QUALITY OF LIFE IN PATIENTS WITH LOWER EXTREMITIES DEEP VENOUS THROMBOSIS USING VEINES-QOL/SYM QUESTIONNAIRE

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Acute venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE), is a common disorder with an annual incidence rate of 1-2 cases per 1000 persons. Health-related quality of life in patients after having DVT is impaired if not treated correctly. The VEINES - QOL (Sym) is a disease-specific instrument used to assess health-related quality of life in patients with chronic venous disease of the legs. A descriptive cross-sectional study was conducted on 32 patients diagnosed with deep vein thrombosis and treated at Vietnam National Heart Institute and Hanoi Medical University hospital. Our study indicated statistical differences in patients' quality of life (QOL) before and one month after treatment. Mean difference for VEINES-QOL was 1.4 (p-value = 0.02), for VEINES-Sym was 1.6 (p-value = 0.01). Our study brought conclusions: anticoagulation therapy increased QOL in patients with DVT; and the principal factors influencing long-term QOL were oldage, BMI, recurrent DVT, and proximal DVT.

Keywords: Quality of life; deep venous thrombosis; VEINES-QOL/Sym score.

I. INTRODUCTION

Deep vein thrombosis (DVT) is the third most common cardiovascular disease, with an annual incidence of about 108 in 100.000 people.[1] Deep vein thrombosis (DVT) is a potentially catastrophic condition caused by thrombosis if left untreated. DVT is a multifactorial disease that represents the interaction between genetic and environmental factors, and the majority of patients with incident DVT have either inherited thrombophilia or acquired risk factors. DVT can be caused by venous stasis circulation, coagulation disorders, and vascular wall damage. [2-7]

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Therapy for lower-extremity DVT is to prevent the extension of thrombus and pulmonary embolism in short term and prevent recurrent events inlong term. Anticoagulation with low-molecular-weight (LMW) heparins in therapeutic dosage should start immediately after diagnosis. [8-11]

The World Health Organization (WHO) defines the quality of life (QoL) as "an individual's perception of their position in life in the context of the culture and value systems in which they live and about their goals, expectations, standards, and concerns." Health-related QoL encompasses physical and occupational function, psychological state, social interaction, and bodily sensation.[12] DVT has been demonstrated to impair the patient's physical, social, and psychological QoL.[13]

There were studies worldwide about patients' quality of life with deep vein thrombosis. But there was no such study in Viet Nam. Thus, we conducted this study to assess the quality of life in patients with deep vein thrombosis before and one month after treatment and to identify factors related to the quality of life among these patients.

II. SUBJECTS AND METHODS

1. Study population

All patients diagnosed with lower extremities deep venous thrombosis (DVT), and treated with anticoagulation therapy at Cardiovascular Center in HMUH and C6 Department at Vietnam National Heart Institute.

Inclusion criteria

- Patients with available medical record with comprehensive general information, admission, discharge information, doppler ultrasonic deep venous result, and diagnosis.

- Patients older than 18 years old with good contact information.

- Patients agreed to participate in the study after being explained the purpose and progress of the study.

Exclusion criteria

- Patients with incomplete medical records or no medical record.

- Patients who did not return to the hospital for a 1-month follow-up visit,

- Patients with an expected lifespan less than a month,

- Patients did not agree to participate in the study or were not able to answer questions cognitively.

2. Methods

- This was a descriptive cross-sectional study.

- Patients were recruited to the study by convenient sampling with 32 participants.

- Study timeline: 01/05/2019 - 15/09/2019

- Study setting: Cardiovascular Center in HMUH and C6 Department at Vietnam National Heart Institute.

- Instruments: VEIN-QOL/SYM questionnaire is used to assess the quality of life typically applied for diseased venous patients. It includes 26 questions about symptoms (10 items), limitations in daily activities (9 items) and psychological (5 items), change during the past year, and time of the day when the leg problem is most intense. The higher score, the better QOL. The VEINES-QOL summary score (25 items) estimates the respondent's overall QOL, including the impact of chronic venous diseases of the leg (CVDL) on quality of life, symptoms, and the change in the respondent's leg problem over a year. An item that asks about the time of day that the leg problem is most intense provides only descriptive information and is not scored. The VEINES-SYM score (10 items) includes questions on the frequency of 9 CVDL symptoms: heavy legs, aching legs, swelling, night cramps, heat or burning sensation, restless legs, throbbing, itching, and tingling sensation, as well as the intensity of leg pain.

The standard method to create summary scale scores uses z-score equivalents or transformations of raw scores. Raw scores are transformed to standard z-scores which can then be summed to form summary scales with mean 0 and standard deviation 1. Because changing raw scores to z-scores generates negative scores which are not readily interpretable, z-scores are transformed to T-scores for reporting purposes. T-scores are based on a mean of 50 and a standard deviation of 10 to give an easily understood range of scores. [14,15]

Statistical analysis: The information obtained from the study was processed according to the biomedical statistical algorithm on STATA

software 14.0. The results are expressed in percentage (%) for the categorical variables, the mean value, and the quantitative variables' standard deviation. When appropriate, compare two or more independent groups with the mean of VEINS-QOL/Sym by the ANOVA test or T-test instead of whether there is any relative. Compare two mean values before and after treatment (VEIN-QOL/Sym) by paired-samples T-test to determine any statistically significant difference. The difference was statistically significant when the p-value was < 0.05.

3. Ethics approval

We strictly followed Medical Ethics Council; human rights and privacy were protected, and confidential and voluntary participation. The study was conducted under participants' permission and agreement.

III. RESULTS

Patient characteristics

From May 2019 to September 2019, 38 consecutive patients objectively diagnosed as having DVT were approached for participation in the study. Of these patients, 6 were excluded for the following reasons: refusal or inability to provide informed consent (n = 1), estimated life expectancy of less than 1 month (n = 2), geographic inaccessibility for follow-up (n = 1), and others (n = 2).

Table 1. Baseline characteristics of 32 study participants

Characteristic	Value
Gender	
Male	13 (41%)
Female	19 (59%)
Age (year)	56.3 ± 20.1
Unemployed	18 (56%)
BMI (body mass index) (kg/m^2)	22.6 ± 2.0
Smoker	10 (31.3%)
Location of DVT	
Proximal DVT	24 (75%)
Distal DVT	8 (25%)
DVT diagnosis situation	
Recurrent DVT	27 (81%)
First DVT	6 (19%)

In table 1, the data for female was considerably higher than for male;. The mean age was 56.3 ± 20.1 years. Deep vein thrombosis was located in the proximal venous segments in 75% of the patients and in distal (infrapopliteal) elements in 25%: recurrent DVT represented 18.75% and initial DVT represented 84%.

Clinical follow-up

At admission and 1-month follow-up visits, 93.8% and 36.7% of patients were still taking anti-vitamin K anticoagulation. Elastic compress stocking use of any frequency was reported by 65.8% of patients during the 1-month visit. the DVT site (proximal or distal) did not influence these results (75% and 25% p> 0.05) *(table 2).*

Baseline QOL

For all QOL measures, female had significantly lower scores than male . Patients

with a higher BMI had significantly lower VEINES-QOL and VEINES-Sym scores than patients with a lower BMI. VEINES-QOL scores of patients under 40 years were more elevated than middle-aged and elderly patients; VEINES-Sym scores of patients under 40 years old were higher than middle-aged and elderly patients. VEINES-Sym and VEINES-QOL scores for smoking, and cancer patients were lower than non-smoking and non-cancer patients, and VEINES-Sym scores were lower in patients with proximal DVT than in patients with distal DVT. Moreover, QOL scores were influenced by whether DVT was initial or recurrent.

Table 2. Baseline QOL by patient characteristics

Characteristics	n=32	VEINES-QOL		VEINES-Sym	
		Mean ± SD	p-value	Mean ±SD	p-value
Gender					
Male	13	52.3± 9.5	0.29	53.7±7.3	0.06
Female	19	48.4±10.4		47.3±10.6	
Age (years)					
<40	8	52.0 ± 9.2		53.9 ± 6.7	
40-59	6	51.4 ± 8.4	0.71	53.5 ± 14.2	0.19
≥60	18	48.8 ± 11.1		47.3 ± 8.7	
BMI					
<23	14	51.3±9.9		50.9±11.9	
23-25	16	49.4±10.4	0.74	49.1±7.9	0.89
>25	2	45.9±14.4		49.7±13.9	
Smoking	10	48.4±13.3	0.56	49.0±7.2	0.74
Non-smoking	22	50.7±8.5		50.3±10.9	
Cancer	2	49.7±5.4	0.76	48.1±11.5	0.79
Non-Cancer	30	50.0±10.4		50.0±9.9	
Diagnosis situation					
First	26	50.76±8.99	0.38	50.20±10.19	0.72
Recurrent	6	46.72±14.59		48.60±8.80	
Location of DVT					
Proximal	24	49.8±11.0	0.84	50.2±10.3	0.74
Distal	8	50.6±7.1		48.9±8.9	

Change in QOL

Quality-of-life scores were available at all two-time points for 32 patients. There were no significant changes in mean QOL scores from the enrollment (baseline) visit to the 1-month visit. The mean VEINES-QOL score improved by 1.4 points in which heavy score, aching score, and swelling score grew up (from 1.8±0.9 to 1.9±0.9, from 1.7±0.6 to 1.8±0.6, and from 1.66±0.9 to 1.72±0.8 respectively). Night cramps score, heat or burning score,

and restless score increased (from 3.5±0.9 to 3.9±0.8, from 3.1±1.0 to 3.2±0.9, and from 3.3 ± 1.0 to 3.4±1.1 respectively). Throbbing score, itching score, and tingling sensation score increased (from 4.1±0.9 to 4.2±0.8, from 4.2±0.6 to 4.3±0.6, and from 3.88±0.8 to 3.91±0.8), and the mean VEINES-Sym score improved by 1.6 points (P < .001 for time trend for all 2 QOL measure) (Figure 1).

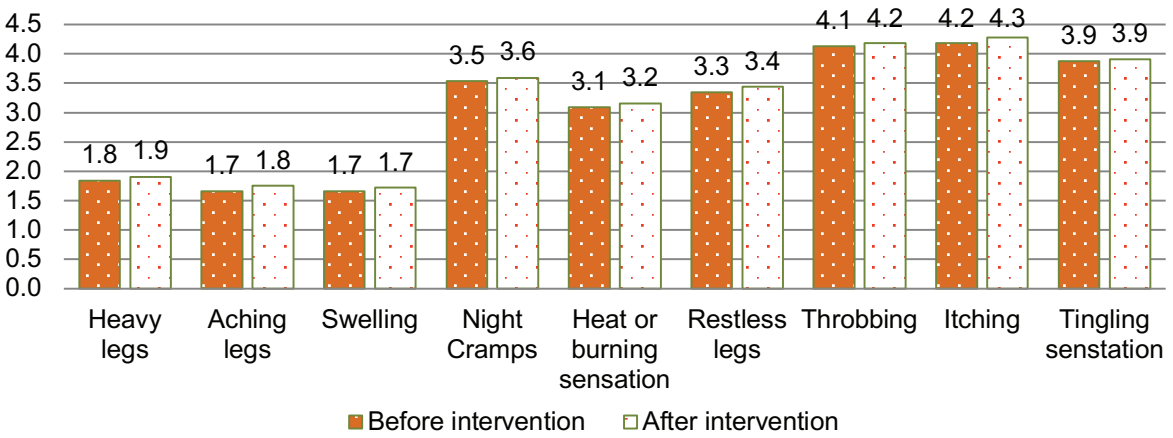

Figure 1. Mean of venous symptoms score of VEINES-Sym before and one month after treatment

Our result indicated that VEINES-QOL scores improve after treatment. Improvement of QoL scores in our study group was statistically significant (paired samples T-test, p<0.05).

IV. DISCUSSION

This study was conducted at two medical centers in Hanoi; we prospectively evaluated health-related QOL during the one-month acute DVT. We found that, on average, venous disease-specific QOL scores tended to enhance over time. However, one month after diagnosis, physical health status did not significantly improve.

Assessment at one month after DVT, might be premature to assume whether persistent venous symptoms and signs show slow resolution of the acute DVT process or the development of the chronic post-thrombotic syndrome. Nevertheless, our findings indicate that a lack of resolution or worsening of venous symptoms and signs during the first month after DVT has a considerable adverse influence on disease-specific QOL. We did not find the location of DVT (proximal vs. distal) to be a factor in anticipating the improvement of QOL scores in patients during the 1-month follow-up. This is associated with a recent review that was unable to demonstrate a consistent parallel with other studies. We found obesity to be associated with impaired HRQoL.[16] Obesity affects physical activity and bodily pain and significantly impacts physical well-being.[17] Our study's mean BMI (kg/m2) was 22.6 ± 2.0, 18 patients with pre-obesity or obesity class I, collated on WHO BMI for the Asian population. However, obesity was not associated with impaired QoL. In other studies using generic instruments such as EQ-5D, unemployment was associated with poor QoL.[18] The disease-specific VEINES-QOL/Sym employment status was not associated with impaired QoL. This seems logical as the disease-specific tool captures different aspects of QoL from the

generic questionnaire. Unemployment in our study was not associated with poor QOL. In line with previous studies, our result indicated that the type of DVT did not influence the VEINES-QOL/Sym score. VEINES-QOL score of patients who first had DVT (50.76±8.99) was higher than patients who had recurrent DVT (46.72±14.59), p=0.38. A VEINES-Sym score of patients with first DVT (50.20±10.19) was higher than the figure for patients with recurrent DVT (48.60±8.80), p=0.72.[16] In line with most previous studies, the location of DVT in our study did not influence VEINES-QOL/ sym score. VEINES-QOL score of patients with proximal DVT (49.8± 11.0) was lower than the figure for patients with distal DVT (50.6 ±7.1), p=0.84. A VEINES-Sym score of patients who had proximal DVT (50.2±10.3) was higher than the figure for patients who had distal DVT (48.9±8.9), p=0.74.[16] In contrast with other studies, comorbidities (heart failure and COPD) were not associated with impaired QoL when adjusting for other factors, probably because very few patients had these comorbidities in our study sample, leading to low power.[16]

V. CONCLUSIONS

In conclusion, we found that, on average, QOL improves during the one month following DVT if well treated. Principal factors influencing long-term QOL were older age, higher BMI, recurrent DVT, and proximal DVT. Although widely considered an acute condition, our findings indicate that DVT has a detrimental impact on QOL that persists beyond the short-term phase and illustrates evidence to support the evaluation of QOL in conjunction with clinical endpoints in trials comparing treatments for DVT.

LIMITATIONS

Since our study has a small sample size and a rather short time follow- up, we recommend a larger study with a long term follow up to further validate our findings.

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