People with CVD and Ulceration

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MEDICARE EVIDENCE DEVELOPMENT AND COVERAGE ADVISORY COMMITTEE (MEDCAC) MEETING

JULY 20, 2016

Dr. Gary Gibbons, MD, FACS

- Medical Director, South Shore Hospital, Center for Wound Healing
- Professor of Surgery, Boston University School of Medicine
- Vascular Surgeon
- Board Member the Association for the Advancement of Wound Care [AAWC]
  - Multi-professional clinical association /2,500 clinicians and researchers specialized in wound care

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- No conflict of interest or financial conflict
- No involvement in federal or nonfederal advisory committee

CVD and Venous Ulcers

- Population: sick, complex patients w/ multiple co-morbidities
- CVI common disease; 1% population[1]
  - approx.1-2% (adults) develop venous ulcer [VU]
- High recidivism rates
- Negative impact on person's QOL
- Requires life-time management of post-healed ulcers
  - reduce complications, recurrence & maintain QOL

1. Bongiovanni CM. Effects of Hypochlorous Acid Solutions on Venous Leg Ulcers (VLU): Experience With 1249 VLUs in 897 Patients. *J Am College Clin Wound Specialists* 2014;6(3):32–37.

CVD Patients with Ulcer: Comorbidities

RCT Study Participants

- RCT[2] data (*2015*): **83%** had 4 or > comorbidities:
  - 67% Hypertension
  - 61% Edema
  - 35% Diabetes
  - 25% Arthritis
  - 14% Anemia
  - 7% CAD
  - 6% Pulmonary Disease
  - 6% Autoimmune Disease
  - 5% Kidney disease
  - BMI 36.5
- **56% recurrent ulcers**

2. Gibbons GW, Orgill DP, Serena TE, Novoung A, O'Connell JB, Li WW, Driver VR. A Prospective, Randomized, Controlled Trial Comparing the Effects of Noncontact, Low-frequency Ultrasound to Standard Care in Healing Venous Leg Ulcers. Ostomy Wound Manage 2015;61(1):16–29.

CVD Patient with Venous Ulcer: Comorbidities

Wound Clinic Patient Data

- Wound Clinic Data[1] [*2014*]:
  897 patients w/1,249 VUs
  - 67% PAD w ABI < 0.8
  - 44% Diabetes
  - 59% Varicose veins
  - 74% Edema/stasis dermatitis
  - 35% Lipodermatosclerosis
  - 22% CHF
  - 76% Morbid obesity [BMI>45]
  - 69% Smokers
- **24% Recurrent ulcers**

- QCDR Registry[3] [*2016*]: 126 Wound Clinics /19,151 patients/59,116 VUs
  - 7.9% PAD
  - 33.6% Diabetes
  - 8% Autoimmune disease – Prednisone Tx
  - 8% Dialysis
  - 7.6 CHF
  - 30% Obese
  - 47% Edema moderate – high
- **34.4% Recurrent ulcers**

1. Bongiovanni CMJ *Am College Clin Wound Specialists* 2014;6(3):32–37.

3. Venous Ulcer Registry [sponsored by US Wound Registry, /www.uswoundregistry.com/

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Complex Patients: CVD w/ Ulcer & ADLs

- 547 patients with VU from a wound care database* with recorded Activity of Daily Living (ADL)
  - **55%** of patients required assistance with ADLs including with ambulation[4]
  - Majority had issues with dressing and toileting

4. Fife CE, Carter, MJ, Walker D. Why is it so hard to do the right thing in wound care? *Wound Rep Reg* 2010;18:154–158.

*Intellicure Research Consortium users of Intellicure Inc.'s (The Woodlands, Tex) wound care software.

Venous Ulcer Registry Data 2016

Qualified Clinical Data Registry for Meaningful Use[3]

- 19,151 patients w/ 59,116 VUs
  - 126 Wound Clinics/ 2,000 physicians:
- Average patient - **3** ulcers
- Average surface area **34cm^2** [initial visit to clinic]
- VU **present 5 months** before seen in Wound Center [mean]
- Ulcers took additional 2.9 months to heal [mean]
- VUs that healed (78%) present nearly **8 months** [mean]
- **21%** not heal during the time followed

3. Venous Ulcer Registry [sponsored by US Wound Registry /www.uswoundregistry.com/

Venous Ulcer Healing

- VU are hard-to-heal wounds[1,2,3]
- Ulcer size directly correlates with time to heal[1,2]
- Healing time extended when one significant comorbidity is present[1]
- High recurrence rates[1,2,3]

1. Bongiovanni CM. *J Am College Clin Wound Specialists* 2014;6(3):32–37.

2. Gibbons GW, Orgill DP, Serena TE, Novoung A, O'Connell JB, Li WW, Driver VR. *Ostomy Wound Manage* 2015;61(1):16–29.

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Patient Centered QOL

- QOL:
  - Increase pain, drainage, odor, skin irritation
  - Reduced physical function & mobility
  - Increased feelings of depression & social isolation
  - Loss of work days or social encounters
  - Disturbed sleep
  - Anxiety
  - Feeling of low self-worth/ poor body image
  - Tolerance to treatment regime

Patients with VU – Lower QOL

- QOL reported for patients in VU RCT[2] *[2015]* had **lower scores** [SF-36] than in colorectal & breast CA patient studies:[5,6,7]
  - 7-41% lower in physical scores
  - 7-31% lower in mental scores
  - 28-31% more pain [VSS]

2. Gibbons GW, Orgill DP, Serena TE, Novoung A, O'Connell JB, Li WW, Driver VR. Ostomy Wound Manage 2015;61(1):16–29.

5. Ganz PA, Desmond KA, et. al. Quality of life in long-term, disease-free survivors of breast cancer: a follow-up study. *J Natl Cancer Inst.* 2002;94(1):39–49.

6. Sampaio E, Albuquerque I, Linhares J. Assessing the quality of life in women with breast cancer through the questionnaire SF-36. *Appl Clin Res.* 2008;28(3):93–98.

7. Trentham-Dietz A, Remington, et. al. Health related quality of life in female long-term colorectal cancer survivors. *Oncologist.* 2003;8(4):342–349.

Patient Centered Issues

- Poorly coordinated care
  - many specialties treat patient during course of disease
  - varied adherence of evidence-based care
  - frequent medical visits; Diagnosis, Tx, & follow-up
- Duration of ulcer closure - cost, time, work loss
- Control of pain, drainage, odor, skin irritation
- Compliance to effective Tx
- Recurrence of ulcers
- Healing w/ associated PAD and diabetes[1]

1. Bongiovanni CM. J Am College Wound Specialists 2014;6(3):32–37.

Socioeconomics CVD & Venous Ulcers

- Disease process costly if not managed early w/ appropriately interventions
- Cost for Tx approx. $10,000/ ulcer[1]
  - [excludes hospitalization, work loss]
- Annual estimated U.S. economic burden - up to $18 billion[8,9]

1. Bongiovanni CM. *J Am College Clin Wound Specialists* 2014;6(3):32–37.

8. Kom P, Patel ST, Heller JA, Deitch JS, Krishnasastry KV, Bush HL et al. Why insurers should reimburse for compression stockings in patients with chronic venous stasis. *J Vasc Surg*. 2002;35(5):950–957.

9. Rice JB, Desai U, Cummings AKG, Birnbaum HG, Skornicki M, Parsons N. Medical, drug, and work-loss costs of venous leg ulcers. Poster presentation, Symposium on Advanced Wound Care. New Orleans, LA. May18–22, 2013.

Early Diagnosis & Treatment of VU

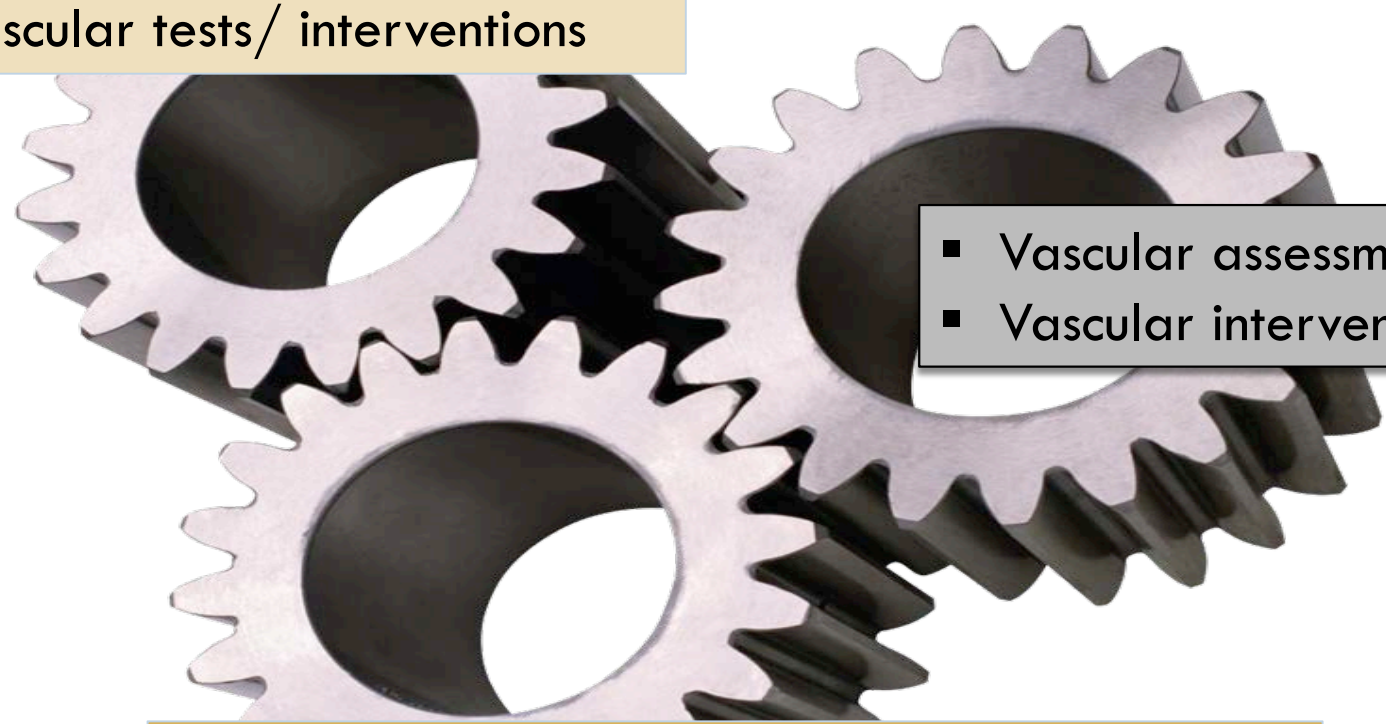
- Need WC Specialist engaged early: prevent & treat
  - evaluate potential to heal
  - expedite initiation of evidence-based care
  - remove devitalized tissue & bioburden
  - determine adjunct therapy - based on healing trajectory
  - refer for vascular assessment / interventions

- CVD under-diagnosed: need early, consistent identification
  - ABI standard - LE wounds & skin changes /routine annual test all CVD patients w/ diabetic
    - normal ABI; should evaluate further w/ skin perfusion pressures/ toe pressures/ TcO_2M before any treatment procedure

Wound Care Specialists

Facilitate Multi-pronged, Multi-professional VU Care

- Assessment
- Evaluate & Tx comorbidities
- Tx ulcer: evidence-based Guidelines
- Refer for vascular tests/ interventions



- Vascular assessment
- Vascular interventions

- Tx wound post-procedure
- Coordinate w/ other physicians
- Ensure compliance to evidence-based care

Access to WC Specialists Reduces Costs

- Patients with VUs [215] had shorter time to healing and greater percent of ulcers healed with access to wound care specialists/ teams in wound clinic[10]

Clinic Visit Freq.	1X/ Week	2 X/ Month
% healed @ 4weeks	52%	0%
Days to healing	25	55

10. Warriner RA, Wilcox JR, Carter MJ, Stewart DG. More frequent visits to wound care clinics result in faster times to close diabetic foot and venous leg ulcers. *Adv Skin Wound Care* 2012;25(11):494-501.

‘Partnership’ for Healing

- Multi-specialty teams need to ‘partner’ to address factors critical to healing:
  - Over-all risk level & clinical severity
  - Patient specific goals
  - Adherence to life style recommendations
  - Pain assessment/ plan
  - Psychosocial / financial aspects
  - Optimize patient’s limb & wound prior to vascular interventions