Non-Interventional Management Of CLTI: With Optimal Medical Treatment And Good Wound Care Many Amputations Can Be Prevented: When Is It The Best And Most Cost Effective Treatment?

VEITH 2018
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CLTI mgmt in value based care

• Patient management to optimize quality of life while not expending all of dollars allocated to that patient’s care

• Avoidance of
  – Multiple readmissions
  – Multiple procedures
  – Failed procedures
  – Complications

Premium placed on decision making

• Status Quo
  – Endovascular first strategy
  – If it fails can always move to bypass

• ACO – will Status quo play well?
  – Now need to choose best strategy to manage patient over “long term”
  – Maybe…

Typical CLT1 case

• 44 YO male presents with L heel ulcer present 3 months despite attempted offloading and moist wound healing
• H/o DM, ESRD
• ABI/Doppler studies
  – ABI 0.37
  – Toe pressure 20

Procedural record

• SFA PTA/stenting 6/12
• Repeat SFA PTA/stent 3/13
• Atherectomy/PTA SFA 7/13
• Popliteal stent 1/14
• ALI, lysis, repeat PTA 3/14
• Proximal SFA stent extension 7/14
• Toe amputation x 2 8/14

Disclosures

• Scientific Consultant
  – Veniti/Boston Scientific
  – Inari Medical
  – Tactile Medical

• Clinical Trial Investigator
  – Factor Therapeutics, Avadim
Procedural record

- Fem-Bkpop bypass PTFE/patch 11/14
- Graft thrombosis/lysis/revision 1/16
- Re-thrombosis 6/16
  - Fem-PT bypass PTFE/patch
- Trans met amputation 7/16
- Graft thrombosis - BKA 12/16

12 procedures in <4 years ending in amputation

Choices for CLI patients complex

- Severity of symptoms
  - Rest pain
- Depth/complexity of wound
  - Can the wound heal without revasc

Other key considerations

- Patient’s suitability/risk for revascularization
  - Renal insuff
  - Cardiac status
  - Patient’s ambulatory status
- Should we be discussing life expectancy with CLTI pts?

CLI patients are believed to be at high risk for limb loss without revascularization

<table>
<thead>
<tr>
<th>Control group outcomes</th>
<th>Amputation rate at 12 months</th>
<th>Amputation rate in rest pain group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restore –CLI J Vasc Surg 2011:54:1032</td>
<td>24%</td>
<td>14%</td>
</tr>
<tr>
<td>BMAC CLI Phase II J Vasc Surg 2011:54:1650</td>
<td>28.6%</td>
<td>12%</td>
</tr>
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</table>

UNC CLI Natural History Study

- Determine risk of limb loss and mortality in patients with CLI who are not successfully revascularized
- Evaluate the accuracy of currently accepted hemodynamic criteria for CLI in predicting patients who are at high risk of limb loss
- Vallabhaneni et al, JVS 2016;63:105-12.

Results

- Final patient cohort 345 limbs in 296 patients
  - ABI < 0.5: 119 of 345 (34%)
  - Toe P < 50: 282 of 345 (82%)

Tibial vessel calcification limits usefulness of ankle pressures and ABIs
Limb salvage by initial TP

<table>
<thead>
<tr>
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<th>6 month</th>
<th>1 year</th>
<th>2 year</th>
<th>3 year</th>
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<tr>
<td>All Limbs</td>
<td>81%</td>
<td>76%</td>
<td>72%</td>
<td>69%</td>
</tr>
<tr>
<td>Toe P 31-50</td>
<td>91%</td>
<td>85%</td>
<td>82%</td>
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</tr>
<tr>
<td>Toe P 11 – 30</td>
<td>86%</td>
<td>80%</td>
<td>77%</td>
<td>72%</td>
</tr>
<tr>
<td>Toe P 0-10</td>
<td>58%</td>
<td>54%</td>
<td>48%</td>
<td>40%*</td>
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Adjusted HR, Toe P 0-10: 3.70 (1.78,7.68), p=0.0004*

Patient survival by initial TP

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Difference between groups P < .001

WIFI outcome prediction

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<th>Wound Healing</th>
<th>Amputation-free survival</th>
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Who is appropriate for palliative care?

Predictors of early mortality

- ESRD
- CHF, if severe and not responsive to Rx
- Non-ambulatory status
- Of these ESRD is strongest predictor

When is non-interventional care a good choice?

- Toe pressure > 20-30 mm Hg
- Less extensive wound
- High risk of procedural care
- High risk of early mortality

Is it actually less expensive?
  - Depends on how you treat them

From the Society for Vascular Surgery

An early validation of the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System

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