugar level is higher than the normal	100	97	100	100
2	Diabetes is caused due to increased intake of sugar or sugar products.	50	65	56	97
3	Knowledge about the symptoms of diabetes	91	88	97	97
4	Knowledge about the consequences of diabetes	23	35	36	97
5	Most accurate method of monitoring glucose control is checking blood sugar than urine sugar	97	91	100	100
6	Blood sugar and urine sugar tests tell about your control of diabetes.	100	100	100	100
7	Do you accept that a diabetic patient should have a regular blood glucose checking at least once in a month?	97	97	97	100
8	A diabetic patient should not get measured his /her blood pressure at least once in two months	33	26	39	88
9	Do you know that suitable dietary changes; regular exercise and other lifestyle modifications are essential for blood glucose control?	100	97	100	100
10	Regular exercise improves blood circulation and there by helps in utilization of excess amount of glucose by tissues	75	85	78	97
11	Do you know that diabetic patients need not take care of their foot?	66	74	69	94
12	Foot care includes keeping your foot clean and wearing footwear of proper size with more comfort.	100	94	100	97
13	Smoking and alcohol drinking can worsen your diabetes condition	91	91	91	97
14	Do you know that diabetic patients may experience blurred vision, confusion, and sweating, increased heartbeat due to fall in blood glucose than normal?	91	88	91	100
15	In order to overcome the above situation, the patients should eat a teaspoonful sugar or a sugar candy	91	82	91	100
16	Health education is not important to control diabetes?	63	56	67	94

Figure 1. Difference between test and control group patients with regard to glycemic control
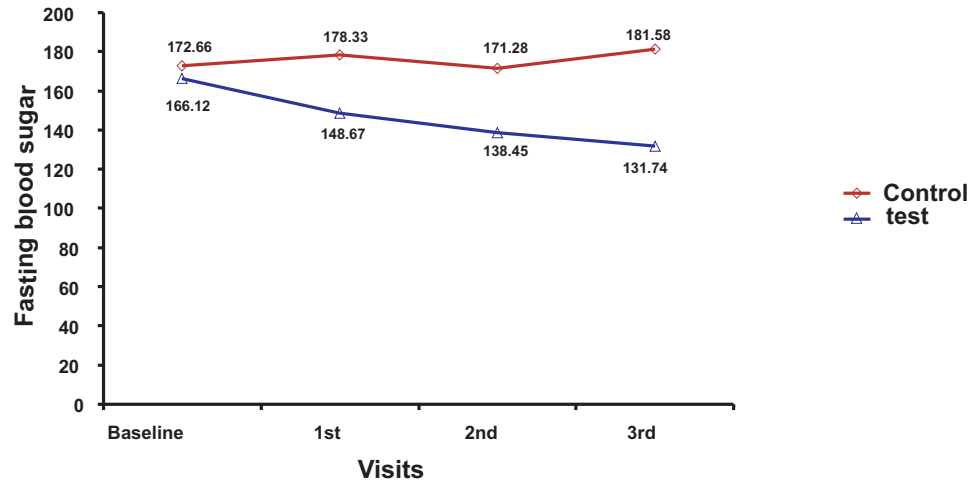

Figure 2. Difference between test and control group patients with regard to overall QoL scores.
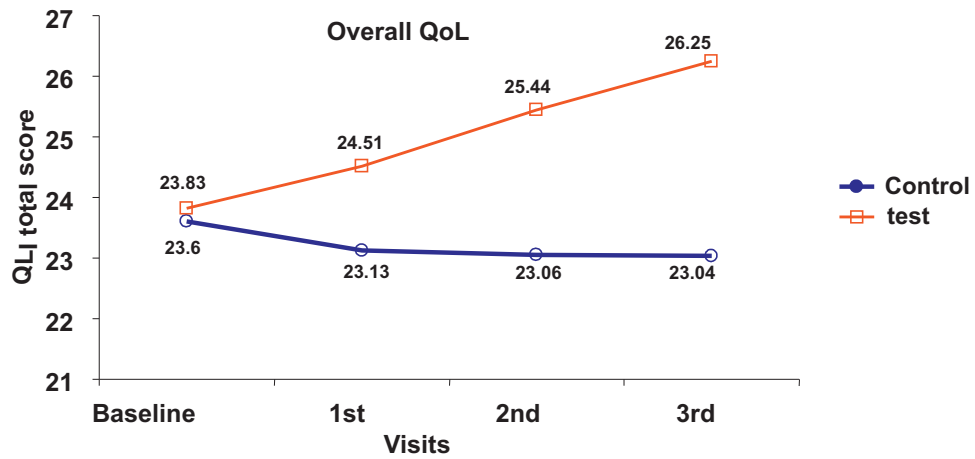

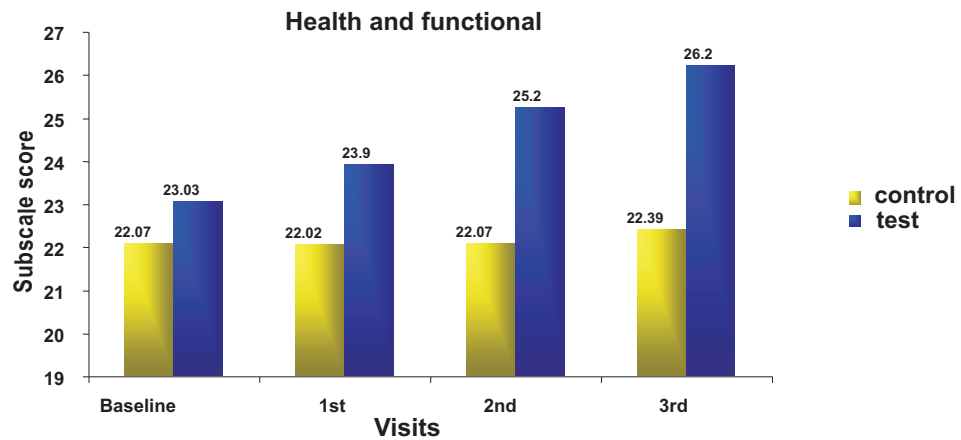**Figure 3. Difference between test and control group patients with regard to health & functional subscale**

Figure 4. Difference between test and control group patients with regard to social & economic subscale
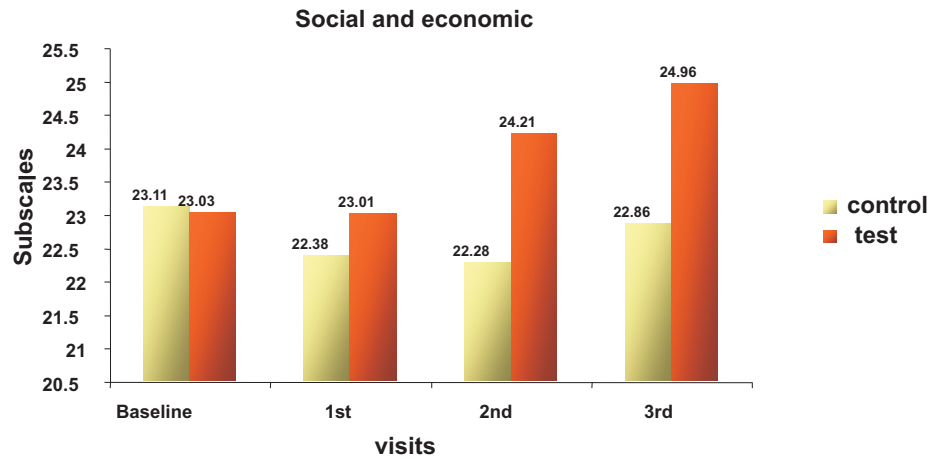

Social and economic

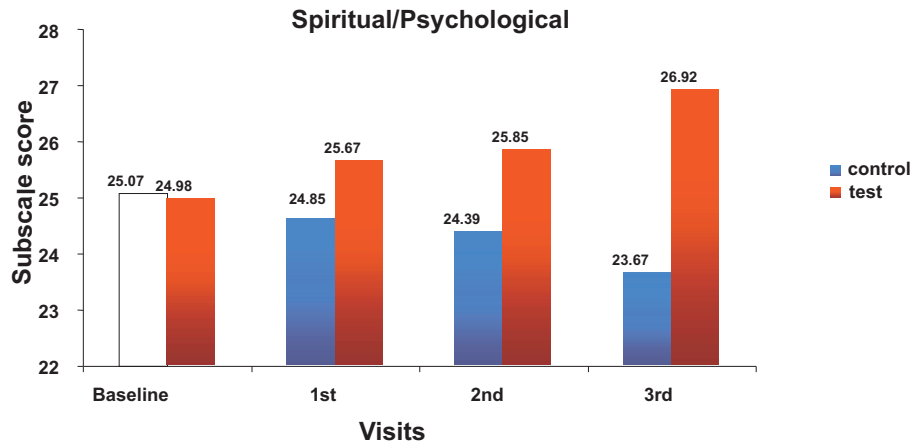**Figure 5. Difference between test and control group patients with regard to spiritual or psychological subscale**

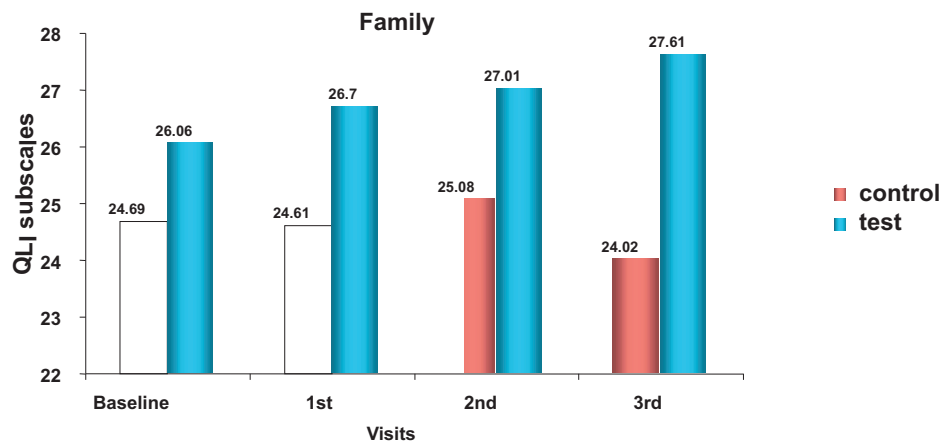**Spiritual/Psychological**

Figure 6. Difference between test and control group patients with regard to family subscale

Family

DISCUSSION

Scientific studies have suggested that, counseling has shown positive impact on health and decreased the mortality and morbidity[13,14]. The present nine month study also demonstrated the influence of structured education on knowledge, attitude and practices, various domains of quality of life and clinical and physiological parameters of diabetes mellitus.

The demographic details of patients enrolled into the study shows that majority of patients are males (61%) and visit the pharmacies on their own. But female patients enrolled into the study were housewives and are dependent on their family members or relatives for refilling the prescriptions and information. Almost all the enrolled patients were literates and majority were having high school level of education and in the age group of 29 to 70 years with average disease duration of 5.3 years. Twenty four percent of the enrolled patients were found to be hypertensive and were on treatment. Nine percent of the patients were without any medication and found to have their glycemic control with diet and exercise. The number of patients enrolled in the test and control group was almost similar. Majority of diabetic patients were in the normal range of body mass index (BMI).

Therapeutic management of the patients enrolled in the study (44%) reveal that patients were either on monotherapy (Sulphonyl Urea) or on dual therapy (Sulphonyl urea + Biguanides). Patients who were only on diet and lifestyle modification for managing their diabetes showed greater improvement in blood glucose control and improved quality of life with education. Micro as well as macro vascular complications are commonly produced in patients with poor control of diabetes due to lack of medication adherence, lack of awareness, and inadequate self-management skills. This ultimately affects the quality of life and showed an influence on family life, professional life and economy of the society on a long run.

Knowledge Attitude and Practice

The KAP questionnaire that consisted of questions regarding diabetes, its causes, symptoms, complications and life style changes have given lot of information on how the patients live with the disease and how well interventions can be done to achieve better therapeutic outcome. The patient–pharmacist interaction can also be improved based on this evaluation. In this study, there was improvement in knowledge of the patients regarding basic concepts of the disease like accurate method for monitoring glucose control and the necessity of checking

blood sugar at least once in a month, effect on different organs by untreated diabetes, importance of foot care in diabetic patients, management of hypoglycemic episodes etc.[15] after providing patient education. Some patients in control group have been provoked in knowing certain facts like organs affected during diabetes, importance of checking blood pressure etc after they are being asked at baseline. This is the reason why there is slight improvement in knowledge of control group patients after the study even though no patient education is provided.

Fasting blood glucose level

The fasting blood glucose of the patients in test and control group patients were non significant (P value > 0.05) at the baseline and showed both groups are similar and comparable. No significant changes were observed in the fasting blood sugar of the control group patients (p>0.05) from baseline to last follow up whereas in test group the fasting capillary blood glucose was significantly (p<0.05) reduced from the baseline to the last follow-up. The individual follow-ups of both test and control group was compared. When compared to control group patients the test group patients showed significant (p<0.05) reduction in FBS from base line to final follow up. This significant change is due to the influence of patient education and counseling aids that helped the patients to understand more about the long term complications of poorly managed diabetes that in turn improved their compliance, diet maintenance and life style modifications.[16]

Health related quality of life (HRQoL)

Ferrans and Powers diabetic specific questionnaire was used to assess the QOL of the enrolled diabetic patients. All domains of the QOL instrument were affected in diabetes patients of both the study groups. Significant improvement (p<0.05) in the overall QOL and subscales like health and functional, social and economic, physiological or spiritual and family was observed in the test group when compared to the baseline.

The overall QOL of both the test 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 3rd 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.[17,18,19]

Subscales

The overall improvement was seen in quality of life score, which is a subtotal of the four subscales of the QLI instrument. Health and functional subscale of the QOL questionnaire was also compared among the control and test group. In the baseline, the scores of both groups are similar (P value > 0.05). In the 1st follow-up, the health and functional subscale of the test group is not improved significantly (P value > 0.05) The health and functional subscale scores increased significantly (P value < 0.05) in the 2nd and 3rd follow-ups when compared with the baseline. This is attributed to the control of glycemic level attained during the follow-ups.

The social and economic subscale of the QOL questionnaire showed similar base line characteristics, which shows both the test and control groups were similar when, compared at baseline (P value > 0.05). In the 1st and 2nd follow up, the social and economic subscale of the test group did not show significant improvement (P value > 0.05). There was significant improvement (P value < 0.05) in the scores during the 3rd follow up in test group when compared with the baseline (P value < 0.05).

The spiritual or psychological subscale scores of the QOL questionnaire were also compared among the control and test groups. In the base line, the scores of both groups are similar (P value > 0.05). In the first and second follow-ups, the spiritual and psychological subscale of the test group were not improved significantly (P value > 0.05) when compared to the baseline. The spiritual or psychological subscale scores increased significantly in the 3rd follow-up when compared with the baseline.

In the family subscale, the baseline characteristics are similar when both the test and control were compared. The 1st and 2nd follow-ups the family subscale score of the test group was not improved significantly (P value > 0.05) when compared with the baseline. But the family subscale score improved significantly in the 3rd follow up (P<0.05) when compared with the baseline. The proper control of the disease has created happiness in enjoying the family life of patients that has reflected in the improvement in the family subscale.[20]

CONCLUSION

The study concluded that chronic diseases like diabetes affect the quality of life of patients and the education has a major role in improving the health care outcomes like glycemic control and quality of life. It also improved the medication adherence behavior. Maintenance of diet and exercise improved the patients' enjoyment in day-to-day life activities and that has reduced the morbidity and mortality rates. The study also concluded that the Malayalam version of F&P QLI instrument is reliable and valid to assess the quality of life in diabetes, which is similar to that of the original version in construct.

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