

Health-related quality-of-life scales specific for chronic venous disorders of the lower limbs

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Objective: We conducted a systematic review of the literature about quality-of-life (QOL) scales in chronic venous disorders (CVDs) comprising leg ulcers to identify the respective advantages and deficits of existing tools.

Methods: A research protocol was built following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement and the PICO (population, intervention, comparator, and outcome) criteria. The following databases were screened: MEDLINE, SCOPUS, EMBASE, CINAHL, and Cochrane. Psychometric and linguistic validation studies in English were included, as were clinical trials that have used QOL scales in CVDs. The data search was up to date as of October 31, 2013.

Results: Inclusion criteria were met in 103 of the 511 recorded references, in which 10 scales were identified: two for the full spectrum of CVDs, three for patients with CVDs without leg ulceration, four for leg ulcers, and one exclusively for patients with varicose veins. Among them, the ChronIc Venous Insufficiency Questionnaire (CIVIQ), Aberdeen Varicose Vein Questionnaire (AVVQ), and VEnous INSufficiency

Epidemiological and Economic Study on Quality of Life (VEINES-QOL) scales were the most highly used according to the literature, and CIVIQ and VEINES-QOL were the most extensively validated scales and had the longest iterative validation process. A total of 31 psychometric and linguistic validations of the 10 QOL scales and 66 clinical trials that have used these scales were identified. The validation studies were based on acceptability, content validity, construct validity, reliability, and responsiveness. The clinical trials were composed of 25 randomized controlled trials and 41 observational studies. Only the randomized controlled trials are considered in the present article.

Conclusions: This systematic review confirmed that CVDs have an important effect on QOL. The majority of the studies addressed the application rather than the validation of the 10 identified scales. Two scales, CIVIQ and VEINES-QOL, emerged as being thoroughly validated instruments, although factorial stability was not demonstrated for the VEINES-QOL. Our findings confirm a paucity of validation studies. (*J Vasc Surg: Venous and Lym Dis* 2015;3:219-27.)

Quality of life (QOL) is a broad, multidimensional, and subjective construct that covers a number of dimensions commonly described as patient-reported outcomes. In the particular cases of chronic venous disorders (CVDs) and chronic venous insufficiency (CVI), there are a plethora of specific scales that can be used to assess the QOL of patients. QOL assessment in this field has become an important end point to distinguish, for example, the most beneficial endovenous treatment for varicose veins (such treatments are expected to be equivalent in terms of efficacy) or to take into account the disappearance of pain after treatment (pain that worsens the QOL). In this article, we define CVD as a disease that encompasses the full spectrum of morphologic and functional abnormalities of the venous system. CVD includes the C0s to C6 clinical classes of the clinical, etiologic, anatomic, and pathophysiologic (CEAP) classification.¹ CVI is defined as functional

abnormalities of the venous system that produce edema, skin changes, or venous ulcers (ie, reserved for advanced CVD stages, from CEAP classes C3 to C6). These terms have had variable interpretations in reports in the venous literature and have often been inappropriately used in most acronyms of the disease-specific QOL tools.

There have been some reviews of instruments for assessing the impact of CVDs and venous leg ulcers on the QOL, yet there are still no comprehensive systematic reviews that overlap tools devoted to the whole spectrum of CVDs. This could help investigators choose the appropriate scale according to their needs. Therefore, we found it necessary to summarize the findings regarding validation of the scales and to suggest recommendations for their use.

This review had the following aims: to study how specific QOL scales for CVD and CVI were validated both psychometrically and linguistically; to document the indications for which these scales were used; to understand the design of the studies in which the scales were used; and to identify the advantages and knowledge gaps in the scales that are currently available.

METHODS

To frame this review, we formulated the research question using the four components of the PICO acronym, that is, population, intervention, comparator, and outcome. Including these concepts in the search strategy helped us retrieve the most relevant articles to answer the research

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question and to identify any published research reports that exist.

Data were sourced from MEDLINE, EMBASE, SCOPUS, CINAHL, and Cochrane and by review of the references of relevant literature.

We included all reviews, randomized controlled trials (RCTs), prospective comparative observational studies, and psychometric validation studies in English. We excluded nonoriginal articles, narrative reviews, editorials, and abstract-only articles. The data search was up to date as of October 31, 2013.

Psychometric properties of the selected scales were checked according to the following criteria:

Acceptability verifies that patients correctly complete a questionnaire. It is assessed by response rates to each question and by the number of questionnaires completed.

Content validity assesses the appropriateness of a questionnaire by ensuring that the entire range of a patient's complaints are included and that the selected items are representative.

Reliability means that the scale is able to provide reproducible and consistent measures. The reliability comprises the *reproducibility* of the measure by the test-retest method and the *internal consistency* assessed by calculation of Cronbach α .

Construct validity: two approaches are available to analyze the construct validity of a scale: its factorial stability and its congruency with other clinical and QOL measures. Factorial and within-scale analyses correspond to the former, and known-groups and convergent validities correspond to the latter.

Responsiveness is the ability to detect changes in the patient's health state, for instance, in response to a treatment. Change in the effect size is the preferred method to demonstrate responsiveness.

We deemed it inappropriate to perform a meta-analysis on the retrieved studies because of the heterogeneity that would result from introducing all of the different scales. Therefore, the results of the literature search were subject to a qualitative synthesis. In this review, each selected article was indexed on a card containing the following information: name of the scale, study acronym, journal and date of publication, targeted population and population description at the entry in the study by the CEAP classification, inclusion and exclusion criteria for the surveyed population, duration of study, data on acceptability of the used tool, and both clinical and QOL results from the study.

RESULTS

Identification and screening. A total of 511 records were identified through the database search, with an additional 53 records identified by a manual search. Only 432 records were retrieved after removal of the duplicates. In accordance with our defined criteria, the studies that fulfilled the inclusion criteria had reported nonuniform results. Whereas some of them reported both pretreatment and post-treatment QOL, some reported only postoperative

QOL, and others did not even report QOL results. Overall, 300 records were excluded for missing data or inappropriate psychometric properties. Finally, 132 full-text articles were eligible for the review, of which 29 were excluded for reasons ranging from noncomparable results to the absence of a comparator group. As such, 103 studies were finally included in the qualitative synthesis for full reading. The Fig summarizes the flow diagram for identification and screening of retrieved articles in the present systematic review according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.²

Scale characteristics. Ten scales measuring the health-related QOL of patients suffering from CVDs and CVI were identified. Table I illustrates the main characteristics of the scales. Two scales were identified for CVDs: the Assessment of Burden in Chronic disease—Venous (ABC-V) questionnaire and the Venous Insufficiency Epidemiological and Economic Study on Quality of Life (VEINES-QOL) questionnaire. Three scales are for patients with venous leg symptoms or signs but without ulcers (C0s to C4 of the CEAP classification): the Freiburg Life Quality Assessment (FLQA), the Specific Quality of life and Outcomes Response—Venous (SQOR-V) questionnaire, and the Chronic Venous Insufficiency Questionnaire (CIVIQ). In this category, the Tübingen questionnaire for measuring QOL in patients with CVI was subject to one validation study in the German language and was therefore not retained in the analysis. The FLQA has also been used to assess the effect of lymphedema on the QOL and the VEINES-QOL to assess the effect of deep venous thrombosis on the QOL. A total of four scales dedicated to venous leg ulcer patients (C5 to C6) were found: the Venous Leg Ulcer Quality Of Life questionnaire (VLU-QOL), the Leg and Foot Ulcer Questionnaire of Hyland (LFUQ), the Sheffield Preference-based Venous leg Ulcer questionnaire with five Dimensions (SPVU-5D), and the Charing Cross Venous leg Ulceration Questionnaire (CCVUQ). Finally, the Aberdeen Varicose Vein Questionnaire (AVVQ) is devoted exclusively to the QOL measurement of patients suffering varicose veins.

The number of dimensions ranges from two in the AVVQ to six in the ABC-V and the FLQA, and the number of items ranges from 13 in the AVVQ to 83 in the FLQA. All the tools described in Table II are patients' self-reported questionnaires. Time to complete questionnaires is often not reported. When it is, it ranges from 5 minutes for CIVIQ to 15 minutes for the VEINES-QOL/Symptoms (VEINES-QOL/Sym) subquestionnaire.

The scoring procedures, a primary feature of standardization required for the measurement instrument, are not clearly explained for all scales. Most of the values go from 0 for the highest QOL score to 100 for the worst score.

Psychometric and linguistic validation. All the scales cited in Table III have been psychometrically validated, with 31 studies identified for their psychometric validation.

A unique validation study was performed for the following scales: the SQOR-V,³ the SPVU-5D,⁴ and the VLU-QOL.⁵ The ABC-V questionnaire^{6,7} and the LFUQ^{8,9} were validated twice. The validations of the

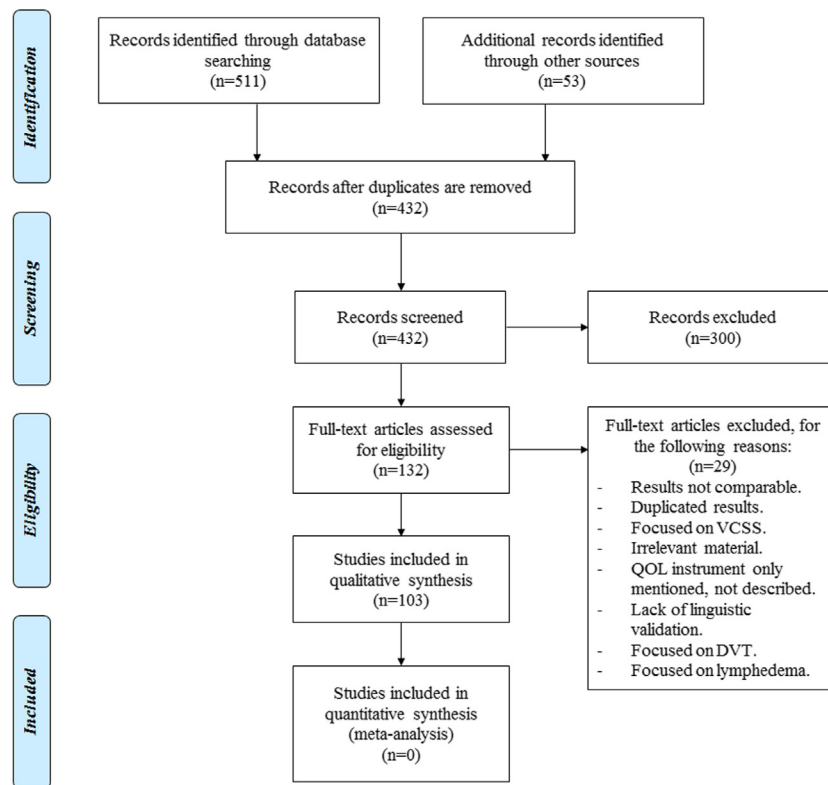


Fig. Flow diagram for identification and screening of retrieved articles in the present systematic review according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. *DVT*, Deep venous thrombosis; *QOL*, quality of life; *VCSS*, venous Clinical Severity Score.

CCVUQ,¹⁰⁻¹² AVVQ,¹³⁻¹⁵ and FLQA¹⁶⁻¹⁸ were subject to three publications. The FLQA is a modular instrument consisting of a core module of generic items and items specific for a distinct skin disease. Validity of the modules for lymphedema and chronic venous ulcers was performed in separate

studies. The steps in the development of the VEINES-QOL were published in 2003.¹⁹ Since then, both the core questionnaire (VEINES-QOL) and the subscale questionnaire VEINES-QOL/Sym have been extensively validated both in deep venous thrombosis (Supplementary Table I,

Table I. Characteristics of chronic venous disorders (CVDs)-specific and chronic venous insufficiency (CVI)-specific questionnaires

Scale acronym	All CVDs		Without ulcer			With ulcer			Varicose veins	
	ABC-V	VEINES-QOL	FLQA	SQOR-V	CIVIQ	VLU-QOL	LFUQ	SPVU-5D	CCVUQ	AVVQ
Author	Guex ⁷	Lamping ¹⁹	Augustin ¹⁶	Guex ³	Launois ²⁴	Hareendran ⁵	Hyland ⁸	Palfreyman ⁴	Smith ¹¹	Garratt ¹³
Year	2010	2003	1997	2007	1996	2007	1994	2008	2000	1993
Country	France	Various	Germany	France	France	U.K.	U.K.	U.K.	U.K.	U.K.
Indication	All	All	No ulcer	No ulcer	No ulcer	Ulcer	Ulcer	Ulcer	Ulcer	Varicose veins
Domains	6	3	6	5	4	3	3	5	4	2
Items	36	35	83	46	20	34	34	16	32	13
Time, minutes	Not known	10-15	20	—	<5	—	—	—	≈ 10	—
Best score	0	Max	Min	0	100	0	12	0	0	0
Worst score	90	Min	Max	100	0	100	Max	80	100	100

ABC-V, Assessment of Burden in Chronic disease—Venous; *AVVQ*, Aberdeen Varicose Vein Questionnaire; *CCVUQ*, Charing Cross Venous Ulceration Questionnaire; *CIVIQ*, ChronIc Venous Insufficiency Questionnaire; *FLQA*, Freiburg Life Quality Assessment; *LFUQ*, Leg and Foot Ulcer Questionnaire (Hyland); *SPVU-5D*, Sheffield Preference-based Venous leg Ulcer questionnaire with 5 Dimensions; *SQOR-V*, Specific Quality of life and Outcomes Response—Venous; *VEINES-QOL*, VEInous INSufficiency Epidemiological and Economic Study on Quality of Life; *VLU-QOL*, Venous Leg Ulcer Quality of Life questionnaire.

Table II. Psychometric and linguistic validation of the disease-specific questionnaires

Scale acronym	All CVDs		Without ulcer			With ulcer				Varicose veins	Total
	ABC-V	VEINES-QOL	FLQA	SQOR-V	CIVIQ	VLU-QOL	LFUQ	SPVU-5D	CCVUQ	AVVQ	
Author	Guex ⁷	Lamping ¹⁹	Augustin ¹⁶	Guex ³	Launois ²⁴	Hareendran ⁵	Hyland ⁸	Palfreyman ⁴	Smith ¹¹	Garratt ¹³	
Year	2010	2003	1997	2007	1996	2007	1994	2008	2000	1993	
Country	France	Various	Germany	France	France	U.K.	U.K.	U.K.	U.K.	U.K.	
Versions	1	1	1	1	2	1	1	1	1	1	
Psychometric validation	2	5	3	1	10	1	2	1	3	3	31
Linguistic validation	4	2	1	1	17	1	1	1	2	2	
Nonvalidated translation	0	0	0	1	11	0	0	0	0	0	
Implementation studies	0	3	0	1	32	0	0	0	1	29	66
Systematic review											6
No. of articles included											103
Correlations with	CES-D ⁷ SQOR-V ⁷	SF-36 ^{19,20,22,23}	NHP ¹⁶ EQ-5D ¹⁷	SF-12 ³	SF-36, SF-12 ^{26,27,32}	SF-36 ⁵	SF-12, SF-36, EQ-5D ⁸	EQ-5D ⁴	SF-36 ^{10,11,35}	SF-12, SF-36 ¹⁴ EQ-5D ^{36,38}	

ABC-V, Assessment of Burden in Chronic disease—Venous; AVVQ, Aberdeen Varicose Vein Questionnaire; CCVUQ, Charing Cross Venous Ulceration Questionnaire; CES-D, Center for Epidemiologic Studies Depression Scale; CIVIQ, Chronic Venous Insufficiency Questionnaire; CVDs, chronic venous disorders; EQ-5D, European Quality of Life—5 Dimensions; FLQA, Freiburg Life Quality Assessment; LFUQ, Leg and Foot Ulcer Questionnaire (Hyland); NHP, Nottingham Health Profile; SF-12, Short Form 12-Item Questionnaire; SF-36, Short Form 36-Item Questionnaire; SPVU-5D, Sheffield Preference-based Venous leg Ulcer questionnaire with 5 Dimensions; SQOR-V, Specific Quality of life and Outcomes Response—Venous; VEINES-QOL, Venous Insufficiency Epidemiological and Economic Study on Quality of Life; VLU-QOL, Venous Leg Ulcer Quality Of Life questionnaire.

online only) and in CVDs.²⁰⁻²³ The CIVIQ-20 consisting of 20 items was developed in the 1990s²⁴; its short-form, the CIVIQ-14, includes 14 items and was developed in 2012.²⁵ A total of eight published papers dealing with psychometric and linguistic validation of CIVIQ-20 came up more recently,²⁶⁻³³ and CIVIQ-14 was subject to two additional studies.^{25,34} Regarding the psychometric validation, the most citations were for VEINES-QOL/Sym and CIVIQ.

Most specific scales are validated in the French or English language, except for the German FLQA as shown in Table II. Several scales were translated into different languages as follows: ABC-V to Romanian⁶; VEINES-QOL to four languages (English, French, Italian, French Canadian)¹⁹; VEINES-QOL/Sym to Dutch,²³ Portuguese,²⁰ and Turkish²¹; AVVQ to Dutch version^{14,15}; CCVUQ to Portuguese¹⁰ and Chinese¹²; and CIVIQ to 17 forward-backward validated languages and 11 simple translated versions from the French source questionnaire.³³

Psychometric tests described in the validation studies are presented in detail in Table III. We identified five psychometric properties: *acceptability*, *content validity*, *reliability*, *construct validity*, and *responsiveness*.

Acceptability was investigated in nine of the 10 scales except the LFUQ. *Content validity* was verified in all scales except the ABC-V. With regard to *reliability*, the test-retest method and internal consistency were analyzed in seven scales (FLQA, SQOR-V, CIVIQ, VLU-QOL, CCVUQ, AVVQ, and VEINES-QOL). The reliability of the SPVU-5D was investigated regarding its internal consistency only, whereas it was not analyzed for the LFUQ and the ABC-V.

Simple exploratory factor analyses were applied to analyze *construct validity* in four of the 10 scales (CIVIQ, CCVUQ, LFUQ, and VLU-QOL). The “within-scale analysis” is not subject to consensus; the term refers to the calculation of a Cronbach α for VEINES-QOL, whereas it corresponds to a multitrait/multi-item analysis for CIVIQ. Five of the 10 included scales (ABC-V, FLQA, AVVQ, SQOR-V, SPVU-5D) were subject to neither factorial nor within-scale analysis.

Convergent validity (ie, the agreement between QOL scales) was assessed for all the instruments, with the exception of SPVU-5D. The Short Form 36-Item and 12-Item Questionnaires (SF-36 and SF-12, respectively) were the tools chosen most often and have been used in association with specific tools such as the VEINES-QOL,^{19,20,22,23} AVVQ,¹⁴ CIVIQ,^{26,27,32} SQOR-V,³ and CCVUQ.^{10,11,35} The FLQA was tested with the Nottingham Health Profile.¹⁶ The European QOL—5 Dimensions (EQ-5D) tested the validity of AVVQ,³⁶⁻³⁸ FLQA,¹⁷ and SPVU-5D.⁴ Other scales dealing with assessment of the clinical signs of CVDs, such as the Venous Clinical Severity Score of Vasquez³⁹ and the Homburg Varicose Vein Severity Score,³² and even psychological instrument scales such as the Center for Epidemiologic Studies Depression Scale, also tested some of the specific QOL tools.^{7,40,41}

Whereas an analysis of variance is recommended to demonstrate *known-groups validity*, additional methods, such as correlations analysis or simple score assessment, were identified. Known-groups validity was investigated in six scales (FLQA, VEINES-QOL, AVVQ, CIVIQ, SQOR-V, and VLU-QOL), with either the CEAP classification or the presence of severe signs such as ulcers. It is

Table III. Detailed psychometric validation of disease-specific questionnaires

Scale acronym	All CVDs		Without ulcer			With ulcer				Varicose veins
	ABC-V	VEINES-QOL	FLQA	SQOR-V	CIVIQ	VLU-QOL	LFUQ	SPVU-5D	CCVUQ	AVVQ
Author	Guex ⁷	Lamping ¹⁹	Augustin ¹⁶	Guex ³	Launois ²⁴	Hareendran ⁵	Hyland ⁸	Palfreyman ⁴	Smith ¹¹	Garratt ¹³
Year	2010	2003	1997	2007	1996	2007	1994	2008	2000	1993
Acceptability	Guex	Lamping	Augustin	Guex	Launois	Hareendan		Palfreyman	Smith	Klem ¹⁵
	2010	2003	1997	2007	1996	2007		2008	2000	2009
Content validity										
Relevance		Lamping	Augustin	Guex	Launois	Hareendan	Iglesias ⁹	Palfreyman	Smith	Garratt
		2003	1997	2007	1996	2007	2005	2008	2000	1993
Reliability										
Coherent test-retest		Lamping	Augustin	Guex	Launois	Hareendan			Smith	Klem ¹⁵
		2003	2005	2007	1996	2007			2000	2009
Internal consistency		Lamping	Augustin	Guex	Launois	Hareendan		Palfreyman	Smith	Garratt
		2003	1997	2007	1996	2007		2008	2000	1993
Construct validity										
1. Factorial analysis					Launois	Hareendan	Iglesias		Smith	Garratt
					1996	2007	2005		2000	1993
2. Within-scale analysis					Launois ²⁹					
					2010					
3. Known-groups validity		Lamping	Augustin	Guex	Launois	Hareendan				Klem
		2003	1997	2007	1996	2007				2009
4. Convergent validity	Guex	Lamping	Augustin	Guex	Launois	Hareendan	Iglesias		Smith	Klem
	2010	2003	1997	2007	1996	2007	2005		2000	2009
Responsiveness										
Effect size		Lamping	Augustin		Launois	Hareendan	Iglesias		Smith	Klem
		2003	1997		1996	2007	2005		2000	2009

ABC-V, Assessment of Burden in Chronic disease—Venous; AVVQ, Aberdeen Varicose Vein Questionnaire; CCVUQ, Charing Cross Venous Ulceration Questionnaire; CIVIQ, ChronIc Venous Insufficiency Questionnaire; CVDs, chronic venous disorders; FLQA, Freiburg Life Quality Assessment; LFUQ, Leg and Foot Ulcer Questionnaire (Hyland); SPVU-5D, Sheffield Preference-based Venous leg Ulcer questionnaire with 5 Dimensions; SQOR-V, Specific Quality of life and Outcomes Response—Venous; VEINES-QOL, VEnous INsufficiency Epidemiological and Economic Study on Quality of Life; VLU-QOL, Venous Leg Ulcer Quality Of Life questionnaire.

acknowledged that CEAP is not suited for quantifying changes in response to treatment. However, the C of CEAP can be used to discriminate between various clinical presentations of subjects at a given time (known-groups differences). Thus, we observed that the difference between known-groups validity and convergent validity is not always clearly stated in the publications: analysis of correlations between the QOL score and the presence/absence of a symptom is more related to the convergent validity than to the known-groups validity.

Responsiveness was investigated in seven of the 10 scales (FLQA, VEINES-QOL, AVVQ, CIVIQ, CCVUQ, LFUQ, and VLU-QOL).

Fields of application. We identified 25 RCTs (Table IV), of which 11 used the AVVQ^{36-38,40-47} and 13 used the CIVIQ.⁴⁸⁻⁶⁰ In seven RCTs, the AVVQ was used in parallel with generic QOL tools, mainly the SF-36 and the EQ-5D,^{36,38,41,43,44,46,47} whereas two RCTs used either the SF-36⁵⁴ or the EQ-5D⁵⁰ in association with the CIVIQ.

In the unique RCT with CCVU-Q, SF-12 was chosen.³⁵ The domains of application were the ablation of varicose veins for the AVVQ and venous ulcer healing for the CCVU-Q, whereas it was more extended for the CIVIQ, which measured various treatments present over the full spectrum of the disease from C1 to C6 patients. The CIVIQ was used to measure the outcomes of various

varicose vein ablation procedures in six RCTs (endovenous laser ablation, foam, radiofrequency ablation, bipolar coagulation),^{48,51-54,60} compression therapy in two RCTs,^{49,58} drug therapy in three RCTs,^{55,57,59} and physical therapy⁵⁰ and lymphatic drainage⁵⁶ in one RCT.

Forty-one observational studies (Table V and Supplementary Table II, online only) assessed the effects of treatment on the QOL and used SQOR-V (one trial), VEINES/QOL (three trials), AVVQ (18 trials), and CIVIQ (19 trials). These trials confirm the domains of applications reported from the RCTs. AVVQ was used in these trials to assess the effect on the QOL of varicose vein recurrence and varicose vein ablation, either by open surgery or by endovenous procedures. The VEINES-QOL was used to assess the effect of treatment in patients with deep venous thrombosis (Supplementary Table I, online only). The CIVIQ compared various surgery techniques for varicose veins with different treatments in CVD patients, including venous stenting, iliac vein graft, compression therapy, electrostimulation, and drugs. Most of these trials were conducted in C2 to C5 patients.

DISCUSSION

The aim of this study was to investigate how well the QOL scales specifically designed for CVD and CVI were validated. Both psychometric and linguistic validations were considered. A total of 10 QOL scales were included

Table IV. Fields of application of the disease-specific questionnaires for chronic venous disorders (CVDs) in randomized controlled trials

Specific QOL tool	Author, year	Indication	Type of treatment	Sample size	Generic QOL tool	Other assessment tools	Duration of study
AVVQ	Yang (2013) ⁴¹	VV	EVLA + SF ligation vs open surgery	108 limbs	None	VCSS	24 months
	Samuel (2013) ³⁸	VV (GSV)	12-w vs 14-w EVLA	76 pts	SF-36, EQ-5D	VCSS, VAS	5 years
	Lattimer (2013) ⁴⁰	VV	EVLA + phlebectomies vs UGFS	100 pts	None	VCSS	15 months
	Kalodiki (2012) ⁴⁵	VV (GSV)	UGFS + SF ligation vs open surgery	73 pts (82 limbs)	SF-36	VCSS, VSDS	5 years
	Nordon (2011) ³⁷	VV	RFA vs EVLA	159 pts	None	VCSS	3 months
	Carradice (2011) ⁴³	VV (GSV)	EVLA vs conventional surgery	280 pts	SF-36	VCSS	52 weeks
	Christenson (2010) ⁴⁴	VV (GSV)	EVLA vs conventional surgery	204 limbs	SF-36	VCSS	2 years
	Shepherd (2010) ⁴⁷	VV	RFA vs EVLA	134 pts	SF-12	VCSS	6 weeks
	Klem (2009) ⁴⁶	VV (GSV)	Cryostripping vs conventional stripping	494 pts	SF-36		6 months
	Carradice (2009) ³⁶	VV	EVLA + sequential vs EVLA + concomitant phlebectomies	50 pts	SF-36, EQ-5D	VCSS	1 year
CIVIQ	Bountouroglou (2006) ⁴²	VV (GSV)	UGFS + SF ligation vs open surgery	60 pts	None	VCSS	3 months
	Carpentier (2014) ⁵⁰	Chronic venous insufficiency CEAP, C4 to C5	Standard therapy (ST) vs ST + physical therapy	425 pts (2013)	EQ-5D	VCSS, VAS	4 weeks
	Molski (2013) ⁵⁶	VV	Manual lymphatic drainage (MLD) before surgery vs no MLD	59 (2009) 70 pts	None	CEAP, foot volumetry and venous refilling time	1 month
	Vuylsteke (2012) ⁶⁰	VV (GSV)	EVLA with tulip fiber vs EVLA with bare fiber	174 pts		VAS, hematomas	1 year
	Blaise (2010) ⁴⁸	VV (GSV) CEAP, C2 to C5	1% vs 3% polidocanol sclerosant	143 pts	None	VCSS	3 years
	Brizzio (2010) ⁴⁹	Recalcitrant venous ulcers CEAP, C6	Low-strength compression stockings vs bandages	55 pts	None	VAS	6 months
	Gale (2010) ⁵¹	VV (GSV)	RFA vs EVLA	118 pts	None	VCSS, CEAP	1 year
	Hamel (2010) ⁵²	VV (GSV or SSV)	UGFS alone vs UGFS + compression therapy	55 pts	None	DUS	1 month
	Kalteis (2008) ⁵³	VV (GSV) CEAP, C2 to C4	Open surgery + high ligation (HL) vs EVLA + HL	100 pts	None	DUS, VAS	16 weeks
	Martinez-Zapata (2008) ⁵⁵	CVDs, full spectrum	Drug treatment (calcium dobesilate) vs placebo	246 pts	None	Presence of symptoms and signs	12 months
	Saveljev (2008) ⁵⁷	VV (GSV)	Open surgery + drug therapy (MPFF) vs open surgery alone	245 pts	None	VAS, hematomas	4 weeks
	Lorenz (2007) ⁵⁴	VV (GSV)	Open surgery vs bipolar coagulation	200 pts	SF-36	DUS, VAS	1 day
	Vevertkova (2006) ⁵⁹	VV (GSV)	Open surgery + drug therapy (MPFF) vs open surgery alone	181 pts	None	VAS, hematomas, analgesics consumption	14 days
	Vayssairat (2000) ⁵⁸	CVDs CEAP, C1 to C3	Elastic compression stockings (10-15 mm Hg) vs placebo stockings	341 pts	None	VAS, limb volumetry	1 month
	CCVU-Q	Wong (2012) ³⁵	Venous ulcer CEAP, C6	Standard treatment + short-stretch compression vs standard treatment + four-layer compression bandaging	321 pts	SF-12	Photogrammetry, Brief Pain Inventory, and Frenchay Activity Index

AVVQ, Aberdeen Varicose Vein Questionnaire; CEAP, clinical, etiologic, anatomic, pathophysiologic (classification); CDT, catheter-directed thrombolysis; CCVUQ, Charing Cross Venous Ulceration Questionnaire; CIVIQ, ChronIc Venous Insufficiency Questionnaire; DVT, deep venous thrombosis; DUS, duplex scan; EQ-5D, European Quality of Life-5 Dimensions; EVLA, endovenous laser ablation; GSV, great saphenous vein; MPFF, micronized purified flavonoid fraction; PTS, post-thrombotic syndrome; pts, patients; QOL, quality of life; RFA, radiofrequency ablation; SF, saphenofemoral; SF-12, Short Form 12-Item Questionnaire; SF-36, Short Form 36-Item Questionnaire; SSV, small saphenous vein; UGFS, ultrasound-guided foam sclerotherapy; VAS, visual analog scale; VCSS, Venous Clinical Severity Score; VSDS, Venous Segmental Disease Score; VV, varicose veins.

Table V. Summary of application studies

Scales	Observational studies	RCTs	Total per scale
ABC-V	0	0	0
AVVQ	18	11	29
CCVUQ	0	1	1
CIVIQ	19	13	32
FLQA	0	0	0
LFUQ	0	0	0
SPVU-5D	0	0	0
SQOR-V	1	0	1
VEINES-QOL/Sym	3	0	3
VLU-QOL	0	0	0
Total of studies	41	25	66

ABC-V, Assessment of Burden in Chronic disease—Venous; AVVQ, Aberdeen Varicose Vein Questionnaire; CCVUQ, Charing Cross Venous Ulceration Questionnaire; CIVIQ, Chronic Venous Insufficiency Questionnaire; FLQA, Freiburg Life Quality Assessment; LFUQ, Leg and Foot Ulcer Questionnaire (Hyland); RCTs, randomized controlled trials; SPVU-5D, Sheffield Preference-based Venous leg Ulcer questionnaire with 5 Dimensions; SQOR-V, Specific Quality of life and Outcomes Response—Venous; VEINES-QOL/Sym, VEINous INsufficiency Epidemiological and Economic Study on Quality of Life/Symptoms; VLU-QOL, Venous Leg Ulcer Quality Of Life questionnaire.

in this review. Whereas they were all subject to validation, our study highlighted the great differences observed in the degree of validation, definitions, and methods used in the process.

The verification of the five psychometric properties that assume a scale is fully validated was not achieved for all instruments. For example, *acceptability* was not investigated in the LFUQ, nor was *content validity* in the ABC-V. *Reliability* was not analyzed for these last two scales, and this was investigated for the SPVU-5D regarding its internal consistency only. According to the Food and Drug Administration, internal consistency only is not sufficient to demonstrate the reliability of the scale. Factorial and within-scale analyses were performed in CIVIQ, CCVUQ, LFUQ, and VLU-QOL. Within-scale analysis of VEINES-QOL used the calculation of Cronbach α , which is controversial. A recommended approach to analyze the factorial stability of a scale is to conduct a confirmatory factor analysis to confirm an a priori model, either hypothesized or obtained from a previous exploratory factor analysis, with data. Our study revealed that this methodology has never been used for CVD QOL scales (a confirmatory factor analysis was conducted for CIVIQ). Known-groups validity was not tried in four scales (ABC-V, LFUQ, SPVU-5D, CCVUQ), and convergent validity was not tested in the SPVU-5D. Finally, *responsiveness* was not included in the verifications of ABC-V, SQOR-V, and SPVU-5D.

Our findings must be interpreted in light of the following limitations. The VEINES-QOL questionnaire was subject to two validations: one for CVD patients and the other for deep venous thrombosis patients. References about deep venous thrombosis patients were not included in this review as it aimed to focus only on CVD. Thus, we identified six publications from Kahn et al that were

excluded in the selection process. We acknowledge that some important information regarding the validation of the VEINES-QOL questionnaire might be found in those articles.

CONCLUSIONS

The goal of such a review article was to put forward the quality and completeness of the validation studies that have been performed for each scale. Our recommendation is to use the most comprehensively validated scales (among which are CIVIQ, AVVQ, and VEINES-QOL) and then to choose the most appropriate tool according to the nature of research. Because tables of the present article include the targeted indications of each instrument and the indications in which each scale has been used, they should give clues for the choice of the most appropriate tool. Of great interest is the fact that some of the analyzed scales are not fully validated. For instance (Table III), four scales (ABC-V, VEINES-QOL, FLQA, SPVU-5D) remain with a nonvalidated factorial structure. This is a problem in case of multicenter studies in different countries. The known-groups validity is not validated in three scales (LFUQ, SPVU-5D, CCVUQ), meaning that we do not know if such scales can discriminate between severity of patients' disease at baseline. The responsiveness (ie, the ability of a scale to respond to treatment) is not validated for SQOR-V and SPVU-5D. Therefore, these last scales are at risk of being unsuitable for assessing response to treatment. We hope this review and its detailed tables might help those interested in assessing patients' QOL choose the most suitable scale according to the aim of their research.

AUTHOR CONTRIBUTION

Conception and design: RL
 Analysis and interpretation: RL
 Data collection: RL
 Writing the article: RL
 Critical revision of the article: RL
 Final approval of the article: RL
 Statistical analysis: RL
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 Overall responsibility: RL

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Additional material for this article may be found online at www.jvsvenous.org.

Supplementary Table I (online only). Excluded deep venous thrombosis references

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Supplementary Table II (online only). Included observational studies and systematic reviews

Application studies: Observational studies

AVVQ

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CIVIQ

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Supplementary Table II (online only). Continued.*Application studies: Observational studies*

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AVVQ, Aberdeen Varicose Vein Questionnaire; *CIVIQ*, Chronic Venous Insufficiency Questionnaire; *SQOR-V*, Specific Quality of life and Outcomes Response—Venous; *VEINES-QOL*, VEnous INSufficiency Epidemiological and Economic Study on Quality of Life.