THE BURDEN AND ECONOMIC COST OF PERIPHERAL ARTERY DISEASE

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THE SAGE GROUP
Disclosures

Research Clients:
Bard
Cardiovascular Systems Inc.
Otivio AS
Pluristem
Rexgenero Ltd London
Shockwave Medical
Terumo
2015 U.S. PREVALENCE OF SELECTED CHRONIC DISEASES
(Millions)

## COMPARISON OF US PAD ESTIMATES—2015

<table>
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<tr>
<th>YEAR</th>
<th>CRIQUI/PARTNERS (Mill)</th>
<th>DIABETES METHOD (Mill)</th>
<th>NEHLER (Mill)</th>
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<td>2015</td>
<td>11-18</td>
<td>20</td>
<td>18</td>
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PAD ANNUAL ECONOMIC BURDEN*
*Total Costs Inpatient and Outpatient in 2015

$223†-$414‡ BILLION

†U.S. REACH population inpatient costs + outpatient medication = $11,280 X 19.8 Mil PAD in 2015
‡Margolis managed care population all-cause hospitalizations + medications + other =
$20,895 x 19.8 Mil PAD. Per pt. costs in 2015 $.

HOSPITAL COSTS REPRESENT MAJORITY OF PAD COSTS

Costs in 2015 Dollars (Billions)

REACH

Total Costs $223 B
Hospital Costs $147 B

Managed Care

Total Costs $414 B
Hospital Costs $363 B

WHO PAYS THE PAD BILL?

2014 PAD Patient Discharges by Payer

- Medicare: 71%
- Private: 16%
- Medicaid: 9%
- Other: 4%

Source: HCUP Query. ICD-9 diagnosis codes PAD 440.20-29, 443.9 & 443.81.
**PAD PATIENTS IN MEDICARE**

10%-21% Medicare Patients Treated for PAD
(2003-2012)

$22,756-$72,159* Expenditure per Patient
(Range reflects definition of PAD and types of treatments included, i.e. LT Care)

AK Amputation
Third Most Commonly Performed Procedure

*2015$ X 2015 Medicare beneficiaries w/ PAD

2015 ANNUAL MEDICARE EXPENDITURES

$72,159

$10,986*

PAD
Average Beneficiary

*2014 Expenditures
Source: Jaff MR. Ann Vasc Surg 2010;24:577-87, CMS NHE Table 21 and Yost ML Real cost of PAD 2011 THE SAGE GROUP.
POLYVASCULAR DISEASE IN PAD PATIENTS

- PAD Only: 30%
- PAD + CAD: 46%
- PAD + CVD: 7%
- PAD + CAD + CVD: 17%

POLYVASCULAR DISEASE COSTS MORE

2015 Total Annual Cost

- PAD: $11,280
- PAD+CVD: $11,316
- PAD+CVD+CAD: $15,582
- PAD+CVD+CAD: $19,930

Source: Mahoney EM. Circ Cardiovasc Qual Outcomes 2010;3:642-51 and THE SAGE GROUP.
Asymptomatic = 14.8 Million  CLI = 3.4  IC = 1.6 Million

Source: Yost ML. PAD. Interventional market analysis based on treatment with angioplasty or atherectomy. THE SAGE GROUP. 2012.
ASYMPTOMATIC PATIENTS COST MORE THAN IC PATIENTS

IC

Cost 2-year $13,242

Costs Due to:

PAD Hospitalizations, Revascularizations & Amputations

Asymptomatic

Cost 2-year $14,084

Costs Due to:

CVD Events, Hospitalizations & Revascularizations

2015 ANNUAL ECONOMIC BURDEN*
(Billions $)


PAD/CLI AMPUTATION & MORTALITY INCREASE WITH DISEASE SEVERITY

4-Year Amputation Rates

R 1-3: 4.6%
R 4: 12.1%
R 5: 35.3%
R 6: 67.3%

4-Year Mortality Rates

R 1-3: 18.9%
R 4: 37.7%
R 5: 52.2%
R 6: 63.5%

CLI PREVALENCE 2015

2.0-3.4 Million

400,000-700,000 Treated w/
Revascularization or Amputation-Major & Minor

CLI COSTS ARE THE MAJORITY OF PAD COSTS

U.S. REACH $134 Billion

U.S. Managed Care $248 Billion

WHY IS CLI SO COSTLY?

❖ COSTS INCREASE WITH SEVERITY OF RUTHERFORD CATEGORY TREATED

❖ RISK FACTORS UNDERTREATED → INCREASED MORBIDITY & MORTALITY

❖ HIGH RATE OF UNPLANNED READMISSIONS

❖ TREATMENT W/ AMPUTATION VERSUS REVASCULARIZATION — REVASCULARIZATION UNDERUTILIZED EVEN VS IC PTS!

TREATMENT COSTS INCREASE WITH DISEASE SEVERITY

Mean Inpatient Treatment Costs by Rutherford Category (in Euros)

- R 1-3: €3,662
- R 4: €5,316
- R 5: €6,021
- R 6: €8,461

CLI PATIENTS UNDERTREATED FOR RISK FACTORS

RISK FACTOR MODIFICATION THEAPIES UNDERUTILIZED
Statins prescribed in 50%-62%,
Antiplatelets in 60%-90%
Anti-hypertensives in only 53%-71%

GLUCOSE INADEQUATELY CONTROLLED IN 40%

SMOKING PERSISTS IN 27%-52% OF CLI PATIENTS

RISK FACTORS UNDERTREATED EVEN COMPARED WITH IC PATIENTS!

INADEQUATE MEDICAL MANAGEMENT INCREASES MAJOR ADVERSE EVENTS & DEATH

❖ SUBOPTIMAL MEDICAL MANAGEMENT INCREASES RISK OF AMPUTATION AND/OR DEATH 8X

❖ LEADS TO MAJOR ADVERSE CARDIAC AND LEG EVENTS AND INCREASES COSTS

HIGH RATE OF CLI READMISSIONS INCREASES COSTS

- **READMISSION RATES**: 30-DAY 20%-27% & 6-MO 57% VS ISCHEMIC STROKE 12% @ 30 DAY

- **MAJORITY OF READMISSIONS UNPLANNED**

- **ONLY 22%-33% DUE TO PRIMARY CLI-RELATED CAUSES, REST DUE TO VARIOUS NON-CLI REASONS: INFECTIONS, PROCEDURE COMPLICATIONS, CVD EVENTS, DIABETES-RELATED NON-VASCULAR PROBLEMS AND OTHER COMORBIDITIES**

- **UNPLANNED READMISSIONS INCREASE MORTALITY, MALE & COSTS ($624 MILLION)**

Amputation costs more than revascularization.

Per Patient Total Cost* of Major Amputation, Endovascular & Bypass

*Total Cost = Procedure Cost + Morbidity, Mortality & Revisions

Source: THE SAGE GROUP estimates.
Frequently the first and only therapy for CLI

60%-71% No Revascularization

51%-73% No Angiogram—Despite fact that angio ↓ the odds by 90%

MAJOR AMPUTATION

65,000-80,000 Major Amputations Performed Annually

25%-33% CLI Patients Undergo Primary Amputation (PA)

MAJOR AMPUTATION ANNUAL 2015 ECONOMIC COST*

$11.3 BILLION

*Total Direct Inpatient and Outpatient Costs in 2015 $
TOTAL AMPUTATIONS 200,000
COST $29.9 BILLION

2015 Amputation Cost by Type

- Minor Amputation: $18.6 B
- Major Amputation: $11.3 B

Source: Dillingham TR. Arch Phys Med Rehabil 2005; 86: 480-6, HCUP Queries Amputation, Medicare 5% sample and THE SAGE GROUP estimates.
$11 BILLION UNDERSTATES MAJOR AMPUTATION COSTS

Total Costs: $67* Billion
❖ $46 billion life-time costs
❖ $9-$10 billion annual patient costs (eg, medical, home care, handyman, architectural modifications, wheelchair, lift or ramp van, medical equipment, prostheses)

Economic costs of death to society – How much?

Probability of major amputation depends on who you are and where you live—”Amputation Lottery”

Amputation varies by: race, sex, age, socioeconomic status, hospital volume, geographic location

Medicare & Medicaid-More likely than private, Medicaid most likely!

ENDOVASCULAR PATIENT OUTCOMES

❖ Discharge status: 65% home; 17% skilled nursing facility or rehabilitation; 16% home healthcare

❖ In-hospital mortality: 1.7%

❖ Ambulation (2-year)
  ❖ 81% walking
  ❖ 88% living independently

❖ Revascularization (18-month): 30%-40%

❖ Mortality (2-year): 16%-24%

AMPUTATION PATIENT OUTCOMES

- Discharge status: Only 11%-24% go home routinely, majority (73%) go to another institution (skilled nursing facility, rehabilitation)

- In-hospital mortality: 3.4%

- Ambulation: 60%-80% cannot walk

- Depression: 35%

- Mortality (2-year): 30%-50% (frequently MI)

- Contralateral amputation: 36%-50%

AMPUTATION: MORE PATIENT OUTCOMES

❖ Lengthy healing process
   ❖ At 100 days, 45% BKA and 24% AKA not healed

❖ Quality of life reduced
   ❖ Severe physical impairment in ambulation, body care, movement, and mobility

❖ Chronic pain 95%
   ❖ Phantom limb pain: 79%-80%
   ❖ Residual limb pain: 68%-74%
   ❖ Back pain: 52%-62%

PAD IS HIGHLY PREVALENT AND COMMONLY UNDERESTIMATED

PAD MACROECONOMIC COST IS HIGH $223-$414 BILLION

HOSPITAL COSTS ACCOUNT FOR THE MAJORITY OF TOTAL PAD COSTS

HOSPITAL COSTS ARE SIGNIFICANTLY INCREASED BY CARDIOVASCULAR AND NON-PAD EVENTS

2015 ECONOMIC BURDEN OF PAD EXCEEDS THAT OF DIABETES, CAD AND ALL CANCERS COMBINED
CONCLUSIONS

❖ ASYMPTOMATIC PATIENTS COST MORE THAN IC PATIENTS—COSTS DUE TO CARDIOVASCULAR EVENTS AND HOSPITALIZATIONS

❖ MORTALITY AND AMPUTATION INCREASE WITH DISEASE SEVERITY

❖ PAD COSTS INCREASE WITH DISEASE SEVERITY—EARLIER DIAGNOSIS AND TREATMENT LIKELY TO REDUCE COSTS

❖ CLI ACCOUNTS FOR MAJORITY OF PAD COSTS—$134 TO $248 BILLION
CONCLUSIONS

❖ CLI COSTS INCREASED BY: TREATMENT AT MORE SEVERE DISEASE STAGES, UNDERTREATMENT OF RISK FACTORS, UNPLANNED READMISSIONS AND TREATMENT WITH PRIMARY AMPUTATION

❖ OPTIMAL MEDICAL MANAGEMENT UNDERUTILIZED IN CLI—INCREASES RISK OF AMPUTATION AND/OR DEATH 8X

❖ 65,000-80,000 MAJOR AMPUTATIONS COST $11 TO $67 BILLION

❖ PATIENT OUTCOMES AFTER AMPUTATION ARE POOR VERSUS ENDOVASCULAR REVASCULARIZATION

❖ MORE RESEARCH IS NEEDED ON PAD & CLI COSTS & CONSEQUENCES