Quality of life in patients with diabetes mellitus before and after their participation in an educational program

ABSTRACT
This quasi-experimental study aimed to evaluate the health-related quality of life in individuals with diabetes mellitus before and after their participation in a five-month educational program in a primary care service in Brazil in 2008. The sample consisted of 51 individuals, 56.9% female and 43.1% male, who had a mean age of 57.65 ± 11.44 years. Data were collected using the Portuguese version of the SF-36 questionnaire. The instrument had adequate reliability estimates for the study sample. Cronbach’s alpha for the two components of the instrument, physical and mental, were 0.83 and 0.89, respectively. The findings suggested improvements in all the domain components; however, only the general health domain, before (63.96 ± 19.03) and after (70.59 ± 17.82) the educational program, presented statistically significant mean differences, t(50) = 2.16, p<0.05. Participation of the subjects in the educational program also contributed to improvements in the perceptions of the individuals regarding their general health status.

DESCRITORES
Diabetes mellitus
Quality of life
Health education
Nursing care

RESUMEN
Estudio cuasi-experimental objetivando evaluar la calidad de vida relacionada a la salud de personas con diabetes mellitus, antes y después de participar de un programa educativo de cinco meses. Participaron 51 sujetos, predominantemente de sexo femenino (56,9%), promedio etario y des-vio estándar de 57,65±11,44 años, en un servicio de atención primaria del interior paulista durante 2008. Datos recolectados mediante cuestionario SF-36. El instrumento se demostró confiable para la población estudiada, el Alpha de Cronbach para componentes físicos y mentales fue de 0.83 y 0.89, respectivamente. Los resultados mostraron discreta mejora en casi todos los dominios, a pesar de que el estado general de salud antes (63,96±19,03) y después (70,59±17,82) del programa educativo haya presentado diferencia estadísticamente significativa t(50)=2,16; p<0,05. La participación de los sujetos en el programa educativo en diabetes mellitus contribuyó también para mejorar la percepción acerca de su estado general de salud.
INTRODUCTION

Diabetes mellitus (DM) represents a public health problem because of its increasing incidence and prevalence. Because it is a progressive disease, the health status of the affected individual tends to deteriorate over time, when complications begin to appear arising from poor glycemic control[1]. This situation can lead to a depreciation in the quality of life (QoL), as it is reflected in different aspects, such as a weakened physical state, impaired physical functioning, lower limb pain, lack of vitality, difficulty in social relationships, and emotional instability.

It is estimated that 15 years after the onset of DM, 2% of affected individuals present blindness, 10% severe visual impairment, 30% to 45% some degree of retinopathy, 10% to 20% nephropathy, 20% to 35% neuropathy and 10% to 25% cardiovascular disease[2]. These health problems significantly increase the costs of caring for individuals with DM and impair their QoL, considering the pain and anxiety generated by the gradual emergence of these complications[2].

Patients with DM, particularly type 2 (DM2), face many adjustment difficulties, which can affect the subjective assessment they make of their living conditions, according to the development stage of the complications related to the disease. Furthermore, it is a chronic condition that persists throughout life and is sometimes accompanied by other comorbidities. Acute complications arising from DM also have a direct impact on QoL because they increase the predisposition to depressive disorders and anxiety, as well as interfering in the work relationships, in the performance of household and school tasks, and in the independence of the individual[3].

Because of the complexity and extent of the problem of living with a chronic disease, studies have focused on investigating the impact of the disease on the health-related quality of life (HRQoL) of the patients affected. Thus, it can be investigated in relation to treatment choice, symptom relief, knowledge about the disease, future perspectives and skills to manage its complications, psychological adaptation to the problems faced and the social impact of the increasing incidence and prevalence. These factors are directly or indirectly related to the HRQoL of the population[4].

Quality of life has been defined as a concept deeply influenced by subjectivity; it includes several factors, such as the perception of well-being and satisfaction of the individual in relation to their physical condition, their emotional and spiritual states, and their performance of functions, which are essential components of the human condition and involve values, attitudes and skills that impact on the quality of the participation in the various dimensions of social life. HRQoL reflects the intention to quantify the impact of a disease and its treatment, according to the perceptions that people have about their abilities to develop their potential and lead a full life. Its measurement is subjective because its domains cannot be measured directly by physical means. Health-related quality of life is related to the perception that the person has of both the impact of their dysfunction and their existence[5].

DM educational programs have been advocated as one of the care strategies that contribute to improving the indicators related to the perception of the physical aspects, functionality, pain, general health condition, vitality, and social, emotional and mental health aspects that affect the health-related quality of life of the patients. However, a literature review found that there is still a lack of studies that evaluate HRQoL before and after the provision of an educational program in DM2. Investigations of this nature can contribute to improving the design of diabetes care and healthcare integrity. Furthermore, measures of HRQoL can support the planning of educational programs and intervention strategies for DM2[6-7].

Given the above statements, the present study aimed to evaluate the health-related quality of life of patients with type 2 diabetes mellitus before and after implementing an educational program.

METHOD

This quasi-experimental, prospective, comparative study has a before and after design[8]. It is quasi-experimental because it consisted of offering an education group for patients with DM2, and the sample was not randomly selected. In this study, the patients constituted their own control, before and after the educational program. Thus, the results of the HRQoL domains before and after the implementation of the program were compared.

The study was conducted in a primary healthcare service of a municipality in São Paulo state in 2008. The study population consisted of all the patients enrolled in this service. The sample consisted of 51 patients who had at least 75% attendance in the activities. The educational program was conducted by a multidisciplinary team consisting of nurses, nutritionists, psychologists, a physical educator and undergraduate students in nursing and psychology. It lasted for five months and took place on Tuesdays from 14h00 to 17h00. It was implemented using the following teaching strategies: in groups, through classroom educational activities, and individually conforming
to the needs of each participant. This program followed the guidelines recommended by the Standards and Norms for Diabetes Education Programs for People with Diabetes in the Americas(7).

The patients were divided into four groups, three groups with 13 members and one with 12. This division into small groups aimed to facilitate the communication between the patients and the team. At each weekly meeting, a scheme of rotation was operated following the specialties: nursing, nutrition, psychology and physical education. Thus, the four groups were treated simultaneously. Twenty meetings were conducted for each group. Individual sessions were conducted according to the needs identified during the group work and aimed to reinforce the strategies proposed in the group meetings. Individual consultations were conducted with approximately 15 participants who had difficulties maintaining metabolic control or inclusion in the group activity.

The contents of the educational lectures were organized considering the difficulties identified by the professionals during the patient care. The topics covered were concept, pathophysiology and treatment of the DM, physical activity, nutrition, care and examinations of the feet, self-monitoring, hypoglycemia, chronic complications, special situations, and family support. For the content development, various teaching strategies were used, such as simulations, role play, experience reports, commemorative celebrations, lectures and demonstrations. The teaching materials included posters, pictures, transparencies, slides, handouts and materials for demonstration, such as syringes, needles, blood glucose monitor, lancets, cotton wool, alcohol, and scales. Thus, the patients were encouraged to assume an active role in the educational process.

The following instruments were used: a questionnaire containing sociodemographic variables and the Portuguese version of the SF-36 Generic Quality of Life Evaluation Questionnaire(10). The choice of this instrument accounted for the fact that it is a generic questionnaire used to evaluate the health profile and can, therefore, be used with various types of diseases and populations. It is an instrument adapted and validated for the Brazilian context and has been used in studies related to the field of health. Although various instruments exist in the international literature to evaluate the HRQoL of people with diabetes, few have been validated for Portuguese(7,11).

The easy to use and comprehend SF-36 instrument, is composed of 36 items grouped in two components: physical and mental. The Physical Component (PC) consists of four domains: Physical Functioning (ten items), Physical Role (four items), Bodily Pain (two items), and General Health (five items). The Physical Component (CM) also consists of four domains: Vitality (four items), Social Functioning (two items), Emotional Role (three items) and Mental Health (five items). The questionnaire also includes an evaluation question comparing the perceived current health status with that of a year ago, which is not added to the domains of the instrument. These components are involved, although differently, in diverse diseases(12).

The SF-36 evaluates both negative aspects of health (disease or infirmity) as well as positive aspects (well-being). It presents a final score ranging from 0 to 100, where zero corresponds to the worse general health status and 100 to the best health status. The scores are computed for each domain and can be presented in a summarized form: PC, which involves the physical functioning, physical role, bodily pain and general health domains, and CM, which encompasses the social functioning, emotional role, mental health and vitality domains. The general health and vitality domains are related, indirectly, to both the PC and the CM.

The data were collected after obtaining the free prior informed consent of the subjects at the study site through individual applications at two different times: G0 at the beginning of the educational program during the patient enrollment stage before starting the education program, and later G1) at the end of the program in the week following the 20th group session.

For the data analysis, descriptive statistics were used to characterize the subjects and the study variables. Pearson’s correlation index for each domain of the questionnaire was calculated, and a paired t-test was used to evaluate differences between the HRQoL domains before and after participating in the educational program. The internal consistency of the two components of the SF-36 was verified using the Cronbach’s alpha values for each of the components and domains of the questionnaire, namely: a) overall for the Physical Component (α = 0.83) and for each of its domains; Physical Functioning (α = 0.85), Physical Role (α = 0.68), Bodily Pain (α = 0.80), General Health (α = 0.67); b) overall for the Mental Component (α = 0.89) and for each of its domains: Vitality (α = 0.76), Social Functioning (α = 0.54), Emotional Role (α = 0.84) and Mental Health (α = 0.82).

The project was approved by the Research Ethics Committee under protocol No. 0667/2006.

RESULTS

Characterization of the subjects

Of the 51 DM patients investigated, their ages ranged from 33 to 80 years, with a mean and standard deviation of 57.65 ± 11.44 years, with 29 (56.9%) females and 22 (43.1%) males. Regarding education, 27 (52.9%) patients had complete elementary education, 13 (25.5%) incomplete/complete high school education and 11 (21.6%) incomplete/complete higher education. The predominant occupations were: work in the home - 14 (27.5%), self-employed - 14 (27.5%), urban salaried workers - 13 (25.5%) and retired - 10 (19.6%).
Self-perception of the health and health-related quality of life

When investigating the self-perception of health, after participating in the educational program, 33.3% of the subjects considered their health to be much better, 33.3% somewhat better, 21.6% about the same, 9.8% a little worse and 2% much worse.

Table 1 shows the domains of the Physical and Mental Components of the SF-36 before and after the subjects had participated in the educational program.

Table 1 - Mean scores of the Physical and Mental Components of the SF-36, before and after the subjects participated in the educational program - Ribeirão Preto, 2007.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Before the Program M ± SD</th>
<th>After the Program M ± SD</th>
<th>Cronbach's Alpha</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Component</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical Functioning</td>
<td>72.74 ± 21.07</td>
<td>73.53 ± 21.54</td>
<td>0.83</td>
</tr>
<tr>
<td>Physical Role</td>
<td>70.10 ± 32.41</td>
<td>61.76 ± 40.42</td>
<td>0.85</td>
</tr>
<tr>
<td>Bodily Pain</td>
<td>57.85 ± 23.48</td>
<td>59.31 ± 24.36</td>
<td>0.68</td>
</tr>
<tr>
<td>General Health</td>
<td>63.96 ± 19.03</td>
<td>70.59 ± 17.82</td>
<td>0.89</td>
</tr>
<tr>
<td>Mental Component</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitality</td>
<td>62.63 ± 19.57</td>
<td>63.53 ± 22.63</td>
<td>0.76</td>
</tr>
<tr>
<td>Social Functioning</td>
<td>73.25 ± 24.63</td>
<td>73.76 ± 24.15</td>
<td>0.54</td>
</tr>
<tr>
<td>Emotional Role</td>
<td>67.33 ± 21.93</td>
<td>62.08 ± 38.88</td>
<td>0.84</td>
</tr>
<tr>
<td>Mental Health</td>
<td>67.33 ± 21.93</td>
<td>67.45 ± 22.55</td>
<td>0.82</td>
</tr>
</tbody>
</table>

In relation to the HRQoL domains of the Physical Component investigated before and after the educational program, the mean scores for Physical Functioning, Physical Role and Bodily Pain remained similar. Conversely, it was found that there was an improvement in the perception of the subjects in relation to the General Health before (63.96 ± 19.03) and after (70.59 ± 17.82) the program.

Regarding the HRQoL domains of the Mental Component, the scores also remained similar for Vitality, Social Functioning, and Mental Health and decreased for the Emotional Role domain, which was 67.33 ± 21.93 before and 62.08 ± 38.88 after the program. This result indicates that perceiving the real health condition can lead individuals to experience psychological discomfort.

Concerning the evaluation of the HRQoL of the patients studied (Table 1), before the educational program, the mean values obtained for the eight components of the SF-36 ranged from 57.85 (Bodily Pain) to 73.25 (Social Functioning). In this first evaluation, three domains of the HRQoL measure showed low mean scores: Bodily Pain (57.85), Vitality (62.63) and General Health (63.96). The domains that had higher mean scores were: Social Functioning (73.25), Physical Functioning (72.74) and Physical Role (70.10).

After the five-month educational program, the mean scores obtained for the eight domains of the SF-36 ranged from 59.31 for Bodily Pain to 73.76 for Social Functioning. In the second evaluation, it was observed that four HRQoL domains had low means: Bodily Pain (59.31), Physical Role (61.76), Emotional Role (62.08) and Vitality (63.53). The results show that the participants felt harmed by the limitations imposed by their physical health. The domains with the higher mean scores were Social Functioning (73.76), Physical Functioning (73.53) and General Health (70.59). The calculation of the Cronbach’s alpha indices proved to be acceptable for the majority of the domains investigated, except for the Physical Role (α = 0.68), General Health (α = 0.67) and Social Functioning (α = 0.54) domains.

Table 2 shows the matrix of Pearson correlations between the SF-36 domains. In relation to the Pearson correlations calculated between the domains, the majority presented statistically significant correlations, with p≤0.05.

Table 2 - Pearson’s correlations matrix between the SF-36 domains - Ribeirão Preto, 2007.

<table>
<thead>
<tr>
<th>Domains</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Physical Functioning</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2. Physical Role</td>
<td>.21</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>3. Bodily Pain</td>
<td>.42**</td>
<td>.34*</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. General Health</td>
<td>.44**</td>
<td>.09</td>
<td>.28*</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Vitality</td>
<td>.45**</td>
<td>.28*</td>
<td>.31*</td>
<td>.49**</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>6. Social Functioning</td>
<td>.27*</td>
<td>.11</td>
<td>.27</td>
<td>.41**</td>
<td>.55**</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Emotional Role</td>
<td>.98</td>
<td>.52**</td>
<td>.09</td>
<td>.27*</td>
<td>.43**</td>
<td>.42**</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>8. Mental Health</td>
<td>.19</td>
<td>.24</td>
<td>.30*</td>
<td>.51**</td>
<td>.80**</td>
<td>.54**</td>
<td>.44**</td>
<td>.44**</td>
</tr>
</tbody>
</table>

Regarding the analysis of the HRQoL domains before and after the participation in the educational program, the results indicated that only the General Health domain before (63.96 ± 19.03) and after (70.59 ± 17.82) showed a statistically significant difference t(50) = -2.16, p ≤ 0.05.

**DISCUSSION**

The sociodemographic characteristics of the subjects showed a predominance of females (56.9%) with a mean age and standard deviation of 57.65 ± 11.44 years, schooling equivalent to complete and incomplete elementary education (47%) and occupations related to activities in the home (27.5%) and self-employment (27.5%). These characteristics are relevant to comprehending the HRQoL domains. The data support the literature, considering that the female global population is larger than that of males, which would partly explain the higher proportion of female participants in the study. Furthermore, women are characterized as more frequently seeking healthcare services.

The age data from this study corroborated those found in the national multicentric study of DM prevalence, which found that the frequency of the disease gradually increases after age 50; this finding relates to the progressive trend of population aging currently observed in Brazil. Regarding education, the majority of the patients had complete elementary education, a higher level than that found in other studies. Concerning occupation, the data showed that nearly half of the subjects were members of the labor market.
When analyzing how the patients perceive their health, it is considered that a positive self-perception enables greater involvement in the treatment and control of the disease. Improvement was observed in 66.6% of the subjects (33.3% much better and 33.3% a little better) after their participation in the educational program. However, to better comprehend this issue, there is a need for further studies to identify the variables that determine the positive or negative perception of the health condition[16]. Regarding the eight domains of the SF-36 investigated, it was found that domains relating to the physical component affected the HRQoL of the patients with DM more than those related to the mental health. In the subjective assessment of the subjects prior to the educational program, the pathophysiological problems relating to health prevailed in relation to the domains of the mental health component.

DM can adversely affect the physical well-being because of the acute and chronic complications and of the treatment demands. The chronic complications in people with DM2 may affect the quality of life; however, actions that aim for intensive control of glycemia and arterial pressure may avoid these repercussions. In a study conducted in southeastern Mexico, applying the SF-36 to people with chronic health conditions, the highest value was obtained for the Physical Functioning dimension and the lowest for the General Health domain. For the control group, in which one of the inclusion criteria was not having a chronic condition, the highest value was obtained in the Physical Role domain and the lowest value in the General Health domain[17]. In assessing the impact of chronic conditions on the HRQoL of populations of eight countries, through the SF-36, a notable impact of DM was observed in the score of the dimension related to General Health[18]. In a study aiming to evaluate the HRQoL and DM2, the domains that obtained the lowest scores were General Health and Vitality[19].

In contrast, in this study the domains that obtained the lowest scores were Bodily Pain, Vitality and General Health, which suggested that the subjects studied perceived impairments, such as depression, weakness and discomfort, related to poor metabolic control. Conversely, the higher mean scores obtained in the Social Functioning and Physical Functioning domains may reflect the peculiar situation of the sample, considering that the majority of the subjects maintained work activities.

In summary, participation in the educational program contributed to improvements in the General Health domain and a decline in the Physical Role domain. A study evaluating the QoL of 46 patients with DM showed that 39 (84.8%) reported that the disease changed their QoL, while seven (15.2%) reported no changes. Fifteen (35.5%) individuals reported changes in the areas related to work, study and home activities, and 10 (25.6%) indicated that the main changes were in Physical Functioning[20]. However, a study of 65 patients undergoing treatment for DM2 examined the relationship between sociodemographic variables, locus of control and self-esteem; it showed that the subjects presented preserved self-esteem, despite their health problems and unfavorable sociodemographic and clinical conditions[21].

A study of 495 patients with DM2 evaluated the influence of glycemic control and cardiovascular risk factors on the HRQoL; lower scores were found in four domains of the SF-36: Physical Role, Bodily Pain, General Health and Vitality. Thus, the patients performed worse in the physical dimensions, while preserving the social aspects and mental health. Hypertension, obesity and poor metabolic control were associated with a worse subjective assessment of the health status[19].

By comparing the domains before and after the five-month educational program, improvements were obtained in the quality of life in four of the SF-36 domains, namely: Physical Functioning (73.53), General Health (70.59), Vitality (63.53) and Bodily Pain (59.31). It was found that only the General Health domain of the HRQoL Physical Component of the patients improved over the five months of the program, with a statistically significant difference between the values obtained before and after the program. The Social Functioning and Mental Health domains maintained virtually the same mean scores before and after the educational program. The changes in attitudes and the increased knowledge about the disease and the proposed treatment requires time, which varies from person to person, for the development and incorporation of the knowledge that results in self-care actions to improve glycemic control, which in turn may be reflected in better HRQoL. The Bodily Pain domain presented the lowest mean scores, both before and after the educational program. Note that DM is an asymptomatic disease, in which pain can manifest in the advanced stages of chronic complications.

The internal consistency of the SF-36 was <0.70 for three domains: Social Functioning (Cronbach’s alpha of 0.54), General Health (0.67) and Physical Role (0.68), which may indicate a lack of consistency in the responses of the subjects. One of the factors that possibly affected the comprehension of the subjects in relation to the items of the SF-36 may be related to the educational level and age of the study population. For the other domains, the internal consistency of the SF-36 ranged from 0.76 to 0.85. The dimension that presented the highest Cronbach’s alpha value was Physical Functioning (α = 0.85), followed by the Emotional Role, Mental Health, Bodily Pain, and Vitality domains.

Regarding the correlations encountered (Table 2), note that the higher scores indicate less compromise in that domain. It was observed that the correlation was positive and statistically significant between all the domains, indicating good internal consistency among them. For this analysis, the correlation values considered were according to the classification: very low (0 to 0.25), low (0.26 to 0.49), moderate (0.50 to 0.69), high (0.70 to 0.89) and very high (0.90 to 1.00)[22]. In the present study the lowest value was 0.09 between General Health and Physical Role and between Emotional role and Bodily Pain, and the highest (0.98) between Emotional Role and Physical Functioning. Maintaining the HRQoL should be one of the main goals in treating DM. Currently, despite its recognition as an important concept for achieving the therapeutic goal, HRQoL is rarely evaluated in educational programs for DM[23].
CONCLUSION

The data obtained in this study showed a slight improvement in the HRQoL in almost all the domains, although only the General Health before (63.96 ± 19.03) and after (70.59 ± 17.82) the educational program presented statistical significance - t(50) = -2.16, p <0.05. The instrument was shown to be reliable for the population studied, with the Cronbach’s alpha values obtained for the two components of the instrument (PC and MC) being 0.83 and 0.89, respectively. It was concluded that subject participat-
ing in the DM educational program also contributed to improving their perception of their general health status.

One limitation of this study that should be mentioned was not using a specific instrument to evaluate the HRQoL of people with DM because the generic instrument is not targeted toward the specific characteristics of the disease under study or the people affected. It is recommended that healthcare professionals recognize the need to investig-
tate QoL using an instrument that is specifically designed for people with DM, as well as performing further studies with the same proposal, with longer education programs for future comparisons.

REFERENCES


