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Management of Venous Leg Ulcers

Clinical Practice Guidelines of the Society for Vascular Surgery® and the American Venous Forum

Mosby
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SVS – AVF Clinical Practice Guidelines Venous Ulcer

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    - **Union Internationale de Phlébologie**

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SVS – AVF Clinical Practice Guidelines Methodology

- Target audience - specialists who treat vascular disease and/or wounds.
- Methodology
  - Subcommittee Structure
    - Clinical Evaluation
    - Wound Care
    - Compression
    - Surgery
    - Ancillary
    - Primary Prevention:
  - Evidence Review
  - Recommendations
  - GRADE – strength of recommendation / level of evidence
  - Knowledge and Evaluations Research Unit at the Mayo Clinic, Rochester MN
    - Corroborate proper strength of evidence and quality of evidence for each guideline
    - Commissioned for systematic review: surgery/endovascular and compression

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Grade	Description of Recommendation	Benefit vs Risk	Methodological Quality of Supporting Evidence	Implications
1A	Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs without important limitations or overwhelming evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1B	Strong recommendation, moderate quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational	Strong recommendation, can apply to most patients in most circumstances without reservation
1C	Strong recommendation, quality or very low-qualit evidence			
2A	Weak recommendation, h quality evidence			
2B	Weak recommendation, moderate-quality evidence	with risks and burdens	(inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	depending on circumstances or patients' or societal values
2C	Weak recommendation, low-quality or very low-quality evidence	Uncertainty in the estimates of benefits and risk, and burdens; Risk, benefit, and burdens may be closely balanced	Observational studies or case series	Very weak recommendations; Other alternatives may be reasonable

[BEST PRACTICE]

- Recommendation deemed necessary to provide a comprehensive guideline that encompasses all the details needed for providing care for patients with venous ulcers
- When there are no comparable alternatives to a recommendation, or evidence is lacking
- Case series supplemented by the best opinion of a panel of experts

SVS – AVF Clinical Practice Guidelines Definition – Venous Ulcer

- **<u>Guideline 1.1</u>: <u>Venous Leg Ulcer Definition</u>**

We suggest use of a standard definition of venous ulcer as an open skin lesion of the leg or foot that occurs in an area affected by venous hypertension. [BEST PRACTICE]

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SVS – AVF Clinical Practice Guidelines Anatomy - Pathophysiology

- **Guideline 2.1: Venous Anatomy Nomenclature**

We recommend use of the International Consensus Committee on Venous Anatomical Terminology for standardized venous anatomy nomenclature. [BEST PRACTICE]

- **Guideline 2.2: Venous Leg Ulcer Pathophysiology**

We recommend a basic practical knowledge of venous physiology and venous leg ulcer pathophysiology for all practitioners caring for venous leg ulcers. [BEST PRACTICE]

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Table II. The International Consensus Committee on Venous Anatomical Terminology for standardized venous anatomy nomenclature of the leg

Superficial venous system	*Deep venous system*	*Perforating venous system*
Superficial inguinal veins	Common femoral vein	Gluteal perforators
External pudendal vein	Femoral vein	Superior gluteal
Superficial circumflex iliac vein	Deep femoral vein	Midgluteal
Superficial epigastric vein	Medial circumflex femoral vein	Lower gluteal
Superficial dorsal vein (clitoris/penis)	Lateral circumflex femoral vein	Thigh perforators
Anterior labial veins	Deep femoral communicating veins	Medial thigh
Anterior scrotal veins	Sciatic vein	Femoral canal
Great saphenous vein	Popliteal vein	Inguinal
Saphenofemoral junction	Genicular venous plexus	Anterior thigh
Terminal valve	Anterior tibial veins	Lateral thigh
Preterminal valve	Posterior tibial veins	Posterior thigh
Anterior accessory great saphenous vein	Fibular or peroneal veins	Posteromedial
Posterior accessory great saphenous vein	Sural veins	Sciatic
Superficial accessory great saphenous vein	Soleal veins	Posterolateral
Anterior thigh circumflex vein	Gastrocnemius veins	Pudendal
Posterior thigh circumflex vein	Medial	Knee perforators
Small saphenous vein	Lateral	Medial knee
Saphenopopliteal junction	Intergemellar	Suprapatellar
Terminal valve	Medial plantar veins	Lateral knee
Preterminal valve	Lateral plantar veins	Infrapatellar
Cranial extension of small saphenous vein	Deep plantar venous arch	Popliteal fossa
Superficial accessory small saphenous vein	Deep metatarsal veins (plantar/dorsal)	Leg (calf) perforators
Intersaphenous veins	Deep digital veins (plantar/dorsal)	Medial leg
Lateral venous system	Pedal vein	Paratibial
Dorsal venous network of the foot		Posterior tibial
Dorsal venous arch of the foot		Anterior leg
Superficial metatarsal veins (dorsal/plantar)		Lateral leg
Plantar venous subcutaneous network		Posterior leg
Superficial digital veins (dorsal/plantar)		Medial gastrocnemius
Lateral marginal vein		Lateral gastrocnemius
Medial marginal vein		Intergemellar
		Para-achillean
		Ankle perforators
		Medial ankle
		Anterior ankle
		Lateral ankle
		Foot perforators
		Dorsal foot
		Medial foot
		Lateral foot
		Plantar foot

Modified from Caggiati A, Bergan JJ, Gloviczki P, Eklof B, Allegra C, Partsch H. Nomenclature of the veins of the lower limb: Extensions, refinements, and clinical application J Vasc Surg 2005;41:719-24.

Table III. The International Consensus Committee on Venous Anatomical Terminology for standardized venous anatomy nomenclature of the pelvis

Main collector	*Draining veins*	*Plexus and peripheral veins*
Inferior vena cava	Ovarian/testicular veins	Pampiniform plexus
Common iliac vein	Median sacral vein Iliolumbar vein Internal iliac (hypogastric) External iliac	Sacral venous plexus
Inferior mesenteric vein	Superior rectal vein Middle rectal vein Inferior rectal vein Superior gluteal vein Inferior gluteal vein Lateral sacral vein	External rectal plexus Internal rectal plexus
Internal iliac vein	Internal pudendal vein Obturator veins Vesical veins Uterine veins Vaginal veins	Deep perineal veins Superficial perineal veins Deep dorsal veins of clitoris/penis Deep veins of clitoris/penis Urethral bulb veins Pudendal plexus Vesical/prostatic plexus Uterine plexus Vein of the broad ligament Vaginal plexus
External iliac vein	Pubic veins (accessory obturator veins) Sovrapubic veins Inferior epigastric vein Deep circumflex iliac vein	

Modified from Caggiati A, Bergan JJ, Gloviczki P, Eklof B, Allegra C, Partsch H. Nomenclature of the veins of the lower limb: Extensions, refinements, and clinical application J Vasc Surg 2005;41:719-24.

SVS – AVF Clinical Practice Guidelines Clinical Evaluation

- **Guideline 3.1: Clinical Evaluation**

We recommend that for all patients with suspected leg ulcers fitting the definition of venous leg ulcer, clinical evaluation for evidence of chronic venous disease be performed. [BEST PRACTICE]

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SVS – AVF Clinical Practice Guidelines
Clinical Evaluation

- **Guideline 3.2: Nonvenous Causes Leg Ulcers**

We recommend identification of medical conditions that affect ulcer healing and other non-venous causes of ulcers. [BEST PRACTICE]

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Table IV. Differential diagnosis for leg ulcers

Vascular disease
- Venous: post-thrombotic syndrome, varicose veins, chronic venous reflux
- Arterial: peripheral arterial occlusive disease, hypertension, arteriovenous fistulas, arterial thrombosis, embolism, dysplasia, thromboangiitis obliterans, aneurysm
- Lymphatic: lymphedema
- Microangiopathy: diabetes mellitus, livedoid vasculopathy
- Vasculitis
- Hypertensive arteriolopathy

Neuropathic
- Peripheral neuropathy: diabetes mellitus, alcohol, medication, hereditary
- Central neuropathy: tabes dorsalis, myelodysplasia, syringomyelia, spina bifida, poliomyelitis, multiple sclerosis

Metabolic
- Diabetes mellitus, gout, prolidase deficiency, Gaucher disease, amyloidosis, calciphylaxis, porphyria, hyperhomocysteinemia

Hematologic
- Sickle cell anemia, thalassemia, polycythemia vera, leukemia, thrombocythemia, lymphoma, myeloplastic disorders, disorders of coagulation factors (factors I-XIII), coagulation inhibitors (antithrombin III, activated protein C resistance, protein C and S), or fibrinolysis factors (tissue plasminogen activator, plasminogen activator inhibitor, plasmin)

Autoimmune
- Rheumatoid arthritis, leukocytoclastic vasculitis, polyarteritis nodosa, Wegener granulomatosis, Churg-Strauss syndrome, systemic lupus erythematosus, Sjögren syndrome, scleroderma, Behçet disease, cryoglobulinemia

Exogenous
- Heat, cold, pressure, ionizing radiation, chemical, allergens, trauma

Neoplasia
- Basal cell carcinoma, squamous cell carcinoma (Marjolin ulcer), malignant melanoma, angiosarcoma, cutaneous lymphoma, papillomatosis cutis carcinoides, keratoacanthoma

Infection
- Bacterial: furuncles, ecthyma, mycobacterioses, syphilis, erysipelas, anthrax, diphtheria, chronic vegetative pyodermia, tropical ulcer
- Viral: herpes, variola virus, cytomegaly
- Fungal: sporotrichosis, histoplasmosis, blastomycosis, coccidioidomycosis
- Protozoal: leishmaniasis

Medication
- Hydroxyurea, leflunomide, methotrexate, halogens, coumarin, vaccinations, ergotamine, infiltration cytostatic agents

Genetic defect
- Klinefelter syndrome, Felty syndrome, TAP1 mutation, leukocyte adhesion deficiency, inherited hypercoagulable factors

Skin disorder
- Pyoderma gangrenosum, necrobiosis lipoidica, sarcoidosis, perforating dermatosis, Langerhans cell histiocytosis, papulosis maligna atrophicans, bullous skin diseases

Modified from Dissemond J, Korber A, Grabbe S. Differential diagnosis of leg ulcers. J Dtsch Dermatol Ges 2006;4:627-34.

SVS – AVF Clinical Practice Guidelines Clinical Evaluation - Wound

- **Guideline 3.3: Wound Documentation**

We recommend serial venous leg ulcer wound measurement and documentation. [BEST PRACTICE]

- **Guideline 3.4: Wound Culture**

We suggest against routine culture of venous leg ulcers and to only obtain wound cultures when clinical evidence of infection is present. [GRADE - 2; LEVEL OF EVIDENCE - C]

- **Guideline 3.5: Wound Biopsy**

We recommend wound biopsy for venous leg ulcers that do not improve with standard wound and compression therapy after 4-6 weeks of treatment and for all ulcers with atypical features. [GRADE -1 ; LEVEL OF EVIDENCE - C]

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SVS – AVF Clinical Practice Guidelines Clinical Evaluation - Arterial

- **Guideline 3.7: Arterial Testing**

We recommend arterial pulse examination and measurement of ankle brachial index (ABI) on all patients with venous leg ulcer. [GRADE -1; LEVEL OF EVIDENCE -B]

- **Guideline 3.8: Microcirculation Assessment**

We suggest against routine microcirculation assessment of venous leg ulcers, but suggest selective consideration as an adjunctive assessment for monitoring of advanced wound therapy. [GRADE -2; LEVEL OF EVIDENCE -C]

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SVS – AVF Clinical Practice Guidelines Clinical Evaluation – Venous Imaging

- **Guideline 3.9: Venous Duplex Ultrasound**

We recommend comprehensive venous duplex ultrasound examination of the lower extremity in all patients with suspected venous leg ulcer. [GRADE -1 ; LEVEL OF EVIDENCE -B]

- **Guideline 3.10: Venous Plethysmography**

We suggest selective use of venous plethysmography in the evaluation of patients with suspected venous leg ulcer if venous duplex ultrasound does not provided definitive diagnostic information. [GRADE -2; LEVEL OF EVIDENCE -B]

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SVS – AVF Clinical Practice Guidelines Clinical Evaluation – Venous Imaging

- **Guideline 3.11: Venous Imaging**

We suggest selective computed tomography venography, magnetic resonance venography, contrast venography, and/or intravascular ultrasound in patients with suspected venous leg ulceration if additional advanced venous diagnosis is required for thrombotic or non-thrombotic iliac vein obstruction, or for operative planning prior to open or endovenous venous interventions. [GRADE -2; LEVEL OF EVIDENCE - C]

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SVS – AVF Clinical Practice Guidelines Clinical Evaluation – Classification

- **Guideline 3.12: Venous Disease Classification**

We recommend that all patients with venous leg ulcer should be classified based on venous disease classification assessment including clinical CEAP, revised venous clinical severity scoring (VCSS), and venous disease specific quality of life (QOL) assessment. [BEST PRACTICE]

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Table V. Basic CEAP classification system

Clinical classification	
	C0 No visible or palpable signs of venous disease
	C1 Telangiectases or reticular veins
	C2 Varicose veins
	C3 Edema
	C4a Pigmentation and/or eczema
	C4b Lipodermatosclerosis and/or atrophie blanche
	C5 Healed venous ulcer
	C6 Active venous ulcer
	CS Symptoms, including ache, pain, tightness, skin irritation, heaviness, muscle cramps, as well as other complaints attributable to venous dysfunction
	CA Asymptomatic
Etiologic classification	
	Ec Congenital
	Ep Primary
	Es Secondary (post-thrombotic)
	En No venous etiology identified
Anatomic classification	
	As Superficial veins
	Ap Perforator veins
	Ad Deep veins
	An No venous location identified
Pathophysiologic classification	
	Pr Reflux
	Po Obstruction
	Pr,o Reflux and obstruction
	Pn No venous pathophysiology identifiable

Modified from Eklöf B, Rutherford RB, Bergan JJ, Carpentier PH, Gloviczki P, Kistner RL, et al. Revision of the CEAP classification for chronic venous disorders: Consensus statement. J Vasc Surg 2004;40:1248-52.

Table VI. Revised Venous Clinical Severity Scoring (VCSS) system

	None: 0	*Mild: 1*	*Moderate: 2*	*Severe: 3*
Pain or other discomfort (ie, aching, heaviness, fatigue, soreness, burning) Presumes venous origin		Occasional pain or other discomfort (ie, not restricting regular daily activities)	Daily pain or other discomfort (ie, interfering with but not preventing regular daily activities)	Daily pain or discomfort (ie, limits most regular daily activities)
Varicose veins "Varicose" veins must be ≥3 mm in diameter to qualify in the standing position		Few: scattered (ie, isolated branch varicosities or clusters) Also includes corona phlebectatica (ankle flare)	Confined to calf or thigh	Involves calf and thigh
Venous edema Presumes venous origin		Limited to foot and ankle area	Extends above ankle but below knee	Extends to knee and above
Skin pigmentation Presumes venous origin Does not include focal pigmentation over varicose veins or pigmentation due to other chronic diseases	None or focal	Limited to perimalleolar area	Diffuse over lower third of calf	Wider distribution above lower third of calf
Inflammation More than just recent pigmentation (ie, erythema, cellulitis, venous eczema, dermatitis)		Limited to perimalleolar area	Diffuse over lower third of calf	Wider distribution above lower third of calf
Induration Presumes venous origin of secondary skin and subcutaneous changes (ie, chronic edema with fibrosis, hypodermitis). Includes white atrophy and lipodermatosclerosis		Limited to perimalleolar area	Diffuse over lower third of calf	Wider distribution above lower third of calf
Active ulcer number	0	1	2	≥3
Active ulcer duration (longest active)	N/A	<3 mo	>3 mo but <1 y	Not healed for >1 y
Active ulcer size (largest active)	N/A	Diameter <2 cm	Diameter 2-6 cm	Diameter >6 cm
Use of compression therapy	0 Not used	1 Intermittent use of stockings	2 Wears stockings most days	3 Full compliance: stockings

Modified from Vasquez MA, Rabe E, McLafferty RB, Shortell CK, Marston WA, Gillespie D, et al. Revision of the venous clinical severity score: Venous outcomes consensus statement: Special communication of the American Venous Forum Ad Hoc Outcomes Working Group. J Vasc Surg 2010;52:1387-96.

Table VII. Villalta scoring for post-thrombotic syndrome

Symptoms and clinical signs	*None*	*Mild*	*Moderate*	*Severe*
Symptoms				
Pain	0	1	2	3
Cramps	0	1	2	3
Heaviness	0	1	2	3
Paresthesia	0	1	2	3
Pruritus	0	1	2	3
Clinical signs				
Pretibial edema	0	1	2	3
Skin induration	0	1	2	3
Hyperpigmentation	0	1	2	3
Redness	0	1	2	3
Venous ectasia	0	1	2	3
Pain on calf compression	0	1	2	3
Venous ulcer	Absent			Present

Villalta score ≥5 or if venous ulcer present: Villalta score of 5-9 mild, 10-14 moderate, and ≥15 severe.

Modified from Villalta S, Bagatella P, Piccioli A, Lensing AW, Prins MH, Prandoni P. Assessment of validity and reproducibility of a clinical scale for the postthrombotic syndrome [abstract]. Haemostasis 1994;24:158a.

SVS – AVF Clinical Practice Guidelines Clinical Evaluation – Venous Outcomes

- **Guideline 3.13: Venous Procedural Outcome Assessment**

We recommend venous procedural outcome assessment including reporting of anatomic success, venous hemodyamic success, procedure-related minor and major complications, and impact on venous leg ulcer healing. [BEST PRACTICE]

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Wound Care - Categories

Wound bed preparation
- Wound cleansers
- Debridement
- Surgical debridement
- Anesthesia for debridement
- Hydrosurgical debridement
- Ultrasonic debridement
- Enzymatic debridement
- Biologic debridement
- Nutritional assessment and management
- Measurement of wound progress

Wound infection and bacterial control
- Wound culture
- Indications for culture
- Method of wound culture
- Management of limb cellulitis
- Wound colonization and bacterial biofilms
- Treatment of wound infection
- Topical antibiotics
- Systemic antibiotics

Primary wound dressings
- Topical dressing selection
- Antimicrobials in topical dressings
- Peri-ulcer skin management
- Anti-inflammatory dressings

Adjunctive wound therapies
- Indications for adjunctive therapies
- Split-thickness skin grafting
- Cellular Therapy
- Use of cellular therapy
- Preparation for cellular therapy
- Frequency of cellular therapy application
- Negative pressure therapy
- Electrical stimulation
- Ultrasound therapy

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SVS – AVF Clinical Practice Guidelines Wound Care - Cleansers

- **Guideline 4.1: Wound Cleansers**

We suggest that venous leg ulcers be cleansed initially and at each dressing change using a neutral, nonirritating, nontoxic solution, performed with a minimum of chemical or mechanical trauma. [GRADE -2; LEVEL OF EVIDENCE -C]

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SVS – AVF Clinical Practice Guidelines Wound Care - Debridement

- **Guideline 4.2: Debridement**

We recommend that venous leg ulcers receive thorough debridement at their initial evaluation to remove obvious necrotic tissue, excessive bacterial burden, and cellular burden of dead and senescent cells. [GRADE -1; LEVEL OF EVIDENCE -B] We suggest additional maintenance debridement be performed to maintain the appearance and readiness of the wound bed for healing. [GRADE -2; LEVEL OF EVIDENCE -B] We suggest that the health care provider choose from a number of debridement methods including sharp, enzymatic, mechanical, biological, or autolytic. More than one debridement method may be appropriate. [GRADE -2; LEVEL OF EVIDENCE -B]

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SVS – AVF Clinical Practice Guidelines Wound Care - Debridement

- **Guideline 4.3: Anesthesia for Surgical Debridement**

We recommend that local anesthesia (topical or local injection) be administered to minimize discomfort associated with surgical venous leg ulcer debridement. In selected cases, regional block or general anesthesia may be required. [GRADE -1; LEVEL OF EVIDENCE -B]

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- **Guideline 4.4: Surgical Debridement**

We recommend that surgical debridement be performed for venous leg ulcers with slough, non-viable tissue or eschar. Serial wound assessment is important in determining the need for repeat debridement(s). [GRADE -1; LEVEL OF EVIDENCE -B]

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- **Guideline 4.5 Hydrosurgical Debridement**

We suggest hydrosurgical debridement as an alternative to standard surgical debridement of venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE -B]

- **Guideline 4.6: Ultrasonic Debridement**

We suggest against ultrasonic debridement over surgical debridement in the treatment of venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE -C]

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- **Guideline 4.7: Enzymatic Debridement**

We suggest enzymatic debridement of venous leg ulcers when no clinician trained in surgical debridement is available to debride the wound. [GRADE -2; LEVEL OF EVIDENCE -C] We do not suggest enzymatic debridement over surgical debridement. [GRADE -2; LEVEL OF EVIDENCE -C]

- **Guideline 4.8: Biologic Debridement**

We suggest larval therapy for venous leg ulcers can be used as an alternative to surgical debridement. [GRADE -2; LEVEL OF EVIDENCE -B]

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SVS – AVF Clinical Practice Guidelines Wound - Infection

- **Guideline 4.9: Management of Limb Cellulitis**

We recommend that cellulitis (inflammation and infection of the skin and subcutaneous tissue) surrounding the venous leg ulcer be treated with systemic gram-positive antibiotics. [GRADE -1; LEVEL OF EVIDENCE -B]

- **Guideline 4.10: Wound Colonization and Bacterial Biofilms**

We suggest against systemic antimicrobial treatment of venous leg ulcer colonization or biofilm without clinical evidence of infection. [GRADE -2; LEVEL OF EVIDENCE -C]

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SVS – AVF Clinical Practice Guidelines Wound - Infection

- **Guideline 4.11: Treatment of Wound Infection:**

We suggest that venous leg ulcers with >1x10^6 CFU/g of tissue and clinical evidence of infection should be treated with antimicrobial therapy. [GRADE -2; LEVEL OF EVIDENCE – C] We suggest antimicrobial therapy for virulent or difficult to eradicate bacteria (such as beta hemolytic streptococci, pseudomonas, and resistant staphylococal species) at lower levels of CFU/g of tissue. [GRADE -2; LEVEL OF EVIDENCE – C] We suggest a combination of mechanical disruption and antibiotic therapy as most likely to be successful in eradicating venous leg ulcer infection. [GRADE -2; LEVEL OF EVIDENCE – C]

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SVS – AVF Clinical Practice Guidelines Wound Care - Infection

- **Guideline 4.12: Systemic Antibiotics**

We recommend that venous leg ulcers with clinical evidence of infection be treated with systemic antibiotics guided by sensitivities performed on wound culture. [GRADE -1; LEVEL OF EVIDENCE -C] Oral antibiotics are preferred initially and the duration of antibiotic therapy should be limited to 2 weeks unless persistent evidence of wound infection is present. [GRADE -1; LEVEL OF EVIDENCE -C]

- **Guideline 4.13: Topical Antibiotics for Infected Wounds**

We suggest against using topical antimicrobials agents for the treatment of infected venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE – C]

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SVS – AVF Clinical Practice Guidelines Wound Care - Dressings

- **Guideline 4.14: Topical Dressing Selection**

We suggest applying a topical dressing that will manage venous leg ulcer exudate and maintain a moist warm wound bed. [GRADE -2; LEVEL OF EVIDENCE -C] We suggest selection of a primary wound dressing that will absorb wound exudate produced by the ulcer (alginates, foams) and protect the peri-ulcer skin. [GRADE -2; LEVEL OF EVIDENCE -B]

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SVS – AVF Clinical Practice Guidelines Wound Care - Dressings

- **Guideline 4.15: Topical Dressings Containing Antimicrobials**

We recommend against the routine use of topical antimicrobial containing dressings in the treatment of non-infected venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE -A]

- **Guideline 4.16: Peri-Ulcer Skin Management**

We suggest application of skin lubricants underneath compression in order to reduce dermatitis that commonly affects peri-ulcer skin. [GRADE -2; LEVEL OF EVIDENCE -C] In severe cases of dermatitis associated with venous leg ulcers, we suggest topical steroids to reduce the development of secondary ulcerations and to reduce the symptoms of dermatitis. [GRADE -2; LEVEL OF EVIDENCE -C]

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SVS – AVF Clinical Practice Guidelines Wound Care – Anti-inflammatory

- **Guideline 4.17: Anti-Inflammatory Therapies**

We suggest against using anti-inflammatory therapies for the treatment of venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE -C]

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SVS – AVF Clinical Practice Guidelines Wound Care – Adjuvant Therapy

- **Guideline 4.18: Indications for Adjuvant Therapies**

We recommend adjuvant wound therapy options for venous leg ulcers that fail to demonstrate improvement after a minimum of 4-6 weeks standard wound therapy. [GRADE -1; LEVEL OF EVIDENCE -B]

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SVS – AVF Clinical Practice Guidelines Wound Care – Skin Graft

- **<u>Guideline 4.19:</u> <u>Split Thickness Skin Grafting</u>**

We suggest against split thickness skin grafting as primary therapy in treatment of venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE -B] We suggest split thickness skin grafting with continued compression for selected large venous leg ulcers that have failed to show signs of healing with standard care for 4-6 weeks. [GRADE -2; LEVEL OF EVIDENCE -B]

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SVS – AVF Clinical Practice Guidelines Wound Care – Cellular Therapy

- **Guideline 4.20: Cellular Therapy**

We suggest the use of cultured allogeneic bilayer skin replacements (with both epidermal and dermal layers) to increase the chances for healing patients in patients with difficult to heal venous leg ulcers in addition to compression therapy in patients that have failed to show signs of healing after standard therapy for 4-6 weeks. [GRADE -2; LEVEL OF EVIDENCE -A]

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SVS – AVF Clinical Practice Guidelines Wound Care – Cellular Therapy

- **Guideline 4.21: Preparation for Cellular Therapy**

We suggest a therapeutic trial of appropriate compression and wound bed moisture control prior to application of cellular therapy. [GRADE -2; LEVEL OF EVIDENCE -C] We recommend that prior to the application of a bilayered cellular graft that adequate wound bed preparation be completed including complete removal of slough, debris and any necrotic tissue. [GRADE -1; LEVEL OF EVIDENCE -C] We recommend additional evaluation and management of increased bio-burden levels prior to the application of cellular therapy. [GRADE -1; LEVEL OF EVIDENCE -C]

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- **Guideline 4.22: Frequency of Cellular Therapy Application**

We suggest re-application of cellular therapy as long as the venous leg ulcer continues to respond based on wound documentation. [GRADE -2; LEVEL OF EVIDENCE -C]

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SVS – AVF Clinical Practice Guidelines Wound Care – Tissue Substitutes

- **Guideline 4.23: Tissue Matrices, Human Tissues or Other Skin Substitutes**

We suggest the use of a porcine small intestinal submucosal tissue construct in addition to compression therapy for the treatment of venous leg ulcers that have failed failed to show signs of healing after standard therapy for 4-6 weeks. . [Grade 2; Level of Evidence – B]

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SVS – AVF Clinical Practice Guidelines Wound Care – Additional Therapy

- **Guideline 4.24: Negative Pressure Therapy**

We suggest against routine primary use of negative pressure wound therapy for venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE -C]

- **Guideline 4.25: Electrical Stimulation**

We suggest against electrical stimulation therapy for venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE -C]

- **Guideline 4.26: Ultrasound Therapy**

We suggest against routine ultrasound therapy for venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE -B]

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SVS – AVF Clinical Practice Guidelines Compression – Healing/Recurrence

- **Guideline 5.1: Compression – Ulcer Healing**

In a patient with a venous leg ulcer, we recommend compression therapy over no compression therapy to increase venous leg ulcer healing rate. [GRADE -1; LEVEL OF EVIDENCE -A]

- **Guideline 5.2: Compression – Ulcer Recurrence**

In a patient with a healed venous leg ulcer, we suggest compression therapy to decrease the risk of ulcer recurrence.

[GRADE -2; LEVEL OF EVIDENCE -B]

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SVS – AVF Clinical Practice Guidelines Compression – Multi-Component

- **Guideline 5.3: Multi-Component Compression Bandage**

We suggest the use of multi-component compression bandage over single component bandages for the treatment of venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE -B]

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SVS – AVF Clinical Practice Guidelines Compression – Arterial Insufficiency

- **Guideline 5.4: Compression – Arterial Insufficiency**

In a patient with a venous leg ulcer and underlying arterial disease, we do not suggest compression bandages or stockings if ABI is 0.5 or less or if absolute ankle pressure is less than 60mmHg. [GRADE -2; LEVEL OF EVIDENCE -C]

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SVS – AVF Clinical Practice Guidelines Compression – Intermittent Pneumatic

- **Guideline 5.5: Intermittent Pneumatic Compression**

We suggest using intermittent pneumatic compression (IPC) when other compression options are not available, cannot be used, or have failed to aid in venous leg ulcer healing after prolonged compression therapy. [GRADE - 2; LEVEL OF EVIDENCE -C]

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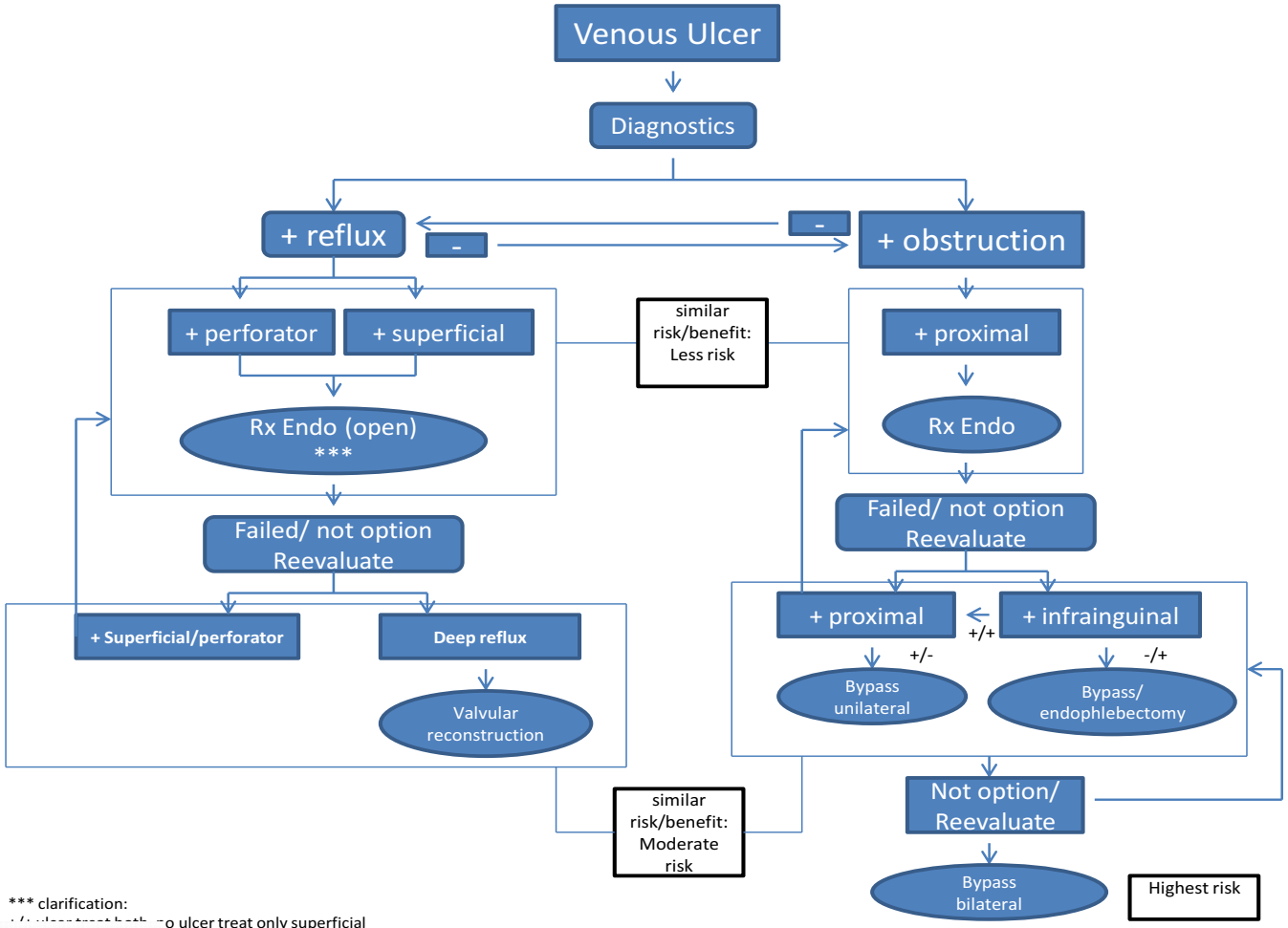

*** clarification:
+/- ulcer treat both – o ulcer treat only superficial

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SVS – AVF Clinical Practice Guidelines Operative / Endovascular - Superficial

- **Guideline 6.1 Superficial Venous Reflux and Active Venous Leg Ulcer – Ulcer Healing**

In a patient with a venous leg ulcer (C6) and incompetent superficial veins that have axial reflux directed to the bed of the ulcer, we suggest ablation of the incompetent veins in addition to standard compressive therapy to improve ulcer healing. [GRADE -2; LEVEL OF EVIDENCE -C]

- **Guideline 6.2 Superficial Venous Reflux and Active Venous Leg Ulcer – Prevent Recurrence**

In a patient with a venous leg ulcer (C6) and incompetent superficial veins that have axial reflux directed to the bed of the ulcer, we recommend ablation of the incompetent veins in addition to standard compressive therapy to prevent recurrence. [GRADE -1; LEVEL OF EVIDENCE-B]

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- **Guideline 6.3 Superficial Venous Reflux and Healed Venous Leg Ulcer**

In a patient with a healed venous leg ulcer (C5) and incompetent superficial veins that have axial reflux directed to the bed of the ulcer, we recommend ablation of the incompetent veins in addition to standard compressive therapy to prevent recurrence. [GRADE -1; LEVEL OF EVIDENCE -C]

- **Guideline 6.4: Superficial Venous Reflux with Skin Changes at Risk for Venous Leg Ulcer (C4b):**

In a patient with skin changes at risk for venous leg ulcer (C4b) and incompetent superficial veins that have axial reflux directed to the bed of the affected skin, we suggest ablation of the incompetent superficial veins in addition to standard compressive therapy to prevent ulceration. [GRADE -2; LEVEL OF EVIDENCE –C]

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SVS – AVF Clinical Practice Guidelines Operative / Endovascular - Perforator

- **Guideline 6.5: Combined Superficial / Perforator Venous Reflux With or Without Deep Venous Reflux and Active Venous Leg Ulcer.**

In a patient with a venous leg ulcer (C6) and incompetent superficial veins that have reflux to the ulcer bed in addition to pathologic perforating veins (outward flow of >500 msec duration, with a diameter of >3.5mm) located beneath or associated with the ulcer bed, we suggest ablation of both the incompetent superficial veins and perforator veins in addition to standard compressive therapy to aid in ulcer healing and prevent recurrence. [GRADE -2; LEVEL OF EVIDENCE -C]

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- **Guideline 6.6: Combined Superficial and Perforator Venous Reflux With or Without Deep Venous Disease and Skin Changes at Risk for Venous Leg Ulcer (C4b) or Healed Venous Ulcer (C5)**

In a patient with skin changes at risk for venous leg ulcer (C4b) or healed venous ulcer (C5) and incompetent superficial veins that have reflux to the ulcer bed in addition to pathologic perforating veins (outward flow of >500 msec duration, with a diameter of >3.5mm) located beneath or associated with the healed ulcer bed, we suggest ablation of the incompetent superficial veins to prevent the development or recurrence of a venous leg ulcer. [GRADE -2; LEVEL OF EVIDENCE -C] Treatment of the incompetent perforating veins can be performed simultaneously with correction of axial reflux or can be staged with re-evaluation of perforator veins for persistent incompetence after correction of axial reflux. [GRADE -2; LEVEL OF EVIDENCE -C]

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- **Guideline 6.7: Pathologic Perforator Venous Reflux in the Absence of Superficial Venous Disease, With or Without Deep Venous Reflux, and a Healed or Active Venous Ulcer:**

In a patient with isolated pathologic perforator veins (outward flow of >500 msec duration, with a diameter of >3.5mm) located beneath or associated with the healed (C5) or active ulcer (C6) bed regardless of the status of the deep veins, we suggest ablation of the "pathologic" perforating veins in addition to standard compression therapy to aid in venous ulcer healing and to prevent recurrence. [GRADE -2; LEVEL OF EVIDENCE -C]

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- **Guideline 6.8: Treatment Alternatives for Pathologic Perforator Veins**

For those patients who would benefit from pathologic perforator vein ablation, we recommend treatment by percutaneous techniques that include ultrasound guided sclerotherapy or endovenous thermal ablation (radiofrequency or laser) over open venous perforator surgery to eliminate the need for incisions in areas of compromised skin. [GRADE -1; LEVEL OF EVIDENCE -C]

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SVS – AVF Clinical Practice Guidelines Operative / Endovascular - Deep

- **Guideline 6.9: Infrainguinal Deep Venous Obstruction and Skin Changes at Risk for Venous Leg Ulcer (C4b), Healed (C5) or Active (C6) Venous Leg Ulcer**

In a patient with infrainguinal deep venous obstruction and skin changes at risk for venous leg ulcer (C4b), healed venous leg ulcer (C5), or active venous leg ulcer (C6), we suggest autogenous venous bypass or endophlebectomy in addition to standard compression therapy to aid in venous ulcer healing and to prevent recurrence. [GRADE -2; LEVEL OF EVIDENCE -C]

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- **Guideline 6.10: Deep Vein Reflux with Skin Changes at Risk for Venous Leg Ulcer (C4b), Healed (C5) or Active (C6) Venous Leg Ulcer – Ligation**

In a patient with infrainguinal deep venous reflux and skin changes at risk for venous leg ulcer (C4b), healed venous leg ulcer (C5), or active venous leg ulcer (C6), we suggest against deep vein ligation of the femoral or popliteal veins as a routine treatment. [GRADE -2; LEVEL OF EVIDENCE -C]

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- **Guideline 6.11: Deep Venous Reflux with Skin Changes at Risk for Venous Leg Ulcer (C4b), Healed (C5), or Active (C6) Venous Leg Ulcer – Primary Valve Repair**

In a patient with infrainguinal deep venous reflux and skin changes at risk for venous leg ulcer (C4b), healed venous leg ulcer (C5), or active venous leg ulcer (C6), we suggest individual valve repair for those who have axial reflux with structurally preserved deep venous valves in addition to standard compression therapy to aid in venous ulcer healing and to prevent recurrence. [GRADE -2; LEVEL OF EVIDENCE -C]

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- **Guideline 6.12: Deep Vein Reflux with Skin Changes at Risk for Venous Leg Ulcer (C4b), Healed (C5) or Active (C6) Venous Leg Ulcer - Valve Transposition or Transplantation**

In a patient with infrainguinal deep venous reflux and skin changes at risk for venous leg ulcer (C4b), healed venous leg ulcer (C5), or active venous leg ulcer (C6), we suggest valve transposition or transplantation for those with absence of structurally preserved axial deep venous valve(s) when competent outflow venous pathways are anatomically appropriate for surgical anastomosis in addition to standard compression therapy to aid in venous leg ulcer healing and to prevent recurrence. [GRADE -2; LEVEL OF EVIDENCE -C]

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- **Guideline 6.13: Deep Vein Reflux with Skin Changes at Risk for Venous Leg Ulcer (C4b), Healed (C5), or Active (C6) Venous Leg Ulcer – Autogenous Valve Substitute**

In a patient with infrainguinal deep venous reflux and skin changes at risk for venous leg ulcer (C4b), healed venous leg ulcer (C5), or active venous leg ulcer (C6), we suggest consideration of autogenous valve substitutes by surgeons experienced in these techniques to facilitate ulcer healing and to prevent recurrence in those with no other option available in addition to standard compression therapy to aid in venous ulcer healing and to prevent recurrence. [GRADE -2; LEVEL OF EVIDENCE -C]

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SVS – AVF Clinical Practice Guidelines Operative / Endovascular – Occlusion

- **Guideline 6.14: Proximal Chronic Total Venous Occlusion / Severe Stenosis with Skin Changes at Risk for Venous Leg Ulcer (C4b), Healed (C5) or Active (C6) Venous Leg Ulcer - Endovascular Repair**

In a patient with inferior vena cava and/or iliac vein chronic total occlusion or severe stenosis, with or without lower extremity deep venous reflux disease, which is associated with skin changes at risk for venous leg ulcer (C4b), healed venous leg ulcer (C5), or active venous leg ulcer (C6), we recommend venous angioplasty and stent recanalization in addition to standard compression therapy to aid in venous ulcer healing and to prevent recurrence. [GRADE -1; LEVEL OF EVIDENCE -C]

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SVS – AVF Clinical Practice Guidelines Operative / Endovascular – Occlusion

- **Guideline 6.15: Proximal Chronic Venous Occlusion / Severe Stenosis (Bilateral) with Recalcitrant Venous Ulcer - Open Repair**

In a patient with inferior vena cava and/or iliac vein chronic occlusion or severe stenosis, with or without lower extremity deep venous reflux disease, which is associated with a recalcitrant venous leg ulcer and who have failed endovascular treatment, we suggest open surgical bypass using an externally supported ePTFE graft in addition to standard compression therapy to aid in venous leg ulcer healing and to prevent recurrence. [GRADE -2; LEVEL OF EVIDENCE -C]

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- **Guideline 6.16: Unilateral Iliofemoral Venous Occlusion / Severe Stenosis With Recalcitrant Venous Ulcer – Open Repair:**

In a patient with unilateral iliofemoral venous occlusion/severe stenosis with recalcitrant venous leg ulcer who failed attempts at endovascular reconstruction, we suggest open surgical bypass using saphenous vein as a crosspubic bypass (Palma procedure) to aid in venous ulcer healing and to prevent recurrence. A synthetic graft is an alternative in the absence of autogenous tissue. [GRADE -2; LEVEL OF EVIDENCE -C]

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- **Guideline 6.17: Proximal Chronic Total Venous Occlusion / Severe Stenosis (Bilateral or Unilateral) With Recalcitrant Venous Ulcer – Adjunctive arteriovenous fistula:**

For those patients who would benefit from an open venous bypass, we suggest the addition of an adjunctive arteriovenous fistula (4 to 6 mm in size) as an adjunct to improve inflow into autologous or prosthetic cross over bypasses when the inflow is judged to be poor to aid in venous leg ulcer healing and to prevent recurrence. [GRADE -2; LEVEL OF EVIDENCE -C]

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SVS – AVF Clinical Practice Guidelines Ancillary Measures - Nutrition

- **Guideline 7.1: Nutrition Assessment and Management:**

We recommend that nutrition assessment be performed in any patient with a venous leg ulcer who has evidence of malnutrition and that nutritional supplementation be provided if malnutrition identified. [BEST PRACTICE]

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SVS – AVF Clinical Practice Guidelines Ancillary Measures - Medications

- **Guideline 7.2: Systemic Drug Therapy**

For long-standing or large venous leg ulcer we recommend treatment with either pentoxifylline or micronized purified flavonoid fraction used in combination with compression therapy. [GRADE -1; LEVEL OF EVIDENCE – B]

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SVS – AVF Clinical Practice Guidelines Ancillary Measures - Physiotherapy

- **Guideline 7.3: Physiotherapy**

We suggest supervised active exercise to improve muscle pump function and reduce pain and edema in patients with venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE - B]

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SVS – AVF Clinical Practice Guidelines Ancillary Measures – Lymphatic

- **<u>Guideline 7.4</u>: <u>Manual Lymphatic Drainage</u>**

We suggest against adjunctive lymphatic drainage for healing of the chronic venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE - C]

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SVS – AVF Clinical Practice Guidelines Ancillary Measures - Balneotherapy

- **<u>Guideline 7.5</u>: <u>Balneotherapy</u>**

We suggest balneotherapy to improve skin trophic changes and quality of life in patients with advance venous disease. [GRADE -2; LEVEL OF EVIDENCE - B]

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SVS – AVF Clinical Practice Guidelines Ancillary Measures - Ultraviolet

- **Guideline 7.6: Ultraviolet light**

We suggest against using ultraviolet light for the treatment of venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE - C]

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SVS – AVF Clinical Practice Guidelines Primary Prevention – Primary Reflux

- **<u>Guideline 8.1:</u> <u>Primary Prevention - Clinical CEAP C3-4 Primary Venous Disease</u>**

In patients with Clinical CEAP C 3-4 disease due to primary valvular reflux, we recommend 20-30 mmHg compression, knee or thigh high. [GRADE -2; LEVEL OF EVIDENCE - C]

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SVS – AVF Clinical Practice Guidelines Primary Prevention – Post-Thrombotic

- **Guideline 8.2: Primary Prevention - Clinical CEAP C1-4 Post-Thrombotic Venous Disease**

In patients with Clinical CEAP C1-4 disease related to prior DVT, we recommend compression, 30 - 40 mmHg, knee or thigh high. [GRADE -1; LEVEL OF EVIDENCE - B]

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SVS – AVF Clinical Practice Guidelines Primary Prevention – Acute DVT

- **Guideline 8.3. Primary Prevention – Acute DVT Treatment**

As post thrombotic syndrome (PTS) is a common preceding event for venous leg ulcers, we recommend current evidence based therapies for acute DVT treatment. [GRADE -1; LEVEL OF EVIDENCE - B] We suggest use of low molecular weight heparin (LMWH) over vitamin k antagonist therapy of 3 month duration to decrease PTS [GRADE -2; LEVEL OF EVIDENCE - B] We suggest catheter directed thrombolysis in low bleeding risk patients with iliofemoral DVT of duration <14 days [GRADE -2; LEVEL OF EVIDENCE - B]

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SVS – AVF Clinical Practice Guidelines Primary Prevention - Education

- **Guideline 8.4: Primary Prevention – Education Measures**

In patients with C1-4 disease, we suggest patient and family education, regular exercise, leg elevation when at rest, careful skin care, weight control and appropriately fitting foot wear. [BEST PRACTICE]

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SVS – AVF Clinical Practice Guidelines Primary Prevention - Operative

- **Guideline 8.5: Primary Prevention – Operative Therapy**

In patients with asymptomatic C1-2 disease from either primary or secondary causes, we suggest against prophylactic interventional therapies to prevent venous leg ulcer. [GRADE -2; LEVEL OF EVIDENCE - C]

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