Quality of Life and Self-care Activities in Diabetic Ulcer Patients, Grade 3: Gender Differences

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Introduction
Diabetes mellitus type II (DMT2) is one of the leading chronic and non-communicable diseases, worldwide. According to estimates, in 2010 the number of patients with DMT2 reached approximately 200 million globally which is anticipated to increase to 266 million in a period of 25 years.1 DMT2 seems to vary globally due to differences regarding predisposition, development, and clinical presentation which are mainly attributed to diversities in biology, culture, lifestyle, environment, and socioeconomic status.2 Individuals above 40 years old1 and males are diagnosed more often with DMT2. Specifically, in 2013, about 14 million more men than women estimated to have DMT2.3 Mortality rates are higher in men since they have more life-threatening chronic diseases such as cardiovascular diseases.4

Diabetic foot ulcer (DFU) is a common and long-term complication of DMT2 which is associated with morbidity and disability5 and emotional disturbance.6 Annually, more than 1 million individuals with DMT2 worldwide lose a leg as a complication of this disease.5

DFU is more prevalent in males.7 Predominance of male gender is partially explained by the fact that men have more outside activity than women, which in turn leads to more foot exposure to risks and more plantar feet pressure.8

From clinical perspective, quality of life (QoL) is a key-measurement to evaluate treatment effectiveness and inform decision making.9 However, DFU clinical care demands effective self-care activities by patients10 which are strongly associated with improved overall health and better QoL.11 The demographic factor of gender may influence behavior regarding foot care. Interestingly, women and men with DMT2 may exhibit differences in the way they encounter with self-care activities. For instance, men pay less attention to foot care, thus resulting in a higher proportion of amputations whereas women face difficulties in lifestyle changes or physical activity, thus maintaining less glycemic and lipid control.12 Meanwhile DFU severity is associated with poor QoL. Wagner's...
staging is a clinical measurement which is strongly associated with disease-specific QoL. The routine use of this classification is suggested for prompt recognition and prevention of DFU deterioration.19

Considering these aspects, the changing landscape is to emphasize on interventions for different sexes with ultimate goal to improve QoL. Nowadays, there is noticed a demand of gender inclusion in research, thus improving scientific quality of the produced knowledge or innovation. Gender assessment may provide useful information for treatment decisions in DFU patients and be precious when designing interventions to improve QoL.

To address these gaps, the aim of this cross-sectional study was to explore gender differences among DFU patients (grade 3) regarding QoL and adherence to self-care activities.

Materials and Methods
In this cross-sectional study were enrolled DFU outpatients (135 male and 135 females), attending follow up visits in an outpatient clinic of a public hospital in Attica. Study participants were selected using convenience sampling. The study included patients during the period December 2018 to October 2019.

Criteria for patients’ inclusion in the study were: a) adult with DM type II having a foot ulcer Grade 3 according to Wagner classification scale, b) outpatients attending follow-up visits and not hospitalized ones and c) the ability to write and read the Greek language fluently. The exclusion criteria were patients: a) with a history of mental illness, b) with traumatic foot lesion, c) with other severe or chronic disease, d) not able to communicate throughout the study period and e) classified to some other Wagner grade and not grade 3.

More in detail, before a patient recruitment in the study, the Wagner scale was used to classify the severity of foot ulcers, as following14: grade 0- intact Skin; grade 1- superficial ulcer of skin or subcutaneous tissue; grade 2- ulcers extend into tendon, bone, or capsule; grade 3 - deep ulcer with osteomyelitis, or abscess; grade 4 - partial foot gangrene; grade 5 - whole foot gangrene.

Wagner's scale is a widely used instrument among DFU patients which is also recommended for monitoring to prevent further deterioration. The use of Wagner classification may enable meaningful and comparative research across large and diverse populations, worldwide.14

The interview lasted approximately 15 minutes and took place for all participants while waiting for their follow-up in the outpatient clinical setting.

Prior to data collection, patients were explained about the nature and the objectives of the study. All patients participated in the study voluntarily and had their anonymity preserved. Written informed consent was obtained from all patients being interviewed.

Data collection was performed by the method of interview using the following: a) Short Form Health Survey (SF-36) to measure QoL15 and b) Diabetes Self-care Activities Questionnaire16 to measure adherence to self-care. The demographic characteristics of both genders were: age, marital status, educational level, occupation, and number of their children.

For the assessment of QoL of participants, the “Short Form Health Survey (SF-36)” questionnaire was used. The SF-36 evaluates the physical and mental health. It consists of 36 questions which are grouped in 8 dimensions: Physical functioning, Role physical, Role emotional, Energy/fatigue, Emotional well-being, Social functioning, Bodily Pain and General Health (range of values for each dimension 0-100, the lower the score the worse QoL) Respondents have the ability to answer every question on Likert-type scales. The scores attributed to the questions are summed separately for the questions that evaluate the 8 dimensions. Higher score values indicate better QoL.15

In terms of reliability of the Greek translation of the SF-36 questionnaire, Cronbach's alpha exceeded, in all scales, the 0.70.17

For the assessment of self-care activities, the “Diabetes Self-Care Activities Questionnaire” was used. More in detail, adherence included the following 4 categories: (a) Diet (Range: 0-35), (b) Exercise (Range: 0-14), (c) Blood-Examination (Range: 0-14) and (d) Foot check (Range: 0-35). Patients were able to answer every question in an 8-point Likert scale from 0-7. The scores attributed to the questions are summed separately for these 4 scales. Higher score values indicate better adherence to self-care activities. Cronbach's alpha exceeded the accepted value of 0.70.16

Categorical data are presented in absolute and relative (%) frequencies, while continuous data are presented with median and interquartile range (IQR). Normality of continuous data was checked with Kolmogorov-Smirnov test and graphically with Q-Q plots. None of the continuous variables followed the normal distribution.

Reliability of participants answers were assessed with Cronbach alpha coefficients. Non-parametric tests Kruskal-Wallis, Mann-Whitney, were used to evaluate the association between QoL and patients’ characteristics. Additionally, Spearman rho coefficient was used to evaluate the association between QoL and patients’ adherence to self-care activities. The observed level of significance was set to 5%. Data analysis was performed using SPSS version 20 (SPSS Inc, Chicago, IL, USA).

Results
Of the total sample of 135 male participants, 71.8% were over 60 years old, while 77% were married and 20.7% had primary education. The majority of the respondents (67.9%) was pensioners, lived in Attica (59.3%) and had two children (49.6%).

Of the total sample of 135 female participants, 68.9% were over 60 years old, while 60% were married and 24.4% had primary education. The majority of the respondents...
(78.6%) was pensioners and had two children (52.6%). (Table 1)

Table 2 presents the distribution of QoL of the 135 men patients. Male participants had moderate to high levels of QoL in the categories of energy/fatigue, emotional wellbeing, social functioning and bodily pain (medians: 60, 68, 62.5 and 67.5, respectively), while they had low levels of QoL in the categories of physical functioning, role physical and role emotional (medians: 21, 0 and 33.3, respectively). Finally, male participants had moderate levels of QoL in general health (median 50).

Cronbach alpha values were above 0.6, indicating high reliability of male participants’ answers.

Table 3 presents the distribution of QoL of the 135 women patients. Female participants had moderate QoL in the categories of energy/fatigue and social functioning (medians: 55 and 50 respectively), whereas they had low QoL in the categories of physical functioning, role physical, role emotional, emotional well-being and bodily pain (medians: 22, 25, 0, 34 and 37.5 respectively). Finally, female participants had moderate to low QoL in general health (median 37).

Similarly as men, Cronbach alpha values were above 0.6, indicating high reliability of female participants’ answers.

Male participants had high levels of adherence in the category of blood-examinations (median: 14) and low levels of adherence in the categories of diet, exercise and foot check (median 14, 3 and 12 respectively). Female participants had moderate levels of adherence to diet (median: 22), high levels of adherence to blood examination and foot check (median 14 and 29, respectively), and low levels of adherence to exercise (median 2). (Table 4)

Male patients’ adherence with diet and foot care had no statistically significant association with QoL. On the contrary, adherence with exercise had a statistically significant association with all sub-categories of QoL apart from those of role (physical and emotional). This association was positive which means that an increase of QoL in aforementioned dimensions the better adherence to self-care activities regarding exercise. Additionally, it was found a statistically significant association between adherence with blood examinations and emotional well-being. The better QoL in emotional well-being, the better adherence with blood examination (check-up) (rho = 0.18). Table 5 presents the association of male patients’ QoL with adherence to self-care activities.

Table 6 presents the association between QoL and adherence to self-care activities of female participants. Adherence to diet, blood examination and foot check was not found to be statistically significantly associated with QoL. On the contrary, adherence to exercise was found to be statistically significantly associated to all the subscales of QoL, apart from those of role (physical and emotional) and general health. The association was positive, meaning that increase in the score of QoL indicates increase in adherence to exercise and vice versa.
Discussions

In the current study, both men and women had low QoL in the categories physical functioning, physical and emotional role. Men had moderate to high QoL in energy/fatigue and social functioning whereas women had moderate QoL in these categories. Regarding general health, men had moderate QoL while women had moderate to low QoL. Additionally, in emotional well-being and bodily pain, men had moderate to high QoL while women had low QoL.

Gender differences regarding QoL is a matter of controversy. A recent study conducted by Del Core et al., who measured QoL by SF-36 among 120 male patients matched with 120 female showed worse physical functioning and bodily pain among women and a trending decrease in general health score. Alshayban and Joseph indicated the female gender as an independent predictor of poor QoL. According to D’Souza et al., men had lower QoL in all domains compared to women and attributed this finding to gender differences in personal and clinical characteristics. Possibly men experience more restrictions in daily life due to unexplained physical and emotional problems.

Men seem to have diminished QoL since they are less healthy, have lower life expectancy at all ages and a greater likelihood of suffering from life-threatening diseases. Men more often seek help for acute problems, discuss more foot-related problems, have a pessimistic view of future, display a passive attitude and use more complementary care from the lay sector (wife) and/or the professional sector (health professionals). However Siddiqui et al., indicated that men are living more effectively with DMT2.

Table 4. Evaluation of adherence with self-care activities

| Variable           | Mean (SD) | Median (IQR) |
|--------------------|-----------|--------------|
| **Male participants** |           |              |
| Diet               | 15.3 (5.2) | 14 (11-24)   |
| Exercise           | 3.3 (3.0)  | 3 (1-5)      |
| Blood examination  | 12.1 (3.6) | 14 (12-14)   |
| Foot check         | 14.1 (6.7) | 12 (9-24)    |
| **Female participants** |       |              |
| Diet               | 22.9 (6.3) | 23 (19-26)   |
| Exercise           | 2.8 (2.7)  | 2 (0-5)      |
| Blood examination  | 11.4 (3.9) | 14 (10-14)   |
| Foot check         | 28.6 (6.1) | 29 (22-33)   |

SD: Standard deviation; IQR: Interquartile range.

Table 5. Association between QoL and adherence to self-care activities in male DFU patients (N = 135)

| Variable            | Adherence to |  
|---------------------|--------------|
|                     | Diet  | Exercise | Blood examination | Foot check  |
|                     | Rho   | P value  | Rho   | P value  | Rho   | P value  | Rho   | P value  |
| Physical functioning| -0.11 | 0.16    | 0.30 | 0.001*   | -0.05 | 0.50    | 0.08  | 0.32    |
| Role physical       | -0.05 | 0.51    | 0.14 | 0.09     | 0.06  | 0.47    | 0.04  | 0.58    |
| Role emotional      | -0.07 | 0.40    | 0.08 | 0.35     | 0.09  | 0.27    | 0.10  | 0.21    |
| Energy/fatigue      | 0.05  | 0.54    | 0.43 | 0.001*   | 0.01  | 0.88    | -0.01 | 0.90    |
| Emotional well being| 0.06  | 0.49    | 0.21 | 0.01*    | 0.18  | 0.02*   | 0.07  | 0.36    |
| Social functioning  | 0.03  | 0.65    | 0.35 | 0.001*   | 0.06  | 0.47    | 0.03  | 0.66    |
| Bodily pain         | -0.02 | 0.81    | 0.24 | 0.004*   | 0.11  | 0.18    | -0.10 | 0.20    |
| General health      | 0.14  | 0.10    | 0.23 | 0.007*   | -0.01 | 0.86    | 0.07  | 0.40    |

* Spearman’s rho correlation coefficient was used; * Statistically significant.

Table 6. Association between QoL and adherence to self-care activities in female DFU patients (N = 135)

| Variable            | Adherence to |  
|---------------------|--------------|
|                     | Diet  | Exercise | Blood examination | Foot check  |
|                     | Rho   | P value  | Rho   | P value  | Rho   | P value  | Rho   | P value  |
| Physical functioning| -0.08 | 0.50    | 0.54 | 0.00*    | 0.20  | 0.11    | 0.19  | 0.12    |
| Role physical       | -0.07 | 0.56    | 0.19 | 0.12     | -0.11 | 0.36    | 0.22  | 0.08    |
| Role emotional      | -0.14 | 0.27    | 0.21 | 0.10     | -0.06 | 0.59    | 0.21  | 0.10    |
| Energy/fatigue      | -0.06 | 0.61    | 0.31 | 0.01*    | -0.02 | 0.87    | 0.02  | 0.83    |
| Emotional well-being| -0.02 | 0.86    | 0.36 | 0.004*   | 0.03  | 0.79    | 0.17  | 0.19    |
| Social functioning  | -0.10 | 0.40    | 0.37 | 0.003*   | 0.02  | 0.87    | 0.21  | 0.11    |
| Bodily pain         | -0.04 | 0.74    | 0.38 | 0.002*   | 0.17  | 0.17    | 0.21  | 0.09    |
| General health      | -0.02 | 0.83    | -0.03 | 0.80    | -0.02 | 0.83    | -0.13 | 0.29    |

* Spearman’s rho correlation coefficient was used; * Statistically significant.
have more energy and better positive wellbeing. The same researchers showed men to be more satisfied with disease management and women to need a more positive attitude towards the disease.

Another possible contributor to gender dissimilarities might be the perceived impact of disease on daily life which is mainly attributed to roles and stressors unique to each gender. For instance, women maintain the duties within household with the additive responsibilities of caring for their own disease.

Results also revealed that participants (both male and female) showed low adherence to exercise which is explained by the advanced stage of ulcer (stage 3). Possibly, individuals may not endure the discomfort associated with exercise. One more impediment in low adherence to exercise may be the emotional burden since patients with DMT2 have twice the prevalence of depression than nondiabetic.24 Notably, barriers in adherence are multifactorial and need elaborate evaluation25 since DFU patients have decreased capacities for exercise and increased need for exercise instruction and monitoring.

Both men and women had high adherence in the category of blood examination. Furthermore, male participants had low adherence in the categories of diet, and foot check while female participants had moderate adherence to diet and high adherence to foot check.

Several barriers are responsible for gender differences related to self-care among DFU patients. Male report performing self-monitoring of blood glucose more frequently than female counterparts.26 Women may experience lack of self-confidence when performing self-care activities and inadequate support from immediate friends and family.27 Furthermore, barriers to self-management are primarily social for women, whereas for men, are mainly aspects related to work.28 Social support29 and education30 may enhance adherence to self-care and DFU management.

In terms of association between QoL and self-care activities, results showed that adherence with exercise had a significant association with all sub-categories of QoL apart from role physical and emotional, both in male and female. Physical activity contributes to higher QoL through multiple direct and indirect pathways. For example, physical activity helps to regulate normal glucose uptake into peripheral tissues, and increases insulin receptors and insulin sensitivity, thus contributing to blood glucose control.31 Furthermore, aerobic exercise with bicycle ergometer among 61 DFU individuals (31 males) is increasing oxygen percentage saturation, thus resulting in wound healing after twelve weeks intervention.32 After, a 10-week non-weight bearing exercise program, the ability to perform activities of daily living was improved in men with severe peripheral neuropathy and active foot ulcer and specifically more, maximal isometric knee-extension muscle strength improved by 23%.33 A non-weight bearing exercise should be encouraged as part of treatment of DFU.34 Increasing the strength of foot ankle and mobility is included in recommendation for people at risk of a DFU. An intervention health program along with supervised exercise is reducing symptoms of neuropathy.35 Moreover, an educational booklet for foot care is a tool that enables patients to perform exercises and increase foot muscle strengthening.36

Exercise improves muscle weakness which is associated with physical disability, less daily walking activity, balance deficit and higher risk of falls37 thus indirectly improving QoL. Developing interventions to safely increase exercise in this vulnerable population may help patients to attain control of ulceration and ultimately improve QoL.

This study has some limitations. We should, acknowledge a number of methodological caveats that need to be considered when interpreting the present results. Convenience sampling is one of the limitations in this study. This method is not representative of all population with DFU living in Greece, thus limiting the generalizability of results. Other limitations are related to the study design which was cross-sectional and not longitudinal, thus not permitting investigation for causal relation between self-care activities and QoL. Moreover, there was no other following measurement that would allow evaluation of possible changes in all dimensions under assessment (QoL and self-care activities).

A strength of the study is the use of a reliable, valid and widely used instrument for the assessment of QoL that may permit comparisons across the world. The sample size was relatively small, although many significant associations were observed.

Conclusion

Grade-3 male participants had low QoL in physical functioning, role physical and emotional. Grade-3 female participants had low QoL in physical functioning, role physical and emotional, emotional well-being and bodily pain. Both genders had moderate to low QoL in general health.

Male and female participants had low adherence to exercise. Men had also low adherence in diet and foot check. In both genders, a positive association was found between exercise and the most QoL dimensions. Only in male participants, the better QoL in emotional well-being, the better adherence with blood examination.

The current findings offer a significant contribution to the literature identifying gender dissimilarities regarding QoL and self-care activities among DFU patients, grade 3 according to Wagner classification system.

A comprehensive understanding of the relationship between self-care activities and level of QoL will support the development of tailored interventions to reduce ulceration burden and improve QoL.

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Ethical Issues
The study was approved by the medical research ethics committee of GORNA, Greece (REG NUB 7/11.10.2020). This study took place and it was conducted in accordance with the Declaration of Helsinki (1989) of the World Medical Association.

Conflict of Interest
The authors declare that they have no conflict of interest.

Authors’ Contributions
MP, GV, IK: Conceptualization; MP, GV, IK: Formal analysis; ED, GP, VD, GG: Investigation; ED, GP, VD, GG, MP: Writing-review and editing; MP: Supervision; MP: Project administration. All authors have read and agreed to the published version of the manuscript.

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