THE USE OF THE VEINES-QOL/SYM QUESTIONNAIRE IN PATIENTS OPERATED FOR VARICOSE VEINS

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Venous insufficiency is a common, chronic disease that affects nearly half of the population in highly developed countries. The vast majority of affected patients suffer from varicose veins (VV). Recently, the priority in medicine has been patient satisfaction with treatment and high quality of life. Therefore, disease-specific questionnaires that measure quality of life have been developed. One of these is VEINES-QOL/Sym with two subscales that assess quality of life and disease symptoms. To date, it has been used to examine patients with venous ulcers and thrombosis. No data are available concerning the use of VEINES to assess patients after VV surgery.

The aim of the study was to investigate the change in QOL after VV surgery and verify the usefulness of VEINES in daily phlebological practice.

Material and methods. The study recruited 69 patients (CEAP class C2-C3) in need of surgery for VV. The patients responded 2 hours before surgery and after 3 months. Patients were differentiated into several categories according to CEAP stage, age, sex, BMI, the use/lack of compression therapy, and education level.

Results. The quality of life increased significantly in C3 patients and in patients over the age of 50. Quality of life increased significantly in all patients regardless of education. There were no differences between groups differentiated according to sex, the use or lack of compression therapy, or BMI.

Conclusions. The VEINES-QOL/Sym questionnaire can be used in daily phlebological practice to assess patients before and after surgical treatment of VV. VEINES-QOL/Sym is reliable and highly valid.

Key words: varicose veins, quality of life, VEINES Qol/Sym, BMI, education, compression therapy
SF-36. It was developed in the USA in the 1980s and 1990s and has been repeatedly used to assess quality of life in conditions ranging from cancer to some mental illnesses (12). However, due to its versatility, SF-36 is not suitable to determine health-related quality of life as it does not assess the particular aspects of a given disease. Therefore, other questionnaires have been developed. One of these is the Venous Insufficiency Epidemiological and Economic Study-Quality of Life/Symptoms (VEINES-QOL/Sym) which is based on SF-36. To date, VEINES has been used to assess patients with other venous diseases, primarily thrombosis and more advanced stages of CVI, namely venous ulcers (13). Patients in early stages of venous insufficiency, i.e. CEAP class C2-C3, have not been well studied. There are no papers in literature that discuss the use of this scale to assess the change in quality of life following surgery for varicose veins in the lower extremities. Neither has any Polish adaptation of this test been found in the available literature. This is therefore the first attempt at translating it into Polish.

Aims of the study: 1. To assess the change in the quality of life of CEAP class C2-C3 patients 3 months after surgery for venous insufficiency using the VEINES-QOL/Sym questionnaire. 2. To assess the usefulness of the VEINES-QOL/Sym questionnaire in patients operated for varicose veins in the lower extremities (CEAP class C2-C3) according to some variables: gender, age, BMI, the use of compression therapy, and level of education.

MATERIAL AND METHODS

This prospective study included 69 subsequent CEAP class C2-C3 patients who were qualified for surgery for venous insufficiency. The patients were divided into several groups depending on gender, age, BMI, the use or lack of compression therapy, and the level of education (tab. 2).

Patients with primary varicose veins of the lower extremities with no prior surgical interventions and no incidents of deep vein thrombosis met the inclusion criteria.

The exclusion criteria included patients with active or healed venous ulcers, concomitant atherosclerosis of the lower extremities, osteoarthritis of the hip and/or knee joints, and sciatica.

Disease progression was assessed using CEAP and patients were classified as C2 or C3

<table>
<thead>
<tr>
<th>Variable</th>
<th>Number of patients</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEAP</td>
<td></td>
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</tr>
<tr>
<td>C2</td>
<td>42</td>
<td>60,9</td>
</tr>
<tr>
<td>C3</td>
<td>27</td>
<td>39,1</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>52</td>
<td>75,4</td>
</tr>
<tr>
<td>Men</td>
<td>17</td>
<td>24,6</td>
</tr>
<tr>
<td>Age (26-77 years, average: 52.1 years)</td>
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<td></td>
</tr>
<tr>
<td>&lt; 50 YOA</td>
<td>29</td>
<td>42</td>
</tr>
<tr>
<td>50 YOA</td>
<td>40</td>
<td>58</td>
</tr>
<tr>
<td>Compression therapy (class II)</td>
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<td></td>
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<tr>
<td>Yes</td>
<td>42</td>
<td>60,9</td>
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<td>27,5</td>
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<tr>
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<td>8</td>
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<tr>
<td>BMI (kg/m²)</td>
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<td></td>
</tr>
<tr>
<td>&lt; 25</td>
<td>26</td>
<td>37,7</td>
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<tr>
<td>&gt; 25</td>
<td>43</td>
<td>62,3</td>
</tr>
<tr>
<td>Education level</td>
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<td>Primary education</td>
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<td>24,6</td>
</tr>
<tr>
<td>Secondary education</td>
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<td>29</td>
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<tr>
<td>Higher education</td>
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<td>40,6</td>
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<td>No data</td>
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<td>5,8</td>
</tr>
</tbody>
</table>
The use of the VEINES-Qol/Sym questionnaire in patients operated for varicose veins

Ep As2-3 Pr, where C2 means patients with varicose veins >3 mm, C3: the same plus oedema, Ep: primary etiology of venous insufficiency, As: saphenous vein insufficiency above (2) or below the knee (3), and Pr: venous reflux.

The questionnaire which included VEINES-QOL/Sym and SF-36 was completed on the day of surgery and after 3 months. Stripping of the femoral section of the saphenous vein with avulsion phlebectomy was performed in 92% of patients and crossectomy of the saphenous vein with avulsion phlebectomy in the remaining 8%.

The study was approved by the Bioethics Committee at the Regional Medical Chamber in Lodz (K.B. No 6/13 of 8 May 2013).

VEINES-QOL/Sym is a standardised, 26-item, patient-reported questionnaire to assess the severity and frequency of venous insufficiency symptoms (questions 1, 7; 10 items: heaviness, pain, leg swelling, night cramps, fatigue, burning sensation, throbbing sensation, itching, numbness in the legs, pain intensity), time of day when the symptoms are most pronounced (1 item, question 2), changes in the severity of symptoms during the past year (1 item, question 3), limitations in daily activities associated with venous insufficiency (9 item, questions 4, 5, 6), and the psychological impact on the functional status of patients with venous insufficiency measured during the previous 4 weeks (5 items, question 8). The scores are transformed as described in (14); the higher the result the better the quality of life. A separate score is obtained for the QOL and Sym subscales. The VEINES-QOL/Sym scale is available in several language versions. The questionnaire has been comprehensively verified in publications and found to be a valid, dependable and reliable measure of quality of life in relation to venous diseases (14-19).

The SF-36 questionnaire is used for self-reported health assessment. It comprises 11 questions with 36 statements that allow to determine 8 components in 2 domains: physical (Physical Component Summary, PCS) and mental (Mental Component Summary, MCS). The physical aspect includes: 1) limitations in physical functioning (at work, in daily activities e.g. cleaning, shopping), 2) bodily pain, 3) subjective health perception (during the past year, compared to others). Physical functioning is assessed using questions concerning: 1) limitations in social activity (limitations in contacts with family and friends due to emotional state), 2) general assessment of mental state (vitality, happiness, fatigue, sadness, vigour, etc.). The higher the score the better the quality of life. The maximum score is 171. The score is transformed as recommended by Quality Metric Incorporated who licensed the use of the test (license No QM018063).

The obtained results were subjected to statistical analysis. Basic descriptive statistics such as arithmetic mean, standard deviation and structure index were included. A Student’s test for two groups or variance analysis for more than two groups were performed for statistical comparison of independent groups (and if the assumptions of these tests were not met, their nonparametric counterparts were used: the Mann-Whitney U test or the Kruskal–Wallis test). In cases where differences were found between more than two groups, appropriate post hoc analyses were performed. To compare the results obtained in two moments in time, the t-test for dependent samples was used (or its nonparametric counterpart, the Wilcoxon signed-rank test if the assumptions of the initial test were not met).

The assumptions were verified using the Shapiro–Wilk test (normality) and Levene’s test (equality of variances).

The box plot charts show the mean in the central point, the box represents the mean +/- the standard error of the mean, and the whiskers show the confidence interval for the mean.

The STATISTICA 10PL package (StatSoft Inc., USA) was used for statistical analysis. The results were found to be statistically significant when p<0.05 (in charts: * refers to p<0.05 and ns, no statistically significant difference).

RESULTS

VEINES vs CEAP

A statistically significant improvement in quality of life was observed in both groups of patients differentiated according to CEAP classification, in both the QOL and Sym subscales (in both groups and for both scales, p<0.001). The differences between the groups
The mean improvement in Sym in the C3 group was 27.9 points, more than twice as high as in the C2 group (13.4 points). A similar difference was observed in QOL (26.2 vs 13.2).

VEINES vs gender

A statistically significant improvement in quality of life was observed in both groups of patients differentiated according to gender, in both the QOL and Sym subscales (women: in both scales, p<0.001, men: Sym p=0.005, QOL p=0.002). There are no statistically significant differences between the groups in either subscale. The mean improvement in Sym in the group of women was 19 points, slightly higher than in the group of men (18.5 points). Similar results were observed for QOL (17.9 vs 18.7).

VEINES vs age

A statistically significant improvement in quality of life was observed in both groups of patients differentiated according to age, in both the QOL and Sym subscales (patients over 50 years: for both scales, p<0.001, patients below 50 years: Sym p=0.028; QOL p=0.009). The differences between the groups are statistically significant in both subscales. The mean improvement in Sym in the older age group was 24.9 points, nearly 2.5 times higher than in the younger age group (9.6 points). A similar difference was observed in QOL (24.2 vs 8.7).

VEINES vs compression therapy

A statistically significant improvement in quality of life was observed in both groups of patients differentiated according to the use or lack of compression therapy, in both the QOL and Sym subscales (compression therapy: in both scales, p<0.001, lack of compression therapy: Sym p=0.002, QOL p<0.001). There are no statistically significant differences between the groups in either subscale. The mean improvement in Sym in the group of patients with compression therapy was 20 points,
slightly higher than in the group without compression therapy (16.3 points). Similar results were observed for QOL (18.8 vs 16.6).

VEINES vs BMI

A statistically significant improvement in quality of life was observed in both groups of patients differentiated according to BMI, in both the QOL and Sym subscales (overweight patients: in both scales, p<0.001, patients with BMI<25: Sym p=0.017, QOL p<0.002). The mean improvement in Sym in the group of overweight patients was 22.4 points, higher than in the group of patients with BMI<25 (12.7 points), but this difference was not statistically significant. Similar differences were observed for QOL (20.7 vs 13.5), but, as in the case of Sym, this difference was not statistically significant.

VEINES vs education

A statistically significant improvement in quality of life was observed in all groups of patients differentiated according to the level of education, in both the QOL and Sym subscales (primary education: for both scales, p<0.001, secondary education: Sym p=0.010; QOL p<0.001; higher education: Sym p=0.002, QOL p=0.002). There were differences between the groups in particular subscales. Post hoc tests were performed to determine these groups. The average improvement in Sym in the group of patients with primary education was 30.8 points and was not statistically significantly different from the group of patients with higher education (18.8), but a statistically significant difference was observed compared to the group of patients with secondary education (10.9). The results were somewhat different for the QOL subscale: the greatest
improvement was also observed in the group of patients with primary education (32.1) and this group was statistically significantly different than the group of patients with secondary (12.5) and higher education (14.1).

**DISCUSSION**

The VEINES-QOL/Sym questionnaire was developed in Canada and Belgium (20). However, it has been adapted for use in many other countries, such as Italy, Turkey, Brazil, Portugal, Germany and Norway. Its validity and reliability in patients with CVI were confirmed by a study carried out in Turkey. A number of publications are available concerning the use of VEINES for the assessment of quality of life in patients with venous thrombosis (13, 14, 17, 18). The usefulness of VEINES-QOL/Sym in patients with venous thrombosis aged >65 was assessed in 2014. The study found the obtained data to be reliable and the test to be an easy to use research tool (13).

Few papers report the use of the VEINES-QOL/Sym test in patients with varicose veins of the lower extremities (CEAP class C2-C3). In our study, quality of life according to VEINES improved in both subscales, QOL and Sym while no change was found according to SF-36 (neither PCS nor MCS). A 2014 publication presented a Dutch adaptation of this test (21). The investigators assessed patients according to CEAP; C1-C3 patients constituted 94%. SF-36 was the point of reference. The researchers found a better correlation between the clinical symptoms and VEINES-Sym than SF-36 PCS. The authors conclude that reduced quality of life in relation to varicose veins of the lower extremities is mainly associated with the physical rather than mental aspect. Contrary to the results of our study, the Dutch researchers found no statistically significant differences between different CEAP classes, but the authors themselves suggested that it
could have been due to the small number of C3 participants. Meanwhile, a study by Kahn et al. showed that the higher the CEAP class the worse the disease-related quality of life, with no effect on the overall quality of life (22). In the same study, women reported worse quality of life than men (in the QOL and MCS subscales). Our study yielded different results: there were no gender differences after surgery according to VEINES-QOL/Sym while postoperative overall quality of life improved in women according to SF-36 MCS. Ortega-Santana et al. assessed the CIVIQ questionnaire in C2-C3 patients with venous insufficiency and found statistical differences according to gender: men reported better quality of life in all four studied domains (23). No differences were found depending on BMI in this study either, confirming our observations: although overweight patients (BMI>25) scored less in VEINES-Sym, the results were not statistically significant. Kahn et al. (22) found a statistically significant correlation between lower (worse) VEINES-QOL and Sym scores and higher BMI, patient age and worse level of education. A study was published in 2014 that assessed the usefulness of VEINES in patients aged over 65 with venous thrombosis (13) and found it useful in daily practice. Our study additionally assessed whether the level of education influenced quality of life after surgery. We found a similar improvement in quality of life in all 3 groups according to SF-36 PCS, VEINES-QOL and Sym, although patients with primary education reported relatively the greatest improvement in quality of life. This may be explained by the fact that this group was the oldest (average age in groups: primary education 60.6, secondary education 52.4, higher education 42.8) and characterised by higher CEAP classification (C3 patients constituted 58.8% of the primary education group, 28.6% of the secondary education group and 45% of the higher education group).

CONCLUSIONS

The VEINES-QOL/Sym questionnaire is a helpful and useful tool in daily phlebology practice for the assessment of quality of life in patients after varicose vein surgery. Its versatility stems from the fact that results are not altered by variables such as gender, BMI, the use or lack of compression therapy, and patient education level. The only difference was found in relation to age: patients over the age of 50 assessed quality of life after surgery better.

REFERENCES

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