ORIGINAL ARTICLE

Impact of the mechanical hyperkeratotic lesions and its association with quality of life: An observational case– control study

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Abstract

Background Mechanical hyperkeratotic lesions (MHL) are common condition amongst population of all ages. Such problems may be associated with pain, reduction in mobility, changes of gait and risk of falls and is believed to affect the quality of life (QoL), general health and optimal foot health.

Objective The main aim of this study was to describe and compare both foot and general health-related QoL in two groups of participants: (i) with MHL and (ii) healthy controls.

Method A total sample of 150 patients, mean age 49.50 ± 36.50 years, was recruited from an outpatient clinic. Demographic data, medical history and clinical characteristics of overall health were determined, and the obtained values were compared by the Foot Health Status Questionnaire (FHSQ).

Results The FHSQ scores of the sample with MHL showed lower scores than control subjects in sections one and two for footwear, general and foot health, foot pain, foot function and physical activity (P < 0.01), but not for social capacity and vigour (P > 0.01).

Conclusions People with MHL showed a decrease in QoL, based on FHSQ scores, regardless of gender. Received: 22 January 2018; Accepted: 14 March 2018

Conflicts of interest

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

Funding

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

Introduction

Mechanical hyperkeratotic lesions (MHL) may be considered as the ultimate dermatologic alterations produced as a result of an

A statement of all funding sources that supported the work: The authors did not receive any sponsor's role in the design, methods, subject recruitment, data collections, analysis and preparation of study or have any personal relationships with other people or organizations that could inappropriately influence (bias) their work. anomalous mechanical stresses on the foot skin, which represents a commonly foot condition in all ages and may be associated with high cost, and increased economic burden due to MHL is one of the leading motivations for physicians and podiatrists care visits regarding the diagnosis and treatment of these foot conditions.^{1,2}

Furthermore, such problem may alter foot integrity due to changes in physiological function which may develop balance impairment over the foot and produce soft tissue atrophy and deformity.³ Also, this problem can be an indicator of poor overall health, loss of personal activity and dysfunction, and its increase may be associated with inappropriate shoes,⁴ foot pain,⁵ changes of parameters of the gait,⁶ increases in plantar pressures ⁷ and risk of falls,⁸ and may be recognized as a main health concern for individuals and all population.

Also, the high prevalence of MHL around 71% and 90% is consequence of longer lifespan expectancy,^{9,10} and their multifactorial aetiology is related to chronic disease, sedentary lifestyle, physiological changes of ageing and variations on the foot width and length and could be affected in multitude of other foot pathologies such as (i) lesser toes, (ii) hallux valgus, (iii) flat foot, (iv) tailor's bunions, (v) plantar fasciitis, (vi) heel pain, (vii) nails disorders, (viii) foot ulceration, (ix) foot infections and (x) pes cavus which receive insufficient preventive care in the general people.

Despite this, no study has been underwent so far to show the effect experienced on the QoL related to foot health in people with MHL. Finally, the main aim of this study was to describe and compare both foot and general health-related QoL in two groups of participants: (i) with MHL and (ii) healthy controls. We hypothesized that participants with MHL may present a worse QoL based on FHSQ scores, regardless of gender.

Methods

Design and sample

A total sample of 150 participants was recruited for this research. This descriptive and observational case–control study was carried out in a private Podiatry Medicine Foot Care Unit that provides assessment of illness and deformities on the feet, in the town of Ferrol, Spain, from June 2015 to June 2016. The sampling frame consisted in a non-randomly selection and consecutive sampling method to recruit the 150 subjects. The inclusions criteria were eighteen years or over, participants with MHL (for the case group), healthy participants (for the control group) and signed consent inform document. The exclusions criteria were younger than eighteen years old, autoimmune illness, medical history of surgery or foot trauma, neuro disorders and refuse or not understanding the instructions to perform the study.

Procedure

At enrolment, each patient was interviewed by a single experienced researcher who recorded details related to overall health and information about disease such as (i) arthritis, (ii) depression, (iii) diabetes, (iv) obesity, (v) musculoskeletal alterations, (vi) vascular disease, (vii) sports in the daily activities and (viii) demographic characteristics (age and sex). Then, all subjects removed their footwear and the clinician examined and measured anthropometrics values such as height, weight and body mass index (BMI), which was calculated from weight in kilograms divided by the square of height in metres (kg/m²).¹¹

Next, the physician examined the foot to determine the presence of MHL and the structural integrity through palpation, mobility, presence of bony deformities, tenderness, strength testing on the foot and the electronic chart of the patient to check for any other foot pathology and systemic diseases. Finally, the volunteers self-administered to evaluate and compare the foot health and health in general impact using the Foot Health Status Questionnaire (FHSQ).¹² This tool on health-related QoL is intended specifically for the foot health status which is recognized as a validated test that present three sections.¹³ In the first section, thirteen questions were related to four domains about foot health: (i) foot function, (ii) foot pain, (iii) footwear and (iv) overall foot health. This first section showed a high degree regarding content, criterion and construct validity (the Cronbach α varies from 0.89 to 0.95) and high retest reliability (the intraclass correlation coefficient ranges from 0.74 to 0.92).14 In the second section, four domains were related to overall health: (i) general health, (ii) physical function, (iii) social function and (iv) vitality. The domains and questions in this section were validated and adapted from the Medical Outcomes Study 36-Item Short-Form Health.¹⁵ Each response was registered by a software program entitled FHSQ (1.03 version) which, after data processing, provided a score from 0 to 100. A 0 score showed the worst foot health status and a 100 score reflected the best possible status. Furthermore, outcome graphical images were provided by this software. In the ultimate section, sociodemographic and medical record data were registered. This study was conducted according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.¹⁶

Ethical considerations

This research protocol was granted from research ethics committee in the Universidade da Coruña, A Coruña (Spain), application data CEI 08/05/2015. All volunteers gave written informed consent before being part of this study. In addition, human and ethical standards experimentation of the Declaration of Helsinki and other organizations were respected at all the moments.

Sample size calculation

The sample size calculation was based on the difference between two independent groups using the G*Power 3.1.9.2 software and the foot pain domain scores (mean \pm SD) from the Foot Health Status Questionnaire (FHSQ) from a pilot study (n = 40) with two groups. A case group of 20 patients with MHL (FHSQ foot pain domain score = 75.59 \pm 17.56) and a healthy control group of 20 participants (FHSQ foot function domain score = 61.84 \pm 27.13) were utilized for the data analysis. In addition, a one-tailed hypothesis, an effect size of 0.60, an α error probability of 0.01, a power (1- β error probability) of 0.90 and an allocation ratio (N2/N1) of 1 were considered for the sample size calculation. Thus, a total sample size of 148 participants with 74 in each group was estimated.

Statistical analysis

All data were analysed for normality of distribution by means of the Kolmogorov–Smirnov test and considered to present a normal distribution if P > 0.01. Demographic data (age, BMI, height and weight) and FHSQ domains (foot pain, foot function, footwear, general foot health, general health, physical activity, social capacity and vigour) were described. Considering the quantitative data, mean and standard deviation (SD) for parametric data and median and interquartile range (IR) for nonparametric data as well as maximum and minimum (range) values were utilized to describe the total sample, patients with MHL (case group) and healthy participants (control group). Regarding the categorical variable, frequencies and percentages were used to describe the sex of the participants.

With respect to quantitative data, Student's *t*-tests for independent samples were used to establish if differences were statistically significant for parametric data, and Mann–Whitney *U*-tests were used to obtain if differences were statistically significant for nonparametric data. With regard to the categorical variable, the chi-square (χ^2) test was used to assess sex differences between both groups. The Foot Health Status Questionnaire (FHSQ) Version 1.03 was utilized to determine foot-health-related QoL scores. For all analyses, statistical significance was set at *P*-value < 0.01 and a 99% confidence interval (CI). In addition, all analyses were carried out with the SPSS 19.0 (Chicago, IL, USA) commercially available software.

Results

Demographic data

A total sample of 150 participants between 18 and 83 years old with a median \pm IR of 49.50 \pm 36.50 years completed the research course. This sample was divided into 75 patients with MHL (for the case group) and 75 healthy matched participants (for the control group). Regarding Table 1, the demographic characteristics of the sample did not show statistically significant differences (P > 0.01), except for the age (P < 0.001) showing older participants in the group with MHL.

FHSQ domains scores

The results of the comparison of the FHSQ scores between both groups were shown in Table 2. In Section 1 of the FHSQ, there were statistically significant differences ($P \le 0.001$) between both groups for all the specific foot domains (pain, function, health and footwear). In Section 2 of the FHSQ, there were statistically significant differences for the domains of general well-being such as general health (P = 0.004) and physical activity (P < 0.001), showing higher scores of these FHSQ domains in favour of the sample with MHL with respect to healthy controls. The rest of domains, such as social capacity and vigour, did not show statistically significant differences (P > 0.01).

Discussion

The main aim of this study was to describe and compare both foot and general health-related QoL in two groups of participants: (i) with MHL and (ii) healthy controls. Foot skin is a first barrier in the human body, and its function is related with mechanisms of protection, thermoregulation and sensitivity.¹⁷ Although previous researches have been undertaken to assess the impact of the QoL related to foot health in patients with hallux valgus, children with foot arch, population with flat foot, menopausal women, sea workers and pregnant women,^{18–24} no study has previously focused on the relationships with MHL.

This is the first research outlined that showed lower scores in the QoL for all the specific foot health domains (pain, footwear, foot health, foot function) as well as the general well-being domains (overall health, vigour, physical activity and social capacity).

Thus, this results showed important implications for medical practice in the regular maintain of the foot care and may be very important for the persons for such QoL increase, autonomy and wellness as several researches showed little preventive attention on the control of the feet in all the people.^{9,25–27} Currently, although the cut-off points regarding the FHSQ have not been yet established for these foot conditions, the second section of

 Table 1
 Comparison of demographic characteristics of the total sample, patients with MHL and healthy matched controls with normalized reference values.

	Total group <i>N</i> = 150	MHL <i>N</i> = 75	Healthy <i>N</i> = 75	P-value
Sex, m/f (%)	34/116 (22.66/77.33)	17/58 (22.66/77.33)	17/58 (22.66/77.33)	1.000‡
Age, years	49.50 ± 36.50 (18–83)	61.00 ± 19.00 (24–83)	30.00 ± 27.00 (18–82)	<0.001 †
Weight (kg)	63.00 ± 18.50 (46–120)	64.00 ± 16.00 (46–108)	63.00 ± 21.00 (47–120)	0.748†
Height (m)	$1.65\pm0.10~(1.451.88)$	$1.62\pm0.12~(1.451.80)$	$1.65\pm0.12~(1.491.88)$	0.039†
BMI (kg/m ²)	24.47 \pm 4.03 (16.65–38.86)	24.86 ± 3.80 (18.43–35.27)	$24.07\pm4.23(16.6538.86)$	0.230*

*Mean \pm SD (range) and Student's *t*-test for independent samples were performed.

†Median \pm IR (range) and Mann–Whitney U-test were utilized. [‡]Frequencies (percentages) and chi-square (χ^2) test were utilized.

^{*}Frequencies (percentages) and chi-square (χ^2) test were utilized.

BMI, body mass index; MHL, mechanical hyperkeratosis lesions; IR, interquartile range; m/f, male/female; SD, standard deviation. In all the analyses,

P < 0.01 (with a 99% confidence interval) was considered statistically significant.

	Total group Median ± IR <i>N</i> = 150	MHL Median ± IR <i>N</i> = 75	Healthy Median ± IR <i>N</i> = 75	Mann–Whitney <i>U</i> -test <i>P</i> -value
Foot pain	84.37 \pm 30.00 (0–100)	78.12 \pm 39.38 (0–100)	87.50 \pm 75.00 (25–100)	<0.001
Foot function	93.75 ± 18.95 (0–100)	87.50 \pm 25.00 (0–100)	100.00 \pm 12.50 (37–100)	0.001
Footwear	50.00 ± 50.00 (0–100)	33.33 \pm 41.67 (0–100)	66.66 ± 41.67 (0–100)	<0.001
General foot health	60.00 \pm 42.50 (0–100)	60.00 \pm 47.50 (0–100)	85.00 ± 32.50 (12–100)	<0.001
General health	70.00 ± 40.00 (10–100)	60.00 ± 30.00 (10-100)	80.00 \pm 40.00 (20–100)	0.004
Physical activity	88.88 ± 22.22 (11–100)	83.33 ± 27.78 (11–100)	94.44 ± 11.11 (11–100)	<0.001
Social capacity	87.50 ± 25.00 (0–100)	87.50 ± 25.00 (0–100)	87.50 ± 25.00 (37–100)	0.394
Vigour	56.25 \pm 25.00 (0–100)	$50.00\pm25.00\;(0100)$	56.25 \pm 31.25 (12–100)	0.405

 Table 2
 Comparison of FHSQ scores of the total sample, patients with MHL and healthy matched controls with normalized reference values.

FHSQ, Foot Health Status Questionnaire; MHL, mechanical hyperkeratosis lesions; IR, interquartile range. In all the analyses, *P* < 0.01 (with a 99% confidence interval) was considered statistically significant.

Bold numbers denoted P-values < 0.01.

the FHSQ was largely adapted from the Medical Outcomes Study 36-Item Short-Form Health.¹⁵

Nevertheless, there are some limitations of the study that should be acknowledged. Firstly, a larger sample size and more diverse subjects from various countries would be beneficial to strengthen this study and would help to identify differences attending different cultures and involved mechanism. Secondly, although 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. Finally, although the presence of older participants in the group with MHL may influence the outcome measurements, the problems associated with MHL seem to appear with higher frequency in older adults.⁴ In addition, although foot pain and physical function were evaluated by means of the FHSQ specific domains, pain intensity and physical activity should be measured in future studies.¹² Lastly, expanding data collection to other countries would be beneficial to strengthen this study.

This highlights the need for further research on the presence and severity of MLH and how it influences on the presence on the foot to improve patient's health, QoL and autonomy of all persons.

Conclusion

In conclusion, measurable differences of association between patients with MHL and healthy controls were revealed showing an impaired QoL for all the specific foot health domains as well as the general well-being domains such as general health and physical activity.

Ethics approval and consent to participate

This research was granted from Research Ethics Committee at the Universidade da Coruña, A Coruña (Spain), application data

CEI 08/05/2015. All volunteers gave written informed consent before being part of this study.

Consent for publication

The authors declare that they consent for publication.

Availability of data and supporting materials section

The data set supporting the conclusions of this article is available in the daniellopez@udc.gal in the Research, Health and Podiatry Unit, Department of Health Sciences, Faculty of Nursing and Podiatry, Universidade da Coruña, Spain.

Author contributions

All authors contributed to concept, design, analyses, interpretation of data, drafting of manuscript or revising it critically for important intellectual content.

Acknowledgements

To all patients who had participate in the research.

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