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ORIGINAL ARTICLE

Specific foot health-related quality-of-life impairment in patients with type II versus type I diabetes

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The aims of this research were to evaluate and compare the effect in a matched sample of patients with type II and type I diabetes scores using a specific quality-of-life (QoL) tool related to overall and foot health (Foot Health Status Questionnaire [FHSQ]). A sample of 62 patients with an age median of 59.00 ± 19.00 y were divided into type I ($n = 31$) and type II ($n = 31$) diabetes groups. Socio-demographics data include: (1) age, (2) gender, (3) body mass index, (4) professional activity, (5) study level, and (6) civil status. The FHSQ was used to evaluate foot (pain, function, footwear, and general health section I domains) and overall (general health, social capacity, physical activity, and vigour section II domains) health related to QoL. Differences between groups were assessed by means of a *t* test or Mann-Whitney *U* test for independent samples. There were no statistically significant differences ($P > 0.05$) for any socio-demographic data. Regarding the FHSQ section II of the specific foot health-related QoL, the only statistically significant differences ($P = 0.042$) were observed for the general foot health showing a QoL impairment (lower median ± interquartile range) in patients diagnosed with type II diabetes (60.00 ± 60.00 points) compared with patients who suffered from type I diabetes (25.00 ± 72.50 points). The other domains did not show any statistically significant differences ($P > 0.05$). Patients with type II diabetes present a negative impact on the specific foot health-related QoL compared with patients who suffered from type I diabetes.

KEYWORDS

diabetes mellitus, diabetic foot, foot deformities, foot diseases, quality of life

1 | INTRODUCTION

Diabetes is a common and complex chronic illness with many consequences related to physical activity, psychological aspects, and clinical complications; for patients who presented with this condition,[1] it may be associated with a marked presence of foot problems and complications.[2]

The frequency of both type II and type I diabetes in the Spanish population is approximately 5.6% and 15.9%,[3] with an incidence of over 11–12 in 100 000 people annually.[4] The growth and severity of many of the diabetes symptoms appear to be associated with foot complications.[5] In addition, the International Diabetes Foundation recognised this condition as a substantial threat to public health because of its negative impact on patients and families and the global medical and economic costs.[6]

However, no existing research has been carried out so far to evaluate the quality-of-life (QoL) associated with foot health in patients with type II versus type I diabetes.

Diabetic foot problems may present as injuries on the surface and also in the deep tissues related to neurological conditions and vascular problems in the legs,[7] and may affect both mortality and morbidity in people with diabetes, with a global incidence over 1%–4% in all the world.[8,9]

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Furthermore, approximately 85% of amputations are related to foot ulcers, and an amputation is carried out every 20 s in the world because of this illness.[10]

Based on this background, and taking into account this important problem related to control in diabetic foot care, it is important to consider style of life, diet, alterations of the foot, and other illnesses risk factors in order to prevent complications and improve the management of the diabetic foot to improve the QoL and well-being of the diabetic population.

Thus, the aims of the research aim were to evaluate and compare the effect in a matched sample of patients with type II versus type I diabetes scores using a specific QoL tool related to overall and foot health (Foot Health Status Questionnaire [FHSQ]). We hypothesised that patients with types I versus II diabetes may display different impairments related to QoL and foot health.

Key Points

- we have evaluated the quality-of-life (QoL) impact in a matched sample of patients with type II versus type I diabetes
- people with diabetes type II showed a specific foot health-related QoL impairment for general foot health
- preventive care in people with type I or II diabetes is extremely important to control foot and general health.

2 | METHODS

A total of 62 patients were enrolled in an observational study carried out at the Clinic of Podiatric Medicine and Surgery that provides treatment for diseases and disorders of the foot at the University of Extremadura in the city of Plasencia, Cáceres (Spain) during the period April, 2017 to December, 2017. Cases subject to research were selected using the consecutive sampling technique. The inclusion criteria comprised a prior diagnosis of type I or II diabetes by a medical specialist, and the ages of the people included in the study ranged from 30 to 86 y. Disregarded cases included: patients who had experienced acute pathological fracture; previous amputations or trauma and feet surgery records; active systemic neoplastic, infectious, autoimmune, or neurological alterations; lack of or partial autonomy in daily activities, the refusal to sign an informed consent form, or were incapable of understanding the instructions necessary to carry out the present study; and participants of other nationalities (non-Spain) who did not know Spanish.

2.1 | Procedure

A single trained researcher with 20 years' full-time experience in the podiatric medical service recorded baseline measurements; the first step included an interview about disease and clinical characteristics, which included age, gender, and presence of predisposing factors (diabetes, obesity, depression, vascular disease, trauma, osteoarticular pathology, or participation in sports).

Following this interview, patients removed their footwear and hosiery, after which a single researcher assessed height and weight with the subject barefoot and wearing light clothing, and the body mass index (BMI) was calculated from the height (m) and weight (kg^2), applying Quetelet's equation as follow: BMI = weight/height^2.[11]

Then, the physician examined foot disorders and the structural integrity through palpation, mobility, and strength testing on the foot. Diagnosis of the foot problems was also assessed using ultrasonography or prior radiographic evidence, and the researcher had full access to the electronic chart of the patient to check for any other foot pathology and systemic diseases.

Finally, the FHSQ was used to assess and compare the QoL related to foot health and health regarding general impact.[12] This self-administered questionnaire on health-related QoL is intended specifically for the foot and is recognised as a validated test, as previously described in detail .[13,14]

This self-administered tool is comprised of three sections.[15,16] Section 1 includes 13 questions about four foot health-related subcategories: foot function, foot pain, footwear, and general foot health. Each domain comprises a questions-specific number: four questions considering pain, four questions regarding function, three questions on footwear, and two questions on general foot health. The pain and function assessment is composed based on physical phenomena, and the footwear assessment determines practical aspects with respect to availability and shoes comfort, while the foot's general health perception depends on the patients' self-evaluation of their feet state. Each question has several options, and a Likert-type ordinal scale is presented (words/phrases according to a numeric scale). The scales' descriptors vary for each subscale or domain, and the subject completing the questionnaire must to choose only one response item, whichever he or she thinks is the most appropriate. The questionnaire does not show a global score but, rather, provides an index for each subscale or domain. Consequently, the responses are obtained by a computer programme (FHSQ, 1.03 Version), which, after data processing, provides a score from 0 to 100. A score of 0 shows the worst foot health state, and a score of 100 reflects the best possible condition. Furthermore, graphical images of the outcomes are provided by this software.

This section has shown a high degree of content, criterion, and construct validity (the Cronbach α varies from 0.89 to 0.95) and high retest reliability (the intra-class correlation coefficient ranges from 0.74 to 0.92).[14]

Section 2 spans the four subscales or domains of overall health: general health, physical function, social function, and

vitality. The domains and questions in this section are largely adapted from the Medical Outcomes Study 36-Item Short-Form Health, which has been demonstrated to be valid.[17]

Finally, section 3 collects data on socio-economic status, comorbidity, service utilisation and satisfaction information and the patient's medical record.

This study was conducted according to the Strengthening the Reporting of Observational Studies in Epidemiology guidelines (STROBE).[18]

2.2 | Ethical considerations

The protocol study was approved by the Institutional Research and Ethical Committee at public University of Extremadura, in the city of Badajoz, located in the southwest of Spain, with the registered number 31/2017. In addition, the guidelines of the World Medical Association (W.M.A.) and the Declaration of Helsinki and those of other institutions were followed at all times. Furthermore, all participants gave their informed consent before being included in our research.

2.3 | Sample size calculation

A sample size calculation was carried out by using the difference between two independent groups using the G*Power 3.1.9.2 software and based on the Foot Function domain of the FHSQ from a pilot study ($n = 20$) with two groups (mean ± SD). A group of 10 patients with type I diabetes (92.50 ± 17.62) and a group of 10 patients with type II diabetes (71.87 ± 30.08) were used for the analysis. Two-tailed hypothesis, an effect size of 0.83, an α error probability of 0.05, a power (1-β error probability) of 0.90, and an allocation ratio (N2/N1) of 1 were used for the sample size calculation. Therefore, a total sample size of 62 patients with diabetes, 31 for each group, was estimated.

2.4 | Statistical analysis

The Shapiro–Wilk test was used to evaluate normality, and data were established as normally distributed if $P > 0.05$. Regarding the quantitative data, the normality test results showed a non-normal distribution, except for age and height, of the demographic data. For the non-parametric data, median, interquartile range (IR), and minimum–maximum (range) were used to describe the data, except for the parametric data (age and height), which were described as mean, SD, and minimum–maximum (range). Considering the categorical variables (professional activity, study level, civil status, and gender), frequency and percentages were use to describe the sample.

For the comparison of quantitative data between both groups, independent Student t tests were used to established whether there were statistically significant differences regarding the parametric data (age and height), while Mann-Whitney U tests were used for the non-parametric data (rest of variables). Regarding the categorical variables, Chi-squared test (for professional activity, study level, civil status, and BMI ranges) and Fisher exact test (for gender) were used to demonstrate whether a significant difference was obtained between all observed frequencies.

In all analyses, statistically significant differences were obtained if a P-value < 0.05, with a 95% confidence interval (CI). All analyses were performed using the SPSS software (version 22.0) for Windows (SPSS Inc., Chicago, Illinois).

3 | RESULTS

3.1 | Socio-demographic data

A total sample of 62 matched-paired patients diagnosed with type I ($n = 31$) and type II ($n = 31$) diabetes, with an age range from 30 to 86 y, completed the research. The sample comprised 60 (64.5%) females and 22 (35.5%) males. There were no statistically significant differences ($P > 0.05$) for

TABLE 1 Demographic and descriptive data of the patients with diabetes

Demographic data		Total group ($n = 62$)	Type I ($n = 31$)	Type II ($n = 31$)	P-value
Age (y)		59.00 ± 19.00 (30–86)	56.00 ± 29.00 (30–79)	60.00 ± 14.00 (32–86)	0.269[a]
Weight (kg)		75.35 ± 13.61 (48–115)	76.58 ± 14.86 (48–115)	74.13 ± 12.39 (55–115)	0.483[b]
Height (m)		1.63 ± 0.08 (1.51–1.83)	1.63 ± 0.08 (1.55–1.77)	163.00 ± 0.00 (1.51–1.83)	0.799[a]
BMI (kg/m^2)		27.91 ± 4.43 (19.98–40.75)	28.43 ± 4.93 (19.98–38.87)	27.38 ± 3.86 (20.70–40.75)	0.359[b]
BMI range	Normal	18 (29.0%)	8 (25.8%)	10 (32.3%)	0.333[c]
	Overweight	29 (46.8%)	13 (41.9%)	16 (51.6%)	
	Obese	15 (24.2%)	10 (32.3%)	5 (16.1%)	
Gender	Male	22 (35.5%)	9 (29.1%)	13 (41.9%)	0.426[d]
	Female	40 (64.5%)	22 (70.9%)	18 (58.1%)	

Abbreviations: BMI, body mass index. In all the analyses, $P < 0.05$ (with a 95% confidence interval) was considered statistically significant.
[a] Median ± interquartile range, range (min–max), and Mann-Whitney U test were used.
[b] Mean ± SD, range (min–max), and Student's t test for independent samples were applied.
[c] Frequency, percentage (%), and Chi squared (χ^2) test were used.
[d] Frequency, percentage (%), and Fisher's exact test were used.

TABLE 2 Social characteristics of the patients with diabetes

Social characteristics		Total group ($n = 62$)	Type I ($n = 31$)	Type II ($n = 31$)	P-value[a]
Professional activity	Student	0 (0%)	0 (0%)	0 (0%)	0.083
	Freeland	5 (8.1%)	5 (16.1%)	0 (0%)	
	Employed	20 (32.3%)	9 (29.0%)	11 (35.5%)	
	Unemployed	6 (9.7%)	4 (12.9%)	2 (6.5%)	
	Retired	31 (50%)	13 (42.0%)	18 (58.0%)	
Study level	I. primary	17 (27.4%)	10 (32.2%)	7 (22.6%)	0.118
	C. primary	16 (25.8%)	4 (12.9%)	12 (38.7%)	
	Secondary	15 (24.2%)	10 (32.2%)	5 (16.1%)	
	Degree	8 (12.9%)	3 (9.8%)	5 (16.1%)	
	S. degree	6 (9.7%)	4 (12.9%)	2 (6.5)	
Civil status	Single	9 (14.5%)	5 (16.1%)	4 (12.9%)	0.620
	Divorced	2 (3.2%)	0 (0%)	2 (6.5%)	
	Widowed	10 (16.1%)	5 (16.1%)	5 (16.1%)	
	Couple	8 (12.9%)	5 (16.1%)	3 (9.7%)	
	Married	33 (53.2%)	16 (51.7%)	17 (54.8%)	

Abbreviations: C, complete; I, incomplete; S, superior. In all the analyses, $P < 0.05$ (with a 95% confidence interval) was considered statistically significant.
[a] Frequency, percentage (%), and Chi-squared test (χ^2) were used.

any socio-demographic data. Tables 1 and 2 demonstrate the demographic and social characteristics of the sample.

3.2 | FHSQ between types I and II diabetes

The FHSQ scores and domains between patients diagnosed with type I and type II diabetes are shown in Table 3. Regarding the FHSQ section II of the specific foot health-related quality of life, the only statistically significant differences ($P = 0.042$) were observed for general foot health, showing a QoL impairment (lower median ± IR) in patients diagnosed with type II diabetes (60.00 ± 60.00 points) compared with patients who suffer from type I diabetes (25.00 ± 72.50 points). The other domains did not show any statistically significant differences ($P > 0.05$).

4 | DISCUSSION

The aim of our study were to evaluate and compare the effect in a matched sample of patients with type II versus type I diabetes using a specific QoL tool related to overall and foot health, the FHSQ.

Foot health is essential to people with diabetes, largely because of the growth prevalence of foot ulcers and amputation. Diabetic foot problems have been recognised as an important public health problem, as stated by Al-Rubeaan et al., who analysed 62.681 patients with diabetic foot and risk factors, reporting 1285 patients (62.05%) with foot ulcers and 677 patients (32.20%) with foot gangrene, which increased with the age, duration of the diabetes, and male gender.[5] Other research has also indicated moderate or decreased satisfaction with the QoL related to health.[19,20]

However, based on our findings and the lack of research reporting on the impact of the QoL related to foot health in patients with type II and type I diabetes, the findings of our study confirmed that people with type II diabetes presented with a specific foot impact on the QoL dimension related to general foot health compared with patients who suffered from type I diabetes.

TABLE 3 Comparisons of FHSQ scores in patients with diabetes

FHSQ domains	Total group ($n = 62$) Median ± IR (range)	Type I ($n = 31$) Median ± IR (range)	Type II ($n = 31$) Median ± IR (range)	P-value Type I versus type II[a]
Foot pain	78.75 ± 51.88 (6.25–100)	87.50 ± 45.63 (29.38–100)	68.75 ± 58.13 (6.25–100)	0.143
Foot function	78.12 ± 37.50 (0–100)	100.00 ± 25.00 (0–100)	75.00 ± 37.50 (6.25–100)	0.057
Footwear	50.00 ± 52.08 (0–100)	50.00 ± 41.67 (0–100)	50.00 ± 58.33 (0–100)	0.446
General foot health	60.00 ± 60.00 (0–100)	60.00 ± 60.00 (0–100)	25.00 ± 72.50 (0–100)	**0.042**
General health	50.00 ± 50.00 (10–100)	50.00 ± 40.00 (20–90)	50.00 ± 50.00 (10–100)	0.426
Physical activity	83.33 ± 44.44 (5.56–100)	83.33 ± 38.89 (5.56–100)	77.77 ± 88.89 (11.11–100)	0.221
Social capacity	87.50 ± 37.50 (25–100)	75.00 ± 37.50 (25–100)	100.00 ± 37.50 (25–100)	0.351
Vigour	56.25 ± 39.06 (0–100)	50.00 ± 37.50 (0–93.75)	62.50 ± 31.25 (0–100)	0.073

Abbreviations: FHSQ, Foot Health Status Questionnaire; IR, interquartile range. In all the analyses, $P < 0.05$ (with a 95% confidence interval) was considered statistically significant (bold).
[a] Median ± interquartile range, range (min–max), and Mann–Whitney U test were used.

Thus, these findings showed the importance of diabetic foot and podiatric care to prevent foot problems and amputations and improve the QoL and autonomy.

It is more difficult to analyse the impact of these findings with other investigations because of the several differences related with methodological variations as we have not been able to find any articles in the literature studying QoL and foot health of diabetic people comparing types I and II diabetes.

This research had several limitations, such as a sample with only patients from one country, which could be improved in future studies in order to strengthen the research methodology. The influence of other cultures and the identification of other involved mechanisms should also be considered. Moreover, although a sample size calculation was carried out, consecutive sampling bias should be considered, and a simple randomisation sampling process would be better. Further research is necessary to deepen the understanding of the presence of foot complications in diabetes and to study how to improve the QoL and mental health of these patients.

5 | CONCLUSIONS

The patients with type II diabetes present a negative impact on the specific foot health-related QoL compared with patients who suffered from type I diabetes.

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Conflict of interest

The authors did not receive any financial assistance from or have any personal relationships with other people or organisations that could inappropriately influence (bias) their work.

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