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## QUALITY OF LIFE OF DIABETIC PATIENTS ON DIFFERENT TYPES OF ANTIDIABETIC MEDICATIONS

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### Keywords:

Health related quality of life (HRQL), Diabetes Mellitus, Antidiabetic medications, SF-36 questionnaire, control subjects

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**ABSTRACT:** Diabetes mellitus (DM) was found to impair all dimensions of health except mental health and pain and in a more recent multinational study, DM was found to have a notable impact on general health, measured using the Medical Outcomes Short-Form 36 (SF-36). A cross-sectional, randomized study conducted in Ajman and Sharjah, October 2012 to May 2013, using a self-completed questionnaire and SF-36 health related quality of life (HRQL) questionnaire by 150 diabetic patients on different types of medications and 220 control subjects. Forty four percent of patients used Insulin for their treatment, 34% used Metformin, 14.7% used combination therapy of Insulin with Metformin and only 6% used Gliclazide. The mean values of Physical Functioning (PF), Role-Physical (RP), Bodily Pain (BP), General Health (GH), Vitality (V), Social Functioning (SF), Role Emotional (RE), Mental Health (MH), Physical Components Summary (PCS), and Mental Components Summary (MCS) scores were 61.2, 19.5, 59.2, 56.5, 53.0, 55.4, 57.3, 55.6, 4, and 42.1, respectively. Patients taking an oral therapy had better quality of life than those using an injection of insulin to control their blood sugar. A combination therapy of Insulin with Metformin didn't improve the quality of life of patients. Patients who were using a combination therapy of Metformin with Angiotensin converting enzyme inhibitors (ACEI) had the highest quality of life on all scales of SF-36. There were no significant differences between other types of medications. The present study showed that diabetic patients reported comparably limited HRQL in all dimensions of SF-36, compared with healthy individuals and disease imposes negative limitations in physical and mental functioning. The present study will help to implement intervention strategies to improve the HRQL in diabetic patients.

**INTRODUCTION:** DM is a chronic illness that requires continuing medical care and ongoing patient self-management education and support to prevent acute complications and to reduce the risk of long-term complications<sup>1</sup>.

Accordingly, it is a major public health problem, affecting hundreds of millions of people worldwide, and represents an enormous personal problem and has a substantive economic impact on society, with substantial direct and indirect costs<sup>2</sup>. It is a major risk factor for heart disease, stroke, hypertension, dyslipidemia, metabolic syndrome, and end stage renal disease<sup>3</sup>.

In the United Arab Emirates (UAE), DM constitutes a major health problem and is well recognized as a major and increasing burden to the

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country's resources due to its severe, long term debilitating effects on individuals, families and the society at large. One out of every four citizens of the United Arab Emirates has diabetes, at a rate of roughly 20 % for residents, 25% for Emirati nationals<sup>4</sup> and the number is expected to increase over the coming years; recent studies estimate that the percentage of people suffering from diabetes in the UAE rises with increasing age reaching as high as 40% in the age group 60 and above. DM constitutes 75% of deaths among UAE nationals and 31% among non-nationals<sup>4</sup>.

Also, DM has detrimental effects on a range of health outcomes including health related quality of life (HRQL)<sup>5, 6</sup>. For example, in the Medical Outcomes Study, DM was found to impair all dimensions of health except mental health and pain<sup>7</sup>. In a more recent multinational study, DM was found to have a notable impact on general health, using the Medical Outcomes Short-Form 36 (SF-36)<sup>8</sup>. The magnitude of impact of DM on HRQL was reported to be equivalent to that of having cardiovascular conditions, cancer and chronic respiratory disease<sup>9</sup>. There have been a number of studies examining the impact of cardiovascular diseases either single or co-morbid conditions on the HRQL, especially the co-morbidity of diabetes<sup>10, 11</sup>. However, none of these studies aimed to elicit this problem in people with diabetes in the UAE. The aims and subjects of the present study are to compare the HRQL between diabetic and healthy subjects in the UAE using the SF-36 short form questionnaire and investigate which class of Antidiabetic medications improves patients' quality of life more than other classes.

#### **MATERIALS AND METHODS:**

A descriptive cross-sectional, randomized study was conducted in Ajman and Sharjah in UAE over a period of eight months (October 2012 to May 2013). Interviews carried out by trained pharmacists with proper skills for the study and distributed the questionnaires and recollected them after self-completion by the participants. The study was approved by Ajman University Ethical Committee. The permission to use the Health quality survey form of SF-36 v2 and its scoring system was requested and obtained from Quality Metric Inc. center in US. (License agreement#

QM018670 & QM019018). All subjects were asked to sign consent form in order to participate in the study.

A total of 150 diabetic patients and 220 healthy subjects were randomly selected. Inclusion criteria were healthy subjects and patients with age of 35 years old or older, male or female and the patients were diagnosed with diabetes only. The exclusion criteria were all subjects who were less than 35 years old, patients with co morbidity conditions other than diabetes, pregnant women and individuals with severe acute or chronic mental disorders. The response rate was 75%.

The SF-36 v2 Health Survey Questionnaire was used for evaluating the HRQL in healthy and non-healthy general population. SF-36 is a fixed-format self-completed questionnaire that contains 36 items integrated in multi-item scales measuring eight general health scales: physical functioning (PF); role-physical (RP); bodily pain (BP); general health (GH); vitality (VT); social functioning (SF); role-emotional (RE) and mental health (MH). These eight scales may be further aggregated into two summary measures: the physical component summary measure (PCS) and the mental component summary measure (MCS), which were used to compare the HRQL between control and patients group.

The questionnaire included two parts. The first part was composed of 6 questions which covered the Socio-demographic characteristics: age, gender, marital status, disease state, medications used along with their side effects. The second part was related to general physical and emotional health and it included 36 questions used to evaluate the quality of life in healthy subjects and diabetic patients population that participated in the study.

#### **Data analysis:**

All Socio-demographic data was analyzed using the Statistical Package for the Social Sciences (SPSS, version 20 for Windows) computer program. Descriptive analysis included calculations of means, 95% confidential intervals (CI) of means and frequencies of categorical variables. Parametric tests and comparative means tests (T-test; ANOVA) were used for the analysis and

evaluation. The SF-36 v2 questions were analyzed by the Quality Metric Health Outcomes™ Scoring software 4.5. The software uses all the 36 items to produce scores for the PCS-36 and the MCS-36 scales and applies a norm-based scoring algorithm empirically derived from the data of a US general population survey.

In theory, the subscale scores of SF-36 range from 0 to 100, with higher scores signifying greater perceived health and the lower one reflecting lower health; 0: the worst and 100: the best. P-value ≤0.001 was considered statistically significant. To test reliability, the internal consistency for the eight scales domains and for summary measures were estimated using Cronbach’s alpha coefficient and alpha equal to or greater than 0.70 was considered satisfactory. The Cronbach’s alpha exceeded 0.9 for all scales, which indicates high internal consistency.

**RESULTS:**

**Socio-demographic and clinical characteristics:**

Only respondents with complete data sets were included in this study. Participants’ Socio-demographic and clinical characteristics are presented in **Table 1**. The range of age of participants was 41-50 years; 55% control group and 71.3% patients group. Majority of the participants, were female in both control and patients groups, 64.5% and 57.3%, respectively. Most of the participants were married, 89.1% and 88% in control and patients groups, respectively. Most of healthy subjects didn’t use any medications. Almost all patients used medications for their disease control and only 0.7% of them didn’t take any medicine.

**TABLE 1: SOCIO-DEMOGRAPHIC DATA OF THE RESPONDENTS**

Variables	Control Group (220) N (%)	Diabetic Patients (150) N (%)
Age		
35-40	56 (25.5)	8 (5.3)
41-50	121 (55)	107 (71.3)
≥51	43 (19.5)	35 (23.3)
Gender		
Male	78 (35.5)	64 (42.7)
Female	142 (64.5)	86 (57.3)
Marital status		
Single	12 (5.5)	16 (10.7)
Engaged	5 (2.3)	2 (1.3)
Married	196 (89.1)	132 (88)

Divorced	7 (3.2)	0
Usage of any medications	10 (4.5)	149 (99.3)
Yes	210 (95.5)	1 (0.7)
No		

**Tables 2** summarized the types of medications taken by diabetic patients and the side effects they experienced with their medications if they have any of them according to their own evaluation. Forty four percent of patients used Insulin for their treatment, 34% used Metformin, 14.7% used combination therapy of Insulin with Metformin and only 6% used Gliclazide medicine. Sixteen percent of them suffered from nausea (16.7%) and weakness (16.7%) as side effects from their medications used.

**TABLE 2: TYPES OF MEDICATIONS USED BY DIABETIC PATIENTS AND ANY SIDE EFFECTS THEY SUFFERED**

Types of medications used	N (%)
No medications	1(0.7)
Hormone (Insulin)	67 (44.7)
Metformin	51 (34)
Gliclazide	9 (6)
Hormone (Insulin) + Metformin	22 (14.7)
<b>Side effects</b>	
Yes	50 (33.3)
No	100 (66.7)
<b>Types of side effects</b>	
No any side effects	100 (66.7)
Nausea	25 (16.7)
Weakness	25 (16.7)

**Health Related Quality of Life Outcomes: SF-36 profiles by total population:**

**Table 3** displays the mean (± S.D) of the Medical Outcomes Study Short Form 36 questionnaire and the physical and mental components summary scores among control group and disease group. Each of the eight subscales and physical and mental components summary scales were scored on a scale from 0-100, zero being the lowest and poorest score and 100 the highest and best possible score. The highest scores were reported for control group in all scales measured.

ANOVA test was performed and the results showed that there were a very high significance differences (p≤0.001) in the eight scales of quality of life and in physical and mental components summary scores among control group and disease

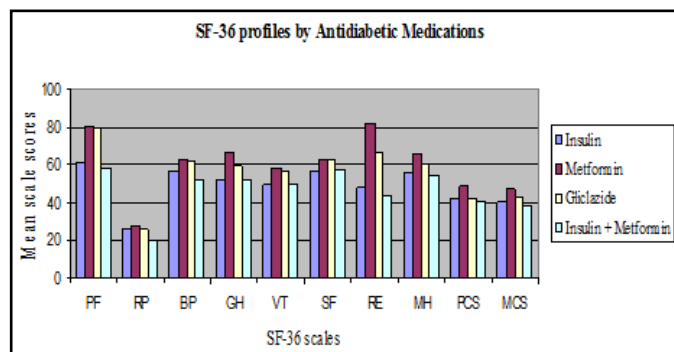
group; control group had higher scores than diabetic patients.

**TABLE 3: MEAN (±S.D) OF RESPONDENTS' QUALITY OF LIFE (QOL) DOMAIN SCORE**

Scale / Number of sample	Control Participants (220)	Diabetic Patients (150)
Physical Functioning	96.7(3.9)	61.2(12.1)
Role-Physical	96.8(8.7)	19.6(19.1)
Bodily Pain	91.5(12)	59.3(11.9)
General Health	80.8(11.6)	56.5(11.6)
Vitality	83.2(11.2)	53(9.6)
Social Functioning	90.3(13.1)	55.4(13.8)
Role Emotional	97.6(90)	57.4(31.1)
Mental Health	85.5(8.7)	55.6(9.1)
Physical Components Summary	57.3(2.4)	41.1(3.9)
Mental Components Summary	56.1(4.1)	42.1(5.6)

**SF-36 profiles by Types of medications used in Diabetic patients:**

Sometimes using the medication itself can reduce the quality of life for patient more than the disease itself. **Fig.1** illustrates that diabetic patients taking an oral therapy had better quality of life than those using an injection of insulin to control their blood sugar. Also a combination therapy of Insulin with Metformin didn't improve the quality of life of patients.



**FIG.1: SF-36 PROFILES BY TYPES OF MEDICATIONS USED IN DIABETIC PATIENTS:**

**DISCUSSION:** Measuring HRQL can help determine the burden of preventable disease, injuries, and disabilities, and it can provide valuable new insights into the relationships between HRQL and risk factors, such as self-reported chronic diseases (diabetes, breast cancer, arthritis, and hypertension), and their risk factors

(body mass index, physical inactivity, and smoking status)<sup>12</sup>.

This study shows that in the UAE, despite a modern and accessible health infrastructure, the level of diabetes is high which is similar to the situation found in many other places in the world, both in developed and developing countries. It shows that participants with diabetes had lower scores on all scales of SF-36, compared with healthy individuals and this explains that this condition impose negative limitations in physical and mental functioning, while other study<sup>13</sup> suggests that diabetes in its early stages has no impact on perceived HRQL of the affected individuals. This might suggest that assessing HRQL may be beneficial even in the early stages of treatment for hypertension and diabetes.

The correct treatment for the disease state can help in raising the quality of life of patients and prevent future complications. In this study the HRQL scores were different among different types of medications used for diabetic patients. The results revealed that using an oral therapy to control blood sugar such as Metformin and Gliclazide improve HRQL for patients more than Insulin therapy and this result is similar to results reported by other studies<sup>14, 15</sup>, which showed that DM patients who are using insulin having worse HRQL than those on oral medications or diet.

**CONCLUSION:** Diabetes is an important preventable cause of death and the treatment of this disease is a key strategy for the prevention of cardiovascular diseases. Early recognition of participants with this chronic disease might therefore be considered to be of importance, not only in clinical disease management, but also in participant education and empowerment aimed at improving their HRQL. Also it can be useful in the prevention of complications associated with diabetes (such as: microvascular and macrovascular complications), which lead to further reduction in HRQL. Results from this study revealed that diabetes has an adverse impact on participants' well-being and functioning.

**Recommendations:**



Based on the present study, the HRQL of patients having DM can be improved by healthy life style and using suitable medications. There are several recommendations that can be offered to improve income and education levels, regular check up, which can help in early diagnosis of any health problem and maintaining the HRQL of the individual in high level, following the guidelines in the priority of choosing the medications used in treatment of patients with DM. Also, increasing the sample size in patient group to get more clear information about each class of medications used and their effects on quality of life of patients.

### Limitations:

There are several limitations that may have influenced the results of this study. The SF-36 form is a questionnaire designed for self-administration, but in many cases in our study, the forms were administered to the subjects by an interview, which could have affected the results. It has been shown that interviewers (e.g. relatives, friends, etc) tend to underestimate the condition of subjects. Also, because of the self-reported of sf-36 data, more detailed information on disease duration, adherence to treatment and other complications were not available. As these are generic instruments, they may not be as responsive to a change in treatment as other more specific instruments<sup>16</sup>. Another factor that could have affected the results of this study was the mood state of subjects at the time of the interview. The psychological state of the subjects like anxiety and depression could have affected the data provided by them especially the respondents who were staying in the hospital recently.

### Suggestions for further reasearches:

Further research on appropriate interventions aimed at HRQL of these participants is needed. Also, additional future works are needed to increase adherence to lifestyle counseling for all diabetic patients.

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the HRQL among these patients; increase awareness on health promotion and DM among population, especially those people with low

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