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## Quality of Life: A Buzz Word?

- QoL: "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).
- HRQoL (Health related quality of life) confines the domain to the repercussions of disease and its treatment
- HRQoL is a broad, multidimensional and subjective construct that synthesizes a number of dimensions commonly described as patient-reported outcomes (PROs)
- 2 types of scales: generic and disease-specific scales
- Many scales available in Chronic Veinous Disease (CVD). Which one should we recommend?
- Until now, no comprehensive systematic review has compared the psychometric properties of the available CVD-specific scales



## Objectives

- To study how the specific CVD-specific Qol scales were both psychometrically and linguistically validated
- To document the indications in which these scales have been used and the design of the corresponding studies that were implemented
- To identify the respective advantages and gaps in the scales used for CVD





# METHODS



### Electronic Searches

### Systematic reviewReview

The review question is structured around the 5 components of the of PICOS acronym Patient ,Intervention, Comparator,outcome, study design

- 1. Literature search
  - > At least two databases required
- 2. Eligibility and exclusion criteria
  - > to minimize bias
- 3. Studies selection
  - 2 Independent reviewers
- 4. Critical appraisal following the full text selection stage
  - > Quality assessment; poor quality studies were excluded

#### **Data Extraction**

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

**Meta-analysis** (deemed inappropriate in this case due to large heterogeneity – 11 different scales)



## Summary of Findings

Original Article	Author	Country							
	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.2003 37(2): 410-419								
Objective of the study	To develop a practical and scientifically rig	orous patient-reported outcome measure to	evaluate QoL and symptoms						
Objective of the study	in chronic venous disorders of the leg								
Qol instrument and version	VEINES-QOL/Sym								
Language versions	French, Italian, French Canadian								
CEAP range covered	C0-C6								
Target population	Patients with 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								
Method of administering	Auto questionnaire								
Length of questionnaire	36 items								
Time required to fill questionnaire	≈ 10 minutes								
Conditions for validation Checked	Reliability	Construct validity	Responsiveness						
Conditions for validation checked	Yes	'es	Yes						
Number of items modified	Added	Removed	Updated						
Number of items modified	N.A. N.A. N.A.								
Number of patients	615								
Mean[SD] age of the subjects	54 (CI 95% : 20-75)*								
Acceptability	Good acceptability for all four language versions, low proportion of missing data (<5%)								
Posults from the study	The VEINES-QOL/sym was reported to be a	a practical and scientifically sound instrumen	t to measure outcomes in						
Results from the study	chronic venous disorders of the leg								



## Psychometric Properties

### Reliability (Precision):

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

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

- Dimensions stability: Are the factors cover the same set of questions across various populations?
- Within-scale analysis: Are individual items more highly correlated with their own dimension compared to others dimensions?
- Mean known group differences: Are QOL scores significantly different across groups known to be different (ie. 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 unstable patients?
- Measured by the effect size, values ≥0.70 are acceptable





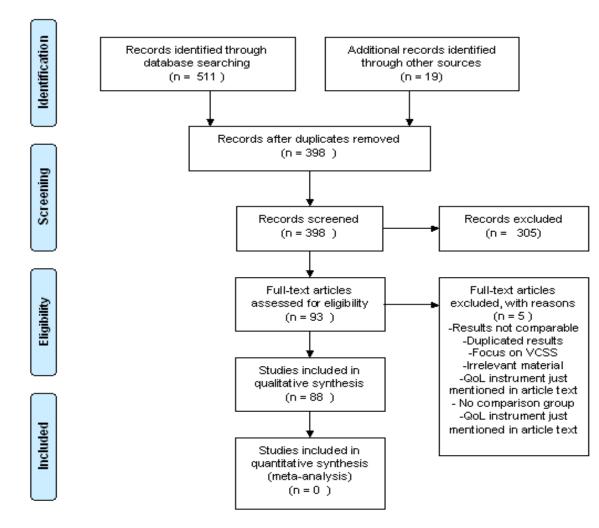
# RESULTS



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## Identification & Screening

PRISMA-format flow diagram





### **Descriptive Characteristics**

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

AVVQ – Aberdeen Varicose Vein Questionnaire, ABC-V – Assessment of Burden in Chronic disease-Venous, VEINES-QOL/SYM – VEINES Quality Of Life/ symptoms questionnaire, FLQA – Frieburg Life Quality Assessment, SQOR-V – Specific Quality of life and Outcomes Response-Venous, TLQ-CVI – Tübingen questionnaire for measuring quality of lifr IN CVI, CIVIQ – ChronIc Venous Insufficiency Questionnaire, VLU-QOL – Venous Leg Ulcer Quality Of Life. LFUQ – Leg and Foot Ulcer Questionnaire, SPVU-5D – Sheffield Preference-based Venous leg Ucer-5D, CCVUQ – Charing Cross Venous Ulceration Questionnaire, VS – Vascular surgery, A – Angiology, GM – General medicine, SS – Sports science, B – Balneotherapy, P – Phlebology, I – Insurance, Gy – Gynecology, N – Nursing and Wound management.



## Validation and Application Studies

	For	For all CVD patients For CVD patien					cers	Fo	For CVD patients with ulcers			
Author	Garatt	Guex	Lamping	Augustin	Guex	Klyscz	Launois	Hareendran	Hyland	Palfreyman	Smith	
Year	1993	2010	2003	1997	2007	1998	1996	2007	2003	2008	2000	
Country	U.K.	France	Various	Germany	France	Germany	France	U.K.	U.K.	U.K.	U.K.	
Scale acronym	AVVQ	ABC-V	VEINES-QOL	FLQA	SQOR-V	TLQ-CVI	CIVIQ	VLU-QOL	LFUQ	SPVU-5D	ccvuq	
Versions	1	1	1	1	1	1	3	1	1	1	1	
Psychometric validation	2	1	6	2	2		10	1	2	1	2	29
Linguistic validation	2	2	5	1	2	1	14	1	1	1	3	
Non-validated translations		0			0	0	11	0	0	0	1	
Implementation studies	16		9		1	1	27					54
Systematic review												5
Number of article included												88
Correlations with	SF-12, SF-36, EQ5D (2)	CES-D, SQOR-V (1)	SF-36 (3)	NHP (5)	SF-12, CES- D (6)		SF-36, SF- 12 (4)			EQ-5D (8)	SF-36 (7)	

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, TLQ-CVI – Tübingen questionnaire for measuring quality of life in CVI, CCVUQ – Charing Cross Venous Ulveration Questionnaire, LFUQ – Leg and Foot Ulcer Questionnaire, SPVU-5D – Sheffield Preference-based Venous leg Ucer-5D, VLU-QOL – Venous Leg Ulcer Quality Of Life

(1) Guex, J.J., et al. The patient's burden of Chronic Venous disorders: Construction of a questionnaire. Phlebology . 2010: 25:280–285; (2) Samuel, N., et al. Endovenous laser ablation in the treatment of small saphenous varicose veins: Does site of access influence early outcomes? Vascular and Endovascular Surgery 2012. 46(4): p. 310-314; Shepherd, A.C., et al. Randomized clinical trial of VNUS (registered trademark) ClosureFAST (trademark) radiofrequency ablation versus laser for varicose veins British Journal of Surgery 2010. 97(6): p. 810-818 (3) Lamping, D.L., et al. 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 of Vascular Surgery. 2003. 37(2): p. 410-419. (4) Biemans, A.A.M., et al. Validation of the chronic venous insufficiency quality of life questionnaire in Dutch patients treated for varicose veins European Journal of Vascular Surgery. 2011. 42(2): p. 246-253; Lorenz, D., et al. Randomized clinical trial comparing bipolar coagulating and standard great saphenous stripping for symptomatic varicose veins. British Journal of Surgery. 2007. 94(4): p. 434-440; Guex, J.J., et al. Chronic venous disease: Health status of a population and care impact on this health status through quality of life questionnaires. International Angiology. 2005. 24(3): p. 258-264; Andreozzi, G.M., et al. Effects of elastic stocking on quality of life of patients with chronic venous insufficiency. An Italian pilot study on Triveneto Region. International Angiology. 2005. 24(4): 325-329. (5) Darvall, K.A.L., et al. Changes in health-related quality of life after ultrasound-guided foam sclerotherapy for great and small saphenous varicose veins Journal of Vascular Surgery 2010. 51(4): p. 913-920. (6) Guex J.J., et al. Construction and validation of a patient-reported outcome dedicated to chronic venous disorders: SQOR-V (specific quality of life and outcome response-venous). Journal des Maladies Vasculaires.



## Psychometric properties

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

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



# **Application Studies**

Study Design	Number of Studies
Randomized Control Trials (RCT)	
AVVQ	9
CIVIQ	12
VEINES-QOL/sym	2
Total RCTs	23
Observational Studies (OS)	
AVVQ	7
CIVIQ	15
SQOR-V	1
VEINES-QOL/sym	7
TLQ-CVI	1
Total OS	31
Total Application Studies	54





# DISCUSSION



## Limitations

Our findings must be interpreted in light of the following limitations.

- First, a number of records could not be reviewed given that many of those were written foreign language articles and others could presumably be part of the grey literature
- Second, due to the nonuniform nature of the validation results and the general lack of consensus on definitions, it is not possible to conduct a meta-analysis
- Third, we used a smaller time frame compared with the standard time frame used in systematic reviews.



# Conclusion

- Our study revealed 11 CVD-specific scales that are currently used as a means to assess and measure health-related quality of life among CVD patients
- The CIVIQ, AVVQ and VEINES-QOL/SYM scales were the most frquently used and validated in the literature. The choice of scale depends on the general objective of the study
- Furthermore, we confirmed both the effect of CVD on health-related quality of life, and the the factorial structure of the CIVIQ-14 questionnaire



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