The Influence of the CIVIQ Dimensions on Quality of Life of Patients with Primary Superficial Venous Incompetence

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WHAT THIS PAPER ADDS
This article shows that, in the case of primary superficial venous incompetence, the QoL impairment as measured with the CIVIQ is mainly a result of the presence of pain and the limitation of physical ability. Gender, age, occupation, and clinical class of the CEAP should be taken into account at the time of patient’s clinical assessment to give instructions that could improve their quality of life. The systematic use of duplex has allowed the correct classification of patients within the clinical and anatomical categories of the CEAP.

Objectives: To get to know the influence of the four domains of the Chronic Lower Limb Venous Insufficiency Questionnaire (CIVIQ) on the quality of life (QoL) of patients with primary superficial venous incompetence, and their behaviour in relation to age, gender, occupation, body mass index (BMI), and also with respect to the clinical and anatomical classes of the CEAP.

Material and methods: The sample was composed of 468 patients with primary superficial venous reflux (135 male and 333 female) who answered 100% of the questions in the Short Form-12 (SF12) and CIVIQ questionnaires. After a clinical and duplex examination, the patients were categorized as C0 – 6, E, A, and A or A,p and P according to the CEAP classification. The relationships between CIVIQ domains and gender, age, occupation, BMI, and the clinical and anatomical classes of the CEAP classification were analyzed.

Results: Men reported better QoL than women (33.2 vs. 46.3) and this was also true for each of the CIVIQ’s domains (p < .00). Pain (50.6) and physical restriction (45.3) were the dimensions with a greater influence on QoL, whereas social (41.7) and psychological (38.1) dimensions had a lesser influence. Patients aged between 45 and 64, household activities, and patients with C2–3 clinical classes were the patient groups with the worst scores in all the CIVIQ dimensions and those where significant differences were found. The BMI and anatomical distribution of the reflux had no influence on the QoL.

Conclusions: Pain and physical restriction were the CIVIQ domains with greater influence on the QoL of patients with primary superficial venous reflux. Age increase (up to 64 years), female gender, household activities, and C2–3 CEAP clinical class were the main factors associated with the worst QoL perception.

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Keywords: Quality of life of primary superficial venous reflux, CIVIQ dimensions, Gender, Age, Occupation, CEAP clinical class

INTRODUCTION
The interest in QoL associated with chronic venous disorders (CVD) has led to the development of various disease-specific measuring instruments.1–4 Thanks to this, it is known that increasing CEAP clinical class is significantly associated with a worse patient-reported QoL5–9 when it is measured with specific tools, but not with generic questionnaires.5,8 Moreover, age, female gender, duration of CVD, country, body mass index (BMI), level of education, and presence of various comorbid conditions are also associated with the QoL of the venous patients.8,10

The Chronic Lower Limb Venous Insufficiency Questionnaire (CIVIQ)4 is an internationally contrasted specific test that measures QoL in patients with CVD.11,12 It consists of 20 questions comprising four QoL domains: pain (four items), physical (four items), social (three items), and psychological (nine items). Three scores can be calculated in
these domains: score per item (value 1–5), score per dimension (value 0–100), and global score (value 0–100). However, the reported clinical studies evaluate only the overall result, which indicates a patient’s QoL but does not reveal the influence that any of the dimensions listed in the test has on the end result.

To the authors’ knowledge, the influence that each one of the dimensions has on the QoL of patients with CVD has not been previously reported. The objective of this study was to investigate the influence of any of the four domains of the CIVIQ2 on the final score, and their behaviour in relation to the age, gender, occupation, BMI, and the clinical and the anatomical classes of the CEAP.

**MATERIAL AND METHODS**

**Sample**

This observational and cross-sectional study was carried out on the island of Gran Canaria (Canary Islands, Spain) as part of GRANCAVEINS (GRAN CAnaria VENous INsufficiency Study), a project devoted to knowledge of the venous disorders and developed by CliniVar, a phlebological centre associated with Las Palmas de Gran Canaria University.

Gran Canaria has a population of about 880,000 inhabitants, and the sample was selected from 820 consecutive patients who attended between May 2009 and May 2013. All the patients were informed and written consent was obtained. However, because of the investigation design, it was not necessary to obtain the ethical approval of Las Palmas de Gran Canaria University.

Inclusion criteria were: adult patients (both sexes and over 18 years old) who requested treatment for primary superficial venous disorders included in any of the clinical groups of the CEAP classification (C0–C6), and who had the ability to fill in two quality of life questionnaires. Although questionnaires may have had some unanswered questions, only patients who answered 100% of the questions in both questionnaires were admitted to the study. Exclusion criteria included: deep venous reflux, previous history of deep or superficial venous thrombosis, previous treatment of venous reflux (surgery or sclerotherapy), hormonal therapy, pregnancy, and other severe diseases not related to the chronic venous disorders.

Four hundred and sixty-eight patients (135 male and 333 female), categorized as C0–6, Ep, As, Ap or As,p and Pr according to CEAP classification, were included and 352 patients (42.9%) were excluded. Of these, 136 (16.6%) did not answer all the questions, and 216 (26.3%) presented one or more of the other exclusion criteria.

**Methods**

**Health-related quality of life measurement.** In agreement with a widely accepted recommendation, all the patients filled in the validated Spanish version of two standardized questionnaires: a generic one, the SF12, and a disease-specific one, the CIVIQ2. The global score and the score of each of the four CIVIQ2 dimensions (pain, physical, social, and psychological) were used (0 representing the highest quality of life and 100 the lowest).

Responses to the SF-12 were used to calculate both the physical and mental summary component scores (PCS, MCS), with the aim of determining whether the sample characteristics differed from those of the reference population by sex, age, or body weight. The mean PCS and MCS for the general population is 50, with higher scores indicating a better QoL.

**Data collection and formation of groups.** The clinical and anatomical CEAP classification, the age, sex, occupation, BMI, and the results of a detailed duplex ultrasound examination of the venous system of the lower extremities, were recorded in a database (File Maker Pro 11.0v1, FileMaker Inc, CA, USA).
With the aim of comparing the results with those of the reference population, the age groups were the same as those in the SF-12 questionnaire. The occupation was coded based on the following criteria: household activities, jobs which require to be seated, jobs which require standing, jobs which require mobility but without effort (active group), and jobs with physical effort. Five clinical groups, C0—C1, C2, C3, C4, and C5—C6 were defined in order to have a sufficient number of patients in each group, and the anatomical groups were in accordance with the CEAP (Superficial, Perforator, and Superficial plus perforator reflux). Finally, the BMI subgroups were the same as those proposed by the World Health Organization (BMI <20 = low weight, BMI 20–25 = normal weight, BMI >25–30 = overweight, and BMI >30 = obesity).

Statistical analysis. The data were exported to SPSS 20.0 (IBM Corporation, SPSS, Chicago, IL, USA). First, the factors were explored by univariate analysis. For data which followed a normal distribution, a t test and one way ANOVA plus posthoc Student Newman Keuls were used to establish variation across the groups. When data differed from the normal distribution, a Kruskal-Wallis test was performed. A p value of .05 was accepted as significant.

RESULTS
Characteristics of the sample
Table 1 summarizes the distribution of the patients within each of the subgroups and the results of preliminary univariate analysis related to sex.

| Gender and age. Complete data sets from 468 patients were analyzed, including 135 men and 333 women with mean ages of 42.7 and 45.1 years, respectively. Of these, 282 (60%) were aged between 34 and 54 years, and the remaining 176 (40%) were distributed in a progressive and homogeneous way between the groups of minor and major age. No statistical differences were observed.

Occupation. Whereas the household activities group was the largest and mainly composed of women (43.8% vs. 31.4%), in the other groups the presence of men prevailed, mainly in the active group (17.8% men vs. 2.9% women) and in the effort group (20.0% men vs. 5.8% women).

BMI. The BMI values did not vary with gender and the sample was predominantly obese: 38.4% had a normal weight or were underweight, and 61.6% of the patients were overweight or obese.

Clinical CEAP. Patients with clinical classes C2 (47.5%) and C3 (40.6%) were the largest, with similar figures between genders. Nevertheless, whereas all the patients who consulted for C0—1 were women (7.7% of the sample, 10.8% of the women), those who consulted for advanced disease were, predominantly, men (27% men vs. 7.6% women). At the same time, men with C5—6 were older than women (71.0 vs. 52.5 years), whereas in the other clinical groups there were no differences (data not shown).

Anatomical CEAP. Isolated incompetence of the superficial venous system was the most common condition (59.6%) with a clear predominance in females (66.6% vs. 42.2%), whereas the combination of incompetent superficial and perforator veins was more common in men (57.8% vs. 32.4%). However, all the patients with isolated incompetence in a perforator vein were women.

Health-related quality of life
Disease-specific questionnaire. CIVIQ. Global Score and Gender perception. Univariate analysis showed that the health-related QoL was affected in a very important way (CIVIQ = 42.6). The men’s QoL perception was better than the women’s (33.2 vs. 46.3), and this was also true for each of the CIVIQ domains. Table 2 and Fig. 1 show that pain was the domain associated with the worst scores, followed by physical limitation, social aspects, and psychological affection, in that order. The differences were statistically significant among both sexes and between domains (p <.00).

Multivariate analysis (Table 3) showed that the patient’s perception of QoL differed depending on age, type of work, and the CEAP clinical class, whereas it did not differ when BMI or reflux distribution were considered. Differences between subgroups were in accordance with the differences observed in the domain analysis.

Pain perception. Pain was the domain that showed the highest score of all the considered factors, with a sample mean value of 50.6. As age increased, so did the perception of pain and the 45—64 age range was the one in which patients reported worst outcomes, even worse than those indicated by patients over 65 years of age. Moreover, occupation was the risk factor with the highest perception of pain, mainly in the household activity group which had a mean value of 58.1, whereas the active group reported the best score (44.4) (p = .03). With respect to the CEAP clinical

Table 2. Sample, men and women mean values ± standard deviation of CIVIQ, CIVIQ’s dimensions and Physical and Mental Summary Components (PCS, MCS) of SF-12 test.

<table>
<thead>
<tr>
<th>Group</th>
<th>Pain</th>
<th>Physical</th>
<th>Social</th>
<th>Psychological</th>
<th>CIVIQ</th>
<th>PCS</th>
<th>MCS</th>
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</thead>
<tbody>
<tr>
<td>Total Sample</td>
<td>50.6 ± 25.4</td>
<td>45.3 ± 26.7</td>
<td>41.7 ± 27.0</td>
<td>38.1 ± 25.0</td>
<td>42.6 ± 23.2</td>
<td>50.4 ± 9.5</td>
<td>50.2 ± 9.1</td>
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<tr>
<td>Men</td>
<td>42.7 ± 25.0</td>
<td>34.5 ± 24.8</td>
<td>34.7 ± 25.9</td>
<td>27.9 ± 21.9</td>
<td>33.2 ± 21.5</td>
<td>52.9 ± 9.0</td>
<td>53.0 ± 8.4</td>
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<tr>
<td>Women</td>
<td>53.7 ± 24.7</td>
<td>49.5 ± 26.3</td>
<td>44.4 ± 27.0</td>
<td>42.2 ± 24.9</td>
<td>46.3 ± 22.8</td>
<td>49.3 ± 9.5</td>
<td>49.2 ± 9.1</td>
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<tr>
<td>CI (95%)</td>
<td>(−15.98 to 6.12)</td>
<td>(−20.21 to 9.92)</td>
<td>(−15.03 to 4.41)</td>
<td>(−19.09 to 9.50)</td>
<td>(−17.58 to 8.65)</td>
<td>(1.61 to 5.34)</td>
<td>(2.13 to 5.56)</td>
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<td>t test p value</td>
<td>.00</td>
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</table>

Values in parentheses are 95% confidence intervals.
class, evidence existed for three groups: patients with clinical classes C0–1 had the best QoL (40.8), patients in the C4–6 groups showed an intermediate value (49.8–45.3), and patients within the C2–3 degrees were those that perceived the most pain (56.5–60.4) (p < .00). There were no differences between the BMI and the anatomical groups.

**Physical restriction.** The mean value of this domain was 45.3 and differences were significant between age, occupation, and clinical groups (p < .00). Younger patients (18–44 years) had better scores than older patients, and the patients with an active occupation reported the lowest reduction of physical activity (38.8) as opposed to the household activity group (55.5). With respect to the CEAP clinical class, it is important to note that physical restriction increased with clinical class, except for C5-6 patients where a score as low as 25.0 was found, even lower than the score reported by C0-1 patients (35.0). No differences were observed between either BMI or CEAP anatomical subgroups, but physical restriction increased with BMI and was higher when the reflux was present in the superficial and superficial plus perforator veins.

**Social restriction.** The mean value was 41.7. Statistical differences were not found when both occupation and anatomical classification were considered. Nevertheless, significant differences were noted in the other groups, including patients aged between 44 and 64 years, patients with a BMI higher than 20 kg/m², and C2 and C3 patients who had the worst scores.

**Psychological restriction.** This dimension exerted the least influence on quality of life of patients with primary venous reflux (mean value of 38.1). Data showed that differences were present only between age and clinical subgroups. Psychological involvement increased until 54 years of age, while patients of a greater age experienced better perceptions. With reference to clinical class, patients included in the C0–1 group indicated that the disease did not influence their psychological mood (26.2) but the rest of the patients were affected significantly and similarly (36.9–41.7) (p = .01).

**General questionnaire.** There were no differences for gender, age, and BMI groups between both the PCS and MCS of the sample and the Spanish reference population (data not shown). Tables 2 and 3 show that although gender and clinical class affected both the PCS and MCS, the age and occupation groups had a clear influence only on the physical component and the BMI had an influence on the mental component.

**DISCUSSION**

Numerous studies have examined the QoL of patients with venous reflux using the CIVIQ questionnaire, but in their conclusions the authors consider only the QoL value and not the scores of the CIVIQ dimensions. To the authors’ knowledge, this study is the first that pays attention to the relationship between the four CIVIQ domains and risk factors associated with the development of CVD, such as gender, age, occupation, and BMI together with clinical and anatomical degrees of CEAP classification. Furthermore, to correctly classify each patient in their clinical and anatomical CEAP category and to rule out any warning signs of thrombophlebitis or deep venous incompetence, which were reasons for exclusion from the sample, duplex ultrasound was performed in all patients.

This analysis indicates that patients with superficial primary venous reflux have poor QoL. The presence of pain and decreased physical ability are the two main factors contributing to their deterioration, while the alteration of social and psychological factors have less influence on the QoL. However, patient behaviour in relation to the studied factors is not homogeneous or progressive within the groups, as might be expected, as patients’ perceptions of pain, limited physical ability, and social and psychological components are different when considering gender, age, occupation, and CEAP clinical class. Nevertheless, patient behaviour is similar when BMI and the anatomical classification of CEAP are considered.

Women with superficial primary venous incompetence have worse values than men in both global perception and in each of the CIVIQ domains, as well as worse scores in both the physical and mental summary components of the SF12. These results agree with those found by Kahn and Staniszewska, using the VEINES and Aberdeen specific tests, respectively. Generic test results agree with those of Kahn, but do not match those for Darvall, who found no differences between the sexes. However, it must be noted that, in this environment, it has been documented that women have a worse quality of life than men. This suggests a need to analyze the relationship between gender and the different factors associated with venous disease.

Older age, poor scores on the four CIVIQ domains, and perceived poor QoL are all closely associated. This agrees with the findings by Lozano and Carradice, that higher age is strongly associated with poor QoL. However, the results for patients over 65 are similar to those who are 44, which can be seen in all CIVIQ dimensions. From the specific point of view of venous disease, this could be related to most patients over 65 already being retired and either facing CVD with a better attitude or believing that it is other pathologies that impair their QoL. This would explain why the
### Table 3. Mean scores ± standard deviation of each of the studied groups for CIVIQ, CIVIQ domains, and Physical and Mental Summary Components (PCS, MCS) of SF-12 test.

<table>
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<th>Age (years)</th>
<th>Pain</th>
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<th>p</th>
<th>Social</th>
<th>p</th>
<th>Psychological</th>
<th>p</th>
<th>CIVIQ</th>
<th>p</th>
<th>PCS</th>
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<th>MCS</th>
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<td>18–24</td>
<td>43.8 ± 23.0</td>
<td>34.9 ± 27.9</td>
<td>38.1 ± 20.6</td>
<td>24.3 ± 21.3</td>
<td>36.0 ± 21.6</td>
<td>53.1 ± 10.4</td>
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<td>25–34</td>
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<td>43.0 ± 25.5</td>
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<td>35–44</td>
<td>47.1 ± 25.4</td>
<td>37.7 ± 26.8</td>
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<td>45–54</td>
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<td>50.8 ± 25.2</td>
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<td>55–64</td>
<td>57.7 ± 26.1</td>
<td>54.0 ± 24.4</td>
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<td>38.6 ± 30.1</td>
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<td><strong>Occupation</strong></td>
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<td>Household</td>
<td>58.1 ± 22.3</td>
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<td>44.4 ± 26.3</td>
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<td>Sedentary</td>
<td>49.3 ± 26.7</td>
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<td>Standing</td>
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<td>42.9 ± 26.6</td>
<td>39.1 ± 25.4</td>
<td>38.6 ± 25.7</td>
<td>41.8 ± 22.8</td>
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<td>Active</td>
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<td>Effort</td>
<td>51.5 ± 29.4</td>
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<td>&lt;20</td>
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<td>36.2 ± 16.3</td>
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<td>&gt;25–30</td>
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<td>47.3 ± 25.0</td>
<td>43.5 ± 25.3</td>
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<td>42.9 ± 20.9</td>
<td>50.0 ± 9.5</td>
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<td>&gt;30</td>
<td>52.8 ± 24.6</td>
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<td>49.5 ± 25.9</td>
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<td><strong>CEAP</strong></td>
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<td>CD—C1</td>
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<td>26.2 ± 20.5</td>
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<td>48.9 ± 27.9</td>
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<td>60.4 ± 23.1</td>
<td>60.9 ± 25.7</td>
<td>47.8 ± 26.9</td>
<td>41.5 ± 23.9</td>
<td>50.5 ± 22.0</td>
<td>47.6 ± 8.7</td>
<td>48.8 ± 9.2</td>
<td>.05ab</td>
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<td>C4</td>
<td>49.8 ± 26.4</td>
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<td>39.2 ± 23.5</td>
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<td>40.8 ± 21.8</td>
<td>48.3 ± 7.1</td>
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<td>C5—C6</td>
<td>45.3 ± 28.7</td>
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<td>42.0 ± 30.6</td>
<td>41.7 ± 33.2</td>
<td>44.6 ± 27.3</td>
<td>50.7 ± 11.5</td>
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<td>As</td>
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<td>As,p</td>
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<td>46.4 ± 24.6</td>
<td>37.4 ± 25.9</td>
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* a p value for ANOVA  b p value for Kruskal-Wallis. When different, the represented p value is the highest of both.
behaviour scores of both the physical and mental components of the SF12 questionnaire are different, showing worse values within the higher age group.

The work activity results show that patients who have jobs requiring physical activity (groups marked as active and effort) have better scores than those with sedentary occupations (household, sedentary, and standing activities), which coincides with the epidemiological observation that sedentary and standing professions are risk factors in the development of venous reflux. In this case the physical and psychological components are those showing different behaviour among groups, although the influence of the CIVIQ’s domains is present, as previously stated. The explanation might be purely physiological, as performing physical activity as part of the regular work favours the venous return, improving associated symptoms and QoL perception. However, it should be noted that household activities show the greatest deterioration of the CIVIQ domains and the QoL, when measured with both the specific and the general test. In this case, it is believed that the explanation must be sought outside venous disease, which also helps to understand why women show poorer QoL than men, as previously noted. It is shown that attitude to the disease differs between men and women as manifested, among others, by women’s higher tendency to seek medical care, or to report acute and chronic pain.

In other words: C0 classes are not merely an aesthetic problem and must be treated to improve the QoL. Patients with C2–3 classes form the second group and they present the worst scores. In this case, the perception of pain and the physical limitation values increase about 20 points with respect to the C0–1 classes. The third group is formed by patients with C4–6 classes who, paradoxically, show better scores in all parameters studied. Andreozzi and Dunić28 found a similar pattern, but only in the C5–6 classes. This pattern is very interesting, and may be justified by a progressive adaptation and acceptance of a chronic disease.

In conclusion, these observations confirm that pain and physical limitation are the CIVIQ domains that most affect the QoL of the patients with primary superficial venous incompetence and these are the main questions one should ask patients. The perception of each of the CIVIQ dimensions differs with gender, age, CEAP clinical class and work style, whereas the BMI and the anatomical class do not.

FUNDING
None.

CONFLICT OF INTEREST
None.

REFERENCES
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