Venous Ulcers and Ulcerations in Patients with Diabetes:
Applying the Evidence

Brian Rayala, MD

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Brian Rayala, MD

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Dr. Rayala has received multiple awards for excellence in teaching and clinical care, including the 2017 UNC Distinguished Teaching Award for Post-Baccalaureate Instruction, the 2014 and 2016 UNC Family Medicine Residency Teaching Award, and the 2015 and 2017 UNC Health Care and Faculty Physicians Award for Carolina Care Excellence. In addition, he has been named among the "Best Doctors in America" since 2009. He has special training and interest in dermatology, wound medicine, and medical procedures.
Learning Objectives

1. Establish protocols to systematically and routinely evaluate all patients at risk of developing diabetic or venous ulcers.

2. Develop collaborative care plans with diabetic patients emphasizing diabetic foot ulcer prevention strategy adherence; and develop collaborative care plans with patients with venous ulcers, emphasizing adherence to strategies aimed at prevention of recurrence.

3. Apply current evidence-based recommendations and guidelines for treatment of diabetic or venous ulcers, coordinating referral to subspecialists as indicated.

4. Establish and coordinate multidisciplinary teams, utilizing a patient-centered care approach, for the care and management of patients with diabetic and venous ulcers.

Audience Engagement System
Poll Question 1

Primary care providers who practice in Wound Care Centers:

• YES
• NO

Presentation Topics

• Evaluation of diabetic and venous ulcers
• Management of diabetic and venous ulcers
• Engaging the patient
Presentation Topic #1: Evaluation of Diabetic and Venous Ulcers

Learning objective:
• Establish protocols to systematically and routinely evaluate all patients at risk of developing diabetic or venous ulcers.

Evaluation of Diabetic and Venous Ulcers: Detailed Wound Assessment

Location → Wound stage or classification → Measurement → Wound edge or margin → Wound exudate → Wound bed

Periwound (Surrounding skin) → Infection → Pain

Etiology
## Wound Assessment: Etiology

<table>
<thead>
<tr>
<th>Location</th>
<th>Diabetic</th>
<th>Venous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foot</td>
<td></td>
<td>Above malleolus (poster area)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Color (base)</th>
<th>Normal</th>
<th>Ruddy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Granulation tissue</td>
<td>Present</td>
<td>Present</td>
</tr>
<tr>
<td>Necrotic tissue</td>
<td>Variable</td>
<td>Rarely present</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exudate</th>
<th>Variable</th>
<th>Moderate to heavy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depth</td>
<td>Variable</td>
<td>Usually shallow</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Wound margins</th>
<th>Well defined</th>
<th>Irregular</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surrounding skin</td>
<td>Erythematous, scaly, excoriated, hyperpigmented (stasis dermatitis)</td>
<td></td>
</tr>
<tr>
<td>Edema</td>
<td>Variable</td>
<td>Moderate to severe</td>
</tr>
<tr>
<td>Skin temperature</td>
<td>Normal or warm</td>
<td>Normal or warm</td>
</tr>
<tr>
<td>Infection</td>
<td>Frequent</td>
<td>Less common, variable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pain</th>
<th>Painless</th>
<th>Minimal unless infected or desiccated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral pulses</td>
<td>Present/palpable</td>
<td>Present/palpable</td>
</tr>
<tr>
<td>Capillary refill</td>
<td>Normal (&lt;3 secs)</td>
<td>Normal (&lt;3 secs)</td>
</tr>
</tbody>
</table>

### Wound Assessment: Etiology

Diabetic Foot Ulcer
Poll Question 2

Risk assessment tools for the diabetic foot help screen at-risk patients. Validation studies measuring their diagnostic accuracy have found them to have:

A. Good positive predictive value (PPV) and positive likelihood ratio (+LR)
B. Good negative predictive value (NPV) and negative likelihood ratio (-LR)
C. Both A and B
D. None of the above
Evaluation of Diabetic Ulcers: Who to Screen

- **Diabetic Foot Ulcer (DFU)**
  - **Evidence** to support screening for primary prevention of ulceration or amputation among diabetics? **Insufficient** (*SORT A*)\(^1\)
  - **Evidence** for secondary prevention? **YES** (*SORT B*)\(^2,3\)
  - **Recommendation:**
    - Screen all diabetics yearly, or more frequently if with risk factors for ulceration. (*SORT C*)\(^4\)
    - Prescribe **therapeutic footwear** w/ demonstrated pressure relief for pts w/ prior plantar foot ulcer. (*SORT B*)\(^2,3\)


Evaluation of Diabetic Ulcers: How to Screen

- **DFU**
  - **Recommendation:** Use any of the several **diabetic foot risk stratification systems** (e.g., UT, ADA, IWGDF, SIGN, Seattle) [*SORT C*]\(^5\)
    - Accurate, most have been validated, excellent for screening (good NPV and –LR)
    - If patient does not have neuropathy, PVD, foot deformity, prior ulcer or amputation – very low risk of ulcer or amputation within 12-24 months
    - Note: if test is positive, post-screening interventions are not effective for primary prevention, but some evidence for **secondary prevention**.

Evaluation of Diabetic Ulcers: How to Screen

• DFU
  – History:
    • Prior DFU
    • Prior amputation
    • Age, duration of diabetes
  – Clinical Exam:
    • Neuropathy – 10g monofilament/SWM (5 areas each foot); 128Hz tuning fork (distal phalanx, great toe)
    • PVD – check dorsalis pedis and posterior tibial pulses
    • Foot deformity – able to use off-shelf shoes?

Evaluation of Diabetic Ulcers: Post-screening Intervention (SORT C)\textsuperscript{6}

<table>
<thead>
<tr>
<th>ADA Category</th>
<th>Definition</th>
<th>Recommendations</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No loss of protective sensation (LOPS), No PAD, No deformity</td>
<td>• Pt education on foot care, including appropriate footwear</td>
<td>Yearly (PCP or specialist)</td>
</tr>
</tbody>
</table>
| 1            | LOPS w/wo deformity | • Consider prophylactic surgery if shoes cannot accommodate deformity  
• Pt education  
• Prescriptive or accommodative footwear | q3-6 mos (PCP or specialist) |
| 2            | PAD w/wo LOPS | • Accommodative footwear  
• Consider vascular consult | q2-3 mos (specialist) |
| 3            | H/o ulcer or amputation | • Pt education on foot care  
• Consider vascular consult | q1-2 mos (specialist) |

Poll Question 3

Strong evidence supports interventions toward:

A. Primary prevention of venous leg ulcers
B. Secondary prevention of venous leg ulcers
C. Both A and B
D. None of the above

Evaluation of Venous Ulcers: Who to Screen

- Venous Leg Ulcer (VLU)
  - Evidence to support screening for secondary prevention of VLU? YES (SORT A)\(^7\)
  - Recommendation:
    - Identify patients in your practice with prior VLU; they are good candidates for compression therapy to prevent recurrence. (SORT A)\(^7\)
    - Insufficient evidence on use of compression for primary prevention of VLU. (SORT A)\(^8\)

Evaluation of Diabetic Ulcers:
Systematic Evaluation

- Evaluation of diabetic pt with foot ulcer
  - Assess neurologic and vascular status of foot
  - Cleanse, debride
  - Detailed wound assessment, probe ulcer
  - Assess for purulence or signs of inflammation
  - Obtain appropriate specimens for culture
  - Consider x-ray or MRI
  - Obtain other appropriate labs (ESR, CBC, Bld cx)
  - Consider ABI or LE arterial dopplers
  - Assess medical comorbidities and psychosocial factors
  - Determine need for surgical consultation


Evaluation of Diabetic Ulcers:
DFU Risk Stratification

Diabetic Foot Infection (DFI) Classification

<table>
<thead>
<tr>
<th>Clinical description</th>
<th>Infectious Diseases Society of America</th>
<th>International Working Group on the Diabetic Foot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound without purulence or any manifestations of inflammation</td>
<td>Uninfected</td>
<td>1</td>
</tr>
<tr>
<td>Manifestations of inflammation (erythema or edema, pain, tenderness, warmth, or</td>
<td></td>
<td></td>
</tr>
<tr>
<td>irritation); any cellulitis or erythema extends over adjacent skin and infection is</td>
<td></td>
<td></td>
</tr>
<tr>
<td>limited to skin or superficial subcutaneous tissue; no local complications or systemic illness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infection in a patient who is systemically well and metabolically stable but has one of the following: cellulitis extending → lymphangitis, spread beneath fascia, deep tissue abscess, gangrene, muscle, tendon, joint, or bone involvement</td>
<td>Moderate</td>
<td>3</td>
</tr>
<tr>
<td>Infection in a patient with systemic toxicity or metabolic instability (e.g., fever, chill, shock, cardiogenic shock, hypotension, confusion, vomiting, ketonuria, acidosis, hyperglycemia, or azotemia)</td>
<td>Severe</td>
<td>4</td>
</tr>
</tbody>
</table>

- Prospectively validated in 1,166 pts
- Reliably predicts hospitalization and amputation

Evaluation of Venous Ulcers: Systematic Evaluation

• Evaluation of pt with venous leg ulcer
  – Assess vascular status of foot
  – Cleanse, debride, detailed wound assessment
  – Assess for signs of clinical infection
  – Obtain appropriate specimens for culture
  – Consider ABI or LE arterial dopplers; venous reflux studies
  – Assess medical comorbidities and psychosocial factors
  – Determine need for surgical consultation
  – Consider use of classification and scoring methods (e.g., CEAP, VCSS, QoL) to quantify burden of disease (SORT C)\textsuperscript{11}


Presentation Topic #2: Management of Diabetic and Venous Ulcers

Learning objectives:
• Establish and coordinate multidisciplinary teams, utilizing a patient-centered care approach, for the care and management of patients with diabetic and venous ulcers.
• Apply current evidence-based recommendations and guidelines for treatment of diabetic or venous ulcers, coordinating referral to subspecialists as indicated.
Poll Question 4

Primary care providers who practice inpatient medicine:

- YES
- NO

Management of Diabetic Ulcers: Patient-centered Team-based Approach

- Multidisciplinary foot care team
  - For inpatient care of pts w/ DFI (SORT C)\textsuperscript{12}
    - Primary care, surgery, podiatry, ID, endocrine, nursing, nutrition, rehab, social work, care manager
  - Primary care – experts in care coordination
  - Need for a care pathway for managing each pt (SORT C)\textsuperscript{13,14}
  - Approach must be centered on the patient

\textsuperscript{12} BMJ. 2011;342:d1280.
\textsuperscript{13} Vasc Surg. 2010;52(3 suppl):3S–16S.
\textsuperscript{14} Endocrine. 2010;38(1):87–92.
### Management of Diabetic Ulcers: Treatment Based on Severity\(^{15}\)

<table>
<thead>
<tr>
<th>IDSA Class</th>
<th>Pathogen</th>
<th>Antibiotics</th>
<th>MRSA Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uninfected</td>
<td></td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Mild, Moderate</td>
<td>G+ cocci</td>
<td>Oral (1-2wks duration)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Amoxicillin/clavulanate, Cefdinir, Cephalexin, Dicloxacillin, Levofloxacin, Clindamycin*</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Doxycycline, TMP-SMX, Clindamycin*, Linezolid</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Moderate, Severe</td>
<td>G+ cocci; G-rods; anaerobes</td>
<td>Intravenous (2-3 wks duration)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ampicillin/sulbactam, Cefoxitin, Ceftriaxone, Clindamycin/fluoroquinolones*, Ertapenem, Imipenem/cilastin, Moxifloxacin, Piperacillin/tazobactam, Ticarcillin/clavulanate</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vancomycin, Daptomycin, Tigecycline, Linezolid</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>


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### Management of Diabetic Ulcers: Diabetic Foot Osteomyelitis\(^{16}\)

<table>
<thead>
<tr>
<th>Bone or Joint Infection</th>
<th>Route of Admin</th>
<th>Duration of Tx</th>
</tr>
</thead>
<tbody>
<tr>
<td>No residual infected tissue (e.g., postamputation)</td>
<td>PO or IV</td>
<td>2-5 days</td>
</tr>
<tr>
<td>Residual infected soft tissue (but not bone)</td>
<td>PO or IV</td>
<td>1-3 weeks</td>
</tr>
<tr>
<td>Residual infected (but viable) bone</td>
<td>Initially IV, then oral</td>
<td>4-6 weeks</td>
</tr>
<tr>
<td>No surgery, or residual dead bone postop</td>
<td>Initially IV, then oral</td>
<td>≥ 3 months</td>
</tr>
</tbody>
</table>

- No regimen, route, or duration has been found to be superior

Management of Diabetic Ulcers: Moderate to Severe DFI

• Surgical Interventions:
  – I & D of abscess
  – Debridement
  – Revascularization
  – Amputation

Poll Question 5
Which DFU treatment is supported by the strongest evidence?
A. Hyperbaric oxygen therapy (HBOT)
B. Negative pressure wound therapy (NPWT)
C. Off-loading with non-removable cast
### Management of Diabetic Ulcers: Dressings

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Comments</th>
<th>Cochrane Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hydrogel</strong></td>
<td>• Effective for low-grade DFU compared to gauze dressing (possible bias in studies)</td>
<td>17. Cochrane Database Syst Rev. 2013;(3):CD009101.</td>
</tr>
<tr>
<td></td>
<td>• Use may be justified by cost and wound mx properties (e.g., exudate mx)</td>
<td>19. Cochrane Database Syst Rev. 2013;(3):CD009110.</td>
</tr>
<tr>
<td><strong>Silver-containing dressings</strong></td>
<td>• Insufficient evidence to treat DFU or to treat/prevent wound infection in general</td>
<td>21. Cochrane Database Syst Rev. 2006;(2):CD005082.</td>
</tr>
<tr>
<td></td>
<td>• May be effective for partial thickness burns and infected post-op wounds (low-quality evidence)</td>
<td></td>
</tr>
</tbody>
</table>

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### Management of Diabetic Ulcers: Topical Therapies

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Comments</th>
<th>Cochrane Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Growth factors</strong></td>
<td>• May be effective (low-quality evidence)</td>
<td>27. Cochrane Database Syst Rev. 2015;(10):CD008548.</td>
</tr>
<tr>
<td><strong>Platelet-rich plasma (PRP), autologous</strong></td>
<td>• May be effective (low-quality evidence)</td>
<td>28. Cochrane Database Syst Rev. 2016;(5):CD006899.</td>
</tr>
<tr>
<td><strong>Negative pressure wound therapy (NPWT)</strong></td>
<td>• May be effective for post-op wound healing compared to moist dressings (low-quality evidence)</td>
<td>29. Cochrane Database Syst Rev. 2018;(10):CD010318.</td>
</tr>
</tbody>
</table>

### Management of Diabetic Ulcers: Systemic Therapy

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Comments</th>
<th>Cochrane Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• not effective for ulcer healing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Reduces need for surgery (amputations) and duration of hospitalization</td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Consider adding G-CSF to usual care for limb-threatening infection</td>
<td></td>
</tr>
</tbody>
</table>
## Management of Diabetic Ulcers: Other Therapies

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Comments</th>
<th>Cochrane Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperbaric oxygen therapy (HBOT)</td>
<td>• <strong>May be effective</strong> for healing DFU in the short-term but NOT long-term (low-quality evidence)</td>
<td>31. Cochrane Database Syst Rev. 2015;(6):CD004123.</td>
</tr>
</tbody>
</table>
| Off-loading (pressure relief)                  | • **Non-removable casts** more effective than removable casts or dressings  
| Debridement                                    | • **Autolytic: hydrogel** increases healing rate compared to gauze or usual care  
   • **Enzymatic (e.g., collagenase):** insufficient evidence  
   • **Biologic (e.g., larval therapy):** insufficient evidence  
   • **Surgical:** no better than standard tx | 33. Cochrane Database Syst Rev. 2010;(2):CD03556. |
| Phototherapy                                   | • **May be effective** (low-quality evidence)                              | 34. Cochrane Database Syst Rev. 2017;(6):CD011979. |
# Management of Venous Ulcers: Dressings

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Comments</th>
<th>Cochrane Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alginate, foam</td>
<td>• Insufficient evidence of superiority over other dressings</td>
<td>35. Cochrane Database Syst Rev. 2015;(8):CD010182.</td>
</tr>
<tr>
<td></td>
<td>• Use may be justified by cost and wound mx properties (e.g., exudate mx)</td>
<td>36. Cochrane Database Syst Rev. 2013;(5):CD009907.</td>
</tr>
<tr>
<td>Silver-containing dressings</td>
<td>• Insufficient evidence to treat or prevent wound infection</td>
<td>22. Cochrane Database Syst Rev. 2010;(3):CD006478.</td>
</tr>
</tbody>
</table>

# Management of Venous Ulcers: Topical Therapies & Physical Modalities

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Comments</th>
<th>Cochrane Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative pressure wound therapy (NPWT)</td>
<td>• Insufficient evidence</td>
<td>40. Cochrane Database Syst Rev. 2015;(7):CD011354.</td>
</tr>
<tr>
<td>Electromagnetic therapy</td>
<td>• Insufficient evidence</td>
<td>42. Cochrane Database Syst Rev. 2015;(7):CD002933.</td>
</tr>
</tbody>
</table>
## Management of Venous Ulcers: Systemic & Other Therapies

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Comments</th>
<th>Cochrane Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pentoxifylline</strong></td>
<td>• Effective adjunct to compression</td>
<td>44. Cochrane Database Syst Rev. 2012;(12):CD001733.</td>
</tr>
<tr>
<td></td>
<td>• May be effective monotherapy</td>
<td></td>
</tr>
<tr>
<td><strong>Sulodexide</strong></td>
<td>• May be effective but dose and adverse effects need to be studied</td>
<td>45. Cochrane Database Syst Rev. 2016;(6):CD010694.</td>
</tr>
<tr>
<td><strong>Flavonoids</strong></td>
<td>• May be effective (low-quality evidence)</td>
<td>47. Cochrane Database Syst Rev. 2013;(5):CD006477.</td>
</tr>
</tbody>
</table>

## Management of Venous Ulcers: Surgery

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Comments</th>
<th>Cochrane Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Debridement</strong></td>
<td>• Autolytic: hydrogel may be effective (low-quality evidence)</td>
<td>50. Cochrane Database Syst Rev. 2015;(9):CD008599.</td>
</tr>
<tr>
<td></td>
<td>• Enzymatic: insufficient evidence</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Biologic: larvae may be effective (low-quality evidence)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Surgical: insufficient evidence</td>
<td></td>
</tr>
</tbody>
</table>
Management of Venous Ulcers: Compression Therapy

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Comments</th>
<th>Cochrane Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Multilayer (w/ elastic component) more effective than unilayer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Higher compression better than lower compression</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Compliance is low</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Insufficient evidence as a substitute to compression bandages</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Limited evidence: IPC + compression more effective than compression alone</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Rapid IPC more effective than slow IPC</td>
<td></td>
</tr>
</tbody>
</table>

Presentation Topic #3: Engaging the Patient

**Learning objective:**

- Develop **collaborative care plans** with diabetic patients emphasizing diabetic **foot ulcer prevention** strategy adherence; and develop collaborative care plans with patients with **venous ulcers**, emphasizing adherence to strategies aimed at **prevention of recurrence**.
Presentation Topic #3: Engaging the Patient

• Collaborative Care Plan
  – Diabetic Ulcer and Amputation Prevention
    • Primary and secondary prevention: Patient education interventions improve foot care knowledge and behavior in the short term, but NOT rates of amputation or ulceration. (SORT A)\textsuperscript{54,55}
  – Venous Leg Ulcer Prevention
    • Insufficient evidence that pt education increases compliance with compression therapy. (SORT A)\textsuperscript{56}

Practice Recommendations

• Perform, at least, yearly diabetic foot exams and consider use of diabetic foot risk stratification tools to identify pts at risk for DFU (SORT C). Prescribe therapeutic footwear for pts with prior DFU to prevent recurrence (SORT B). Identify pts with prior VLU; they will benefit from lifelong compression therapy to prevent recurrence (SORT A).
• Systematic evaluation of pts with DFU and VLU includes neurologic (DFU only) and vascular foot assessment, cleansing, debridement, detailed wound assessment, probing (DFU only), obtaining culture, imaging & labs, assessing comorbidities, considering consultation, and using DFU and VLU risk classification tools (SORT C).
• Weak evidence supports the establishment of multidisciplinary foot care teams that utilize care pathways for inpatient management of DFI (SORT C). The primary care physician carries the important role of coordinating care among different specialties and of advocating for patients and their holistic treatment (SORT C).

Practice Recommendations

- Evidence-based therapies for DFUs include non-removable casts w/wo Achilles tendon lengthening (SORT A), use of hydrogel for dry low-grade ulcers, antimicrobial dressings, and NPWT postoperatively (SORT B). Evidence-based therapies for VLUs include compression therapy, oral pentoxifylline, bilayer artificial skin w/ compression, and early endovenous ablation (SORT A). Cadexomer iodine dressings may improve healing (SORT B). Ibuprofen dressings and EMLA are helpful for pain control (SORT B).

- Among diabetics, collaborative care plans that focus on pt education improve knowledge and behavior in the short-term, but NOT rates of ulceration or amputation (SORT A). For VLU, compliance to compression therapy remains challenging and the role of pt education to address this remains unclear (SORT A).

Questions
References


29. Cochrane Database Syst Rev. 2018; (10):CD010318
References

42. Cochrane Database Syst Rev. 2015; (7):CD002933.
50. Cochrane Database Syst Rev. 2015; (9):CD008599.

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