RESEARCH ARTICLE

HEALTH RELATED QUALITY OF LIFE SCREENING WITH MEDICAL OUTCOMES STUDY 12-ITEM SHORT-FORM HEALTH SURVEY (MOS SF 12) AND 14-ITEM SHORT-FORM HEALTH SURVEY FOR CHRONIC VENOUS INSUFFICIENCY (MOS CIVIQ 14) THAI VERSIONS

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ABSTRACT

Background: Chronic venous disease (CVD) was a high incidence meanwhile patients did not seek treatment at early stage. Relevance leg symptoms spotted for primary screening remains clinical challenges.

Method: The medical outcomes study (MOS) with health-related quality of life, a12-Item Short-Form Health Survey (MOS SF12) and a 14-Item Health Short-Form Health Survey for Chronic Venous Insufficiency (MOS CIVIQ14) were employed in hospital-setting together with physical examinations for an interventional study.A cross-sectional analysis was performed to assess reliability and correlation of the questionnaires with specific implication of leg symptoms.

Result: Overall 120 patients were screened, out of this 48 patients clinically diagnosed CVD. For inter-scale correlation and internal consistency reliability interpreting with Cronbach's alpha coefficients, the MOS CIVIQ-14 Thai version were reliable with Cronbach's alpha coefficient of 0.914(for 14-item global score), 0.867(for 7-item physical and pain score) and 0.787(for 7-item psychological score), whereas the MOS SF-12 were reliable with the above 0.810(for 12-item for global score), 0.939(for 7-item physical and pain score) and 0.661(for 5-item mental score). The two questionnaires were well correlated for physical score, interpreting with bivariate Pearson correlation coefficient, with a 95% CI of 0.713(0.663 to 0.790), p<0.001 and for global score, 0.745 (0.640 to 0.819), p<0.001). No significant correlation of psychological score of -0.062(-0.197 to 0.091), p=0.501. The major leg symptoms significantly have rendered impacts on the raw score of physical components and global score but not for mental component. Patients with MOS CIVIQ-14 score lower than 75.7 would be more likely to have been diagnosed CVD.

Conclusion: Both the MOS CIVIQ-14 and the MOS SF 12 were highly correlate for scoring on physical function, useful for primary screening of chronic venous disease. Should the procedures be use in a larger population, the majority of leg symptoms and adjustment of appropriate threshold scores may be a useful tool for screening CVD. The MOS CIVIQ-14 was useful but larger heterogeneous patient exploration confirmation is suggested.

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INTRODUCTION

Chronic venous disease (CVD) is a globalhealth burden especially in the Westwhichreported the presence of varicose veins as high as 20-33%. In many cases, clinical history and

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physical examination looking for patient's symptoms and severity could help confirm diagnosis of CVD (Onida and Davies, 2016; Nicolaides, 2000). In Thailand, the high incidence of superficial varicose vein of32.99% or so may not be presenting with leg symptoms and patients did notseek medical treatment as had been reportedamong femalefactory workers (Jutarat Rakprasit, 2008). In most hospitalized leg ulcer patients were also ofvenous originwhich possibly

relevance to the untreated CVD (Kessiri Wongkongkam, 2009). Nevertheless, leg symptoms reported by specialists still varied differently among young CVD patients (Kanchanabat *et al.*, 2010). A large epidemiological study at primary care setting for cases possible of chronic venous insufficiency had reported some leg symptoms such as heaviness in the legs, itching as common symptoms (Callejas and Manasanch, 2004). The gross appearance of cutaneous skin finding such as varicose veins was still essential to confirm chronic venous disease together with related troubling symptoms though has been suggested (Wolinsky and Heidi, 2009). Though manypatients with venous insufficiency did not receive treatment (Akbulut *et al.*, 2012), theirhealth-related quality of life had been widely assessed and well perceived as poor (Lozano *et al.*, 2014; Paul *et al.*, 2011; Hopman *et al.*, 2013; Ceviker *et al.*, 2016; Amsler *et al.*, 2013). We assessedthe health-related quality of life of participants using both general and disease-specific health-survey questionnaires with leg symptoms in hospital-setting together with physical examination during recruitment of an interventional study (Vuylsteke *et al.*, 2015).

Objective

To explore reliability and correlations ofthe generic and the specific health-related quality of life scale, the impacts of leg symptoms and clinical diagnosis staging of chronic venous insufficiencyby assessment with two medical outcomes studiesas (i) a 12-Item self-administered Short-Form Health Survey, MOS SF-12 and (ii) a 14-Item HealthShort-Form Health Survey for Chronic Venous Insufficiency (MOS CIVIQ14).

Methods

Study design and setting

This was aprospective cross-sectional analysis among participants recruited for intervention study of the registered trial for a 3-month clinical trial of herbal medicine combination intended for topical application in patients with leg symptoms due to chronic venous insufficiency with registered numbers ISRCTN 54360155 (http://www.isrctn.com/ISRCTN54360155?q=&filters=conditionCategory:Circulatory%20System&sort=&offset=35&totalResults=1438&page=1&pageSize=50&searchType=basic-search).

Sample and Population

Individual participants complainingmajor leg symptoms eligible in the inclusion criteria were assessed with health-related quality of life tools. Eligibility criteria were any participants, both gender age above 18 years old with any leg symptoms seeking medical treatmentat ambulatory surgical clinics. The conduct was an observational basis and medical interview were cross-checked withmedical records. They were prospectively screenedacross a 6-month period.Any of researcher nursesprovided study details to participants, obtained informed consentsfollowed by assessments with either one of the two health-related quality of life questionnaire, the disease-specific questionnaireMOS CIVIQ-14 Thai version or ageneral 12-Item Short-Form Health Survey (MOS SF12) separately. One researcher assessed with general whereas the other assessed with disease-specific scale. All participants werelatere subjected to physical examination and clinically diagnosed and classified for staging of chronic venous insufficiencystaging by surgeon. There were 120 participants completed for screening and provided informed consents, 52 of which were diagnosed chronic venous disease. All detailbaseline characteristic of participants was givenin Table 1.

The health-related quality of life assessment tools

Two typesof health-related quality of life tools were employed.The original tools were instruments developed, validatedfor theirpsychometric properties in terms of face validity, content and construct validity byoriginal investigators (Ware *et al.*, 1996; Ware and Sherbourne, 1992; Le Moine *et al.*, 2016). The Thai version acquired from a translation of originalThai version, adapted touse specifically for medical outcomes study by a generic scale 12-Item Short-Form Health Survey (MOS SF-12) anda disease-specificscale14-Item Short-Form Health Survey of Chronic Venous Insufficiency Questionnaires (MOS CIVIQ14). The MOS SF12 known as SF-12, Was originally published by Ware *et al.* (1996, 1992) whereasthe original Thai versionearlier validated by Kasemsup *et al.* (2009). The MOS CIVIQ14, known as CIVIQ-14 was a specific scaleoriginally developed by Launois *et al.* (2016), validated for its stability for items and dimensions with highreliability and validity in chronic venous insufficiency patients whereas the original Thai version adapted from a version suggested by vascular consortium (Kanchanabat *et al.*, 2010). The SF-12 is a self-administered questionnaire. It employs two items each to estimate scores for four of the eight health concepts (physical functioning, role physical, role emotional, and mental health). Meanwhile, the other four health concepts (bodily pain, general health, vitality, and social functioning) are estimated by using one-items each. There are two types of score, Physical Component Summary score (PCS) and Mental Component Summary score (MCS). The properties and scoring were correlated with the SF-36 (Ware and Sherbourne, 1992). The CIVIQ-14 is a 14-item health survey questionnaires covered in three dimensions, Physical (7-item), Pain (1-item), Psychological (6-item) and then scoring with five response choices (Le Moine *et al.*, 2016). TheCIVIQ-14 was correlate ed with the American Varicose Vein Questionnaire (AAVQ) reported by Kuet *et al.* (2014). Therefore, CIVIQ-14 is mostly adaptive with participants with leg symptoms whether diagnosed chronic venous insufficiency in the presence of varicose vein.

Assessment of medical outcomes study of SF-12 and CIVIQ-14

The assessments of medical outcomes study were analyzedwith descriptive exploratory statisticsincluded (a) the reliability ofscores, (b) the correlation of the twoquestionnaires, (c) the correlation of leg symptoms and questionnaire scores, (d) the impacts of leg symptoms with respectto questionnaire scoresand a predictive ifsecured with clinical diagnosisbased on CEAP,a Classification of Venous disease staging and questionnaire score based on the assumed at the sensitivity and specificity above 75 percentage points.

Data Collection

The participants were recruited from Wiang Chai SPDY Chiang Rai Hospital during October 2015 to March 2016. Participants were medically interviewed in a standardized approach by experienced researcher nurses before participating to the assessment of questionnaire.

Table 1. Baseline demographic and clinical characteristics of the individual samples with complaints of leg symptoms visiting the ambulatory care setting

Demographic and Clinical Characters			(mean, ± SD, Min‒Max)
Gender	Men	16 (16 %)	
	Women	104(84%)	
Age, years	<65	104(84%)	50.38, ±12.65, 21-77
	≥65	16(16%)	
Body Mass Index (Kg/m2)	<25	73(59%)	24.36, ± 4.52, 16.44 - 39.16
Number (%)	≥25	47(41%)	
Employment Status	Fulltime	67(55.8%)	
Number (%)	Part-time 3 (2.5%)		
	Unemployed 5 (4.2%)		
	Retired 9 (7.5%)		
	Others 36(30%)		
Leg symptoms of parents	No 94 (78.4%)		
Number (%)	Father and Mother	1(0.8%)	
	Father only	6(5%)	
	Mother only	19(15.8%)	
Life style/Exercise adapted	No	67(55.8%)	
Number (%)	Yes	53(44.2%)	
Smoking Status	No	117 (97.5%)	
Number (%)	Yes	3(2.5%)	
Long standing (hours)			4.18±2.84
Long sitting (hours)			3.94±2.64
Used Medical Products	Yes8 (6.7%)		
Number (%)	No112 (93.3%)		
Compression Treatment	Yes31 (25.8%)		
Number (%)	No89 (74.2%)		
Major health complaints	Pain in the leg	22.8 %	93
Reported Frequency (%)	Night cramp	19.9 %	81
	Heavy Leg	19.7 %	72
	Leg Swelling	14.0 %	57
	Burning in leg	13.5 %	55
	Pin in leg	9.3 %	38
	Itching	2.7 %	11
Co-morbidity			26
			18
	Hypertension	26 (21.7%)	7
	Musculoskeletal	18 (15 %)	
	T2DM7 (5.8%)		
Clinical Diagnosis of CEAP Class	Right Leg C0-1	107 (89.2%)	
Number (%)	C2	13 (10.8%)	
	Left Leg C0-1	120 (100%)	

Participants were assessed twice separately by two different researcher nursesemploying with either an MOS SF-12 or the MOS CIVIQ-14 to ensure the uninterrupted process of data collection for a unified understanding of questionnaire by all participants. All participants were undergone routine physical examinationsin surgery clinics. The collecteddata in case record form and questionnaires were filed separately by each researcher nurses.

Statistical analysis

Data were validated for completion of filing at research unitfor analysis by independent investigator. The Statistical Package for Social Sciences (SPSS for Windows, version 17.0, SPSS Inc.Chicago, IL) was used for all analysis.All descriptive data

analysis was performed for all independent variablesas cross-sectional analysis as follows(a) the inter-class and intra-class correlation using the Cronbach's alpha correlation coefficient (b) the Pearson correlation coefficient, with bootstrap 1000 for bivariate correlation of two types of questionnaire.(c) the correlation matrix by factor analysis through dimension reduction for correlation of scores withleg symptoms.(d) the receiver operating curve (ROC) at true positive impacts of leg symptomsat cut-point score of at least 90% sensitivity with the Null hypothesis testing which assuming no impact from positive leg symptom complaints at an area under curve (AUC) not less than 0.5 whereas rejecting of the Null hypothesis with AUC less than 0.5, significant different at p-value <0.05 and a predictive of the ROCat true positive CEAP

stage1 (N=35) and 2 (N=13) for right leg with the cut-point scoreat least 75%sensitivity for the scales with the Null hypothesis testing for the clinical diagnosisof chronic venous disease of CEAP classification assumed nonparametric distribution with 95% Confidence interval with coordinate points of the ROC and the questionnaire scores.

RESULTS

There were 120 participants, 53 of whom reported to have lifestyle modifications for relief such as exercise adaptation, 28 and 31 participants employed unspecified medical treatment available andthe other used surgical bandage supports. Heavy leg and leg pain were dominant symptoms, many of which had multiple symptoms.

The reliability correlation of the two scales employed a descriptive cross-sectional analysis and exploratory analysis for the stability of scores by inter-scale correlations and internal consistency reliability intra-class correlation with Cronbach's alpha coefficient. For MOS CIVIQ14, the average mean score for pain score alone reflected lower mean score from item CV1 to CV8 which were ranged from 72 to 81.83. The MOS CIVIQ Pain score revealed higher reliability with the inter-item Cronbach alpha's coefficient above 0.5 reportingthe score as low as 72. In the contrary, Cronbach's alpha coefficient for MOS CIVIQ Psychological score was far less than 0.5. Overall, individual item with inter-scale correlations and internal consistency Cronbach's alpha coefficient were presented in Figure 1. For MOS SF12, the average mean score for physical function items RP1, RP2, PF1 and PF2 reflected the mean score ranged from 71.16 to 95.83,

	Item	CV 1	CV 2	CV 3	CV 4	CV 5	CV6	CV 7	CV 8	CV 9	CV 10	CV 11	CV 12	CV 13	CV 14	CVQ 14
PAIN	CV1	1.000														
	CV2	0.641	0.641													
	CV3	0.504	0.529	0.504												
PHYS	CV4	0.396	0.519	0.490	0.396											
	CV5	0.239	0.298	0.280	0.574	0.239										
	CV6	0.271	0.449	0.337	0.641	0.430	0.271									
	CV7	0.258	0.467	0.388	0.580	0.392	0.649	0.258								
	CV8	0.323	0.438	0.372	0.634	0.430	0.663	0.676	0.323							
PSYC	CV9	0.405	0.553	0.610	0.447	0.277	0.323	0.422	0.403	0.405						
	CV10	0.428	0.578	0.483	0.414	0.249	0.488	0.413	0.523	0.619	0.428					
	CV11	0.058	0.077	-0.001	0.013	0.076	0.033	0.073	-0.017	0.130	0.181	0.058				
	CV12	0.349	0.518	0.401	0.413	0.169	0.344	0.379	0.452	0.630	0.338	0.338	0.349			
	CV13	0.178	0.308	0.361	0.353	0.231	0.251	0.398	0.336	0.291	0.077	0.077	0.426	0.178		
	CV14	0.331	0.419	0.293	0.451	0.349	0.368	0.561	0.529	0.341	0.028	0.028	0.515	0.520	0.331	
GLOB	CIVIQ14	0.585	0.734	0.651	0.773	0.583	0.701	0.730	0.761	0.693	0.211	0.211	0.687	0.519	0.659	0

Note. PHYS =Physical, PSYC=Psychological,GLOB=Global CIVIQ14 score, CV=CIVIQItem no., CVQ 14 =CIVIQ 14 total score.
For "PAIN"CV1 Pain in the leg,CV2 Impairment at work,CV3 Sleeping poorly (3 Items Cronbach's alpha 0.791);
For "PHYSICAL"CV4 Climbing several floors, CV5 Squatting/Kneeling,CV6 Walking at a good pace,CV7 Going to party,CV8 Performing athletic activities(5 Items Cronbach's alpha 0.867);
For "PSYCHOLOGICAL"CV9 Feeling nervous,CV10 Having the impression of being a burden,CV11 Being embarrassed to show legs,CV12 Becoming easily irritable,CV13 Having the impression of being disabled;CV14 Having no desire to go out (6 Items Cronbach's alpha 0.787);
GLOB CIVIQ 14 score (14 Items Cronbach's alpha 0.914)

Figure 1.The inter-scale correlations and internal consistency reliability (Cronbach's alpha coefficients, on the diagonal) of the CIVIQ 14

	GH	RP1	RP2	PF1	PF2	RE1	RE2	BP	MH1	VT	MH2	SF	GLOBAL SF12
GH	1.000												
RP1	0.623	0.623											
RP2	0.603	0.836	0.603										
PF1	0.588	0.663	0.562	0.588									
PF2	0.541	0.796	0.693	0.593	0.541								
RE1	0.199	0.089	0.060	0.107	0.323	0.199							
RE2	0.023	-0.077	-0.003	-0.030	-0.061	-0.060	0.023						
BP	0.695	0.767	0.684	0.539	0.708	0.177	-0.065	0.695					
MH1	0.068	0.016	0.049	-0.038	0.055	-0.039	0.490	-0.025	0.068				
VT	-0.023	-0.087	-0.102	-0.065	-0.074	-0.031	0.359	-0.117	0.495	-0.023			
MH2	-0.066	-0.025	0.004	0.065	-0.074	-0.031	0.281	-0.007	0.495	0.366	-0.066		
SF	-0.090	-0.038	-0.010	-0.078	-0.088	-0.037	0.035	-0.062	0.009	0.158	0.158	-0.090	
GLOBAL SF 12	0.753	0.851	0.825	0.683	0.787	0.184	0.276	0.810	0.296	0.185	0.134	0.753	0.753

Note. GH=General Health, RP=Role Physical,PF=Physical Function, RE=Role Emotion, BP=Bodily Pain, MH=Mental Health, VT=Vitality Energy/Fatigue, SF=Social Function; With Cronbach's alpha for Role Physical (0.791), for Physical Function (0.867), for Role Emotion (-0.040), for Mental Health (0.787), for Physical Component Score (PCS) 0.939, for Mental Component Score (MCS) 0.661, for Global MOS SF 12 score (0.810)

Figure 2.The inter-scale correlations and internal consistency reliability (Standardized Cronbach's alpha coefficients, on the diagonal) of the SF 12

It was found that right legs revealed significant 35% of clinical diagnosis of chronic venous disease with CEAP class stage 1 and 2 combined whereas left leg was not relevance. As such the ROC of CEAP staging and scoring shall be based on right legs. Overall summary of baseline characteristics of participants was provided in Table 1.

Cronbach's alpha coefficient above 0.5, whereas mean score for mental functionitems RE1, RE2, MH1, MH2 and VT reflected with Cronbach's alpha coefficient less than 0.5.The overall inter-scale correlations internal consistency Cronbach's alpha coefficient were presented in Figure 2. The mean (SD) score for MOS CIVIQ Physical and Pain was 80.33(15.5) with score ranged from 42.5 to 100, with 10 points lower than

physical component summary (PCS) of MOS SF12 which reflected mean (SD) score of 90.0(13.3), with score ranged from 35.5 to 100. The global score for MOS CIVIQ-14 and SF-12were correlated with bivariate Pearson correlation coefficient at 0.713, 0.745 respectively. Lower correlation coefficient for both the mental component summary (MCS) and MOS CIVIQ Psychological were observed and overall results were presented in Table 2.

The factor analysis of correlation matrix (CM) with dimension reduction wereassessed forcorrelation of scales with leg symptomsfor both MOS SF-12 and MOS CIVIQ 14 presentedin Table 3. Both the MOS CIVIQ-14 and MOS SF-12, CVQ pain combined withCVQ Physical and physical component summary (PCS) were significant correlated for major leg symptoms (CM coefficient above 0.7, $p < 0.001$), other results were presented in Table 3.

Table 2. Health related Quality of Life Assessment with General Scale (SF-12), Specific Scale (CIVIQ-14) with emphasis on Physical Score, Psychological Score and its Global Score

Parameters	Physical Score		Psychological Score		Global Score	
	PCS SF-12	CIVIQ Physical	MCS SF-12	CIVIQ Psychological	SF 12	CIVIQ 14
Mean ± SD,	90.02±13.32	80.33±15.50	97.29±5.22	90.88±11.53	93.65±7.05	84.71±12.60
Min-Max,	35.50-100,	42.50-100,	75-100,	53.33-100,	67.75-100,	51.43-100,
Range,	64.50,	57.50,	25,	46.67,	32.25,	48.57,
Median						
Standardized Cronbach's	0.945,	0.897,	0.725,	0.861,	0.798,	0.914,
Alpha Coefficient, 95% CI, ICC	0.921 - 0.954	0.867 - 0.922	0.560 - 0.746	0.785 - 0.867	0.756 - 0.857	0.878 - 0.928
Correlation Coefficient, (95% CI)and p-Value	0.713, (0.633 to 0.790), p<0.001**		-0.062, (-0.197 to 0.091), p=0.501		0.745, (0.640 to 0.819), p<0.001**	

Note. **p-Value with 95% Confidence Interval for a significant level <0.001 with Pearson Correlation Coefficient ICC = Intra-Class Correlation denoted with 95% Confidence Interval for both lower and upper value

Table 3. Comparison of impact of symptoms of leg complaint on the

HRQOL Score	Pain in the Leg		Swelling in the Leg	
	Yes	No		
CIVIQ 14				
CVQ pain and physical				
CVQ Pain				
CVQ Psychological				
SF 12				
PCS				
MCS				

Pain Symptoms

T-Test

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Group Statistics

	BMIStat	N	Mean	Std. Deviation	Std. Error Mean
ALLCIVOQ14	no	73	87.4951	11.55383	1.35227
	yes	47	80.3951	13.07511	1.90720
GlobalSF12_R	no	73	94.1941	7.25617	.84927
	yes	47	92.8298	6.73179	.98193
PCSSF12	no	73	90.8767	13.76968	1.61162
	yes	47	88.6915	12.62890	1.84211
MCSSF12	no	73	97.5114	4.97194	.58192
	yes	47	96.9681	5.63971	.82264
CVQPainANDPHYSICAL	no	73	84.6233	12.49077	1.46193
	yes	47	73.6702	17.41322	2.53998
CVQPain	no	73	83.0137	14.05637	1.64517
	yes	47	75.0355	18.14957	2.64739
CVQPsychological	no	73	91.8721	12.19677	1.42752
	yes	47	89.3617	10.37086	1.51275

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means					95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
ALLCIVOQ14	Equal variances assumed	3.763	.055	3.120	118	.002	7.09997	2.27590	2.59307	11.60687
	Equal variances not assumed			3.037	89.436	.003	7.09997	2.33796	2.45481	11.74514
GlobalSF12_R	Equal variances assumed	.027	.870	1.034	118	.303	1.36428	1.31966	-1.24901	3.97757
	Equal variances not assumed			1.051	103.543	.296	1.36428	1.29825	-1.21033	3.93889
PCSSF12	Equal variances assumed	.067	.796	.876	118	.383	2.18522	2.49416	-2.75390	7.12434
	Equal variances not assumed			.893	104.320	.374	2.18522	2.44759	-2.66827	7.03871
MCSSF12	Equal variances assumed	.464	.497	.554	118	.581	.54333	.98041	-1.39815	2.48481
	Equal variances not assumed			.539	89.273	.591	.54333	1.00765	-1.45877	2.54543
CVQPainANDPHYSICAL	Equal variances assumed	13.522	.000	4.009	118	.000	10.95307	2.73200	5.54298	16.36317
	Equal variances not assumed			3.737	76.184	.000	10.95307	2.93066	5.11639	16.78976
CVQPain	Equal variances assumed	6.830	.010	2.704	118	.008	7.97824	2.95090	2.13465	13.82183
	Equal variances not assumed			2.560	80.700	.012	7.97824	3.11693	1.77617	14.18030

	assumed					
CVQPsychological	Equal variances assumed	.213	.645	1.165	118	.246	2.51044	2.15433
	Equal variances not assumed			1.207	109.120	.230	2.51044	2.07996

1.165	118	.246	2.51044	2.15433	-1.75571	6.77660
1.207	109.120	.230	2.51044	2.07996	-1.61191	6.63280

Heavy Leg Symptoms

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 I-ILDI GROUPS legpro1_heavyleg(0 1)
  /MISSING=ANALYSIS
  /VARIABLES=ALLCIVOQ14 GlobalSF12_R PCSSF12 MCSSF12 CVQPainANDPHYSICAL CV
  /CRITERIA=CI(.95).
```

T-Test

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Group Statistics

	legpro1 heavyleg	N	Mean	Std. Deviation	Std. Error Mean
ALLCIVOQ14	no	48	86.3690	12.11451	1.74858
	yes	72	83.6111	12.89169	1.51930
GlobalSF12_R	no	48	94.1163	7.40660	1.06905
	yes	72	93.3553	6.85232	.80755
PCSSF12	no	48	90.8715	13.77359	1.98805
	yes	72	89.4537	13.08164	1.54169
MCSSF12	no	48	97.3611	5.81515	.83934
	yes	72	97.2569	4.83782	.57014
CVQPainANDPHYSICAL	no	48	81.8750	15.84919	2.28763
	yes	72	79.3056	15.29765	1.80284
CVQPain	no	48	84.0278	15.11122	2.18112
	yes	72	77.1296	16.39979	1.93273
CVQPsychological	no	48	93.1944	9.40193	1.35705
	yes	72	89.3519	12.59255	1.48405

The ROCat true positive impacts of leg symptoms with cut-off score, at least 90% sensitivity for the scales was analyzed. This sensitivity, as a true positive leg symptoms assumed a nonparametric distribution with 95% confidence interval, by coordinated points of the ROC included cut-off value for positive symptoms. With the Null Hypothesis testing, where at least obtaining AUCat least 0.5and for rejecting whenever AUC less than 0.5 and was significant different at p-value <0.05. The ROC summary raw scores were provided in Table 4. It wasindicated that participants with selected leg symptoms were sensitive to MOS CIVIQ-14 as with raw score less than 63.57 (p<0.001) but this casenot sensitive for MOS SF-12 which observed for both leg pain and burning sensation.

The ROCat true positive impacts of clinically diagnosis of CVD for the right leg with CEAP stage 1(N=35) and 2 (N=13) were analyzed with at least 75% sensitivity as well as their specificity for the scales. The sensitivity, as true positive diagnosis assumed a nonparametric distribution, with 95% confidence interval with coordinate points of the ROC included cut-off value for positive symptoms, with the Null Hypothesis testing where at least obtaining AUC at least 0.5for rejecting when the AUC less than 0.5, and was significant different at p-value <0.05. These raw scores and diagrams were summarized in Figure 3. It was indicating that participants with CEAP stage2 reflected 10 points raw score (<70) lower as compared with CEAP stage 1, raw score (<80).

Swelling Symptoms

→ **T-Test**

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Group Statistics

	legpro3 swelling	N	Mean	Std. Deviation	Std. Error Mean
ALLCIVOQ14	no	63	87.0295	10.62033	1.33804
	yes	57	82.1554	14.15018	1.87424
GlobalSF12_R	no	63	94.9048	5.49839	.69273
	yes	57	92.2836	8.29021	1.09807
PCSSF12	no	63	92.2169	10.31665	1.29978
	yes	57	87.5936	15.74688	2.08573
MCSSF12	no	63	97.5926	5.23445	.65948
	yes	57	96.9737	5.24601	.69485
CVQPainANDPHYSICAL	no	63	83.4524	13.35336	1.68237
	yes	57	76.8860	17.04302	2.25740
CVQPain	no	63	84.0212	14.49458	1.82614
	yes	57	75.3216	16.85441	2.23242
CVQPsychological	no	63	92.4339	10.11061	1.27382
	yes	57	89.1813	12.80626	1.69623

Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
			Lower	Upper
.034	4.87409	2.27063	.37762	9.37056
.037	4.87409	2.30285	.30713	9.44105
.042	2.62114	1.27309	.10007	5.14220
.046	2.62114	1.29832	.04391	5.19836
.057	4.62336	2.40857	-.14625	9.39298
.063	4.62336	2.45757	-.25554	9.50227
.519	.61891	.95788	-1.27795	2.51576
.520	.61891	.95798	-1.27837	2.51618
.020	6.56642	2.78159	1.05811	12.07472
.022	6.56642	2.81535	.98468	12.14815
.003	8.69953	2.86249	3.03101	14.36804
.003	8.69953	2.88418	2.98438	14.41468
.123	3.25258	2.09660	-.89926	7.40441
.128	3.25258	2.12128	-.95287	7.45803

Burning Symptoms

→ **T-Test**

[DataSet3] C:\Users\Satellite\Desktop\spss\ChiangRai_CIVIQSF12Datarevision28Jun

Group Statistics

	legpro4_burning	N	Mean	Std. Deviation	Std. Error Mean
ALLCIVOQ14	no	65	86.9231	10.96211	1.35968
	yes	55	82.1039	13.96696	1.88330
GlobalSF12_R	no	65	94.9474	5.93552	.73621
	yes	55	92.1379	7.98011	1.07604
PCSSF12	no	65	92.0615	10.70698	1.32804
	yes	55	87.6091	15.63295	2.10795
MCSSF12	no	65	97.8333	4.60648	.57136
	yes	55	96.6667	5.85753	.78983
CVQPainANDPHYSICAL	no	65	82.2308	13.49279	1.67357
	yes	55	78.0909	17.45340	2.35342
CVQPain	no	65	81.9487	14.46850	1.79460
	yes	55	77.4545	17.84667	2.40644
CVQPsychological	no	65	93.1795	9.49106	1.17722
	yes	55	88.1818	13.14400	1.77234

Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference Lower	95% Confidence Interval of the Difference Upper
.036	4.81918	2.27690	.31030	9.32806
.041	4.81918	2.32284	.21166	9.42670
.029	2.80956	1.27264	.28939	5.32972
.034	2.80956	1.30379	.22231	5.39681
.068	4.45245	2.41684	-.33355	9.23845
.077	4.45245	2.49141	-.49499	9.39989
.225	1.16667	.95570	-.72587	3.05921
.234	1.16667	.97483	-.76695	3.10028
.146	4.13986	2.82731	-1.45898	9.73870
.155	4.13986	2.88781	-1.58898	9.86870
.130	4.49417	2.95019	-1.34800	10.33635
.137	4.49417	3.00192	-1.45896	10.44730
.017	4.99767	2.07214	.89426	9.10108
.021	4.99767	2.12768	.77445	9.22089

→ **T-Test**

→ T-Test

[DataSet3] C:\Users\Satellite\Desktop\spss\ChiangRai_CIVIQSF12Datarevision28Jun

Group Statistics

	legpro5_nightcramp	N	Mean	Std. Deviation	Std. Error Mean
ALLCIVOQ14	no	39	88.1319	11.06641	1.77204
	yes	81	83.0688	13.03275	1.44808
GlobalSF12_R	no	39	95.1923	5.59446	.89583
	yes	81	92.9218	7.58594	.84288
PCSSF12	no	39	92.9060	10.56737	1.69213
	yes	81	88.6317	14.31789	1.59088
MCSSF12	no	39	97.4786	5.14230	.82343
	yes	81	97.2119	5.29701	.58856
CVQPainANDPHYSICAL	no	39	84.8718	14.52028	2.32510
	yes	81	78.1481	15.57631	1.73070
CVQPain	no	39	85.1282	15.55684	2.49109
	yes	81	77.3663	15.97495	1.77499
CVQPsychological	no	39	93.5043	8.88355	1.42251
	yes	81	89.6296	12.47219	1.38580

			Difference	
Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
.039	5.06309	2.42331	.26426	9.86191
.030	5.06309	2.28847	.51467	9.61150
.099	2.27050	1.36561	-.43379	4.97478
.068	2.27050	1.23002	-.17032	4.71131
.100	4.27430	2.57791	-.83066	9.37925
.069	4.27430	2.32254	-.33450	8.88309
.795	.26670	1.02278	-1.75869	2.29209
.793	.26670	1.01214	-1.74866	2.28206
.025	6.72365	2.97113	.84001	12.60728
.023	6.72365	2.89852	.95551	12.49179
.013	7.76195	3.08754	1.64778	13.87612
.013	7.76195	3.05878	1.67109	13.85281
.085	3.87464	2.22969	-.54075	8.29004
.054	3.87464	1.98594	-.06488	7.81417

Itching Sensation

→ **T-Test**

[DataSet3] C:\Users\Satellite\Desktop\spss\ChiangRai_CIVIQSF12Datarevision28June16

Group Statistics

	legpro6 itching	N	Mean	Std. Deviation	Std. Error Mean
ALLCIVOQ14	no	109	84.7969	12.75907	1.22210
	yes	11	83.8961	11.51912	3.47315
GlobalSF12_R	no	109	93.5581	7.20922	.69052
	yes	11	94.6667	5.50820	1.66079
PCSSF12	no	109	89.7844	13.70186	1.31240
	yes	11	92.3636	8.84333	2.66637
MCSSF12	no	109	97.3318	4.95969	.47505
	yes	11	96.9697	7.70347	2.32268
CVQPainANDPHYSICAL	no	109	80.5275	15.57566	1.49188
	yes	11	78.4091	15.38151	4.63770
CVQPain	no	109	79.6942	16.61437	1.59137
	yes	11	81.8182	11.58194	3.49209
CVQPsychological	no	109	90.8563	11.78864	1.12915
	yes	11	91.2121	9.10100	2.74406

Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
			Lower	Upper
.822	.90075	4.00470	-7.02965	8.83115
.811	.90075	3.68188	-7.07844	8.87995
.622	-1.10856	2.24012	-5.54461	3.32748
.548	-1.10856	1.79862	-4.97366	2.75653
.543	-2.57923	4.22619	-10.94824	5.78978
.399	-2.57923	2.97185	-8.90107	3.74260
.828	.36211	1.66030	-2.92574	3.64995
.881	.36211	2.37077	-4.86459	5.58880
.668	2.11843	4.92233	-7.62913	11.86599
.671	2.11843	4.87175	-8.48029	12.71715
.680	-2.12399	5.14035	-12.30329	8.05531
.588	-2.12399	3.83759	-10.32691	6.07892
.923	-.35585	3.66505	-7.61365	6.90195
.906	-.35585	2.96729	-6.73599	6.02429

Pins in the Leg

➜ **T-Test**

[DataSet3] C:\Users\Satellite\Desktop\spss\ChiangRai_CIVIQSF12Datarevision28Ju

Group Statistics

	legpro7_pins	N	Mean	Std. Deviation	Std. Error Mean
ALLCIVOQ14	no	82	87.5436	10.94726	1.20892
	yes	38	78.6090	13.88824	2.25297
GlobalSF12_R	no	82	94.8811	5.92187	.65396
	yes	38	91.0241	8.54543	1.38625
PCSSF12	no	82	92.0996	11.27569	1.24519
	yes	38	85.5351	16.19736	2.62756
MCSSF12	no	82	97.6626	4.71848	.52107
	yes	38	96.5132	6.18124	1.00273
CVQPainANDPHYSICAL	no	82	83.4146	14.09575	1.55662
	yes	38	73.6842	16.48850	2.67479
CVQPain	no	82	82.9268	14.48134	1.59920
	yes	38	73.3333	17.87511	2.89973
CVQPsychological	no	82	93.5366	9.70551	1.07179
	yes	38	85.1754	13.14501	2.13240

Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
			Lower	Upper
.000	8.93453	2.34462	4.29154	13.57752
.001	8.93453	2.55683	3.81857	14.05049
.005	3.85697	1.34494	1.19363	6.52032
.015	3.85697	1.53276	.78407	6.92988
.011	6.56451	2.55521	1.50450	11.62451
.028	6.56451	2.90767	.73555	12.39346
.264	1.14944	1.02466	-.87967	3.17856
.313	1.14944	1.13004	-1.11277	3.41166
.001	9.73042	2.92155	3.94497	15.51588
.003	9.73042	3.09476	3.54605	15.91480
.002	9.59350	3.06628	3.52142	15.66557
.005	9.59350	3.31147	2.97042	16.21657
.000	8.36115	2.13932	4.12472	12.59757
.001	8.36115	2.38660	3.58097	13.14132

At daytime

➜ T-Test

[DataSet3] C:\Users\Satellite\Desktop\spss\ChiangRai_CIVIQSF12Datarevision28Ju

Group Statistics

	legint1 daytime	N	Mean	Std. Deviation	Std. Error Mean
ALLCIVOQ14	no	73	87.4168	11.02373	1.29023
	yes	47	80.5167	13.83585	2.01817
GlobalSF12_R	no	73	94.8801	5.48592	.64208
	yes	47	91.7642	8.70318	1.26949
PCSSF12	no	73	92.8653	9.56507	1.11951
	yes	47	85.6028	16.82984	2.45488
MCSSF12	no	73	96.8950	5.52467	.64661
	yes	47	97.9255	4.71684	.68802
CVQPainANDPHYSICAL	no	73	83.4932	13.71675	1.60542
	yes	47	75.4255	16.94235	2.47130
CVQPain	no	73	83.0137	15.43769	1.80685
	yes	47	75.0355	16.29843	2.37737
CVQPsychological	no	73	93.1963	9.89822	1.15850
	yes	47	87.3050	13.01501	1.89843

Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
			Lower	Upper
.003	6.90011	2.28110	2.38290	11.41732
.005	6.90011	2.39535	2.13542	11.66480
.018	3.11595	1.29422	.55305	5.67886
.032	3.11595	1.42263	.27835	5.95355
.003	7.26246	2.41129	2.48744	12.03748
.009	7.26246	2.69810	1.87448	12.65044
.294	-1.03055	.97709	-2.96546	.90435
.277	-1.03055	.94418	-2.90192	.84081
.005	8.06762	2.81583	2.49150	13.64374
.008	8.06762	2.94698	2.20673	13.92851
.008	7.97824	2.95090	2.13465	13.82183
.009	7.97824	2.98606	2.04964	13.90683
.006	5.89138	2.09771	1.73734	10.04543
.010	5.89138	2.22400	1.46513	10.31763

Patients with DM and HT 3/117

Case Processing Summary

	Cases					
	Included		Excluded		Total	
	N	Percent	N	Percent	N	Percent
ALLCIVOQ14 * healthpro1_diabetes * healthpro2_highbloodpressure	120	96.8%	4	3.2%	124	100.0%
GlobalSF12_R * healthpro1_diabetes * healthpro2_highbloodpressure	120	96.8%	4	3.2%	124	100.0%
PCSSF12 * healthpro1_diabetes * healthpro2_highbloodpressure	120	96.8%	4	3.2%	124	100.0%
MCSSF12 * healthpro1_diabetes * healthpro2_highbloodpressure	120	96.8%	4	3.2%	124	100.0%
CVQPainANDPHYSICAL * healthpro1_diabetes * healthpro2_highbloodpressure	120	96.8%	4	3.2%	124	100.0%
CVQPain * healthpro1_diabetes * healthpro2_highbloodpressure	120	96.8%	4	3.2%	124	100.0%
CVQPsychological * healthpro1_diabetes * healthpro2_highbloodpressure	120	96.8%	4	3.2%	124	100.0%

DM － HT

Report

healthpro1_diabetes	healthpro2_highbloodpressure		ALLCIVOQ14	GlobalSF12_R	PCSSF12	MCSSF12	CVQPainAND PHYSICAL	CVQPain	CVQPsycholo gical
no	no	Mean	85.2857	94.1065	90.1019	98.1111	81.1944	80.6667	91.1852
		N	90	90	90	90	90	90	90
		Std. Deviation	12.71177	7.25812	14.12550	4.25249	15.53913	15.54824	11.45268
	yes	Mean	83.6025	91.6812	90.0652	93.2971	78.5870	75.9420	90.2899
		N	23	23	23	23	23	23	23
		Std. Deviation	11.96679	6.79835	11.50151	7.27125	14.63235	18.61238	12.14030
	Total	Mean	84.9431	93.6128	90.0944	97.1313	80.6637	79.7050	91.0029
		N	113	113	113	113	113	113	113
		Std. Deviation	12.52990	7.20434	13.58454	5.34283	15.33123	16.24195	11.54602
yes	no	Mean	88.5714	96.7083	93.4167	100.0000	87.5000	88.3333	90.0000
		N	4	4	4	4	4	4	4
		Std. Deviation	13.85051	3.25000	6.50000	.00000	13.69306	11.38550	14.14214
	yes	Mean	70.9524	91.3611	82.7222	100.0000	58.3333	75.5556	87.7778
		N	3	3	3	3	3	3	3
		Std. Deviation	7.86796	3.91785	7.83570	.00000	5.20416	21.43034	11.70628
	Total	Mean	81.0204	94.4167	88.8333	100.0000	75.0000	82.8571	89.0476
		N	7	7	7	7	7	7	7
		Std. Deviation	14.32647	4.30896	8.61792	.00000	18.59659	16.26500	12.12806

yes	no	Mean	88.5714	96.7083	93.4167	100.0000	87.5000	88.3333	90.0000
		N	4	4	4	4	4	4	4
		Std. Deviation	13.85051	3.25000	6.50000	.00000	13.69306	11.38550	14.14214
	yes	Mean	70.9524	91.3611	82.7222	100.0000	58.3333	75.5556	87.7778
		N	3	3	3	3	3	3	3
		Std. Deviation	7.86796	3.91785	7.83570	.00000	5.20416	21.43034	11.70628
	Total	Mean	81.0204	94.4167	88.8333	100.0000	75.0000	82.8571	89.0476
		N	7	7	7	7	7	7	7
		Std. Deviation	14.32647	4.30896	8.61792	.00000	18.59659	16.26500	12.12806
Total	no	Mean	85.4255	94.2172	90.2429	98.1915	81.4628	80.9929	91.1348
		N	94	94	94	94	94	94	94
		Std. Deviation	12.69929	7.14380	13.88392	4.17765	15.45201	15.42570	11.49051
	yes	Mean	82.1429	91.6442	89.2179	94.0705	76.2500	75.8974	90.0000
		N	26	26	26	26	26	26	26
		Std. Deviation	12.16385	6.47382	11.27148	7.16212	15.30114	18.48261	11.88837
	Total	Mean	84.7143	93.6597	90.0208	97.2986	80.3333	79.8889	90.8889
		N	120	120	120	120	120	120	120
		Std. Deviation	12.60810	7.05843	13.32355	5.22710	15.50594	16.19174	11.53676

ROC

PCS12 vs CVIQPAINANDPHYSICAL

```
ROC PCSSF12 CVQPainANDPHYSICAL BY legpro2_paininleg (0)
  /PLOT=CURVE(REFERENCE)
  /PRINT=SE COORDINATES
  /CRITERIA=CUTOFF(INCLUDE) TESTPOS(LARGE) DISTRIBUTION(FREE)
  /MISSING=EXCLUDE.
```

ROC Curve

[DataSet3] C:\Users\Satellite\Desktop\spss\ChiangRai_CIVIQSF1

Case Processing Summary

legpro2_paininleg	Valid N (listwise)
Positive[a]	27
Negative	93
Missing	4

Larger values of the test result variable(s) indicate stronger evidence for a positive actual state.

ROC Curve
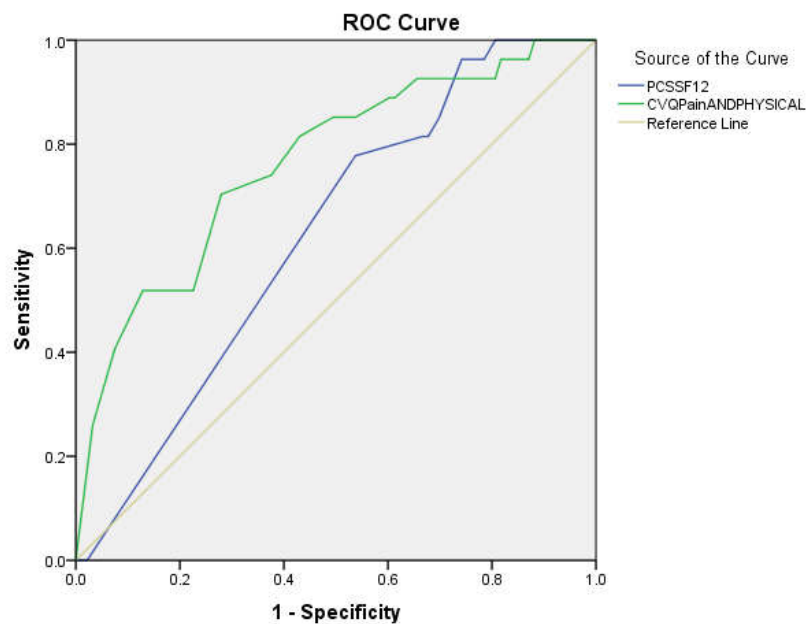
Diagonal segments are produced by ties.
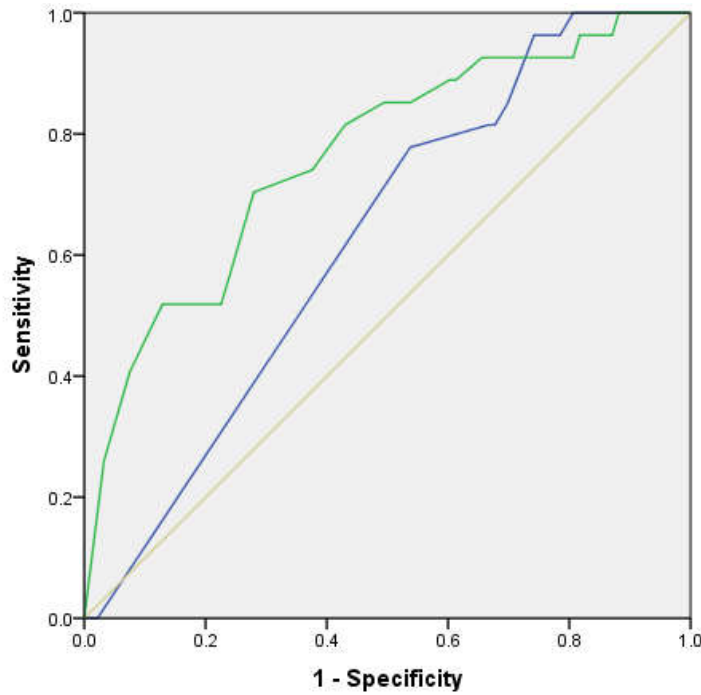
Area Under the Curve

Test Result Variable(s)	Area	Std. Error[a]	Asymptotic Sig.[b]	Asymptotic 95% Confidence Interval	
				Lower Bound	Upper Bound
PCSSF12	.625	.055	.048	.518	.733
CVQPainANDPHYSICAL	.763	.053	.000	.659	.868

The test result variable(s): PCSSF12, CVQPainANDPHYSICAL has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased.
a. Under the nonparametric assumption
b. Null hypothesis: true area = 0.5

The CEAP staging was sensitive for MOS CIVIQ 14 but not for MOS SF 12 (raw score between 89 and 90 for both CEAP stage 1 and 2). Since the 75% specificity for both scales were not very much different (<95 and <93), the physical and other clinical examinations of individual were demanding to secure clinical diagnosis of chronic venous disease.

DISCUSSION

In this exploration, women were majority of participants with 84% as compared with men 16%. Participants were relatively at young, mean age of 50.38 (±12.65 years) with 84% lower than 65 years old, ranged from 21 to 77 years old. Majority were under fulltime employment (55.8%). Though certain limitationsdue to explorationbetween patients clinically diagnosed and participants presenting only leg symptoms whom may inevitably exposure to risk of comorbidity exist, this wasmerely a practical investigation of disease problemsnot a diagnostic purpose. Disturbance leg symptoms was a major cause that bring patient to seek medical treatment. This study assessedpopulation at risk as a descriptive investigation by prospective, cross-sectional approach. The study was aiming for selection participants with leg symptoms. The cross-sectional analysis of the cohortprovidedperspective and should devoid of time management constraint.In addition, there was a true public health implication, since chronic venous disease patients needearly diagnosis and treatment. Some leg symptoms such as aching, edema, cramps, heavy leg, numbness, itching (http://www.wma.net/en/30publications/10policies/b3/index.html; Bradbury, 1999; Wrona *et al*., 2015; Auzky *et al*., 2011; Howlader and Coleridge, 2003) founded in many epidemiological surveys could be good rationale for enrollment of participants.

Likewise, probable systematic bias for patient-centered outcomesshould be minimized, suchthat medical interviewsand assessmentswere conducted by two individual researchersemploying different questionnaires. Thus, the assessments should provide a more unifyinterpretation among participants to avoid systematic bias. Nevertheless, the recall bias was unavoidable due to patients' intuitive plausibility perception since participants not yet confirmed diagnosis as CVD patients, instead they were medically documented interviewedthough not significantly relevance to their symptoms status. They did not present with illnessesyet, as such lack of validatedmedical records during recruitment may be encountered. However, this study was not intended for comparative effectiveness research especially the influence of intervention per se, such that patient-centered outcomes data collection may not as detailed, as should comply with stringent guidelines suggested by Reeve *et al*. (2013).

This exploration found thatphysical components score of MOS CIVIQ 14-Physicaland the physical component summary score-PCS reflected with Cronbach's alpha higher at 0.867 and 0.939 whereas psychological components MOS CIVIQ 14-Psychological and the mental component summary score-MCS at 0.787 and 0.661. These results were different from the West such as the Bonn vein study (Amsler *et al*., 2013), when psychic component was higher than physical componentrated as of 0.73 Vs 0.67, as urged by authors, whether this was probably due to the aging group. In this investigation, the physical score for both MOS CIVIQ-14 and MOS SF-12 were reliable (Cronbach's alpha of 0.949 and 0.897) significantly correlated with mean, 95% CI of Pearson correlation coefficient of 0.713 (0.633 to 0.790), p<0.001.

Test Result Variable(s)	Positive if Greater Than or Equal To[a]	Sensitivity	1 - Specificity
PCSSF12	34.5000	1.000	1.000
	37.1667	1.000	.989
	40.5000	1.000	.978
	42.5833	1.000	.968
	47.8333	1.000	.957
	54.3333	1.000	.946
	57.0833	1.000	.935
	59.1667	1.000	.925
	61.2500	1.000	.914
	65.4167	1.000	.903
	68.9167	1.000	.892
	70.0000	1.000	.882
	72.0000	1.000	.871
	73.6667	1.000	.860
	76.0833	1.000	.839
	79.9167	1.000	.828
	82.6667	1.000	.817
	84.3333	1.000	.806
	86.4167	.963	.785
	88.0833	.963	.753
	88.7500	.963	.742
	90.1667	.852	.699
	91.8333	.815	.677
	92.9167	.815	.667
	95.0000	.778	.538
	98.3333	.000	.022
	101.0000	.000	.000
CVQPainANDPHYSICAL	41.5000	1.000	1.000
	43.7500	1.000	.978
	47.5000	1.000	.968
	51.2500	1.000	.925
	53.7500	1.000	.882
	56.2500	.963	.871
	58.7500	.963	.849
	61.2500	.963	.817
	63.7500	.926	.806
	66.2500	.926	.785
	68.7500	.926	.699
	71.2500	.926	.656
	73.7500	.889	.613
	76.2500	.889	.602
	78.7500	.852	.538
	81.2500	.852	.495
	83.7500	.815	.430
	86.2500	.741	.376
	88.7500	.704	.280
	91.2500	.519	.226
	93.7500	.519	.129
	96.2500	.407	.075
	98.7500	.259	.032
	101.0000	.000	.000

The test result variable(s): PCSSF12, CVQPainANDPHYSICAL has at least one tie between the positive actual state group and the negative actual state group.

a. The smallest cutoff value is the minimum observed test value minus 1, and the largest cutoff value is the maximum observed test value plus 1. All the other cutoff values are the averages of two consecutive ordered observed test values.

Moreover, global score of the samereflected a Cronbach's alpha of 0.798 and 0.914, with Pearson correlation coefficient of 0.745 (0.640 to 0.819), p<0.001. We observed that only physical score of MOS CIVIQ-14 demonstrated similar patterns as its global score (Table 2). The finding of CIVIQ-14 and CIVIQ-20 reliability werealso in line with the Lozano *et al.* (2012), with a high correlation coefficient of 0.81 among diagnosed CVD patients. The score also strongly correlated with Venous Clinical Severity Score, VCSS (Lozano *et al.*, 2012). Moreover, an epidemiology survey with symptoms-based using CIVIQ-14 as comparison againsta GP-screened of CVD patients were reliable in the West as reported by

Vuylsteke *et al.* (2015) and Van der Velden *et al.* (2014). We founded that the impacts of four leg symptoms including leg pain, heavy leg, swelling and burning sensation were significantly correlated with the both physical component scoreby CM of 0.722,0.683,0.715, 0.747 all with p<0.001 and the global score by CM of 0.762,0.723,0.765,0.787 all with p<0.001for both MOS CIVIQ-14 and MOS SF-12. However, these were not observed for mental component of psychological score -0.037, p=0.362; -0.050, p=0.340; -0.024, p=0.431 and -0.144, p=0.147 (Table 3). These observations were similar in an assessment attempted by Biemans AAM *et al* which confirmed high correlation of CIVIQ 14 and SF 12 for global score and physical component summary score whereas moderately correlate for psychological or mental component summary (Biemans *et al.*, 2011). It was founded that though both generic and disease specific health-related quality of life as patient-reported outcomes may be used interchangeably, in clinical setting the disease -specific health-related quality of life was more suitable as it detects changes of disease symptoms status especially useful for follow-up treatment, as reported earlier (Susan *et al.*, 2004; Fortin *et al.*, 2006; Teresa and Phyllis, 2008). Respecting the ROC prediction of MOS CIVIQ-14 and MOS SF-12 raw score, there were no sufficient evidence to reject the Null Hypothesis with mean (SD) and 95% CI, AUC was 0.513(0.054), 0.407 to 0.619, p=0.812 for MOS CIVIQ-14 and was 0.513(0.055), 0.405 to 0.621, p=0.805 for MOS SF-12. As such we assume that any Thai patient with MOS CIVIQ-14 score less than 75.7 would be 75% sensitivity and less than 95.0 with more than 75% specificity to have been diagnosed with chronic venous disease, CEAP staging 1 and 2 regardless of leg symptoms.

Conclusion

The disease specific health-related quality of life a 14-Item Short-Form Health Survey for chronic venous insufficiency, MOS CIVIQ-14 Thai version were reliable with inter-scale correlation and internal consistency reliability, Cronbach's alpha coefficients of 0.914 (for 14-item for global score), 0.867 (for7-item score for physical and pain score) and 0.787 (for7-item score for psychological score). The generic version MOS SF-12 were reliable with the same of 0.810 (for12-item for global score), 0.939 (PCS item GH, 2RP, 2PF, BP,VT for 7-item score for physical and pain score) and 0.661 (MCS item 2RE,2MH,SFfor5-item score for mental score). The two types of questionnaires score werecorrelated offor physical score, MOS CIVIQ-14 and MOS SF-12 with bivariate Pearson correlation coefficient, 95% CI of 0.713(0.663 to 0.790), p<0.001 and for global score, 0.745 (0.640 to 0.819), p<0.001). However, no significant correlation of psychological score of -0.062 (-0.197 to 0.091), p=0.501. We found that all four major leg symptoms significantly have impacts on the raw score of both physical components and global score but not for mental component of both scales. Patients with MOS CIVIQ-14 score lower than 75.7 would be more likely to have been diagnosed with chronic venous disease, a CEAP staging 1 and 2 regardless of leg symptoms in this exploration.

Abbreviations

CEAP is a staging for classification of chronic venous disease (CVD) based on the Clinical manifestations (C), Ethiologic factors (E), Anatomic distribution of disease (A), and underlying Pathophysiologic findings (P), or CEAP. The severity scoring system was based on 3 elements: number of anatomic segments affected, grading of symptoms and signs,

and disability. CIVIQ-14 is the Chronic Venous Insufficiency Questionnaire (CIVIQ) firstly developed by iterative process by Launois *et al*. An important features of quality of life affected by venous insufficiency, other than physical symptoms of discomfort were screened involving a large pool of subjects which later test-retest and validated internationally among patients diagnosed with chronic venous disease. The original CIVIQ-20 contained 20 items was later adapted to a shorter version of 14 items and adjusted to CIVIQ-14 which highly correlated in application as widely used for quality of life research for chronic venous disease. SF-12 is the 12-Item Short Form Health Survey **(**SF-12**)** was developed for the Medical Outcomes Study (MOS) with a multi-year study of patients with chronic conditions. This short-form survey helps limiting restrict survey length while the scales was widely internationally used to assess health-related quality of life with good respondent and reliability.

Authors' contribution: This is an original research investigation in healthy volunteers. This clinical investigation was conformed with the investigation in human which followed the guidelines of the Declaration of Helsinki and Tokyo for humans which institutionally approved and informed consent obtained. All below authors are equally participated and contributed in this clinical investigation.

Competing interest

All authors declared no any commercial associations that might create a conflict of interest in connection with this submitted manuscript.

Ethics approval and consent to participate

All participants had signed an informed consent form prior to the start of this screening study. The present study was conducted in accordance with the Declaration of Helsinki (20). The research has been supported by the National Research University, Office of the Higher Education Commission (WCU-58-035-AS) for Chulalongkorn University Research Fund under the research cluster in the Ageing and attended approval from the College of Public Health, Chulalongkorn University and ethical approval for patients access at Wiang Chai, SPDY Chiang Rai Hospital with registration via ISRCTN 54360155.

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