Journal of Tissue Viability 31 (2022) 790–793

Contents lists available at ScienceDirect

Journal of Tissue Viability

journal homepage: www.elsevier.com/locate/jtv

# The implications of diabetic foot health-related with quality of life: A retrospective case control investigation

Luis López-López [a], Marta Elena Losa-Iglesias [b], Juan Gómez-Salgado [c,d], Ricardo Becerro-de-Bengoa-Vallejo [e], Carlos Romero-Morales [f], Daniel López-López [a,*], Carmen de Labra [g], Emmanuel Navarro-Flores [h]

[a] Research, Health and Podiatry Group, Department of Health Sciences, Faculty of Nursing and Podiatry, Industrial Campus of Ferrol, Universidade da Coruña, Ferrol, Spain
[b] Faculty of Health Sciences, Universidad Rey Juan Carlos, Alcorcón, Spain
[c] Department of Sociology, Social Work and Public Health, Faculty of Labour Sciences, University of Huelva, Huelva, Spain
[d] Safety and Health Postgraduate Programme, Universidad Espíritu Santo, Guayaquil, Ecuador
[e] School of Nursing, Physiotherapy and Podiatry, Universidad Complutense de Madrid, Madrid, Spain
[f] Faculty of Sport Sciences, Universidad Europea de Madrid, Villaviciosa de Odón, Madrid, Spain
[g] NEUROcom, Centro de Investigaciones Científicas Avanzadas (CICA), Instituto de Investigación Biomédica de A Coruña (INIBIC), Faculty of Nursing and Podiatry, University of A Coruna, Spain
[h] Faculty of Nursing and Podiatry, Department of Nursing, University of Valencia, Frailty Research Organizaded Group (FROG), Valencia, Spain

ARTICLE INFO

*Keywords:*
Diabetic foot
Diabetes mellitus
Foot diseases
Quality of life

ABSTRACT

*Background:* The diabetes people show a significant presence of foot health problems are usually all over the world, causing in big economic effects for these persons, their families and world population
*Objective:* The purpose of this research is to evaluate and relate the impact of foot health associated with the quality of life (QoL) in a group of people with and without diabetes
*Material and methods:* A total of 150 persons of a mean age of 71.45 ± 11.93 years came to a foot and ankle specialist outpatient center. Self-reported data were medical records where persons'with and without diabetes was evaluated. All findings obtained was compared with scores quality of life using the tool Foot Health Status Questionnaire, spanish version
*Results:* The diabetes group revealed a reduction of QoL linked to overall health and to foot health in particular. Differences among both groups were analyzed by means of a independent Student's t-test samples, displaying a p-value lower than 0.05 statistically significant for the domains of foot pain, foot function footwear and social capacity
*Conclusions:* Diabetes people recorded a negative influence on the QoL related with foot health, that seems to be linked with the presence of chronic disease in diabetes people.

## 1. Introduction

The diabetes people show a significant presence of foot health problems are found around 3% to 13% all over the world [1,2], causing a big economic effects for these individuals, their families and the world population [3], this being identified by the institutes of health, policy makers and governments as a main issue threat to public health due to its influence on the independence [4], welfare on persons and the increase others variables that continue unknown in a diabetic patients setting [5].

Currently, diabetic foot health problem is a complication of this chronic disease who reveale a increase prevalence to 6.3% [6], which is correlated with a most a important mortality, morbidity and predictor for lower-limb amputations [7]. The most typical problems consist of

* Corresponding author. Universidade da Coruña, Industrial Campus of Ferrol, Research, Health and Podiatry Group, Faculty Nursing and Podiatry, Department of Health Sciences, 15403, Ferrol, Spain.
*E-mail addresses:* luis.lopezl@udc.es (L. López-López), marta.losa@urjc.es (M.E. Losa-Iglesias), salgado@uhu.es (J. Gómez-Salgado), ribebeva@ucm.es (R. Becerro-de-Bengoa-Vallejo), carlos.romero@universidadeuropea.es (C. Romero-Morales), daniellopez@udc.es (D. López-López), c.labra@udc.es (C. de Labra), emmanuel.navarro@uv.es (E. Navarro-Flores).

https://doi.org/10.1016/j.jtv.2022.07.003
Received 15 January 2022; Received in revised form 2 July 2022; Accepted 11 July 2022
Available online 14 July 2022

destruction of tissues, infections and ulcerations associated both neurological disease and peripheral disorders in the lower extremities [8]. All of them are preventable by a regular good foot care made by the diabetic patient and annual screening to examination the any risk for diabetic foot complications [9,10].

Despite it no investigations have been realized until this date that analyse the foot health specifically associated with the quality of life (QoL) in a group of people with and without diabetes.

Based on these previous reports that show the presence of a need of check of diabetic foot health in persons who suffer from this non communicable disease, where is demonstrated the importance the key role of foot healthy as determinant to improve the autonomy, the overall health indicators and welfare of these patients. We hypothesized that diabetic foot patients may present a poor impact on all domains related with foot health-related quality of life.

Thus, the purpose of this research is to evaluate and relate the impact of foot health associated with the QoL in a group of people with and without diabetes with standardised reference values.

## 2. Materials and methods

### 2.1. Design and sample

This is a descriptive a retrospective case control investigation carried out in a foot and ankle specialist outpatient center in the town of A Coruña (Spain), realized during thirteen months, since January 2017 to February 2018. Also, our investigation followed the criteria to the Strengthening the Reporting of Observational Studies in Epidemiology guidelines [11]. The registry of the election of the cases group and control group in this investigation was prepared applying a non-probabilistic convenience sampling protocol.

Furthermore, the criterion for inclusion in the control group were next: 1) being aged eighteen or over, 2) healthy persons without relevant medical disease records, 3) informed written consent and 4) finished all phases of this research. The criterion for exclusion comprised: 1) persons with immunodepression, 2) previous trauma and foot surgery history, 3) psychiatric and neurological alterations, 4) loss autonomy in its independence daily, 5) negative to sign the informed consent form and 6) incapable to complete this investigation.

Regarding, the criterion for inclusion in the cases group were next: 1) being aged eighteen or over, 2) diabetic persons without relevant medical disease records, 3) informed written consent and 4) finished all phases of this investigation. For the exclusion criteria being a: 1) diabetic person with immunodepression, 2) previous trauma, orthopaedic and or surgery foot treatment history, 3) psychiatric conditions, 4) loss of daily independence, 5) rejection to sign the informed consent document and 6) incapable to complete this study.

### 2.2. Procedure

All baseline measurements consisted of an inform related with: 1) overall health status, 2) anthropometric characteristics (age, body mass index and sex), 3) medical and surgical history, 4) type of medical illness, 5) current medication list and 6) participation of daily activities.

Next, a one single clinican was assesment the overall foot health status for determine the structural integrity via palpation of foot pulses, muscle strength, joint mobility, tenderness exam and as well also had full access to the electronic medical record of the each patient to revised for any foot condition and or their medical general health.

After that, all patients filled out the spanish version of the Foot Health Status Questionnaire (FHSQ) [12]. This self-administered test is a known as a validated tool for to evaluate specifically the foot health and the overall health associated to QoL [13]. FHSQ, which, when scored, provides three sections results with a range of 0–100, with 100 being the maximum puntuaction. The first section measures foot pain, foot function, footwear, general foot health and has showed a strong degree in the content, the criterion, and the construct validity with a cronbach range of 0.89–0.95, and a elevate retest reliability with a intraclass correlation coefficient with a range of 0.74–0.92 [14]. The second section focuses at general health, physical activity, social capacity, vitality, tool-based of Medical Outcomes Study 36-Item Short-Form Health, which has showed validated [15]. The last section evaluate anthropometric characteristics as age, sex and their medical and surgical history [16].

### 2.3. Sample size

The sample number size was determined for this descriptive a retrospective case-control investigation using a software package accessible Epidat (version 4.2); SERGAS Corp., Santiago de Compostela, Spain [17].

A total sample size of 132 participants (66 per each group) was required assuming a 95% confidence level, a 85% of power, to detect a 3.0 odds ratio and an estimated proportion in the control group of 50% and in the cases group of 75%. Finally, in this present investigation was included a total sample of 150 persons.

### 2.4. Ethics considerations

This research was authorized and written approval by the Clinical Research Ethics Committee of Galicia (Spain), record code number 2016/205. All persons signed the document consent, ahead of their participation in this research. Furthermore, the ethical standards for investigation on human beings associated on the guidelines of Declaration of Helsinki, as wel as of the confidentiality of the protected data was applied in accordance with law 3/2018, from 5 of december of the Spain government.

### 2.5. Statistical analysis

A descriptive analysis was performed of the all variables included in this research was performed. Categorical variables were expressed as absolute values and percentages 95%. Quantitative variables were summarized as median, mean ± standard deviation, range (minimum and maximum) values and compared between groups of diabetics persons and no diabetics persons.

All variables were contrasted for normality of distribution applying the Kolmogorov-Smirnov (K–S) test and statistical data were considerated normally distributed if p-value lower than 0.05.

A chi-square test was used to compare categorical variables, whereas an independent Student's t-test was contrasted to find if differences are statistically significative when revealing a normal distribution. If any of the measurements were not normally distributed were test contrasts non-parametric Mann-Whitney *U* test.

The scores of the FHSQ was calculated with the software of the Foot Health Status Questionnaire, data analysis software, version 1.03 (CareQuest, Brisbane, Australia) and supported by Microsoft Windows™.

In all of the statistical analyses the significance was accepted with a p-value lower than 0.05. The IBM SPSS Statistics 25 package (IBM Corp, Armonk, NY,USA) was applied for the treatment of the statistical of the data.

## 3. Results

A total of 150 people of aged eighteen or over the study course. The sample analyzed includes 98 (41.2%) women and 52 (21.8%) men between 27 and 91 years of age. Also, the diabetes group showed 94.7% were DM2 and 5.3% were DM1. The mean duration of diabetes was 12.24 ± 7.60 years.

Table 1 shows the baseline characteristics of the sample population, patients with or without diabetes. As can be seen, most persons are overweight (BMI = 26.77 kg/m$^2$).

**Table 1**
Baseline characteristics of the sample population, patients with or without diabetes.

| Parameters | | Total Group Mean ± SD (range) = 150 | Control Group Mean ± SD (range) n = 75 | Case Group Mean ± SD (range) n = 75 | P-Value |
|---|---|---|---|---|---|
| Age (years) | | 71.45 ± 11.93 (27–91) | 67.89 ± 12.27 (27–88) | 75.01 ± 10.50 (43–91) | < 0.001[a] |
| Weight (kg) | | 73.81 ± 13.26 (45–120) | 70.63 ± 11.48 (46–95) | 76.99 ± 14.19 (45–120) | 0.009[a] |
| Height (m) | | 1.66 ± 0.1 (1.45–1.86) | 1.65 ± 0.1 (1.45–1.84) | 1.67 ± 0.10 (1.50–1.86) | 0.313[a] |
| BMI (kg/m$^2$) | | 26.77 ± 4.01 (18.43–41.52) | 25.86 ± 3.51 (18.43–34.22) | 27.68 ± 4.29 (20.00–41.52) | 0.015[a] |
| Sex (%) | Male | 52 (21.8%) | 17 (22.7%) | 35 (46.7%) | 0.003[b] |
| | Female | 98 (41.2%) | 58 (77.3%) | 40 (53.3%) | |

Abbreviations: BMI, body mass index; SD: standard deviation; P < 0.05 with a 95% confidence interval was considered statistically significant.
[a] Mann-Whitney *U* test was used.
[b] Fisher exact test was used.

In what regards of the values of the sample population, patients with or without diabetes obtained with the FHSQ, findings show on Table 2. These values were higher for the group of people without diabetes, with normalised reference values, both in the one section of the tool, which determine the persons' QoL specifically to foot health, and in the two section, which determine the persons' overall health.

The differences among the groups of people without or with diabetes were a p-value lower than 0.05 statistically significant, for those dimensions in the tool which assessed foot pain, foot function footwear and social capacity.

## 4. Discussion

The purpose of this research is to evaluate and relate the impact of foot health associated with the QoL in a group of people with and without diabetes.

**Table 2**
Comparisons of FHSQ scores of the sample population, patients with or without diabetes.

| FHSQ Domains | Total Group Mean ± SD (range) n = 150 | Control Group Mean ± SD (range) n = 75 | Case Group Mean ± SD (range) n = 75 | P-Value |
|---|---|---|---|---|
| Foot pain | 58.33 ± 26.54 (0–100) | 63.77 ± 24.07 (10.63–100) | 52.89 ± 27.91 (0–100) | **0.016†** |
| Foot function | 68.25 ± 26.79 (0–100) | 76.00 ± 22.16 (18.75–100) | 60.51 ± 28.85 (0–100) | **0.002†** |
| Footwear | 37.46 ± 31.73 (0–100) | 42.82 ± 31.17 (0–100) | 32.10 ± 31.59 (0–100) | **0.016†** |
| General foot health | 42.52 ± 27.41 (0–100) | 45.21 ± 20.60 (0–100) | 39.59 ± 27.40 (0–100) | 0.274† |
| General health | 54.10 ± 23.37 (10–100) | 54.20 ± 21.38 (0–100) | 54.00 ± 25.99 (0–100) | 0.956† |
| Physical activity | 70.95 ± 25.09 (0–100) | 71.11 ± 25.03 (0–100) | 70.78 ± 25.32 (0–100) | 0.953† |
| Social capacity | 70.01 ± 29.86 (0–100) | 81.67 ± 21.59 (0–100) | 58.35 ± 32.46 (0–100) | **< 0.001†** |
| Vigor | 47.30 ± 19.93 (0–100) | 49.00 ± 21.53 (0–100) | 45.61 ± 18.18 (0–100) | 0.207† |

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

Foot health have a positive effect to diabetic patients reducing foot complication, major amputations and also due to the high prevalence of this chronic disease increasing rapidly in all the world as stated by Saeedi et al. who predicted that half a billion million population are living with diabetes (10.2% of the global people) and the percentage is projected rising to 25% for 2030 and 51% for 2045 with more the 700 million diabetic persons around the world [18,19].

However, based on the findings of the few investigations performed in the diabetes persons specific foot health and QoL this determinants of the health matter to assessment and control to illness. Furthermore, our outcomes of the our novel investigation revealed in the diabetes group a reduction of QoL linked to overall health and to foot health in particular in comparison in the group without persons diabetes. In the same way Palomo-López et al., showed in your investigation a similar results in all domains of FHSQ scores in patients with type II diabetes compared with patients who suffered from type I diabetes [20].

Taking into consideration these results, it seems essential to point out the vital of the care and check of the foot health in what regards podiatric and medical care in order to improve and to prevent the appearance or development of chronic diseases, foot complications, alterations, deformities and amputations, this being a significant factor that would allow increased the QoL, the indepence in the daily activities and welfare in diabetic population.

In addition, the current investigation have any limitations. In first place, a larger sample size with people various states would be increase the strength of our research.

In second place, despite a sample size calculation was carried out, the consecutive sampling bias should be considered and a simple randomization sampling process could be more adequate for future studies.

The last place, a multicenter study could help to found others factors involved with the foot health in this populations settings.

This highlights the necessity for further than studies for analized different strategies interventions in medical and podiatric care for improve overall foot health and QoL, not only in people with diabetics but also in the general people.

## 5. Conclusions

Diabetes people recorded a negative influence on the QoL related with foot health, that seems to be linked with the presence of chronic disease in diabetes population.

## Author contributions

All authors: concept, design, analyses, interpretation of data, drafting of manuscript or revising it critically for important intellectual

content.

## Conflicts of interest

All authors declare there is no conflict of interest with the article publication and are agree with this journal copyright.

## Funding

The authors did not receive any sponsor's role in the design, methods, subject recruitment, data collections, analysis and preparation of paper or have any personal relationships with other people or organizations that could inappropriately influence (bias) their work.

## Data sharing statement

The dataset supporting the conclusions of this article is available in the daniellopez@udc.gal in the Research, Health and Podiatry Group. Department of Health Sciences. Faculty of Nursing and Podiatry. Industrial Campus of Ferrol, Universidade da Coruña, Ferrrol, Spain.

## Acknowledgements

Funding for open access charge: Universidade da Coruña/CISUG.

## References

[1] Boulton AJ, Vileikyte L, Ragnarson-Tennvall G, Apelqvist J. The global burden of diabetic foot disease [Internet] Lancet 2005;366(9498):1719–24 [cited 2018 Jul 13];366(9498):1719–24. Available from: http://www.ncbi.nlm.nih.gov/pubmed/16291066.

2 Zhang P, Lu J, Jing Y, Tang S, Zhu D, Bi Y. Global epidemiology of diabetic foot ulceration: a systematic review and meta-analysis † [Internet] Ann Med 2017 Feb 17 [cited 2022 Jan 9]; 49(2):106–16. Available from: https://pubmed.ncbi.nlm.nih.gov/27585063/.

3 Driver VR, Fabbi M, Lavery LA, Gibbons G. The costs of diabetic foot: the economic case for the limb salvage team [Internet] J Vasc Surg 2010 [cited 2022 Jan 8]; 52(3 Suppl):17S–22S. Available from: https://pubmed.ncbi.nlm.nih.gov/20804928/.

[4] Narayan KMV, Gregg EW, Fagot-Campagna A, Engelgau MM, Vinicor F. Diabetes-a common, growing, serious, costly, and potentially preventable public health problem [Internet] Diabetes Res Clin Pract 2000;50(2):S77–84 [cited 2022 Jan 8]; 50 Suppl 2(SUPPL. 2). Available from: https://pubmed.ncbi.nlm.nih.gov/11024588/.

[5] Lin C, Liu J, Sun H. Risk factors for lower extremity amputation in patients with diabetic foot ulcers: a meta-analysis [Internet] PLoS One 2020 Sep 1 [cited 2022 Jan 8];15(9). Available from: https://pubmed.ncbi.nlm.nih.gov/32936828/.

[6] Zhang P, Lu J, Jing Y, Tang S, Zhu D, Bi Y. Global epidemiology of diabetic foot ulceration: a systematic review and meta-analysis [Internet] Ann Med 2017 Feb 17 [cited 2018 Jul 8];49(2):106–16. Available from: http://www.ncbi.nlm.nih.gov/pubmed/27585063.

[7] Jeon BJ, Choi HJ, Kang JS, Tak MS, Park ES. Comparison of five systems of classification of diabetic foot ulcers and predictive factors for amputation [Internet] Int Wound J 2017 Jun 1 [cited 2022 Jan 9];14(3):537–45. Available from: https://pubmed.ncbi.nlm.nih.gov/27723246/.

[8] Brocco E, Ninkovic S, Marin M, Whisstock C, Bruseghin M, Boschetti G, et al. Diabetic foot management: multidisciplinary approach for advanced lesion rescue [Internet] J Cardiovasc Surg 2018 Oct 1 [cited 2022 Jan 9];59(5):670–84. Available from: https://pubmed.ncbi.nlm.nih.gov/29808982/.

[9] Bus SA, Lavery LA, Monteiro-Soares M, Rasmussen A, Raspovic A, Sacco ICN, et al. Guidelines on the prevention of foot ulcers in persons with diabetes (IWGDF 2019 update) [Internet] Diabetes Metab Res Rev 2020 Mar 1 [cited 2022 Jan 9];36 Suppl 1(S1). Available from: https://pubmed.ncbi.nlm.nih.gov/32176451/.

[10] Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes [Internet] JAMA 2005 Jan 12 [cited 2022 Jan 9];293(2):217–28. Available from: https://pubmed.ncbi.nlm.nih.gov/15644549/.

[11] White RG, Hakim AJ, Salganik MJ, Spiller MW, Johnston LG, Kerr L, et al. Strengthening the reporting of observational studies in epidemiology for respondent-driven sampling studies: "STROBE-RDS" statement. J Clin Epidemiol 2015 Dec;68(12):1463. 71.

[12] Sirera-Vercher MJ, Sáez-Zamora P, Sanz-Amaro MD. Traducción y adaptación transcultural al castellano y al valenciano del Foot Health Status Questionnaire [Internet] Rev Española Cirugía Ortopédica Traumatol 2010 Jul [cited 2018 Jul 14];54(4):211–9. Available from: http://linkinghub.elsevier.com/retrieve/pii/S1888441510000500.

[13] Paez-Moguer J, Budiman-Mak E, Cuesta-Vargas AI. Cross-cultural adaptation and validation of the foot function index to Spanish. Foot Ankle Surg 2014 Mar;20(1):34–9.

[14] Bennett PJ, Patterson C, Wearing S, Baglioni T. Development and validation of a questionnaire designed to measure foot-health status [Internet] J Am Podiatr Med Assoc 1998 Sep [cited 2016 Dec 16];88(9):419–28. Available from: http://www.japmaonline.org/doi/abs/10.7547/87507315-88-9-419.

[15] Palomo-López P, López-López D, Becerro-De-Bengoa-Vallejo R, Losa-Iglesias ME, Rodríguez-Sanz D, Fernández-Carnero J, et al. Concurrent validity of the foot health status questionnaire and study short form 36 for measuring the health-related quality of life in patients with foot problems [Internet] Med 2019 Nov 1 [cited 2020 Aug 21];55(11). Available from: https://pubmed.ncbi.nlm.nih.gov/31752435/.

[16] Bennett PJ, Patterson C. The Foot Health Status Questionnaire (FHSQ): a new instrument for measuring outcomes of footcare. Australas J Podiatr Med 1998;32(3):87–92.

[17] Epidat: programa para análisis epidemiológico de datos. Versión 4.2, julio 2016. Consellería de Sanidade, Xunta de Galicia, España; Organización Panamericana de la salud (OPS-OMS). Colombia: Universidad CES; 2016.

[18] 9 th edition Saeedi P, Petersohn I, Salpea P, Malanda B, Karuranga S, Unwin N, et al. Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: results from the international diabetes federation diabetes atlas [Internet] Diabetes Res Clin Pract 2019. Nov 1 [cited 2022 Jan 14];157. Available from: https://pubmed.ncbi.nlm.nih.gov/31518657/.

[19] Kröger K, Moysidis T, Feghaly M, Schäfer E, Bufe A. Association of diabetic foot care and amputation rates in Germany [Internet] Int Wound J 2016 Oct 1 [cited 2022 Jan 15];13(5):686–91. Available from: https://pubmed.ncbi.nlm.nih.gov/25185970/.

[20] Palomo-López P, Losa-Iglesias ME, Becerro-de-Bengoa-Vallejo R, López-López D, Rodríguez-Sanz D, Romero-Morales C, et al. Specific foot health-related quality-of-life impairment in patients with type II versus type I diabetes [Internet] Int Wound J 2019 Feb;16(1):47–51. https://doi.org/10.1111/iwj.12984 [cited 2019 Mar 24]; Available from:.