How Far Should We Go with the Endovascular Treatment of Advanced PAD in the Era of Health Care Reform?

An Endocompetent Vascular Surgeon’s View

Bruce A. Perler, MD, MBA

Peripheral Revascularization (Medicare): 1996 - 2006

Endovascular Procedures: Specialty

FINANCIAL DISCLOSURE

I Have No Financial Relationships to Disclose
How Far Should We Go with the Endovascular Treatment of Advanced PAD?

**TASC II**

- **TASC TYPE A**
  - Disease is diffuse or short
  - Complex lesion (e.g., aortic disease)
  - Endovascular therapy is the treatment of choice.

- **TASC TYPE B**
  - Lesion is long or complex
  - Disease is not amenable to bypass
  - Endovascular therapy is the preferred treatment for good risk patients.

- **TASC TYPE C**
  - Lesion is long or complex
  - Disease is not amenable to bypass
  - Endovascular therapy is the treatment of choice.

- **TASC TYPE D**
  - Lesion is short or complex
  - Disease is not amenable to bypass
  - Bypass surgery is the treatment of choice.

**Femoro-POPliteal Revascularization**

**Bypass Surgery**
- Vein
- Prosthetic

**Endovascular Therapy**
- Balloons
- PTA +/− Stent
- Stent
- Cutting Balloons
- Drug-Coated Balloons
- Drug-Eluting Stents
- Covered Stents
- Covered Beabsorbable Stents
- Cryoplasty
- Brachytherapy
- Laser
- Atherectomy
- Percutaneous Bypass

**Published Outcomes: OPEN vs ENDO**
103 Reports: 1976 - 2006

**DURATION OF FOLLOW-UP**

- Open: 50 months
- Endo: 30 months

Lipsitz, VEITH 2008
AFFORDABLE CARE ACT

- 3 Goals -

- Health Care Coverage for the Uninsured
- Increase Regulation of Private Health Insurers
- Reduce Healthcare Spending ("bend the curve")

Impact of ACA on Medicare Spending

Some analysts have a name for the wave of change that’s coming — they call it the "silver tsunami."

Source: Kaiser Family Foundation
HEALTH CARE REFORM: Medicare Spending

“Today health care is moving away from the old-fashioned, volume-driven, fee-for-service, fragmented health care approach towards a value-based, health-based system.”

Ronald R. Peterson, President
The Johns Hopkins Hospital & Health System

Report: Kill Fee-For-Service by Decade’s End
By David Pittman, Washington Correspondent, MedPage Today
Published: March 04, 2013

WASHINGTON -- Fee-for-service payments to physicians should be eliminated by the end of this decade, fundamentally changing the way doctors are paid, according to a report released today.

The National Commission on Physician Payment Reform called for replacing standalone fee-for-service with a blended payment system based on new delivery and reimbursement models. They outlined a number of recommendations to change the way doctors are paid and discourage incentives that may lead to higher cost as well as higher volumes of care.

"The commission concluded that our nation cannot control runaway medical spending without fundamentally changing how physicians are paid, including the inherent incentives built into the current fee-for-service pay system," the 24-page report stated. The commission was convened by the Society of General Internal Medicine in March 2012.

As the healthcare system transitions from a fee-for-service model over the next 5 years, policymakers, providers, and insurers should consider:

*The evaluation and management (E&M) services are relatively under compensated and the technological services are relatively over compensated," Schroeder added. "For those specialties...

How Far Should We Go with the Endovascular Treatment of Advanced PAD?

TASC II

TASC TYPE A
Complete revascularization if there is a long-term benefit

TASC TYPE B

could be considered for: 1. Operative treatment

TASC TYPE C

could be considered for: 2. Operative treatment with or without balloon angioplasty

TASC TYPE D

could be considered for: 3. Balloon angioplasty or surgical intervention to achieve a flow-limiting lesion

Surgery is the preferred treatment for good risk patients.

Surgery is the treatment of choice.


Society for Vascular Surgery Lower Extremity Guidelines Writing Group, Michael S. Conte, MD, (Co-Chair)
Frank B. Pongrace, MD, (Co-Chair), David G. Chao, MD, Patrick J. Grogghey, MD,
James F. McHenry, MD, J. Michael, MD, Gregory S. Moore, MD, and Hassan Albadawi, MD.
Richard J. Possel, MD, Amy B. Reiss, MD, Andrea Schanzer, MD, and Annem N. Robey, MD, MPH, for

Invasive treatments for IC should provide predictable functional improvements with reasonable durability. A minimum threshold of a 35% likelihood of sustained efficacy for at least 2 years is suggested as a benchmark.
Patients: 110
Bypass Grafts: 124
  - AK (32%)
  - BK (59%)
  - Tibial (18%)

30-Day Mortality: 0.8%
Follow-Up (mean): 77 mos

University Hospital, Basel
World J Surg, 2011

The Success of Endovascular Therapy for All TransAtlantic Society Consensus Graded Femoropopliteal Lesions

Patients: 427
Lesions: 499
TASC
A: 26 (5.2%)  
B: 140 (28.1%)  
C: 168 (33.7%)  
D: 165 (33.1%)

Primary Patency: Cumulative Survival
Assisted Primary Patency: Cumulative Survival

Mt. Sinai Hospital, New York
Ann Vasc Surg, 2011

Clinical outcomes and implications of failed infrapopliteal endovascular stents

Patients: 192
PTA / Stent Procedures: 239

Primary Patency

Huntington Memorial Hosp. U Southern California
J Vasc Surg, 2011

Patency: Vein Diameter

Huntington Memorial Hosp. U Southern California
J Vasc Surg, 2011
Primary Patency

Patients: 127
Limbs: 139
PTFE Fem-Pop: 46
PTA/S: 93

Claudication: 37%
Mortality: 0.8%
F/U: 0-48 (median, 12.4) mos.

Pancreatic Cancer

Survival

Procedures: 506
Patients: 472
Procedures: 495
Patients: 482

Outcomes of reinterventions after subintimal angioplasty

Subintimal angioplasty: Our experience in the treatment of 506 infrapopliteal arterial occlusions

Subintimal angioplasty

25%

33%
Recurrent Glioblastoma

Survival

BMJ, 2004

Full Metal Jacket Stenting of the Superficial Femoral Artery: A Retrospective Review

Patients: 63
Claudication: 65%
TASC C/D: 89%

Ann Vasc Surg, 2011

Patients (C/D):
VIABAHN: 76
Stent: 72
Lesion Length (mean): 18 cm.

J Vasc Surg, 2009

Baylor University Medical Center

TASC C & D

Group: Femoral popliteal bypass
At procedure (day 0)
Postoperative (0.31 d): 15
1.3 mo (11.317 d): 15
1.4 mo (12.154 d): 15
1.6 mo (17.108 d): 15
9 mo (8.52 d): 9
9 mo (8.52 d): 9
9 mo (8.52 d): 9
12 mo (10.506 d): 9
18 mo (18.52 d): 8
18 mo (18.52 d): 8
36 mo (36.52 d): 8
60 mo (60.52 d): 8

Covered Stents

Primary Patency

Assisted Primary Patency

25.9%
70%
p = .392
p = .04

Secondary Patency

J Vasc Surg, 2013

J Vasc Surg, 2013

Baylor University Medical Center

Primary Patency

Secondary Patency

Assisted Primary Patency

Covered Stents

89%
80%
p = .04
p = .304

89%
89%
p = .392
p = .304
Heparin-Bonded Covered Stents

- Patients: Viabahn 72 (19 cm), BMS 69 (17 cm)

Drug Eluting Stents

- Patients: 474
  - DES: 236 (Length: 66 mm)
  - PTA: 238 (Length: 63 mm)
  - PTA Failure: 100
    - DES: 61
    - BMS: 59

Fem-Pop Bypass Grafts

- Drug Eluting Stents
  - DES: 236 (Length: 66 mm)
  - PTA: 238 (Length: 63 mm)

Zilver PTX

- 1:1 randomization
- 220 patients
- Tasc C & D lesions

Surgical bypass

A prospective, randomized, multi-center study.
Preliminary results of the first 114 patients

Demographics & characteristics

<table>
<thead>
<tr>
<th>Gender</th>
<th>Total</th>
<th>ZILVER PTX</th>
<th>BYPASS</th>
<th>Signif</th>
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<tbody>
<tr>
<td>Female</td>
<td>35 (30.7%)</td>
<td>17 (29.8%)</td>
<td>18 (31.6%)</td>
<td>P = 0.839</td>
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<tr>
<td>Male</td>
<td>79 (69.3%)</td>
<td>40 (70.2%)</td>
<td>39 (68.4%)</td>
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<table>
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<th>Rutherford Baseline</th>
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<th>3</th>
<th>4</th>
<th>5</th>
<th>Missing</th>
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<td>2</td>
<td>11 (9.6%)</td>
<td>8 (14.0%)</td>
<td>8 (14.0%)</td>
<td>6 (11.3%)</td>
<td>0</td>
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<tr>
<td>3</td>
<td>65 (57%)</td>
<td>34 (59.6%)</td>
<td>31 (54.4%)</td>
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<tr>
<td>4</td>
<td>16 (14.0%)</td>
<td>4 (7.0%)</td>
<td>12 (21.1%)</td>
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</tr>
<tr>
<td>5</td>
<td>22 (19.3%)</td>
<td>11 (19.3%)</td>
<td>11 (19.3%)</td>
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<td>Missing</td>
<td>0</td>
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Drug Coated Balloons

CMS Approves Add-on Payment for Lutonix® Drug-Coated Balloon for Inpatient Use

August 03, 2015 07:00 AM Eastern Daylight Time

MURRAY HILL, N.J. - (BUSINESS WIRE) - C. R. Bard, Inc. (NYSE: BCR) today announced that the U.S. Centers for Medicare and Medicaid Services (CMS) has approved a new technology add-on payment for the Lutonix® Drug-Coated Balloon (DCB) under the Medicare hospital inpatient prospective payment system. The purpose of the reimbursement is to help cover additional cost to U.S. hospitals for treating Medicare beneficiaries with the Lutonix® DCB in the inpatient setting. CMS determined the amount of the add-on payment to be a maximum of $1,036 when DCBs are used for inpatient peripheral procedures and the total device costs exceed the allowance for existing DRG reimbursement. The add-on payment is effective October 1, 2015.

The Lutonix® 0.035 DCB—the first FDA-approved DCB—is an angioplasty balloon coated with a therapeutic dose of the drug paclitaxel, and also utilizes standard mechanical dilatation of the vessel to restore blood flow to patients with peripheral arterial disease (PAD) in the femoropopliteal arteries. Recall is expected on October 1, 2015.
**IN.PACT SFA**
- Patients: 331
- Stenosis Length: < 18 cm
- Occlusion Length: < 10 cm
- Mean Lesion Length
  8.94 vs 8.81 cm

**Limb Salvage**

**Drug Coated Balloons**

- Primary Patency
  - 55%
  - P < .001

"The definition of insanity is doing the same thing over and over and expecting a different result."

*Albert Einstein*
Consequences of Stent Failure

<table>
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<tr>
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<th>TASC A, B</th>
<th>TASC C, D</th>
<th>P value</th>
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<tbody>
<tr>
<td>Stent failure</td>
<td>27</td>
<td>42</td>
<td>&lt;0.0001</td>
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<tr>
<td>Loss of run-off vessels</td>
<td>4</td>
<td>11</td>
<td>.0032</td>
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<tr>
<td>Stent failed with</td>
<td>8</td>
<td>18</td>
<td>.0001</td>
</tr>
<tr>
<td>Occlusion</td>
<td>3</td>
<td>7</td>
<td>.0344</td>
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<tr>
<td>Required open revascularization</td>
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</table>


BASIL TRIAL

Patients: 452
Bypass vs Endovascular

Amputation-Free Survival

J Vasc Surg, 2010

VSGNE

Patients: 1,880 LEBs
Prior PVI: 603 (32%)
Years: 2003 - 2009

Graft Occlusion Rate

Amputation Rate

J Vasc Surg, 2017
Deductibles

Copayments and Coinsurance Rise Under The ACA

More Employee Responsibility, More Unpaid Bills? The Rise of High-Deductible Health Plans and What It Means for Hospitals
Written by Sidney A. Kolodner (Twitter: @Newsbase) | September 26, 2013

Employers Increasing Worker Deductibles And Copayments to Slash Rising Health Costs
Monday, March 24, 2014

Obamacare shock: $12,600 deductible, 40 percent co-pay, zero competition

Deductibles have risen more than six times faster than workers’ earnings since 2010.

What concerns policy experts and employers is evidence that higher deductibles are making people forgo care, even when they have serious conditions.

Copayments

Cost of Treatment May Influence Doctors

Saying they can no longer ignore the rising prices of health care, some of the most influential medical groups in the nation are

And the American College of Cardiology and the American Heart Association recently announced that they would begin to use cost data to rate the value of treatments in their joint clinical practice guidelines and performance standards.

patients to exerting influence on how health care dollars are spent.
## Femoral-Popliteal Disease

<table>
<thead>
<tr>
<th></th>
<th>Open (n=183)</th>
<th>Endo. (n=198)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Patency (12 mos)</td>
<td>77%</td>
<td>65%</td>
<td>&lt; .01</td>
</tr>
<tr>
<td>1st Assisted Patency (12 mos)</td>
<td>93%</td>
<td>80%</td>
<td>&lt; .01</td>
</tr>
<tr>
<td>Hospital Costs</td>
<td>$12,389</td>
<td>$6,739</td>
<td>&lt; .001</td>
</tr>
</tbody>
</table>

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## COSTS: Per Day of Patency

### Claudicants

- **PTA**
  - 2007 Costs: $13,903
- **Bypass Surgery**
  - 2007 Costs: $12,681

### Limb Salvage

- **PTA**
  - 2007 Costs: $23,196
- **Bypass Surgery**
  - 2007 Costs: $22,910

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## National Inpatient Sample

- Patients: 563,143

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## Pornography

- You know when you see a patient who is best served by a bypass graft.
- Patients with TASC D and most patients with TASC C lesions should undergo a bypass graft.
- Patients after multiple failed endovascular procedures should undergo a bypass graft.
- ...and there’s nothing wrong with doing a bypass graft in the endovascular era!
HEART BEAT

New Tacties To Treat Artery Disease That Harms Legs

By RON WINGLOW
Oct. 15, 2012 7:05 p.m. ET

Doctors are seeking better ways to help patients suffering from artery blockages that obstruct blood flow to the legs—an area of treatment that has been lacking despite well-established methods for preventing and treating the same disease when it occurs in the heart.

As many as 12 million Americans suffer from peripheral artery disease, or PAD. The disease, which affects the foot and leg, is caused by the same accumulation of fatty deposits called plaque that in the coronary arteries leads to chest pain and heart attacks. Because leg arteries are subject to different physical forces than coronary arteries, some treatments derived from heart disease aren’t as effective when applied to PAD.

What’s more, many PAD patients aren’t even aware they have the disease because they may initially overlook the most common symptoms—leg or foot pain while walking. In advanced stages, PAD carries a threat of amputation and even death.

Now, fresh approaches are raising the possibility of improved treatments for PAD patients. Medical devices, such as balloons and scaffolds called stents, are increasingly being developed to open up obstructed vessels and restore blood flow to patients’ lower extremities. Meanwhile, a recent National Institutes of Health study showed that a program of supervised exercise may be at least as effective as interventions with devices in alleviating walking pain for many people suffering from PAD.