

Impact of Pharmaceutical Care Activities on Health Related Quality of Life (HRQoL) of Diabetic Patients at a Private Corporate Hospital

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Abstract: *Background:* Diabetes is a disease that desperately needs more pharmacist involvement. Pharmaceutical care and 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. Studies have shown that type 2 diabetes is associated with impaired QoL and all domains of HRQoL are affected with diabetes, particularly in terms of physical wellbeing as diabetes increases morbidity and decreases life expectancy. *Objective:* To evaluate the impact of pharmaceutical care on HRQoL in patients with type 2 Diabetes mellitus and to provide education and information regarding the disease and life style modification. *Methods:* A prospective comparative 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 6 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 "short form survey -36" 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 SPSS software to find out the 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 $8.63 \pm 2.27\%$ to $7.24 \pm 1.39\%$ ($p < 0.05$). There was a significant decrease in the fasting blood glucose from 203.05 ± 89.05 mg/dl to 115.55 ± 39.03 mg/dl between the baseline and the final interview in the intervention group ($p < 0.05$). The average BMI values also decreased from $25.06 \pm 3.6\%$ to $24.21 \pm 3.3\%$ ($p < 0.05$). *Conclusion:* The study concluded that pharmacist mediated patient counseling and the disease, medications and lifestyle modifications will improve the Quality of life and Glycemic control. The assessment of quality of life in patients with diabetes could help to improve patient's wellbeing.

Keywords: Patient counseling, BMI, SF 36 questionnaire, patient information leaflet and Quality of life.

1. Introduction

Diabetes is a chronic condition that can lead to serious and costly complications. Every 7 seconds a person dies from diabetes. In 2014, diabetes caused 4.9 million deaths globally.

The International Diabetes Federation estimates that 246 million adults worldwide have diabetes mellitus. The world prevalence of diabetes among adults (aged 20–79 years) was 6.4%, affecting 285 million adults, in 2010, and will increase to 7.7%, and 439 million adults by 2030. Between 2010 and 2030, there will be a 69% increase in numbers of adults with diabetes in developing countries and a 20% increase in developed countries¹.

The inexorable rise of diabetes parallels that of the obesity pandemic spreading throughout both the industrialized and developing countries. Diabetes accounts for around 6% of total global mortality, with 50% of diabetes associated deaths attributed to cardiovascular disease². By 2025 India will be dubbed as the 'DIABETIC CAPITAL OF THE WORLD'. According to recent WHO estimates presently India has 32 million diabetic subjects, and this is projected to increase to 100 million by 2035. Currently 1 in 12 people are diabetic in India. The countries with the largest number of diabetic people will be India, China and USA by 2030³.

Diabetes is epidemic in India as a result of societal influence and changing lifestyles. Diabetes has been known in India for centuries as a disease of rich man, but now spreading among all masses. The studies in Indian population showed that major risk factor for high prevalence of type 2 diabetes mellitus are genetic disposition, insulin resistance, obesity, central obesity (greater abdominal adiposity), urbanization with change in diet habits like fast food culture and sedentary life style. Rapid urbanisation and industrialization have produced advancement on the social and economic front in developing countries such as India which have resulted in dramatic lifestyle changes leading to lifestyle related diseases.

Diabetes mellitus describes a metabolic disorder of multiple aetiology characterized by chronic hyperglycaemia with disturbances of carbohydrate fat and protein metabolism resulting from defects in insulin secretion, insulin action or both. Hyperglycemia leads to spillage of glucose into urine, hence the term diabetes-sweet urine. DM involve not only a deficiency of insulin but also an excess of certain other hormones such as growth hormones, glucocorticoids and glucagons⁴. Though diabetes mellitus was recognized several centuries ago, it was HP HIMSWORTH who first proposed that DM could be differentiated into *insulin sensitive* (Juvenile onset) and *insulin insensitive* (Maturity onset) types in 1936. The WHO Expert committee on

Diabetes made changes in 1980. This classification separates DM into 2 main categories based on insulin dependency: Insulin dependent (Type 1 DM) and Non Insulin dependent (Type 2 DM). In type 1 DM pancreas undergoes an autoimmune attack (T-cell mediated) by the body itself, and is rendered incapable of making insulin. In type 2 DM patients can still produce insulin but is insufficient – either absolutely or relative to the body's need. A major feature of type 2 DM is lack of sensitivity to insulin by the cells of the body (particularly fat and muscle cells) – insulin resistance⁵.

People with diabetes should receive DSME and diabetes self-management support (DSMS) according to National Standards for Diabetes Self Management Education and Support when their diabetes is diagnosed and as needed thereafter. Effective self-management and quality of life are the key outcomes of DSME and DSMS and should be measured and monitored as part of care. The overall objectives of DSME and DSMS are to support informed decision making, self care behaviors, problem solving, and active collaboration with the health care team to improve clinical outcomes, health status, and quality of life in a cost-effective manner. DSME and DSMS are essential elements of diabetes care and the current National Standards for Diabetes Self- Management Education and Support are based on evidence for their benefits. Education helps people with diabetes initiate effective self-management and cope with diabetes when they are first diagnosed.

HRQoL refers to the broadest range of human experience. In addition to the influence of health, it includes personal finances, job, housing, personal relationship, political and cultural climate, traffic, environmental considerations, and much more. HRQoL is primarily concerned with only one particular aspect of quality of life – how it may be affected by health and diseases. 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. QoL is an important outcome in its own right, but also because it may influence the patient's self – care activities, which may consequently impact their diabetes control.

Health related Quality of life (HRQoL) questionnaire (SF-36) with its 36 questions measures physical, mental, social, emotional and general health status along with the vitality and bodily pain. The questionnaire has eight domains i.e. physical functioning (PF), role physical (RP), bodily pain (BP) general health (GH), vitality (VT), social functioning (SF), role emotional (RE) and mental health (MH). This is an effective and standard tool to understand individual's mental, emotional, social, physical and general health status. All variables like age, sex, height, duration, family history of diabetes etc and 36 questions of SF-36 will be entered in Statistical Package for Social Sciences (SPSS version 13.0) software. Observations may be presented as Mean \pm SD and number with percentages. Continuous and categorical variables can also be analyzed for significance by ANOVA and Chi square respectively¹⁰.

Pharmaceutical care is a professional practice recommended by the WHO and other national and international entities. It contributes to the resolution of medical conditions and can

help avoid undesirable outcomes in relation to patients' drug therapy problems DTP, resulting in benefits to patients and to society. Humanistic outcomes, also known as patients' reported outcomes, involve the effect of treatment and pathology on the patient's functional status, quality of life and satisfaction with the particulars of their care. Evaluation of humanistic outcomes, often little valued by professionals, is important, along with clinical outcomes, especially in chronic diseases such as Diabetes Mellitus.

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.

2. Materials and Methods

Study Site: Department of Diabetology of a 700 bedded tertiary care private corporate hospital.

Study Design: Prospective Comparative study.

Study Period: The prospective Comparative study was conducted over a period of 6 months December 2014 – March 2015.

Study Sample: 120 patients

Study Criteria:

Inclusion Criteria: Newly diagnosed or patients with history of Type 2 DM, admitted in department of Diabetology, receiving at least one oral hypoglycemic agent and willing to participate in the study.

Exclusion Criteria: Type 1 Diabetic patients and patients who are not willing to participate in the study and patients with insufficient data in their records.

Sources of Data

All necessary data was collected from the following sources

1. Patient data collection form
2. Patient case history
3. Patient prescriptions
3. Laboratory data
4. Treatment profiles
5. Microbiological data
6. Patient counselling details - (Patient information leaflets, Patients SF 36 profile).

Consent from hospital Authority

The study was approved by the Hospital authority, by submitting a protocol of the study which includes the objectives, methodology, and the study was conducted with the expert guidance of seniors and junior physicians of the department selected.

Literature Survey

The literatures supporting the study were gathered from various sources such as British Medical Journal, American Medical Journal, Journal of Clinical Pharmacy and Therapeutics, Journal of Pharmacy Practice, The Annals of pharmacotherapy, Journal of national medical association, Indian journal on medical microbiology.

3. Methodology

A prospective Comparative study on impact of pharmaceutical care on HRQoL in patients with type 2 DM is planned to be conducted in a 700 bedded private tertiary care corporate hospital in South India for a period of six months. The study was planned on a 120 eligible patients with type 2 DM enrolled randomly in the interventional group (60 patients) and the control (60 patients). The interventional group patients received pharmaceutical care through diabetes education, medication counseling, and instructions on lifestyle that needed modifications whereas the control group patients were deprived of any pharmaceutical care till the end of the study. The –SF-36” standard questionnaire was used to assess the relevant parameters and to evaluate the impact of pharmaceutical care on the subjects. The study was divided into baseline, 2nd and 3rd visit with a difference of two months for each visit. All the baseline parameters are equally distributed in both test and control with a *p* value more than 0.05.

Assessments were made based on 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 is also to be assessed. Data will be subjected to statistical analysis using suitable statistical tool.

Body Mass Index (BMI) was calculated by dividing weight in kilogram with height in meters square, patients with BMI ≥ 25 kg/m² were considered as obese were noted. SF-36 questionnaire (Tamil version) was used as an instrument for the assessment of HRQOL; All patients were asked to answer the prevalidated QOL questionnaire. The questionnaire took approximately 15 minutes to complete. The questionnaire contained 36 questions comprising eight domains i.e. physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional(RE) and mental health (MH). The scoring of all domains was from 0 to 100 considering ‘0’ as the worst possible status and ‘100’ as the best possible status.

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.

The paired t-student test was used for intragroup 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.

4. Results

The age range of the participants in both groups was between 32 to 85 years old. 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 average fasting blood glucose for the control group was 197 ± 89.10 mg/dl and that for the intervention group was 203.05 ± 89.05 mg/dl (**Table 2**). 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 134 ± 38.68 mg/dl which was significantly different from the basal values (*p* < 0.05). In the intervention group the levels were 115.55 ± 39.03 mg/dl and that was significantly different from the basal values (*p* < 0.05).

The average HbA1c values for the control group was 8.95 ± 2.47 % and that for the intervention group was 8.63 ± 2.27 % (**Table 2**). 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 HbA1c levels of 8.00 ± 1.71 % which was significantly different from the basal values (*p* < 0.05). In the intervention group the levels were 7.24 ± 1.39 mg/dl and that was significantly different from the basal values (*p* < 0.05).

The body mass index was found to be 29.62 ± 25.87 kg/m² and 23.89 ± 4.70 kg/m² (**Table 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 25.94 ± 3.44 in the control group (*p* > 0.05 when compared with basal values) and 24.21 ± 3.34 in the intervention group (*p* < 0.05 when compared with basal values) which was significant.

The eight domains of quality of life were analyzed for different groups of age, sex, duration of diabetes. Significant higher scores of physical functioning 76.38% (*p* < 0.0001), vitality 62.93% (*p* = 0.041), mental health 72.03% (*p* = 0.039), bodily pain 77.47% (*p* = 0.012) and general health scores 66.75% (*p* < 0.0001) were found in males as compared to females. Physical functioning score was significantly high in people under 35-40 years of age compared to the older age groups 85.3% (*p* = 0.001). Higher scores of physical functioning 86.1% was also observed in patients who are newly diagnosed with diabetes compared to other groups (*p* = 0.048). Bodily pain scores were found higher in males as compared to females (*p* = 0.012) while general health scores also have the same trend (*p* < 0.0001) (**Table 3**).

All eight domain scores were further compared with control and intervention groups & between before pharmaceutical care activities and after providing the same. The domains of QoL assessed by the SF-36® also shows significant differences between patients baseline and final evaluation scores.

5. Discussion

Pharmacist is part of a multi disciplinary team. This team normally consists of pharmacist, physician, nurse, technician, nutritionist, and other health care professions. All of the members in multidisciplinary team have important roles in diabetes management in achieving the goal of treatment, improving quality of life, controlling disease and its complications, delaying complication, and decreasing mortality and morbidity. Pharmacists' interventions are an important factor to improve glycemic control in diabetic patients. Pharmacists' interventions include diabetes education and counseling on drug, disease, diet, exercise, life style modification, and self-management, assessment and adjustment of anti-diabetic medications, identifying and solving drug-related problems, co-operation with physician and other diabetes health care team, providing materials that reinforce patients to achieve a target goal, providing additional information on smoking cessation. All of these interventions aimed at improving glycemic control. In our study, HbA1c levels, Fasting Blood Glucose levels and Body Mass Index values significantly reduced with pharmacists' interventions compared with usual care. The pooled mean difference in the change of HbA1c was 0.76% ,

FBG 19.13% and BMI 1.73%. This would help patients meeting the target of their treatment.

Table 3 shows the mean scores of all domains of QoL was found to be significantly higher ($p < 0.05$) in intervention group except in the vitality and mental health scores. There was non-significant association observed with these two domains of QoL ($p > 0.05$).

Table 1: Demographic and epidemiological characteristics of diabetic patients

Characteristics	N	%
Gender		
Male	63	52.5
Female	57	47.5
Age (years)		
35-40	13	10.8
41-45	11	9.1
46-50	14	11.6
>50	52	68.6
Duration of diabetes (years)		
Newly diagnosed	19	15.6
1-5 years	50	41.6
>5 years	51	42.5

Table 2: Comparative analysis of baseline and final values between patients in the intervention and control groups who completed the study

Parameters	Control Group		Intervention Group	
	Baseline Interview	Final Interview	Baseline Interview	Final Interview
FBG (mg/dl)	197 ± 89.10	134 ± 38.68	203.05 ± 89.05	115.55 ± 39.03
HbA1c (%)	8.95 ± 2.47	8.00 ± 1.71	8.63 ± 2.27	7.24 ± 1.39
BMI (kg/m ²)	29.62 ± 25.87	25.94 ± 3.44	23.89 ± 4.70	24.21 ± 3.34

Values are expressed as Mean ± SD (n=60 for each group)

Table 3: Comparison of Responses to Qol domains of SF 36 in Control and Intervention group.

	<i>Control group without Diabetes Education</i>	<i>Intervention group with Diabetes Education</i>	
SF-36 Components	Control(%)	Intervention(%)	p- value
Physical Functioning (PF)	68.84±22.38	84.18 ± 16.50	0.000
Role Physical (RF)	57.30± 28.10	71.14 ± 25.73	0.006
Role Emotional (RE)	60.41 ± 28.48	73.33± 24.53	0.009
Mental Health (MH)	69.02± 17.78	71.5± 18.11	0.451
Bodily Pain (BP)	69.36± 22.29	83.00 ±22.54	0.001
General Health (GH)	62.28± 15.25	68.41±15.98	0.034
Vitality (VT)	59.37± 16.04	64.79± 19.62	0.101
Social Functioning (SF)	76.25± 19.89	84.37± 18.64	0.023

6. Conclusion

Diabetes is a chronic illness that requires a combination of pharmacological and nonpharmacological measures for better glycemic control. Patient adherence to medication and lifestyle modifications plays an important role in diabetes management.

Pharmacist plays a major role in management of chronic disorders by providing Pharmaceutical care service. The available evidence suggests that pharmacists' interventions are more effective than usual care in decreasing HbA1c levels in diabetes patients. High quality of life represents the ultimate goal and an important outcome of all medical interventions in diabetic patients. The present six month study also demonstrated the positive impact of

pharmaceutical care activities on various domains of quality of life and clinical and physiological parameters of diabetes mellitus. Our study concludes that pharmacist mediated individualised pharmaceutical care services have a positive impact on HRQoL, Glycemic control, and medication adherences which improves the therapeutic outcome of the patients. Overall outcome would be cost effectiveness in health care system and better life of the sufferer.

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