



PROSPECTIVE STUDY ON DIABETES RELATED QUALITY OF LIFE AND IMPACT OF PHARMACEUTICAL CARE

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ABSTRACT

Diabetes Mellitus (DM) places a tremendous financial burden on patients as well as on healthcare system because of its chronic nature and over time becomes one of the most expensive diseases. Studies have shown that DM individually and in combination with co-existing chronic medical conditions significantly impaired the health-related quality of life (HRQoL) of individuals with DM. While all trials of pharmaceutical care and pharmacist disease management diabetes services have included clinical outcomes measures, few have focused on humanistic outcomes such as HRQoL. A prospective observational survey study was carried out for a period of 9 months in the General Medicine Department of a tertiary care hospital to study the impact of pharmaceutical care on improving the health-related quality of life of patients with type II Diabetes Mellitus.

KEY WORDS

Diabetes, Life domain, intervention, Pharmaceutical care.

Introduction

Diabetes Mellitus is a group of common metabolic disorders that share the phenotype of hyperglycemia. Several distinct types of DM are caused by a complex interaction of genetics and environmental factors. Depending on the etiology of the DM, factors contributing to hyperglycemia include reduced insulin secretion, decreased glucose utilization, and increased glucose production. The metabolic deregulation associated with DM causes secondary pathophysiologic changes in multiple organ systems that impose a tremendous burden on the individual with diabetes and on the healthcare system. DM is the leading cause of end-stage renal disease (ESRD), non-traumatic lower extremity amputations, and adult blindness. It also predisposes to cardiovascular diseases.^[1] Studies have shown that DM individually and in combination with co-existing chronic medical conditions significantly impaired the health-related quality of life (HRQoL) of individuals with DM. DM, places a tremendous financial burden on patients as well as on healthcare system

because of its chronic nature and over time becomes one of the most expensive diseases. The worldwide prevalence of DM has risen dramatically over the past two decades, from an estimated 30 million cases in 1985 to 177 million in 2000. The total number of people with diabetes is projected to rise from 177 million in 2000 to 366 million in 2030. The most important demographic change to diabetes prevalence across the world appears to be the increase in the proportion of people >65 years of age.^[2] Although the prevalence of both type 1 and type 2 DM is increasing worldwide, the prevalence of type 2 DM is rising much more rapidly because of increasing obesity and reduced activity levels as countries become more industrialized. The countries with the largest number of diabetic people will be India, China and USA by 2030.^[3] Once the diagnosis of diabetes has been established, the therapy becomes essential. Along with therapy patient education also plays an important role. Diabetes care is best provided by a multidisciplinary team of health

professionals with expertise in diabetes, working in collaboration with the patient and family.^[4]

Quality of life

Quality of life (QOL) is a popular term that conveys an overall sense of wellbeing, including aspects of happiness and satisfaction with life as a whole. It is broad and subjective rather than specific and objective. Although health is an important domain of overall quality of life, there are other domains as well—for instance, jobs, housing, schools, and the neighborhood. HRQoL is a pure measure of health and functional status of the individual and excludes factors such as happiness and financial situation. In the past two decades, HRQoL as a patient reported outcome (PRO) has gained its importance in healthcare.^[5] This is because HRQoL encompasses physical, psychological and social aspects of diabetic patients. There is a growing interest in literature and medical practices to assess chronic diseases (e.g. diabetes) in relation to their impacts on quality of life (QoL) in addition to medical outcomes (e.g. morbidity and mortality).^[6,7] The QOL is an important outcome on its own right and, because it may influence the patient's self-care activities, it may consequently impact their diabetes control.^[8] Many studies support the use of HRQoL as a measure because subjective health is perceived as a better predictor of survival than objective health.^[9] In addition; associations between chronic diseases and lower levels of HRQoL are evident. This is because if a chronic patient is to be better, the patient will need to change his or her lifestyle significantly.^{[10] [11]} Thus, the measurement of HRQoL is an important activity. The ADDQoL is an individualized instrument aiming at measuring the individual's feelings about the impact of diabetes and it includes life domains that may be affected by diabetes for the better or, more likely, for the worse.^{[5] [12] [13]} No longer is it satisfactory to provide patients who have diabetes with brief instructions and a few pamphlets and expect them to manage their disease adequately. Instead, education of these patients should be an active and concerted effort involving the physician, nutritionist, diabetes educator, and other health professionals. Moreover, diabetes education needs to be a lifetime exercise; believing that it can be accomplished in 1 or 2 encounters is misguided. 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.^[14] Clinical pharmacy grew with the concept of pharmaceutical care. The chronic complications of diabetes are known to affect the QoL of diabetic patients. Various factors like understanding of the patients about their disease, socioeconomic factors, dietary regulation, self-monitoring of blood glucose is known to improve the QoL of these patients. Thus, pharmaceutical care can help improve the quality of life of patients with diabetes mellitus through bedside care.

Methods

A prospective observational survey study was carried out for a period of 9 months (November 2013 – August 2014) in the General Medicine Department of a tertiary care hospital. All type II DM patients with at least 5 years of duration since diagnosis was included in the study. Patients with type I Diabetes and gestational diabetes were excluded from the study. The participants were randomly divided into control and intervention groups. The study used version-19 of ADDQoL questionnaire to assess the QoL of type II DM patients. ADDQoL-19 questionnaire was provided to the patients, at the time of admission and during review. At the time of admission, the intervention group was provided with 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 and they were given patient information leaflets on the disease, whereas the control group patients were deprived of any pharmaceutical care till the end of the study. The copyright of the questionnaire is owned by Prof. Clare Bradley and the license to use the questionnaire was granted by Health Psychology Research Ltd. University of London on 17th January 2014. Approval for this study was given by the Institutional Ethics Committee of the Hospital. All statistical analyses were performed with SPSS for Windows, version 19.0 and Microsoft Excel 2010. For

descriptive statistics, means, standard deviations and frequencies were calculated. The t-test was used for the comparison of mean score values between groups. P values of less than 0.01 were considered statistically significant.

Results and Discussion

106 patients were selected, 51% being male. The control group comprised of 26 males and 27 females and the intervention group comprised of 25 males and 28 females. Age ranged from 32 -80 years with a mean age of 60.21 (SD=10.045) and a median age of 61 years. The respondents were divided into 5 groups based on their age. Majority of the respondents were within the age group 61-70yrs (n=37), followed by 51-60 yrs (n=31), 71-80 yrs (n=19), 41-50 yrs (n=17). Only 2 respondents were under the age group of 40 yrs. 22 and 15 patients respectively from the intervention and control group lied within 61-70 years of age. The duration since diagnosis was 5-23 years for control group with an average duration of 10.19 ± 4.59 years. The duration since diagnosis was 5-21 years for intervention group with an average duration of 9.94 ± 4.01 years. The duration since diagnosis was 5-10 years for most of the participants (n=71), 10-20 years for 31 participants and >20 years for the remaining (n=4).

BASELINE INTERVIEW RESULTS

During the baseline interview the QoL of the patients was assessed using ADDQoL questionnaire prior to any counseling. Table 1 showed that unweighted impact of diabetes on individual domains before pharmaceutical care. The highest unweighted negative impact of diabetes was found to be on the domain "freedom to eat" (C= -2.40, I = -2.42) followed by "freedom to drink" (C=-2.09, I= -2.15) and "physical activity" (C= -1.62, I= -2.06). The least impact of diabetes was on "peoples' reaction" (C= -0.02, I = -0.01). Table 2 indicated that the

weighted impact of diabetes on different domains of life. The domain "freedom to eat" (C= -4.28, I= -4.83) showed the highest negative weighted impact. The domains "employment" (C=2.72, I=2.74), "family life" (C=2.64, I = 2.70) and "personal relationships" (C=2.47, I= 2.30) were reported as the most important items and "physical appearance" (C=0.74, I=0.53) as the least important item (Table 3).

FINAL INTERVIEW RESULTS

Table 4 showed that un-weighted impact of diabetes on different domains of life after pharmaceutical care was provided. Thus, during the final interview the highest unweighted negative impact of diabetes was found to be on the domain "freedom to eat" (C= -2.32, I = -2.26) followed by "freedom to drink" (C=-2.04, I= -1.94) and "physical activity" (C= -2.62, I= -1.92). The least impact of diabetes was on "peoples' reaction" (C= -0.02, I = -0.01).

Table 5 indicated that the weighted impact of diabetes on different domain of life after pharmaceutical care was provided. The domain "freedom to eat" (C= -4.28, I= -4.83) showed the highest negative weighted impact. The domains "employment" (C=2.70, I=2.74), "family life" (C=2.64, I = 2.70) and "personal relationships" (C=2.47, I= 2.30) were reported as the most important items and "physical appearance" (C=0.74, I=0.53) as the least important item.

The mean impact of diabetes on Quality of Life (QoL) of the patients was found to be -1.53 ± 0.749 for the control group and -1.6 ± 0.689 for the intervention group. The AWI score during baseline interview was found to be -1.7453 ± 0.553 and -1.7526 ± 0.563 for the control and intervention group respectively. During the final interview the AWI scores were found to be 1.7191 ± 0.51617 and -1.6688 ± 0.48013 respectively for the control and intervention groups. During final interview a variation in AWI scores for two groups were observed (Table 6).

Table 1: Comparison of unweighted impact of diabetes on individual life domains before providing pharmaceutical care

DOMAIN	CONTROL	INTERVENTION
Peoples Reaction	-0.02	-0.01
Family Life	-0.21	-0.30
Friendships	-0.30	-0.19
Leisure	-0.42	-0.19
Personal Relationship	-0.36	-0.40
Holidays	-0.59	-0.42
Self Confidence	-0.83	-0.42
Motivation	-1.40	-0.77
Physical Appearance	-1.08	-1.13
Future	-1.17	-0.96
Finance	-0.91	-1.38
Living Condition	-1.15	-1.13
Sex Life	-1.31	-1.00
Employment	-0.64	-1.35
Dependence	-1.15	-1.64
Journeys	-1.51	-1.55
Physical Activity	-1.62	-2.06
Freedom to Drink	-2.09	-2.15
Freedom to Eat	-2.40	-2.42

Table 2: Comparison of weighted impact of diabetes on individual life domains before providing pharmaceutical care

DOMAIN	CONTROL	INTERVENTION
Peoples Reaction	0	0
Leisure	-0.43	-0.25
Friendships	-0.49	-0.30
Holidays	-0.51	-0.28
Physical Appearance	-0.85	-0.53
Family Life	-0.57	-0.91
Personal Relationship	-0.79	-0.75
Self Confidence	-1.26	-0.45
Sex Life	-0.74	-0.28
Motivation	-2.51	-1.28
Future	-2.43	-1.85
Living Condition	-2.21	-2.17
Dependence	-1.68	-2.74
Finance	-1.72	-2.91
Journeys	-2.17	-2.57
Freedom to Drink	-3.36	-3.36
Employment	-1.69	-1.62
Physical Activity	-3.75	-4.47
Freedom to Eat	-4.28	-4.83

Table 3: Comparison of importance of individual life domains before providing pharmaceutical care

DOMAIN	CONTROL	INTERVENTION
Physical Appearance	0.74	0.53
Holidays	1.07	0.96
Leisure	1.04	1.11
Sex Life	1.23	1.00
Friendships	1.42	1.32
Self Confidence	1.57	1.21
Peoples Reaction	1.83	1.17
Freedom to Drink	1.60	1.53
Motivation	1.72	1.57
Journeys	1.58	1.77
Future	1.83	1.74
Freedom to Eat	1.75	1.91
Living Condition	1.96	1.91
Dependence	1.87	2.04
Finance	1.98	1.98
Physical Activity	2.34	2.08
Personal Relationship	2.47	2.30
Family Life	2.64	2.70
Employment	2.72	2.74

Table 4: Comparison of unweighted impact of diabetes on individual life domains after providing pharmaceutical care

DOMAIN	CONTROL	INTERVENTION
Peoples Reaction	-0.02	-0.01
Family Life	-0.21	-0.30
Friendships	-0.30	-0.19
Leisure	-0.42	-0.19
Personal Relationship	-0.36	-0.40
Holidays	-0.59	-0.39
Self Confidence	-0.83	-0.42
Physical Appearance	-1.08	-1.13
Future	-1.17	-0.96
Motivation	-1.40	-0.77
Sex Life	-1.31	-1.00
Finance	-0.91	-1.38
Living Condition	-1.15	-1.13
Employment	-1.39	-1.35
Dependence	-1.15	-1.64
Journeys	-1.51	-1.42
Physical Activity	-2.62	-1.92
Freedom to Drink	-2.04	-1.94
Freedom to Eat	-2.32	-2.26

Table 5. Comparison of importance of individual life domains after providing pharmaceutical care

DOMAIN	CONTROL	INTERVENTION
Physical Appearance	0.74	0.53
Holidays	1.07	0.96
Leisure	1.04	1.11
Sex Life	1.23	1.00
Friendships	1.42	1.32
Self Confidence	1.57	1.21
Peoples Reaction	1.83	1.17
Freedom to Drink	1.58	1.53
Motivation	1.72	1.57
Journeys	1.58	1.77
Future	1.72	1.74
Freedom to Eat	1.58	1.91
Living Condition	1.81	1.91
Dependence	1.72	2.04
Finance	1.96	1.98
Physical Activity	2.34	2.08
Personal Relationship	2.47	2.30
Family Life	2.64	2.70
Employment	2.70	2.74

Table 6: Comparison of average weighted impact scores before and after pharmaceutical care was provided

AVERAGE WEIGHTED IMPACT SCORE			
CONTROL		INTERVENTION	
BASELINE	AFTER COUNSELING	BASELINE	AFTER COUNSELING
-1.7453 ± 0.55314	-1.7191 ± 0.51617	-1.7526 ± 0.56315	-1.6688 ± 0.48013
P ≥ 0.01		P ≤ 0.01	

The highest unweighted negative impact of diabetes was found to be on the domain “freedom to eat” followed by “freedom to drink” (C=-2.09, I= -2.15) and “physical activity”. The least impact of diabetes was on “peoples’ reaction”. It was encouraging that subjects with DM did not think that they would be very affected by people’s reaction, as a high level of self-esteem is associated with better adherence to therapy and better treatment outcomes. The domain “freedom to eat” showed the highest negative weighted impact, showing that it was not dramatically enhanced by the importance rating. Given that obesity is an important contributing factor to the development of DM, it was not surprising that the domain “freedom to eat” had the maximum negative unweighted impact score as well as the maximum weighted impact score. The domains “employment”, “family life” and “personal relationships” were reported as the most important items and “physical appearance” as the least important item. All domains had a negative mean value indicating

that diabetes had a negative impact on all the different domains of life. The domains “working life”, “sex life”, and “holidays” showed some missing responses. No change was observed in the ranking of impact and importance rating of different domains before and after providing pharmaceutical care. But after the pharmaceutical care was provided a variation in AWI scores for two groups were observed during the final interview. Paired t-test was carried out to assess the significance of the difference between means. Calculated t value was greater than the table value for t at 0.01level of significance. Hence the null hypothesis was rejected and the research hypothesis accepted. Thus, the research hypothesis that pharmaceutical care has a significant impact on improving the quality of life among Type II diabetic patients was accepted.

Conclusion

Quality of Life (QoL) is impaired in patients with diabetes, especially for the 'freedom to eat' domain, indicating that an intervention to improve dietary freedom might be a good way of improving QoL. The study also showed that patient counseling played an important role in improving QoL of diabetes patients. Future research on diabetes should include measures of QOL since assessing patients' QOL has numerous benefits. It allows health care providers and researchers to better understand what aspects of the illness and treatment the patient views as having the greatest impact on their QOL. QOL effects of various diabetes treatments may impact patients sustaining health care activities and health care providers decision-making. Understanding QOL may also be useful in communicating to future patients about expectations of the impact treatment has on QOL.

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