Optimal care pathway for a leg ulcer patient

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Disclosure

Speaker name:
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I have the following potential conflicts of interest to report:

✔ Consulting / Honoraria: Cook Medical, Medtronic, Gore, Endologix

☐ Employment in industry

☐ Stockholder of a healthcare company

☐ Owner of a healthcare company

✔ Other(s): Research award (Laboratoires Urgo)
Introduction

Major healthcare issue
Neglected area
Increasing in prevalence
Introduction

Chronic venous hypertension

- Superficial venous reflux
- Deep venous obstruction

- Deep venous reflux

- Obesity
- Dependency

Immobility

Stiff ankle

VENOUS ULCER
Introduction

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Chronic venous hypertension

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Deep venous occlusion
Superficial venous interventions 2016

- EVLA
- Segmental RFA
- UGFS
- Cyanoacrylate glue
- MOCA

Not approved in the US
Superficial venous interventions 2016

Long term results of compression therapy alone versus compression plus surgery in chronic venous ulceration (ESCHAR): randomised controlled trial

OBJECTIVES To determine whether recurrence of leg ulcers may be prevented by surgical correction of superficial venous reflux in addition to compression. Design Randomised parallel trial.

Setting General practice and hospital. Participants 500 patients (50 legs) with open or recently healed ulcers and superficial venous reflux. Interventions Compression alone or compression plus axillary vein ligation. Main outcome measures Primary: ulcer closures at 6 weeks. Secondary: healing times. Results After healing at 6 weeks, 87% of the compression group and 93% for the compression plus group (P = 0.32, log rank test). Rates ulcer recurrence at 4 years were 16% for the compression group and 32% for the compression plus group (P = 0.003). For patients with isolated superficial reflux, recurrence rates at 4 years were 15% for the compression group and 27% for the compression plus group (P = 0.02). For patients who had superficial reflux with segmental deep reflux, recurrence rates at 4 years were 12% for the compression group and 24% for the compression plus group (P = 0.04). For patients with isolated deep reflux, recurrence rates at 4 years were 14% for the compression group and 35% for the compression plus group (P = 0.04). Patients with superficial venous reflux in addition to compression ligation alone or compression ligation plus vein ligation showed a greater proportion of ulcer closure at 6 weeks than those treated with compression alone (P = 0.002, Mann Whitney U test).

Conclusion Surgical correction of superficial venous reflux in addition to compression ligation alone or compression ligation plus vein ligation reduces the recurrence rates of ulcer at 4 years and results in a greater proportion of ulcer closure.

Treating superficial reflux reduces venous ulcer recurrence
Early Venous Reflux Ablation (EVRA) study

450 PATIENTS
Venous ulceration <6 months
Superficial reflux

Compressio...  

Compression + EVRA (<2 weeks)

Primary outcome: time to ulcer healing
Early Venous Reflux Ablation (EVRA) study

Prof A Davies (CI) - London Cambridge Cheltenham Birmingham Worcester Harrow Hull Bournemouth Frimley Park Plymouth Manchester Sheffield Bradford Wolverhampton York Leeds Salisbury
Deep venous interventions 2016
The Effect of Deep Venous Stenting on Healing of Lower Limb Venous Ulcers

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WHAT THIS PAPER ADDS
This study reports ulcer healing outcomes following deep vein stenting. It will guide decision makers in treatment choices for venous ulcer management.

Objective: To report the outcomes of endovascular interventions on deep veins in patients with venous ulcers (C6).

Methods: This was a retrospective review of a case series. All patients with active venous ulceration who underwent endovascular interventions to the deep venous system from February 2011 to June 2013 were included. Patients with C6 disease who failed a trial of adequate compression therapy or superficial vein interventions were considered for evaluation of the deep veins. Patients with deep vein reflux or without significant venous reflux or with a previous history of deep vein thrombosis underwent computed tomographic venogram or ascending venogram. In the absence of intravenous ultrasound trial ballooning to look for a “waist” to identify subtle lesions was used. Lesions were stented with long Nitinol stents.

Results: Thirty-eight patients underwent deep vein stenting of 44 limbs with venous ulcers. The lesions were considered to be post-thrombotic in 31 limbs and non-thrombotic iliac vein lesions in 13 limbs. A mean of 1.8 stents were used per patient. There were no significant complications associated with the interventions. At a median follow-up of 15 months, the primary and assisted primary patency rates were 94% and 97%, respectively. Sustained ulcer healing was achieved in 60% of limbs. A further 20% of ulcers had reduced in size. Recurrent ulcers developed in 13% of limbs, and half of these healed with interventions for newly developed incompetence in superficial veins.

Conclusion: Endovascular interventions to the deep veins appear to be an effective adjunct in achieving the healing of recalcitrant ulcers.
Leg ulcer care pathway

“Care pathway”

A healthcare process designed to standardize care, provide evidence based treatment and improve outcomes.
AVF / SVS guidelines 2014


Endorsed by the American College of Phlebology and the Union Internationale de Phlébologie

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75 guidelines covering assessment, wound care, compression, superficial & deep venous interventions, prevention of ulceration
SUMMARY OF GUIDELINES FOR MANAGEMENT OF VENOUS ULCER

DEFINITION VENOUS LEG ULCER
Guideline 1.1: Venous Leg Ulcer Definition
We recommend use of a standardized definition of venous leg ulcer as an open skin lesion of the leg that occurs in an area affected by venous hypertension. [BEST PRACTICE]

VENOUS ANATOMY AND PATHOPHYSIOLOGY
Guideline 2.1: Venous Anatomical Nomenclature
We recommend use of the International Committee on Venous Anatomical Terminology for standard venous anatomy nomenclature. [BEST PRACTICE]

Guideline 2.2: Venous Leg Ulcer Pathophysiology
We recommend use of a basic understanding of venous physiology and venous leg ulcer pathophysiology for all practitioners caring for venous leg ulcers. [BEST PRACTICE]

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 venous hypertension be performed. [BEST PRACTICE]

Guideline 3.2: Noninvasive Causes of Leg Ulcers
We recommend identification of medical conditions that affect ulcer healing and other noninvasive causes of leg ulcers. [BEST PRACTICE]

Guideline 3.3: Wound Documentation
We recommend serial venous leg ulcer wound measurement and documentation. [BEST PRACTICE]

Guideline 3.4: Wound Culture
We recommend against routine culture of venous leg ulcers and only to obtain wound culture specimens when clinical evidence of infection is present. [GRADE 2; LEVEL OF EVIDENCE - C]

Guideline 3.5: Wound Biopsy
We recommend against routine biopsy of venous leg ulcers that do not improve with standard wound and compression therapy after 4 to 6 weeks of treatment and for all ulcers with sternal features. [GRADE 1; LEVEL OF EVIDENCE - C]

Guideline 3.6: Laboratory Evaluation
We recommend laboratory evaluation for rheumatologic for patients with a history of recurrent venous thromboembolism and chronic recurrent venous leg ulcers. [GRADE 1; LEVEL OF EVIDENCE - B]

Guideline 3.7: Arterial Testing
We recommend arterial examination and measurement of ankle-brachial index on all patients with venous leg ulcers. [GRADE 1; LEVEL OF EVIDENCE - B]

Guideline 3.8: Microcirculation Assessment
We recommend 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]

Guideline 3.9: Venous Doppler Ultrasound
We recommend routine ultrasonic examination of the lower extremities in all patients with suspected venous leg ulcers. [GRADE 1; LEVEL OF EVIDENCE - C]

Guideline 3.10: Venous Phlebography
We recommend selective use of venous phlebography in the evaluation of patients with suspected venous leg ulcers when ultrasound does not provide definitive diagnostic information. [GRADE 2; LEVEL OF EVIDENCE - B]

Guideline 3.11: Venous Imaging
We recommend use of a Doppler-computed tomography angiography, magnetic resonance venography, contrast venography, and/or intravascular ultrasound in patients with suspected venous leg ulceration if advanced venous imaging techniques are not available or if a specific vascular lesion or deep vein thrombosis is under consideration for operative planning before open or cadaveric interventions. [GRADE 2; LEVEL OF EVIDENCE - C]

Guideline 3.12: Venous Disease Classification
We recommend that all patients with venous leg ulcer be classified on the basis of venous disease classification to select the most appropriate clinical care approach and to apply Clinical Venous Clinical Severity Score, and venous disease-specific quality of life assessment. [BEST PRACTICE]

Guideline 3.13: Venous Procedural Outcome Assessment
We recommend use of the validated Venous Clinical Outcome Assessment tool within a clinical care setting to evaluate objective outcomes of Venous Leg Ulcer Care. [BEST PRACTICE]

WOUND CARE
Guideline 4.1: Wound Cleansers
We recommend that venous leg ulcers be cleansed initially and at each dressing change with a neutral, nonirritating, antimicrobial solution, performed with a minimum of chemical or mechanical trauma. [GRADE 1; LEVEL OF EVIDENCE - B]

Guideline 4.2: Debrecement
We recommend that venous leg ulcers receive thorough debrecement at their initial evaluation to remove obvious necrotic tissue, excessive bacterial burden, and cellular debris of dead and unattached cells. [GRADE 1; LEVEL OF EVIDENCE - B]

Guideline 4.3: Debridement
We recommend use of a standardized definition of debridement. In selected cases, regional block or general anesthesia may be required. [GRADE 1; LEVEL OF EVIDENCE - B]

Guideline 4.4: Surgical Debridement
We recommend that surgical debridement be performed for venous leg ulcers with slow, necrotic tissue, or ulcer. Serial wound assessment is important in determining the need for expanded debridement. [GRADE 1; LEVEL OF EVIDENCE - B]

Guideline 4.5: Hydrodynamic Debridement
We recommend use of hydrostatic debridement as an alternative to standard surgical debridement of venous leg ulcers. [GRADE 2; LEVEL OF EVIDENCE - B]

Guideline 4.6: Ultrasonic Debridement
We recommend use of ultrasonic debridement over surgical debridement in the treatment of venous leg ulcers. [GRADE 2; LEVEL OF EVIDENCE - C]

Guideline 4.7: Pressure Wound Debridement
We recommend against ultrasonic debridement over surgical debridement for venous leg ulcers. [GRADE 2; LEVEL OF EVIDENCE - C]

Guideline 4.8: Biologic Debridement
We recommend that larval therapy for venous leg ulcers can be used as an alternative to surgical debridement. [GRADE 2; LEVEL OF EVIDENCE - B]

Guideline 4.9: Management of Leg Cellulitis
We recommend early use of antibiotics in the event of infection of the skin and subcutaneous tissue surrounding the venous leg ulcer be treated with systemic gram-positive antibiotics. [GRADE 1; LEVEL OF EVIDENCE - A]

Guideline 4.10: Wound Colonization and Bacterial Biofilm
We recommend against systemic antimicrobial treatment of venous leg ulcer colonization or biofilms without clinical evidence of infection. [GRADE 2; LEVEL OF EVIDENCE - C]

Guideline 4.11: Treatment of Wound Infection
We recommend that venous leg ulcers with >10^8 CFU/g of tissue and clinical evidence of infection be treated with a combination of a broad-spectrum antibiotic and an agent active against aerobic bacteria (such as betahemolytic streptococci, pseudomona, and resistant staphylococcal species) at lower levels of colony-forming units per gram of tissue. [GRADE 2; LEVEL OF EVIDENCE - B]

Guideline 4.12: Wound Debridement
We suggest a combination of mechanical debridement and antibiotic therapy as most likely to be successful in eradicating venous leg ulcer infection. [GRADE 2; LEVEL OF EVIDENCE - C]

Guideline 4.13: 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 - A]

Guideline 4.14: Topical Antibiotics for Infected Wounds
We recommend use of topical antimicrobial agents for the treatment of infected venous leg ulcers. [GRADE 2; LEVEL OF EVIDENCE - C]

Guideline 4.15: Topical Debridement Containing Antimicrobial
We recommend against the routine use of topical antimicrobial-containing dressings in the treatment of infected venous leg ulcers. [GRADE 1; LEVEL OF EVIDENCE - A]

Guideline 4.16: Pressure Skin Management
We recommend the application of skin lubricants undercuts compression to reduce dermabrasion that commonly afflicts perforator skin. [GRADE 2; LEVEL OF EVIDENCE - C]

Guideline 4.17: Antihypertensive Agents
We recommend selection of secondary ulcerations and to reduce the symptoms of venous hypertension. [GRADE 2; LEVEL OF EVIDENCE - C]

Guideline 4.18: Indication forAdjunctive Therapies
We recommend that adjunctive therapies be used for venous leg ulcers that fail to demonstrate improvement after a minimum of 4 to 6 weeks of standard wound therapy. [GRADE 1; LEVEL OF EVIDENCE - B]

Guideline 4.19: Splint-Thickness Skin Grafting
We recommend use of splint-thickness skin grafting as primary therapy in treatment of venous leg ulcers. [GRADE 2; LEVEL OF EVIDENCE - B]

Guideline 4.20: Cellular Therapy
We recommend use of cultured autologous skin replacements (with both epidermal and dermal layers) to increase the chances for healing in patients with difficult to heal venous leg ulcers in addition to reconstructive surgery in patients who have failed to show signs of healing after standard therapy for 4 to 6 weeks. [GRADE 2; LEVEL OF EVIDENCE - B]

Guideline 4.21: Preparatory for Cellular Therapy
We recommend use of topical growth factors and mild wound bed moisturizer control before application of cellular therapy. [GRADE 2; LEVEL OF EVIDENCE - C]

Guideline 4.22: Preparatory for Cellular Therapy
We recommend use of topical growth factors and mild wound bed moisturizer control before application of cellular therapy. [GRADE 2; LEVEL OF EVIDENCE - C]

Guideline 4.23: Anesthesia for Surgical Debridement
We recommend that local anesthesia (topical or local injection) be administered to minimize discomfort associated with local wound debridement. In selected cases, regional block or general anesthesia may be required. [GRADE 1; LEVEL OF EVIDENCE - B]

Guideline 4.24: Multimodal Compression Bandage
We recommend use of the multimodal compression bandage over single-component bandages for the treatment of venous leg ulcers. [GRADE 2; LEVEL OF EVIDENCE - B]

Guideline 4.25: Anticoagulant Protocols
We recommend against the use of anticoagulant protocols when other compression options are not available. Anticoagulant protocols are not recommended for use in venous leg ulcer healing after postoperative compression therapy. [GRADE 1; LEVEL OF EVIDENCE - B]

Guideline 4.26: OPEN/ENDOVASCULAR MANAGEMENT
We recommend against the use of interventional radiology when other compression options are not available. Anticoagulant protocols are not recommended for use in venous leg ulcer healing after postoperative compression therapy. [GRADE 1; LEVEL OF EVIDENCE - B]

Guideline 4.27: Venous Ulcer Etiology
We recommend that in a venous ulcer leg and underlying arterial disease, we do not suggest compression bandages or anticoagulants. If leg edema is less than 5.0 or if edema alleviates pressure to less than 40 mm Hg. [GRADE 2; LEVEL OF EVIDENCE - B]

Guideline 4.28: Venous Ulcer Etiology
We recommend that in a venous ulcer leg and underlying arterial disease, we do not suggest compression bandages or anticoagulants. If leg edema is less than 5.0 or if edema alleviates pressure to less than 40 mm Hg. [GRADE 2; LEVEL OF EVIDENCE - B]

Guideline 4.29: Venous Ulcer Etiology
We recommend that in a venous ulcer leg and underlying arterial disease, we do not suggest compression bandages or anticoagulants. If leg edema is less than 5.0 or if edema alleviates pressure to less than 40 mm Hg. [GRADE 2; LEVEL OF EVIDENCE - B]

Guideline 4.30: Venous Ulcer Etiology
We recommend that in a venous ulcer leg and underlying arterial disease, we do not suggest compression bandages or anticoagulants. If leg edema is less than 5.0 or if edema alleviates pressure to less than 40 mm Hg. [GRADE 2; LEVEL OF EVIDENCE - B]

Guideline 4.31: Venous Ulcer Etiology
We recommend that in a venous ulcer leg and underlying arterial disease, we do not suggest compression bandages or anticoagulants. If leg edema is less than 5.0 or if edema alleviates pressure to less than 40 mm Hg. [GRADE 2; LEVEL OF EVIDENCE - B]
Key components of leg ulcer pathway

1. Early assessment of ankle brachial pressure index (ABPI)

2. If ABPI normal, use of effective compression therapy

3. Assessment and treatment of superficial venous reflux

4. Consideration of complex adjunctive treatments (such as deep vein stenting) in selected patients
Key components of leg ulcer pathway

- Reduced venous ulcer recurrence
- Potentially improved ulcer healed

3. Assessment and treatment of superficial venous reflux

Long-term reduction of venous hypertension
Optimal leg ulcer pathway

**PRIMARY CARE**

- **INITIAL PRESENTATION**
- **EARLY ABPI + START COMPRESSION**
- **ONGOING COMPRESSION / NURSING CARE**

**SECONDARY CARE**

- **SPECIALIST ASSESSMENT FOR VARICOSE VEIN TREATMENT**
- **SPECIALIST INTERVENTION**
Improving leg ulcer pathways

Education and training of all healthcare professionals involved in venous ulcer care

More innovative collaboration between primary and secondary care services

On going research and building of evidence base

Supportive commissioning landscape
Conclusions

There are many options for treating superficial reflux and deep venous occlusive disease.

Implementation of best practice is poor.

More innovation is needed to deliver these interventions to this patient group.
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