IMPACT OF PERIPHERAL ARTERY DISEASEON THE QUALITY OF LIFE OF PATIENTS WITH DIABETES MELLITUS

ABSTRACT

Background

Diabetes Mellitus (DM) has become one of the main problems of health, which might lead to a series of complications, such as peripheral vasculopathy.

Purpose

The objectives of this study were to determine whether peripheral artery disease affects the quality of life and pain level and functionality of the foot in patients with DM.

Methods

The sample consisted of 150 participants: with peripheral vasculopathy and DM, with DM, without peripheral vasculopathy, with neither DM nor peripheral vasculopathy. Questionnaires SF-12, EuroQol 5D, FFI, and the Manchester Foot Pain and Disability Index were used.

Results

There were significant differences in the physical component of SF-12, in the visual health scale of EuroQol 5D and the functional component of the Manchester Foot Pain and Disability Index the best score was obtained by group C.

Conclusion

Peripheral vasculopathy influences the quality of life of patients with DM and causes functional limitations.

KEY WORDS

Peripheral artery disease; Diabetes Mellitus; Quality of life; Diabetic foot.

INTRODUCTION

Over time, the life expectancy of society has increased, mainly due to the advances in health sciences. This, in combination with unhealthy lifestyles, cause the appearance of chronic diseases; among the most prevalent of these, diabetes mellitus (DM) is notable.[1]

DM has become one of the main problems of the 21st century. Each year, the prevalence of this disease increases, which might lead to a series of complications, such as peripheral vasculopathy.[2]

Regarding the problems caused by DM in the arteries, these range from systemic to local complications. Patients might feel unable to walk long or short distances due to an oxygen demand from the muscles that cannot be met because of the insufficient blood flow, which translates into painful walking. This can make it impossible for these patients to move around, which increases their social isolation. Vasculopathy can also lead to the appearance of ulcers, which is physically a very limiting complication. It is worth mentioning that the treatment of these complications also entails a high cost in financial and human resources.[3]

Several studies confirm that the quality of life of patients with DM might influence their adherence to the treatment, which would increase their clinical recovery and reduce the morbidity and mortality of the disease. The evaluation of DM is recognized as an important area of knowledge from the health-based concept: physical, psychological, socio-economic, and cultural satisfaction and well-being.[4–7]

Regarding the influence of peripheral artery disease on the quality of life of patients with DM, some authors have stated that the main problem is related to functional limitation,[3,8,9] whereas others have concluded that the quality of life does not necessarily have to be affected by these elements [10,11]; thus, it is not clear to what extent the consequences of peripheral artery disease influence the quality of life of patients with DM. The scientific evidence in this topic is insufficient.

PURPOSE

The main hypothesis is that people with DM and peripheral artery disease has worse quality of life, pain level and functionality of the foot than people without this disease.

The main objectives of the present study were to determine whether peripheral artery disease affects the quality of life of people with DM and to verify whether the pain level and functionality of the foot in patients with DM were different in the presence and absence of peripheral vasculopathy.

METHODS

Study design

This was a cross-sectional study. We analyzed the associations between peripheral vasculopathy and the quality of life in DM by comparing three groups: 1) participants with DM and peripheral vasculopathy (Group A), 2) participants with DM and without peripheral artery disease (Group B), and 3) a matched control group of healthy participants with none of these pathologies (Group C).[12]

The study was carried out in the Podiatry Clinical Area of the University of Seville (Spain) and was approved by the Bioethics Committee of the Virgen Macarena and Virgen del Rocío University Hospitals of Seville (Spain). The gathering of data was conducted from January 2017 to July 2018.

Participants

Inclusion criteria

For groups A and B, the participants were required to have a previous diagnosis of DM and be over 18-years-old. In addition, group A also had to show peripheral vasculopathy.[3,8] For group C, the participants had to be over 18-years-old, and have no diagnosis of DM or peripheral vasculopathy.[8]

The DM diagnosis criterion was based on those established by the American Diabetes Association.[13]

Exclusion criteria

Patients with open ulcer and/or amputation,[14] and neoplasia we not included in the study. Since the patients were required to answer questionnaires, we also added dementia [15,16] and expression difficulties [3,8] as exclusion criteria.

The sample size was calculated using the variable "analog scale of pain" as the reference, since the pain caused by peripheral vasculopathy is a limiting symptom in the life of the patient, and the sample size was obtained to compare two measurements (with vasculopathy and without vasculopathy). The formula applied was:

$$n = \frac{2s^2(z_{\frac{\alpha}{2}} + z_\beta)^2}{d^2}$$

where s is the estimation of the typical deviation based on previous studies, α is Type I error, β is Type II error, and d is the minimum difference to be detected. Therefore, the final equation was:

$$n = \frac{2s^2(z_{\frac{\alpha}{2}} + z_\beta)^2}{d^2} = \frac{2 \cdot 3{,}25^2 \cdot (1{,}96 + 0{,}84)^2}{2^2} = 41{,}405 \cong 42$$

Groups A and B had to include at least 42 patients each, and group C was required to have the same number of participants with similar characteristics regarding gender, age, and BMI as those in groups A and B.

Finally, the sample was made up of 150 participants. Group A included 49 individuals diagnosed with peripheral vasculopathy and DM. Group B was composed of 57 participants with DM and without peripheral vasculopathy. Group C was made up of 44 participants with neither DM nor peripheral vasculopathy.

Group allocation procedure

Vasculopathy was diagnosed through the ankle-brachial index (ABI), which is defined as the ratio between foot arterial pressure (pedal or posterior tibial) and brachial arterial pressure. Thus, two results were obtained, one for each foot. The normality values range between 0.9 and 1.3; those below 0.9 (ischemia) or above 1.3 (calcification) were considered as indicators of peripheral artery disease.[14,17–19]

The participants with DM and vasculopathy (uni or bilateral) were allocated in group A, those with DM and without vasculopathy were included in group B, and group C was made up of those with neither DM nor vasculopathy.

Data gathering procedure

The selected participants were asked to complete the following questionnaires:

The SF-12 Health Questionnaire, which is divided into two components, physical and mental, both with a maximum score of 50. The sum of these two components ranges from zero (worst health state) to 100 (perfect health state).[1,20]

The EuroQol 5D, which comprises five dimensions: mobility, self-care, capacity to carry out daily life activities, pain, and anxiety-depression. The second part of the questionnaire is based on an analog visual scale in which the patient values their health state from zero to 100.[1,21]

The MFPDI (Manchester Foot Pain and Disability Index), which is used to measure the level of pain and functionality. This consists of 19 items, of which the first 10 are related to functional limitation, the following five correspond to the intensity of pain, and the last two refer to personal appearance. The total value of the questionnaire ranges between zero and 38.[22]

The FFI (Foot Function Index). This is a questionnaire developed to measure the impact of foot pathologies on foot functionality, distributed in three subscales: disability, activity limitation, and pain. The values range from 0 and 100, with higher values corresponding to greater pain, disability, and limitation. [23]

In addition, for further measurement of foot pain, the WHO's Numeric Pain Rating Scale was used. This consists in a line divided into 10 equal parts in which the participants establish the level of pain they are suffering, which can be no pain (0), mild (1-3), moderate (4-7) or severe (8-10) pain.[24]

Statistical analysis

The statistical analysis was carried out using IBM SPSS Statistics 22 for Windows. The qualitative variables were expressed through frequency tables and the quantitative variables through centralization and dispersion measurements: mean, median, standard deviation, and maximum and minimum values.

For the normality tests of the distribution of quantitative variables, we conducted the Kolmogorov-Smirnov test in group B, as the sample size of this was over 50 (57); for groups A and C, the normality was verified using the Shapiro-Wilk test, as the sample size of these was below 50 (49 and 44, respectively).

The group with DM and peripheral vasculopathy showed a normal distribution in BMI, glycosylated hemoglobin, and in the physical component of SF-12. The group with DM and without vasculopathy presented a normal distribution in BMI, glycosylated hemoglobin, the ABI of the right leg, the ABI of the left leg, the mental component of the SF-12, and in the total of the MFPDI. The control group had a normal distribution in the ABI of the right leg and in the mental component of SF-12.

To determine the existence of significant differences in the values of the different variables, between groups, we used the following statistical tests: If the variables are normal quantitative, T-test for independent samples; If the variables are non-normal quantitative, Mann-Whitney's U-test; If the variables are qualitative, Chi-square test. For this type of analysis, a confidence interval of 95% was established. It was considered that there were statistically significant differences if $p < 0.05$.

RESULTS

The sample was constituted by 150 individuals, 78 men (52%) and 72 women (48%), divided into three groups.

Group A shows an evolution of DM between 1- and 50-years-old (16.53 ± 13.30 years) and 51.02% of the individuals of this group did not know their levels of glycosylated hemoglobin. Group B shows an evolution of DM between 1- and 46-years-old (15.61 ± 10.29 years) and 38.59% of the individuals of this group did not know their levels of glycosylated hemoglobin.

Tables 1 and 3 show the descriptive data of questionnaires: SF-12, EuroQol-5D, FFI, and MFPDI, respectively, in the three groups.

In the analog health scale of EuroQol 5D, groups A, B, and C obtained a mean score of 65.6 ± 23.1, 65.1 ± 16 and 72.8 ± 18.6, respectively.

There were no significant differences between the three groups in the FFI values obtained.

On the other hand, there were significant differences in the SF-12 results, specifically in the physical component, with a significance of 0.002. Group C showed a higher quality of life, followed by group B, with the worst result being obtained by group A.

Moreover, there were significant differences in the values obtained in the EuroQol-5D questionnaire, although only for the analog health scale, with a significance of 0.042. Group C obtained the highest score with respect to the other groups.

There were also significant differences regarding the results of the functional component of the MFPDI, with a significance of 0.007. The highest score was obtained by group A, followed by group B and C. For the remaining variables, no significant differences were detected.

DISCUSSION

The aim of this study was to determine whether peripheral artery disease affects the quality of life of people with DM and whether the pain level and functionality of the foot in patients with DM is different with and without vasculopathy. Significant differences were found in the quality of life of the participants, with the worst results being found in the group of patients with DM and vasculopathy; in this group, according to the results of the MFPDI, foot functionality obtained the lowest score.

In the present study, the physical component of SF-12 decreased as the number of problems increased; peripheral vasculopathy can play an important role in the quality of life of patients with DM. Oka and Sanders observed that patients with DM and vasculopathy showed a worse perception of their own health state and a decrease in functionality.[3] Furthermore, Amer et al. concluded that peripheral artery disease significantly affects the quality of life and functionality of older patients with DM.[8] Venkataraman et al. established that the physical component was affected by macrovascular and microvascular problems. The quality of life of patients with DM is undermined by a higher number of complications, among which the most influential is vasculopathy.[9] These studies are consistent with the present study regarding the data

obtained in the SF-12 questionnaire (i.e., there are significant differences in the physical component). On the other hand, there is no evidence on the relevance of the mental component of SF-12 in the quality of life of people with DM and vasculopathy, which is in line with the present work, as there were no significant differences in such component between the study groups. The observation of Oka and Sanders about health state perception is different from that of the present study, according to the results provided by the visual health scale of EuroQol-5D; i.e., suffering from vasculopathy does not influence the scale, whereas Oka and Sanders do establish the importance of suffering from vasculopathy in the perception of the health state. This could be due to the use of a different measuring instrument. Venkataraman et al. highlight peripheral artery disease over other problems.

Fernández-Bolaños and Hidalgo concluded that the quality of life of people with DM is not necessarily lower than that of people without DM. The factors associated with vasculopathy are related to a decrease in the quality of life of people with DM.[10]

These authors used the EuroQol-5D questionnaire, which provides a more global view of the quality of life.[1] The results obtained in the present study do not show significant differences in any of the domains of EuroQol-5D. Thus, they would be in agreement with the results of Fernández-Bolaños and Hidalgo regarding the fact that the quality of life of patients with DM does not necessarily have to be worse than that of people without DM. However, the results obtained in the SF-12 questionnaire show a difference in the physical component. Thus, the use of this questionnaire might influence the results. Nevertheless, Fernández-Bolaños and Hidalgo highlight the influence of peripheral artery disease in the quality of life of people with DM.

Sales et al. (2015) carried out a transversal descriptive study in 73 patients with DM who did not have a previous diagnosis of vasculopathy. To analyze the quality of life, they used the SF-36 questionnaire. No significant differences were observed between the sample groups (with vasculopathy and without vasculopathy).[25]

In that article, the results are different from the ones obtained in the present study. These authors detected no significant differences. If the group of patients with artery problems was similar in size to the other group, perhaps the results would have been different.

According to the literature review conducted, two characteristic symptoms of peripheral vasculopathy are functional limitation and pain in the lower limbs. These two problems

are present in the population studied, and they might have a strong influence on the quality of life of people with this disease.[3,9,22,23]

In this regard, Gardner et al. became interested in studying the economy in walking before and after the pain caused by vasculopathy. These authors concluded that this depends on the severity of the disease, the presence of DM, and arterial hypertension.[26] Then, Garg et al., after reporting that the presence of arteriopathy affects the innervation of the calf muscles, they observed that the peroneal nerve was less functional in patients with lower muscle mass and peripheral artery disease and that these patients had lower mobility.[27]

Gengo and Silva et al., after a histological study in 63 patients with vasculopathy, analyzed the distance walked, free of pain, finding that this distance decreased as the severity of the disease increased.[28] Cheung, Lam, and Cheung observed that patients with DM and vasculopathy had less support and walking speed compared to patients without DM or arteriopathy.[29]

Lastly, in 2016, Yeboah et al. described that prevalence of vasculopathy was greater in individuals with DM, although the pain caused by arteriopathy was more prevalent in the group without DM. These authors concluded that peripheral artery disease in patients with DM tends to be asymptomatic.[30]

There were no statistically significant differences between the two groups in the FFI questionnaire. Regarding the MFPDI, statistically significant differences were obtained in the functional component, with the most affected group being the one with DM and vasculopathy, followed by the group of patients with DM and without vasculopathy. According to this, arteriopathy might cause functional limitation in the patient. These results are in line with those of the studies previously mentioned regarding functionality since all the authors that studied this symptom agree that peripheral artery disease produces functional limitation. With respect to pain, there are coincidences with Yeboah et al., who reported that vasculopathy is asymptomatic in patients with DM. The rest of the studies mention the presence of pain and its relevance in walking; the results of the importance of pain were likely different due to the use of different questionnaires.

The findings of the present study could help design the treatment of patients with DM and vasculopathy based on their quality of life and create new treatment techniques that help improve the functional limitations present in the disease.

The main limitation found in this study was the lack of a questionnaire on the quality of life specific to peripheral vasculopathy, which could have generated different results.

It is worth mentioning that a large percentage of patients did not know their level of glycosylated hemoglobin. Thus, it was not possible to determine whether DM was controlled. Therefore, it was not possible to associate the complications or symptoms with the control of DM.

CONCLUSION

The quality of life of people with DM in this study might have been affected by the presence of peripheral vasculopathy. According to the results obtained in the MFPDI, this disease caused functional limitation in the participants of this study.

BRIEF SUMMARY

What Is Already Known

DM has become one of the main problems of the 21st century.

The problems caused by DM in the arteries range from systemic to local complications.

Peripheral artery disease on the quality of life of patients have stated that the main problem is related to functional limitation.

What This Study Adds

The quality of life of people with DM in this study might have been affected by the presence of peripheral vasculopathy.

Peripheral vasculopathy caused functional limitation in the participants of this study.

The physical component of SF-12 decreased as the number of problems increased.

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TABLE 1. Description of the SF-12 and FFI questionnaires results in the sample.

		Mean	Standard Deviation	Minimum	Maximum
Group A	SF-12 Mental	42.65	12.57	13.10	64.20

	SF-12 Physical	38.53	9.85	16.20	58.30
	FFI Pain	27.25	29.64	0	91.11
	FFI Disability	34.53	29.53	0	92.22
	FFI Functional limitation	10.32	20.05	0	96
	FFI Total	26.43	23.28	0	86.52
Group B	SF-12 Mental	40.84	9.67	18.50	55.50
	SF-12 Physical	42.93	9.20	18.90	56.90
	FFI Pain	25.68	26.71	0	100
	FFI Disability	29.48	28.52	0	86.66
	FFI Functional limitation	7.64	14.83	0	68.00
	FFI Total	22.97	21.71	0	82.17
Group C	SF-12 Mental	43.82	43.82	43.82	43.82
	SF-12 Physical	45.16	45.16	45.16	45.16
	FFI Pain	21.20	25.04	0	85.55
	FFI Disability	23.05	26.50	0	95.55
	FFI Functional limitation	5.00	10.74	0	60.00
	FFI Total	18.42	19.64	0	82.17

TABLE 2. Description of the EuroQol-5D questionnaire results in the sample.

EuroQol-5D	Mobility	Self-care	Daily activities	Pain/discomfort	Anxiety/depression

Group A	No problems	53.1%	87.8%	75.5%	44.9%	67.3%
	Some problems	46.9%	12.2%	16.3%	40.8%	22.4%
	Several problems	0%	0%	8.2%	14.3%	10.2%
Group B	No problems	63.2%	91.2%	71.9%	49.1%	61.4%
	Some problems	36.8%	8.8%	28.1%	38.6%	33.3%
	Several problems	0%	0%	0%	12.3%	5.3%
Group C	No problems	68.2%	95.5%	84.1%	50.0%	63.6%
	Some problems	31.8%	4.5%	15.9%	38.6%	31.8%
	Several problems	0%	0%	0%	11.4%	4.5%

TABLE 3. Description of the Modified Manchester Questionnaire results in the sample.

Manchester Questionnaire	**Mean**	**Standard Deviation**	**Minimum**	**Maximum**

Group A	Functionality	8.27	6.06	0	19
	Personal appearance	0.65	1.26	0	4
	Pain	2.86	3.24	0	10
	Work	1.20	1.51	0	4
	Total	12.98	10.48	0	37
Group B	Functionality	7.12	5.75	0	20
	Personal appearance	0.35	0.83	0	4
	Pain	3.14	2.90	0	10
	Work	1.18	1.59	0	4
	Total	11.79	9.37	0	31
Group C	Functionality	4.75	5.38	0	19
	Personal appearance	0.50	1.15	0	4
	Pain	2.73	3.16	0	10
	Work	0.61	1.22	0	4
	Total	8.59	9.47	0	36