"Consensus Conference on Standardizing Terminology for Venous Leg Ulcers: Increasing Clarity and Communication in Clinical Practice"

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Significance: Establishing a standardized terminology via mixed research approach to enhance a better way to understand and describe chronic conditions and their related consequences, such as venous insufficiency and related Venous Leg Ulcers that are typically long-lasting and without a permanent cure, using an expert-based recommendation approach.

Recent Advances: A panel of experts have developed clinical questions using the PICO method. Literature review has been conducted for relevant documents using CINAHL via EBSCO and MEDLINE via PubMed. Two authors have independently scanned the literature retrieved for eligible documents, following GRADE guidelines for relevance. The eligible documents were included in an evidence synthesis form. A jury of sixteen experts voted on the formulated recommendations using the Delphi method, and a grade of strength was achieved for each recommendation in accordance with the GRADE methodology.

Critical Issues: Electronic search conducted retrieved 448 articles via all the clinical queries developed. The research strategy limits included randomised control trial (RCTs) and systematic reviews, not older than ten years, involving only human and written in English as the only language. Zero documents were pertinent to the purpose of this project after the screening. Six recommendations were developed; four of them were approved with strong agreement and two were weakly not recommended.

Future Directions: The findings highlight the need for the revision of certain terms used to describe epithelialized venous leg ulcers. This document aims to initiate a discourse, explicitly refraining from advocating the imposition of a new terminology in the field of the venous leg ulcers assessment and management upon the existing lexicon. Limits to our work have been elucidated within the manuscript.

Keywords: venous leg ulcers, remission, quiescence, consensus conference, assessment, and management, CEAP classification, sustained remission.

Scope and significance

Venous leg ulcers (VLUs) are the direct consequence of the underlying chronic venous disease (CVD) and venous hypertension[1]. Prevalence in general population is reported with 0.32%[2] and the outcomes are not always optimal despite an appropriate treatment. Furthermore, they may have a very slow trajectory and sometimes be resistant to several approaches[3].

After a venous ulcer is completely epithelialized, relapses are one of the most undesirable but very common results caused by the underlying disease, with recurrence rate of 70% within 3 months after healing[3] and an overall 70% in a period of 5 years[4].

Several strategies have been set out to prevent VLUs recurrences such as the surgical approach, the usage of a long-term compression via stockings or other compression garments[5], in a disease that will become a life-long problem and a challenge for patients and clinicians.

The terms used in scientific literature to describe an acute, chronic, and recurring disease can sometimes be inconsistent. The need to clarify this issue has been attempted in several studies for other diseases such as chronic obstructive pulmonary disease (COPD)[6], traumas in orthopaedic field[7], surveillance-based studies of sports injuries[8], with the aim of gaining a formal consensus on terminology.

Translation Relevance

Our evidence-based consensus conference aims to redefine/reconsider current terms used to describe an epithelialized VLU, with the aim to enhance clarity and communication in clinical practice. Based on describing chronic disease in other areas of medicine, we adopted the notion that the term "healed", for describing a repaired VLU, could be misleading due to the permanent underlying condition.

A build-on-purpose organization committee has formulated the hypothesis of employing alternative terminology to describe a reepithelialised VLU which could be more pertinent and relevant in raising awareness among patients and clinicians. Approximately 28% of patients with VLUs will experience 10 episodes of recurrence in their lifespan[9]. Therefore, due to the underlying chronic disease, the use of the term "healing" should be avoided, or at least a better term could be suggested to describe the perennial triad of ulceration, healing, and recurrence in a self-perpetuating cycle. Additional terms have been proposed and will be described in this paper.

Clinical relevance

Key treatment goal for a repaired VLU should be its definitive and permanent disappearance. However, as explained, "the healing" might be a very hard outcome to achieve in a long-term run. For this reason, a more appropriate term hypothesised by the committee could be "in remission".

Several other areas of medicine use the term remission to describe a dormant period in a chronic disease, such as: rheumatoid arthritis[10], cancers[11], psoriatic arthritis[12], inflammatory bowel disease[13], vasculitis[14] and even the cured diabetic foot ulcers[15]. The lack of standardized terminology in describing a recovered VLU and the related heterogeneity in the way it can be described, have prompted the committee to create six recommendations with the sole purpose of reducing conflicting opinions, enhancing clarity, and establishing uniform scientific lexicon.

Background

In May 2023 the International Centre for Wound Care Nursing (CINV) convened with the organization committee with the intention of exploring the need to redefine the entire realm associated with the inconsistent and contradictory terminology related to cured VLUs. An initial attempt to present this project was made in 2020 by two members of the committee via a preliminary literature review[16], which ultimately evolved into this formal consensus conference.

The approach used via an evidence-based recommendation consensus conference aims to provide sufficient granularity to answer specific questions:

- Is the term "healed" correct to describe a dormant period of an underlying chronic disease?
- Is the term "in remission" a better and more consistent way to describe an epithelialized VLU?
- Are there available criteria to define a "sustained remission"?
- Is there another ancillary term that can be used instead of "remission" such as "quiescence"?
- Should the fifth CEAP classification item be changed with "ulcer in remission" instead of "ulcer healed"?

These are the main evidence-based recommendations we developed in this project to be approved or rejected.

Method

This project is based on guidelines published in literature regarding the development of a consensus conference[17]. The main goal is to create evidence-based recommendations to enhance clarity in describing an epithelialized VLU and provide additional suggestions for setting criteria for better classification.

Two distinct phases were adopted in the project development: 1) issue identification, gap analysis in the literature, information retrieval/literature search, and recommendation creation; 2) voting process via Delphi method with an appointed jury and assignment of strength for each recommendation.

Phase 1)

Organization committee divided the research subject into three operational areas to be explored:

1) Definition and appropriateness of the terms healing, remission, and quiescence in describing epithelialized VLUs.

2) Development of criteria for "sustained remission" using two temporal frameworks.

3) Hypothesis of amending the fifth CEAP item.

The PICO[18] method was employed developing clinical queries and was voted on by the organization committee to assess the relevance of each clinical question. Two databases were explored: CINAHL via EBSCO and MEDLINE via PubMed using sensitive research technique.

Two members of the organisation committee independently screened all the abstract articles for pertinence, searching for any document to be included in the eligibility phase. None of the 448 articles were deemed relevant to the scope of our project.

Evidence summaries were prepared including all clinical questions, limits, and findings to be sent to the jury (1 - 2 - 3 - 4 - 5).

Six recommendations were discussed and formulated by the organization committee with the specific intention of avoiding any conflicts or equivocal terms.

Additional notes were added to the recommendations and the possibility to add comments during the voting phase was provided.

Phase 2)

A balanced multiprofessional and interdisciplinary jury consisting of 16 clinicians (vascular consultants, wound care nurses and one podiatrist), each with well-recognized experience in managing VLUs, was appointed.

All recommendations developed in accordance with the GRADE methodology were prepared with a Likert scale ranging from 1 (*Strongly NOT RECOMMENDED*) to 9 (*Strongly RECOMMENDED*) for the jurors to vote.

Median, Interquartile (IQR) and percentage of agreement were calculated for each recommendation.

The Likert scale was set up as follow:

1-2: SNR: Strongly NOT RECOMMENDED

3-4: WNR: Weakly NOT RECOMMENDED

5: U: Uncertain

6-7: WR: Weakly RECOMMENDED

8-9: SR: Strongly RECOMMENDED

Two rounds of Delphi were used during the voting process, with all names concealed to avoid biases.

After the first vote, a preliminary results file was sent to all jurors for a general overview and possible comments.

Discussion of findings and relevant literature

Appropriateness of terms healed, remission, and quiescence.

Rationale

Chronic Venous Disease (CVD) is a debilitating condition, and it is the result of inflammatory processes, venous hypertension, and insufficiency; the disease progression is primarily observed when the deep venous system is affected rather than the superficial[19]. Usually, another adjunctive classification can be added in the CVD such as 1) primary and 2) secondary, respectively when 1) there are non-thrombotic causes (functional problems in the valves) and when 2) there are obstructive and post-thrombotic causes (deep venous thrombosis DVT)[19].

Several risk factors can also be found as predisposing mechanisms for CVD such as: obesity, hormonal therapy, standing position, pregnancy[19].

VLUs are a direct consequence of the CVD, indicating that an underlying chronic disease is the real cause, leading to a cascade effect resulting in skin changes/ulceration and often a subsequent hard-to-heal wound. Furthermore, CVD is a progressive disease[20]. A risk assessment tool for predicting likelihood of venous leg ulcers recurrence has been developed and published in medical literature, reinforcing, and corroborating the concept of the inevitability of relapses[9].

Due to the high recurrence rate of VLUs caused by the underlying CVD, the term "healed", commonly used in clinical setting to describe the disappearance of a visible problem (the ulceration), can be misleading and not appropriate for describing a dormant and unresolved disease. Chronicity and long-lasting problems will not disappear even if the skin is completely epithelialized after a long period of ulcerations. Signs and symptoms

such as hemosiderin staining, lipodermatosclerosis and atrophie blanche, which are considered the last steps (CEAP 4b) before the ulceration breaks down, will persist for the rest of the patient's life and approximately 28% of patients will be experiencing 10 episodes of venous leg ulcerations during their entire lifespan[9].

Based on pragmatic evidence, a lack of comprehension regarding fundamental concepts of chronicity linked with CVD may result in the perception, among both patients and clinicians, that a successfully treated VLU represents a resolved issue rather than acknowledging it as a manifestation of an enduring chronic condition.

This is the reason that led the expert committee to consider the need to modify the term "healed" with a more pertinent one as per several areas of medicine have already successfully done, including the discipline of diabetic foot management. As stated by Prof. David Armstrong: "when people with diabetic foot ulcers heal, just like with cancer, they are not really healed. Our patients are in remission. We tend to think about wounds when they are open but why don't we think about them when they are closed?"[21].

Terminology is crucial in describing a problem, particularly in the medical field. A clear understanding of information both in the diagnostic and long-term management phases is essential for direct patient involvement. Conversely, misunderstanding medical information and incomprehension lead to anxiety and lack of involvement in the process of care[22].

The organization committee has therefore decided to create three recommendations regarding the appropriateness of terminology used to describe an epithelialized VLU having in mind that the term "healed" can be misleading and inappropriate as explained above, and that the term "in remission" can be more effective in defining a temporary resolved problem. Additionally, an ancillary term ("quiescence") was added instead of "in remission" to assess the jury's preference between the two.

RECOMMENDATION 1: *In patients with epithelialized venous leg ulcers, the use of the term "healed" should/must be avoided to describe the occurred tissue repair.* **Grade: Strongly Recommended.**

RECOMMENDATION 2: *In patients with epithelialized venous leg ulcers, the term "healed" must be avoided, and the use of the term "in remission" should/must be used to describe the occurred tissue repair.* **Grade: Strongly Recommended.**

RECOMMENDATION 3: *In patients with epithelialized venous leg ulcers, the term "quiescence" should/must be used instead of "in remission" as more appropriate to describe the occurred tissue repair.* **Grade: Weakly NOT Recommended.**

No. of Rec		Median IQR	Agreement	GRADE
1	*In patients with epithelialized venous leg ulcers, the use of the term "healed" should/must be avoided to describe the occurred tissue repair.*	**9** (IQR 1)	81,25%	**Strongly Recommended**
2	*In patients with epithelialized venous leg ulcers, the term "healed" must be avoided, and the use of the term "remission" should/must be used to describe the occurred tissue repair.*	**9** (IQR 1,25)	75%	**Strongly Recommended**
3	*In patients with epithelialized venous leg ulcers, the term "quiescence" should/must be used instead of "remission" as more appropriate to describe the occurred tissue repair.*	**4** (IQR 2)	50%	**Weakly NOT Recommended**

Table n.1

The first two recommendations have shown strong agreement in favour of changing the term "healed" to "in remission" for describing an epithelialized VLU. However, there was a weakly not recommended agreement for using the term "quiescence" instead of "in remission" in the third recommendation.

Development of "sustained remission" criteria

Rationale

Annual general cost for treating VLUs in UK per person is estimated to be approximately £ 4787.70 with a national cost of £102 million[23]. The average amount of visits received by patients from district nurse is of 1.9 per week with a time dedicated of 34.9 minutes, and the most expensive costs are associated with the community staff accounting for 70.9% of the total expenditure[23]. Being able to delay the recurrence of a VLU for a month will save 8% of community nursing time, as showed in one of the early studies published on this topic[24].

The percentage of VLUs relapse, as described previously in this article, is overwhelming and the ultimate treatment goal in managing VLUs should be a prolonged period of remission or a "sustained remission".

Based on the above-mentioned data, the organization committee has endeavoured to establish criteria for defining the concept of "sustained remission" in epithelialized VLUs. Sustained remission is a fundamental endpoint in management of VLUs as it indicates the long-term effectiveness of preventative interventions put in place and the ability of assessing long-term compression treatment outcomes.

Consistent and significant outcomes allow clinicians to measure and compare the efficacy/effectiveness of different treatments in reducing the recurrence of ulcerations; furthermore, they can be used in future creation of evidence-based guidelines.

Another fundamental aspect of this hypothesis was the importance of the patient education and engagement in managing a chronic condition proactively. The empowerment of the patient can lead to better compliance and more stable outcome improving quality of life.

Finally, it may help to improve the economic impact of preventing VLUs recurrences while evaluating the cost-effectiveness of the intervention.

In this area, we set two temporal criteria: 1) consolidated tissue repair for a period of at least 6 continuous months, 2) consolidated tissue repair for a period of at least 12 or more continuous months.

RECOMMENDATION 4a: *In patients with epithelialized venous leg ulcers, the term "sustained remission" should/must be used to describe the occurred tissue repair for a period of at least 6 continuous months.* **Grade: Weakly NOT Recommended**

RECOMMENDATION 4b: *In patients with epithelialized venous leg ulcers, the term "sustained remission" should/must be used to describe the occurred tissue repair for a period of at least 12 or more continuous months.* **Grade: Strongly Recommended**

No. of Rec		Median IQR	Agreement	GRADE
4a	*In patients with epithelialized venous leg ulcers, the term "sustained remission" should/must be used to describe the occurred tissue repair for a period of at least 6 continuous months.*	**4** (IQR 0)	59,375%	**Weakly NOT Recommended**
4b	*In patients with epithelialized venous leg ulcers, the term "sustained remission" should/must be used to describe the occurred tissue repair for a period of at least 12 or more continuous months.*	**9** (IQR 2)	65,625%	**Strongly Recommended**

Table n.2

Consensus among the panel indicates that for a VLU deemed to have achieved "sustained remission" a duration of 12 or more continuous months post-epithelialization should be the desirable requisite.

On the contrary, the criterion suggesting a 6-month period for sustained remission was considered to lack sufficient agreement.

Hypothesis of amending the fifth CEAP item

Rationale

CEAP classification is an internationally adopted standard for describing signs and clinical manifestations of venous disorder[25]. In 2020, an update of the CEAP was made by a CEAP Task Force created by the American Venous Forum during which they added the Corona Phlebectatica, introduced recurrent varicose veins and recurrent venous ulcers along with replacing numeric description of the venous segments by their common abbreviation[25]. See table n.4.

The organization committee has considered the hypothesis of amending the fifth item of the CEAP classification, currently labelled C5: "Healed"[25], to "in remission" as more appropriate term following the discussion occurred with the other previous recommendations.

An ad-hoc recommendation was created and added to the others:

RECOMMENDATION 5: *In patients with epithelialized venous leg ulcers, the fifth item of CEAP classification named "healed ulcer" should/must be changed with "ulcer in remission" as more appropriate to describe the occurred tissue repair.* **Grade: Strongly Recommended**

No. of Rec		Median IQR	Agreement	GRADE
5	*In patients with epithelialized venous leg ulcers, the fifth item of CEAP classification named "healed ulcer" should/must be changed with "ulcer in remission" as more appropriate to describe the occurred tissue repair.*	**9** (IQR 1)	93,74	**Strongly Recommended**

Table n.3

Among all the recommendations, the suggestion to change the fifth item received the highest level of support, with 93.74% agreement as can be seen in table above.

Adapted CEAP Classification[25]

C Class	Description
C0	No visible or palpable signs of venous disease
C1	Telangiectasias or reticular veins
C2	Varicose veins
C2r	Recurrent varicose veins
C3	Oedema
C4	Changes in skin and subcutaneous tissue secondary to CVD (Chronic Venous Disease)
C4a	Pigmentation or eczema
C4b	Lipodermatosclerosis or atrophie blanche

C4c	Corona Phlebectatica
C5	Healed
C6	Active venous ulcer
C6r	Recurrent active venous ulcer

Table n. 4

Future directions

VLUs are debilitating, typically chronic, and a recurrent disease that affect a large population and have a long-lasting duration ranging from several weeks to more than 10 years[26].

We have received some comments from jurors that we took into consideration, and we want to add for future discussion.

One juror stated that the term sustained remission should have a more thorough discussion on how to translate it in the clinical practice. An attempt to provide the rationale has been offered in the section: "Development of "sustained remission" criteria".

Another juror has underlined the hypothesis that amending the fifth item of CEAP classification could add confusion to the current scientific literature and has highlighted that there is a big debate on the endpoint to be used for an epithelialized VLU such as wound closure or healed.

Furthermore, an author suggested the need to divide patients with VLUs in two populations: a) "*population of patients who are fully mobile and have superficial +/- perforator vein reflux, with competent and unobstructed deep veins, who are then truly curable by surgical intervention"* b) "*population of patients who are not curable surgically due to a variety of factors – Ie: not being offered curative surgery, not being suitable for curative surgery (ie: deep venous disease that is unable to be corrected, immobile/poorly mobile."*

In accordance with another juror *"several terms are used to describe VLUs such "hard-to-heal" wounds or "well leg" when VLUs are epithelialized leading to misunderstanding the chronicity of a person underlying health status and vulnerability of recurrence".*

The main aim of this consensus conference is raising awareness about the need to use appropriate terms in the field of epithelialized VLUs, using common lexicon, making patients and clinicians more informed of the chronicity and progressivity of the CVD, and setting up common outcomes for preventing recurrences.

This project does not aim to modify the current CEAP classification, which we believe should be endorsed by the official vascular societies. Our intention is to offer an additional way of thinking and new perspectives about epithelialized VLUs for future analysis.

What emerges in this scientific project is the wide consensus on the need to avoid using the term "healed" for epithelialized VLUs and the strong agreement in using the term "in remission" instead.

Harmonizing terminology should ensure that all stakeholders (clinicians, researchers, or educators) use a common lexicon promoting and supporting clear communication. Moreover, patient care can be positively improved by reducing misinterpretation leading to more accurate patient monitoring in a long-term management. One of the cascade effects can be related to the enhanced research and clinical collaboration among the multidisciplinary teams streamlining the sharing of data, findings, and promoting best practices especially on targeted compression strategies to adopt to prevent VLUs relapse.

Clarity in documentations is another field of interest we considered, where the need to collect data requires a standardized terminology to simplify the process and implements quality standards and good practices.

Finally, patients and caregivers' education/perception of the problem can have a beneficial impact via dedicated educational materials to increase awareness about the condition, available treatment options and the importance of engagement in pro-active self-management of their disease.

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Authors disclosure and Ghostwriting

This article has been written by the organization committee and a draft of this paper was sent to each juror to collect additional notes and receive the definitive endorsement.

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