Quality of Life among Patients with Chronic Venous Disease (CVD) as Measured by the VEINES-QOL/SYM and the EuroQol-5D-5L Questionnaires, A Descriptive-Comparative Design Study

Cabahug, Reagan F.[1*], Montalan, Gina L.[2], Yape, Irma Marie P.[3] and Laurenciana, Maria Cristina M.[4]

[1]*San Pedro Hospital, Davao City, Philippines.*
[2]*Ateneo de Davao University, Davao City, Philippines.*
[3]*St Luke's Medical Center, Quezon City, Philippines.*
[4]*Metro Davao Medical and Research Center, Davao City, Philippines.*

Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Objective: To determine the efficacy (sensitivity, specificity, and accuracy) of the VeinesQol/Sym with metric statements fewer than the EQ5D in detecting the quality of life of patients with Chronic Venous Disease (CVD) before and after treatment.
Methods: This is a descriptive-comparative design in collecting the necessary data to arrive at conclusions that respond to the specific questions of the study in 2 private hospitals. The responses gathered from patients through EQ5D and VeinesQol/Sym, before and after they received treatment were utilized in describing and comparing the efficacy of the health questionnaires. Data were further subjected to a comparative analysis to elaborate the efficacy of the VeinesQol/Sym.
Results: A total of 114 CVD patients completed the study after the exclusion of 13 patients due to failure to follow up after eight weeks of treatment. The study showed that VeinesQol/Sym and EQ5D has similar efficacy in determining quality of life of CVD patients. However, VeinesQol/Sym

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Corresponding author: E-mail: rfcabahug@email.dmsf.edu.ph, doc_reygun@yahoo.com;

has higher accuracy (84.96% vs 76.99%), higher sensitivity (87.85% vs 83.87%), detects greater level of impairment in mobility, anxiety/depression, pain and discomfort, disruptions in usual activity and lower quality of current state of health condition than EQ5D

Conclusion: With the responses to the metric statements of the indicators of quality life in both VeinesQol/Sym and EQ5D, VeinesQol/Sym was found to have a greater efficacy in establishing the accurate status of quality of life of patients with CVD than the EQ5D.

Keywords: Chronic venous disease; Veines Qol/Sym; EQ5D; quality of life; CEAP.

1. INTRODUCTION

Early identification and adequacy of treatment would enhance the quality of life and symptomatology of patients with chronic venous disease. Chronic venous disease (CVD) has a prevalence rate of > 60% in the adult population. Major risk factors include age, female gender, obesity with BMI of>30, family history, ethnicity, multiple pregnancies, confirmed family history, previous pregnancy, constipation, environment and job-related factors that require prolonged standing for a more extended period [1]. Male and female are both affected, indicence increases with age [2]. CVD commonly presents as varicose veins posing a significant health problem with socio-economic impact in developed countries [3]. The severity of the disease is strongly connected with significant deterioration of quality of life and loss of days at work [4,5]. Treatment options for CVD include the use of micronized purified flavonoid fraction (MPFF), compression modalities, sclerotherapy, laser, surgery, and gait training with physical rehabilitation. Medical treatment with vasoactive drugs has shown to alleviate symptoms in as early as four weeks [6,7]. Venous treatment guidelines have recommended the use of vasoactive drugs in different stages of chronic venous disease. Response to treatment can be measured objectively using quality of life (Qol) questionnaires. The "Venous Insufficiency Epidemiological and Economic Study- Quality of Life" (VEINES-QOL/Sym) and EuroQol-5D-5L (EQ5D) have been utilised to measure the quality of life and improvement of symptomatology of the disease based on Clinical, Etiology, Anatomy, and Pathophysiology classification (CEAP). Both have been validated extensively to capture outcome measures [8,9]. There are few studies using the VeinesQol/Sym and EQ5D questionnaires to assess treatment response in CVD. The research was done to evaluate the variations in the quality of life and improvement of symptoms of patients with CVD at baseline and eight weeks after initiating treatment. The results of the study add knowledge in utilizing

treatment strategies to improve CVD patient's quality of life.

1.1 Review of Related Literature

Chronic venous disease is a cosmetic disease that can affect self-esteem and emotional well-being [10]. A study by Kaplan et al. [11] has shown using "Medical Outcomes Study 36-item Short Form" (SF-36) that elderly patients had lower physical health scores, and the disparity in quality of life are secondary to disease severity and category. Ethnicity, gender, and age can predict the quality of life unrelated to the disease category. Migdalski et al. [12] found that patients with CVD had improved quality life after varicose vein surgery as measured by VEINES-Qol/Sym than using the SF-36. Clinical symptoms and VEINES scores have a better correlation than SF-36. There is a progressive decline in quality of life in both physical and emotional aspects as the CEAP class increases [13].

A Philippine English Version of the EQ5D, a generic quality of life questionnaire can be used for CVD and other diseases. Currently, VeinesQol/Sym detects the quality of life specifically for chronic venous disease. The study is aimed at determining the efficacy (sensitivity, specificity, and accuracy) of VeinesQol/Sym against EQ5D. Results will guide physicians in providing appropriate treatment strategies for both physical and psychological symptoms of patients with CVD.

The result can also be used to develop health policies to address the gap between disease identification, treatment, and enhancement of quality of life of patients with CVD.

1.2 Research Questions

To determine the efficacy (sensitivity, specificity, and accuracy) of the VeinesQol/Sym with metric statements fewer than the EQ5D, a survey was done based on the following specific questions:

1. What is the efficacy of the VeinesQol/Sym as compared with the EQ5D in detecting the quality of life of patients with chronic venous disease?
2. Does the VeinesQol/Sym able to detect quality of life of patients with CVD similar with that of using the EQ5D before and after their treatment?

1.3 Significance of the STUDY

In determining the quality of life and severity of symptoms in chronic venous disease, physicians can identify patients who are at higher risks of poor quality of life and worse symptoms. It guides in the planning of appropriate strategies that are directed toward improving overall health-related quality of life. With the results and findings of the study, physicians are informed that the disease-specific questionnaire remains the appropriate tool to use in outlining treatment plans than the disease-generic questionnaire. Thus, addressing the varying needs of patients to a better quality of life.

2. METHODOLOGY

This section provides information on how the study has been designed, conducted, and data interpreted and analyzed.

2.1 Research Design

A descriptive-comparative design was used to collect date to answer specific questions of the study.

The responses gathered from patients through EQ5D and the VeinesQol/Sym, before and after they have received treatment for CVD were utilized in describing and comparing the efficacy of the health questionnaires.

The patients responses to the indicators of quality of life were further subjected to a comparative analysis to elaborate the efficacy of VeinesQol/Sym.

2.2 Study Setting

The study was conducted in two tertiary private hospitals in Davao City. A total of 114 patients were recruited in the study with 13 patients excluded in the analysis for failure to follow up and answer the questionnaires after eight weeks of treatment. The Cluster Research Ethics Review Committee of the MDMRC reviewed the study protocol. Physicians were invited to participate, recruit, and enrol their patients. Recruitment and data gathering happened between March 5, 2019 to October 30, 2019. Then data analysis was done.

2.3 Inclusion and Exclusion Criteria

All consecutive patients diagnosed with CVD from March 5, 2019 to October 30, 2019 were included after giving written consent. A total of 114 patients included with 13 patients excluded because of failure to follow up and fill out the questionnaires.

2.3.1 Inclusion criteria

1. Newly diagnosed CVD or previously diagnosed with CVD
2. Treatment-Naive
3. Age 18-75 years old
4. Can understand written English language questionnaire
5. Agree to participate in the study

2.3.2 Exclusion criterion

1. Previously diagnosed CVI patients who received continuous treatment

2.4 Sampling Technique

Patients who have sought for medical consultation from the two tertiary private hospitals during the period of data gathering were initially considered for the study. However, only those who have satisfied the inclusion-exclusion criteria of the study were included as respondents. Thus, a purposive sampling technique was used in gathering the patient-respondents.

2.5 Data Collection Procedures

VEINES-QOL/SYM questionnaire derived from the studies of Abenhaim L, Kurz X (The VEINES Study), Lamping DL, Schroder S, and Kahn SR [14,15,16] a disease-specific health-related qualify of life instrument and validated among Filipinos [17] and EQ5D, a generic instrument were used in gathering data that are necessary in answering the specific questions of the study.

The VeinesQol/Sym questionnaire had been validated to be a sound and dependable disorder-specific quality of life measure for CVD, including varicose veins and deep venous

thrombosis [18,19] The EQ5D is an instrument that evaluates the non-specific health-related quality of life for each of the five aspects that include usual activities, self-care, mobility, anxiety/depression, and pain/discomfort [20,21]. To detect the quality of life of patients with CVD, the two health questionnaires were used as data gathering instruments.

Patients included in the study were asked to answer the VeinesQol/Sym and EQ5D questionnaires:

1. Before the start of treatment
2. After eight weeks of treatment. Treatment would either be the use of flavonoid extract, compression stocking, vein stripping, sclerotherapy, or the combination of any of the treatment regimens as prescribed by the attending physicians.
3. The purpose of the study and answering the questionnaire were explained by MG (Sub PI), and his trained assistant (JS).
4. MG did the signing of the Informed consent
5. RFC did the signing of the informed consent for other physicians allowing their patients to be included in the study.
6. Venous Duplex scan was done by a vascular technician (LG).

Demographic data, symptoms, treatment received, and quality of life data before the start of treatment and eight weeks of treatment were gathered.

2.6 Data Collection Instruments

Permission to use the two questionnaires (VeinesQol/Sym and EQ5D) was granted (Appendix).

2.7 Outcome Measures

Quality of life of patients with CVD was determined using the VeinesQol/Sym questionnaire, which measures vein symptoms that are present and resulted to limitations in doing their daily activities, symptom change for the past year, and psychological impact brought by the discomforts of the disease.

The EQ5D questionnaire is a standardized and generic measure of health used to evaluate the clinical and economic appraisal, which involves five variables, namely self-care, activities of daily living (ADL), mobility, usual care, psychological effects and pain and discomfort of the disease.

All these indicators of quality of life that are articulated in the VeinesQol/Sym and EQ5D were used to detect the quality of life of patient-respondents before and after treatment for CVD. The same indicators were utilized in determining the efficacy of disease specific VeinesQol/Sym, against the disease-generic EQ5D, for quality of life.

2.8 Data Handling, Management, and Analysis

The personal information of patients that are relevant to the study were subjected to descriptive statistical tools. These tools were utilized in describing the demographics including clinical classification, risk factors, and treatment intervention received of the patient-respondents.

Apart from the sensitivity, specificity, and accuracy calculator, the chi-square test of independence was used in determining the efficacy of the VeinesQol/Sym against the EQ5D in detecting the quality of life of patient-respondents who have CVD. T-test was used in elaborating further the efficacy test result of VeinesQol/Sym, in detecting the quality of life of the patients before and after treatment interventions for CVD. This was used in comparing the retrieved quality of life of patients through the metric statements of indicators that are common in both the VeinesQol/Sym and EQ5D.

3. RESULTS AND FINDINGS

In this section, the interpreted data are presented.

First, it presents the demographics of the patient-respondents and is followed by the clinical classifications, risk factors and the treatment interventions received. Second, it presents the efficacy (sensitivity, specificity, and accuracy) of the VeinesQol/Sym as compared with that of EQ5D and provides an answer to the first specific research question. Third, it presents the summary of statistically processed data that showed both VeinesQol/Sym and EQ5D can measure quality of life of patients with CVD before and after treatment.

3.1 Demographics of Patient-Respondents

3.1.1 Personal health information

A total of 114 completed the study after exclusion of 13 patients who failed to follow up after eight

weeks of treatment. 67% were females, 83% of whom had previous pregnancies, and 97% had multiple pregnancies (Table 1). The mean age was 66 years (± 25-87 years), mean waist to hip ratio was 0.86. Fifty-three percent (53%) were college graduates, and 55% were unemployed. On average, majority of patients spend 5 hours sitting and 3 hours standing (Table 1.1).

3.2 Clinical Classification

According to the CEAP classification, 42% had edema, 35% had varicose veins, and 17% had lipodermatosclerosis, eczema, skin changes, and hyperpigmentation. Healed and active ulcers were present in 2% of patients with CVD. There were no patients included in the C0 classification and 4.4% had presence of telangiectasia or reticular veins (Table 1.2).

3.3 Risk Factors

Thirty-two percent (32%) had a family history of varicosities in both male and female relatives. A sedentary lifestyle and lack of exercise in 30% of patients, while 35% had a history of previous deep venous thrombosis. Other risk factors noted include diabetes, hypertension, and smoking (Table 2 and Table 2.1). On average, most of the patients spent more than 3 hours standing and about 5 hours sitting. (Table 2.1).

Table 1. Demographic data of patients included in the study

Variables		f	%
Hospital	Private	114	100
	Government	0	0
	Total	114	100
Sex	Male	38	33.3
	Female	76	66.7
	Total	114	100.0
Civil Status	Married	73	64.0
	Single	22	19.3
	Widowed/Widower	18	15.8
	Annulled/Divorced	1	0.9
	Total	114	100.0
Education	Doctorate/Masteral	10	8.8
	College graduate	60	52.6
	College undergraduate	21	18.4
	Vocational course	3	2.6
	High school graduate	5	4.4
	High school undergraduate	6	5.3
	College graduate	5	4.4
	Elementary undergraduate	4	3.5
	Total	114	100.0
Employment Status	"Employed (regular/8 hours a day)"	13	11.4
	"Employed but not regular/casual."	3	2.6
	"Self-employed (entrepreneur/own business)"	22	19.3
	On disability	3	2.6
	"Working full time."	8	7.0
	"Working part-time."	2	1.8
	"Not working."	63	55.3
	Total	114	100.0

Table 1.1. Demographic data of patients included in the study

Variables	Min	Max	Mean
Age (years)	25	87	66
Waist Circumference (in)	22	43	32
Hip Circumference (in)	28	48	37
Waist-Height Ratio	0.10	0.95	0.86
Standing (Hrs spent)	1	12	3.31
Sitting (Hrs spent)	1	24	4.97

Table 1.2. Clinical classification using clinical class, etiology, anatomic and pathology (CEAP)

Clinical classification (CEAP)	f	%
C0: no visible or palpable signs of venous disease but with CVD symptoms	0	0
C1: reticular veins and telangiectasia	5	4.4
C2: varicose veins	40	35.1
C3: edema	48	42.1
C4: skin changes, pigmentation, eczema, lipodermatosclerosis,	19	16.7
C5: healed venous ulcer	1	0.9
C6: active venous ulcer	1	0.9
Total	114	100.0
Mean		

Table 2. Risk factors for chronic venous disease

Risk Factors	Present		Absent	
	f	%	f	%
Diabetes	45	39.5	69	60.5
Hypertension	91	79.8	23	20.2
Current smoking	9	7.9	105	92.1
Father or brother with venous disease	17	14.9	97	85.1
Mother or sister with venous disease	19	16.7	95	83.3
Sedentary lifestyle/lack of exercise	30	26.3	84	73.7
Previous DVT History	35	30.7	79	69.3

Table 2.1. Additional risk factors for chronic venous insufficiency

Variables	Min	Max	Mean
Standing (Hrs spent)	1	12	3.31
Sitting (Hrs spent)	1	24	4.97

Most patients recruited had reasonable control of blood pressure (50%). Eighty-three percent (83%) of females had multiple pregnancies (97%) (Table 2.2)

3.4 Treatment Interventions Received

Fifty-seven percent (57%) of patients with CVD were treated with flavonoid extracts. Compression stockings (16%), Vein stripping (2%), and sclerotherapy (2%) were the other treatment modalities these patients received. None of the patients included received hormonal replacement therapy. Antiplatelet (49%) and other maintenance medicines like statins, antihypertensives, hypoglycaemic drugs are for the other risk factors these patients have like hypertension, dyslipidaemia, and diabetes (Table 3).

Table 4 shows that VeinesQol/Sym and EQ5D efficacy to evaluate the true quality of life of patients with CVD is not statistically significant ($\chi^2 = 0.654 < \chi^2_{0.05} = 3.841$). However, VeinesQol/Sym can correctly identify quality of life indicators in patients with CVD than the EQ5D (Sensitivity of 87.85% against 83.87% of the EQ5D). VeinesQol/Sym gives higher

accuracy and sensitivity than the EQ5D despite of its low specificity. The findings imply that the VeinesQol/Sym is indeed a better tool in evaluating the quality of life of patients with CVD than the EQ5D.

3.5 Comparison of Veines Qol/Sym and EQ5D using Indicators of Quality of Life

Indicators of quality of life of patients with CVD that are present in both VeinesQol/Sym and EQ5D are further evaluated to strengthen the sensitivity of VeinesQol/Sym. The level of mobility, conduct of usual activities, pain/discomfort, anxiety/depression, and current health condition as perceived by patients with CVD using VeinesQol/Sym and EQ5D are compared before and after treatment.

Table 5 shows that patients are able to relay better the levels of impairment in mobility and anxiety/depression before and after treatment for CVD with VeinesQol/Sym than EQ5D and the difference is statistically significant (t-prob$_{a=0.05}$ = 0.000 < a=0.05). Thus, the VeinesQol/Sym is superior in detecting impairment of mobility and

anxiety/depression experienced by patients as they struggle with the challenges brought by CVD. Levels of discomfort while doing usual activities and levels of pain/discomfort even with treatment are better captured using VeinesQol/Sym than EQ5D (t-prob$_{a=0.05}$ = 0.000 < a=0.05). The poor quality of life as reflected by the lower quality of the current state of health of patients is significantly identified by VeinesQol/Sym than EQ5D (t-prob$_{a=0.05}$ = 0.000 < a=0.05). VeinesQol/Sym is more sensitive and accurate than the EQ5D in detecting the true quality of life using clusters of indicators in patients with CVD.

4. DISCUSSION

The severity of the disease is strongly correlated with significant deterioration of quality of life and loss of days at work. Early detection and intervention of such deterioration will improve overall patient's well-being which is crucial in their day-to-day living. EQ5D has often been used to evaluate quality-adjusted life years in a cost-utility analysis (QALY's) and overall well-being without reference to CVD. Higher preassessment scores in the EQ5D were associated with better health-related outcomes [22,23]. Kahn et al. established a substantial correlation between low (worse) VeinesQol/Sym score and higher BMI, older patients, and low levels of education [24]. It has also been shown to correlate well with baseline CEAP classification and response to treatment of CVD. VeinesQol/Sym, is a disease-specific questionnaire to measure the quality of life of CVD patients, answers to questions are not influenced by age, gender, BMI, therapy, and educational levels.

Table 2.2. Additional risk factors for chronic venous insufficiency

Variables			f	%
Blood Pressure	Normal	[120 and below/80 and below]mmHg	57	50.0
	Prehypertension	[120-139/ 80/89] mmHg	13	11.4
	Hypertension (1)	[140-159/90-99] mmHg	34	29.8
	Hypertension (2)	[160-180/100-110] mmHg	10	8.8
	Total		114	100.00
Previous Pregnancy (For female only)	Yes		63	82.9
	No		13	17.1
	Total		76	100.0
How many pregnancies	Less than 1		2	3.2
	More than 1		61	96.8
	Total		63	100.0

Table 3. Different treatment interventions received by the patients

Intervention	Present		Absent	
	f	%	f	%
Flavonoid extracts	65	57.0	49	43.0
Compression stockings	18	15.8	96	84.2
Antiplatelet	56	49.1	58	50.9
Vein stripping	2	1.8	112	98.2
Sclerotherapy	2	1.8	112	98.2
Hormonal Replacement Therapy	0	0	114	100.0
Other maintenance Medicines	114	100	0	0

Table 4. Descriptive summary of the efficacy of Veines Qol with EQ5D

	VeinesQol/Sym	EQ5D	Comparison Value
Sensitivity	87.85%	83.87%	
True Positive	94	78	χ^2= 0.654 < $\chi^2_{0.05 = 3.841}$
False Negative	13	15	
Specificity	33.33%	45.00%	
True Negative	2	9	χ^2= 0.257 < $\chi^2_{0.05 = 3.841}$
False Positive	4	11	
Accuracy	84.96%	76.99%	t-prob$_{a=0.05}$ = 0.50

Table 5. Comparative summary of quality of life of patients with CVD as detected by VeinesQol/Sym and EQ5D

Quality of Life Cluster of Indicators	VeinesQol/Sym		EQ5D		Comparison Value
	$\bar{x}$	SD	$\bar{x}$	SD	t-prob$_{a=0.05}$
Mobility					
Before Treatment	3.613	0.891	2.018	0.831	0.000
After Treatment	4.852	0.925	1.149	0.382	0.000
Usual Activities					
Before Treatment	1.882	0.508	1.947	0.891	0.450
After Treatment	1.783	0.563	1.105	0.361	0.000
Pain/Discomfort					
Before Treatment	1.857	0.621	2.132	0.927	0.021
After Treatment	2.728	0.453	1.140	0.373	0.000
Anxiety/Depression					
Before Treatment	4.218	1.1052	1.377	0.745	0.000
After Treatment	5.038	0.522	1.018	0.132	0.000
Current Health Condition					
Before Treatment	2.430	1.688	75.640	14.614	0.000
After Treatment	1.211	0.825	88.886	7.681	0.000

In determining the efficacy of the VeinesQol/Sym, the responses of 114 patients were recorded during the interview, according to the metric statements of the indicators of quality of life, as specified in VeinesQol/Sym and in EQ5D before and after treatment intervention. Data collected were subjected to statistical analysis to determine the sensitivity, specificity, and accuracy of the VeinesQol/Sym against the EQ5D in determining quality of life of patients. Apart from the common demographics, presence of risk factors and treatment received ensure credibility of responses they provide to determine the current state of quality of life.

VeinesQol/Sym efficacy is statistically similar to EQ5D in identifying the true current state of quality of life of patients with CVD ($\chi^2= 0.654 < \chi^2_{0.05} = 3.841$). However, VeinesQol/Sym can correctly identify the discomforts related to CVD than the EQ5D (Sensitivity of 87.85% against 83.87% of the EQ5D) giving it higher accuracy despite its low specificity. The mean score of other studies was lower than this study (50.3% vs 87.85%) [25]. Analysis revealed a statistically significant increase in mobility, decrease level of perceived anxiety/depression and improvement in doing usual activities before and after treatment for CVD using VeinesQol/Sym than EQ5D (t-prob$_{a=0.05}$ = 0.000 < a=0.05). Improvement in the quality of life of patients with CVD is better captured using VeinesQol/Sym than the EQ5D. VeinesQol/Sym can evaluate CVD, its different symptomatology, impact on the quality of life, and therapeutic effects leading to the better and effective management of the disorder. With the use of this instrument, physicians can appropriately coach CVD patients on how to improve quality of life while coping with the impact of CVD on their physical and psychological psyche [26,27,28]. This creates a positive outlook in taking care of themselves as they follow treatment strategies for CVD. Correct health questionnaire retrieves reliable information followed by appropriate treatment strategies.

5. CONCLUSION AND RECOMMENDA-TION

Based on the results of the study, the disease-specific VeinesQol/Sym has statistically similar efficacy (sensitivity, specificity and accuracy) with that of the disease-generic EQ5D health questionnaire. However:

1. VeinesQol/Sym has a greater ability in determining the true condition of quality of life of patients with CVD than the EQ5D. Though the difference is not statistically significant, VeinesQol/Sym health questionnaire has higher accuracy (84.96% vs 76.99%) and higher sensitivity (87.85% vs 83.87%) than the EQ5D. Thus, VeinesQol/Sym has a higher efficacy than the EQ5D.
2. VeinesQol/Sym is able to detect a greater level of:
   a. Impairments in mobility,
   b. Anxiety/depression before and after their treatment than with the use of the EQ5D.
3. VeinesQol/Sym is able to detect a greater level of:
   c. pain/discomforts,

d. Disruption in usual activities due to discomfort/pain after treatment than with the use of the EQ5D.

4. VeinesQol/Sym is able to detect a lower quality of current state of health condition than with the use of the EQ5D.

The efficacy of the VeinesQol/Sym in detecting the quality of life of patients with CVD can be further evaluated by considering the demographics of the patients, particularly age, sex, civil status, employment status, body mass index, clinical classification, and risk factors. By cross tabulating these variables, physicians can provide therapeutic strategies to patients with CVD to improve overall quality of life.

6. LIMITATION OF THE STUDY

First, the total duration of observation was short at eight weeks. A prolonged treatment and observation time would increase VeinesQol/Sym, and EQ5D mean scores for patients, thus reflecting better health-related outcomes. Second, there was no control group of healthy subjects. Third, using venous disease-specific questionnaires such as VeinesQol/Sym should be used alone since it's a better measure for health-related venous symptom outcomes.

CONTRIBUTION TO THE LITERATURE

VeinesQol/Sym has been used to determine changes in the quality of life of patients with deep venous thrombosis and after surgical therapy for varicose veins. Contrary to some literatures, VeinesQol/Sym has been demonstrated by this study to be a valuable screening tool for CVD as reflected by its high sensitivity rate. Thus, is a better tool to detect the true current state of quality of life that is being experienced by patients than a disease-generic health questionnaire.

DISCLAIMER

The drugs and interventions mentioned in this research are commonly used for the treatment of chronic venous insufficiency. The treatment strategies were given by their attending physicians and not by the authors. The research was not funded by any of the pharmaceutical companies marketing the drugs, rather it was funded by the investigators.

CONSENT

As per international standard or university standard, patients' written consent has been collected and preserved by the authors.

ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the authors.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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APPENDIX

Definition of terms:

To facilitate better understanding of the study, the following important terminologies are provided:

1. VEINES-Qol/Sym: "Venous Insufficiency Epidemiological and Economic Study- Quality of Life Questionnaire is a tool to measure the quality of life and symptoms related to chronic venous disease."
2. "Chronic Venous Disease": a spectrum of venous disorders with manifestations ranging from telangiectasia (C0) of the lower extremities to development of non-healing active ulcer (C5) and healed ulcers (C6)
3. EQ5D: "Euro Quality of life questionnaire is a tool to measure the quality of life of patients with any disease" (generic quality of life questionnaire)
4. "Quality of life: It is a standard level that consists of the expectations of an individual or society for a good life."
5. CEAP classification: This is the Clinical, Etiology, Anatomy and Pathophysiology rating of CVD describing the physical findings, causes, location and mechanisms responsible for the disease
6. "Descriptive research refers to research that describes a phenomenon or else a group under study. It explores the different characteristics of the group or event".

Descriptions of the 2 questionnaires

The "VeinesQol/Sym consists of 26 items, ten items are related to venous symptoms, nine items assessed limitations in daily activities, one assessed time of day has the highest symptom intensity, one estimated change during the past year, and five items covered psychological impact of venous disease. Two scores are calculated from the completed questionnaire: the QoL score (25 items), which measures the overall effect of the venous disease on the patient's QoL, and the Sym score (10 items), which measures symptoms severity. Responses are rated on two-point to seven-point Likert response scales of intensity, frequency, or agreement".

The "EQ5D descriptive system is a preference-based HRQL measure with one question for each of the five dimensions that include mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The answers are given to ED5D permit to find 243 different health states or can be converted into EQ5D index utility scores anchored at 0 for death and 1 for perfect health. The EQ5D questionnaire also includes a Visual Analog Scale (VAS), by which respondents can report their perceived health status with a grade ranging from 0 (the worst possible health status) to 100 (the best possible health status)".

Table A1. Euro QoL measurement

Level of perceived problems	
Level 1	Indicating no problem
Level 2	Indicating slight problems
Level 3	Indicating moderate problems
Level 4	Indicating severe problems
Level 5	Indicating unable to/ extreme problems

EQ-5D Dimensions		Before Treatment		After Treatment	
		f	%	f	%
Mobility	Level 1	36	31.6	98	86.0
	Level 2	42	36.8	15	13.2
	Level 3	34	29.8	1	0.9
	Level 4	2	1.8	0	0.0
	Level 5	0	0.0	0	0.0
	Total	114	100.0	114	100.0
	Mean	2.0		1.1	
Taking care of yourself	Level 1	65	57.0	103	90.4

EQ-5D Dimensions		Before Treatment		After Treatment	
		f	%	f	%
	Level 2	24	21.1	10	8.8
	Level 3	22	19.3	1	0.9
	Level 4	2	1.8	0	0.0
	Level 5	1	0.9	0	0.0
	Total	114	100.0	114	100.0
	Mean	1.7		1.1	
Usual Activities	Level 1	40	35.1	104	91.2
	Level 2	47	41.2	8	7.0
	Level 3	21	18.4	2	1.8
	Level 4	5	4.4	0	0.0
	Level 5	1	0.9	0	0.0
	Total	114	100.0	114	100.0
	Mean	1.9		1.1	
Pain Discomfort	Level 1	31	27.2	99	86.8
	Level 2	47	41.2	14	12.3
	Level 3	27	23.7	1	0.9
	Level 4	8	7.0	0	0.0
	Level 5	1	0.9	0	0.0
	Total	114	100.0	114	100.0
	Mean	2.1		1.1	
Anxiety/Depression	Level 1	84	73.7	112	98.2
	Level 2	21	18.4	2	1.8
	Level 3	6	5.3	0	0.0
	Level 4	2	1.8	0	0.0
	Level 5	1	0.9	0	0.0
	Total	114	100.0	114	100.0
	Mean	1.4		1.0	

Your Health today	Before	After
Min	30.00	50
Max	100.00	100
Mean	75.64	88.9

Table A2. VeinesQol/sym

Variables		Before Treatment		After Treatment	
		f	%	f	%
1. During the past four weeks, how often have you had any of the following leg problems?					
Heavy Legs	(1) Everyday	17	14.9	1	0.9
	(2) Several times a week	21	18.4	1	0.9
	(3) About once a week	19	16.7	6	5.3
	(4) Less than once a week	31	27.2	15	13.2
	(5) Never	26	22.8	91	79.8
	Total	114	100.0	114	100.0
	Mean	3.2		4.7	
Aching Legs	(1) Everyday	20	17.5	2	1.8
	(2) Several times a week	23	20.2	1	0.9
	(3) About once a week	20	17.5	2	1.8
	(4) Less than once a week	34	29.8	13	11.4
	(5) Never	17	14.9	96	84.2
	Total	114	100.0	114	100.0
	Mean	3.0		4.8	
Swelling	(1) Everyday	17	14.9	3	2.6
	(2) Several times a week	12	10.5	1	0.9
	(3) About once a week	24	21.1	4	3.5
	(4) Less than once a week	31	27.2	10	8.8
	(5) Never	30	26.3	96	84.2
	Total	114	100.0	114	100.0
	Mean	3.4		4.7	

Variables		Before Treatment		After Treatment	
		f	%	f	%
Night Cramps	(1) Everyday	8	7.0	1	0.9
	(2) Several times a week	17	14.9	0	0.0
	(3) About once a week	20	17.5	4	3.5
	(4) Less than once a week	51	44.7	13	11.4
	(5) Never	18	15.8	96	84.2
	Total	114	100.0	114	100.0
	Mean	3.5		4.8	
Heat/ Burning sensation	(1) Everyday	13	11.4	1	0.9
	(2) Several times a week	11	9.6	0	0.0
	(3) About once a week	18	15.8	4	3.5
	(4) Less than once a week	27	23.7	5	4.4
	(5) Never	45	39.5	104	91.2
	Total	114	100.0	114	100.0
	Mean	3.7		4.9	
Restless legs	(1) Everyday	12	10.5	1	0.9
	(2) Several times a week	16	14.0	2	1.8
	(3) About once a week	18	15.8	4	3.5
	(4) Less than once a week	34	29.8	5	4.4
	(5) Never	34	29.8	102	89.5
	Total	114	100.0	114	100.0
	Mean	3.5		4.8	

Variables		Before Treatment		After Treatment	
		f	%	f	%
2. At what time of day is your leg problem most intense?	(1) On waking	14	12.3	12	10.5
	(2) During the night	11	9.6	2	1.8
	(3) At mid-day	14	12.3	7	6.1
	(4) At any time of day	23	20.2	11	9.6
	(5) At the end of the day	46	40.4	10	8.8
	(6) Never	6	5.3	72	63.2
	Total	114	100.0	114	100.0
	Mean	3.8		4.9	

Variables		Before Treatment		After Treatment	
		f	%	f	%
3. Compared to one year ago, how would you rate your leg problem in general now?	(1) Much better now than one year ago	51	44.7	105	92.1
	(2) Somewhat worse now than one year ago	20	17.5	2	1.8
	(3) Somewhat better now than one year ago	13	11.4	3	2.6
	(4) Much worse now than one year ago	15	13.2	2	1.8
	(5) About the same now as one year ago	3	2.6	0	0.0
	(6) I did not have any leg problem last year	12	10.5	2	1.8
	Total	114	100.0	114	100.0
	Mean	2.4		1.2	

Variables		Before Treatment		After Treatment	
		f	%	f	%
4. Does your leg problem now limit you in these activities?					
	(0) I do not work	32	28.1	18	15.8
Daily activities at work	(1) YES, Limited a lot	18	15.8	3	2.6
	(2) YES, Limited a little	40	35.1	9	7.9
	(3) NO, not limited at all	24	21.1	84	73.7
	Total	114	100.0	114	100.0
	Mean	1.5		2.4	
Daily activities at home	(1) YES, Limited a lot	25	21.9	3	2.6
	(2) YES, Limited a little	58	50.9	14	12.3
	(3) NO, not limited at all	31	27.2	97	85.1
	Total	114	100.0	114	100.0
	Mean	2.1		2.8	

Variables		Before Treatment		After Treatment	
		f	%	f	%
Social or leisure activities(standing)	(1) YES, Limited a lot	33	28.9	4	3.5
	(2) YES, Limited a little	57	50.0	10	8.8
	(3) NO, not limited at all	24	21.1	100	87.7
	Total	114	100.0	114	100.0
	Mean	1.9		2.8	
Social or leisure activities (Sitting)	(1) YES, Limited a lot	32	28.1	3	2.6
	(2) YES, Limited a little	54	47.4	11	9.6
	(3) NO, not limited at all	28	24.6	100	87.7
	Total	114	100.0	114	100.0
	Mean	2.0		2.9	

Variables		Before Treatment		After Treatment	
		f	%	f	%
5. During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of your leg problem?					
Cut down the amount of time you spent on work or other activities	Yes	73	64.0	9	7.9
	No	41	36.0	105	92.1
	Total	114	100.0	114	100.0
Accomplished less than you would like	Yes	73	64.0	11	9.6
	No	41	36.0	103	90.4
	Total	114	100.0	114	100.0
Were limited in the kind of work or other activities	Yes	75	65.8	9	7.9
	No	39	34.2	105	92.1
	Total	114	100.0	114	100.0
Had difficulty performing the work or other activities	Yes	67	58.8	9	7.9
	No	47	41.2	105	92.1
	Total	114	100.0	114	100.0

Variables		Before Treatment		After Treatment	
		f	%	f	%
6. During the past four weeks, to what extent has your leg problem interfered with your normal social activities with family, friends, neighbors, or groups?	(1) Not at all	29	25.4	79	69.3
	(2) Slightly	37	32.5	15	13.2
	(3) Moderately	26	22.8	1	0.9
	(4) Quite a bit	18	15.8	19	16.7
	(5) Extremely	4	3.5	0	0.0
	Total	114	100.0	114	100.0
	Mean	2.4		1.6	

Variables		Before Treatment		After Treatment	
		f	%	f	%
7. how you feel and how things have been with you during the past four weeks as a result of your leg problem	(1) None	16	14.0	93	81.6
	(2) Very mild	33	28.9	12	10.5
	(3) Mild	14	12.3	6	5.3
	(4) Moderate	41	36.0	3	2.6
	(5) Severe	7	6.1	0	0.0
	(6) Very severe	3	2.6	0	0.0
	Total	114	100.0	114	100.0
	Mean	3.0		1.3	

Variables		Before Treatment		After Treatment	
		f	%	f	%
8. how you feel and how things have been with you during the past four weeks as a result of your leg problem					
Have you felt concerned about the appearance of your leg(s)?	(1) All of the time	14	12.3	1	0.9
	(2) Most of the time	12	10.5	3	2.6
	(3) A good bit of the time	5	4.4	1	0.9
	(4) Some of the time	24	21.1	3	2.6
	(5) A Little of the time	32	28.1	12	10.5
	(6) None of the time	27	23.7	94	82.5

Variables		Before Treatment		After Treatment	
		f	**%**	**f**	**%**
	Total	114	100.0	114	100.0
	Mean	4.1		5.7	
Have you felt irritable?	(1) All of the time	7	6.1	1	0.9
	(2) Most of the time	11	9.6	1	0.9
	(3) A good bit of the time	5	4.4	2	1.8
	(4) Some of the time	20	17.5	3	2.6
	(5) A Little of the time	41	36.0	5	4.4
	(6) None of the time	30	26.3	102	89.5
	Total	114	100.0	114	100.0
	Mean	4.5		5.8	
Have you felt a burden to your family or friends?	(1) All of the time	5	4.4	0	0.0
	(2) Most of the time	12	10.5	1	0.9
	(3) A good bit of the time	3	2.6	2	1.8
	(4) Some of the time	17	14.9	3	2.6
	(5) A Little of the time	36	31.6	2	1.8
	(6) None of the time	41	36.0	106	93.0
	Total	114	100.0	114	100.0
	Mean	4.7		5.8	
Have you been worried about bumping into things?	(1) All of the time	5	4.4	0	0.0
	(2) Most of the time	14	12.3	2	1.8
	(3) A good bit of the time	3	2.6	2	1.8
	(4) Some of the time	25	21.9	2	1.8
	(5) A Little of the time	35	30.7	3	2.6
	(6) None of the time	32	28.1	105	92.1
	Total	114	100.0	114	100.0
	Mean	4.5		5.8	
Has the appearance of your leg(s) influenced your choice of clothing?	(1) All of the time	10	8.8	1	0.9
	(2) Most of the time	11	9.6	1	0.9
	(3) A good bit of the time	2	1.8	1	0.9
	(4) Some of the time	14	12.3	2	1.8
	(5) A Little of the time	33	28.9	2	1.8
	(6) None of the time	44	38.6	107	93.9
	Total	114	100.0	114	100.0
	Mean	4.6		5.8	

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