De-feet Diabetic Foot Complications Prevention

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Division of ENDOCRINOLOGY, DIABETES, METABOLISM & NUTRITION
Disclosures

• No relevant financial relations
• No off label discussions
• AMP Shoes from DiABETES UK
Defects - Diabetic Foot Complications
Background Community

• Life time risk of Foot Ulcer as high as 25%
• Annual risk 0.6% to 2.2% affecting 382 million people world wide
• Higher in individuals with peripheral neuropathy

Boulton et al Lancet 2005 v366 p1719
Singh et al JAMA 2005 v293 p217
Cost- Human Suffering and Health Care Dollar

• Approximately 80% of diabetes LE amputations are preceded by foot ulcer

• 5 year mortality following amputation  80%

• **Diabetes** accounts for the majority of non traumatic LE amputation world wide

• North America and Europe: 20% of total diabetic costs

• Annual cost of diabetes foot disease in the United States is estimated to be greater than $6 billion

Ragnarson et al Clin Infect Dis 2004 v39(S2); S132
Hingoranni et al J Vas Surg 2016 v63, 3S
Diabetic Foot Ulcers are Preventable

Goal

aware of the importance of:

1. foot inspection, examination, risk assessment
2. access to and use of appropriate foot-ware
3. access to appropriate foot care and treatment
4. education of patient, family, health care team
SMART
Objectives: BE SMART

• Be aware of risk factors
• Educated patients and care giver team
• Structured clinical assessment
• Metabolic evaluation
• Assess Risk
• Team Care
Be Aware of Risk Factors

Diabetic Foot Ulcer

-is a multifactorial process resulting in complex interactions of several etiologic factors that act synergistically to cause tissue breakdown
Be Aware of Risk Factors

- Foot Ulceration-Amputation*
- Neuropathy*
- Deformity*
- Vascular Ischemia*
- Minor Trauma*
- Callus-Pressure Points
- Limb-Toe-Planter Pressures
- Visual Acuity
- AB Index
- HgA1c
- Edema
- Limited Joint Motion
- Renal Function
- Sex
- Marital Status
- Religion
- Living Area
- Occupation
- Education
- Smoking
- Diabetes Duration
- ETOH
- BMI
- Age
- CAD
- Race
- Taking Insulin
- Taking OHAs
- Frequency of visits
- Retinopathy
- Decreased reflexes
- Visit Frequency
- TrO2
- Foot Exam
- Hypertension
- Tinea
- Obesity
- Nail Pathology
- Foot ulcer

Crawford et al QJ Med 2007 v100, 65
Be Aware of Risk Factors

- Retrospective/Prospective study of 146 patients (30-85 yrs) with first foot ulcer (1990-1994)
- Demographic, health, diabetes and ulcer data
  - Seattle Washington
  - Manchester UK
- Multidisciplinary study group of foot specialists
- Component analysis

Adopted from Reiber et al D Care 1999 v22 157
### Be Aware of Risk Factors

<table>
<thead>
<tr>
<th>Component</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neuropathy</td>
<td>78</td>
</tr>
<tr>
<td>Minor Trauma</td>
<td>77</td>
</tr>
<tr>
<td>Deformity</td>
<td>63</td>
</tr>
<tr>
<td>Edema</td>
<td>37</td>
</tr>
<tr>
<td>Ischemia</td>
<td>35</td>
</tr>
<tr>
<td>Callus</td>
<td>30</td>
</tr>
</tbody>
</table>
Be Aware of Risk Factors

- Foot Ulceration-Amputation*
- Neuropathy*
- Deformity*
- Vascular Ischemia*
- Minor Trauma*
- Callus-Pressure Points
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- Foot ulcer

Crawford et al QJ Med 2007 v100, 65
Be Aware of Risk Factors

Neuropathy: Loss Protective Sensation LOPS

- The neurological exam performed as part of the foot examination is designed to identify LOPS rather than early neuropathy.

- The 10-g monofilament is the most useful test to diagnose LOPS.

- Ideally, the 10-g monofilament test should be performed with at least one other assessment (temperature or vibration sensation using a 128-Hz tuning fork, or ankle reflexes).

- Absent monofilament sensation suggests LOPS, while at least two normal tests (and no abnormal test) rule out LOPS.
Neuropathy Deformity and Limited Joint Mobility

- Autonomic Dyshydrosis, cracking of the skin and loss of protective barrier
- Intrinsic motor/muscular atrophy
- Deformity-limited joint mobility
- Loss of shock absorber function
- Higher arches
- Pressure points (peak >10 kg/cm)
- Tissue trauma
Be Aware of Risk Factors

- Hx Foot Ulceration-Amputation
- Visual Acuity
- Neuropathy
- Deformity
- Vascular Ischemia
- Callus-Pressure Points
- Limited Joint Motion
- Limb-Toe-Planter Pressures
- AB Index
- HgA1c
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Crawford et al QJ Med 2007 v100, 65
## BE SMART

<table>
<thead>
<tr>
<th>Component</th>
<th>Be Aware of Prevention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neuropathy</td>
<td>Patient Ed Protectiv Foot ware Glycemic Control</td>
</tr>
<tr>
<td>Ischemia</td>
<td>Patient Ed CV Risk Factor Control</td>
</tr>
<tr>
<td>Deformity</td>
<td>Patient Ed Appropriate Foot ware Inserts</td>
</tr>
<tr>
<td>Minor Trauma</td>
<td>Patient Ed Protectiv Foot ware Home Environment</td>
</tr>
<tr>
<td>Callus</td>
<td>Patient Ed Regular Removal Foot ware</td>
</tr>
<tr>
<td>Edema</td>
<td>Patient Ed Pharma, Stockings, Bedrest</td>
</tr>
</tbody>
</table>

Adopted from Reiber et al D Care 1999 v22 157
**BE SMART**

- Promote Personal
  - Foot Knowledge
  - Self Examination

- Alternate senses
  - Vision
  - Touch

- Formats (simple/effective)
  - Foot care classes
  - Lectures
  - Work shop
  - Behavioral Mod
  - Reminders

- Available body of evidence has been inconclusive
- Significant heterogeneity to evaluate/group interventions
- “lack of evidence rather than evidence of no effect”

BE SMART Foot Exam

aware of the importance of:

1. foot inspection, examination, risk assessment
2. access to and use of appropriate foot-ware
3. access to appropriate foot care and treatment
4. education of patient, family, health care team
During 2009, 2084 diabetes patients received care in the Department of Family Medicine Rochester.

- NLP identified 389 patients without FE in EMR randomized to:
  - postal survey & patient education brochure ($n=163$)
  - postal survey ($n=157$)
  - control group ($n=69$)
Patients receiving the education brochure were twice as likely to have foot exam in the year 2010.
People with neuropathy or evidence of increased plantar pressures (erythema, warmth, or calluses)
- well-fitted walking or athletic shoes
- cushion the feet and redistribute pressure.

People with bony deformities (e.g., hammertoes, prominent metatarsal heads, bunions)
- extra-wide or -deep shoes.

People with bony deformities - Charcot foot
- commercial therapeutic footwear
- custom-molded shoes

BE SMRT
Policy and Individualized initiatives
BE **SMART**
Structured Clinical Assessment

### History
- Duration of Diabetes
- Loss of Protective Sensation-LOPS
- Previous Ulcer/Amputation
- Decrease Visual Acuity
- Increased A1c
- Trauma

### Exam
- Neuropathy-LOPS
- Peripheral Vascular Disease
- Structural change
- Foot-ware
BE SMART
Structured Clinical Assessment

Deformity and Limited Joint Mobility

Trauma
- Trauma associated with LOPS
- Mechanical or Thermal
- Callus

Monofilament testing sites
Metabolic-Glycemic Control

Prospective cohort study (2000-2012) for 35,368 patients with diabetes (LSU HCSD)

Adjusted Hazard Ratio-LEA

Glucose Lowering Agent

Yes

No

P for trend

<0.001

0.007

Baseline HgbA1c

<6 6-6.9 7-7.9 8-8.9 9-9.9 ≥ 10

Adapted from Zhao et al D Care 2013 v36 3591
BE SMART
Metabolic-Glycemic Control

- Adler et al Meta-analysis
- 14 prospective trials (94,640 patients)
- Each percentage point increase in A1c associated with 26% increase risk of lower extremity amputation
- Interventions for improved glucose are limited and inconclusive
- Complex association with neuropathy, trauma

Adler et al Diabetologia 53; 840-849. 2010
BE SMART
Assess Risk

Survey instruments for sensorimotor neuropathy

- Michigan Neuropathy Screening Instrument
- Neuropathy Disability Score
- CHANT (Clinical HIV-associated Neuropathy Tool)
- Utah Early Neuropathy tool
- Toronto Clinical Neuropathy Scoring System

Bril et al Diabet Med 26 240-246, 2009
Woldeamanuel et al PLOS ONE 10.1371, 2016
## Toronto Clinical Neuropathy Scoring System

<table>
<thead>
<tr>
<th>Symptom Scores</th>
<th>Present = 1</th>
<th>Absent = 0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Numbness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tingling</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weakness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ataxia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper-Limb Symptoms</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reflex Scores</th>
<th>Absent = 2</th>
<th>Reduced = 1</th>
<th>Normal = 0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knee Reflexes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ankle Reflexes</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sensory Test Scores</th>
<th>Abnormal = 1</th>
<th>Normal = 0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pinprick</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temp</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Light Touch</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vibration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Position</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Totals | |
|--------||

### Scoring:
- No neuropathy: 0-5 points
- Mild neuropathy: 6-8
- Moderate neuropathy: 9-11
- Severe neuropathy: 12+

Adopted from Bril Diabet Med 26 240-246, 2009
### Assess Risk

#### ADA and AACE

<table>
<thead>
<tr>
<th>Risk Categories</th>
<th>Recommendations</th>
<th>Recommended F/U</th>
</tr>
</thead>
<tbody>
<tr>
<td>No LOPS, PAD, Deform</td>
<td>Ed and advice foot ware</td>
<td>Annually</td>
</tr>
<tr>
<td>LOPS ± foot deformity</td>
<td>Prescriptive foot ware Surgery</td>
<td>Every 3-6 months</td>
</tr>
<tr>
<td>PAD ± LOPS</td>
<td>Prescriptive foot ware Surgery</td>
<td>Every 2 to 3 months</td>
</tr>
<tr>
<td>Hx DFU or Amputation</td>
<td>Prescriptive foot ware Surgery</td>
<td>Every 1-2 months</td>
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BE SMART
Team Effort

• Multidisciplinary foot care team
  • Callus Nails
  • Foot Deformities
  • Primary Care, Endocrinology, Physical Medicine, Neurologist, Behavioral Medicine, Podiatrist, Orthopedist, Vascular Surgeon

• High Risk Random assignment (n=128)
  • Weekly Foot Clinic
  • Podiatry Care
  • Daily Hygiene Ed
  • Protective Foot ware

• Amputation RR 0.5 (95% CI 0.13 to 0.41)

Mccabe et al; Diab Med 2004: 15, 80
BE SMART

- Team approach is effective
- What are the costs with implementing team effort
- Cost of diabetes foot ulcer (ER, Hospitalization)
  - 5.4x year 1 (8x highest-grade)
  - 2.8x year 2
BE SMART

• Cost-utility simulation - Markov model
  • Intensified (International Consensus on the Diabetic Foot)
    • foot inspection, examination, risk assessment
    • access to and use of appropriate foot-ware
    • access to appropriate foot care and treatment
    • education of patient, family, health care team

• Assessed Risk
  • Level 1 Φ
  • Level 2 sensory neuropathy (sn)
  • Level 3 sn + PVD and/or foot deformity
  • Level 4 prior DFU or Amputation
• Results
  • An intensified prevention strategy including 1) patient education, 2) foot care, and 3) foot-ware is cost-effective/saving if the risk of foot ulcers and lower extremity amputations can be reduced by 25% (all but lowest level of risk)
In Summary  BE SMART

• Be aware of risk factors
• Educated patients and care giver team
• Structured clinical assessment
• Metabolic evaluation
• Assess Risk
• Team Care
Be Aware of Risk Factors

- Foot Ulceration-Amputation*
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- Tinea
- Obesity
- Nail Pathology
- Foot ulcer

Crawford et al QJ Med 2007 v100, 65
Keep in mind Pathways to Foot Ulceration

- Pathology
- Neuropathy
- Pathos
- Deformity
- Event
- Minor Trauma
- Ulceration

Adopted from Reiber et al D Care 1999 v22 157
Questions?

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BE Aware of Risk Factors- Question 1

A 65 year old male is seeing you for follow up diabetes care. He is experiencing stable exertional angina over the last 6 months and has missed several clinic appointments. He has a history of Peripheral Sensory Neuropathy, Diabetic Background Retinopathy, Hypertension and Foot Ulcer. His most important risk for developing additional Foot Ulcer is (choose one)

A. LOPS on physical exam
B. Decreased pedal pulses
C. Prior Foot Ulcer
D. Infrequent clinic visits
BE Aware of Risk Factors- Question 1

A 65 year old male is seeing you for follow up diabetes care. He is experiencing stable exertional angina over the last 6 months and has missed several clinic appointments. He has a history of Peripheral Sensory Neuropathy, Diabetic Background Retinopathy, Hypertension and Foot Ulcer. His most important risk for developing additional Foot Ulcer is (choose one)

A. LOPS on physical exam
B. Decreased pedal pulses
C. Prior Foot Ulcer
D. Infrequent clinic visits
BE Aware of Risk Factors- Question 2

You explain to your patient that because of his past foot ulcer, the American Diabetes Association and the American Association of Clinical Endocrinologists recommend he be seen for foot assessment (choose one)

A. Annually
B. 1-2 months
C. 2-3 months
D. 3-6 months
BE Aware of Risk Factors- Question 2

You explain to your patient that because of his past foot ulcer, the American Diabetes Association and the American Association of Clinical Endocrinologists recommend he be seen for foot assessment (choose one):

A. Annually
B. 1-2 months
C. 2-3 months
D. 3-6 months
Extra slides
Defeet- Diabetic Foot Complications
Community Intervention

• AMP Footware- DiABETES UK

Be aware of the importance of:

1. foot inspection, examination, risk assessment
2. access to and use of appropriate foot-ware
3. access to appropriate foot care and treatment
4. education of patient, family, health care team
Objectives

• Provide an overview of available evidence on preventive diabetic foot care
• Identify those at risk
• Effective implementation of preventive care
• DE-FEET diabetic foot complications
Be Aware of Risk Factors

Neuropathy- Loss Protective Sensation LOPS

<table>
<thead>
<tr>
<th></th>
<th>Monofilament</th>
<th>Biothesiometer</th>
<th>Tuning Fork</th>
<th>Plantar Pressure</th>
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</thead>
<tbody>
<tr>
<td>Sens(%)</td>
<td>66-91</td>
<td>83-86</td>
<td>55-61</td>
<td>57,70,64</td>
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<tr>
<td>Spec(%)</td>
<td>34-86</td>
<td>57-63</td>
<td>50-72</td>
<td>70,65,46</td>
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<tr>
<td>PredVal</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>18-39</td>
<td>20-32</td>
<td>16</td>
<td>31,40,17</td>
</tr>
<tr>
<td>Negative</td>
<td>94-95</td>
<td>95-97</td>
<td>93</td>
<td>87,82,90</td>
</tr>
</tbody>
</table>

Singh et al; JAMA 2005; 293: 217-228
BE SMART
Team Effort

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  • Callus Nails
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Mccabe et al; Diab Med 1998: 15, 80
Ischemia Peripheral Arterial Disease ABI<0.9

- Tobacco
- HTN
- Diabetes
- Hyperlipidemia

- Prolonged healing
- Recurrent Amputation
- Amputation

BE SMART

• Transition Probabilities
  • EMR dataset
    • 1677 patients with diabetes (Sweden)
    • Mean age 66 years (24-97)
    • Male 53%
  • Survey
  • Published literature

• Outcomes
  • Cumulative incidences of
    • Foot Ulcers
    • Amputations
    • Death
    • Cost-QOL

Tennaval Apelqvist. Diabetologia v44 p2077, 2001