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Authors

Isseroff, Roslyn

Dahle, Sara

Link, Daniel

et al.

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Outcome of Surgical and Percutaneous Interventions to Treat Venous Leg Ulcers: A Single-Center Retrospective Study



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Julianne Rizzo, MS2

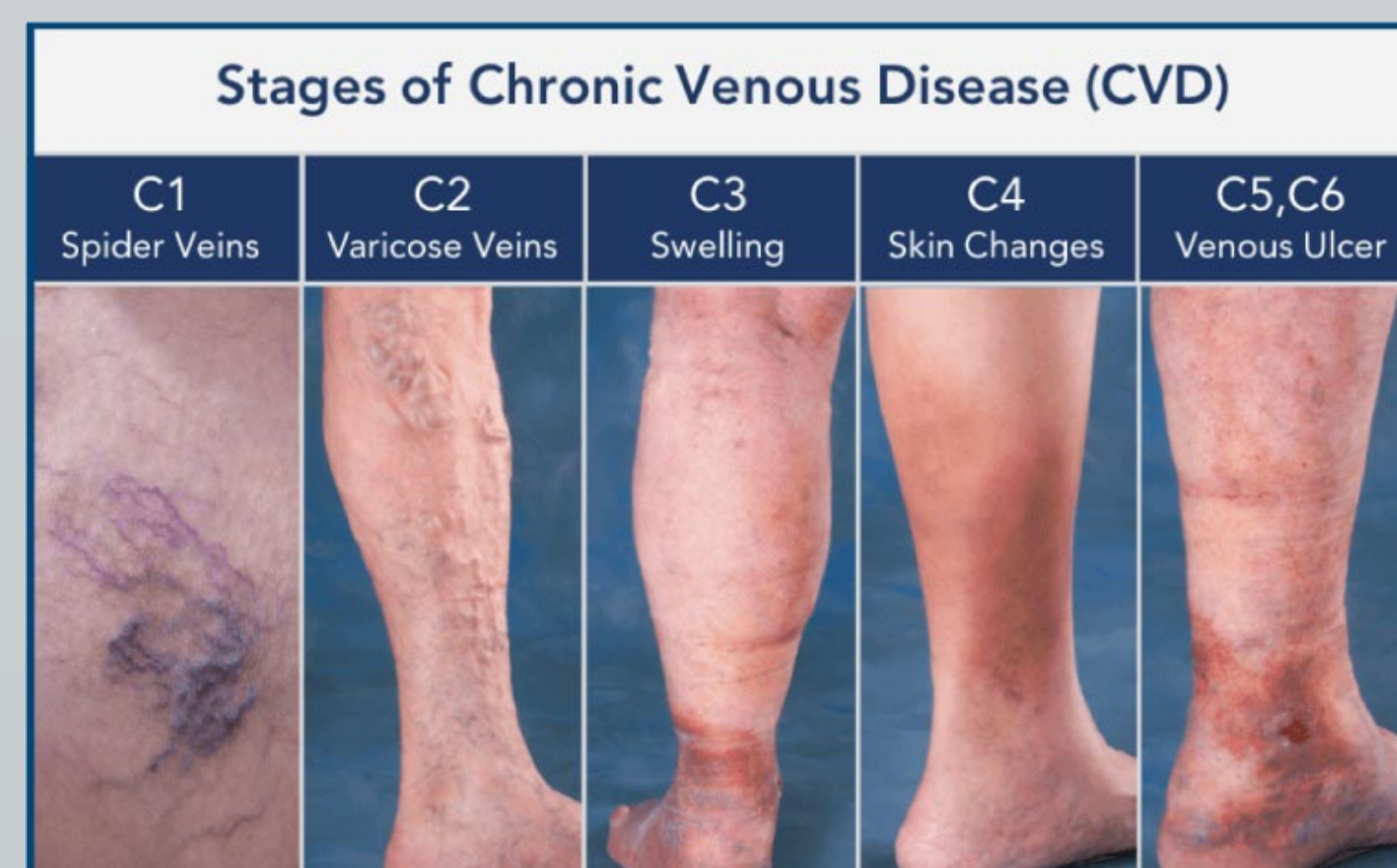
Roslyn Rivkah Isseroff, MD, Sara E. Dahle, DPM, Daniel Link, MD, Nasim Hedayati, MD, Ramanjot Kaur, MD, and Daniel Yoon, BS
University of California, Davis - School of Medicine & VA Northern California Health System - Mather

Background

Chronic wounds remain a serious burden in our health system, with limited therapeutic options available to improve healing. Approximately 2.5 million people experience chronic venous insufficiency (CVI) in the U.S. alone, of which 20% develop venous leg ulcers (VLU)¹. Venous leg ulcers (VLU) are among the most common etiologies of chronic wounds, accounting for approximately 70% of ulcers².

Pathophysiology of CVI:

The exact pathogenesis of chronic venous insufficiency is not yet fully understood, but can be classified by “reflux”, “obstruction”, or a combination of the two⁹. Venous reflux is hypothesized to be multifactorial, depending on location (superficial, deep, or perforating vascular systems)³ and is attributed to a number of mechanisms including valvular incompetence, inflammation of vessel wall, and failure of the calf muscle pump system⁴.



Diagnosis and Treatment:

Diagnostic tools used to diagnose CVI including ankle brachial index (ABI) tests, duplex ultrasound, and pulse oximetry^{5,6}.

Compression therapy is an effective and non-invasive mainstay standard of care in treating CVI⁷.

Percutaneous interventions are now recommended and include radiofrequency therapy, endovascular laser ablation, and ultrasound-guided foam sclerotherapy.

Though these procedures have been regarded as safe and minimally invasive, the use of catheters, particularly those that are chronic indwelling has been associated with risks such as sepsis and thrombosis⁸.

The risk of life-threatening complications of catheter-based therapy for VLU treatment is rare (1/1000000), but risk of ulceration from catheter use has not been evaluated.

It is possible that the puncturing of skin with a catheter may cause recurring ulceration in healing-impaired patients, especially those with underlying disease and susceptibility to chronic wounds.



Objectives

- 1) Explore the correlation(s) between catheter-based vascular intervention procedures for VLU treatment and ulceration.
- 2) Evaluate the efficacy of vascular intervention procedures.

Hypothesis

We hypothesize that 10% of patients will develop a secondary wound from the insertion site that undergoes percutaneous vascular intervention.

Study Design

Single-center, retrospective medical record review of patients who underwent venous percutaneous intervention(s) for the treatment of VLU between 2009 and 2019 at the VA Northern California Health Care System (VANCHS).

Patient charts will be screened and included in the study based on a limited chart review.

Inclusion criteria:

- 1) male or female subject of any race 18 years old or older
- 2) has had a venous leg ulcer or varicose veins
- 3) has received treatment with surgical or percutaneous vascular interventions for venous leg ulcers or venous insufficiency.

Exclusion criteria:

- 1) patient has a wound of non-venous etiology (i.e. arterial, burn trauma)
- 2) has medically documented history of HIV
- 3) is immunodeficient, as defined by serum IgG, IgA, and IgM less than one-half the lower limit of normal
- 4) is a prisoner, institutionalized individual, or part of any other vulnerable population as defined by the International Conference on Harmonization (ICH) Good Clinical Practices (GCP).

We anticipate there to be approximately 500 cases that underwent these vascular procedures in the last ten years.

After chart review, a total of 100 patients are anticipated to be needed for this review.

Future Implications

- Currently, there are no studies evaluating risks of cutaneous complications with catheter-based interventions for VLU treatment.
- Findings from this study will allow physicians to better estimate patient risk and outcome pertaining to catheter-based vascular intervention and VLU .
- If there is little or no correlation between the therapeutic interventions and ulceration at the site of catheter insertion, then a strong argument can be made promoting their continued use.
- Risks found in association with use of these interventions may lead to development of safer medical devices or procedures in the future.

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