**MHIF FEATURED STUDY: PIONEER III**

**DESCRIPTION:**
A prospective, multicenter, global randomized (2:1) controlled trial assessing safety and efficacy of the BuMA Supreme™ Biodegradable Drug Coated Coronary Stent System (made of cobalt chromium with sirolimus) for coronary PCI or coronary stenting in patients with stable coronary artery disease or non-ST segment elevation acute coronary syndromes.

**CRITERIA LIST/QUALIFICATIONS:**

**Inclusion**
1) Male or non-pregnant female ≥20 and not greater than 99 years of age
2) Symptomatic ischemic heart disease-chronic stable angina, UA, NSTEMI requires elective or urgent PCI
3) Comply with specified follow-up evaluation
4) De novo lesion, 2 target lesions per epicardial vessel and max of 3 target lesions

**Exclusion**
1) History of bleeding, on chronic anticoagulation therapy
2) STEMI at index or within 7 days
3) LVEF < 30%, eGFR < 30 mL/min/1.73 m2
4) Previous 3 months PCI in target vessel with stent placement
5) Discontinuation of DAPT within 6 months of index procedure
6) Transplant or on waitlist, receiving immunosuppressant therapy
7) No CTO, LM or graft

<table>
<thead>
<tr>
<th>CONDITION:</th>
<th>Stable CAD, acute coronary syndromes without ST-segment elevation-UA, NSTEMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI:</td>
<td>M. Nicholas Burke, MD</td>
</tr>
</tbody>
</table>
| RESEARCH CONTACT: | Carmen Chan-Tram  
carmen.chan-tram@allina.com | 612-863-5507 |
| SPONSOR:   | Sino Medical Sciences Technology |

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Sino Medical Sciences Technology

**OPEN AND ENROLLING:**
Please Refer Patients!

**Please Refer Patients!**
Minneapolis Heart Institute Foundation® Cardiovascular Grand Rounds

Title: Critical limb ischemia (CLI): Advances and our experience at the Minneapolis Heart Institute

Speaker(s): Joseph Karam, MD, FSVS, FACS, RPVI
Vascular Surgeon
Minneapolis Heart Institute® at Abbott Northwestern Hospital

Date: May 20, 2019
Time: 7:00 – 8:00 AM
Location: ANW Education Building, Watson Room

OBJECTIVES
At the completion of this activity, the participants should be able to:
1. Describe advances in treatment of CLI.
2. List the different treatment modalities available at Minneapolis Heart Institute.

ACCREDITATION
Physician - Allina Health is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. Allina Health designates this live activity for a maximum of 1.0 AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Nurse - This activity has been designed to meet the Minnesota Board of Nursing continuing education requirements for 1.0 hours of credit. However, the nurse is responsible for determining whether this activity meets the requirements for acceptable continuing education.

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The ACCME defines a commercial interest as “any entity” producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The ACCME does not consider providers of clinical service directly to patients to be commercial interests - unless the provider of clinical service is owned, or controlled by, an ACCME-defined commercial interest.

Moderator(s)/Speaker(s)
Dr. Joseph Karam has disclosed that he DOES NOT have any real or apparent conflicts with any commercial interest as it relates to presenting their content in this activity/course.

Planning Committee
Dr. Alex Campbell, Jake Cohen, Jane Fox, Dr. Mario Gössl, Dr. Kevin Harris, Dr. Kasia Hryniewicz, Rebecca Lindberg, Amy McMeans, Dr. Michael Miedema, Dr. JoEllyn Moore, Pamela Morley, Dr. Scott Sharkey, and Jolene Bell Makowesky have disclosed that they DO NOT have any real or apparent conflicts with any commercial interest as it relates to the planning...
of this activity/course. Dr. David Hurrell has disclosed the following relationship – Boston Scientific: Chair, Clinical Events Committee.

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We would like to thank the following company for exhibiting at our activity.

**Bristol-Myers Squibb**

**Janssen Pharmaceutical Companies**

of Johnson & Johnson

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**PLEASE SAVE YOUR SERIES FLIER**

When you request a transcript this serves as your personal tracking of activities attended. Most professional healthcare licensing/certification boards **will not accept** a Learning Management System (LMS) transcript as proof of credit; there are too many LMS’s across the country and their validity/reliability are always in question.

If audited by a licensing board or submitting for license renewal or certification renewal, boards will ask you not the entity providing the education for specific information on each activity you are using for credit. You will need to demonstrate that you attended the activity with a copy of **your certificate/evidence of attendance, a brochure/flier and/or the conference handout.**

Each attendee at an activity is responsible for determining whether an activity meets their requirements for acceptable continuing education and should only claim those credits that he/she actually spent in the activity.

Maintaining these details are the responsibility of the individual.

**PLEASE SAVE A COPY OF THIS FLIER AS YOUR CERTIFICATE OF ATTENDANCE.**

| Signature: ____________________________________________________________________________ |
| My signature verifies that I have attended the above stated number of hours of the CME activity. |

Allina Health - Learning & Development - 2925 Chicago Ave - MR 10701 - Minneapolis MN 55407
Critical limb ischemia (CLI)

- Any patient with chronic ischemic rest pain, ulcers, or gangrene attributable to objectively proven arterial occlusive disease.

- “End-stage” of peripheral arterial disease
### CLI

<table>
<thead>
<tr>
<th>Classification</th>
<th>Stage</th>
<th>Clinical Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fontaine</td>
<td>I</td>
<td>Asymptomatic</td>
</tr>
<tr>
<td></td>
<td>IIa</td>
<td>Mild claudication</td>
</tr>
<tr>
<td></td>
<td>IIb</td>
<td>Moderate-to-severe claudication</td>
</tr>
<tr>
<td></td>
<td>III</td>
<td>Rest pain</td>
</tr>
<tr>
<td></td>
<td>IV</td>
<td>Ulceration or gangrene</td>
</tr>
<tr>
<td>Rutherford</td>
<td>0</td>
<td>Asymptomatic</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Mild claudication</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Moderate claudication</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Severe claudication</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Rest pain</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Minor tissue loss</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Severe tissue loss or gangrene</td>
</tr>
</tbody>
</table>

---

**Image Description:**
- The image shows a table illustrating the classification and stages of CLI, with corresponding clinical descriptions.
- A visual representation of CLI is also present, showing a foot with visible signs of ischemic changes.
- The table highlights stages III (Rest pain) and 5 (Minor tissue loss) with circled text for emphasis.
Natural history of PAD

• Patients with CLI represent 1% of the total number of patients with PAD
  - Prevalence 0.23% (Medicare)

• Significant morbidity:
  - Cardiovascular event rates surpass those in patients with symptomatic CAD.

• Overall mortality approaches 50% at 5 years and 70% at 10 years.

• More than 5 billion dollars annually spent on CLI care in the US.
Outcomes of Patients With Critical Limb Ischemia

Primary Treatment → One Year Later

- Medical Treatment 25%
  - Stable, uncomplicated tissue loss
  - Poor surgical candidate
- Revascularization 50%
- Primary Amputation 25%
- Amputation: Unreconstructable disease, Terminal illness, Limited life expectancy, Dementia, Spreading infection, Non-ambulatory pre-operatively, Poor surgical candidate
- Revascularization:
  - Not in any of the other arms
  - Ambulatory pre-op
- CLI Resolved 25%
- Died 25%
- Continuing CLI 20%

CLI algorithm

Confirmatory testing
- CTA/MRA
- Angiogram

Medical therapy alone:
- Stable, uncomplicated tissue loss
- Poor surgical candidate

Amputation:
- Unreconstructable disease
- Terminal illness
- Limited life expectancy
- Dementia
- Spreading infection
- Non-ambulatory pre-operatively
- Poor surgical candidate

Revascularization:
- Not in any of the other arms
- Ambulatory pre-op

TASC II (2007). JOURNAL OF VASCULAR SURGERY
Volume 45, Number 1, Supplement S
Outcomes of Patients With Below-the-Knee Amputations

TASC II. (2007). JOURNAL OF VASCULAR SURGERY. Volume 45, Number 1, Supplement S

LE amputation 30-day outcomes

<table>
<thead>
<tr>
<th>Post-op Morbidity</th>
<th>BKA</th>
<th>AKA</th>
<th>p</th>
<th>OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound Infection</td>
<td>3.6%</td>
<td>2.4%</td>
<td>P&lt;0.05</td>
<td>0.643</td>
</tr>
<tr>
<td>Wound Dehiscence</td>
<td>1.9%</td>
<td>1.1%</td>
<td>P&lt;0.05</td>
<td>0.597</td>
</tr>
<tr>
<td>PE</td>
<td>0.4%</td>
<td>0.8%</td>
<td>P&lt;0.05</td>
<td>2.171</td>
</tr>
<tr>
<td>Failure to wean</td>
<td>3.7%</td>
<td>6.5%</td>
<td>P&lt;0.05</td>
<td>-</td>
</tr>
<tr>
<td>UTI</td>
<td>4.2%</td>
<td>6%</td>
<td>P&lt;0.05</td>
<td>-</td>
</tr>
<tr>
<td>CVA</td>
<td>0.4%</td>
<td>1.3%</td>
<td>P&lt;0.05</td>
<td>-</td>
</tr>
</tbody>
</table>

BKA vs. AKA
Mortality 6.5% vs. 12.7% (OR 2.1)
ANW Amputations

- Jan 2014-March 2019: 141 amputations
- Avg LOS: 11.9 days
- Avg ICU days: 5.5
- Avg total cost: $44,539
CLI algorithm

Confirmatory testing
CTA/MRA
Angiogram

Medical therapy alone:
Stable, uncomplicated tissue loss
AND
Poor surgical candidate

Amputation:
Unreconstructable disease
Terminal illness
Limited life expectancy
Dementia
Spreading infection
Non-ambulatory pre-operatively
Poor surgical candidate

Revascularization:
Not in any of the other arms
AND
Ambulatory pre-op

Seen through the eyes of a patient
BASIL trial (1999-2004)

- 450 patients randomized to bypass or balloon angioplasty for the initial treatment of infrainguinal disease.
- No difference in overall survival (OS) and amputation free survival (AFS) at 2 years.
- For patients surviving more than 2 years, open bypass has significantly increased OS and a trend towards increased AFS.
- Prosthetic grafts performed poorly compared to vein.
- Bypass after angioplasty had worse outcomes than bypass as initial therapy.

Help is on the way (?)

- BEST CLI
  - US & Canada
  - 140 sites
  - 1700 patients (2100)
  - MHI Vascular Surgery
Help is on the way (?)

- **BASIL 2**
  - Multicenter RCT
  - ‘vein bypass first’ vs ‘best endovascular first’
  - Clinical efficacy and cost-effectiveness
  - CLI
  - Tibial disease
  - 300 patients to date (2020)
- **BASIL 3**
  - Multicenter RCT
  - Clinical efficacy and cost-effectiveness of DCB, DES and PBA for severe limb ischemia (SFA/POP)
  - PAUSED

SVS WIFI System

- Wound, Ischemia, and Foot Infection.
- More accurately represents the complete status of the threatened ischemic limb.
- Based on existing literature and Delphi consensus.

Wound

- **Grade 0**: no ulcer/gangrene
- **Grade 1**: small, shallow ulcer, no gangrene (coverage or digit amp)
- **Grade 2**: ulcer with tendon/bone, digital gangrene (multiple digit amps or TMA)
- **Grade 3**: deep heel ulcer, extensive forefoot/midfoot gangrene (complex foot reconstruction vs need for major amp)

Ischemia

- **Grade 0**: ankle > 100 mm Hg; toe > 60 mm Hg
- **Grade 1**: ankle 70-100 mm Hg; toe 40-59 mm Hg
- **Grade 2**: ankle 50-70 mm Hg; toe 30-39 mm Hg
- **Grade 3**: ankle < 50 mm Hg; toe < 30 mm Hg
Foot Infection

- **Grade 0**: no signs/symptoms of infection
- **Grade 1**: swelling, erythema, purulence, tenderness—but superficial
- **Grade 2**: erythema margin of > 2 cm, extending deep to skin and subcutaneous tissues
- **Grade 3**: local infection + SIRS (temp, HR, WBC)

The Angiosome concept

Lida et al, J Vasc Surg 2012
Angiosomal Revascularization

- **Direct vs indirect** revascularization of the affected angiosome in isolated BTK disease results in substantial outcome improvements
  - AFS (49% vs 29%)
  - Freedom from MALE (51% vs 28%)
  - Freedom from major amp (82% vs 68%)

- Iida et al., J Vasc Surg 2012
Open revascularization: Aortoiliac disease

Hybrid procedures
Open revascularization: Infrainguinal disease

- Femoral endarterectomy/Profundaplasty:
  - Sometimes performed to augment collateral flow in severe distal disease.
  - Open Profunda artery is needed to heal a below knee amputation.

- Above knee/Below Knee/Pedal bypass:
  - Donor vessel
  - Target
  - Conduit
  - Need in-line flow to heal wounds.

The Vein
The Vein

- A greater saphenous vein of adequate caliber is the conduit of choice for open bypass.
- Superior durability compared with all other conduit choices.
- In the absence of a good-caliber greater saphenous vein for bypass, endovascular revascularization becomes a more attractive option.
ANW LE Bypasses

- Jan 2014-March 2019: 301 Bypasses
- Avg LOS: 7.6 days
- 30 day readmissions: 23.8%
- ICU admission %: 29.6%
- ICU days: 3.9
- Average total Variable costs: $25,425
CLI

ENDOVASCULAR REVASCULARIZATION

Endovascular Revascularization
Endovascular devices

- Wires
- Catheters
- Crossing devices
- Atherectomy devices
- Re-entry devices
- Balloons
  - Drug eluting balloons (Paclitaxel)
- Stents
  - Balloon expandable.
  - Self expanding.
  - Stent grafts
  - Drug eluting stents (Paclitaxel)
Crossing the lesion

Intraluminal Angioplasty

Subintimal Angioplasty

Intraluminal angioplasty
subintimal angioplasty

subintimal angioplasty
CLI: Endovascular revascularization

RE-ENTRY TECHNIQUES
Outback® LTD Re-Entry Catheter

Pioneer Catheter

- Requires Volcano IVUS
CLI: Endovascular revascularization

**ACCESS**

- **Contralateral Access**
  - Retrograde approach
    - Most common (80-90%)
    - Easier technique
    - Can address iliac disease also
    - Must be used if anatomy unknown
    - Crossover sheath
    - Problems with:
      - Steep bifurcation
      - Iliac tortuosity
Antegrade Access

- Less frequently used
- Difficult in the obese pt
- Higher risk for complication
- Natural wire course is into PFA

CLI: Endovascular revascularization

RETROGRADE/PEDAL ACCESS
Retrograde access

- Ultrasound guided micropuncture of pedal/distal calf artery
- Wire will often traverse “uncrossable” chronic total occlusion (CTO).
- Can perform some interventions via pedal access
- Risks include compartment syndrome, occlusion of access vessel
CLI: Endovascular revascularization

**STENTS**

- **Viabahn**
  - Heparin bonded, PTFE stent graft
  - RCT:
    - Viabahn vs Bypass
    - 30% CLI patients
    - Equivalent results at 1 year
      - PP 65%
      - 100% limb salvage
Mimic Stent

- Designed to promote natural swirling blood flow
- Protect the endothelium
- Enable coil-spring shortening of the stented segment during knee bending to reduce the risk of stent fracture
- Freedom from (CD-TLR) @ 24 months was 84.2%,
  - Comparable with the performance at 2y of DES and DCB
  - Claudication/SFA
• @ 12 and 24 months, the overall primary patency rates were 81.5% and 67.2%
• Primary assisted patency was 94.9% and 84.8%. 
CLI: Endovascular interventions

SPECIALTY BALLOONS
Chocolate

- Semi-compliant balloon encased in a nitinol-constraining cage.
- Allows for 1:1 vessel sizing.
- No flow limiting dissection in chocolate BAR study
- 1.6% bail-out stenting
- 78.5% freedom from TLR @1year
- 97.2% freedom from major amputation @ 1year

Chocolate Balloon

POPLITEAL CTO
Chocolate Balloon

TIBIAL DISEASE
TP TRUNK RUPTURE
CLI: Endovascular revascularization

ATHERECTOMY

DIRECTIONAL AHERECTOMY
Final Result:

palpable pulse
84 yo with gangrene right foot

SFA, POP CTO: DIRECTIONAL AHERECTOMY AND DCB
PERONEAL AHERECTOMY
AT and PT

- Chocolate
ANW Endo CLI interventions

![Graph showing ANW Endo CLI interventions from 2014 to 2019. The graph indicates the average variable costs and the number of cases performed over the years. The costs are represented in dollars, with a peak in 2017 and a decline in 2018 and 2019.](image)
ANW Endo

- Jan 2014-March 2019: 980 procedures
- 40% outpatient status
- Avg LOS: 5.3 days
- ICU admission % 18.8
- ICU days: 4.2
- Avg total variable costs 17,285 (25425 for LEB)

CLI: Endovascular revascularization

DRUG ELUTION
Re-stenosis prevention

- Our Achilles’ heel is the *maintenance* of that arterial flow
- Biologic modification of restenosis takes PAD treatment to the “next level”
Drug coated devices (FDA approved)

- Coronary DES do not possess indication for noncoronary use
  - Off label use of coronary DES platforms for focal lesions and PTA salvage in distal popliteal/tibials
- DES: SFA Zilver PTX (Cook Medical), Eluvia (Boston Scientific)
- Bard/Lutonix and Medtronic Admiral paclitaxel-coated balloons approved for use in SFA/Pop

Zilver PTX Paclitaxel-Eluting Stent

- Approved in US, EU, Japan
- Scaffold plus drug
  - Mechanical scaffold:
    - Zilver Flex® Stent Platform
  - Drug therapy: Paclitaxel only
    - No polymer or binder
    - 3 µg/mm² dose density

- Image courtesy of Cook Medical
Eluvia

IN.PACT Admiral

Platform
Admiral™ PTA balloon
4-7 mm diameters
40, 60, 80, 120, 150, 200, 250 mm lengths

Drug
Paclitaxel
Proven anti-proliferative drug
3.5 µg/mm² dose density

Excipient
Urea
Facilitates drug transfer
Naturally occurring, non-toxic

Process
Medtronic
Reliable, scalable, uniform
drug coating process

12-MONTH KAPLAN-MEIER ESTIMATE PRIMARY PATENCY RATE

Cumulative Event-Free (%)

Log rank
p=0.0119

Eluvia
88.5%

Zilver PTX
79.5%

IN.PACT Admiral

MINNEAPOLIS HEART INSTITUTE
NORTHWESTERN MEMORIAL HOSPITAL

56 of 65
IN.PACT Global Complex Lesion Analysis
Freedom from CD-TLR¹ through 360 Days

Number at risk: 227 213 192
93.0%

1. Clinically-driven TLR adjudicated by an independent Clinical Events Committee, blinded to the assigned treatment based on any re-intervention at the target lesion due to symptoms or drop of ABI of ≥20% or >0.15 when compared to post-procedure baseline ABI.
2. Number at risk represents the number of evaluable subjects at the beginning of each 30-day window.

IN.PACT Global Study
24-month Freedom from CD-TLR¹

Number at risk: 808 1406 1232 199
83.3%

1. Clinically-driven TLR adjudicated by an independent Clinical Events Committee, based on any re-intervention at the target lesion due to symptoms or drop of ABI of ≥20% or >0.15 when compared to post-procedure baseline ABI.
2. Number at risk represents the number of evaluable subjects at the beginning of each 60-day window.
Is There a Role for **Infrapopliteal DCBs**?

- Schmidt performed paclitaxel DCB (InPact) treatment of 109 pts with long (17 cm) lesions

- Historic POBA comparison group had patency of 31% at 3 month angio

- New DCB cohort had patency of 73% over same time frame and amp rate of less than 5%
  
  - Schmidt, J Amer Coll Cardiol 2011:58:1105-09
  - Schmidt, Cathet Cardiovasc Intervention 2010: 76:1047-1054

**In.Pact DEEP**

- 12 month data presented at LINC 2014

- **No signal of expected biologic activity**
  - Failed to meet primary efficacy endpoints
  - No difference in LLL, TLR, occlusion rates

- Trend towards higher amputation rates in DCB arm

- Amphirion DEEP product removed from EU market
  
  *Data presented by Zeller at LINC 2014*
LUTONIX BTK TRIAL

**PRIMARY ENDPOINTS**
- Safety at 30 days
- Limb salvage & primary patency at 12 months

**NUMBER OF PATIENTS/SITES**
- 480 patients at 55 global sites (US, EU, Japan)

**FOLLOW-UP**
- **Clinical:** 1, 6, 12, 24, and 36 Months
- **Duplex Ultrasound (DUS):** 0–30 days, 6, 12, 24, & 36 months
- **Angiography in subset of patients:** 12 months
- **Telephone:** 48 and 60 Months

**NATIONAL PRINCIPAL INVESTIGATORS**
- **Patrick Geraghty:** Washington University, St. Louis, MO
- **Jihad Mustapha:** Metro Health Hospital, Wyoming, MI
- **Marianne Brodmann:** Medical University Graz, Austria

**SPONSOR**
- Lutonix Inc., Minneapolis, MN

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Coronary DES: BTK Trials

Use of coronary stents in the tibial arteries is NOT APPROVED by the FDA

DES shows improved one year primary patency in 2-3 cm length lesions

Applicability to broader CLI patient population likely limited
- Multiple long lesions
- Device costs

---

BTK DES

• Saval Boston Scientific
• Study completion: 2024

SYSTEMATIC REVIEW AND META-ANALYSIS

Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

Konstantinos Katsanos, MD, PhD, MSc, EBIR; Stavros Sillipoukos, MD, PhD; Panagiotis Kritsi, MD, PhD; Mitasadis Keskidis, MD, PhD; Dimitros Kanellis, MD, PhD

Conclusions—There is increased risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the lower limbs. Further investigations are urgently warranted.
Paclitaxel doses

- 3.5×32 mm coronary TAXUS stent contains around 200 μg paclitaxel compared with:
  - 1.2 mg for the ZILVER-PTX 6.0×120 stent
  - 4.5 mg for the LUTONIX 6.0×120
  - 8.5 mg for the IN.PACT 6.0×120 balloon

FDA March 2019

- “Discuss the risks and benefits of all available PAD treatment options with your patients. For most patients, alternative treatment options to paclitaxel-coated balloons and paclitaxel-eluting stents should generally be used until additional analysis of the safety signal has been performed.”
CLI
INVESTIGATIONAL THERAPIES

Venous arterialization

A  B  C
Cell-Based Therapies

- Several trials of circulating pluripotent cells, harvested/expanded stem cells, etc.

- No FDA-approved therapies yet

Implications on CLI practice

- Endovascular first has become the approach of the majority of interventionalists and surgeons.

Table 1: One-year outcomes for critical limb ischemia patients undergoing infrapopliteal bypass versus percutaneous vascular intervention.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>1-year primary patency (%)</th>
<th>1-year target vessel patency (%)</th>
<th>p-value</th>
<th>OR ratio</th>
<th>OR ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bypass</td>
<td>75.0 (75%-78%)</td>
<td>71.5 (69%-74%)</td>
<td>0.017</td>
<td>1.17</td>
<td>0.98-1.50</td>
</tr>
<tr>
<td>Angioplasty</td>
<td>68.0 (64%-72%)</td>
<td>57.5 (54%-61%)</td>
<td>0.001</td>
<td>0.85</td>
<td>0.73-1.00</td>
</tr>
</tbody>
</table>

Below-knee endovascular interventions have better outcomes compared to open bypass for patients with critical limb ischemia. CW Hicks, A Najafian, A Farber, MT Menard, MB Malas, JH Black III, ... Vascular Medicine 22 (1), 28-34.
Implications on CLI practice

- BEST CLI / BASIL 2 and 3 trial results are important in establishing standards of care
- With the increasing cost of medical devices, total cost of care should be given significant consideration.

Device Trials: MHI vascular surgery

- Mimic
- IN.Pact
- Best CLI
- Transcend