

SYSTEMATIC REVIEW

The Relationship Between Vein Diameters, Clinical Severity, and Quality of Life: A Systematic Review

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WHAT THIS PAPER ADDS

This review summarises the evidence showcasing the weak direct correlation between truncal vein diameter and clinical severity of disease, and further elucidates the lack of association between diameter and health related quality of life. The authors report evidence that cautions against using predetermined diameters as thresholds for venous intervention and highlight the importance of both clinical and quality of life assessments in patients with venous disease. This review also highlights specific areas for further investigation, with a focus on the relationship between anatomical assessments and chronic venous disease progression.

Objective/background: The aim was to summarise the evidence for the relationship between vein diameters and clinical severity, and elucidate the relationship between diameters and health related quality of life (HRQoL)

Methods: A systematic review was performed according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) guidelines. The MEDLINE and Embase databases were searched from 1946 to 31 August 2018. Reference lists of included studies were searched for further relevant papers. Full text studies in English reporting the relationship between great and small saphenous vein diameters and clinical severity and/or HRQoL scores measured using validated instruments were included. All study designs were included. Studies that did not include relationships between these parameters, non-English studies, and studies focusing on non-truncal veins were excluded. Two reviewers independently performed the study selection, data extraction, and risk of bias assessment.

Results: Eleven eligible studies were identified, reporting on 2,732 limbs (range 22–681). Four studies correlated truncal vein diameter with both clinical severity and HRQoL, while seven reported only on clinical severity measures. Multiple instruments were used to quantify HRQoL and clinical severity. Seven studies assessed the relationship with CEAP class, with the majority observing a positive correlation between vein diameter and disease severity. Four studies found weak correlations with VCSS, with one showing correlations with VCSS components. No significant relationship between diameters and HRQoL scores was reported. One study also revealed no correlation with Aberdeen Varicose Vein Questionnaire improvements post-treatment. The majority of studies failed to include C₀ and C₁ participants.

Conclusions: While further studies are required to improve the level of evidence, the existing literature suggests that truncal vein diameters correlate with clinical severity. Diameters are a poor predictor of HRQoL, with no relationship to patients' perceived impact of chronic venous disease. As such, vein diameter should not be used as a measure to decide who needs venous intervention.

Keywords: Patient reported outcome measures, Quality of life, Varicose veins, Venous insufficiency

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INTRODUCTION

Chronic venous disease (CVD) represents a spectrum of clinical presentations increasing in severity from telangiectasia to varicose veins, oedema, skin changes, and, ultimately, venous ulceration.¹ These presentations often have a significant negative impact on patients' lives, stemming

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from chronic pain, decreased mobility, social isolation, and other psychosocial issues.

CVD is a common condition, with varicose veins affecting up to 40% of the population and up to 4% of elderly patients above the age of 65 suffering from venous ulceration.² This represents a significant financial burden—venous ulcers alone take up to 2% of the total healthcare budget in developed countries.³ Treatment of venous disease represents its own costs; nevertheless, intervention has been found to be cost effective in multiple trials,^{4,5} and is endorsed by national and international guidance. Nonetheless, in the UK, depending on the area, clinical commissioning groups may discourage referrals to secondary care or treatment of venous insufficiency.⁶ In the USA, insurers use vein diameter, ranging from 3.5 - 5 mm for small saphenous veins (SSVs),^{7,8} and from 4.5 - 5.5 mm for great saphenous veins (GSVs),^{7,8} to ration eligibility for treatment.

The intent of such criteria, presumably, is to provide an objective measure to differentiate patients who want interventions for aesthetic reasons from those who need interventions owing to CVD having a significant impact on their health related quality of life (HRQoL). While there is some evidence that CEAP (Clinical, Etiological, Anatomical and Pathophysiological) clinical class is associated with larger diameters^{9–11} and HRQoL scores,^{9,12} the literature is less clear in relating HRQoL scores to truncal vein diameters. Truncal vein diameters are likely to be related to clinical severity, but owing to the multifactorial nature of HRQoL, vein diameters may not correlate as well with HRQoL scores. Therefore, this systematic review aimed to summarise the available evidence for the relationship between truncal vein diameters and clinical severity, as well as to elucidate the relationship between diameter and HRQoL.

MATERIALS AND METHODS

A systematic review was performed in accordance to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) guidelines.¹³

Search strategy

The MEDLINE and Embase databases were searched from 1946 to 31 August 2018 using terms related to truncal venous diameters, clinical severity, and HRQoL scores (Fig. S1; see Supplementary Material). The reference lists of included papers were then searched to include other relevant studies.

Two reviewers (MT, SS) performed the systematic literature search and reviewed the full texts independently to ensure that the inclusion and exclusion criteria were met. Conflicts between reviewers were discussed in person and any unresolved discrepancies were referred to a senior reviewer (SO).

Inclusion and exclusion criteria

Full text studies were included if they were in English language and reported on the relationship between GSV and

SSV diameters and clinical severity (e.g., CEAP classification,¹ Venous Clinical Severity Score [VCSS])¹⁴ and/or HRQoL scores (e.g., Aberdeen Varicose Vein Questionnaire [AVVQ],¹⁵ Chronic Venous Insufficiency Quality of Life Questionnaire [CIVIQ],¹⁶ and VEnous INsufficiency Epidemiological And Economic Study-QoL/Symptoms [VEINES-QoL/Sym])¹⁷ measured using validated instruments in adult patients.

Studies were excluded if they were non-English, failed to report on the relationship between the aforementioned parameters, or focused on non-truncal venous diameters or paediatric patients.

Data extraction

Data from chosen studies were independently extracted by two reviewers (MT, SS). Any discrepancies were discussed in person and any unresolved issues referred to a senior reviewer (SO).

The data extracted included author, year of publication, study period, study type, research question, participant number and demographics, truncal veins assessed, instruments used to measure clinical severity and HRQoL, and the relationship between truncal diameters and clinical severity and/or HRQoL.

Risk of bias assessment

Studies were assessed using the National Institute of Health Quality Assessment Tool for Observational Cohort and Cross sectional Studies.¹⁸ Risk of bias across studies was not performed as only a qualitative synthesis was planned in this review.

Principal summary measures

An initial literature search showed a small number of relevant papers with heterogenous methods, different parameters measured, and various instruments and statistical methods employed. As such, a meta-analysis was not planned, with this review performing a qualitative summary of the available evidence.

Protocol registration

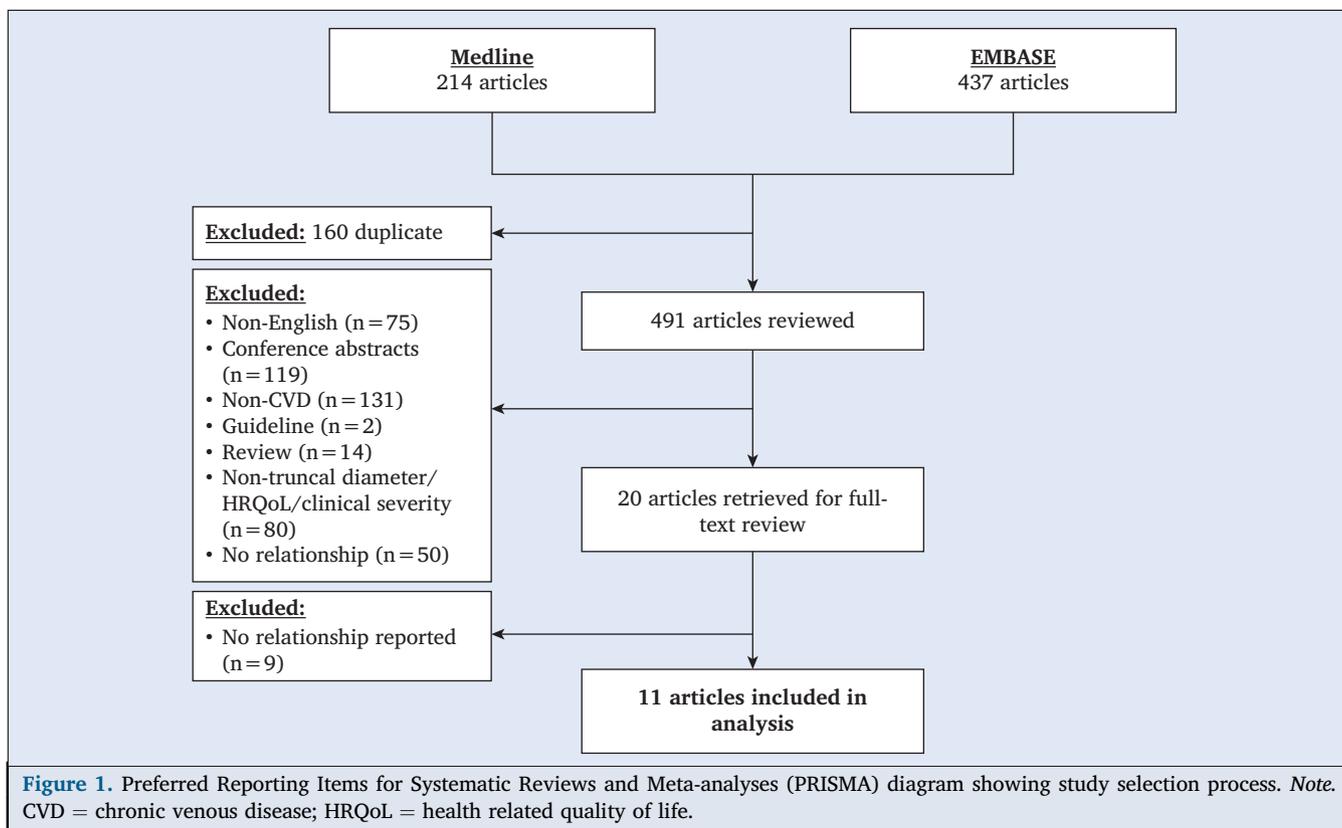
The research protocol was registered on the PROSPERO database (ID: CRD42018108759).

RESULTS

Selected studies

The literature search identified 651 studies from which a total of 11 studies were included in this review (Fig. 1).^{9–12,19–25} Data from these studies are summarised in Table S1 (see Supplementary Material).

Nine were cross sectional studies,^{9–12,19–21,23,25} one was a prospective cohort study,²⁵ and one was a pre-post study.²² These studies recruited a total of 2,732 limbs presenting with a distribution of CVD severity (Table 1). Eight studies assessed only GSV diameters,^{10,17–23} while three



measured both GSV and SSV diameters.^{9,11,12} Maximum diameters were recorded in five studies,^{9,12,22,23,25} while the remaining six measured diameters at specific locations along the vein's length.^{10,11,19–21,24}

Four studies observed the relationship between truncal venous diameters and both HRQoL and clinical severity scores (n limbs = 900),^{9,23–25} while seven only reported on clinical severity (number of limbs = 1,687).^{10–12,19–22} Notably, the majority assessing HRQoL relationships did not include C_{0–1} patients in their analysis, with only six C₁ patients included by Lane et al.⁹ Morbio et al. also excluded 145 limbs in the correlation analysis owing to missing CEAP data.²¹

Risk of bias assessment

Eight studies were subjectively considered to be of “good” quality,^{9–12,20,22,23,25} while three were considered to be of “fair” quality (Table 2).^{19,21,24} No study was rated “poor” quality in the risk of bias assessment.

Clinical severity

Seven studies observed the relationship between truncal venous diameter and CEAP classification,^{9–12,19,20} while four described its relationship to VCSS.^{9,20,22,23}

CEAP classification

Consistently, all studies reported a positive correlation between truncal venous diameters and CEAP clinical class. Studies showed that GSV diameters increased with clinical class.^{9,10,19–22} Importantly, three studies also showed that

this relationship was consistent at pre-defined measurement locations along the length of the GSV and not just with maximum truncal venous diameter.^{10,20,21}

Three studies also divided their patient populations into two groups based on CEAP stage,^{9,11,12} representing mild (C_{1–3}/C_{2–3}) and advanced (C_{4–6}) CVD. Conway et al.¹² and Labropoulos et al.¹¹ both reported significantly greater truncal vein diameters in patients with C_{4–6} disease compared with C_{2–3} disease. However, Lane et al. showed no significant difference in median maximum GSV and SSV diameters between patients with C_{1–3} and C_{4–6} disease,⁹ which may be due, in part to the large number of C₄ patients recruited, as well as the non-significant differences observed when comparing the other groups.

VCSS

All studies assessing the relationship between truncal vein diameter and VCSS showed a positive correlation, albeit with varying strengths. Gibson et al.²³ and Lane et al.⁹ both showed weak but significant correlations with maximum diameters, while Mendoza et al.²⁰ reported a strong significant correlation with diameters at the saphenofemoral junction and proximal thigh. In a very small cohort of 22 limbs, Barros et al. also described a directly proportional relationship between these two parameters, but did not report specific statistical values.²² Additionally, Mendoza et al. were able to show significant correlations between every single component of the VCSS and GSV diameter at both the saphenofemoral junction and proximal thigh.²⁰

Table 1. Distribution of limbs by Clinical, Etiological, Anatomical and Pathophysiological (CEAP) clinical class

Class	Number of limbs												
	Health related quality of life and clinical severity						Clinical Severity only						
	Gibson et al., 2012 ²³	Lane et al., 2017 ⁹	Lattimer et al., 2014 ²⁵	Mallick et al., 2017 ²⁴	Barros et al., 2015 ²²	Conway et al., 2011 ¹²	Labropoulos et al., 2010 ¹¹	Mendoza et al., 2013 ¹⁹	Mendoza et al., 2016 ²⁰	Morbio et al., 2010 ²¹	Navarro et al., 2002 ¹⁰	Total	
C ₀	—	—	—	—	—	—	—	29	13	—	27	69	
C ₁	6	6	—	—	1	—	—	28	23	1	26	85	
C ₂	6	83	28	165	9	339	427	63	43	35	18	1,622	
C ₃	75	78	13	127	10	—	—	44	17	36	6	—	
C ₄	8	135	31	88	2	85	254	17	11	20	14	811	
C ₅	2	16	7	15	—	—	—	1	3	30	9	—	
C ₆	—	12	5	—	—	—	—	—	1	33	12	—	
C ₀₋₆	91	330	84	395	22	424	681	182	111	155	112	2,587	

HRQoL

Four studies described the relationship between truncal vein diameters and HRQoL scores measured using the AVVQ,^{9,25} VEINES-QoL/Sym,^{23,25} CIVIQ,²³ and EuroQoL-5D.⁹ In summary, all studies failed to show a significant correlation between these two variables.

AVVQ scores were shown by Lane et al. to have a very weak and statistically non-significant correlation with truncal vein diameter.⁹ AVVQ improvements post-intervention, while showing greater improvement with worse baseline AVVQ and VCSS scores, also were not correlated with baseline GSV diameter in a study by Lattimer et al.²⁵ at the three week and three month follow ups.

Similarly, for VEINES-QoL/Sym scores, studies were unable to show any significant relationship with truncal vein diameter. Gibson et al. found very weak, non-significant correlations to VEINES-QoL and VEINES-Sym scores.²³ Mallick et al. showed that larger truncal venous diameters had no predictive value for both functional limitation and psychological impact scores as measured using the m-VEINES-QoL/Sym instrument.²⁴

These findings are echoed in the very weak and non-significant correlations seen for CIVIQ²³ and EuroQoL-5D⁹ scores.

Specific study findings for the relationships between truncal diameters, clinical severity and HRQoL scores are summarised in Table S1 (see Supplementary Material).

DISCUSSION

Truncal vein diameter is a common parameter often measured and recorded in the assessment of patients with CVD. On an initial literature search, the variety of instruments used, anatomical locations of vein diameter measurements, and statistical methods employed suggested study heterogeneity, which precluded a planned meta-analysis at this time. This systematic review has therefore summarised qualitatively the evidence investigating this hypothesis that larger truncal veins are more symptomatic with greater clinical severity and have a greater impact on patients' HRQoL and present a more complex relationship than direct correlation.

The evidence available suggests that while truncal venous diameters have a weak positive correlation to clinical severity described using the CEAP classification or VCSS, they hold no relationship or predictive value of patients' HRQoL. This is in contrast to the significant relationships between clinical severity and HRQoL, with most studies showing correlation between clinical severity classification systems,^{9,27,28} and HRQoL scores^{29,30} measured using both generic and disease specific tools.^{27,29-32} The definitive intent of any medical or surgical intervention is to improve patients' HRQoL and not anatomical or haemodynamic values quantified in the clinic. It is likely that using truncal venous diameters as a surrogate measure to limit referrals or treatment is inappropriate and ineffective.

Current National Institute for health and Care Excellence guidance on varicose veins recommends referral to

Table 2. Risk of bias assessment using the National Institutes of Health quality assessment tool for observational cohort and cross sectional studies

	Gibson et al., 2012 ²³	Lane et al., 2017 ⁹	Lattimer et al., 2014 ²⁵	Mallick et al., 2017 ²⁴	Barros et al., 2015 ²²	Conway et al., 2011 ¹²	Labropoulos et al., 2010 ¹¹	Mendoza et al., 2013 ¹⁹	Mendoza et al., 2016 ²⁰	Morbio et al., 2010 ²¹	Navarro et al., 2002 ¹⁰
1. Was the research question or objective in this paper clearly stated?	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
2. Was the study population clearly specified and defined?	Yes	Yes	Yes	No	Yes	No	No	No	No	No	Yes
3. Was the participation rate of eligible persons at least 50%?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
4. Were all the subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study pre-specified and applied uniformly to all participants?	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5. Was a sample size justification, power description, or variance and effect estimates provided?	No	No	No	No	No	No	No	No	No	No	No
6. For the analyses in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured?	NA	NA	Yes	NA	Yes	NA	NA	NA	NA	NA	NA
7. Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed?	NA	NA	Yes	NA	Yes	NA	NA	NA	NA	NA	NA
8. For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)?	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
9. Were the exposure measures (independent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
10. Was the exposure(s) assessed more than once over time?	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
11. Were the outcome measures (dependent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
12. Were the outcome assessors blinded to the exposure status of participants?	No	No	No	No	No	No	No	No	No	No	No
13. Was loss to follow up after baseline 20% or less?	NA	NA	Yes	NA	Yes	NA	NA	NA	NA	NA	NA
14. Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)?	No	No	No	No	No	No	No	No	No	No	No
Overall	Good	Good	Good	Fair	Good	Good	Good	Fair	Good	Fair	Good

specialist services based on symptoms, not CEAP class, VCSS, or any HRQoL scoring systems.³³ This is supported by Darvall et al.,³⁴ who, interestingly, showed that HRQoL decreased significantly simply with the presence of lower limb symptoms, independent of clinical class. Additionally, presentation to healthcare services is not driven by large truncal venous diameters but by symptoms—truncal venous diameters are only measured after patients are assessed using duplex ultrasound following presentation for symptoms such as pain or itching, or clinical signs such as varicose veins and ulceration. Little is known about how truncal venous diameters relate to the size of superficial varicosities, and while work has been done to elucidate the relationship between anatomical and haemodynamic factors and disease progression,^{35,36} more studies are required to prove conclusively the role such parameters have in CVD presentation, investigation, and management.

Studies have shown that interventional treatment of varicose veins is more cost effective than conservative management,^{33,37} with early treatment of small, symptomatic veins preventing disease progression and costlier future management.³⁸ Without definitive evidence based guidelines identifying appropriate patients and timelines for intervention, CVD treatment stratified by GSV or SSV diameters will continue to be poorly directed and ill-timed, risking inadequate provision of interventions to patients with CVD deemed to have insufficiently severe disease based on non-evidence based arbitrary diameter cut offs, a flawed assumption, as evidenced by the weak relationships shown in the studies included in this review. Indeed, a recent retrospective study by Raju et al. showed that only 30% of varicose vein patients in the USA received interventional management and delayed intervention led to clinical progression and greater morbidity.³⁹ Furthermore, withholding treatment until CVD changes manifest has been demonstrated by Caradice et al. to lead to a greater risk of recurrence and permanent morbidity,⁴⁰ providing short-term cost savings but ultimately leading to a longer term financial burden.

However, it must be noted that the included studies exhibit some limitations, one of which is a deficiency of C₀ and C₁ participants. Of the four papers reporting on HRQoL scores, no C₀ patients were included and only six C₁ patients were included by Lane et al.⁹ This stems from most patients being recruited in a healthcare setting, where patients with C₀ and C₁ are less likely to be seen. This does not detract from the conclusions found in the studies entirely; the weak associations found with clinical severity and the lack thereof for HRQoL are still important for patients who are likely to receive intervention. Additionally, a different distribution of CEAP classes was also seen between studies, perhaps reflecting the current referral practices unique to each geographical region. These skewed study populations are unlikely to represent faithfully the true patient population seen in a typical clinic. While these issues may have been overcome through a pooled analysis, the lack of a common instruments used, and different endpoints precluded such statistical methods. Additionally, with the majority of studies recording cross sectional data, the question still

remains whether large truncal vein diameters have a role to play in the progression of CVD, currently estimated at around 4.3% annually using long-term follow up data from the Edinburgh Vein Study.²⁶ Cohort studies or interrupted time series should be performed to not only clarify this role, but also to see if changes in vein diameters following intervention correlate with clinical severity or HRQoL improvements.

The authors propose that further research firstly corrects the limitations that have been discussed above. Should future studies aim to characterise truncal venous diameters, a standardisation of measurement points is required, with assessment at pre-defined distances from anatomical landmarks. It is also important for researchers to acknowledge that venous diameters are likely to be variable as a result of changing venous compliance and stiffness in CVD. Additionally, the measurement of venous diameters is further challenged by the variability contributed by scanning technique (e.g., sitting vs. standing, inter-assessor reproducibility) and patient characteristics (e.g., time of day scanned, menstrual cycle, hydration). It is therefore likely that other haemodynamic parameters, such as reflux drainage patterns, may play a larger role in predicting clinical severity or HRQoL changes. Finally, the decision to treat CVD may also be influenced by complications that may develop in the absence of intervention. Therefore the relationship between truncal venous diameters and complication rates also should be characterised in future research.

In conclusion, truncal venous diameter is weakly correlated with clinical severity but has no relationship to patients' perceived impact of CVD and HRQoL scores. Its use as a surrogate measure to stratify patients for referral or treatment is currently unsuitable, particularly in patients without skin changes who have significant symptoms and reduced quality of life in the context of smaller vein diameters.

CONFLICT OF INTEREST

None.

FUNDING

None.

APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ejvs.2019.01.024>.

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