Type 2 diabetes mellitus patients with poor glycaemic control have lower quality of life scores as measured by the Short Form-36

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ABSTRACT

Introduction: This study aimed to compare the quality of life based on the Short Form-36 (SF-36) between two different groups of type 2 diabetes mellitus patients with glycaemic control: those with a glycosylated haemoglobin (HbA1c) level at or below 7.5 percent and those above 7.5 percent.

Methods: In this cross-sectional study, a generic SF-36 questionnaire was self-administered to patients with type 2 diabetes mellitus. Based on the HbA1c level, the mean SF-36 scale scores were compared. The analysis of covariance was used to obtain the adjusted mean scores of the SF-36 scales while controlling for age and duration of type 2 diabetes mellitus.

Results: 150 patients with type 2 diabetes mellitus were analysed. There were 63 (42 percent) women and 87 (58 percent) men, and their mean HbA1c level was 8.9 percent (SD 2.4 percent). When comparing the two groups of patients with different HbA1c levels, the adjusted means of four scales: physical health functioning, general health, social functioning and mental health, differed significantly between the two. The SF-36 scale scores in type 2 diabetes mellitus patients were also lower than those of the SF-36 norms for the Malaysian population.

Conclusion: Type 2 diabetes mellitus patients with poor glycaemic control had lower mean SF-36 scores in physical functioning, general health, social functioning and mental health, and the SF-36 scores in these patients were also lower than the SF-36 norms of the Malaysian population.

Keywords: diabetes mellitus, glycaemic control status, HbA1c level, quality of life, short form 36, type 2 diabetes mellitus

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INTRODUCTION

The prevalence of diabetes mellitus has increased more rapidly in South Asia than in any other region of the world, and the actual figures are likely to be higher as the population has a high risk of developing diabetes mellitus at lower levels of body mass index than Western populations.[1,2] With advancements in medical services and treatment strategies, the lifespans of patients with diabetes mellitus have increased. Hence, the problems of complications resulting from diabetes mellitus, treatment, medical histories, glycaemic control and psychological aspects may all have adverse effects on many aspects of the patient's life, including the quality of life and the physical and social wellbeing.[3,4] Recently, there has been an increasing interest in the association between the quality of life of patients with diabetes mellitus and their glycaemic control.[5] Even though the association is inconclusive, poor glycaemic control may result in a substantial increase in a diabetic patient's risk of developing complications that will lead to poor quality of life.[6]

Fortunately, quality of life can be measured with instruments such as questionnaires. Health-related quality-of-life questionnaires can supplement the information obtained from traditional measures of clinical endpoints and provide a clearer picture of the outcomes of care by taking patients' points of view into account. Short Form-36 (SF-36), one of the standard evaluation tools that is used to measure quality of life, is short, practical, and possesses good psychometric properties.[7] The SF-36 is probably the most widely used measure of health status around the world. It assesses eight health concepts and has been used in large population and clinical studies involving a wide variety of patient populations.[8-11]

The aim of our study was to compare the health functional status using the Malay version of SF-36 to

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reflect the quality of life among type 2 diabetes mellitus patients with a glycosylated haemoglobin (HbA1c) level of greater than 7.5% (poor control) and those with a HbA1c level of 7.5% or less (good and optimal control) of glycaemic control.

METHODS

This was a cross-sectional study which took one year to complete. In order to choose the diabetes clinics for the study, a list of local diabetes clinics with proper diabetes care, i.e. having at least one available primary care physician, proper record-keeping, a good diabetes registry and a good follow-up system, was initially drawn up. From this list, four diabetes clinics were chosen: two in local general hospitals and two from local primary care clinics. The study received ethical approval from the Ethics and Research Committee, School of Medical Sciences, Universiti Sains Malaysia. 157 patients with type 2 diabetes mellitus attending the selected diabetes clinics were selected during the study period. Patients who had type 2 diabetes mellitus for at least one year, who were aged 18 years or older and who were literate in the Malay language were included. The questionnaires were self-administered, and the exclusion criteria were those with a history of cognitive impairment or substance abuse and complications unrelated to diabetes mellitus based on a personal declaration or information from their medical records. However, no patients had to be excluded based on those criteria. Four patients could not understand the Malay version of SF-36, while three patients refused to participate. Hence, seven patients were eventually excluded, resulting in a response rate of 95.6%.

Systematic random sampling was used to select the patients from a list of those who were to be seen on their follow-up day (sampling frame). On the diabetes clinic day, the SF-36 questionnaire was administered to selected patients in the clinics selected. An informed consent form containing all the necessary information about the study, including the objective, rationale and methods, was provided to the selected patients. A witness, either a staff nurse or a relative of the patient, was also present during the informed consent stage. Patients who were agreeable to participate signed the consent form.

The Malay version of the SF-36 questionnaire was used as a health survey tool to measure the quality of life of patients in the study. It is a well-known and widely utilised health status measure,[12-14] which measures physical aspects (Physical Health Components) and psychosocial aspects (Mental Health Components) of quality of life. The Physical Health Components are categorised into four scales: Physical Health, Role Physical, Bodily Pain and General Health, while the Mental Health Components scales are made up of Vitality, Social Functioning, Role Emotional and Mental Health.[7,8,12,15] The Malay version of the SF-36 used in this study was translated and validated, and The Public Health Institute of Malaysia had produced the norms for the Malaysian population based on a nationwide study using the SF-36.[16]

Table I. Category of HbA1c levels based on the Asia Pacific Type 2 Diabetes Policy Group 2002.[18]

HbA1c level (%)	Frequency (%)
> 7.5*	47 (31.3)
≤ 7.5¶	103 (68.7)
Total	150 (100.0)

* Poor control
¶ Good/optimal control

In the SF-36, Bodily Pain refers to the severity of pain and its impact on daily activities. General Health is a rating of one's own health, a comparison with other's health and proneness to illness. Mental Health refers to the degree of nervousness or calmness and happiness or sadness. Physical Functioning refers to the ability to perform activities (walking, climbing stairs, bending and stretching, lifting and carrying objects) without limitation. Role Limitation (emotional) refers to limitations that emotional problems place on the range and extent of activities one is able perform. Role Limitation (physical) refers to the limitations that reduced physical health has on the range and extent of physical activities that one is able to perform. Social functioning refers to the impact of physical and emotional health on the ability to perform normal social activities.[17]

The selected patients completed the SF-36 using the pencil and paper method in a separate and quiet room while waiting for their turn to see the doctor. Relatives and friends were not allowed to be present in order to avoid bias. On average, each patient took about 10–15 min to complete the SF-36. However, the amount of time taken by each patient was not recorded. During the administration of the questionnaire, a researcher was readily available to assist the patients in understanding the SF-36 if required. The researchers were instructed to minimise the explanation, and the patients were asked to answer the question according to their understanding. After completion of the questionnaire, the researcher determined the completeness of the returned SF-36.

The Statistical Package for Social Sciences (SPSS) version 12.0.1 (SPSS Inc, Chicago, IL, USA) was used for data entry and analysis. The dependent variable was

Table II. The difference in the means of the scales in the SF-36 between the two groups of patients.

Scale in SF-36	Mean ± SD		95% CI of mean difference	p-value
	HbA1c ≤ 7.5% (n = 103)	HbA1c > 7.5% (n = 47)		
Physical Health Component				
Physical functioning	57.6 ± 25.61	63.7 ± 25.16	−15.0,2.7	0.172
Role physical	45.6 ± 41.48	55.9 ± 44.00	−24.9,4.5	0.172
Bodily pain	56.2 ± 23.82	59.3 ± 23.30	−11.1,4.9	0.445
General health	52.2 ± 19.11	58.1 ± 18.92	−12.6,0.76	0.082
Mental Health Component				
Vitality	55.2 ± 19.38	60.4 ± 19.78	−12.0,1.6	0.130
Social functioning	66.3 ± 22.20	72.3 ± 22.80	−13.8,1.9	0.138
Role emotional	59.2 ± 19.38	61.0 ± 43.58	−16.9,13.4	0.818
Mental health	65.5 ± 18.92	71.6 ± 15.36	−12.4,0.11	0.054

SF: Short Form; HbA1c: glycosylated haemoglobin; SD: standard deviation; CI: confidence interval

made up of the scores for each of the eight scales in the SF-36. The patients were categorised into two groups based on their glycaemic control status. Glycaemic control was defined using the Asia Pacific Type 2 Diabetes Policy Groups definition. Patients with a HbA1c level ≤ 7.5% were categorised as the good control group and those with a HbA1c level > 7.5% were categorised as the poor control group.[18] All the scales scores ranged from zero to 100. In scoring the SF-36, the guidelines published by the author of the SF-36 were followed. A few items needed reverse scoring.[7] At the univariable analysis, the independent *t*-test was used to compare the unadjusted means of the eight-scale score of the SF-36 between the two groups. For the multivariable analysis, the analysis of covariance (ANCOVA) was used to adjust the confounding effects of age (years) and duration (years) of being diabetic. In SPSS, these two continuous variables were considered as the covariates and the glycaemic control variable was the fixed effect. No interaction was deemed important in the analysis. Adjusted or estimated marginal means were compared between the two groups of controls for all eight scales in the SF-36. The Levenes' test was used to check for the assumption of equal variances. Model diagnostic statistics were analysed using residual plots. Multiple comparison tests using Bonferroni adjustment were used if the ANOVA showed a significant F-test. The level of statistical significance was set at less than 0.05 (two-sided).

RESULTS

A total of 150 patients, comprising 63 (42%) females and 87 (58%) males, were included in the analysis. The mean HbA1c level was 8.9%, with a standard deviation (SD) of 2.4%. The distribution of HbA1c levels is presented in Table I. Table II shows the unadjusted means and SDs in the scores of the eight scales in the SF-36 based on the independent *t*-test. Those in the poor glycaemic control group (HbA1c level > 7.5%) consistently scored lower than those with a HbA1c level ≤ 7.5%. However, none was statistically significant.

The ANCOVA was used to control for the confounding effect of age and duration of being diabetic when comparing the two groups based on their adjusted means. Table III shows the adjusted means of the SF-36 scores, the adjusted mean differences and the p-values. The glycaemic control groups were considered to be the main effect in the ANCOVA analysis for SPSS, while age and duration of having diabetes were the covariates. The results showed that two scales in the Physical Health Component-Physical Functioning and General Health, differed significantly in their adjusted means between the two HbA1c level groups. Two scales in the Mental Health Component-Social Functioning and Mental Health, also differed significantly in their adjusted means. All other scales scores, although not statistically different in their adjusted means, were consistently lower in the poor glycaemic control group. Even though the duration of having type 2 diabetes mellitus was not significantly different in the univariable analysis, its confounding effect was adjusted, as a previous study has shown that this variable is associated with quality of life, along with the status of complications and the number of comorbidities and hospitalisations.[4]

DISCUSSION

It is generally known that the overall quality of life in patients with diabetes mellitus is poorer than in the normal population; however, the extent of this decline related to the level of glycaemic control remains debatable as the results of previous studies have been inconsistent. Among studies that have found no association between quality of life and glycaemic control, one study has shown that despite the overall quality of life scores being

Table III. The difference in estimated marginal means of the scales in the SF-36 between patients adjusted for age and duration of being diabetic.

Scale in SF-36	Adjusted mean		Mean difference	95% CI of mean difference	F-stat	p-value
	HbA1c ≤ 7.5% (n = 103)	HbA1c > 7.5% (n = 47)				
Physical Health Component						
Physical functioning	56.3	65.4	9.0	0.2,17.9	4.07	0.046
Role physical	43.9	57.8	13.9	−0.7,28.4	3.54	0.062
Bodily pain	55.1	60.6	5.6	−2.7,13.8	1.78	0.184
General health	51.6	58.9	7.3	0.4,14.3	4.36	0.039
Mental Health Component						
Vitality	54.6	60.9	6.3	−0.8,13.3	3.09	0.081
Social functioning	65.4	73.9	8.4	0.4,16.5	4.27	0.041
Role emotional	58.0	62.0	4.0	−11.2,19.3	0.27	0.062
Mental health	64.9	71.8	6.9	0.4,13.3	4.38	0.038

SF: Short Form; HbA1c: glycosylated haemoglobin; CI: confidence interval

highest in non-diabetics and a gradual decrease in the mean scores across categories of glucose tolerance, the specific association between glycaemic control (based on Hba1 c levels) and the quality of life scores is not clearly evidenced.[17,19,20] In a stratified population with diabetes mellitus and who have regular health checkups based on the status of their HbA1c levels (< 7.0% v.s ≥ 7.0%), the relationship between the HbA1c level and health-related quality of life was weak, and the HbA1c level was found to be a poor indicator of treatment success.[21,22]

In a prospective study that found a positive association between glycaemic control and quality of life, it was shown that after one year of treatment, patients with controlled HbA1c levels improved in their health functional status based on their RAND-36 scores.[23] The improvements were consistent across almost all aspects of quality of life, although some scales did not show any statistical significance. In another clinical assessment, the improved glycaemic control was associated with improvements in all quality of life domains with the exception of two scales, mental and emotional health, which did not quite reach statistical significance.[19] Therefore, due to these inconclusive results, more studies are needed to examine the relationship between glycaemic control and quality of life. Furthermore, there are many countries that have established the norms of quality of life in their population, usually based on the SF-36. Because of this, the quality of life of type 2 diabetes mellitus patients can be assessed and compared directly with the quality of life of the general population. This information is very important in determining how badly the life of the type 2 diabetes mellitus patients is affected by the disease.

This study compared the results of SF-36 scales scores between two groups with good and poor glycaemic controls. A HbA1c level ≤ 7.5% was defined as good glycaemic control and a Hba1c level > 7.5% as poor glycaemic control. Table III shows that the scores of four scales out of the total of eight in the SF-36 were significantly different between the two groups of patients. Both the Physical Health Component and the Mental Health Component showed statistically significant lower quality of life scores in the poor glycaemic control group. The other four scales scores showed a similar pattern but did not reach statistical significance. This suggests that patients with poor glycaemic control have poorer quality of life in at least some aspects of their lives. The results may have been significant statistically in all the scales if the sample size of the good glycaemic control group had been bigger.

Although this study showed that glycaemic status is negatively associated with quality of life, the issue of whether glycaemic status influences quality of life must be carefully assessed. Since this was a cross-sectional study, the scores of the SF-36 may not be directly influenced by glycaemic status. In addition, during the analysis, the confounding effects of age and the duration of being diabetic were adjusted for. However, since diabetes mellitus affects many systems, there were a few other confounders that were not adjusted. Other factors such as complications, the treatment regime, gender, socioeconomic factors and comorbidities, may have important roles to play.

Complications, which are more common in patients with poorer glycaemic control, decrease the quality of life. Improved quality of life was positively associated with a decrease in hyperglycaemic incidences, which may be a reflection of better glycaemic control.[19,23] In comparison to HbA1c levels, hyperglycaemic symptoms are more clearly associated with the health-related quality, as found in a few studies.[21,22] Complications, such as coronary heart disease, nephropathy, retinopathy, neuropathy or peripheral arterial disease, pose a greater risk to patients with diabetes mellitus who are in the

Table IV. SF-36 scales scores in two groups of glycaemic control in comparison with the SF-36 norms in Malaysian population.

Scale in SF-36	Unadjusted mean ± SD		
	HbA1c ≤ 7.5% (n = 103)	HbA1c > 7.5% (n = 44)	General Malaysian population[16] (n = 3071)
Physical Health Component			
Physical functioning	57.6 ± 25.61	63.7 ± 25.16	85.98 ± 17.91
Role physical	45.6 ± 41.48	55.9 ± 44.00	82.03 ± 32.12
Bodily pain	56.2 ± 23.82	59.3 ± 23.30	69.96 ± 17.59
General health	52.2 ± 19.11	58.1 ± 18.92	66.74 ± 19.99
Mental Health Component			
Vitality	55.2 ± 19.38	60.4 ± 19.78	66.79 ± 17.68
Social functioning	66.3 ± 22.20	72.3 ± 22.80	83.73 ± 19.28
Role emotional	59.2 ± 19.38	61.0 ± 43.58	79.23 ± 35.92
Mental health	65.5 ± 18.92	71.6 ± 15.36	74.6 ± 17.19

SF: Short Form; HbA1c: glycosylated haemoglobin; SD: standard deviation

lowest quartile of the physical functioning dimension of the SF-36 scale, especially in the physical and social functioning and vitality dimensions.[17]

Intensive treatment, although expected to compromise the quality of life of patients with type 2 diabetes mellitus, is associated with an improvement to the quality of life.[23] It is possible that patients who are more satisfied with life adhere better to the treatment regimen, hence resulting in better glycaemic control.[22,24] In another study, it was shown that intensive treatment using insulin among patients with type 2 diabetes mellitus had a more negative impact on the quality of life than for those on oral medications or dietary modifications only, and for patients with type 1 diabetes. However, it was difficult to conclude that insulin usage was an independent factor that led to poorer quality of life, because complications and failure to adhere to dietary changes and oral medications were not adjusted for.[4]

The quality of life of patients with type 2 diabetes mellitus may also be affected by depression. Depression is an important comorbidity in diabetes, as it has been shown that 24% of diabetics are depressed.[17,20] Poor family warmth, uncaring behaviours and inadaptability or a lack of cohesion may be contributors to depression.[22] In a cross-sectional study using different sets of questionnaires, statistically important associations were found between the glycaemic level and several symptoms and mood scores. Patients with higher glycaemic levels were associated with lower wellbeing scores.[25] Similarly, our study showed that two scales in the Mental Health Components-Social Functioning and Mental Health, have significantly lower scores in the poor glycaemic control group (Table IV).

This study used the norms of the SF-36 scores for the Malaysian population to determine the level of quality of life in patients with type 2 diabetes mellitus compared to the general population. Our findings, presented in Table IV, show that all the SF-36 scales scores among type 2 diabetes mellitus patients in our settings were considerably lower than the scales scores of SF-36 norms for the Malaysian population.[16] The results also showed that among the three populations, patients with poor glycaemic control had the lowest scores in all the scales of the SF-36. The two scales that were most severely compromised were the Physical Functioning and Role Physical scales.

Our results add to the body of evidence that poor glycaemic control is associated with lower quality of life in both its physical and mental aspects. This study, however, could not conclude that glycaemic control is the independent factor that leads to poor quality of life (cause-effect relationship) because of its cross-sectional nature.[4] The confounders discussed in this study may affect quality of life, and should be considered in future studies. The socio-demographic and medical-history-disease-severity relationship, such as complications, gender, insulin use and educational levels, are additional factors that should be adjusted, but were not done in this study.[4,23,24,26,27] We also think that the experimental data in a more controlled environment is preferrable so as to establish a clearer effect of glycaemic control on quality of life.[25]

The findings also suggest that the ultimate objective of care is towards a full and productive life.[28] Medical practitioners should be encouraged to ensure intensive treatment with the goal of achieving glycaemic control as close to normal levels as possible. Their patients may not necessarily face deterioration in their quality of life despite the increasing demands of their diabetes care and the increased frequency of hypoglycaemia.[29] In conclusion, this study has shown that type 2 diabetes mellitus patients with poor glycaemic control had lower

quality of life scores in Physical Functioning, General Health, Social Functioning and Mental Health based on the SF-36, when age and the duration of being diabetic were adjusted for. The patients with type 2 diabetes mellitus in this study also had lower quality of life scores than the general Malaysian population, with patients with poor glycaemic control scoring the lowest in all scales.

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