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University of Huddersfield.**ADMINISTRATIVE INFORMATION****Support** - University of Huddersfield.**Review Stage at time of this submission** - Completed but not published.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202560058**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 June 2025 and was last updated on 14 June 2025.**INTRODUCTION**

**Review question / Objective** To estimate the global prevalence of VLUs, both healed and active, alongside chronic venous diseases (CVDs) and chronic venous insufficiency (CVIs), and to explore differences by age, sex, and geographical region.

**Rationale** Chronic Venous Disease (CVD) is a prevalent condition characterised by impaired venous return, leading to a spectrum of symptoms, ranging from mild discomfort to severe complications such as venous leg ulcers (VLUs). VLUs represent the most advanced stage of chronic venous disease and impose a significant burden on individuals and healthcare systems. However, global prevalence estimates have been inconsistent due to variations in study designs and case definitions. This gap underscores the necessity for a systematic review and meta-analysis to assess the global prevalence of venous leg ulcers, as well as to provide country- and continent-specific estimates of the disease burden.

**Condition being studied** Global prevalence of chronic venous disease (CVD), chronic venous insufficiency (CVI) and venous leg ulcer (VLU), both healed and active.

**METHODS**

**Search strategy** The initial search was carried out on the following databases: PubMed, Google Scholar, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane Library and Scopus with the last update on 30th September 2023, adopting PRISMA guidelines. Bibliographic reference lists of all articles were also searched, and relevant studies were included and eligible for further evaluation. Search terms were applied including “venous leg ulcers”, “venous leg ulceration”, “leg ulcer”, “lower extremity ulcer”, “varicose ulcer”, “chronic wound”, “chronic venous insufficiency” or “chronic venous disorders” in combination with “prevalence” “epidemiology”, “epidemiological”, “incidence”, “occurrence” or “population” in the title, abstract or list of medical subjects heading terms.

**Participant or population** Population with any form of CVD, CVI or VLU.

**Intervention** Not applicable.

**Comparator** Not applicable.

**Study designs to be included** Studies that reported the prevalence of venous leg ulcers (VLUs) or explored regional differences in the prevalence of CVD, CVI and VLU across different stages (C0 to C6), as classified by the CEAP classification system.

**Eligibility criteria** We excluded all the studies belonging to the followings: (i) Systematic reviews, meta-analyses, conference presentations, and letters or correspondences, editorials, letters, case studies, case series, and animal studies were excluded; (ii) Studies regarding to pathophysiology, lifestyle approaches or interventions, and evaluations of clinical data were excluded; (iii) Studies report prevalence of VLUs in non-general population (nursing homes, hospitals, home care and care units); (iv) Studies report data of prevalence of leg ulcers that originate from mix-aetiology.

**Information sources** PubMed, Google Scholar, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane Library and Scopus.

**Main outcome(s)** To estimate the global prevalence of venous leg ulcers (VLUs), including both healed and active cases, as well as the prevalence of chronic venous diseases (CVDs) and chronic venous insufficiency (CVI), and to examine variations across different age groups, sexes, and geographical regions.

**Data management** The data were organised using Microsoft Excel and Microsoft Word, and stored using the OneDrive system on the University of Huddersfield server.

**Quality assessment / Risk of bias analysis** The quality of the eligible studies included in this systematic review was assessed using the Newcastle-Ottawa Quality Assessment Scale (NOS), which evaluates the studies based on three main criteria: selection, comparability, and outcome.

**Strategy of data synthesis** A meta-analysis of proportions was performed to pool the prevalence of venous leg ulcers (VLUs), as three or more eligible studies were available. The analysis was carried out using R software (version 4.1.2) with

the 'meta' and 'metafor' packages. Given the statistical heterogeneity among the studies, a random-effects model was applied.

**Subgroup analysis** Using the UN geoscheme and 2022 World Population Prospects, we estimated the number of people affected by CVDs, CVIs, and VLUs in each region by applying pooled prevalence rates to corresponding population data.

**Sensitivity analysis** Sensitivity analysis was performed by conducting separate subgroup analyses to assess the consistency of the findings across different eligible studies.

**Language restriction** No language restriction was imposed.

**Country(ies) involved** United Kingdom.

**Keywords** Global prevalence; Epidemiology; Chronic venous disease (CVD); Chronic venous insufficiency (CVI); Venous leg ulcer (VLU).

#### Contributions of each author

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