

# BMJ Open Evaluation of foot health related quality of life in individuals with foot problems by gender: a cross-sectional comparative analysis study

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## ABSTRACT

**Objective** Foot problems (FP) may be considered to be a prevalent conditions in people but there is limited evidence of their effect on the quality of life (QoL) related to foot health in men and women. The aim of this study was to assess the impact of FPs on both overall foot health and QoL, stratified by gender.

**Design** A cross sectional study.

**Setting** Clinic of Podiatric Medicine and Surgery at University of A Coruña in the city of Ferrol (Spain).

**Subjects** The sample consisted of 1647 participants with FP; the total population of the sample had a mean age of 43.24±19.89 years, with mean ages 44.09±21.36 years and 42.94±19.34 years for men and women, respectively.

**Methods** Measurement of sociodemographic characteristics include age, sex and body mass index. The Foot Health Status Questionnaire (FHSQ) was used to evaluate the general health and foot health. Differences between groups were evaluated by means of a t-test for independent samples.

**Results** Women with FP showed significantly lower scores in the domains of Foot Pain, Foot Function, Footwear, General Foot Health, Physical Activity and Vigour, and there was no difference compared with men in the domains of Overall Health and Social Capacity.

**Conclusions** Women with FP present a negative impact on QoL related to foot health as compared with men except in the domains of Overall Health and Social Capacity, which appears to be associated with the presence of foot conditions.

## INTRODUCTION

Foot problems (FP) are frequently observed in the general population, with higher prevalence rates of 61.3%–79% reported in institutional and clinical settings.<sup>1–3</sup> However little is known about the burden of these problems from a public health perspective and the overall burden within the general population remains unclear.<sup>4–6</sup>

Thus, FP may be one of the most frequent reasons for people seeking consultations at primary care units, and many of these

## Strengths and limitations of this study

- This research presents a new framework for evaluating the impact of foot problems (FPs) on overall health and foot health.
- This method provides identification of FPs stratified by gender, related to quality of life (QoL).
- This study has been the first to show how people with FP experience a negative impact on their QoL related to foot health.
- A case-control study and a sample of people from other countries would improve the strength of this research.
- Preventative foot care is extremely important in the management of general health and foot health.

conditions may be chronic, decrease the ability to undertake activities of daily living, generate problems with balance and gait and increase the risk of falls.<sup>6–8</sup> Further, these FPs may show an increased prevalence in women and in older age groups (>65 years),<sup>8,9</sup> and present with notable health problems related to obesity, diabetes, vascular alterations, depression, risk of falls and difficulty putting on shoes, and pose to be major contributors towards the costs for foot surgery.<sup>10</sup>

In the initial approach, any FP should be considered as a specific pathology in which there are no two conditions that can be considered identical because the medical history and family history affect its evolution and prognosis.<sup>11</sup>

Despite the high prevalence of FPs in the population, their impact on overall foot health and quality of life (QoL), as stratified by gender, has not previously been studied. A meta-analysis by Thomas *et al* conducted on 75 505 people showed that 24% of people above 45 years of age exhibited foot and ankle pain, which increased in prevalence

with age, especially in female populations. The most frequent anatomical sites for foot pain were the toes and forefoot, which increased with age and among women.<sup>11</sup> Furthermore, Garrow *et al* showed that foot disability was also associated with pain in other body parts such as the shoulder, axial skeleton, hip, upper leg and knee along with other poor general health indicators.<sup>12</sup>

According to these antecedents, and considering the existence of the attention and follow-up necessity in foot care of patients with FP, the role of the physician is important in recognising and treating the underlying condition, preventing further injury or deformities, and educating the patient about his/her disease,<sup>2</sup> to achieve better QoL and state of well-being for people.

There is little published information on the effects of FP on QoL in the general population and especially in men and women. We hypothesised that FPs affecting QoL varied by gender. Therefore, the aim of this study was to assess the impact of FPs on both, overall foot health and QoL as determined by gender.

## MATERIALS AND METHODS

### Design and sample

A total of 1647 patients took part 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 A Coruña in the city of Ferrol (Galicia, North-Western Spain) during the period January 2012 and June 2016. The selection of the cases subject to the research was made by a consecutive sampling technique. The ages of the people included in the study ranged from 18 years to 96 years. Disregarded and excluded cases included: patients who had experienced acute pathological fracture; previous trauma and feet surgery records; active systemic neoplastic conditions; infectious, autoimmune or neurological alterations; lack of or partial autonomy in daily activities; the refusal to sign an informed consent form or those who were incapable of understanding the instructions necessary to carry out the present study; and participants of other nationalities (non-Spanish) who did not adequately understand Spanish.

### Procedure

A single trained researcher (DL-L) recorded baseline measurements. The first step included an interview about disease and clinical characteristics included age, sex and the presence of predisposing factors (diabetes, obesity, depression, vascular disease, trauma, osteoarticular pathology or participation in sports).

In the second step, patients removed their footwear and hosiery. Following this a single researcher (DL-L) assessed height and weight with the subject barefoot and wearing light clothing, and determined the body mass index (BMI).<sup>13</sup>

Then, the physician (DL-L) examined foot disorders and the structural integrity of the foot through clinical

assessment, neurovascular palpation, musculoskeletal mobility and strength testing on the foot using the de Kendall test. Also, diagnosis of the FPs was assessed using ultrasonography or previous radiographic evidence, since full access to the clinical records of the patient was available, to check for any other foot pathology and systemic diseases of the patient.

Lastly, impact on the foot health and overall health was assessed and compared using the Foot Health Status Questionnaire (FHSQ).<sup>14 15</sup> This self-administered questionnaire on health-related QoL, intended specifically for the foot, is recognised as a validated test as described in detail previously.<sup>16 17</sup> This questionnaire consists of three sections. Section 1 has 13 questions about four foot health related subcategories: foot function, foot pain, footwear and general foot health. Section 2 includes the four subscales or domains of overall health: general health, physical function, social function and vitality.

Finally, Section 3 collects socioeconomic status, comorbidities, service utilisation and satisfaction information and their medical records.

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 program (FHSQ V.1.03) which, after data processing, provides a score from 0 to 100. A 0 score shows the worst foot health state and a 100 score reflects the best possible condition. Furthermore, outcomes using graphical images are provided by this software.

### Patient and public involvement

Patients were not involved in the conceived and designed of this research. Currently, there is no plan to transfer these results to study participants.

### Ethical considerations

Participation in the study was voluntary and all participants provided written informed consent before the start of the study. Human research ethical standards according to the Helsinki Declaration, the human rights and biomedicine statements of the Convention of the Council of Europe, as well as human genome and rights from the Unesco Universal Declaration and other appropriate national or institutional organisations were followed.

### Sample size

The sample size was calculated using the software from Unidad de Epidemiología Clínica y Bioestadística, Complejo Hospitalario Universitario de A Coruña, Universidade da Coruña ([www.fisterra.com](http://www.fisterra.com)).<sup>18</sup> The calculations were based on the total population of the city of Ferrol, that is 69 452 (<http://www.ine.es/jaxiT3/Datos.htm?t=2868>), 95% CI, an  $\alpha$  level of 0.05, and a proportion of 50% and a precision of 1%, a minimum final sample size of 453 participants was calculated. Assuming a dropout of 15% of participants, at least 533 participants must be studied. Finally, a total of 1647 people were included in the study.

### Statistical analysis

Demographic characteristics, including subject age, height, weight and BMI, and independent variables were summarised as mean and SD, and maximum and minimum values. For categorical variables, the frequency and percentage were used.

The Kolmogorov-Smirnov test was used to evaluate normality, and data were determined as normally distributed if  $p > 0.05$ . The results of these tests indicated that the data were normally distributed and that parametrical statistical tests were most appropriate. Independent Student's t-tests were performed to determine whether statistically significant differences were obtained in all variables between the two groups, that is, men and women. The  $\chi^2$  test was used to determine whether a significant difference was shown between the observed frequencies.

FSHQ V.1.03 was used to determine QoL scores with respect to foot health. In all analyses, statistical significance was considered with a p value  $< 0.01$  with a 99% CI.

For demonstrating the effect size of the comparisons, Cohen's d coefficient was calculated. The standard interpretation offered by Cohen and expanded by Sawilowsky<sup>19</sup> is as follows: 0.01 = verysmall; 0.20 = small; 0.50 = medium; 0.80 = large; 1.20 = verylarge; and 2.0 or higher = huge.

A p value  $< 0.01$  with a CI of 99% was considered statistically significant for all tests (SPSS for Windows, V.20.0; SPSS, Chicago, Illinois, USA).

All analyses were carried out with a commercially available statistical software (SPSS V.19.0, Chicago, Illinois, USA).

### RESULTS

A total of 1647 participants ranging in age from 18 years to 96 years completed the research course. The sample analysed included 1215 (73.77%) women and 432 (26.23%) men.

All variables showed a normal distribution ( $p > 0.05$ ).

Table 1 shows the clinical and sociodemographic characteristics of the informants. There were no statistically significant differences between sex and age ( $p = 0.30$ ) and sex and BMI ( $p = 0.48$ ).

According to the WHO BMI classification,<sup>20</sup> 17 (1.03%) participants proved to be underweight with a BMI  $< 18.0$ ; another 945 (57.37%) had normal weight with values between 18.5 and 24.9; another 518 (31.45%) showed preobesity with values between 25.0 and 29.9; another 157 (9.53%) had obesity class I with values between 30.0 and 34.9; another 9 (0.54%) had obesity class II with values between 35.0 and 39.9 and only 1 participant (0.06%) was classified as obesity class III with values above

**Table 1** Sociodemographic and clinical characteristics of the sample population

	Total group Mean±SD Range n=1647	Men Mean±SD Range n=432	Women Mean±SD Range n=1215	P values Men versus women
Age, years	43.24±19.89 (18-96)	44.09±21.36 (18-96)	42.94±19.34 (18-94)	0.30*
Weight (kg)	68.71±12.40 (45-121)	76.88±11.73 (47-115)	65.80±11.29 (45-121)	0.001*
Height (m)	1.66±0.08 (1.40-1.93)	1.75±0.06 (1.50-1.91)	1.63±0.06 (1.40-1.93)	0.001*
BMI (kg/m <sup>2</sup> )	24.76±3.77 (18.04-40.00)	24.87±3.53 (18.10-35.90)	24.72±4.85 (18.04-40.0)	0.48*
Keratosis	550 of 1647 (33.3%)	182 of 432 (42.1%)	368 of 1215 (30.3%)	0.001**
Metatarsalgia	91 of 1647 (5.5%)	33 of 432 (7.6%)	61 of 1215 (5.0%)	0.001**
Hallux valgus	492 of 1647 (29.8%)	330 of 1215 (27.2%)	162 of 432 (37.5%)	0.001**
Toe deformities	52 of 1647 (3.15%)	14 of 432 (3.2%)	38 of 1215 (3.1%)	0.001**
Flat feet	188 of 1647 (30.9%)	0 of 432 (0%)	188 of 1215 (15.5%)	0.001**
Cavus foot	30 of 1647 (1.82%)	0 of 432 (0.0%)	30 of 1215 (2.5%)	0.001**
Onychocryptosis	63 of 1647 (3.8%)	0 of 432 (0.0%)	63 of 1215 (5.2%)	0.001**
Heel pain	88 of 1647 (5.3%)	16 of 432 (3.7%)	72 of 1215 (5.9%)	0.001**
Morton's neuroma	35 of 1647 (2.12%)	four of 432 (0.9%)	31 of 1215 (2.6%)	0.001**
Tinea pedis	55 of 1647 (3.33%)	21 of 432 (4.9%)	34 of 1215 (2.8%)	0.001**

In all the analyses,  $p < 0.01$  (99% CI) was considered statistically significant.

\*Independent Student's t-test was used.

\*\* $\chi^2$  test was used.

BMI, body mass index.

**Table 2** Comparisons of FHSQ scores in the total group and gender groups

	Total group Mean (SD) Range (n=1647)	Men Mean (SD) Range (n=432)	Women Mean (SD) Range (n=1215)	P values Men versus women	Cohen's d Effect size
Foot pain	74.61±21.94 (0–100)	79.11±19.51 (0–100)	73.01±22.53 (0–100)	<0.001	0.289
Foot function	82.19±21.17 (0–100)	85.48±18.45 (0–100)	81.03±21.94 (0–100)	<0.001	0.219
Footwear	50.75±30.60 (0–100)	58.58±29.31 (0–100)	47.96±30.58 (0–100)	<0.001	0.354
General foot health	57.35±27.44 (0–100)	64.56±25.76 (0–100)	54.79±27.57 (0–100)	<0.001	0.366
Overall health	66.63±23.39 (0–100)	66.88±22.31 (0–100)	66.55±23.77 (0–100)	0.80	0.014
Physical activity	82.98±22.09 (0–100)	87.01±18.98 (0–100)	81.55±22.93 (0–100)	<0.001	0.259
Social capacity	80.22±23.60 (0–100)	81.51±22.72 (0–100)	79.77±23.90 (0–100)	0.18	0.074
Vigour	55.09±21.54 (0–100)	59.90±19.68 (0–100)	53.38±21.92 (0–100)	<0.001	0.313

In all the analyses,  $p < 0.01$  (with a 99% CI) was considered statistically significant. FHSQ, Foot Health Status Questionnaire.

40. Also, 100% (n=1647) of the participants stated they had suffered one or more FP; this was determined in the study procedure by the physician (DL-L) and the clinical characteristics are as shown in [table 1](#).

Moreover, the total population showed that 29.9% (n=492) had hallux valgus, 11.4% (n=188) had flat foot, 5.7% (n=94) had metatarsalgia, 5.5% (n=91) had keratosis, 5.3% (n=88) had heel pain, 3.8% (n=63) had onychocryptosis, 3.2% (n=52) had toe deformities, 1.8% (n=30) had cavus foot, 2.1% (n=35) had Morton's neuroma, 55 of 1647 (3.33%) had tinea pedis, and all of these conditions were shown to be significantly higher in women than in men ( $p < 0.01$ ).

Furthermore, 27.9% of the patients who participated in the research presented with predisposing factors including 11% (n=181) with vascular disease, 9.1% (n=150) osteoarticular pathology, 3.8% (n=62) diabetes, 2.7% (n=45) obesity and 1.2% (n=20) suffered from depression.

The results of FHSQ scores between men and women with FP are shown in [table 2](#). Women with FP showed significantly lower scores in the domains of foot pain, foot function, footwear, general foot health, physical activity and vigour with  $p < 0.001$  in all of them, and there was no difference by gender in the domains of overall health and social capacity with  $p > 0.01$  in both.

The effect sizes are shown in [table 2](#). A small effect size was found by gender at general foot health, footwear, vigour, foot pain, physical activity, foot function with values of 0.366, 0.354, 0.313, 0.289, 0.259 and 0.366, respectively. The effect sizes were very small for social capacity and overall health with values of 0.074 and 0.014, respectively.

## DISCUSSION

The purpose of this study was to assess and compare the impact of foot health in a sample of people with FPs, with the help of scores obtained with regard to foot health and health in general between men and women.

Foot care is an essential need, given the high prevalence (100%) of people who complain of foot disorders. Also, these findings are consistent with previous epidemiological research from other authors.<sup>3 21 22</sup> Furthermore, a systematic review about foot pain concurred with our results, also recognising that the prevalence of foot pain was higher in women than in men.<sup>11</sup> These findings are similar to ours with regard to the QoL related to foot health, where women also showed lower and worse scores than men.

Therefore, it is recommended that foot health should be managed by physicians/podiatrists well before FPs limit the individuals' ability with respect to foot function and ability to self-manage. Also, our results showed the negative impact of the QoL related to foot health in people with FP. This is consistent with the results of other studies linking QoL to other foot diseases. These studies have demonstrated that hallux valgus, calcaneal apophysitis, foot arch height, heel pain, chronic ankle instability and onychomycosis negatively affect foot function and foot health.<sup>23–27</sup>

This study has been the first to examine the impact related to foot health in a sample of people with FP between men and women.

The findings of this study need to be interpreted in the context of several inherent limitations that should be acknowledged. A sample with diverse patients from other countries and cultures would be beneficial to improve the strength of the research and may help to identify if there is a culture or location where this association does not exist

and identify if other factors could influence the differences between men and women in relation to foot pathology and thus impact on QoL: sociodemographics, types of employment, levels of physical activity, potential impact of pregnancy and child bearing on joints, and medical health insurance. Furthermore, a case-control study could clarify the QoL differences related to foot health between subjects with and without FP, in order to stratify both groups by sex. These limitations should be addressed in future studies.

In light of these findings, further continuous research on this trend of FPs is required in order to evaluate the effectiveness of the available treatments, improve the examination routine of patients' feet by podiatrist and physicians, reduce the burden of these foot conditions and improve the QoL in the general population and specifically in women who present a worse QoL related to foot health.

When comparing the domains of social capacity and overall health between men and women to find out the effect size, we found that the means of two groups don't differ by 0.2SD, so the difference is very small or trivial. When comparing general foot health, footwear, vigour, foot pain, physical activity and foot function dimensions, the effect sizes were small, even though they were statistically significant.

Further work is necessary to better understand the extent and type of unmet needs and how patients, especially women, presenting with symptoms of disabling foot pain should best be managed.

## CONCLUSIONS

Women with FPs present a negative impact on the QoL related to foot health with respect to men, except in the domains of overall health and social capacity, which appear to be associated with the presence of foot conditions.

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