INTERVENCIÓN PARA LA MEJORA DE LA SALUD Y EL BIENESTAR BASADA EN LA INVESTIGACIÓN

Comps.

África Martos Martínez
María del Mar Molero Jurado
José Jesús Gázquez Linares
Pablo Molina Moreno

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Introduction

Over the past decade, there has been a notable surge in interest regarding the health-related quality of life (HRQoL), both in clinical practice and research. HRQoL encompasses the subjective perception of physical, psychological, and social well-being, as well as aspects such as material well-being, harmonious relationships with the physical and social environment, community involvement, and overall general health. It reflects a comprehensive sense of balance in various dimensions of an individual's life. This increased interest in HRQoL underscores its significance as a holistic measure for understanding and assessing the overall well-being and satisfaction of individuals (Ardila, 2003; Badia & Baró, 2001).

Health professionals are increasingly required to utilize health questionnaires due to several compelling factors. Firstly, there is a significant increase in the average age of the population, resulting in a higher prevalence of chronic conditions that were once fatal. This demographic shift necessitates a comprehensive assessment of patients' HRQoL to address their evolving needs. Secondly, the transformation of diseases into chronic conditions highlights the importance of regularly evaluating patients' HRQoL to effectively manage their long-term care. Lastly, there is a growing demand for high-quality healthcare from patients, who now actively seek greater involvement in their treatment decisions. By incorporating health questionnaires into practice, health professionals can gather valuable patient-reported data to personalize care, enhance patient satisfaction, and ultimately improve overall healthcare outcomes (García, Alfaro, & Moreno, 2009; Prieto & Badia, 2001).

HRQoL questionnaires are utilized to identify patients with poor quality of life and assess variations in HRQoL over time. They also serve as a predictive tool. While not universally implemented, the use of health questionnaires is becoming more common. The objective is to assess all dimensions that influence HRQoL, including subjective factors such as pain, motor capacity, and emotional well-being. Incorporating these subjective elements is essential for understanding and evaluating patients' overall health status (Arribas, 2004; Badia & Baró, 2001; Llach, 2004; Prieto & Badia, 2001).

Diabetes mellitus (DM) is a common chronic condition that affects a large number of people worldwide, with an expected increase in prevalence by 2025. The impact of DM on patients' health-related quality of life (HRQoL) is significant and should be recognized. Understanding the influence of DM on HRQoL enables healthcare professionals to develop appropriate interventions and support to enhance the well-being of individuals with this condition (i Martí, Giralt, i Mas, & Arxé, 2002; Seguel, 2013).

According to the World Health Organization (WHO), diabetic foot is defined as a condition characterized by infection, ulceration, and tissue damage in the lower limb, often accompanied by neurological and vascular abnormalities. It is considered a significant complication of DM, frequently leading to prolonged hospitalizations and, unfortunately, amputations that can result in partial or complete disability for the patient (Rincón, Gil, Pacheco, Benítez, & Sánchez, 2012).

Foot ulceration is a common and serious complication in diabetic patients, with a 15% prevalence rate. The risk of amputation in individuals with diabetic foot ulcers is 25 times higher compared to non-diabetic individuals.

Additionally, there is a 50% probability of developing a new ulcer or requiring amputation of the opposite limb within 2-5 years after a lower limb amputation. Early detection, timely treatment, and comprehensive care are crucial in preventing complications and improving outcomes for diabetic patients with foot ulcers (Rincón et al., 2012; Seguel, 2013).

A comprehensive clinical history is essential for diabetic patients seeking podiatry consultation. This history should encompass general information, foot medical history, and assessments of dermatological, neurological, vascular, and musculoskeletal aspects. Conducting a thorough risk assessment is crucial, as it has the potential to significantly reduce amputations by 49% to 85%. The WHO and the International Diabetes Federation have set the goal of achieving a 50% reduction in risk, highlighting the importance of proactive measures and interventions in diabetic foot care (i Martí et al., 2002; Rincón et al., 2012; Seguel, 2013).

Diabetic foot complications have a profound impact on patients' lives. Among these complications, chronic wounds (CW) pose a significant health burden, affecting epidemiology, economy, and society as a whole. Managing CW presents a challenge for healthcare professionals, as their occurrence and progression are primarily influenced by the patient's lifestyle choices. Addressing the underlying causes and effectively managing CW is crucial to mitigate the detrimental effects they have on patients and society at large (Domínguez-Olmedo, Pozo-Mendoza, & Reina-Bueno, 2017; González-Consuegra & Verdú, 2010).

Ulcers, particularly CW, pose challenges in healing and management due to factors like chronicity, pain, mobility limitations, exudate, susceptibility to infection, isolation, and depression. Effective treatment should aim for complete healing while preserving the patient's HRQoL. This includes promoting well-being, reducing pain, preventing long-term physical damage, facilitating rehabilitation, and promoting social inclusion (Domínguez-Olmedo et al., 2017; González-Consuegra & Verdú, 2010; Moreno, Ximénez, Buela-Casal, Caballo, & Sierra, 1996; Navarro-Flores, 2013).

A variety of HRQoL questionnaires are available, enabling the selection of the most appropriate one for each patient. This assists in treatment selection and follow-up. Based on the preceding information, the primary aim of this study is to conduct a systematic review of the quality of life among patients with diabetic foot, using health questionnaires as an assessment tool. Additionally, the secondary objectives include describing the key health questionnaires used for diabetic foot patients, examining the correlation between HRQoL and podiatric self-care in individuals with diabetes, and highlighting the significance of health questionnaires in the field of podiatry. We hypothesize that the questionnaires will indicate that patients with diabetic foot have decreased quality of life.

Method

A systematic review (SR) was conducted according to the Preferred Reported Items for Systematic Reviews and Meta-Analysis (PRISMA), to minimize the risk of publication and selection bias (Urrútia & Bonfill, 2010). The SR protocol was registered at the International Prospective Register of Systematic Reviews (PROSPERO: CRD 42021282265).

Data Sources and Searches

One researcher performed a scoping search to make sure that this objective had not been addressed by previous studies. Also, searches in the following databases were carried out: CINAHL, Cochrane Library, Latin, American and Caribbean Health Sciences Literature (Lilacs), Pubmed, sciELO, Web of Science (WoS) and the search Google Scholar, from the inception to April 2022. The following Medical Subject

Headings (MeSH) and keywords were the used search terms: “patient health questionnaire”, “quality of life”, “diabetic foot”, “foot ulcer” and “amputation”

Every study had to meet some inclusion criteria:

Studies published in Spanish, English or French.

Studies published from 2015 to 2022.

Studies carried out including diabetic patients older than 18 years of age.

Studies which used health questionnaires to assess quality of life.

Observational studies.

Studies were excluded if depending on the following criteria:

Diabetic patients without lower limb impairment.

Patients with concomitant diseases such as rheumatoid arthritis.

Study Selection

Two researchers carried out the study selection. Once all the studies were selected after carrying out the search in the databases, the duplicated records were eliminated. The remained studies were screened by their titles, and those by their abstracts applying the inclusion/exclusion criteria. Finally, full texts of potentially eligible studies were analysed.

Data Extraction and Quality Assessment

To answer the stablished objective, the following data was extracted from each included study: type of study, design, country and year of publication, author, sample size (years of age, gender, involvement derived from diabetic foot, general treatment), inclusion/exclusion criteria, health questionnaire used and results. Meta-analysis was not appropriate due to heterogeneity of studies.

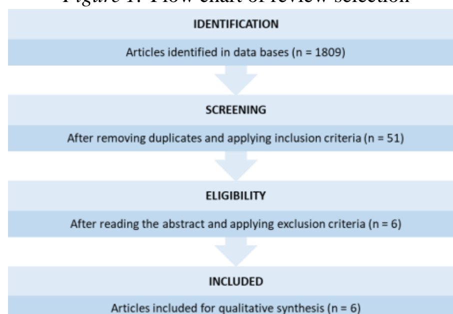
The risk of bias of the included studies was analysed with the modified version of the Newcastle-Ottawa Scale (NOS) for observational studies. This scale classified studies within high (from 0 to 6), moderate (from 7 to 13) and low risk of bias (from 14 to 21) (Shea, Robertson, Peterson, Welch, & Losos, 2012).

The Canadian Task Force on Preventive Health Care was used to assess the levels of scientific evidence of the included studies, which classified studies within I (high level of evidence) to III (low level of evidence) (Manterola & Zavando, 2009).

Results

After carrying out the search strategy explained before, 1809 references were identified. After inclusion criteria were applied, 51 potentially relevant studies remained. After reading the abstract and applying exclusion criteria, the number was reduced to 6 studies to be included in the present systematic review (Figure 1).

Figure 1. Flow chart of review selection



Risk of bias in the studies included

In order to minimize the risk of bias, evaluation of included studies was carried out with the use of the modified NOS scale. The included studies showed results between 09/21 and 15/21, classified as moderate or low, but never high risk (Table 1).

Table 1. Risk of bias assessment with the NOS modified version

Study	Representativity of the population	Sample size	Variables that mayinfluence the outcome	Appropriate statistical analysis	Missing data	Methodology of the outcome measurement	Objective assessment	Total
Formosa et al.	1	0	2	2	2	1	1	09/21
Rodríguez et al.	1	0	1	2	2	1	2	09/21
Pickweel et al.	2	3	2	2	2	1	3	15/21
Siersma et al.	3	3	2	2	2	2	3	17/21
Bôas et al.	2	2	2	2	2	2	2	14/21
Spanos et al.	2	2	1	2	2	1	2	12/21

General characteristics of the studies included

A table with the main general characteristics of included studies is available in Table 2.

Table 2. Sample size characteristics

Author	Year	Type of study	Country	Sample size	Evidence level	Disease	Health questionnair	Conclusion
Formosa et al.	2016	Observational prospective study	Spain	(n=39) men and women >19 years of age	II-3	DM 2 and DFU >3 months or lower limb amputation >6 months	SF-36	Decreased health status in patients with DFU
Rodríguez et al.	2017	Observational descriptive study	Spain	(n=50) 63% men 69,16 years of age	III	DM 1 or 2 without affectation, DFU or lower limb amputation	SF-12 and APD-UMA	Better health conditions mean greater self-care
Pickwell et al.	2016	Observational prospective and multicentre study	USA	(n=821) 63,86% men 64,33 years of age	II-3	DM with new DFU	EQ-5D	Amputation is a viable treatment option to improve HRQoL
Siersma et al.	2017	Observational prospective cohort study	The Netherlands	(n=1232) 57,74% men 67,03 years of age	II-2	DM with new DFU	EQ-5D	Healing improves HRQL, comorbidity improves HRQL
Bôas et al.	2018	Observational descriptive controlled and multicentre study	UK	(n=150) 84% women 67,7 71,5 years of age	III	1. No DM and no DFU 2. DM and no DFU 3. DM and DFU	Sociodemographic questionnaire, Edmon Frail Scale and HAQ-20	DFU causes fragility and difficulty in ADLs
Spanos et al.	2016	Observational prospective cohort study	UK	(n=103) 77% men 69,7 years of age	II-2	DFU	DFS-SF	HRQoL improves with DFU or amputation healing

Year of publication, author, language and country of publication

The range of years of publication was from 2016 to 2021, both inclusive.

It should be noted that the studies published by Pickwell et al. (Pickwell et al., 2017) and Siersma et al. (Siersma et al., 2017) shared 17 authors.

Focusing on the language, all of the studies were published in English, except for Rodríguez et al. (Moreno, Ballesteros-Mora, & Reina-Bueno, 2017), which was published in Spanish.

Pickwell et al. (Pickwell et al., 2017) publication was in the USA, Formosa et al. (Formosa, Simiana, & Gatt, 2016) and Rodríguez et al. (Moreno et al., 2017) in Spain, Spanos et al. (Spanos et al., 2017) and Bôas et al. (Bôas, Salomé, & Ferreira, 2018) in the UK, and Siersma et al. (Siersma et al., 2017) in the Netherlands.

Study design

6 observational studies were included: a prospective study, a multicenter prospective study, a multicenter prospective cohort study, a non-randomized multicenter prospective cohort study and two descriptive studies.

Level of evidence

Siersma et al. (Siersma et al., 2017) and Spanos et al. (Spanos et al., 2017) show a level of evidence II-2; Formosa et al. (Formosa et al., 2016) and Pickwell et al. (Pickwell et al., 2017) have a level of evidence II-3; and Rodríguez et al. (Moreno et al., 2017) and Bôas et al. (Bôas et al., 2018) reach a level of evidence III.

Characteristics of the sample

A total of 2395 individuals were included. The mean age is 65.04 years old and 57.28% of participants were males. In the study by Formosa et al. (Formosa et al., 2016) the only provided specification was that the individuals were males and females over 45 years of age, and Bôas et al. (Bôas et al., 2018) only explained that their sample included participant from 67.7 to 71.5 years old. In the study by Pickwell et al. (Pickwell et al., 2017) 63.86% of participants were males and the mean age was 64.33 years. Rodríguez et al. (Moreno et al., 2017) included a sample formed by 66% males and a mean age of 69.16 years. Spanos et al. (Spanos et al., 2017) included a sample formed by 77% males and a mean age of 69.7 years. Female participants were mainly included in the study of Bôas et al. (Bôas et al., 2018) (over 84%) and ages between 67.7 and 71.5 years. Siersma et al. (Siersma et al., 2017) included a sample formed by 57.74% males and a mean age of 67.03 years.

Type of involvement derived from diabetic foot

In the studies by Pickwell et al. (Pickwell et al., 2017) and Siersma et al. (Siersma et al., 2017), the participants were diabetic patients with a new ulcer on their feet, treated in different 14 specialized centers from 10 different European countries. Bôas et al. (Bôas et al., 2018) included in their study three groups of people with different characteristics: the first one formed by patients without a diabetes history or ulcers on lower limbs, the second one with diabetic patients but no ulcers on lower limbs, and the third one with diabetic patients who had developed diabetic foot ulcer. Formosa et al. (Formosa et al., 2016) included type 2 diabetic participants with chronic foot ulcers for at least 3 months or digital or transmetatarsal amputation during at least 6 months. Rodríguez et al. (Moreno et al., 2017) included participants with type 1 and type 2 diabetes without any derived involvement, people with foot ulcers or amputation of lower limb. Spanos et al. (Spanos et al., 2017) included patients with diabetic foot ulcer.

General treatment

In the studies by Pickwell et al. (Pickwell et al., 2017) and Siersma et al. (Siersma et al., 2017), the participants were treated with conservative therapy including offloading, regular debride of the wounds, diagnosis and treatment of infections, critical ischemia and foot deformity. Pickwell et al. (Pickwell et al., 2017) also included participants with a minor amputation, (i.e. distal to the middle part of the foot). All participants included in the study of Spanos et al. (Spanos et al., 2017), were assessed by a vascular surgeon who decided the type of treatment (i.e. open surgery, endovascular surgery, hybrid procedure or conservative procedure). Bôas et al. (Bôas et al., 2018), Rodríguez et al. (Moreno et al., 2017) and Formosa et al. (Formosa et al., 2016) did not specify the general treatment applied to the sample patients in their studies.

Inclusion criteria

In the studies by Pickwell et al. (Pickwell et al., 2017) and Siersma et al. (Siersma et al., 2017), the individuals were hospitalised and non-hospitalised diabetic patients who presented their written consent. Bôas et al. (Bôas et al., 2018) included patients of both sexes over 60 years, without diabetes or lower limb ulcer history, with diabetes but no ulcers on lower limbs or with diabetes and diabetic foot ulcer. Rodríguez et al. (Moreno et al., 2017) included diabetic patients who had previously signed the informed consent. The participants in the study by Formosa et al. (Formosa et al., 2016) were individuals with type 2 diabetes who had been living with a chronic ulcer for at least 3 months or with a healed minor foot amputation, including digital or transmetatarsal amputation during the previous 6 months at least. Spanos et al. (Spanos et al., 2017) included patients with type 2 DM with ulceration of lower limbs, who had been sent to a foot clinic.

Exclusion criteria

In the studies by Pickwell et al. (Pickwell et al., 2017) and Siersma et al. (Siersma et al., 2017), the individuals excluded if they were treated for ipsilateral foot ulcer during the 12 months prior to the study, people with a life expectancy under 1 year and patients with a major amputation (i.e. ankle to proximal). Bôas et al. (Bôas et al., 2018) did not include people with venous, arterial, pressure or ulcers and patients who refused to sign consent. Rodríguez et al. (Moreno et al., 2017) excluded people with alterations in their psychic abilities or disorientation or any other alteration which prevent understanding the questionnaires by themselves or with the help of a nurse. Formosa et al. (Formosa et al., 2016) excluded subjects who did not give their informed consent and those who could not communicate. Spanos et al. (Spanos et al., 2017) did not include patients with malnutrition (i.e.body-mass index <18), people with mobility problems (i.e.in bed, in a wheelchair or with cerebrovascular accident affecting a limb), people treated with immunosuppression or those who, because of lack of mental capacity, could not give their consent to the study.

Characteristics of the intervention

Type of intervention

Questionnaire EQ-5D was used in the studies by Pickwell et al. (Pickwell et al., 2017) and Siersma et al. (Siersma et al., 2017). Bôas et al. (Bôas et al., 2018) used the following 3 questionnaires: sociodemographic questionnaire, validated Brazilian versions by Edmont Frail Scale and Stanford Health Assessment Questionnaire 20-item Disability Scale (HAQ-20). Rodríguez et al. (Moreno et al., 2017) administered the SF-12 Health Questionnaire and the diabetic foot self-care questionnaire by the University of Málaga (APD-UMA) to assess the level of foot self-care. Formosa et al. (Formosa et al., 2016) administered the SF-36 questionnaire and Spanos et al. (Spanos et al., 2017) the Greek version of the DFS-SF.

Duration and monitoring

Pickwell et al. (Pickwell et al., 2017) and Siersma et al. (Siersma et al., 2017) provided the questionnaire when the individuals were included in the study and at the end of the monitoring, collecting data monthly for 12 months until healing, minor amputation, major amputation or death. Bôas et al. (Bôas et al., 2018), Formosa et al. (Formosa et al., 2016) and Rodríguez (Moreno et al., 2017) provided the questionnaires only at the beginning of the study. Spanos et al. (Spanos et al., 2017) carried out periodic consultations all along the study, depending on the process of ulcer healing and the patients were given the questionnaire during the first test and after 12 months of monitoring.

Results and conclusions

Pickwell et al. (Pickwell et al., 2017) concluded that HRQL was not significantly different among patients treated with conservative therapy and patients with a minor amputation. For patients with minor amputation whose wounds healed from 6 to 12 months after the first visit, their HRQL was slightly improved, concluding that a minor amputation cannot be considered as a failure of the treatment, but rather a viable option.

Siersma et al. (Siersma et al., 2017) demonstrated that patients HRQL improved during the treatment for those diabetic foot ulcers that healed. The significant difference among patients with and without factors of comorbidity showed that comorbidity does not influence HRQL during treatment, in fact, HRQL improves in patients with certain factors of comorbidity and ulcers of difficult or slow healing.

Bôas et al. (Bôas et al., 2018) found that in group I (people with no diabetes/no ulcer) 64% of the patients did not show evidence of fragility, in group II (people with diabetes/no ulcer) 36% were apparently vulnerable and 24% were mildly fragile, and in group III (people with diabetes/diabetic foot ulcer) 42% showed moderate fragility and 22% showed severe fragility. The results obtained in HAQ-20 were 0.24, 0.52 and 2.44 for groups I, II and III respectively. Therefore, elder diabetic patients with foot ulcer showed fragility and disability in Activities of Daily Living (ADLs), showing the importance of performing assessments to detect patient weakness.

Rodríguez et al. (Moreno et al., 2017) did not show a significant relationship among any of the dimensions of the study and all patients reached a high score in the self-care questionnaire. They noted that better levels of physical health generated higher levels of self-care, showing a positive relationship between the parameters of self-care and physical health.

Formosa et al. (Formosa et al., 2016) showed statistically significant differences in terms of general health condition between patients with chronic foot ulcer and patients with a minor amputation. They concluded that diabetic foot ulcers are an important concern for patients, doctors and relatives as well. Patients with diabetic foot ulcers have a reduced physical condition, including physical, emotional and social functions, thus emphasizing the importance of an improvement in prevention strategy.

Spanos et al. (Spanos et al., 2017) noted that the loss of a limb was linked to non-palpable popliteal artery and extended hospitalization. Quality of life improved in all patients regardless they had major or minor amputation or ulcer healing and they demonstrated a significant improvement in all sections of self-care and hygiene by the end of monitoring.

Limits of the study

The main limitation is the difficulty related to finding studies related to the topic of the present SR. The exclusion criteria in terms of year of publication was the main reason that other potential studies were not included, excluding several old studies.

Furthermore, we have been able to verify that HRQoL is not always consider in terms of treating patients since there are more studies focused on the treatment of the pathology itself than to the damage it has on people's quality of life.

It is important to investigate more about the quality of life of patients with diabetic foot in longitudinal studies with large sample sizes, using validated and reliable questionnaires.

Discussion/Conclusions

HRQoL of patients with diabetic foot with is more fragile than in healthy people without lower limb impairment, due to this pathology detriment their health in terms of physical, emotional and social functions, as well as adding serious difficulties in the development of the ADLs.

The main health validated questionnaires included in patients with diabetic foot assessment by a multidisciplinary team are EQ-5D, HAQ-20, Edmont Frail Scale, SF-12, SF-36 and DFS-SF.

Optimal physical health conditions lead to a better level of quality in podiatric self-care, both in diabetic patients suffering from chronic ulcers and in patients with an amputated lower limb.

It is important to assess HRQoL through health questionnaires to detect health and thus detect physical, emotional and social weakness in time, allowing an adequate treatment to be carried out as a prevention strategy.

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