

# **International Union of Phlebology**

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### **A Systematic Review Of Health-Related Quality Of Life Scales In Chronic Venous Disease Of The Lower Limb.**

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# Burden of disease

- **Chronic Venous Disease (CVD):** any long duration abnormalities in morphology and function of the venous system
- **Chronic Venous Insufficiency (CVI):** the more severe form of CVD
- **Severity Stratification:** according to the Clinical-Etiology-Anatomy-Pathophysiology (CEAP) scale
- **Risk factors:** family history, smoking, inactivity, increasing age, genetic predisposition, being female, current and previous pregnancy for younger women, obesity
- **Prevalence:** Up to 65% of women and 50% of men age  $\geq 50$  yrs in developed countries
- **Argument:** should receive more attention than it currently does

# Quality of Life: A Buzz Word?

- **HRQoL:** “Individuals perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards & concerns” (WHO).
- Broad, multi-dimensional and subjective
- Usually assessed by HRQoL is a subset of Patient Reported Outcomes (PROs)
- 2 types of scales: Generic and Disease-specific
- Many scales available in CVD, which should we recommend?
- No comprehensive systematic review to summarize the statistical validation of the available disease-specific scales

# Objectives

- To identify the respective advantages and lacunae of the scales that have been used
- To document how they were validated both psychometrically and linguistically
- To document the contexts in which these scales have been used
- To confirm the factor structure of the most used and most validated among the documented scales using confirmatory factor analysis
- To confirm the evidence of the effect of Chronic Venous Disease on Quality of Life

# METHODS

# Systematic Review

## Systematic Review

1. Determine question
2. Determine eligibility criteria
3. Population, intervention, comparator, outcome
4. Literature search
  - At least two databases needed
5. Selection of Studies
  - 2 Independent reviewers
6. Critical appraisal
  - Quality assessment

## Data Extraction

7. Summary of Findings (SOF) + Plain Language Summary (PLS)

## IF APPROPRIATE – Meta-analysis

*(judged inappropriate in this case due to large heterogeneity – 11 different scales)*

# Literature Search Strategy

- **Guidelines:** Cochrane handbook (2011, v 5.1.0), QUORUM (1999) and PRISMA (2009), PICOS criteria
- **Database:** EMBASE, CINHAL, Cochrane, VEIN CONSULT
- **Software:** EndNote® Version X3
- **Inclusion Criteria:** Systematic reviews, RCTs, prospective comparative studies, psychometric/linguistic validation studies in English and French
- **Exclusion Criteria:** Non-original articles, narrative reviews, editorials, abstract-only
- **Screening Procedure:** Titles → Abstracts → Full article

# Summary of Findings

Original Article	Author	Country	Year		
	Lamping, D.L., et al.	France, Belgium, Italy, Canada	2003		
Title	Evaluation of outcomes in chronic venous disorders of the leg: Development of a scientifically rigorous, patient-reported measure of symptoms and quality of life				
Journal	Journal of Vascular Surgery. 37(2): p. 410-419				
Objective of the study	To develop a practical and scientifically rigorous patient-reported outcome measure to evaluate QoL and symptoms in chronic venous disorders of the leg				
QoL Instrument and version	VEINES-QOL/Sym				
Language of translation	French, Italian, French Canadian				
Method of validation	Standard Psychometric validation				
CEAP range covered	C0-C6				
Target Population	Patients with chronic venous disorders of the leg				
(Total number)	615				
Mean[SD] age of the subjects	54 (20-75)*				
Number of items modified	Added	Removed	Updated		
	N.A.	N.A.	N.A.		
Method of administering	Auto questionnaire				
Listed use	To evaluate QoL and symptoms in chronic venous disorders of the leg				
Inclusion Criteria	18-75 years of age, written informed consent				
Exclusion criteria	Not having given written infromed consent, age <18 or >75 years				
Follow up Period	12 months				
Conditions for validation Checked	Relevance	Acceptability	Reliability	Sensitivity	Construct validity
	Yes	Yes	Yes	Yes	Yes
Length of questionnaire	26 items				
Time required to fill questionnaire	≈ 10 minutes				
Acceptability	Good acceptability for all four language versions, low proportions of missing data (<5%)				
Results from the study	The VEINES-QOL/Sym was reported to be a practical and scientifically sound instrument to measure outcomes in chronic venous disorders of the leg				



# Psychometric Validation

## **Reliability (*Precision*):**

- Do answers to the same questions remain unchanged over time in clinically stable patients?
- Measured by the Cronbach's alpha, Values  $\geq 0.70$  acceptable

## **Construct Validity (*Accuracy*):**

- Within-scale analysis: Are individual items more highly correlated with their own dimension compared to others?
- Known group mean differences: Are QoL scores significantly different across groups known to be different (i.e. different disease severity) at a given point of time?
- Convergent validity: Do QoL correlations with clinical criteria and/or other validated quality of life scales fit expected results?

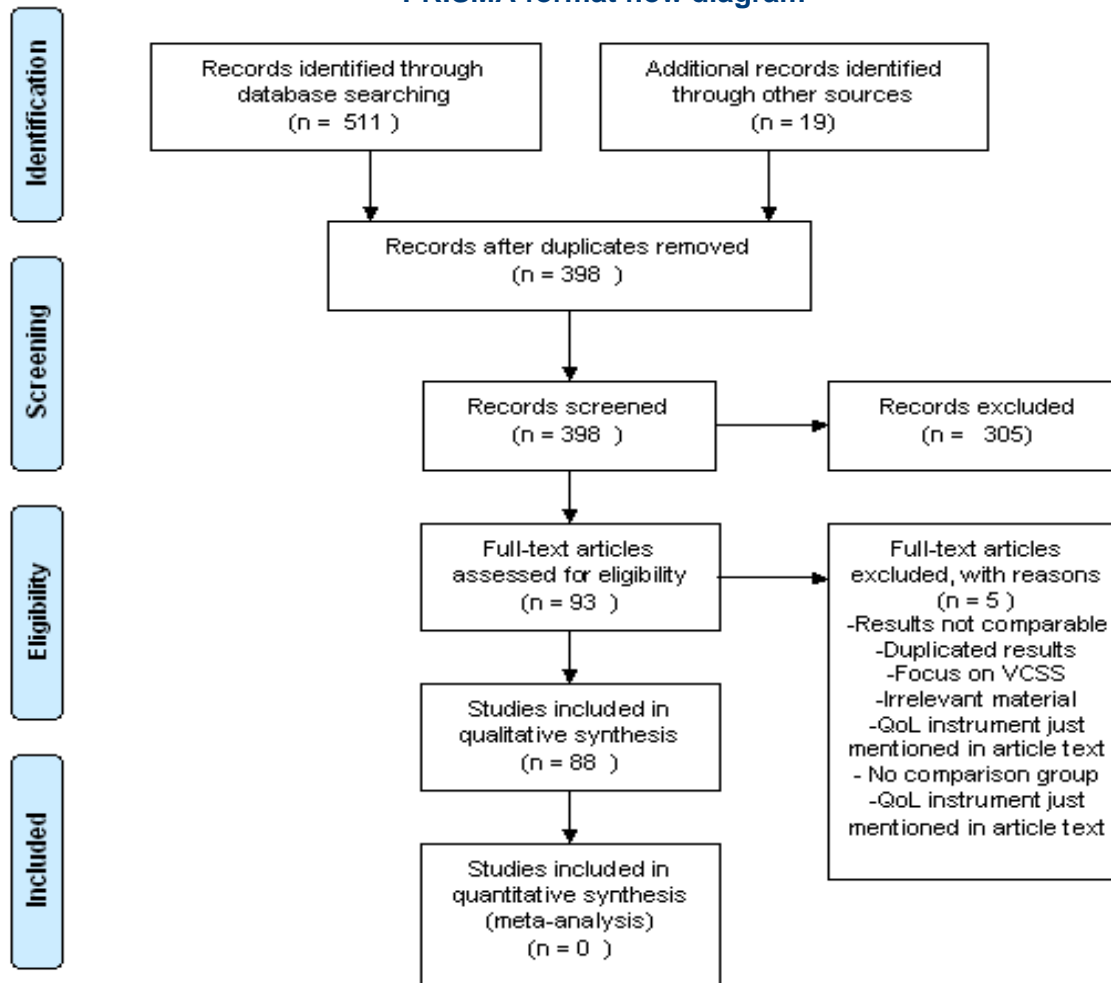
## **Responsiveness (*Sensitivity*):**

- Do QoL scores change over time, beyond the noise caused by measurement error, in clinically non-stable patients?
- Measured by the effect size, Values  $\geq 0.70$  are acceptable

# RESULTS

# Identification & Screening

PRISMA-format flow diagram



Moher D;, Liberati, A., Tetzlaff J., et al and the PRISMA Group :Preferred Reporting Items for Systematic Reviews and Meta-Analyses:The PRISMA Statement Ann Intern Med. 2009;151(4) : 264-269

Robert Launois

# Scale Characteristics

	For all CVD patients			For CVD patients without ulcers				For CVD patients with ulcers			
Author	Guex	Garatt	Lamping	Launois	Augustin	Guex	Klyszcz	Smith	Hyland	Palfreyman	Hareendran
Year	2010	1993	2003	1996	1997	2007	1998	2000	1994	2008	2007
Country	France	U.K.	-Various-	France	Germany	France	Germany	U.K.	U.K.	U.K.	U.K.
Scale	ABC-V	AVVQ	VEINES-QOL/Sym	CIVIQ	FLQA	SQOR-V	TLQ-CVI	CCVUQ	LFUQ	SPVU-5D	VLU-QOL
Indication	All	All	All	No ulcer	No ulcer	No ulcer	No ulcer	Ulcer	Ulcer	Ulcer	Ulcer
Domains	6	2	3	4	6	5	4	4	3	5	3
Items	36	13	35	20	83	46	-	32	34	16	34
Time (min)	-	-	10-15	<5	20	-	-	≈ 10	-	-	-
Best Score	0	0	max	0	min	0	min	0	12	0	0
Worst Score	90	100	Min	100	max	100	max	100	max	80	100
Field of Use	VS	VS, A, SS	GM, A, VS, SS	VS, A, B, P, I, GM, Gy	VS	VS	VS	A, N, W	A, W	N, W	N, W

ABC-V – Assessment of Burden in Chronic disease-Venous, AVVQ – Aberdeen Varicose Vein Questionnaire, VEINES-QOL/SYM – VEINES Quality of Life/ Symptoms questionnaire, CIVIQ – ChronIc Venous Insufficiency Questionnaire, FLQA – Frieberg Life Quality Assessment, SQOR-V – Specific Quality of life and Outcomes Response-Venous, Tübingen – Tübingen questionnaire, CCVUQ – Charing Cross Venous Ulceration Questionnaire, LFUQ – Leg and Foot UlcerQuestionnaire, SPVU-5D – Sheffield Preference-based Venous leg Ucer-5D, VLU-QOL – Venous Leg Ulcer Quality Of Life.

VS – Vascular surgery, A – Angiology, GM – General medicine, SS – Sports science, B – Balneotherapy, P – Phlebology, I – Insurance, Gy – Gynaecology, N – Nursing and W – Wound management.

# Study Types

	For all CVD patients			For CVD patients without ulcers				For CVD patients with ulcers				Total
Author	Guex	Garatt	Lamping	Launois	Augustin	Guex	Klyscz	Smith	Hyland	Palfreyman	Hareendran	
Year	2010	1993	2003	1996	1997	2007	1998	2000	2003	2008	2007	
Country	France	U.K.	-Various-	France	Germany	France	Germany	U.K.	U.K.	U.K.	U.K.	
Scale	ABC-V	AVVQ	VEINES-QOL/Sym	CIVIQ	FLQA	SQOR-V	TLQ-CVI	CCVUQ	LFUQ	SPVU-5D	VLU-QOL	
Versions	1	1	1	3	1	1	1	1	1	1	1	
Psychometric validation	1	2	6	10	2	2		2	1	1	1	28
Linguistic validation	2	2	5	14	1	2	1	3	1	1	1	
Non-validated translations	0			11		0	0	1	0	0	0	
Application studies		16	9	27		1	1					54
Systematic review												6
Number of article included												88
Correlations with	CES-D, SF-12, SF-SQOR-V (1)	SF-12, SF-36, EQ5D (2)	SF-36 (3)	SF-36, SF-12 (4)	NHP (5)	SF-12, CES-D (6)		SF-36 (7)		EQ-5D (8)		

ABC-V – Assessment of Burden in Chronic disease-Venous, AVVQ – Aberdeen Varicose Vein Questionnaire, VEINES-QOL/SYM – VEINES Quality of Life/ Symptoms questionnaire, CIVIQ – ChronIc Venous Insufficiency Questionnaire, FLQA – Frieburg Life Quality Assessment, SQOR-V – Specific Quality of life and Outcomes Response-Venous, Tübingen – Tübingen questionnaire, CCVUQ – Charing Cross Venous Ulveration Questionnaire, LFUQ – Leg and Foot UlcerQuestionnaire, SPVU-5D – Sheffield Preference-based Venous leg Ucer-5D, VLU-QOL – Venous Leg Ulcer Quality Of Life

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# Validation Studies

	For all CVD patients			For CVD patients without ulcers				For CVD patients with ulcers			
Author	Guex	Garatt	Lamping	Launois	Augustin	Guex	Klyscz	Smith	Hyland	Palfreyman	Hareendran
Year	2010	1993	2003	1996	1997	2007	1998	2000	2003	2008	2007
Country	Fr	U.K.	-Various-	Fr	Ger	Fr	Ger	U.K.	U.K.	U.K.	U.K.
Scale	ABC-V	AVVQ	VEINES-QOL/Sym	CIVIQ	FLQA	SQOR-V	TLQ-CVI	CCVUQ	LFUQ	SPVU-5D	VLU-QOL
<b>Content validity</b>											
Relevance			✓	✓	✓	✓		✓	✓		✓
<b>Reliability</b>											
Coherent Test Re-test		✓	✓	✓	✓	✓		✓	✓	✓	✓
<b>Construct validity</b>											
Factorial validity				✓				✓	✓		✓
Within-scale analysis				✓							
Known-groups validity			✓	✓	✓	✓		✓			✓
Convergent validity	✓	✓	✓	✓	✓	✓		✓	✓		✓
<b>Responsiveness</b>											
Effect size		✓	✓	✓	✓	✓		✓	✓		✓
<b>Acceptability</b>		✓	✓	✓	✓	✓		✓		✓	✓

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# Application Studies

Study Design	Number of Studies
<b>Randomized Control Trial (RCT)</b>	
<i>AVVQ</i>	9
<i>CIVIQ</i>	12
<i>VEINES-QOL/Sym</i>	2
<i>Total RCT</i>	23
<b>Observational Studies (OS)</b>	
<i>AVVQ</i>	7
<i>CIVIQ</i>	15
<i>SQOR-V</i>	1
<i>VEINES-QOL/Sym</i>	7
<i>TLQ-CVI</i>	1
<i>Total OS</i>	31
<b>Total Application Studies</b>	54

# DISCUSSION



# Limitations

- ✦ Focus on disease-specific scales, Foreign Language articles (n=22) and Grey literature
- ✦ Non-uniform validation procedure results (No meta-analysis), and lack of consensus on definitions
- ✦ Small time frame compared to standard time for systematic reviews
- ✦ Use of CEAP as assessment tool in some studies
- ✦ Threshold of RMSEA (  $< 0.06$  vs  $< 0.08$  )

# Conclusion

- 11 disease-specific scales
- CIVIQ, AVVQ and VEINES-QOL/SYM most used and validated
- Choice depends on the purpose of the study
- Effect of CVD on HRQoL was confirmed
- Factorial structure of the CIVIQ-14 confirmed

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