Effect of Glycaemic Control on Quality of Life(HRQoL) in Diabetes

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A B S T R A C T

INTRODUCTION: Intensified glycaemic control is recommended in diabetes type 2 patients as it prevents or postpones chronic diabetic complications, but its effect on quality of life in the short and long term is still not clear.

AIMS: To study effect of various anti diabetic treatment regimens on level of glycaemic control and Quality of life in patients of type 2 diabetes mellitus.

MATERIALS AND METHOD: Patients with type 2 diabetes mellitus aged 30-70 years of either gender on oral anti-diabetic therapy for at least 1 year were enrolled. After taking written informed consent, patients were interviewed according to a pre-validated questionnaire regarding quality of life and responses along with investigations and treatment given were noted in the performa. Data obtained was analysed using percentage, mean, standard deviation and unpaired t tests.

RESULTS:A total of 48 patients were enrolled. Patients were assigned to one of the three groups depending on number of anti-diabetic drugs prescribed. Fasting blood sugar was better controlled in patients taking one anti diabetic drug. Overall Quality of life was better in patients on dual drug therapy while overall impression in comparison to first visit to OPD was significantly better in patients on triple drug therapy from monotherapy and dual drug regimen patients.

CONCLUSION: Overall Quality of life was better in patients on dual drug therapy while overall impression in comparison to first visit to OPD was significantly better in patients on triple drug therapy from monotherapy and dual drug regimen patients.

KEYWORDS: Quality of Life, Type 2 diabetes, treatment regimen

INTRODUCTION

Diabetes mellitus (DM) is associated with multiple complications and increased age adjusted mortality rates. Conventional outcome assessment for diabetes mellitus was based primarily on haemoglobin A1c (HbA1c), fasting, post prandial, random blood sugar and complications of diseases. Intensified glycaemic control is an important way of reducing risk of complications and improving health-related quality of life (HRQoL) in diabetes type 2 patients. However, the complexity of regimens aimed at achieving better glycaemic control may have impact on patients HRQoL. Therefore, clinical outcomes does not necessarily indicate patients perceptions of their health. Treatment regimens that require changes of lifestyles and behaviors may influence patients daily functioning and wellbeing. Therefore, HRQoL is an important and upcoming outcome indicator alongside conventional biomedical measures.[1]

HRQoL is considered a patient-assessed or patient-centered outcome that relates to the individual's health perceptions, wellbeing and functioning. Moreover, health perceptions reflect cultural and value systems. Various societal and individual determinants influence physical functioning, psychological state, social relationships, environmental factors, awareness and beliefs. HRQoL is lower in people diagnosed with diabetes than for non-diabetic patients. Furthermore, evidences suggests that the level of HRQoL depends on the presence of comorbidities and the severity and the number of complications and has been significantly correlated with socioeconomic and/or familial barriers.[2]

There are several instruments available for assessing diabetes mellitus HRQoL, including generic and diabetes-specific instruments. Generic instruments measure HRQoL domains which are universally important while diabetes-specific instruments measure specific impacts of diabetes on functioning and well-being. Specific instruments are more sensitive to patient score changes over time[1]. The Diabetes Quality of Life Questionnaire- Respondent Self Report Version is reliable, valid and comprehensive HRQoL instrument. It includes both generic and diabetes-specific domains which cover the important aspects of patient's HRQoL including physical state, emotional state, stress evaluation and life enjoyment.[3]

Diabetes mellitus is a chronic metabolic disease that requires continuous medical care, life style modifications and patient self-management education to prevent acute complications and to reduce the risk of long-term complications[4]. Complications associated with type 2 diabetes mellitus are the main cause of morbidity and mortality. The macro vascular effects give rise to cardiac, cerebrovascular and peripheral vascular dysfunction. These complications lead to compromised health-related quality of life along with loss of physical function and cost. Subjects with diabetes and less comorbid conditions have better HRQoL than those with more comorbid conditions. For example, subjects with diabetes and co-existing cardiovascular diseases had significantly lower scores on social functioning, vitality and health-change scales[5]. In another study, subjects with diabetes and co-existing coronary artery disease, peripheral sensory neuropathy and peripheral vascular diseases had significantly lower scores[6].

People with diabetes often feel hampered by their disease and its day to day diabetes management demands. Jacobson et al reported that patients taking oral medications had more diabetes quality of life-assessed diabetes-related worries than those controlling their diabetes with diet and exercise[7]. HRQoL not only is an important outcome indicator, but it may also influence the patient's self-care activities, which may consequently impact their diabetes control and management[8]. It is increasingly accepted that the patient's own attitude and perception of change in her or his health status is an important indicator of the success of treatment. Low quality of life and psychosocial status of patients with diabetes may affect metabolic control by decreasing compliance either due to not being able to buy medication or properly follow treatment regimens. The objective of the study was to find effect of various anti diabetic treatment regimens on Quality of life and level of glycaemic control in patients of Type 2 diabetes mellitus.

SUBJECTS AND METHODS

The study was conducted in type 2 diabetes mellitus patients attending Endocrinology Outpatient Department (OPD) in a hospital of Northern India. Patients with type 2 diabetes mellitus, aged 30-70 years of either gender on oral anti-diabetic therapy for at least 1 year were included in study. Pregnant, lactating and patients on insulin therapy were not enrolled.

STUDY DESIGN

It was an open labelled, one point in time study. A written informed consent was taken from the patients who met inclusion criteria. Each patient was interviewed according to a pre validated questionnaire regarding their quality of life and their responses were noted in the performa.[3] Fasting plasma glucose concentration was measured by enzymatic reference method with hexokinase.

Data obtained was analysed using descriptive statistics including percentage, mean, standard deviation and unpaired t test. Analysis was performed using 2 tailed test at a significant level of 0.05.

RESULTS

A total of 2038 patients with type 2 diabetes mellitus were screened, out of which 48 patients, 34 males and 14 females, on oral anti-diabetic therapy for at least 1 year, were enrolled. (Fig.1)
Each patient was assigned to one of the three groups depending on number of drugs he/she was being prescribed:

Group 1: Sulfonylureas/ Biguanides/ DPP-4 inhibitors alone (n=4)

Group2: Sulfonylureas+ Biguanides (Dual drug therapy) (n=30)

Group3: Sulfonylureas+ Biguanides + Thiozolidinedione / Alpha Glucosidase inhibitors (Triple drug therapy) (n=14)

Figure 2 shows the Mean ± SD of FBS of different treatment regimens at the end of 1 year of therapy respectively. Our study has shown that FBS was better controlled in group 1 (84 mg/dl) i.e. patients on monotherapy while in dual and triple drug therapy patients, the FBS was 172 and 167 mg/dl respectively. Quality of life parameters in different treatment regimens are shown in figure 3 and Table 2. Physical state, mental state, life enjoyment and overall QoL is better in group 2 as compared to groups 1 and 3, although the difference is not statistically significant (p=0.78, 0.56 and 0.95 for physical state, p=0.21, 0.5 and 0.3 for mental state, p=0.14, 0.59 and 0.53 for life enjoyment, p=0.12, 0.32 and 0.88 for overall QoL in comparison group 1 with 2, 2 with 3 and 1 and 3

respectively). Stress evaluation score is better in group 3 as compared to groups 1 and 2(p=0.39 and 0.86). Overall impression in comparison to first visit to OPD was better in group 3 groups as compared to 1 and 2 and was statistically significant(p=0.006 and p=0.036 respectively).

Physical state evaluation included incidence of physical pain, falling or accidents, allergy or skin rashes, dizziness, nausea and constipation. Mental state was evaluated according to presence of negative feelings, depressive feelings, overly worried behaviour, difficulty in concentration or thinking, experience of fear or anxiety and temper. Stress evaluation was done according to stress related to family, health, finance and work. Life enjoyment assessment was done according to feeling of joy/happiness, relaxation, level of confidence, positive feeling and time devotion to enjoying things.

Overall QoL was assessed according to persons view about his personal life, job, co-workers, working conditions and handling problems. Scoring was done on a scale of 1 to 4, according to incidence of these parameters by giving score of 1 to regularly occurring event while 4 to event which has never occurred.

DISCUSSION

A total of 48 patients with type 2 diabetes mellitus, on oral anti-diabetic therapy for at least 1 year, were enrolled and assigned to one of the three groups depending on number of drugs prescribed. Patients in group 1 were taking one drug; two of them were taking metformin while glimepiride and Sitagliptin was taken by one patient each. This is according to American diabetes association guidelines for management of Type 2 diabetes patients to give metformin as first choice drug in treatment of diabetes while we have to look for patient factors and adverse effects of drug [9]. In Group 2, we had 30 patients who were on 2 drugs, metformin along with sulfonylureas, like glimepiride, glipizide and gliclazide.

According to American diabetes association guidelines, in dual drug therapy metformin should be combined with anyone of anti-diabetic agents from sulfonylureas, DPP4 inhibitors, SGLT 2 Inhibitors, GLP 1 Analogues, alpha glucosidase inhibitors, thiazolidinedione or meglitinides according to patient factors and adverse effects of drug.[9] In our study, glimepiride and metformin

were most commonly given together to 22 patients followed by gliclazide and metformin was given to 3 patients while glipizide and sitagliptin was given to 1 patient only. In group 3, we had 14 patients who were given metformin along with sulfonylureas and third drug was pioglitazone in 12 patients, voglibose in 2 and sitagliptin in 1 patient.

Diabetes itself has an impact on HRQoL and it influences factors important in outcome. Association between diabetes, particularly Type 2 diabetes, and impact on HRQoL, in comparison with undiagnosed diabetes was evaluated by various studies. Introduction of anti-diabetic medications and practices designed to facilitate the development of diabetes-specific coping skills, can improve glycemic control and quality of life in people with diabetes.[10]

According to American diabetes association guidelines, fasting blood glucose levels should be between 70 -130 mg/dl [9]. In our study, patients were started with different treatment regimens to achieve this goal based on decision of treating diabetologist and patient factors like affordability and availability of drug. Patients who did not respond to single drug adequately, were given second drug and those not responding to dual drug therapy were prescribed a third drug[9]. Our study has shown that FBS was better in group 1 patients on monotherapy (84 mg/dl) while in dual and triple, the FBS was 172 and 167 mg/dl respectively. This can be due to relatively short history of onset of diabetes in group 1 patients as compared to group 2 and 3.

Overall impression of Quality of life was significantly better in patients on triple drug regimen from single and dual drug therapy as compared to their first visit to OPD. These results are similar to various studies done earlier. VanDeKoppel et al. observed that despite effective monotherapy with metformin or sulfonylureas, approximately 50% of type 2 diabetes patients require additional medications after 3 years to achieve target glycosylated haemoglobin <7%. Add on therapy of thiazolidinediones is safe and effective for patients with type 2 diabetes who are either at the maximum doses of metformin and sulfonylureas and it was observed that there was decrease in HbA1c by at least 0.5-1%.[12] These results are in concordance with American diabetes association guidelines, i.e. patients who do not

respond to single drug adequately, should be given second drug and third drug subsequently to attain better glycaemic control and improve QoL.[11]

The interpretation of these results needs to consider the limitations of our study. HbA1c is considered as a marker of long term control of diabetes[13]. We could not get data regarding the levels of glycosylated haemoglobin of our patients which is as this was one point in time study, although efforts were made to check investigation reports from older prescriptions. Also, the sample size in group 1 was small (n=4). So results cannot be generalised. Also, as our study is based on patient experiences, so recall and interviewer bias cannot be ruled out.

CONCLUSION

Health-related quality of life (HRQoL) is a multi-dimensional concept that includes domains related to physical, mental, life enjoyment and stress evaluation. Quality-of-life issues are crucially important, because they may powerfully predict an individual's capacity to manage his disease and maintain long-term health and well-being. Quality-of-life research in diabetes potential will be realized when we can design, implement and evaluate interventions that influence factors that affect quality of life.

Overall impression of Quality of life was significantly better in patients on triple drug regimen from single and dual drug therapy (both having almost equivalent score) as compared to their first visit to OPD. Physical state, mental state, life enjoyment and overall QoL is better in dual drug therapy as compared to monotherapy and triple drug therapy, although the difference is not statistically significant. It is important to have a better QoL in diabetic patients, as both the disease itself as well as the antidiabetic drugs play a significant role in QoL of the patient. So, the treatment regimens should be planned in such a way which have a positive impact on the QoL of the patients.

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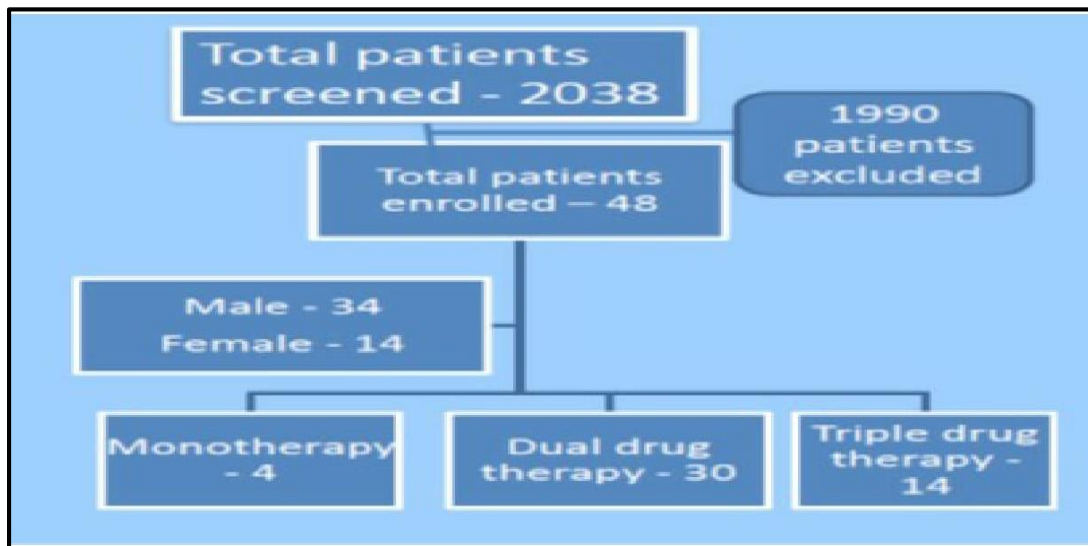+91 8146559031
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LEGENDS

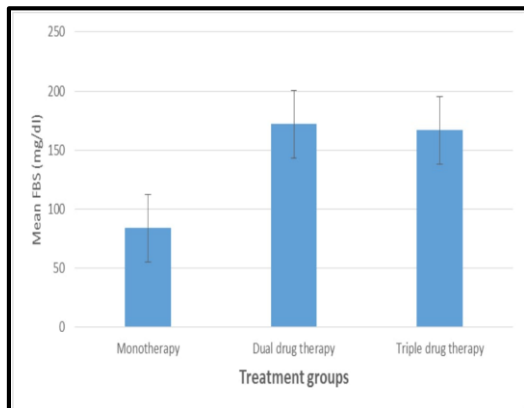**Figure 1.**Enrollment of study subjects

Figure 2. Mean ± SD of FBS of different treatment regimens at the end of 1 year of therapy
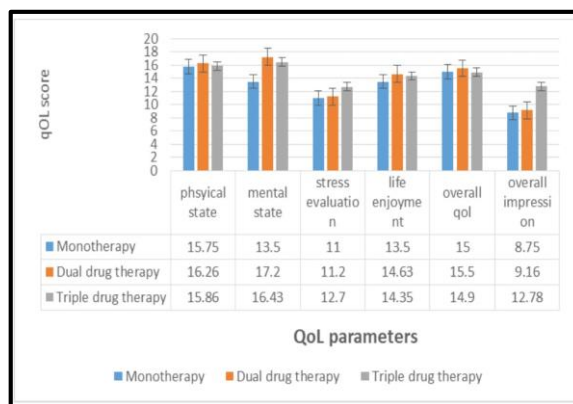

Figure 3. Quality of life parameters in different treatment regimens

Group	Treatment group	Males	Females	Mean Age± SD (Years)
1	Single drug therapy (n=4)	2	2	40 ± 6.56
2	Dual drug therapy (n=30)	22	8	51.6 ± 10.38
3	Triple drug therapy (n=14)	10	4	51.6 ± 11.19
		34	14	

Table 1. Gender distribution in different groups.

Parameters evaluated	Monotherapy	Dual drug therapy	Triple drug therapy
Physical state	15.8	16.3	15.9
Mental state	13.5	17.2	16.4
Stress evaluation	11	11.2	12.7
Life enjoyment	13.5	14.6	14.3
Overall Qol	15	15.5	14.9
Overall impression	8.75	9.16	12.78

Table 2. Quality of life parameters in different treatment regimens